SHAPES

Smart and **H**ealthy **A**geing
through **P**eople **E**ngaging in supportive **S**ystems

D6.4 – Medicine Control and Optimisation Pilot Activities Report

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Table 1 Revision History

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0.1	28.09.2020	Sonja Grigoleit (FhG)	ToC
0.2	24.02.2021	Maureen Spargo (NHSCT)	ToC & separation of section 2 into 4 use cases
0.3	30/11/2021	Maureen Spargo (NHSCT) Nicola Goodfellow (NHSCT)	Incorporation of all use case information, formatting and final edit of interim deliverable
0.4	03/04/2023	Nicola Goodfellow	General update to deliverable
0.5	20/06/2023	Use case leads	Update of outcome data
0.6	30/06/2023	Maureen Spargo (NHSCT) Nicola Goodfellow (NHSCT)	Draft for final review
1.0	31/07/2023	Maureen Spargo (NHSCT) Nicola Goodfellow (NHSCT)	Final version for submission

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Table of Acronyms and Abbreviations

Table 3 Acronyms and Abbreviations

Acronym	Full Term
AI	Artificial intelligence
ACR	Urine albumin to creatinine ratio
A&E	Accident and Emergency
API	Application Programming Interface
BLE	Bluetooth low energy
BMI	Body Mass Index
BMQ	Beliefs about Medicines
BP	Blood pressure
CAT	COPD Assessment test
CE-IB	Comitè d'Ètica de la Investigació de les Illes Balears
CH	Clinica Humana
COPD	Chronic obstructive pulmonary disease
COVID-19	Coronavirus
CRF	Case Report Form
CSF	Critical success factor
DOB	Date of birth
DPIA	Data protection impact assessment
ECG	Electrocardiogram
EGFR	Estimated Glomerular Filtration Rate
EHFScB	European Heart Failure Self-Care Behaviour Scale
EU	European Union
EQ-5D-5L	European Quality of Life 5 dimensions 5 level version
FDA	Federal Drug Administration
FNOL	Fakultni Nemocnice Olomouc
GEWI	Institut Fur Gesundheitswirtschaft
GDPR	General Data Protection Regulation
GSES	General self-efficacy scale
GUI	Graphical user interface
HbA1c	Glycated haemoglobin
H&C	Health and care
HCP	Health care professional
HDL	High density lipoprotein
HF	Heart failure
HFPred	Heart failure decompensation predictor
HLM1	Health literacy measure

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Acronym	Full Term
HR	Heart rate
ICT	Information and communications technology
ISO	International Standards Organisation
IRAS	Integrated Research Application System
IT	Information technology
KPI	Key performance indicator
KG	Kilogram
LDL	Low density lipoprotein
LVEF	Left Ventricular Ejection Fraction
MAFEIP	Monitoring and Assessment Framework of the EIP
MARS	Medication adherence report scale
MAST	Model for Assessment of Telemedicine
MEAAP	Mid- and East-Antrim Agewell Partnership
MMOL/L	Millimoles per litre
MMHG	Millimetres of mercury
MHRA	Medicines and Healthcare Products Regulatory Agency
MOIC	Medicines Optimisation Innovation Centre
NASSS-CAT	Non-adoption, Abandonment, Scale-up, Spread, and Sustainability
NHSCT	Northern Health and Social Care Trust
NICHS	Northern Ireland Chest Heart and Stroke
NYHA	New York Heart Association
ORECNI	Office for Research Ethics Northern Ireland
OSSS-3	Oslo Social Support Scale
PACT	People activities context technology
PMB	Programme Management Board
PO	Primary objective
PT3	Pilot theme 3
RAM	Random access memory
REC	Research ethics committee
RISC	Risk instrument for screening in the community
SDK	Software development kit
SHAPES	Smart and Healthy Ageing through People Engaging in supportive Systems
SO	Secondary objective
SUS	System usability scale
TAM	Technology assessment model
TO	Tertiary objective
TP	Technology platform

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Acronym	Full Term
UC	Use case
UEQ-S	User experience questionnaire – short
UI	User interface
UK	United Kingdom
UN	United Nations
UNRF	University of Nicosia Research Foundation
US	United States
UX	User experience
WP	Work package
WHO QOL-BREF	World Health Organisation abbreviated Quality of Life Questionnaire

Keywords

Medicines optimisation; Adherence; Digital solutions; Medicines management; Remote monitoring; Self-management

Disclaimer

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Executive Summary

This deliverable contains the work completed by Pilot Theme 3 of the SHAPES Pan-European Pilot Campaign. It details the planning and outcomes of all activities and tasks that have been completed in Phases 1 to 5 of the pilot campaign.

The work described here is the result of the collaboration and dedication of the whole of Pilot Theme 3 including the pilot site leaders, replicating sites and technical partners as well as significant contribution and assistance from other work packages within the SHAPES consortium.

This report contains the following information:

1. An introduction and description of the rationale and purpose of Pilot Theme 3.
2. Detailed description of the work undertaken in Phases 1 to 5 by the four use-cases evaluated in this pilot theme.
3. An ethical requirements check.

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1 Introduction

Pilot Theme 3 aims to address and improve deficiencies in the adherence to medicines and treatments of older individuals living with permanent or temporarily reduced functions or capabilities due to chronic age-related illnesses and living at home.

The anticipated benefit of this highly personalised approach to delivering healthcare is to help participants self-monitor their health condition(s), physiological parameters and medicines adherence. The personalisation approach advocated in this pilot theme and practised in the different pilot activities will consider the early identification of side effects and worsening of symptoms, and in some cases provide the opportunity to adjust medicines and treatments so as to deliver a safer and more effective use of medicines in-home, thus improving the quality of life of the care recipients and reducing re-hospitalisation occurrences.

1.1 Rationale and purpose of the deliverable

This deliverable describes the work undertaken for Task 6.4: Pilot Theme 3: Medicine Control and Optimisation. It describes the activities undertaken during each of the five phases of the pilot, which closely followed the methodology outlined in Deliverable 6.1.

Pilot theme 3 was led by the Northern Health and Social Care Trust (NHSCT) in Northern Ireland. Within this pilot theme there were multiple 'use cases' each deploying and evaluating different digital solutions according to the type of support required. Four use-cases were used to represent this pilot theme:

UC-PT3-General: Supporting multi-morbid older patients (lead site; NHSCT: replicating site; UNRF)

UC-PT3-001: In-home decompensation prediction for heart failure patients (lead site; CH: replicating site; GEWI)

UC-PT3-001c: Advanced telemonitoring of patients with heart failure in home environment (lead site; FNOL)

UC-PT3-copd: Advanced telemonitoring of patients with chronic obstructive pulmonary disease (COPD) in home environment (lead site; FNOL)

1.1.1 Deliverable Objectives

The objectives of this Deliverable were:

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- Introduce the 4 use cases in pilot theme 3 and describe all work completed on the pilot theme.
- Describe the methodology used to conduct Phases 1–5 (Figure 1) at each of the pilot sites involved in PT3.
- Report on the key findings at each phase.

1.1.2 Key inputs and outputs

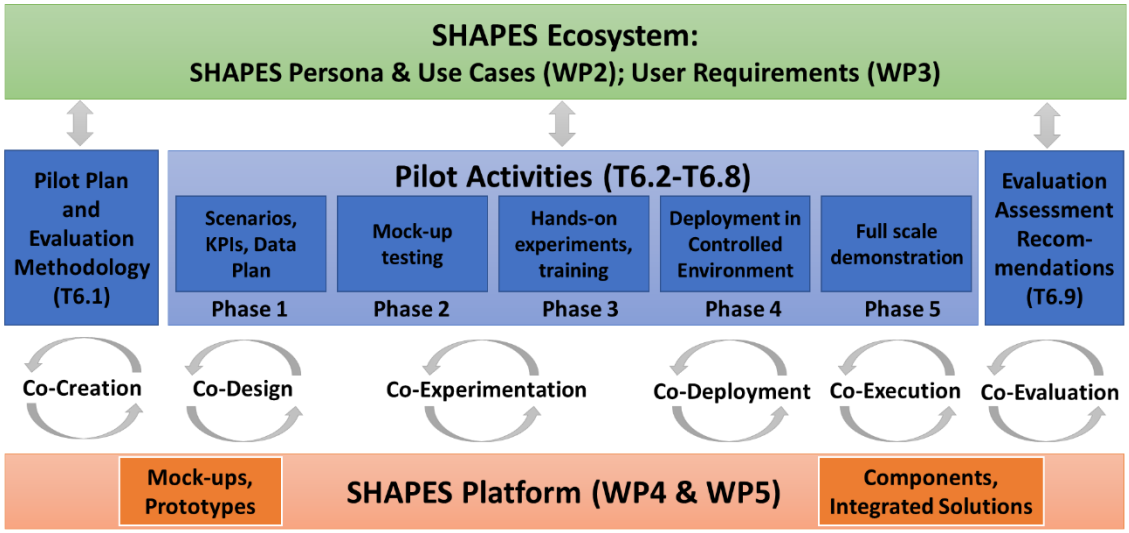

Figure 1 Overview of Work Package 6

This deliverable built on the general evaluation methodology developed in Task 6.1 and is intended to support the overall evaluation of SHAPES in Task 6.9.

In this task the digital solutions of WP5 and the overall platform developed in WP4 were co-designed, tested and co-executed. The outcome of the co-evaluation process is presented in Task 6.9.

The design of the pilots further builds on the persona and use cases, which were developed in WP2, as well as on the user requirements, which were presented in D3.7 – D3.9.

1.2 Structure of the document

This document has been structured to present the activities undertaken and key outcomes of each of the 4 use cases in their entirety. Main outcomes from each use case are then brought together in the conclusion.

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2 Use case PT3-General

2.1 Introduction

This Chapter describes the pilot activities of UC-PT3-General: Supporting multi-morbid older patients. Target users of this use case were aged 60 and older, lived at home and had no cognitive impairment at recruitment to the study. They had multiple illnesses e.g., heart failure, diabetes, hypertension and were android smartphone users with access to the internet. The SHAPES Persona for this pilot theme was Persona 2: 'Roberto' (1), a man in his early 70s who lived in his own home with his wife. Roberto had multiple health conditions, including diabetes and hypertension.

The main objectives of this use case were to investigate user engagement with the SHAPES App and Digital Solutions and to validate the capability of the SHAPES Platform and Digital Solutions to:

- Implement a personalised approach to achieve safe and effective use of medicines at home.
- Achieve better patient outcomes by initiating, developing and sharing best practice with regards to medicines use.
- Address and improve deficiencies with adherence to medicines and treatments.
- Identify associations between precursor signs of deterioration and unscheduled healthcare resource use.
- Improve data collection to develop predictive algorithms for heart failure decompensation.
- Improve older individuals' quality of life.

Furthermore, this use case explored the integration of the SHAPES platform and Digital Solutions to align with current and developing care pathways and user trust and acceptance of the SHAPES platform and Digital Solutions.

The Northern Health and Social Care Trust in Northern Ireland was the use case leader and the University of Nicosia Research Foundation (UNRF) in Cyprus replicated Phase 5 of the use case.

2.2 Description

Older individuals tend to have a number of concurrent medical conditions resulting in the need to take a larger number of prescribed medicines to help control these conditions. There is a need to have a personalised approach to the safe and effective use of these medicines to ensure the best possible outcomes. Specifically, we focused

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on patients over 60 years of age with heart failure and/or diabetes who needed to be monitored to avoid decompensations and hyper/hypoglycaemic events.

2.3 Digital solutions used in this use case

eHealthpass (GNO)

Health and Wellbeing App for the registration of vital signs and physical measurements, provision of questionnaires to patients, medication list and medication reminders. This was tested up to Phase 4 but not used in Phase 5 at NHSCT. This is explained further in Section 2.8.5 of this deliverable.

eCare (EDGE)

Remote monitoring platform which collects and displays wellbeing and health data gathered manually or automatically (using connected devices like blood pressure monitor and weight scale) in the home environment.

HFPred (VICOM); Vitals control (TREE)

Analysis of medicine optimisation by prediction of worsening disease based on clinical device readings, patient feedback and modelling to allow timely intervention and medication review (prediction of heart failure decompensation by VICOM; vitals statistical control: dynamic thresholds and out of range controls by TREE).

Researcher dashboard (GNO; EDGE; TREE; VICOM)

Browser-based dashboard to monitor participant adherence to interventions during the pilot period. This links to data and analyses provided by TREE and VICOM.

More information about the digital solutions for this use case can be found in Deliverable 5.2: SHAPES Digital Solutions.

2.3.1 Digital solutions used for COVID-19 response

There were no digital solutions used for the COVID-19 response in UC-PT3-General.

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2.3.2 Equipment and medical devices used (from third parties)

Three external devices were used in UC-PT3-General at the NHSCT lead pilot site.

1. Blood pressure meter: OMRON M7 Intelli IT blood pressure monitor.
2. Body composition monitor: OMRON VIVA Smart Scale.
3. Pulse oximeter: Beurer GmbH PO60 Bluetooth pulse oximeter.

[Glucometer: Roche Accu-Chek Instant - was *tested up to Phase 4 but not used in NHSCT phase 5 explained in Section 2.8.5. This device was used at replicating site UNRF.]*

Further details on these devices are provided in section 2.8.2. The third-party devices purchased for use in this use case were specifically identified by technical partners EDGE and Gnomon. The manufacturers of the devices and the digital solution providers (EDGE/Gnomon) had agreements in place to permit direct data transfer (i.e., no 3rd party involvement) and provision of their APIs to permit integration with the SHAPES App.

To ensure that the devices met certain medical device standards for Northern Ireland (OMRON M7 Intelli IT blood pressure monitor, Roche Accu-chek Instant, Beurer GmbH PO60 Bluetooth pulse oximeter) and appropriate study standards (OMRON VIVA Smart Scale), the NHSCT Clinical Engineering team liaised directly with the device manufacturers to complete a Pre-Acquisition Questionnaire. This allowed the devices to be procured with confidence ensuring that all regulatory aspects were in place.

The following equipment and devices were used in UC-PT3-General at the UNRF replicating site.

1. Tablet device: LENOVO TABLET TAB M10 TB-X306F HD 2ND GEN (for the participants that do not own a tablet or laptop).
2. Wi-Fi plug sockets (for the participants that do not have access to Wi-Fi).
3. Blood pressure meter: OMRON M7 Intelli IT blood pressure monitor.
4. Glucometer: Roche Accu-Chek Instant.
5. Accu-Chek Instant test strips.

2.4 Data plan

The data plan for Phase 5 of the pilot for UC-PT3-General can be found here, https://shapes2020.eu/wp-content/uploads/2023/06/UC-PT3-gen_data-plan-final_20062023.xlsx

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The data architecture diagram for UC-PT3-General is shown in Figure 2.

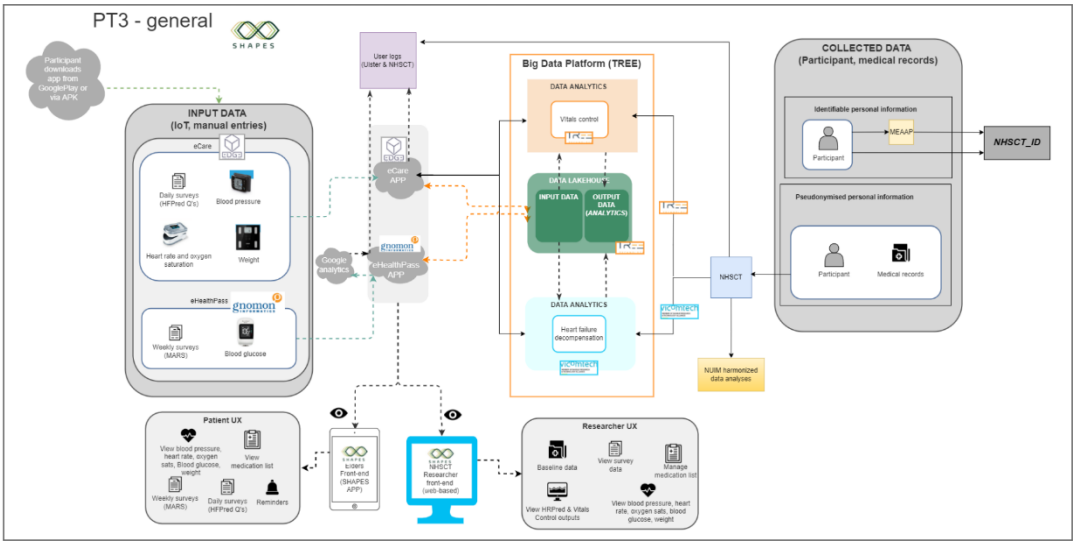

Figure 2 Data architecture diagram (PT3-gen).

2.4.1 Data capture methods to be used

A range of data capture methods were used during this pilot and are listed below. Further information on each method is provided where relevant, later in this deliverable. Supporting documents are available to view in the Annexes where indicated in the relevant sections of this deliverable.

Phase 1

No data capture methods were applied.

Phase 2

- Digital recording of video call with participants

Phase 3

- Digital recording of video call with participants
- User experience questionnaire-short version (UEQ-S) (2)
- Participant interviews (recorded)

Phase 4

- Participant error reporting log

Phase 5

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- Case report form to capture the following data:
  - Participant data (see Data Plan)
  - Harmonised questionnaires (more details on harmonised data will be provided in Deliverable D6.9)
    - WHOQOL-BREF (3)
    - EQ-5D-5L (4)
    - General Self-Efficacy Scale (5)
    - Oslo Social Support Scale (6)
    - Single item health literacy scale (7)
    - Participation questions
    - System Usability Scale (SUS) (8)
    - Technology acceptance questions (9)
  - Questionnaires for the HFPred algorithm by VICOM
    - Barthel Index (10)
    - Gijon socio family assessment scale (11)
    - EHFScB (12)
  - Pilot 3 questionnaires
    - Beliefs about Medicines Questionnaire (13)
    - UEQ-S (2)
- The SHAPES App (eCare and eHealthpass) to capture the following data:
  - Clinical parameters:
    - blood pressure
    - heart rate
    - oxygen saturation
    - weight (as well as body mass index, body fat, visceral fat, skeletal muscle, basal metabolic rate)
  - VICOM HFPred 8 questions
  - MARS (14)
  - Prescribed medication updates
  - Tracking data (e.g., user logs)
- Service user and healthcare professional interviews

2.4.2 Planning of evaluation

MAST

The MAST framework (15) was used to evaluate the effectiveness and contribution of UC-PT3-general to quality of care. MAST is described as a multidisciplinary process that summarises and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine.

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A review of the 7 dimensions of MAST revealed that 3 of the 7 multidisciplinary dimensions/domains were of specific relevance to the pilot of UC-PT3-General. They were: Clinical Effectiveness; Patient Perspectives; and Economic Aspects. Table 4 contains the data required for the MAST evaluation.

Table 4: Data required for MAST evaluation (PT3-gen)

MAST Domain	Topic	Outcome	Data required	Time point
Clinical Effectiveness	Effects on mortality	Mortality rate	Number of deaths	End of pilot
	Effects on morbidity	Will not be measured		
	Physical health	Will not be measured		
	Mental health	Will not be measured		
	Effects on health related quality of life	Health related quality of life	EQ-5D-5L scores	Baseline and end of pilot
	Behavioural outcomes	Concerns about medicines	BMQ scores	Baseline and end of pilot
		Necessity beliefs about medicines	BMQ scores	Baseline and end of pilot
		Self-reported adherence	MARS scores	Baseline and end of pilot
	Utilisation of health services	Hospitalisations	Number of hospitalisations	Baseline (past 3 months) and at end of pilot
		A&E attendances	Number of A&E attendances	Baseline (past 3 months) and at end of pilot
Patient perspectives	Satisfaction and acceptance	User Experience	UEQ-S scores	End of pilot

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MAST Domain	Topic	Outcome	Data required	Time point
	Understanding of information Confidence (in the treatment) Ability to use the application Access	Usability of application	SUS Scores	End of pilot
	Empowerment Self-efficacy	Self-efficacy	General self-efficacy scale	Baseline and end of pilot
Economic aspects	Amount and cost of resources used	Cost of devices	Cost as per medical device purchasing invoice	End of pilot
		Cost of using digital solutions and SHAPES platform	Costs to be provided by SHAPES	End of pilot
		Cost of staffing	Timesheets and costing data	End of pilot
	Related changes in use of healthcare resources	Cost of hospitalisations	Cost of length of stay per admission and medical bed day cost	End of pilot
		Cost of A&E attendances	Attendance cost	End of pilot

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MAFEIP

Due to the evaluation methodology (small-scale deployment, non-case controlled) the MAFEIP tool (16) will not be used to evaluate UC-PT3-general.

2.4.2.1 Final check of the use case by using the CSFs of MOMENTUM and the NASSS framework

MOMENTUM

The MOMENTUM blueprint (17) was applied to check if UC-PT3-General had the critical success factors (CSFs) needed to take it from the pilot phase to large-scale deployment (see Annex 1 for the completed blueprint). On review of the blueprint (and in line with guidance provided in the WP6 Evaluation Manual) it was agreed that 6 out of 18 CSFs were more relevant to explore and address at a later stage of the SHAPES programme. These include CSFs concerned with the cultural readiness for the telemedicine service (CSF 1), the consensus position on the advantage of telemedicine in meeting compelling need (CSF 2), ensuring leadership through a champion (CSF 3), preparing and implementing a business plan (CSF 9), preparing and implementing a change management plan (CSF 10) and guaranteeing that the technology has the potential for scale-up (CSF 12). The CSFs below were deemed either to be in place or would be in place, before the pilot began. Further details on each CSF are provided below.

CSF 4. Involve healthcare professionals and decision-makers

Health professionals and decision-makers were partially involved in the development of the content of the project in Phases 1-3 and more input was sought in Phase 4 and 5 of the pilot. Healthcare professionals' views on the value of the technology associated with this use case and how it may work within existing care pathways was explored in qualitative feedback obtained after the pilot.

CSF 5. Put the patient at the centre of the service

Patients were involved in the development of the digital solutions through Phase 2 and 3 activities of the pilot — mock-ups and prototyping. Such activities helped the investigators to identify and produce information materials and training, to support patients to use the app and get the best possible results from taking part in the pilot.

CSF 6. Ensure that the technology is user-friendly

Patients and health professionals were specifically asked about user friendliness of the digital solutions during Phases 2, 3 and 5 of the pilot. Results from Phases 2 and 3 led to adaptions to enhance the user experience before the use-case was piloted in

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Phase 5. Questions were guided by the standard ISO 14915, which specifies 4 principles for the design of multimedia applications. Extensive training to use the digital solutions of this use-case was not required by participants.

CSF 7. Pull together the resources needed for deployment

The resources required for the deployment of the digital solutions for the pilot were available for the most part. However, research nurse availability to recruit individuals was not in place by September 2021, due to the COVID-19 pandemic. A six-month no-cost extension for PT3 was requested to delay the start of Phase 3 from May to August 2021 and the start of Phase 4 from September to December 2021 as well as to allow more time to recruit to Phase 5. It was hoped that research nurse availability may have been greater at this time. Further contingency measures included the ability to purchase research nurse time. However, research nurse time was not available for Phase 3 and Phase 4, instead a community partner (Mid and East Antrim Agewell Partnership) assisted with recruitment for Phase 3. Phase 4 was adapted to be tested on SHAPES naïve research staff rather than patient volunteers. Future deployment will require further negotiation with decision-makers and stakeholders.

There was sufficient time to deliver training to implement the digital solutions for use in the pilot. The devices had been identified and purchased with the exception of a pulse oximeter for use in Phase 4, this was still required as of May 2021. Identification of a suitable pulse oximeter was subsequently achieved in July 2021.

CSF 8. Address the needs of the primary client(s)

The primary clients of the PT3-gen use case were older individuals with multimorbidity. The use case was specifically developed to meet the needs of a persona that represented the primary client. The use case and digital solutions were adapted in response to feedback to user testing conducted with the primary clients. The solution offered addressed the needs of the health sector in that it served to offer health professionals a reliable way of monitoring their patients remotely and optimising their medication accordingly.

CSF 11. Assess the conditions under which the service is legal

Review of the legal requirements in Northern Ireland concerning the use of digital solutions revealed significant concerns regarding the planned piloting of UC-PT3-general use-case. If, as originally planned, healthcare professionals were to actively monitor and change treatment of participants using the information provided by the digital solutions this would mean that the digital solutions involved in UC-PT3-general would be classified as medical devices. These ‘medical devices’ would not be CE-marked and therefore the research sponsoring organisation would need to set aside a substantial fee for potential damages for each non-CE marked application. Furthermore, the use of non-CE marked medical devices in healthcare research would

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require NHSCT to partake in a detailed and lengthy approval process for a clinical trial of a non-CE marked device, which was outside of the remit of the pilot. For this reason, the use-case was revised in March 2021 to prevent the data collected being used to inform treatment. As the devices were now planned only to store and display data, rather than inform treatment, they were no longer classified as medical devices and there was no requirement for health professional oversight during the pilot, but to rather include healthcare professionals in the analysis and evaluation stage of the pilot.

Completion of a Data Protection Impact Assessment (DPIA) identified risks associated with the pilot. Additional input was sought from other work packages and the SHAPES Data Protection Officer at NHSCT. Data processing agreements were established with relevant partners to permit access to pseudonymised data.

CSF 13. Identify and apply relevant legal and security guidelines

Legal and security guidelines have been consulted and were applied accordingly. The main areas for consideration included data protection, ethical approval, compliance of devices with standards, penetration testing of software and storage of data. Penetration testing was conducted and NHSCT submitted a detailed ethical application to the Office for Research Ethics Committees Northern Ireland (ORECNI) and the NHSCT Research Governance office where it received approval to proceed. UNRF submitted a plan for the pilot activities to the respective National Bioethics Committee of Cyprus and received a positive response.

CSF 14. Involve legal and security experts

We worked with SHAPES partners together with legal and security experts to ensure that we had full confidence in the legality and security of the project.

CSF 15. Ensure that telemedicine doers and users are privacy aware

The protocol for the pilot detailed all the steps that were taken to ensure patients' privacy was protected. The Phase 5 of the pilot had received full independent ethical evaluation before permission was granted to undertake the study.

CSF 16. Ensure that the information technology infrastructure and eHealth infrastructure are available

The IT infrastructure for deployment of the technology was provided through the SHAPES platform. An appropriate infrastructure for deployment of the digital solutions within the organisation was in place for the pilot.

CSF 17. Put in place the technology and processes needed to monitor the service

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A system to monitor the pilot was set up with support from WP4 and WP5 partners. Local IT and community support were also available to help address minor issues with the use of the digital solutions. A system to monitor and mitigate incidences was established. It was not possible to predict all incidents that may occur in a research project, it was more appropriate to assess the relative risks of certain incidences and have an appropriate plan in place for mitigating and managing incidents. The local research project team and community support officers were available to support participants in resolving any issues they might experience with the digital solutions.

CSF 18. Establish and maintain good procurement processes

Standard local procedures which complied with all the requisite regulations were followed for the procurement of devices. Service level and maintenance agreements were in place as per contract.

NASSS

The NASSS framework (18) was used to detect areas of complexity in the project plan for piloting UC-PT3-gen and if needed, to make adaptations to the plan. Both the short and long versions of the NASSS-CAT questionnaire were considered and completed by the pilot team (Annex 2 and Annex 3). At the time the NASSS framework (18) was applied, of the 7 domains, there were 2 domains ('Technology' and 'Intended adopters') in which significant complexities were identified that, if not mitigated or addressed, were likely to affect the project's success at the piloting stage of the use case (Table 5).

Complexities were identified in other domains; however, these were related to a larger scale implementation and deployment of the use case into practice and so were not considered to be relevant at this stage of the project. They provide a useful basis for further exploratory research (Table 5).

Table 5: Complexities and mitigation measures identified using the NASSS framework (PT3-gen)

NASSS complexity domain	Uncertainties detected	Mitigation measures taken
Technology	Overlap of functionalities between eCare and eHealthpass (concerning vitals monitoring).	Commencement of fortnightly meetings between technical partners and use case leaders to discuss and decide upon technical aspects of the use case (points 1, 2).
Technology	Responsibility for building the Front-end App and HCP portal that presents the functionalities of the	

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NASSS complexity domain	Uncertainties detected	Mitigation measures taken
	digital solutions had not yet been assigned.	By May 2021, uncertainties regarding overlap in features (e.g. vitals monitoring) were addressed and resolved. EDGE assumed responsibility for developing and deploying the Front-end App. With the removal of the HCP oversight, the HCP dashboard functioned as a researcher portal during the pilot. For these purposes, an integrated portal was not necessary.
Technology	A pulse oximeter had not been identified for use during the pilot.	Inclusion of a pulse oximeter in the 1st SHAPES Open Call and PMB notified of potential delay to timeline.
Technology	There was no contingency plan for device procurement should any issues arise.	A small number of devices were procured and on-site by September 2021 to facilitate prototype testing and to maximize the manufacturers' 1-year warranty. This provided an early indication regarding potential delays in procuring the additional units needed for phase 4 and 5 of the pilot.
Technology	The flow of data and data storage location was not yet confirmed.	Cross work package alignment meeting set up between work package

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NASSS complexity domain	Uncertainties detected	Mitigation measures taken
Technology	The exact role and functionality of the platform had not yet been defined/communicated to the use case leaders.	leads and pilot leaders to discuss data flow and functionality of the SHAPES platform.
Technology	Compliance with governance, standards and regulations needed to be addressed for each component in the system.	Expert opinion on medical device regulations sought and a method of highlighting and tracking the progress of key governance issues created. A review of medical device regulations in Northern Ireland and the indemnity arrangements identified that the way the use case was originally set-up required extensive indemnity to be put in place to conduct a clinical trial of non-CE marked medical devices. By changing the way in which the data were used, i.e., data was stored and displayed without any changes and did not inform medical treatment, this allowed the devices to be re-categorised and they were no longer classified as medical devices. Expert opinion from the MHRA was sought in March 2021 and NHSCT were advised the revised pilot plan complied

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NASSS complexity domain	Uncertainties detected	Mitigation measures taken
		with the medical device regulations.
Intended adopters	The intended adopters of the technology are primarily multi-morbid older individuals. The input required from this group will be substantial but could vary between users and still be of benefit. Input may range from taking measurements using devices but not actually logging into the App to full engagement with all the available features.	User testing and prototyping in Phase 2 and 3 aimed to help enhance the user experience before the technology was piloted in Phases 4 and 5.
Intended adopters	Level of digital literacy in the intended patient participant population. As a minimum requirement service users will need to have Wi-Fi already installed in their home and have their own android device to access the technology.	User experience evaluation will aim to capture how well the technology was accepted by patients.

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2.5 Phase 1

2.5.1 PACT and FICS Scenario

Table 6: PACT (PT3-gen)

Code	UC_PT3-gen	Version	1.0	Date	2021/05/18
Applicable SHAPES Persona	Roberto				
Applicable SHAPES use case	UC-PT3-gen Supporting multi-morbid patients, older patients				
People *Roles and/or actors of typical users involved in delivering and receiving the telemedicine intervention*	• Patient: 65+, lives at home. No cognitive impairment at recruitment to the study. Multiple illnesses e.g., heart failure, diabetes, hypertension, chronic obstructive pulmonary disease and has multiple daily medications. Android smartphone user with access to the internet.				
Activities *Activities to be performed by the actors in order to successfully provide and receive the telemedicine intervention procedures for the professional and the patient; Parameters that determine the measures used in the intervention*	**Patient** • Measure blood pressure daily • Measure blood glucose as required • Measure weight daily • Measure heart rate daily • Measure oxygen saturation daily • Complete daily/weekly/monthly/one-off questionnaires • Send the data from the clinical devices to the SHAPES App (and automatic upload to SHAPES platform) • View list of medication • Daily medication reminders available				
Context *Social-medical relevance of the telemedicine intervention; privacy issues; risks for the patient; locations*	• Smart clinical devices to be used in patient's own home to help patients with multiple health conditions to self-monitor these diseases. • SHAPES App will help patients track and self-manage their conditions. This data will not be reviewed by healthcare professionals to perform active monitoring. • Maintaining privacy of data is of the utmost importance and will be upheld by allocating each participant a unique study number. An identification list (including name and DOB) will be held at the local pilot site. • GDPR and ethics in line with WP8. • Data and servers will be located within the EU.				

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Code	UC_PT3-gen	Version	1.0	Date	2021/05/18
	• English and Greek language. • Locations; NHSCT in Northern Ireland, UK. University of Nicosia Research Foundation, Cyprus.				
Technology *Type of information/parameter that are relevant in monitoring the health status; type and frequency of accessibility of information; feedback modalities (communication)*	• More detailed information can be found in the data plan for UC-PT3-gen. • Baseline demographic information Age (year not DOB) Sex (M/F) Smoking history (never smoked/used to smoke/current smoker) Height (cm) Education • Baseline medical history- Medicine (number of medicines/chronic or as required/name/ strength/ frequency/ date) Diagnoses (medical condition) Supplemental oxygen (yes/no) Implanted cardiac device (pacemaker/ implanted cardioverter defibrillator/ cardiac resynchronization therapy) Left ventricular ejection fraction (%) Rhythm (atrial fibrillation/ sinus rhythm/ atrial flutter) Pacemaker present (yes/no) • Changes to medication as the pilot progresses (stop/start/change strength/change frequency) • Heart rate (beats per minute) once daily • Oxygen saturation (%) once daily • Blood pressure diastolic and systolic (mmHg) once daily • Blood glucose (mmol/L) • Weight (kg) once daily • Questionnaires • Reminder/alert to complete questionnaires, use clinical devices and take medication • Feedback via app to participant on whether tasks have been completed. • Feedback via browser to researchers to monitor adherence to the intervention				
Scenario	*Older individual*				

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Code	UC_PT3-gen	Version	1.0	Date	2021/05/18

John is 70 years old and lives with his wife in their own home with a garden. He has some basic activity — short walks outside home and wandering around his home and garden. He can eat, get dressed and have a shower independently. John spends most of his day at home.

John lives with heart failure, diabetes and several other chronic conditions. He is prescribed around 5-10 pills per day, 2-3 of which control his heart failure. He also takes insulin to control his blood glucose levels. He usually takes his medication as prescribed. Once a week he takes a medication before breakfast for his bones. He takes this on a Monday. John and his wife store their medicines in baskets, 1 for each of them, in the kitchen.

John has recently been discharged from hospital after becoming acutely unwell due to a decompensation event. This was John's third decompensation event in the past year. While in hospital he was started on a new type of insulin and a new tablet for his blood pressure. John is happy to participate in the UC-PT3-gen pilot so that he can learn more about managing his conditions and receive some help remembering to take his new tablet. Once John has consented to take part and has been trained on the equipment provided he is keen to see how the devices will help to keep him healthy. He also is trained on the different sections within the SHAPES App where he can view his information. There is a list of his current medication and a calendar display where he can see what medications he is due to take each day.

A typical day during the SHAPES pilot for John proceeds as follows:

- John wakes up at around 8.00am. On Mondays he takes the pill for his bones and he has to sit upright for 30 minutes before getting up. John's wife sometimes has to remind him to take this particular tablet before he gets up, but when he started the SHAPES pilot he can check his

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Code	UC_PT3-gen	Version	1.0	Date	2021/05/18

SHAPES App to see what medications he is due to take today.

- At around 8.30am he washes and shaves, weighs himself using the **SHAPES weight scale** and gets dressed.

Having recently changed his insulin it is important that John monitors his blood glucose before meals to ensure he is using the correct amount of insulin.

- John uses his new **SHAPES glucometer** to measure his blood glucose level and is able to adjust his insulin himself. He can administer his insulin himself, but sometimes asks for assistance from his wife.
- After administering his insulin, John eats breakfast. Around half an hour after breakfast, John takes his blood pressure using the **SHAPES blood pressure monitor**, and measures oxygen saturation level and heart rate using the **SHAPES pulse oximeter**. He was told that the readings will automatically appear in the SHAPES App so he doesn't really pay attention to what each one says just yet. He can check them on his phone later.

Before the pilot, John had not used a blood pressure monitor or a pulse oximeter before. He is familiar with getting his blood pressure taken in clinic and using the monitor he has at home is much the same. When John was in hospital, a nurse used a pulse oximeter to monitor his heart rate and the amount of oxygen in his blood, so he is familiar with the device and it is quick to use.

Since starting the pilot, John has been answering some questions every day through his phone. John's answers to the questions will help to develop a new technology that might be used in the future by his health care team to review his heart failure and predict decompensation episodes. The questions are easy to complete and are similar to the questions he gets asked

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Code	UC_PT3-gen	Version	1.0	Date	2021/05/18

when he visits the heart failure clinic. By answering them every day, it increases John's awareness of his own health. When he started the pilot, John chose to answer his daily questions at 11am. This is when he and his wife usually have a coffee together. John could answer these questions alone but he likes having his wife to check his answers with.

- At 11am, John sits down to answer his daily questions. The questions are:

1. Compared to the last 3 days, your legs-feet or any other part of the body are? Less swollen, the same, more swollen
2. Compared to the last 3 days, you feel… worse, the same, better
3. In the last 3 days, did you take any additional medication without supervision? Yes, no

If there is nothing unusual, the questions stop here. While he is on his phone, John looks at his readings for that day. He looks at his weight, blood pressure, heart rate and oxygen levels every day. He doesn't bother looking at his blood glucose because he saw it earlier when he was working out how much insulin to use.

His weight is important to John as he knows that if his heart failure gets worse, he starts to retain fluid and his weight increases. By using the scales each day he can track if there are any changes in weight and see how this changes over time. John has a record of what his previous values are for blood pressure, heart rate and oxygen levels. He likes being able to look at these readings and is feeling more confident about what they mean for his health.

Today, he notices that his blood pressure reading looks a little high but doesn't think too much more about it as he is going out for a short walk with his wife to post some letters before lunch.

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- At 1pm, again before eating, John measures his blood glucose. His new insulin regimen means he only needs to inject insulin twice a day, which he does before breakfast and dinner. He checks it anyway as he is used to doing this and he has only been using the new insulin for a few weeks.

John spends the rest of the day in the house or out in the garden. He doesn't think about the SHAPES App at all until after dinner.

- At 6pm, John measures his blood glucose again and administers his insulin accordingly.
- He takes his evening medicines.

There is a task list section of the app where he likes to check whether he has any outstanding tasks to complete. It's the same most days but once a week there is an extra survey to answer about his medications.

Local researcher

A researcher will review the **SHAPES dashboard** regularly to help the participants adhere to the intervention. On this dashboard they are able to view:

1. The list of participants taking part in the pilot at their site. The dashboard presents the participant's unique identification number only. They have a separate list that links identification numbers to the participants' names and contact details.

2. Participants' profiles:

- Baseline demographic data and data required for VICOM HF Predictor.
- Medicines list including all treatments, doses and frequencies — editable by researcher
- History of clinical parameters that require daily monitoring including: blood pressure, weight, oxygen saturation, heart rate, blood glucose
- History of questionnaire responses

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Code	UC_PT3-gen	Version	1.0	Date	2021/05/18
	• History of daily tasks/reminders • Dynamic thresholds • Use of unscheduled care including hospitalisation details • Check how the participant has used the App e.g. how often they log in, what sections of the App they use most frequently.				

Table 7: FICS (PT3-gen)

Category	Details
Function and events *Functionality of the intended system which is capable to realize actor's activities*	1) The system will offer the user the devices and the functionality to: • Measure blood pressure daily • Measure blood glucose twice daily (or more, as prescribed) • Measure weight daily • Measure heart rate daily • Measure oxygen saturation daily 2) In addition, the system will provide the option to send specific questionnaires that the user shall fill in including the daily VICOM questions and the Medication Adherence Report Scale (MARS). 3) Using the "notifications" functionality, the user can follow their daily tasks. 4) Medication list 5) These functionalities will be provided via an android application (App) for use by older individuals and a browser-based system for the researcher dashboard. 6) User event logs to allow monitoring of how the participant uses the App Older individual functionalities:

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Category	Details
	• App authenticates the user • Patient account and social profile including consent module • Record of blood pressure, weight, oxygen saturation, heart rate (EDGE) • Blood glucose (Gnomon) • Medication list (Gnomon) • Daily tasks/reminders (EDGE and Gnomon) • Questionnaire data (EDGE) - VICOM questions • Questionnaire data (Gnomon) – MARS questionnaire Researcher dashboard: • App authenticates the user • New patient registration interface • Patient list • Patient profile including consent module • Patient monitoring dashboard to include blood pressure, weight, oxygen saturation, heart rate, blood glucose, history of notifications • Medication list (Gnomon) • Questionnaire data (EDGE/Gnomon) • Display personal dynamic ranges of weight, blood pressure, heart rate, blood glucose and oxygen saturation (TREE), will be displayed through the Researcher dashboard. • HF Decompensation Prediction tool (VICOM) - results blinded to researcher until data collection complete
Interactions and usability issues *User-system or system-component interactions meditating actor's activities; Types of the*	In this use case, we expect to have 2 users: - Older person - Researchers There will be 2 front-ends: 1 for the older person and another for the researcher. The system will interact with the user in a single front-end with the functionalities as described above. Patient list shows those patients who have given consent, along with the patient's profile (baseline information, medication list etc.)

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Category	Details
interactions, e.g. unidirectional data streaming service or reliable messaging service	The researcher will be able to view the same data as the older person. In addition, they will be able to view baseline data, user event logs and the results of the analytics (prediction of HF and out of range measurements for the different vitals). A medication list will be populated at baseline and can be viewed by the older person. Any updates can be made by the researcher, informed by the older individual, throughout the pilot.
Content and structure *Variables of the interaction*	The front-end for the older individuals will be an Android App. The researcher front-end will be a browser-based web Portal. The SHAPES App will be the main entry point for the older individuals and in this use case it makes connection to eCare (from EDGE) and eHealthpass (from Gnomon). Separate dashboards will provide the results from the analytics made by TREE – vitals control - and VICOM - HF decompensation. These analytics work as back-end services and their results are visible via the researcher dashboard. For full usability, the patient must download the mobile application and use the clinical devices provided.
Style and aesthetics *Look and feel of the system*	UC-PT3-general clinical devices 1. Weight scale  2. Glucometer

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Category	Details

3. Blood pressure monitor

4. Pulse oximeter

Mock up images of the SHAPES App (see details in D5.4).

These images were presented as the mock-ups for phase 2 and were subject to change.

SHAPES App login

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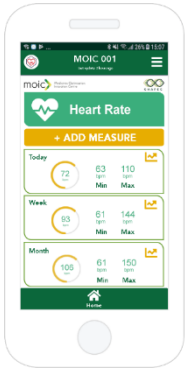
Category	Details

SHAPES App menu

SHAPES App – EDGE HR display



SHAPES App – EDGE HR manual entry

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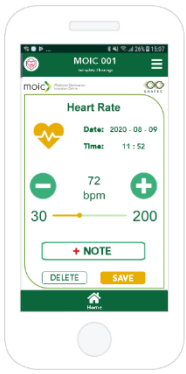
Category	Details



SHAPES App - Gnomon blood glucose display

SHAPES App – Gnomon blood glucose manual entry

SHAPES App – EDGE daily survey

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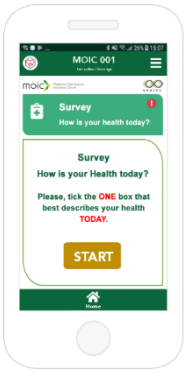
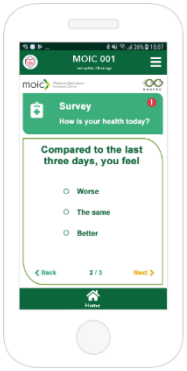
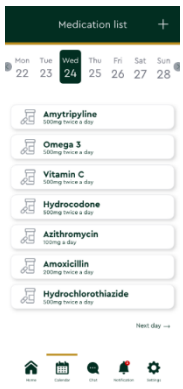
Category	Details





SHAPES App – Gnomon medication list



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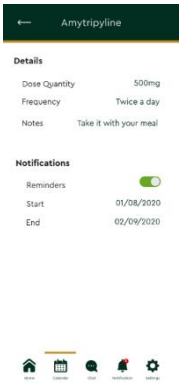
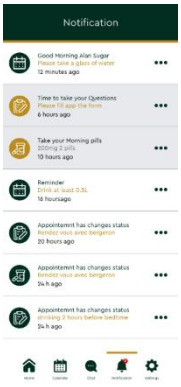
Category	Details



SHAPES App- Gnomon notifications



2.5.2 Key performance indicators

Key Performance Indicators (KPIs) are defined as a set of measures that focus on the factors most critical to a project's success. KPIs are measurable and quantifiable with a target or threshold. They measure a performance in critical areas by showing the progress or lack of it, towards realising the objectives of each specific use case. The following KPIs have been chosen to determine whether or not the pilot for UC-PT3-general has been successful.

Failure to meet 4 or more of the KPIs will indicate that major revisions to the use case and associated digital solutions are needed before further evaluation or deployment.

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Recruitment and retention

1. At least 80% of the target cohort were successfully recruited into the pilot during the recruitment period (i.e., 24 participants were recruited in NHSCT (lead site) and 8 participants recruited in UNRF (replicating site).
2. At least 80% of recruited participants remained enrolled in the pilot until the end of the study.

User engagement and acceptance

3. The overall user experience quality of the app as measured using the short version of the UEQ-S (2) was classified as 'Excellent', 'Good' or 'Above average' based on published benchmark data.
4. At least 60% of participants continued to login to use the App daily after 2 weeks of the pilot.
5. At least 60% of participants scored an above average rating (>68) in the SUS (8).

Collection of data

6. Sufficient data was collected from participants to allow the HF decompensation prediction tool to generate a percentage risk of decompensation at least once per week for at least 60% of participants.
7. At least 60% of participants completed the MARS (14) at least once a month during the pilot.

2.5.3 Timeline of pilot activities

The original timeline of pilot activities according to the Description of Work was to conduct Phase 1 and 2 between November 2020 and April 2021, then start with Phase 3 (prototype testing and hands-on training) in May 2021 with Phase 4 (deployment in controlled environment) starting in September 2021 and Phase 5 (large scale pilot activity) in January 2022. NHSCT were responsible for conducting Phases 1–5 and UNRF had input into Phases 1–4 and conducted Phase 5 locally.

Two formal requests to extend Pilot Theme 3 were approved by the Project Officer. The first extension request was requested for Phase 3 (hands-on training) where the SHAPES partners needed to be in direct contact with the participants, therefore the start of phase 3 was postponed from May 2021 until it was safer, with relation to COVID-19, to November 2021. At this point, an acceptable remote method was agreed and implemented as COVID-19 was still preventing in-person meetings in this vulnerable population in Northern Ireland at this time.

Additionally, a further use case was incorporated into Pilot 3 in December 2020, investigating participants with chronic obstructive pulmonary disease. This increased

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the scope of use of the SHAPES platform and gained a valuable insight to a cohort of respiratory patients. The additional time allowed the full work-up of this use case.

Phases 4 and 5 involved training participants on the use of medical devices and recruiting from outpatient clinics. The COVID-19 pandemic continued to result in significant clinical staff redeployment and only essential outpatient services were running in a number of sites. This impacted on our ability to recruit using outpatient clinic lists at this time and an extension to the start of phase 4 and 5 from September 2021 to December 2021 provided time to identify alternative recruitment processes, adapt methods and identify resources to achieve this.

An additional extension was granted due to technical issues arising from Phase 4. These were specifically encountered by PT3-general, the issues were associated with medication function and login issues due to expired tokens. Unfortunately, these issues were unable to be resolved in the timeframes and resulted in part of the functionality, provided by eHealthpass, not being used in PT3-General at the NHSCT. As a result of these technical issues, an extension was granted to permit this deliverable D6.4 to be submitted in M45, July 2023.

	2020		2021											2022											2023						
	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
Planned timeline: PT3	phase 1		phase 2				phase 3			D	phase 4				phase 5				D													
Actual timeline: UC-PT3-gen	phase 1		phase 2				phase 3							D	phase 4				phase 5													D
UNRF replication																										phase 5							D

Figure 3 Planned and actual timeline of pilot activities (PT3-gen)

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2.6 Phase 2: Testing of mock-ups and prototypes

2.6.1 Methodology of testing

During Phase 2, validation was sought on the design of the user-facing digital solutions intended for deployment in UC-PT3-general. These comprised of the SHAPES Front-end app (EDGE), eCare App (EDGE) and the eHealthpass App (Gnomon), which were specifically adapted for the purposes of UC-PT3-general.

Remote sessions were conducted with participants via video call using the Zoom video telephone software program. A PowerPoint presentation was shown via screen share during which participants were presented with brief background information about the SHAPES project and an overview of the purpose and features of the PT3-general use case digital solutions. Mock-ups, e.g., visual images of all the types of screens a patient was likely to encounter when using the App, were then presented to participants. PowerPoint presentations can be viewed in Annex 4.

At predefined intervals throughout the presentation, a researcher asked the participants questions on the design and layout of the mock-ups. These questions were a combination of open and closed questions designed to obtain both general and specific feedback about the mock ups. Questions were guided by the standard ISO 14915, which specified 4 principles for the design of multimedia applications. The principles were:

a) Suitability for the communication objective — the presentation of the information is suitable for achieving the goals of the providers and visitors.

b) Suitability for perception and understanding — the information transmitted is easy to understand and can be easily recorded.

c) Suitability for exploration — the participant is able to find the desired information or complete their task without any previous knowledge or experience regarding the presentation or structure of the information offered.

d) Suitability for user motivation — a participant must be encouraged to act. By focusing on the needs of the participants, an appealing presentation and goal-oriented guidance, the participant can be motivated.

Hard copy versions of the mock-ups were provided if requested and participants, (particularly the target users), were offered the opportunity to view the materials off-line and a second video call was scheduled (if needed) to continue gathering feedback.

Participants

Phase 2 was conducted in at least 2 participants from each of the 3 different types of user groups:

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1. Target users (≥ 65 years' old; diagnosis of HF and diabetes; living at home; owns an android smartphone or tablet; live internet connection and able to video call);
2. Healthcare practitioners (nurse, doctor or pharmacist from the diabetes and heart failure clinical networks);
3. Support service providers (IT support professional, community support officer).

Identification of participants

Eligible participants from the service user and support services groups were identified by the Mid- and East-Antrim Agewell Partnership (MEAAP), which had established links with the community (see https://www.meaap.co.uk/). MEAAP is a local inter-agency based partnership aimed at improving the lives of Older People aged 50 years and over. MEAAP community support officers reviewed the eligibility criteria and identified eligible individuals within their client base. Eligible healthcare practitioners were identified by the NHSCT through professional contacts and liaison with heart failure and diabetes clinical networks. MEAAP nominated a community support officer to participate in the study and provided feedback from a 'Support services' perspective. NHSCT contacted suitable charitable healthcare organisations to identify suitable support service providers in the community to participate in the study.

Informed consent procedure

Eligible target users were provided with a participant information sheet (Annex 5) explaining the background and purpose to the study and what they can expect to happen if they agree to participate. Those who agreed to take part were given a consent form (Annex 6) by a MEAAP officer. Signed consent forms and contact details were provided to the NHSCT researchers to proceed with the study activities.

Eligible healthcare practitioners and support service providers were provided with a participant information sheet (Annex 5) explaining the background and purpose to the study and what they could expect to happen if they agree to participate. Those who agreed to take part were given a consent form (Annex 6) by a NHSCT researcher.

Informed consent for all participants were taken remotely with the following format of signatures collected where appropriate:

- Typewritten;
- Scanned;
- An electronic representation of a handwritten signature;
- Handwritten signature posted to research personnel.

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Data collection and analysis

Video calls were digitally recorded — capturing both the audio and visual responses (e.g., frowning, smiling) of the participants.

Recordings were played back and used to complete a feedback report. No identifiable information was recorded on the feedback reports. Recordings were transcribed if necessary and any identifiable information was anonymised during the transcription process.

2.6.2 Results of testing

A full feedback report from the Phase 2 mock-up presentations including recommendations made to technical partners is provided in Annex 7. An overview is provided below.

The Phase 2 mock-up presentations with recruited participants were conducted between 22nd March and 13th April 2021. Presentations were conducted remotely via the Zoom video conferencing software. All sessions were recorded and the recordings used to generate a feedback report for each participant.

Participants

Seven participants consented to take part in the study. They included 3 male and 4 female participants. The breakdown of participant type was as follows:

- Two target users (TU1 and TU2) who were recruited via the Mid- and East-Antrim Agewell Partnership (MEAAP). Both target users were aged over 65 years' and had diagnosed heart failure and type 2 diabetes. TU1 reported confidence at using their smart phone to be 2 or 3 out of 5. TU2 rated themselves at 4 or 5 out of 5. Both primarily used their phones for messaging and calls. TU1 additionally used their device for social media and TU2 for reading news.
- Two healthcare professionals (HCP1 and HCP2) were recruited via contacts at the NHSCT. Both HCPs were registered pharmacists. One worked in diabetes care and the other in acute heart failure. Both healthcare practitioners reported a confidence rating of 5 out of 5 for using their smart phone. Social media, messaging, calls and browsing the internet were cited as main uses. HCP2 additionally reported using their phone for simple word games.
- Three support service providers (SSP1, SSP2, SSP3) were recruited from staff at MEAAP, a community support provider for older people, and the Northern Ireland Chest Heart and Stroke (NICHS), a charitable organisation that provide support for people with heart failure. All rated their confidence at using their

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phones as 5 out of 5 and reported calls and messaging, with the additional uses of internet shopping and browsing (SSP1) and banking (SSP3).

Overview of feedback

Using the feedback collected during the presentations and interviews with participants, the Phase 2 mock-ups of the SHAPES App, eCare and eHealthpass components of the PT3-general use case user App were assessed using the ISO Standards for multimedia design (ISO 14915).

1. **Suitability for the communication objective** *(i.e., suitability of the presentation of the information for achieving the goals of the providers and visitors).*
   - There were issues with the size of text on every mock-up presented to participants.
   - The target users both found it difficult to see and read the information presented on each screen.
   - The screens that contained minimal, simple information or instructions (e.g., the survey screens) were generally favoured over those that had multiple sections/compartments (e.g., the HR screen).

2. **Suitability for perception and understanding** *(i.e., is the information transmitted easy to understand and can be easily recorded?)*
   - The purpose of each screen and what information it was transmitting to the user was understood by the health professionals and support service providers. The target users required additional explanation to understand the purpose of the screens and the information.
   - Target users were generally confused over the purpose of the App and how the user was meant to engage with it.

3. **Suitability for exploration** *(i.e., is the participant able to find the desired information or complete his task without any previous knowledge or experience regarding the presentation or structure of the information offered).*
   - The target users had difficulty or were unable to describe how they would complete many of the tasks within the App.
   - Instructions for the user need to be simple, direct and use recognisable terminology (e.g., click here, type in this box).
   - Explanations need to be provided to users. The target users may not be as familiar with certain icons or features as more proficient users.

4. **Suitability for user motivation** *(i.e., a participant must be encouraged to act. By focusing on the needs of the participants, an appealing presentation and goal-oriented guidance, the participant can be motivated).*
   - Participants generally liked the simplicity of the design of the App.
   - One participant (SSP1) felt that the colours could be more engaging.

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- Screens where there was lots of information were deemed to be potentially overwhelming for users and could be off-putting.
- One user felt that the amount of recording required would be off-putting to many older people.
- Opinions about motivation to use the App differed between the 2 target users: TU1 was particularly motivated by participating/using the App for their health yet TU2 was unsure of motivation to take part if no HCP oversight.

2.7 Phase 3: Hand-on Experiments

2.7.1 Methodology of hands-on experiments

Hands-on experiments were conducted remotely due to restrictions on in-home visits during the COVID-19 pandemic. Participants were invited to join a 2-part online video conference (supported by Zoom video conferencing software) with NHSCT researchers in order to take part in the hands-on experiments. A relative, friend or carer could accompany them during the call if requested. Prior to the call, researchers identified any connectivity or technical issues that may have prevented the participant taking part and issues were managed as necessary. The research plan was approved by Head of Service, Professor Michael Scott.

Participants

Phase 3 hands-on experiments were conducted with 3 target users of the SHAPES App (i.e., ≥ 65 years' old; diagnosis of heart failure and/or diabetes; living at home; owns an android smart phone or tablet; live internet connection and able to video call). Gender equality was sought but not achieved in the group of older person participants.

Eligible participants were identified by MEAAP which had established links with the community. MEAAP community support officers reviewed the eligibility criteria and identified eligible individuals within their client base. Informed consent for all participants was taken remotely (see Annex 8 and Annex 9 for participant information sheets and consent forms).

Method

The prototype was accessed by participants via an internet-enabled tablet device provided by NHSCT. The device was disinfected between uses using the recommended local process. Technologies were presented as a functioning prototype with the eCare and eHealthpass digital solutions accessed via the SHAPES Front-end App. During the first session, a researcher guided the participant through a series of steps and tasks to demonstrate the different functionalities of the App and trained the participant on how to use it. Instructions were presented on screen during the call and

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participants were also sent a user training manual prior to the session that described each step using words and images (Annex 10).

The steps and tasks demonstrated were:

1. Accessing the prototype;
2. Navigating to different features from 'Menu';
3. Navigating to 'Menu' from within the App;
4. View and enter heart rate;
5. View and enter blood glucose;
6. View medication list;
7. View and complete daily survey;
8. View and complete weekly survey;
9. View eHealthpass 'daily to-do list';
10. View eCare 'daily to-do list'.

The pace of the session was determined by the participant. After the demonstrations there was a break to allow the participant to rest, process the information provided, and familiarise themselves with the app.

When the second session began, participants were asked about their experiences using the App and if they had any questions or queries. Feedback about the App was collected as detailed below.

Collection of feedback

Feedback was collected at different time-points during Phase 3 using a number of different methods.

A concurrent 'think out loud' approach was used to collect reactions to the App and identify any areas that will require particular attention during the demonstration of the App and user training. The participants were encouraged to verbalise their reactions, thoughts, feelings and opinions about the prototype throughout their engagement with the researchers. Notes were taken by the researchers and the session was recorded to capture feedback accurately.

Participants' use of the prototype was digitally tracked through the generation of user event logs. These logs were maintained, managed, reviewed and analysed by technical partners to monitor performance of the prototype and not for the purposes of assessing user engagement. Therefore, the findings from these analyses are not reported here.

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When participants returned for the second session, they were asked to complete a short activity under observation, i.e., a moderated test. During the test, the participants were asked to 'think out loud' and thereby point out 'stumbling blocks'.

After the test, participants were asked to complete the UEQ-S (2) to collect quantitative data about the impression of the participants' user experience. There are 8 items and respondents mark on a 7-stage scale between 2 terms in each item (e.g., attractive ○ ○ ○ ○ ○ ○ ○ unattractive).

Participants were then interviewed by the researcher to collect the participants' views about using the prototype. A schedule was followed during the interview but the researcher may also have referred to conversations and topics raised during the sessions. Semi-structured questions explored users' general feedback about the App including:

a) Ease of use;
b) Design;
c) Utility;
d) Gender equality;
e) Quality of training;
f) Overall satisfaction.

Data analysis

Video calls were digitally recorded and automatically audio transcribed by the Zoom video conferencing software. Transcripts were checked and edited for accuracy, used to aid analysis and then deleted.

Results of the UEQ-S (2) were reported alongside interview data in a feedback report. No identifiable information was recorded on the feedback reports.

A completed report including practical recommendations, was presented to and discussed with technical partners.

2.7.2 Results of the hands-on experiments

Recruitment

MEAAP assisted in the recruitment of target user participants for Phase 3. It was anticipated MEAAPs flagship project IMPACTAgewell® would provide a database of people aged over 65, who would potentially be interested in participating in the research. From the outset, MEAAP faced difficulties in recruiting participants due to the eligibility criteria namely age, specific combination of long-term health conditions

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and the ability to use a tablet/computer i.e., digitally literate. The IMPACTAgewell® database contains approximately 1800 older people in the Mid and East Antrim area. Of these, only 29 service users have both diabetes and heart failure. Furthermore, 4 service users had declined the IMPACTAgewell® project and were not contacted and 2 service users were unfortunately deceased. The remaining 23 service users were contacted to discuss interest in the project. MEAAP recruited 2 service users from this pool of potential candidates, while the remainder declined due to issues with vision, hearing and digital abilities amongst other issues.

MEAAP also put out a call for participants across all social media channels, including Instagram, Twitter and Facebook, which reached approximately 3350 people. Unfortunately, there was no interest received from this approach. Additionally, MEAAP reached out to local charities including Northern Ireland Chest Heart and Stroke (NICHS) and Diabetes UK for help with recruitment but this was not feasible within the short timeframe available. Due to the difficulty recruiting the remaining 2 participants, the eligibility criteria were then reduced to 1 long term health condition, i.e., diabetes or heart failure. MEAAP identified 3 potential candidates, 1 of which successfully participated in the research. This change in recruitment criteria was not considered as potentially altering the overall results of the use case.

Participants

Three male service users (PT1, PT2 and PT3) were recruited by MEAAP to participate in the Phase 3 hands-on experiments. One female participant was recruited but withdrew before the interview could take place. Reason for withdrawal was inability to take part in the remote interview. PT1 and PT2 had both diabetes and heart failure and had previously taken part in Phase 2 and were familiar with the SHAPES project. PT3 had no prior knowledge of SHAPES and had diabetes alongside other heart-related comorbidities. PT3 did not have heart failure. All 3 participants were computer literate and interested in technology. PT3 had no prior experience of using an App.

Service user feedback

The Phase 3 hands-on experiments were conducted with the recruited participants between 8th and 16th November 2021. Overall, feedback about the App was positive. Participants were able to use the App easily, were happy with the design, and understood the purpose of each function. Participants experienced difficulties navigating out of the various features within the App and returning to the SHAPES menu page. This was exacerbated by the different navigation systems used by the 2 Apps deployed in this use case. Confusion also arose with regards to the separate 'to-do list' functions within the App. A full feedback report is available to view in Annex 11. Detailed service user feedback from each participant is presented in Table 8.

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Table 8 Service user feedback from hands-on testing (PT3-gen)

Participant	PT1	PT2	PT3
Ease of use	Password difficulty using capital letters	eCare data input no problems. Preference for slider	Intuitive asked ahead about the next step, e.g., 'save'
	Password difference between zero and letter 'o'	Navigation back to menu page — confused by extra pages that appeared in both eCare and eHealthpass	eCare data input no problems. Slider difficult to get precise but +/- buttons complement nicely. No preference
	Navigation to menu page — difficulty remembering the different methods provided by different app providers	Navigation between pages — participant sometimes inadvertently skipped pages	Confusion over functions of the App vs. features of device. Asked about 'tick' on keyboard (participant was tablet naïve)
	Navigation from HF survey page — no back arrows present	Navigation back — back arrow consistently worked for participant. Success of swipe function was inconsistent.	Pop-up boxes — didn't seem to come up when expected to when exiting the surveys.
	HF survey — participant tapped where it said 'surveys you have 1 survey' rather than HF predictor	eHealthpass data input - no problems	Home button — 'handy'
	Navigation to 'to do' lists and between different App provider sections	Answering survey questions — all fine	Computer literacy needed — those with no experience would be scared to use
	Straightforward/easily understood/simple with practice	Navigation out of HF Predictor — no back arrow or home button. Couldn't perform swipe	No concerns about ease of use. Easier than anticipated

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Participant	PT1	PT2	PT3
		function. Had to come out of App completely.	
	User must be digitally literate	Two finger swipe – reveals side panel.	
	Easier than anticipated	Navigation out of MARS survey – 'home' button works well when it's there. PT unable to get swipe to work.	
		eCare dashboard – delay to load.	
		Navigation out of blood glucose/HF Pred/MARS survey - complicated patient found workaround. Took 20 mins of 'playing around' to discover workaround.	
		Computer literacy and interest – needed for people to be able to use.	
		Navigation should be easier. Should be a home or back button on every page.	
Design	Blood glucose graph- easily understood	Medication list – some information not displayed. Only sections with data in them displayed?	HF Pred- hard to select correct answer. Would prefer gap between options.

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Participant	PT1	PT2	PT3
	MARS - confusion with the term MARS consider changing to 'Weekly survey' on menu page	Fit for purpose	Text versus icon- Participant looked for text rather than icon.
	MARS questionnaire layout - understood very easily	Colours – green on white is good. Avoid black on white.	Terminology inconsistent between Apps for accessing to-do lists (today/calendar)
	Improvement from mock-ups	Text size – all ok on tablet. Would expect it to be more difficult to read on phone. Dislikes using accessibility features.	Simple and straightforward design. No problems reading.
	Clear display	Clear display	Colours not appropriate for those who are colour blind, Better black and white.
	Appropriate size (on tablet)		Perfect design. Wouldn't change at all.
			Smaller text on phone – may need glasses to read.
Utility	Slider function – training required on this	Medication list – not useful. Maintains own list. Useful for people with memory problems. Details about what the medicines is for may be useful.	eCare 'notes' section - Quickly understood what this was for

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Participant	PT1	PT2	PT3
	Max/min values- unclear that these were max/min values	Motivation to use - people would get bored. Data input would be a burden. Bluetooth connection would reduce burden.	Good comprehension of use of App.
	To do lists are useful	Interpretation of readings – would like info on meaning of readings.	Medication list - good to see that information
	Broad application to health (lots of functions available)	Suitable to needs – provided a doctor was getting the info. Less concerned with self-management.	Medication list- queried what the delete button was for
	Exercise measurement as an additional functionality	Exercise and diet measurement as an additional functionality	Push notifications/ medication reminders - would not use and not good for older people. Shouldn't replace physical help with medications
			Wouldn't like if it got too invasive or complicated
			Privacy and security of personal information very important
			Appropriate for needs and age- participant only has diabetes but was interested in the heart monitoring due to other comorbidities
			Already monitors heart rate using

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Participant	PT1	PT2	PT3
			wearable monitor but does not keep a record. If it linked to this app and was able to show to doctor - would be excellent.
	Medication list not so useful perceived that doctors look after that		Information- good to have information in one place. Can be shown to doctor.
			Big scope- Could be extended to other conditions.
Gender neutrality	Appeals to men and women the same	Appeals to men and women the same	No difference
Quality of training	Measurements - training required to understand physiological measurements	Devices and self-monitoring – training would be needed to use the devices and how to self-monitor in general	Hands-on help - good to have someone face-to-face to help at start of training. Would have struggled without.
	Questionnaires - important to explain that the submit/next icon doesn't activate until questions are answered	Training manual – no problems. Helpful. Should contain more information on navigation	Informative. Simple. Not confusing. Straight to the point.
	Trainers – clarity between asking participant to do something vs. showing them what can be done on the App	Live training – very helpful. Stepwise a good approach	Online technical support- would be helpful

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Participant	PT1	PT2	PT3
	User manual display-discrepancy on Medicines information page on App vs. manual	Training for pilot - Quite a lot will be needed	
	User training essential		
	Training required on use of devices		
	Training was simple		
Overall satisfaction	Convenient	No problems using this App	Exciting
	Time efficient	Would continue using	Enjoyable
	Good	Concern over keeping people interested	Informative
	Self-management	Met expectations	Information at the touch of a button.

The moderated tests were performed well by participants. Tasks including entering dummy data, navigating to specific pages and completing questionnaires were completed with minimal/no prompts.

Participants' responses to the UEQ-S generally leaned towards positive attributes. The only attribute that was scored in the lower half of the scale was on the 'complicated-easy' pairing. UEQ-S responses are shown in Figure 4.

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PT1

obstructive	❍❍❍❍●❍❍	supportive
complicated	❍❍❍●❍❍❍	easy
inefficient	❍❍❍❍❍●❍	efficient
confusing	❍❍❍●❍❍❍	clear
boring	❍❍❍❍❍●❍	exciting
not interesting	❍❍❍❍❍●❍	interesting
conventional	❍❍❍❍❍●❍	inventive
usual	❍❍❍❍❍●❍	leading edge

PT2

obstructive	❍❍❍❍❍●❍	supportive
complicated	❍●❍❍❍❍❍	easy
inefficient	❍❍❍❍❍●❍	efficient
confusing	❍❍❍❍●❍❍	clear
boring	❍❍❍❍❍●❍	exciting
not interesting	❍❍❍❍❍●❍	interesting
conventional	❍❍❍❍❍●❍	inventive
usual	❍❍❍❍❍●❍	leading edge

PT3

obstructive	❍❍❍❍❍❍●	supportive
complicated	❍❍❍❍●❍❍	easy
inefficient	❍❍❍❍❍❍●	efficient
confusing	❍❍❍❍❍●❍	clear
boring	❍❍❍❍❍●❍	exciting
not interesting	❍❍❍❍❍❍●	interesting

Figure 4 UEQ-S responses to the SHAPES app after hands-on experiments (PT3-gen)

Recommendations for technical partner

A meeting was held on 23rd November 2021 to present service user feedback to technical partners. No specific recommendations were made rather, a follow-up meeting was arranged to discuss collaboratively how the issues that arose during the hands-on testing, particularly with navigation, could potentially be mitigated. It was agreed that the 'back' arrow would be present on all pages to avoid the need for participants to use the 'swipe back' function, which they found difficult to master. It was also agreed that the 'home' icon would bring the user to the SHAPES menu page on both Apps. Other suggested changes included modifying the wording in certain sections of the Apps, deactivating redundant pages and fixing bugs.

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2.7.3 Conclusion

The hands-on training was the second of 2 user engagement activities involving target users that were conducted for the PT3-general use case. It built upon the findings from Phase 2 wherein feedback on the physical appearance of the patient-facing aspects of the Apps was sought. For this activity, target users were able to interact with the Apps and test their functionality and how they interact with them. For the first time, all 3 components (SHAPES Front-end, eCare and eHealthpass) of the use-case were interlinked and presented to users as 'one' App. This allowed for any potential navigation issues or inconsistencies to be detected at an early stage and incorporated into feedback provided to the technical partners. Through collaboration and discussion, changes were agreed between the pilot site and technical partners to ensure that a balance could be struck between retaining the distinguishing features and functionality of each individual App and making the user experience as consistent as possible. Overall, the different Apps worked well together and, with the modifications mentioned in this section, the solution being brought forward into the next phase is fit for purpose.

Additionally, due to the difficulties in recruiting appropriate participants to Phase 3 resulting in large numbers screened and exhaustive efforts made to identify potential participants, it was discussed and agreed to change a number of eligibility criteria for Phase 5 of the pilot to assist in this regard. These changes were made with the intention of widening the pool of potentially eligible participants. Instead of participants ≥65 years, diagnosed with heart failure **and** diabetes, the NHSCT eligibility criteria was amended to include participants ≥60 years, diagnosed with heart failure **or** diabetes. It was hoped that this would greatly improve recruitment at later phases of the pilot.

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2.8 Phase 4: Small Scale Live Demonstration

A small-scale live demonstration of the SHAPES Platform and digital solutions being deployed in the Pilot theme 3 general use case (UC-PT3-Gen) was undertaken during Phase 4 of the SHAPES pan-European pilot campaign at the NHSCT. Phase 4 provided the opportunity to test the functionality of the App together with the clinical devices in a real-world environment. The demonstration tested the methods and procedures that were used in the larger scale (Phase 5) in the target population. The solution was tested in a real-world environment and sought to identify any issues with connectivity and transfer of data. It explored if amendments were needed to be made to processes, logistics or documentation that were used in the large-scale pilot (Phase 5).

Phase 4 also tested the strategy for the recruitment of participants for the pilot in Phase 5. This assessed the ability of the research team to identify the correct cohort of participants and intended to indicate whether, or not, changes to the eligibility criteria or approach to recruitment were needed.

2.8.1 Recruitment of participants

The Phase 4 small-scale live demonstrations were conducted with 2 participants who were not intended to be representative of the target population but who were able to test the solutions at home in a real-life environment. This adaptation to the originally planned methodology was due to limited healthcare staff availability and outpatient clinics after the COVID-19 pandemic which hampered our efforts to recruit target users. Instead, eligible participants were recruited internally from NHSCT staff at the Medicines Optimisation Innovation Centre (MOIC).

Inclusion criteria

- Stable self-reported Wi-Fi connection at home
- Self-reported as healthy, the participant feels well enough to take part in the pilot
- Self-reported confident user of smartphone/tablet
- Employee of the NHSCT

Exclusion criteria

- Wears an electronic medical device or implant (e.g., pacemaker, electrocardiogram)
- Allergic to rubber products

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Informed consent was gained from each participant.

2.8.2 Technical aspects & Logistics

An Android tablet device was purchased for the purposes of hands-on testing of the SHAPES, eCare and eHealthpass Apps (presented to user as one app) in Phase 3 and was also used for the small-scale live demonstrations in Phase 4. Specifications of the Android device are those specified in the protocol for the large-scale pilot study.

Android tablet specifications

- Android version 8 or above;
- Processor speed 2GHz or more;
- RAM 3GB+;
- Storage 64GB or above;
- Support Wi-Fi;
- Support BLE;
- Front facing camera for facial recognition.

Four CE-marked, Bluetooth-enabled medical devices were purchased for the purposes of the large-scale pilot study and were used in Phase 4, they were:

- A body composition monitor (OMRON VIVA Smart Scale);
- A glucometer (Roche Accu-chek Instant);
- A blood pressure monitor (OMRON M7 Intelli IT);
- A pulse oximeter (Beurer GmbH PO60 Bluetooth pulse oximeter).

The SHAPES App (comprising the SHAPES Front-end App, the eCare App and the eHealthpass App) tailored for the UC-PT3-Gen was downloaded onto the purchased tablet and given to the participants to use at home along with one of each of the 4 CE-marked, Bluetooth-enabled medical devices. Appropriate infection control measures were taken with the devices between participants. Researchers provided full training on how to use each device and user manuals were provided. A SHAPES user manual was also provided for using the App (Annex 12).

Participants were asked to use the devices to take daily readings of their weight, blood pressure, heart rate, oxygen saturation and blood glucose, for 3 days. The readings from the devices were electronically transferred to the SHAPES App via Bluetooth. Participants could view their data via the App and had the ability to enter readings manually. Participants were asked to enter at least 1 reading per parameter over the course of the 3 days to test this functionality. Participants were also asked to complete a daily survey containing questions about health status, and a weekly survey about

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use of medicine. For the purposes of Phase 4, the participants entered example data to complete these questionnaires.

An example medication regimen was uploaded to the App by researchers and was available to view, both as a comprehensive list of all medicines, and a daily list to serve as a reminder of what has to be taken that day. Participants were asked to view this information daily.

Participants' data was uploaded to a browser-based researcher dashboard. Researchers were able to view each participant's clinical and survey data.

Participants were asked to keep a user log (Annex 13) during their 3 days' of using the solution. During this time, they were asked to record the time of each interaction, activities undertaken and if any errors occurred during use. Errors may have included but were not limited to:

- System crashes;
- Error messages;
- Dead links;
- Unsaved data.

The logs were then reviewed by the pilot site researchers together with the technical partners to determine what the cause of any errors were and how they could be rectified or prevented in future.

In a short, unstructured interview, participants were asked to describe their experience in testing the App and devices and suggest any amendments or additions they felt were needed in the user manual for the SHAPES App so that changes could be actioned before the documentation was used in the large-scale pilot.

The pilot site researchers (and if necessary, the technical partners) were available during the live demonstrations to provide support. A log of all requests for support was kept and analysed after the demonstration. This process informed the type of technical support that may be required during the run-in period of the large-scale pilot, and allowed the study team to make necessary arrangements.

Recruitment strategy assessment

The recruitment strategy for Phase 5 was tested in Phase 4 to determine how many potentially eligible patients could be identified during the recruitment period. Heart failure clinic attendees were reviewed over a specified period of time. Client lists from MEAAP were reviewed to identify the number of potentially eligible participants they could approach when recruitment began for Phase 5. Although the full eligibility of potential participants could not be assessed without approaching people directly, this

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activity helped to estimate how many eligible participants were likely to be identified during the time allocated to recruitment.

Patients were not approached for the purposes of this assessment and no personal data were recorded. A clinician and member of the MEAAP team completed a pre-screening log (Annex 14) using medical notes and what they already knew about the patient. The log featured the eligibility criteria that could be reasonably determined without directly questioning the patient.

2.8.3 Roles and Responsibilities

The SHAPES pilot site researchers at NHSCT were responsible for recruiting and consenting participants to take part in the live demonstration. NHSCT provided training and acted as a single point of contact for the participants. Technical partners EDGE and Gnomon were responsible for providing technical support (via NHSCT) to participants if needed.

2.8.4 Ethical considerations

An ethical self-assessment for Phases 1–5 of this use case was completed (Annex 15). For Phase 4, an information sheet (Annex 16) specifying the nature of the research and pilot, including also the processing of personal data as part of the research and/or on the SHAPES platform, was provided. A consent form (Annex 17) for each participant was obtained manually before any use of the digital solutions and devices.

As this was a non-representative sample, not involving service users or changing treatment, Phase 4 of the Pilot 3 general use case (UC-PT3-gen) did not meet the definition of ‘research’ and as such did not require specific local ethics board approval or DPIA documentation.

Approvals from necessary authorities

The Head of Service at the Medicines Optimisation Innovation Centre (MOIC) at the NHSCT, Professor Michael Scott, was responsible for oversight of the project and his approval was obtained on this project plan (Annex 18) before proceeding with the live demonstrations. NHSCT information governance also reviewed the plan to identify any data protection issues.

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2.8.5 Outcome of the Small-Scale Live Demonstration

The small-scale live demonstration of the PT3-gen use case took place between 11th and 29th April 2022. Prior to conducting the demonstrations with participants, the NHSCT team performed extensive in-house testing of the applications and were in frequent communication with technical partners to address any issues arising during this process. This approach was continued through into the live demonstrations. Technical issues identified during the in-house testing of the applications caused a brief delay to the commencement of Phase 4 and called for further testing to be conducted outside of this distinct timeframe. All information gathered during the planning and execution of Phase 4 contributed to preparations for conducting Phase 5.

Participants

Two female members of NHSCT staff (moic+005 and moic+006) were recruited to participate in the Phase 4 small-scale live demonstration. Both participants were pharmacists with experience in medicines management research but had little to no prior connection to the SHAPES project. Neither participant had viewed the SHAPES App prior to receiving training. Participants used the test tablet device to conduct the testing.

Outcomes

Outcomes of the Phase 4 small-scale live demonstrations are presented in Table 9.

Table 9: Outcomes of the Phase 4 small-scale live demonstrations (PT3-gen)

Outcome	Moic+005	Moic+006	Comments
Each participant used the 4 clinical devices each day for 3 days.	Yes	Yes	
100% of data for heart rate, blood pressure, blood glucose, weight and questionnaires are successfully transmitted via Bluetooth to the SHAPES App.	Issues reported	Issues reported	BP monitor failed to synchronise on day 3 for moic+005. Multiple eCare synchronisation issues reported for user moic+006. EDGE confirmed it was due to the

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Outcome	Moic+005	Moic+006	Comments
			same medical devices having been used between participants.
Participants viewed their medication list daily.	Issues reported	Issues reported	Moic+005 could not get access to the medication list on day 3 Moic+006 logged out of eHealthpass app on day 3.
All participant data received by the SHAPES app was securely transferred to Edge and Gnomon servers.	Yes	Yes	
All participant data received by Edge and Gnomon servers was securely transferred to TREE.	Yes	Yes	Transfer was completed using SHAPES TP (from Gnomon) and eCare (from EDGE) as the Symbiote connector was not yet stable to be used.
All participant data received by EDGE and Gnomon servers was securely transferred to VICOM.	Yes	Yes	VICOM was able to provide one risk estimate per participant

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Recruitment strategy assessment

MEAAP client lists were reviewed in March 2022 to determine the number of potentially eligible participants for the recruitment of Phase 5. Out of approximately 1,500 people, 399 were aged over 60 years and had heart failure and/or diabetes.

From January to March 2022, patients were screened for potential eligibility as they attended a heart failure clinic run by the consultant cardiologist on the research team. There were 16 patients identified as being potentially eligible. Full eligibility could not be determined without contacting potential participants directly which wasn't permitted at this stage as this was a scoping exercise and full ethical approval had not been sought for this purpose. Nevertheless, these numbers gave a positive indication that recruitment of 30 people to Phase 5 over the time period of 3 months was achievable. Neither MEAAP nor the consultant cardiologist had any concerns about reaching the recruitment target for Phase 5.

Recommendations for technical partners

Some of the issues that arose before, during and after the live demonstrations, were very minor and straightforward to resolve. In contrast, some issues were larger and required further investigation and/or additional testing. Below is a summary of the key findings from Phase 4 and the actions that were taken to optimise the digital solution that would be taken forward into Phase 5. Please note that specific details of all the technical issues encountered before, during and after this phase and steps taken to rectify have not been provided.

EDGE

There were some issues with synchronisation of the medical devices to the eCare components of the App. It was quickly identified that these issues were caused by the participants sharing the same set of devices during their testing periods, without properly resetting the devices. The sharing of these devices by different users introduced synchronisation errors that compromised the results of this testing phase. Further in-house testing with a new set of devices was completed to provide additional confirmation that this issue would not occur in Phase 5.

Another issue that arose was regarding the App timing out during completion of the 'Daily Survey' in the eCare App, which was addressed and rectified.

A recommendation to add an automatic reading option (in addition to allow manual input) when clicking on a specific task in the To-do list was acted upon and was present in all future versions of the App.

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Following a series of discussions between NHSCT and EDGE and one additional testing phase, all issues with the eCare and Front-end Apps were resolved by the end of August 2022.

GNOMON

With regards to the eHealthpass components of the solution there were three main areas where issues were identified before, during and after the small-scale live demonstrations of the PT3-gen use case. They were: the capability of the system to include accurate information about users' medications; synchronisation of data captured using the smart glucometer and accessing eHealthpass features of the App via the Front-end App. Resolution of some of the issues raised was complex and prolonged with multiple versions of the eHealthpass App being released and tested over a period of nine months.

Regarding the capability of the system to include accurate information about users' medications, feedback on concerns raised by the Phase 4 participants regarding the display of medication details, was provided to the technical partner. After multiple discussions and negotiations, a number of workarounds were agreed in order for the use case to be able to proceed to Phase 5.

Shortly before Phase 4 began, there was an unexpected technical issue between the eHealthpass App and the Roche Accu-Chek Instant glucometer wherein the glucometers distributed to the UK were programmed to measure blood glucose in mmol/L rather than mg/dL as they do in the rest of Europe. This caused some major issues with the synchronisation of blood glucose readings into the eHealthpass system. Addressing this particular issue was difficult due to the hardware not being available in Greece for testing by Gnomon. When hardware became available, this issue was resolved promptly. However, due to this delay, only 1 of the participants was able to test this functionality in Phase 4. NHSCT performed additional in-house testing after Phase 4 to confirm functionality prior to Phase 5.

During Phase 4 testing there had been issues reported by participants regarding accessing the eHealthpass components of the App on the third day of testing. Subsequent in-house testing of newer versions of the Apps revealed further ongoing issues with regards to the links between eHealthpass, the Front-end App and access to the SHAPES Platform via the ASAPA module (supplied by HMU). From a user's perspective, particularly in an older demographic, navigation into and through the SHAPES App needed to be as simple and straightforward as possible. Despite much effort on the part of all technical partners and NHSCT, by February 2023 multiple logins to the Front-end App where still being required per session to access the eHealthpass components. This issue could not be resolved in time for the already delayed Phase 5 to commence and NHSCT made the decision to exclude eHealthpass functions from the PT3-general use case in Phase 5.

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VICOM

VICOM was able to deliver one risk estimate for each participant, indicating that the risk was null and that all required information to provide the risk estimate was in place to adequately calculate risks.

TREE

TREE was responsible for the receipt of data from eHealthpass, eCare, and storing this data in the SHAPES datalake, to be further processed (by TREE and VICOM). The datalake was ready and received the data collected, however, the final SHAPES TP was not used as one of the connectors was not stable at this point. TREE received the data and conducted tests of their own algorithms related to vitals control analysis.

Lessons learned for Phase 5 of the pilot campaign

The Phase 4 small-scale demonstrations and the subsequent in-house testing performed by NHSCT proved to be a useful activity in preparing the use case for large scale testing in Phase 5.

- No major concerns regarding meeting the recruitment target were identified using the strategy adopted during Phase 4.
- All technical issues that were able to be resolved were identified and fixed.
- Certain features of the App were optimised for a better user experience.
- The pilot site learned that the medical devices should not be paired with more than 1 Android device without being fully reset or else synchronisation issues would occur.
- The pilot site was able to test the user manual, identify errors and make improvements to its content.
- There was a delay between Phase 4 and Phase 5 to allow issues identified in Phase 4 to be addressed before starting Phase 5. This should be factored into future project designs.
- Multiple logins for digital solutions provided by more than 1 partner was not considered appropriate for our service user population despite this being a requirement of the SHAPES platform for security reasons.
- Regrettably, a key outcome of Phase 4 was the exclusion of the eHealthpass component from the PT3-general use case at the NHSCT pilot site. This included use of the blood glucose meter, weekly medication adherence questionnaire and medication list.

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2.9 Phase 5: Large-scale pilot activity

In Phase 5, a non-randomised, single-armed, cross-sectional interventional pilot study with an optional qualitative interview component was conducted. The pilot aimed to recruit 30 participants at the NHSCT lead pilot site and 10 participants at the UNRF replicating site.

The pilot was conducted with service users in Northern Ireland from the NHSCT who resided in their own home or supported living environment. Additionally, interviews were conducted with clinical or policy leads in the NHSCT. The pilot was managed by researchers from the MOIC in the NHSCT.

The pilot was replicated in Cyprus and included service users from the Strovolos Day Centre and the surrounding community in Nicosia. The pilot was managed by researchers from the University of Nicosia Research Foundation (UNRF).

Intervention

The intervention piloted was a novel system supporting older individuals with multiple long-term conditions to self-manage their chronic conditions through the daily use of a digital health product that also facilitated the remote monitoring of a person's health status.

The goals of the intervention were to help people self-monitor their health conditions, physiological parameters and medicines adherence to promote safer and more effective use of medicines in their own home. In future, the intervention may facilitate the remote monitoring of people by health and social care practitioners and use artificial intelligence (AI) algorithms to predict deterioration in a person's health status. However, this functionality was not investigated in the present study.

Participants were asked to download the SHAPES App to an appropriate smartphone or tablet. Mock-up images of the App were provided as a supporting document. Four CE-marked, Bluetooth-enabled medical devices, specifically a body composition monitor (OMRON VIVA Smart Scale – NHSCT only), glucometer (Roche Accu-Chek Instant- UNRF only), blood pressure monitor (OMRON M7 Intelli IT) and pulse oximeter (Beurer GmbH PO60 Bluetooth pulse oximeter – NHSCT only), were provided, as appropriate, to participants to use at home. Participants diagnosed with heart failure were provided with the body composition monitor (OMRON VIVA Smart Scale – NHSCT only), blood pressure monitor (OMRON M7 Intelli IT) and pulse oximeter (Beurer GmbH PO60 Bluetooth pulse oximeter – NHSCT only). Participants diagnosed with diabetes (UNRF) were provided with the glucometer (Roche Accu-chek Instant) and given the option to use the other devices according to preference. Participants were encouraged to use the devices to take daily readings of their weight, blood pressure, heart rate and oxygen saturation, and readings of their blood glucose as per their existing diabetes care plan (if applicable). The readings were electronically

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transferred to the SHAPES App via Bluetooth. Participants viewed their data via the App and had the ability to enter readings manually, if required. Participants were also encouraged to complete a daily survey containing questions about their health status (participants with heart failure only), and a weekly survey about their use of medicine (UNRF only). At UNRF, the participant's medication regimen was uploaded to the App by researchers and was available to view both as a comprehensive list of all medicines, and a daily list to serve as a reminder for what was to be taken that day. Participants were asked via the App on a weekly basis if any changes had been made to their treatment that week so that their medication regimen can be amended accordingly.

Participants received a one-on-one, face-to-face introduction to the App and training on how to use both it and the connected medical devices. A user manual contained detailed step-by-step supportive guidance and information and was provided to participants in hard-copy format for reference during the pilot. There was a run-in period of approximately 1 week wherein the participant could familiarise themselves with the App and liaise with the researchers to troubleshoot any problems they may have experienced with the technology. Participants were asked to use the App and connected medical devices for 12 weeks. Researchers contacted participants by telephone at the end of week 1, if there were 3 or more consecutive days where no data had been received (up to a maximum of 4 times during the pilot) and monthly (if required) thereafter. These telephone contacts were to enable the researchers to support participants with their use of the technology and troubleshoot any issues they may have experienced (no health advice or clinical support was provided by the researchers. If participants had any health concerns, they were encouraged to contact their specialist care team).

All data entered or transferred into the SHAPES App (i.e., clinical readings, survey responses) was pseudonymised and was stored in the technical partners' (EDGE and GNOMON) servers and then uploaded to the SHAPES big data platform. Selected data was then processed by 2 further SHAPES digital solutions; a heart failure decompensation risk prediction algorithm (VICOM) and an analytic tool that generated personalised dynamic thresholds for participants' clinical parameters (TREE). These digital solutions had not yet been validated or CE-marked for use as medical devices. Therefore, the outputs were not used to inform clinical care, but rather to determine whether the digital solutions are capable of producing outputs reliably using the available data, and to indicate if there were any associations between the risk scores generated and the participants' use of unscheduled care.

Participants' data and outputs from VICOM and TREE digital solutions were uploaded to a browser-based researcher dashboard. Researchers were able to view each participant's clinical and survey data, and manage participants' medication regimens as needed. Researchers viewed the available data and information for purposes of monitoring usage of the App and inputting changes to medication regimens only.

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Primary objective

- To investigate user engagement with the SHAPES App and Digital Solutions

Secondary objectives

The following objectives are specific to the 'Supporting multi-morbid older individuals' use case:

- To validate the capability of the SHAPES Platform and Digital Solutions to;
  - implement a personalised approach to achieve safe and effective use of medicines at home.
  - achieve better patient outcomes by initiating, developing and sharing best practice with regards to medicines use.
  - address and improve deficiencies with adherence to medicines and treatments.
  - identify associations between precursor signs of deterioration and unscheduled healthcare resource use.
  - improve data collection to develop predictive algorithms for heart failure decompensation.
  - improve older individuals' quality of life.

- To explore the integration of the SHAPES Platform and Digital Solutions to align with current and developing care pathways.

- To explore user trust and acceptance of the SHAPES Platform and Digital Solutions.

Tertiary objectives

The following objectives align with the general purposes of the SHAPES large-scale piloting campaign:

- To validate the capability of the SHAPES Platform and Digital Solutions to;
  - support and extend healthy and independent living for older individuals who are facing permanently or temporarily reduced functionality and capabilities.
  - improve the older individuals' health outcomes and quality of life.
  - gain the older individuals' trust and acceptance.
  - gain the care professionals' trust and acceptance.
  - contribute to the reduction of the workload of medical professionals.
  - deliver efficiency gains in health and care delivery across Europe.

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Primary outcome

Participants' engagement with the SHAPES App during the pilot as defined by the number of times the App was opened per day over 3 months.

Secondary outcomes

- Participants' user experience with the SHAPES App as measured using the User Experience Questionnaire –short version (UEQ-S).
- Usability of the SHAPES App as measured using the SUS.
- Number and rate of successful registrations of each clinical parameter per participant, per day (heart rate, blood pressure, weight, oxygen saturation, blood glucose).
- Number and rate of control limits (upper and lower) successfully generated by the 'Vitals Control' analytic tool per person (rate defined as number of pairs of limits generated per week during the pilot).
- Number and rate of heart failure decompensation prediction (HFPred) risk scores successfully generated per person (rate defined as number of scores generated per week during the pilot).
- Change in hospitalisation rate per person (hospitalisations/month) and A&E attendance rate (attendance/month) three months prior to baseline compared with 3 months during the pilot.
- Participants' self-reported medication adherence as measured using the MARS at baseline and at the end of the pilot.
- Participants' beliefs about medicines as measured using the BMQ at baseline and at the end of the pilot.
- Correlation between participants' self-reported medication adherence and beliefs about medicines.
- Number and rate (score/week) of heart failure decompensation prediction (HFPred) risk scores successfully generated per person during the pilot.
- Correlation between HFPred scores and unscheduled care during the pilot (unscheduled care defined as composite of hospitalisations, A&E attendances, specialist contacts, out-of-hours contacts).
- Health-related quality of life as measured using the EQ-5D-5L questionnaire (4) at baseline and at the end of the pilot.
- Exploration of healthcare practitioners' views on integration and alignment of the SHAPES Platform and Digital Solutions with current care pathways.
- Exploration of healthcare practitioners' views about their trust and acceptance of the SHAPES Platform and Digital Solutions.
- Exploration of participants' views about their trust and acceptance of the SHAPES App.
- Exploration of user engagement behaviours.

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Tertiary outcomes

The following outcomes align with the general purposes of the SHAPES large-scale piloting campaign and data will be harmonised with outcome data from all pilots in the campaign:

- Participants' self-efficacy as measured using the general self-efficacy scale.
- Participants' extent of social support as measured using the Oslo Social Support Scale (OSSS-3).
- Participants' health literacy as measured using the Single-item Health Literacy Measure (HLM1).
- Participation in society as measured using non-validated participation questions.
- Participants' quality of life as measured using the WHOQOL-BREF.
- Health-related quality of life as measured using the EQ-5D-5L.
- Usability of the SHAPES App as measured using the SUS.
- Technology Acceptance.
- Exploration of participants' views about their trust and acceptance of the SHAPES Platform and Digital Solutions.
- Exploration of healthcare practitioners' views about their trust and acceptance of the SHAPES Platform and Digital Solutions.
- Change in health service utilisation for unscheduled care related to heart failure and diabetes as measured by:
    - Number of hospitalisations;
    - A&E attendances;
    - Out of hours contacts;
    - Contacts with specialist services.
- Economic impact of the intervention as measured by comparing the cost of the intervention (devices, SHAPES Platform and Digital Solutions; staffing) versus the cost of unscheduled care related to heart failure and diabetes during the pilot.

Data collection, management and analysis

Service user data collection methods

The majority of data collection was conducted remotely. The exception to this was the face-to-face, one-to-one introduction to the app and devices. This was conducted in person. The procedures below were completed in person or remotely dependant on COVID-19 guidelines and participant preference.

Service user prior to baseline procedures

- Screening;
- Eligibility confirmation;
- Informed consent;
- Training on use of SHAPES App and connected medical devices;

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- Run-in, familiarisation with medical devices;
- Contact details — name, address, email, phone number, alternative contact name and phone number, Health and Care number (NHSCT).

Service user baseline procedures

- Questionnaires — Barthel Index, Gijon Scale, EHFS, MARS, BMQ, EQ-5D-5L, GSES, OSSS-3, HLM1, participation measure, WHOQOL-BREF.
- Medical history data — height, weight, left ventricular ejection fraction, heart rhythm, implanted devices, medical conditions, heart failure stage, dyspnoea level, smoking status, leg pain symptom question.
- Demographic data — including DOB, education, sex, marital status, occupational status, caregiver status, housing details.
- Technical data — device monitoring details e.g., model, manufacturer, serial number and preferred time of day for reminders/questionnaires, make and model of the participants' own smartphone/tablet.
- Laboratory results — urea, creatinine, sodium, potassium, haemoglobin, cholesterol, eGFR, HbA1c, ACR, urine creatinine, urinary albumin-creatinine ratio.
- Unscheduled care — hospitalisations (previous 3 months), and previous month hospital readmissions, A&E attendances, out of hours care, specialist service contacts, emergency ambulance call outs.
- Current prescribed medication — name, frequency, strength, chronic or as required, stop date if stopped during the pilot, start date if started during the pilot.

Service user study visits and procedures

- During the pilot, the participant was asked to record the following at least once daily, as appropriate, via the SHAPES App; blood pressure, heart rate, oxygen saturation, weight (as well as body mass index, body fat, visceral fat, skeletal muscle, basal metabolic rate).
- Participants diagnosed with diabetes and monitoring blood glucose regularly were requested to record their blood glucose with the same frequency as directed by their doctor on the SHAPES App (UNRF only).
- Participants diagnosed with heart failure were asked a series of daily questions about their heart failure symptoms administered via the SHAPES App.
- All participants at UNRF were asked about their adherence to medication with a weekly MARS questionnaire. This was planned to be administered via the SHAPES App, however it was completed in paper format as explained in Table 28.
- During the pilot, the UNRF patients could view their medication list.
- Unscheduled care updates — any updates to baseline hospitalisations, hospital readmissions, A&E attendances, out of hours care, specialist service contacts, emergency ambulance call outs were recorded from medical notes.

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- Prescribed medication updates — any updates to prescribed medications notified by participant.
- Tracking data — data was logged about how the participant used the SHAPES App e.g., date/time of usage, what functionalities were accessed.
- Adverse events — date, start time, injury description, incident description, action taken, location of incident (private home or healthcare facility).
- Researchers documented any contact received/provided regarding support required to facilitate the pilot (date, duration, reason).

Service user end of pilot visit (+14 days)

- Questionnaires — UEQ-S, SUS, MARS, BMQ, EQ-5D-5L, GSES, OSSS-3, HLM1, participation measure, WHOQOL-BREF, technology acceptance measure.
- Participant may participate in an interview at this time or a separate date may be accommodated.
- Demographic data — marital status, occupational status, caregiver status, housing details.

Service user follow-up study visits and procedures

- If an interview was consented to this occurred at a mutually convenient time after the intervention was completed.
- 3-month follow-up data collection (+/- 7days) completed at UNRF only:
- Questionnaires — EQ-5D-5L, GSES, OSSS-3, HLM1, participation measure, WHOQOL-BREF.

Healthcare professional data collection

The interviews carried out with health care professionals were conducted remotely using video-conferencing software.

Health and Social Care staff prior to baseline procedures

- Screening;
- Eligibility confirmation;
- Informed consent.

Health and Social Care staff interview

- The interview included background on the SHAPES innovation action, information on the intervention applied and demonstration of data collection.
- A semi-structured interview guide, framed the conversation which was recorded (audio and video).
- The interview was transcribed and thematic analysis conducted.

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Data collection tools

Service user data was documented using a case report form (CRF). Paper questionnaires formed part of the CRF and the CRF was the source for questionnaires. The source for all data points can be found in the data plan. The CRF was then transcribed onto an online database. Specific data was securely shared with other SHAPES partners and appropriate Data Processing Agreements were in place.

Data collection for the interviews with healthcare professionals were audio and visually recorded. These were completed using videoconferencing software. Interviews were transcribed and the transcript validated by a second researcher.

Adverse incidents

Adverse incident definition: *Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation arising during the course of the business of a Health and Social Care organisation/Special Agency or commissioned service.*

No adverse incidents occurred during the pilot.

The research team were not made aware of any product recalls regarding the medical devices used in this pilot.

Clinicians did not have access to the data collected and participant treatment was not changed due to taking part in this pilot. This was clearly noted in the participant information sheet. If participants were concerned in any way about the readings on their devices, they were directed to follow their normal mechanisms for seeking healthcare.

Protocol deviations

Data collection was monitored by the research team through the researcher dashboard. Participants were contacted via phone after a week of starting the intervention to see if they need any assistance. Thereafter, the participants were encouraged to contact the research team if they had any technical difficulties. If no data were uploaded for 3 consecutive days, the research team contacted the participant to see if there was a technical issue. Additionally, if there were significant issues with data collection, participants were contacted monthly to act as a reminder or to troubleshoot any issues that may have occurred. If the participant notified researchers that there was a change to their medication, the participant was contacted to confirm the change and the medication list was updated by researchers.

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This pilot examined the real-world use of the SHAPES App and associated medical devices. Therefore, if participants did not enter data as requested in the pilot, this was not documented as a protocol deviation; rather this provided an insight into how the participants used the digital solutions.

Data management

Personal data minimisation and purpose limitation principles were followed so that this use case only processed data that was adequate, relevant and limited to what was necessary to deliver the objectives of the pilot. Personal data was processed only for these purposes. Only personal data strictly necessary to the completion of this pilot was retained.

Further details regarding personal data were described in the DPIA, Personal Data Processing Descriptions document and DPIA risk assessment document for this pilot. Additionally, a detailed description of all data (including but not limited to personal data) collected can be located in the data plan for this pilot.

Missing data

The VICOM heart failure prediction algorithm required a number of data fields to be completed each day in order to provide a decompensation risk. If one of these values was missing, no risk prediction was performed. It was necessary on occasion to populate a participant's average value, e.g., if a participant is bed bound it was difficult to provide a daily weight value. These exceptions were documented. If a complete data set was not obtained, data was imputed. It was clear to the researcher which risk scores were based on fully completed data versus partially completed and imputed data.

Data duplication

Heart rate was collected by both the blood pressure monitor and the pulse oximeter. A decision was made by NHSCT for the heart rate data collected by the pulse oximeter, to be recorded.

2.9.1 Recruitment (NHSCT)

Service users

Potential participants were either identified from hospital in-patient and clinic lists in NHSCT by their direct care team or by a project officer from MEAAP. Alternatively, they could contact the research team directly from a recruitment poster or the research team could contact potential participants if consent to contact was obtained. An

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information sheet (Annex 19), study summary (Annex 20) and privacy notice (Annex 21) were provided to potentially eligible participants. Once eligibility was confirmed, written consent (Annex 28) was obtained.

HSC staff recruitment

A list of appropriate professionals was identified from the research team's knowledge and contacts. An invitation email containing information about SHAPES and a request to conduct an interview and demonstrate the intervention was sent. An information sheet (Annex 23) and privacy notice (Annex 24) were provided to those that accepted the request and the research team obtained consent (Annex 25).

2.9.1.1 Eligibility criteria

Service user inclusion criteria

At point of consent;

- NHSCT service user;
- ≥60 years;
- Diagnosed with heart failure and/or diabetes mellitus;
- If diagnosed with diabetes mellitus (and not heart failure), treatment includes regular monitoring of blood glucose;
- Lives at home or in supported living accommodation (category 1 or 2):
    - Category 1 — self-contained accommodation for the more active older people, which may include an element of scheme supervisor support and/or additional communal facilities;
    - Category 2 — scheme supervisor supported self-contained accommodation for the less active older people, which includes the full range of communal facilities.
- Has stable self-reported Wi-Fi connection at home;
- Has access to an appropriate android smartphone or tablet:
    - Android device running version 6 or above; supports Wi-Fi; supports BLE; front facing camera for facial recognition.
- Self-reported stable disease state, the participant feels well enough to take part in the pilot;
- Self-reported confident user of smartphone/tablet.

Service user exclusion criterion

At point of consent:

- Participant report of cognitive impairment;
- Wears an electronic medical device or implant (e.g., pacemaker, electrocardiogram);

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- Allergy to rubber products.

HSC staff inclusion criterion

- Knowledge of patient care pathways;
- Employed by the NHSCT service in Northern Ireland.

HSC staff exclusion criteria

- Unwilling or unable to provide consent.

2.9.2 Recruitment (UNRF)

Potential participants who stay in the Strovolos Day Centre and surrounding community were invited to participate in the pilot in Cyprus. On this note and because the numbers are small, participants were selected on the basis of convenient and random sampling. Sampling was convenient because participants were available at the day centre. Ten (10) participants were selected to participate in the pilot acceptability study in Cyprus.

2.9.2.1 Eligibility criteria

Inclusion criteria

The following inclusion criteria were applied:

- age ≥ 65 years;
- presence of digital skills;
- signed informed consent;
- preserved basic functional independence;
- adequate compliance with study protocol;
- have been diagnosed with diabetes and hypertension.

Exclusion criteria

The following exclusion criteria were applied:

- subjects not living in the catchment area (Nicosia);
- any acute medical condition;
- any surgery in the last 3 months;
- major neurocognitive disorder;
- moderate and severe depression;

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- existing disability (needs human help in one or more basic activities of daily living);
- heart failure;
- angina pectoris;
- uncontrolled high blood pressure (>160 mmHg systolic);
- heart arrhythmias that could interfere with functionality;
- peripheral arterial disease;
- any terminal illness;
- frailty syndrome;
- risk of falls;
- any condition that might limit mobility (e.g., Parkinson's disease, severe arthritis, stroke sequela);
- visual impairment (best corrected visual acuity of worse than either 20/40 or 20/60).

Exclusion criteria were documented by medical history.

An information sheet (Annex 26), and privacy notice (Annex 27) were provided to potentially eligible participants. Once eligibility was confirmed, written consent (Annex 28) was obtained. If a person gave informed consent, the person was included in the study and continued with the Compliance Form. If the person did not fully complete baseline questionnaires, the person was excluded from the study. If the person did not fully comply with SHAPES instructions or did not appropriately use SHAPES items, the person was excluded from the study.

Key differences between lead site and replicating site:

There were several key differences in how PT3-General was replicated in UNRF, these included the provision of an android tablet and Wi-Fi to participants who did not previously have access to this technology. It was decided not to provide participants with an android tablet at NHSCT for several reasons, firstly, the high cost of these items for 30 participants and relatively short duration of the use case. Also, 78% of the UK population over 55 years old own a smartphone, therefore, it did not seem like a necessary additional expense (19). Additionally, in terms of the participant population, eligible participants in Cyprus were ≥ 65 years (≥ 60 years NHSCT), diagnosed with diabetes and hypertension and so used consumables and a blood glucose monitor to measure blood glucose and a blood pressure meter to measure blood pressure. Due to issues described in Phase 4, NHSCT decided not to use the eHealthpass component of the SHAPES App in Phase 5 and therefore did not include participants diagnosed with diabetes. In contrast, Cypriot participants did not have heart failure so did not use the body composition monitor, the pulse oximeter and the HFPred algorithm.

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2.9.3 Communication and dissemination of pilot activities

Any data that arose from the pilot study were owned by the NHSCT and UNRF respectively. On completion of the study, all data was analysed and tabulated and used to prepare a final report, available as Deliverable D6.4 of the SHAPES Innovation Action. This deliverable (and all other agreed deliverables) are available to the public for review and accessible via the SHAPES website (www.shapes2020.eu). Participants were notified of the outcome of the study via a specifically designed newsletter. NHSCT and UNRF will seek to disseminate the findings from this study at conferences and in the scientific literature. As per the SHAPES Publication Protocol, all publications arising from this study will reflect the range of effort that has made them possible; including conceptualisation of the research project and research task, methodology development, data collection and analysis, interpretation and discussion of results; as well as project management. Any publications will be reviewed and receive meaningful contribution by all named authors. NHSCT and UNRF will also seek to communicate the findings of this study via social media, and in other, non-peer reviewed, media outlets. Participating SHAPES partners will have the rights to use data from this study in their own analysis and dissemination plans. As detailed under 'Access to Data', Data Processing Agreements were in place to facilitate the sharing of pseudonymised data with specific SHAPES partners for specific purposes.

2.9.4 Risk management

All foreseeable data-related risks were compiled into detailed risk assessment documents which formed part of the Data Protection Impact Assessments for Phase 5 PT3-gen conducted in NHSCT and UNRF. For each risk identified, a risk classification, root cause, name and consequences were assigned. Once identified, each risk was then analysed and attributed a score from 1 (unlikely/minor) –4 (almost certain/critical) for probability and impact. Subsequently, appropriate mitigation actions were assigned and an appropriate person responsible was identified. These risks were reviewed periodically.

In addition to data risks, there was a risk identified relating to the lone working of the research team, especially when conducting home visits. Any NHSCT staff carrying out lone working while undertaking the SHAPES pilot were required to follow the NHSCT lone workers policy. A potential risk to participants due to the unlikely occurrence of a device malfunction was also identified. IAny such, incidents occurring in NHSCT participants were expected to be reported in-line with the NHSCT policy 'Adverse incident management policy (including serious adverse incidents). Approval to conduct the pilot in NHSCT was sought from an independent Research Ethics Committee (REC) before the start of the pilot. The protocol and all other relevant documents (e.g., participant information sheets, consent forms, user manuals etc.)

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were submitted alongside an Integrated Research Application System (IRAS) form for REC review. Approval to conduct Phase 5 of the pilot in UNRF was obtained from the Cyprus National Bioethics Committee.

Finally, a full internal ethical review of Pilot 3 was conducted and is detailed in Section 7 of this deliverable. This enabled all contributors to review how all use cases in Pilot 3 aligned with the ethical frameworks applied to the SHAPES project and identify any further risks.

2.9.5 Outcome of large-scale pilot activity

2.9.5.1 NHSCT (lead site)

Overview

Screening and recruitment to Phase 5 large-scale pilot of the SHAPES UC-PT3-general use-case was conducted between December 2022 and March 2023 and participants were actively involved between March and June 2023.

A consultant cardiologist reviewed 20 cardiology clinics retrospectively (N=200 patients) and 11 cardiology clinics prospectively (N=110 patients). Fifty-nine potentially eligible participants were identified.

MEAAP screened their client database and identified 89 potentially eligible participants.

Therefore, a total of 148 potentially eligible participants were identified at the NHSCT site, however only 4 participants took part in the pilot due to the reasons described below in Table 10.

Additionally, 3 healthcare practitioners were interviewed. They included, a male diabetes service improvement manager, a female heart failure specialist pharmacist and a male acute medicine consultant.

Table 10 Recruitment and retention of participants at NHSCT (PT3-gen)

Recruitment and retention of older adult participants at NHSCT	
Screened prior to eligibility assessment	**N=148**
Excluded	**N=144**
Does not live at home or in supported living accommodation	N=4

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Recruitment and retention of older adult participants at NHSCT	
Does not have stable self-reported Wi-Fi connection at home	N=4
Does not have access to an appropriate android smartphone or tablet	N=26
Does not have self-reported stable disease state	N=1
Is not a self-reported confident user of smartphone/tablet	N=34
Wears and electronic medical device or implant (e.g. pacemaker, electrocardiogram)	N=14
Other (please specify) **Reason 1: Ill health/complex mental health** **Reason 2: Deceased** **Reason 3: Consultant did not think pilot was appropriate** **Reason 4: Paperwork was too much** **Reason 5: Not interested in participating** **Reason 6: Going away/on holiday over pilot period** **Reason 7: Android device issues (viruses)** **Reason 8: Could not make contact with patient**	N=61 N=22 N=21 N=2 N=6 N=6 N=2 N=1 N=1
Allocated to intervention	**N=4**
Lost to follow-up	**N=0**
Discontinued Intervention	**N=1**
Reason 1: Electronic medical device implanted	N=1
Assessment of KPIs	
Assessed for KPI 1	N=4
Assessed for KPI 2	N=4
Assessed for KPI 3	N=4
Assessed for KPI 4	N=4
Assessed for KPI 5	N=4
Assessed for KPI 6	N=4
Assessed for KPI 7	Not assessed

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Table 11 Baseline characteristics of Phase 5 participants (PT3-gen)

Variable	Number of participants	Value
Age (years)	4	66.0 (±1.41)
Male	4	4 (100%)
BMI (kg/m^2)	4	31.6 (±4.60)
Heart failure	4	4 (100%)
Heart failure stage	4	2.5 (± 0.5)
LVEF (%)	4	38.0 (±7.39)
Dyspnoea level	4	1.5 (±1.29)
Diabetes	4	2 (50%)
Type 1 diabetes	4	0 (0%)
Hypertension	4	4 (100%)
Smoking	4	0 (0%)
Values are mean (±SD) or n (%) *LVEF= left ventricular ejection fraction*		

The primary outcomes of the large-scale pilot activity were to measure a predefined set of KPIs, i.e., a set of measures that focus on the factors most critical to the success of the UC-PT3-general pilot, and to evaluate the UC-PT3-general use case using the MAST evaluation tool.

Key performance indicators

Seven KPIs were identified for evaluation in the PT3-general use case. They were divided into 3 categories: recruitment and retention; user engagement and acceptance; and collection of data. Tables 12 to 17 present the data used to determine the success of each KPI. Table 18 provides an overview of the success of the pilot with regards to KPIs.

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Recruitment and retention

KPI 1 At least 80% of the target cohort were successfully recruited into the pilot during the recruitment period

Table 12 Number and percentage of target participants recruited into Phase 5 (PT3-gen)

Parameter	MEAAP	NHSCT	Total
Target number of participants	10	20	30
Number of participants recruited	0	4	4
Percentage recruited	0%	20%	13%

KPI 2 At least 80% of recruited participants remained enrolled in the pilot until the end of the study.

Table 13 Participant retention during Phase 5 (PT3-gen)

Parameter	Value
Number of participants at baseline	4
Number of withdrawals	1
Number of participants at end of study	3
Percentage retained	75%

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User engagement and acceptance

KPI 3 The overall user experience quality of the App as measured using the short version of the UEQ-S was classified as 'Excellent', 'Good' or 'Above average' based on published benchmark data.

Table 14 Mean pragmatic and hedonic quality UEQ-S scores and their comparison to published benchmark data (PT3-gen)

Scale	Mean	Comparison to benchmark
Pragmatic quality	2.63	Excellent
Hedonic quality	1.56	Good
Overall	2.09	Excellent

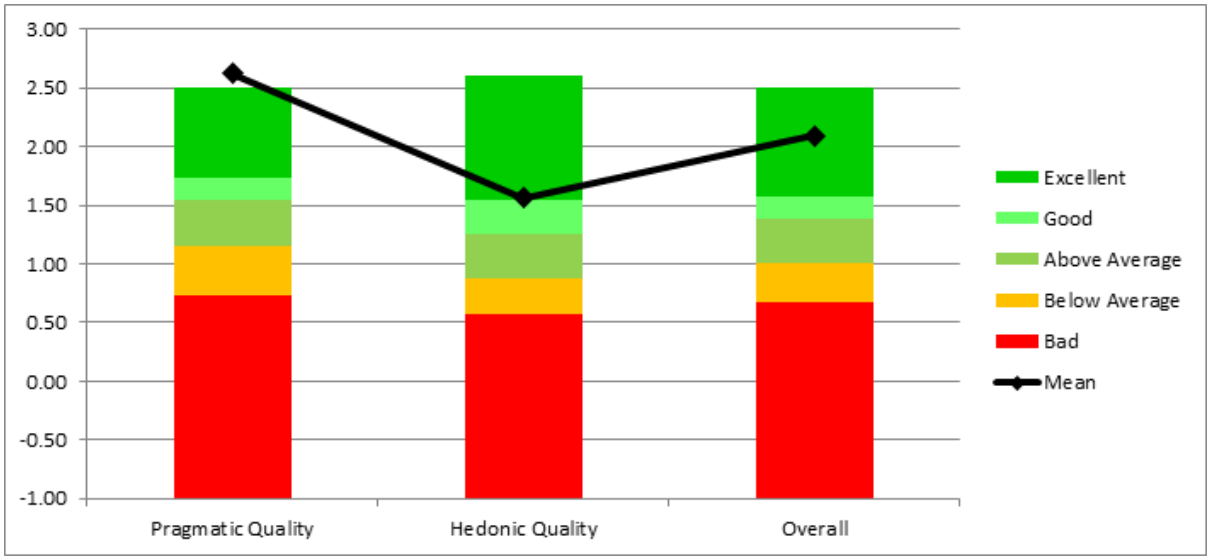

Figure 5 Mean UEQ-S and benchmark scores for the usability of the app (PT3-gen)

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KPI 4 At least 60% of participants continued to login to use the App daily after two weeks of the pilot.

Table 15. Number and percentage of participants using the app daily after two weeks (PT3-gen)

Parameter	Value
Number of participants who logged in daily for at least 2 weeks after baseline	3
Total number of participants	4
Percentage using the App daily after two weeks	75%

KPI 5 At least 60% of participants scored an above average rating (>68) in the SUS.

Table 16. Number and percentage of participants scoring higher than 68 in the System Usability Scale (PT3-gen)

Parameter	Value
Number of participants at end of pilot	4
Number (%) of participants scoring >68 in SUS	4 (100%)

Collection of data

KPI 6 Sufficient data was collected from participants to allow the heart failure decompensation prediction tool to generate a percentage risk of decompensation at least once per week for at least 60% of participants.

Table 17. Number and percentage of heart failure participants with at least one successful HFPred score generated from a full data set per week (PT3-gen)

Parameter	Value
Number of heart failure participants with at least 1 successful HFPred score generated from full data collection per week?	4
Number (%) of heart failure participants	4 (100%)

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KPI 7 At least 60% of participants completed the MARS at least once a month during the pilot.

This KPI was unable to be assessed due to the weekly medication adherence questionnaire functionality from Gnomon that was removed for Phase 5.

Overview of KPI achievement

Table 18. Overview of the success of Phase 5 of the pilot with regards to KPIs (PT3-gen).

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	No	Despite screening a large number of potentially eligible participants our recruitment target was unable to be met. Not being a confident user or having access to an appropriate android device was a significant barrier.
KPI 2	No	Due to the small number of participants and the loss of a single participant due to the insertion of a medical device (thus making them ineligible to continue in the pilot) meant that this KPI was not achieved.
KPI 3	Yes	
KPI 4	Yes	
KPI 5	Yes	
KPI 6	Yes	
KPI 7	Not assessed	Not assessed. The MARS questionnaire was a functionality from eHealthpass (Gnomon) which was not incorporated into Phase 5.

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Evaluation of use case using MAST

The MAST framework (15) was used to evaluate the effectiveness and contribution of UC-PT3-general to quality of care. MAST is described as a multidisciplinary process that summarises and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine.

Three of the 7 multidisciplinary dimensions/domains of the MAST framework were of specific relevance to the pilot of UC-PT3-General. These were: Clinical Effectiveness; Patient Perspectives; and Economic Aspects. Completed MAST table can be found in Table 19. All the results presented below are based on data from 4 participants.

Table 19.Completed MAST evaluation (PT3-gen)

Domain	Topic	Outcome	Baseline *Mean (SD)*	End of pilot *Mean (SD)*	***Mean change*** *(95% CI)*
Clinical effectiveness	Effects on health-related quality of life	EQ-5D-5L Utility Score	6 (0)	6.75 (1.5)	0.75 (-0.72, 2.22)
		EQ-5D VAS	81.25 (13.15)	78.75 (7.5)	-2.5 (-17.34, 12.34)
	Behavioural outcomes	BMQ Necessity Score	22.75 (2.63)	22.5 (2.38)	-0.25 (-3.73, 3.23)
		BMQ Concerns Score	12.25 (2.22)	14.0 SD: 6.27	1.75 (-4.77, 8.27)
		BMQ differential score (Necessity – Concerns)	10.50 (3.87)	8.5 (8.19)	-2 (-10.87, 6.87)
	Self-reported adherence	MARS Score	24.75 (0.50)	24.5 (1.00)	-0.25 (-1.35, 0.85)
		Hospitalisations	0 (0)	0 (0)	0 (0,0)

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Domain	Topic	Outcome	Baseline *Mean (SD)*	End of pilot *Mean (SD)*	*Mean change (95% CI)*
	Utilisation of health services	A & E attendances	0.25 (0.5)	0.25 (0.5)	0 (-0.69, 0.69)
Patient perspectives	Satisfaction and acceptance	UEQ-S Score	-	2.09 (0.62)	-
	Understanding of information / Confidence (in the treatment) / Ability to use the application / Access	SUS Score	-	83.13 (12.48)	-
	Empowerment / Self-efficacy	General self-efficacy scale	38.0 (2.83)	35.25 (3.86)	-2.75 (-7.44, 1.94)
Economic evaluation	Related changes in use of healthcare resources	Cost of hospitalisations Cost of A&E attendances	-	No change No change	-
	Cost of resources used	Cost of devices	• Omron M7 Intelli IT blood pressure (upper arm) €118.65 per unit incl. VAT • Omron VIVA body composition monitor €167.50 per unit incl. VAT		

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Domain	Topic	Outcome	Baseline *Mean (SD)*	End of pilot *Mean (SD)*	*Mean change (95% CI)*
			• Beurer Bluetooth pulse oximeter PO60 €85.08 per unit incl. VAT		
		Cost of using SHAPES digital solutions and SHAPES platform	• Digital solutions from EDGE (eCare), VICOM HFPred and TREE (vitals control) were highly customised for each use case and as the Digital Solutions and the SHAPES platform are not yet commercial entities it is not possible to attribute a cost at this stage.		
		Cost of staffing	NHSCT staff time • Baseline visit time = 1 hour (additional 0.75 hour travel) • Maintenance/ troubleshooting time via phone = Average 0.08 hour per participant • End visit time = 1 hour (additional 0.75 hour travel)		

Evaluation of UC-PT3-general primary and secondary outcomes

The pilot also sought to measure additional outcomes pertinent to testing the hypothesis that the SHAPES Platform and Digital Solutions are capable of providing opportunities for supporting medicine control and optimisation in older people with multiple chronic health conditions.

Table 20 describes the main findings from each evaluated outcome.

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Table 20 Evaluation of primary and secondary outcomes (PT3-gen)

<table>
<tr><th>Outcome</th><th>Finding</th></tr>
<tr><td>Participants' engagement with the SHAPES App during the pilot as defined by the number of times the App was opened per day over three months.

This was the primary outcome.</td><td>Out of the four participants recruited to the pilot in NHSCT there was very good engagement with the SHAPES App. The SHAPES App was opened by every participant on more than half of the days that the participants were active in the pilot. Two participants opened the App every single day of the 12 week pilot.

<table>
<tr><td>Participant</td><td>Number of days missed logins</td><td>Total number of days</td><td>% days login</td></tr>
<tr><td>1SU</td><td>0</td><td>85</td><td>100</td></tr>
<tr><td>2SU</td><td>7</td><td>43</td><td>83.72</td></tr>
<tr><td>3SU</td><td>42</td><td>85</td><td>50.59</td></tr>
<tr><td>5SU</td><td>0</td><td>85</td><td>100</td></tr>
</table>
</td></tr>
<tr><td>Participants' user experience with the SHAPES App as measured using the User Experience Questionnaire – short version (UEQ-S)</td><td>Mean UEQ-S score for the four participants was 2.09 (SD 0.62). This finding indicates that the user experience was 'excellent' when compared with benchmark data.

Please see Figure 5, Table 14 & Table 19 for more detailed information about the UEQ-S findings.</td></tr>
<tr><td>Usability of the SHAPES App as measured using the System Usability Scale</td><td>Mean SUS score for the four participants was 83.13 (SD 12.48). A score of over 68 in the SUS is considered above average, therefore this finding suggests an acceptable level of usability.

Please see Table 16 and Table 19 for more information about the SUS findings.</td></tr>
<tr><td>Number and rate of successful registrations of each clinical parameter per</td><td>The number of successful registrations of clinical parameters ranged from 42 to 97. The rate of successful registrations per participant per day did not fall below 0.55.</td></tr>
</table>

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<table>
<tr><th>Outcome</th><th>Finding</th></tr>
<tr><td>participant, per day (heart rate, blood pressure, weight, oxygen saturation, blood glucose*)

*Blood glucose was not monitored at NHSCT</td><td>
<table>
<tr><td></td><td colspan="4">Number of successful registrations (rate/day)</td></tr>
<tr><td>Clinical parameter</td><td>Blood pressure</td><td>Heart rate</td><td>Weight</td><td>Oxygen saturation</td></tr>
<tr><td>1SU</td><td>88 (1.04)</td><td>97 (1.14)</td><td>89 (1.05)</td><td>97 (1.14)</td></tr>
<tr><td>2SU</td><td>48 (1.12)</td><td>70 (1.63)</td><td>42 (0.98)</td><td>70 (1.63)</td></tr>
<tr><td>3SU</td><td>52 (0.61)</td><td>94 (1.11)</td><td>47 (0.55)</td><td>84 (0.99)</td></tr>
<tr><td>5SU</td><td>91 (1.07)</td><td>95 (1.12)</td><td>92 (1.08)</td><td>95 (1.12)</td></tr>
</table>
</td></tr>
<tr><td>Number and rate of control limits (upper and lower) successfully generated by the ‘Vitals Control’ analytic tool per person (rate defined as number of pairs of limits generated per week during the pilot)</td><td>The number of control limits sucessfully generated by the
<table>
<tr><td></td><td colspan="4">Number of control limits (pairs of limits/day)</td></tr>
<tr><td>Clinical parameter</td><td>Blood pressure</td><td>Heart rate</td><td>Weight</td><td>Oxygen saturation</td></tr>
<tr><td>1SU</td><td>85 (1.00)</td><td>85 (1.00)</td><td>85 (1.00)</td><td>85 (1.00)</td></tr>
<tr><td>2SU</td><td>34 (0.79)</td><td>34 (0.79)</td><td>36 (0.84)</td><td>34 (0.79)</td></tr>
<tr><td>3SU</td><td>44 (0.52)</td><td>44 (0.52)</td><td>44 (0.52)</td><td>44 (0.52)</td></tr>
<tr><td>5SU</td><td>77 (0.91)</td><td>77 (0.91)</td><td>76 (0.89)</td><td>78 (0.92)</td></tr>
</table>
Vitals control analytic tool per person ranged from 34 to 85.</td></tr>
<tr><td>Number and rate of heart failure decompensation prediction (HFPred) risk scores successfully generated per</td><td>All four participants had their HFPred risk score sucessfully generated at least once per week during the pilot.</td></tr>
</table>

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Outcome	Finding		
person (rate defined as number of scores generated per week during the pilot)	Participant	Number of heart failure decompensation prediction risk scores	Number of risk scores per week
	1SU	84	7
	2SU	41	6.8
	3SU	77	6.4
	5SU	83	6.9
Change in hospitalisation rate per person (hospitalisations/ month) and A&E attendance rate (attendance/month) three months prior to baseline compared with three months during the pilot	There was no change in hospitalisation or A&E attendance rate three months prior to baseline compared with three months during the pilot.		
Participants' self-reported medication adherence as measured using the Medication Adherence Report Scale (MARS) at baseline and at the end of the pilot	A high level of self-reported adherence to prescribed medications was observed at baseline and end of the pilot. See Table 19 for more details.		
Participants' beliefs about medicines as measured using the Belief's about Medicines	Findings showed that participants had a high level of necessity and a low level of concern about the medications prescribed for them, there was negligible change in these beliefs from baseline to the end of the pilot. See Table 19 for more details.		

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<table>
<tr><th>Outcome</th><th>Finding</th></tr>
<tr><td>Questionnaire (BMQ) at baseline and at the end of the pilot</td><td></td></tr>
<tr><td>Correlation between participants' self-reported medication adherence and beliefs about medicines</td><td>Due to the small number of participants, a true correlation was not calculated. High medication adherence was observed alongside participants with high levels of necessity beliefs and low levels of concern beliefs about their medicines.</td></tr>
<tr><td>Number and rate (score/week) of heart failure decompensation prediction (HFPred) risk scores successfully generated per person during the pilot</td><td>
<table>
<tr><td>Participant</td><td>Number of heart failure decompensation prediction risk scores</td><td>Number of risk scores per week</td></tr>
<tr><td>1SU</td><td>84</td><td>7</td></tr>
<tr><td>2SU</td><td>41</td><td>6.8</td></tr>
<tr><td>3SU</td><td>77</td><td>6.4</td></tr>
<tr><td>5SU</td><td>83</td><td>6.9</td></tr>
</table>
</td></tr>
<tr><td>Correlation between HFPred scores and unscheduled care during the pilot (unscheduled care defined as composite of hospitalisations, A&E attendances, specialist contacts, out-of-hours contacts)</td><td>1SU had no instances of unscheduled care during the pilot, the maximum risk prediction was 49% during the 12-week pilot
2SU had no instances of unscheduled care during the pilot, the maximum risk predicted during the 6-week pilot was 19%
3SU had no instances of unscheduled care during the pilot, the maximum risk predicted during the 12-week pilot was 20%
5SU had one unscheduled visit to A&E during the pilot this was not in response to a cardiac decompensation. During the same week their decompensation risk prediction was 3%. They had a maximum decompensation risk prediction of 41% during the pilot.

Due to the small number of participants, no correlations could be determined. No participant experienced a decompensation during the pilot and the highest decompensation risk score was 49%.</td></tr>
</table>

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Outcome	Finding
	The risk scores were indicative of no decompensations occurring and none of the participants experienced a cardiac decompensation during the pilot.
Health-related quality of life as measured using the EQ-5D-5L questionnaire (4) at baseline and at the end of the pilot	EQ-5D-5L utility scores increased during the pilot, whereas scores on the EQ-5D Visual Analogue Scale decreased. See Table 19 for more details.
Exploration of healthcare practitioners' views on integration and alignment of the SHAPES platform and Digital Solutions with current care pathways	There was a number of differing opinions expressed in terms of the way healthcare practitioners could implement this technology into current care pathways. Firstly, HCP1 raised concerns that it may be more straightforward to use in certain diseases e.g. heart failure compared to diabetes as the clinical care is very well defined in heart failure whereas diabetes was felt to be more multi-factorial. *'…whereas with diabetes, if they're up or down there's 10-15 things it could be you know so have they been out taking alcohol, have they been eating a lot, have they been fasting a lot, have they been doing a lot of exercise, has it been better weather, because better weather makes your insulin work better, so there's a lot of problems with that.' [HCP1]* A common issue highlighted by all three healthcare practitioners was about where the responsibility lay for reviewing the data. If this responsibility lay with the patient who could bring any concerns to their healthcare team as and when they arose, this was thought to be much more manageable in terms of workload but equally there were concerns over whether patients in this population *'…have enough autonomy and agency themselves' [HCP3]* to act on the data presented. HCP1 and HCP2 stressed that this system would create a large volume of data if this was to be incorporated into standard care for all patients and may need cover for a *'seven-day service' [HCP2]*. HCP3 highlighted that the information presented could result in *'alert fatigue'* in both service users and healthcare practitioners and suggested that this technology would be best used in specific patients for *'defined*

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Outcome	Finding
	periods of time to stabilise people or at least to get a snapshot'[HCP3]. If this technology was to be integrated into standard outpatient care an individualised care pathway may need to be implemented depending on which disease specialties and healthcare teams were implementing it.
Exploration of healthcare practitioners' views about their trust and acceptance of the SHAPES platform and Digital Solutions	The healthcare practitioners interviewed were generally very trusting of the digital solutions demonstrated. They mentioned that as long as the technology met all relevant governance requirements (data protection, cybersecurity, and password protection) they would be happy to use it. HCP1 and HCP3 mentioned familiarity with different digital technologies already embedded into clinical care. *'I think it's becoming increasingly easier and safer. You know obviously you have your DPIAs and I think a lot of people are collecting health data now anyway, the phones are doing it; step counts and all the rest of it. I think if patients are adequately consented and informed about how their data is being managed and it is actually secure.'[HCP3]* In terms of acceptance of the solutions HCPs were generally accepting of new technologies: *'I think we have to be accepting now, you know …everything is going to be changing and we can't do anything about it, we just have to go with it'[HCP2], 'We are very confident, very competent at it, we are happy with it' [HCP1].* It was also mentioned that the use of this type of technology was well supported, however, their previous experiences of implementing new technology had resulted in unforeseen challenges. To increase acceptance among healthcare practitioners, the need for specific funding to allow adequate staff resourcing was a key factor. At present, the healthcare service in Northern Ireland is recovering from COVID-19, which has resulted in staffing shortages, high workloads and expanding waiting lists. As a result, unless capacity is built-in, healthcare practitioners stated that there was no additional capacity at present to take on new systems, training and new care pathways.

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Outcome	Finding
	'…we wouldn't have any capacity to do anything like this at the moment. And so if you're thinking about pharmacist doing it, you know there's so many clinics we would love to set up in cardiology between cardiac rehab and heart failure and titration of meds and management. But the answer is just constantly there's no money, there's no money. We need funding. So there is absolutely no way they would be able to take anything on unless there was specific funding and I think you probably would need people you know who had a background of cardiology or were able to be trained and obviously to deal with the heart failure patients and then intervene and give the correct advice to the patients when things aren't good, but yeah, I know it sounds brilliant and hopefully it's the way forward...'[HCP2]
Exploration of participants' views about their trust and acceptance of the SHAPES App.	In terms of trusting the App, none of the participants surveyed had any issue or concern with it collecting, storing and displaying their health information. All participants welcomed the potential future inclusion of healthcare practitioners in viewing their data. All participants were very accepting of the SHAPES App and indeed most would choose to continue using the SHAPES digital solutions if it was available and if they could use it at a lower frequency than was requested of them during the pilot (every day for 12 weeks). The participants perceived the App as useful for self-monitoring their health indicators. However, they described the frequency of using the devices and App every day as too burdensome and monotonous. *'Yes well it [the App] told me things every day but it was a bit of a nuisance doing it every day, basically' [1SU]* *'it [the App] was very useful, sort of storing all that information' [2SU]* *'…the only thing as I say, would be trying to get it to do it on a regular basis, but then if I'm doing it all the time, I suppose eventually... you get used to it' [3SU]*

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Outcome	Finding
	'Mostly it supported me, with obviously to check my bloods, oxygen, weight, which is the main thing I wanted, to make sure that was right.' [5SU] All participants perceived the App as easy to use once it was set-up on their tablet and linked to the 3rd party devices. *'I found it was quite easy to use and everything went smoothly' [2SU]* *'…it was very, very easy. And it wasn't very hard. Even if you're not computer literate. And it's still quite easy to use. It's, um, it's pretty straightforward.'[5SU].* *'there was nothing to dislike about it [the App], as I said like, as I said, the thing is, I use a lot of technology myself' [3SU]*
Exploration of user engagement behaviors	The participants were highly engaged with using the SHAPES digital solutions as evidenced by the very low number of days that participants missed logging into the SHAPES App, particularly 1SU and 5SU who did not miss any days over the 3-month period. Additionally, it is worth noting that 3 out of the 4 participants remained in the pilot for the full 3 months and 2SU had to be withdrawn for medical reasons.

2.9.5.2 UNRF (replicating site)

Overview

Screening and recruitment to Phase 5 large-scale pilot of the SHAPES UC-PT3-general use-case was conducted by UNRF in September 2022 and participants were actively involved between October 2022 and March 2023.

Researchers reviewed 25 potential participants from the Strovolos Day Centre and the surrounding community in Nicosia and recruited 10 eligible participants to the pilot. Fifteen potentially eligible participants were excluded for the reasons shown below in Table 21.

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Table 21 Recruitment and retention of Phase 5 participants at UNRF replicating site (PT3-gen)

Recruitment and retention of older adult participants at UNRF	
Screened prior to eligibility assessment	**N=25**
Excluded	**N=15**
Reason 1: Barriers to SHAPES technology adoption	N=10
Reason 2: Unstable medical condition	N=3
Reason 3: Declined to consent	N=2
Allocated to intervention	**N=10**
Lost to follow-up	N=0
Discontinued Intervention	N=0
Assessment of KPIs	
Assessed for KPI 1	N=10
Assessed for KPI 2	N=10
Assessed for KPI 3	N=10
Assessed for KPI 4	N=10
Assessed for KPI 5	N=10
Assessed for KPI 6	Not assessed
Assessed for KPI 7	Not assessed

Table 22 Baseline characteristics of Phase 5 participants at UNRF replicating site (PT3-gen)

Variable	**Number of participants**	**Value**
Age (years)	10	76.6 (6.76)
Male	4	4 (40%)
BMI (kg/m^2)	4	26.52 (4.02)

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Variable	Number of participants	Value
Diabetes	10	10 (100%)
Type 1 diabetes	10	10 (100%)
Hypertension	10	10 (100%)
Smoking	0	0 (0%)
Values are mean (SD) or n (%)		

Key performance indicators

Seven KPIs were identified for evaluation in the PT3-general use case. They are divided into 3 categories: recruitment and retention; user engagement and acceptance; and collection of data. Tables 23 to 28 present the data used to determine the success of each KPI. Table 28 provides an overview of the success of the pilot with regards to KPIs.

Recruitment and retention

KPI 1 At least 80% of the target cohort were successfully recruited into the pilot during the recruitment period

Table 23 Target and actual numbers and percentages of participants recruited into Phase 5 of pilot at UNRF (PT3-gen)

Parameter	Total
Target number of participants	10
Number of participants recruited	10
Percentage recruited	100%

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KPI 2 At least 80% of recruited participants remained enrolled in the pilot until the end of the study.

Table 24 Participant retention during Phase 5 of pilot at UNRF (PT3-gen)

Parameter	Value
Number of participants at baseline	10
Number of withdrawals	0
Number of participants at end of study	10
Percentage retained	100%

User engagement and acceptance

KPI 3 The overall user experience quality of the App as measured using the short version of the UEQ-S was classified as 'Excellent', 'Good' or 'Above average' based on published benchmark data.

Table 25. Mean pragmatic and hedonic quality UEQ-S scores and their comparison to published benchmark data at UNRF (PT3-gen)

Scale	Mean	Comparison to benchmark
Pragmatic quality	0.73	Below average
Hedonic quality	0.65	Below average
Overall	0.69	Below average

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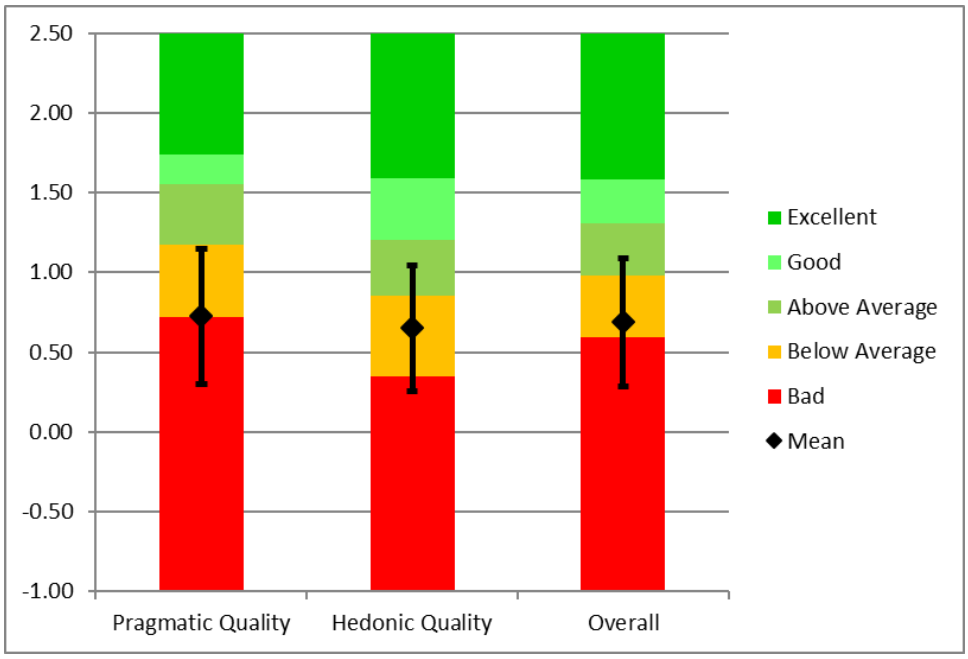

Figure 6 Mean UEQ-S and benchmark scores for the usability of the app at UNRF (PT3-gen)

KPI 4 At least 60% of participants continued to login to use the App daily after two weeks of the pilot.

Table 26. Number and percentage of participants using the app daily after two weeks at UNRF (PT3-gen)

Parameter	Value
Number of participants who logged in daily for at least 2 weeks after baseline	10
Total number of participants	10
Percentage using the App daily after two weeks	100%

KPI 5 At least 60% of participants scored an above average rating (>68) in the SUS.

Table 27. Number and percentage of participants scoring higher than 68 in the SUS at UNRF (PT3-gen)

Parameter	Value
Number of participants at end of pilot	10
Number of participants scoring >68 in SUS	0

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Parameter	Value
Percentage of participants scoring > 68 in SUS	0%

Collection of data

KPI 6 Sufficient data was collected from participants to allow the heart failure decompensation prediction tool to generate a percentage risk of decompensation at least once per week for at least 60% of participants.

Not assessed HFPred was not used at UNRF as patients with heart failure were not recruited.

KPI 7 At least 60% of participants completed the MARS at least once a month during the pilot.

This KPI was planned to assess a functionality within the eHealthpass part of the SHAPES Front-end App. This could not be assessed as initially the MARS questionnaire was not assigned within the App and the requirement to sign in each time the participants wanted to use the App for this task was deemed too complicated.

Overview of KPI achievement

Table 28. Overview of the success of Phase 5 of the pilot at the UNRF with regards to KPIs (PT3-gen)

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	Yes	Twenty five potential participants were screened, following exclusions, the target number of 10 participants was achieved.
KPI 2	Yes	We managed to surmount the obstacles of communicating with participants and the technological barriers, retaining 100% of the participants.
KPI 3	No	Benchmarking of data revealed that the usability was below the average.
KPI 4	Yes	After contacting participants either remotely or in person, we achieved daily

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Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
		data acquisition over a period of at least 2 weeks.
KPI 5	No	Due to multiple usability difficulties that participants faced during the use of the technology, none of the participants scored an above-average rating (>68) on the SUS.
KPI 6	Not assessed	N/A
KPI 7	Not assessed	The MARS was completed in hard copy version from all the participants at least once a month during the pilot. Initially the MARS questionnaire was not assigned within the App and the requirement to sign in each time the participants wanted to use the App for this task was deemed too complicated.

Evaluation of use case using MAST

The MAST framework (15) was used to evaluate the effectiveness and contribution of UC-PT3-general to quality of care. MAST is described as a multidisciplinary process that summarises and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine.

Three of the 7 multidisciplinary dimensions/domains of the MAST framework were of specific relevance to the pilot of UC-PT3-General. These were: Clinical Effectiveness; Patient Perspectives; and Economic Aspects. Completed MAST table can be found in Table 29Table 19. All the results presented below are based on data from 10 participants.

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Table 29. Completed MAST evaluation at UNRF (PT3-gen)

Domain	Topic	Outcome	Baseline *Mean (SD)*	End of pilot *Mean (SD)*	*Mean change (95% CI)*
Clinical effectiveness	Effects on health-related quality of life	EQ-5D-5L Utility Score	9 (1.90)	7.7 (1.55)	1.3 (-0.52, 2.82)
		EQ-5D VAS	57.5 (9.81)	62 (16.61)	-4.5 (7.46,16.46)
	Behavioural outcomes	BMQ Necessity Score	21.1 (3.45)	19.8 (2.48)	1.3 (-1.33,3.93)
		BMQ Concerns Score	13.5 (4.01)	15.8 (2.93)	-2.3 (-5.38,0.78)
		BMQ Differential Score (Necessity-Concerns)	7.6 (6.14)	4 (5)	3.6 (-1.31,8.51)
	Self-reported adherence	MARS Score	18.4 (4.76)	19.6 (5.48)	-1.2 (-5.7,3.3)
	Utilisation of health services	Hospitalisations	0	1	1

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Domain	Topic	Outcome	Baseline *Mean (SD)*	End of pilot *Mean (SD)*	*Mean change (95% CI)*
		Accident & Emergency attendances	0	0	
Patient perspectives	Satisfaction and acceptance	UEQ-S Score	-	0.71 (0.44)	-
	Understanding of information / Confidence (in the treatment) / Ability to use the application / Access	SUS Score	-	47 (2.79)	-
	Empowerment / Self-efficacy	General self-efficacy scale	29.6 (3.69)	29 (4.22)	0.6 (-2.87,4.07)
Economic evaluation	Related changes in use of healthcare resources	Cost of hospitalisations Cost of	Not available	Not available	-
		A&E attendances	Not available	Not available	-

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Domain	Topic	Outcome	Baseline *Mean (SD)*	End of pilot *Mean (SD)*	*Mean change* *(95% CI)*
	Cost of resources used	Cost of devices	• 7 units Lenovo Tablet Tab M10 TB-X306F (€1015) • 10 units OMRON M7 INTELLI IT BPM (€1178.10) • 10 units Accu-Check INSTANT & 60 packets strips 50/pack (€2310.03) • 8 units Huawei Wi-Fi Router E5783-330 (€552) • 4G Services Activation Fee (once-off) Basic Monthly Fee VMB 2GB (€866.56)		
		Cost of using digital solutions and SHAPES platform	Digital solutions from EDGE (eCare), GNOMON (eHealthpass, TREE (vitals control) were highly customised for each use case and as the Digital Solutions and the SHAPES platform are not yet commercial entities it is not possible to attribute a cost at this stage.		
		Cost of staffing	UNRF staff time: Recruitment, training, baseline visit, technical support, end visit, travel = 85 hours in total for 10 participants.		

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Performance of the eCare platform

During the pilot timeframe, eCare collected 1,155 measurements, including blood pressure and heart rate measurements, distributed as follows:

Table 30 Number of measurements collected by eCare of UC-PT3-General (UNRF)

Participant	Number of blood pressure measurements collected	Number of heart rate measurements collected
1SU	30	24
2SU	110	30
3SU	25	26
4SU	59	58
5SU	127	98
6SU	62	60
7SU	54	51
8SU	61	58
9SU	57	55
10SU	56	54
Total	**641**	**514**

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3 Use case PT3-001

3.1 Introduction

This chapter describes the pilot activities of UC-PT3-001 In-home decompensation prediction for heart failure patients. Target persons of this use case were aged 60 and older, living at home, they had heart failure at stage 2 or 3. Target users were the same older adults or any caregiver which lived with them or visited them at least 5 times a week. They were android smartphone users with access to the internet. The SHAPES Persona for this pilot theme was 'Roberto' (1), a man in his early 70s who lived in his own home with his wife. Roberto had multiple health conditions, including diabetes and hypertension.

- Older adult;
- Heart condition;
- Other pathologies, although not an inclusion criterion, most participants were expected to have multi-pathologies;
- Obese, although not an inclusion criterion, many participants were expected to be overweight;
- Several medications;
- They forget to take blood pressure pills.

Objectives

Primary objectives

- To investigate user engagement with the SHAPES App and Digital Solutions (PO1).
- To investigate the user-perceived usefulness with the SHAPES App and Digital Solutions (PO2).

Secondary objectives

- To investigate the capability of the SHAPES Platform and Digital Solutions to optimise use of medicines in homes in terms of:
    - Modifying pharmacological treatments (SO1);
    - Improving adherence (SO2).
- To investigate the capability of the SHAPES Platform and Digital Solutions to improve the management of the conditions (SO3).
- To investigate the identification of associations between precursor signs of deterioration and unscheduled healthcare resource use (SO4).
- To investigate the association between the computed dynamics thresholds and unscheduled healthcare resource use (SO5).

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- To investigate the association between the computed degree of physical activity and unscheduled healthcare resource use (SO6).
- To investigate the association of the VICOM's heart failure decompensation prediction score with unscheduled healthcare resource use, particularly hospitalisations (SO7).
- To investigate the capability of the SHAPES Platform and Digital Solutions to improve older adults' quality of life, wellbeing and psychological and psychosocial aspects (SO8).
- To explore the integration of the SHAPES Platform and Digital Solutions to align with current care pathways (SO9).
- To explore user trust and acceptance of the SHAPES Platform and Digital Solutions (SO10).

Tertiary objectives

The following objectives align with the general purposes of the SHAPES large-scale piloting campaign. To validate the capability of the SHAPES Platform and Digital Solutions to:

- Support and extend healthy and independent living for older individuals who are facing permanently or temporarily reduced functionality and capabilities (TO1).
- Improve the older individuals' health outcomes and quality of life (TO2).
- Gain the older individuals' trust and acceptance (TO3).
- Gain the care professionals' trust and acceptance (TO4).
- Contribute for the reduction of the workload of medical professionals (TO5).
- Deliver efficiency gains in health and care delivery across Europe (TO6).

Clinika de Kay, known as Clínica Humana and referred in this Deliverable as CH, has been the use case leader and a replication of the use case was planned to be performed by the Gewi-Institut für Gesundheitswirtschaft e.V (GEWI), however, due to recruitment issues detailed later in this document, this use case was not replicated.

3.2 Description

Older adults (>60 years old) living with from heart failure need a thorough control of the disease in order to avoid decompensations. When decompensations occur, these patients are normally transferred to hospitals incurring high expenses for health systems, a decrease in their quality of life and an overall decrease of productivity for caring relatives. Most severe cases can have one decompensation episode per month on average. Others may have one decompensation episode every 6–12 months.

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Medication adherence has been associated with fewer heart failure symptoms and fewer hospitalisations and deaths[1]. Medication is usually re-adjusted after a regular medical visit or emergency call. Due to the number of decompensations, further re-adjustments are needed with methodologies that do not overload the health system. Smart monitoring and visualisation systems can help.

3.3 Digital solutions used in this use case

The digital solutions implemented in this use case are presented hereafter.

eCare (EDGE)

Remote monitoring platform which collects and displays wellbeing and health data gathered manually or automatically (using Bluetooth connected medical and health devices like blood pressure monitors, pulse oximeters, weight scales and activity wristbands) in home environment. The platform includes a smartphone App for the target user and a control panel for the healthcare professional.

ROSA and Adilib chatbot (CH and VICOM)

Chatbot which interacted with the target user. The chatbot launched questionnaires to target users at times scheduled by the health professional. The user could also provide specific data to the chatbot at any time. The chatbot engine was supported by VICOM's Adilib and smartphone App was supported by CH's ROSA. ROSA included a control panel for the health care professional to visualise collected data from the target user.

HFPred (VICOM); Vitals control (TREE)

Analysis of medicine optimisation by prediction of worsening disease based on clinical device readings, patient feedback and modelling to allow timely intervention and medication review (prediction of heart failure decompensation by VICOM; vitals statistical control: dynamic thresholds and out of range controls by TREE).

Centralised data from eCare and ROSA allowed the computation of heart failure predictions.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5714687/].

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3.3.1 Digital solutions used for COVID-19 response

There were no digital solutions used for the COVID-19 response in UC-PT3-001.

3.3.2 Equipment and devices used (from third parties)

Four external devices were used in UC-PT3-001:

- Blood pressure meter: OMRON M7 Intelli IT blood pressure monitor;
- Weight scales: OMRON VIVA Smart Scale;
- Pulse oximeter: Beurer PO60;
- Activity wristband: Xiaomi Mi 3 band.

Specifications can be found in section 3.8.2 (Technical Aspects & Logistics).

3.4 Data plan

The data plan for PT3-001 includes the:

- DPIA document that assesses whether the processing of personal data is on a right level from GDPR point of view and describes the potential corrective actions that has been taken.
- Personal Data Processing Descriptions that provide detailed information about how personal data is collected, processed, and stored.
- DPIA risk assessment that identifies all the risks, its impact and probability and proposes actions for risk mitigation.
- Data Processing Agreement that defines the responsibilities and obligations of the data controller and the data processor regarding the processing of personal data.
- Data Sharing Agreement that sets out the purpose, type and scope of data sharing within PT3-001.

The data plan for Phase 5 of the pilot for UC-PT3-001 can be found here; https://shapes2020.eu/wp-content/uploads/2023/06/UC-PT3-001_data-plan-final_20062023.xlsx

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3.4.1 Data capture methods to be used

A range of different data capture methods was used throughout the 5 phases of this pilot. Below is a list of these methods detailed in the sections describing each pilot phase. All documents can be found in the Annex and are referred to throughout this document where relevant.

Phase 1

No data capture methods were applied.

Phase 2

Semi-structured interview with annotations on an electronic file. An online interview took place, alternating between demo slides and direct questions. The participants were invited to express any opinions or thoughts that they had during the presentation or suggested by the direct questions. Answers to direct questions were annotated on the slides and additional comments were annotated in the comments section of the PowerPoint file.

Phase 3

- Unstructured interview with annotations on paper while performing a demo of the digital solutions and as required at any time during the session.
- Researcher annotated doubts and abnormal use of SHAPES App and dashboards by participant while using them.
- Digital recording of participant's hands and phone/computer screen while using the digital solutions.
- Semi-structured interview that took place at the end of the session.
- UEQ-S (2).

Phase 4

- Data capture via the digital solutions with the objective of analysing the robustness of data flow in and between the digital solutions. Captured data consisted of:
    - MARS questionnaire via SHAPES App.
    - Daily medical questions via SHAPES App.
    - Events of change of medication, hospitalisation, health professional contact and lab tests (yes/no) via SHAPES App.
    - Weight and timestamp via scale and SHAPES App.
    - O2 saturation and timestamp via pulse oximeter and SHAPES App.
    - Diastolic and systolic blood pressure and heart rate, along with their timestamps, via blood pressure meter and SHAPES App.

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    - Activity (accumulated steps per minute, type of activity, heart rate) and timestamp via wristband and SHAPES App.
    - Sleep-related data (sleep latency index, sleep duration index, efficiency index, disturbance level index) via wristband and SHAPES App.
- Questionnaires for the HFPred algorithm by VICOM:
    - Barthel Index (10);
    - Gijon socio family assessment scale (11);
    - EHFScB (12).
- Data capture via the SHAPES platform: user and password.
- Personal data registered by researchers and related to devices: model, manufacturer and serial number of devices; time of the day older persons prefer to answer chatbot's questions.
- Unstructured interview to collect participant's feedback on the digital solutions.

Phase 5 data capture methods

- Data capture via the digital solutions with the objective of analysing the robustness of data flow in and among the digital solutions. Captured data will consist of:
    - MARS (14) questionnaire via SHAPES App.
    - VICOM's heart failure decompensation predictor questionnaire via SHAPES App.
    - Questions about urine quantity change, palpitation events and drowsiness via SHAPES App.
    - Events of change of medication, hospitalisation, health professional contact and lab tests (yes/no) via SHAPES App.
    - Weight and timestamp via scale & SHAPES App.
    - O2 saturation and timestamp via pulse oximeter & SHAPES App.
    - Diastolic and systolic blood pressure and heart rate, along with their timestamps, via blood pressure meter and SHAPES App.
    - Activity (accumulated steps per minute, type of activity, heart rate) and timestamp via wristband and SHAPES App.
    - Sleep-related data (sleep latency index, sleep duration index, efficiency index, disturbance level index) via wristband and SHAPES App.
- Data capture via the SHAPES platform: user and password.

CRF to capture the following data:

- Participant data (see Data Plan).
- Harmonised questionnaires (more details on harmonised data will be provided in Deliverable D6.9):
    - WHOQOL-BREF (3);
    - EQ-5D-5L (4);
    - General Self-Efficacy Scale (5);

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  - Oslo Social Support Scale (6);
  - Single item health literacy scale (7);
  - Participation questions;
  - SUS (8);
  - Technology acceptance questions (9);
  - Socio-demographic data (see Data Plan).
- Questionnaires for the HFPred algorithm by VICOM:
  - Barthel Index (10);
  - Gijon socio family assessment scale (11);
  - EHFScB (12).
- Other data for the HFPred algorithm by VICOM:
  - Blood and urine lab tests (see Data Plan);
  - Medical history (see Data Plan).
- Pilot 3 questionnaires:
  - BMQ (13);
  - UEQ-S (2).
- Pilot 3-001 questionnaires:
  - Eadon grading scale (19);
  - Risk Instrument for Screening in the Community (20).
- Use of health care resources:
  - Hospitalisation dates;
  - Type of hospitalisation;
  - Reason of hospitalisation;
  - Use of other health care resources and dates.
- Unstructured interview to collect participant's feedback on the digital solutions.
- SHAPES App use tracking data:
  - Login timestamp;
  - Identification of pages seen, page login and logout timestamps;
  - Measurement insertion type (manual/automatic) and timestamp;
  - Type of chatbot interaction (initiated by user or chatbot) and timestamp.

3.4.2 Planning of evaluation

MAST

The MAST framework (15) was used to evaluate the effectiveness and contribution of UC-PT3-001 to quality of care. MAST is described as a multidisciplinary process that summarises and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine.

A review of the dimensions of MAST revealed that 4 of the 7 multidisciplinary dimensions/domains were of specific relevance to the pilot of UC-PT3-001. These

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were: Health problem description; Clinical Effectiveness; Patient Perspectives; and Economic Aspects. Table 31 contains the data required for the MAST evaluation.

Regarding use of health care resources, as they are evaluated at baseline and end of pilot (collecting data during pilot with assistance of the digital solutions), collected data are both useful for the description of the current consequences of the disease (health problem description) and to evaluate outcomes of the adoption of the digital solutions (clinical effectiveness).

Table 31: Data required for MAST evaluation (PT3-001)

MAST Domain	Topic	Outcome	Data required	Time point
Health problem and description of the application	Definition of target condition	Will not be measured		
	Symptoms and consequences & Burden of disease	Use of health care resources	Number of hospitalisations	Baseline, during pilot, end of pilot
			Number of A&E visits	Baseline, during pilot, end of pilot
			Number of GP contacts	Baseline, during pilot, end of pilot
			Number of nurse contacts	Baseline, during pilot, end of pilot
			Number of out-of-hours contacts	Baseline, during pilot, end of pilot
			Number of ambulance calls	Baseline, during pilot, end of pilot
	Epidemiology	Will not be measured		
	Current management of health condition	Will not be measured		
	Features of the application	Not applicable		

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MAST Domain	Topic	Outcome	Data required	Time point
Clinical Effectiveness	Effects on mortality	Mortality rate	Number of deaths	End of pilot
	Effects on morbidity	Will not be measured		
	Physical health	Risk of hospitalisation	RISC score	Baseline and end of pilot
	Mental health	Psychosocial and psychological wellbeing	WHOQOL-BREF	Baseline, end of pilot, 3-month follow up
			GSES	Baseline, end of pilot, 3-month follow up
	Effects on health-related quality of life	Health related quality of life	EQ-5D-5L scores	Baseline, end of pilot, 3-month follow up
	Behavioural outcomes	Concerns about medicines	BMQ scores	Baseline and end of pilot
		Necessity beliefs about medicines	BMQ scores	Baseline and end of pilot
		Self-reported adherence	MARS scores	Baseline and end of pilot
	Utilisation of health services	Use of health care resources	Number of hospitalisations	Baseline (past 6 months), during pilot, end of pilot
			Number of A&E visits	Baseline (past 3 months), during pilot, end of pilot
			Number of GP contacts	Baseline (past 3 months), during pilot, end of pilot
			Number of nurse contacts	Baseline (past 3 months),

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MAST Domain	Topic	Outcome	Data required	Time point
				during pilot, end of pilot
			Number of out-of-hours contacts	Baseline (past 3 months), during pilot, end of pilot
			Number of ambulance calls	Baseline (past 3 months), during pilot, end of pilot
	Intervention benefits	Intervention benefits	Eadon scale	During pilot
Patient perspectives	Satisfaction and acceptance	User Experience	UEQ-S scores	End of pilot
		User acceptance	TAM score	End of pilot
	Understanding of information Confidence (in the treatment) Ability to use the application Access & Accessibility	Usability of application	SUS Scores	End of pilot
	Empowerment Self-efficacy	User engagement	Number of logins	During pilot
			Visited pages + time in pages	During pilot
			Insertion of data (automatic/manual)	During pilot
Economic aspects	Amount and cost of resources used	Cost of devices	Cost as per medical device purchasing invoice	End of pilot

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MAST Domain	Topic	Outcome	Data required	Time point
		Cost of using digital solutions and SHAPES platform	Costs to be provided by SHAPES	End of pilot
		Cost of staffing	Timesheets and costing data	End of pilot
	Related changes in use of healthcare resources	Cost of hospitalisations	Cost of length of stay per admission and medical bed day cost	End of pilot
		Cost of A&E attendances	Attendance cost	End of pilot

MAFEIP

Due to the evaluation methodology (small-scale deployment, non-case controlled) the MAFEIP tool (16) will not be used to evaluate UC-PT3-001.

3.4.2.1 Final check of the use case by using the CSFs of MOMENTUM and the NASSS framework

MOMENTUM

The MOMENTUM blueprint (17) was applied to check if UC-PT3-001 had the critical success factors (CSFs) needed to take it from the pilot phase to large-scale deployment. Outcome of the process can be found in Annex 29. Details of each CSF are provided below.

CSF 1. Cultural readiness for the telemedicine service

The leader of the use case, CH, has been working with telemedicine solutions for +7 years on a daily basis. In addition, data sharing and collaborative work is part of the methodology. Deployment of PT3-001 solution in other sites may involve a slower process.

CSF 2. Advantages of telemedicine in meeting compelling need(s)

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Remote monitoring is a clear opportunity for a tighter follow-up of older adults with a heart failure condition while addressing the shortage of skilled health professionals and keeping costs reasonable.

CSF 3. Ensure leadership through a champion

The CEO of CH is directly involved in the definition and deployment of the use case. CH is committed to incorporate such a monitoring system within their services.

CSF 4. Involvement of health care professionals and decision-makers

Health professionals and decision-makers from CH have been involved in the definition and development of the content of the project. In addition, healthcare professionals were participants of Phase 2, 3 and 4 and their feedback was collected.

CSF 5. Put the patient at the centre of the service

Patients were involved with the development of the digital solutions through the planned activities for Phases 2 and 3 of the pilot — mock-ups and prototyping — at CH. Such activities helped the investigators identify and produce information materials and training to support patients using the App and getting the best possible results from taking part in the pilot. All pilot sites agreed that the service was based on the patient's needs.

CSF 6. Ensure that the technology is user-friendly

Patients and health care professionals were specifically asked about user friendliness of the digital solutions during Phase 2 and 3 of the pilot and adaptations were made to enhance the user experience before the use case was piloted. Extensive training to use the digital solutions of this use case was not required. User-friendliness was tackled for all technologies addressed to the older adults. Regarding professionals, eCare and embedded TREE and VICOM HFPred technologies followed the same strategy. CH's professional tools were developed for the sake of completion of monitoring; the design followed usefulness guidelines but friendliness was not achieved at this stage. As far as possible, we used mainstream technology to develop the dashboards and control panels that were used by the health professionals. Additionally, there was collaboration with CH's health professionals in order to co-create and define the design of the interfaces. The final system was tested was also tested with health professionals. Usability and acceptance metrics (SUS) were used to evaluate the final usability of the system.

CSF 7. Pull together the resources needed for deployment

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The resources required for deployment of the digital solutions for the pilot were available, thanks to SHAPES funding and internal resources allocated. The technical partners of the use case provided all IT competences.

CSF 8. Address the needs of the primary client(s)

First evaluations identified insurance providers as the primary clients. They are very much in need of a reduction in health costs for their users with chronic conditions, based on direct experience at CH. Cost of service could be a barrier, mainly due to the human resources needed in monitoring. However, the solution allowed flexibility in the monitoring protocol and this was evaluated (in terms of health professional cost) during the pilot. The solution addressed the needs for enhanced efficiency and improvement of quality in the health sector (mainly through a reduction of decompensations and hospitalisations with a cost-effective monitoring service).

CSF 9. Prepare and implement a business plan

A business plan for the solution will be developed in D7.3 SHAPES Business Plan within WP7.

CSF 10. Prepare and implement a change management plan

To be developed in D3.10 SHAPES Change Management and Implementation Handbook within WP3.

CSF 11. Assess the conditions under which the service is legal

Review of the legal requirements with the Spanish Medicines Agency revealed that the HFPred module was classified as a medical device. Since the HFPred was a non-CE marked medical device, the results of the predictor were not shown to the medical doctor to avoid influencing clinical decisions. Older adults participating in the use case also did not see the results of the HFPred, however, they agreed through the informed consent form to provide personal data to run the predictor. The HFPred was run only for research purposes.

Completion of a DPIA identified and minimised any risks associated with the pilot with input sought from other work packages and the SHAPES Data Protection Officer at CH. Data processing agreements were established with relevant partners to permit access to pseudonymised data.

CSF 12. Guarantee that the technology has the potential for scale-up

Although the participants in the pilot were limited, the solution was designed with the intention to scale it to a pan-European level. The use of human resources was evaluated during the pilot, with a proper analysis of resources needed in relationship

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to the monitoring protocol. Pending satisfactory pilot results, 1 potential outcome is that CH will contact relevant local and national key players in order to deploy it at large-scale level.

CSF 13. Identify and apply relevant legal and security guidelines

GDPR was applied. The system provided implemented all security and privacy-related regulations.

CSF 14. Involve legal and security experts

We worked with SHAPES partners (for example LAUREA, with extensive expertise in this field), specifically because we were dealing with health data. VICOM was awarded the ISO 27001 certification for information security management. HMU and VICOM have extensive expertise in IT infrastructure security.

CSF 15. Ensure that telemedicine doers and users are privacy aware

The protocol for the pilot details all the steps that have been taken to ensure patients' privacy was protected. The project has undergone a full ethical evaluation before permission was granted to undertake the study.

CSF 16. Ensure that the information technology infrastructure and eHealth infrastructure are available

SHAPES is developing a technology platform for pan-European distribution of health and care digital solutions and services.

The pilot was designed to cope with this requirement as well.

CSF 17. Put in place the technology and processes needed to monitor the service

The IT system was designed to work 24/365. In case of any bugs or issues the development and maintenance team were available to rectify any such problem. CH, EDGE and VICOM are the owners of all the software used in the pilot. This meant that we didn't have any software dependencies with third parties, and that we could fix the source code at any point. The system logged all activities so any incident could be identified and solved quickly. In addition to the user manual, we had access to the software developers of the system in case of doubts or questions we could receive the answers to them directly from EDGE and VICOM.

CSF 18. Establish and maintain good procurement processes

The requirements needed from the devices used in the pilot were defined and vendors fulfilling them were identified. The SHAPES project provided the servers that were

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needed to run the solution. Those servers met the service level needed to run the pilot successfully.

NASSS

The NASSS framework (18) was used to detect areas of complexity in the project plan for piloting UC-PT3-001 and, if needed, to make adaptations to the plan. The short version of the NASSS-CAT and the NASSS-CAT Project questionnaires were considered and completed by the pilot team (see Annex 30 and Annex 31). Of the 6 domains, there were 4 domains in which significant complexities were identified that, if not mitigated or addressed, were likely to affect the project's success at the piloting stage of the use case.

At the time the NASSS framework was applied (January 2021) there were significant uncertainties identified in 3 domains. Their description, along with the mitigation action that have been or are being undertaken are listed in Table 32.

Table 32: Complexities and mitigation measures identified using the NASSS framework (PT3-001)

NASSS complexity domain	Uncertainties detected	Mitigation measures taken
Technology	Many interdependencies are being developed. Bugs and crashes are expected. Resources are allocated but constant check is needed to keep developing times.	Infrastructure for Phase 3 was fully defined. Several actions were completed in order to increase efficiency in the development, i.e. monthly technical meetings and, so far, 2 hackathons to assure alignment among technical partners.
Technology	Missing features within the technologies have been detected, particularly those necessary for full visualisation of gathered data.	A database manager was developed by CH. ROSA dashboard will incorporate further data for display.
Value Proposition	The time of the pilot must be carefully re-evaluated to reach KPIs in terms of reduction of costs in use of health care resources. We need to re-evaluate the	After mock up presentations it was detected that the solution had value for the following caregiver types: informal/family and those

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NASSS complexity domain	Uncertainties detected	Mitigation measures taken
	design of the pilot to maximise the outcome it can provide. Several questions were raised: do we need a control group? Does the study need to be a longitudinal study to evaluate weight of interventions vs. life-style changes? Finally, the value of the solution for formal caregivers needs to be further discussed.	who stay most of the day/all day with patients. The KPIs were redefined to address the acceptance of the technology as a first step to evaluate a longer pilot in the future.
Intended adopters	The technology requires answering questions on a daily basis. As heart failure is a chronic disease, the technology is intended to be used for a long time. We need to re-evaluate the adequateness of questions to avoid drop-outs (older adults/caregiver getting tired of answering questions).	An alternative chatbot protocol was evaluated: instead of chatbot launching daily questions, the user had an option on the chat to start the process. The user was informed that if everything was ok, they didn't need to start the question process.
External context	Regulatory needs to be further evaluated.	Internal discussion and contact with the Spanish Medicines Agency re-defined the legal deployment of solution. Some parts required CE-marking and medical device classification if the solution was to be used by health professionals to inform clinical decisions.

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3.5 Phase 1

3.5.1 PACT and FICS Scenario

Table 33: PACT (PT3-001)

Code	UC-PT3-001	Version	1	Date	2021/01/14
Applicable SHAPES Persona	Roberto (P2)				
Applicable SHAPES use case	UC6: In-home heart monitoring UC2: Digital Nurse				
Point of contact (pilot site)	Clinika de Kay (CH)				
Point of contact (technical provider)	VICOMTECH				
People *Roles and/or actors of typical users involved in delivering and receiving the telemedicine intervention*	• Older adults, 65+ years old, care recipient, living independently in their own home in urban environments. They usually live alone or with their partner and are visited by a caregiver on a regular basis (2-3h a day). They will have none to little digital literacy level but have a basic smartphone. Caregivers: although the older adult is the preferred person to be involved as user of the chatbot, one caregiver may take over this role if the use of the App in the smartphone is a barrier. In addition, any caregivers may introduce missing data manually. • Health professionals: they are the team of health professionals giving assistance to the participants on a regular basis. They will also collect data regarding the use of health resources and medication.				
Activities *Activities to be performed by the actors in order to successfully provide and receive the telemedicine*	**Older adults / care receiver** • Takes the following measurements on a daily basis: weight, BP, O2 saturation, heart rate • Wears an activity band constantly • Has a smartphone that acts as gateway of data from devices • If contact person:				

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intervention procedures for the professional and the patient; Parameters that determine the measures used in the intervention	○ Interacts with chatbot on a daily basis (fills questionnaires) ○ May initiate interaction with the chatbot occasionally ("My doctor has changed my medication plan") ○ Provides data about use of health care resources and medication (telephone call interview) **Caregiver(s)** • If contact person: ○ Interacts with chatbot on a daily basis ○ Provides data about use of health care resources and medication (telephone call interview) • Fills missing data **General Practitioner** • Checking older adult health status using a dashboard which reflects health data (at least once daily) • Managing the interventions coming out from the previous point: ○ Interventions regarding medical assistance as described in the health centre protocol and services, using own system and procedures • Collects data about any change in medication and use of health care resources (even related to other/non-SHAPES pilot health centres).
Context *Social-medical relevance of the telemedicine intervention; privacy issues; risks for the patient; locations*	The older adult will be provided the following devices/software and respective connectivity with the SHAPES platform: • Body weight scale, pulse oximeter, BP monitor, activity band • Mobile App - chatbot One of the key goals is to optimise the medication plan, which will lead to fewer decompensations. The main objectives are: • Monitor vitals, health status, symptoms and medication adherence (chatbot questionnaires) to plan interventions accordingly • Update list of medicines to provide: ○ Medicine reconciliation

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	○ To carry our interventions (including pharmaceutical interventions) to prevent decompensations from occurring Fewer decompensations are expected to lead to a decrease of the use of health care resources. To evaluate this, related data will be collected during the pilot. Other context points: • Maintaining privacy of data is of the utmost importance. An identification list (including name and DOB) will be held at the local pilot site • GDPR and ethics in line with WP8 • Data and servers must be located within the EU • Spanish language • Location: Mallorca, Spain
Scenario	*Older adult (and sometimes caregiver in alternative scenarios)* Roberto is a 70-year-old person, living with his wife. He suffers from heart failure, stage 2-3, and experiences one decompensation a month. He regularly needs to contact CH's doctor to adjust his medication, for example; adding a diuretic. He has some activity basically short walks outside home with scheduled stops, and wandering at home, also along established stretches and stops. He can eat, get dressed and have a shower independently or with little help. For these activities, he has a caregiver who goes 2/3h a day, usually at the same times. The rest of the day, he is most of the time sitting, watching TV and chatting with his wife. He usually takes his medication properly, although sometimes he misses a dose. This routine has actually improved since the pharmacist offered him a pill organiser. He has several chronic conditions for which he takes 5-10 pills, 2-3 of them to control his heart failure. Roberto wakes up at 8.00. Caregiver comes at 8.30 and assists him in morning activities: 1) Wash, bath 2) He weighs himself (the result is saved in the App) 3) He gets dressed 4) He has breakfast 5) He takes his medications

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6) After half an hour, he takes his blood pressure, O2 saturation level and heart rate. If values are not normal:
    a. Blood pressure: he waits 15 min while sitting and takes the measurement again (the result is saved in the App).
    b. O2 saturation/heart rate: He massages his finger and takes the measurement again (the result is saved in the App).

At 10.00-10.30h they have usually finished all morning tasks and sit together and chat. Roberto receives a notification in his cell phone. It's the time to answer the questions of his chatbot. They are easy and quick to do, and make him feel at ease because he knows his answers help his doctor to know his state better (in an alternative scenario, it's Roberto's caregiver who has the App, receives the notification and answers the questions).

- Regarding swelling periods (edema), in the last 3 days your legs/feet or any other parts of your body are better, worse or the same?
- In comparison with the last 3 days, today you feel better, worse or the same?
- In the last 3 days, have you taken any medication not ordered by a doctor?

If there is nothing unusual the questionnaire finishes here. He also likes to comment with his caregiver while he's answering. Last week, he suffered a decompensation and stayed in hospital for 2 days, where he didn't feel like answering chatbot's questions. CH personnel called him to check whether everything was ok, as they couldn't see any activity. He explained everything to them. (In an alternative scenario, a caregiver fills missing data on Roberto's behalf through the application).

At 11.00h he gets a notification in his cell phone. It's a piece of advice from the chatbot:

- "Remember to be active, try to walk 2000 steps a day"

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He knows, but it's summer and it's very warm lately. Maybe next time he sees his doctor will ask what to do at home instead of walking outside.

Today at 12.00h, he has an appointment with his rheumatologist, his knee arthrosis is not so well lately. He walks to the bus stop, only a 10-minute walk. He wears the bracelet that records his steps. He doesn't have to think about it too much, just once a week to recharge it. In the visit, the specialist replaces a medication he is taking with a new generation drug, apparently more effective.

Back at home, he remembers that he has been instructed to notify any change in his pharmacological treatment. The chatbot reminds him every week, but the sooner it is notified, the better:

- "Hello, I have changes in my medication"
- "If I'm not mistaken, you are saying your medication has changed, right? YES/NO"
- "Yes"
- "Thanks for letting us know, it's been registered, CH will call you"

In addition to changes in the pharmaceutical treatment, other questions that are regularly asked to the older adult to detect that new important events have happened are: hospitalisation (every 7 days) and blood analysis (every 7 days). Roberto has always has the option to have the initiative to notify them before the reminder.

Because he suffered a decompensation and was hospitalised last week, he usually takes his blood pressure again in the evening.

Next day, he gets a call from CH asking him about the changes regarding his medication.

A few days later, he starts to feel more tired. It happens sometimes. He answers in a chatbot's question that he is feeling worse, and a slightly longer questionnaire is completed.

- Are you able to walk or to do activities like in the previous day? Yes, no

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- Do you feel fatigued or have trouble breathing when you are lying down in bed? Yes, no
- Do you feel you have more cough and / or mucus (phlegm)? Yes, no
- Does the medication work for you? “No” if you relate your medication with any side effect, such as dizziness or low blood pressure, for instance. Yes, no
- Are you following the diet and exercise recommendations indicated by your doctor or nurse? Yes, no
- Have you noted that you are urinating less, more or the same? Less, the same, more
- Have you had palpitations on your chest or neck? Yes, no
- Are you more sleepy during the day? Yes, no

“You have finished the follow up questionnaire. Thank you! I taken note of everything.”

While answering, he realises that he may be going less often to the toilet.

Next day, he receives a call from CH, they suggest adding a diuretic to his pharmaceutical treatment, because the new arthritis drug may be retaining body liquids. In addition, they will also visit him on the following day.

Health professionals

The physician has access to a dashboard where they can see:

- Profile of participants, including medical data and pharmacological treatments, collected at baseline
- Historic evolution of parameters (weight, blood pressure, oxygen level, heart rate, number of steps, answers to questionnaire, hospitalizations, history of warnings, …)
- Which older adult has informed about: changes in medication, use of health care resources, blood analysis
- Lack of collection of data
- Warnings: who has presented values out of the normal range (ranges can be modified by the physician).

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	The physician uses the dashboard every day at first hour to: • Check for availability of updates (medication, use of health care resources, blood analysis) or lack of collection of data ○ Which leads to the task of calling the older adult/caregiver to collect data, which is introduced in the system • Reconcile pharmaceutical treatments ○ Which leads to the intervention of changing pharmacological treatments, communication to the respective older adult/caregiver and registration in the system • Supervise patient evolution and associated warnings ○ Which may lead to any intervention according to the clinics procedure (registered in the internal system of the clinic) *Caregivers* If they are the App users, they have access to the App where they can fill missing data: • To introduce vitals • To introduce answers to questionnaires • To provide updates (changes in medication, uses of health resources, new lab tests)
Technology *Type of information / parameter that are relevant in monitoring the health status; type and frequency of accessibility of information; feedback modalities (communication)*	*Older adult* • Socio-demographic data (collected at baseline) • Data about medical history (collected at baseline) • Data about medication (collected at baseline and during the pilot if there is any change) • Lab results (collected at baseline and during the pilot if there is any change) • Answers to questionnaires (baseline, end of pilot, 3-months follow up) • Answers to chatbot questions (collected during the pilot, daily questions through the ROSA App) • Device measurements: Weight, blood pressure, heart rate, O2 saturation, sleep information, physical activity information (collected during the pilot through the eCare App, inserted manually or collected automatically through Bluetooth).

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	• App usage: login/logout information, App activity In case the caregiver is the App user, the older adult's information will be provided by him/her. *Health professional* • Eadon intervention scale: Change in treatments / medication, etc. (during the pilot) • RISC questionnaire • End of pilot questionnaires

Table 34: FICS (PT3-001)

Category	Details
Function and events *Functionality of the intended system which is capable to realize actor's activities*	In this pilot there are two main actors: 1) Roberto, the target old adult (and optionally an informal caregiver) and 2) the health care professional team (HCP). The system provides different functionalities for these two main actors. For Roberto: 1) Roberto uses an App in a smartphone or tablet connected to the internet, plus several health devices (BP meter, weight scale …) to report its status to the HCP and to get personalized feedback from them. 2) The App authenticates the user. 3) The system offers the devices and the functionality to: • Measure blood pressure daily • Measure weight daily • Measure heart rate daily • Measure oxygen saturation daily • Measure activity daily using a wristband • Answer questionnaires • Receive reminders & notifications

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Category	Details
	Measurement values are retrieved automatically from the measurement devices through Bluetooth connection. In case of any issue, the values can be reported manually as well. The App collects all this information and delivers it to the HCP Control Panel. For HCP: 4) The system provides a control panel that allows the HCP to monitor the status of their patients, the adherence to their care plans, to personalize their care plans/medications/treatments and to fully control of the system. The system also delivers alerts to the HCP. The system also predicts heart failure decompensations through the HFPred, however, this information is not available to the HCP. The HFPred is run during the pilot and the results will be analysed after the pilot to study the accuracy of predictions. 5) In detail, the functionalities that are integrated in the control panel are: • New patient registration interface • Patient list and patient profile viewer; it allows the entry of baseline data as well • Patient care plan prescription tool (patient to-do list). It includes all vital signs measurements, activities, questionnaires, medications to take or treatments to follow and their timing through the day • Patient monitoring dashboard. This dashboard displays the collected data (BP, O2Sat, weight, HR, activity, answers to questionnaires …). Appropriate visual analytics tools / charts are used to display each variable and to report adherence to the care plan • Questionnaire authoring tool • Alerts dashboard, includes history of alerts • HF decompensation risk prediction tool (not showed to participants) • Chatbot control tool (ROSA)

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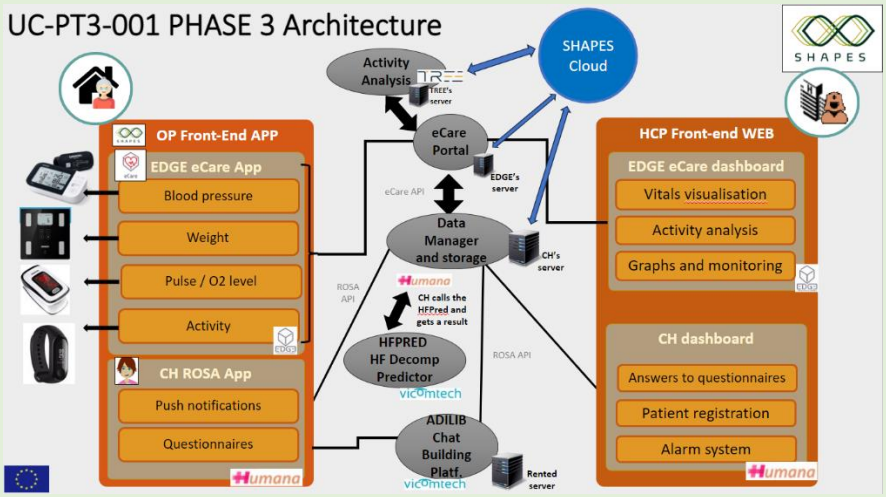
Category	Details
	6) The system stores all data related to the use case and allows its exploitation in the future.
Interactions and usability issues *User-system or system-component interactions meditating actor's activities; Types of the interactions, e.g. unidirectional data streaming service or reliable messaging service*	In order to facilitate the interaction to the maximum, a chatbot has been integrated in the user's App and used as the main interaction method with the system. The chatbot has one mode: text-based interaction. From now on, the chatbot will be called ROSA. ROSA remembers and requests the user all the tasks that he/she has to do to complete the care plan provided by his/her HCP. The user reports his/her feedback through ROSA. Additionally, the user can also initiate dialog with ROSA to notify or request relevant information or situations. The HCP configures ROSA so that it delivers the care plan, collects the corresponding answers from the user and sends reminders. ROSA is a bidirectional communication tool, and the communication can be started from both sides.
Content and structure *Variables of the interaction*	The following picture describes the system concept:  The data to collected is:

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Category	Details
	• BP • Weight • Pulse heart rate • O2 Saturation • Activity related measurements • Answers to questionnaires Each datapoint will be timestamped. The dialogs that will be launched from the App to the user are: • Push notifications: ○ Take vital measurement (BP, weight, pulse, ...) (automatic connectivity) • Questionnaires: ○ Complete a specific questionnaire. Questionnaires will be scheduled by date/time, or by values in database. The dialogs launched from the user to the HCP are: • Specific dialogs: ○ “My doctor has changed my medication plan” ○ “I am not feeling well“ ○ “I want to call Clinica Humana“ ○ ...
Style and aesthetics *Look and feel of the system*	

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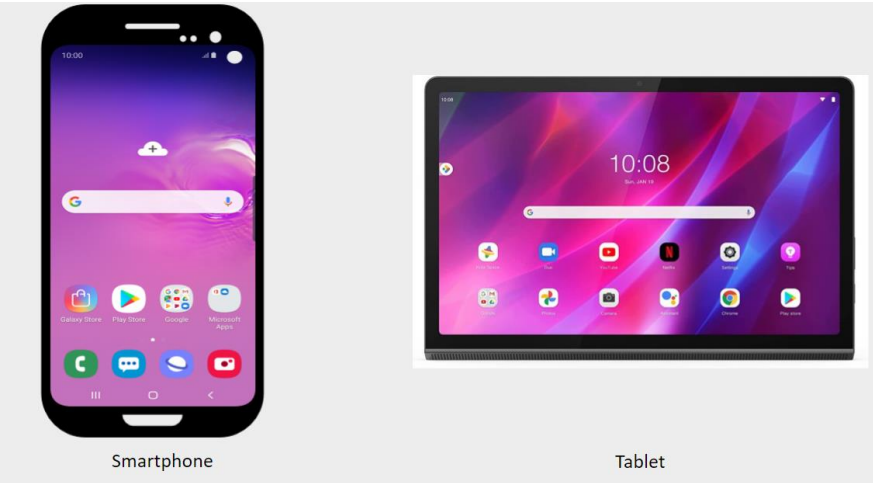
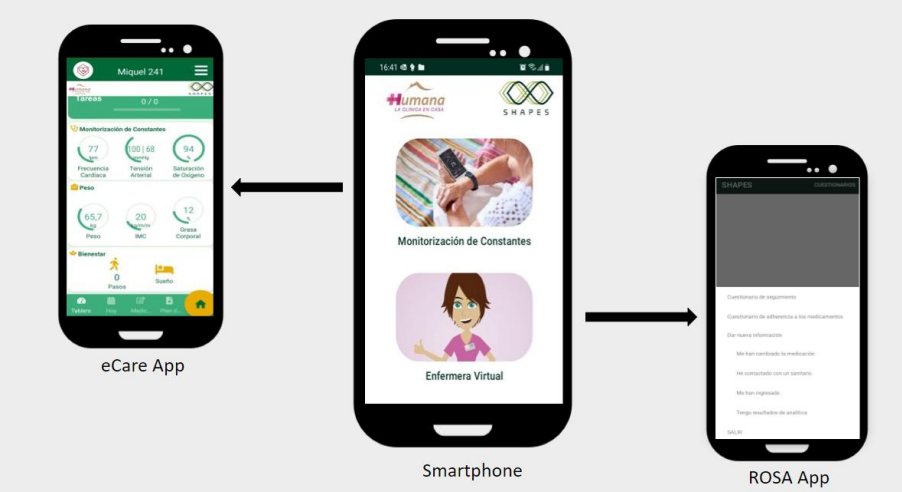
Category	Details





3.5.2 Key performance indicators

KPIs were defined as a set of measures that focus on the factors most critical to a project's success. KPIs are measurable and quantifiable with a target or threshold. They measure performance in critical areas by showing the progress or lack of it towards realising the objectives of each specific use case. The following KPIs were chosen to determine whether, or not, the pilot for UC-PT3-001 was successful.

Failure to meet four or more of the KPIs will indicate that repetition or major revisions to the use case and associated digital solutions are needed before entering further development oriented to commercialisation.

Recruitment and retention

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1. At least 80% of the target cohort (older adults) were successfully recruited into the pilot during the recruitment period.
2. At least 80% of recruited participants within the target cohort remained enrolled in the pilot until the end of the study.

Technical performance

3. There is no re-start of any of the components of the technology, except for the blood pressure meter, pulse oximeter or activity wristband, for at least 90% of the days.

User engagement and acceptance

4. The overall user experience quality of the App as measured using the short version of the UEQ-S (2) was classified as 'Excellent', 'Good' or 'Above average' based on published benchmark data.
5. At least 60% of the older adults/caregiver provides all measures from blood pressure, O2 saturation and heart rate at least 50% of the days.
6. At least 60% of the older adults/caregiver provides answers to set1 (Follow up questionnaire) / set2 (Adherence to medication questionnaire) questions at least 50% of the days.
7. At least 60% of participants using the App scored an above average rating (>68) in the SUS (8).
8. At least 60% of HCP rated the technology as "Agree" or "Strongly Agree" when asked "Does the technology improve the quality of your clinical practice?"

Benefit of interventions

9. Interventions by HCP are graded 4 ("Intervention is significant and results in an improvement in the standard of care") or above as measured using the Eadon scale (19) in at least 30% of the records.
10. No intervention by HCP is graded 1 ("Intervention which is detrimental to the patient well-being").

3.5.3 Timeline of pilot activities

The original timeline of pilot activities according to the Description of Work was to conduct Phase 1 and 2 between November 2020 and April 2021, then start with Phase 3 (prototype testing and hands-on training) in May 2021 and with Phase 4 (deployment in controlled environment) in September 2021. It was planned that CH would conduct Phases 1–5 and GEWI would replicate Phase 5.

In Phase 3 (hands-on training), the SHAPES partners needed to be in direct contact with the participants, the COVID-19 situation at the time made this very difficult

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especially in this vulnerable population of service users. A formal request to extend Pilot Theme 3 was approved by the Project Officer, therefore the start of Phase 3 was postponed until it was safer for the older adults to have in-person meetings with the SHAPES research team. Phase 4 and 5 involved training participants on the use of clinical devices and recruiting from outpatient clinics. The COVID-19 situation resulted in significant clinical staff redeployment and only essential outpatient services were running in a number of sites. The restrictions did not allow for in-person meetings. This impacted on our ability to recruit using outpatient clinic lists and an extension to the start of Phase 4/5 provided time to identify alternative recruitment processes and resources to achieve this.

	2020		2021											2022											2023						
	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
Planned timeline: PT3	phase 1		phase 2				phase 3			D	phase 4				phase 5				D												
Actual timeline: UC-PT3-001	phase 1		phase 2				phase 3							D	phase 4												phase 5						D

Figure 7 Planned and actual timeline of pilot activities (PT3-001)

3.6 Phase 2: Testing of mock-ups and prototypes

3.6.1 Methodology of testing

The aim of Phase 2 was to validate the functionalities of technologies in UC-PT3-001 and their implementation plan, including the interaction with the users, based on the feedback collected from participants. In addition, this research study also aimed to collect data on new functionalities addressed to end-users needs. The outcome of this research study provided technical partners with the opportunity to integrate user feedback at an early stage of the technological development process.

During this phase, the eCare App and Dashboard, ROSA App and Dashboard and related assisting technologies for UC-PT3-001 underwent a co-design and user-testing process to validate the functionalities offered and their usability. Mock-ups of the digital solution, its behaviour while the functionalities were in use and the vitals measurement procedure were shown to participants:

Presentation of mock-ups

Validation was sought on the utility and usability of:

- Use of devices by older adults/caregivers;
- Use of SHAPES App by older adults/caregivers;
- Use of dashboards for monitoring by HCP;

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- Process of registration of interventions by HCP.

In addition, the presentation allowed users to propose ideas for new functionalities.

Remote sessions were conducted with participants via video call. In the case of older adults, personnel of CH were physically with them to establish the video-call connection and provide a hard copy of material if requested. A PowerPoint presentation was shown via screen share during which participants were presented with brief background information about the SHAPES project and an overview of the purpose and functionalities of the UC-PT3-001 use case technologies. Mock-ups (images and text descriptions were inserted in the presentations) of functionalities were then presented to participants. In the case of sessions with older adults, mock-ups of the cell phone applications were also shown on paper in order to provide real size pictures.

After each functionality, the SHAPES manager at CH asked participants questions about the utility of the functionalities according to their needs in several scenarios. These questions were a combination of open and closed questions designed to obtain both general and specific feedback about the functionalities. Some closed questions required an evaluation from 1 to 5 and others required the ranking of several options. The PowerPoint presentation files are included in

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Annex 32:

- Presentation for older adults and caregivers;
- Presentation for HCP.

After the presentation, participants were given a copy of the slides with the notes taken by the personnel of CH. They were told to review the notes and send more feedback, corrections or clarification if they had time to do so (contact details were provided during the presentation). Further comments were requested to be sent back within 15 days. The copy was electronic or physical, depending on what was agreed and the contact details they wanted to share (email or address, respectively).

The following number of sessions and time duration, was expected:

- Older adults: 1 session, 45min;
- HCP: 1 session, 2h.

Data collection and analysis

Notes were collected during the interview by personnel of CH. A report was developed, which included a table with all questions and corresponding answers. Similar questions throughout the different types of users were grouped together. Other comments and opinions collected at the interviews were presented after the table or within a particular cell if the information was related to the question. Completed reports and collated findings, including recommendations, were presented to technical partners.

Participants

This research study was conducted in two different types of user groups:

- Older adults: 1) ≥ 65 years' old; 2) they are independent, although they may receive caregiving some hours a day; 3) living at home (it could be in a sheltered apartment); 4) have access to internet connection. At least 2 people were expected to be recruited. In this group, informal/formal caregivers were expected to accompany the older person if the latter were not expected to use the mobile App. Caregivers could participate as App users in case older adults couldn't manage to use the App.
- HCP: professional to monitor patients through the dashboard and decide the scheduling of visits or contacts. At least 1 person was expected to be recruited.

Identification of participants

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Older adults

Eligible participants were identified within patients of CH.

HCP

Eligible participants were identified among personnel from CH.

Informed consent procedure

Eligible individuals were provided with a participant information sheet explaining the background and purpose to the study and what they could expect to happen if they agreed to participate.

- Older adults: participant information sheet for older adults;
- Caregivers: participant information sheet for caregivers;
- HCP: participant information sheet for HCP (see Annex 33 for all Phase 2 participant information sheets).

Those who agreed to take part were then given a consent form by personnel of Clinika de Kay. Signed consent forms and contact details were provided to Clinika de Kay to proceed with the study activities.

- Older people consent form;
- Caregivers consent form;
- HCP consent form (see Annex 34 for all Phase 2 participant consent forms).

Informed consent for all participants were taken with the following accepted forms of signatures:

- Physical handwritten signature;
- An electronic representation of a handwritten signature.

The informed consent signed by participants was signed by the SHAPES manager at CH to acknowledge receipt and a physical or electronic copy of the document was provided to the participants by personnel of CH.

The consent process collected the following information:

- Name: in the consent form, for the purpose of identification of the accepted consent.
- Email (optional): if the signed consent form was sent to CH by email, the same email was used to return a countersigned copy. The email was kept as contact information and was deleted for the purpose of this study when the results were provided to the participant.

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- Address (optional): the participant may have provided a physical address to receive the countersigned copy of the consent form. The address was kept as contact information and was deleted for the purpose of this study when the results were provided to the participant.

3.6.2 Results of testing

A feedback report from Phase 2 mock-up presentations including recommendations developed for technical partners is provided in Annex 35. An overview is provided below.

Phase 2 mock-up presentations with recruited participants (3 target users and 1 HCP) were conducted between 28th April and 3rd May 2021. Presentations were conducted remotely via the Google Meet video conferencing platform. Notes were taken during the session and shared, after removal of personal data, with partners.

Report overview

- Older adult (1 interviewee)
  - Low e-literacy but they have a smartphone and they feel comfortable with the options they use
  - Would not participate if it triggers anxiety
  - Too much information in App would be stressing
  - There should be no obligations
  - "I'm not gonna use it if I feel bad that day"
- Caregiver informal (2 interviewees)
  - Very interested in eCare App
  - Informal caregiver didn't like the idea of daily tasks and they proposed a weekly frequency. However, professional caregiver did accept the idea of daily tasks
- HCP (1 interviewee)
  - Will check control panel first time in the morning, so interested in warnings from the previous day
  - Would be nice to have history of warnings available
  - Scaling-up (not pilot): they would need someone in charge of the monitoring
- All general conclusions
  - App configurable to user expectations (show/hide on/off options)
  - App adaptable to Android accessibility configuration (font size, zoom)
  - HCP constant contact available in Control Panel development

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- Protocol for questionnaires and vitals that can be adapted to App user and HCP needs
- User triggers questionnaires when feeling bad
- Button in chatbot to start questionnaires
- Regarding vitals, HCP would prefer daily
- HCP: “users will get tired answering daily questions after a few days”

3.7 Phase 3: Hand-on Experiments

3.7.1 Methodology of hands-on experiments

Hands-on experiments were performed in Phase 3 of the SHAPES Pilot Campaign to collect feedback from end-users and evaluate the performance of the digital solution in the actual pilot setting. End-users were presented with prototypes of the digital solutions that had been developed and improved during Phases 1 and 2.

Hands-on training

Phase 3 had the following goals:

- To collect feedback (user experience) from end-users by giving them the option to try the digital solutions deployed in the use case PT3-001 in a close-to-final version prototype.
- To train HCPs in the digital solutions they would be using in the use case.
- To collect feedback about the stability of the digital solutions and their connections.
- To validate the display of weight, pulse oximeter and blood pressure measurements on the eCare App and eCare dashboard.

Participants were invited to individual sessions with CH personnel to take part in the hands-on experiments. Older adults and their caregivers participated together. Sessions were conducted at:

- Older adults/caregivers: at their homes or at CH centre, as they wished.
- Health care professionals: at CH centre.

Participants

Phase 3 hands-on experiments were to be conducted with at least four target users of the SHAPES App (i.e., either ≥ 65 years’ old; diagnosis of heart failure; living at home or a caregiver of an older adult with the same criteria). Gender equality was sought in the group of older adults' participants.

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Phase 3 hands-on experiments were to be conducted with at least 1 HCP from CH.

Phase 3 hands-on experiments were also conducted with at least 1 staff member of CH who was using the devices and App for 5 days in a manner close to the use case.

Identification of participants

Eligible participants were identified by CH within patients and personnel. Information sheets were provided to participants (Annex 36).

Informed consent procedure

Informed consent (Annex 37) for all participants was taken with the following format of signatures collected where appropriate:

- Typewritten;
- An electronic representation of a handwritten signature;
- Handwritten signature.

Procedure

For the older adults and/or caregivers, technologies were presented as a functioning prototype with the eCare and ROSA digital solutions accessed via the SHAPES App, as well as the models of blood pressure monitor (OMRON M7 Intelli), pulse oximeter (Beurer PO60) and weight scale (OMRON VIVA) devices which were used in the use case. The SHAPES project manager at CH guided the participant through a series of steps and tasks to demonstrate the different functionalities of the App.

The App was accessed by participants via an internet-enabled mobile phone device provided by CH. The devices were provided by CH. The HCP dashboards were accessed by participants via an internet-enabled laptop computer provided by CH.

The steps and tasks included:

Demonstration to older adults and/or caregivers:

1. Accessing the prototype App
2. Logging into the SHAPES App
3. Navigating to different features from ‘Menu’
4. Navigating to ‘Menu’ from within the App
5. View and provide blood pressure, automatically and manually
6. View and provide heart rate, automatically and manually
7. View and provide oxygen saturation, automatically and manually
8. Activate chatbot questionnaires
9. Simulation of answering chatbot questionnaires

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The pace of the session was determined by the participant. After the demonstrations the participant was encouraged to use the App and devices following the same points in the demonstration, with the presenter still present and available to be asked questions and troubleshoot any issues.

Demonstration to HCP:

1. Accessing the prototype eCare and ROSA dashboard
2. Navigation through dashboard simulating a daily monitoring task

After the demonstrations the participant was encouraged to use the dashboard following the points in the demonstration, with the presenter still present and available to be asked questions and troubleshoot any issues.

In the case of the personnel of CH who used the App for 5 days:

1. Taking vitals once a day. Registering data on photo/video directly from the device
2. Answering questionnaire on chatbot once a day
3. Answering other questionnaires once during the period
4. Comparing data directly from the device with the ones displayed on the eCare App and eCare dashboard

Feedback about the App was then collected as detailed below.

Collection of feedback

Older people, caregivers and health care professionals

In the sessions, feedback was collected at different time-points during Phase 3 using a number of different methods.

A concurrent ‘think out loud’ approach was used to collect reactions to the app and identify any areas that required particular attention during the demonstration of the app and user hands-on experience. Participants were encouraged to verbalise their reactions, thoughts, feelings, and opinions about the prototype throughout their engagement with the presenter. Notes were taken by the presenter. Video recordings were taken when the user was interacting with the App, dashboard or devices, and only when the participant explicitly accepted this in the consent form.

After the hands-on experience, participants were asked to complete the UEQ-S (2) to collect quantitative data about the impression of the participants about user experience. The UEQ-S assesses six aspects of user experience (attractiveness, perspicuity, efficiency, dependability, stimulation and novelty). There are 26 items and

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respondents mark on a seven-stage scale between two terms in each item (e.g., attractive ○ ○ ○ ○ ○ ○ ○ unattractive).

At the end of the session, participants were interviewed by the researcher to collect the participant's experience using the prototype. An interview schedule / topic guide was followed during the interview but the researcher may have also referred at times to conversations and topics raised during the sessions. Semi-structured questions (Annex 38) explored users' general feedback about the App including:

- Ease of use;
- Design;
- Utility;
- Gender equality;
- Quality of hands-on experience;
- Overall satisfaction.

Tester for 5 days

Participant reported values obtained with the devices with photos or videos, general comments about their daily use of the devices and any incidents that occurred during the testing period.

Data analysis

Results of the UEQ-S (2) were compared against published benchmark data and findings reported alongside interview data in a feedback report. No identifiable information was recorded on the feedback reports.

A completed report, including practical recommendations, was presented to and discussed with technical partners.

3.7.2 Results of the hands-on experiments

Older adults / caregivers

Four target users were recruited for the hand-on training sessions, representing older adults with ages between 76 and 91 years old (75% female) with heart failure at stages 2–3. In one case, the caregiver was the App user (family, co-habiting, female).

Table 35 lists other comments coming from different participants and referring to particular aspects of the different Digital Solutions.

Table 35: Feedback from older people/caregivers while using the digital solutions (PT3-001).

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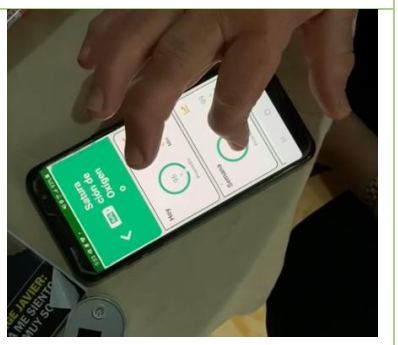
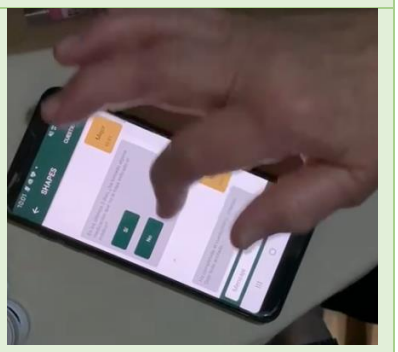
Digital Solution	Comment
SHAPES App	Font size of input data a little small (font size 2 in Android Galaxy 6+).
	Email is long, and 2 participants did not know where the '@' was.
eCare App	Titles in menu at the bottom are not complete.
	O2 data sync shows an error message before synchronising. O2 sync failed once without a reason.
	In the tests (formulated as "try to see your XX data for the last week"; were XX was blood pressure or O2 saturation), participants managed to navigate the right statistics (Mean values of Today/Week/Month).
	In the tests (formulated as "try to see your XX data for the last week"; were XX was blood pressure or O2 saturation), 2 participants found difficult to go the chart. 1 participant went to the first chart (Today, without realising they could change to Week) and another tried to tap on the 'Mean value', instead of the 'yellow chart'. 
ROSA	2 participants said the font size was small (font size 2 in Android Galaxy 6+).
	No participants were familiar with the idea of a chatbot and had to be explained that it was like WhatsApp but having on the other side a machine.
	All participants could follow the questionnaires, with just little help (see below).
	3 participants were confused with questions of the following type: 'Have you xxx and CH is not aware of?'; being xxx anything.
	1 participant did not understand correctly the medical meaning of palpitations (if they feel anything on the chest, they would answer 'yes').
	When the questionnaire was finished, 100% of participants were not sure if they had to do anything else; 1 participant tried to answer the previous question again. 

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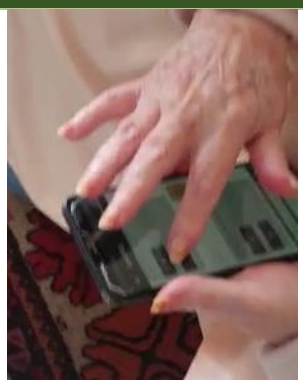
Digital Solution	Comment
	2 participants tried to answer the same question twice. They did not realise there was a new question below. 
	100% of participants preferred to select the questionnaire in the menu, instead of telling ROSA through the chat ("I want to do the daily questionnaire").

Interview

Table 36: Summary of the interviews that took place after the hands-on training session with older person/caregiver (PT3-001).

Topic/Theme	Opinions and researcher's comments
Ease of use	The participants found the Apps easy to use, but they were not sure if they will remember everything. They thought they will need a few days to know if they can adapt to the system. The participants found the Apps intuitive. Two participants said that the concept of talking to a chatbot was strange. The devices are easy to use. The BP monitor and scale are familiar to them. Two participants were familiar to pulse oximeters. Connectivity of devices to App (tested with pulse oximeter) was easy, but participants were not sure if they will remember the process. In one case the connectivity failed and the participant

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Topic/Theme	Opinions and researcher's comments
	thought they could not do it, but it was actually a failure of the connection, as it worked the second time. None of the participants found the use of the wrist band interesting. One participant said they didn't even like wearing watches. Another participant expressed that he did not know what to do. The medical doctor present in the interview intervened at this point of the interview with two participants explaining the importance for the professionals to know the number of steps. Participants indicated agreement. One participant was very concerned about their health and admitted that they may not feel like using the Apps when feeling bad. Another participant, who currently uses a blood pressure monitor, does not take this measure on a daily basis and wondered if this was necessary.
Design	Participants liked the design of the Apps, although they didn't comment much about it. One participant said they liked the green colours very much. Two participants said that the font size in ROSA was small (size 2 in Android Galaxy A6+). When changed to size 3 in mobile settings, they said it was OK. Two participants said that some words in eCare were cut out.
Utility	Two participants showed interest in the curve or historic data. All participants found it valuable that they could show the historic data to professionals. Participants thought that the digital solutions were useful for the professionals. They expected that the professionals would be able to manage their condition better. When discussing that the digital solutions could be also a tool for them to control their disease, they expressed that they will follow their medical doctor's directions. They will need guidelines to know what to do in some scenarios.
Gender neutrality	Virtual nurse icon was feminine. All participants found this to be neutral.
Quality of training	Training was useful to have a first contact. They all thought that they would need help when starting using the Apps and devices.

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Topic/Theme	Opinions and researcher's comments
Overall satisfaction	Three participants liked the App and imagined themselves using it. One participant liked the App but was not sure if they will be using it as they were not usually feeling well. Two participants commented that they would not use the App if it meant that they lost contact with the medical professional. They said the App is OK but there are many details that cannot be transferred through this system. For example, they may feel well but still would like to talk to their doctor about their concerns or doubts about the treatment (including for other conditions). All participants commented that other people of their age and with heart failure may or may not use the App. They knew many people who didn't use a smartphone (for example, 1 participant's spouse). In addition, they commented it may be a lot of work to take measurements and answer questions on a daily basis, and that people who feel bad are less prone to keep active. Caregivers can be a valuable support on this. The participants said they will use the App between 2 and 4 times a week, because it is the frequency at which they are taking some of the measurements today. The participants said they would use the chatbot 1–2 times a week. They thought the answers would be the same most of the times. They liked the idea of selecting the option in the chatbot when they want to communicate anything.

UEQ-S questionnaire

Table 37: Results of the UEQ-S questionnaire filled by older people/caregivers (PT3-001).

Adjective pair	Mean (SD)
Obstructive / Supportive	5.7 (2)
Complicated / Easy	6.1 (1.5)
Inefficient / Efficient	6.1 (1.5)
Confusing / Clear	6.7 (0.5)
Boring / Exciting	6.7 (0.5)
Not interesting / Interesting	6.1 (1.5)

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Adjective pair	Mean (SD)
Conventional / Inventive	7.0 (0)
Usual / Leading edge	7.0 (0)
UEQ-S scored are marked on a scale of 0 to 7. Higher mean scores reflect a positive user experience.	

Healthcare professional

There was 1 participant, a medical doctor from CH. The participant was instructed to navigate through the several features of ROSA and eCare dashboards. The researcher explained the main purpose of each screen and the participant was invited to verbally feedback what she understood from the displayed information.

ROSA dashboard

Home

The participant started testing the main home screen (Figure 8). Here, the number of patients with values deviating from normal ranges (indicator) were mentioned. The participant largely understood the different colours, the classification of colours and could easily navigate through the options which provided a deployment of every single indicator within a group. The participant got confused with the *yellow* indicators (least severe). The participant was expecting a *green* indicator, that is, a colour displaying the number of patients who have all values within normal ranges. As there was no indicator which referred to this state, the participant assumed the least severe indicator, the *yellow*, was displaying this. The participant also commented that we should state that the indicators refer to heart failure as all the design has been completed in this context. It could prevent misuse by professionals in a context where different professionals may have access to the tool.

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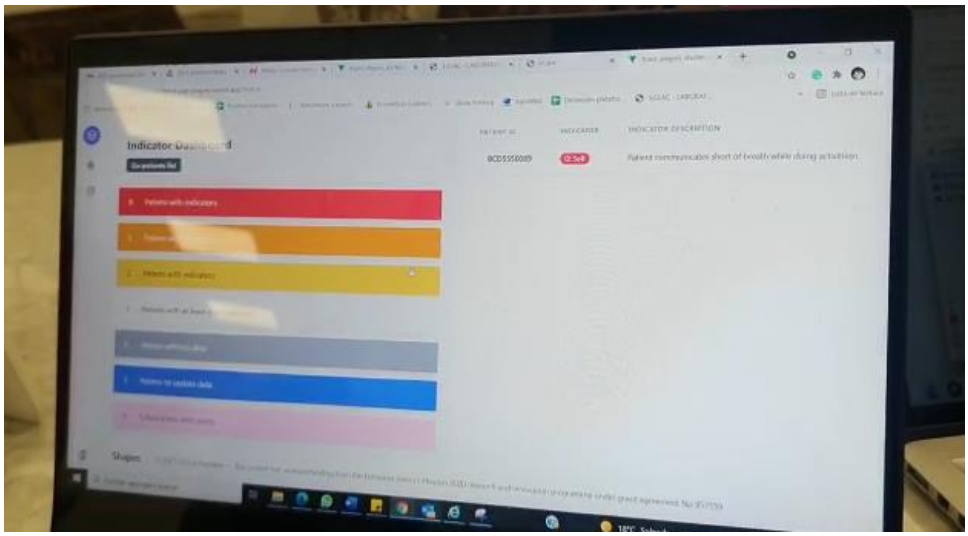

Figure 8 Home screen in ROSA dashboard (PT3-001).

The participant was missing an option that leads to the actual data which triggers the indicator.

Finally, the participant suggested that there was a need for information about the timeframe defining the indicators, that is, if they are triggered with today's data, considering a time window or any other criteria.

Patient's page

The participant commented that the data provided was complete and gave a detailed view of patient state. A professional could see both a summary of the medical reports relevant to heart failure and charts where the evolution of answers to ROSA's questions could be easily checked.

The participant suggested some changes:

- The format of tables displaying information could be improved. There were column misalignments.
- The information given under *heart rhythm*, *atrial fibrillation* and *flutter* should indicate if the patient has had episodes of these types. They do not indicate that they are suffering these symptoms/conditions at the moment of visualisation.
- The participant suggested a format for providing lab test results at different points of time. The participant also suggested that normal ranges were displayed on the tables.
- The participant would appreciate seeing the date of the medical report next to the values.
- The active indicators for a particular patient should be indicated at the top of the page.

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Regarding charts, the participant liked the differentiation between blue (the answer does not show any worsening of the patient's health state within the domain of the question) and red (the answer may indicate a worsening of patient's health state). The participant commented that the first 3 questions are the most important. In case they were all *blue*, the participant will review the rest very quickly. The participant commented that they would not check MARS questionnaires and assumed that they are only gathered for statistics. To make the page clearer, we could hide MARS charts.

List of patients

The participant commented that healthcare professionals may not use this page very often. They will probably go to a particular patient directly from the home page, where there are links related to the indicator. However, as there was no green indicator (all parameters within normal ranges) in the home page, this list was useful to quickly check those patients with no indicators.

eCare dashboard

As a general comment, the participant would like to have a page where the definitions of states were defined.

Dashboard

The participant commented that it was quick to view the latest vitals from participants. However, the participants were unsure if all values came from the same day or were taken on different days. Values in the table should perhaps be limited to a time window.

Other more specific comments were:

- *gluc* and *T* should be removed from this use case.
- An option to order by state would be appreciated.
- Participant would need clarification about the definition of *late events* and *status numbering*.

Alerts

The participant said that this page was a good way to look quickly at the overall status of the patients. It had the similar function as the ROSA home page. The participant suggested that we could show information about the timeframe defining the states, that is, if they were triggered with today's data, latest data, considering a time window or any other criteria.

Patients

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The participant commented that the function of this page looked similar to the *dashboard* page. Thus, this page could be completed with the other information appearing in the dashboard section (adding more columns).

Particular patient's page

The participant understood the page and commented that the charts gave a clear view of the change in vitals. The table on the right was empty. Some specific comments:

- When clicking on details of latest values (boxes on the left), the menu on the very left hand-side changes, which makes navigation confusing.
- Title of blood pressure chart should be general if systolic and diastolic are shown. In addition, each type has its maximum and minimum for normal ranges. The participant would like to set up this value (for all patients and for particular patients).
- Thresholds for weight should be defined as increase/decrease of weight.
- Thresholds for O2 and heart rate do not have medical sense.
- Participant commented that the scale in some charts was too big (this was due to out-of-range values; as it may happen during pilot –for example device used in the wrong way- an option to remove values could be useful).
- *Today* option does not change view of charts. Time frame was not highlighted in the top selection menu.

Care Plan

The participant found the scheduling of frequency to be a bit confusing (further training may be needed if this feature is to be used). An example was made with medication (Figure 9):

- The participant understood that duration, frequency and daily frequency referred to medication, not to care plan
- Duration could include an option to define a specific number of days
- Daily frequency should describe every X hours, after lunch
- Because of the last option, *Notify at*, the participant understood that it was done once, or once daily, but the participant wasn't sure.

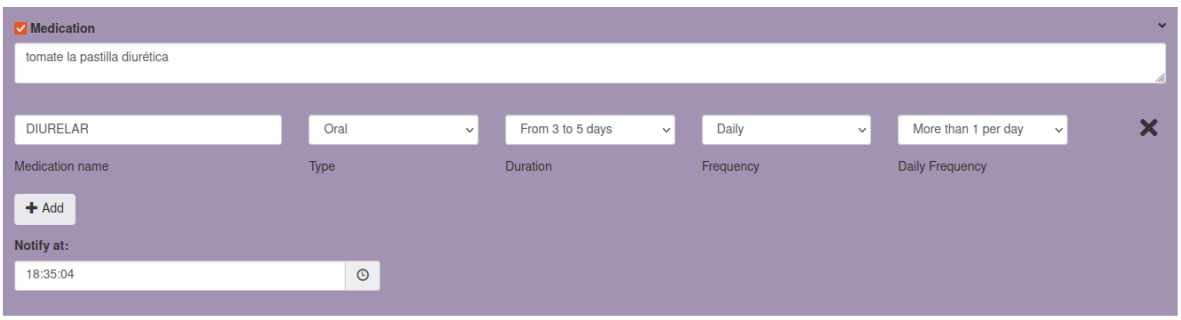

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Figure 9 eCare dashboard displaying the input and scheduling of medication (PT3-001)

Finally, the tick on Monitoring could not be removed (Figure 10).

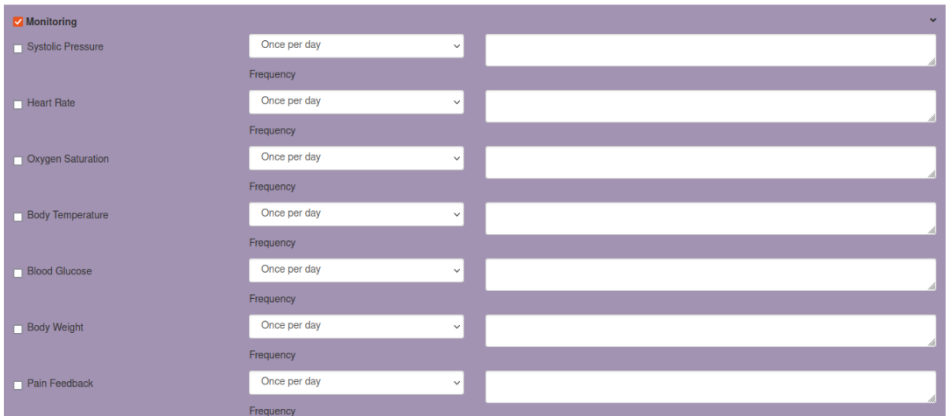

Figure 10 eCare dashboard displaying the parameters and frequency of monitoring (PT3-001)

The participant commented that in this use case, the options in the monitoring section were the most useful and their definition was clear.

Whole process

The participant simulated the scenario of the daily task of checking the patients with the digital solutions. The participant would use first ROSA and then eCare because it was the usual procedure in professionals: first they talk with the patient to have a general picture of their health state and after this they check vitals and other parameters.

1. The participant first went to ROSA dashboard, home page. Red indicators to be prioritised.
2. The participant clicked on quick view to check the patients and their related indicator descriptions.
3. The participant used their clinical view to prioritise patients with the same colour of alerts and then went to the patient's page clicking on the patient's code.
4. On the patient's page, the participant looked at the medical history and lab tests to have an image of the profile of the patient.
5. Then the participant scrolled down to the charts (chatbot answers) to check what is *red* and may attract the participant's attention in terms of what may go wrong with the patient. The objective was to know what the acute problem could be, to understand the alterations (that are leading the patient to have a sign in the indicator) and whether there is any reason for contacting the patient. At 1 moment during the demonstration the participant said that the first 3 questions

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were more important, but during this test the participant commented that *red bars* on the charts were guiding the analysis.

6. The participant commented that patients with missing data would be checked every 2–3 days (whether there is any technical issue or the patient has been hospitalised).
7. The participant commented that patients with data to update would be checked every week.
8. Then the participant went to eCare dashboard. The participant started in the Alerts page and prioritised the red ones first.
9. Then the participant checked the evolution of the parameters to complete the picture of the patient's state to make a final decision regarding contacting the patient.

During the process, the researcher noticed that there was no way that the professional could go from patient's page in eCare to the same patient's page in ROSA, and vice versa. The professional carried out 2 independent processes without being able to focus on 1 single patient and all their collected data (chatbot + vitals).

Table 38: Summary of the interviews that took place after the hands-on training session with the health professional (PT3-001).

Topic/Theme	Opinions and researcher's comments
Ease of use	The participant found the 2 dashboards easy to use. The participant didn't like the fact that there are 2 solutions to show the profile of a patient. Changing from 1 platform to another makes the process more complicated in terms of analysing the profile of a single patient.
Design	The participant found the design correct and very functional and appreciated the colour system very much. The participant would like to see an information page of the meaning of the colours.
Utility	The participant had no current tool to collect these types of data and saw the digital solution as an opportunity of organising contacts with their patients in a more systematic and clinical way. The participant was not sure about the profile of patients that could be included in the pilot: "some people are always feeling bad". In this sense, vitals are more objective.
Gender neutrality	The participant saw the dashboards neutral in terms of gender equality.
Quality of training	Training was useful. More data would have useful to have the feeling of a real scenario.

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Topic/Theme	Opinions and researcher's comments
Overall satisfaction	The dashboards are easy to follow by a HCP. Most important is that out-of-range values are clearly marked, as they were with red bars in chatbot's questionnaires and threshold lines in vitals. Professionals who visit their patients on a regular basis and therefore, know them, would like to change thresholds to personalise analysis. For training new personnel, and also for refreshing information when required, an info page where alerts are described would be appreciated. Being able to modify alert definitions would help further personalise the tools.

UEQ-S questionnaire

Table 39: Results of the UEQ-S questionnaire filled by health care professional (n=1) (PT3-001)

Adjective pair	Score
Obstructive / Supportive	6
Complicated / Easy	6
Inefficient / Efficient	6
Confusing / Clear	5
Boring / Exciting	5
Not interesting / Interesting	6
Conventional / Inventive	5
Usual / Leading edge	5
UEQ-S scored are marked on a scale of 0 to 7. Higher mean scores reflect a positive user experience.	

Tester

The SHAPES project manager from CH was testing the App and devices from November 15th to November 21st, 2021.

Devices — eCare

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A simple testing was performed in order to validate the transfer of data from devices to the eCare Platform. Ten measurements were taken with the blood pressure monitor, 11 with the weight scale and 10 with the pulse oximeter. Data provided on the display of the devices was recorded on photos or videos. The wristband was not used in the experiment because Mi Band 3 was not available at the time. In addition to small differences between the time of the photo/video and the 1 registered in eCare (due to the time lapse between the measurement and the taking of the picture), and the fact that times are registered in Portuguese time, there was only 1 measure that did not match: on the 15th of November at 8:35 am, a picture taken from the pulse oximeter shows a value of 96 (O2 saturation) while the value registered in eCare is 88. The technical team investigated this disagreement.

The tester would like to comment that values obtained depended on several aspects (for example, position of arm while using the blood pressure monitor). Although the right procedure was known, the fact that these devices are to be used by older adults or their caregivers at home, reinforcement of good practices is recommended.

Chatbot

The tester activated the follow up questionnaire on a daily basis as well as adherence, hospitalisation, medication change, lab test and medical appointment questionnaires twice during the testing period. In this case, correct recording of answers could not be tested, as this technical point was still under implementation. All conversations worked as expected.

3.7.3 Conclusions

After the end of Phase 3, feedback collected from participants was analysed and a detailed report was developed by the research team at CH. Then, it was shared and discussed with the technical team to implement the feasible suggestions made by users.

Older adults

Users managed well most times when navigating through the Apps (eCare and ROSA), although they were constantly guided (except unless it was strictly necessary during the exercises). They usually felt insecure and constantly expressed that they did not know if they would be able to do it alone. In addition to proper training, based on the hand-on training experiences, CH recommended that: 1) well-designed, step-by-step, picture-based material to be given to participants, so they can use it as reference; in addition, a reference contact person during the pilot should be available for any technical issue or barrier; the idea is that older adults do not feel overwhelmed by technical barriers; 2) finally, active strategies from the pilot site use case

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management team should be taken with the same objective, for example run-in periods and follow-up contacts during the first days/week of the pilot.

Another comment from older adults was that they did not know if they would use the App and the devices when they feel bad, as their situation was frustrating sometimes and they would lose motivation. The participants did not like the idea of wearing the wristband. One participant could not use the weight scale and another participant would not be able to use the scale on a daily basis (only when the caregiver was at home). It is important to consider real scenarios to design a digital solution which can cover a wider section of the population. The retrospective analysis should also consider this and design proper methodologies for data gap filling or the definition of assumptions if necessary.

All participants liked the idea that there was a medical doctor checking the values and answers on a daily basis. All of them admitted they would look at the latest values (one liked the history chart but did not know if it was going to be useful).

Healthcare professionals

The participant found the tools intuitive and did not need much guidance to navigate through the dashboards. The 2 main comments were that 1) they would like to see the number of patients with all values within the normal range (already in eCare but not in ROSA) and 2) even though some data was to be collected once during the pilot, the date should be displayed, as there will be a history in any future deployment.

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3.8 Phase 4: Small Scale Live Demonstration

A small-scale live demonstration of the SHAPES Platform and digital solutions being deployed in the Pilot theme 3 Use Case 001 (UC-PT3-001) was undertaken during Phase 4 of the SHAPES pan-European pilot campaign at CH. Phase 4 aimed to test the functionality of the App and the dashboards together with the clinical devices in a real-world environment. The demonstration tested the methods and procedures that were to be used in Phase 5. The digital solution was tested in a real-world environment and facilitated the identification of technical issues that would interfere with the smooth functionality of the technology. The main goal was to determine whether any amendments were needed before proceeding to the large-scale pilot (Phase 5). To test the complete data flow, we created a collaborating tool between all technical partners and the pilot leader, where tests were documented.

Phase 4 also tested the strategy to recruit participants for Phase 5. This assessed the ability of the research team to identify the correct cohort of participants and intended to indicate whether, or not, changes to the eligibility criteria or approach to recruitment were needed.

3.8.1 Recruitment of participants

The recruitment was performed among the patients and medical doctors at CH.

- Older adults:
  - Inclusion criteria:
    - Older adults 60 years old or above;
    - Heart failure diagnosis at stage 2–3 (NYAH functional classification)
    - Living at home or in sheltered apartments
    - Accepts to wear the activity wristband 24h
    - Accepts to use (with the help of the caregiver if necessary) the provided devices at least once every two days, and preferably once a day
    - Self-reported consent capacity
  - Exclusion criteria:
    - No consent capacity
- App user (who could be older adults or caregivers):
  - Inclusion criteria:
    - Self-reported confident user of smartphone
    - Has stable self-reported Wi-Fi connection at home, at the home of the older person or has a mobile data plan

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        - Has access to android smartphone, with android version greater or equal to 6
        - Accepts to answer follow-up questionnaires at least once every 2 days
        - Has the consent from the older adult (if app user is the caregiver) to use the App on their behalf
        - Provides self-reported capacity to consent
    - Exclusion criteria:
        - No consent capacity
- Healthcare professional:
    - Inclusion criteria:
        - Medical doctor from CH
        - Accepts to use the digital solution to monitor patients once a day
        - Self-reported consent capacity
    - Exclusion criteria:
        - No consent capacity

It was recommended to be monitored with at least 2 of the following devices (by Medical Director of CH):

- Blood pressure monitor;
- Pulse oximeter;
- Weight scale.

People with the following conditions cannot use the scale (this unit could cause these devices to malfunction, posing a considerable health risk to users):

(1) Medical electronic implants such as pacemakers;

(2) Electronic life support systems such as artificial heart/lung;

(3) Portable electronic medical devices such as an electrocardiograph.

There was the option for caregivers to join the study as users of the App but this was not the case in Phase 4.

Sample size

The target sample size for Phase 4 was 4–5 target users and 1 medical doctor but just 2 target users and 1 medical doctor were recruited.

Duration of the pilot

The target duration of Phase 4 was 1–2 weeks depending on adaptation and acceptance by app/device users. At the end, Phase 4 had a 1-week duration because

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this time was enough to complete all technical checks and collect complete feedback from participants. Phase 4 started on the 3rd of August 2022 until the 11th of August 2022.

Method

Recruitment of older adults and caregivers

No financial incentives were provided for participating in this pilot.

Screening: Members of the direct care team at CH screened their patient lists for potentially eligible participants.

Invitation: The first communication about the pilot was from the direct care team in routine home visits.

Information sheets: Information sheets (

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Annex 39) were provided to potentially eligible participants that showed interest and then we waited 24 hours to allow time to consider the information provided before consent was obtained.

Consent to contact: Verbal consent to be contacted was provided by 2 potential participants to their direct care team to allow the use of their registered contact data at the clinic for reasons regarding the pilot. This was documented by the direct care team. Then, the research team contacted the potential participant by phone and both answered the first time.

Eligibility confirmation: Eligibility of both participants was confirmed by the direct care team in person.

Consent: Participants were required to provide written consent (Annex 40), which was obtained handwritten and in-person by the research team. The SHAPES project manager at CH countersigned the informed consent and delivered a copy to participants as acknowledgment of reception.

Methods: Recruitment of HCP

No financial incentives were provided for participating in this pilot.

Screening: The management team at CH identified a list of appropriate medical doctors within employees and regular collaborators.

Invitation: The management team at CH sent an invitation email containing information about SHAPES and the pilot.

Information sheet: If the request was accepted by one medical doctor, the information sheet (Annex 41) was provided.

Consent: Informed consent for the medical doctor participant was obtained handwritten and in-person (Annex 42). The SHAPES project manager at CH countersigned the informed consent and delivered a copy to the participant as acknowledgment of reception.

3.8.2 Technical aspects & Logistics

Validations

Several experiments were designed and carried out before the pilot with participants to validate necessary aspects of the digital solutions:

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- Transfer of data between devices and digital solutions databases (and visualisation on respective interfaces).
- Proper visualisation of data (colouring and classification) based on rules defined by CH.

Devices

Devices were provided to target users. Personnel of CH brought them to user's homes. In addition to the wristband Xiaomi Mi 3, each participant was provided with the following medical devices:

- Blood pressure monitor (OMRON M7 Intelli);
- Pulse oximeter (Beurer PO60);
- Weight scale (OMRON VIVA).

Table 40 Xiaomi Mi Band 3 specifications (PT3-001)

Short Name	**Xiaomi Mi Band 3**
Link to tech specifications	Mi Band 3 Specs | Xiaomi UK - Xiaomi UK
Picture	
Summary description	Fitness tracker suitable for health and wellbeing monitoring. • Fancy design • Robust • Comfortable • Water resistant • Pedometer (number of steps; distance; calories burned) • Activity tracker • Heart rate monitoring (as low as every 2 minutes) • Sleep quality monitoring (light and deep sleep; total sleep hours)

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Short Name	Xiaomi Mi Band 3
	• Long-life battery (30-60 days) • Reliable measurements • Cost efficient
Connectivity & Interoperability features	Bluetooth eCare App
Price (approx.)	30-50 €

Table 41 OMRON M7 Intelli IT blood pressure monitor specifications (PT3-001)

Short Name	OMRON M7 Intelli IT blood pressure monitor
Link to tech specifications	https://www.omron-healthcare.pt/en/blood-pressure-monitors/M7_Intelli_IT.html#start=1
Picture	
Summary description	Blood pressure monitor • Comfortable • Stores up to 60 readings • Precise measurements • Alerts to irregular heartbeats • Hypertension indicator
Connectivity & Interoperability features	Bluetooth eCare App

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Short Name	OMRON M7 Intelli IT blood pressure monitor
Price (approx.)	60-65 €

Table 42 Beurer PO 60 Bluetooth® pulse oximeter specifications (PT3-001)

Short Name	Beurer PO 60 *Bluetooth*® pulse oximeter	
Link to tech specifications	https://www.beurer.com/web/gb/products/medical/ecg-and-pulse-oximeter/pulse-oximeter/po-60-bluetooth.php	
Picture		
Summary description	Product designation	Pulse oximeter
	Connect	yes
	Available views	4
	Battery-operated	yes
	Batteries	2 x 1.5 V AAA batteries
	Beurer Connect	yes
	Colour display	yes
	Graphic pulse display	yes
	Compatible from	iOS 10.0 and Android 5.0 by Bluetooth® 4.0
	Medical device	yes
	Memory spaces	100
	Transfer with	Bluetooth® low energy technology

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Short Name	Beurer PO 60 *Bluetooth*® pulse oximeter
Connectivity & Interoperability features	Bluetooth
Price (approx.)	70-100 €

Table 43 OMRON VIVA Smart Scale Specifications (PT3-001)

Short Name	OMRON VIVA Smart Scale
Link to tech specifications	https://www.omron-healthcare.pt/en/category/digital-scales
Picture	
Summary description	Smart scale • Body Weight • Body Fat (in %) • Visceral Fat (up to 30 levels) • Skeletal Muscle (in %) • Basal Metabolic Rate / Resting Metabolism (in kcal) • Body Mass Index (BMI)
Connectivity & Interoperability features	Bluetooth eCare App

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Short Name	OMRON VIVA Smart Scale
Price (approx.)	65-70 €

The SHAPES App was downloaded and installed by the user in the presence of the SHAPES project manager at CH on the first day of the pilot. The same day, the project manager set up devices and paired them with the SHAPES App.

Training

App/device users were trained in the use of the SHAPES App on the first day of their participation in the pilot. User manuals and troubleshooting info pages were provided to the users for reference including the following information:

- Username (SHAPES ID);
- Password;
- Objective of the study;
- Duration of the study;
- Material provided;
- Description of how to use the digital solution.

User manuals can be found in Annex 43

Users were called at day 2 and 4 to resolve any concerns or technical issues during the course of Phase 4. Users were given the contact telephone number of the project manager at CH and were encouraged to call in case of any issue.

3.8.3 Roles and Responsibilities

The pilot was carried out with users of CH as participants. CH personnel were in charge of the set up and training process. The SHAPES project manager at CH was the contact point for participants for any technical issues. All technical issues were communicated to the technical team, led by VICOM, who took the appropriate actions when required. No extra face-to-face visits were necessary during Phase 4, except the first visit on day 1 to set up the technology and provide training and the last visit on day 7 to uninstall the technology and collect feedback from participants.

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3.8.4 Ethical considerations

Approval of local committee (Comitè d'Ètica de la Investigació de les Illes Balears, CE-IB) was obtained before the start of the recruitment process.

This includes approval of:

- Information sheet for participants;
- Consent form;
- Study protocol.

Data Protection Impact Assessment and Data Processing Agreements were finished before the start of the recruitment of participants (including data risk assessment).

In this study, CH was the data controller and as such had access to the full dataset, and technical partners were data processors. Data Processing Agreements were put in place to facilitate the sharing of pseudonymised data with specific SHAPES partners for specific purposes.

Ethical self-assessment was rechecked before sending the final protocol to local ethics committee.

Trustworthy Artificial Intelligence assessment list was also checked before the start of the recruitment process.

3.8.5 Outcome of the Small-Scale Live Demonstration

During the recruiting process some personal data to check eligibility of participants was collected. Then, the first day of Phase 4, on the training day, the following data was collected from participants, which is required to run the HFPred:

- ECFScBS (12);
- Barthel (10);
- Gijón (11);

The small-scale live demonstration took place in August 2023 and lasted one week. The outcomes and how each of them was analysed are presented in Table 44.

Table 44 Phase 4 outcomes and analysis (PT3-001)

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Outcome	Measurement	Instrument
App performance	Technical information about App performance, reception of data from devices, ROSA questionnaires and HF pred.	Log internal files and correct receipt of data.
Adverse events and technical issues	Question about the occurrence of any adverse event or system errors.	Errors reported.
Trust and technology acceptance	Scale Score	TAM (9)
Self-perceived usability	Scale Score	SUS (8), UEQ-S (2)
User engagement	Internal check of number of log ins per user per day and feedback collected at the end of the phase.	Time stamp and number of log ins. Notes taken at an unstructured interview.
Participants' perception	The perception of the digital solution and its purpose of increasing adherence to treatment.	Open interview

3.8.6. Results of the Small-Scale Live Demonstration

Participants were asked to use the application (older adults) / dashboard (medical doctor) ideally daily and to test its functionalities to provide feedback, paying special attention to the technical performance of the digital solution.

At the end of Phase 4, feedback was collected in the form of questionnaires and interviews, which is summarised in the following tables.

Participants: older adults

Table 45 summarises the feedback from older adults regarding technical aspects. The opinions of participant 1 (P1) and participant 2 (P2) are shown hereafter.

Table 45 Feedback from older adults about functionality and technical aspects during Phase 4 (PT3-001)

Digital Solution	Older adults' comments about functionality and technical aspects
SHAPES Front-end App	• P1: "Password is too complex to type, and I don't know where to find symbol $ in my keyboard."

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Digital Solution	Older adults' comments about functionality and technical aspects
	• P2: "I cannot visualise whether I entered password correctly."
eCare App	• P1: "Information about activity band is not transferred immediately." • P2: "I forget the steps to register the vital signs from devices". • P2: "Data from oxygen doesn't always get registered in the App".
ROSA	• P1/P2: "I don't know how to check push notification; I didn't realise the App had sent me".

Table 46 summarises the feedback from older adults regarding specific aspects of the App.

Table 46 Feedback from older adults about general experience in different aspects during Phase 4 (PT3-001)

Topic	Older adults' comments
Ease of use	• P1: "It is a little bit hard to remember all steps to use the App and register the vital signs." • P2: "Once you get used to the App and you know where every function is, it is quite easy to use."
Design	• P1/P2: "I like the colours and general aesthetics." • P1: "Some features appeared cut or overlapped."
Utility	• P1: "I like the application because it is a good to control your health." • P2: "I like the application but when doesn't work because I cannot enter the password or because the data is not well registered it is a bit frustrating."
Gender neutrality	• P1/P2: "Yes, the App is gender neutral."
Quality of training	• P1: "The training was nice and completed." • P2: "I liked to have the training information in paper so I could check the steps if I forget." • P1: "I liked the idea of get a video of myself following all the steps, this way I could refer to the video in case of any doubt."

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Topic	Older adults' comments
Overall satisfaction	• P1/P2: "Quite positive, I liked using the App." • P1: "I like the App but including the improvements proposed it would be much better."

Table 47 shows the results of TAM and SUS questionnaires.

Table 47 Trust, acceptance and self-perceived usability of Phase 4 participants (older adults) (PT3-001)

Older adults	TAM	SUS
Older adult 1	18	82.5
Older adult 2	19	92.5
Mean (SD)	18.5 (0.71)	87.5 (7.07)
The technology acceptance model (TAM) is scored out of a maximum of 21. The System Usability Scale (SUS) is scored out of a maximum 100.		

Table 48 and Figure 11 show the results of UEQ-S questionnaire from older adult participants compared with benchmark data.

Table 48 UEQ-S for Phase 4 participants (older adults) in relation to existing values from a benchmark data set (PT3-001)

Scale	Mean	Comparison to benchmark	Interpretation
Pragmatic Quality	1.13	Below average	50% of results better, 25% of results worse
Hedonic Quality	2.63	Excellent	In the range of the 10% best results
Overall	1.88	Excellent	In the range of the 10% best results

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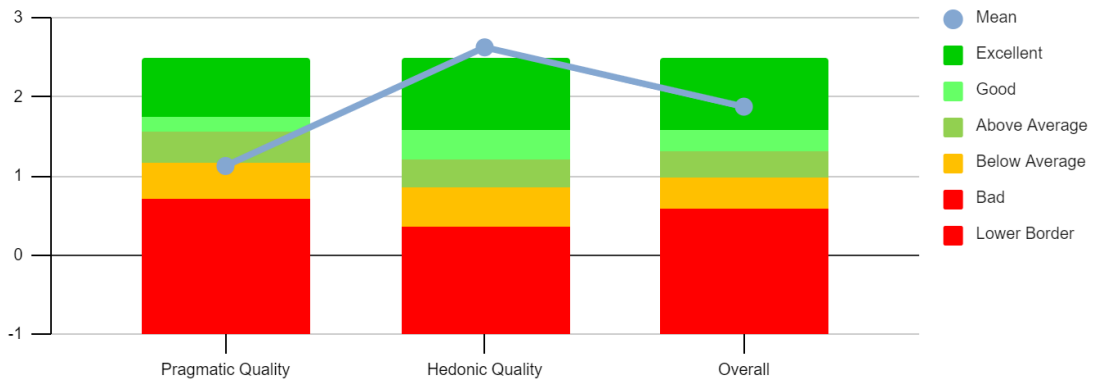

Figure 11 UEQ-S graph for Phase 4 participants (older adults) (PT3-001)

Participants: HCP (medical doctor)

Table 49 summarises the feedback from the medical doctor regarding technical aspects.

Table 49 Feedback from medical doctor about functionality and technical aspects in Phase 4 (PT3-001)

Digital Solution	Medical doctor's comments about functionality and technical aspects
eCare Dashboard	• "Sometimes the adherence percentage (adherence of participants to their health plan) was not properly calculated".
ROSA Dashboard	• "Some data was not properly saved within the ROSA dashboard; this would need to be check."

Table 50 summarises the feedback from the medical doctor regarding specific aspects of the dashboards.

Table 50 Feedback from medical doctor about general experience in different aspects in Phase 4 (PT3-001)

Topic	Medical doctor's comments
Ease of use	• "Dashboards are very intuitive and easy to use."
Design	• "I like the design. Clean and clear."
Utility	• "It would be better to have both dashboards integrated together to avoid professionals having to access two different sites."
Gender neutrality	• "Yes, it is gender neutral."

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Topic	Medical doctor's comments
Quality of training	• "The training session was easy to follow, and I got the contact of the trainee in case I had any question; however, this was not necessary."
Overall satisfaction	• "I like it, it is a very useful to for remote monitoring of patients."

Table 51 shows the results of TAM and SUS questionnaires.

Table 51 Trust, acceptance and self-perceived usability of Phase 4 participant (HCP) (PT3-001)

HCP	TAM	SUS
HCP 1	16	77.5
The technology acceptance model (TAM) is scored out of a maximum of 21. The System Usability Scale (SUS) is scored out of a maximum 100.		

Table 52 shows the results of UEQ-S questionnaire from the HCP participant.

Table 52 UEQ-S for Phase 4 participant (HCP) in relation to existing values from a benchmark data set (PT3-001)

Scale	Mean	Comparison to benchmark	Interpretation
Pragmatic Quality	1	Below average	50% of results better, 25% of results worse
Hedonic Quality	2.25	Excellent	In the range of the 10% best results
Overall	1.63	Excellent	In the range of the 10% best results

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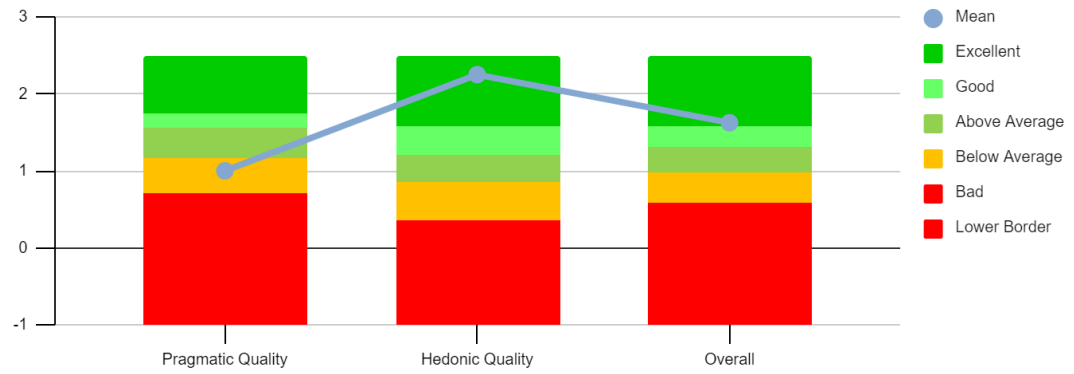

Figure 12 UEQ-S graph for Phase 4 participant (HCP) (PT3-001)

In general terms, the feedback collected was positive, however the older adult's application was better rated than the health care professional's dashboards due to the low level of integration between eCare and ROSA dashboards. Analysing the results of the UEQ-S questionnaire, we see that both older adults and health care professionals think that pragmatic quality of the digital solution is worse than hedonic quality.

Considering the feedback from Phase 4 participants, we list the following recommendations:

General recommendations:

- Provide written material and audiovisual material representing the steps to use the digital solution. In this case it was useful for participants to be recorded during the training so after they could follow in their own steps.

For technical partners:

- To have the option of visualising the password while typing it to make sure it is the correct one.
- To have the option of saving the password to avoid typing it every time accessing the App.
- Improve the App responsiveness regarding the font size.
- Improve the Bluetooth connection between devices and App, especially with respect to the oximeter performance.
- Improve the time needed for data transferring from activity band to App.
- In the future, full integration of the different components. Users had to download 3 Apps on their phones and although through the SHAPES App they had access to all the three Apps (SHAPES Front-end app, eCare and ROSA). The installation is not very user friendly.

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- Integration of eCare and ROSA dashboard to ensure a better user experience of medical doctors and provide more efficiency.
- Calibration of adherence rates in the eCare Dashboard.
- Correct data storage and visualization in the ROSA Dashboard.

All these errors and / or suggestions were addressed and solved collectively by EDGE, VICOM, TREE and CH to get the digital solution ready for Phase 5. The project manager at CH prepared a detailed feedback report that was shared with technical partners, was discussed and the technology updated based on these discussions. The new version of the technology was then tested by the project manager at CH to ensure the proper function of the new App version.

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3.9 Phase 5: Large-scale pilot activity

In Phase 5, a non-randomised, single-armed, cross-sectional interventional pilot study with an optional qualitative interview component was conducted.

The pilot was conducted with service users and medical doctors in Mallorca, Spain from Clínica Humana (CH). The pilot was managed by researchers from CH. The pilot was not replicated by GEWI due to recruitment difficulties. This is explained in more detail in the following section.

This study intended to test the hypothesis that the SHAPES Platform and Digital Solutions (novel system) can provide opportunities for supporting the management of the heart failure condition, by both older adults/caregivers and healthcare professionals.

Objectives

Primary objectives (PO1-PO2)

- To investigate user engagement with the novel system (PO1).
- To investigate the user-perceived usefulness of the novel system (PO2).

Secondary objectives (SO1-SO10)

The secondary objectives aim to investigate:

- The capability of the novel system to optimise the use of medicines in homes:
  - Novel system triggers contacts between health professionals and patients resulting in medication change (SO1);
  - Improving adherence (SO2).
- The capability of the novel system to improve the management of conditions (SO3).
- The identification of associations between precursor signs of deterioration and unscheduled healthcare resource use (SO4).
- The use of Statistical Process Control (SPC) techniques to find associations between blood pressure, weight, heart rate and O2 saturation and unscheduled healthcare resource use (SO5).
- The association of the VICOM's heart failure decompensation prediction score with unscheduled healthcare resource use, particularly hospitalisations (SO6).
- The association of the first (active / sedentary behaviour) and second level (active in activities of daily living / intermediate activity / exercise) of physical activity classification and sleep quality analysis with unscheduled healthcare resource use (SO7).

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- The capability of the novel system to improve older individual's quality of life, wellbeing and psychological and psychosocial aspects (SO8).
- The integration of the novel system to align with current care pathways (SO9).
- The user trust and acceptance of the novel system (SO10).

Tertiary objectives (TO1-T06)

The following objectives align with the general purposes of the SHAPES large-scale piloting campaign. The tertiary objectives aim to validate the capability of the SHAPES Platform and Digital Solutions to:

- Support and extend healthy and independent living for older individuals who are facing permanently or temporarily reduced functionality and capabilities (TO1).
- Improve the older individuals' health outcomes and quality of life (TO2).
- Gain the older individuals' trust and acceptance (TO3).
- Gain the care professionals' trust and acceptance (TO4).
- Contribute for the reduction of the workload of medical professionals (TO5).
- Deliver efficiency gains in health and care delivery across Europe (TO6).

3.9.1 Recruitment (Clínica Humana)

The recruitment was performed among patients and medical doctors from CH.

Sample size

The pilot aimed to recruit 10 participants (older adults/caregivers) and 1 health care professional at the CH lead pilot site and 10 participants (older adults/caregivers) and 1 healthcare professional at the GEWI replicating site. These sample sizes were selected pragmatically to be as representative as possible of the target population, large enough to provide valid answers and within the scope of resources available. In CH, 9 older adults and 1 healthcare professional were recruited. As mentioned, GEWI did not replicate this use case.

Duration of the pilot

The target duration of Phase 5 was 3 months, which was achieved, being performed between November 2022 and January 2023 (both months inclusive).

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Methods

Recruitment of older adults and caregivers

No financial incentives were provided for participating in this pilot.

Screening: Members of the direct care team at CH screened their patient lists for potentially eligible participants.

Invitation: The first communication about the pilot was from the direct care team in routine home visits.

Information sheets: Information sheets Annex 44 UC-PT3-001 Phase 5 Participant information sheets (older people and caregivers; Healthcare professionals)were provided to potentially eligible participants that showed interest and then we waited 24 hours to allow time to consider the information provided before consent was obtained.

Consent to contact: Verbal consent to be contacted was provided by potential participants to their direct care team to allow the use of their registered contact data at the clinic for reasons regarding the pilot. This was documented by the direct care team. Then, the research team contacted the potential participant by phone and both answered the first time.

Eligibility confirmation: Eligibility of both participants was confirmed by the direct care team in person.

Consent: Participants were required to provide written consent (Annex 45 UC-PT3-001 Phase 5 Participant consent forms (older people and caregivers; Healthcare professionals), which was obtained handwritten and in-person by the research team. The SHAPES project manager at CH countersigned the informed consent and delivered a copy to participants as acknowledgment of reception.

Recruitment of healthcare professionals

The HCP participating in Phase 5 was the same one that had participated in Phase 4. The same procedure was followed, information sheet was provided (Annex 44) and informed consent was obtained (Annex 45). No financial incentives were provided for participating in this pilot.

3.9.1.1 Eligibility criteria

- Older adults:
  - Inclusion criteria:

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        - Older adults 60 years old or above;
        - Heart failure diagnosis at stage 2–3 (NYAH functional classification)
        - Living at home or in sheltered apartments
        - Accepts to wear the activity wristband 24h
        - Accepts to use (with the help of the caregiver if necessary) the provided devices at least once every two days, and preferably once a day
        - Self-reported consent capacity
    - Exclusion criteria:
        - No consent capacity
- App user (who could be older adults or caregivers):
    - Inclusion criteria:
        - Self-reported confident user of smartphone
        - Has stable self-reported WIFI connection at home, at the home of the older person or has a mobile data plan
        - Has access to android smartphone, with android version greater or equal to 6
        - Accepts to answer follow-up questionnaires at least once every 2 days
        - Has the consent from the older adult (if App user is the caregiver) to use the App on their behalf
        - Provides self-reported capacity to consent
    - Exclusion criteria:
        - No consent capacity
- Healthcare professional:
    - Inclusion criteria:
        - Medical doctor from CH
        - Accepts to use the digital solution to monitor patients once a day
        - Self-reported consent capacity
    - Exclusion criteria:
        - No consent capacity

It was recommended to be monitored with at least 2 of the following devices (by Medical Director of CH):

- Blood pressure monitor;
- Pulse oximeter;
- Weight scale

People with the following conditions cannot use the scale (This unit could cause these devices to malfunction, posing a considerable health risk to users):

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(1) Medical electronic implants such as pacemakers.

(2) Electronic life support systems such as artificial heart/lung.

(3) Portable electronic medical devices such as an electrocardiograph.

There was the option for caregivers to join the study as users of the App.

3.9.2 Recruitment (GEWI)

For the replication of UC-PT3-001, a GP was involved from the beginning to medically supervise participants by regularly monitoring their health data and making contact if needed. For the replication of UC-PT3-001, he and his team further supported the recruitment process by identifying appropriate participants from their practice. As his practice was located in the reference site, he was considered to have direct contact with potential participants. Information material (flyer with a summary of key information, information sheet and the informed consent sheet) was shared with the GP to provide to interested participants in June 2022. As such, first contact was made by the GP and further communication was conducted by the research team once interested individuals agreed to be contacted.

During the recruitment process several challenges were encountered:

Due to a summer break, as well as the permanently difficult working conditions, it was challenging for the practice team to incorporate the recruitment process into their working practice. Contact was made by the researcher several times to support the activities as much as possible. Another challenge referred to finding participants with appropriate mobile devices during the pilot. Initially it was planned that participants would use their own mobile devices (android) for accessing the DS. The digital solution was limited to the android system, therefore, patients with other systems (Apple) could not participate. This hindered the recruitment of participants as many older individuals were using different systems (mostly Apple). To overcome this challenge, supplementary android mobile devices were purchased to hand out to potential participants. Despite these mitigation actions, it was not possible to recruit sufficient participants via the GP for the pilot.

Subsequently, additional recruitment activities were conducted to draw attention to the project towards the end of 2022. These included displaying articles in regional newspapers and newsletters, using mailing lists and contacting relevant gatekeepers (mainly doctors) from the network by applying face-to-face recruitment. Three different

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clinics specialised in the treatment of patients with heart failure were contacted to involve them in the recruitment to the pilot as well as additional GPs.

The first clinic did not have the capacity to incorporate additional research activities into their working processes. Two of the clinics were rehabilitation clinics, only treating their patients for the time of their hospitalisation. Upon discharge, the patient's previous GP took over the treatment. Due to the legal situation in Germany, medical doctors from the rehabilitation clinic were then no longer responsible and thus not legally protected to complete any further pilot intervention. Since the UC was planned for the home-setting, the involvement of clinic doctors for the monitoring of patients' data was not possible. The specialisation of clinics further indicated that the origin of their patients was not regionally limited therefore involving each patients' previous GPs in the replication wasn't feasible.

For the third clinic, discussions were ongoing until the mid of May 2023. Again, due to workload as well as the holiday situation, no approval from the person in charge was able to be obtained.

This communication process was very time consuming and required great effort. Despite the numerous attempts and mitigation activities, it was not feasible to replicate the UC-PT3-001 in the German setting.

3.9.2.1 Eligibility criteria

Inclusion criteria:

- person aged 60 years old or older at the time of recruitment
- diagnosed with heart failure at stage 2–3
- living in the Oberbergischer Kreis
- living on their own
- self-reported capacity (alone or with help) to use at least 2 devices among blood pressure monitor, weight scale and pulse oximeter
- self-reported capacity to consent
- has daily access to internet

Exclusion criteria:

- none

3.9.3 Communication and dissemination of pilot activities

Any data that arose from the pilot study is owned by the sponsor, CH. On completion of the study, all data were analysed and tabulated and used to prepare the final report,

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available as one of the agreed deliverables of the SHAPES Innovation Action — Deliverable D6.4. This deliverable (and all other agreed deliverables) are available to the public for review and accessible via the SHAPES website (www.shapes2020.eu). Participants will be notified of the outcome of the study. CH will seek to disseminate the findings from this study at conferences and in the scientific literature. As per the SHAPES Publication Protocol, all publications arising from this study will reflect the range of effort that has made them possible; including conceptualisation of the research project and research task, methodology development, data collection and analysis, interpretation and discussion of results; as well as project management. Any publications will be read and meaningfully contributed to by all named authors. CH will also seek to communicate the findings of this study via social media, and in other, non-peer reviewed, media outlets. Participating SHAPES partners will have the rights to use data from this study in their own analysis and dissemination plans through the Data Processing Agreements that are in place to facilitate the sharing of pseudonymised data with specific SHAPES partners for specific purposes.

3.9.4 Risk management

Risk assessment

All foreseeable data-related risks were compiled into detailed risk assessment documents which formed part of the Data Protection Impact Assessments for Phase 5 PT3-001 conducted in CH. For each risk identified, a risk classification, root cause, name and consequences were assigned. Once identified, each risk was then analysed and attributed a score from 1 (unlikely/minor) to 4 (almost certain/critical) for probability and impact. Subsequently, appropriate mitigation actions were assigned, and the responsible person was identified. These risks were reviewed periodically during all phases of the project.

Adverse incidents

It was very unlikely that any adverse incidents due to the use of the SHAPES App or devices would occur in this pilot. However, if any participant reported an adverse incident the participants were told to stop the participation in the pilot temporarily until further notice. If medical assistance was required, it was covered by CH.

If the research team were notified of a product recall regarding the devices used in this pilot the participant would be notified as soon as practicable and requested not to use the device. Arrangements would be made to physically remove the device and replace it if possible.

HCP did not have access to the data collected and participant treatment was not changed due to taking part in this pilot. This was clearly noted in the participant

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information sheet. If participants were concerned in any way about the readings on their devices, they were to follow their normal mechanisms for seeking healthcare.

Moreover, the CH team followed the ethical framework applied to the SHAPES project, which is detailed in Section 7 of this deliverable.

Data management

Data processed in this pilot was subject to the GDPR (679/2016) and the Spanish regulation (Ley Orgánica (3/2018) about personal data protection and warranties on digital rights, in agreement with GDPR.

CH was the data controller for all data collected during this pilot. The data flow for this pilot was complex and as such multiple Data Processing Agreements were put in place between the data controller (CH) and the data processors, each SHAPES partner who processed this data.

Personal data minimisation and purpose limitation principles were followed so that this pilot only processed data that was adequate, relevant and limited to what was necessary to deliver the objectives of the pilot. Personal data was processed only for these purposes and only personal data strictly necessary to the completion of this pilot was retained.

The data collected for this pilot was contemporaneous and accurate. If a participant withdrew from the study, clarification was sought as to what data may need to be erased. This data would be identified and erased without delay. Personal data will be de-identified at the end of the SHAPES Innovation Action (Oct 2023) and this anonymous data may be used for further research if required. The de-identified data set may be retained for a period of five years after October 2023 and then deleted.

The data for this pilot was stored securely. The location of each data point was listed in the data plan for this pilot. Personal data was kept in a form which permitted identification of data subjects until October 2023.

All data in this pilot is traceable using the pilot data plan. This meant that the research team were able to identify the origin of the data, how it was processed, where it was stored and if it had been transferred or disclosed to a third party.

Further details regarding personal data were described in the DPIA, Personal Data Processing Descriptions document and DPIA risk assessment document for this pilot. Additionally, a detailed description of all data (including but not limited to personal data) collected is located in the data plan for this pilot.

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Every effort was made to reduce the potential for missing data, however, if missing data occurred it was coded '999' or if applicable, the missing data protocol for the questionnaire was followed.

The VICOM heart failure prediction algorithm required a number of data fields to be completed each day to provide a decompensation risk. If a complete data set was not obtained, data may be imputed. Imputed data was not saved or shared with partners and only used for the validation and analysis of the predictor. VICOM predictor used personal data of the use case for validation.

Regarding data duplication, the heart rate measurement could be collected by the blood pressure monitor, the pulse oximeter and the wristband. Only the heart rate from the blood pressure monitor was used for visualisation purposes and as input to VICOM's heart failure prediction algorithm.

Ethical considerations

As explained in section 3.8.4 of this Deliverable, approval of local committee (Comitè d'Ètica de la Investigació de les Illes Balears, CE-IB) was obtained before starting recruitment of participants.

3.9.5 Outcome of large-scale pilot activity

The outcomes in relation to at least one primary objective (related objectives in brackets) are the following:

- O1. Timestamps of login into the novel system (PO1).
- O2. Regarding the App, identification of pages seen (with access time, thus allowing to construct the user's overall navigation history), page login timestamp; page logout timestamp; measurement insertion timestamp; identification if measurement is manual or automatic (PO1).
- O3. Timestamps of chatbot/questionnaires and initiator of action (App user or chatbot) (PO1).
- O4. Technology Acceptance Model (TAM) questionnaire (PO2, SO10, TO3, TO4).
- O5. Short version of UEQ-S (PO2, SO10, TO3, TO4).
- O6. Notes taken at an unstructured interview at the end of the use of the novel system (PO1, PO2).

The outcomes in relation to the secondary and tertiary objectives (related objectives in brackets) are the following:

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- O7. Eadon grading system for the interventions (when health professional contacts patient) (SO1, SO2, SO3, SO9, TO6). The following data to be collected to describe the intervention: date, type (telephone/visit; doctor/nurse) problem detected in intervention, result of intervention and grade of the intervention which is assigned by HCP participant different from the one who performed the indication.
- O8. Beliefs about BMQ (SO2).
- O9. MARS (SO2).
- O10. Use of health care resources by older adults' participants: hospitalisation dates, type of hospitalisation (hospital, home), hospitalisations due to heart failure, use of other health resource types (A& E, emergency ambulance call-outs, out of hours, general practitioner, nurse, specialist) and date (SO3, SO4, SO5, SO6, TO5, TO6, HCP).
- O11. Weight, O2 saturation, diastolic and systolic blood pressure and heart rate, along with their timestamps (SO3, SO4, SO5, SO6, TO2, HCP).
- O12. Physical activity along with timestamp: accumulated steps per minute, type of activity (1-25), heart rate (SO4, SO7).
- O13. Sleep parameters along with timestamp: sleep latency index, sleep duration index, efficiency index, disturbance level index (SO4, SO7).
- O14. Chatbot questionnaires (SO3, SO4, SO6, TO2, HCP).
- O15. Risk Instrument for Screening in the Community (RISC) questionnaire (SO3, TO2).
- O16. Barthel questionnaire (SO4, SO6, HCP).
- O17. The European Heart Failure Self-Care Behaviour Scale (EHFsCBS) questionnaire (SO4, SO6, HCP).
- O18. Social risk — Escala de valoración sociofamiliar de Gijón questionnaire (SO4, SO6, HCP).
- O19. Medical history data from patient’s medical reports: height, gender (male/female), left ventricular rejection fraction, heart rhythm (sinusal/no sinusal), atrial fibrillation, flutter; device type (none/MCP/DAI/TRC/DAI-TRC), type of heart disease, year of diagnosis of heart failure, heart failure stage (NYAH functional classification and ACC/AHA structural anomaly)19, conditions other than heart failure, year of diagnosis of other conditions, smoking status (smoker/never smoked/ex-smoker), claudication pain(yes/no)(SO4, SO6, HCP).
- O20. Blood analysis from patient’s medical reports: urea, creatinine, sodium, potassium, haemoglobin, total cholesterol, LDL cholesterol, HDL cholesterol, eGFR (SO4, SO6, HCP).
- O21. Urine analysis from patient’s medical report: proteinuria. (SO4, HCP).
- O22. The following questionnaires: WHOQOL-BREF20, EQ-5D-5L21, GSES22, OSSS-323, SHAPES participation questions (1-I participate enough in activities that are important to me (1-5 scale); 2-Using this technology makes participating in the activities that are important to me Much more difficult / A

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little more difficult / About the same / A little easier / Much easier) (SO8, TO1, TO2).
- O23. SUS (SO10, TO3, TO4).

Outcomes for technical reasons (including medical data which is visualised by healthcare professional but not related to the objectives).

- O24. Pharmaceutical treatment (medicine name, strength, regime) (HCP).
- O25. Model, manufacturer and serial number of devices (technical).
- O26. Time of the day app user prefers to receive chatbot messages (technical).

In order to relate objectives to socio-demographics of App users (older adults / caregivers):

- O27. Number of years of formal education; DOB; gender (male/female/other); marital status (married/cohabiting/single-never married/separated/divorced/widowed); occupational status (full time employment/part time employment/unemployed/retired); caregiver status (full time/part time/no); help from family (never/rarely/sometimes/often); professional help (never/rarely/sometimes/often), neighbourhood environment (urban/rural); residence type (own home/caregiver's home/long-term care facility/other); co-living with someone (yes/no); country.
- O28. SHAPES health literature measure (How confident are you filling out medical forms by yourself?).

In order enable login process in the novel system:

- O29. User (non-identifiable) and password.

In order to contact participants (data only kept at CH):

- O30. Name, telephone number, address.

HCP class refers to outcomes that are necessary for the health professional's role in revising patient's health through the dashboards in the novel system.

Table 53 summarises the outcomes of Phase 5 detailing who the outcome is addressed to, how and when it is collected and the pilot objective that it refers to.

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Table 53 Outcomes collected in the pilot (PT3-001)

Code	Outcome	Addressed to	Conducted by	Collection time	Objective
O1, O2, O3	Use of features in novel systems	Novel system users	Automatic	I	PO1
O4	TAM	Novel system users	Self-complete	E	PO2, SO10, TO3, TO4
O5	UEQ – S	Novel system users	Self-complete	E	PO2, SO10, TO3, TO4
O6	Unstructured interview	Novel system users	Researcher	E	PO1, PO2
O7	Eadon grading system	Older person	HCP-Researcher	I	SO1, SO2, SO3, SO9, TO6
O8	BMQ	Older person	Self-complete	B, E, F	SO2
O9	MARS	Older person	Researcher (baseline) and App user/self-complete (during pilot via app)	B, I	SO2
O10	Use of health care resources	Older person	HCP	B, I, E, F	SO3, SO4, SO5, SO6, TO5, TO6, HCP
O11, O12, O13	Data from devices	Older person	App user (Automatic or self-complete via App)	I	SO3, SO4, SO5, SO6,

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Code	Outcome	Addressed to	Conducted by	Collection time	Objective
					SO7, TO2, HCP
O14	Chatbot questionnaires	Older person	App user	I	SO3, SO4, SO6, TO2, HCP
O15	RISC	Older person	HCP-Researcher	B, E, F	SO3, TO2
O16, O17, O18	Barthel, EHFsCBS, Gijón	Older person	Researcher	B	SO4, SO6, HCP
O19, O20, O21	Medical history data and lab tests	Older person	HCP-Researcher (baseline) / HCP (during study)	B, I	SO4, SO6, HCP
O22	WHOQOL-BREF, EQ-5D-5L, GSES, OSSS-3, SHAPES Participation Questionnaire	Older person	Self-complete	B, E, F	SO8, TO1, TO2
O23	SUS	Novel system users	Self-complete	E	SO10, TO3, TO4
O24	Pharmaceutical treatment	Older person	Researcher (baseline) / HCP (during study)	B, I	HCP
O25	Device technical data	NA	Researcher	B, I	Technical
O26	Scheduling time for chatbot questions	Older person	Researcher (baseline) / HCP (during study)	B, I	Technical

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Code	Outcome	Addressed to	Conducted by	Collection time	Objective
O27	Socio-demographic data: Number of years of formal education; DOB; gender; marital status; country.	Older person / Caregiver (App user)	Researcher	B	Socio-demographic analysis
O27, O28	Socio-demographic data Literature measure	Older person / Caregiver (App user)	Researcher	B, E, F	Socio-demographic analysis
O29	User and password	Novel system user	Self-complete	B	Login
O30	Contact details	Novel system user	Researcher	R	Contact
'Novel system user' is any participant who uses any component of the technology at any time, it might be older adults, caregivers or HCP. B: Baseline; I: During intervention; E: At the end of the intervention; F: 3-month follow-up; R: Recruitment; Self-complete questionnaires by older persons or caregivers are always done with the support of a researcher.					

The SHAPES Project Manager at CH visited older adults' participants at their homes, brought them the medical devices and wristband and helped them to download the application and pair all devices. Participants received training and instruction on how to use the App and devices. A user manual was also provided.

The SHAPES Project Manager at CH provided training and instructions on how to use the Dashboards to the HCP participant in Phase 5. A user manual was also provided.

Participants were contacted via phone after a week of starting the intervention to see if they needed any assistance. Thereafter the participants were encouraged to contact the SHAPES project manager at CH if they had any technical difficulties. After the first week, participants were contacted monthly to troubleshoot any issues that occurred.

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This pilot examined the real-world use of the SHAPES App and associated clinical devices therefore if participants did not enter data as requested in the pilot this was not documented as a protocol deviation, rather this provided an insight into their use of this digital solution.

3.9.6. Results of the large-scale pilot activities

Participants were asked to use the application (older adults / caregivers) / dashboards (medical doctor) ideally daily to examine the real-world use of the SHAPES App and paying special attention to the usability and user-perceived usefulness of the solution.

At the end of Phase 5, the SHAPES project manager at CH visited participants to collect feedback, uninstall the application and collect devices (in case of App users).

The following tables summarise the results of Phase 5.

Table 54 Recruitment and retention of Phase 5 participants (PT3-001)

Recruitment and retention of older adult participants at CH	
Screened prior to eligibility assessment	**N=25**
Excluded	**N=16**
Not having a smartphone	N=10
Not having full capacity to consent	N=6
Allocated to intervention	**N=9**
Lost to follow-up	N=0
Discontinued Intervention Reason(s) **Death**	N=1 N=1
Assessment of KPIs	
Assessed for KPI 1	N=8
Assessed for KPI 2	N=8
Assessed for KPI 3	N=8

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Recruitment and retention of older adult participants at CH	
Assessed for KPI 4	N=8
Assessed for KPI 5	N=8
Assessed for KPI 6	N=8
Assessed for KPI 7	N=8

Table 55 Baseline characteristics of Phase 5 participants (PT3-001)

Variable	Number of participants	Value
Age (years)	9	8.7 (6.84)
Male	9	5 (55.5%)
BMI (kg/m^2)	9	25.40 (5.06)
Heart failure	9	9 (100%)
Heart failure stage	9	2.22 (0.44)
LVEF (%)	0	-
Dyspnoea level	9	2.33 (0.67)
Diabetes	9	1 (11.11%)
Type 1 diabetes	9	0 (0%)
Hypertension	9	6 (66.67%)
Smoking	9	0 (0%)
Values are mean (SD) or n (%) *LEVF= left ventricular ejection fraction*		

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Key performance indicators

Recruitment and retention

KPI 1 At least 80% of the target cohort were successfully recruited into the pilot during the recruitment period

Table 56 Number and percentage of target participants recruited into Phase 5 (PT3-001)

Parameter	Total
Target number of participants	10
Number of participants recruited	9
Percentage recruited	90%

KPI 2 At least 80% of recruited participants remained enrolled in the pilot until the end of the study.

Table 57 Retention of participants (PT3-001)

Parameter	Value
Number of participants at baseline	9
Number of withdrawals	1
Number of participants at end of study	8
Percentage retained	88.9%

Technical performance

KPI 3 There is no re-start of any components of the technology, except for the blood pressure monitor, pulse oximeter or activity wristband, for at least 90% of the days

This KPI was 100% accomplished as there were no re-start of any components of the technology.

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User engagement and acceptance

KPI 4 The overall user experience quality of the App as measured using the short version of the UEQ-S was classified as 'Excellent', 'Good' or 'Above average' based on published benchmark data.

Table 58 Mean and comparison to benchmark UEQ-S scores from older adults' participants (PT3-001)

Scale	Mean	Comparison to benchmark
Pragmatic quality	1.53	Above average (25% of results better; 50% of results worse)
Hedonic quality	2.12	Excellent (In the range of the 10% best results)
Overall	1.83	Excellent (In the range of the 10% best results)

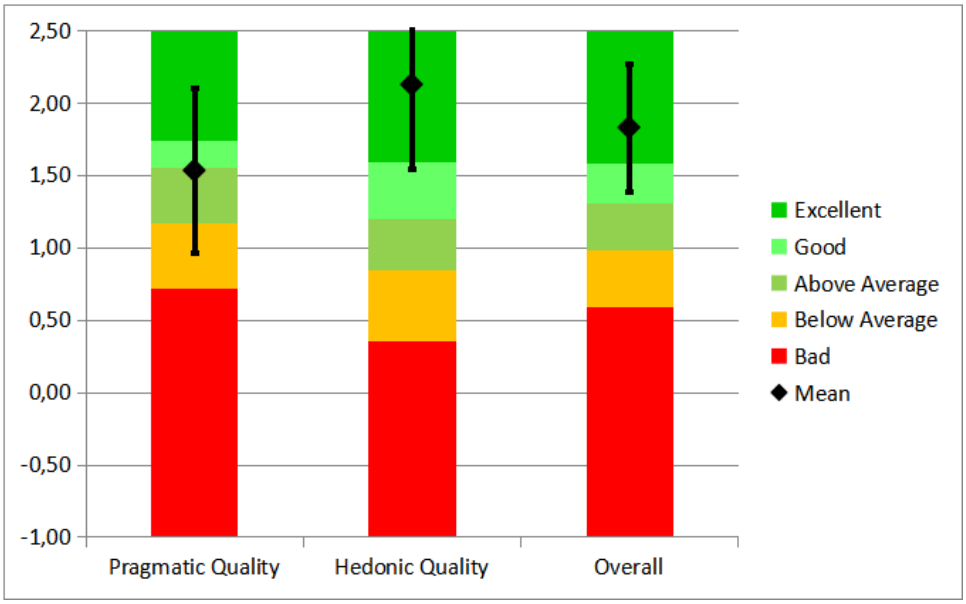

Figure 13 Mean UEQ-S and benchmark scores for the usability of the app from older adults' participants (PT3-001)

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KPI 5 At least 60% of participants provided all measures from blood pressure, O2 saturation and heart rate at least 50% of the days.

Table 59 Percentage of participants who provided all required measures at least 50% of days' during the pilot (PT3-001)

Parameter	Value
Total number of participants	8
Number of participants who provided all measures for 50% of the days	4
Percentage of participants who provided all measures for 50% of the days	50%

This KPI was not achieved because just 50% of participants provided all measures at least 50% of the days. However, 4 participants had a very good engagement; one of them provided all measures 52% of days, another one 74% of days and 2 participants provided measures 100% of days.

KPI 6 At least 60% of the older participants provided answers to set1/set2 questions for 50% of the days

Table 60 Percentage of participants who provided answers to set1/set2 questions for 50% of days during the pilot (PT3-001)

Parameter	Value
Total number of participants	8
Number of participants who provided all measures for 50% of the days	0
Percentage of participants who provided all measures for 50% of the days	0%

KPI 6 was not achieved because no participants provided answers to set 1 and set 2 daily questions for 50% of the days.

For set 1 questions, which were questions related to wellbeing, 6 out of 8 participants answered at least one day during the pilot and the % of responses of those participants was 46.81% but the total % of responses considering the 8 participants was 26.01%.

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For set 2 questions, which are questions related to medication adherence, 4 out of 8 participants answered at least one day during the pilot and the % of responses of those participants was 7.69% but the total % of responses considering the 8 participants was only 2.56%.

When we asked participants about the reason why they didn't answer the questions on the daily basis, they said that, even if the questionnaires were useful to send information to health professionals, the request to answer on daily basis was to demanding and pointless if there were no changes in their medical condition. Specially, they said that the adherence to medication is something that doesn't change on daily basis so they didn't find it useful to answer this questionnaire every day.

KPI 7 At least 60% of participants scored an above average rating (>68) in the SUS.

Table 61 Percentage of participants who scored the app an above average rating in the System Usability Scale (PT3-001)

Parameter	Value
Number of participants at end of pilot	8
Number of participants scoring >68 in SUS	7
Percentage of participants scoring > 68 in SUS	87.5%

KPI 8 At least 60% of healthcare professionals rated the technology as "Agree" or "Strongly agree" when asked "Does the technology improve the quality of your clinical practice?"

Table 62 Percentage of healthcare professionals who rated the technology as "Agree" or "Strongly agree" when asked "Does the technology improve the quality of your clinical practice?" (PT3-001)

Parameter	Value
Number of healthcare professional participants	1
Number of healthcare professional participants rating "Agree" or "Strongly agree"	1
Percentage of healthcare professional participants rating "Agree" or "Strongly agree"	100%

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Benefit of interventions

KPI 9 Interventions by healthcare professionals are graded 4 ("Intervention is significant and results in an improvement in the standard of care") or above as measured using the Eadon Scale in at least 30% of the records.

KPI 10 No intervention by healthcare professional was graded 1 ("Intervention which is detrimental to the patient's well-being").

One healthcare professional participated in UC-PT3-001 and all the medical interventions made during the pilot were graded 4 or above using the Eadon scale system. In total, 16 interventions were reported, 11 were graded 4 (68.75%), 4 were graded 5 (25%) and 1 was graded 6 (6.25%).

Therefore, both KPI 9 and KPI 10 were achieved.

Overview of KPI achievement

Table 63 Overall achievement of KPIs (PT3-001)

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	Yes	
KPI 2	Yes	
KPI 3	Yes	
KPI 4	Yes	
KPI 5	No	The inability to achieve this KPI reveals a lower engagement level than expected.
KPI 6	No	The inability to achieve this KPI reveals a lower engagement level than expected.
KPI 7	Yes	
KPI 8	Yes	
KPI 9	Yes	
KPI 10	Yes	

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Evaluation of use case using MAST

Table 64 provides an overview of the evaluation of the PT3-001 use case using MAST.

Table 64 Completed evaluation of use case using MAST (PT3-001)

Domain	Topic	Outcome	Baseline *Mean (SD)*	End of pilot *Mean (SD)*	***Mean change*** *(95% CI)*
Health problem and description of the application	Symptoms and consequences & Burden of disease	Use of health care resources (hospitalisations, A&E, GP, nurse, out-of-hours contacts, ambulance calls)	24.00 (1.32)	16.00 (1.09)	-0.56 (-1.79, 0.68)
Clinical Effectiveness	Effects on mortality	Mortality rate (deaths)	-	0.11 (0.33)	-
	Physical health	Risk of hospitalisation (RISC score)	3.00 (0.53)	2.25 (0.71)	-0.25 (-0.92, 0.42)
	Mental health	Psychosocial and psychological wellbeing (WHOQOL-BREF)	82.62 (8.73)	82.67 (8.54)	0.11 (-0.59, 0.81)
		Psychosocial and psychological wellbeing (GSES)	31.25 (6.45)	31.50 (6.32)	0.38 (-0.10, 0.85)
	Effects on health-related quality of life	Health related quality of life (EQ-5D-5L scores)	85.00 (14.14)	85.00 (14.14)	0

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Domain	Topic	Outcome	Baseline *Mean (SD)*	End of pilot *Mean (SD)*	***Mean change*** *(95% CI)*
	Behavioural outcomes	BMQ Necessity Score	23.25 (1.04)	23.50 (0.93)	0.86 (0.12, 1.60)
		BMQ Concerns Score	10.75 (2.38)	10.13 (2.10)	-0.5 (-1.16, 0.16)
		BMQ differential score (Necessity – Concerns)	12.50 (3.12)	13.38 (2.67)	0.88 (0.24, 1.51)
		Self-reported adherence (MARS scores)	24.13 (1.13)	24.88 (0.35)	0.75 (-0.07, 1.57)
	Utilisation of health services	Use of health care resources (hospitalisations, A&E, GP, nurse, out-of-hours contacts, ambulance calls)	24.00 (1.32)	16.00 (1.09)	-0.56 (-1.79, 0.68)
	Intervention benefits	Eadon scale	-	4.38 (0.62)	-
Patient's perspective	Satisfaction and acceptance	User experience (UEQ-S scores)	-	1.83 (0.72)	-

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Domain	Topic	Outcome	Baseline *Mean (SD)*	End of pilot *Mean (SD)*	*Mean change (95% CI)*
		User experience (TAM score)	-	16.63 (2.72)	-
	Understanding of information Confidence (in the treatment) Ability to use the application Access & Accessibility	Usability of application (SUS score)	-	73.73 (12.5)	-
	Empowerment Self-efficacy	Number of logins	Not assessed- this data was not reliable as some participants would choose not to log-out.		
		Visited pages + time in pages	Not assessed- this was not considered relevant as users had a guided routine to follow.		
		User engagement (% days participant entered all vitals in the Front-end App)	55% of days (0.34)		
Economic aspects	Amount and cost of resources used	Cost of devices	• Body weight scale OMRON BODYFAT VIVA: €80.04 per unit incl VAT; 9 units (€720.36) • Blood pressure monitor OMRON TENSIOM BR M7 INT IT: €69.88		

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Domain	Topic	Outcome	Baseline *Mean (SD)*	End of pilot *Mean (SD)*	***Mean change*** *(95% CI)*
			per unit incl VAT; 9 units (€628.92) • Beurer bluetooth pulse oximeter PO60: €52.03 per unit incl VAT; 9 units (€468.27) • Activity band Xiami MiBand 3: €27.18 per unit incl VAT; 9 units (€244.62)		
		Cost of using digital solutions and SHAPES platform	Digital solutions from EDGE (eCare), VICOM (HFPred), CH (ROSA) and TREE (vitals control) were highly customised for each use case and as the Digital Solutions and the SHAPES platform are not yet commercial entities it is not possible to attribute a cost at this stage.		
		Cost of staffing (Timesheets and costing data)	CH staff time • Baseline visit time (including travel) = 4 hours per visit per 9 visits = 36 hours • Maintenance/ troubleshooting time via phone = 5 hours per week during 12 weeks = 60 hours • End visit time = 4 hours per visit per 9 visits = 36 hours		
	Related changes in use of healthcare resources	Cost of hospitalisations	9 hospitalisations in total registered in the previous 3 months to the	4 hospitalisations in total registered during the pilot = 4 * €3612 (average	The total cost reduction regarding hospitalisation was €18060. This calculation

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Domain	Topic	Outcome	Baseline *Mean (SD)*	End of pilot *Mean (SD)*	***Mean change*** *(95% CI)*
			pilot = 9 * €3612 (average cost in Spain per hospitalisation; data from 2004) = €32508	cost in Spain per hospitalisation; data from 2004) = €14448	is an estimation.
		Cost of A&E attendances	No A&E attendances registered in the previous 3 months to the pilot = 0€	2 A&E attendances in total registered during the pilot.	There is no public information of the cost of A&E attendances in Span, therefore, the cost change due to the pilot cannot be calculated.

Performance of the digital solutions deployed in PT3-001

Sleep and activity (TREE)

When the data collected by the wristband was analysed, it was noted that participants didn't wear it as much as requested. Participants were asked to have the wristband on every day for as much time as possible, but just 4 out of 9 participants wore it enough time to get meaningful data. From the sleep information, the most relevant data were the hours of sleep, health care professionals used this information to detect potential sleep issues and refer to a specialist, if needed. From the physical activity

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information, the most relevant data were the number of steps per day. Health care professionals used this information to set a personal plan and follow up with patients.

HFPred (VICOM)

Table 65 HFPred data (PT3-001)

Participant	Number of heart failure decompensation prediction risk scores	Number of risk scores per week
P1	76	6.08
P2	77	6.17
P3	6	0.5
P4	54	6.25
P5	32	3.88
P6	35	3.40
P7	80	6.33
P8	72	5.92
P9	1	0.08

P1 had no instances of unscheduled care during the pilot, the risk prediction was 15% on average during the 12 weeks pilot. However, the algorithm occasionally predicted a high risk for this patient due to high blood pressure. When the doctor at CH contacted the participant on those occasions, the participant stated that they were feeling well but they got nervous and that was the cause of the high blood pressure. When they waited for a while and checked again, their blood pressure was lower but the algorithm predicted a high risk, in this case a false positive. In the final interview this participant explained that they were deeply invested in the project and when they didn't know how to work something out or some of the devices failed, the participant got nervous.

P2 had no instances of unscheduled care during the pilot, the risk prediction was 22% on average during the 12 weeks pilot. The predicted risk for this participant was occasionally high due to a low oxygen saturation. However, this participant had no breathing issues, even on those specific days. In fact, the participant stated that the pulse oximeter was not very accurate with the readings, as the system registered a lower level than the actual level.

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P3's level of engagement was really low and they just sent data during the first two week of the pilot, this is why there are just six heart failure decompensation prediction risk scores, as the system didn't have enough data to run the HFPred. Due to the lack of data, we cannot get any conclusions in this case.

P4 had one episode of unscheduled care (hospitalisation) due to cardiac decompensation on December 18th. On the previous day, they had a red risk predicted of 86% and the risk continued being high on the coming days, 98% risk on December 19th, 84% risk on December 21st and 92% risk on December 22nd). These risk scores were high due to weight gain and low oxygen saturation. The participant then had a green risk of 16% on December 23rd, when the vital signs went back to normal. On January 2nd this participant had a risk score of 98% and 86% on January 3rd, after this the participant passed away. In this case the algorithm correctly predicted the two decompensations that the participant had, predicting a 45% risk on average for this participant. Analysing the data, we see another high risk predicted at the beginning of November due to a huge weight gain of 10kg in 2 days; there was no medical treatment because there was no decompensation but the algorithm correctly detected the weight gain based on the data provided.

P5 had no instances of unscheduled care during the pilot, the risk prediction was 18% on average during the 12-week pilot. The risks predicted for this participant were usually low but analysing the data we can see that they had a high risk predicted on November 16th, 17th and 18th due to a weight gain of 30kg. The doctor contacted the participant and they explained that another person used the weight scale. Therefore, it was decided that the data set for those days would not be considered.

P6 had three unscheduled care episodes during the pilot, the risk prediction was 27% on average during the 12-week pilot. On November 29th, the participant was hospitalised due to a urinary tract infection (UTI) and aspiration, having a risk score of 40% on the 26th and 30% on the 28th due to low oxygen saturation and 82% on the 30th due to low oxygen saturation and weight gain. Then, on December 11th the participant had a A&E visit due to abdominal pain, they had a risk prediction of 40% on the previous day due to high heart rate and low oxygen saturation. Even though the unscheduled visits where not directly related to heart failure, the fact that the algorithm was triggered around those episodes was appropriate as medical assistance was required.

P7 had no instances of unscheduled care during the pilot, the risk prediction was 18% on average during the 12-week pilot. The participant had red risks predicted occasionally due to high blood pressure, which were correctly calculated.

P8 had no instances of unscheduled care during the pilot but the risk prediction was 83% on average during the 12-week pilot. This was due to the fact that the basal oxygen saturation of this participant was around 90% and they were prescribed oxygen therapy. The participant didn't always use the oxygen because it bothered her.

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After analysing this situation, we concluded that the basal values for patients should be considered and the ranges of values of the HFPred should be adapted to represent the reality. In this pilot, the HFPred model could not be corrected as the results were not analysed until the end of the piloting activities.

P9's level of engagement was really low and they just sent data during the first week of the pilot, this is why there is just one heart failure decompensation prediction risk score, as the system didn't have enough data to run the HFPred.

It can be concluded that the HFPred accurately predicted the medical decompensations when they were true, but it gave many false positives due to the fact that external factors were not controlled in the pilot. These factors may trigger some of the vital signs and cause a false high-risk prediction (high blood pressure due to nervousness, low oxygen saturation due to incorrect lecture by the oximeter or some participants may have basal vital signs which are "out of range"). Therefore, these potential factors should be controlled and medical intervention should always be required to double check the prediction.

eCare (EDGE)

During the pilot timeframe, eCare collected 31,213 measurements, including blood pressure, heart rate, oxygen saturation, weight, sleep duration measurements and step counts, distributed as follows:

Table 66: Number of Measurements in eCare (PT3-001)

Participant	Blood pressure	Heart rate	Oxygen Saturation	Weight	Sleep Duration	Step Count
P1	97	97	138	88	39	19,537
P2	96	95	143	-	39	7,133
P3	6	-	4	-	-	-
P4	77	50	55	53	-	44
P5	36	36	44	32	-	-
P6	36	32	72	35	-	47
P7	134	130	194	69	2	2,177
P8	51	50	76	67	8	50
P9	5	4	6	-	-	29
Total	**538**	**494**	**732**	**344**	**88**	**29,017**

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It was noted that participants P2, P3 and P9 did not use the body composition scale and that participants P3 and P5 did not wear the activity band for the duration of the pilot. In addition, participants P3, P4, P5 P6 and P9 did not wear the activity band for monitoring sleep for the duration of the pilot. These situations may be directly related with the specific health and wellbeing conditions of the involved participants during the pilot timeframe.

User experience

Table 67 Trust, acceptance and self-perceived usability of Phase 5 participants (older adults) (PT3-001)

Participant	TAM	SUS
P1	18	82.5
P2	19	92.5
P3	12	75
P4	No feedback	No feedback
P5	16	77.5
P6	18	92.5
P7	19	90
P8	13	60
P9	18	70
TOTAL (mean / SD)	16.63 (2.72)	73.73 (12.5)
The technology acceptance model (TAM) is scored out of a maximum of 21. The System Usability Scale (SUS) is scored out of a maximum 100.		

Table 68 shows the perceived impact of participants using the DS.

Table 68 Overall perceived impact of participants (older adults) in Phase 5 (PT3-001)

How has the use of the digital solution impacted your everyday life?	% of participants
Health-literacy	55.6%
Self-management of health condition	55.6%

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How has the use of the digital solution impacted your everyday life?	% of participants
Support for active and healthy ageing	33.3%
Improving quality of life	11.1%
Supporting extended living at home	44.4%
Another	0%
No impact	0%

Table 69 and

Table 70 gather health cost data, they show the willingness to pay of participants to use the digital solution and their opinions about who should pay for it.

Table 69 Willingness to pay of participants (older adults) in Phase 5 (PT3-001)

If this innovation was available to use in the future, how much would you be willing to pay for it per month?	% of participants
5-10€	0%
11-20€	37.5%
51-100€	0%
>100€	0%
I would not be willing to pay for it	62.5%

Table 70 Opinions of Phase 5 participants about financing options (PT3-001)

Who should pay for this DS?	% of participants
Individual end-user	0%
Health insurance (private)	50%

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Who should pay for this DS?	% of participants
Health insurance (public)	12.5%
Government-funded	37.5%
Other	0%

Table 71 Qualitative outcomes (semi-structured interview) (PT3-001)

Questions	Participant's comments
What did you like most about the technology tested?	**Older adults:** **"**I liked that the use of the App and the devices encouraged me to have better habits, such as walk more." "It empowered me over my health." "It has supported me in tracking my health and meeting my goals." "The values were displayed quickly, and they synced well. From a technical standpoint, we liked it except for isolated errors." **HCP: "**Following this methodology, it is more difficult to miss relevant information from patients and it is a good way to prevent exacerbations."
What did you like least about the technology tested?	**Older adults:** **"**It stresses me out a bit when some of the devices don't connect properly because I don't know if it's me who's doing it wrong." "I found it uncomfortable to take measurements every day. It doesn't seem practical to me, and I become obsessed with it." "The scale is very sensitive and sometimes fails if you don't do it exactly right. Maintaining balance is difficult, and it's easy to slip because you must be barefoot. I haven't used the activity bracelet much because it has a delay, meaning the data is sent to the App with a delay and it causes confusion."

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Questions	Participant's comments
	HCP: "I didn't like the fact that I had to access two different dashboards to check the data from patients. This was quite time-consuming; however, it is true that within each dashboard the data was well organised."
How have you perceived the usefulness of technology?	**Older adults:** **"**Very useful because apart from being able to send information, we could also visualise it ourselves, me, my caregivers and family members. It is important to know the historical data of the vital signs, which I usually don't record, and I liked being able to know it." "Very useful to control my weight. I have renal insufficiency, so it was helpful for monitoring fluid retention." "It was useful because I carry oxygen intermittently, and monitoring my oxygen saturation helps me determine whether I need to use it or not." **HCP:** "It is very useful because it sets a routine for the doctor. It is very intuitive what to do and the steps to follow."
Will you be willing to use the technology tested in the future?	**Older adults:** "Yes, I would be willing to use it because I would like to have a system to control my own health." "Yes, but maybe with different terms, I think measuring the vitals and answering the questions every day is too much." "I like the application but I don't think I would use it. I am not used to phones and I get tired of it." **HCP:** "Yes, totally, however, I would make the changes / improvements mentioned to get a more efficient solution."

After analysing all the data, we can conclude that most participants thought that the novel system was useful for them. In respect of participants, 55.6% thought that the

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use of the digital solution supports them increasing health-literacy and self-managing their health condition, 44.4% thought that it supports extended living at home and 33.3% thought that it supported an active and healthy aging. However, just 11.1% thought that the use of the digital solution has improved their quality of life. This might be due to the brevity of the pilot, as quality of life is perceived in mid and long terms.

In general, the qualitative opinions of participants were quite positive but some were polarised. On the one hand, some older adults were very motivated and engaged throughout the project and reported positive opinions about the DS. On the other hand, some older adults didn't really get used to the routine proposed with low App usage and a low engagement level. This highlighted the importance of background, e-literacy and profile of participants when introducing a technology.

The final recommendations to pursue the exploitation of the digital solution are as follows:

1. Adapt solutions to end user's needs. In this use case measurements had to be done on a daily basis for research and harmonisation proposes but the use of the technology should be fully adapted to each person.
2. Include end users in the design process, focussing on solving their needs. Two of the participants in Phase 5 had already participated in Phases 2, 3 and 4 and they were much more engaged in the process.
3. Improve the integration of the different parts: Specifically, the interface for HCPs should be integrated to have a better user experience and perceived usefulness.
4. Develop clear and understandable user manuals aiming a smooth adaptation of end user to the technological development.

3.9.5.1 GEWI (replicating site)

Due to the challenges encountered and elaborated with respect to the recruitment process (see chapter 3.9.2), UC-PT3-001 was not replicated in the German setting.

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4 Use case PT3-001c

4.1 Introduction

This chapter describes the pilot activities of UC-PT3-001c: Advanced telemonitoring of patients with heart failure in the home environment. The target user group was 25 patients older than 60 years of age, diagnosed with chronic heart failure with possible comorbidities. This user group had relatively low ICT literacy therefore the digital solution aimed to provide optimal user experience to allow ease of use of the whole system including the application and accompanying medical devices for monitoring selected biomedical signals/parameters. Monitoring was conducted in the patient's home environment.

The main goal was to decrease the probability of patient decompensation through regular monitoring of selected biomedical signals, which may raise awareness of an imminent threat to the patient's health status. It was hypothesised that this may lead to improvement of older individuals' quality of life. Concurrently, the need for regular hospital visits may decrease.

Use case leader was University Hospital Olomouc (Fakultní Nemocnice Olomouc, FNOL). There were no replicating sites.

Use case is based on the Personas Alena and Jan (1), Jan was a patient diagnosed with heart failure living in a small town away from a larger regional agglomeration, where his specialist and clinical centre were located.

4.2 Description

Participants chosen from the group of FNOL patients over 60 years of age were provided with the digital solution based on the mobile application working with the tablet and several medical devices to routinely measure selected biomedical signals/parameters, e.g.: body weight, blood pressure, electrocardiogram, physical activity (daily steps). Measurements were accompanied by specific questionnaires that measured patients' clinical state, adherence to medicine, social status, achieved level of user satisfaction with the provided digital solution etc.

Data collected by the provided tablet were retranslated to a remote server located within the EU in accordance with the personal data protection and cybersecurity technical standards and recommendations.

Recorded data were checked on a regular basis by clinical personnel (doctor or nurse). If there were any unexpected deviations from recommended values, patients were contacted by the member of the clinical team. In parallel, the collected data were analysed by the automated assessment tools and methods provided by other technical

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partners to minimise risk of any patient decompensations and, hence, follow-up hospital readmissions.

4.3 Digital solutions used in this use case

Medimonitor (FNOL)

Telemedicine System Medimonitor is a platform that provided remote care assistance and monitoring of patients. It was specifically developed for patients diagnosed with chronic heart failure. The Medimonitor platform collected patient health data, vital and physical signs as well as wellbeing and environmental parameters. The overall aim of the platform was to improve patient quality of life and to empower and support them to adopt a lifestyle reducing risk of deterioration. All the data and measurements were gathered through smartphones/tablets, sensors and devices (e.g. weight scales, blood pressure monitor, oximeter etc.). The platform provided service users with an overview of their daily health status, tasks and treatment plan assigned by medical staff, medication administration and requests, notifications, personalised questionnaires and it offered the possibility to communicate with the medical staff and to manage medical appointments through video call. Health care professionals were able to remotely monitor the health and wellbeing parameters of their patients and to identify deterioration signs early and to intervene promptly.

HFPred (VICOM)

Analysis of medicine optimisation by prediction of worsening disease based on clinical device readings, patient feedback and modelling to allow timely intervention and medication review (prediction of heart failure decompensation by VICOM).

More information about the digital solutions for this use case can be found in Deliverable 5.2: SHAPES Digital Solutions.

4.3.1 Digital solutions used for COVID-19 response

There were no digital solutions used for the COVID-19 response in UC-PT3-001c.

4.3.2 Equipment and devices used (from third parties)

The following external devices are deployed in UC-PT3-001c:

- Diagnostic weight scales Beurer BF600
- Oximeter Beurer PO60
- Blood pressure monitor Beurer BM54
- ECG Beurer ME90
- Smartwatch Xiaomi Mi Band 6

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Further details on these devices are provided in section 4.8.2. The aforementioned devices were procured as per Czech legislation. This meant that for each device, the University Hospital Olomouc (a public institution), required 3 offers and the cheapest offer was chosen. Technical parameters of the devices were included in the public procurement description and provision of the APIs was required within the procurement to permit direct data transfer and integration with the SHAPES App.

4.4 Data plan

The data plan for Phase 5 of the UC-PT3-001c pilot can be found here; https://shapes2020.eu/wp-content/uploads/2023/06/UC-PT3-001c_data-plan_04082022_v4.xlsx

4.4.1 Data capture methods to be used

A range of different data capture methods were used during the 5 phases of this pilot including participant data (see Data Plan), harmonised questionnaires (see Deliverable 6.9), questionnaires for the HFPred algorithm by VICOM, Pilot 3 questionnaires and clinical measurements. Specific details can be found under the sections describing Phases 1 to 5.

The questionnaires used in this pilot are following: SUS (8), MARS (14), VICOM Predictor questions, EuroQol EQ-5D-5L & VAS (4), BMQ (13), Barthel Index (10), Gijon Socio-family Assessment Scale (11), EHFScBS (12), Eadon Scale (19), Meister Questionnaire (21), WHOQOL-Bref (3), General Self-efficacy Scale (GSES) (5), OSSS-3 (social support) & life events (6), 1-item health literacy (7), Participation questions, Technology acceptance questions (9), UEQ-S (2).

4.4.2 Planning of evaluation

MAST

The MAST framework (15) was used to evaluate the effectiveness and contribution of UC-PT3-001c to quality of care. MAST is described as a multidisciplinary process that summarises and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine.

A review of the seven dimensions of MAST revealed that 3 of the 7 multidisciplinary dimensions/domains were of specific relevance to the pilot of UC-PT3-001c. These were: Clinical Effectiveness; Patient Perspectives; and Economic Aspects.

Table 72 contains the data required for the MAST evaluation.

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Table 72: Data required for MAST evaluation (PT3-001c)

MAST Domain	Topic	Outcome	Data required	Time point
Clinical Effectiveness	Effects on mortality	Mortality rate	Number of deaths	End of pilot
	Effects on health-related quality of life	Health related quality of life	EQ-5D-5L scores	Baseline and end of pilot
	Behavioural outcomes	Concerns about medicines	BMQ scores	Baseline and end of pilot
		Necessity beliefs about medicines	BMQ scores	Baseline and end of pilot
		Self-reported adherence	MARS scores	Baseline and end of pilot
	Utilisation of health services	Hospitalisations	Number of hospitalisations	Baseline (past 3 months) and at end of pilot
Patient perspectives	Satisfaction and acceptance	User Experience	UEQ-S scores	End of pilot
	Understanding of information Confidence (in the treatment) Ability to use the application Access	Usability of application	SUS Scores	End of pilot
	Empowerment Self-efficacy	Self-efficacy	General self-efficacy scale	Baseline and end of pilot

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MAST Domain	Topic	Outcome	Data required	Time point
Economic aspects	Amount and cost of resources used	Cost of devices	Cost as per medical device purchasing invoice	End of pilot
		Cost of maintenance	Costs per device maintenance (IT support, medical device regular rechecks, calibrations etc.)	End of pilot
		Cost of using digital solutions and SHAPES platform	Costs to be provided by SHAPES	End of pilot
		Cost of staffing	Timesheets and costing data	End of pilot
		Cost of travel	Saved patients' travel expenses	End of pilot

MAFEIP

Due to the evaluation methodology (small-scale deployment, non-case controlled) the MAFEIP tool (16) was not used to evaluate UC-PT3-001c.

4.4.2.1 Final check of the use case by using the CSFs of MOMENTUM and the NASSS framework

MOMENTUM

The MOMENTUM (17) blueprint was applied to check if UC-PT3-001c had the critical success factors (CSFs) needed to take it from the pilot phase to large-scale deployment.

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On review of the blueprint (and in line with guidance provided in the WP6 Evaluation Manual) it was agreed that 6 out of 18 CSFs were more relevant to explore and address at a later stage of the SHAPES programme. These included CSFs concerned with the cultural readiness for the telemedicine service (CSF 1), the consensus position on the advantage of telemedicine in meeting compelling need (CSF 2), ensuring leadership through a champion (CSF 3), preparing and implementing a business plan (CSF 9), preparing and implementing a change management plan (CSF 10) and guaranteeing the technology has the potential for scale-up (CSF 12). All remaining CSFs were deemed either to be in place or would be before the pilot began. A summary of the MOMENTUM blueprint is provided in Annex 46). Further details on each CSF are provided below.

CSF 4. Involve healthcare professionals and decision-makers

Health professionals and decision-makers were involved in the development of the content of the pilot. They were involved with the planning, design and implementation phases. Healthcare professionals' views on the value of the technology associated with this use case were explored in qualitative feedback obtained at the end of Phase 5.

CSF 5. Put the patient at the centre of the service

Patients were involved in the development of the digital solutions through the planned activities for Phase 2 and 3 of the pilot — mock-ups, prototyping and hands-on experiment. It was important to focus mainly on the education of the patients how to use the App and what benefits it could bring them.

CSF 6. Ensure that the technology is user-friendly

User experience was improved by the team consisting of both IT experts and a psychologist. Design was based on good practices and its adaptation was supported by experiments with focus groups containing the service users – patients and healthcare professionals. This area was mainly addressed during Phase 2 and 3 of the pilot and possible issues were resolved immediately based on the user feedback. Questions were guided by the standard ISO 14915, which specified four principles for the design of multimedia applications.

CSF 7. Pull together the resources needed for deployment

The resources required for deployment of the digital solutions for the pilot were, in the most part, available. However, experienced IT experts employed in the government sector were extremely difficult to find. Consequently, the existing IT teams endured a large workload. This was probably the major bottleneck of the project. A possible future solution could be motivating future IT experts via internships in the telemedicine IT

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team. The COVID-19 pandemic also placed greater demands on medical staff, both in terms of time and effort in providing routine care.

CSF 8. Address the needs of the primary client(s)

The primary clients of the PT3-001c use case were older individuals with chronic heart failure. The use case was specifically developed to meet the needs of a persona that represented the primary client. The use case and digital solutions were adapted in response to user testing feedback conducted with the primary clients. A user centric approach was applied in all stages of the development process. The solution also addressed the needs of the healthcare professionals by monitoring patients remotely and informing them about any decompensation.

CSF 11. Assess the conditions under which the service is legal

Review of the legal requirements of the Czech Republic concerning the use of digital solutions was conducted and it revealed that for the purposes of a scientific research project any devices that were of non-medical nature ("wellbeing devices" — wearables, weight scales, adherence monitoring devices etc.), however, certified in EU or US (FDA) could be used with the approval of an ethics committee together with the patients' voluntarily participation. In the pilot voluntary participation was demonstrated by obtaining informed consent and patients were free to leave the pilot if they wanted to, without any effect on the healthcare provided to them by the Czech legislation.

Completion of a DPIA identified and minimised any risks associated with the pilot. Data processing agreements were established with relevant partners to permit access to pseudonymised data.

CSF 13. Identify and apply relevant legal and security guidelines

Legal and security guidelines were reviewed and were applied accordingly. Main areas for consideration included data protection, ethical approval, compliance of devices with standards, penetration testing of software and storage of data.

Moreover, during the COVID-19 pandemic the Czech government institutes involved in cybersecurity issued several guidelines related to telemedicine and the requirements mentioned there were implemented in the digital solution tested in the pilot.

CSF 14. Involve legal and security experts

There was cooperation with SHAPES partners together with legal and security experts to ensure that we had full confidence in the legality and security of this pilot.

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CSF 15. Ensure that telemedicine doers and users are privacy aware

Telemedicine system designers were aware of GDPR and related privacy issues. They prepared the telemedicine system in concordance with the requirements. However, there was no certainty that the service users were equally experienced. Creators made all the relevant information available directly from the application, so the important information could be easily found and understood, especially for older people. Future improvements in this area are expected as this topic is steadily changing and evolving.

CSF 16. Ensure that the information technology infrastructure and eHealth infrastructure are available

An appropriate infrastructure for deployment of the digital solutions within the organisation was available for the pilot and prepared for scale-up process.

CSF 17. Put in place the technology and processes needed to monitor the service

A system to monitor the pilot was set up with support from WP4 and WP5 partners. There was also support from the local IT team to help address any issues with the use of the digital solutions. The IT team also developed their own service monitoring system to mitigate any incidents. A risk assessment was also conducted. The local project team were available to support participants in resolving any problems they experienced with the digital solutions.

CSF 18. Establish and maintain good procurement processes

Procurement processes for any public organisation, like the University Hospital Olomouc, were well defined by Czech legislation. Despite the processes being well defined and personnel in place to assist with implementation, these processes can be rigid and slow. Nevertheless, they were mandatory and were followed.

NASSS

The NASSS framework (18) was used to detect areas of complexity in the project plan for piloting UC-PT3-001c and, if needed, to make adaptations to the plan. The long version of the NASSS-CAT questionnaire was considered and completed by the pilot team (Annex 46). Of the 7 domains, there were 4 domains (‘Technology’, ‘Value proposition’, ‘Intended adopters of the innovation’, ‘The organisation implementing the technology’) in which significant complexities were identified that, if not mitigated or addressed, were likely to affect the project’s success at the piloting stage of the use case.

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Table 73: Complexities and mitigation measures identified using the NASSS framework (PT3-001c)

NASSS complexity domain	Uncertainties detected	Mitigation measures taken
Technology	Due to the complicated procurement processes it was challenging to firstly purchase the test product and subsequently to purchase the rest of the devices, as there was a high risk that devices would not be the same product.	By December 2021, uncertainties regarding the procurement process were addressed and resolved, IT Department and the Department of public procurement of UHO took over the responsibility for the procurement of all required devices. All devices were either procured or sales contracts with gradual delivery were mutually signed.
Technology	Procurement process might not be able to reach to all possible manufacturers of the devices intended to be used within the pilot.	
Technology	Uncertain outcome of device integration, which might be more complicated than envisaged by the internal IT experts.	SDKs for all of the devices were obtained with support from manufacturers and were implemented.
Technology	The amount of IT experts available for the task is limited.	During the phase 2 an additional IT expert was hired, however, it was still not sufficient as the hospital needed to solve other problems (tests and vaccinations) connected to the COVID-19

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NASSS complexity domain	Uncertainties detected	Mitigation measures taken
		pandemic and an increased amount of hacker attacks. Another IT expert and IT project manager were planned to be hired by the end of 2021.
Technology	The exact role and functionality of the platform had not yet been defined/communicated to the use case leaders.	By the participation on cross-WP meetings the major questions regarding the platform functionality and data storing were clarified.
Technology	The flow of data and data storage location was not yet confirmed.	
Value proposition	Uncertain value to the patient and clinician/healthcare system.	Value to the stakeholders was assessed after the pilot using specific questionnaires.
Intended adopters	Uncertain level of digital literacy.	Simple education was provided to all users. Some of the prospective users were also involved in the test phase, when the user experience and GUI design was being tuned so they could directly participate in the final shape of the application. All the benefits of the solution were presented to the stakeholders and
Intended adopters	Negative opinions on technology acceptance among some individuals.	
Intended adopters	Uncertain acceptance among healthcare professionals (concerns about overload).	

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NASSS complexity domain	Uncertainties detected	Mitigation measures taken
		discussed with them whether they were relevant or not.
Intended adopters	Availability of Wi-Fi network at the point-of-care location is uncertain.	Participants of the pilot were required to have Wi-Fi already installed in their home.
Intended adopters	Security measures on the patient's side of the network might introduce security threats.	Simple education was provided to all users to ensure the security and acceptance.
Intended adopters	System as a whole – hardware and software – might be too "modern" and complicated for the intended user group.	
Organisation implementing the technology	Traditionalists among the hospital staff were not ready yet to embrace the possibilities of modern technology.	Members of the Czech National eHealth Centre were increasing the knowledge about the telemedicine benefits among the employees of the University hospital Olomouc through seminars, workshops and other activities.

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4.5 Phase 1

4.5.1 PACT and FICS Scenario

Table 74: PACT (PT3-001c)

Code	UC-PT1-001c
People *Roles and/or actors of typical users involved in delivering and receiving the telemedicine intervention*	• Patient - 60+, living at home. No cognitive impairment at recruitment to the study. Advanced (based on NYHA classification) heart failure patient with possible comorbidities like diabetes, hypertension, chronic obstructive pulmonary disease with multiple daily medications. Very limited use of technology, most have never used a smartphone/tablet before. • Healthcare professionals (HCPs) - nurse and doctor planning and assessing medical treatment plan and specific tasks as parts of medical treatment plans. In the cases of results being below or above (based on the observed parameter) desired thresholds, they will alert the patient and adjust the medical treatment plan. HCPs have average level of computer literacy allowing them to conduct daily routine without major problems. • Biomedical engineer or IT technician – providing technical support for both patients and healthcare professionals in the cases of connectivity issues, medical device malfunctions, software issues etc.
Activities *Activities to be performed by the actors in order to successfully provide and receive the telemedicine intervention procedures for the professional and the patient; Parameters that determine the measures used in the intervention*	**Patient** • Measure systolic and diastolic blood pressure once a day • Measure weight once a day • Measure heart rate once a day • Measure oxygen saturation once a day • Measure daily activity with use of a pedometer • Measure ECG once a day • Complete daily/weekly/monthly/one-off questionnaires (HF related questionnaires, Quality of Life related questionnaire, user acceptance related questionnaire) • Send the data from the aforementioned measurements to the cloud/platform **Healthcare professional**

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Code	UC-PT1-001c
	• Review of clinical data on a regular basis, making changes to patient care as required • Assign tasks to patients • Possibility to provide video consultation via telemedicine application • Use predictive model to identify if patient's health condition is deteriorating and interventions taken to avoid this e.g. decompensations in heart failure **Technical support** • Provide introductory tutorial for both patients and healthcare professionals to achieve their correct use of hardware and software solutions • Provide support to resolve technical issues related to both connectivity and functionality • Provide regular maintenance of the hardware and software tools where applicable
Context *Social-medical relevance of the telemedicine intervention; privacy issues; risks for the patient; locations*	• Smart clinical devices to be used in patient's own home to monitor several patients' parameters that are relevant to monitor condition of patients with heart failure. Measured data are being assessed by healthcare professionals and also analysed by digital analytical tool. • Particular goals are as follows: ○ Optimise treatment plans ○ Improve patients' outcomes and reduce probability of possible readmissions ○ Reduce frequency of regular check-ups in hospital. ○ Increase use of digital telemedicine tools (e.g. video consultation) • Maintaining high standards of data privacy handling • GDPR and ethics in line with WP8 • Data and servers must be located within the EU • Translation into the Czech language will be provided by the local team • Location: University hospital Olomouc, Olomouc region, Czech Republic
Technology *Type of information/parameter*	• More detailed information can be found in the data plan for UC-PT3-001c

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Code	UC-PT1-001c
that are relevant in monitoring the health status; type and frequency of accessibility of information; feedback modalities (communication)	• Baseline demographic information: Age (year not DOB) Sex (M/F) Smoking history (Never smoked/used to smoke/current smoker) Height (cm) • Baseline medical history: Medicine (number of medicines/chronic or as required/name/ strength/ frequency/ date) Diagnoses (medical condition and date of diagnoses) Implanted cardiac device (pacemaker/ implanted cardioverter defibrillator/ cardiac resynchronization therapy) Left ventricular ejection fraction (%) Rhythm (atrial fibrillation/ sinus rhythm/ atrial flutter) Admission to hospital within 30 days Readmissions Heart disease NYHA classification • Changes to medication as the pilot progresses (stop/start/change strength/change frequency) • Heart rate (beats per minute) once daily • Oxygen saturation (%) once daily • Blood pressure diastolic and systolic (mmHg) once daily • Weight (kg) once daily • ECG once daily • Blood test (Urea, creatinine, Sodium, Potassium, Glycated Haemoglobin, etc.) • Questionnaires • Reminder/alert to complete questionnaires and use clinical devices • Feedback to participant that their clinical parameters are within or the normal range • Feedback via app to participant on whether all tasks have been completed • Feedback via browser to HCP to highlight clinical parameters outside the normal range

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Table 75: FICS Scenario (PT3-001c)

Category	Details
Function and events *Functionality of the intended system which is capable to realize actor's activities*	The system will provide users with the following capabilities: • Measure body weight and composition once daily • Measure blood pressure once daily • Measure ECG and heart rate once daily • Measure oxygen saturation once daily • Monitor physical activity thorough the day (aided by a pedometer inside smartwatches) • Assign specific questionnaires (e.g. wellbeing, system usability, etc.) • Assign tasks within the medical treatment plan • Show alerts, notification, reminders etc. • Video consultation • Medicine ordering • Medication list • Prediction of decompensation
Interactions and usability issues *User-system or system-component interactions meditating actor's activities; Types of the interactions, e.g. unidirectional data streaming service or reliable messaging service*	In this use case, we plan to work with following end-users: • Older person (a heart failure patient) • Healthcare professionals (nurse, doctor) Front-end is available for patients and healthcare professionals, whereas each of the users is able to see only a part of the system which is intended for them. The system will manage following data and information: • Physical activity (pedometer) • Vital signals (e.g. ECG) • Providing alerts, reminders, notification etc. • Wellbeing and other surveys • Treatment plan Healthcare professionals are able to create treatment plans, check the alerts and analytics provided through the predictive model for heart failure patients. Patients are able to upload data from the medical devices they are using, check-up on their treatment plans.
Content and structure *Variables of the interaction*	• Users' front end with teleconsultation and medicine ordering is available through the regular web browser

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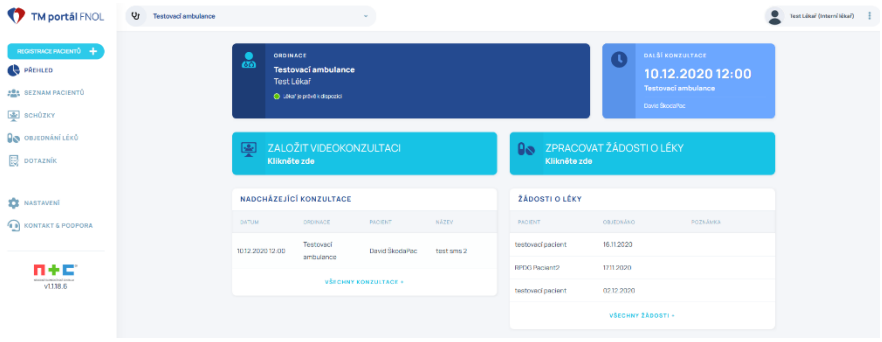
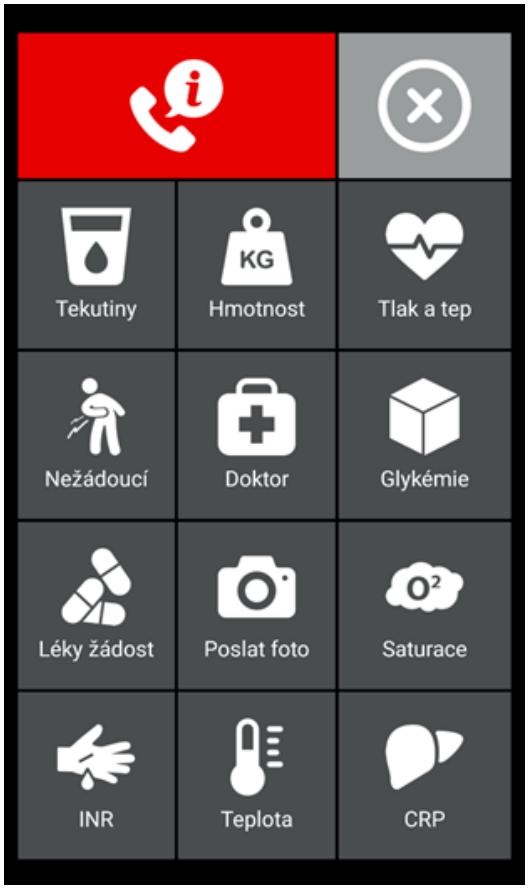
Category	Details
	• Monitoring of biophysical signals, dissemination of wellbeing and other questionnaires is aided via application available for Android devices
Style and aesthetics *Look and feel of the system*	Part of the system available via browser:  Part of the system available as an app for Android: 

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4.5.2 Key performance indicators

Key Performance Indicators (KPIs) were defined as a set of measures that focused on the factors most critical to the project's success. KPIs were measurable and quantifiable with a target or threshold. They measured performance in critical areas by showing the progress or lack of it towards realising the objectives of each specific use case. The following KPIs were chosen to determine whether, or not, the pilot for UC-PT3-001c was successful.

Failure to meet four or more of the KPIs will indicate that major revisions to the use case and associated digital solutions are needed before further evaluation or deployment.

Recruitment and retention

1. At least 80% of the target cohort were successfully recruited into the pilot during the recruitment period.

2. At least 80% of recruited participants remained enrolled in the pilot until the end of the study.

User engagement and acceptance

3. The overall user experience quality of the app as measured using the short version of the UEQ-S (2) was classified as 'Excellent', 'Good' or 'Above average' based on published benchmark data.

4. At least 60% of participants continued to use the app daily after 2 weeks of the pilot.

5. At least 60% of participants scored an above average rating (>68) in the SUS (8).

6. At least 60% of healthcare professionals' mental load and workload decreased during the three months of the pilot among the doctors using the platform in comparison with the baseline (Meister questionnaire) (21).

Collection of data

7. Sufficient data was collected from participants to allow the heart failure decompensation prediction tool to generate a percentage risk of decompensation at least once per week for at least 60% of participants.

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4.5.3 Timeline of pilot activities

The original timeline of pilot activities according to the Description of Work was to conduct Phase 1 and 2 between November 2020 and April 2021, then start with Phase 3 (prototype testing and hands-on training) in May 2021 and with Phase 4 (deployment in controlled environment) in September 2021.

Phase 1 was conducted as originally planned as this phase was mainly focused on document preparation (personas, KPIs, scenarios, pilot description etc.)

In Phase 2 (mock-up user experience testing) the FNOL team invited prospective users to test the initial wireframe models and also high-resolution models of the Medimonitor application. Direct demonstration on the tablet devices together with the targeted interviews was used. This phase was finished in April 2021.

In Phase 3 (hands-on training) the FNOL team needed to be in direct contact with the prospective users, therefore the start of phase 3 was postponed until it was safer for the older people to have in-person meetings with the FNOL team. This phase was finished in August 2022. A formal request to extend Pilot Theme 3 was approved by the Project Officer.

Phase 4 and 5 involved training participants on the use of clinical devices and recruiting from outpatient clinics. The COVID-19 situation continued to result in significant clinical staff redeployment and only essential outpatient services were running. Also, the IT support staff were redeployed to COVID-19 related services, maintenance and to respond to the increasing number of hacker activities. Phase 4 started with a delay in September 2022 due to technical issues with devices and our application. Phase 5 was conducted immediately after in November 2022.

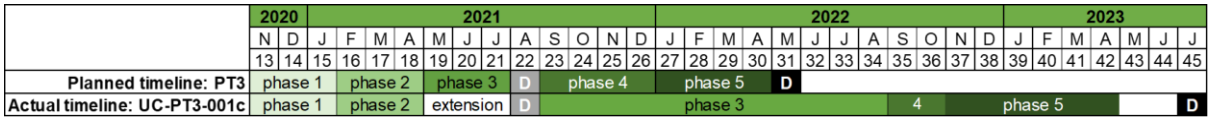

Figure 14 Planned and actual timeline of pilot activities (PT3-001c).

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4.6 Phase 2: Testing of mock-ups and prototypes

4.6.1 Methodology of testing

Aim

The aim of this phase was to validate prototypes of the application's (Medimonitor) GUI, cooperate with IT experts (designers and programmers) and use the opportunity to integrate user feedback at an early stage of the technological development process.

Overview

The digital solutions for UC-PT3-001c underwent a user-testing process to optimise their usability and acceptability to the end-users. There were several GUI prototype solutions that were presented to the end users – patients and health care professionals. End users were given simple tasks (order medicine or a video consultation) to be conducted within the application environment. Feedback was collected through direct user observation and interviews.

Recruitment

Phase 2 was conducted with 9 participants from 2 different types of user groups:

- Target users (≥ 60 years' old; living at home) (n=5)
- Healthcare practitioners (nurse or doctor) (n=4)

Identification of participants

Target users

The first group of target user participants were identified within the social networks of Market and Advertisement Psychology students from local universities. Each of the students was able to identify several eligible participants within their families. The students were also well educated to perform the prepared mock-up test and to conclude the main results which were sent to the principal investigator in the next step.

The second group of target user participants were identified through the University Hospital Olomouc. The second group were invited to participate in the intensive workshop conducted on hospital premises.

Healthcare practitioners

Four healthcare practitioners were identified via the cardiology department in University Hospital Olomouc. Two HCPs were doctors with specialisations in cardiology two HCPs were nurses. One of the medical doctors was a male. All of the

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HCP users were confident in using their smartphones or tablets as they regularly use them.

Informed consent procedure

Target users

The first group of participants were recruited from the family members and friends of cooperating students. No personal data was collected from participants, nor were any invasive experiments/procedures conducted on the participants. They were simply asked about their opinions related to the applications GUI, its colours, font sizes, language and terminology used. Therefore, no written consent was collected. Participants were verbally informed by the cooperating students, however, no signed documents were required.

A second group of participants were invited for an intensive workshop with the developers and user experience (UX) experts. General consent that was recommended by the SHAPES consortium was used. Eligible individuals were provided with verbal information/instruction explaining the background and purpose to the study and what they could expect to happen if they agreed to participate. Those who agreed to take part were given a consent form by a FNOL researcher.

Healthcare practitioners

The healthcare practitioners were recruited from hospital employees. Eligible individuals were provided with a verbal information/instruction explaining the background and purpose to the study and what they could expect to happen if they agreed to participate. Those who agreed to take part were given a consent form by a FNOL researcher.

Informed consent for all participants was taken on-site. Template consent forms are available to view in Annex 48.

Method

Presentation of mock-ups

Validation of the user-facing digital solutions design intended for deployment in UC-PT3-001c Advanced telemonitoring of patients with heart failure in home environment was conducted. These solutions were as follows:

Medimonitor GUI

Students were asked to reach older people in their social network to cooperate on the Medimonitor GUI optimization.

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Students showed a presentation that demonstrated the FNOL digital solutions developed within SHAPES (Medimonitor) including its main features and functionality. Students also presented several screenshots with different variants of the GUI. This included the use of specific terminology and language with the intention to identify the text that allowed the highest possible level of understanding among the target group. Students interviewed the participants and collected notes with participant's feedback — which consisted of choosing the best GUI out of all presented variants and writing participants' own ideas to improve the terminology, language and GUI graphical shape.

It was important to stress that all the participants were told that they were not the subject under test — the application was. They were the experts telling the developers how to improve the digital solution to maximize its utility and ease of handling by the target group.

Students were instructed to show the screenshot in a different sequence for each participant to avoid order bias.

In the second step the users were asked how they would interact with different application's functionalities (scheduling video consultation, ordering medicine) of the digital solution. Ease of use among the participants was observed and the feedback was collected.

The second group were invited directly to the hospital premises, where an intensive workshop with developers took place.

The second group of invited participants were divided into two distinct subgroups. The first subgroup already had hands-on experience with the original telemedicine solution of FNOL, whereas the second subgroup had not. A total of 6 participants were contacted — 4 women aged ≥65 and 1 man attended; 1 participant did not attend. The whole testing took place in a single room and lasted approximately 1 hour per respondent. A UX expert and a psychologist were present during the course of testing. The entire testing was also streamed to the neighbouring room so other employees of the development team could unobtrusively observe the whole testing session. The participants observed a GUI prototype created in Figma on a device that was later used within the pilot verification. Testing was conducted with a structured interview that had two parts. The first part was moderated by the UX experts and was directly connected with observation of the user interacting with the mock-up GUI. Questions were mainly related to the part of the system dedicated to measurements, monitoring, medicine prescriptions and video consultation. The second part of the interview was moderated by the psychologist and was related to more general questions and issues regarding the possible functionalities, GUI appearance, terminology and language. All the interviews were recorded and can be used for further analysis.

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Data collection and analysis

Data were analysed through qualitative analysis based on short transcriptions of interviews with the end users. The only personal information collected was sex and age.

Interviews conducted with the group invited to the hospital premises were observed not only by the direct interviewers, but also by the other experts in the second room. Therefore, it was possible to simultaneously write down notes and discuss possible improvements in real-time. This enabled immediate testing of the improvements and assessments of their appropriateness for handling by a population of older people.

Completed reports and collated findings, including recommendations, were presented to the technical experts responsible for the Medimonitor development (designers, programmers etc.).

4.6.2 Results of testing

A full feedback report from the Phase 2 mock-up presentations including recommendations made to technical partners is provided in Annex 49. An overview is provided below.

Overview of feedback

Using the feedback collected during the presentations and interviews with participants, the Phase 2 mock-ups of the SHAPES FNOL component of the PT3-001c and PT3-COPD use case user app were assessed using the ISO Standards for multimedia design (ISO 14915).

Suitability for the communication objective *(i.e., suitability of presentation of the information for achieving the goals of the providers and visitors).*

In older users we encountered a lack of confidence with using technology. An important point was that there should be a clearly designed application, but we should not forget the motivating conversation with the user. For older users who were concerned about working the tablet, it was advisable to introduce the application and motivate them in person (not just by a brochure or leaflet). This introductory interview can have a major impact on the future use of the application.

Positive feedback

- Create screens with a small number of elements.
- Direct the user's attention to only one task at a time.
- Use a contrast sans-serif font.

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- Use simple design.
- Show important information (doctor's reports, etc.) with a priority.

Negative feedback

- Do not use icons (or limit their use), respondents often did not understand icons.
- The colours used in the application should be justified and in order. Using colour coding with no reason is not recommended, as this confused users.

Suitability for perception and understanding *(i.e., is the information transmitted easy to understand and can be easily recorded?)*

The clearer the application, the higher the willingness of users to use the application. This is in line with the Technological Acceptance Model; the assumption that people make more use of technologies for which they perceive benefits and are easily accessible to control (UX, UI). The application should combine a pleasant appearance, ease of use, trustworthiness and thus bring an overall positive experience with the application.

Positive feedback

- Use one-click confirmation (not double-click).
- Use the familiar hospital logo and match the application to the colours that users have associated with this logo (greater credibility).
- Create space for the user's "errors", typos, incorrectly selected surgeries, etc. - these user errors must be taken into account by the application and be able to respond to them correctly.

Negative feedback

- Do not use complex gestures to control (do not use a slider or double-click) in the application.
- Beware of clickable elements too close to each other (older people had trouble hitting them).
- Test the application properly before its release, when the application is launched to the public, do not change it.

Suitability for exploration *(i.e., is the participant able to find the desired information or complete his task without any previous knowledge or experience regarding the presentation or structure of the information offered).*

In the majority of cases the application consisted of several predefined scenarios which guided the user through the whole process and avoided too much unstructured exploration. However, the application also consisted of several navigation elements

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that could be accessed with ease. Nevertheless, the alternate routes should not be confusing.

Positive feedback

- Wizards (a user interface that led the user through a sequence of small steps) were useful tools to guide the users through the measurement process.

Negative feedback

- Alternative paths to the destination may confuse users, pay increased attention to whether they are justified.

Suitability for user motivation *(i.e., a participant must be encouraged to act. By focusing on the needs of the participants, an appealing presentation and goal-oriented guidance, the participant can be motivated).*

The application should be designed in such a way that patients gained better control over their health condition, thus increasing user adherence, improving health status and thus reducing healthcare costs. Immediate feedback on deviations in health (fluctuations in weight, pressure, etc.) supported early intervention (dietary adjustment, change of drugs, new exercise regimen, etc.).

Positive feedback

- Create a connection with something that users already know and like to use (e.g. e-prescription).
- Present the application as an "extended hand of a doctor", the application complements the contact with the doctor (does not replace it).
- The application should include doctor's feedback for the tasks completed by the patient (it can also be added automatically); then users will understand the application as meaningful.

Negative feedback

- Lower confidence of older people in the electronic data form (deeper trust in paper notes).
- When introducing the application to the public, attention should be paid to possible misinformation, some users expressed uncertainty as to why such an application was being created ("is there a risk of healthcare collapse?").

4.7 Phase 3: Hand-on Experiments

4.7.1 Methodology of hands-on experiments

Introduction

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Hands-on experiments were performed in Phase 3 of the SHAPES Pilot Campaign to collect feedback from end-users and evaluate the performance of the digital solution in the actual pilot setting. The end-users were presented with the tools that have been developed and improved during Phases 1 and 2. In order to ensure the solutions took into account the feedback given in the previous phases, different types of evaluation were carried out.

Aim

The aim was to train end-users to use a close-to-final version of the user-facing digital solutions to be deployed in the pilot of UC-PT3-001c and UC-PT3-COPD, provide end-users with the opportunity to challenge their functionalities and user-friendliness, and provide feedback indicating what changes still needed to be made.

Overview

Hands-on experiments were conducted on-site while applying highest pandemic precautions. If required by an increase in pandemic risk, the hands-on experiments could have been also delivered remotely via the internal video consultation platform. The same participants from the group of patients and HCP from the previous testing were invited to provide follow-up feedback regarding the updated version of the digital solutions. End users were asked to conduct several tasks reflecting typical use case scenarios like ordering medication or video consultations and conducting measurements.

Approval

All project activities were approved by the internal ethics committee together with the hospital management. All involved patients/volunteers signed informed consent forms and were exercising their free will to participate in the project activities.

Participants

Phase 3 hands-on experiments were conducted with two specific groups – patients and healthcare professionals.

The first group of participants (patients) were identified through the University Hospital Olomouc and were invited to the hospital premises.

The second group of participants were eligible HCP's who were identified by employees of the Czech National e-Health Centre (University Hospital Olomouc). The cooperating doctors were involved in the development project activities.

Informed consent procedure

Target users

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Participants from the patient group were invited for an intensive workshop with the developers and UX experts. General consent that was recommended by the SHAPES consortium was used. Eligible individuals were provided with verbal information/instruction explaining the background and purpose of the study and what they could expect to happen if they agreed to participate. Those who agreed to take part were given a consent form by a FNOL researcher.

Healthcare practitioners

Participants from the HCP group were recruited from hospital employees. Eligible individuals were provided with verbal information/instruction explaining the background and purpose of the study and what they could expect to happen if they agreed to participate. Those who agreed to take part were given a consent form by a FNOL researcher.

Informed consent for all participants was obtained on-site. Participant information sheets and consent forms are available to view in Annex 50 and Annex 51.

Method

The technologies were presented as a functioning prototype of the FNOL digital solution. A researcher guided the participant through a series of steps and tasks to demonstrate the different functionalities of app and trained the participant on how to use it. Instructions were presented verbally while the participant was at the hospital premises.

The prototype was accessed by participants via a borrowed tablet.

The steps and tasks demonstrated included:

1. Assessing the colour perception
2. Accessing the prototype
3. Navigating to different features from ‘Dashboard’
4. Navigating to ‘Dashboard’ from within the App
5. View and enter measured biomedical signals (blood pressure, heart rate, oxygen saturation etc.)
6. View medication list
7. View ‘daily to-do list’

The pace of the session was determined by the participant. After the demonstrations the participant was encouraged to use the app with the researcher still present and available to ask questions and troubleshoot any issues.

There was a break to allow the participant to rest, process the information provided, and familiarise themselves with the App. The user training manual (Annex 52) included

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an example task for the participant to complete, containing mock data for entering readings into the App.

When the second session started, the participant was asked how they got on with completing the tasks and if they had any questions or queries about using the App. Feedback about the App was then collected as described below.

Collection of feedback

Feedback was collected at different time-points during Phase 3 using a variety of different methods. Participant responses were analysed through the qualitative analysis based on short transcriptions of interviews with the end users. The only personal information collected was gender and age. A concurrent 'think out loud' approach was used to collect reactions to the app and identify any areas requiring particular attention during the demonstration of the App and user training. The participants were encouraged to verbalise their reactions, thoughts, feelings, and opinions about the prototype throughout their engagement with the researchers. Notes were taken by the researchers and the sessions were recorded to capture feedback accurately.

The researcher dashboard was reviewed to check if set tasks were completed (and if so, correctly) by the participants during the break between sessions when participants were familiarising themselves with the App. This information was used to identify any problem areas for using the app and discussed with participants later in the session.

When participants returned for the second session, they were firstly asked to complete a short activity under observation, i.e., a moderated test. During the test, the participant was asked to 'think out loud' and thereby point out 'stumbling blocks'. Facial expressions and movements of the user were observed and noted, and the observer documented how often the participant asked for help and if there are specific points where many users needed support. It was observed whether the buttons or items on a touchscreen are considered to be used easily or not, and whether the response of the app corresponded to what was expected by the user or not.

Participants were interviewed by the researcher to collect the participant's experience using the prototype. An interview schedule / topic guide was followed during the interview but the researcher also referred to conversations and topics raised during the sessions. Semi-structured questions explored users' general feedback about the app including:

1. Overall satisfaction
2. Ease of use
3. Design
4. Utility
5. Gender equality

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6. Quality of training

Data analysis

Interviews conducted with the group invited to the hospital premises were observed not only by the direct interviewers, but also by other experts in a second room. Therefore, it was possible to simultaneously write down notes and discuss possible improvements in real-time. This enabled immediate testing of the improvements and assessment of their appropriateness for use by an ageing population.

Completed reports and collated findings, including any recommendations, were presented to technical experts responsible for the Medimonitor development (designers, programmers etc.).

4.7.2 Results of the hands-on experiments

Overview of feedback

The Phase 3 hands-on experiments of the SHAPES FNOL user App for the PT3-001c and PT3-COPD use cases was assessed using the feedback collected during interviews with the participants. This feedback was assessed against the ISO Standards for multimedia design (ISO 14915). General feedback was provided first followed by specific feedback and recommendations for each mock-up screen. Recommendations for the technical partners were provided for each screen.

Testing of the user App was conducted on the same respondents as in Phase 2. In total, 5 respondents participated in the testing, 4 women and 1 man. This group included patients and healthcare professionals. The Phase 3 hands-on experiment with recruited participants was conducted on 14th October 2021. Tests were conducted personally on-site while following elevated pandemic precautions. The whole testing took place at the University Hospital Olomouc, Internal Cardiology Clinic. The respondents were given the same tasks to perform sequentially:

1. Blood pressure measurement (measure the blood pressure, find the measurement history).
2. Medical aid ordering (what aids are approved or rejected, order new medical aids)
3. Connection with the doctor (it is time for a consultation with the doctor, make a connection with the doctor)
4. Medication (take the medicine/ointment/drops, don't take medication, take the medication later)

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After testing on the first 4 respondents, it was decided to modify the screens based on the feedback and show the modified version to the last respondent. Mainly, the home screen was redesigned, where tiles were created with less text (containing only the section title and appropriate pictogram). The last respondent was given the same tasks and had to choose a tablet (screen) to do it on. The respondent immediately chose the tile option. Further testing involved testing the tile and signpost concept on a larger sample of respondents.

After the evaluation of this first round of testing, there was a second round of testing organised by psychology students. They focused on testing of colours and the position of action buttons. In total, 33 respondents participated in this second round and they were usually family members of involved students.

Conclusions using ISO standard

1. Homepage

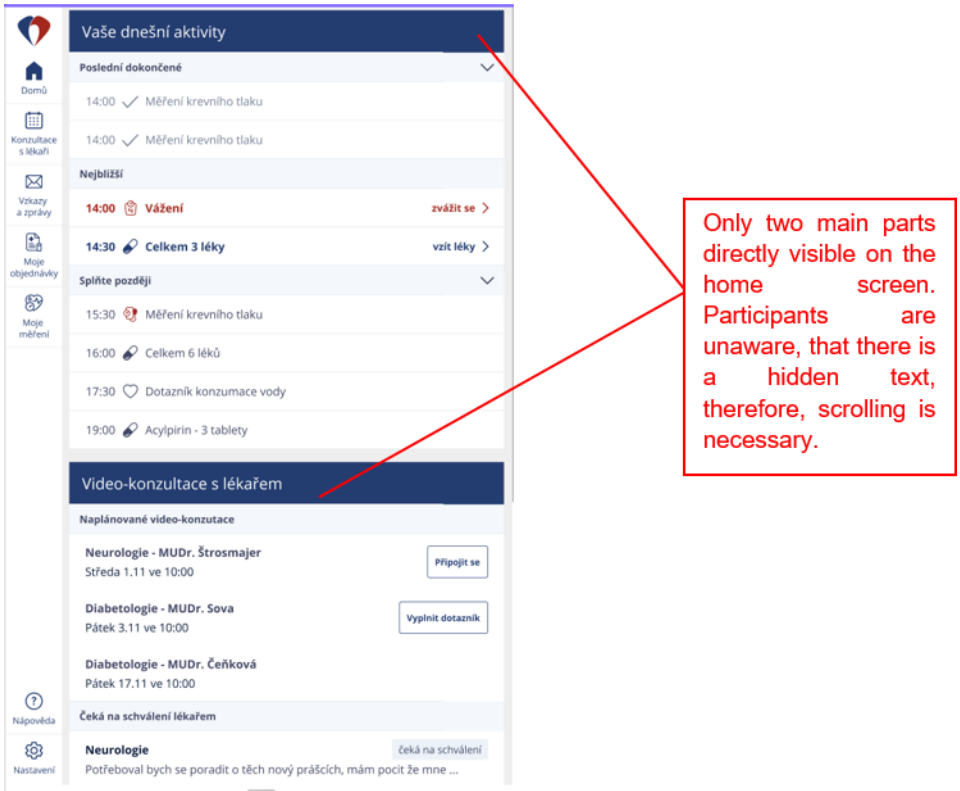

Figure 15 Medimonitor homepage (PT3-001c/COPD)

Table 76: Recommendations for homepage (PT3-001c/COPD)

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a) Suitability for the communication objective	b) Suitability for perception and understanding	c) Suitability for exploration	d) Suitability for user motivation
Necessity of scrolling on the home page does not seem to be feasible for the ageing population. It should be either graphically well interpreted that the scrolling is necessary or even better it should be avoided completely.	Currently the application is not easily understood at first glance.	Necessity of scrolling is not well communicated. An arrow or text "show more" is needed.	Simplification of the application while incorporating more pictograms is needed. The current amount of text is too overwhelming.

Recommendations

1. First contact between the user and the application should be positive – the application should be well-arranged and simple to navigate.
2. Homepage will be redesigned into the new tiles scheme with pictograms (effect of image priority and simplicity of understanding)
3. Sidebar will be moved in the lower part of the screen and containing fewer information (home, settings).

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2. Take blood pressure measurement task

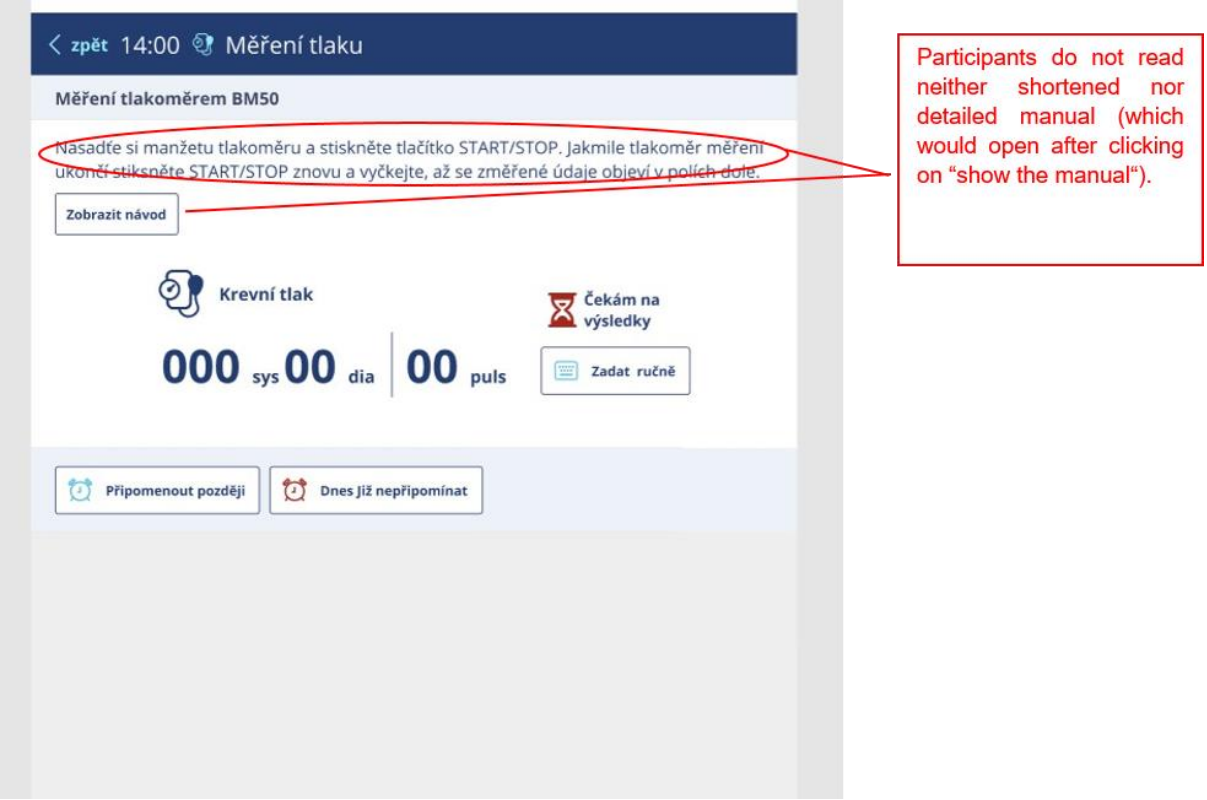

Figure 16 Blood pressure measurement in manual (PT3-001c/COPD)

Table 77: Recommendations for blood pressure measurement task (PT3-001c)

a) Suitability for the communication objective	b) Suitability for perception and understanding	c) Suitability for exploration	d) Suitability for user motivation
All respondents put a pressure gauge on their arm. They didn't want to read the instructions, they wanted to measure straight away. **However, they always put the**	Text instructions are not appropriate for the prospective users. Simple picture scheme needs to be added. Three steps accompanied by an image visible directly on the side	When the respondents were asked if there was a guide somewhere, they always looked for the guide directly on the device (blood pressure monitor).	Users feel that they are doing everything right. Usually, they already have experience with measuring blood pressure, but in fact in all cases, they put on the pressure gauge incorrectly. A

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a) Suitability for the communication objective	b) Suitability for perception and understanding	c) Suitability for exploration	d) Suitability for user motivation
pressure gauge incorrectly and the procedure in their case did not lead to the correct connection of the pressure gauge with the application.	with the blood pressure measurement.	Therefore, it was necessary to add a diagram and test whether the respondents were able to proceed correctly with the image diagram.	solution could be to add for example an arrow or other visible instructions directly on the device.

Recommendations

1. Respondents act intuitively, they immediately try things rather than read instructions.
2. Instructions are better perceived when displayed graphically than shown as a text.
3. Emphasis also on education when handing over the device (training by a nurse / doctor).

Recommendations for the application development

1. It should be started from the colour variant that respondents liked the most and adjusted according to knowledge from the light and dark variants.
2. Respondents rated the graph in the upper left of the dark version very positively. It would be appropriate to put it in the colour version as well.
3. Respondents positively rated the warm welcome in the dark version (Welcome, <Name>, you still have 5 activities to complete). They negatively evaluated the cold welcome in the colour version (<Name>, you still have 5 activities to complete).
4. Respondents in the dark version perceive the processing of alerts (2 new, 4 to be collected…) as the clearest and most comprehensible. It is therefore recommended to remove the "show more" arrows in the colour version, which are confusing there.
5. Respondents could not find the new order button. It needs to be enlarged and emphasized. It must be placed at the top of the screen.

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6. It is not recommended to use the term "consultation". The texts in the dark version were rated the best. So, the texts from the dark version should be used (video calls, conversations, medical aids, prescriptions).
7. Test users liked the red colour. It encourages them to take action (with the light version they often said that nothing forced them to do something, that it was dull and not urgent). Therefore, it is suggested to place the conversion buttons to complete the task above and to make it red (take a total of 3 drugs, measure blood pressure etc.).
8. Respondents liked the logic of the colour version. It was important to decide what section had what colour (focusing on the psychology of colours and choosing the right one).

4.7.3 Conclusion

User testing of mHealth application design for patients over the age of 65 was important to create an effective mobile application that reflected the needs of the target group but was also applicable to other age groups. The testing of the mobile application took place at the same time as the testing of the telemedicine portal, which is available in web form. The development of the mobile application consisted of the “patient centric” approach in order to create an intuitive easy-to-use application from the point of view of UX/UI. Emphasis was placed on the appropriate medical colour scheme based on the psychology of colours and healthcare fonts as well as on making decisions about important design elements and details. However, the mobile application was also created in such a way as to copy the trends that currently exist. Testing of the application took place in cooperation with psychologists with an emphasis on the qualitative part of data collection, which was to serve for a better understanding of what respondents think. The latest version of the application was in light tones, which evoked the hospital environment and it was redesigned from a line form to a tile design. The tile design with pictograms was best perceived by the respondents and the individual colours increased the feeling of comfort. A stronger link to the application was induced by addressing the patients by their name and a motivation scheme, showing what percentage of tasks were already completed. It was repeatedly necessary to test the correctness and meaning of the used CTA buttons in both mobile and web form. All the above recommendations were implemented in the solution and tested again.

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4.8 Phase 4: Small Scale Live Demonstration

Introduction

A small-scale live demonstration of the SHAPES platform and digital solutions was performed in Phase 4 of the SHAPES Pilot Campaign at University Hospital Olomouc. The aim of the demonstration was to collect feedback from end-users and evaluate the performance of the digital solution and transfer of data in a real-world environment before the large-scale pilot was conducted. The demonstration also tested the methods and procedures that were to be used when Phase 5 of the pilot started. The end-users were presented with the tools that were developed and improved during phases 1, 2 and 3. If needed, there was also a chance to make adjustments to the solution before the large-scale pilot started.

For the best evaluation, a sample of 4 people from diverse age groups was selected, including a 45-year-old male (an economist and engineer), a 40-year-old female (a senior nurse in a healthcare setting), a 62-year-old female (a retired individual), and a 14-year-old female (a high school student). By examining the insights gained from this participant sample, we aimed to highlight the importance of considering demographic factors in research studies and draw valuable conclusions for future studies targeting different populations.

Aim

To test the final version of the digital solutions to be deployed in Phase 5 pilot of UC-PT3-001c and UC-PT3-COPD in real-world conditions. To test the overall pilot process from recruitment of eligible participants, education of participants, correct use of the digital solution by participants, data transfer and connectivity. To implement final changes of digital solutions if any issues arose.

Overview

The small-scale live demonstration was conducted at the participant's own home. Only the education of the participants, signing the informed consent forms and handing over the devices was conducted onsite while applying the highest pandemic precautions. If required by an increase in pandemic risk, the education could have also been delivered remotely via the internal video consultation platform and the devices delivered by mail. Participants were asked to use the digital solution each day, to conduct several planned tasks reflecting typical use case scenarios like ordering medication or video consultations, to conduct vitals measurements and to complete questionnaires.

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4.8.1 Recruitment of participants

Phase 4 small-scale live demonstration was conducted with 4 participants who tested the solutions at home in a real-life environment. Recruited participants were not representative of the target user group but were able to use the solution at home for the duration of Phase 4. Eligible participants were identified and recruited internally by the staff of the Czech National eHealth Centre of University Hospital Olomouc. Participants were required to have a stable Wi-Fi connection at home, to be in good health status to be able to take part in the pilot and to be a user of a smartphone or tablet.

Informed consent for all participants was obtained for each participant. Participant information sheets and participant consent forms for Phase 4 can be viewed in Annex 53 and Annex 54, respectively.

4.8.2 Technical aspects & Logistics

Participants were provided with a tablet:

- Android Tablet Lenovo M10 HD

Android tablet specifications:

- Android version 9 or above
- Processor speed 2GHz or more
- RAM 3GB+
- Storage 64GB or above
- Support Wi-Fi
- Support BLE
- Screen 10'' or above

Participants are also provided with following set of devices to measure their vital signs:

- Diagnostic weight scales Beurer BF600
- Oximeter Beurer PO60
- Blood pressure monitor Beurer BM54
- ECG Beurer ME90
- Smartwatch Xiaomi Mi Band 6

All the devices enabled the transfer of data via Bluetooth and were CE-marked.

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Eligible participants were invited to an education meeting which took place in the University Hospital Olomouc. Instructions were presented verbally while the participant was present at the hospital premises. A researcher, technician and nurse were present during the education meeting. The researcher introduced the SHAPES project and the main aim of this testing. Participants gave their informed consent to take part in the testing. Participants were provided with an android tablet with the downloaded Medimonitor App, blood pressure meter, pulse oximeter, weight scale, pedometer and ECG meter to use at home. The researcher explained how to work the Medimonitor App and the devices and guided the participant through a series of steps and tasks to demonstrate the different functionalities of the App. A user manual (Annex 55) was provided along with the digital solution.

The pace of the session was determined by the participant. After the demonstrations, the participant was encouraged to use the App with the researcher still present and available to ask questions and troubleshoot any issues. Participants were informed that researchers or technicians were available during the live demonstration if necessary and they were provided with phone and email contact details. Researchers kept records of requests for support.

Participants performed the following daily tasks for 1 week:

1. Vitals readings – weight, blood pressure, heart rate, oxygen saturation, ECG, activity level
2. Questionnaires
3. Video consultation
4. Medication ordering
5. View medication list
6. View ‘daily to-do list’

The readings from the devices were electronically transferred to the Medimonitor App via Bluetooth, participants, as well as researchers, were able to see all the data saved in the App. Participants’ data were uploaded to a browser-based researcher dashboard. Mock data about medication, daily tasks and daily questions were entered into the App by the researcher or technician to test the reminder function. Participants were also asked to complete questionnaires using example data (for the purposes of Phase 4 only). HCPs also scheduled testing video consultation so they could check whether the audio and video signals are coming flawlessly through the application.

Participants were asked to write down any errors that occurred during the one-week testing. This was reviewed by the researcher as well as any discrepancies in the researcher dashboard.

Participants were also asked to suggest any improvements or adjustments in the overall process of the demonstration.

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4.8.3 Roles and Responsibilities

The SHAPES pilot site researchers at FNOL were responsible for recruiting and consenting participants to take part in the live demonstration. FNOL provided training and were a single point of contact for the participants for all the support needed.

4.8.4 Ethical considerations

All project activities were approved by the internal ethics committee together with the hospital management. All involved participants signed informed consents and were exercising their free will to participate in the pilot activities.

An ethical self-assessment for Phases 1–5 of this use case was completed (Annex 56). For Phase 4, an information sheet specifying the nature of the research and pilot, including the processing of personal data as part of the research and/or on the SHAPES platform, was provided.

4.8.5 Outcome of the Small-Scale Live Demonstration

Following aspects were evaluated:

1. Each participant used all the provided clinical devices and tablet each day for seven days.
2. 100% of data for heart rate, blood pressure, oxygen saturation, ECG, activity level, weight and questionnaires are successfully transmitted via Bluetooth to the Medimonitor App.
3. Participants viewed their medication list daily.
4. Participants tried to contact healthcare professionals.
5. Participants tried to order medication.
6. Participants viewed the reminders and completed their tasks.
7. All participant data received by the Medimonitor App was securely transferred to FNOL servers and researcher dashboard.
8. Number of errors noted by participants.
9. Feedback provided by participants.
10. Digital monitoring available through researcher dashboard and user event logs.

Recommendations for technical partners

The predictor model envisaged to be used as a predictor and developed by VICOM had been already tested. Hence, unlike the COPD use case there were no further

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recommendations towards the technical partner. The mobile application itself was developed internally.

We were able to adjust the manual for the user App based on the feedback of respondents. Regarding the Medimonitor application as many technical errors as possible were identified and resolved. All the errors noted by participants regarding the interface of the application were resolved and are detailed below.

The testing process revealed that respondents' comprehension was influenced by their ability to grasp the overall context. By including additional context or instructions, researchers could enhance respondents' understanding and accuracy in interpreting tasks. This consideration was particularly important when dealing with complex or multi-step tasks, where providing adequate context could improve respondents' performance and decrease ambiguity.

All 4 respondents unanimously agreed on the variant that highlighted incomplete tasks in a red frame at the top. The testing approach employed slight variations to evaluate the clarity, comprehension speed, and understanding of the overall context among the participants. In all aspects, the variant with the highlighted incomplete tasks emerged as the clear winner. The respondents' comments reflected a common understanding, such as "Oh, I see, this is what I need to do" when presented with the second variant, and "There's nothing to do here; there are no tasks" when viewing the first version. Furthermore, all respondents unequivocally indicated their preference for a green checkmark to signify a completed task.

The older respondents unanimously preferred the white button version (dark text on a white background), while the young respondent expressed a preference for the dark version, citing its logical association. This highlighted the importance of considering colour perception and visual preferences across different age groups. However, due to limitations in testing, the comprehension aspect could not be fully evaluated for the dark version, as the text content remained consistent across both versions.

4.9 Phase 5: Large-scale pilot activity

In Phase 5 a non-randomised, single-armed, cross-sectional prospective interventional pilot study with a qualitative interview component was conducted. The pilot aimed to recruit 25 participants at the FNOL pilot site. Replication of the pilot was not intended.

The intervention piloted in this study was a Medimonitor application aided with several medical devices, from which the data are being collected by the Medimonitor and further transferred to servers and analysed. Hence, the main purpose is monitoring of

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health status in patients with chronic conditions, with ability to contact the patients in case they might need additional check-up in hospital.

The pilot was conducted with service users and medical doctors in Olomouc, Czech Republic from University Hospital Olomouc. The pilot was managed by researchers from UHO and NTMC.

This study intended to test the hypothesis that the SHAPES platform and Digital Solutions (novel system) can provide opportunities for supporting the management of the heart failure condition, by both older adults/caregivers and health care professionals.

Intervention

The goals of this intervention were to help people self-monitor their health conditions and medicines adherence in their own home. Participants diagnosed with heart failure were provided with 5 CE-marked, Bluetooth-enabled medical devices to use at home; specifically, a blood-pressure monitor (Beurer BM54), Smartwatch (Xiaomi MIBand 6), ECG (Beurer ME90 ECG), weight scale (Beurer BF600) and a pulse oximeter (Beurer PO60) and a tablet Lenovo Tab M10 HD.

Participants received a face-to-face introduction to the Medimonitor App and training on how to use both the App and the connected medical devices. A user manual contained detailed step-by-step supportive guidance and information, and was provided to participants in hard-copy format for reference by participants during the pilot. Participants were asked to use the App and connected medical devices for 12 weeks

4.9.1 Recruitment

Participants

- Target users: people older than 60 years with heart failure and living at home.
- Health professionals: medical doctors and nurses who work for University Hospital Olomouc

Sample size

In terms of evaluating the Digital Solutions, the target sample size for this pilot study was 25 service user participants and up to 2 medical doctors and nurses. These sample sizes were selected to be both as representative as possible to provide valid answers and still within the scope of resources available.

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Inclusion criteria

The inclusion criteria for the patients were the following:

• LVEF ≤ 50%

• Exclusion of obstructive coronary artery disease

• NTproBNP ≥ 125pg/ml

• ≥ 60 years of age

• Informed written and verbal consent

Exclusion criteria

The exclusion criteria for patients were the following:

• LVEF ≥ 50%

• NTproBNP ≤ 125pg/ml

• Severe psychological disturbances

• Absence of collaboration (informed consent)

• BP ≤ 110mmHg without hypertensive medication

If the participant gave informed consent, they were included in the study and continued with the Compliance Form. If the person did not fully complete baseline questionnaires, they were excluded from the study. If the participant did not fully comply with SHAPES instructions or did not appropriately use SHAPES items, the person was excluded from the study.

Potential participants were selected based on the eligibility criteria described above from the ambulatory patients at the Department of Cardiology at the University Hospital Olomouc. Participants were selected based on convenience and random sampling. Sampling was convenient because participants were available during their regular in-patient visits. Twenty-five patients were selected to participate in the pilot study in Olomouc. Participants were given an information sheet (Annex 57), privacy notice (Annex 59) and once the eligibility was confirmed, a consent form (Annex 58) was obtained.

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4.9.2 Communication and dissemination of pilot activities

Any data that arose from the pilot study was owned by the Sponsors and FNOL. On completion of the study, all data were analysed, tabulated and used to prepare a final report, available as one of the agreed deliverables of the SHAPES Innovation Action — Deliverable D6.4. This deliverable (and all other agreed deliverables) is available to the public for review and is accessible via the SHAPES website (www.shapes2020.eu). Participants will be notified of the study outcome upon their personal request. FNOL is keen to share the findings from this study at conferences and in the scientific literature. FNOL will also use this opportunity to communicate the findings of this study via social media, and in other, non-peer reviewed, media outlets. Participating SHAPES partners will have the rights to use data from this study in their own analysis and dissemination plans. As detailed under 'Access to Data', Data Processing Agreements are in place to facilitate the sharing of pseudonymised data with specific SHAPES partners for specific purposes.

4.9.3 Risk management

All foreseeable risks related to privacy, security, data management and other risks were assessed and compiled into detailed risk assessment documents which form part of the Data Protection Impact Assessments for Phase 5 PT3-001c conducted within FNOL. For each risk identified, a risk classification, root cause, name and consequences were assigned. Once identified, each risk was then analysed and attributed a score from 1 (unlikely/minor)-4 (almost certain/critical) for probability and impact. Subsequently, appropriate mitigation actions were assigned and an appropriate person responsible was identified. These risks were reviewed periodically.

Finally, a full ethical review of PT3-001c was conducted by the ethics committee of the University Hospital Olomouc.

A potential risk to participants due to the unlikely occurrence of a device malfunction was also identified. Any such, incidents occurring in FNOL participants were reported in-line with the FNOL incident management policies (including serious adverse incidents).

4.9.4 Outcome of large-scale pilot activity

Overview

The Phase 5 large-scale pilot of the SHAPES UC-PT3-001c use-case was conducted between November 2022 and April 2023.

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Potential participants were identified by healthcare professionals in hospital and by other contacts. The invitation was completed either personally or via mobile phone. After a brief introduction and summary of the pilot, participants were given an information sheet, privacy notice and once the eligibility was confirmed a consent form was obtained.

Regarding the healthcare professionals, there were a total of three HCPs in this study, including a male cardiologist (age 32), a female cardiologist (age 33) and a female cardiologic nurse (age 40). All of them were recruited mainly because they have experience in participating in other studies and projects.

Table 78 Recruitment and retention of participants (PT3-001)

Recruitment and retention of older adult participants at FNOL	
Screened prior to eligibility assessment	**N=34**
Excluded	**N=9**
Reason 1: LVEF ≥ 50%	N= 4
Reason 2: Allergies (could not wear any wrist bands)	N= 1
Reason 3: Not having time to participate (still employed)	N= 2
Reason 4: NTproBNP ≤ 125pg/ml	N= 2
Allocated to intervention	**N=25**
Lost to follow-up Reason(s) **Reason 1: Health reasons** **Reason 2: Did not specify**	N=3 N=1 N=2
Discontinued Intervention Reason(s) **Reason 1: Could not continue due to personal reasons**	N=1 N=1
Assessed for KPI 1	N=24
Assessed for KPI 2	N=24
Assessed for KPI 3	N=24
Assessed for KPI 4	N=24

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Recruitment and retention of older adult participants at FNOL	
Assessed for KPI 5	N=24
Assessed for KPI 6	N=24
Assessed for KPI 7	N=24

Table 79 Baseline characteristics of participants in phase 5 (PT3-001c)

Variable	Number of participants	Value
Age (years)	25	69.5 (5.2)
Male	25	17 (68%)
BMI (kg/m^2)	25	30.6 (4.6)
Heart failure	25	25 (100%)
Heart failure stage	25	2.04 (0.83)
LVEF (%)	25	36.5 (8.2)
Diabetes	25	10 (40%)
Hypertension	25	7 (28%)
Smoking	25	10 (40%)
Values are mean (SD) or n (%) *LVEF= left ventricular ejection fraction*		

The primary outcomes of the large-scale pilot activity were to measure a predefined set of KPIs, i.e., a set of measures that focused on the factors most critical to the success of the UC-PT3-001c, and to evaluate the UC-PT3-001c use case using the MAST evaluation tool.

Key performance indicators

Seven KPIs were identified for evaluation of the PT3-001c use case. They were divided into 3 categories: recruitment and retention; user engagement and acceptance; and collection of data. Table 80 to Table 86 present the data used to

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determine the success of each KPI. Table 87 provides an overview of the success of the pilot with regards to KPIs.

Recruitment and retention

KPI 1 At least 80% of the target cohort were successfully recruited into the pilot during the recruitment period

Table 80 Percentage of target number of participants recruited into the pilot (PT3-001c)

Parameter	Value
Target number of participants	25
Number of participants recruited	25
Percentage recruited	100%

KPI 2 At least 80% of recruited participants remained enrolled in the pilot until the end of the study.

Table 81 Retention of participants (PT3-001c)

Parameter	Value
Number of participants at baseline	25
Number of withdrawals	1
Number of participants at end of study	24
Percentage retained	96%

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User engagement and acceptance

KPI 3 The overall user experience quality of the App as measured using the short version of the UEQ-S was classified as 'Excellent', 'Good' or 'Above average' based on published benchmark data.

Table 82 Mean pragmatic and hedonic quality UEQ-S scores and their comparison to published benchmark data (PT3-001c)

Scale	Mean	Comparison to benchmark
Pragmatic quality	0.66	In the range of the 25% worst results
Hedonic quality	1.06	25% of results better, 50% results worse
Overall	0.86	50% of results better, 25% results worse

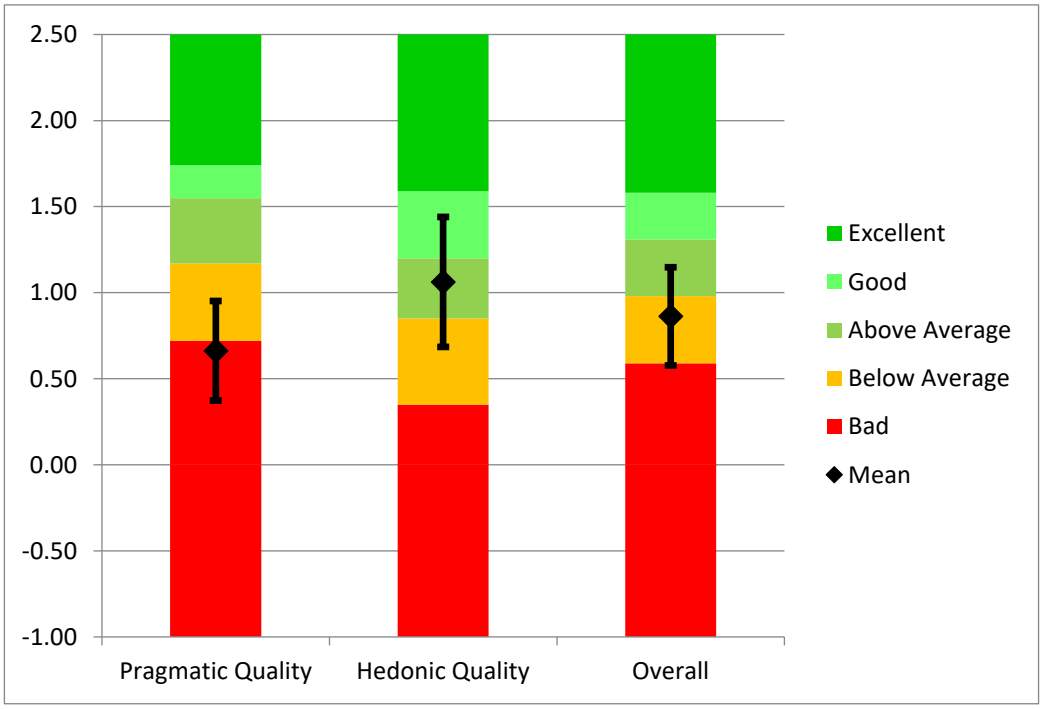

Figure 17 Mean UEQ-S and benchmark scores for the usability of the app (PT3-001c)

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KPI 4 At least 60% of participants continued to use the App daily after two weeks of the pilot.

Table 83 Number and percentage of participants using the app daily after two weeks (PT3-001c)

Parameter	Value
Number of participants who logged in daily for at least 2 weeks after baseline	19
Total number of participants	25
Percentage using the App daily after two weeks	76%

KPI 5 At least 60% of participants scored an above average rating (>68) in the SUS.

Table 84 Number and percentage of participants scoring higher than 68 in the System Usability Scale (PT3-001c)

Parameter	Value
Number of participants at end of pilot	24
Number of participants scoring >68 in SUS	13
Percentage of participants scoring > 68 in SUS	54.2%

KPI 6 At least 60% of healthcare professionals' burden decreased while using the solution during the three months of the pilot in comparison with the baseline (Meister questionnaire).

Unlike the patients, HCPs were assessed also from the perspective of their work burden. The burdening domain was represented specifically by the Meister questionnaire. All items in the Meister questionnaire can be linked to one of the three factors of psychological work burden: overload, monotony and non-specific factor. The first factor, overload, is obtained by the summation of item No. 1—time pressure, 3—high responsibility, 5—problems and conflicts. The second factor, monotony, is the summation of items No. 2—low contentment, 4—mind-numbing work, 6—monotony. The third and last is the non-specific factor (stress response), which is the summation of items No. 7—nervousness, 8—mental satiation, 9—exhaustion and 10—long-term bearability.

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Table 85 Number and percentage of healthcare professionals whose mental load and workload decreased during the three months of the pilot as measured using the Meister Questionnaire (PT3-001c)

Parameter	Amount of HCPs experiencing decrease in corresponding parameter
Overload	1
Monotony	1
Non-specific factor	1
Raw score	1
Percentage	25%
Number of participants	4

Collection of data

KPI 7 Sufficient data was collected from participants to allow the heart failure decompensation prediction tool to generate a percentage risk of decompensation at least once per week for at least 60% of participants.

Table 86 Number and percentage of heart failure participants with at least one successful HFPred score generated from a full data set per week (PT3-001c)

Parameter	Value
Number of HF participants with at least one successful HFPred score generated from full data collection per week?	23
Number of HF participants	25
Percentage	92%

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Overview of KPI achievement

Table 87 Overview of the success of Phase 5 of the pilot with regards to KPIs (PT3-001c)

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	Yes	
KPI 2	Yes	
KPI 3	No	Though the solution was discussed with UX experts thoroughly it was not sufficient from the user perspective. It is likely that issues with Bluetooth connection with the devices was also projected into their perception of the technical solution.
KPI 4	Yes	
KPI 5	No	Same as the KPI 3.
KPI 6	No	It is likely that the HCPs projected other types of burden into the assessment of the solution during the pilot. It was rather complicated to assess the burden of the solution in separation from their other work.
KPI 7	Yes	

Evaluation of use case using MAST

The MAST framework (15) was used to evaluate the effectiveness and contribution of UC-PT3-001c to quality of care. MAST was described as a multidisciplinary process

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that summarises and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine.

Three of the seven multidisciplinary dimensions/domains of the MAST framework were of specific relevance to the pilot of UC-PT3-001c. These were: Clinical Effectiveness; Patient Perspectives; and Economic Aspects.

Table 88 Completed MAST evaluation (PT3-001c)

Domain	Topic	Outcome	Baseline (N=24) *Mean (SD)*	End of pilot (N=21) *Mean (SD)*	*Mean change (SD)*
Clinical effectiveness	Effects on health-related quality of life	EQ-5D-5L Utility Score	0.85 (0.09)	0.82 (0.13)	-0.04
		EQ-5D VAS	71.96 (16.08)	73.14 (17.89)	5.63
	Behavioural outcomes	BMQ Necessity Score	10.23 (2.97)	10.16 (2.28)	0.10 (2.59)
		BMQ Concerns Score	21.64 (4.25)	20.21 (2.97)	-0.76 (2.28)
		BMQ differential score (Necessity – Concerns)	-11.65 (4.86)	-9.91 (4.00)	0.87 (3.27)
	Self-reported adherence	MARS Score	23.57 (SD = 1.51)	23.61 (SD = 1.59)	0.04 (1.67)
	Utilisation of health services	Hospitalisations	0	0	0
		Accident & Emergency attendances	0	1	0

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Domain	Topic	Outcome	Baseline (N=24) *Mean (SD)*	End of pilot (N=21) *Mean (SD)*	*Mean change (SD)*
Patient perspectives	Satisfaction and acceptance	UEQ-S Score	-	0.86 (0.65)	-
	Understanding of information / Confidence (in the treatment) / Ability to use the application / Access	SUS Score	-	76.88 (18.67)	-
	Empowerment / Self-efficacy	General self-efficacy scale	33.24 (3.96)	34.00 (4.40)	0.77 (3.82)
Economic evaluation	Related changes in use of healthcare resources	Cost of hospitalisations	-	0	-
		Cost of A&E attendances		€129.80 (1 patient)	
	Cost of resources used	Cost of devices	• Blood-pressure meter (25 pcs) €1815 • ECG (25 pcs) €2662 • Weight scale (25 pcs) €1331 • Xiaomi wristband (25 pcs) €987 • Tablet (25 pcs) €4237 • Oximeter (25 pcs) €2057 • Calibration €2142 Total €15232		
		Cost of using digital solutions	€1597.20		

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Domain	Topic	Outcome	Baseline (N=24) *Mean (SD)*	End of pilot (N=21) *Mean (SD)*	*Mean change (SD)*
		and SHAPES platform			
		Cost of staffing	(Doctors cost an average of 200 EUR per month, as did nurses. The monthly payment varied according to the participation rate in the pilot study. The cost of permanent workers was calculated on average for the entire duration of the pilot. (Respecting the Czech salary standards and standards of the University Hospital Olomouc) **€35183.94**		

Qualitative findings

Patient satisfaction

Several participants expressed enjoyment and positive experiences throughout the study. Patients mentioned that they "enjoyed" the study and found it "excellent." Some even stated that they participated in the study "for themselves." This high level of satisfaction indicates that the study design and implementation were well-received by the participants.

Perceived benefits for patients

A key theme that emerged was the improved awareness of their health status and the value of having access to regular measurements. Patients emphasised the importance of having an overview of their health, mentioning that they had become accustomed to this information and missed it when it was no longer available. They appreciated knowing how they were doing and mentioned that they could monitor their weight effectively.

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Sense of control with healthcare professionals

One patient highlighted the sense of control they experienced regarding their health status due to the involvement of healthcare professionals. This suggests that the study helped patients feel more empowered and supported in managing their heart failure. The collaboration with HCP likely contributed to the overall positive perception of the study.

Challenges and technical issues

Despite the overall satisfaction, patients reported several challenges and technical issues. Some patients mentioned that the measurements continued outside the study, leading them to perceive no additional benefit from their participation other than providing data for research purposes. Technical issues were also encountered, particularly with data transfer and specific study devices such as ECG, weight scales, and smartwatches. Patients expressed frustration with the delays in data transfer, which ranged from 15 minutes to 1–2 hours. The delays in data transfer and technical problems with study devices indicated the need for better device functionality and more reliable data transmission methods. Addressing these technical issues may enhance the overall experience for participants and improve the quality of data collected. Several patients expressed the absence of professional feedback on the conducted measurements, including ECG and others. They felt that the data was sent without any final evaluation.

Other specifics

One patient mentioned needing approximately 1 week to adapt to working with the devices.

Patients mentioned the impact of seasonal variations on their willingness to perform measurements, with more time available during winter compared to spring when they spent more time outdoors.

Summary

In conclusion, this qualitative evaluation provided valuable insights into the experiences and perspectives of patients with heart failure participating in the pilot. The overall satisfaction expressed by the participants, along with the perceived benefits of self-monitoring, emphasised the importance of patient-centred approaches in heart failure management. However, challenges related to technical issues and time demands need to be addressed to optimise the participant experience in future roll out. The following findings contribute to the growing body of knowledge on patient experiences in heart failure research and can inform the development of more effective and patient-centred interventions and healthcare practices. Highlights of pilot activities qualitative assessment can be summarised into the following dimensions.

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Patient satisfaction

- Positive experiences with the study: Several patients expressed satisfaction with the study process and mentioned enjoying it, finding it excellent, and doing it for themselves.
- Interest in self-monitoring: One patient mentioned considering purchasing a step-counting smart band.

Benefits for patients

- Health status overview and regular measurements: The majority of patients emphasised the benefits of having an overview of their health status, current data, and regular measurements. Some mentioned that they had gotten used to it and missed it when it was no longer available. They appreciated knowing how they were doing and keeping track of their weight.
- Feeling of control with healthcare professionals: One patient highlighted the sense of control they experienced regarding their health status due to the involvement of healthcare professionals.
- Comparing measured values with personal experiences: Some patients found value in comparing the measured values with their own subjective perception of their health status.

Lack of benefits for patients

- Some patients mentioned that the measurements should continue outside the study, so they didn't perceive any additional benefit from their participation, as it only provided data for the study.
- A few patients felt that the study did not bring any benefits to them personally, apart from providing data for the research.

Specifics of working with devices

- Adaptation time required: One patient mentioned needing approximately 1 week to adapt to working with the devices.

Time demands

- Seasonal impact on willingness to perform measurements: Some patients mentioned that their willingness to perform measurements varied depending on the season. They had more time during the winter but spent more time outdoors during the spring.
- Time constraints while working: Some patients mentioned that performing measurements alongside work posed greater time demands. They also noted different time availability for measurements.

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Technical issues:

- Data transfer and waiting time: Several patients experienced technical issues with data transfer, leading to longer waiting times, ranging from 15 minutes to 1-2 hours.
- Technical problems with specific devices: Patients reported issues with ECG, weight scales, and smartwatches, mentioning that for example the user parameters of the blood pressure monitor were worse than the ones they are typically used to.

Lack of feedback:

- Absence of feedback: Several patients expressed the absence of feedback on the conducted measurements, including ECG and others. They felt that the data was sent without any final evaluation.

After study completion:

- One patient mentioned a decrease in the number of measurements performed after the study.
- Absence of personal measurement devices: One patient noted the absence of their own blood pressure monitor after returning devices used within the study

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5 Use case PT3-COPD

5.1 Introduction

This chapter describes the pilot activities of UC-PT3-COPD: Advanced telemonitoring of patients with COPD in home environment. The target user group consisted of 25 patients older than 60 years of age, diagnosed with COPD and possible comorbidities. This user group was characterised by its relatively low ICT literacy therefore the digital solution aimed for an optimal user experience to allow ease of use of the whole system — including the application and accompanying medical devices for monitoring selected biomedical signals/parameters. Monitoring was conducted in the patient's home environment.

The main goal of the use case was to decrease the probability of patient exacerbation through regular monitoring of selected biomedical signals which could indicate an imminent threat to the patient's health status. This may also lead to an improvement of older individuals' quality of life. Concurrently, the need for regular hospital visits may be decreased.

Use case leader was University Hospital Olomouc (Fakultní Nemocnice Olomouc, FNOL). There were no replicating sites.

This use case was based on the Persona Jarda (1), a patient with COPD living in a city with heavy industry and significant air pollution.

5.2 Description

Participants chosen from the group of FNOL patients over 60 years of age were provided with the digital solution based on the mobile application working with the tablet and several medical devices to routinely measure selected biomedical signals/parameters, e.g., blood pressure or spirometry. In addition, environmental parameters as dust particulate matters concentration, humidity, temperature and air pressure were collected inside and outside of the participant's home. Measurements were accompanied by specific questionnaires that measured the patients' clinical state, adherence to medicine, social status, achieved level of user satisfaction with the provided digital solution etc.

During the pilot, data collected by the tablet were transferred to a remote server located within EU in accordance with the personal data protection and cybersecurity technical standards and recommendations.

Recorded data were checked on a regular basis by clinical personnel (doctor or nurse). In case of any unexpected deviations from the recommended values, patients were

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contacted by a member of the clinical team. In parallel, the collected data were analysed by automated assessment tools and methods provided by other technical partners to minimise the risk of any patient decompensations and, hence, follow-up hospital readmissions.

5.3 Digital solutions used in this use case

Medimonitor (FNOL)

The telemedicine system, Medimonitor, is a platform providing remote care assistance and monitoring of patients developed for patients diagnosed with chronic heart failure. The Medimonitor platform enabled the collection of patient health data, vital and physical signs as well as wellbeing and environmental parameters. The overall aim of the platform was to improve patient quality of life and to empower and support them to adopt a lifestyle that reduced their risk of deterioration. All the data and measurements were gathered through smartphones/tablets, sensors and devices (e.g., weight scales, blood pressure monitor, oximeter etc.). The platform provided an overview of a user's daily health status, tasks and treatment plan assigned by medical staff, medication administration, requests, notifications, personalised questionnaires and it also offered the possibility to communicate with the medical staff and to manage medical appointments through video call. Health care professionals could remotely monitor the health and wellbeing parameters of their patients, they were able to identify deterioration signs early and to intervene promptly.

The system was originally designed for the patients with chronic heart failure, nevertheless, it was enhanced with several important features that are relevant to those with COPD. These features were connected specifically to different set of medical devices that corresponded to different variables that were useful to monitor when pulmonary, rather than cardiac disease was present. Among these devices were a ring oximeter, spirometer and smart inhaler. Together with the environment monitoring focused on particulate matter concentrations and predictor model taking into account biophysical signals and subjective responses collected via the Medimonitor in combination with environmental parameters it provided a comprehensive solution to monitor patients with chronic obstructive pulmonary disease.

Prediction of exacerbation/ chest infection in patients with COPD (TREE)

An exacerbation in COPD is a worsening of the COPD symptoms commonly caused by an infection in the lungs or airways. Exacerbations can lead to doctor and hospital visits and can cause long-term declines in lung function and health. The ability to predict an oncoming exacerbation could mitigate the impact of exacerbations on the health of the patient. TREE Technology provided a predictive algorithm that could

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predict in advance the onset of an exacerbation of COPD (contingent on data availability for predictive model training).

The input for this digital solution was the relevant daily vital signs of users that were collected using sensors. The output was an alarm when an exacerbation was predicted to occur in the next day(s) and the level of risk of an exacerbation in the next day(s). That would be beneficial information for HCPs as they can hypothetically adjust the patient‘s therapy or directly admit the patient to the hospital, if necessary.

Unlike the HF use case the COPD predictor was not readily available from the beginning of the project. Therefore, the goal here, was to collect the data necessary to design an exacerbation predictor using the relevant data provided from measured biophysical signals, questionnaires and environmental parameters. The main limitation and risk were, that if no patient had an exacerbation during the course of the pilot, no data would be available to successfully design the predictor model. As such, the COPD predictor was not an integral part of the Medimonitor and the predictions were not available to HCPs during the course of the pilot. An assessment of the designed predictor was conducted after the pilot activities when all the data were already collected.

More information about the digital solutions for this use case can be found in Deliverable 5.2: SHAPES Digital Solutions.

5.3.1 Digital solutions used for COVID-19 response

There were no digital solutions used for the COVID-19 response in UC-PT3-COPD.

5.3.2 Equipment and devices used (from third parties)

Following external devices were deployed in UC-PT3-COPD:

- Oximeter Circul
- Spirometer MIR Spirobank Smart
- Smart inhaler FindAir
- Blood pressure monitor Beurer BM54
- Particulate matter monitoring system

Further details on these devices were provided in section 5.8.2. All the devices were procured as per the Czech legislation. For a public institution, the University Hospital

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Olomouc, it means that three offers were required and the cheapest offer was chosen as the winning one. Technical parameters of the devices were included in the public procurement description and provision of the APIs was required within the procurement to permit direct data transfer and integration with the SHAPES App.

5.4 Data plan

The data plan for phase 5 of the UC-PT3-COPD pilot can be found here; https://shapes2020.eu/wp-content/uploads/2023/06/UC-PT3-001COPD_data-plan_04082022_v4.xlsx

5.4.1 Data capture methods to be used

A range of different data capture methods was used during the five phases of this pilot including participant data (see Data Plan), harmonised questionnaires (more details on harmonised data will be provided in Deliverable 6.9), Pilot 3 questionnaires, COPD questionnaires and clinical measurements. More details can be found under the sections describing Phases 1 to 5.

The questionnaires used in this pilot are following: SUS (8), MARS (14), EuroQol EQ-5D-5L & VAS (4), BMQ (13), COPD CAT (22), Modified Medical Research Council (mMRC) dyspnoea scale (23), Eadon scale (19), Meister Questionnaire (21), WHOQOL-Bref (3), GSES (5), OSSS-3 (social support) & life events (6), 1-item health literacy (7), Participation questions, Technology acceptance questions (9), UEQ-S (2).

5.4.2 Planning of evaluation

MAST

The MAST framework (15) was used to evaluate the effectiveness and contribution of UC-PT3-COPD to quality of care. MAST is described as a multidisciplinary process that summarises and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine.

A review of the seven dimensions of MAST revealed that three of the seven multidisciplinary dimensions/domains were of specific relevance to the pilot of UC-PT3-COPD. These were: Clinical Effectiveness; Patient Perspectives; and Economic Aspects. Table 89 contains the data required for the MAST evaluation.

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Table 89: Data required for MAST evaluation (PT3-copd)

MAST Domain	Topic	Outcome	Data required	Time point
Clinical Effectiveness	Effects on mortality	Mortality rate	Number of deaths	End of pilot
	Effects on morbidity	Will not be measured		
	Physical health	Will not be measured		
	Mental health	Will not be measured		
	Effects on health-related quality of life	Health related quality of life	EQ-5D-5L scores	Baseline and end of pilot
	Behavioural outcomes	Concerns about medicines	BMQ scores	Baseline and end of pilot
		Necessity beliefs about medicines	BMQ scores	Baseline and end of pilot
		Self-reported adherence	MARS scores	Baseline and end of pilot
	Utilisation of health services	Hospitalisations	Number of hospitalisations	Baseline (past 3 months) and at end of pilot
Patient perspectives	Satisfaction and acceptance	User Experience	UEQ-S scores	End of pilot
	Understanding of information Confidence (in the treatment) Ability to use the application	Usability of application	SUS Scores	End of pilot

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MAST Domain	Topic	Outcome	Data required	Time point
	Access			
	Empowerment Self-efficacy	Self-efficacy	General self-efficacy scale	Baseline and end of pilot
Economic aspects	Amount and cost of resources used	Cost of devices	Cost as per medical device purchasing invoice	End of pilot
		Cost of maintenance	Costs per device maintenance (IT support, medical device regular rechecks, calibrations etc.)	End of pilot
		Cost of using digital solutions and SHAPES platform	Costs to be provided by SHAPES?	End of pilot
		Cost of staffing	Timesheets and costing data	End of pilot
		Cost of travel	Saved patients' travel expenses	End of pilot

MAFEIP

Due to the evaluation methodology (small-scale deployment, non-case controlled) the MAFEIP tool (16) was not used to evaluate UC-PT3-COPD.

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5.4.2.1 *Final check of the use case by using the CSFs of MOMENTUM and the NASSS framework*

MOMENTUM

The MOMENTUM (17) blueprint was applied to check if UC-PT3-COPD had the critical success factors (CSFs) needed to take it from the pilot phase to large-scale deployment.

On review of the blueprint (and in line with guidance provided in the SHAPES WP6 Evaluation Manual) it was agreed that six out of eighteen CSFs were more relevant to explore and address at a later stage of the SHAPES programme. These included CSFs concerned with the cultural readiness for the telemedicine service (CSF 1), the consensus position on the advantage of telemedicine in meeting compelling need (CSF 2), ensuring leadership through a champion (CSF 3), preparing and implementing a business plan (CSF 9), preparing and implementing a change management plan (CSF 10) and guaranteeing the technology had the potential for scale-up (CSF 12). All remaining CSFs were deemed either to be in place or would be before the pilot began. Further details on each CSF are provided below. A summary of the MOMENTUM blueprint for UC-PT3-COPD is provided in Annex 60.

CSF 4. Involve healthcare professionals and decision-makers

Health professionals and decision-makers were involved in the development of the content of the project. They were involved within the planning, design and implementation phases. Healthcare professionals' views on the value of the technology associated with this use case were explored in qualitative feedback obtained after the pilot.

CSF 5. Put the patient at the centre of the service

Patients were involved in the development of the digital solutions through the planned activities for Phase 2 and 3 of the pilot — mock-ups, prototyping and hands-on experiment. It was important to focus mainly on the education of the patients how to use the App and what benefits it could bring them.

CSF 6. Ensure that the technology is user-friendly

User experience was improved by the team consisting of both IT experts and psychologist. Design was based on the good practices and its adaptation was supported by experiments on focus groups containing the real users — patients and healthcare professionals. This area was mainly addressed during Phase 2 and 3 of the pilot and possible issues were resolved immediately based on the user feedback. Questions were guided by the standard ISO 14915, which specified 4 principles for the design of multimedia applications.

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CSF 7. Pull together the resources needed for deployment

The resources required for deployment of the digital solutions for the pilot were, in the most part, available. However, experienced IT experts willing to be employed in the government sector were extremely difficult to find. Consequently, the existing IT teams were overloaded. A possible future solution could be motivating future IT experts via internships in the telemedicine IT team. At the same time, the COVID-19 pandemic placed greater demands on medical staff, both in terms of time and effort in providing routine care.

CSF 8. Address the needs of the primary client(s)

The primary clients of the PT3-COPD use case were older individuals with COPD. The use case was specifically developed to meet the needs of a persona that represented the primary client. The use case and digital solutions were adapted in response to feedback to user testing conducted with the primary clients. A user centric approach was applied in all stages of the development process. The solution also addressed the needs of the healthcare professionals by way of monitoring patients remotely and informing them about any decompensation.

CSF 11. Assess the conditions under which the service is legal

A review of the legal requirements of the Czech Republic concerning the use of digital solutions was conducted and it revealed that for the purposes of a scientific research project any devices that were of a non-medical nature ("wellbeing devices" – wearables, weight scales, adherence monitoring devices etc.), however, certified in EU or US (FDA) could be used with the approval of ethics committee together with the patients' voluntarily participation within the project that is demonstrated by the signed, informed consent. Patients were free to leave the project whenever they wanted to, without any risk of decreasing the amount of care they were provided by the Czech law.

Completion of a DPIA identified and minimised any risks associated with the pilot. Data processing agreements were established with relevant partners to permit access to pseudonymised data.

CSF 13. Identify and apply relevant legal and security guidelines

Legal and security guidelines were reviewed and were applied accordingly. The main areas for consideration included data protection, ethical approval, compliance of devices with standards, penetration testing of software and storage of data.

Moreover, during the COVID-19 pandemic the Czech government institutes involved in cybersecurity issued several guidelines related to the realm of telemedicine and the requirements mentioned were implemented in the digital solution tested in the pilot.

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CSF 14. Involve legal and security experts

There was cooperation with SHAPES partners together with legal and security experts to ensure that we had full confidence in the legality and security of this project.

CSF 15. Ensure that telemedicine doers and users are privacy aware

Telemedicine system designers were aware of GDPR and the related privacy issues and they prepared the telemedicine system in concordance with the requirements. However, there was no 100% certainty that the users were equally experienced. Creators made all the relevant information available directly from the application, so important formation could be easily found and understood, especially for older people. Future improvements in this area were expected as this topic is steadily changing and evolving.

CSF 16. Ensure that the information technology infrastructure and eHealth infrastructure are available

An appropriate infrastructure for deployment of the digital solutions within the organisation was already available for the pilot and prepared for scale-up process.

CSF 17. Put in place the technology and processes needed to monitor the service

A system to monitor the pilot was set up with support from WP4 and WP5 partners. There was also support from local IT team to help address any issues with the use of the digital solutions. The IT team also developed their own service monitoring system to mitigate any incidences. Risk assessment was also conducted. The local project team were available to support participants in resolving any problems they experienced with the digital solutions.

CSF 18. Establish and maintain good procurement processes

Procurement processes for the public organisation, University Hospital Olomouc, were well defined by the Czech law. Despite being defined and the human resources available for their implementation, these processes can be rigid and slow. Nevertheless, they were mandatory and were followed.

NASSS

The NASSS framework (18) was used to detect areas of complexity in the project plan for piloting UC-PT3-COPD and, if needed, to make adaptations to the plan. The long version of the NASSS-CAT questionnaire was considered and completed by the pilot team (Annex 61). Of the seven domains, there were four domains (‘Technology’, ‘Value proposition’, ‘Intended adopters of the innovation’, ‘The organisation

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implementing the technology') in which significant complexities were identified that, if not mitigated or addressed, were likely to affect the project's success at the piloting stage of the use case. A summary is provided in Table 90.

Table 90: Complexities and mitigation measures identified using the NASSS framework (PT3-copd)

NASSS complexity domain	Uncertainties detected	Mitigation measures taken
Technology	Due to complicated procurement processes it was challenging to firstly buy the test product and then to buy the rest of the devices needed, as there was a high risk that devices will not be the same product.	By December 2021, uncertainties regarding the procurement process were addressed and resolved, IT Department and the Department of public procurement of UHO took over the responsibility for the procurement of all required devices. All devices were either procured or sales contracts with gradual delivery were mutually signed.
Technology	Procurement process might not be able to reach to all possible manufacturers of the devices intended to be used within the pilot.	
Technology	Uncertain outcome of device integration, which might be more complicated than envisaged by the internal IT experts.	SDKs for all the devices were obtained with support of manufacturers and were implemented.
Technology	The amount of IT experts available for the task is limited.	During Phase 2 an additional IT expert was hired, however, it was still not sufficient due to the hospital requirement to solve other problems (tests and vaccinations)

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NASSS complexity domain	Uncertainties detected	Mitigation measures taken
		connected to the COVID-19 pandemic and an increased amount of hacker attacks. Another IT expert and IT project manager were planned to be hired by the end of 2021.
Technology	The exact role and functionality of the platform had not yet been defined/communicated to the use case leaders.	By the participation on cross-WP meetings the major questions regarding the platform functionality and data storing were clarified.
Technology	The flow of data and data storage location was not yet confirmed.	
Value proposition	Uncertain value to the patient and clinician/healthcare system.	Value to the stakeholders was assessed after the pilot with use of specific questionnaires.
Intended adopters	Uncertain level of digital literacy.	Simple education was provided to all users. Some of the prospective users were also involved in the test phase, when the UX and GUI design was being tuned so they could directly participate in the final shape of the application. All the benefits of the solution were presented to the stakeholders and
Intended adopters	Uncertain acceptance among healthcare professionals (concerns about overload).	

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NASSS complexity domain	Uncertainties detected	Mitigation measures taken
		discussed with them whether they are relevant or not.
Intended adopters	Availability of Wi-Fi network at the point-of-care location is uncertain.	Participants of the pilot were required to have Wi-Fi already installed in their home.
Intended adopters	Security measures on the patient's side of the network might introduce security threats.	Simple education was provided to all users to ensure the security and acceptance.
Intended adopters	System as a whole – HW and SW – might be too "modern" and complicated for the intended user group.	
Organisation implementing the technology	Traditionalists among the hospital staff were not ready yet to embrace the possibilities of modern technology.	Members of the Czech National eHealth Centre were increasing the knowledge about the telemedicine benefits among the employees of the University hospital Olomouc through seminars, workshops and other activities.

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5.5 Phase 1

5.5.1 Key performance indicators

Key Performance Indicators (KPIs) were defined as a set of measures that focused on the factors most critical to a project's success. KPIs were measurable and quantifiable with a target or threshold. They measured a performance in critical areas by showing the progress or lack of it towards realising the objectives of each specific use case. The following KPIs were chosen to determine whether, or not, the pilot for UC-PT3-COPD was successful.

Failure to meet four or more of the KPIs will indicate that major revisions to the use case and associated digital solutions are needed before further evaluation or deployment.

Recruitment and retention

1. At least 80% of the target cohort were successfully recruited into the pilot during the recruitment period.

2. At least 80% of recruited participants remained enrolled in the pilot until the end of the study.

User engagement and acceptance

3. The overall user experience quality of the App as measured using the short version of the UEQ-S (2) was classified as 'Excellent', 'Good' or 'Above average' based on published benchmark data.

4. At least 60% of participants continued to use the App daily after two weeks of the pilot.

5. At least 60% of participants scored an above average rating (>68) in the SUS (8).

6. At least 60% of healthcare professionals' burden decreased while using the solution during the three months of the pilot in comparison with the baseline (Meister questionnaire). (21).

Collection of data

7. Sufficient data was collected from participants to allow COPD decompensation prediction tool to generate a percentage risk of decompensation at least once per week for at least 60% of participants.

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5.5.2 PACT and FICS Scenario

Table 91: PACT (PT3-copd)

Code	PT3-COPD
People Roles and/or actors of typical users involved in delivering and receiving the telemedicine intervention	• Patient - 60+, living at home. No cognitive impairment at recruitment to the study. Both new and advanced stage of chronic obstructive pulmonary disease and has multiple daily medications. Very limited use of technology, most have never used a smartphone/tablet before. • HCPs - nurse and doctor planning and assessing medical treatment plan and specific tasks as parts of medical treatment plans. In the cases of results being below or above (based on the observed parameter) desired thresholds they will alert the patient and adjust the medical treatment plan. HCPs have average level of computer literacy allowing them to conduct daily routine without major problems. • Biomedical engineer or IT technician – providing technical support for both patients and healthcare professionals in the cases of connectivity issues, medical device malfunctions, software issues etc.
Activities Activities to be performed by the actors in order to successfully provide and receive the telemedicine intervention *procedures for the professional and the patient; Parameters that determine the measures used in the intervention*	**Patient** • Measure systolic and diastolic blood pressure once a day • Measure heart rate once a day and continuously thorough the whole night (during sleep) with use of a ring-like SpO2 sensor • Measure oxygen saturation once a day and continuously thorough the whole night (during sleep) with use of a SpO2 ring-like sensor • Measure daily respiratory related parameters with use of a spirometer • Measure each use (emergency and regular) of an inhaler by a smart inhaler • Complete daily/weekly/monthly/one-off questionnaires (The COPD Assessment Test, Quality of Life related questionnaire, user acceptance related questionnaire etc.) • Send the data from the aforementioned measurements to the cloud/platform **Environment (smart-home)**

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Code	PT3-COPD
	• Measure particulate matter (dust) concentration levels inside and outside the patient's flat by the PM2.5 sensor • Measure temperature inside and outside the patient's flat by the temperature sensor • Measure humidity inside and outside the patient's flat by the humidity sensor **Healthcare professional** • Review of clinical data on a regular basis, making changes to patient care as required • Assign tasks to patients • Possibility to provide video consultation via telemedicine application • Use predictive model to identify if patient's health condition is deteriorating and interventions taken to avoid this e.g. COPD exacerbation **Technical support** • Provide introductory tutorial for both patients and healthcare professionals to achieve their correct use of hardware and software solutions • Provide support to resolve technical issues related to both connectivity and functionality • Provide regular maintenance of the hardware and software tools where applicable
Context *Social-medical relevance of the telemedicine intervention; privacy issues; risks for the patient; locations*	• Smart clinical devices and environment sensors to be used in patient's own home to monitor several patients' and environment parameters that are relevant to monitor condition of patients with COPD. Measured data are being assessed by healthcare professionals and also analysed by digital analytical tool. • Particular goals are as follows: ○ Optimise treatment plans ○ Improve patients' outcomes and reduce probability of possible readmissions ○ Reduce frequency of regular check-ups in hospital. ○ Increase use of digital telemedicine tools (e.g. video consultation) • Maintaining high standards of data privacy handling

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Code	PT3-COPD
	• GDPR and ethics in line with WP8 • Data and servers must be located within the EU • Translation into the Czech language will be provided by the local team • Location: University Hospital Olomouc, Olomouc region, Czech Republic
Technology *Type of information/parameter that are relevant in monitoring the health status; type and frequency of accessibility of information; feedback modalities (communication)*	• More detailed information can be found in the data plan for UC-PT3-COPD • Baseline demographic information: Age (year not DOB) Sex (M/F) Smoking history (Never smoked/used to smoke/current smoker) Height (cm) • Baseline medical history: Medicine (number of medicines/chronic or as required/name/ strength/ frequency/ date) Diagnoses (medical condition and date of diagnoses) Admission to hospital within 30 days Readmissions • Changes to medication as the pilot progresses (stop/start/change strength/change frequency) • Heart rate (beats per minute) once daily and continuously throughout the night • Oxygen saturation (%) once daily and continuously throughout the night • Spirometry (FVC, FEV1, FEV6, FEV1/FVC, PEF, FEF25, FEF50, FEF75, FEF25-75, FET, BEV) • Smart inhaler (drug intake, peak flow, symptoms, notes) • Particulate matter sensor to measure PM2.5 concentration inside and outside the patient's flat • Temperature and humidity sensor to measure temperature and humidity inside and outside the patient's flat • Blood pressure diastolic and systolic (mmHg) once daily • Questionnaires (The COPD Assessment Test, CAT, mMRC) • Reminder/alert to complete questionnaires and use clinical devices • Feedback to participant that their clinical parameters are within or the normal range

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Code	PT3-COPD
	• Feedback via App to participant on whether all tasks have been completed • Feedback via browser to HCP to highlight clinical parameters outside the normal range

Table 92: FICS Scenario (PT3-copd)

Category	Details
Function and events *Functionality of the intended system which is capable to realize actor's activities*	The system will provide users with the following capabilities: • Measure blood pressure once daily • Measure SpO2 and heart rate once daily and continuously through the night • Measure spirometry (FVC, FEV1, FEV6, FEV1/FVC, PEF, FEF25, FEF50, FEF75, FEF25-75, FET, BEV) • Monitor physical activity thorough the day (aided by a pedometer inside smartwatches) • Monitor environment parameters (PM2.5 concentration, temperature and humidity) inside and outside the patient's flat • Assign specific questionnaires (e.g., wellbeing, system usability, etc.) • Assign tasks within the medical treatment plan • Show alerts, notification, reminders etc. • Video consultations • Medicine ordering • Medication list • Prediction of decompensation
Interactions and usability issues *User-system or system-component interactions meditating actor's activities; Types of the interactions, e.g. unidirectional data streaming service or reliable messaging service*	In this use case, we plan to work with following end-users: • Older person (COPD patient) • HCP (nurse, doctor) Front-end is available for patients and healthcare professionals, whereas each of the users is able to see only a part of the system which is intended for her/him. The system will manage following data and information: • Environmental parameters (PM2.5) • Vital signals (e.g. SpO2) • Providing alerts, reminders, notification etc. • Wellbeing and other surveys • Treatment plan

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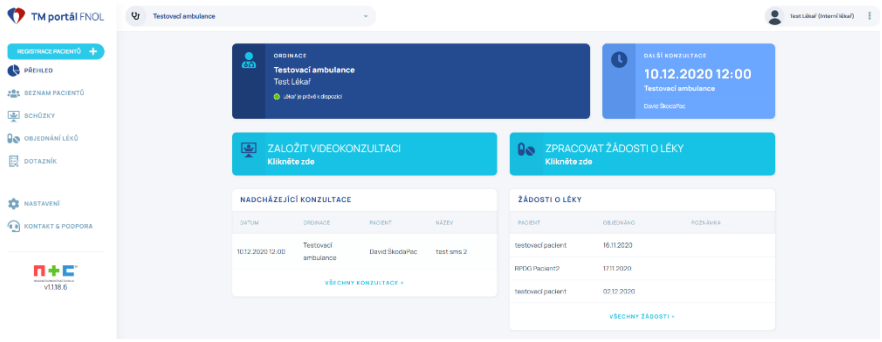
Category	Details
	Healthcare professionals are able to create treatment plans, check the alerts and analytics provided through the predictive model for heart failure patients. Patients are able to upload data from the medical devices they are using, check-up on their treatment plans.
Content and structure *Variables of the interaction*	• Users' front end with teleconsultation and medicine ordering is available through the regular web browser • Monitoring of biophysical signals, dissemination of wellbeing and other questionnaires is aided via application available for Android devices
Style and aesthetics *Look and feel of the system*	Part of the system available via browser:  Part of the system available as an App for Android:

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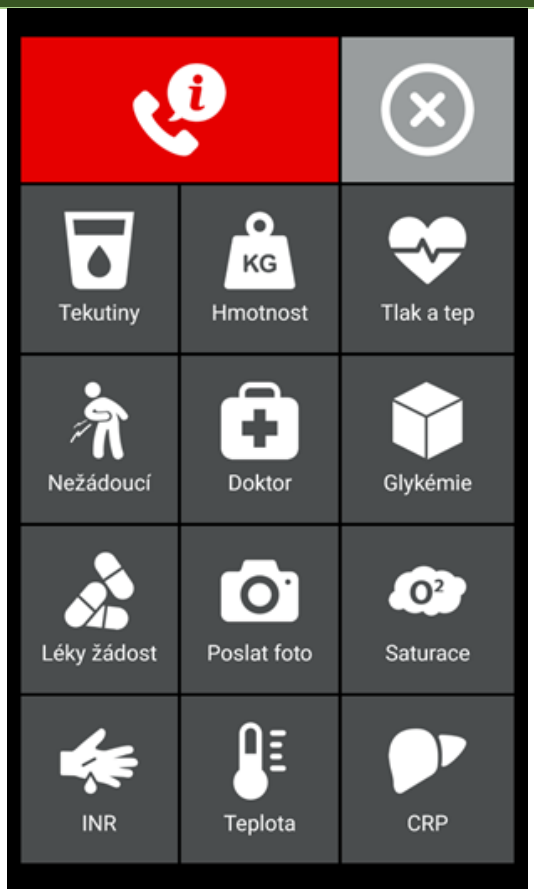
Category	Details



5.5.3 Timeline of pilot activities

The original timeline of pilot activities according to the Description of Work was to conduct Phase 1 and 2 between November 2020 and April 2021, then start with Phase 3 (prototype testing and hands-on training) in May 2021 and with Phase 4 (deployment in controlled environment) in September 2021.

Phase 1 was conducted as originally planned as this phase was mainly focused on the document preparation (personas, KPIs, scenarios, pilot description etc.)

In Phase 2 (mock-up user experience testing) the FNOL team invited prospective users to test the initial wireframe models and also high-resolution models of the Medimonitor application. Direct demonstration on the tablet devices together with the targeted interviews was used. This phase was finished in April 2021.

In Phase 3 (hands-on training) the FNOL team needed to be in direct contact with the prospective users, therefore the start of phase 3 was postponed until it was safer for the older people to have in-person meetings with the FNOL team. A formal request to

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extend Pilot Theme 3 was approved by the Project Officer. This phase was finished in August 2022.

Phase 4 and 5 involved training participants on the use of clinical devices and recruiting from outpatient clinics. The COVID-19 situation was continuing to result in significant clinical staff redeployment and only essential outpatient services were running. Also, the IT support staff were redeployed to COVID-19 related services, maintenance and to respond to the increasing number of hacker activities. Phase 4 started with a delay in September 2022 due to technical issues with devices and our application. Phase 5 was conducted immediately after in November 2022.

	2020		2021											2022											2023						
	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
Planned timeline: PT3	phase 1		phase 2				phase 3			D	phase 4				phase 5				D												
Actual timeline: UC-PT3-copd	phase 1		phase 2				extension			D	phase 3												4	phase 5							D

Figure 18 Planned and actual timeline of activities for UC-PT3-COPD.

5.6 Phase 2: Testing of mock-ups and prototypes

The Medimonitor used within UC-PT3-COPD was equivalent to that of UC-PT3-001c and therefore activities and findings relating to Phase 2 that are described in Section 4.6 relate to both use cases.

5.7 Phase 3: Hand-on Experiments

The Medimonitor used within UC-PT3-COPD was equivalent to that of UC-PT3-001c and therefore activities and findings relating to Phase 3 that are described in Section 4.7 relate to both use cases.

5.8 Phase 4: Small Scale Live Demonstration

Introduction

A small-scale live demonstration of the SHAPES platform and digital solutions was performed in the Phase 4 of the SHAPES Pilot Campaign at the University Hospital Olomouc. The aim of the demonstration was to collect feedback from end-users and evaluate the performance of the digital solution and transfer of data in a real-world environment before the large-scale pilot is conducted. The demonstration also tested the methods and procedures that are to be used when the pilot starts. The end-users

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were confronted with the tools that have been developed and improved during phases 1, 2 and 3. If needed, there was also a chance to make adjustments to the solution before the large-scale pilot started.

For the best evaluation, a sample of four people from diverse age groups was selected, including a 45-year-old male (an economist and engineer), a 40-year-old female (a senior nurse in a healthcare setting), a 62-year-old female (a retired individual), and a 14-year-old female (a high school student). By examining the insights gained from this participant sample, we aimed to highlight the importance of considering demographic factors in research studies and draw valuable conclusions for future studies targeting different populations.

Aim

To test the final version of the digital solutions to be deployed in the pilot of UC-PT3-COPD in the real-world conditions. To test the overall pilot process from recruitment of eligible participants, education of participants, correct use of the digital solution by the participant, data transfer, connectivity. To implement final changes of digital solutions if any issues arise.

Overview

The small-scale live demonstration was conducted at the participant's home. Only the education of the participants, signing of the informed consent and handing over of the devices was conducted onsite while applying the highest pandemic precautions. If required by an increase in pandemic risk, the education could have been also delivered remotely via the internal video consultation platform and the devices delivered by mail. Participants were asked to use daily the digital solution, to conduct several planned tasks reflecting typical use case scenarios like ordering medication or video consultations, to conduct vitals measurements, to fill up questionnaires.

5.8.1 Recruitment of participants

Phase 4 small-scale live demonstration was conducted with 4 participants who tested the solutions at home in a real-life environment. Recruited participants were younger than the target user group and were able to use the solution at home for the duration of phase 4. Eligible participants were identified and recruited internally by the staff of the Czech National eHealth Centre of University Hospital Olomouc. It was required to have a stable Wi-Fi connection at home, to be in good health status to be able to take part in the pilot, and to be a user of a smartphone or tablet. The decision to work with slightly younger participants was taken to prevent further delays in the development and to prevent any more delays that would be caused by waiting for the volunteers from the target group of older adults.

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Informed consent for all participants was obtained from each participant. Informed consent forms were collected in paper form directly from the patients as it was not possible to administer them in electronic form in the Czech Republic. The template can be viewed in Annex 62.

5.8.2 Technical aspects & Logistics

Participants were provided with a tablet:

- Android Tablet Lenovo M10 HD

Android tablet specifications:

- Android version 9 or above
- Processor speed 2GHz or more
- RAM 3GB+
- Storage 64GB or above
- Support Wi-Fi
- Support BLE
- Screen 10'' or above

Participants are also provided with following set of devices to measure their vital signs:

- Oximeter Circul
- Blood pressure monitor Beurer BM54
- Spirometer MIR Spirobank Smart
- Smart inhaler FindAir

It was planned that participants would be provided with a device to measure particulate matter concentration to provide information on levels inside and outside their home environment. Only the prototype was tested as the system was designed to work with the Raspberry Pi computer. Due to the COVID-19 outbreak and the current war situation in Ukraine these computers were not available in the required amount. Therefore, as a mitigation, data from the sensor stations of the Czech Hydrometeorological institute were acquired from the nearest station of each pilot participant to minimise the differences from the real values observable in the patient environment.

All the devices enable the transfer of data via Bluetooth and were CE-marked.

Eligible participants were invited to an education meeting which took place in the University Hospital Olomouc. Instructions were presented verbally while the participant was present at the hospital premises. A researcher, technician and nurse

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were present during the education meeting. The researcher introduced the SHAPES project and the main aim of this pilot. Participants provided informed consent to take part in the pilot. Participants were provided with an Android tablet with downloaded Medimonitor App, blood pressure meter, pulse oximeter, spirometer, smart inhaler, particulate matter monitoring system to use at home. The researcher explained how the Medimonitor App and the devices worked and they guided the participant through a series of steps and tasks to demonstrate the different functionalities of the App and trained the participant on how to use it. A user manual was provided along with the digital solution (Annex 55).

The pace of the session was determined by the participant. After the demonstrations, the participant was encouraged to use the App with the researcher still present and available to ask questions and troubleshoot any issues. Participants were informed that researchers or technicians would be available during the pilot if necessary and they were provided with phone and email contact. Researchers kept records of requests for support.

Participants performed the following daily tasks for 1 week:

Vitals readings — blood pressure, heart rate, oxygen saturation, spirometry, usage of inhaler

1. Questionnaires
2. Video consultation
3. Medication ordering
4. View medication list
5. View ‘daily to-do list’

The readings from the devices were electronically transferred to the Medimonitor App via Bluetooth, participants, as well as researchers, were able to see all the data saved in the App. Participants’ data were uploaded to a browser-based researcher dashboard. Mock data about medication, daily tasks and daily questions were entered into the App by the researcher or technician to test the reminder’s function. Participants were also asked to complete a questionnaire using example data (for the purposes of Phase 4 only). HCPs also scheduled testing video consultation so they could check whether the audio and video signals were clear in the application.

Participants were asked to write down any errors that occurred during the one-week testing. This was reviewed by the researcher as well as any discrepancies in the researcher dashboard.

Participants were also asked to suggest any improvements or adjustments in the overall process of the demonstration.

Participants did not interact with the particulate matter monitoring system and therefore this was tested by researchers on-site. During the large-scale pilot the

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monitoring system was planned to be installed at participant's home by researchers. The Particulate matter monitoring system is not CE-marked, but it is constructed of CE-marked components and its utilisation within the pilot was approved by the local ethics committee.

5.8.3 Roles and Responsibilities

The SHAPES pilot site researchers at FNOL were responsible for recruiting and consenting participants to take part in the live demonstration. FNOL provided training and were a single point of contact for the participants for all the support needed.

5.8.4 Ethical considerations

All project activities were approved by the internal ethics committee together with the hospital management. All participants involved provided their written informed consent to participate in the pilot activities.

An ethical self-assessment for phases 1–5 of this use case was completed. For Phase 4, an information sheet specifying the nature of the research and pilot, including also the processing of personal data as part of the research and/or on the SHAPES platform, was provided.

5.8.5 Outcome of the Small-Scale Live Demonstration

Following aspects were evaluated:

1. Each participant used all the provided clinical devices and tablet each day for seven days.
2. 100% of data for heart rate, blood pressure, oxygen saturation, spirometry, inhaler usage and questionnaires are successfully transmitted via Bluetooth to the Medimonitor App.
3. Participants viewed their medication list daily.
4. Participants tried to contact healthcare professionals.
5. Participants tried to order medication.
6. Participants viewed the reminders and completed their tasks.
7. All participant data received by the Medimonitor App was securely transferred to FNOL servers and researcher dashboard.
8. Number of errors noted by participants.
9. Feedback provided by participants.

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10. Digital monitoring available through researcher dashboard and user event logs.

Recommendations for technical partners

The major recommendation for further work on the field implementation came from the lack of availability of Raspberry Pi computers, originally envisaged to be used for the monitoring of indoor and outdoor particulate matter concentrations and other environmental parameters planned to be measured in the patients' homes. An alternative approach had to be adopted. This alternative approach consisted of using data from the public monitoring stations, specifically those that were managed by the Czech Hydrometeorological Institute. Other recommendations for technical partners are specifically related to the predictor model. Exacerbations prediction should be completed with the use of data coming from all of the available medical devices and publicly available databases if relevant (for instance environmental data). Besides the standard statistical models, it was recommended to apply more advanced mathematical methods. In the context of the heart rate variability and oxygen saturation, multi-scale entropy and detrended fluctuation analysis seemed to be effective metrics. Also, Haussdorf and Higuchi fractal dimensions applied to those signals might provide the required information on trend changes. Similarly, several parameters were recommended to be calculated from the available spirometry data. These were peak expiratory flow, forced vital capacity, peripheral and global concavity, beta angle, area under curve (Au) and rectangular area ratio (RAR). Where possible the resulting metrics should be compared with the standard values, available for example, those from the European Respiratory Society. Outcomes should be correlated with both environmental parameters and the data on patients' adherence to inhalation therapy.

Lessons-learned from Phase 4 of the pilot campaign

Considering that there was only one application interface for both use cases, the key findings and lessons learned from Phase 4 are detailed in the previous use case PT3-001c under section 4.8.5 Outcome of the small-scale live demonstration.

5.9 Phase 5: Large-scale pilot activity

5.9.1 Study design

Non-randomised, single-armed, cross-sectional prospective observational pilot study with an optional qualitative interview component.

The pilot was conducted with service users and medical doctors in Olomouc, Czech Republic from University Hospital Olomouc. The pilot was managed by researchers from UHO and NTMC.

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This study intended to test the hypothesis that the SHAPES platform and Digital Solutions (novel system) can provide opportunities for supporting the management of the COPD condition, by both older adults/caregivers and health care professionals.

Intervention

The goals of this intervention were to help people self-monitor their health conditions and medicines adherence in their own home. Participants diagnosed with COPD were provided with 5 CE-marked, Bluetooth-enabled medical devices to use at home; specifically a blood-pressure monitor (Beurer BM54), spirometer (Spirobank), smart inhaler (FindAir), pulse ring oximeter (BodiMetrics Circul) and a tablet Lenovo Tab M10 HD.

Participants received a face-to-face introduction to the Medimonitor App and training on how to use both the App and the connected medical devices. A user manual contained detailed step-by-step supportive guidance and information, and was provided to participants in hard-copy format for reference by participants during the pilot. Participants were asked to use the App and connected medical devices for 12 weeks. Participants were given an information sheet (Annex 63), privacy notice (Annex 65) and once the eligibility was confirmed, a consent form (Annex 64) was obtained.

Participants

- Target users: people older than 60 years with COPD and living at home.
- Health professionals: medical doctors and nurses who work for University Hospital Olomouc

Sample size

In terms of evaluating the Digital Solutions, the target sample size for this pilot study was 25 service user participants and up to 2 medical doctors and nurses. These sample sizes were selected to be both representative as possible to provide valid answers and still within the scope of resources available.

Inclusion Criteria

• COPD

• ≥ 60 years of age

• Informed written and verbal consent

• Ability to participate in study activities

Exclusion Criteria

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• Active smoking

• Respiratory failure requiring oxygen therapy or ventilation support

• Severe psychological disturbances

• Absence of collaboration (informed consent)

• Other comorbid pulmonary disease

• Symptomatic heart failure

• Motor neuron diseases (e.g. amyotrophic lateral sclerosis etc.)

If participants gave informed consent, they were included in the study and continued with the Compliance Form. If the participant did not fully complete baseline questionnaires, they were excluded from the study. If the participant did not fully comply with SHAPES instructions or did not appropriately use SHAPES items, they were also excluded from the study.

Recruitment

Potential participants were selected based on the eligibility criteria described above from the ambulatory patients at the Department of Pulmonary Diseases at the University Hospital Olomouc. Participants were selected on the basis of convenient and random sampling. Sampling was convenient because participants were available during their regular in-patient visits.

5.9.2 Communication and dissemination of pilot activities

Any data that arose from the pilot study are owned by FNOL. On completion of the study, all the data were analysed and tabulated and used to prepare a final report, available as one of the agreed deliverables of the SHAPES Innovation Action — Deliverable D6.4. This deliverable (and all other agreed deliverables) will be available to the public for review and accessible via the SHAPES website (www.shapes2020.eu). Participants will be notified of the study outcome upon their personal request. FNOL is interested to share the findings from this study at conferences and in the scientific literature. FNOL will also use an opportunity to communicate the findings of this study via social media, and in other, non-peer reviewed, media outlets. Participating SHAPES partners will have the rights to use data from this study in their own analysis and dissemination plans. As detailed under ‘Access to Data’, Data Processing Agreements will be in place to facilitate the sharing of pseudonymised data with specific SHAPES partners for specific purposes.

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5.9.3 Risk management

All foreseeable risks related to privacy, security, data management and other risks have been assessed and compiled into detailed risk assessment documents which form part of the Data Protection Impact Assessments for Phase 5 PT3-COPD conducted within FNOL. For each risk identified, a risk classification, root cause, name and consequences were assigned. Once identified, each risk was then analysed and attributed a score from 1 (unlikely/minor)–4 (almost certain/critical) for probability and impact. Subsequently, appropriate mitigation actions were assigned and an appropriate person responsible was identified. These risks were reviewed periodically.

Finally, a full ethical review of PT3-COPD has been conducted by the ethics committee of the University Hospital Olomouc.

A potential risk to participants due to the unlikely occurrence of a device malfunction was also identified. Any such, incidents occurring in FNOL participants was reported in-line with the FNOL incident management policies (including serious adverse incidents).

5.9.4 Outcome of large-scale pilot activity

Overview

The phase 5 large-scale pilot of the SHAPES UC-PT3-COPD use-case was conducted between November 2022 and January 2023.

Potential participants were identified by healthcare professionals in hospital and by other contacts. The invitation was completed either face-to-face or via mobile phone. After the brief introduction and summary of this study, participants were given an information sheet, privacy notice and once eligibility was confirmed a consent form was provided.

A total of five HCPs participated in this study, including; 4 male doctors (age 32, 32, 33 and 35), female nurse (age 37). They were all recruited because they had research experience.

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Table 93 Recruitment and retention of participants (PT3-copd)

Recruitment and retention of older adult participants at FNOL	
Screened prior to eligibility assessment	**N=42**
Excluded	**N=17**
Reason 1: not technically skilled	N=7
Reason 2: no internet connection	N=10
Allocated to intervention	**N=25**
Lost to follow-up Reason(s) **Reason 1: Health reasons**	N=1 N=1
Discontinued Intervention Reason(s) **Reason 1: Did not have time** **Reason 2: Did not specify**	N=5 N=1 N=4
Assessment of KPIs	
Assessed for KPI 1	N=20
Assessed for KPI 2	N=20
Assessed for KPI 3	N=20
Assessed for KPI 4	N=20
Assessed for KPI 5	N=20
Assessed for KPI 6	N=20
Assessed for KPI 7	N=20

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Table 94 Baseline characteristics of Phase 5 participants (PT3-copd)

Variable	Number of participants	Value
Age (years)	25	69.40 (5.11)
Male	25	22 (88%)
BMI (kg/m^2)	25	30.27 (6.77)
Dyspnoea level (In accordance to MRC)	25	1.49 (1.18)
Values are mean (±SD), median (IQR) or n (%)		

The primary outcomes of the large-scale pilot activity were to measure a predefined set of KPIs, i.e., a set of measures that focus on the factors most critical to the success of the UC-PT3-COPD, and to evaluate the UC-PT3-COPD use case using the MAST evaluation tool.

Key performance indicators

Seven KPIs were identified for evaluation of the PT3-COPD use case. They are divided into three categories: recruitment and retention; user engagement and acceptance; and collection of data. Table 95 to Table 101 present the data used to determine the success of each KPI. Table 102 provides an overview of the success of the pilot with regards to KPIs.

Recruitment and retention

KPI 1 At least 80% of the target cohort were successfully recruited into the pilot during the recruitment period

Table 95 Number and percentage of target participants recruited into Phase 5 (PT3-copd)

Parameter	Value
Target number of participants	25
Number of participants recruited	25
Percentage recruited	100%

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KPI 2 At least 80% of recruited participants remained enrolled in the pilot until the end of the study.

Table 96 Participant retention during Phase 5 (PT3-copd)

Parameter	Value
Number of participants at baseline	25
Number of withdrawals	5
Number of participants at end of study	20
Percentage retained	80%

User engagement and acceptance

KPI 3 The overall user experience quality of the App as measured using the short version of the UEQ-S was classified as 'Excellent', 'Good' or 'Above average' based on published benchmark data.

Table 97 Mean pragmatic and hedonic quality UEQ-S scores and their comparison to published benchmark data (PT3-copd)

Scale	Mean	Comparison to benchmark
Pragmatic quality	0.48	In the range of the 25% worst results
Hedonic quality	0.73	50% of results better, 25% of results worse
Overall	0.60	50% of results better, 25% of results worse

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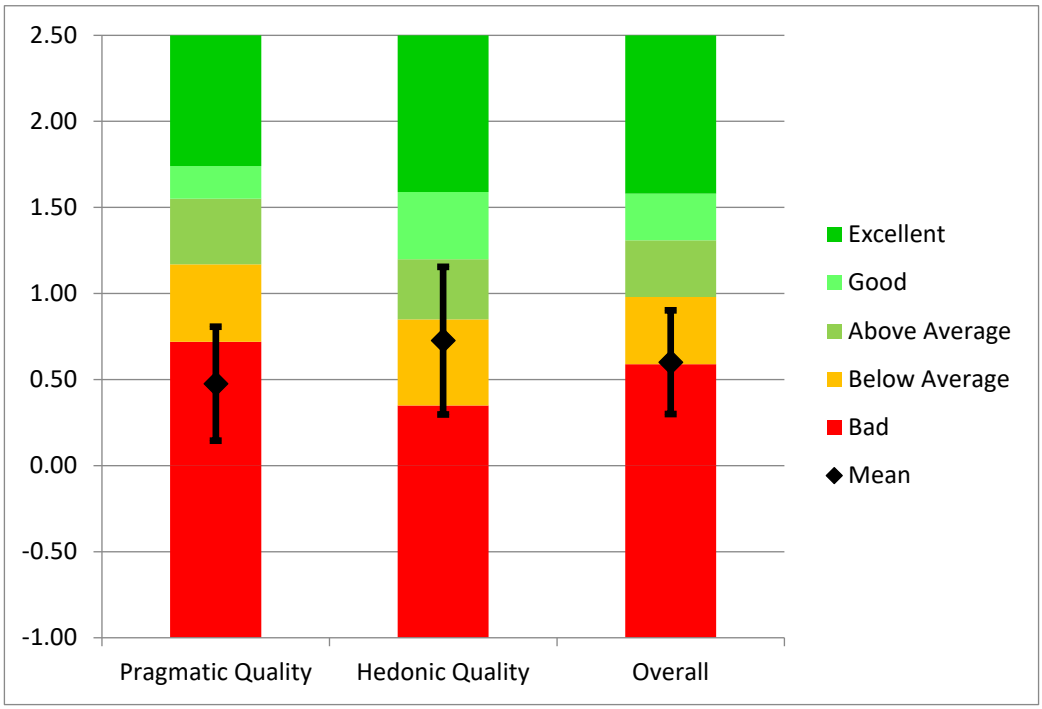

Figure 19 Mean UEQ-S and benchmark scores for the usability of the app (PT3-COPD)

KPI 4 At least 60% of participants continued to use the App daily after two weeks of the pilot.

Table 98 Number and percentage of participants using the app daily after two weeks (PT3-copd)

Parameter	Value
Number of participants who logged in daily for at least 2 weeks after baseline	7
Total number of participants	25
Percentage using the App daily after two weeks	28 %

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KPI 5 At least 60% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Table 99 Number and percentage of participants scoring higher than 68 in the System Usability Scale (PT3-copd)

Parameter	Value
Number of participants at end of pilot	20
Number of participants scoring >68 in SUS	10
Percentage of participants scoring > 68 in SUS	50 %

KPI 6 At least 60% of healthcare professionals' burden decreased while using the solution during the three months of the pilot in comparison with the baseline (Meister questionnaire).

Unlike the patients, HCPs were assessed also from the perspective of their work burden. The burdening domain was represented specifically by the Meister questionnaire. All items in the Meister questionnaire can be linked to one of the three factors of psychological work burden: overload, monotony and non-specific factor. The first factor, overload, was obtained by the summation of item No. 1-time pressure, 3-high responsibility, 5-problems and conflicts. The second factor, monotony, is the summation of items No. 2-low contentment, 4-mind-numbing work, 6-monotony. The third and last is the non-specific factor (stress response), which is the summation of items No. 7-nervousness, 8-mental satiation, 9-exhaustion and 10-long-term bearability.

Table 100 Number and percentage of healthcare professionals whose mental load and workload decreased during the three months of the pilot as measured using the Meister Questionnaire (PT3-COPD)

Parameter	Amount of HCPs experiencing decrease in corresponding parameter
Overload	1
Monotony	1
Non-specific factor	1
Raw score	1

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Parameter	Amount of HCPs experiencing decrease in corresponding parameter
Percentage	25%
Number of participants	4

Collection of data

KPI 7 Sufficient data was collected from participants to allow the COPD exacerbation prediction tool to generate a percentage risk of exacerbation at least once per week for at least 60% of participants.

Table 101 Number and percentage of participants with at least one successful COPDPred score generated from a full data set per week (PT3-copd)

Parameter	Value
Number of COPD participants with at least one successful COPDPred score generated from full data collection per week?	N/A
Number of COPD participants	25
Percentage	N/A

Overview of KPI achievement

Table 102 Overview of the success of Phase 5 of the pilot with regards to KPIs (PT3-copd)

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	Yes	
KPI 2	Yes	
KPI 3	No	Though the solution was discussed with UX experts thoroughly it was not sufficient from the user perspective. It is likely that the issues with Bluetooth connection with

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Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
		the devices was also projected into their perception of the technical solution.
KPI 4	No	
KPI 5	No	Same as KPI 3.
KPI 6	No	
KPI 7	Not assessed	Predictor model was trained through the pilot, therefore, the KPI is not applicable. Nevertheless, the post-hoc test of the early-stage development predictor model showed 1 patient in exacerbation risk from 3 actually hospitalised exacerbating patients (2 of them were not uploading their measurements regularly) out of the 20 patients able to participate until the end of the clinical trial.

Evaluation of use case using MAST

The MAST framework (15) was used to evaluate the effectiveness and contribution of UC-PT3-COPD to quality of care. MAST is described as a multidisciplinary process that summarises and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine.

Three of the seven multidisciplinary dimensions/domains of the MAST framework were of specific relevance to the pilot of UC-PT3-COPD. These were: Clinical Effectiveness; Patient Perspectives; and Economic Aspects.

Table 103 Completed MAST evaluation (PT3-copd)

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Domain	Topic	Outcome	Baseline (N=21) *Mean (SD)*	End of pilot (N=17) *Mean (SD)*	*Mean change (SD)*
Clinical effectiveness	Effects on health-related quality of life	EQ-5D-5L Utility Score	0.75 (0.21)	0.73 (0.23)	-0.01
		EQ-5D VAS	65.71 (16.51)	63.27 (17.91)	-4.83
	Behavioural outcomes	BMQ Necessity Score	11.55 (2.11)	11.31 (2.66)	0.33 (2.48)
		BMQ Concerns Score	21.60 (3.63)	21.63 (3.70)	-1.13 (2.73)
		BMQ differential score (Necessity – Concerns)	-10.05 (4.74)	-9.53 (6.18)	2.19 (5.02)
	Self-reported adherence	MARS Score	23.32 (1.56)	23.91 (1.39)	0.59 (1.51)
	Utilisation of health services	Hospitalisations	0	2	1 (1.41)
		Accident & Emergency attendances	0	0	0
Patient perspectives	Satisfaction and acceptance	UEQ-S Score	-	0.60 (0.70)	-

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Domain	Topic	Outcome	Baseline (N=21) *Mean (SD)*	End of pilot (N=17) *Mean (SD)*	*Mean change* *(SD)*
	Understanding of information / Confidence (in the treatment) / Ability to use the application / Access	SUS Score	-	68.33 (13.40)	-
	Empowerment / Self-efficacy	General self-efficacy scale	30.29 (2.40)	29.57 (3.72)	-0.71 (4.71)
Economic evaluation	Related changes in use of healthcare resources	Cost of hospitalisations	-	€1069 (2 patients)	-
		Cost of A&E attendances	-	0	-
	Cost of resources used	Cost of devices	Total €25079 • Tablet (25 pcs) €4237 • Spirometer (25 pcs) €3920 • Blood-pressure monitor (25 pcs) €1815 • Ring oximeter (25 pcs) €7426.90 • FindAir Inhaler (25 pcs) €5599.94 • Calibration of devices €313 • Equipment accessories €74 • Modules for dust sensors €1692.79		
		Cost of using digital solutions and	€1597		

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Domain	Topic	Outcome	Baseline (N=21) Mean (SD)	End of pilot (N=17) Mean (SD)	Mean change (SD)
		SHAPES platform			
		Cost of staffing	€38383.94 (Doctors cost an average of €200 per month, as did nurses. The monthly payment varied according to the participation rate in the pilot study. The costs of permanent workers were calculated on average for the entire duration of the pilot. respecting the Czech salary standards and standards of the University hospital Olomouc)		

Qualitative findings

Patient satisfaction

The patients' experiences with the Medimonitor App used for COPD monitoring were generally positive. The majority of patients expressed satisfaction with the process, stating that they were glad to participate. This indicates a high level of engagement and willingness to use the technology for their healthcare. One patient shared specifically positive feedback which highlighted the psychological comfort experienced during the study, smooth communication, and the user-friendly nature of the devices. These aspects are crucial for patient acceptance and adherence to the Medimonitor intervention.

However, there were some areas of dissatisfaction. One patient reported frequent outages and malfunctions, leading to discomfort. Technical issues, such as problems with the ring sensor, application login, blood pressure monitor, inhaler, and tablet, were mentioned by multiple patients. Connectivity problems and the need for manual data entry were also reported. These technical challenges should be addressed to ensure a seamless user experience and minimise frustration.

Despite these challenges, the Medimonitor application provided several benefits for COPD patients. Patients appreciated the increased frequency and regularity of

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measurements during the study compared to their usual practice. The availability of current information about their health status was seen as valuable. Detailed feedback from the treating doctor regarding their health status helped refine diagnoses and provided patients with a deeper understanding of their condition. The ability to have contact with healthcare professionals and the convenience of remote measurements and medication ordering were also cited as positive aspects of the Medimonitor application.

Some patients, however, did not perceive any direct benefits from the application. They mentioned having other applications on their phones that provided similar data monitoring capabilities, making the COPD monitoring App redundant. This highlighted the importance of ensuring that the Medimonitor application offered unique and significant advantages over existing tools to encourage patient adoption.

Patients also provided feedback on the specifics of using the devices. They mentioned an adaptation period of approximately one week to become familiar with the devices. This underscores the need for adequate training and support during the initial stages of using the Medimonitor application to enhance patient usability and comfort.

The time demands of the study were mentioned by some patients, who found the repetitive questionnaires unnecessary and the overall measurement process time-consuming. Streamlining the data collection process and optimising questionnaire administration may alleviate these concerns and improve overall user experience.

One aspect that was notably absent for some patients was the lack of feedback on the conducted measurements. Patients expressed a desire for more comprehensive evaluation and analysis of the data they provided. Including a feedback mechanism to provide patients with personalised insights and recommendations based on their measurements could enhance patient engagement and motivation.

Overall, the patients' experiences with the Medimonitor application for COPD monitoring were positive, with some technical issues and areas for improvement identified. Addressing the technical challenges, optimising the user interface, providing adequate training and support, and incorporating personalised feedback mechanisms can further enhance patient satisfaction and engagement with the Medimonitor intervention.

Challenges and technical issues

Technical problems with the ring oximeter were reported by 7 patients, including issues with data retrieval or unsuccessful data transmission, leading to frustration. Five patients encountered technical problems with the application and logging in. Issues with the BP monitor were mentioned by 3 patients, while 2 patients experienced problems with the inhaler. Some patients encountered problems with the tablet, requiring multiple restarts. Occasionally, patients faced connectivity issues due to

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multiple devices connected to the network. One patient mentioned the inconvenience of manually entering measured values.

Overall, the technical support provided was positively perceived in terms of speed and problem resolution.

Summary

In conclusion, the results indicated a positive overall reception of the Medimonitor application for COPD monitoring among the patients. However, several technical challenges and areas for improvement were identified, including addressing technical issues, optimising the user interface, providing adequate training and support, and incorporating personalised feedback mechanisms. These findings can guide further development and refinement of the Medimonitor intervention to enhance patient satisfaction and engagement. Highlights of qualitative evaluation can be summarised into the following dimensions.

Satisfaction

- Most patients expressed satisfaction with the process, stating they were glad to participate.
- One patient mentioned experiencing psychological comfort during the study.
- Smooth communication and user-friendly devices were appreciated by some patients.

Dissatisfaction

- One patient reported dissatisfaction due to frequent outages or malfunctions, leading to discomfort.

Benefits for patients

- Increased frequency and regularity of measurements compared to usual practice were seen as beneficial by four patients.
- Current information about their health status was valued by three patients.
- Detailed feedback from the treating doctor regarding their health status was mentioned by 2 patients, with one patient noting that it helped refine the diagnosis.
- One patient appreciated the contact with HCP.
- The ability to perform remote measurements and avoid physical visits to the doctor was highlighted by one patient.
- One patient mentioned the convenience of ordering medication through the Medimonitor portal.

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Lack of benefits for patients

- Two patients felt that the eHealth application did not offer any direct benefits and merely provided data for the study.
- One patient mentioned having a standard application on their phone to monitor sleep data, which made the COPD monitoring App redundant.

Specifics of device usage

- Patients required an adaptation period of approximately 1 week to become familiar with the devices.

Time demands

- Two patients found the repetitive questionnaires unnecessary.
- One patient mentioned the time-consuming nature of the measurements.

Technical issues

- Technical problems with the finger sensor were reported by seven patients, including issues with data retrieval or unsuccessful data transmission, leading to frustration.
- Five patients encountered technical problems with the application and logging in, with some finding it overly complicated at times.
- Issues with the BP monitor were mentioned by three patients, while two patients experienced problems with the inhaler.
- Four patients encountered problems with the tablet, requiring multiple restarts.
- Occasionally, patients faced connectivity issues due to multiple devices connected to the network.
- One patient mentioned the inconvenience of manually entering measured values.
- Poor tablet readability due to vision problems was mentioned by 1 patient.
- The technical support provided was positively perceived in terms of speed and problem resolution (mentioned by three patients).

Lack of feedback

- Two patients expressed a lack of professional feedback on the conducted measurements, as data was sent without any final evaluation.

Although not all of the KPIs were met in this study, overall, the participants were quite satisfied with our Medimonitor application and found it beneficial because of the overview of their health status.

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6 Conclusion

In summary, all 4 use-cases successfully completed Phases 1–5. Necessary preparatory work conducted in Phase 1 contributed to the effective planning of the pilots and many of the hurdles encountered early in the pilot campaign were resolved. Engagement with service users, carers and health professionals in Phases 2, 3 and 4 resulted in adaptations to the user-facing components of the digital solutions deployed in Phase 5.

The constantly changing environment that the pilots operated in with respect to COVID-19 and the different legal framework of the pandemic response plans throughout Europe called for a flexible approach and this was successfully achieved by adapting methods, clear communication and true collaboration with all partners.

This pilot tested seven digital solutions aimed at optimising medicines use in older people in a breadth of geographical locations (United Kingdom, Czech Republic, Spain, and Cyprus) and disease states (heart failure, diabetes, hypertension, COPD). Pilot activities were adapted for each use case and at each pilot site to permit optimal integration of the technology and evaluation of the pilot outcomes.

The results of the large-scale pilot activity in Phase 5 showed that over half of the KPIs set within Pilot Theme 3 were met, indicating a successful project. However, the pilot has also highlighted certain areas that did not work and would need to be addressed prior to any future sale-up and roll out of the digital solutions.

UC-PT3-General achieved a really high level of engagement and user satisfaction in the pilot at NHSCT, however, participant recruitment was a particular challenge at this site. When this use case was replicated at UNRF, the recruitment target was achieved, however, engagement and user satisfaction was lower.

UC-PT3-001 achieved successful recruitment, retention and usability metrics. Nevertheless, user engagement was slightly lower than aimed for in the KPIs set *a priori*. Unfortunately and despite numerous efforts with different clinics over a long period of time, this use case could not be replicated in Germany due to difficulties in obtaining support from the necessary healthcare institutions operating under high workloads. COVID-19 has had a lasting impact in this respect and healthcare systems Europe-wide are struggling to cope with the huge demand for healthcare.

UC-PT3-001c and UC-PT3-COPD both met recruitment and retention metrics, however, user engagement and experience KPIs showed a mixed success with patients with heart failure having a higher engagement and user experience than those with COPD.

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Qualitative interviews highlighted a consistent theme of the digital solutions providing reassurance to the service user groups and while a general willingness to continue to use the digital solutions was perceived this pilot required daily use of the digital solutions and this was perceived as burdensome for the participants.

The results presented in this Deliverable (D6.4) will be further discussed and assessed in Deliverable 6.9: Comprehensive Assessment of the SHAPES Pan-European Pilot Campaign.

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7 Ethical requirements check

Table 104 Ethical requirements check

Ethical issue (corresponding number of D8.4 subsection in parenthesis)	How we have taken this into account in this deliverable (if relevant)
Fundamental Rights (3.1)	Central to this pilot is to maximise autonomy of the older individual and improve self-management of their chronic conditions. In this way, the SHAPES Platform and Digital Solutions help promote the fundamental rights of older individuals and care givers. It is of vital importance that the SHAPES Platform and Digital Solutions employed in this pilot do not violate any fundamental rights of older persons and/or other stakeholders (e.g., non-discrimination, dignity, integrity and privacy). All members of this pilot are aware of both the importance and challenges with the terminology regarding older persons and the imperative not to use stigmatising language. Feedback was collected during Phase 2, Phase 3 and Phase 4 of the pilot. Feedback was collected relating to services that may be considered intrusive (e.g. video calling), a potential risk for autonomy (e.g. facial recognition) or for depersonalisation or for sense of security (e.g. chatbots). There was no use of automatic surveillance-type services. All services require input from the service user with the exception of environmental monitoring in PT3-COPD. The environmental monitoring is fully automated and collects data including temperature, humidity, pressure & particle matter concentration).

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Ethical issue (corresponding number of D8.4 subsection in parenthesis)	How we have taken this into account in this deliverable (if relevant)
	A user-centred approach has been taken to design this pilot to maximise accessibility. However, a base level of digital literacy was required in order to participate in this pilot e.g. confident smartphone user. In UC-PT3-001, there may be instances where a caregiver undertakes this role. The digital solutions employed in this pilot ensure equal and non-discriminatory access to technology and its support services by using well-designed user interfaces and authentication. The digital solutions used in this pilot consider cultural diversity of users by allowing users to participate in their language. Iconography is culturally-agnostic and the use of colours follows international codes. The end-user has the choice to use (i.e. switch off/on) various sensors and services whenever they want to (e.g. body composition scales, blood glucose monitor, physical activity monitor, pulse oximeter, blood pressure monitor). The user can also choose to withdraw from the pilot at any point and not to use their clinical devices in the knowledge that their clinical parameters will not be monitored.
Biomedical Ethics and Ethics of Care (3.2)	**Beneficence** — the primary aim of this pilot is to improve medicine adherence and control. This is to improve participants' health and wellbeing. **Non-maleficence —** a key aim of this pilot is to improve the health and wellbeing of participants using the SHAPES Platform and Digital Solutions. Every effort was

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Ethical issue (corresponding number of D8.4 subsection in parenthesis)	How we have taken this into account in this deliverable (if relevant)
	committed to doing no harm. All medical devices used were CE marked and complied with all relevant medical device regulations. **Autonomy —** each participant in Pilot 3 (D6.4) was provided with information about the pilot in order to make an informed, voluntary choice to provide consent to take part. All participants must have capacity to provide consent or processes must be put in place to allow consent to be provided on the participant's behalf by an appropriate representative. Informed consent was obtained for each participant involved in Phases 2, 3, 4, and 5. **Justice —** in order to participate in this pilot, older individuals or their carers must have access to a smartphone/tablet and WIFI (or mobile data plan) with compatible operating systems. This may create inequitable access to the SHAPES solution. However, there is a growing population of older individuals who have access to this technology and this will continue to expand in the future.
CRPD and supported decision-making (3.3)	A key focus of Pilot 3 is monitoring and improving adherence to medication and optimizing medicines use. It is acknowledged that participants may intentionally be non-adherent to medication. Capacity to provide consent to the pilot was self-certified by participants prior to recruitment to the pilot. Participants were provided with plain language materials and information in visual form (including information on each

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Ethical issue (corresponding number of D8.4 subsection in parenthesis)	How we have taken this into account in this deliverable (if relevant)
	service, how it operates and what data it collects). Further, the digital solutions used in this pilot observe accessibility principles and feature accessibility elements, including the use of the devices' built-in accessibility features (e.g. font size selection, display augmentation and content zoom features).
Capabilities approach (3.4)	Participants recruited to Pilot 3 had permanently or temporarily reduced capabilities due to multiple long-term conditions. This pilot aimed to protect and expand participant capabilities with respect to: life, to be able to live to the end of a human life of normal length; bodily health, being able to maintain one's own health; practical reason, being able to understand one's own status of health and wellbeing. Further, the digital solutions used in this pilot promote the older individuals' internal capabilities and active agency, including fostering self-management and health literacy, the follow-up of the pilot research protocol activities and the manual insertion of data.
Sustainable Development and CSR (4.1)	Pilot 3 aimed to contribute to the following UN sustainable development goals. • Good health and wellbeing — this is central to Pilot 3. • Good education — Pilot 3 is aiming to improve patient empowerment around health conditions and medications, resulting in increased confidence for self-management of such conditions. • Gender equality — participants from all gender groups were welcomed to participate in this pilot.

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Ethical issue (corresponding number of D8.4 subsection in parenthesis)	How we have taken this into account in this deliverable (if relevant)
	• Sustainable consumption and production — this pilot aims to identify areas where healthcare resource use can be reduced or used more efficiently.
Customer logic approach (4.2)	The service users were actively involved in the co-creation and piloting of the SHAPES solutions in Phase 2, Phase 3 and 4 of this pilot. Irrespective of the type of service users, e.g. patients, carers, clinicians, support staff, involved in Pilot 3, the main focus of the intervention will always have user-centric service at its core.
Artificial intelligence (4.3)	Data from Pilot 3 were entered into a heart failure decompensation and a COPD exacerbation algorithms. Based on a number of parameters, these algorithms calculate the risk of decompensation/ exacerbation for each participant. The risk level for future decompensation/ exacerbation was populated. In PT3-001c and PT3-COPD, this risk level was reviewed by clinicians to determine whether any changes to medication or care plans should be implemented. The aim of these algorithms is to prevent worsening of heart failure or COPD and provide an 'early warning' of deterioration to prevent an acute decompensation episode. The following has been taken into account in terms of AI ethics for the heart failure decompensation and COPD exacerbation algorithm: 1. **Human agency and oversight** AI algorithm has been developed under the supervision of qualified health staff. 2. **Technical robustness and safety** Sound database has been used for the development of the AI algorithm

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Ethical issue (corresponding number of D8.4 subsection in parenthesis)	How we have taken this into account in this deliverable (if relevant)
	and its metrics provide a high level of reliability, robustness and safety. 3. **Privacy and Data Governance** The AI algorithm is private by design. It only uses pseudonymised data and it only uses data to compute the decompensation risk. After the computation of the risk, the data provided is erased from memory, and no storage of it is maintained. 4. **Transparency** A public API (data interchange is provided) for its control is provided. The API can be used to audit the system. Additionally, the original AI algorithm has been published in a relevant open journal. 5. **Diversity, non-discrimination and fairness** The heart failure AI algorithm has been developed using a database populated with more than 400 people. This database follows the diversity, non-discrimination and fairness principles. 6. **Societal and Environmental Wellbeing** The use of this AI algorithm supports societal and environmental wellbeing because it aims to avoid readmissions to hospitals leading to better quality of life of the patients and helps reducing avoidable resource consumptions such as travel and hospital costs. 7. **Accountability** The AI Algorithm does not replace the corresponding health professionals, rather, this tool

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Ethical issue (corresponding number of D8.4 subsection in parenthesis)	How we have taken this into account in this deliverable (if relevant)
	supports them to deliver better outcomes for patients. In UC-PT3-001, a chatbot was employed. The following has been taken into account in terms of AI ethics for the chatbot: 1. **Human agency and oversight** The older person/caregiver were always aware that they are talking to virtual chatbot with the aim of collecting data on a daily basis. Efforts were made to reduce chatbot-user interaction to the minimum necessary and not interfere with user daily activities. As well, efforts were made to empower the user to control when the interaction with the chatbot is established. Any interaction the chatbot cannot resolve would be clearly notified to the user. The user had a mechanism to notify any incorrect behaviour of the chatbot. 2. **Technical robustness and safety** User-chatbot conversations were limited to specific domains and clinical data was based only on closed answers. Any interaction the chatbot cannot resolve would be clearly notified to the user. The user had a mechanism to notify any incorrect behaviour of the chatbot. 3. **Privacy and Data Governance** Data collected was saved on the SHAPES Platform, which complies with all EU data protection and governance requirements. 4. **Transparency** All user-chatbot conversations were saved for all necessary traceability actions. In the chat

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Ethical issue (corresponding number of D8.4 subsection in parenthesis)	How we have taken this into account in this deliverable (if relevant)
	window, it is always clearly stated who is the sender of the message (an automatic chatbot or human professional). Any interaction the chatbot cannot resolve would be clearly notified to the user. 5. **Diversity, non-discrimination and fairness** The chatbot sentences were inclusive in terms of gender, race, religion and age. 6. **Societal and Environmental Wellbeing** The chatbot was designed not as a separate entity but as a module integrated in a health care circuit. The chatbot was designed and evaluated to benefit all stakeholders of the ecosystem. As any software running on electrical devices, chatbots consume energy, mainly through the use of internet. Transfer of data was designed to avoid overuse of the network and related servers. 7. **Accountability** The pilot sites were accountable for the proper functioning of the chatbot, and warning the respective partners in case it is not working properly. The pilot sites had the rights to stop or pause the system if necessary according to their criteria.
Digital transformation (4.4)	**ICT support to health & wellbeing** Pilot 3 focused on the management of chronic conditions using the SHAPES platform and Digital Solutions. Using health and wellbeing Apps, participants were able to view their health parameters

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Ethical issue (corresponding number of D8.4 subsection in parenthesis)	How we have taken this into account in this deliverable (if relevant)
	and make these available to local clinicians if desired. This pilot consisted of four use cases that were implemented in four European countries to demonstrate access to health data across borders. The SHAPES Platform and Digital Solutions are GDPR compliant and provide users with secure access to and sharing of health data. **Telehealth** Health parameters were monitored remotely, personalised 'normal' ranges can be set for each participant to ensure a patient-centred approach. Participants may choose to set medication reminders. UC-PT3-001, UC-PT3-001c and UC-PT3-COPD employed wearables (wristband activity monitors ring oximeters) to remotely monitor activity levels. **Education** A key factor in this pilot is to improve self-management in older individuals with chronic conditions. Self-management is encouraged by access to key health parameter data and medication information. **Smart homes and age-friendly environment** An important correlate to assess patients' COPD diagnosis evolution is the knowledge of the environment, especially the particulate matter concentration. This information is gathered together with the data on temperature, humidity and pressure. All of the mentioned parameters are being monitored inside and outside patients' premises.

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Ethical issue (corresponding number of D8.4 subsection in parenthesis)	How we have taken this into account in this deliverable (if relevant)
	Social or peer support N/A to this pilot
Privacy and data protection (5)	Pilot 3 was conducted in accordance with GDPR. This pilot processed sensitive, personal data and consent was as sought explicitly for this purpose. The secure transfer of pseudonymised data was conducted through clinical devices/wearables [3rd party] and recorded via the digital solutions (health and wellbeing Apps) [technical partners] and be securely stored on the SHAPES Platform. The data collected was described in a data plan for each use case. A Data Protection Impact Assessment was completed for each use case. The information provided to participants in all use cases in this pilot state clearly, openly and honestly how each participant's data would be accessed. Consent was explicitly sought for the use of participant data in accordance with the information provided. The principle of data minimization was used to ensure only relevant, justifiable data is processed. The retention of personal data was stated in the information provided to participants. All reasonable efforts were made to ensure that data processed is accurate and the source of the data was recorded. In each use case, consent was obtained for each participant. Consent must be

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Ethical issue (corresponding number of D8.4 subsection in parenthesis)	How we have taken this into account in this deliverable (if relevant)
	informed, voluntary, and the person providing consent must have capacity to do so. Consent was recorded and stored securely at each pilot site and/or via the SHAPES Platform and Digital Solutions. Data subjects were informed about their rights and on the descriptions of the processing of personal data via the services on the SHAPES webpages. All efforts were taken to avoid a data breach. If one would occur, a process was in place to notify the relevant supervisory authorities no later than 72 hours after becoming aware of the breach.
Cyber security and resilience (6)	The SHAPES project developed and piloted a platform for health and care services, and that platform is cyber-secure. A security management plan and a resilience management plan were developed for the SHAPES Platform. All appropriate security technologies were employed, the adequacy and quality of security information was ensured, situational awareness was up to date and penetration testing was undertaken for the Digital Solutions used. The Network and Information Systems Directive 2016 applies to SHAPES. As this is a minimum directive the legislation of each country participating in this pilot was checked before Phase 4 of the pilot could commence.
Digital inclusion (7.1)	It was recognised that a range existed in the readiness and capability of older adults to use digital devices. All SHAPES consortium members of Pilot 3 are aware of this and mindful not to draw any

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Ethical issue (corresponding number of D8.4 subsection in parenthesis)	How we have taken this into account in this deliverable (if relevant)
	preconceptions that older adults in general may be less willing or have a perceived lack of interest in using digital technologies. Phase 2 and Phase 3 of the Pilot included older adults in decisions about technology use and the development process of the SHAPES Platform and Digital Solutions. Phase 4 and Phase 5 included older adults in the testing of the SHAPES Platform and Digital Solutions. Interaction and dissemination from WP2 deliverables created an understanding of the diversity and complexity of ageing within the SHAPES consortium.
The moral division of labor (7.2)	The participants in this pilot may have permanent or temporary reduced capabilities due to their chronic condition(s). Part of the selection of the clinical devices employed was their ease of use. A small number of end-users were invited to provide feedback and participate in the development of the SHAPES Platform and Digital Solutions in Phase 2 and Phase 3 of the Pilot. The end-users were not held accountable for development choices rather, their views informed development choices. Further, the digital solutions used in this pilot support citizen empowerment and person-centred care, thus fostering the conditions to enable older individuals to be better informed and make informed choices concerning their health and care.

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Ethical issue (corresponding number of D8.4 subsection in parenthesis)	How we have taken this into account in this deliverable (if relevant)
Care givers and welfare technology (7.3)	The technology used within Pilot 3 was appropriately integrated into the current clinical workflow in Phases 4 and 5. Training was provided both to the older individuals and carers involved and the clinicians managing their care. The clinicians whose work was impacted by the new technology had the opportunity to provide feedback as part of Phase 2, 3, 4 and 5 of the pilot. The NASSS and MOMENTUM frameworks were used in Pilot 3 to identify the social and organisational factors that have that have a significant impact on technology implementation and use.
Movement of caregivers across Europe (7.4)	Certain data from Pilot 3 was stored on the SHAPES Platform and made available to authorised personnel to view regardless of their geographic location within the EU. Use cases were tested in four European countries to demonstrate use and applicability of remote health monitoring across Europe.

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Annex 1 UC-PT3-gen MOMENTUM blueprint

CONTEXT	
CSF 1. Ensure that there is cultural readiness for the telemedicine service	
In my organisation/region doctors and other healthcare professionals are ready to share clinical information with each other and with the patient i.e., there is a level of trust among all the stakeholders.	
In my organisation/region patients and providers (healthcare professionals) are ready to use ICT (e.g., computers, tablets, mobile phones).	
In my organisation/region financial and other incentives are aligned with the service to be deployed.	
In my organisation/region an underpinning culture embraces technology.	
In my organisation/region an underpinning culture welcomes and even promotes change, innovation and shows openness to new ideas.	

PT3-UC-General_MOMENTUM FRAMEWORK

CSF 2. Come to a consensus on the advantages of telemedicine in meeting compelling need(s)	
In my region/organisation there is general consensus on the current telemedicine solution being the best available solution for meeting a compelling need.	
The current telemedicine solution is the best available solution for meeting a compelling need.	

PEOPLE

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CSF 3. Ensure leadership through a champion	
In my region/organisation there is one or several influential person(s) who take(s) on a leading role and leads the way towards deployment of the telemedicine solution tested in our project.	

CSF 4. Involve healthcare professionals and decision-makers	
Healthcare professionals have been involved in the development of the content of this project.	Yes
Healthcare professionals have been involved in the development of the process and time schedule for this project.	Yes – limited, will increase
Decision-makers have been involved in the development of the content of this project.	Yes
Decision-makers have been involved in the development of the process and time schedule for this project.	Yes

CSF 5. Put the patient at the centre of the service	
In this project the patients have been sufficiently involved in the development of the telemedicine solution.	Yes – they will be
In this project telemedicine service is based on the patient´s needs.	Yes
In this project enough information and training is provided for the patients in order for them to obtain the best results possible from using the telemedicine solution.	Yes – there will be

CSF 6. Ensure that the technology is user-friendly	
The telemedicine technology used in our project is user-friendly for patients.	Yes – user testing will be performed
The telemedicine technology used in our project is user-friendly for health professionals.	Yes – user testing will be performed
The telemedicine technology used in our project does not need an extended training process prior to using it.	Yes – extended training will not be required

PLAN

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CSF 7. Pull together the resources needed for deployment	
In my region/organisation the financial resources needed for deployment of the telemedicine solution are available.	Yes, for the pilot.
In my region/organisation the IT competences needed for deployment of the telemedicine solution are available.	Yes, query regarding resourcing
In my region/organisation enough time for the training needed in order to implement the telemedicine solution is available.	Yes, there will be

CSF 8. Address the needs of the primary client(s)	
The telemedicine solution addresses the needs of the primary clients.	Yes
The telemedicine solution is sufficiently adapted to the needs of the primary users.	Yes, phase 2/3 will address this
The telemedicine solution addresses the needs of the health sector.	Yes

CSF 9. Prepare and implement a business plan	
A business plan for the project has been developed.	
A business plan for the project has been implemented.	
The business plan has been approved by the relevant management level.	

CSF 10. Prepare and implement a change management plan	
A change management plan for the project has been developed.	
A change management plan for the project has been implemented.	
A change management plan has been approved by the relevant management level.	

CSF 11. Assess the conditions under which the service is legal	
Prior to the start of the project, we assessed the conditions under which the service is legal.	Yes, being managed in other WPs

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CSF 12. Guarantee that the technology has the potential for scale-up	
We are fully aware of what it takes for the technology to be deployed on a large scale.	
In our region/organisation we are ready for large-scale deployment of the technology.	
The project will supply the documentation needed to ensure that there is a basis for large-scale deployment of the project.	

RUN

CSF 13. Identify and apply relevant legal and security guidelines	
The project is carried out in accordance with the relevant guidelines on legal matters.	Yes
The project is carried out in accordance with the relevant guidelines on security matters.	Yes

CSF 14. Involve legal and security experts	
We have received advice on the project from legal experts.	Yes
We have received advice on the project from experts on data security matters.	Yes
In this project we are not experiencing any data security problems.	Yes
I have confidence in the legality of this project.	Yes
I have confidence in the security of this project.	Yes

CSF 15. Ensure that telemedicine doers and users are privacy aware	
In this project the telemedicine doers are aware of protecting the patients´ privacy in terms of health information and other information collected during the course of the pilot.	Yes

CSF 16. Ensure that the information technology infrastructure and eHealth infrastructure are available	
We have ensured that the IT infrastructures needed are in place for deployment and large-scale implementation.	Yes, elsewhere

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We have ensured that the eHealth infrastructures needed are in place for deployment and large-scale implementation.	Yes

CSF 17. Put in place the technology and processes needed to monitor the service	
We have set up a system to monitor our telemedicine service ensure that it is running smoothly at all times.	Yes, through tech support from WP4 and WP5 (globally), and locally
We have set up a system to solve any incident that may occur during the service.	A system to monitor incidences will be set up. Impossible to predict any incident
We have a system which supports the end-users in resolving any doubts that they might experience with the telemedicine solution.	Yes, project team

CSF 18. Establish and maintain good procurement processes	
We have clear agreements regarding the quality of the deliveries provided by our vendors.	Yes, standard local procedures for devices.
We have clear agreements regarding the service level provided by our vendors.	Yes, service level as per contract

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Annex 2 UC-PT3-gen NASSS-CAT (SHORT VERSION)

NASSS-CAT (SHORT)
IDENTIFYING COMPLEXITIES IN YOUR TECHNOLOGY PROJECT

The questions below help you think about the various complexities of your project and how they all interact. Use your responses and notes as the basis for a team discussion.

Name of your project: SHAPES Pilot Theme 3 general use case (UC-PT3-gen)

THE ILLNESS OR CONDITION

Think about the illness or other condition that the technology is designed for – and what sort of person has that condition.

There are significant uncertainties about the condition e.g. poorly-defined, variable manifestations, uncertain course

Many people with the condition have other co-existing illnesses or impairments that could affect their ability to benefit from this solution

Many people with the condition have social or cultural factors that could affect their ability to benefit from the technology or service

The population with the condition, and/or how the condition is treated, is likely to change significantly over the next 3-5 years

SUMMARY: The condition has significant complexity which is likely to affect the project's success

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THE TECHNOLOGY

Think about the technology (e.g. a tool or piece of software), and how it might affect care.

	Agree	*Disagree*	*Not applicable or don't know*
There are significant uncertainties in what the technology is (e.g. it hasn't been fully developed yet)	X		
There are significant uncertainties in where the technology will come from (e.g. supply chain issues, substitutability)	X		
There are significant uncertainties about the technology's performance and dependability (e.g. bugs, crashing, cutting out)	X		
There are significant uncertainties about the technology's usability and acceptability (e.g. key people don't trust the data it provides)	X		
There are significant technical interdependencies	X		
The technology is likely to require major changes to organisational tasks and routines	X		
The technology (and/or the service model it supports) is likely to change significantly within the next 3-5 years	X		
SUMMARY: The technology has significant complexity which is likely to affect the project's success			

THE VALUE PROPOSITION

Think about what kind of value the technology might generate for different groups of people. ('Value' can be financial, such as profit, or non-financial, such as control of symptoms)

	Agree	*Disagree*	*Not applicable or don't know*
The commercial value of the technology is uncertain	X		
The value to the intended users (e.g. patients, clinicians) is uncertain			X

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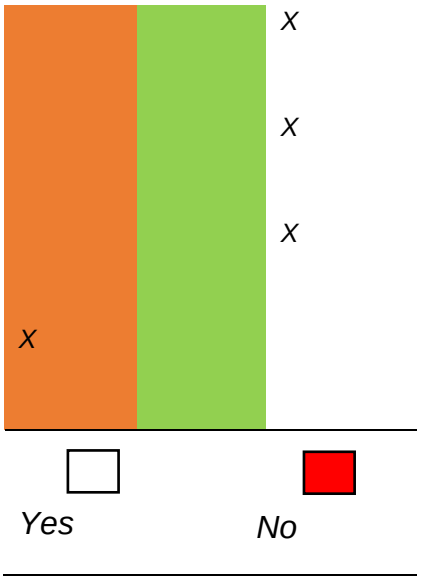
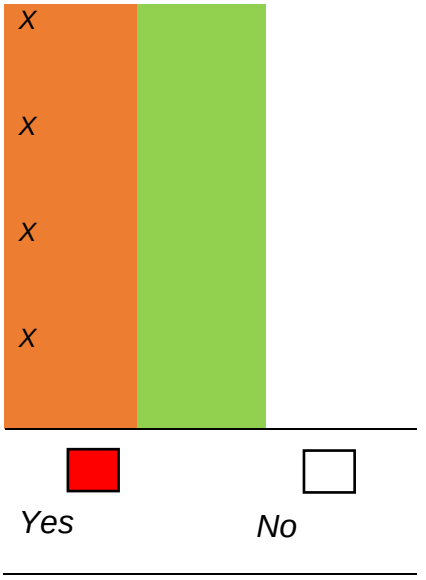
The value to the healthcare system (e.g. from efficacy and cost-effectiveness studies) is uncertain	X
The value to this particular healthcare organisation, given the current situation locally, is uncertain	X
The technology could generate a negative value (costs are likely to outweigh benefits) for some stakeholders	X
The value proposition is likely to change significantly over the next 3-5 years	X
SUMMARY: The value proposition has significant complexity which is likely to affect the project's success	



THE INTENDED ADOPTERS

Think about who is intended to use the technology and what changes it will bring for them.

	Agree	Disagree	Not applicable or don't know
There is uncertainty about whether and how patients/citizens will adopt the technology [if applicable]	X		
There is uncertainty about whether and how front-line staff will adopt the technology	X		
There is uncertainty about the implications for people who might be indirectly affected by the technology	X		
There will be significant changes to individual users' perceptions of the technology over the next 3-5 years	X		
SUMMARY: There is significant complexity relating to intended adopters which is likely to affect the project's success			



THE ORGANISATION(S) IMPLEMENTING THE TECHNOLOGY

Some organisations are better at taking up innovations than others. What about yours?

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	Agree	Disagree	Not applicable or don't know
The organisation's capacity to take on technological innovations is limited		X	
The organisation is not ready for this particular innovation		X	
The organisation would find it hard to commission/purchase the innovation			X
The work needed to introduce and routinise the innovation has been underestimated and/or inadequately resourced		X	
The organisation(s) involved are likely to have significant restructurings or changes in leadership, mission or strategy over the next 3-5 years	X		

SUMMARY: There is significant complexity relating to one or more participating organisations which is likely to affect the project's success

☐ Yes ■ No

THE EXTERNAL CONTEXT FOR INNOVATION

Think about external conditions that could complicate adoption and spread of the innovation.

	Agree	Disagree	Not applicable or don't know
The political and/or policy climate is adverse		X	
Professional bodies are opposed to the innovation or don't actively support it		X	
Patient organisations and lobbying groups are opposed to the innovation or don't actively support it		X	
The regulatory context is adverse		X	
The commercial context is adverse		X	
Opportunities for learning from other (similar) organisations are limited		X	
Introduction of the technology/innovation could be threatened by external changes that impact on the organisation			X

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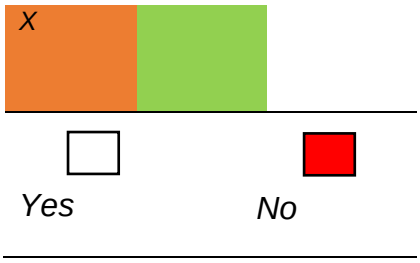
The policy, regulatory and economic context for this innovation is likely to be turbulent over the next 3-5 years

SUMMARY: There is significant complexity relating to the external context which is likely to affect the project's success



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Annex 3 UC-PT3-gen NASSS-CAT (LONG VERSION)

NASSS-CAT (LONG VERSION)

ASSESSING AND HANDLING COMPLEXITY IN TECHNOLOGY PROJECTS

Introduction

This evidence-based guide has been developed from a systematic literature review and extensive primary research. It is designed to help you reflect on your ideas and goals for a **technology-supported change project** in health or social care and work towards a project plan. A high proportion of such projects fail, but there are ways of improving the chances that your project will succeed.

Technology projects are characterised by **complexity** – i.e. they have multiple interacting components that cannot be tightly controlled. Complex projects are unpredictable and risky, hence less likely to succeed than simple ones. This guide will help you to identify the different areas of complexity (that is, the uncertainties, interdependencies and possible unintended consequences) in your project and think of ways to reduce or manage these (e.g. by making some aspects simpler or mitigating risks)

How to use this guide

We recommend that you start using this guide as early as possible and keep revisiting it as your project unfolds. It will only take you a few minutes to skim through it and gain an initial orientation, but working carefully through the detail of the guide will take much

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longer. There is no 'right' way to use the guide; it is intended to prompt conversations and help you bring together different areas of expertise (such as clinical, technical and business development). For example, you could assign different parts of the guide to different people to fill in in detail, then reconvene and compare your responses. You may wish to employ a facilitator to run a workshop with the project team.

Structure of this guide

PART 1 of this guide is divided into 6 domains, each in two parts:

- **A free-text box for you to present this domain in your own words**. This will help surface the issues, technologies, people and activities relevant to *your* project and how they seem to fit together. Make it flow like a story (i.e. write in sentences rather than using tables or bullet points), so as to capture the messiness (non-linearity) of the project. Telling a brief story will allow you to draw out the 'plot' of what's happened so far and identify interdependencies and tricky issues that may contribute to the project's success or failure (or something in between).
- **Some questions to help you estimate key areas of complexity** (most of which should have come up in your narrative). The more red boxes you tick, the more complex this domain is (though the boxes don't carry equal weight, so adding up the ticks won't give you a quantitative score). The top-level questions are quite broad, but if a question is particularly relevant to your proposed project, you can 'drill down' with the more detailed questions. Ideally, you should be able to back up your answers with evidence, such as published figures or research, or data you have collected yourself (for example from interviews or focus groups). Some questions will not apply to your project, so tick 'not applicable' for these. If a question seems relevant but you're not sure how to answer it, tick 'don't know' – and perhaps discuss this one with colleagues later. Can you distinguish the things you don't *yet* know (but could find out) from the things that are unknowable (inherently uncertain), which you have to handle with creativity and judgement as the project unfolds?

Note: [1] No single individual will be able to answer all the questions but you should find that if you involve a range of people across your organisation, you will be able to address all the domains. For each domain, we've suggested who might be best placed to answer the questions. [2] The tick-box questions will give an artificially structured and linear perspective. Bear in mind that complex change is an inherently messy and unpredictable process, but the box-ticking may help you find a 'way in' to your narrative.

PART 2 is designed to help your team handle the different kinds of complexity in your project. It consists of prompts to help you plan and manage an implementation project and think about how to

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- **Reduce complexity** where possible (e.g. by limiting the scope of the project)
- **Respond to complexity** where it can't be reduced (e.g. by bringing staff together to make sense of a situation, strengthening relationships, or collecting and analysing real-time data)

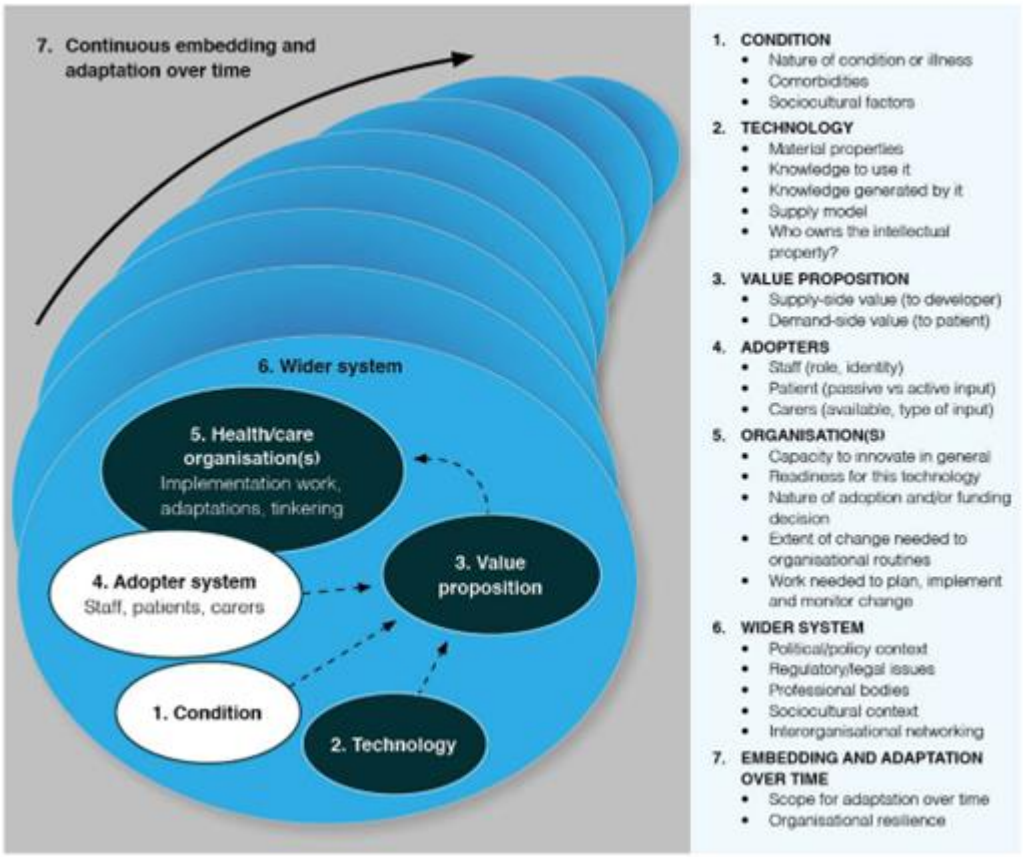

Diagram: The NASSS framework (© Greenhalgh at al J Med Internet Research 2017; 19 (11): e367)

PART 1: ANALYSING COMPLEXITY IN YOUR PROJECT

1. THE ILLNESS OR CONDITION

[a clinician, social worker or researcher might be the best person to complete this section]

Briefly describe the condition(s) for which the innovation or technology has been designed (e.g. heart failure, mental health, social isolation). In some situations, there won't be a specific

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illness
or condition.

The UC-PT3-general use case has been designed for older individuals with multimorbidity, i.e., people who are aged 65 years and older who have two or more long-term medical conditions. Conditions can be any defined physical and mental health condition e.g., diabetes or schizophrenia; ongoing conditions such as learning disability; symptom complexes such as frailty or chronic pain; sensory impairment such as sight or hearing loss; and alcohol and substance misuse. Whereas the management of each individual condition may be different, there is an increasing awareness of the need to manage multimorbidity as a condition or health status in itself. Guidance from the National Institute for Health and Care Excellence describes how to assess for and manage multimorbidity. It recommends delivering an approach to care that encompasses a review of disease and treatment burden, identification of patient goals, values and priorities, review of medicines and other treatments, and the development of an individualised management plan. Such plans should include goals and plans for future care, identify a person responsible for the coordination of care, permit communication of the plan to all services involved with the care of the patient and include details of follow-up and how to access urgent care.

There are significant uncertainties about the illness or condition

- Multimorbidity has been clearly defined and there is published national guidance that informs planning.
- The population has been clearly defined but is broad. With this particular use-case we are focusing on older population.
- The condition does affect people in many different ways – however, this is not so much a complexity of the condition but rather defines it.
- People are likely to be under the care of multiple professionals and in more than one care pathway – again it is this aspect of multimorbidity that were are specifically trying to address/help/overcome with this technology

Many people with the condition have other co-existing illnesses or impairments that could affect their ability to benefit from the technology or service

- Again physical and mental co-morbidities is the hallmark of the condition and so is not considered a complexity in this use case
- Cognitive impairment may be higher in the population but it is not a feature/symptom of the condition (i.e., multimorbidity)

Many people with the condition have social or cultural factors that could affect their ability to benefit from the technology or service.

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- Many people with multimorbidity in the target population will have a lower digital literacy and motivation to use the technology than the wider population. This is a complexity for the use-case.

The following questions should help you summarise whether the condition or illness is straightforward, well-understood, follows a predictable course and has predictable implications for care. This isn't about whether the illness is serious*, but whether you can predict what will happen next. For suggestions for responding to complexity in this domain, see page 13.*

IDENTIFYING COMPLEXITIES IN THE ILLNESS OR CONDITION:	*Agree*	*Disagree*	*Not applicable or don't know*
There are significant uncertainties about the illness or condition *Additional detail – e.g.* • *The condition is not clearly defined, or too little is known about it to inform planning* • *The population affected by the condition is not well-defined* • *The condition affects people in different ways, so a 'one size fits all' solution is unlikely to work* • *People with the condition are likely to be under the care of multiple professionals and/or in more than one care pathway*		X	
Many people with the condition have other co-existing illnesses or impairments that could affect their ability to benefit from the technology or service *e.g.* • *Physical or mental co-morbidities* • *Cognitive impairment*		X	
Many people with the condition have social or cultural factors that could affect their ability to benefit from the technology or service. *e.g.* • *Poverty* • *Social exclusion e.g. drug use, homeless* • *Religious restrictions or expectations on how they manage their illness* • *Low health literacy (limited ability to understand health issues and how to handle them)* • *Low system literacy (limited understanding of how services work and how to navigate them)* • *Low digital literacy (limited ability to use, or learn to use, new IT products)* • *Unable to understand the language used by professional staff*	X		

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The population with the condition, and/or how the condition is treated, is likely to change significantly over the next 3-5 years		X	
SUMMARY: The illness or condition has significant complexity which is likely to affect the project's success	☐ *Yes*	☒ *No*	

2. THE TECHNOLOGY (or other innovation)

[the technology developer might be the best person to complete this section]

Describe the technology/ies or other innovation. It might be an app, a device, a tool, a protocol or pathway, an algorithm, a model, a piece of hardware – or some combination of these.

Highlight what is new apart from the technology (e.g. new way of working). An innovation can be old technology (e.g. telephone) used in a new way.

Link to FICS – technical features.

There are significant uncertainties about what the technology is

The individual technologies in PT3-gen are well-defined digital products. The suppliers of the digital solutions are SHAPES partners and work in collaboration with the pilot site, therefore all uncertainties listed below are being discussed.

- There is overlap of functionalities between the eCare and eHealthpass (concerning vitals monitoring) and it is unknown how the two systems will integrate
- It is unknown which technical partner is responsible for building the 'wrap around' app that presents the functionalities of the EDGE and GNOMON systems
- Where will the HCP portal be hosted?
- The exact role and functionality of the platform has not been defined

There are significant uncertainties about where the technology will come from

- A pulse oximeter has not been identified for use during the pilot. User testing needs to begin in May.

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- There is not enough time to ensure the security, functionality etc. of another platform before October.
- The devices that will be used during the pilot have been specified. There are no 'back-ups' and the procurement process for scaling has not been explored.

There are significant uncertainties about the technology's performance and dependability

- The flow of data is not yet confirmed. At present, the devices take readings and send data via Bluetooth to the eCare (BP, HR, Weight, Oxygen) and eHealthpass (blood glucose) systems. Data is visible in the patient held app and the HCP portal. Data on vital signs also needs to go to TREE and VICOM for further analytics and the findings are sent to the HCP portal and displayed via a dashboard. It is yet to be confirmed where TREE and VICOM retrieve data from and send findings to.
- NB during the pilot there will be no identifiable information entered into the system. Participants will be pseudoanonymised and unique identifiers entered in place of names.
- Compliance with standards and regulations needs to be addressed for each component in the system.

There are significant uncertainties about the technology's usability and acceptability

User testing and prototyping will take place between March and July 2021. Until this takes place these remain uncertainties.

There are significant technical interdependencies

The eCare and eHealthpass systems are currently only available in Android. This reduces the number of potential users. For scalability there will need to be a plan in place to support iOS.

The technology is likely to require major changes to organisational tasks and routines

It is not yet known how the technology would fit within current organisational workflows.

The technology (and/or the service model it supports) is likely to change significantly within the next 3-5 years

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There is a query over how 'futureproof' the technology is with the introduction and adoption of 5G.

The questions below will help you decide if the technology (and how it works to support care) is straightforward, well-understood and will have a predictable effect. For suggestions for responding to complexity in this domain, see page 13.

IDENTIFYING COMPLEXITIES IN THE TECHNOLOGY OR OTHER INNOVATION:	*Agree*	*Disagree*	*Not applicable or don't know*
There are significant uncertainties about what the technology is *e.g.* • *The technology is difficult to define (e.g. connects with hidden infrastructure, supplier does not disclose full details)* • *The technology does not yet exist in a robust and definitive form*	X		
There are significant uncertainties about where the technology will come from *e.g.* • *The technology supply chain is not yet in place* • *The technology is not easily substitutable (i.e. if the supplier withdrew, it would not be obtainable elsewhere)*	X		
There are significant uncertainties about the technology's performance and dependability *e.g.* • *Data collection and transmission (where relevant) are not yet accurate or reliable* • *There are significant privacy or security concerns*	X		
There are significant uncertainties about the technology's usability and acceptability *e.g.* • *It is not possible for people to try out the technology on a small scale before adopting it* • *The data or knowledge generated by the technology is not well understood or trusted* • *There is not yet evidence from prototyping that intended users find the technology easy to use without human support (e.g. clinician, carer or help desk)* • *There is not yet evidence from prototyping that the technology is acceptable to its intended users (e.g. that it generates data that are well-understood and trusted, and which reflect how their condition is normally managed)*	X		
There are significant technical interdependencies *e.g.* • *A key technology needs to be installed across multiple technical systems so as to achieve 'integration'* • *The technology cannot be installed until the organisation's IT system is upgraded or changed (e.g. new hardware, better bandwidth)* • *The technology would require individual users to upgrade their device(s) or home IT system* • *The technology overlaps (unproductively) with an existing technology that performs the same or a similar function*	X		

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The technology is likely to require major changes to organisational tasks and routines *e.g.* • *Implementing the technology means some staff will have to do their jobs in a different way and/or interact with different people* • *Implementing the technology will require new or different steps in the overall care pathway (e.g. new administrative processes)*	X		
The technology (and/or the service model it supports) is likely to change significantly within the next 3-5 years *e.g.* • *The technology has limited potential to be adapted to take account of future clinical developments and other changes* • *The technology supply model may not be sustainable (e.g. the client-supplier relationship is weak, or there are questions about the company's reputation)*	X		
SUMMARY: The technology has significant complexity which is likely to affect the project's success	x *Yes*	 *No*	

3. THE VALUE PROPOSITION (costs and benefits of the technology) [the technology developer and business lead for the organisation might complete this section]

Describe the value (financial or otherwise) that the new technology and care model might generate.
For commercial stakeholders, this may be return on investment. For patients, it may be cure, comfort, or quality of life. For healthcare organisations, it may be improvements in quality of care, efficiency (saving time, freeing up staff), safety (including reduced risk of litigation), or inclusivity.

Commercial stakeholders

Work to define the commercial value of the technology will be addressed in WP7 therefore the commercial value of the technology is currently uncertain.

Patients

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It is anticipated that the technology will positively impact on health related quality of life and health outcomes of patients. The system permits remote monitoring of patients and encourages patient empowerment and self-efficacy. By improving and supporting self-management at home the technology will reduce the demand on face-to-face appointments and allow for better control of symptoms and disease progression. AI technology also aims to predict decompensations and prevent hospitalisation of patients.

The value of the technology to the patient will be investigated during the pilot.

Healthcare professionals

The technology will facilitate the delivery of real-time information and what that might mean for each patient's care to HCPs. This should help HCPs prioritise workloads and help them monitor patients remotely and control and optimise medicines.

The value of the technology to healthcare professionals is under investigation by means of the pilot.

Healthcare Organisation

It is uncertain how or where the technology would fit into the NHSCT organisation. There will need to be changes to care pathways and processes to be able to provide a service that incorporates this type of technology.

The value proposition is likely to change significantly over the next 3-5 years.

The following questions address what kind of value the technology might generate for different groups of people. For suggestions for responding to complexity in this domain, see page 14.

IDENTIFYING COMPLEXITIES IN THE VALUE PROPOSITION:	*Agree*	*Disagree*	*Not applicable or don't know*
The commercial value of the technology is uncertain	X		

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e.g. • *If the technology does not yet exist in a definitive form, the case for investing in its [further] technical development is weak* • *The technology does not have a plausible business case, including up-front investment, a well-defined customer base and market drivers, consideration of competing products and realistic assessment of challenges of implementing at scale in a public-sector health or care environment*			
The value to the patient or client is uncertain *e.g.* • *There are no high-quality studies (e.g. randomised controlled trials) to demonstrate the technology's efficacy for this patient/client group* • *The technology's benefits have not been shown to outweigh its potential harms* • *The technology's efficacy and safety were not measured in terms of an outcome that matters to patients*			X
The value to the clinician or other staff member is uncertain *e.g.* • *The technology may create work (or other hassles) for the front-line staff* • *The technology's benefits have not been shown to outweigh the hassle of using it*			X
The value to the healthcare system is uncertain *e.g.* • *The technology (or the technology-supported care model) is not considered to have any overall advantage over existing practice* • *The technology has not yet been shown to be effective and cost-effective in terms of how much benefit it will bring for a given financial outlay* • *There are safety concerns about the technology or care model* • *This technology-supported care model has not yet been successfully implemented in a similar context to the one being contemplated* • *There are concerns that the technology, whilst improving care for some patients, could widen inequalities* • *Regulatory and other approvals for the technology are not yet in place*			X
The value to this particular healthcare organisation is uncertain *e.g.* • *The technology will require new technical infrastructure before it can be introduced to this organisation (see Technology domain)* • *The technology will require extensive changes to organisational routines and pathways (see Technology and Organisation domains)* • *Aspects of the local procurement processes make it hard to commission this technology (see Organisation domain)*			X
The technology could generate a negative value (i.e. costs are likely to outweigh benefits) for some stakeholders. *e.g.* • *Potential loss of income* • *Destabilising a provider* • *Hidden or knock-on costs*			X
The value proposition is likely to change significantly over the next 3-5 years. *e.g.* • *A new, better technology is on the horizon* • *The market for the technology will change significantly*	X		

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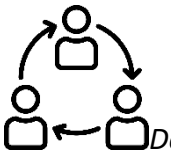
A key regulatory decision could be made or reversed)			
SUMMARY: The value proposition has significant complexity which is likely to affect the project's success	☐ *Yes*	☒ *No*	

4. THE INTENDED ADOPTERS OF THE INNOVATION/TECHNOLOGY

[this section should be completed by, or on behalf of, everyone who might use the technology]



Describe the intended users of the technology or other innovation. Consider: patients/lay people, professionals, administrative and support staff. Are there people who will be impacted indirectly (e.g. clinicians may be the main users but admin staff may need to adapt their procedures)?

Phase 2/3 feedback will investigate user experience and aims to enhance it before the pilot. User experience will be evaluated during the pilot to identify adoption issues and track usage.

There is uncertainty about whether and how patients/carers or citizens will adopt the technology

The intended adopters of the technology are primarily multi-morbid older individuals. The input required from this group will be substantial but could vary between users and still be of benefit. Input may range from the minimum required (i.e., taking measurements using devices but not actually logging into the app) to full engagement with all the available features. User testing and prototyping in Phase 2 and 3 aims to help enhance the user experience before the technology is piloted in Phases 4 and 5. User experience evaluation will aim to capture how well the technology is adopted by patients. Patients may view the technology negatively by reminding them of their medication conditions and need for frequent monitoring of vital signs. A high proportion of intended adopters may be unwilling and unable to learn to use the technology.

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Carers and families may play a role in supporting someone to use the technology, however, the technology has not been specifically developed for this purpose.

There is uncertainty about whether and how front-line staff will adopt the technology

Use of the technology to monitor and care for patients should not be significantly different to the way front-line staff currently practice in secondary care with regards to the type of data they will be monitoring and the interventions they will be making. However, adoption of the technology would require redesigning the service model and it is yet uncertain how this would be viewed by staff.

There is uncertainty about the implications for people who might be indirectly affected by the technology

It is uncertain where the technology would sit within the current service to patients with heart failure and diabetes. Input may be required from carers or family members to support the individual to use the technology and it is uncertain what their views on this are.

It is not know where technical support for use of the technology for HCPs will come from. It may increase the demand on ICT services.

Patients may request help or advice from other local health and care providers who will not be familiar with the technology and so cause confusion.

There will be significant changes to individual users' perceptions of the technology over the next 3-5 years

The use of technology and remote healthcare has dramatically increased since the start of the COVID-19 pandemic. Users perceptions are changing and people are becoming more familiar with using technology to communicate remotely, especially older individuals.

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The following questions will help you summarise whether people directly involved with the technology understand what it is for, think it is worth trying, feel able to use it and are motivated to give it a go, and also what the indirect knock-ons may be for others. For suggestions for responding to complexity in this domain, see page 14.

IDENTIFYING COMPLEXITIES IN THE INTENDED ADOPTERS:	*Agree*	*Disagree*	*Not applicable or don't know*
There is uncertainty about whether and how patients/carers or citizens will adopt the technology *e.g.* • *The technology would require substantial input from the patient or their immediate carer* • *Some patients will view the technology in a negative way (e.g. not appropriate for their home, or reminding them of an illness they'd prefer to forget about)* • *Quite a few people in the intended user group may be unable or unwilling to learn to use the technology*	X		
There is uncertainty about whether and how front-line staff will adopt the technology *e.g.* • *Some staff members question the value proposition for the technology (e.g. they feel that adopting it would jeopardise the quality or safety of patient care, or they believe it is more time-consuming than existing practice)* • *The technology would require staff to do their jobs differently, and perhaps take on a new, unwanted, role and identity (e.g. 'data entry person')* • *Some individuals or teams do not have the resources, time, space or support to learn to use the technology* • *Staff have not been trained or supported to be creative and flexible when implementing technologies*	X		
There is uncertainty about the implications for people who might be indirectly affected by the technology *e.g.* • *The technology would require input from others (e.g. relatives, care home staff), who may be unable or unwilling to learn to use it* • *The technology would make someone else's job obsolete or more difficult*	X		
There will be significant changes to individual users' perceptions of the technology over the next 3-5 years *e.g.* • *Key staff groups are likely to change their views on the technology*	X		

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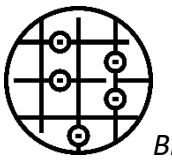
• *Patients or their lay carers are likely to change their views on the technology*			
SUMMARY: There is significant complexity relating to the intended adopters which is likely to affect the project's success	X *Yes*	*No*	

5. THE ORGANISATION(S) IMPLEMENTING THE TECHNOLOGY

[this section is best completed by people who know the organisation and the challenges it faces e.g. board member, human resources lead, staff representative]



Briefly describe the organisation(s) involved in the project (for example, digital agency, healthcare provider, social care provider). What kind of organisation is it? How is it structured – and what is it like to work there? What is its track record of taking up new technologies? How well-resourced is it

(in terms of both staff and funding)? Is there much enthusiasm for this particular technology?
You may need to complete this section separately for the main and partner/ impacted organisations (and use the highest complexity score in your planning, since the initiative will only be as strong as its weakest link).

The pilot site leader is a research and innovation organisation working within a healthcare provider. The organisation has a good culture with regards to taking on technological innovations that are based on evidence. It is too early in the project to determine readiness of the organisation to take on this particular technology.

Although general approach to adopting and commissioning new technologies is good at the organisation there are other factors that need to be considered that could influence the decision to commission the technology. E.g., organisational change, funding streams (resourcing inc. staffing), system administration and infrastructure and care pathway redesign.

The following questions will help you assess whether the organisation is capable and ready to take on the innovation, and whether the work involved has been understood and planned for. For suggestions for responding to complexity in this domain, see page 15.

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IDENTIFYING COMPLEXITIES IN THE ORGANISATION(S):	*Agree*	*Disagree*	*Not applicable or don't know*
The organisation's capacity to take on technological innovations is limited *e.g.* • *Leadership is weak and the organisation's mission and values are unclear* • *Internal relations, especially between managers and clinicians, are poor* • *The structure is top-down and hierarchical, so individual departments are discouraged from horizon-scanning for new products and ideas, and have limited scope to introduce innovations* • *The organisation has a poor track record of introducing any kind of change* • *There are no slack resources (people or money) to channel into innovative projects* • *It is not a learning organisation: staff are not encouraged to meet and talk about new ideas and projects, there are few or no measures in place to capture data and monitor progress, and risk-taking is discouraged* • *Digital maturity is low*		X	
The organisation is not ready for this particular innovation *e.g.* • *The fit between the organisation's mission and the innovation is poor* • *Key people (especially senior management) oppose the innovation or are unconvinced of its value* • *The business case is weak or questioned (see Value Proposition domain)* • *The implications (e.g. work required) of introducing, implementing and evaluating the technology have not been adequately assessed (or have been questioned)* • *Money is needed but a budget line has not been allocated*			X
Organisational routines and processes will need to change very considerably to accommodate the technology *e.g.* • *Different kinds of staff (e.g. new hires) will need to be involved in the process or pathway once the technology has been introduced* • *A new (or radically revised) process or pathway will need to be developed* • *The core process or pathway will need to link differently with other key processes and pathways in the organisation*			X
Procurement processes are in place that make it harder to commission this technology *e.g.* • *The provider is not on the procurement framework* • *Existing contracts need to expire first* • *Aspects of the procurement process are not yet clear (e.g. Who will fund this? Who will be liable for costs? Is there an identified budget? It is capital or revenue ? Is the funding recurrent? Are there issues with timing/accruals of funding?)*			X
The work needed to introduce and routinise the innovation has been underestimated and/or inadequately resourced *e.g.* • *Work to bring people on board and develop a shared, organisation-wide vision for the change* • *Work to develop, implement and mainstream new care pathways and processes* • *Work to coordinate the project across more than one organisation or sector*			X

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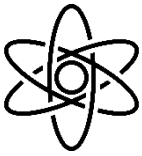
• *Work to evaluate and monitor the change*			
The organisation(s) involved are likely to have significant restructurings or changes in leadership, mission or strategy over the next 3-5 years			
SUMMARY: There is significant complexity relating to one or more participating organisations which is likely to affect the project's success	X *Yes*	*No*	

6. THE EXTERNAL CONTEXT FOR INNOVATION

[this section might be completed by a 'horizon-scanner' who looks beyond the organisation]



Describe the national and local context for your technology or programme (e.g. legal obligations, policy, professional bodies views on best practice, related national initiatives). Think about the key influences on the project beyond the organisation(s) you identified in the previous section.

It is too early in the project to know how the external context are likely to complicate

The policy, regulatory and economic context for this innovation is likely to be turbulent over the next 3-5 years

Although Brexit will have little impact on the current research project that is underway, it is unknown how the SHAPES platform will be able to function within the UK since the UK left the EU. We are also facing economic recession in the wake of the Covid-19 pandemic. There is likely to be a lot of turbulence within the policy, regulatory and economic context over the next 3-5 years.

The following questions will help you summarise whether there are external conditions (such as the state of policy, public/ professional opinion, expected external events such

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as political climate change) likely to complicate the adoption and mainstreaming of the innovation. *For suggestions for responding to complexity in this domain, see page 17.*

IDENTIFYING COMPLEXITIES IN THE EXTERNAL CONTEXT:	*Agree*	*Disagree*	*Not applicable or don't know*
The political and/or policy climate is adverse *e.g.* • *External political or economic changes impacting on the organisation could threaten the introduction of the innovation* • *Current policy priorities conflict with this initiative*		X	
Professional organisations are opposed to the innovation or don't actively support it *e.g.* • *There are concerns about quality or safety of care* • *There are concerns about confidentiality and wider information governance* • *There are concerns about professional workload* • *Priorities are elsewhere*		X	
Patient organisations and lobbying groups are opposed to the innovation or don't actively support it *e.g.* • *There are concerns about quality or safety of care* • *There are concerns about privacy and/or what will happen to the data* • *Priorities are elsewhere*		X	
The regulatory context is adverse *e.g.* • *Quality standards and regulatory requirements for using the technology in a health or care setting have not been fully defined* • *Key stakeholders do not know about or accept these standards and requirements*		X	
The commercial context is adverse *e.g.* • *The technology industry views the innovation (or similar products) negatively* • *The technology does not use industry-standard components* • *There is lack of support for timely updates to the technology to support ongoing work as intended*		X	
Opportunities for learning from other (similar) organisations are limited *Additional detail* • *No other similar organisations are yet using the technology* • *Inter-organisational knowledge exchange networks are weak*		X	
Introduction of the technology/innovation could be threatened by external changes that impact on the organisation			X
The policy, regulatory and economic context for this innovation is likely to be turbulent over the next 3-5 years	X		

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e.g. • *Change of government* • *New policy priorities* • *Economic recession* • *New regulatory framework* • *Withdrawal of industry commitment*			
SUMMARY: There is significant complexity relating to the external context which is likely to affect the project's success	X *Yes*	 *No*	

7. EMERGENCE OVER TIME

[this section pulls together the bottom row of each of the previous domains]

Summarise the main changes which, if they happen, could affect the project over the next
3-5 years. Which of these do you think is most significant? What are the key uncertainties?

- How future-proof the technology is in a rapidly changing industry, e.g., 5G
- The value of the SHAPES ecosystem has not been determined. Longitudinal impact of the platform not currently being explored.
- User experience and engagement is very uncertain. Traditionally age group have been slower to adopt new technologies. This may have changed since COVID.
- Organisational change is inevitable. We don't know what impact this will have.
- The next 3-5 years are likely to be very turbulent and will see much change in the policy, regulatory and economic context. Resources may be directed towards acute care and emergency preparedness and less towards management of chronic conditions.

For suggestions for responding to complexity in this domain, see page 18.

ESTIMATING WHAT THE FUTURE HOLDS:	*Agree*	*Disagree*	*Not applicable or don't know*
The population with the condition, and/or how the condition is treated, is likely to change significantly over the next 3-5 years		X	

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The technology (and/or the service model it supports) is likely to change significantly over the next 3-5 years	X			
The value proposition for the technology is likely to change significantly over the next 3-5 years	X			
There will be significant changes to individual users' perceptions of the technology over the next 3-5 years	X			
The organisation(s) involved are likely to have significant restructurings or changes in leadership, mission or strategy over the next 3-5 years.				
The policy, regulatory and economic context for this innovation is likely to be turbulent over the next 3-5 years	X			

PART 2: ACTION PLANNING AND PROJECT MAGAGEMENT

Taking account all your responses to Part 1, this section prompts you and your team to **plan your implementation project** and consider measures to **reduce or respond to complexity** in the different NASSS domains. Below, we offer some ideas and resources to get you started. The resources and links have been selected for a UK setting but could easily be adapted for other countries.

Planning your implementation project

Skim this section first – but then go on to look at the different complexities and ideas for responding to them. You may end up deciding not to go ahead with the project at all.

Project management in a highly predictable environment is fairly straightforward, but under conditions of complexity, things can't be fully predicted or laid out in advance. You need to set a broad goal, take action on several fronts simultaneously (making sure you attend to the human and political aspects of the project as well as the technical and financial aspects), while periodically reviewing progress and adjusting your strategy.

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For large, ambitious projects, we recommend the Project Initiation Routemap, a guide by the UK government for planning complex projects in the public sector. The Routemap emphasises three linked strategic tasks:

- Assess the complexity and context of the delivery environment (see NASSS questions above, especially Domain 2 'The Technology' and Domain 5 'The Organisation'), and consider how you could respond to this complexity (see suggestions below);
- Assess the capacity and capability of organisations and teams to deliver the project (in particular, sponsor, senior management buy-in and support, dedicated delivery team);
- Work to strengthen and align context and capability (e.g. align requirements, governance, execution strategy, organisation design and development, procurement, risk management, asset management).

See also the NESTA DIY toolkit for bringing ideas to life (designed for social care providers) – a structured way to get from the initial idea for a new technology to a well-designed project to get it up and running in a service.

Due diligence. Before investing in a technology, make sure the company selling it is legal and solvent, that the technology has the requisite regulatory approvals, that personal data is handled sensitively and respectfully, and that any associated risks have been considered. There are numerous due diligence checklists available – see these for example:

UK government digital service standards – a 14-point checklist when planning a service that involves digital technology. Linked to these are UK government technology and digital standards.

How to do due diligence for health care technologies – introductory blog from private company SecureDocs.

Digital Assessment Questionnaire from NHS Digital, a self-assessment checklist for apps and similar technologies.

Medical devices – software applications – Advice from the UK government on when software applications are considered to be a medical device and how they are regulated.

NHS Health and Social Care Data Security Standards (including a full due diligence checklist for suppliers).

UK government code of conduct for data-driven health and care technology – Principles and advice for machine learning applications that use NHS data.

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Commercialising new technologies. If you are developing a new technology and you think it has commercial potential, you will need to systematically demonstrate to investors how it will generate value. Try this resource:

Guidance and Impact tracking System (GAITS) – a web-based project and portfolio management platform designed to support commercialisation of new health technologies, developed by the US consultancy firm CIMIT.

Adoption Readiness Level tool by Liverpool City Region's e-health cluster – a self-assessment tool for tech developers that considers five domains (market, human, systems integration, finance/procurement, motivation).

Responding to complexity in the illness or condition

Your first step in developing technological solutions for an illness or condition is to understand the full range and depth of what the illness *is* and how it affects people.

Find out more about the illness. For example, find the prevalence, likely progression, and current 'best practice' care model. This will allow you to estimate how many users a product is likely to have, how long they can/will use it for, and how this fits with current care. Remember, there will be 'mild' and 'severe' forms of the illness, different age groups, ethnicities, genders and so on. Once you understand how the illness is patterned, this could inform work to 'personalise' the technology for different sub-groups (see 'Responding to complexity in the intended users' below). To learn about the illness, use different data sources, e.g. from national and regional databases, academic and grey literature, health and care practitioners, patient organisations, patients. For example:

NHS Choices – a searchable database of illnesses, including diagnosis, treatment and likely course

NICE guidelines - evidence-based recommendations in a variety of conditions, procedures and technologies across health and social care developed by independent committees

Cochrane library – a database of high-quality systematic reviews of treatments

Healthtalk – a database of patients' accounts of what it's like to live with different illnesses

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Macmillan – a website for people with cancer, with detailed information on prevalence, treatment and prognosis. There are similar patient-facing websites for most conditions. Explore them!

Responding to complexity in the technology(ies)

Don't make the mistake of treating a new technology as a plug-and-play solution. You need to ask a lot of questions about it before you can be sure it's the right tool for the job. New technologies often look appealing and promising until we consider all aspects of the innovation process.

Find out more about the technology and assess its quality and implications. If you are not the creator of the technology, familiarise yourself with all relevant aspects of it or ask an expert. Look at it; play with it; do a 'walk through' the imagined use case. Will this product really help with what you are planning to achieve? Could a different technology (perhaps one that is already tried and tested) do a similar job with less hassle?

NHS apps library – a searchable database of quality-assured smartphone health apps

Publicly available 'curated' databases of apps – for example:

- Psyberguide for mental health apps
- ORCHA, an independent organisation that evaluates apps

Find out more about where the technology will come from and associated challenges. Ideally the building blocks for your chosen technology e.g. coding platform, devices etc can be accessed or purchased easily (no long waiting periods or unreliable supply chains). Ideally, the technology should not depend on a single vendor/device/coding language etc, but work (or have the potential to work with or easily change to) others as well. They will have been tested extensively so you don't have to worry about these components being dependable. Conflicts of interest and claims to intellectual property (IP) should be sorted out before the project begins. It should be clear who will fund the technology, what it will cost and which costs are covered (set up, maintenance, updates etc).

Identify and address the key points where technical complexity will impact on success. Find out about any unknowns and dependencies as soon as possible, and develop a plan to deal with them, including alternatives or workarounds. Reduce unnecessary technical integration. Integration between multiple systems makes everything more complex. Ask whether it is

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really necessary or if there are ways to avoid or delay this, especially during initial testing. But bear in mind that some forms of technical integration (e.g. to make a new piece of software accessible from within a patient's existing electronic record) may make the technology *simpler* for a clinician to use.

Consider how the technology will disrupt the system. Map possible disruptions and take steps to avoid or mitigate them. Can you modify the technology to make it less disruptive? Can you reduce knock-ons by adjusting other systems or processes? What measures might you put in place (e.g. small-scale pilot running in parallel with the old service, on-the-job training, help desk) to deal with the disruption until systems and processes have evolved to accommodate the new technology? We pick up this important point again under 'the organisation' below.

Responding to complexity in the value proposition

This project is only going to work if all stakeholders gain something of value from it.

Consider how to increase the technology's appeal to investors. If the technology is at an early stage of development, what is its likely upstream value as viewed by investors (especially the business case for generating profits, further spin-offs, and highly qualified jobs), drug and device regulators (preliminary evidence of efficacy and safety), and financial regulators (auditable business processes and governance)? Can the technology be 'de-risked' by removing costly but inessential features? See the Guidance and Impact tracking System (GAITS) resource linked above.

Consider how to increase the technology's value to patients or citizens. If a technology is meant to be used by patients or lay people, its potential benefits must be weighed against its costs (and the person's willingness and ability to contribute to these), the work needed to use it (and whether the person or their carer is able and willing to do that work), and the desirability of medicalisation and surveillance. Can the design be improved to make the technology more appealing? Can the data be visualised in a way patients or carers can engage with?

See links above under 'Responding to complexity in the illness'

Getting the most out of PROMS – A guide to using patient-reported outcome measures to assess whether an intervention or technology is actually improving outcomes that are valued by patients

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A guide to PROMs methodology from NHS Digital (using hip and knee replacement as an example)

Identify evidence of effectiveness and cost-effectiveness. If the technology is at a more advanced stage of development, there may be research evidence comparing its effectiveness (does it work?) and cost-effectiveness (is it good value for money?) with 'usual care' and measuring an outcome that is important to patients. Try these resources:

NICE Evidence Standards for digital health technologies – These cover both effectiveness and economic impact.

Consider real-world value issues. Is there a realistic assessment of the challenges of implementing this innovation at scale in a particular public-sector health or care environment? Even when something has been shown to be cost-effective, it may not be locally affordable or a funding priority.

The NICE Evidence Standards website linked above offers a budget impact guide and budget impact template for local cost planning.

Responding to complexity in the intended adopters of the technology

This project is only going to work if the people you want to use the technology are able and willing to do so.

Address acceptability, accessibility and usability for patients and citizens. If the technology requires input from a patient, carer or other lay person, will they find the product aesthetically pleasing and easy to use? Does the technology make sense, for example, in the context of how patients and carers already do things, their routines and existing tools they use to support their work? Remember, everyone is different. Some people have limited vision or dexterity; some people find instructions hard to understand. Can you make the product more accessible? Is it worth building design changes in now or planning to do so in the future (e.g. after proof of concept testing)? If the technology includes several components, can users select what is most relevant for them? These resources may help:

How to do research on user needs in the 'discovery phase' of technology design – a website from the UK government.

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International Design Foundation – a US site offering tips and resources for making websites and apps more accessible.

How to design websites for older people – a guide from the Alzheimers Society.

Address staff motivation and concerns. Assess the level of enthusiasm for the technology from different staff groups, and also how motivated teams are to take on the new technology. Have any of them had experience of using this technology elsewhere? Listen to staff concerns – which may be legitimate – and to their ideas for increasing the project's success. This resource may help:

Higher Education England Digital Capabilities Framework for assessing the digital capability of staff.

Modify staff roles and provide training. Develop new roles and job descriptions where needed, perhaps by adapting ones already in use elsewhere. Set learning objectives (some of which will be about building confidence to make judgements, not about mechanically following protocol). Design and develop training courses. Remember: using a technology usually needs on-the-job and team-based training, not just sitting in classrooms. Allocate sufficient budget for this work, and consider issues such as backfill.

Promote social learning. One way to become confident in using a technology is to shadow someone in the same role who is already an enthusiast for it ('champion') and confident in using it ('super user'). Learning in this way not only develops skills but also helps people develop a positive attitude and identity.

Support collective sensemaking and communities of practice. People need to make sense of new technologies – sometimes by coming together to complain about them initially! Surfacing one's irritation with a technology may be the first step to coming to terms with it. Both staff and patients may benefit from being in 'communities of practice' (groups or networks of people who share an interest in something and are trying to get better at it). Online communities of patients, for example, are often good sources of knowledge and wisdom about how to manage a condition. Try to get these communities on board if introducing a patient-facing technology.

The Kings Fund guide to engaging NHS staff may provide some practical ways of achieving the above.

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Responding to complexity in the organisation

The project is only going to work if the organisation has the capacity to take on innovations and if there is good 'innovation-system fit'. The tips below may help if you are trying to support an organisation to implement a new, technology-supported care model.

Assess the organisation's capacity to innovate. An innovative organisation has strong leadership, good clinician-managerial relations, a devolved management structure, slack resources (money and/or staff) that can be channelled into new projects, good lines of communication and an ethos where it's OK to take risks and learn from failures. If an organisation appears to lack these essential prerequisites for innovation, consider whether you need to strengthen its capacity before pressing ahead. Here are some questions to help you assess capacity to innovate:

- Is there a culture that supports innovation and change (e.g. are staff trusted to introduce new ideas)?
- Does the organization have systems and processes in place that support innovation and change e.g. effective information and communication systems, opportunities for networking and learning across departments/teams?
- Do the senior management team actively seek opportunities for improvement and encourage ideas and feedback from patients, the public and staff?
- Are the organisation's leaders helping to create a facilitative context through providing motivation and support, creating a vision and reinforcing the change process?
- Is there a distributed and devolved style of management?
- Is there a history of introducing successful change in comparable projects at a local level?
- Are there mechanisms in place to support learning and evaluation and to embed changes in routine practice e.g. regular team meetings, audit and feedback processes, professional development opportunities and performance review systems?

Assess innovation-system fit. Even when an organisation is capable of running a successful project to implement a new technology, it might be the wrong technology to introduce in this organisation right now. Has the organisation successfully adopted similar technologies in the past? Are its strategic priorities aligned with the use of the proposed technology? Or are other projects more pressing?

Assess the implications of the technology for the organisation. Careful mapping out of tasks and processes is necessary to surface how the technology or other innovation is likely to change these. The pathway in which the technology is used directly (e.g. clinical care) may have indirect knock-ons for other processes and pathways (e.g. booking, correspondence, billing). You need to estimate costs (both initial and recurrent), and consider how money will need to flow across the system. Before signing off on a project, boards generally want to know how much will it cost up-front, what the likely savings will be, and when these savings will occur. These resources may help:

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Process mapping guide from NHS Improvement. Ideas and tools for mapping the steps in a care pathway. A full list of additional service improvement and redesign tools from NHS Improvement is available here.

Using costing information to support better outcomes – a guide from NHS Improvement.

Assess the level of 'political' backing for the innovation. For an organisational-level adoption decision to be approved, it needs support from both top management (a 'senior sponsor') and the rank-and-file. Supporters of the change must outnumber opponents and be more strategically placed. People with 'wrecking power' can block progress and may need to be brought on board (or worked around). To assess all this, use the NASSS-CAT PROJECT tool and also:

Stakeholder analysis guide from NHS Improvement. This guide will help you construct a table or chart listing all the stakeholders who will need to accept (and, in many cases, start to use) the technology. Consider each key stakeholder's perspective (and their potential wrecking power).

Consider inter-organisational relationships. Costs and benefits of technology projects are hard to predict, and savings may accrue elsewhere in the system. When there is no pre-existing contractual relationship between organisations, it can be hard to reach a satisfactory arrangement for how to manage these uncertainties.

Think how (and by whom) success will be evaluated. If this project is going to happen, you will need to monitor how well the change is going. You will almost certainly need both quantitative metrics (to answer the "how many…?" and "are we on track…?" questions) and also qualitative measures (to answer the "how do people feel about this…?" questions). Evaluation is everyone's job, and data are often best collected by people doing the job. Extensive data collection can be time-consuming and slow the project down (i.e. the perfect may be the enemy of the good).

Evaluation: what to consider – A guide by the Health Foundation. This basic guide includes qualitative and quantitative approaches.

The 'rainbow framework' for evaluation and monitoring by Michael Quinn Patton. It takes you through 7 colour-coded steps, namely Manage (e.g. define stakeholders, secure funding), Define (set a scope for the evaluation), Frame (intended users of the evaluation, what they will use it for, what success will look like), Describe (sample, measures/metrics, data sources, analytic approaches), Understand Causes (deeper analysis to produce explanatory models), Synthesise (combining results), and Report & Support Use (publishing and disseminating).

Evaluation Works and Evidence Works toolkits to guide commissioning decisions, produced by West of England Academic Health Sciences Network and their partners.

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Allocate funding. Studies of 'failed' technology projects often identify inadequate funding as a leading cause. You will probably need substantial set-up funding and possibly a recurrent budget line (for things like licences and IT support). Budget adequately for staff to learn and adjust as the transition occurs (see 'Responding to complexity in the intended adopters' above).

Manage the transition. Good change management involves a combination of 'hard' and 'soft' approaches. As well as setting goals and milestones and using agreed metrics to monitor progress, you also need to create opportunities for staff to come together and talk about the technology and new care model. As noted above, collective sensemaking, training (especially on-the-job training for both individuals and teams) and social learning from champions and super-users is crucial for building capacity. Use creative tools such as flip-charts and post-it exercises to surface people's interpretations and concerns. Invite them to come up with creative ideas and solutions to any problems they identify. Allocate sufficient budget for this work, and consider issues such as backfill. This guide may help:

Leading large-scale change: a practical guide from NHS England.

Responding to complexity in the external environment

Plans for technology-supported change locally are unlikely to work out if there is a major mis-match with national policy or the prevailing political, economic or professional environment.

Try to align your project with current policy priorities. If the technology is actively supported in policy, it will be easier to introduce. If priorities are elsewhere, it may be worth trying to 'rebrand' the work to fit these.

Address regulatory issues and challenges. Consider which regulations (from which regulatory bodies) are relevant to the introduction of this technology. Are all approvals already in place? If not, who do you need to work with to make progress in this regard? See 'Due diligence' section on page 12.

Get the professions on board. If clinicians or social workers believe that the technology compromises the care of their patients or clients, or if they view it as demeaning to their role or a threat

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to their professional jurisdiction or income, their professional bodies may oppose it. Early dialogue with such bodies may avert such a situation.

Establish inter-organisational networks or collaboratives. Complex, organisation-wide change is a lot easier if change agents in one organisation can network with their opposite numbers in comparable organisations – for example in quality improvement collaboratives or learning sets. Here's a resource for that:

Improvement collaboratives in health care – A guide from the Health Foundation.

Keep a close eye on the outer context. External shocks to an organisation (such as economic turbulence) make change precarious. Whist such shocks are often hard to predict, it is a good idea to see what's on the horizon. The following questions may help you:

- Does the new technology and the proposed changes to services align with the strategic priorities for the wider health system e.g. in terms of current health policy, national priorities for action and improvement?
- Are there incentives in the wider health system that reinforce the proposed change e.g. pay for performance schemes, regulatory requirements etc.?
- Are there existing inter-organisational networks (e.g. specialised clinical networks) that will be helpful in terms of supporting the proposed changes?
- How much stability/instability is there in the wider health system – and how might this likely influence the implementation project?

Responding to emergent complexity (new complexities that develop over time)

The point about emergent change is it's difficult if not impossible to predict. So this domain is really about how you might build resilience in your staff and your organisation to enable them to respond to things that come up in the future.

Acknowledge unpredictability. Have you left open the possibility that the project might unfold in one of several different ways? Can you flesh out these different possible futures and talk them through with your stakeholders?

Recognise and support self-organisation. Front-line teams will 'tinker' – that is, try to adapt the technology and the work process to make them work better locally. Are you able to capture data to evaluate and support these efforts?

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Facilitate interdependencies. Have you identified the key interdependencies in the project? Is there anything you can do to strengthen existing interdependencies or develop and strengthen new ones?

Maintain space for experimentation and sensemaking. As complex projects unfold, staff will need to tinker more, and also talk about what's happening. Encourage them to admit ignorance, explore paradoxes, exchange different viewpoints (there's no need for them to agree on a single version of the 'truth'!) and reflect collectively.

Develop adaptive capability in staff and teams. Train your staff to be creative and to adapt to change as it happens. They will sometimes need to make judgements in the light of incomplete or ambiguous data.

Attend to human relationships. Dealing with emergent problems requires give-and-take. It's sometimes a matter of muddling through. This will happen more easily if people know, like and trust each other.

Harness conflict productively. There is rarely a single, right way of addressing a complex problem, so view conflicting perspectives as the raw ingredients for producing multifaceted solutions.

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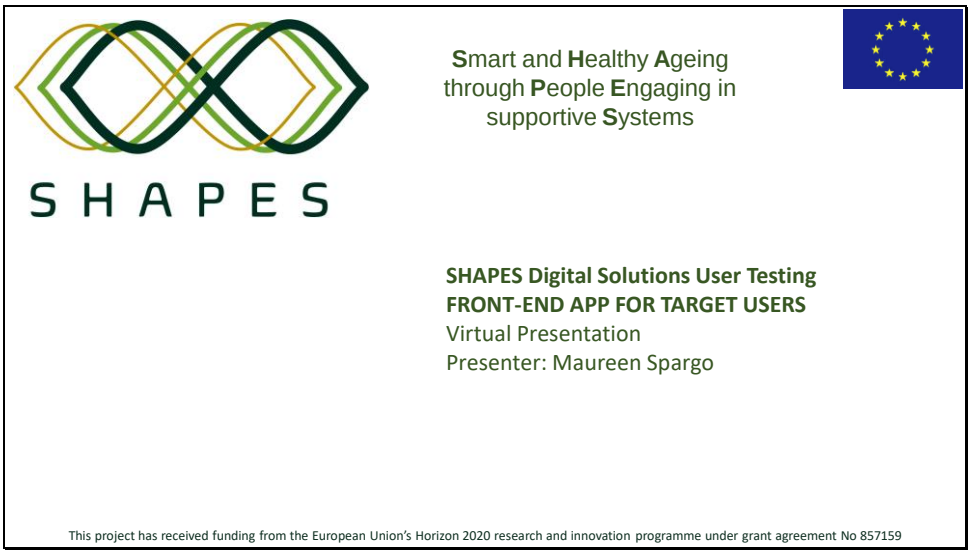
Annex 4 UC-PT3-gen Phase 2 Participant presentations

Slide 1



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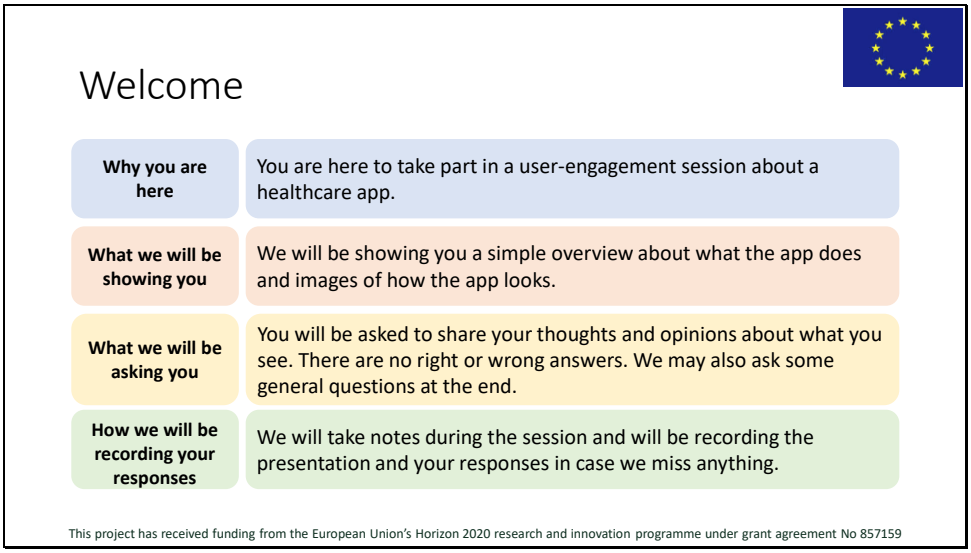

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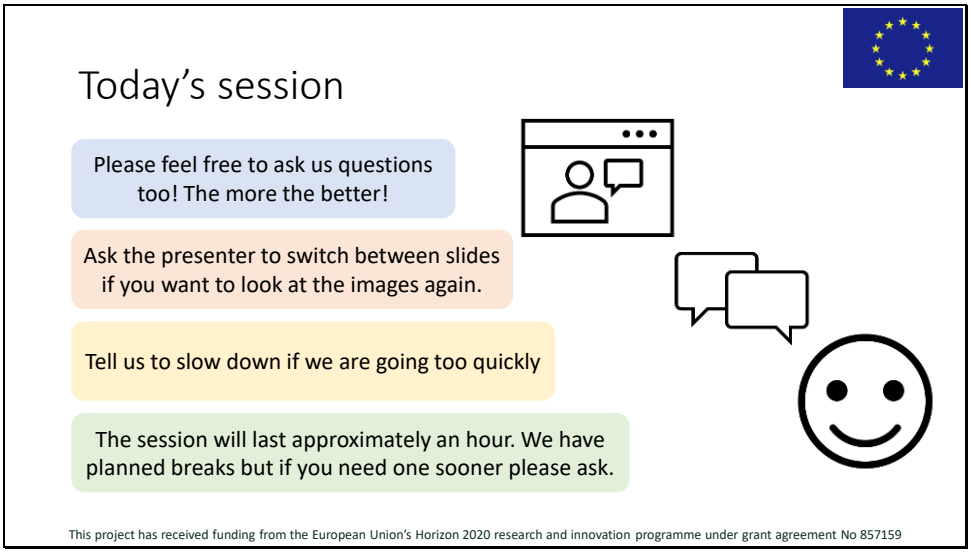

Slide 4

What is SHAPES?

SHAPES is a European research programme that is exploring how technology can enable older people in our communities to live healthier lives for longer at home.

Research studies are being conducted across Europe to determine if certain technologies (e.g., mobile phone apps, home sensors, robots etc.) can helpfully support people aged over 65 years in seven key areas.

Here in Northern Ireland we are investigating how we can use a mobile phone app to support the **safe and effective use of medicines** by people at home.

As per your consent, we are going to start recording this meeting.

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Slide 5

The healthcare app

A mobile phone app is being developed to help people manage their health and medicines from home

Features of the app include:

- Heart and diabetes monitoring
- Daily symptom check
- Medication list
- Medication reminders
- Weekly medicine use review

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Patients will be given a set of devices that they will use at home to monitor their chronic condition.

Scales to measure weight

Glucometer to measure blood glucose

Blood pressure meter

Pulse oximeter to measure heart rate and oxygen

The devices are linked with the app so the readings automatically get recorded in the app. Patients can also manually enter readings if they need to.

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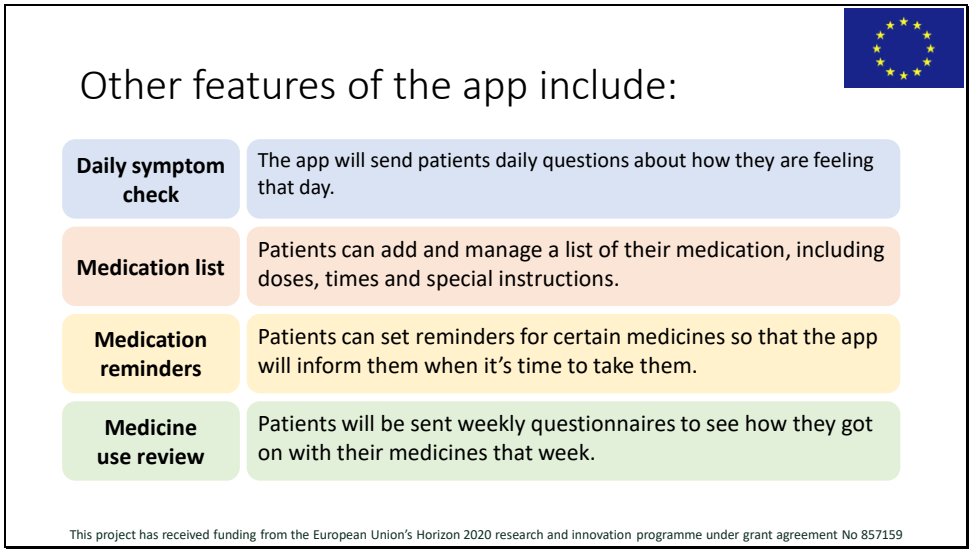
Slide 7



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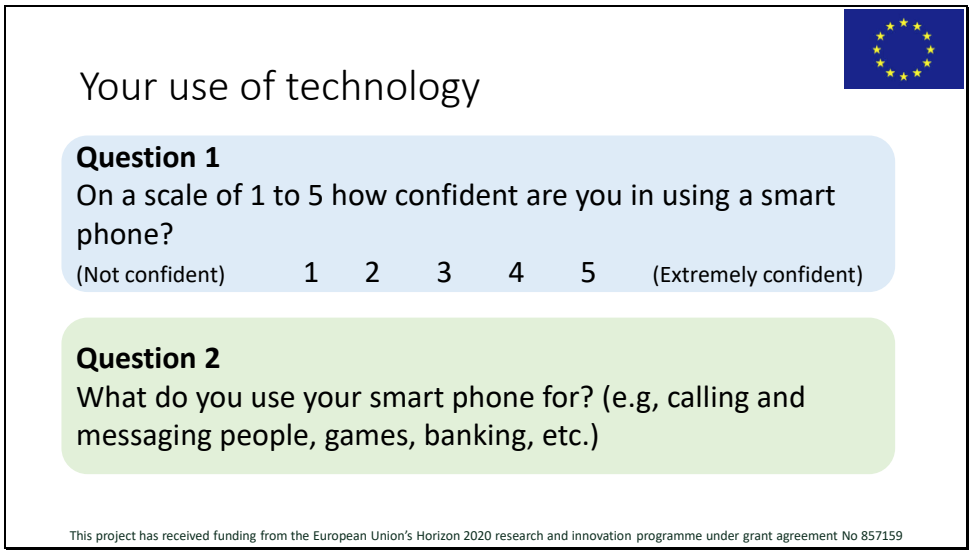

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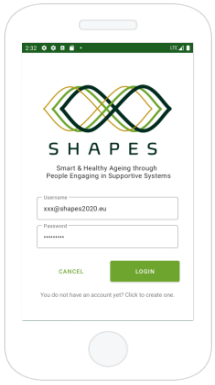
SHAPES App Login



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3. How would you engage with this screen?

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Slide 10

SHAPES App Menu

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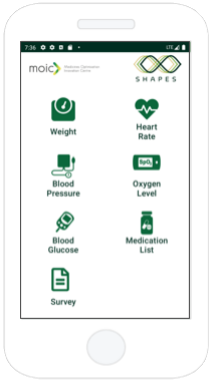

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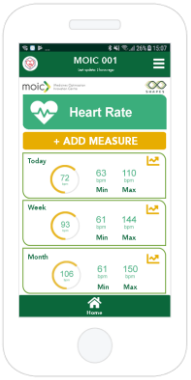
Slide 11

Heart Rate



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Slide 12

Heart Rate

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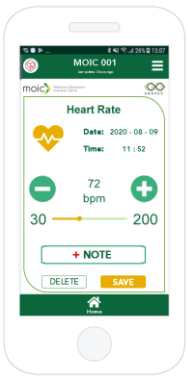

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Slide 13

Blood glucose

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Blood glucose

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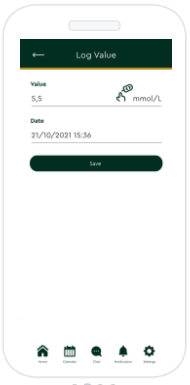

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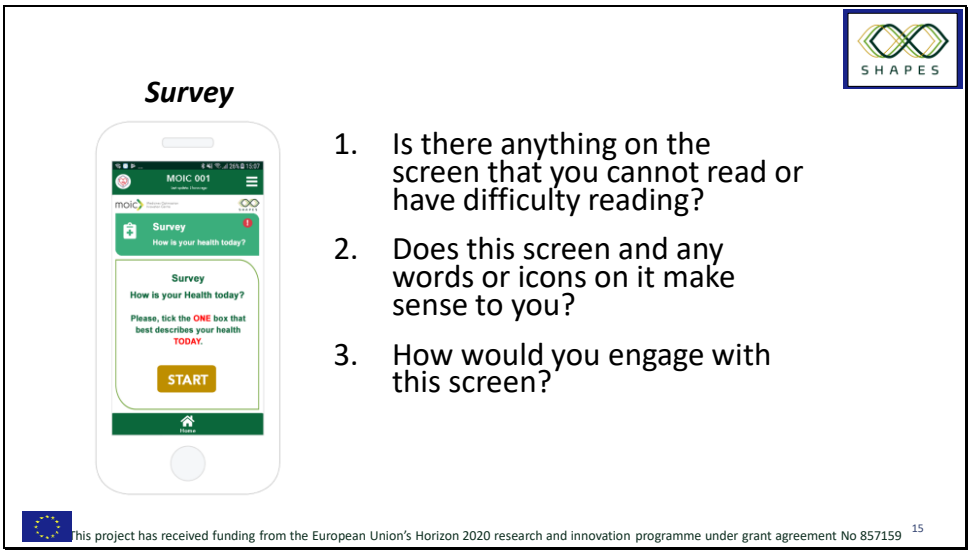

Slide 16

Survey

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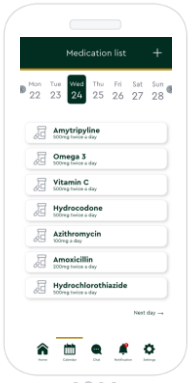
Slide 17

Medication List



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Slide 18

Medication Details

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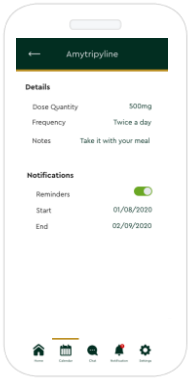

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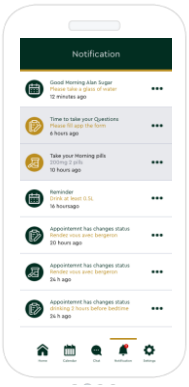
Notification



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Slide 20

General questions

In general, do you think people over 65 years would be confident using this app?

How would you feel about using this app and the clinical devices every day for 12 weeks?

What support do you think people over 65 years old might need to use this app?

What skills and capabilities do you think people over 65 years old need to use this app?

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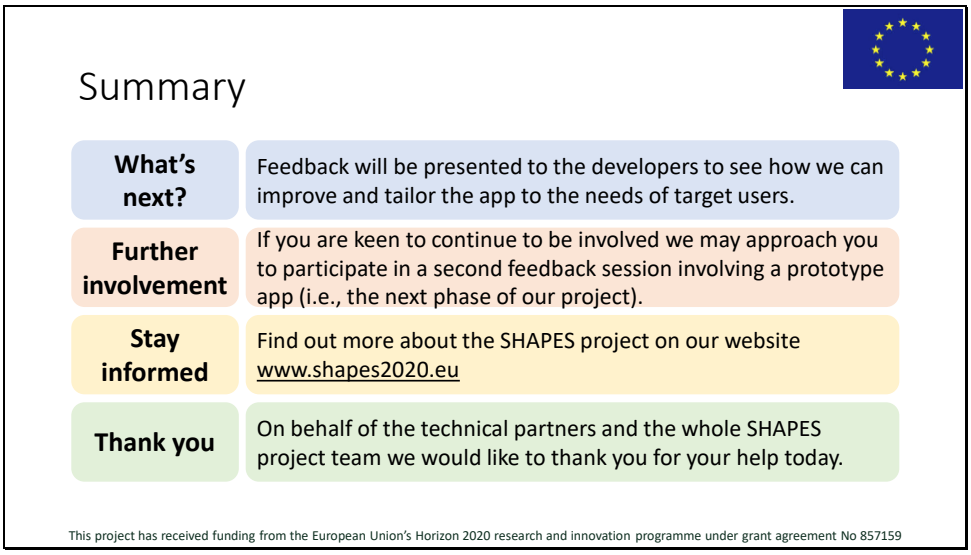

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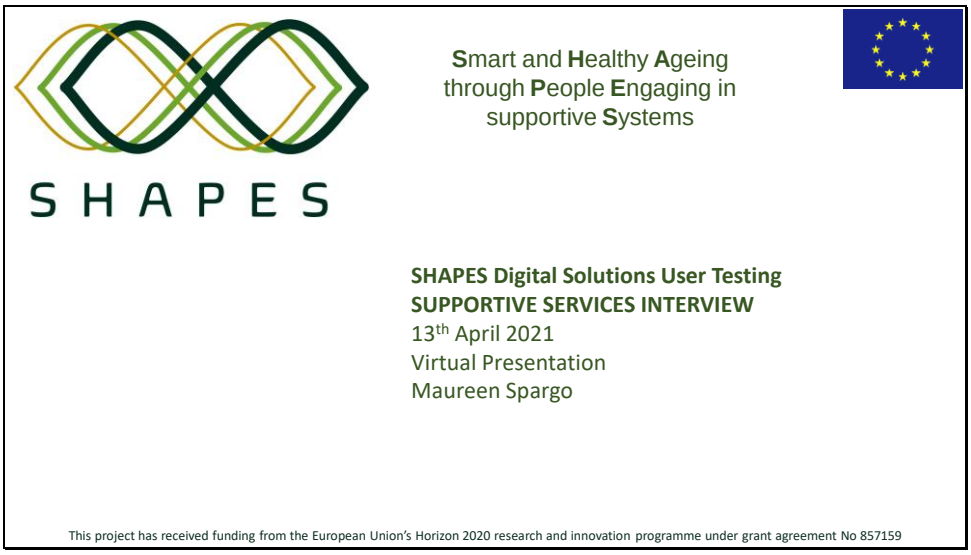

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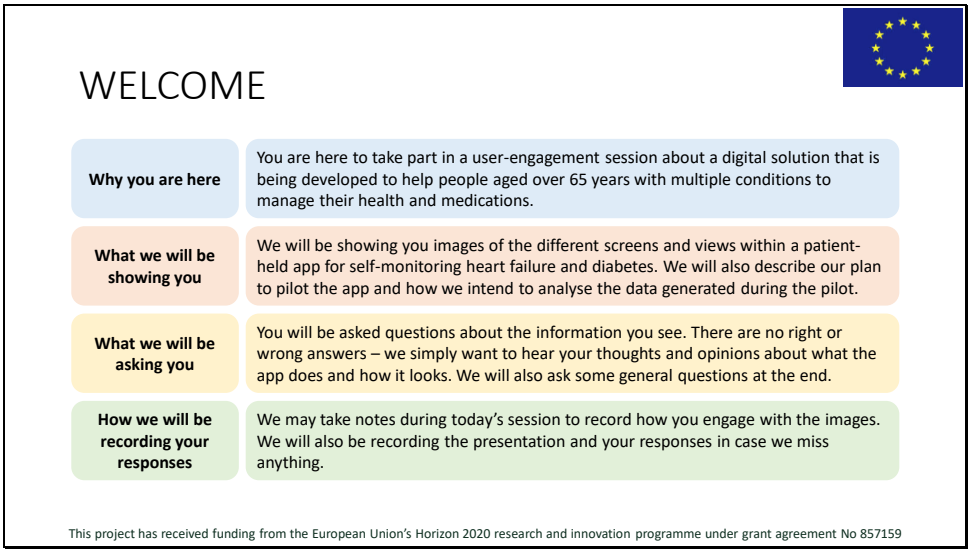

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Slide 3

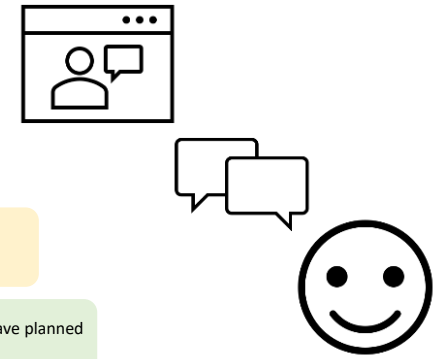
TODAY'S SESSION

Please feel free to ask us questions too! The more the better!

Ask the presenter to switch between slides if you want to look at the images again.

Tell us to slow down if we are going too quickly

The session will last approximately an hour. We do not have planned breaks but if you need one please ask.



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Slide 4

What is SHAPES?

SHAPES is a European research programme that is exploring how technology can enable older people in our communities to live healthier lives for longer at home.

Research studies are being conducted across Europe to determine if certain technologies (e.g., mobile phone apps, home sensors, robots etc.) can helpfully support people aged over 65 years in seven key areas.

Here in Northern Ireland we are investigating how we can use a mobile phone app to support the **safe and effective use of medicines** by people at home.

As per your consent, we are going to start recording this meeting.

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Slide 5

The healthcare app

A mobile phone app is being developed to assist with the self-management and remote monitoring of people with heart failure and diabetes.

Features of the app include:

- Heart and diabetes monitoring
- Survey
- Medication list
- Medication reminders
- Weekly medicine use review

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Slide 6

Patients will be given a set of devices that they will use at home to monitor their condition.

Scales to measure weight

Glucometer to measure blood glucose

Blood pressure meter

Pulse oximeter to measure heart rate and oxygen

The devices are linked with the app so the readings automatically get recorded in the app. Patients can also manually enter readings if they need to.

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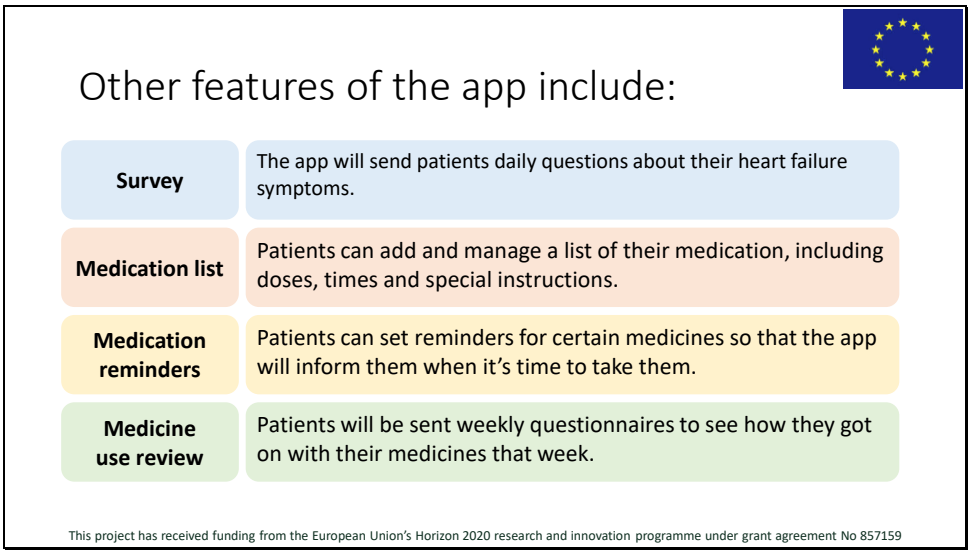
Slide 7



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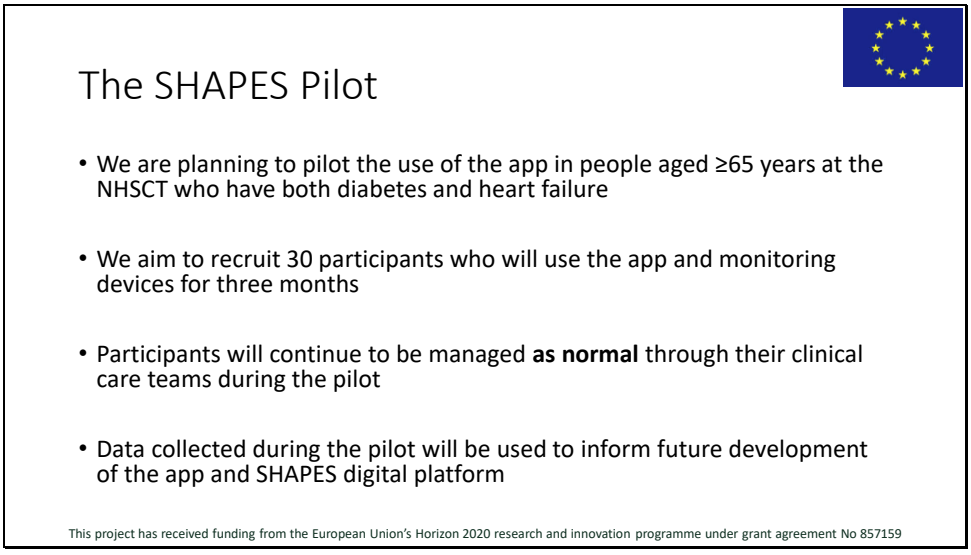

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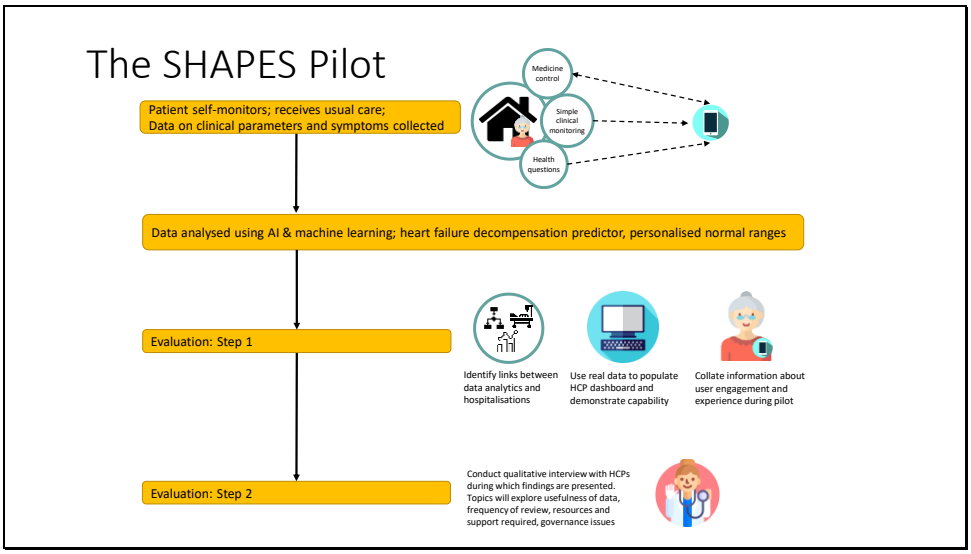
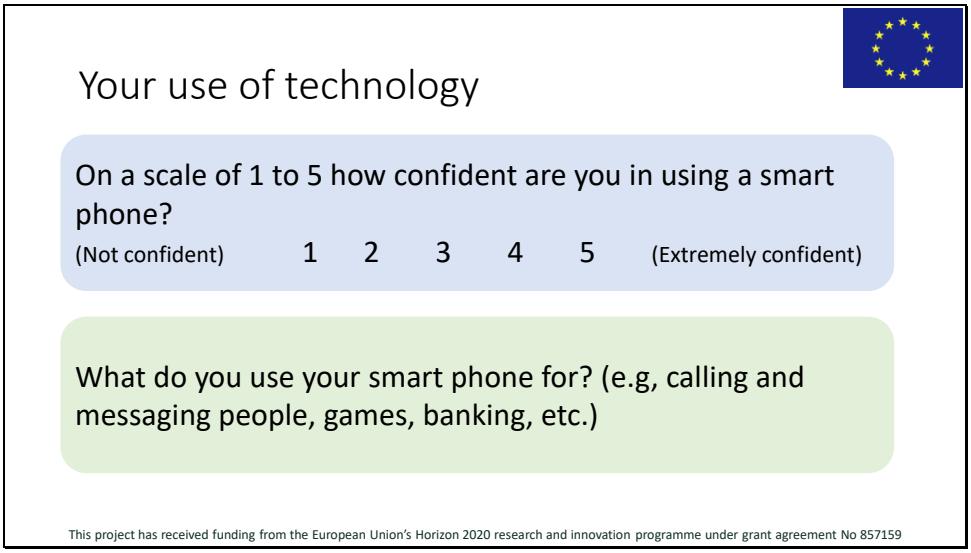
Slide 9



Slide 10



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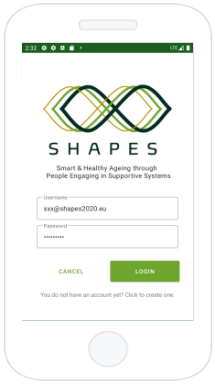
Slide 11

SHAPES App Login



1. Is there anything on the screen that you cannot read or have difficulty reading?
2. Does this screen and any words or icons on it make sense to you?
3. How would you expect someone to engage with this screen?

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Slide 12

SHAPES App Menu

1. Is there anything on the screen that you cannot read or have difficulty reading?
2. Does this screen and any words or icons on it make sense to you?
3. How would you expect someone to engage with this screen?

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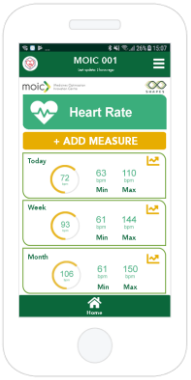
Slide 13

Heart Rate



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2. Does this screen and any words or icons on it make sense to you?
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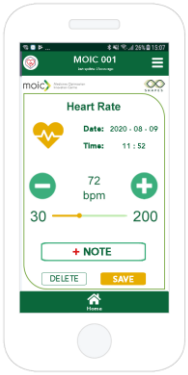
Slide 14

Heart Rate – manual entry

1. Is there anything on the screen that you cannot read or have difficulty reading?
2. Does this screen and any words or icons on it make sense to you?
3. How would you expect someone to engage with this screen?



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Slide 15

Blood glucose

1. Is there anything on the screen that you cannot read or have difficulty reading?
2. Does this screen and any words or icons on it make sense to you?
3. How would you expect someone to engage with this screen?

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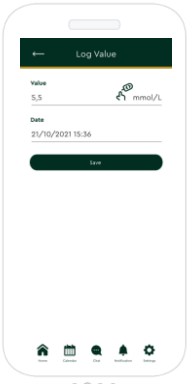
Slide 16

Blood glucose - manual entry



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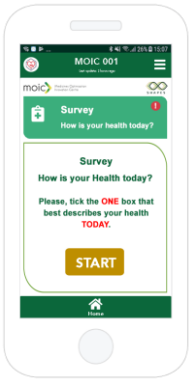
Slide 17

Survey



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Slide 18

1. Is there anything on the screen that you cannot read or have difficulty reading?
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Survey

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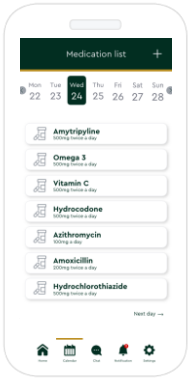
Slide 19

Medication List



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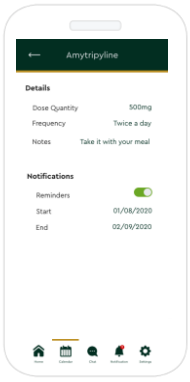
Slide 20

Medication Details

1. Is there anything on the screen that you cannot read or have difficulty reading?
2. Does this screen and any words or icons on it make sense to you?
3. How would you expect someone to engage with this screen?



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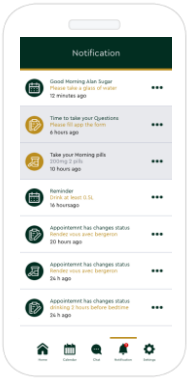
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Slide 21

Notification



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2. Does this screen and any words or icons on it make sense to you?
3. How would you expect someone to engage with this screen?

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Slide 22

General questions - pilot

1. How do you think your patients would feel about using an app and monitoring devices every day for three months?
2. What support do you think people over 65 years old might need to use this app?
3. Our eligibility criteria include recruiting only people who have the digital skills to use an android app. Do you think this is possible?
4. Is there anything else you would like to say about the app?
5. Do you foresee any clinical, logistical or governance issues with our plan to pilot this app?

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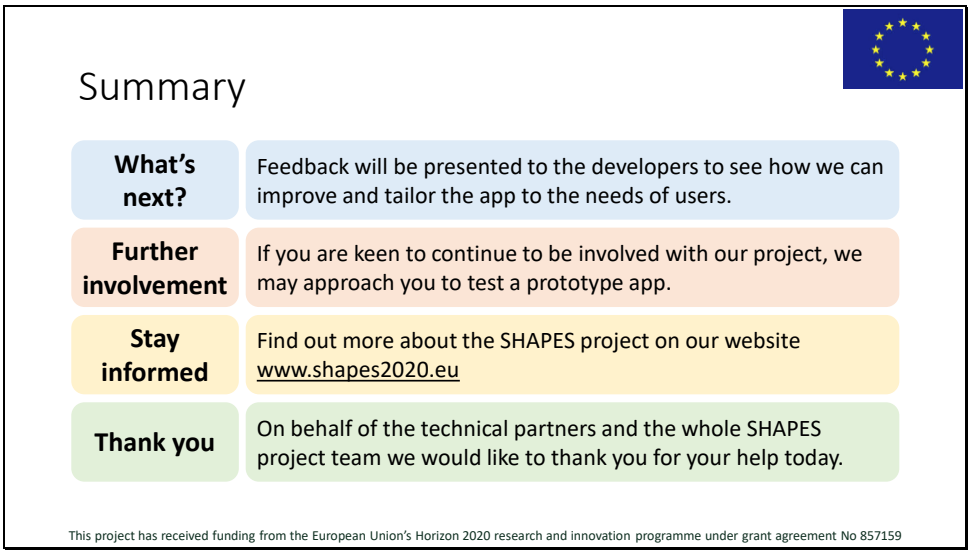
Slide 23



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Annex 5 UC-PT3-gen Phase 2 participant information sheets (target user and healthcare practitioner and support service providers)

SHAPES PARTICIPANT INFORMATION SHEET: target user

Study title: SHAPES Pan-European Pilot Campaign: User engagement and feedback on digital solutions for pilot theme 3 — medicines control and optimisation.

We'd like to invite you to take part in our study, during which we would like to hear your feedback on the design and layout of a healthcare application (an app) that is being developed for people aged 65 years' and over, and who are living with heart failure and diabetes. The study is an opportunity for us to make sure the app is practical and usable from an older person's perspective. We aim to involve at least six individuals in this study, including older individuals with heart failure and diabetes, healthcare professionals, and those who provide support for older people living at home.

You have been identified as being suitable for our study and have been given this information sheet to read and consider if you would like to take part.

This information sheet describes the study and your role in it. Before you decide, it is important that you understand why the study is being done and what it will involve for you. Please take time to read this information and discuss it with others if you wish. If anything is not clear, or if you would like more information, please ask _____who will be in contact with you after you have had time to read this information.

Voluntary nature of participation

Participation in this study is voluntary. You can withdraw from the

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

study at any time without giving any reason and without there being any negative consequences.

Purpose and aims of the study

This study is one part of a larger research project that aims to test different ways of using technology to assist people in their homes as they get older.

The purpose of the study you have been invited to take part in is to provide feedback on a healthcare app that is being developed to assist older persons with heart failure and diabetes is fit for purpose — i.e., can the words be read easily, is it clear what each button does, do the colours work well together, etc. Using this feedback, we will make changes to make the app more user-friendly.

The finished app will then be tested again before it is used in a real-world study to see if it can help people manage their heart failure and diabetes conditions from home, and improve their quality of life and health outcomes.

Who is organising and funding the research?

The Northern Health and Social Care Trust (NHSCT) is organising this study. It is part of a larger research programme called the SHAPES project which is funded by the European Union under the Horizon 2020 Programme (Grant Agreement no 857159).

What will the participation involve?

If you agree to be involved with this study, you will be asked to take part in a video call and interview with local researchers using a computer or internet-enabled mobile phone or tablet device.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

What exactly will happen?

Taking consent

- After you have had time to read this information sheet, _____will be in touch with you to discuss participation.
- If you are happy to take part you will be asked to sign a consent form and _____will return it, along with your contact details, to the researcher.

Before the video call

- The researcher will telephone or email you to arrange a suitable time to conduct the video call.
- The researcher will check if you have the technology needed to conduct the video call and talk you through how to use it (if required).

During the video call

- During the video call you will first be shown information about the study and the wider SHAPES project.
- You will then be shown a set of presentation slides containing pictures of a healthcare app.
- After each set of slides the reseacher(s) will ask you some questions about what you have seen. Some questions will be open for you to answer as you wish (e.g., describe what you liked about the images) and other questions will ask you to choose a response (e.g., could you see where the 'Exit' button was, yes or no).
- As we mentioned before, this is not a test and there are no right and wrong answers. We are looking for your honest opinion and input on what we are showing you.
- The researcher(s) may need to take notes during the call and will be recording the conversation so that we can listen and watch back on it and make more detailed notes.
- The call should not last longer than one hour. We will work at a pace that is set by you and you may take a break at any time during the call.
- If you wish to take longer to look at the pictures, or would prefer

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to see them in hard-copy format, we can arrange this and set-up a second call for you to give us your feedback.

Collection and processing of information after the video call

- Other than your name, contact details and recordings obtained during the interview, no other personal data will be collected.
- All recordings collected during the interview will be transferred to a password-protected computer that only the local researchers will have access to.
- We may transcribe the recordings and will anonymise any identifiable information in the process. Recordings will then be destroyed after use.
- Anonymised findings may be used in further research and/or communication activities (e.g., as part of further research in the SHAPES project, in journal articles, workshops and conferences).
- Your personal contact details will be destroyed by the researchers once you have been provided with a summary of the findings for this study.
- Anonymised raw data will be stored for the duration of the SHAPES project and for five years after it finishes.

Possible benefits of taking part

There are no direct benefits to you as an individual for taking part in this study, besides personal interest and the experience of participating in a study. However, the indirect benefit of this study is that your views and opinions will be used to improve what the app looks like and how it works. Your input will also inform how we use technology to assist people in their homes as they get older. People from all over Europe will benefit from your participation.

Possible disadvantages of taking part

We do not foresee any discomforts or disadvantages for you taking part in this study.

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Financial information

Participation in this study will involve no cost to you. You will receive no payment for your participation.

Informing about the study results

Findings from this study may be used in further research and/or communication activities (e.g. as part of further research in the SHAPES project, in journal articles, workshops and conferences). A summary of the findings will be made available to you.

Termination of the study

The researchers conducting the study can terminate the study, however, at present there are no foreseeable reasons why this study would be terminated. If you would like to withdraw your participation at any point you are free to do so. If this is the case please contact the researcher. We may still use your anonymised data.

Further information

Further information related to the study can be requested from the following people involved with the SHAPES project.

Contact details

Mid & East Antrim Agewell Partnership

Email: info@meaap.co.uk; Telephone: 028 2565 8604

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Northern Health and Social Care Trust

Dr Maureen Spargo (local researcher)

Email: Maureen.spargo@northerntrust.hscni.net; Telephone: 028 9442 4942

Professor Mike Scott (principal investigator)

Email: DrMichael.Scott@northerntrust.hscni.net; Telephone: 028 9442 4942

Nicola Lyons (Data Protection Officer)

Email: Nicola.Lyons@northerntrust.hscni.net

SHAPES PARTICIPANT INFORMATION SHEET: healthcare practitioners and support service providers

Study title: SHAPES Pan-European Pilot Campaign: User engagement and feedback on digital solutions for pilot theme 3 — medicines control and optimisation

We'd like to invite you to take part in our study, during which we would like to hear your feedback on the design and layout of digital solutions that have been developed for health professionals to monitor and support people aged over 65 years' and who are living with heart failure and diabetes. The digital solutions under development consist of a a patient-held app and healthcare practitioner facing dashboard that allows healthcare practitioners to monitor patients' vital signs and health and wellbeing remotely, as well as help them manage their medication. The study is an opportunity for us to make sure the solutions are practical and usable from the perspectives of those people who are likely to use them or those who provide support for people who are using them. We aim to involve at least six individuals in this study, including older individuals with heart failure and diabetes, healthcare practioners and support service providers (IT services, community support).

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You have been identified as being suitable for our study and have been give this information sheet to read and consider if you would like to take part.

This information sheet describes the study and your role in it. Before you decide, it is important that you understand why the study is being done and what it will involve for you. Please take time to read this information and discuss it with others if you wish. If anything is not clear, or if you would like more information, please ask the researcher who will be in contact with you after you have had time to read this information.

Voluntary nature of participation

Participation in this study is voluntary. You can withdraw from the study at any time without giving any reason and without there being any negative consequences.

Purpose and aims of the study

This study is one part of a larger research project that aims to test different ways of using technology to assist people in their homes as they get older.

The purpose of the study you have been invited to take part in is to provide feedback on whether a healthcare app and/or health practitioner facing dashboard that is being developed to assist older persons with heart failure and diabetes is fit for purpose. Using this feedback, we will make changes to make the solutions more user-friendly.

The finished app and dashboard will then be tested again before they are used in a real-world study to see if it can help people manage their heart failure and diabetes conditions from home, and improve their quality of life and health outcomes.

Who is organising and funding the research?

The Northern Health and Social Care Trust (NHSCT) is organising this study. It is part of a larger research programme called the SHAPES project which is funded by the European Union under the Horizon 2020 Programme (Grant Agreement no 857159).

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What will the participation involve?

If you agree to be involved with this study, you will be asked to take part in a video call and interview with local researchers using a computer or internet-enabled mobile phone or tablet device.

What exactly will happen?

Taking consent

- After you have had time to read this information sheet, a researcher will be in touch with you to discuss participation.
- If you are happy to take part you will be asked to sign a consent form and return it to the researcher.

Before the video call

- The researcher will telephone or email you to arrange a suitable time to conduct the video call.
- The researcher will check if you have the technology needed to conduct the video call and talk you through how to use it (if required).

During the video call

- During the video call you will first be shown information about the study and the wider SHAPES project.
- You will then be shown a set of presentation slides containing pictures of the app and/or the healthcare practitioner dashboard. What you will be shown will be tailored to be relevant to your role.
- After each set of slides the reseacher(s) will ask you some questions about what you have seen. Some questions will be open for you to answer as you wish (e.g., describe what you liked about the images) and other questions will ask you to choose a response (e.g., could you see where the 'Exit' button was, yes or no).
- As we mentioned before, this is not a test and there are no right and wrong answers. We are looking for your honest opinion and input on what we are showing you.
- The researcher(s) may need to take notes during the call and will be recording the conversation so that we can listen back to it and make more detailed notes.
- The call should not last longer than one hour. We will work at a pace that is set by you and you may take a break at any time during the call.
- If you wish to take longer to look at the pictures, or would prefer to see them in hard-copy format, we can arrange this and set-up a second call

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for you to give us your feedback.

Collection and processing of information after the video call

- Other than your name, contact details and recordings obtained during the interview, no other personal data will be collected.
- All recordings collected during the interview will be transferred to a password-protected computer that only the local researchers will have access to.
- We may transcribe the recordings and will anonymise any identifiable information in the process. Recordings will then be destroyed after use.
- Anonymised findings may be used in further research and/or communication activities (e.g., as part of further research in the SHAPES project, in journal articles, workshops and conferences).
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- Anonymised raw data will be stored for the duration of the SHAPES project and for five years after it finishes.

Possible benefits of taking part

There are no direct benefits to you as an individual for taking part in this study, besides personal interest and the experience of participating in a study. However, the indirect benefit of this study is that your views and opinions will be used to improve what the app and dashboard look like and how they work. Your input will also inform how we use technology to assist people in their homes as they get older. People from all over Europe will benefit from your participation.

Possible disadvantages of taking part

We do not foresee any discomforts or disadvantages for you taking part in this study.

Financial information

Participation in this study will involve no cost to you. You will receive no payment for your participation.

Informing about the study results

Findings from this study may be used in further research and/or communication activities (e.g. as part of further research in the SHAPES project, in journal

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Further information

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Contact details

Northern Health and Social Care Trust

Dr Maureen Spargo (NHSCT researcher)

Email: Maureen.spargo@northerntrust.hscni.net; Telephone: 028 9442 4942

Professor Mike Scott (principal investigator)

Email: DrMichael.Scott@northerntrust.hscni.net; Telephone: 028 9442 4942

Nicola Lyons (Data Protection Officer)

Email: Nicola.Lyons@northerntrust.hscni.net

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Annex 6 UC-PT3-gen Phase 2 participant consent forms (target user and healthcare practitioner and support service providers)

SHAPES PARTICIPANT CONSENT FORM — target user

Title of the study: SHAPES Pan-European Pilot Campaign: User engagement and feedback on digital solutions for pilot theme 3 — medicines control and optimisation.

Location of the study:

Northern Health and Social Care Trust (NHSCT)

Contact

Dr Maureen Spargo (NHSCT researcher)

Email: Maureen.spargo@northerntrust.hscni.net; Telephone: 028 9442 4942

Mid & East Antrim Agewell Partnership

Email: info@meaap.co.uk; Telephone: 028 2565 8604

Participant declaration

- I have been invited to participate in the above study. The purpose of the study is to collect feedback on the design and layout of a healthcare application (an app) that is being developed for people aged 65 years' and over who are living with heart failure and diabetes. The study

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is an opportunity for the researchers to make sure the app is practical and usable from an older person's perspective.

- I have read and understand the participant information sheet. The participant information sheet has provided me sufficient information about the above study, its purpose and execution of the study, about my rights, and about the possible advantages and disadvantages of taking part.

- I have had the opportunity to ask questions about the study and have had these questions answered satisfactorily.

I have been given sufficient information about the collection, processing, transfer/disclosure and deletion of my responses during the study. I understand that other than my name, contact details and video/voice recordings obtained during the study, no other personal data will be processed during this study.

By signing this form, I confirm that I voluntarily consent to participate in this study and that I also grant consent to the processing of my responses for the purposes described in this document.

I have not been pressurised or persuaded into participation and I have had enough time to consider my participation in the study. I understand that my participation is entirely voluntary and that I am free to withdraw my consent at any time, without providing any reason.

I also have the right to request the removal of my identifiable personal data in accordance with data protection regulation.

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Optional

I agree to be contacted by the Northern Health and Social Care Trust about taking part in future projects related to this study arising within the next year

Yes No

(please circle)

To be completed by the participant

Agreement (please complete the details below to confirm your consent)

Name:

Date:

Signature:

To be completed by study personnel

Please complete the details below to confirm receipt of signed consent

Name:

Date:

Signature:

The original consent signed by the participant will be kept by the research team. The participant information sheet and a copy of the signed consent will be given to the participant.

SHAPES PARTICIPANT CONSENT FORM: healthcare practitioner and support service provider

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Title of the study: SHAPES Pan-European Pilot Campaign: User engagement and feedback on digital solutions for pilot theme 3 — medicines control and optimisation.

Location of the study:

Northern Health and Social Care Trust (NHSCT)

Contact

Dr Maureen Spargo (NHSCT researcher)

Email: Maureen.spargo@northerntrust.hscni.net; Telephone: 028 9442 4942

Participant declaration

- I have been invited to participate in the above study. The purpose of the study is to collect feedback on the design and layout of a healthcare application (an app) and healthcare practitioner facing dashboard that are being developed to support people aged 65 years' and over who are living with heart failure and diabetes. The study is an opportunity for the researchers to make sure the app and dashboard are practical and usable from a healthcare practitioner and support service providers perspective.

- I have read and understand the participant information sheet. The participant information sheet has provided me sufficient information about the above study, its purpose and execution of the study, about my rights, and about the possible advantages and disadvantages of taking part.

- I have had the opportunity to ask questions about the study and have had these questions answered satisfactorily.

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- I have been given sufficient information about the collection, processing, transfer/disclosure and deletion of my responses during the study. I understand that other than my name, contact details and video/voice recordings obtained during the study, no other personal data will be processed during this study.

- By signing this form, I confirm that I voluntarily consent to participate in this study and that I also grant consent to the processing of my responses for the purposes described in this document.

I have not been pressurised or persuaded into participation and I have had enough time to consider my participation in the study. I understand that my participation is entirely voluntary and that I am free to withdraw my consent at any time, without providing any reason.

I also have the right to request the removal of my identifiable personal data in accordance with data protection regulation.

To be completed by the participant

Agreement (please complete the details below to confirm your consent)

Name:

Date:

Signature:

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

To be completed by the research personnel

Please complete the details below to confirm receipt of signed consent

Name:

Date:

Signature:

The original consent signed by the participant will be kept in the records of the research team. The participant information sheet and a copy of the signed consent will be given to the participant.

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Annex 7 UC-PT3-gen Phase 2 feedback report

UC-PT3-general: Phase 2 feedback report for technical partners

The Phase 2 mock-up presentations with recruited participants were conducted between 22nd March and 13th April 2021. Presentations were conducted remotely via the Zoom video conferencing software. All sessions were recorded and the recordings used to generate a feedback report for each participant.

Participants

Seven participants consented to take part in the study. They included three male and three female participants. The breakdown of participant type was as follows:

- Two target users (TU1 and TU2) who were recruited via the Mid- and East-Antrim Agewell Partnership (MEAAP). Both target users were aged over 65 years' and had diagnosed heart failure and type 2 diabetes. TU1 reported confidence at using their smart phone to be 2 or 3 out of 5. TU2 rated themselves at 4 or 5 out of 5. Both primarily used their phones for messaging and calls. TU1 additionally used their device for social media and TU2 for reading news.
- Two healthcare professionals (HCP1 and HCP2) were recruited via contacts at the NHSCT. Both HCPs were registered pharmacists. One worked in diabetes care and the other in acute heart failure. Both healthcare practitioners reported a confidence rating of 5 out of 5 for using their smart phone. Social media, messaging, calls and browsing the internet were cited as main uses. HCP2 additionally reported using their phone for simple word games.
- Three support service providers (SSP1, SSP2, SSP3) were recruited from staff at MEAAP, a community support provider for older people, and the Northern Ireland Chest Heart and Stroke (NICHS), a charitable organisation that provide support for people with heart failure. All rated their confidence at using their phones as 5 out of 5 and reported calls and messaging, with the additional uses of internet shopping and browsing (SSP1) and banking (SSP3).

Overview of feedback

Using the feedback collected during the presentations and interviews with participants, the Phase 2 mock-ups of the SHAPES App, eCare and eHealthpass components of the PT3-general use case user app were assessed using the ISO Standards for multimedia design (ISO 14915). General feedback is provided first followed by specific feedback and recommendations for each mock-up screen.

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Recommendations for the technical partners are provided for each screen. Individual reports from each participant are also provided in the Appendix.

Suitability for the communication objective *(i.e., suitability of the presentation of the information for achieving the goals of the providers and visitors).*

- There were issues with the size of text on every mock-up presented to participants.
- The target users both found it difficult to see and read the information presented on each screen.
- The screens that contained minimal, simple information or instructions (e.g., the survey screens) were generally favoured over those that had multiple sections/compartments (e.g., the HR screen).

Suitability for perception and understanding *(i.e., is the information transmitted easy to understand and can be easily recorded?)*

- The purpose of each screen and what information it was transmitting to the user was understood by the health professionals and support service providers but not by the target user participants, who needed more explanation for each screen.
- Target users were generally confused over the purpose of the app and how the user was meant to engage with it.

Suitability for exploration *(i.e., is the participant able to find the desired information or complete his task without any previous knowledge or experience regarding the presentation or structure of the information offered).*

- The target users had difficulty or were unable to describe how they would complete many of the tasks within the app.
- Instructions for the user need to be simple, direct and use recognisable terminology (e.g., click here, type in this box).
- Explanations need to be provided to users. The target users may not be as familiar with certain icons or features as more proficient users.

Suitability for user motivation *(i.e., a participant must be encouraged to act. By focusing on the needs of the participants, an appealing presentation and goal-oriented guidance, the participant can be motivated).*

- Participants generally liked the simplicity of the design of the app.
- One participant (SSP1) felt that the colours could be more engaging.
- Screens where there was lots of information were deemed to be potentially overwhelming for users, which could be off-putting.
- One user felt that the amount of recording required would be off-putting to many older people.

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- Opinions about motivation to use the app differed between the two target users: TU1 was particularly motivated by participating/using the app for their health yet TU2 was unsure of motivation to take part if no HCP oversight.

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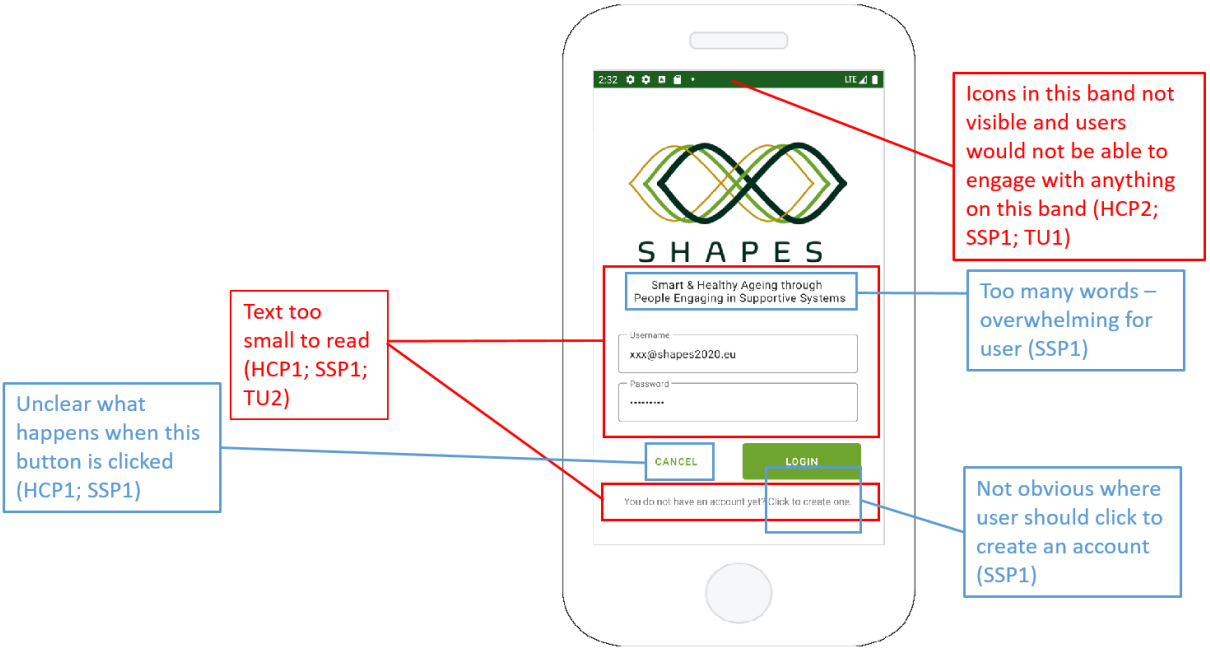
SHAPES APP USER LOGIN



a) **Suitability for the communication objective**	b) **Suitability for perception and understanding**	c) **Suitability for exploration**	d) **Suitability for user motivation**
The font size was considered too small for older users. TU2 could not read anything below the word SHAPES.	All participants understood the purpose of the screen and how they would login to the app. There were items on the screen that participants did not know the purpose of or that were unclear (see below).	No option if password forgotten.	Image was considered eye-catching. However, there are parts of the screen that do not focus on users' needs and could overwhelm or confuse the user.

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Recommendations

1. Increase all text to a standard minimum font size (14pt?)
2. Clarify function of 'Cancel' button. Use more explicit and recognisable terminology.
3. Make it very clear where to click if they do not have an account or have forgotten password – would a 'Help' button cover both? Needs to be obvious (bold or underlined).
4. Remove SHAPES full title. Does not serve a purpose for the user.
5. Clarify purpose of green banner at top of screen (is this part of phone screen?) and remove if possible.
6. Clarify whether the zoom function is a function of the phone or app?

SHAPES APP MENU

a) **Suitability for the communication objective**	b) **Suitability for perception and understanding**	c) **Suitability for exploration**	d) **Suitability for user motivation**

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Participants were able to read the text and interpret the icons easily.	SSP1 thought at images relate to content of app and to text.	All but one participant (SSP1) described the page as helping them get to where they would **input** their data.	More colour would make the screen more engaging (SSP1).
TU2 would prefer the text to be larger.	Screen described as 'easy', 'obvious', and 'good' (SSP1; HCP2)		Green not appealing (HCP2)
Combination of icons and text considered helpful (SSP2; SSP3)	HCP1 thought that non-HCPs may not know what the blood pressure and oxygen level icons were for (but clarified that text provides explanation).	Not obvious to TU2 that this was a menu page and queried where user would enter readings. TU2 also mentioned at this point whether unit of measurement could be selected for weight if using own scales.	*(Researcher observation: could the green colour be misinterpreted as a traffic light colour indicating everything is ok?)*

Recommendations

1. Ensure text is agreed standard minimum font size (14pt)
2. Remove MOIC text – keep logo
3. Consider adding page title and instructions (e.g., Menu – touch/tap an image to view your data)
4. Consider giving icons and text a defined border to make it more obvious that they are buttons to be touched.
5. Consider using variety of colours

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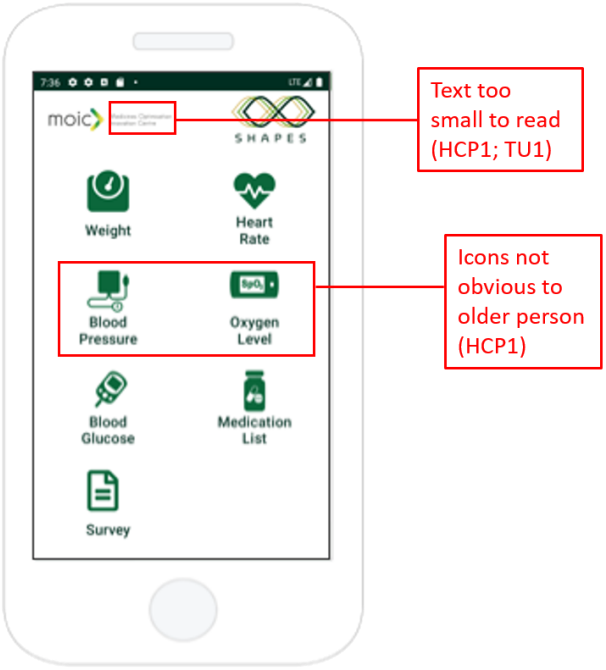
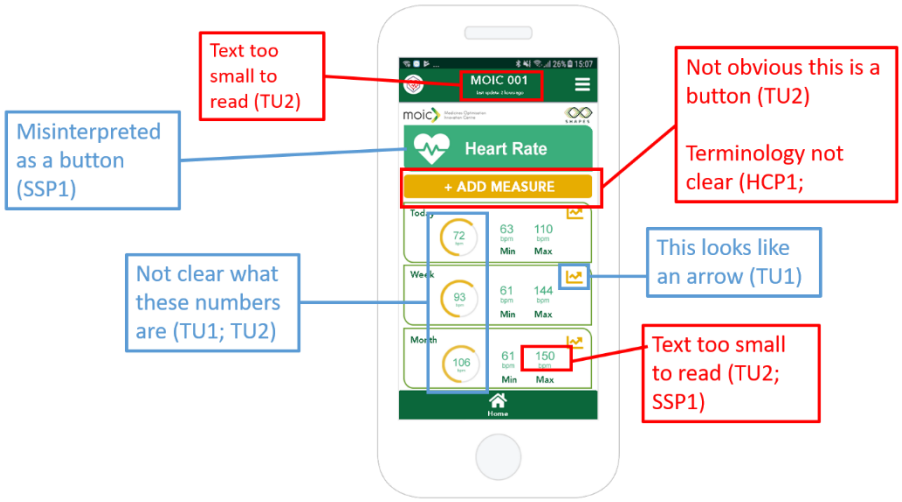


EDGE: HEART RATE



a) **Suitability for the communication objective**	b) **Suitability for perception and understanding**	c) **Suitability for exploration**	d) **Suitability for user motivation**
Text too small to read in places (TU2; SSP1).	HCPs and SSPs understood what this screen was telling them BUT the target users both needed to	The 'Add measure' button was not obvious to TU1.	Overwhelming amount of information – could put user off (SSP1)

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Multiple sections on the screen – participants all focused on different parts. Green heart rate banner very similar to orange 'Add measure' button. SSP1 expected to do be able to press this. SSP2 suggested making 'Add measure larger than 'Heart rate' banner.	have this screen explained to them. TU1 perceived the numbers within the orange circles to be what their HR should be. TU2 asked what the numbers meant. Max and Min – HCP1 queried where do these values come from?	The link to the graph screen was not noticed by most participants. Was perceived to be an arrow by one user. Positioning of 'Add measure' button made it seem to HCP1 and SSP1 like this always needed to be done, rather than only in certain circumstances.	If user doesn't have to 'do' anything with the information they tend to be told by others to avoid it (HCP2) TU2 was mostly concerned that the screen did not explain the significance of the measurements. SSP3 also queried if users could view their target levels. SSP2 and SSP3 suggested having in-app information to support the interpretation of the information presented in this screen (and that of blood glucose). Either a whole feature or clickable information buttons within the screens.

Recommendations

1. Reduce the amount to content on the screen to the daily reading only. Provide links to weekly and monthly.

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2. Remove ‘max’ and ‘min’ from daily view – we are only recommending the user takes HR once a day.
3. Ensure text is agreed standard minimum font size (14pt)
4. Provide an explanation/description of what the user is looking at OR make it obvious.
   I.e., ‘Your heart rate today was X’.
5. Clarify significance of the circle. Is this indicative of something?
6. Button to ‘Add measure’
    a. Change terminology to something more obvious e.g., ‘Click here to enter a reading’
    b. Change position of button to below where HR is displayed.
7. Consider in-app information pages

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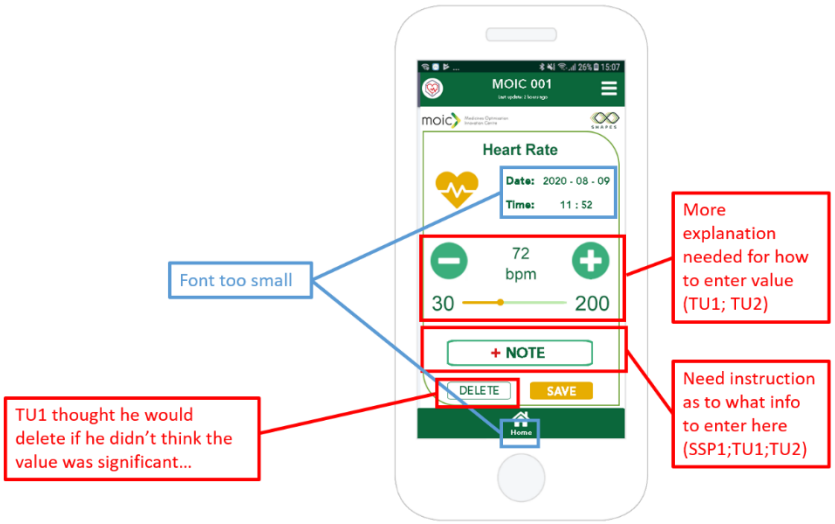
HEART RATE: MANUAL ENTRY



a) **Suitability for the communication objective**	b) **Suitability for perception and understanding**	c) **Suitability for exploration**	d) **Suitability for user motivation**
Font too small to read in places. SSP1 – looks good visually. HCP2 – all clear. SSP2 and SSP3 – visually good. *Researcher observation: if blank will the*	TU2 didn't understand what the purpose of this screen was. Function of note button clear but its purpose was questioned by SSP1, TU1 and TU2. Not clear what information to enter into this section. SSP3 mentioned they recommend diary for recording how patients are	Target users both had to be told how to enter HR using +/- buttons. When they knew how to do it they thought it was straightforward. Sensitivity of +/- buttons questioned by SSP1. Could be tricky for older person. How long would it take them to enter? Manual entry would be easier.	Presence of a value in the centre of the screen caused confusion in the target users – was this their HR that day? What was the significance of it? HCP2 likened the +/- buttons to a game. SSP2 – major factor will be in training. If users receive training they will be able to do this ok.

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heart rate be set at zero?	feeling. Note function would facilitate this.	HCP2 preferred this method of input. Thought it would be easier for an older person.
	Are the date and time automatically timestamped (HCP1)? Looks that way. Could this be done manually?	SSP2 pointed out two ways of inputting HR: moving dot along line and the +/- buttons.

Recommendations

1. Ensure text is agreed standard minimum font size (14pt)
2. Provide clear instruction to user what they are meant to do on this page and how.
3. Consider adding option to manually enter a value.
4. Could write out 'beats per minute' rather than bpm
5. Change 'Note' terminology to 'Comments' or something obvious.
6. Clarify if time and date is automatically entered – if no, provide instruction to enter. If yes, what should a user do to retrospectively enter in a value?

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a) **Suitability for the communication objective**	b) **Suitability for perception and understanding**	c) **Suitability for exploration**	d) **Suitability for user motivation**
Participants all liked this screen. SSP1 stated preference for this over HR screen due to its simplicity.	Graph was well interpreted by all participants. However, TU2 believed many people would not understand it.	Easy to engage with this screen: Daily, weekly, monthly tabs at top preferable than all on one page (SSP1)	Not too busy (SSP1).
With exception of font being too small in places (HCP1; HCP2; TU1;TU2) the information is communicated well.	Axis for longer timeline may become too small to read. No axis labels. (HCP1)	No button for manually entering value *(noticed by researchers during presentation – was this deliberate?)*	TU2 concerned about significance of value. Nothing on screen to tell users if readings are good or bad.
Units for blood glucose are different (HCP1)	SSP1 queried what would be displayed if reading had not been taken that day. Last recorded reading?	What is the purpose of having both the option to view weekly/monthly information AND change the graph	SSP3 queried if user would be notified if they had a high blood glucose level.
			Screen seems to be for information only (HCP2).

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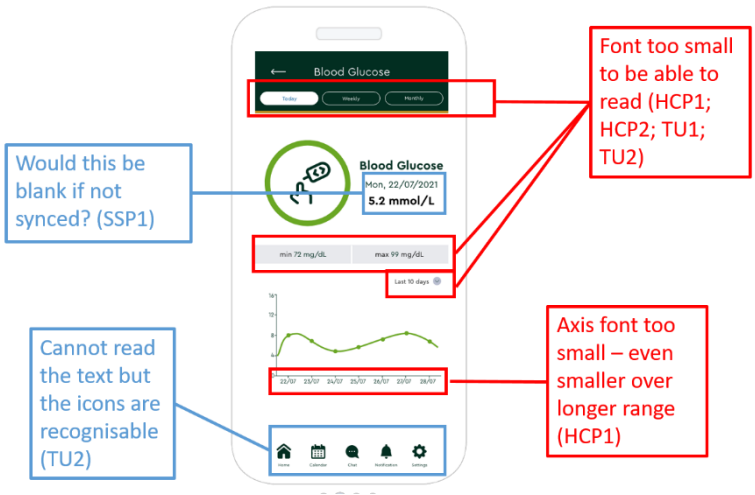
Query from researchers: Blood glucose usually taken multiple times a day - how would these be displayed?	to display 'last 10 days'? SSP2 suggested adding a 'Notes' button.	SSP3 suggested an 'information' button be added to inform user of reference levels (similar to feedback on HR screen).

Recommendations

1. Ensure text is agreed standard minimum font size (14pt)
2. Consider how multiple readings a day would be displayed – may need time of reading too.
3. Clarify what is to be displayed on screens for weekly/monthly view. Do we need to be able to change the graph timeline?
4. Consider providing an explanation/description of what the user is looking at.
5. Consider adding button to take user to manual input page (if deemed necessary)
6. Consider in-app information pages

GNOMON: BLOOD GLUCOSE



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a) **Suitability for the communication objective**	b) **Suitability for perception and understanding**	c) **Suitability for exploration**	d) **Suitability for user motivation**
All text visible but could be larger (TU2).	Screen not well understood by target users but HCP and SSP participants understood what this page was for.	There are no instruction other than 'Log value' – instructions should tell the user what do to clearly (TU1)	Nothing off-putting to any participants.
Straightforward (SSP1)			Described as basic (but in a good way) by SSP1.
Icon was distracting to the target users – thought they needed to engage with it (TU1; TU2).	Terminology not obvious to an older person (e.g., value) (TU1).	Unclear if date and time is automatically entered (HCP1; HCP2; SSP1; SSP2).	TU2 was mostly concerned that the screen did not explain the significance of the measurements.
		Manual entry preferred for older user over +/- buttons (SSP1) SSP3 thought both options would be good.	

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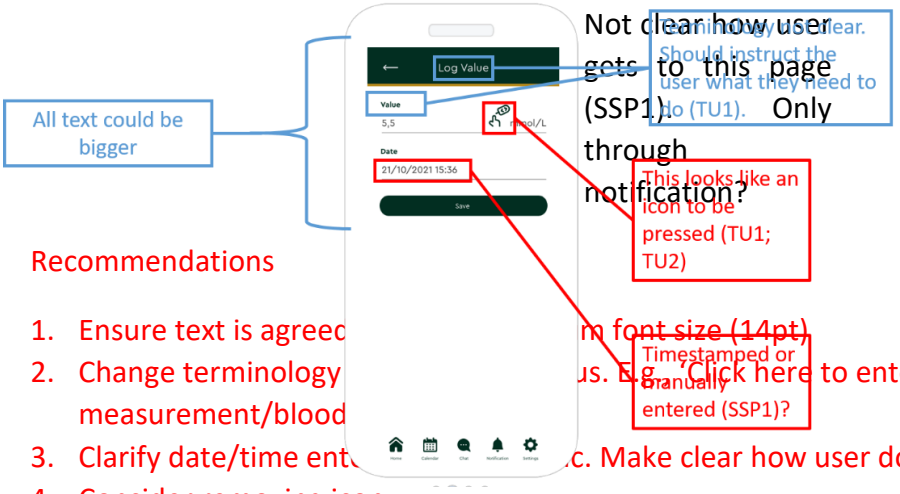

Not clear how user gets to this page (SSP1). Only through notification?

Recommendations

1. Ensure text is agreed m font size (14pt).
2. Change terminology us. E.g. 'Click here to enter measurement/blood
3. Clarify date/time ent c. Make clear how user does this.
4. Consider removing icon.
5. Confirm method by which user gets to this page. Is this through a link on the previous screen or via notification.

GNOMON: BLOOD GLUCOSE ENTRY

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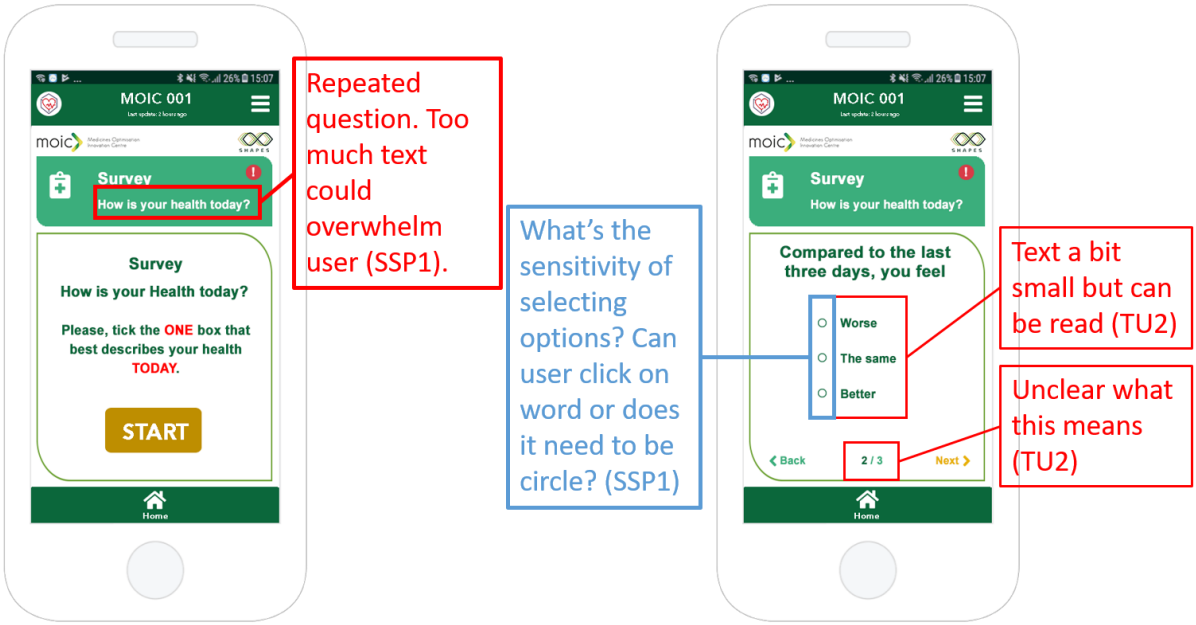
EDGE: SURVEY



a) **Suitability for the communication objective**	b) **Suitability for perception and understanding**	**c) Suitability for exploration**	d) **Suitability for user motivation**
Options well-spaced out (HCP2)	All participants understood what this page was for.	SSP queried sensitivity of tick boxes. Recommended to give biggest range to click on option/	Participants liked the simplicity of these pages.
All text readable. Option text a little small (TU2).	TU2 did not understand what the 2/3 meant.	Make it obvious which option the user has selected (highlighted; bold) (SSP1)	
Big 'Start' button very obvious (SSP2)	SSP2 – 2/3 pages good as tells user how far through the questionnaire they are.		

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Recommendations

1. Ensure text is agreed st… t size (14pt)
2. Consider removing qu…
3. Confirm what happens… d. Ensure obvious to user.
4. Consider changing to '… than '2/3' to reduce confusion.

GNOMON: MEDICATION LIST

a) **Suitability for the communication objective**	b) **Suitability for perception and understanding**	**c) Suitability for exploration**	d) **Suitability for user motivation**

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Text too small to read (HCP1; TU1; TU2).	Most participants misinterpreted that the purpose of this page was to check off taking medicines rather than a list. TU2 thought this would require too much recording.	It was not obvious to TU2 that clicking on the drug name button would take you to 'Medication details' page.	If on many medicines this page could contain +++ words and details on one page. Overwhelming for user (SSP1).
Icons and words at bottom – target users repeatedly mentioned they couldn't read the words.	Daily view not very helpful (one concise list for week better) HCP1; TU2	SSP1 asked where the + would take the user? Presumed to add a medicine but would they need to do that for each day of the week?	TU1 had 'no problem' with this list.
The + button at the top of the page was not noticed by SSP2. Could make it more obvious.	Daily list could be risky. Could be screenshot and used for medicines reconciliation. Non-daily medicines could be missed (HCP1).	Older people would require help to enter medications and manage the list. Would drop down lists be available?	Most difficult of all screens to manage from user perspective (SSP1).

Recommendations

1. Ensure text is agreed standard minimum font size (14pt)
2. Make it obvious where user goes for more information about the medication. Add a … or 'More details' button/text for user.

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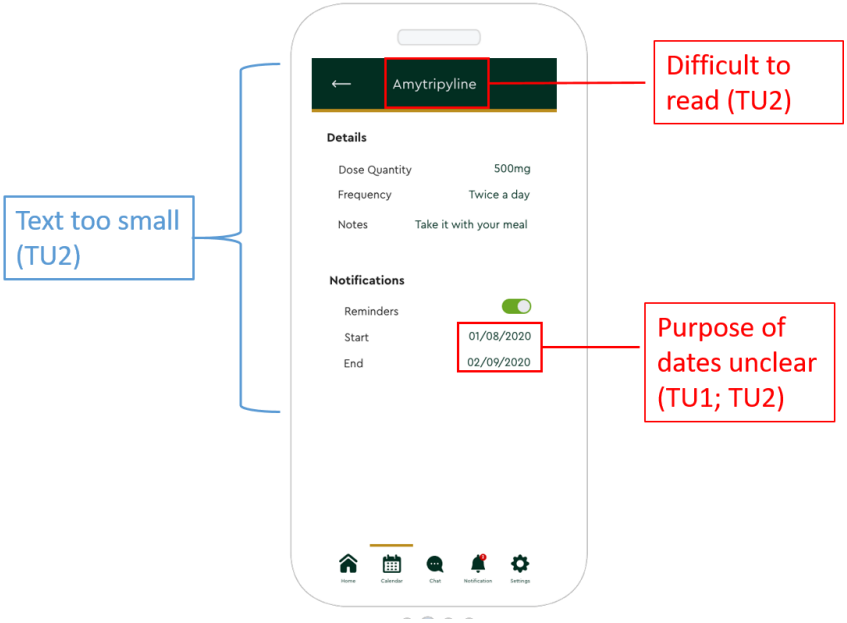
GNOMON: MEDICATION DETAILS



a) **Suitability for the communication objective**	b) **Suitability for perception and understanding**	**c) Suitability for exploration**	d) **Suitability for user motivation**
Text too small (TU1) Generally well presented information. Basic (but good) (SSP1). Useful for people who forget	Target users misinterpreted the dates to be dates during which the medicine was to be taken. TU2 thought that start date meant the start date of taking the medication	All participants knew how to set reminder on or off. All participants concerned how information gets put into the app. HCPs and SSP1 thought users would need assistance. TU1 felt they could do it themselves.	Unclear what the users are meant to 'get out of' viewing their medication details. If not to track adherence then 'what's the point?' (TU1).

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Researcher comment: not clear how to edit the information in the medication details/medication list screens

Researcher comment: when a reminder is set for a medication is there a field to input the time or time(s) if it is taken two/three/four times daily?

Recommendations

1. Ensure text is agreed standard minimum font size (14pt)
2. Make it more obvious what the dates are for: E.g., Add 'Remind me between… and …'.
3. Consider researcher comments/questions regarding editing information on screen and reminder options.

Additional feedback on the 'Medication list' feature of the app

The 'Medication list' feature of the app was discussed at length with the participants. With no healthcare professional oversight being deployed in this use case, the purpose and management of this feature requires further consideration. Participants raised concerns about viewing their medication list daily, rather than weekly or as a complete list of all medicines. One of the healthcare professional participants believed the daily view could put the user at risk if it was used incorrectly and mistaken as a comprehensive list of all medicines, potentially missing medicines taken less frequently than daily (e.g., three times a week, once a week, once a month). It was noted by some participants that the daily view would be useful if the user was using the app the keep track of what they had taken, like an adherence record, but without this function it was confusing. One participant mistakenly presumed that the user would have to enter in each medicine every day and remarked that people would not be prepared to keep those sort of

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records. The alarm function was appreciated with most participants saying it would be helpful to those who forgot to take their medicines.

Management of the medication list was discussed with all participants. Regarding who would be most appropriate to enter the details into the app, it was generally considered that patients would not be able to do this themselves easily and would be a risk, however one target user participant said he would have no problem entering in the information himself. Help from a healthcare professional or researcher to enter this information was considered more appropriate. Some participants commented that this would be one of the most important benefits of a health professional having oversight.

With regards to how medication is added to the app, participants suggested dropdown or prepopulated lists would make the process easier and safer. It was commented that One participant suggested that a list of common medicines in this patient group could be added as a minimum for users to choose from and additional medicines entered manually.

Comments on medication list

- Daily view
  - If being used as an adherence tool then a daily view would be useful, but without that function or need then the daily view is just confusing. Also, potentially a risk to have medicines displayed in a daily screen. If user was sharing this list with family or health services – medicines could be missed. Potential for it to be used for medicines reconciliation (HCP2)
  - Most difficult screen of all to manage from user perspective (SSP1)
  - Lots of writing in one space if patient is on many medications (e.g., 5-10 medicines) (SSP1)
  - Initially viewed this page as being where they could make a note of what they were taking – like a record (TU1)
  - Very useful for people who forget to take their medicines. Also queried if there was an alarm. (Showed participant reminder function on the next screen) Said – very good (SSP3).
  - Prefer own typed list. Weekly view better than a page for every day (TU2).
  - Lot of recording to be done – not sure people would be prepared to do that. If there are 7-8 pages of recording to be done people will get fed up very quickly. Presumed people would use the app to record when they had taken each medicine. Didn't think this would be done by most people (TU2).

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- Patient input
  - Patients wouldn't be able to do this (HCP2)
  - People would need support from family members to manage this list – not always there (HCP2).
  - Many people do not know the medications they are on. Navigating would be difficult (SSP1).
  - Participant would be happy to input the medication in themselves. If someone did it for them, perhaps it could be their GP (TU1).

- Researcher/HCP input
  - Trusting older patients to edit the information when changes are made to their medication would be 'a bit of a stretch' and risky. (HCP2)
  - Help from a HCP would be useful (SSP1).
  - This is one of the most important ways a HCP could be helping the person at home (SSP1)

- Mechanism of entry
  - Drop-down menu needed – free typing leads to errors even in trained professionals. Could be a 'disaster' (HCP2)
  - Entering in medications just once would be easier for user (rather than a new list for every day). (SSP1)
  - Is a dropdown list possible? Pre-populated list would be useful (SSP1)
  - Need to see how the information will be input/edited (SSP1)
  - Suggested that when entering a medicine the user could select that they take it everyday (SSP3).
  - For ease of the user – a list that was already populated would be beneficial. Wouldn't need to be all medicines but perhaps include ones commonly prescribed for this user group. Search an alphabetical list. If a person had to enter in 15 medicines this would be very time consuming (SSP3).
  - Premade searchable database would be good. Difficult for user to get all names and doses correctly inputted (SSP2).

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a) **Suitability for the communication objective**	b) **Suitability for perception and understanding**	**c) Suitability for exploration**	d) **Suitability for user motivation**
TU1 could not read this screen. Text was too small.	TU1 did not understand the purpose of the screen.	All users knew to press the three dots to action the notification and that the greyed out section were 'unread'	Too many notifications can be overwhelming.
Good layout and icons relate to text (SSP1)	Target users unclear why they would be receiving notifications and who/what would be sending them.	How does user access this screen? HCP1 presumed from bell icon at bottom of the page.	Notifications should be beneficial for user and perhaps scheduled for a time of day the user is using their smartphone (SSP1)
		SSP2 thought that the '…' would take the user to a tick-box to indicate task complete.	Not clear what happens to notifications if swiped away or deleted. Is there a risk the patient could take their medication

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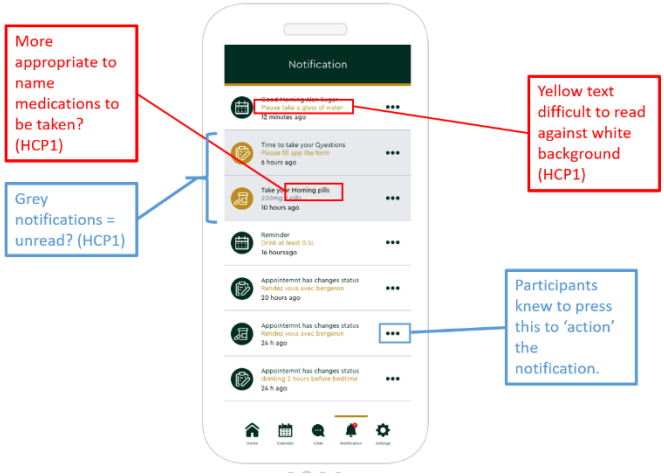
multiple times (SSP2)

Training would help increase confidence in how the app worked (SSP3)

Recommendations

1. Ensure text is agreed standard minimum font size (14pt)
2. Consider changing colour of yellow text.
3. Decisions to be made about how users access notifications from two different apps.

GNOMON: NOTIFICATIONS



Feedback collected on planned protocol for Phase 4/5

Participants were asked to share feedback on the plans to pilot UC-PT3-general during Phases 4 and 5 of the SHAPES pilot campaign. They were specifically questioned on how they would expect people to engage with the digital solutions,

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how feasible the eligibility criteria for the pilot were, what support people might need to help them use the app. Healthcare professionals and support service provider participants were also asked if they could foresee any clinical, logistical or governance issues with conducting the pilot. Other themes that arose during the interviews included accessibility of the app to people aged over 65, the training they would require, and the type and extent of clinical feedback that would be expected to be provided to participants during the pilot. All themes are discussed below.

Engagement

The participants were predominantly in support of the app and believed it would be of benefit to their health or the health of the target users. Level of engagement would largely depend upon how motivated someone was with regards to self-management. Too much time using the app each day and high levels of manual input required could be a burden to some people. The easier the app is to use and the less the user had to enter into the app, the more likely they would be to keep using it during the pilot.

Positive feedback on engagement

- Useful. A motivated person would like the app (HCP1).
- Could be considered a game for some [but annoying for others]. Different personalities will respond differently (HCP2)
- For information purposes it's ok – if it was developed further to have HCP input then it would be an excellent way to keep people out of hospital (HCP2)
- Would download this if it was approved. Believes it would be necessary for health. Would be happy to do anything if it was being done for their benefit or to improve their health (TU1)
- Might take a bit of getting used to but once able to use it would be useful (TU1)
- Saw the benefit of this to the health service (TU1)
- No trouble doing it for 12 weeks (TU1)
- People would definitely engage and use it. A lot of people are probably doing this now manually – using a diary or hr book (SSP3).
- Definitely realistic for people to use the devices every day. Already doing this to some extent. Know of people who would love to use this (SSP2).
- Think the app is great. Very exciting. Very relevant and appropriate at this time (SSP2).

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Negative feedback on engagement

- Could be considered [a game for some] but annoying for others. Different personalities will respond differently (HCP2)
- Wide range of people and abilities in this demographic. For most – it might be a bit too much. Depends on how long they are using the app every day. If there is a lot of manual entry – might be a bit too much (SSP1)
- People would not keep these sorts of records. Would get fed up (TU2)

Recommendations for pilot

1. Minimise the amount of data that needs to be manually entered into the app by the patient.
2. Communicate to participants that the manual entry of clinical readings should be only be used in the event that data was not automatically transferred from device.
3. Provide participants with details about how much time they would need to engage with the app each day.

Accessibility

Participants all believed that prior experience of using a smart phone would be required for people to be able to use this app. Furthermore, one participant added that those who have smartphone but who only use it for writing messages and making calls could get 'frustrated' using the app. Entering information was considered to be the most complex part of the app and may make it more difficult to use for some people.

Positive feedback on accessibility

- Not overly complicated. Would be confident using this app if the issues raised were sorted out (TU1)
- Very important that the technology works and readings don't need to be manually entered (SSP1).
- Great that the readings get transferred automatically. Once you get started it will get easier to use (SSP3).
- Let them get used to it. May take longer to get everyone up and running (SSP3).
- Easy to follow with prior use of smart phone (HCP1)
- Prior knowledge of using a smart phone would be CRUCIAL. (SSP1)

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Negative feedback on accessibility	• Those with only limited experience of using smart phone (i.e., to call or text) – the app could frustrate them (HCP2) • Inputting drug information would be a higher level of engagement for users that might not be appropriate in this age group (HCP2) • Many older people would not be confident using this app. Would depend upon prior use of smartphone (TU2) • Not letting them get frustrated. If that happens they may go back to doing it their own way (SSP3).

Recommendations for pilot

1. Consider screening participants not only for possession of a smart phone but for their confidence in using it. At the minimum, ask participants how confident they are at baseline to help predict what level of support they might require during the pilot.
2. Address specific accessibility issues with mock-ups.

Eligibility

It was generally thought that the proposed eligibility criteria (i.e., ≥65 years, diagnosed with heart failure and diabetes mellitus, self-reported stable Wi-Fi connectivity at their home, possesses their own android smartphone or tablet) were feasible. However, one participant estimated that around 50% of the target age group would 'not know where to start'. Another participant believed that a certain level of health literacy was also needed for people to be able to use the app safely.

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Feedback on eligibility

- Yes, it is possible to get people who are over 65 and who have the digital skills. Recruiting for Phase 2 was difficult BUT they were working with a smaller pool of people. Since COVID people have been upskilling to use smart phones.(SSP1)
- Absolutely reasonable and feasible to ask for this criteria. Minority of people will not have access (SSP2).
- Skills and capabilities needed include;
  - Use a phone
  - Download the app
  - Read the app and understand the meaning of the all the different readings they have been asked to take (TU2)
- There will be many people who do not have a phone or computer. What about them? Estimated about 50% of people their age wouldn't know where to start (TU1)

Recommendations for pilot

1. Consider screening criteria to include assessment of level of health literacy

Training

Most participants considered the app teachable and that people could learn how to use it and the associated digital devices. Effective training was considered to be crucial for getting people to use the app and be confident in doing so. Face-to-face training with supportive materials (see 'Support') would be ideal, with remote training possible if needed. Some participants suggested that given enough time, people would be able to get used to the app. Social support being present during the training could maximise time spent teaching the user how to use the app.

Comments on training

- Users would need to be shown how to use and navigate through the app and the devices. In-person training with leaflets/manual (in diabetes care) (HCP1
- Very teachable (except the medication list) (HCP2)
- Major factor will be the training given to users that will determine how effective and confident they are at using the app (SSP2).

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- (Remote training) when setting people who are not familiar with Zoom they would always to a test-run. They email out a zoom guide or post it out if necessary. It provides step by step instructions. For some people the whole process is really alien so this detailed guidance helps. Factor in at least one session to establish them on Zoom. Then next session introduce the app and share screen to show what they should be seeing. About 10% of people have difficulty (SSP2).
- Takes time to get used to a new app. For someone not savvy with apps, this could be difficult for them (SSP3).
- Having someone else there with them could be helpful to maximise effectiveness of training over zoom (SSP2).
- Give them good training and care in the first few weeks (SSP3).

Recommendations for pilot

1. Prepare comprehensive training package for participants
2. Deliver training face-to-face if permitted (dependent on COVID-19 regulations)
3. Consider giving participants a short period of time (e.g., 1 week) to get used to the app after their initial training. Perhaps completing a small number of training exercises (similar to Phase 3 hands-on training). Research team can provide high-level support and assistance during this period while they are learning to use the app and to troubleshoot any issues before the pilot begins.

Support

The types of support suggested by participants included social support (i.e., support to use the app from a carer or family member), telephone support (e.g., a helpline), written materials (i.e., a user manual), videos and automated notifications. Whilst social support can be permitted and expected in many cases, it cannot be relied upon as it will not always available. Participants supported the provision of written instructions and one target user stressed that these instructions should also include large images of what the user should be able to see on each screen. Videos would be helpful. Automated notifications in response to successful use of the app (e.g., well done for answering your daily questions today) could provide reassurance to users that they are doing it right. Support messages could also be sent to those who have not been active for a number of days.

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Social support	• Family support would be important (HCP2). • Someone to contact if they reach issues. Telephone support is what older people want. With COVID a lot of support has gone online – that has been raised by service users. Older people want to have a voice at the end of the phone. Even just a voice mail with response time (SSP1) • Written support would suffice but someone to help troubleshoot over the phone would help (SSP1)
Support materials	• Set of written instructions that include troubleshooting (HCP2) • Written information would help. Like the printed out Powerpoint slides. (TU1) • Videos would be brilliant support (SSP1).
In-app support	• Queried how the users will be monitored. Would the research team be able to monitor usage (SSP3). • Perhaps send some notifications to let the user know that they are doing it right. Not many, just here and there. Automated. Provides reassurance. Also can see when people haven't been online for a while. Could send a support message that way (SSP2).

Recommendations for pilot

1. User manual to include step-by-step instructions for using the app (including images and troubleshooting).
2. Social support is permitted but the participant should be able to use the app themselves.
3. Consider/discuss the use of automated (or researcher-generated) notifications for providing reassurance and support to participants during the pilot.

Clinical feedback

'Feedback' in this instance refers to the provision of clinical feedback to participants regarding their health. For UC-PT3-general, there is no healthcare professional oversight during the pilot and users will continue to receive standard care. The potential implications of this were discussed with Phase 2 participants.

Oversight by a healthcare professional was deemed to be crucial to one participant and without this they did not see the purpose of the app. Others did not consider the lack of

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health professional oversight to be an issue but saw the potential benefits of health professionals being involved in future. It was also noted that researchers must clearly explain to participants that the app is only for self-monitoring and a healthcare professional would not be remotely viewing their data.

Most participants queried whether, or not, the app would provide feedback about the users clinical measurements or some indication about what a 'normal' reading was and what would be considered out of range. When informed that personalised feedback could not be delivered by the app (as this would make it a medical device), participants suggested that standard explanations and information could be provided to users in lieu of tailored advice. One participant was concerned that users could become anxious about their readings and that this additional information might 'put them at ease'. This information should include what the readings mean and guidelines on what they should be, with advice on when to contact a health professional. One participant suggested that the information could be targeted towards the conditions this group of patients have and/or the medicines they are taking (e.g., people on beta blockers may have a slower heart rate, or, blood glucose will be higher after a meal). The method of delivery of standard information was also discussed with two participants. Suggestions included having a feature within the app that was accessible via the SHAPES menu or having clickable 'information' buttons within the features that provided additional information.

Comments on feedback

- What is done with the inputted information? Does the person get anything back from the app? (HCP1)
- In future, if clinical information was to be fed back to the user through the app it would be really useful (HCP1)
- Explanation of what the readings mean is needed. What is safe and what is concerning (TU2).
- Participant presumed that someone would be seeing the readings and that out of range values would be flagged or incorrectly taken readings pointed out to user via phone call or email (TU2)
- Would the app provide feedback to the user regarding abnormal clinical parameters, e.g., a high blood pressure OR if the reading would go to a HCP as an 'alarm' (SSP2).
- When people take their BP regularly, concerns come with that and they become anxious about it. The last thing you want is for someone to become anxious about the readings – could increase their blood pressure even more (SSP3).
- Information should be tailored to the patient group – for instance, people are likely to be on beta blockers and this lowers heart rate. Users should be made aware of this so that they do not panic (SSP3).

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- Rather than giving personal advice, could add an icon to provide details on what a normal reading would be. Could use guidelines to generate this information. Also could provide advice about what could raise sugar levels. In-app reminder. Frequent reminders and feedback about where they are aiming to be (SSP3).
- Additional information might put them at ease (SSP2).
- No clinical issues if no advice given through app (HCP1).
- Very important to make it clear to the participant that this is just a monitoring app. This is not in place of normal routine (SSP1).
- Participant queried if this would replace regular check-ups with medical professionals (TU2).

Recommendations for pilot

1. It must be made very clear to participants that there will not be a healthcare professional viewing their data every day and the app is not a replacement for usual care. Consider formally checking that the participant has understood this (i.e., check capacity during consent process).
2. Determine most appropriate **content** to include in the information provided to participants regarding their clinical parameters. Liaise with diabetes and heart failure specialists to generate this content.
3. Discuss most appropriate way to **deliver** this information. Options include:
    a. Written information
    b. Section within SHAPES app (i.e., accessed via menu) with information about each clinical parameter
    c. Clickable buttons within each clinical parameter page with pop-up information

Logistical and governance issues

Participants raised queries about how the app would be downloaded and accessed by users. With regards to downloading the app, one of the target user participants mentioned they were hesitant to download new apps for fear of them slowing down or damaging their smartphone. Participants queried how they would login to the app and how they could access forgotten information. Aftercare was also discussed with some participants – i.e., what happens after the trial. As long as investigators were transparent about the app only being available for the duration of the pilot, the participants questions about aftercare thought people would be accepting of that.

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The healthcare professional participants commented on the potential data protection issues with using the app and raised concerns about the risk of incorrect information being entered into the app and then acted upon by a healthcare professional. One participant asked about non-compliance.

Comments on logistical, technical & governance issues

Logistics/technical

- Username and password – what happens if a user has forgotten log-in details? (SSP1)
- Account creation – unclear how the user does this (SSP1)
- What happens if people are not compliant (SSP1)
- How will people download the app? Will they get instructions? (SSP1).
- Careful about downloading apps – some can slow the phone down or mess it up (TU1).
- Aftercare
    - SSP3: Queried aftercare – could they use the app or devices?
    - SSP3: Good thing for them to get started – could transfer use to another source. Might enjoy it so much they will not want to stop.
    - SSP2: If transparent about this from the start then they will be understanding. People usually more than willing to help.

Governance

- Potential for data protection issues (HCP1).
- Patients incorrectly inputting incorrect information is a governance issue. Risk that it is used incorrectly as a full list of medicines and is wrong information (HCP2).

Recommendations for pilot

1. Discuss process for downloading app with technical partners. Questions to cover include:
    a. How will the app be downloaded? Will it be on the Play Store or downloaded via a link. What are the risks associated with this and how can we alleviate any concerns from participants?
    b. Will the app be supported by all Android versions?

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   c. What affect will the app have on the participants smartphone (will it use a lot of battery power, local storage etc.)
   d. What is the process to be followed at the end of the pilot with regards to removing the app from the participants phone?
2. Clarify process for login and what the participant must do if they have forgotten their login information.
3. Discuss and confirm a protocol for managing non-compliance with the pilot activities.

Annex 8 UC-PT3-gen Phase 3 participant information sheet

SHAPES PARTICIPANT INFORMATION SHEET: target user

Study title: SHAPES Pan-European Pilot Campaign: Hands-on experiments and feedback on digital solutions for pilot theme 3 — medicines control and optimisation.

We'd like to invite you to take part in our study, during which we would like to hear your feedback on the functionality of a healthcare application (an app) that is being developed for people aged 65 years' and over, and who are living with heart failure and diabetes. The study is an opportunity for us to make sure the app is practical and usable from an older person's perspective. We aim to involve at least four target users of the app in this study.

You have been identified as being suitable for our study and have been given this information sheet to read and consider if you would like to take part.

This information sheet describes the study and your role in it. Before you decide, it is important that you understand why the study is being done and what it will involve for you. Please take time to read this information and discuss it with others if you wish. If anything is not clear, or if you would like more information, please ask _____who will be in contact with you after you have had time to read this information.

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Voluntary nature of participation

Participation in this study is voluntary. You can withdraw from the study at any time without giving any reason and without there being any negative consequences.

Purpose and aims of the study

This study is one part of a larger research project that aims to test different ways of using technology to assist people in their homes as they get older.

The purpose of the study is to show the app to its target users (i.e., older persons with heart failure and diabetes) and give them the chance to use the different features within the app and test how well it works. Participants will be encouraged to share their initial reactions, thoughts, feelings and opinions about what it is like to use the app and to offer suggestions as to how it could be improved. Using this feedback, we will make changes to make the app more user-friendly for older individuals.

The finished app will then be used in a real-world study to see if it can help people manage their heart failure and diabetes conditions from home, and improve their quality of life and health outcomes.

Who is organising and funding the research?

The Northern Health and Social Care Trust (NHSCT) is organising this study. It is part of a larger research programme called the SHAPES project which is funded by the European Union under the Horizon 2020 Programme (Grant Agreement no 857159).

What will the participation involve?

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If you agree to be involved with this study, you will be asked to take part in a series of two video calls in the same day (one in the morning and one in the afternoon) with local researchers from the Northern HSCT using a computer. You will be provided with a tablet device that has the app installed on it.

What exactly will happen?

Taking consent

- After you have had time to read this information sheet, _____will be in touch with you to discuss participation.
- If you are happy to take part you will be asked to sign a consent form and _____will return it, along with your contact details, to the researcher.

Before the video calls

- The researcher will telephone or email you to arrange a suitable day to conduct the video calls.
- The researcher will check if you have the technology needed to conduct the video call and talk you through how to use it (if required).
- The researcher will also deliver a tablet device to your home for use during the call and a training manual that you can read beforehand and refer to during the video call.

During the video calls

Video call 1 (morning)

- A researcher will guide you through a series of steps and tasks to show you the different things that app can do and explain how to use it.
- Instructions will be presented on screen during the call and will also be printed in the training manual.
- You will be asked to 'think aloud' during this part of the video

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call, expressing your initial reactions to, and thoughts about, the app. We are particularly interested in finding out what doesnt work (rather than hearing only positive feedback).
- We will then end the call and ask you, in your own time, to continue to use the app and test the different functions.

Video call 2 (afternoon)
- When you return for your second call that day, you will be given a simple task to complete unaided. This is not to test you, but rather the researchers will be watching out for any stumbling blocks or issues **with the app.** Again, we will ask you to think out loud during this task.
- Following this task, we will administer a short questionnaire about how you found using the app. By collecting information this way we can compare the app to other apps on the market.
- Finally, you will be asked a few questions by the researcher about your experience using the app. This is your opportunity to tell us in more depth what you like, dislike and would change about the app.

<u>After the video calls</u>
- When the study has been completed a researcher will arrange collection of the tablet device from you.
- Our research group is interested in hearing about the lives of the people who take part in the study, for example, your needs, wishes and experience of taking part in the SHAPES study. This is not part of the research study, but rather a way of hearing personal stories of the people that the study is all about. If you would like to contribute to this collection of participant 'stories', your researcher will be happy to discuss this with you after the video call.

<u>Collection and processing of information after the video calls</u>
- Other than your name, contact details and recordings obtained during the interview, no other personal data will be collected.
- All recordings collected during the interview will be transferred to a password-protected computer that only the local researchers from the Northern HSCT will have access to.
- We may transcribe (write out) the recordings and will anonymise

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(remove your name) any identifiable information in the process. Recordings will then be destroyed after use.

- Anonymised findings may be used in further research and/or communication activities (e.g., as part of further research in the SHAPES project, in journal articles, workshops and conferences).
- Your personal contact details will be either destroyed by the researchers once you have been provided with a summary of the findings for this study, or kept on file with your permission, should you wish to be contacted by the same research team at a later date.
- Anonymised raw data will be stored for the duration of the SHAPES project and for five years after it finishes.

Possible benefits of taking part

There are no direct benefits to you as an individual for taking part in this study, besides personal interest and the experience of participating in a study. However, the indirect benefit of this study is that your views and opinions will be used to improve what the app looks like and how it works. Your input will also inform how we use technology to assist people in their homes as they get older. People from all over Europe will benefit from your participation.

Possible disadvantages of taking part

We do not foresee any discomforts or disadvantages for you taking part in this study.

Financial information

Participation in this study will involve no cost to you. You will receive no payment for your participation.

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Informing about the study results

Findings from this study may be used in further research and/or communication activities (e.g. as part of further research in the SHAPES project, in journal articles, workshops and conferences). A summary of the findings will be made available to you.

Termination of the study

The researchers conducting the study can terminate the study, however, at present there are no foreseeable reasons why this study would be terminated. If you would like to withdraw your participation at any point you are free to do so. If this is the case please contact the researcher. We may still use your anonymised data.

Further information

Further information related to the study can be requested from the following people involved with the SHAPES project.

Contact details

Mid & East Antrim Agewell Partnership

Email: info@meaap.co.uk; Telephone: 028 2565 8604

Northern Health and Social Care Trust

Dr Maureen Spargo (local researcher)

Email: Maureen.spargo@northerntrust.hscni.net; Telephone: 028 9442 4942

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Professor Mike Scott (principal investigator)

Email: DrMichael.Scott@northerntrust.hscni.net; Telephone: 028 9442 4942

Nicola Lyons (Data Protection Officer)

Email: dataprotectionofficer@northerntrust.hscni.net

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Annex 9 UC-PT3-gen Phase 3 participant consent form

SHAPES PARTICIPANT CONSENT FORM

Title of the study: SHAPES Pan-European Pilot Campaign: Hands-on experiments and feedback on digital solutions for pilot theme 3 — medicines control and optimisation.

Location of the study:

Northern Health and Social Care Trust (NHSCT)

Contact

Dr Maureen Spargo (NHSCT researcher)

Email: Maureen.spargo@northerntrust.hscni.net; Telephone: 028 9433 0716

Mid & East Antrim Agewell Partnership

Email: info@meaap.co.uk; Telephone: 028 2565 8604

Participant declaration

- I have been invited to participate in the above study. The purpose of the study is to test the app and challenge how well it works for me as a target user of the app.

- I have read and understand the participant information sheet. The participant information sheet has provided me sufficient information about the above study, its purpose and execution of the study, about

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my rights, and about the possible advantages and disadvantages of taking part.

- I have had the opportunity to ask questions about the study and have had these questions answered satisfactorily.

- I have been given sufficient information about the collection, processing, transfer/disclosure and deletion of my responses during the study. I understand that other than my name, contact details and video/voice recordings obtained during the study by researchers from the Northern HSCT, no other personal data will be processed during this study.

By signing this form, I confirm that I voluntarily consent to participate in this study and that I also grant consent to the processing of my responses for the purposes described in this document.

I have not been pressurised or persuaded into participation and I have had enough time to consider my participation in the study. I understand that my participation is entirely voluntary and that I am free to withdraw my consent at any time, without providing any reason.

I also have the right to request the removal of my identifiable personal data in accordance with data protection legislation.

Optional

I agree to be contacted by the Northern Health and Social Care Trust about taking part in future projects related to this study arising within the next year

Yes No

(please circle)

To be completed by the participant

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Agreement (please complete the details below to confirm your consent)

Name:

Date:

Signature:

To be completed by study personnel

Please complete the details below to confirm receipt of signed consent

Name:

Date:

Signature:

The original consent signed by the participant will be kept by the research team. The participant information sheet and a copy of the signed consent will be given to the participant.

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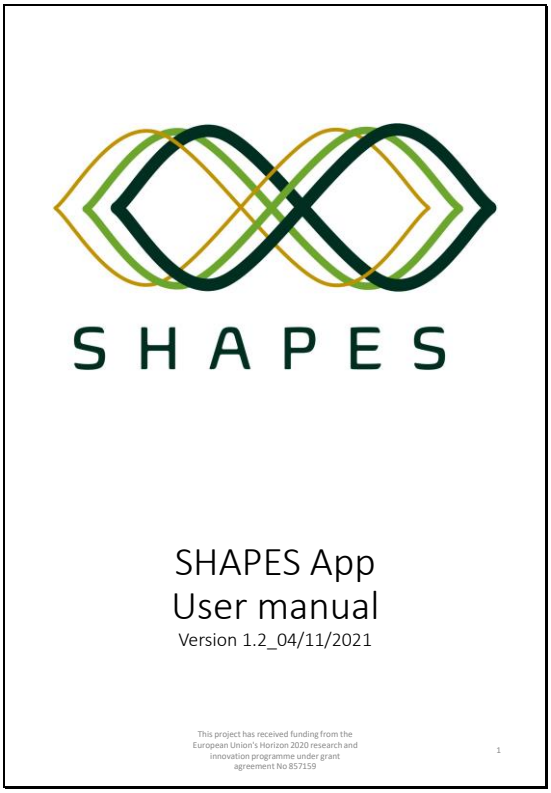
Annex 10 UC-PT3-gen Phase 3 user training manual

Slide 1



Slide 2

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Contents

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Slide 3

About SHAPES

- **SHAPES** is a European research programme that is exploring how technology can enable older people in our communities to live healthier lives for longer at home.
- Research studies are being conducted across Europe to determine if certain technologies (e.g., mobile phone apps, home sensors, robots etc.) can helpfully support people aged over 65 years in seven key areas.
- Here in Northern Ireland we are investigating how we can use a mobile phone app (i.e., the SHAPES App) to support the **safe and effective use of medicines** by people at home.

SHAPES

3

Slide 4

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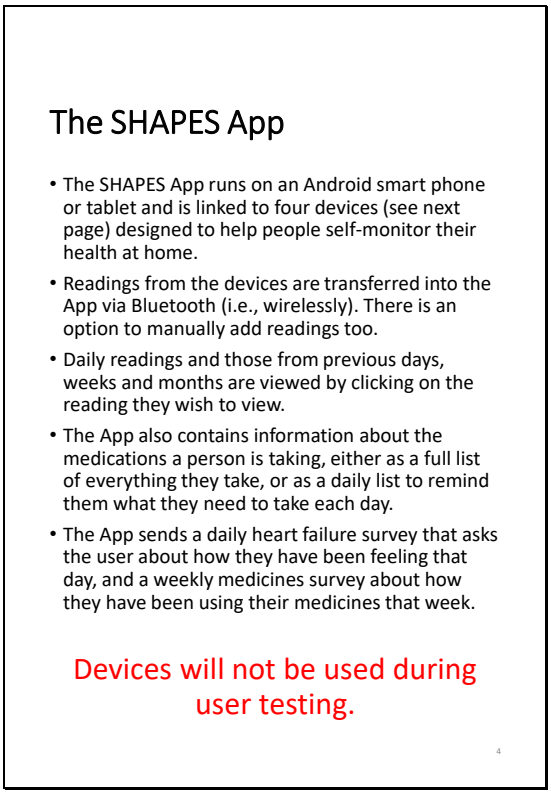

Slide 5

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For information only

1 • The SHAPES devices are:

OMRON VIVA Smart Scale for measuring **weight**

Beurer PO60 Bluetooth pulse oximeter for measuring **heart rate & oxygen saturation**

OMRON M7 Intelli IT for measuring **blood pressure & heart rate**

Roche Accu-Chek Instant for measuring **blood glucose**

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Slide 6

When the SHAPES app is linked to the Bluetooth devices the data for weight, heart rate, blood pressure, oxygen level and blood glucose will be populated automatically into the SHAPES app when each device is used.
For the purposes of this user testing we will show you how to manually enter readings into the app.

Slide 7

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The SHAPES App

- The SHAPES App has been specially created for use in people aged over 65 years and is in fact a combination of two commercially available apps that have been adapted for use in the SHAPES project.
- By having features from both of these apps, we are able to widen the range of functions available to users.
- This does mean that the design of some pages will differ from others.

This user manual describes how to use the SHAPES app. You will be shown how to view information and manually enter readings into the app using a test device.

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The test device

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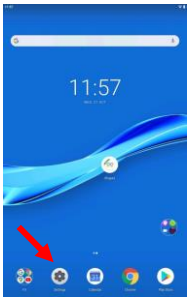
Slide 9

Connect to WiFi

1. On the tablet home screen look for the **SETTING** icon and tap it to enter the device settings (see image on the left below).
2. When in settings, tap **NETWORK & INTERNET**
3. Next, tap **WLAN** (see image on the right below). A list of available networks will appear. Choose yours and enter password if required.



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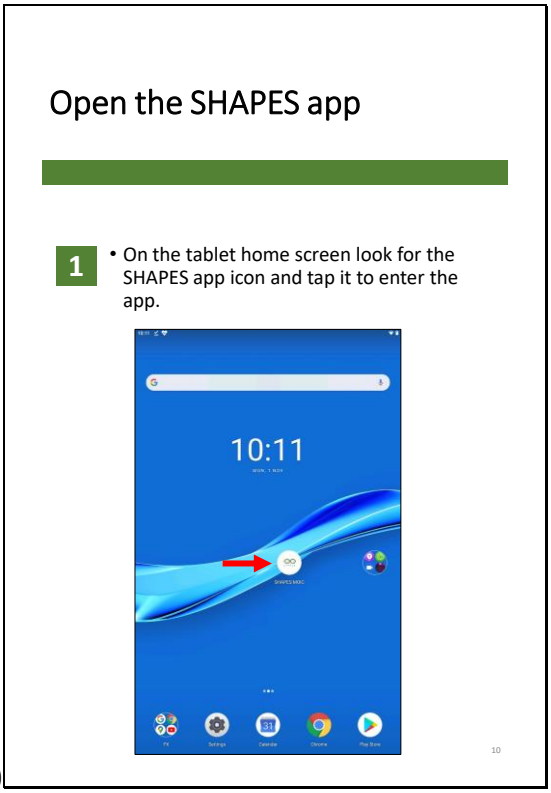

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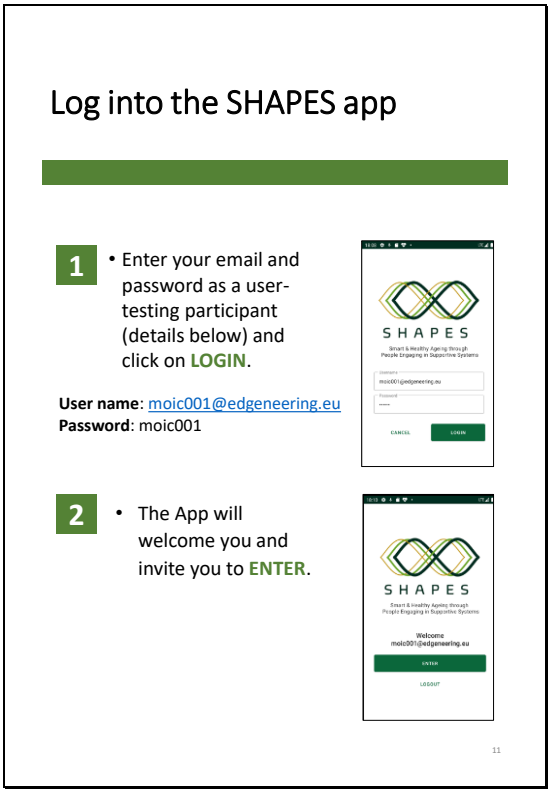
Slide 11



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Navigate to and from the Menu

1 • This is the **MENU** page. It is where you can access the different sections of the App.

2 • To get to this page from anywhere in the App, tap the **HOME** icon and/or swipe back, or tap the back icon. It may take a few steps.

The **HOME** icon will be a picture of a black house in a yellow circle or on its own.

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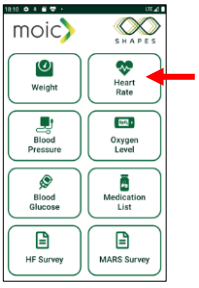
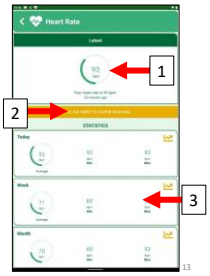
Heart rate

1 • From the **MENU** page. Click the **HEART RATE** icon.



2 • The **HEART RATE** page will appear. From this page you can:

1. View your most recent heart rate reading (in this example the reading is 93 bpm).
2. Enter a new reading.
3. View your heart rate readings from the past day, week and month.



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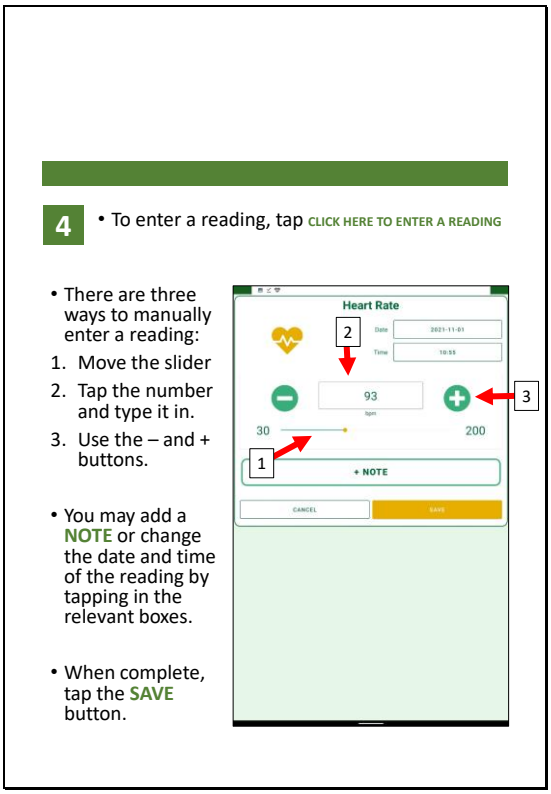

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Blood pressure, oxygen level and weight

- You can navigate to each of these sections from the **MENU** page.
- Entering a reading for blood pressure, oxygen level and weight is a similar process to that followed for **HEART RATE** (see page 13).

BLOOD PRESSURE

OXYGEN LEVEL

WEIGHT

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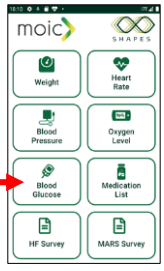
Slide 16

Blood glucose

1 • From the **MENU** page. Click the icon of the reading you would like to view. In this example we will be viewing **BLOOD GLUCOSE**



2 • The **BLOOD GLUCOSE** page will appear. From this page you can:

1. View your most recent blood glucose reading (in this example the reading is 6.2 mg/dL)
2. Log a reading
3. View previous readings

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3

- To view a history of your previous blood glucose readings. Tap the icon.

4

- On this screen you can view a graph of your blood glucose over time.
- You can change the time period by tapping **Last 30 days**.
- Scroll down to view a list of previous readings.

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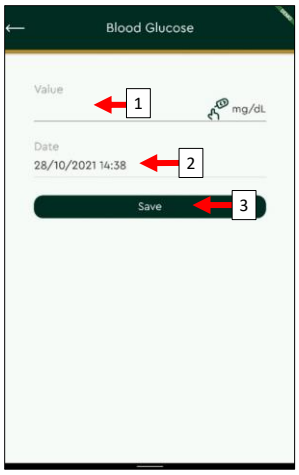
5 To enter a blood glucose reading tap **LOG** on the blood glucose screen.

1. Tap under the word **VALUE** and type in your reading
2. Tap on the date and time (e.g., 28/10/2021 14:38) and type in the date and time the reading was taken (NB the time and date will always default to the current time and date.)
3. Tap **SAVE**



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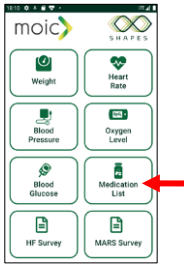
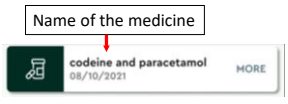
Medication list

1
- From the **MENU** page, tap on the **MEDICATION LIST** icon.



2
- A list of all your medicines will be displayed.
- Tap **MORE** for more information.



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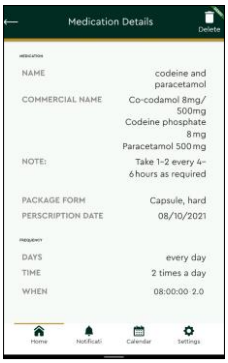
- All the information you need about a medication is detailed on this page including its name, ingredients, and directions for how to take it.
- This information will be managed by the researchers during the pilot. You do not need to do anything on this page.



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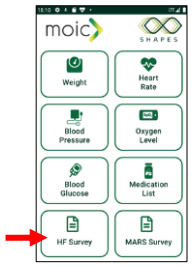
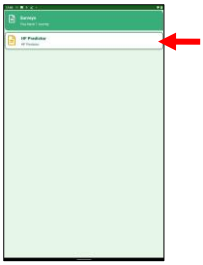
HF survey

The HF predictor is a feature of the App that supports self-management of heart failure symptoms. In future, the information captured in these surveys may be sent to clinical teams and used to monitor people more closely while they are at home.

1. From the **MENU** page, tap on the **HF SURVEY** icon, followed by the **HF Predictor** button on the next page.





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2

- A multiple choice questionnaire will appear.
- Tap your responses to each question and tap **SUBMIT** when complete.
- Selected responses are highlighted in yellow.

3

- A box will pop up asking you to confirm if you would like to submit.
- Tap **CANCEL** if you would like to return to the questions.
- Tap **SUBMIT** to save your responses.

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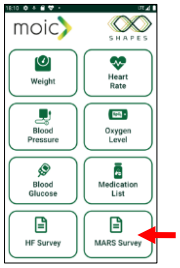
MARS Survey

The MARS survey is a feature of the App that supports self-management medication. In future, the information captured in these surveys may be sent to clinical teams and used to monitor people more closely while they are at home.

1 • From the **MENU** page, tap on the **MARS SURVEY** icon. Then choose a questionnaire from the two options on the next page.



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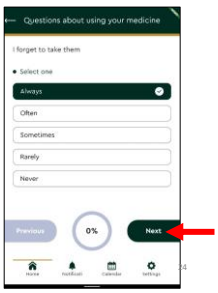
3 • Tap the response you want to choose.

3 • Your chosen response will be highlighted in dark green.

• Click **NEXT** to proceed to the next question.



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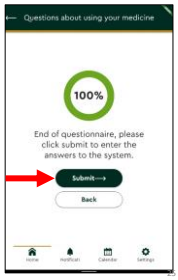
5 • The circle and percentage show you how far you have progressed through the questions.

6 • When you finish the questionnaire tap **SUBMIT** to complete the questionnaire.



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To-do lists

- As mentioned previously, the SHAPES app is in fact two separate commercial apps (**eCare** & **eHealthPass**) that are working together for SHAPES to offer users a wider range of functions to help them manage two different conditions.
- Each of these apps has a function that allows the user to view what tasks they have to do each day.
- However, the tasks are specific to the two individual apps. There is no combined list.
- The lists are accessed via the SHAPES app in different ways.

1. By clicking the < button when in **HEART RATE/WEIGHT/ BLOOD PRESSURE/OXYGEN LEVEL** or **HF SURVEY** pages. This list is provided by eCare.

2. By clicking the **CALENDAR** button when in the **BLOOD GLUCOSE**, **MEDICATION LIST**, or **MARS SURVEY** pages. This list is provided by eHealthPass.

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eCare to-do list

- After tapping the < button, a **DASHBOARD** appears displaying your most recent readings for **HEART RATE, WEIGHT, BLOOD PRESSURE, OXYGEN LEVEL**
- Tap the **TO-DO** icon in the top left corner to access a list of tasks for the day.

- This can also be accessed by tapping the **TODAY** icon at the bottom of the screen.

- A green/blue circle with a tick in it means you have completed the task.

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eHealthPass calendar

- **CALENDAR** allows you to see a list of tasks for the day. 

- A green circle with a tick in it means you have completed the task.
- Tap the **NOTIFICATIONS** icon to display a list of reminders. 

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User Experience Questionnaire

When instructed, please fill out the following questionnaire. The questionnaire consists of pairs of contrasting attributes that may apply to the product. The circles between the attributes represent gradations between the opposites. You can express your agreement with the attributes by ticking the circle that most closely reflects your impression.

For example:

obstructive ○ ⊗ ○ ○ ○ ○ ○ supportive

English version

obstructive	o o o o o o o	supportive
complicated	o o o o o o o	easy
inefficient	o o o o o o o	efficient
confusing	o o o o o o o	clear
boring	o o o o o o o	exciting
not interesting	o o o o o o o	interesting
conventional	o o o o o o o	inventive
usual	o o o o o o o	leading edge

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Annex 11 UC-PT3-gen Phase 3 feedback report

Service user App feedback

	PT1	PT2	PT3
Ease of use	**Password** difficulty using capital letters	**eCare data input** no problems. Preference for slider.	**Intuitive**- asked ahead about the next step, e.g., 'save'
	Password difference between zero and letter 'o'	**Navigation back to menu page** – confused by extra pages that appeared in both eCare and eHealthpass.	**eCare data input** no problems. Slider difficult to get precise but +/- buttons complement nicely. No preference
	Navigation to menu page- difficulty remembering the different methods provided by different app providers	**Navigation between pages** - participant sometimes inadvertently skipped pages	**Confusion over functions of app Vs features of device.** Asked about 'tick' on keyboard (participant was tablet naïve)
	Navigation from HF survey page- no back arrows present	**Navigation back** - back arrow consistently worked for participant. Success of swipe function was inconsistent.	**Pop-up boxes-** didn't seem to come up when expected to when exiting the surveys.
	HF survey- participant tapped where it said 'surveys you have 1 survey' rather than HF predictor	**eHealthpass data input** - no problems	**Home button** – 'handy'
	Navigation to 'to do' lists and between different app provider sections	**Answering survey questions** – all fine	**Computer literacy needed-** those with no experience would be scared to use

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	Straightforward/easily understood/simple with practice **User must be digitally literate** **Easier than anticipated**	**Navigation out of HF Predictor** – no back arrow or home button. Couldn't perform swipe function. Had to come out of app completely. **Two finger swipe** – reveals side panel. **Navigation out of MARS survey** – 'home' button works well when it's there. Pt unable to get swipe to work. **eCare dashboard –** delay to load. **Navigation out of blood glucose/HF Pred/MARS survey-** complicated pt found workaround. Took 20 mins of 'playing around' to discover workaround. **Computer literacy and interest –** needed for people to be able to use. **Navigation should be easier.** Should be a home or back button on every page.	**No concerns** about ease of use. Easier than anticipated
Design	**Blood glucose graph-** easily understood	**Medication list** – some information not displayed. Only sections with data in them displayed?	**HF Pred-** hard to select correct answer. Would prefer gap between options.

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	MARS- confusion with the term MARS consider changing to 'Weekly survey' on menu page	**Fit for purpose**	**Text versus icon-** Participant looked for text rather than icon.
	MARS questionnaire layout- understood very easily	**Colours** – green on white is good. Avoid black on white.	**Terminology inconsistent** between apps for accesing to-do lists (today/calendar)
	Improvement from mock-ups	**Text size** – all ok on tablet. Would expect it to be more difficult to read on phone. Dislikes using accessibility features.	**Simple and straightforward** design. No problems reading.
	Clear display	Clear display	**Colours** not appropriate for those who are colour blind, Better black and white
	Appropriate size (on tablet)		**Perfect design.** Wouldn't change at all.
			Smaller text on phone – may need glasses to read.
Utility	**Slider function** – training required on this	**Medication list** – not useful. Maintains own list. Useful for people with memory problems. Details about what the medicines is for may be useful.	**eCare 'notes' section - Quickly understood what this was for**
	Max/min values- unclear that these were max/min values	**Motivation to use-** people would get bored. Data input would be a burden. Bluetooth connection would reduce burden.	**Good comprehension of use of app.**

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To do lists are useful	**Interpretation of readings** – would like info on meaning of readings.	**Medication list**- good to see that information
Broad application to health (lots of functions available)	**Suitable to needs** – provided a doctor was getting the info. Less concerned with self-management.	**Medication list**- queried what the delete button was for
Exercise measurement as an additional functionality	**Exercise and diet measurement as an additional functionality**	**Push notifications/ medication reminders-** would not use and not good for older people. Shouldn't replace physical help with medications **Wouldn't like if it got too invasive or complicated** **Privacy and security** of personal information very important **Appropriate for needs and age-** participant only has diabetes but was interested in the heart monitoring due to other comorbidities **Already monitors heart rate** using wearable monitor but does not keep a record. If it linked to this app and was able to show to doctor would be excellent.

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	Medication list not so useful perceived that doctors look after that		**Information-** good to have information in one place. Can be shown to doctor. **Big scope-** Could be extended to other conditions.
Gender neutrality	**Appeals to men and women the same**	**Appeals to men and women the same**	**No difference**
Quality of training	**Measurements**- training required to understand physiological measurements	**Devices and self-monitoring** – training would be needed to use the devices and how to self-monitor in general	**Hands-on help-** good to have someone face-to-face to help at start of training. Would have struggled without.
	Questionnaires- important to explain that the submit/next icon doesn't activate until questions are answered	**Training manual** – no problems. Helpful. Should contain more information on navigation	**Informative. Simple. Not confusing. Straight to the point.**
	Trainers – clarity between asking participant to do something vs showing them what can be done on the App	**Live training** – very helpful. Stepwise a good approach	**Online technical support-** would be helpful
	User manual display- discrepancy on Medicines information page on app vs manual	**Training for pilot** - Quite a lot will be needed	
	User training essential		
	Training required on use of devices		
	Training was simple		

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Overall satisfaction	**Convenient**	**No problems using this app**	**Exciting**
	Time efficient	**Would continue using**	**Enjoyable**
	Good	**Concern over keeping people interested**	**Informative**
	Self-management	**Met expectations**	**Information at the touch of a button.**

MOIC App feedback

- Generally the app was very well received and participants thought it easy to use with practice and training.
- Main area of confusion was different methods of navigation to the home/menu page and different locations of 'to do lists'

Single sign-in	• Needed to ensure all 3 apps were signed in for the SHAPES app to work
To-do lists and general navigation	• Users found it difficult to remember the different methods of navigation back to the main menu screen as they differ between eCare and eHealthpass • Having 'to do' lists in separate places is confusing.

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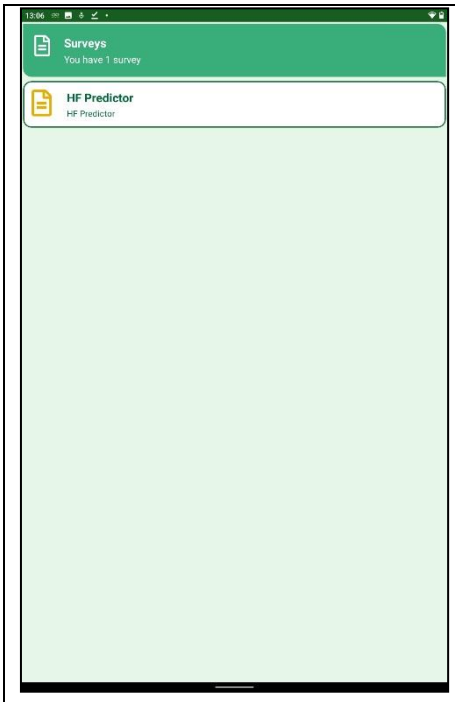

- No back arrow or home icon for navigation
- Participant unclear where to tap (tried tapping the green banner at the top)
- Remove 'Not applicable' as a survey response- this will only be used for participants who do not need to answer the questionnaire i.e. those without HF
- Wording of some questions
    - Daily qu 1: Regarding episodes of swelling (oedema), in the last 3 days, your legs/feet or any other part of your body are better, worse or the same? Responses better|worse|same
    - Daily qu 2: Compared to the last 3 days, today, do you feel better, worse or the same? Responses better|worse|same
    - Daily qu 4: Can you walk or do activities like previous days? Say "No" if now you feel breathless or have more difficulty to breathe. Responses Yes|No
    - Daily qu 6: Did you notice that you started coughing or have phlegm? Responses Yes|No
    - Daily qu 7: Does your medication suit you well? Say "No" if you relate your medication to any non-desired effect, such as feeling dizzy or blood pressure drop. Responses Yes|No
    - Daily qu 8: Are you following the diet and exercise recommendations

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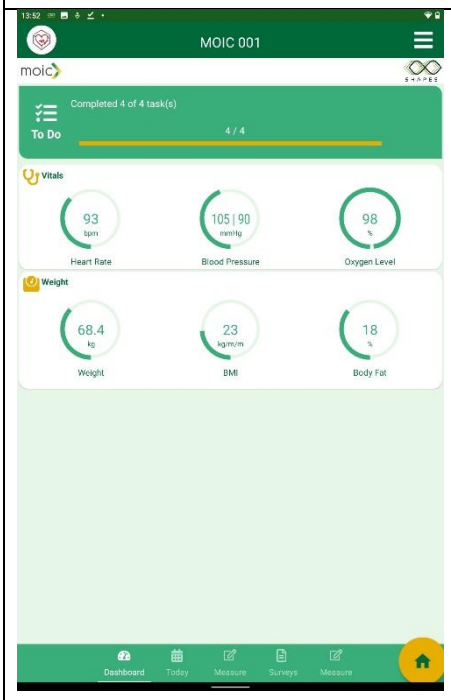
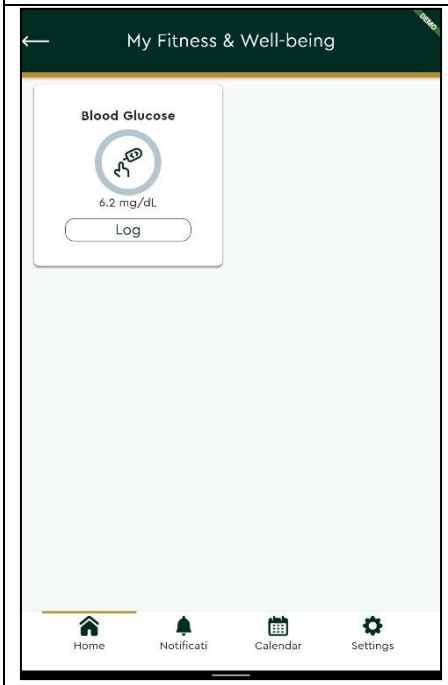
	provided by your doctor and nurse? Yes|No • When in the survey page add an option to cancel or navigate back • Change name on the menu page to 'Daily heart failure survey' or 'Daily survey'
	• We don't require a display for BMI or body fat • Is the left side bar 'dashboard' required? • When selecting '<' button in eCare it brings you back to whatever was the last opened page from those in the bottom navigation
	• 'It is not the right time to complete this to do'- adding blood glucose readings should not be time bound • When changing the time of entry the clock face is unreadable.

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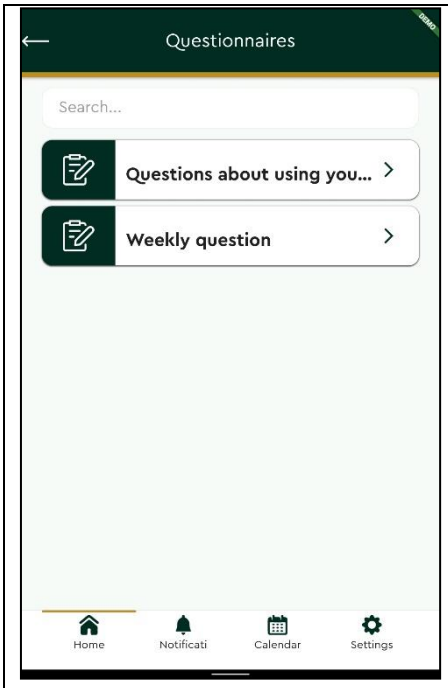

- Weekly questionnaire prompted daily
- Change name on menu page to 'Weekly survey' or Weekly medication survey'
- For the MARS is it possible to include some of the instructional text:
  - Many people find a way of using their medicines which suits them.
  - This may differ from the instructions on the label or from what their doctor has said.
  - We would like to ask you a few questions about how you use your medicines

  - Here are some ways in which people have said that they use their medicines
  - For each of the statements, please tick the box which best applies to you
- Could the weekly medication question be included at the end of the MARS questionnaire? Rather than having 2 separate weekly questionnaires.

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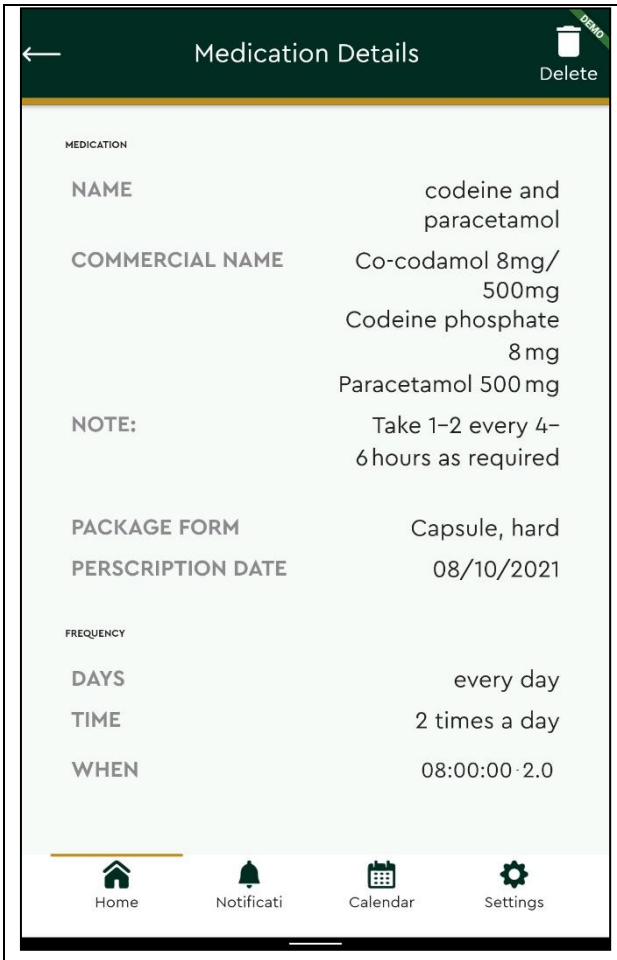

- Please remove the delete function as this will be managed via the dashboard
- Strength – need to allow decimal entry e.g. 2.5mg
- We don't require the 'When' function i.e. time for medication intake. Once/twice per day is sufficient. 'When' doesn't display correctly, it is scrollable.
- In the 2 versions of the app provided the medication display is slightly different, current version does not have commercial name, 'ote- please confirm correct display.
- Need to be able to input a single strength via the dashboard e.g. furosemide 40mg, not 40mg in 40mg in addition to the split strength format e.g. co-codamol 8mg codeine phosphate /500mg paracetamol
- It would be helpful instead of seeing the prescription date under the name of the medication in the medication page to have the directions 'once per day' etc
- Notifications- it is not necessary to have every medication occurrence appear, rather each medication for the day should only appear once as a reminder to take that particular medication

Task completion

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Participant 1	Enter BP of 135/89 mmHg	Navigate to a screen that displays history of **blood glucose** readings	Complete the HF survey
	Completed- participant entered 145/89mmHg	Navigated to the interim blood glucose page instead	Participant indicated they had completed this, can this be confirmed as there is no history of completed surveys on the app
Participant 2	Enter a blood glucose reading of 6.2mg/dL	Navigate to a screen that displays history of **weight** readings	Complete the MARS survey- questions about using your medicine
	Entry of 6.7mg/dL entered	Completed	Participant indicated they had completed this, can this be confirmed as there is no history of completed surveys on the app
Participant 3	Enter an oxygen level of 99%	Navigate to a screen to view information about the **medication** 'bisoprolol'	Complete the MARS survey- weekly question
	Completed	Completed	Participant indicated they had completed this, can this be confirmed as there is no history of completed surveys on the app

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UEQ-S

PT1

obstructive	❍❍❍❍●❍❍	supportive
complicated	❍❍❍●❍❍❍	easy
inefficient	❍❍❍❍❍●❍	efficient
confusing	❍❍❍●❍❍❍	clear
boring	❍❍❍❍❍●❍	exciting
not interesting	❍❍❍❍❍●❍	interesting
conventional	❍❍❍❍❍●❍	inventive
usual	❍❍❍❍❍●❍	leading edge

PT2

obstructive	❍❍❍❍❍●❍	supportive
complicated	❍●❍❍❍❍❍	easy
inefficient	❍❍❍❍❍●❍	efficient
confusing	❍❍❍❍●❍❍	clear
boring	❍❍❍❍❍●❍	exciting
not interesting	❍❍❍❍❍●❍	interesting
conventional	❍❍❍❍❍●❍	inventive
usual	❍❍❍❍❍●❍	leading edge

PT3

obstructive	❍❍❍❍❍❍●	supportive
complicated	❍❍❍❍●❍❍	easy
inefficient	❍❍❍❍❍❍●	efficient
confusing	❍❍❍❍❍●❍	clear

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boring	❍❍❍❍❍●❍	exciting
not interesting	❍❍❍❍❍❍●	interesting
conventional	❍❍❍❍❍●❍	inventive
usual	❍❍❍❍❍●❍	leading edge

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Annex 12 UC-PT3-gen Phase 4 User manuals

Slide 1

Slide 2

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The SHAPES Devices

OMRON VIVA Smart Scale for measuring **weight**

Beurer PO60 Bluetooth pulse oximeter for measuring **heart rate & oxygen saturation**

OMRON M7 Intelli IT for measuring **blood pressure**

Roche Accu-Chek Instant for measuring **blood glucose**

2

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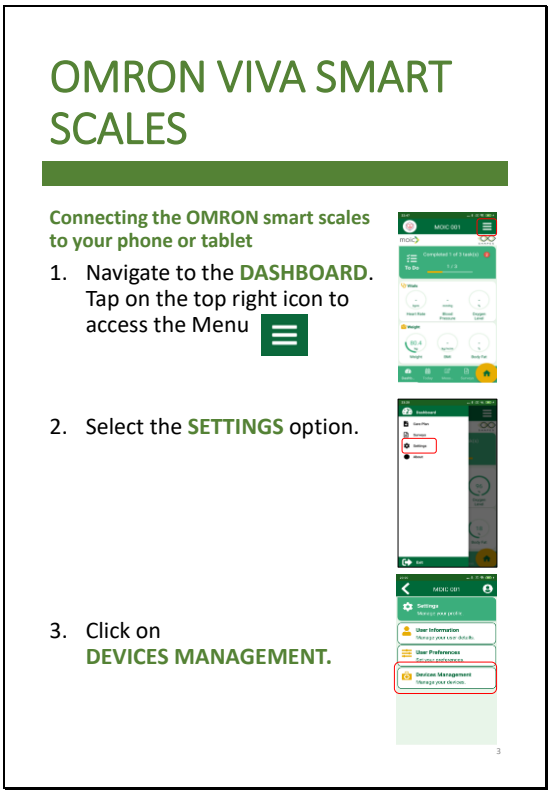
Slide 3



Slide 4

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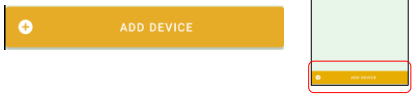
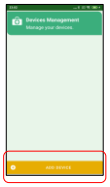
1. In **DEVICES MANAGEMENT**, click on the Add Device button.





2. Two options arise. Click on **ADD OMRON DEVICE**.

3. On your OMRON VIVA scales. Press the **scale's pairing button** until the letter "**P**" is displayed on the screen.

4

Slide 5

1. SHAPES automatically searches and identifies the OMRON VIVA scale.

2. Click on **VIVA (28:FF:B2:CA:D1:21)** NB letters may differ. Follow the instructions on screen. Your phone or tablet may ask for permission to pair with device. Click 'Allow' or 'OK' as appropriate.

3. The app should then begin pairing with the VIVA scales

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Slide 6

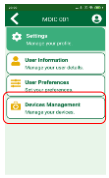
Beurer PO60 pulse oximeter

Connecting the Beurer PO60 pulse oximeter to your phone or tablet

1. Navigate to the **DASHBOARD**
   Tap on the top right icon to access the Menu

2. Select the **SETTINGS** option.

3. Click on
   DEVICES MANAGEMENT.



Slide 7

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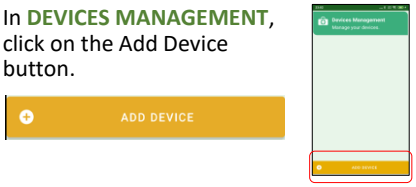
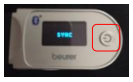
1. In **DEVICES MANAGEMENT**, click on the Add Device button.



2. Two options arise. Click on **ADD BEURER DEVICE**.

3. On your PO60 pulse oximeter. Press the **POWER BUTTON** until the word "**SYNC**" is displayed on the screen



7

Slide 8

1. SHAPES automatically searches and identifies the **Beurer PO60 pulse oximeter.**

2. Click on **PO60 (3C:A3:08:B8:AF:2E)** NB letters may differ. Follow the instructions on screen. Your phone or tablet may ask for permission to pair with device. Click 'Allow' or 'OK' as appropriate.

3. The app should then begin pairing with the pulse oximeter

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Slide 9

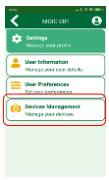
OMRON M7 Intelli IT blood pressure monitor

Connecting the OMRON M7 Intelli IT blood pressure monitor to your phone or tablet

1. Navigate to the **DASHBOARD.** Tap on the top right icon to access the Menu 

2. Select the **SETTINGS** option.

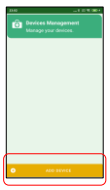
3. Click on **DEVICES MANAGEMENT.**



9

Slide 10

1. In **DEVICES MANAGEMENT**, click on the Add Device button.



2. Two options arise. Click on **ADD OMRON DEVICE.**

3. Press the **blood pressure monitor pairing button** (situated on the top of the device) until the letter "**P**" is displayed on the screen.

10

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Slide 11

1. SHAPES automatically searches and identifies the **OMRON M700 Intelli IT blood pressure monitor.**

2. Click on **M700 Intelli IT (28:FF:B2:2E:59:A1)** NB letters may differ. Follow the instructions on screen. Your phone or tablet may ask for permission to pair with device. Click 'Allow' or 'OK' as appropriate.

3. The app should then begin pairing with the blood pressure monitor

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Slide 12

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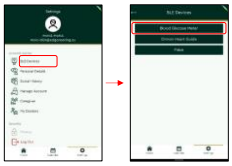
Roche Accu-Chek Instant Glucometer

Connecting the Roche Accu-Chek Instant Glucometer to your phone or tablet

1. From the **MENU** page. Tap the **BLOOD GLUCOSE** icon.

2. Tap on the **SETTINGS** icon in the bottom right corner.

3. Tap on **BLE DEVICES** followed by **BLOOD GLUCOSE MONITOR** on the next page



12

Slide 13

4. Tap on the **CONNECT** button.

5. With your blood glucose monitor OFF, hold and press the lower button on the right side of the device. The Bluetooth pairing symbol will begin to flash.

6. SHAPES will automatically search for and find the device.

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Slide 14

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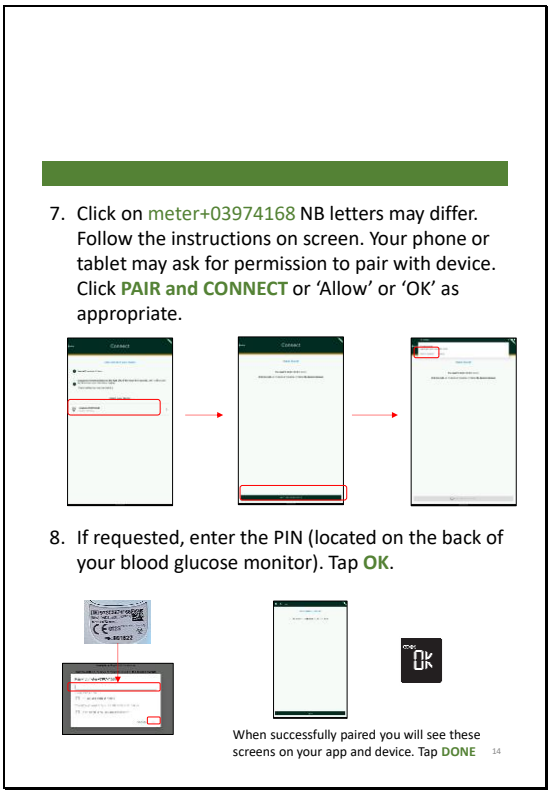
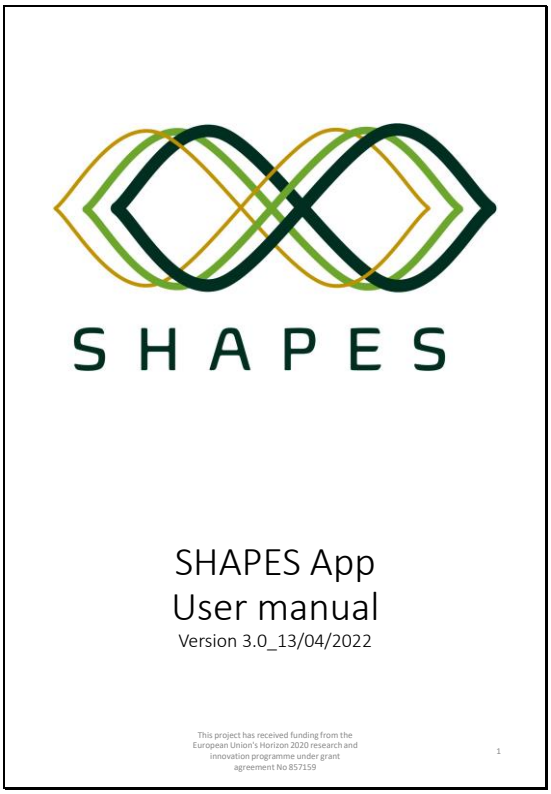

7. Click on meter+03974168 NB letters may differ. Follow the instructions on screen. Your phone or tablet may ask for permission to pair with device. Click PAIR and CONNECT or 'Allow' or 'OK' as appropriate.
8. If requested, enter the PIN (located on the back of your blood glucose monitor). Tap OK.
When successfully paired you will see these screens on your app and device. Tap DONE
14

Slide 1


SHAPES
SHAPES App
User manual
Version 3.0_13/04/2022
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159
1

Slide 2

Slide 3

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The SHAPES App

- The SHAPES App runs on an Android smart phone or tablet and is linked to four devices (see next page) designed to help people self-monitor their health at home.
- Readings from the devices are transferred into the App via Bluetooth (i.e., wirelessly). There is an option to manually add readings too. The automatic upload should be used in preference.
- Daily readings and those from previous days, weeks and months are viewed by clicking on the reading they wish to view.
- The App also contains information about the medications a person is taking, either as a full list of everything they take, or as a daily list to remind them what they need to take each day.
- The App sends a daily survey that asks the user about how they have been feeling that day, and a weekly survey about how they have been using their medicines that week.

3

Slide 4

The SHAPES Devices

OMRON VIVA Smart Scale for measuring **weight**

Beurer PO60 Bluetooth pulse oximeter for measuring **heart rate & oxygen saturation**

OMRON M7 Intelli IT for measuring **blood pressure**

Roche Accu-Chek Instant for measuring **blood glucose**

4

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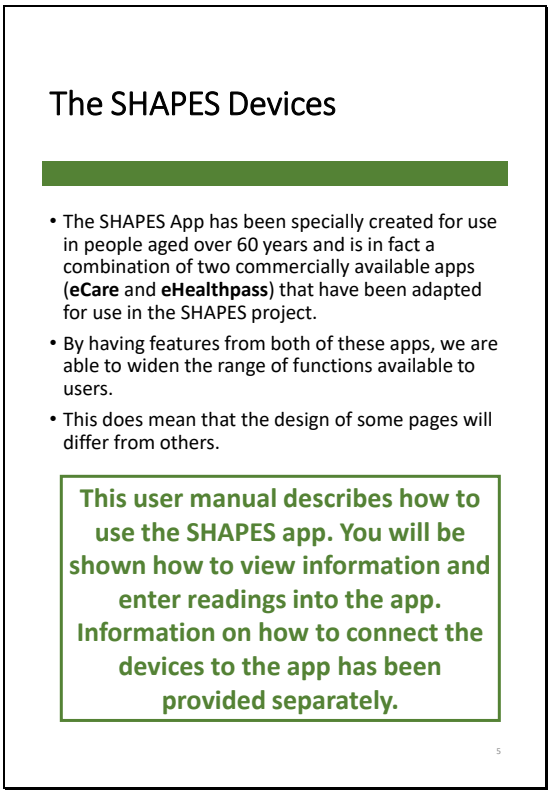
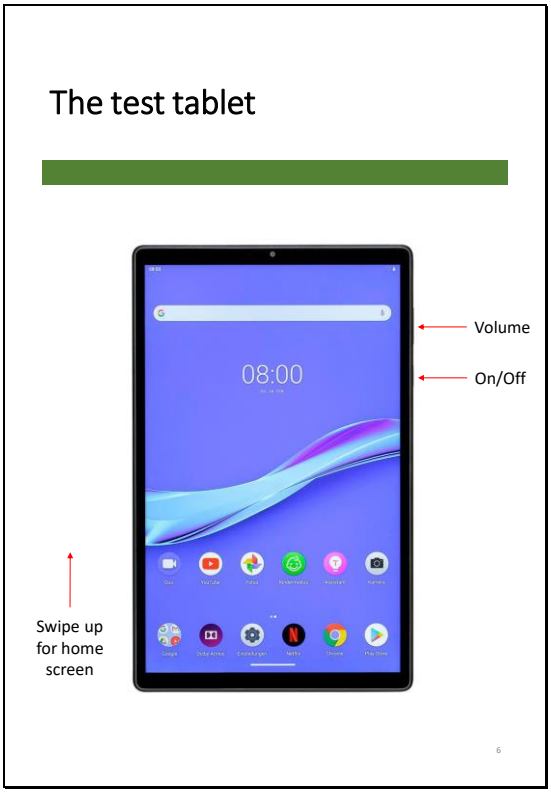
Slide 5

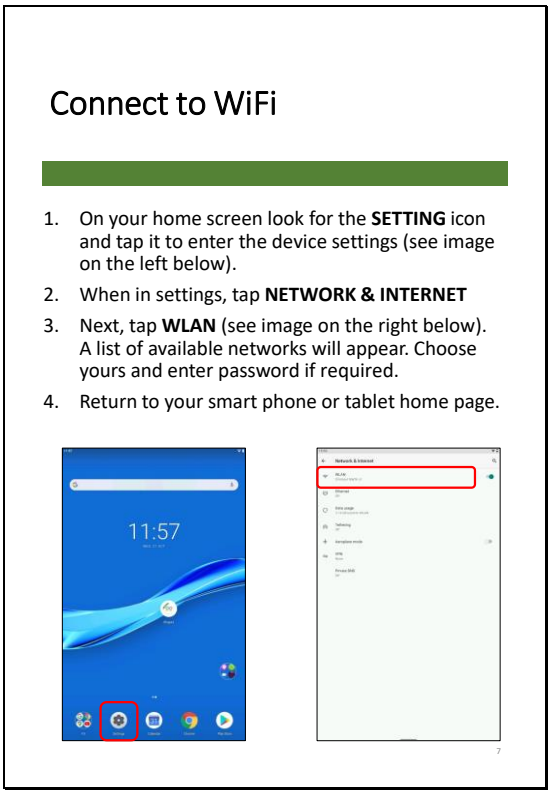


Slide 6

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159



Slide 7



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Slide 8

Open the SHAPES app

1. On the tablet home screen look for the SHAPES MOIC app icon and tap it to enter the app.

2. There will be two other apps installed on your phone or tablet called FluttiSHAPES and eCare for SHAPES. You can ignore these apps as they are accessed via the SHAPES MOIC app above.

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Slide 9

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Log into the SHAPES app

1. Enter your email and password and click on **LOGIN**. Your username and password will be provided to you separately.

2. The App will welcome you and invite you to **ENTER**.

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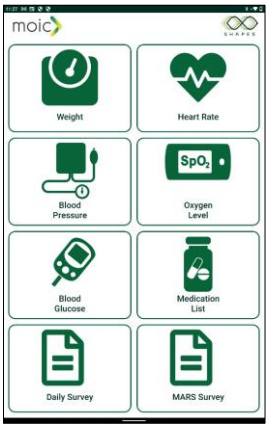
Slide 10

Navigation

This is the **MENU** page. It is where you can access the different sections of the App.



10

Slide 11

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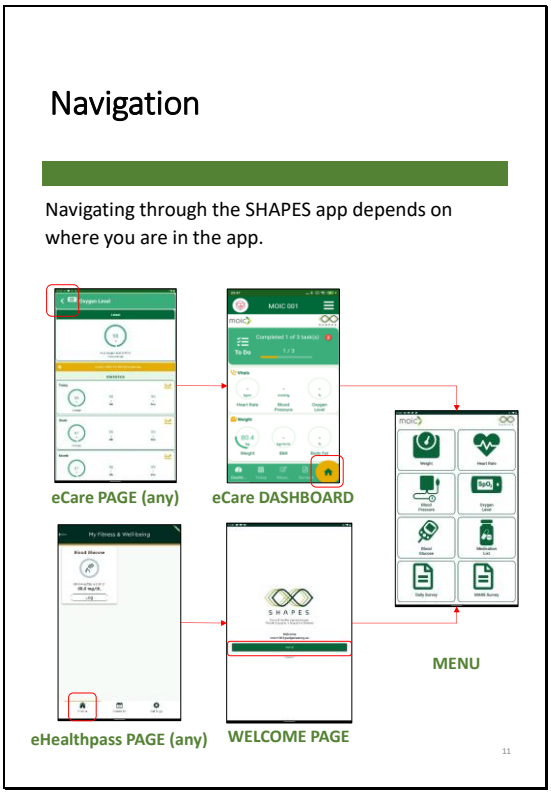
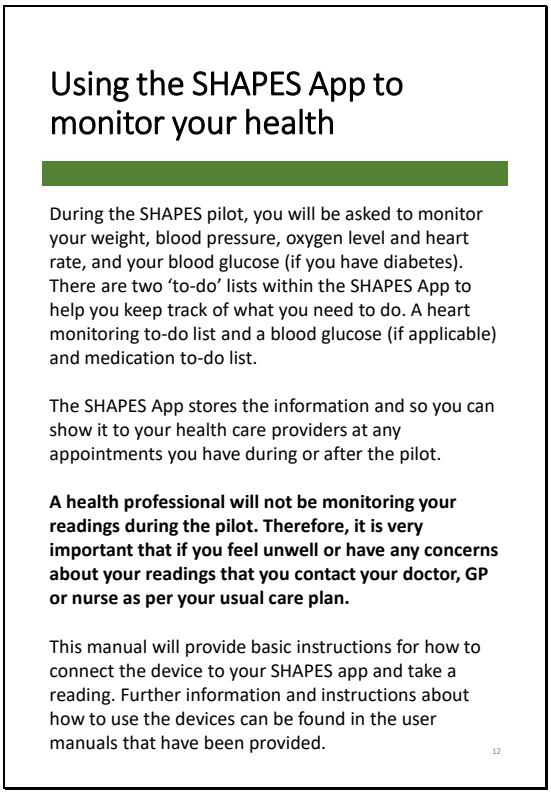


Slide 12



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Slide 13

Weight

Device

OMRON VIVA Smart Scale

What it measures?

- These scales measure total body weight, which is important to monitor regularly in health conditions such as heart failure and diabetes.
- Weight can be measured in kilograms (kg) or stones (st) and pounds (lb).
- These 'smart' scales also automatically measure body mass index, body fat, visceral fat, skeletal muscle and basal metabolic rate. However, for this study we only ask you to monitor your weight.

How often and when should weight be measured?

- For this study, weight should be monitored once a day in the morning after you go to the bathroom and before you eat or drink anything. You should always wear similar clothes when weighing yourself and do so in bare feet (i.e., no socks or shoes).

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Slide 14

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Weight

Information about monitoring your weight

Maintaining a healthy weight and shape will help with managing symptoms of long-term conditions and can help prevent other health problems. Putting on or losing weight over a period of weeks is more likely to be caused by an increase or decrease in body mass (muscle or fat).

Sudden weight gain in heart failure

If you put on weight over 2–5 days, it is probably caused by fluid retention. An extra 1–2 kilogram (2–4lb) can mean that your body is holding on to an extra 1 litre of fluid.
You may also notice more swelling in your ankles, feet or tummy area, and your clothes or shoes might feel tighter.
If you gain about 1 kilo (1–2 lbs) or more in 2–3 days, you may be retaining fluid. Call your doctor, nurse or GP for advice.

British Health Foundation

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Slide 15

Weight

Viewing recent readings using the SHAPES App

1. From the **MENU** page. Tap the **WEIGHT** icon.

2. The **WEIGHT** page will appear. From this page you can:
   - View your most recent reading (in this example the reading is 68.4kg).
   - Enter a new reading.
   - View your average, maximum and minimum readings from the past day, week and month.

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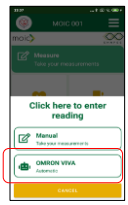
Slide 16

Weight

Entering a reading into the SHAPES App – Automatic (preferred option)

1. To enter a reading, tap **CLICK HERE TO ENTER A READING** and a new screen will appear.



2. Select **OMRON VIVA** to allow the reading to automatically transfer to the app after you have taken your reading using the scales.

3. When you see this screen on your app, you are reading to take a reading. Click **NEXT** and follow the instructions on the next page.

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Slide 17

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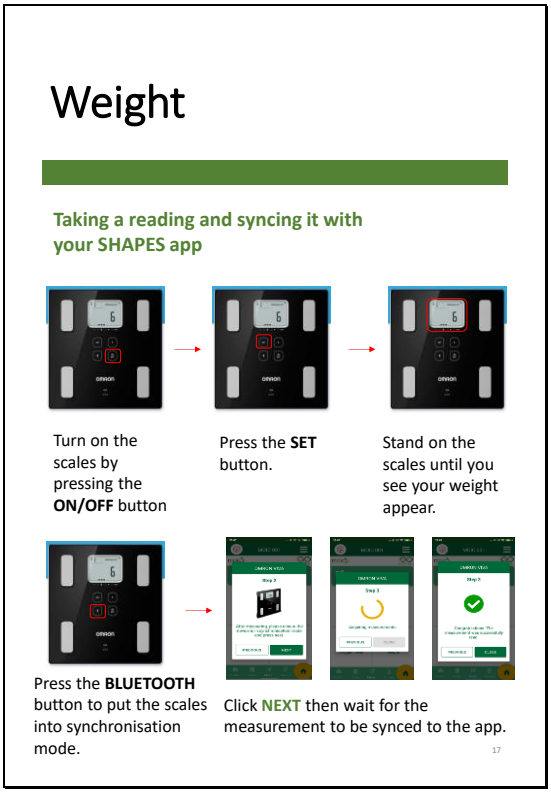
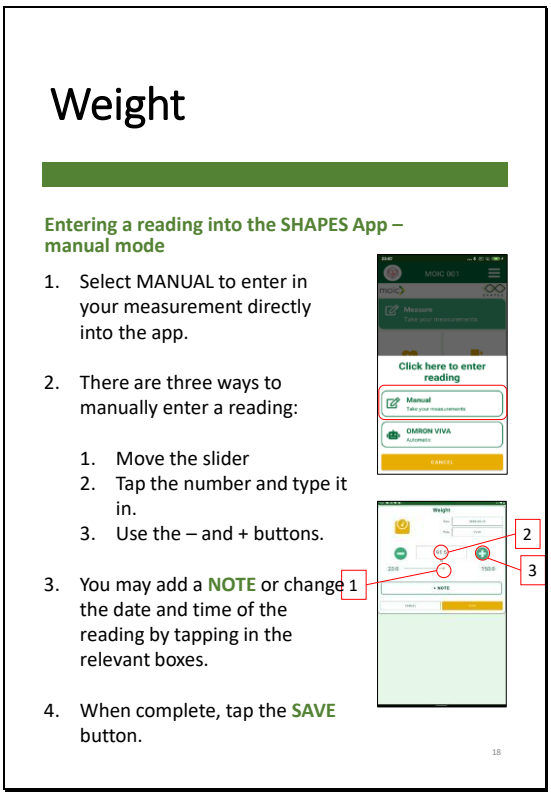


Slide 18



Slide 19

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Oxygen level

Device

Beurer PO60 Bluetooth pulse oximeter

What it measures?

- This device measures both oxygen level and heart rate.
- Your oxygen level (also called oxygen saturation or O_2 sats) indicates the amount of oxygen that is travelling around your body with your red blood cells.
- It is measured as a percentage (%).

How often and when should oxygen level be measured?

- For this study, oxygen level should be monitored every day.
- You should aim to take your oxygen level after you have been sitting down for about 10 minutes and at approximately the same time each day.

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Slide 20

Oxygen level

Information about monitoring your oxygen level

Oxygen is carried around in your red blood cells. A pulse oximeter measures how much oxygen the red blood cells in your blood is carrying. This is called the oxygen saturation and is a percentage (scored out of 100). It's a simple, painless test which uses a sensor placed on your fingertip. For someone who's healthy, the normal blood oxygen saturation level will be around 95–100%.

Monitoring oxygen level during the SHAPES pilot

You are being asked to measure your oxygen level every day during the SHAPES pilot. Researchers will collect this information to help develop new technology for managing long-term conditions in older people.

If you are concerned about your oxygen level at any point during the pilot, or feel unwell, please contact your doctor, GP or nurse for advice as per your usual care plan.

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Slide 21

Oxygen level

Viewing recent readings using the SHAPES App

1. From the **MENU** page. Tap the **OXYGEN LEVEL** icon.

2. The **OXYGEN LEVEL** page will appear. From this page you can:
   - View your most recent reading (in this example the reading is 98%).
   - Enter a new reading.
   - View your average, maximum and minimum readings from the past day, week and month.

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Slide 22

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Oxygen level

Entering a reading into the SHAPES App – Automatic

1. To enter a reading, tap **CLICK HERE TO ENTER A READING** and a new screen will appear.
2. Select BEURER PO60 to allow the reading to automatically transfer to the app after you have taken your reading using the pulse oximeter.
3. When you see this screen on your app, you are reading to take a reading. Click **NEXT** and follow the instructions on the next page.

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Slide 23

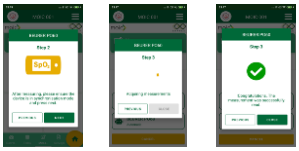
Oxygen level

Taking a reading and syncing it with your SHAPES app

Place the pulse oximeter on your finger and press the power button.

Your oxygen reading and heart rate will appear on the screen.

Remove the device from your finger and the word 'sync' will appear on the screen. The device is now in synchronisation mode



Click **NEXT** then wait for the measurement to be synced to the app.

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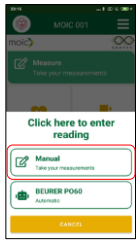
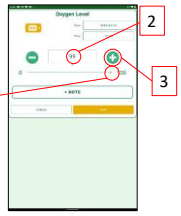
Slide 24

Oxygen level

Entering a reading into the SHAPES App – manual mode

1. Select MANUAL to enter in your measurement directly into the app.
2. There are three ways to manually enter a reading:
    1. Move the slider
    2. Tap the number and type it in.
    3. Use the – and + buttons.
3. You may add a NOTE or change the date and time of the reading by tapping in the relevant boxes.
4. When complete, tap the SAVE button.





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Slide 25

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Heart rate

Device

Beurer PO60 Bluetooth pulse oximeter

What it measures?

- This device measures both heart rate and oxygen level.
- Your heart rate is a measure of how fast your heart is beating. This is often called your pulse rate and is measured in beats per minute (bpm).

How often and when should heart rate be measured?

- For the SHAPES pilot, you should monitor your heart rate every day.
- You should aim to take your heart rate after you have been sitting down for about 10 minutes and at approximately the same time each day.

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Heart rate

Information about monitoring your heart rate

Your heart rate is the number of times your heart beats per minute (bpm). A normal heart rate is between 60 and 100 bpm while you're resting.

However, heart rate will vary depending on when it's measured and what you were doing immediately before the reading. Heart rate changes throughout the day and depends upon many things like how active you have been and what time of day it is.

Some medicines, such as beta blockers, used to treat heart conditions can slow down your heart rate.

Monitoring heart rate during the SHAPES pilot

You are being asked to measure your heart rate every day during the SHAPES pilot. Researchers will collect this information to help develop new technology for managing long-term conditions in older people.

If you are concerned about your heart rate at any point during the pilot, or feel unwell, please contact your doctor, GP or nurse for advice as per your usual care plan.

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Heart rate

Viewing recent readings using the SHAPES App

1. From the **MENU** page. Tap the **HEART RATE** icon.

2. The **HEART RATE** page will appear. From this page you can:
   - View your most recent reading (in this example the reading is 60 bpm).
   - Enter a new reading.
   - View your average, maximum and minimum readings from the past day, week and month.

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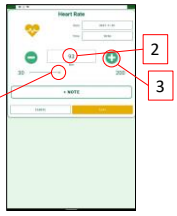
Slide 28

Heart rate

Entering a reading into the SHAPES App

1. When you measure and sync your oxygen level to the app, your HEART RATE will also sync with the app.
2. If you wish to add your heart rate manually, tap **CLICK HERE TO ENTER A READING**
3. There are three ways to manually enter a reading:
   1. Move the slider
   2. Tap the number and type it in.
   3. Use the – and + buttons.



4. You may add a NOTE or change the date and time of the reading by tapping in the relevant boxes.
5. When complete, tap the SAVE button.

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Slide 29

Blood pressure

Device

OMRON M7 Intelli IT
blood pressure monitor

What it measures?

- This device measures blood pressure, which is the pressure at which blood is pumped around your arteries.
- There are two numbers in a blood pressure reading that are often displayed as a fraction 140/85.
- Blood pressure is measured in millimetres of mercury (mmHg).

How often and when should blood pressure be measured?

- For this study, blood pressure should be measured once a day at approximately the same time.

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Blood pressure

Information about monitoring your blood pressure

Having high blood pressure can put a strain on your heart and can contribute to the development of many heart conditions. Blood pressure is routinely monitored in healthcare settings but it is becoming more common for people to also monitor their blood pressure at home.

Most people have a target blood pressure of under 140/80 mmHg. Your doctor may advise aiming for a lower blood pressure depending on other conditions you may have.

Monitoring blood pressure during the SHAPES pilot

You are being asked to measure your blood pressure every day during the SHAPES pilot. Researchers will collect this information to help develop new technology for managing long-term conditions in older people.

If you are concerned about your blood pressure at any point during the pilot, or feel unwell, please contact your doctor, GP or nurse for advice as per your usual care plan.

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Slide 31

Blood pressure

Viewing your blood pressure using the SHAPES App

1. From the **MENU** page. Tap the **BLOOD PRESSURE** icon.

2. The **BLOOD PRESSURE** page will appear. From this page you can:
   - View your most recent reading (in this example the reading is 105/90 mm/Hg).
   - Enter a new reading.
   - View your average, maximum and minimum readings from the past day, week and month.

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Slide 32

Blood pressure

Entering a reading into the SHAPES App – Automatic

1. To enter a reading, tap **CLICK HERE TO ENTER A READING** and a new screen will appear.
2. Select OMRON M700 INTELLI IT to allow the reading to automatically transfer to the app after you have taken your reading using the blood pressure monitor.
3. When you see this screen on your app, you are reading to take a reading. Click **NEXT** and follow the instructions on the next page.

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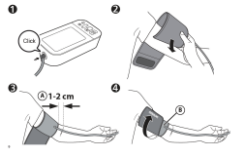
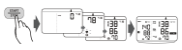
Slide 33

Blood pressure

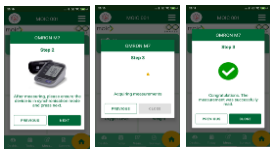


Place the cuff onto your left arm as illustrated above. You may find it easier to slide the cuff over your hand and up your arm.



Press the **START/STOP** button to begin taking a blood pressure measurement.

Press the **blood pressure monitor pairing** button (situated on the top of the device) until the letter "**P**" is displayed on the screen. The device is now in synchronisation mode.



Click **NEXT** then wait for the measurement to be synced to the app.

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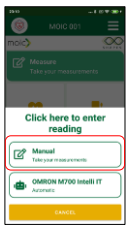
Slide 34

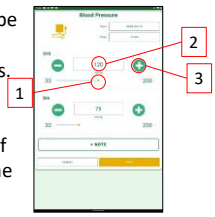
Blood pressure

Entering a reading into the SHAPES App – manual mode

1. Select MANUAL to enter in your blood pressure measurement directly into the app.



2. There are three ways to manually enter a reading:
    1. Move the slider
    2. Tap the number and type it in.
    3. Use the – and + buttons.



3. You may add a NOTE or change the date and time of the reading by tapping in the relevant boxes.
4. When complete, tap the SAVE button.

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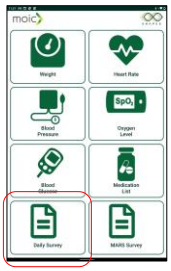
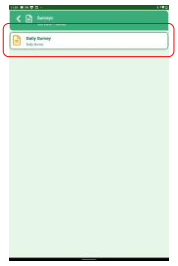
Daily survey (heart failure only)

If you have been diagnosed with heart failure, the SHAPES App contains a **DAILY SURVEY** to help you monitor your symptoms on a daily basis.

1. From the **MENU** page, tap on the **DAILY SURVEY** icon, followed by the 'Daily Survey' button on the next page.





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Daily survey (heart failure only)

1. A multiple choice questionnaire will appear.
   - Tap your responses to each question and tap **SUBMIT** when complete.
   - Selected responses are highlighted in yellow.

2. A box will pop up asking you to confirm if you would like to submit.
   - Tap **CANCEL** if you would like to return to the questions.
   - Tap **SUBMIT** to save your responses.

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Blood glucose

Device

Roche Accu-Chek Instant Glucometer

What it measures?

- This device measures your blood glucose level, which is also called your blood sugar level.
- Blood glucose is measured in millimoles per litre (mmol/L).

How often and when should blood glucose be measured?

- If you have been asked to monitor blood glucose as part of this study you will have already been monitoring your blood glucose regularly using a glucometer as per the advice of your diabetes care team.
- For this study, we ask that you **continue as normal** with your regular monitoring routine. The only change will be that you will be using the device provided to you, which will be linked to the SHAPES app on your smart phone or tablet.

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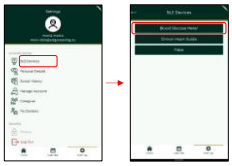
Blood glucose

Connecting the Roche Accu-Chek Instant Glucometer to your phone or tablet

1. From the **MENU** page. Tap the **BLOOD GLUCOSE** icon.

2. Tap on the **SETTINGS** icon in the bottom right corner.

3. Tap on **BLE DEVICES** followed by **BLOOD GLUCOSE MONITOR** on the next page



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Slide 39

Blood glucose

4. Tap on the **CONNECT** button.

5. With your blood glucose monitor OFF, hold and press the lower button on the right side of the device. The Bluetooth pairing symbol will begin to flash.

6. SHAPES will automatically search for and find the device.

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Blood glucose

7. Click on meter+03974168 NB letters may differ. Follow the instructions on screen. Your phone or tablet may ask for permission to pair with device. Click **PAIR and CONNECT** or 'Allow' or 'OK' as appropriate.

8. If requested, enter the PIN (located on the back of your blood glucose monitor). Tap **OK**.

When successfully paired you will see these screens on your app and device. Tap **DONE** 40

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Blood glucose

Viewing recent readings using the SHAPES App

1. From the **MENU** page. Tap the **BLOOD GLUCOSE** icon.

2. A summary page will appear.
   - From this page you can view your most recent blood glucose reading (in this example the reading is 88.0 mg/dL).
   - To view a history of all your previous blood glucose readings. Tap the icon.

3. On this screen you can view a graph of your blood glucose over time.
   - You can change the time period by tapping Last 30 days.
   - Scroll down to view a list of previous readings.

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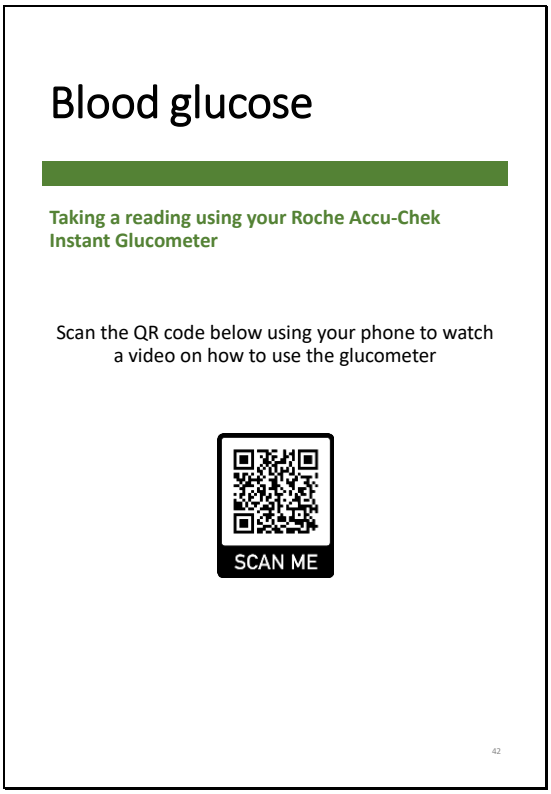
Slide 42



Slide 43

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Blood glucose

Entering a reading into the SHAPES App

1. When the Roche Accu-Chek Instant Glucometer is connected to the SHAPES app, all blood glucose readings are automatically transferred to the app.
2. You can also enter a blood glucose reading manually as follows. Tap **LOG** on the summary page.

3. Tap under the word **VALUE** and type in your reading.
4. The time and date will always default to the current time and date but you can override this by tapping on the date to edit.) Tap **SAVE.**

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Using the SHAPES App to manage your medicines

There are two ways in which the SHAPES App can help you manage your medicines.

1. MEDICATION LIST

The SHAPES App contains a personalised **MEDICATION LIST** of all the medicines that you have been prescribed to take on a regular basis. Details about each medicine, such as how often you take it and when, are also available to view via the app.

2. MEDICATION QUESTIONNAIRE

- Many people find a way of using their medicines which suits them. This may differ from the instructions on the label or from what their doctor has said.
- The SHAPES App contains a **MARS SURVEY** that prompts you to think about how you have been using your medicines over the past week.
- The **MARS SURVEY** is also an opportunity for you to inform the research team if there have been any changes to your medicines that need to be updated in your **MEDICATION LIST**.

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Slide 45

Medication list

1. From the **MENU** page, tap on the **MEDICATION LIST** icon.

2. A list of all your medicines will be displayed.
   Tap **MORE** to see more information about each medicine.

Name of the medicine

Date started OR start date of pilot

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Medication list

- All the information you need about a medication is detailed on this page including its name, ingredients, and directions for how to take it.
- This information will be managed by the researchers during the pilot. You do not need to do anything on this page.
- **You must let the researchers know if there has been any changes to your medication regimen so this list can be kept up-to-date.**

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Medication questionnaire

1. From the **MENU** page, tap on the **MARS SURVEY** icon.

2. Select **MEDICATION QUESTIONNAIRE**

3. There is a description of the questionnaire followed by the first question. Select your response and then tap **NEXT.**

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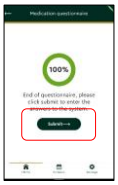
Medication questionnaire

4. Your chosen response will be highlighted. Continue to tap **NEXT** to proceed through the questions.

5. When you finish the questionnaire tap **SUBMIT**.



6. A green tick will appear when submission has been successful.

The **MEDICATION QUESTIONNAIRE** should be completed once a week.

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Keeping track

The SHAPES App can also help you keep track of what measurements and questionnaires you need to do and when.

There are two 'To-do' lists available that list the tasks you are asked to complete each day.

This to-do list includes a reminder to take measurements of weight, oxygen level and blood pressure and to complete your 'daily survey'.

This to-do list includes a reminder to take measurements of blood glucose, take your medicines, and to complete your 'MARS survey'.

Turn to the next page to see how you can access these to-do lists.

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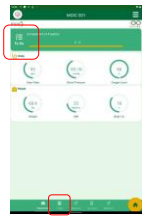
- When in the 'Weight', 'Oxygen level', 'Blood pressure' or 'Heart rate' pages, tap the < button.
- A **DASHBOARD** appears displaying your most recent readings
- Tap the **TO-DO** icon (top left corner) or the **TODAY** icon to access a list of tasks for the day.

VIEW READINGS PAGE



DASHBOARD

TO-DO LIST

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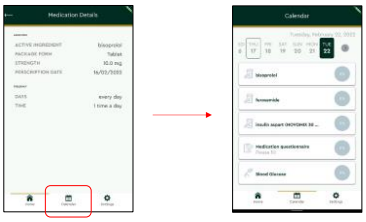
- When in the 'Blood glucose', 'Medication list', 'Medication details' or 'MARS Survey' pages, tap the **CALENDAR** icon in the bottom menu



MEDICATION DETAILS PAGE

CALENDAR PAGE (i.e., to-do list)

PLEASE NOTE: THE TO-DO LISTS SERVE AS A REMINDER ONLY FOR WHAT YOU HAVE BEEN ASKED TO DO DURING THE SHAPES PILOT STUDY AND ARE NOT INSTRUCTIONS FOR MANAGING YOUR CONDITION.

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Annex 13 UC-PT3-gen Phase 4 User log

Daily monitoring activities	Tick when complete	Reading on device	Notes (provide details of any errors, problems or barriers encountered)
Measure **weight** using OMRON VIVA Smart Scale	□		
Measure **blood pressure** using OMRON M7 Intelli IT blood pressure monitor	□		
Measure **oxygen saturation level** using Beurer GmbH PO60 Bluetooth pulse oximeter	□		
Measure **heart rate** using Beurer GmbH PO60 Bluetooth pulse oximeter	□		
Measure **blood glucose** using Roche Accu-chek Instant	□		

Daily app activities	Tick when complete	Notes (provide details of any errors, problems or barriers encountered)
Log in to SHAPES app	□	
Complete 'Daily survey' questions	□	
View **both** to-do lists for today	eCare □ eHealthpass □	

Once-only app activities	Tick when complete	Notes (provide details of any errors, problems or barriers encountered)
Complete 'Weekly survey'	□	

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View medication list □

Annex 14 UC-PT3-gen Phase 4 Pre-screening log

SHAPES Pilot: Phase 4 Pre-screening log

Setting *(e.g., community service users/ outpatient heart failure clinic/ward)* _____

Time period *(e.g., morning clinic/one week/Not applicable)* _____

Please screen all patients encountered over the specified time period. Tick all the criteria that apply to the patient.
NB this is a pre-screening activity. Patients should not be approached and please do not patients' personal details with MOIC.

Patient ID	Aged ≥60 years	Diagnosed with heart failure	Diagnosed with diabetes mellitus	Treatment includes regular monitoring of blood glucose	Stable disease state	Lives at home or supported living	Suspected cognitive impairment	Wears an electronic medical device or implant

Phase 4_Pre-screening recruitment log_V2.1_18022022

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Annex 15 UC-PT3-gen Ethical self-assessment for phases 1–5

ETHICAL SELF-ASSESSMENT FOR THE PILOTS IN PHASES 1-5

This template is based on the ethics self-assessment template of Horizon 2020 projects. (https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf).

The template is modified for the purposes of SHAPES pilots, including also new ethical topics identified in WP11 requirements and in WP8 work. On the other hand a few points (Human foetuses, Human cells/tissues, Dual use etc.) of the original EU Ethical Self-assessment template are left out because they are not relevant for SHAPES pilots.

Ethics self-assessment should be completed for each SHAPES piloting activities as follows:

- each organization collecting any data and/or collaborating with end-users in phases 1-3 will provide its own ethical self-assessment.
- each organization responsible for small scale and/or large scale pilots in phases 4-5 will provide its own ethical self-assessment.
- if the organization is a pilot host both during the phases 1-3 and 4-5, it can provide a joint ethical self-assessment covering all the phases 1-5.

Fill in the template and upload it to WP8 Teams/Pilot - Ethical self-assessments https://teams.microsoft.com/_#/files/WP8?threadId=19%3Abcea934935c74da5bd02c31abcea4e95%40thread.skype&ctx=channel&context=Pilots%2520-%2520ethical%2520self-assessments&rootfolder=%252Fsites%252FSHAPESProject%252FShared%2520Documents%252FWP8%252FPilots%2520-%2520ethical%2520self-assessments

Pilot identification	UC-PT3-gen 'Supporting multimorbid older patients'
Form completed by (name & partner)	Maureen Spargo (NHSCT)
Date	02/12/2020

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HUMANS AND PERSONAL DATA	
Does your pilot involve human participants? (if yes, see steps 1,2, 3 below)	☐ X yes no
Does your research involve personal data collection and/or processing? (if yes, see steps 4,5,6,7,8 below) ☐ X Secondary use of personal data? yes no ☐ X Tracking or observing of participants? yes no ☐ X Processing of health, biometric orgenetic data? yes no	☐ X yes no

1 Human dignity

-Always respect human dignity and the intrinsic value of the individuals.

-The methods and tools to be used in co-creation with the older persons are to be chosen carefully by considering person's capability to function, so that there will be no burden for, e.g., vulnerable participants, or any risk for stigmatisation. All direct costs for participants are to be covered by the project.

(-See Ethical Requirements GE8-GE9 in D8.4.)

2 Research/pilot plan and ethics approvals

-A written research/pilot plan must be provided and available on request, including details of the recruitment, types of vulnerability and diseases, inclusion and exclusion criteria and informed consent

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procedures. If people unable to provide consent will be involved, the procedures for obtaining approval from the legal representative must be described in detail. In addition, the plan must demonstrate appropriate efforts to ensure fully informed understanding of the implications of participation.

-Ethics approvals by local authorities must be acquired and kept on file in WP6 TEAMS/archives (e.g., when involving vulnerable persons and persons unable to give consent) before the work begins.

-This also applies in the situation with Covid-19 pandemic.

3 Consents and agreements with end-users

-The pilot organizations should collect participants' consent forms and provide an information sheet specifying the nature of the research and pilot, including also the processing of personal data as part of the research and/or on the SHAPES platform.

Pilot phases 1-3:

-The main principle is that consent from each participant is to be acquired before the person is involved in the research. However if you are only collecting feedback e.g. in short brain storming sessions – and without any personal data - this is not necessary.

-Avoid any collection of personal data if possible in these phases 1-3.

-The template for the consent, information sheet and privacy policy are attached and available in Teams WP8. The final documents have to be written in the participant's language. Edited & translated templates are to be uploaded to WP6 Teams.

-The researcher/pilot organisation will keep the signed consent forms on file in a safe place until the end of the project (after final review/or time defined in national legislation) and destroy them after that.

Pilot phases 4-5:

-Consent from each participant using SHAPES services is to be acquired before the use of the SHAPES begins, as well as agreements regarding the various digital services. The former includes also consent for the use of person's data on big data analytics.

-The consent (and agreements) will be collected on the SHAPES platform. (See Ethical Requirements GE37 and ET13 in D8.4.)

- If consent functionalities are not yet ready in the beginning of the phase 4/5, they will be collected manually. Template will be co-created (WP8+WP6 pilots) before these phases of pilots will start.

4 Privacy and data protection descriptions

-Researchers should provide details regarding the procedures of the personal data collection, minimization, anonymization & pseudonymisation, storage, protection, retention, transfer and destruction or re-use of data, as well as those regarding data safety procedures, justification for the

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processing of special categories of personal data, data subjects rights, data transfers to third countries and tracking and observing methods.

-In case of further processing of previously collected personal data, an explicit confirmation that the beneficiary has lawful basis for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects must to be confirmed (secondary use of personal data).

Pilots in phases 1-3:

-We recommend not to process any real personal data. However if this is needed, contact Data Protection Manager for further guidelines.

Pilots in phases 4-5:

-Personal Data Processing Descriptions are to be provided an uploaded to WP6 Teams before the pilot begins. Note that the use of secondary data has to be reported already in M12 by using Personal Data Processing Descriptions template that can be found in WP8 Teams.

-The SHAPES functionalities regarding data minimization, anonymization etc. are documented in various SHAPES deliverables.

-(See Ethical Requirements GE23-GE46, ET4-ET20, PE6, ME9-ME13 in D8.4.)

5 Tracking and observing of participants

-Researchers should provide details of the methods used for tracking, surveillance or observation of participants, details of the methods used for profiling, risk assessment for the data processing activities, how will harm be prevented and the rights of the research participants safeguarded and details on the procedures for informing the research participants about profiling, and its possible consequences and the protection measures.

Pilots in phases 1-3:

-We recommend not to perform such activities. However if this is needed, contact Data Protection Manager for further guidelines.

Pilots in phases 4-5:

-This is related e.g. to the facial recognition and home environment monitoring as part of the SHAPES platform. Issue will be analyzed as part of ethics risk assessment in D8.4. and DPIA.

(-See Ethical requirement GE57 in D8.4)

6 Legal compliance with local legislation related to health, genetic & biometrics data and GDPR

-The beneficiary must check if special derogations pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data have been established under the national legislation of the country where the research takes place and submit a declaration of compliance with respective national legal framework(s).

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Pilots in phases 1-3:

-We recommend not to collect any health data. However if this is needed, contact Data Protection Manager for further guidelines.

Pilots in phases 4-5:

-Find out if there is local legislation on the topic.

-If yes, acquire approvals needed and provide compliance check before pilot begins (in that work utilize your Data Processing Descriptions and Data Lifecycle Management Plan.). Upload the documents in WP6 Teams.

(-See updated Ethical Requirement ME2 in D8.4).

7 The Data Protection Officer and Data Owners

-Each pilot in phases 1-5 should nominate Data Owner before the collection of data begins.

-For phases 4-5 also Data protection Officer is needed. She/he typically comes from the same organization as Data Owner (and can be a same person as well). Name of the organization (and the name of the person) is to be confirmed in M12.

(-See Ethical Requirements ME12-ME13 in D8.4.)

8 Privacy and Data Protection Impact Assessment

-The DPIA regarding the phase 5 is to be performed by each pilot in collaboration with SHAPES Data Protection Manager 2 months before the pilot phase 5 begins. DPIA will also be verified during the pilot phase 5.

(-See Ethical Requirement M10 in D8.4).

THIRD COUNTRIES		
Does your research involve non-EU countries?	yes	no
Do you plan to import any material from non-EU countries into the EU?		X
Do you plan to export any material from the EU to non-EU countries?		X

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	yes no ☐ X yes no
If yes: The researchers should provide a risk-benefit analysis, the details of the activities and compliance checks with the EU and local legislations before the collaboration begins. Analysis is to be provided to Ethics Manager and Data Protection Manager.	
INCIDENTIAL AND/OR SENSITIVE FINDINGS	
Does your research involve a risk of incidental findings?	☐ X yes no
If yes, Research plans that may involve a risk of incidental findings must be accepted either by the organisation's own board of ethics (e.g., at universities), or if the organisation does not have such, then at the SHAPES EAB before the research begins. The plan for incidental findings must be sent to the WP8 internal review team for comments. If incidental findings are identified in the context of SHAPES activities, they must be immediately reported to the relevant authority or to the responsible organisational role, as well as to SHAPES Ethics Manager. Pilots in phases 1-3: Acquire approvals before the research if there is a risk for incidental findings. Pilots in phases 4-5: Incidental findings on the SHAPES platform during the pilots have been taken into account in the ethical requirements, see Ethical Requirement M6 in D8.4.	
DATA MANAGEMENT (all data, not only personal data)	
All the pilots are responsible to define their data sets and provide input to WP6 Data Lifecycle Management Plan. (see D8.13) Pilots in phases 1-3: Data Sets are to be identified before the pilot begins.	

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Pilots in phases 4-5: First version of the Data Lifecycle Management plan needs to be ready before pilots phase 4 begins.

Summary of the deadlines for the phases 1-3 and 4-5.

Activity	Phases 1-3	Phases 4-5
Human dignity	Choose methods and tools of co-creation carefully.	Choose methods and tools of co-creation carefully.
Research plans and approvals	Provide/acquire before the research begins	Provide/acquire before the pilot begins
Consents	Collect before person's participation	Collect before person begins to use SHAPES
Privacy and Data protection descriptions, including also secondary use of personal data.	*We recommend not to collect real personal data.* *Contact Data Protection Manager if this is needed.*	Provide before the pilot begins. The secondary use of personal data is to be reported by the end of M12.
Tracking and observing of participants	*We recommend not to perform such activities. Contact Data*	*This information is/will be available on SHAPES technical documents, Personal Data*

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	Protection Manager if this is needed.	*Descriptions, on DPIA and Ethical Risk assessments.*
Legal compliance with local legislation on GDPR	*We recommend not to collect real personal data. Contact Data Protection Manager if this is needed.*	Acquire approvals and provide compliance before the pilot begins.
Data Protection Officer and Data Owners	Nominate Data owner before the collection of data begins.	Nominate the Data Protection Officer (or at least the organization) by the end of M12.
Privacy and Data Protection Impact assessments	N/A	Provide DPIA 2 months before the pilot in phase 5 begins.
Third countries	Provide information before the collaboration/ processing of personal data begins.	Provide information before the collaboration/ processing of personal data begins.
Incidental findings	Acquire approvals before the research if there is a risk for incidental findings.	*The procedures regarding the incidental findings on the SHAPES platform will be defined as part of the Ethical Requirement ME6.*
Data Management	Data sets are to be identified before the pilot begins.	Provide first version of Data Lifecycle Management Plan before the phase 4 begins.

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Annex 16 UC-PT3-gen Phase 4 Participant information sheet

SHAPES PARTICIPANT INFORMATION SHEET: healthy volunteer

Study title: SHAPES Pan-European Pilot Campaign: Phase 4: Small Scale Live Demonstration for pilot theme 3 — medicines control and optimisation

We'd like to invite you to take part in our study, during which we would like you to test the functionality of a healthcare application (an app) and connected clinical devices that have been developed for people aged 65 years' and over, and who are living with heart failure and diabetes. The study is an opportunity for us to test the solution in a real world environment and will identify any issues with connectivity and transfer of data. It will also consider if amendments need to be made to the processes, logistics or documentation that are to be used in the large scale pilot.

This information sheet describes the study and your role in it. Before you decide, it is important that you understand why the study is being done and what it will involve for you. Please take time to read this information.

Voluntary nature of participation

Participation in this study is voluntary. You can withdraw from the study at any time without giving any reason and without there being any negative consequences.

Purpose and aims of the study

This study is one part of a larger research project that aims to test different ways of using technology to assist people in their homes as they get older. The purpose of this study is to test the solution in a healthy volunteer in a real-world environment. The app and clinical devices will be used over three days and we will collect information on how well they work, both from the user's perspective and at the backend of the solution where the researchers will be viewing information transferred from the app.

Who is organising and funding the research?

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

The Northern Health and Social Care Trust (NHSCT) is organising this study. It is part of a larger research programme called the SHAPES project which is funded by the European Union under the Horizon 2020 Programme (Grant Agreement no 857159).

What will participation involve?

You will be given a tablet device that has the app installed to use at home along with one of each of the following four CE-marked, Bluetooth-enabled devices:

- A body composition monitor (OMRON VIVA Smart Scale)
- A glucometer (Roche Accu-chek Instant)
- A blood pressure monitor (OMRON M7 Intelli IT)
- A pulse oximeter (Beurer GmbH PO60 Bluetooth pulse oximeter)

Appropriate infection control measures will be taken with the devices between participants. Researchers will provide full training on how to use each device and user manuals will be provided. There is a SHAPES user manual for using the app too.

You will be asked to use the devices to take daily readings of your weight, blood pressure, heart rate, oxygen saturation and blood glucose, for three days. The readings from the devices will be electronically transferred to the SHAPES app via Bluetooth. You will be able to view your data via the app and have the ability to enter readings manually. You will be asked to enter at least one reading per parameter over the course of the three days to test this functionality. You will also be asked to complete a daily survey containing questions about health status, and a weekly survey about use of medicine. You will use dummy data to complete these questionnaires.

An example medication regimen will be uploaded to the app by researchers and will be available to view both as a comprehensive list of all medicines, and a daily list to serve as a reminder for what has to be taken that day. You will be asked to view this information daily.

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You will be asked to keep a user log during your three days' of using the solution. During this time you will record the time of each interaction, activities undertaken and if any errors occurred during use.

Processing of information collected by or inputted into the devices

Your data on the SHAPES app will be uploaded via wireless connection to secure technical partner servers. The data are then securely shared via direct links with analytics partners for analysis. The transformed data are then securely sent back to technical partner servers and displayed via browser-based dashboard to enable researchers to track your progress through the study. You will not have access to the transformed data or the researcher dashboard.

Only the SHAPES research team at the Northern Health and Social Care Trust will be able to identify you. All other SHAPES partners will be provided with a code and will not be able to personally identify you using this code. Information collected about you will be stored until the next phase of the SHAPES study has commenced (estimated to be within three months). Your information will then be deleted from partner servers and the SHAPES big data platform.

Possible benefits of taking part

There are no direct benefits to you as an individual for taking part in this study, besides personal interest and the experience of participating in a study. Your input will also inform how we use technology to assist people in their homes as they get older. People from all over Europe will benefit from your participation.

Possible disadvantages of taking part

Use of the clinical devices may cause slight discomfort to some people — particularly the glucometer, which requires pricking the skin of the finger with a lancet to create a small droplet of blood. We do not foresee any other discomforts or disadvantages for you taking part in this study.

Financial information

Participation in this study will involve no cost to you. You will receive no payment for your participation.

Informing about the study results

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Findings from this study may be used in further research and/or communication activities (e.g. as part of further research in the SHAPES project, in journal articles, workshops and conferences). A summary of the findings will be made available to you.

Termination of the study

The researchers conducting the study can terminate the study, however, at present there are no foreseeable reasons why this study would be terminated. If you would like to withdraw your participation at any point you are free to do so. If this is the case please contact the researcher. We may still use your anonymised data.

Further information

Further information related to the study can be requested from the following people involved with the SHAPES project.

Contact details

Northern Health and Social Care Trust

Dr Maureen Spargo (local researcher)

Email: Maureen.spargo@northerntrust.hscni.net; Telephone: 028 9442 4942

Professor Mike Scott (principal investigator)

Email: DrMichael.Scott@northerntrust.hscni.net; Telephone: 028 9442 4942

Nicola Lyons (Data Protection Officer)

Email: dataprotectionofficer@northerntrust.hscni.net

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Annex 17 UC-PT3-gen Phase 4 Participant consent form

SHAPES PARTICIPANT CONSENT FORM

Title of the study: SHAPES Pan-European Pilot Campaign. Phase 4: Small Scale Live Demonstration for pilot theme 3 — medicines control and optimisation

Location of the study:

Northern Health and Social Care Trust (NHSCT)

Contact

Dr Maureen Spargo (NHSCT researcher)

Email: Maureen.spargo@northerntrust.hscni.net; Telephone: 028 9433 0716

Participant declaration

- I have been invited to participate in the above study. The purpose of the study is to test the app and clinical devices as a healthy volunteer.

- I have read and understand the participant information sheet. The participant information sheet has provided me sufficient information about the above study, its purpose and execution of the study, about my rights, and about the possible advantages and disadvantages of taking part.

- I have had the opportunity to ask questions about the study and have had these questions answered satisfactorily.

- I have been given sufficient information about the collection, processing, transfer/disclosure and deletion of my data during the study. I understand that other than my name, contact details and data obtained during the study by researchers from the Northern HSCT, no other personal identifiable data will be

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processed during this study.

- By signing this form, I confirm that I voluntarily consent to participate in this study and that I also grant consent to the processing of my responses for the purposes described in this document.

- I have not been pressurised or persuaded into participation and I have had enough time to consider my participation in the study. I understand that my participation is entirely voluntary and that I am free to withdraw my consent at any time, without providing any reason.

- I also have the right to request the removal of my identifiable personal data in accordance with data protection legislation.

To be completed by the participant

Agreement (please complete the details below to confirm your consent)

Name:

Date:

Signature:

To be completed by study personnel

Please complete the details below to confirm receipt of signed consent

Name:

Date:

Signature:

The original consent signed by the participant will be kept by the research team. The participant information sheet and a copy of the signed consent will be given to the participant.

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Annex 18 UC-PT3-gen Phase 4 Head of service approval

Scott, DrMichael | Spargo, Maureen 07/02/

RE: Shapes phase 4

Hi Maureen

I am content that this phase proceeds subject to IG approval of the highlighted section

Thank you

Mike

From: Spargo, Maureen <Maureen.Spargo@northerntrust.hscni.net>
Sent: 07 February 2022 14:11
To: Scott, DrMichael <DrMichael.Scott@northerntrust.hscni.net>
Subject: Shapes phase 4

Hi again Mike,

Please see attached the research plan for Phase 4 for your approval as head of service. I am just waiting final approval on the wording of the highlighted section from Nicola Lyons (we have a meeting with her this afternoon) but on securing that would like to email out a recruitment email to the MOIC team to secure our two volunteers before the end of the week (with a view to starting phase 4 on the 21st February.

Best wishes.

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Annex 19 UC-PT3-gen Phase 5 service user participant information sheet

SHAPES PARTICIPANT INFORMATION SHEET

MEAAP contact person(s): [NAME, JOB TITLE and CONTACT NUMBER/EMAIL to be inserted]

NHSCT contact person(s): [NAME, JOB TITLE and CONTACT NUMBER/EMAIL to be inserted]

Study title: SHAPES pilot: supporting multimorbid older people

Invitation to participate in a pilot study.

This pilot study will involve a number of clinical devices to monitor your vital signs and test a new application (app). You have been invited to participate because you have heart failure or diabetes and are aged 60 or over. Thirty participants from Northern Ireland will have the opportunity to participate in this exciting new pilot.

This information sheet describes the study and your role in it. Before you decide, it is important that you understand why the pilot is being carried out and what it will involve for you. Please take time to read this information and discuss it with others if you wish. If anything is not clear, or if you would like more information, please contact a member of the SHAPES team at the top of this letter. After that we will ask you to sign a consent form in order to participate in the study. During the pilot the Northern Health and Social care Trust staff listed above will be available to support you using the technology and troubleshoot any issues.

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Voluntary nature of participation

Participation in this study is voluntary. You can withdraw from the study at any time without giving any reason and without there being any negative consequences. If you withdraw from the study or withdraw your consent, all your personal data collected for the purposes of the research will be removed. Alternatively, you may permit the personal data collected before withdrawal to be included in the research.

Purpose and aims of the study

The main goal of this pilot is investigate how participants use the SHAPES technology.

Additional aims of the pilot include;

- To help people self-monitor their health conditions, vital signs and medicines use to promote a safer and more effective use of medicines in the home.
- To examine and improve medicines use to improve patient outcomes and develop best practice.
- To develop technology to predict episodic worsening of heart failure and assess the data collection required for this.
- To assess whether use of the SHAPES technology is associated with a change in unscheduled healthcare.
- To improve participants' quality of life
- To explore trust and acceptance of the SHAPES technology
- To determine whether the use of SHAPES technology may extend independent living

Who is organising and funding the research?

The SHAPES project brings together leading research groups, companies and experts across Europe. The consortium of the SHAPES project is formed by 36 partners from 14 European countries. The Northern Health and Social Care Trust is the lead organisation responsible for this pilot in Northern Ireland. Similar pilots are being carried out across Europe. This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 857159.

What will the participation involve?

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Potential participants will be asked some questions to make sure they are eligible and will be asked to provide written, informed consent to participate in the pilot.

Participants will be asked to download the SHAPES app to a smartphone or tablet.

Participants will be provided with CE marked, Bluetooth enabled devices, including a weight scale, glucometer(if applicable), blood pressure monitor and pulse oximeter.

Before the pilot begins, participants will be provided with training by the Northern Health and Social Care Trust members of staff listed above and given some time to get used to the technology. They will also be asked to answer a number of questionnaires and provide some baseline information. This information will include your contact details, health and care number, age, marital status, occupational status, education, support received for daily living, medical history, laboratory results and healthcare resource use for 3 months prior to the pilot and during the pilot. Some of this information may be collected from your medical notes, with your consent. Questionnaires will cover quality of life, self-efficacy, social support, health literacy, activities of daily living, medicine use and beliefs about medicine.

During the 12 week pilot participants will be encouraged to use the devices to take daily readings of their weight (including body mass index, body fat, visceral fat, skeletal muscle, basal metabolic rate), blood pressure, heart rate and oxygen saturation, and readings of their blood glucose as per their existing diabetes care plan. These readings are electronically transferred to the SHAPES app via Bluetooth. Participants can view their data via the app and have the ability to enter readings manually if required. Participants will also be encouraged to complete a daily survey containing questions about their health status, and a weekly survey about their use of medicine. The participant's medication regimen will be uploaded to the app by researchers and will be available to view both as a comprehensive list of all medicines, and a daily list to serve as a reminder for what has to be taken that day. Participants will be asked via the app on a weekly basis if any changes have been made to their treatment that week so that their medication regimen can be updated accordingly. If participants indicate that there has been a change to their medication a researcher will call them to confirm the details and update the information on the app.

Researchers will contact participants by telephone at the end of week 1, if there are 3 consecutive days when no data has been received and monthly (if necessary) to support participants with their use of the technology and troubleshoot any issues. During the pilot your data will be used to help develop technology to help predict worsening of heart failure so that in future this may inform care and your data will also help develop technology aiming to predict personalised normal ranges for blood pressure, weight, blood glucose, blood oxygenation and heart rate. During the pilot your actual use of the SHAPES app

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will be monitored to test its usability and check whether any further support is required. Google Services will be used when downloading (Google Play) and using (Google Analytics) the SHAPES app. Google Services may use geolocating software.

After the 12 week pilot period, researchers will administer a number of questionnaires and gather some end point data. The end point data will be similar to that asked at baseline and will include questions about marital status, occupational status and support received for daily living. The questionnaires administered at this stage will be more focused on what you thought of the technology and some of the same questionnaires administered previously will be asked again.

Three months after completing the pilot, participants will be asked to complete a small number of follow-up questionnaires, these will be questionnaires that have previously been administered.

Participants' data and outputs from analyses will be uploaded to a browser-based researcher dashboard. Researchers will be able to view each participant's clinical and survey data, and manage participants' medication regimens as needed. Researchers will view the available data and information for purposes of monitoring usage of the technology and inputting changes to medication regimens only. **There will be no clinical review of the information provided**.

If the participant has consented to have an interview, researchers will be in contact to discuss and arrange this. The interview will last approximately 1 hour and will be recorded. If the interview occurs face-to-face it will be audio-recorded, if the interview is conducted remotely it will be conducted on a video-conferencing software e.g. Zoom and will be audiovisually recorded. The interview will be transcribed and checked. Once the transcript is approved the recordings will be deleted.

The information collected relating to you will be stored securely and confidentially. Only the people who contact you to invite you to participate in this pilot and the research team at the Northern Health and Social Care Trust will be able to identify you. All other SHAPES partners will be provided with a code and will not be able to personally identify you using this code. Identifiable information will be stored until the end of October 2023 after this point, information will be de-identified and stored for a further 5 years in NHSCT. A de-identified data set may be shared with other members of the SHAPES consortium if an appropriate data sharing agreement is in place. An anonymous, aggregated dataset will be stored indefinitely for future use by researchers.

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Annex 20 UC-PT3-gen Phase 5 service user study summary

Invitation

People who are identified as suitable for the study are invited to take part. Information is provided about the study and the chance to ask questions offered.

Consent

Those people who agree to take part in the study are asked to read and sign a consent form to confirm they are happy to participate. They become participants.

App & device training and practice

Participants are shown how to download and use the SHAPES App and the monitoring devices. They are given some time to practise using them at home before the study begins. NHSCT researchers will be available to help with any issues.

Baseline information collected

Researchers collect information about the participants and their health **before** starting the pilot. Information is collected using questionnaires and from a review of relevant sections of participants' medical records.

At home use of app & devices

Participants are asked to use the App and devices for monitoring diabetes and heart failure at home for **three months.** Researchers will contact participants after a few weeks to see if they need any assistance, if there is more than 3 days of missing data, if participants notify us of a change in medicine, and then monthly if required.

End of pilot information collected

At the end of the pilot researchers will collect information about the participants and their health **after** the pilot to check if anything has changed. Information is collected using questionnaires and from a review of relevant sections of participants' medical records.

Follow-up interview

After the pilot, researchers will interview some participants to hear more about their experience during the pilot. This will take place at the end of the pilot visit with the researcher or within a few weeks of it ending.

Follow-up questionnaires

Three months after the end of the pilot, researchers will collect some more information using questionnaires. After this the study will end.

Study summary

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Possible benefits of taking part

It is hoped that participants in the pilot may increase their ability to effectively self-manage their conditions.

In the future, this technology may be used throughout Europe to assist older individuals manage health conditions.

In future, the intervention may facilitate the remote monitoring of people by health practitioners and use artificial intelligence (AI) algorithms to predict deterioration in a person's health status. However, this functionality will not be investigated in the present study.

Possible disadvantages and risks of taking part

There is no clinical oversight of the information recorded in this pilot. There are no medical staff reviewing the data received from the clinical devices. If you are concerned about your health it is important that you seek care from your normal healthcare providers.

Incidental findings

Although it is very unlikely, participants may discover an underlying medical condition from the monitoring they are carrying out. Any health-related concerns should be independently followed up with a healthcare professional.

Financial information

Participation in this study will involve no cost to you. You will receive no payment for your participation. This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159.

Insurance policies

Insurance and indemnity for pilot participants is in place through the Northern Health

and Social Care Trust.

Informing about the pilot results

A written summary of results will be made available to all participants once the analyses have been completed. Results, including direct quotations may also be published in a report to the funding body, journals, publications and conferences. No participants will be able to be identified from these reports.

Termination of the study

The researchers conducting the study may terminate the study earlier than planned for any reason to protect the safety of the participants or security of participant data.

At the end of the 12 week pilot, the clinical devices (weight scales, glucometer, blood pressure monitor and pulse oximeter) will be returned and access to the SHAPES app will be terminated.

Further information

Further information related to the study can be requested from the researcher / person in charge of the study as per details below.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Contact details of the researchers / person in charge

Research Team

Chief investigator:

Prof Mike Scott DrMichael.Scott@northerntrust.hscni.net

SHAPES researchers:

[Name(s) and email addresses to be inserted]

Telephone: 028 9442 4942

Mid & East Antrim Agewell Partnership

Email: info@meaap.co.uk

Telephone: 028 2565 8604

Data Protection Officer

Nicola Lyons

Email: dataprotectionofficer@northerntrust.hscni.net

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Annex 21 UC-PT3-gen Phase 5 service user privacy notice

Privacy Notice/Policy for SHAPES research data

Within the SHAPES project, your personal data will be processed according to the European Union General Data Protection Regulation and current national regulation Data Protection Act 2018 (UK). The processing of personal data will be described in the following items.

Data controller of the SHAPES project

The data controller for this pilot will be the Northern Health and Social Care Trust

Address: Northern Health and Social Care Trust Head Quarters, Bretten Hall, Bush Road, Antrim, BT41 2RL

Contact person for matters related to the processing of personal data

Data Protection Officer: Nicola Lyons

Email: dataprotectionofficer@northerntrust.hscni.net

Types of personal data that will be collected in this study

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Directly identifiable information including date of birth, name, health and care number, address, audio and/or visual recording of the interview (optional), phone number, facial recognition to enter the SHAPES app and contact details for an alternative contact.

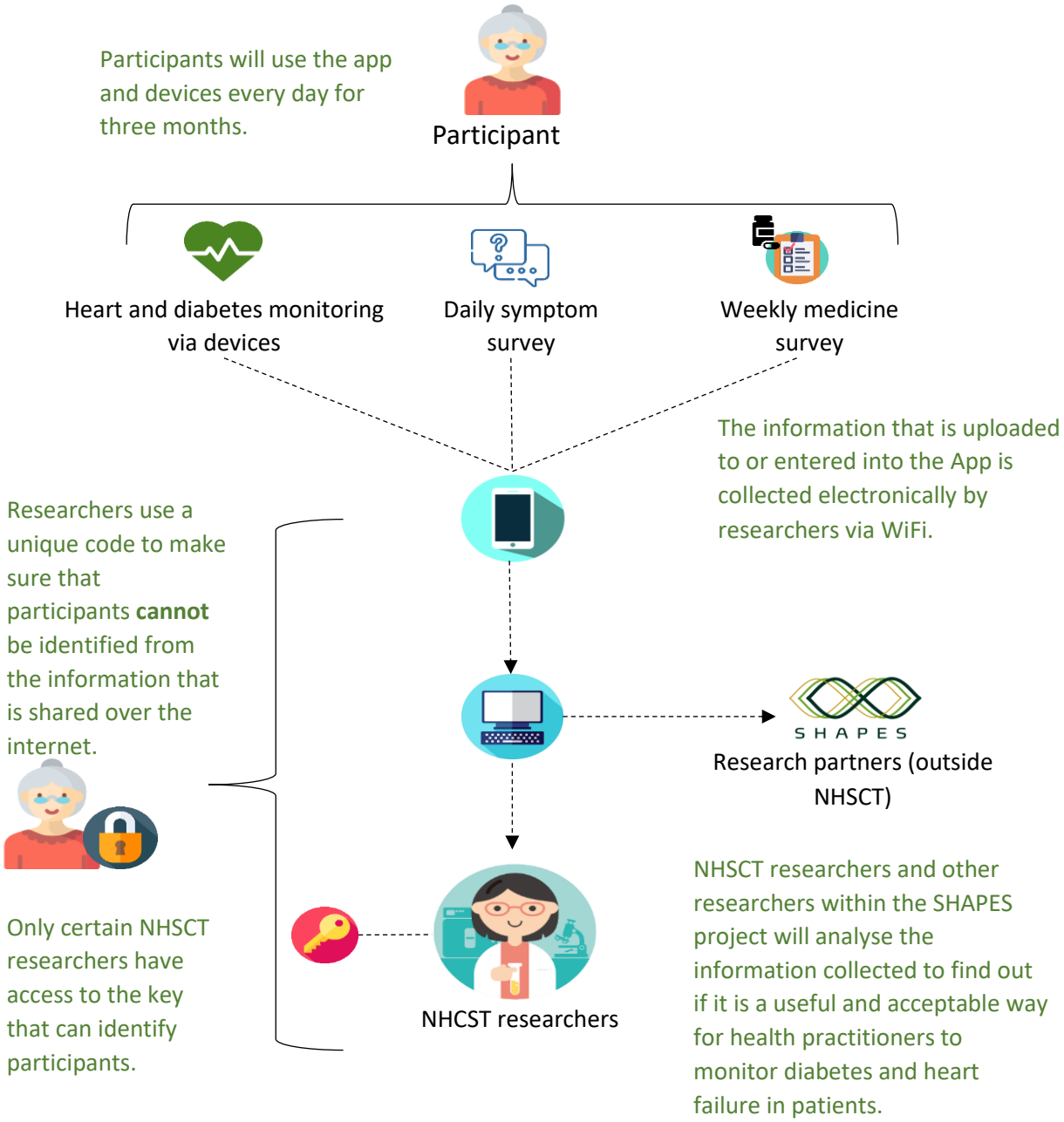
All other information collected will be coded and will include:

- Code/coded username for access to the SHAPES app.
- Demographic data; education, marital status, occupational status, gender, care giving status, care-receiving status, residential information.
- Medical history; height, heart failure details, diabetes details, other existing medical conditions,
- Device data; types of devices provided and serial numbers, make and model of personal smartphone/tablet device. Daily data including heart rate, blood pressure, weight (including body mass index, body fat, visceral fat, skeletal muscle, basal metabolic rate), blood oxygen saturation and blood glucose.
- SHAPES app; contact time preferences, usage details of the app e.g. number and duration of access
- Laboratory results; laboratory tests relating to heart failure and diabetes.
- Questionnaires; covering a variety of different aspects including quality of life, self-efficacy, social support, participation, health literacy, technology usability, technology acceptance, activities of daily living, self-care, heart failure symptoms, medicines use, beliefs about medicines, user experience.
- Health care resource use; use of unscheduled care for 3 months prior to the pilot and 3 months during the pilot.
- Medication data; list of all prescribed medication and any changes during the pilot.
- Safety recording; details of any incidents occurring during the pilot.
- Biometric data; facial recognition to enter the SHAPES app.
- Interview data; coded transcripts of the optional interview
- Google services; Google Play will be used to download the SHAPES app and Google Analytics will be used to track participants' use of the app.

Personal data will be collected from participants, their medical notes and devices connected to the SHAPES app.

Participant data flow diagram

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159



Personal data protection principles

The data that is to be processed in the information systems has been protected using the following:

user ID ✓ password ✓ user registration ✓ access control (physical location) ✓

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

If other methods, please specify:

Data collected from the individual and their medical records will be collected using a paper case report form, the case report form will be stored in a locked office on the Antrim Area Hospital site. The case report form will be transcribed onto an Excel database which will be stored behind the Northern Health and Social Care Trust firewall. Any directly identifiable information will be stored in a locked office on the Antrim Area Hospital site and on a database behind the Northern Health and Social Care Trust firewall and only accessible by approved research team members from the Northern Health and Social Care Trust. Coded information will be shared with specific SHAPES partners and stored securely on their servers and with the SHAPES platform with appropriate data access controls. Any partner who has access to coded data will have a Data Processing Agreement in place and abide by the relevant data protection legislation.

Participants will access the SHAPES app using a username provided to them which contains their unique code. Additionally facial recognition technology will be used to authenticate the user.

Data collected from the participant devices will be transferred via Bluetooth to the SHAPES app where it will be stored for the participant to view their data. This data and answers to questions in the SHAPES app will be securely transferred via Wi-Fi to our partners' servers and will be encrypted in onwards transfer to the SHAPES platform.

For what purpose will personal data be processed?

The main goal of this pilot is investigate how participants use the SHAPES technology.

Additional aims of the pilot include;

- To help people self-monitor their health conditions, vital signs and medicines use to promote a safer and more effective use of medicines in the home.
- To examine and improve medicines use to improve patient outcomes and develop best practice.
- To develop technology to predict episodic worsening of heart failure and assess the data collection required for this.
- To assess whether use of the SHAPES technology is associated with a change in unscheduled healthcare.
- To improve participants' quality of life
- To explore trust and acceptance of the SHAPES technology

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

- To determine whether the use of SHAPES technology may extend independent living

Legal basis of processing personal data

The legal basis for data processing is consent.

You have the right to withdraw consent at any time as described in this notice.

Nature and duration of the study completed within the SHAPES project (how long the personal data will be processed):

✓One-time research ×Follow-up research

Duration of the research:

Identifiable information to be stored until the end of the SHAPES Innovation Action (October 2023). The participant list linking the code to the individual will then be destroyed and directly identifiable data will be deleted. The remaining, de-identified data may be stored for an additional 5 years (within NHSCT) to allow for further analyses and publication. A de-identified data set may be shared with other members of the SHAPES consortium if an appropriate data sharing agreement is in place. An anonymous, aggregated dataset will be stored indefinitely for future use by researchers.

What happens to the personal data after the study within the SHAPES project has ended?

After the pilot has ended personal data will be analysed and results reported to the funder, in scientific publications and conferences, however, this will be grouped data and will not be personally identifiable.

Directly identifiable information e.g. name, phone, number, address, date of birth and the link to the participants' unique code will be destroyed in October 2023.

De-identified data will be retained for an additional 5 years, within NHSCT, to

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

allow for further analyses and publication. The retained data will be archived by Northern Health and Social Care Trust.

Data transfer outside of the research registry:

A small anonymous data set including; medication use and beliefs about medicines questionnaire responses; sex (male|female); age (years); diagnosed illnesses; country will be shared with the School of Pharmacy in University College London to further develop these questionnaires.

Possible transfer of personal data outside the EU or the EEA:

Your data will not be transferred outside of the EU or the EEA the only exception to this are transfers to/from the EU/EEA to/from the UK with your consent.

Your rights as a data subject

Because your personal data will be used in the study taking place within the SHAPES project, you will be entered into the study registry. Your rights as a data subject are the following:

Right to obtain information on the processing of personal data

Right of access

Right to rectification

Right to erasure (right to be forgotten)

Right to withdraw consent regarding processing of personal data

Right to restriction of processing

Notification obligation regarding rectification or erasure of personal data or restriction of processing

Right to data portability

The data subject can allow automated decision-making with his or her specific consent

Right to notify the Data Protection Ombudsman if you suspect that an organisation or individual is processing personal data in violation of data protection regulations.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

If the purposes for which a controller processes personal data do not or no longer require the identification of a data subject by the controller, the controller shall not be obliged to maintain, acquire or process additional information in order to identify the data subject for the sole purpose of complying with this regulation. If the controller cannot identify the data subject, the rights of access, rectification, erasure, notification obligation and data portability shall not apply, except if the data subject provides additional information, enabling his or her identification.

You can exercise your rights by contacting the data controller of the study.

Personal data collected in the SHAPES project for research will not be used for automated decision-making. In this SHAPES project pilot, the processing of personal data is never used in any treatment decisions concerning the participants of the research.

Pseudonymisation and anonymisation

All information collected from you will be handled confidentially and according to the legislation. Individual participants will be given a code, and the data will be stored in a coded form in the SHAPES project files. Results will be analysed and presented in a coded, aggregate form. Individuals cannot be identified without a code key. A code key, which can be used to identify individual research participants and their responses, will be stored by the authorised research team in the Northern Health and Social Care Trust. Coded data will not be given to people outside the SHAPES-project study group. The final research results will be reported in aggregate form, and it will be impossible to identify individual participants. The SHAPES project study registry will be stored in Spain by TREE Technology SA indefinitely, this will only hold anonymous, aggregated data. A larger de-identified dataset will be stored locally in the Northern Health and Care Trust until 2028.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Annex 22 UC-PT3-gen Phase 5 service user Participant consent form

SHAPES PARTICIPANT CONSENT FORM

Title of the study: SHAPES pilot: supporting multimorbid older people

Location of the study: This pilot will take place with service users in the Northern Health and Social Care Trust. You may contact the SHAPES research team by calling 028 9442 4942 or contacting the personnel listed on the information sheet.

I have been invited to participate in the above research study. The purpose of the research is to use the technology developed by the SHAPES consortium to support medicines use in older people with multiple chronic health conditions.

I have read and understand the participant information sheet. The information sheet has provided me sufficient information about the above study, its purpose and execution of the study, about my rights, as well as about the benefits and risks involved. I have had the opportunity to ask questions about the study and have had these answered satisfactorily.

I have been given sufficient information about the collection, processing, transfer/disclosure and deletion of my personal data during the study, and the Privacy Notice have been available as part of the SHAPES project Participant Information documents.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

- By signing this form, I confirm that I voluntarily consent to participate in this study and that I **also** grant consent to the processing of my personal data for the purposes described in this document and in the privacy notice.

- I have not been pressurized or persuaded into participation and I have had enough time to consider my participation in the study. I understand that my participation is entirely voluntary and that I am free to withdraw my consent at any time, without providing any reason.

- I also have the right to request the removal of my identifiable personal data in accordance with data protection legislation. I am also aware that if I withdraw from the study or withdraw my consent, all my personal data collected for the purposes of the research will be removed. Alternatively, I can withdraw my consent for future data collection and permit the personal data collected before my withdrawal to be included in the research.

- I agree to the Northern Health and Social Care Trust research team processing my personal information for the purposes of this pilot.
- I agree that the Northern Health and Social Care Trust research team may collect personal information from my medical records, including the Northern Ireland Electronic Care Record
- I agree to using the SHAPES technology provided and allowing the clinical devices to share the data collected with Partners in the SHAPES consortium.
- I agree to the Northern Health and Social Care Trust research team sharing coded personal information with Partners in the SHAPES consortium.
- I agree to share coded personal data within the EU and EEA and UK.
- I agree to share data with Google Services (Google Play and Google Analytics).
- I agree to anonymous information being used in future ethically approved research.
- I agree to a small, anonymous data set being shared with researchers at University College London to further improve the development of questionnaires relating to medicines use and beliefs about medicines.
- If applicable, I agree to the Mid and East Antrim Agewell Partnership sharing my contact details and consent form with the NHSCT research team.

Optional:

- I agree to participate in an interview about my experience of using the SHAPES technology when the 12 week pilot ends. This interview will be audio-visually recorded.

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- I agree to be contacted about future opportunities to do with SHAPES

Date: _____

Signature of Participant: _____

The original consent signed by the participant and a copy of the participant information sheet will be kept in the records of the researcher. The participant information sheet, privacy notice and a copy of the signed consent will be given to the participant.

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Annex 23 UC-PT3-gen Phase 5 HSC staff participant information sheet

SHAPES HEALTHCARE PROFESSIONAL INFORMATION SHEET

Study title: SHAPES pilot: supporting multimorbid older people

Invitation to participate in a pilot study

This pilot study will involve a number of simple clinical devices to monitor service users' vital signs and test a new application (app). You have been invited to participate in an interview because you have experience caring for patients with heart failure and diabetes.

This information sheet describes the study and your role in it. Before you decide, it is important that you understand why the pilot is being carried out and what it will involve for you. Please take time to read this information and discuss it with others if you wish. If anything is not clear, or if you would like more information, please ask the person responsible for this study. After that we will ask you to sign a consent form in order to participate in the study.

Voluntary nature of participation

Participation in this study is voluntary. You can withdraw from the study at any time without giving any reason and without there being any negative consequences. If you withdraw from the study or withdraw your consent, your personal data collected for the purposes of the research will be removed.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Purpose and aims of the study

The main goal of this pilot is investigate how participants use the SHAPES technology.

Additional aims of the pilot include;

- To help people self-monitor their health conditions, vital signs and medicines use to promote a safer and more effective use of medicines in the home.
- To examine and improve medicines use to improve patient outcomes and develop best practice.
- To develop technology to predict episodic worsening of heart failure and assess the data collection required for this.
- To assess whether use of the SHAPES technology is associated with a change in unscheduled healthcare.
- To improve participants' quality of life
- To explore trust and acceptance of the SHAPES technology
- To determine whether the use of SHAPES technology may extend independent living

The specific aims of this interview include;

- Explore healthcare practitioners' views about their trust and acceptance of the SHAPES platform and Digital Solutions
- Explore of healthcare practitioners' views on integration and alignment of the SHAPES platform and Digital Solutions with current care pathways

Who is organising and funding the research?

The SHAPES project brings together leading research groups, companies and experts across Europe. The consortium of the SHAPES project is formed by 36 partners from 14 European countries. The Northern Health and Social Care Trust is the lead organisation responsible for this pilot in Northern Ireland. Similar pilots are being carried out across Europe. This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159.

What will the participation involve?

<u>Taking consent</u>

- After you have had time to read this information sheet, a researcher will be in touch with you to discuss participation.
- If you are happy to take part you will be asked to sign a consent form and

return it to the researcher.

Before the video call

- The researcher will telephone or email you to arrange a suitable time to conduct the video call.
- The researcher will check if you have the technology needed to conduct the video call and talk you through how to use it (if required).

During the video call

- During the video call you will first be shown information about the study and the wider SHAPES project.
- You will be shown information on the intervention applied
- You will be shown a demonstration of data collection (may include SHAPES front-end app interface and researcher interface)
- You will be asked a number of questions about utility, usability, trust, concept and COVID-19.
- This is not a test and there are no right and wrong answers. We are looking for your honest opinions.
- The researcher(s) may need to take notes during the call and will be recording the conversation so that we can listen back to it and make more detailed notes.
- The call should not last longer than one hour. We will work at a pace that is set by you and you may take a break at any time during the call.
- If you wish to have a longer to look at the information or another demonstration, we can arrange this and set-up a second call for you to give us your feedback.

Collection and processing of information after the video call

- Other than your name, contact details and recordings obtained during the interview, no other personal data will be collected.
- All recordings collected during the interview will be transferred to a password-protected computer that only the local researchers will have access to.
- We may transcribe the recordings and will anonymise any identifiable information in the process. Recordings will then be destroyed after use.
- Anonymised findings may be used in further research and/or communication activities (e.g., as part of further research in the SHAPES project, in journal articles, workshops and conferences).
- Your personal contact details will be destroyed by the researchers once you have been provided with a summary of the findings for this study.
- Anonymised raw data will be stored for the duration of the SHAPES project (until October 2023) and for five years after it finishes.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Possible benefits of taking part

It is hoped that participants in the pilot may increase their ability to effectively self-manage their conditions.

In the future, this technology may be used throughout Europe to assist older individuals manage health conditions.

In future, the intervention may facilitate the remote monitoring of people by health practitioners and use artificial intelligence (AI) algorithms to predict deterioration in a person's health status. However, this functionality will not be investigated in the present study.

Possible disadvantages and risks of taking part

There is no foreseeable risk or disadvantage to you by taking part in this interview.

Incidental findings

There are no foreseeable incidental findings of taking part in this interview.

Financial information

Participation in this study will involve no cost to you, other than your time. You will receive no payment for your participation. This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159.

Insurance policies

Insurance and indemnity for pilot participants is in place through the Northern Health and Social Care Trust.

Informing about the pilot results

A written summary of results will be made available to all participants once the analyses have been completed. Results, including direct quotations may also be published in a report to the funding body, journals, publications and conferences. No participants will be able to be identified from these reports.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Termination of the study

The researchers conducting the study can also terminate the study earlier than planned for any reason to protect the safety of the participants or security of participant data.

Further information

Further information related to the study can be requested from the research team / chief investigator.

Contact details of the researchers / person in charge

Researcher Team:

Prof Mike Scott DrMichael.Scott@northerntrust.hscni.net

[Research programme manager name and email addresses to be inserted]

Telephone: 028 9442 4942

Data Protection Officer:

Nicola Lyons

Email: dataprotectionofficer@northerntrust.hscni.net

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Annex 24 UC-PT3-gen Phase 5 HSC staff Privacy notice

Privacy Notice/Policy for SHAPES research data

Within the SHAPES project, your personal data will be processed according to the European Union General Data Protection Regulation and current national regulation Data Protection Act 2018 (UK). The processing of personal data will be described in the following items.

Data controller of the SHAPES project

The data controller for this pilot will be the Northern Health and Social Care Trust

Address: Northern Health and Social Care Trust Head Quarters, Bretten Hall, Bush Road, Antrim, BT41 2RL

Contact person for matters related to the processing of personal data

Data Protection Officer: Nicola Lyons

Email: dataprotectionofficer@northerntrust.hscni.net

Types of personal data that will be collected in this study

Directly identifiable information including; name, phone number, email address and audio/video recording.

All other information collected will be coded and will include:

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

- Interview data; coded transcripts of the interview

Personal data protection principles

The data that is to be processed in the information systems has been protected using the following:

user ID ✓ password ✓ user registration ✓ access control (physical location) ✓

If other methods, please specify:

The audio/video recordings will be transcribed, these transcriptions will be anonymised and stored behind the Northern Health and Social Care Trust firewall. All directly identifiable information will be stored in a locked office on the Antrim Area Hospital site and on a database behind the Northern Health and Social Care Trust firewall, only accessible by approved research team members from the Northern Health and Social Care Trust.

For what purpose will personal data be processed?

The main goal of this pilot is investigate how participants use the SHAPES technology.

Additional aims of the pilot include;

- To help people self-monitor their health conditions, vital signs and medicines use to promote a safer and more effective use of medicines in the home.
- To examine and improve medicines use to improve patient outcomes and develop best practice.
- To develop technology to predict episodic worsening of heart failure and assess the data collection required for this.
- To assess whether use of the SHAPES technology is associated with a change in unscheduled healthcare.
- To improve participants' quality of life
- To explore trust and acceptance of the SHAPES technology
- To determine whether the use of SHAPES technology may extend independent living

The specific aims of this interview include;

- Explore healthcare practitioners' views about their trust and acceptance of the SHAPES platform and Digital Solutions
- Explore of healthcare practitioners' views on integration and alignment of the SHAPES platform and Digital Solutions with current care pathways

Legal basis of processing personal data

The legal basis for data processing is consent.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

You have the right to withdraw consent at any time as described in this notice.

Nature and duration of the study completed within the SHAPES project (how long the personal data will be processed):

✓One-time research ~~Follow-up research ☐~~

Duration of the research:

This interview is a one-off research opportunity, there will be no follow-up,

What happens to the personal data after the study within the SHAPES project has ended?

Interview recordings will be stored until the interview transcripts have been verified and consent forms will be stored securely until the end of the SHAPES Innovation Action (October 2023). Your personal contact details will be destroyed by the researchers once you have been provided with a summary of the findings for this study. Results, including direct quotations may also be published in a report to the funding body, journals, publications and conferences. No participants will be able to be identified from these reports.

Data transfer outside of the research registry:
There will be no transfer of data to anyone outside the NHSCT.

Possible transfer of personal data outside the EU or the EEA:

Your data will not be transferred outside of the EU or the EEA.

Your rights as a data subject

Your rights as a data subject are the following:

Right to obtain information on the processing of personal data

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Right of access

Right to rectification

Right to erasure (right to be forgotten)

Right to withdraw consent regarding processing of personal data

Right to restriction of processing

Notification obligation regarding rectification or erasure of personal data or restriction of processing

Right to data portability

The data subject can allow automated decision-making with his or her specific consent

Right to notify the Data Protection Ombudsman if you suspect that an organisation or individual is processing personal data in violation of data protection regulations.

If the purposes for which a controller processes personal data do not or no longer require the identification of a data subject by the controller, the controller shall not be obliged to maintain, acquire or process additional information in order to identify the data subject for the sole purpose of complying with this regulation. If the controller cannot identify the data subject, the rights of access, rectification, erasure, notification obligation and data portability shall not apply, except if the data subject provides additional information, enabling his or her identification.

You can exercise your rights by contacting the data controller of the study.

Personal data collected in the SHAPES project for research will not be used for automated decision-making. In the SHAPES project studies, the processing of personal data is never used in any treatment decisions concerning the participants of the research.

Pseudonymisation and anonymisation

All information collected from you will be handled confidentially and according to the legislation. Individual participants will be given a code, and the data will be stored in a coded form in the SHAPES project files. Results will be analysed and presented in a

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

coded, aggregate form. The final research results will be reported in aggregate form, and it will be impossible to identify individual participants.

The data collected from these interviews will not be used for any future research.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Annex 25 UC-PT3-gen Phase 5 HSC staff Participant consent form

Privacy Notice/Policy for SHAPES research data

Within the SHAPES project, your personal data will be processed according to the European Union General Data Protection Regulation and current national regulation Data Protection Act 2018 (UK). The processing of personal data will be described in the following items.

Data controller of the SHAPES project

The data controller for this pilot will be the Northern Health and Social Care Trust

Address: Northern Health and Social Care Trust Head Quarters, Bretten Hall, Bush Road, Antrim, BT41 2RL

Contact person for matters related to the processing of personal data

Data Protection Officer: Nicola Lyons

Email: dataprotectionofficer@northerntrust.hscni.net

Types of personal data that will be collected in this study

Directly identifiable information including; name, phone number, email address and audio/video recording.

All other information collected will be coded and will include:

- Interview data; coded transcripts of the interview

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Personal data protection principles

The data that is to be processed in the information systems has been protected using the following:

user ID ✓ password ✓ user registration ✓ access control (physical location) ✓

If other methods, please specify:

The audio/video recordings will be transcribed, these transcriptions will be anonymised and stored behind the Northern Health and Social Care Trust firewall. All directly identifiable information will be stored in a locked office on the Antrim Area Hospital site and on a database behind the Northern Health and Social Care Trust firewall, only accessible by approved research team members from the Northern Health and Social Care Trust.

For what purpose will personal data be processed?

The main goal of this pilot is investigate how participants use the SHAPES technology.

Additional aims of the pilot include;

- To help people self-monitor their health conditions, vital signs and medicines use to promote a safer and more effective use of medicines in the home.
- To examine and improve medicines use to improve patient outcomes and develop best practice.
- To develop technology to predict episodic worsening of heart failure and assess the data collection required for this.
- To assess whether use of the SHAPES technology is associated with a change in unscheduled healthcare.
- To improve participants' quality of life
- To explore trust and acceptance of the SHAPES technology
- To determine whether the use of SHAPES technology may extend independent living

The specific aims of this interview include;

- Explore healthcare practitioners' views about their trust and acceptance of the SHAPES platform and Digital Solutions
- Explore of healthcare practitioners' views on integration and alignment of the SHAPES platform and Digital Solutions with current care pathways

Legal basis of processing personal data

The legal basis for data processing is consent.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

You have the right to withdraw consent at any time as described in this notice.

Nature and duration of the study completed within the SHAPES project (how long the personal data will be processed):

✓One-time research ~~Follow-up research ☐~~

Duration of the research:

This interview is a one-off research opportunity, there will be no follow-up,

What happens to the personal data after the study within the SHAPES project has ended?

Interview recordings will be stored until the interview transcripts have been verified and consent forms will be stored securely until the end of the SHAPES Innovation Action (October 2023). Your personal contact details will be destroyed by the researchers once you have been provided with a summary of the findings for this study. Results, including direct quotations may also be published in a report to the funding body, journals, publications and conferences. No participants will be able to be identified from these reports.

Data transfer outside of the research registry:
There will be no transfer of data to anyone outside the NHSCT.

Possible transfer of personal data outside the EU or the EEA:

Your data will not be transferred outside of the EU or the EEA.

Your rights as a data subject

Your rights as a data subject are the following:

Right to obtain information on the processing of personal data

Right of access

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Right to rectification

Right to erasure (right to be forgotten)

Right to withdraw consent regarding processing of personal data

Right to restriction of processing

Notification obligation regarding rectification or erasure of personal data or restriction of processing

Right to data portability

The data subject can allow automated decision-making with his or her specific consent

Right to notify the Data Protection Ombudsman if you suspect that an organisation or individual is processing personal data in violation of data protection regulations.

If the purposes for which a controller processes personal data do not or no longer require the identification of a data subject by the controller, the controller shall not be obliged to maintain, acquire or process additional information in order to identify the data subject for the sole purpose of complying with this regulation. If the controller cannot identify the data subject, the rights of access, rectification, erasure, notification obligation and data portability shall not apply, except if the data subject provides additional information, enabling his or her identification.

You can exercise your rights by contacting the data controller of the study.

Personal data collected in the SHAPES project for research will not be used for automated decision-making. In the SHAPES project studies, the processing of personal data is never used in any treatment decisions concerning the participants of the research.

Pseudonymisation and anonymisation

All information collected from you will be handled confidentially and according to the legislation. Individual participants will be given a code, and the data will be stored in a coded form in the SHAPES project files. Results will be analysed and presented in a coded, aggregate form. The final research results will be reported in aggregate form, and it will be impossible to identify individual participants.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

The data collected from these interviews will not be used for any future research.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Annex 26 UC-PT3-gen (UNRF) Phase 5 UNRF Participant information sheet

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ΕΝΗΜΕΡΩΤΙΚΟ ΦΥΛΛΟ ΣΥΜΜΕΤΟΧΗΣ ΣΤΟ SHAPES

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Τίτλος της μελέτης: Πιλοτικό του SHAPES: Υποστήριξη ηλικιωμένων με πολλαπλές παθήσεις

Πρόσκληση για συμμετοχή σε πιλοτική μελέτη
Αυτή η πιλοτική μελέτη θα περιλαμβάνει έναν αριθμό κλινικών συσκευών για την παρακολούθηση των ζωτικών σημείων σας και τη δοκιμή μιας νέας εφαρμογής. Έχετε προσκληθεί να συμμετάσχετε επειδή έχετε διαβήτη και είστε ηλικίας 60 ετών και άνω. Δέκα συμμετέχοντες από τη Κύπρο θα έχουν την ευκαιρία να συμμετάσχουν σε αυτόν τον συναρπαστικό νέο πιλότο.

Αυτό το φύλλο πληροφοριών περιγράφει τη μελέτη και τον ρόλο σας σε αυτήν. Πριν αποφασίσετε, είναι σημαντικό να κατανοήσετε γιατί εκτελείται η πιλοτική μελέτη και τι θα περιλαμβάνει. Αφιερώστε χρόνο για να διαβάσετε αυτές τις πληροφορίες και να τις συζητήσετε με άλλους εάν το επιθυμείτε. Εάν κάτι δεν είναι ξεκάθαρο ή εάν θέλετε περισσότερες πληροφορίες, επικοινωνήστε με ένα μέλος της ομάδας SHAPES που αναφέρεται στην πρώτη σελίδα αυτής της επιστολής. Μετά από αυτό θα σας ζητήσουμε να υπογράψετε ένα έντυπο συγκατάθεσης προκειμένου να συμμετάσχετε στη μελέτη. Κατά τη διάρκεια του πιλοτικού προγράμματος, το προσωπικό του Ερευνητικού Ιδρύματος Πανεπιστημίου Λευκωσίας που αναφέρεται παραπάνω θα είναι διαθέσιμο για να σας βοηθήσει με την χρήση της τεχνολογίας και για την αντιμετώπισησει τυχόν προβλημάτων.

Εθελοντική φύση της συμμετοχής
Η συμμετοχή σε αυτή τη μελέτη είναι εθελοντική. Μπορείτε να αποχωρήσετε από τη μελέτη ανά πάσα στιγμή χωρίς να αναφέρετε κανένα λόγο και χωρίς να υπάρχουν αρνητικές συνέπειες. Εάν αποσυρθείτε από τη μελέτη ή αποσύρετε τη συγκατάθεσή σας, όλα τα προσωπικά σας δεδομένα που συλλέγονται για τους σκοπούς της έρευνας θα διαγραφούν. Εναλλακτικά, μπορείτε να επιτρέψετε τα προσωπικά δεδομένα που συλλέχθηκαν πριν από την απόσυρση να συμπεριληφθούν στην έρευνα.

Σκοπός και στόχοι της μελέτης
Ο κύριος στόχος αυτού του πιλοτικού είναι να διερευνήσει πώς οι συμμετέχοντες χρησιμοποιούν την τεχνολογία SHAPES.

Επιπρόσθετοι στόχοι του πιλότικού προγράμματος είναι:

- Να βοηθήσουν τους ανθρώπους να αυτοπαρακολουθούν την κατάσταση της υγείας τους. Ζωτικά σημεία και φάρμακα θα χρησιμοποιηθούν για την προώθηση της ασφαλέστερης και αποτελεσματικότερης χρήσης των φαρμάκων στο σπίτι.
- Την εξέταση και τη βελτίωση της χρήσης των φαρμάκων.
- Βελτίωση των αποτελεσμάτων των ασθενών και ανάπτυξη βέλτιστων πρακτικών.

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- Να αξιολογήσει εάν η χρήση της τεχνολογίας SHAPES σχετίζεται με μια αλλαγή στην απρογραμμάτιστη υγειονομική περίθαλψη.
- Να βελτιώσει την ποιότητα ζωής των συμμετεχόντων.
- Να διερευνήσει την εμπιστοσύνη και την αποδοχή της τεχνολογίας SHAPES
- Για να προσδιοριστεί εάν η χρήση της τεχνολογίας SHAPES μπορεί να επεκτείνει την ανεξάρτητη διαβίωση

Ποιος οργανώνει και χρηματοδοτεί την έρευνα:
Το έργο SHAPES συγκεντρώνει κορυφαίες ερευνητικές ομάδες, εταιρείες και ειδικούς από όλη την Ευρώπη. Η κοινοπραξία του έργου SHAPES αποτελείται από 36 εταίρους από 14 Ευρωπαϊκές χώρες. Το Ερευνητικό Ίδρυμα Πανεπιστημίου Λευκωσίας αναπαραγάγει αυτό το πιλοτικό πρόγραμμα στη Κύπρο. Το North Health and Social Care Trust είναι ο επικεφαλής οργανισμός που είναι υπεύθυνος για αυτό το πιλοτικό στη Βόρεια Ιρλανδία. Παρόμοια πιλοτικά προγράμματα πραγματοποιούνται σε όλη την Ευρώπη. Αυτό το έργο έχει λάβει χρηματοδότηση από το πρόγραμμα έρευνας και καινοτομίας Horizon 2020 της Ευρωπαϊκής Ένωσης στο πλαίσιο της συμφωνίας επιχορήγησης Αρ. 857159.

Τι θα περιλαμβάνει η συμμετοχή:
Θα τεθούν ορισμένες ερωτήσεις στους πιθανούς συμμετέχοντες για βεβαίωση ότι μπορούν να συμμετάσχουν και θα τους ζητηθεί να υποβάλουν γραπτή, συγκατάθεση για την συμμετοχή τους στο πιλοτικό πρόγραμμα.

Οι συμμετέχοντες θα κληθούν να κατεβάσουν την εφαρμογή SHAPES σε smartphone ή tablet.

Οι συμμετέχοντες θα λάβουν, συσκευές με σήμανση CE και με δυνατότητα συνδεσιμότητας με Bluetooth. Οι συσκευές θα είναι ένας μετρητής σακχάρου με τις αντίστοιχες ταινίες και ένας μετρητή αρτηριακής πίεσης που περιλαμβάνει και καρδιακό παλμογράφο.

Πριν από την έναρξη του πιλοτικού προγράμματος, οι συμμετέχοντες θα λάβουν εκπαίδευση από τα μέλη του προσωπικού του Ερευνητικού Ιδρύματος Πανεπιστημίου Λευκωσίας που αναφέρονται παραπάνω και θα τους δοθεί λίγος χρόνος για να εξοικειωθούν με την τεχνολογία. Θα κληθούν επίσης να απαντήσουν σε ορισμένα ερωτηματολόγια και να παράσχουν κάποιες βασικές πληροφορίες. Αυτές οι πληροφορίες θα περιλαμβάνουν τα στοιχεία επικοινωνίας σας, τα στοιχεία ιατροφαρμακευτικής περίθαλψης, την ηλικία σας, την οικογενειακή σας κατάσταση, την επαγγελματική σας κατάσταση, την εκπαίδευση σας, την υποστήριξη που χρειάζεστε για καθημερινή διαβίωση, το ιατρικό σας ιστορικό, τα εργαστηριακά σας αποτελέσματα και πληροφορίες σχετικά με την χρήση πόρων υγειονομικής περίθαλψης για 3 μήνες πριν από το πιλοτικό και κατά τη διάρκεια του πιλοτικού. Ορισμένες από αυτές τις πληροφορίες ενδέχεται να συλλεχθούν με τη συγκατάθεσή σας από το ιατρικό σας ιστορικό. Τα ερωτηματολόγια θα καλύπτουν την ποιότητα ζωής, την αυτόαποτελεσματικότητα, την κοινωνική υποστήριξη, τον αλφαβητισμό για την υγεία, τις δραστηριότητες της καθημερινής ζωής, τη χρήση φαρμάκων και τις πεποιθήσεις για την ιατρική.

Κατά τη διάρκεια των 12 εβδομάδων του πιλοτικού προγράμματος οι συμμετέχοντες θα ενθαρρύνονται να χρησιμοποιούν τις συσκευές για να λαμβάνουν καθημερινές μετρήσεις της αρτηριακής τους πίεσης και μετρήσεις της γλυκόζης στο αίμα τους σύμφωνα με το υπάρχον πρόγραμμα φροντίδας του διαβήτη. Αυτές οι μετρήσεις θα μεταφέρονται ηλεκτρονικά στην εφαρμογή SHAPES μέσω του Bluetooth. Οι συμμετέχοντες θα μπορούν να δουν τα δεδομένα τους μέσω της εφαρμογής και θα έχουν τη δυνατότητα να εισάγουν μετρήσεις με μη αυτόματο τρόπο, εάν απαιτείται. Οι συμμετέχοντες θα ενθαρρύνονται επίσης να συμπληρώνουν μια καθημερινή έρευνα

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που θα περιέχει ερωτήσεις σχετικά με την κατάσταση της υγείας τους και μια εβδομαδιαία έρευνα σχετικά με τη χρήση φαρμάκων. Η φαρμακευτική αγωγή του κάθε συμμετέχοντα θα ανεβαίνει στην εφαρμογή από τους ερευνητές και θα είναι διαθέσιμη για προβολή τόσο ως ολοκληρωμένη λίστα όλων των φαρμάκων όσο και ως ημερήσια λίστα, για να χρησιμεύσει επίσης ως υπενθύμιση για το τι πρέπει να ληφθεί εκείνη την ημέρα. Οι συμμετέχοντες θα ερωτώνται μέσω της εφαρμογής σε εβδομαδιαία βάση εάν έχουν γίνει αλλαγές στη θεραπεία τους εκείνη την εβδομάδα, ώστε το θεραπευτικό τους σχήμα να μπορεί να ενημερωθεί ανάλογα. Εάν οι συμμετέχοντες υποδείξουν ότι υπήρξε αλλαγή στη φαρμακευτική αγωγή τους, ένας ερευνητής θα τους καλέσει για να επιβεβαιώσει τις λεπτομέρειες και να ενημερώσει τις πληροφορίες στην εφαρμογή.

Οι ερευνητές θα επικοινωνήσουν τηλεφωνικά με τους συμμετέχοντες στο τέλος της 1ης εβδομάδας, εάν υπάρχουν 3 συνεχόμενες ημέρες που δεν έχουν ληφθεί δεδομένα και μηνιαία (εάν είναι απαραίτητο) για να υποστηρίξουν τους συμμετέχοντες στη χρήση της τεχνολογίας και να αντιμετωπίσουν τυχόν προβλήματα. Κατά τη διάρκεια του πιλοτικού προγράμματος, τα δεδομένα σας θα χρησιμοποιηθούν για να βοηθήσουν στην ανάπτυξη τεχνολογίας που στοχεύει στην πρόβλεψη εξατομικευμένων φυσιολογικών ορίων για την αρτηριακή πίεση, τη γλυκόζη του αίματος. και καρδιακός παλμούς. Κατά τη διάρκεια του πιλότου η πραγματική χρήση της εφαρμογής SHAPES θα παρακολουθείται για να ελεγχθεί η χρηστικότητά της και να ελεγχθεί εάν απαιτείται περαιτέρω υποστήριξη. Οι Υπηρεσίες Google θα χρησιμοποιηθούν κατά τη λήψη (Google Play) και τη χρήση (Google Analytics) της εφαρμογής SHAPES. Οι Υπηρεσίες Google ενδέχεται να χρησιμοποιούν λογισμικό γεωγραφικού εντοπισμού.

Μετά την πιλοτική περίοδο των 12 εβδομάδων, οι ερευνητές θα διαχειριστούν έναν αριθμό ερωτηματολογίων και θα συγκεντρώσουν κάποια τελικά δεδομένα. Τα τελικά δεδομένα θα είναι παρόμοια με αυτά που τέθηκαν κατά την έναρξη και θα περιλαμβάνουν ερωτήσεις σχετικά με την οικογενειακή κατάσταση, την επαγγελματική κατάσταση και την υποστήριξη που λαμβάνεται για την καθημερινή διαβίωση. Τα ερωτηματολόγια που θα διανεμηθούν σε αυτό το στάδιο θα εστιάζονται περισσότερο στη γνώμη σας για την τεχνολογία και ορισμένα από τα ερωτηματολόγια που σας δόθηκαν προηγουμένως θα σας ξαναδοθούν.

Τρεις μήνες μετά τη συμπλήρωση του πιλοτικού προγράμματος, οι συμμετέχοντες θα κληθούν να συμπληρώσουν ένα μικρό αριθμό ερωτηματολογίων παρακολούθησης, αυτά θα είναι ερωτηματολόγια που είχαν χορηγηθεί και προηγουμένως.

Τα δεδομένα των συμμετεχόντων και τα αποτελέσματα από τις αναλύσεις θα μεταφορτωθούν στον πίνακα ελέγχου των ερευνητών. Οι ερευνητές θα μπορούν να βλέπουν τα κλινικά δεδομένα και τα δεδομένα της έρευνας κάθε συμμετέχοντα και να διαχειρίζονται τα θεραπευτικά σχήματα των συμμετεχόντων όπως απαιτείται. Οι ερευνητές θα μπορούν να βλέπουν τα διαθέσιμα δεδομένα και τις αντίστοιχες πληροφορίες μόνο για σκοπούς παρακολούθησης της χρήσης της τεχνολογίας και εισαγωγής αλλαγών στην φαρμακευτική αγωγή. **Δεν θα υπάρξει κλινική ανασκόπηση των παρεχόμενων πληροφοριών**.

Εάν ο συμμετέχων έχει συναινέσει σε μια συνέντευξη, οι ερευνητές θα έρθουν σε επαφή για να το συζητήσουν και να το κανονίσουν. Η συνέντευξη θα διαρκέσει περίπου 1 ώρα και θα ηχογραφηθεί. Εάν η συνέντευξη γίνει πρόσωπο με πρόσωπο θα ηχογραφηθεί, εάν η συνέντευξη γίνει εξ αποστάσεως θα διεξαχθεί σε λογισμικό τηλεδιάσκεψης π.χ. Zoom και θα εγγραφεί οπτικοακουστικά. Η συνέντευξη θα απομαγνητοφωνηθεί και θα ελεγχθεί. Μόλις εγκριθεί η μεταγραφή, οι ηχογραφήσεις θα διαγραφούν.

Οι πληροφορίες που θα συλλέγονται σχετικά με εσάς θα αποθηκευτούν με ασφάλεια και

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εμπιστευτικότητα. Μόνο τα άτομα που επικοινωνούν μαζί σας για να σας προσκαλέσουν να συμμετάσχετε σε αυτό το πιλοτικό πρόγραμμα και η ερευνητική ομάδα στο Ερευνητικό Ίδρυμα Πανεπιστημίου Λευκωσίας θα μπορούν να σας αναγνωρίσουν. Όλοι οι υπόλοιποι συνεργάτες του SHAPES θα λάβουν έναν κωδικό και δεν θα μπορούν να σας αναγνωρίσουν χρησιμοποιώντας αυτόν τον κωδικό. Οι αναγνωρίσιμες πληροφορίες θα αποθηκευτούν μέχρι το τέλος Οκτωβρίου 2023 μετά από αυτό το σημείο, οι πληροφορίες θα γίνουν μη αναγνωρίσιμες και θα αποθηκευτούν για άλλα 5 χρόνια στο Ερευνητικό Ίδρυμα Πανεπιστημίου Λευκωσίας. Ένα σύνολο δεδομένων χωρίς ταυτοποίηση μπορεί να κοινοποιηθεί σε άλλα μέλη της κοινοπραξίας SHAPES, εάν υπάρχει κατάλληλη συμφωνία κοινής χρήσης δεδομένων. Ένα ανώνυμο, συγκεντρωτικό σύνολο δεδομένων θα αποθηκευτεί επ' αόριστον για μελλοντική χρήση από ερευνητές.

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Περίληψη μελέτης

Πρόσκληση

Τα άτομα που προσδιορίζονται ως κατάλληλα για τη μελέτη καλούνται να λάβουν μέρος. Παρέχονται πληροφορίες σχετικά με τη μελέτη και τίθενται σχετικές ερωτήσεις.

Συγκατάθεση

Τα άτομα που συμφωνούν να λάβουν μέρος στη μελέτη καλούνται να διαβάσουν και να υπογράψουν ένα έντυπο συγκατάθεσης για να επιβεβαιώσουν ότι είναι πρόθυμοι να συμμετάσχουν. Γίνονται συμμετέχοντες.

Εκπαίδευση και πρακτική εφαρμογή των συσκευών και της εφαρμογής

Παρουσιάζεται στους συμμετέχοντες πώς να κατεβάζουν και να χρησιμοποιούν την εφαρμογή SHAPES και τις συσκευές παρακολούθησης. Τους δίνεται λίγος χρόνος για να εξασκηθούν στη χρήση τους στο σπίτι πριν ξεκινήσει η μελέτη. Οι ερευνητές του Ερευνητικού Ιδρύματος Πανεπιστημίου Λευκωσίας θα είναι διαθέσιμοι για να βοηθήσουν σε οποιοδήποτε θέμα προκύψει.

Συλλέχθηκαν βασικές πληροφορίες

Οι ερευνητές συλλέγουν πληροφορίες για τους συμμετέχοντες και την υγεία τους πριν ξεκινήσουν το πιλοτικό πρόγραμμα. Οι πληροφορίες συλλέγονται χρησιμοποιώντας ερωτηματολόγια και ανασκόπηση των σχετικών ενοτήτων των ιατρικών αρχείων των συμμετεχόντων.

Χρήση εφαρμογής και συσκευών στο σπίτι

Οι συμμετέχοντες καλούνται να χρησιμοποιήσουν την εφαρμογή και τις συσκευές για την παρακολούθηση του διαβήτη στο σπίτι για **τρεις μήνες.** Οι ερευνητές θα επικοινωνήσουν με τους συμμετέχοντες μετά από μερικές εβδομάδες για να δουν εάν χρειάζονται οποιανδήποτε βοήθεια, εάν λείπουν στοιχεία για περισσότερες από 3 ημέρες, εάν οι συμμετέχοντες τους ειδοποιήσουν για μια αλλαγή στην φαρμακευτική τους αγωγή και, στη συνέχεια, κάθε μήνα εάν απαιτείται.

Συλλέχθηκαν οι τελικές πληροφορίες του πιλοτικού προγράμματος

Στο τέλος του πιλοτικού προγράμματος οι ερευνητές θα συλλέξουν πληροφορίες σχετικά με τους συμμετέχοντες και την υγεία τους για να ελέγξουν αν κάτι έχει αλλάξει. Οι πληροφορίες θα συλλέγούν χρησιμοποιώντας ερωτηματολόγια και από ανασκόπηση των σχετικών ενοτήτων των ιατρικών αρχείων των συμμετεχόντων.

Επακόλουθη συνέντευξη

Μετά το πιλοτικό πρόγραμμα, οι ερευνητές θα πάρουν συνέντευξη από ορισμένους συμμετέχοντες για να ακούσουν περισσότερα για την εμπειρία τους κατά τη διάρκεια του πιλοτικού. Αυτό θα πραγματοποιηθεί στο τέλος της πιλοτικής επίσκεψης με τον ερευνητή ή εντός λίγων εβδομάδων από τη λήξη της.

Επακόλουθα ερωτηματολόγια

Τρεις μήνες μετά το τέλος του πιλοτικού προγράμματος, οι ερευνητές θα συλλέξουν περισσότερες πληροφορίες χρησιμοποιώντας ερωτηματολόγια. Μετά από αυτό η μελέτη θα ολοκληρωθεί.

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Πιθανά οφέλη από τη συμμετοχή
Ελπίζεται ότι οι συμμετέχοντες μέσα από το πιλοτικό πρόγραμμα μπορεί να αυξήσουν την ικανότητά τους να αυτοδιαχειρίζονται αποτελεσματικά τις συνθήκες διαβίωσής τους.

Στο μέλλον, αυτή η τεχνολογία μπορεί να χρησιμοποιηθεί σε ολόκληρη την Ευρώπη για να βοηθήσει τα άτομα μεγαλύτερης ηλικίας να διαχειρίζονται την υγείας τους και γενικότερα τις παθήσεις τους.

Στο μέλλον, μπορεί επίσης να διευκολύνει την εξ αποστάσεως παρακολούθηση των ανθρώπων από επαγγελματίες υγείας και να χρησιμοποιεί αλγόριθμους τεχνητής νοημοσύνης για να προβλέψει την επιδείνωση της κατάστασης της υγείας ενός ατόμου. Ωστόσο, αυτή η λειτουργικότητα δεν θα διερευνηθεί στην παρούσα μελέτη.

Πιθανά μειονεκτήματα και κίνδυνοι από τη συμμετοχή

Δεν υπάρχει κλινική εποπτεία των πληροφοριών που καταγράφονται σε αυτό το πιλοτικό πρόγραμμα. Δεν υπάρχει ιατρικό προσωπικό που να εξετάζει τα δεδομένα που λαμβάνονται από τις κλινικές συσκευές. Εάν ανησυχείτε για την υγεία σας, είναι σημαντικό να αναζητήσετε φροντίδα από τους συνήθεις παρόχους ιατροφαρμακευτικής περίθαλψης.

Συμπτωματικά ευρήματα
Αν και είναι πολύ απίθανο, οι συμμετέχοντες μπορεί να ανακαλύψουν μια υποκείμενη ιατρική κατάσταση από την παρακολούθηση που θα πραγματοποιούν. Οποιεσδήποτε ανησυχίες σχετικά με την υγεία θα πρέπει να παρακολουθούνται ανεξάρτητα από έναν επαγγελματία υγείας.

Οικονομικές πληροφορίες
Δεν θα επιβαρυνθείται με κανένα κόστος από την συμμετοχή σας σε αυτή τη μελέτη. Δεν θα έχετε κανένα χρηματικό όφελος από την συμμετοχή σας σε αυτή την μελέτη. Αυτό το έργο έχει λάβει χρηματοδότηση από το πρόγραμμα έρευνας και καινοτομίας Horizon 2020 της Ευρωπαϊκής Ένωσης στο πλαίσιο της συμφωνίας επιχορήγησης Αρ. 857159.

Πολιτική ασφαλείας
Η ασφάλιση και η αποζημίωση για τους συμμετέχοντες στο πιλοτικό πρόγραμμα ισχύουν μέσω του Ερευνητικού Ιδρύματος Πανεπιστημίου Λευκωσίας.

Ενημέρωση για τα πιλοτικά αποτελέσματα
Μια γραπτή περίληψη των αποτελεσμάτων θα είναι διαθέσιμη σε όλους τους συμμετέχοντες μόλις ολοκληρωθούν οι αναλύσεις των δεδομένων. Τα αποτελέσματα, συμπεριλαμβανομένων των άμεσων προσφορών, μπορούν επίσης να δημοσιευθούν σε έκθεση προς τον φορέα χρηματοδότησης, επιστημονικά περιοδικά, δημοσιεύσεις και συνέδρια. Κανένας συμμετέχων δεν θα μπορεί να προσδιοριστεί από αυτές τις αναφορές.

Τερματισμός της μελέτης
Οι ερευνητές που διεξάγουν τη μελέτη μπορούν να τερματίσουν τη μελέτη νωρίτερα από το προγραμματισμένο για οποιονδήποτε λόγο για να προστατεύσουν την ασφάλεια των συμμετεχόντων ή την ασφάλεια των δεδομένων των συμμετεχόντων. Στο τέλος του πιλότικου προγράμματος 12 εβδομάδων, οι κλινικές συσκευές (μετρητής σακχάρου και πιεσόμετρο) θα επιστραφούν και η πρόσβαση στην εφαρμογή SHAPES θα τερματιστεί.

Περαιτέρω πληροφορίες
Περαιτέρω πληροφορίες σχετικά με τη μελέτη μπορούν να ζητηθούν από τον ερευνητή/υπεύθυνο της μελέτης σύμφωνα με τις παρακάτω λεπτομέρειες.

Αυτό το έργο έχει λάβει χρηματοδότηση από το πρόγραμμα έρευνας και καινοτομίας Horizon 2020 της Ευρωπαϊκής Ένωσης στο πλαίσιο της συμφωνίας επιχορήγησης Αρ. 857159.

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Στοιχεία επικοινωνίας των ερευνητών/υπευθύνων

Ερευνητική ομάδα
Επικεφαλής ερευνητής:
Κωνσταντίνος Μαυρομουστάκης, mavromoustakis.c@unic.ac.cy
Ερευνητές του SHAPES:
Αντρέας Αντρέου, andreou.andreas@unic.ac.cy
Κώστας Κωνσταντίνου, constantinou.c@unic.ac.cy

Telephone: +357 96536499

Υπεύθυνος Προστασίας Δεδομένων
Αντρέας Αντρέου
Email: andreou.andreas@unic.ac.cy

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Annex 27 UC-PT3-gen (UNRF) Phase 5 Privacy notice

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Σημείωση απορρήτου/Πολιτική για τα δεδομένα της έρευνας του SHAPES

Στο πλαίσιο του έργου SHAPES, τα προσωπικά σας δεδομένα θα υποβληθούν σε επεξεργασία σύμφωνα με τον Γενικό Κανονισμό Προστασίας Δεδομένων της Ευρωπαϊκής Ένωσης και του περί βιοηθικής νόμου της Εθνικής Επιτροπής Βιοηθικής Κύπρου. Η επεξεργασία των προσωπικών δεδομένων περιγράφεται ως ακολούθως.

Υπεύθυνος επεξεργασίας δεδομένων του έργου SHAPES

Ο υπεύθυνος επεξεργασίας δεδομένων για αυτό το πιλοτικό θα είναι το Ερευνητικό Ίδρυμα Πανεπιστημίου Λευκωσίας
Διεύθυνση: Μακεδονίτισσας 46, Ταχυδρομική Θυρίδα 24005 1700 Λευκωσία, Κύπρος

Υπεύθυνος επικοινωνίας για θέματα που σχετίζονται με την επεξεργασία προσωπικών δεδομένων
Υπεύθυνος Προστασίας Δεδομένων: Αντρέας Αντρέου
Email: andreou.andreas@unic.ac.cy

Τύποι προσωπικών δεδομένων που θα συλλεχθούν σε αυτή τη μελέτη
Άμεσα αναγνωρίσιμες πληροφορίες, όπως ημερομηνία γέννησης, όνομα, στοιχεία ιατροφαρμακευτικής περίθαλψης, διεύθυνση, ηχητική ή/και οπτική εγγραφή της συνέντευξης (προαιρετικό), αριθμός τηλεφώνου, αναγνώριση προσώπου για είσοδο στην εφαρμογή SHAPES και στοιχεία επικοινωνίας εναλλακτικής επαφής.
Όλες οι άλλες πληροφορίες που συλλέγονται θα είναι κωδικοποιημένες και θα περιλαμβάνουν:

- Κωδικό/κωδικοποιημένο όνομα χρήστη για πρόσβαση στην εφαρμογή SHAPES
- Δημογραφικά δεδομένα; εκπαίδευση, οικογενειακή κατάσταση, επαγγελματική κατάσταση, φύλο, κατάσταση παροχής ιατροφαρμακευτικής φροντίδας, κατάσταση λήψης ιατροφαρμακευτικής φροντίδας, πληροφορίες κατοικίας
- Ιατρικό ιστορικό, ύψος, λεπτομέρειες κατάστασης διαβήτη, άλλη υπάρχουσα κλινική κατάσταση
- Δεδομένα συσκευής, τύπους παρεχόμενων συσκευών και σειριακούς αριθμούς, μάρκα και μοντέλο προσωπικής συσκευής smartphone/tablet. Καθημερινά δεδομένα συμπεριλαμβανομένων των καρδιακών παλμών, της αρτηριακής πίεσης, του βάρους και της γλυκόζης του αίματος
- Εφαρμογή SHAPES, προτιμήσεις χρόνου επικοινωνίας, λεπτομέρειες χρήσης της εφαρμογής π.χ. αριθμός και διάρκεια πρόσβασης
- Εργαστηριακά αποτελέσματα; εργαστηριακές εξετάσεις που σχετίζονται με τον διαβήτη
- Ερωτηματολόγια; που καλύπτουν μια ποικιλία διαφορετικών πτυχών, όπως ποιότητα ζωής, αυτοαποτελεσματικότητα, κοινωνική υποστήριξη, συμμετοχή, αλφαβητισμός στην υγεία, χρηστικότητα τεχνολογίας, αποδοχή τεχνολογίας, καθημερινές δραστηριότητες, αυτοφροντίδα, χρήση φαρμάκων, πεποιθήσεις για φάρμακα, εμπειρία χρήστη
- Χρήση πόρων υγειονομικής περίθαλψης, χρήση φροντίδας που δεν είχε προγραμματιστει για 3 μήνες πριν από τον πιλότο και 3 μήνες κατά τη διάρκεια του πιλότου
- Δεδομένα φαρμακευτικής αγωγής, κατάλογο όλων των συνταγογραφούμενων φαρμάκων και τυχόν αλλαγές κατά τη διάρκεια του πιλότου
- Καταγραφή ασφαλείας, λεπτομέρειες για τυχόν περιστατικά που συνέβησαν κατά τη διάρκεια του πιλότου
- Βιομετρικά δεδομένα, αναγνώριση προσώπου για είσοδο στην εφαρμογή SHAPES
- Δεδομένα συνέντευξης. κωδικοποιημένα αντίγραφα της προαιρετικής συνέντευξης
- Οι υπηρεσίες Google, το Google Play θα χρησιμοποιηθεί για τη λήψη της εφαρμογής SHAPES και

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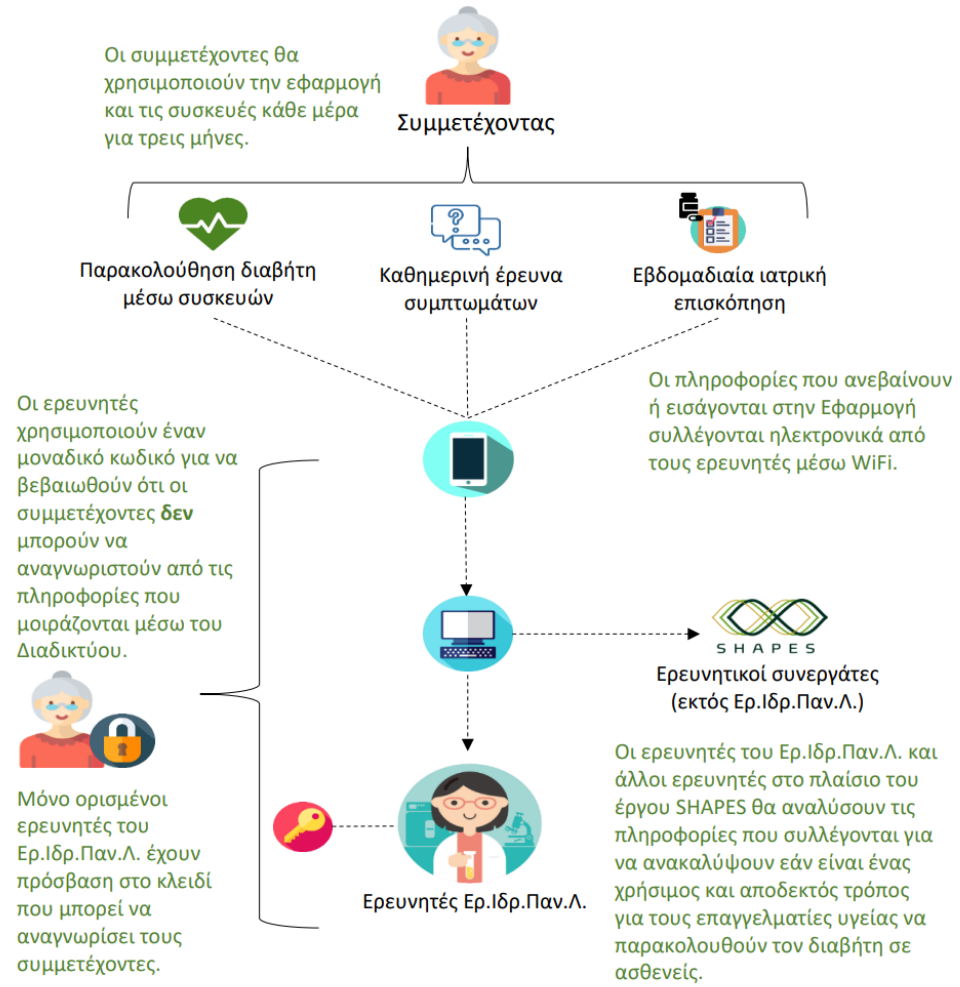
το Google Analytics θα χρησιμοποιηθεί για την παρακολούθηση της χρήσης της εφαρμογής από τους συμμετέχοντες

Τα προσωπικά δεδομένα θα συλλέγονται από τους συμμετέχοντες, τις ιατρικές τους σημειώσεις και τις συσκευές τους που είναι συνδεδεμένες στην εφαρμογή SHAPES

Διάγραμμα ροής δεδομένων συμμετεχόντων



Αρχές προστασίας προσωπικών δεδομένων

Τα δεδομένα που πρόκειται να υποβληθούν σε επεξεργασία στα πληροφοριακά συστήματα

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προστατεύτηκαν χρησιμοποιώντας τα ακόλουθα:
ταυτότητα χρήστη ✓ κωδικός πρόσβασης ✓ εγγραφή χρήστη ✓ έλεγχος πρόσβασης (φυσική τοποθεσία) ✓
Εάν υπάρχουν άλλες μέθοδοι, παρακαλώ διευκρινίστε:
Τα δεδομένα που θα συλλέγονται από τον συμμετέχοντα και τα ιατρικά του αρχεία θα συλλέγονται χρησιμοποιώντας ένα έντυπο αναφοράς περιστατικού σε χαρτί, το έντυπο αναφοράς θα αποθηκεύεται σε ένα κλειδωμένο γραφείο στο Ερευνητικό Ίδρυμα Πανεπιστημίου Λευκωσίας. Όλες οι άμεσα αναγνωρίσιμες πληροφορίες θα αποθηκευτούν σε ένα κλειδωμένο γραφείο του Ερευνητικού Ιδρύματος Πανεπιστημίου Λευκωσίας και σε μια βάση δεδομένων πίσω από το τείχος προστασίας του Ερευνητικού Ιδρύματος Πανεπιστημίου Λευκωσίας, η οποία θα είναι προσβάσιμη μόνο από εγκεκριμένα μέλη της ερευνητικής ομάδας από το Ερευνητικό Ίδρυμα Πανεπιστημίου Λευκωσίας. Οι κωδικοποιημένες πληροφορίες θα κοινοποιηθούν σε συγκεκριμένους συνεργάτες της SHAPES και θα αποθηκευτούν με ασφάλεια στους διακομιστές τους και στην πλατφόρμα SHAPES με κατάλληλους ελέγχους πρόσβασης δεδομένων. Κάθε συνεργάτης που έχει πρόσβαση σε κωδικοποιημένα δεδομένα θα έχει μια Συμφωνία Επεξεργασίας Δεδομένων και θα συμμορφώνεται με τη σχετική νομοθεσία για την προστασία δεδομένων.

Οι συμμετέχοντες θα έχουν πρόσβαση στην εφαρμογή SHAPES χρησιμοποιώντας ένα όνομα χρήστη που τους παρέχεται και το οποίο περιέχει τον μοναδικό τους κωδικό. Επιπλέον, η τεχνολογία αναγνώρισης προσώπου θα χρησιμοποιηθεί για τον έλεγχο ταυτότητας του χρήστη.

Τα δεδομένα που συλλέγονται από τις συσκευές που θα μεταφέρονται μέσω Bluetooth στην εφαρμογή SHAPES όπου θα αποθηκεύονται ώστε ο συμμετέχων να βλέπει τα δεδομένα του. Αυτά τα δεδομένα και οι απαντήσεις σε ερωτήσεις στην εφαρμογή SHAPES θα μεταφέρονται με ασφάλεια μέσω Wi-Fi στους διακομιστές των συνεργατών μας και θα κρυπτογραφούνται κατά τη μεταφορά στην πλατφόρμα SHAPES.

Για ποιο σκοπό θα υποβάλλονται σε επεξεργασία τα προσωπικά δεδομένα;
Ο κύριος στόχος αυτού του πιλοτικού είναι να διερευνήσει πώς οι συμμετέχοντες χρησιμοποιούν την τεχνολογία SHAPES.

Οι πρόσθετοι στόχοι του πιλότου περιλαμβάνουν:

- Ενίσχυση της αυτοπαρακολούθησης της κατάσταση της υγείας των ανθρώπων, ως προς τα ζωτικά σημεία και τα φάρμακα που χρησιμοποιούνται για την προώθηση της ασφαλέστερης και αποτελεσματικότερης χρήσης των φαρμάκων στο σπίτι
- Την εξέταση και τη βελτίωση των φαρμάκων που χρησιμοποιούνται για τη βελτίωση των αποτελεσμάτων των ασθενών και την ανάπτυξη βέλτιστων πρακτικών
- Να αναπτυχθεί τεχνολογία για την πρόβλεψη της επεισοδιακής επιδείνωσης της καρδιακής ανεπάρκειας και την αξιολόγηση της συλλογής δεδομένων που απαιτείται
- Να αξιολογήσει εάν η χρήση της τεχνολογίας SHAPES σχετίζεται με μια αλλαγή στην απρογραμμάτιστη υγειονομική περίθαλψη
- Τη βελτίωση της ποιότητας ζωής των συμμετεχόντων
- Να διερευνήσει την εμπιστοσύνη και την αποδοχή της τεχνολογίας SHAPES
- Για να προσδιοριστεί εάν η χρήση της τεχνολογίας SHAPES μπορεί να επεκτείνει την ανεξάρτητη διαβίωση

Νομική βάση επεξεργασίας προσωπικών δεδομένων
Η νομική βάση για την επεξεργασία δεδομένων είναι η συγκατάθεση.

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Έχετε το δικαίωμα να ανακαλέσετε τη συγκατάθεσή σας ανά πάσα στιγμή όπως περιγράφεται στην παρούσα ειδοποίηση.

Φύση και διάρκεια της μελέτης που ολοκληρώθηκε στο πλαίσιο του έργου SHAPES (για πόσο χρονικό διάστημα θα υποβάλλονται σε επεξεργασία τα προσωπικά δεδομένα):

✓ Έρευνα για μια φορά ✗ Έρευνα που μπορεί να επαναληφθεί

Διάρκεια της έρευνας:
Οι αναγνωριστικές πληροφορίες πρέπει να αποθηκευτούν μέχρι το τέλος της Δράσης Καινοτομίας SHAPES (Οκτώβριος 2023). Στη συνέχεια, η λίστα συμμετεχόντων που συνδέει τον κωδικό με το άτομο θα καταστραφεί και τα άμεσα αναγνωρίσιμα δεδομένα θα διαγραφούν. Τα υπόλοιπα δεδομένα που δεν έχουν ταυτοποιηθεί μπορεί να αποθηκευτούν για επιπλέον 5 χρόνια (εντός του Ερευνητικού Ιδρύματος Πανεπιστημίου Λευκωσίας) για περαιτέρω αναλύσεις και δημοσιεύσεις. Ένα σύνολο δεδομένων χωρίς ταυτοποίηση μπορεί να κοινοποιηθεί με άλλα μέλη της κοινοπραξίας SHAPES, εάν υπάρχει κατάλληλη συμφωνία κοινής χρήσης δεδομένων. Ένα ανώνυμο, συγκεντρωτικό σύνολο δεδομένων θα αποθηκευτεί επ' αόριστον για μελλοντική χρήση από ερευνητές.

Τι συμβαίνει με τα προσωπικά δεδομένα μετά την ολοκλήρωση της μελέτης στο πλαίσιο του έργου SHAPES;
Μετά την ολοκλήρωση του πιλότου, τα προσωπικά δεδομένα θα αναλυθούν και τα αποτελέσματα θα αναφερθούν στον χρηματοδότη, σε επιστημονικές δημοσιεύσεις και συνέδρια, ωστόσο, αυτά θα είναι ομαδοποιημένα δεδομένα και δεν θα είναι προσωπικά αναγνωρίσιμα.
Άμεσα αναγνωρίσιμες πληροφορίες π.χ. όνομα, τηλέφωνο, αριθμός, διεύθυνση, ημερομηνία γέννησης και ο σύνδεσμος με τον μοναδικό κωδικό των συμμετεχόντων θα καταστραφούν τον Οκτώβριο του 2023. Τα δεδομένα που δεν έχουν ταυτοποιηθεί θα διατηρηθούν για επιπλέον 5 χρόνια, στο Ερευνητικό 'Ιδρυμα Πανεπιστημίου Λευκωσίας, για να επιτραπούν περαιτέρω αναλύσεις και δημοσιεύσεις. Τα διατηρούμενα δεδομένα θα αρχειοθετηθούν από το Ερευνητικό 'Ιδρυμα Πανεπιστημίου Λευκωσίας.

Μεταφορά δεδομένων εκτός του ερευνητικού μητρώου:
Ένα μικρό ανώνυμο σύνολο δεδομένων που περιλαμβάνει: τη χρήση φαρμάκων και τις πεποιθήσεις σχετικά με τα φάρμακα απαντήσεις σε ερωτηματολόγιο· φύλο (αρσενικό|θηλυκό), ηλικία (έτη) διαγνωσμένες ασθένειες· χώρα θα κοινοποιηθεί στη Ιατρική Σχολή του Πανεπιστημίου Λευκωσίας για την περαιτέρω ανάπτυξη αυτών των ερωτηματολογίων.

Πιθανή μεταφορά δεδομένων προσωπικού χαρακτήρα εκτός ΕΕ ή ΕΟΧ:
Τα δεδομένα σας δεν θα μεταφερθούν εκτός της ΕΕ ή του ΕΟΧ, η μόνη εξαίρεση σε αυτό είναι οι μεταφορές από την/τον ΕΕ/ΕΟΧ προς/από το Ηνωμένο Βασίλειο με τη συγκατάθεσή σας.

Τα δικαιώματά σας ως υποκείμενο δεδομένων
Επειδή τα προσωπικά σας δεδομένα θα χρησιμοποιηθούν στη μελέτη που πραγματοποιείται στο πλαίσιο του έργου SHAPES, θα εγγραφείτε στο μητρώο μελέτης. Τα δικαιώματά σας ως υποκείμενο δεδομένων είναι τα ακόλουθα:

Δικαίωμα λήψης πληροφοριών σχετικά με την επεξεργασία δεδομένων προσωπικού χαρακτήρα
Δικαίωμα πρόσβασης
Δικαίωμα διόρθωσης

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Δικαίωμα στη διαγραφή (δικαίωμα στη λήθη)
Δικαίωμα ανάκλησης της συγκατάθεσης σχετικά με την επεξεργασία δεδομένων προσωπικού χαρακτήρα
Δικαίωμα στον περιορισμό της επεξεργασίας
Υποχρέωση ειδοποίησης σχετικά με τη διόρθωση ή διαγραφή προσωπικών δεδομένων ή περιορισμό επεξεργασίας
Δικαίωμα στη φορητότητα των δεδομένων
Το υποκείμενο των δεδομένων μπορεί να επιτρέψει την αυτόματη λήψη αποφάσεων με τη συγκεκριμένη συγκατάθεσή του
Δικαίωμα να ειδοποιήσετε τον Διαμεσολαβητή Προστασίας Δεδομένων εάν υποψιάζεστε ότι ένας οργανισμός ή άτομο επεξεργάζεται προσωπικά δεδομένα κατά παράβαση των κανονισμών προστασίας δεδομένων.

Εάν οι σκοποί για τους οποίους ο υπεύθυνος επεξεργασίας δεδομένων, επεξεργάζεται δεδομένα προσωπικού χαρακτήρα τα οποία δεν απαιτούν πλέον την ταυτοποίηση ενός υποκειμένου των δεδομένων από τον υπεύθυνο, ο υπεύθυνος δεν υποχρεούται να διατηρεί, να αποκτά ή να επεξεργάζεται πρόσθετες πληροφορίες προκειμένου να ταυτοποιήσει αποκλειστικά το υποκείμενο των δεδομένων με σκοπό την συμμόρφωσης με τον παρόντα κανονισμό. Εάν ο υπεύθυνος επεξεργασίας δεδομένων δεν μπορεί να προσδιορίσει το υποκείμενο των δεδομένων, τα δικαιώματα πρόσβασης, διόρθωσης, διαγραφής, υποχρέωσης κοινοποίησης και φορητότητας δεδομένων δεν ισχύουν, εκτός εάν το υποκείμενο των δεδομένων παρέχει πρόσθετες πληροφορίες που επιτρέπουν την ταυτοποίησή του.

Μπορείτε να ασκήσετε τα δικαιώματά σας επικοινωνώντας με τον υπεύθυνο επεξεργασίας δεδομένων της μελέτης.

Τα δεδομένα προσωπικού χαρακτήρα που συλλέγονται στο έργο SHAPES για έρευνα δεν θα χρησιμοποιηθούν για αυτοματοποιημένη λήψη αποφάσεων. Στις μελέτες του έργου SHAPES, η επεξεργασία δεδομένων προσωπικού χαρακτήρα δεν χρησιμοποιείται ποτέ σε αποφάσεις θεραπείας που αφορούν τους συμμετέχοντες στην έρευνα.

Ψευδωνυμοποίηση και ανωνυμοποίηση
Όλες οι πληροφορίες που συλλέγονται από εσάς θα αντιμετωπίζονται εμπιστευτικά και σύμφωνα με τη νομοθεσία. Σε μεμονωμένους συμμετέχοντες θα δοθεί ένας κωδικός και τα δεδομένα θα αποθηκευτούν σε κωδικοποιημένη μορφή στα αρχεία του έργου SHAPES. Τα αποτελέσματα θα αναλυθούν και θα παρουσιαστούν σε κωδικοποιημένη, συγκεντρωτική μορφή. Τα άτομα δεν μπορούν να αναγνωριστούν χωρίς το κλειδί του κωδικού. Το κλειδί του κωδικού, το οποίο μπορεί να χρησιμοποιηθεί για την αναγνώριση μεμονωμένων συμμετεχόντων στην έρευνα και τις απαντήσεις τους, θα αποθηκευτεί από την εξουσιοδοτημένη ερευνητική ομάδα στο Ερευνητικό 'Ιδρυμα Πανεπιστημίου Λευκωσίας. Τα κωδικοποιημένα δεδομένα δεν θα δοθούν σε άτομα εκτός της ομάδας μελέτης του έργου SHAPES. Τα τελικά αποτελέσματα της έρευνας θα αναφέρονται σε συγκεντρωτική μορφή και θα είναι αδύνατο να εντοπιστούν μεμονωμένοι συμμετέχοντες. Το μητρώο μελέτης έργου SHAPES θα αποθηκευτεί στην Ισπανία από την TREE Technology SA επ' αόριστον, αυτό θα περιέχει μόνο ανώνυμα, συγκεντρωτικά δεδομένα. Ένα μεγαλύτερο μη αναγνωρισμένο σύνολο δεδομένων θα αποθηκευτεί τοπικά στο Ερευνητικό 'Ιδρυμα Πανεπιστημίου Λευκωσίας μέχρι το 2028.

Αυτό το έργο έχει λάβει χρηματοδότηση από το πρόγραμμα έρευνας και καινοτομίας Horizon 2020 της Ευρωπαϊκής Ένωσης στο πλαίσιο της συμφωνίας επιχορήγησης Αρ. 857159.

Annex 28 UC-PT3-gen (UNRF) Phase 5 Participant consent form

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SHAPES

ΕΝΤΥΠΟ ΣΥΝΑΙΝΕΣΗΣ ΓΙΑ ΣΥΜΜΕΤΟΧΗ ΣΤΟ SHAPES

Τίτλος της μελέτης: Πιλοτικό του SHAPES: Υποστήριξη ηλικιωμένων με πολλαπλές παθήσεις
Τοποθεσία της μελέτης: Το πιλοτικό θα πραγματοποιηθεί με επαγγελματίες υγείας στο Κέντρο Ενηλίκων Στροβόλου και με συμμετέχοντες από την ευρήτερη κοινότητα της περιοχής Λευκωσίας. Μπορείτε να επικοινωνήσετε με την ερευνητική ομάδα SHAPES καλώντας στο +357 96536499 ή στέλνοντας email στους ερευνητές που αναφέρονται στο φύλλο πληροφοριών.

Έχω προσκληθεί να συμμετάσχω στην παραπάνω ερευνητική μελέτη. Σκοπός της έρευνας είναι να αξιολογήσει τη χρήση της τεχνολογίας που αναπτύχθηκε από την κοινοπραξία SHAPES για την υποστήριξη της χρήσης φαρμάκων σε ηλικιωμένους με πολλαπλές χρόνιες παθήσεις.

Έχω διαβάσει και κατανοήσει το φύλλο πληροφοριών συμμετεχόντων. Το φύλλο πληροφοριών μου παρείχε επαρκείς πληροφορίες σχετικά με την παραπάνω μελέτη, τον σκοπό και την εκτέλεσή της, για τα δικαιώματά μου, καθώς και για τα οφέλη και τους κινδύνους που εμπεριέχονται. Είχα την ευκαιρία να κάνω ερωτήσεις σχετικά με τη μελέτη και έλαβα ικανοποιητικές απαντήσεις.

Μου έχουν δοθεί επαρκείς πληροφορίες σχετικά με τη συλλογή, την επεξεργασία, τη μεταφορά/παράθεση και τη διαγραφή των προσωπικών μου δεδομένων κατά τη διάρκεια της μελέτης και η Δήλωση Απορρήτου ήταν διαθέσιμη ως μέρος του Φύλλου Πληροφοριών Συμμετεχόντων στο έργο SHAPES.

Με την υπογραφή αυτής της φόρμας, επιβεβαιώνω ότι συναινώ οικειοθελώς να συμμετάσχω σε αυτήν τη μελέτη και ότι επίσης συναινώ στην επεξεργασία των προσωπικών μου δεδομένων για τους σκοπούς που περιγράφονται σε αυτό το έγγραφο και στη δήλωση απορρήτου.

Δεν έχω πιεστεί ή παραπειστεί να συμμετάσχω και είχα αρκετό χρόνο να εξετάσω τη συμμετοχή μου στη μελέτη. Κατανοώ ότι η συμμετοχή μου είναι απολύτως εθελοντική και ότι είμαι ελεύθερος να αποσύρω τη συγκατάθεσή μου ανά πάσα στιγμή, χωρίς να αναφέρω κανέναν λόγο.

Έχω επίσης το δικαίωμα να ζητήσω την αφαίρεση των αναγνωρίσιμων προσωπικών μου δεδομένων σύμφωνα με τη νομοθεσία περί προστασίας δεδομένων. Γνωρίζω επίσης ότι εάν αποσυρθώ από τη μελέτη ή αποσύρω τη συγκατάθεσή μου, όλα τα προσωπικά μου δεδομένα που συλλέγονται για τους σκοπούς της έρευνας θα αφαιρεθούν. Εναλλακτικά, μπορώ να αποσύρω τη συγκατάθεσή μου για μελλοντική συλλογή δεδομένων και να επιτρέψω τα προσωπικά δεδομένα που συλλέχθηκαν πριν από την απόσυρσή μου να συμπεριληφθούν στην έρευνα.

- Συμφωνώ με την ερευνητική ομάδα του Ερευνητικού Ιδρύματος Πανεπιστημίου Λευκωσίας που επεξεργάζεται τα προσωπικά μου στοιχεία για τους σκοπούς αυτού του πιλοτικού.
- Συμφωνώ ότι η ερευνητική ομάδα του Ερευνητικού Ιδρύματος Πανεπιστημίου Λευκωσίας

Αυτό το έργο έχει λάβει χρηματοδότηση από το πρόγραμμα έρευνας και καινοτομίας Horizon 2020 της Ευρωπαϊκής Ένωσης στο πλαίσιο της συμφωνίας επιχορήγησης Αρ. 857159.

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μπορεί να συλλέγει προσωπικές πληροφορίες από τα ιατρικά μου αρχεία, συμπεριλαμβανομένου του ηλεκτρονικού μου αρχείου από το Γενικό Σύστημα Υγείας (ΓΕΣΥ).

- Συμφωνώ να χρησιμοποιήσω την παρεχόμενη τεχνολογία του SHAPES και να επιτρέψω στις κλινικές συσκευές να μοιράζονται τα δεδομένα που συλλέγονται με τους Συνεργάτες της κοινοπραξίας του SHAPES.
- Συμφωνώ με την ερευνητική ομάδα του Ερευνητικού Ιδρύματος Πανεπιστημίου Λευκωσίας που μοιράζεται κωδικοποιημένες προσωπικές πληροφορίες με τους συνεργάτες της κοινοπραξίας SHAPES.
- Συμφωνώ να κοινοποιώ κωδικοποιημένα προσωπικά δεδομένα εντός της ΕΕ, του ΕΟΧ και του Ηνωμένου Βασιλείου.
- Συμφωνώ να κοινοποιήσω δεδομένα στις Υπηρεσίες Google (Google Play και Google Analytics).
- Συμφωνώ να χρησιμοποιηθούν ανώνυμες πληροφορίες σε μελλοντική ηθικά εγκεκριμένη έρευνα.
- Συμφωνώ να κοινοποιηθεί ένα μικρό, ανώνυμο σύνολο δεδομένων με ερευνητές στο Πανεπιστήμιο Λευκωσίας για περαιτέρω βελτίωση της ανάπτυξης ερωτηματολογίων που σχετίζονται με τη χρήση φαρμάκων και τις πεποιθήσεις για τα φάρμακα.
- Εάν ισχύει, συμφωνώ ότι το Κέντρο Ενηλίκων Στροβόλου κοινοποιεί τα στοιχεία επικοινωνίας και τη φόρμα συγκατάθεσής μου με την ερευνητική ομάδα του Ερευνητικού Ιδρύματος Πανεπιστημίου Λευκωσίας.

Προαιρετικό:

- Συμφωνώ να συμμετάσχω σε μια συνέντευξη σχετικά με την εμπειρία μου από τη χρήση της τεχνολογίας SHAPES όταν τελειώσει το πιλοτικό πρόγραμμα των 12 εβδομάδων. Η συνέντευξη αυτή θα μαγνητοφωνηθεί οπτικοακουστικά.
- Συμφωνώ να επικοινωνήσετε μαζί μου για μελλοντικές ευκαιρίες να ασχοληθώ με το SHAPES

Ημερομηνία: _____

Υπογραφή Συμμετέχοντος: _____

Η πρωτότυπη συγκατάθεση υπογεγραμμένη από τον συμμετέχοντα και ένα αντίγραφο του φύλλου πληροφοριών του συμμετέχοντα θα φυλάσσονται στα αρχεία του ερευνητή. Το φύλλο πληροφοριών του συμμετέχοντα, η ειδοποίηση απορρήτου και ένα αντίγραφο της υπογεγραμμένης συγκατάθεσης θα δοθούν στον συμμετέχοντα.

Αυτό το έργο έχει λάβει χρηματοδότηση από το πρόγραμμα έρευνας και καινοτομίας Horizon 2020 της Ευρωπαϊκής Ένωσης στο πλαίσιο της συμφωνίας επιχορήγησης Αρ. 857159.

Annex 29 UC-PT3-001 MOMENTUM blueprint

7 List of indicators

For ease of use, this section contains a complete list of the 51 indicators already presented sequentially in Sections 3-6 in the context of each individual critical success factor.

7.1 Context

7.1.1 CSF 1. Ensure that there is cultural readiness for the telemedicine service

- In my organisation/region doctors and other healthcare professionals are ready to share clinical information with each other and with the patient i.e., there is a level of trust among all the stakeholders.

CH	GEWI
YES within Clinica Humana Limited sharing between Clinica Humana and specialists from other institutions.	Limited sharing among HCP

- In my organisation/region patients and providers (healthcare professionals) are ready to use ICT (e.g., computers, tablets, mobile phones).

CH	GEWI
YES	To some extent

- In my organisation/region financial and other incentives are aligned with the service to be deployed.

CH	GEWI
To do	No

- In my organisation/region an underpinning culture embraces technology.

CH	GEWI
YES	No

- In my organisation/region an underpinning culture welcomes and even promotes

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change, innovation and shows openness to new ideas.

CH	GEWI
YES.	To some extent

7.1.2 CSF 2. Come to a consensus on the advantages of telemedicine in meeting compelling need(s)

- In my region/organisation there is general consensus on the current telemedicine solution being the best available solution for meeting a compelling need.

CH	GEWI
YES. Tighter monitoring is one of our main objectives. It's in the technology and service roadmap of CH.	Yes. Monitoring at the point of care is considered the best solution to address shortage of skilled health professionals.

- The current telemedicine solution is the best available solution for meeting a compelling need.

CH	GEWI
Not sure. The solution in the pilot is thought to clarify the degree of engagement of patients to technologies which require active actions on a daily basis. To do. The pilot is a clear step forward but its outcomes have to be analyzed in detail. Additional telemedicine approaches may enrich the solution as well.	Not sure.

7.2 People

7.2.1 CSF 3. Ensure leadership through a champion

In my region/organisation there is one or several influential person(s) who take(s) on a leading role and leads the way towards deployment of the telemedicine solution tested in our project.

CH	GEWI
YES	To do.

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7.2.2 CSF 4. Involve healthcare professionals and decision-makers

- Healthcare professionals have been involved in the development of the content of this project.

CH	GEWI
YES	No

- Healthcare professionals have been involved in the development of the process and time schedule for this project.

CH	GEWI
YES	To do.

- Decision-makers have been involved in the development of the content of this project.

CH	GEWI
YES, decision-makers within CH.	No

- Decision-makers have been involved in the development of the process and time schedule for this project.

CH	GEWI
YES, decision-makers within CH.	Yes, decision-makers within Oberbergischer Kreis (pilot region)

7.2.3 CSF 5. Put the patient at the centre of the service

- In this project[17] the patients have been sufficiently involved in the development of the telemedicine solution.

CH	GEWI
Plan to do so (phase 2-4)	Plan to do so.

- In this project telemedicine service is based on the patient´s needs.

CH	GEWI

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YES, clear objective in increasing quality of life and reducing decompensations.	Yes

- In this project enough information and training is provided for the patients in order

  for them to obtain the best results possible from using the telemedicine solution.

CH	GEWI
Planned to do so. To develop in following phases.	Plan to do so.

7.2.4 CSF 6. Ensure that the technology is user-friendly

- The telemedicine technology used in our project is user-friendly for patients.

CH	GEWI
It is the objective and great effort is done within the SHAPES consortium to define requirements to fulfill this. Resources to update chatbot interface needs to be allocated.	NA

- The telemedicine technology used in our project is user-friendly for health

  professionals.

VICOM	CH
At VICOM we use mainstream technology to develop the dashboards and control panels that will be used by the health professionals. Additionally, we will collaborate with them in order to cocreate and define the design of the interfaces. The final system will be tested with them as well. Usability and acceptance metrics can be used here to evaluate the final usability of the system. In this sense we propose to use the SUS score[1].	As we take this as a pilot and our staff is used to technology, level of user-friendliness can be medium.

- The telemedicine technology used in our project does not need an extended training

  process prior to using it.

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CH	GEWI
We expect minimum training. To be defined in mock-up sessions.	TBD

7.3 Plan

7.3.1 CSF 7. Pull together the resources needed for deployment

- In my region/organisation the financial resources needed for deployment of the telemedicine solution are available.

CH	GEWI
YES, from SHAPES and internal resources already allocated.	From SHAPES

- In my region/organisation the IT competences needed for deployment of the telemedicine solution are available.

CH	GEWI
YES. To be further evaluated. YES. VICOM, EDGE and CH provide IT competences.	From SHAPES consortium

- In my region/organisation enough time for the training needed in order to implement the telemedicine solution is available.

CH	GEWI
YES	Yes

7.3.2 CSF 8. Address the needs of the primary client(s)

- The telemedicine solution addresses the needs of the primary clients.

CH	GEWI
YES. Insurances are in need of reduction of health costs of their users with chronic conditions.	To be evaluated.

- The telemedicine solution is sufficiently adapted to the needs of the primary users.

CH	GEWI
YES, although details have still to be developed further (mainly to discuss the design of daily question to reduce burden both to patient and caregivers)	To do

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- The telemedicine solution addresses the needs of the health sector.

CH	GEWI
YES for insurances. Not sure from our perspective in the private health provider sector (mainly, private hospitals). There is conflict of interests. Mainly, private clinics have a business model based on number of hospitalisations, outpatient visist and other tasks related to the use of health care resources by patients.	Yes, due to c

Three example indicators follow (the second indicator is relevant to health care systems where municipalities have a role to play in health care and the third one is specifically relevant to the Norwegian setting).

Indicators for measuring addressing the needs of the health sector

- The telemedicine service addresses the needs for efficiency improvement and improvement of quality in the health sector.

CH	GEWI
YES	Yes

- The telemedicine service is adapted to the need for cooperation between municipalities.

CH	GEWI
NO	To be clarified.

- The telemedicine service is adapted to the need of the health sector for interaction in with the principle of Best Efficient Level of Care.

CH	GEWI
YES	Yes

[17] The wording of these indicators tends to focus on use of the word project. However, in many telemedicine settings, words such as service or initiative or venture might prove to be more suitable. Alternatively, organisation or region might also be considered.

7.3.3 CSF 9. Prepare and implement a business plan

- A business plan for the project has been developed.

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CH	GEWI
To do (D7.3 SHAPES Business Plan WP7)	?

- A business plan for the project has been implemented.

CH	GEWI
To do after the project end.	

- The business plan has been approved by the relevant management level.

CH	GEWI
To do after the project end.	

7.3.4 CSF 10. Prepare and implement a change management plan

- A change management plan for the project has been developed.

CH	GEWI
To do after the project end.	?

- A change management plan for the project has been implemented.

CH	GEWI
To do after the project end.	

- A change management plan has been approved by the relevant management level.

CH	GEWI
To do after the project end.	

7.3.5 CSF 11. Assess the conditions under which the service is legal

Prior to the start of the project, we assessed the conditions under which the service is legal.

CH	GEWI
YES	T do

7.3.6 CSF 12. Guarantee that the technology has the potential for scale-up

- We are fully aware of what it takes for the technology to be deployed on a large scale.

VICOM	CH	GEWI	

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YES. In fact the project is developing a platform intended to scale the telemedicine service to a pan-european level.	To evaluate after the pilot. The use of human resources involved in the collection of data, monitoring and managing interventions has to be evaluated. It is expected to be scalable.	To evaluate after the pilote.	

- In our region/organisation we are ready for large-scale deployment of the technology.

CH	GEWI
No, current number of users of Clinica Humana with heart failure (250 approx) could not be considered large scale. Propuesta: If the pilot provides satisfactory results CH will contact relevant local and national key players in order to deploy it at large-scale level.	Not yet but the project enjoys the support of regional decision makers.

- The project will supply the documentation needed to ensure that there is a basis for large-scale deployment of the project.

CH	GEWI
To do	To do

7.4 Run

7.4.1 CSF 13. Identify and apply relevant legal and security guidelines

- The project is carried out in accordance with the relevant guidelines on legal matters.

CH	GEWI
YES	Yes

- The project is carried out in accordance with the relevant guidelines on security matters.

VICOM	CH	GEWI
YES. GDPR will be applied. The system provided implements all security and privacy related regulations.	YES	Yes

7.4.2 CSF 14. Involve legal and security experts

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- We have received advice on the project from legal experts.

VICOM	CH	GEWI
YES. VICOM awarded the ISO 27001 certification for information security management.	To do	To do

- We have received advice on the project from experts on data security matters.

VICOM	CH	GEWI
YES. VICOM awarded the ISO 27001 certification for information security management.	To do	To do (within SHAPES consortium)

- In this project we are not experiencing any data security problems.

VICOM	CH	GEWI
No.	Yes, we are dealing with health data.	TBD

- I have confidence in the legality of this project.

VICOM	CH	GEWI
YES. It's a H2020 project with partners with extensive expertise in this field (LAUREA for example)	YES	Yes

- I have confidence in the security of this project.

VICOM	CH	GEWI
YES. It's a H2020 project with partners with extensive expertise in this field (HMU and VICOM for example)	YES	Yes

7.4.3 CSF 15. Ensure that telemedicine doers and users are privacy aware

this project the telemedicine doers are aware of protecting the patients´ privacy in terms of health information and other information collected during the course of the pilot.

VICOM	CH	GEWI
YES	YES	Yes

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7.4.4 CSF 16. Ensure that the information technology infrastructure and eHealth infrastructure are available

☐ We have ensured that the IT infrastructures needed are in place for deployment and large-scale implementation.

VICOM	CH	GEWI
YES. SHAPES is developing a technology platform for pan-european distribution of telemedicine services. The pilot is being designed to cope with this requirement as well.	To do (acquisitions of medical devices in process)	To do

We have ensured that the eHealth infrastructures needed are in place for deployment and large-scale implementation.

VICOM	CH	GEWI
YES. SHAPES technology platform will cover it as well. The eHealth devices needed for the pilot are in the market as well.	To do (acquisitions of medical devices in process)	To do

7.4.5 CSF 17. Put in place the technology and processes needed to monitor the service

- We have set up a system to monitor our telemedicine service ensure that it is running smoothly at all times.

VICOM	CH	GEWI
YES. The system will work 24/365. In case of any bugs or issues the development and maintenance team will fix it. CH, EDGE and VICOM are the owners of all the software that is used in the pilot. This means that we don't have any software dependencies with third parties, and that we can fix the source code at any point it's needed quickly.	To do	To do

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- We have set up a system to solve any incident that may occur during the service.

VICOM	CH	GEWI
YES. The system logs all activities so any incident can be identified and solved quickly.	To do.	To do

We have a system which supports the end-users in resolving any doubts that they

might experience with the telemedicine solution.

VICOM	CH	GEWI
YES. Apart from the user manual, we have access to the software developers of the system so in case of doubts or questions we can answer them directly from EDGE and VICOM.	YES	To do

7.4.6 CSF 18. Establish and maintain good procurement processes

- We have clear agreements regarding the quality of the deliveries provided by our vendors.

VICOM	CH	GEWI
Yes. The requirements we need from the eHealth devices that will be used in the pilot have been already defined and vendors that fulfil them have been identified.	To do with final providers of devices.	To do

We have clear agreements regarding the service level provided by our vendors.

VICOM	CH	GEWI
Yes. The SHAPES project provides the servers that are needed to run the telemedicine service. Those servers meet the service level needed to run the pilot successfully.	To do with final providers of devices	To do

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Annex 30 UC-PT3-001 NASSS-CAT (short version)

NASSS-CAT (SHORT)

IDENTIFYING COMPLEXITIES IN YOUR TECHNOLOGY PROJECT

The questions below help you think about the various complexities of your project and how they all interact. Use your responses and notes as the basis for a team discussion.

Name of your project: PT3-001

1. THE ILLNESS OR CONDITION

Think about the illness or other condition that the technology is designed for – and what sort of person has that condition.

	Agree	*Disagree*	*Not applicable or don't know*
There are significant uncertainties about the condition e.g. poorly-defined, variable manifestations, uncertain course The condition and its consequences are known. The consequences, mainly, decompensations and the related high use of health care services, happen regularly when considering long timeframes. This specific point (long timeframe) has to be considered carefully in the design of the pilot for the achievement of significant positive outcomes (to be considered somewhere else in NASSS). For the pilot, we are recruiting older people that usually have one heart failure decompensation per month.		x	
Many people with the condition have other co-existing illnesses or impairments that could affect their ability to benefit from this solution We need to make the technology accessible to people in terms of gathering data on daily basis if possible.	x		

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Monitoring of heart failure should consider situations (including hospitalisations, other illnesses and impairments, among other factors) when older people may have health issues that make them difficult to provide data.				
Many people with the condition have social or cultural factors that could affect their ability to benefit from the technology or service They are minor (diet-traditions, palliative care only at very advance stages).		x		
The population with the condition, and/or how the condition is treated, is likely to change significantly over the next 3-5 years Although the number of older people is increasing, it should not affect the technology in the next 3 years, and the impact should be small in the next 5 years. The changes in treating heart failure in the next 3-5 years are pursuing the same strategy as ours.		x		
SUMMARY: The condition has significant complexity which is likely to affect the project's success		x		
	Yes	*No*		

2. THE TECHNOLOGY

Think about the technology (e.g. a tool or piece of software), and how it might affect care.

	Agree	*Disagree*	*Not applicable or don't know*	
There are significant uncertainties in what the technology is (e.g. it hasn't been fully developed yet) The components of the solution to develop are mainstream technologies (apps, chatbots, servers …) (TRL9). The connectivity of them will be based also in standard technologies. The HF decompensation prediction module has been tested in a real hospital environment and the results have been positive (TRL7). The HF decompensation prediction module is ready to be certified (TRL8) and to be marketed (TRL9). The chatbot interface has been develop but needs to be upgraded for current smartphone operating systems.		x		

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The dashboard to be developed will be based on standard known technologies. In conclusion, although the technology solution hasn't been developed, most of their components have and the rest, along with the component connectivity and necessary upgrades are based on standard technologies and no complexity is expected.				
There are significant uncertainties in where the technology will come from (e.g. supply chain issues, substitutability) Although the right pulse oximeter to be added to the pilot is still missing (to be done through and open call already launched), this issue does not jeopardize the success of this pilot. In case that a pulse oximeter with the right connectivity is not found, a traditional one can be purchased and the data can be added manually. The origin of the other components to build the system are fully defined.		x		
There are significant uncertainties about the technology's performance and dependability (e.g. bugs, crashing, cutting out) The main challenge of the system that will be used in the pilot is that it mixes a set of components which are in different levels of maturity. Some components are already developed, and others will be developed in the next months. Hence, it's true that we might face issues such as bugs and crashings. Nevertheless, due to the experience of the technical team involved in the project and the use of standard well-known technologies (for each component), we expect that they will be solved quickly.		x		
There are significant uncertainties about the technology's usability and acceptability (e.g. key people don't trust the data it provides) We don´t expect significant technology usability and acceptability issues in the project. CH has a long experience in the provision of chatbots to older people with HF. So, this pilot should not make a difference to the health care users (key people making use of the data) compared with previous experiences.		x		
There are significant technical interdependencies Yes. Different technology components will have to work together, but we don't expect that this fact will be an	x			

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issue. Well defined APIs, and standard and mature technologies will be used to interoperate among them such as web services.				
The technology is likely to require major changes to organisational tasks and routines It requires new human resources for monitoring and collecting data. However, the number of older people involved in the pilot (15 approx at CH site and 10 at GEWI site) doesn't make it complex at this stage. The pilot would evaluate this for later scale up.	x			
The technology (and/or the service model it supports) is likely to change significantly within the next 3-5 years Technology is evolving rapidly in the medical sector. However, we think that the current platform could be in use during the following 5 years if appropriate maintenance and updates are provided. Current devices to incorporate, are expected to be available in the next 1-3 years.		x		
SUMMARY: The technology has significant complexity which is likely to affect the project's success	Yes	No X		

3. THE VALUE PROPOSITION

Think about what kind of value the technology might generate for different groups of people. ('Value' can be financial, such as profit, or non-financial, such as control of symptoms)

	Agree	*Disagree*	*Not applicable or don't know*	
The commercial value of the technology is uncertain It's actually one of the KPIs of the pilot, to evaluate the value proposition of cost reduction in use of health care resources.	x			
The value to the intended users (e.g. patients, clinicians) is uncertain We understand that the main value for the patients is that it will increase their security and quality of life. Patients want to avoid rehospitalizations at all cost,		x		

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because they have a very negative impact in the patients and their informal carers. We also understand that clinicians are interested in having the means that allow a tighter monitoring to prevent rehospitalizations and increasing patient security and quality of life.				
The value to the healthcare system (e.g. from efficacy and cost-effectiveness studies) is uncertain Closely align with the value proposition, it will be evaluated during the pilot. The formal caregivers may be indirect users, as they may assist sometimes the older person. We need to work on the value given to the formal caregivers.	x			
The value to this particular healthcare organisation, given the current situation locally, is uncertain CH: it is appealing, but the reduction of use of health resources has to be proven.	x			
The technology could generate a negative value (costs are likely to outweigh benefits) for some stakeholders Will be evaluated during the project, but it is expected very unlikely. It may generate extra tasks to the formal caregivers with no evident benefit (needs to be further discussed).		x		
The value proposition is likely to change significantly over the next 3-5 years No. We expect that the value proposition will maintain during the next 3-5 years.		x		
SUMMARY: The value proposition has significant complexity which is likely to affect the project's success The pilot will be carried out to define value proposition and reduce this type of complexity.	x *Yes*	☐ *No*		

4. THE INTENDED ADOPTERS

Think about who is intended to use the technology and what changes it will bring for them.

	Agree	*Not applicable*

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		Disagree	or don't know	
There is uncertainty about whether and how patients/citizens will adopt the technology [if applicable] Answering repetitive questions on a daily basis for long periods of time is a concern that has to be discussed deeply in the design of the pilot.	x			
There is uncertainty about whether and how front-line staff will adopt the technology CH is a specialized company in the use of cutting-edge technology for the provision of innovative health services. The staff is used to interacting with new technology, so we expect that the technology to be used in the pilot will be adopted quickly by our staff.		x		
There is uncertainty about the implications for people who might be indirectly affected by the technology Collaboration of professional caregivers is essential to scale the technology to a wider population. However, it won't be an issue during the pilot and this aspect will be evaluated.		x		
There will be significant changes to individual users' perceptions of the technology over the next 3-5 years Not expected. Actually, new technologies for a tighter monitoring are increasingly accepted as long as privacy is secured.		x		
SUMMARY: There is significant complexity relating to intended adopters which is likely to affect the project's success				
	Yes	No		

5. THE ORGANISATION(S) IMPLEMENTING THE TECHNOLOGY

Some organisations are better at taking up innovations than others. What about yours?

	Agree	Disagree	Not applicable or don't know	
The organisation's capacity to take on technological innovations is limited		x		

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CH: Although the pilot will serve to evaluate scaling-up				
The organisation is not ready for this particular innovation CH: This pilot fits in with the previous activities carried out in CH and it is aligned with the technology roadmap of the company.		x		
The organisation would find it hard to commission/purchase the innovation We have to see first the results of the pilot, but if the outcomes are promising then CH would engage in the commercialization/use of the technology developed in the pilot. The participation of the different partners in the business model needs to be discussed.		x		
The work needed to introduce and routinise the innovation has been underestimated and/or inadequately resourced It will be analysed in depth at the end of the pilot.			x	
The organisation(s) involved are likely to have significant restructurings or changes in leadership, mission or strategy over the next 3-5 years No big changes are expected at this level in CH in the next 3-5 years.		x		
SUMMARY: There is significant complexity relating to one or more participating organisations which is likely to affect the project's success		x		
	Yes	*No*		

6. THE EXTERNAL CONTEXT FOR INNOVATION

Think about external conditions that could complicate adoption and spread of the innovation.

	Agree	*Disagree*	*Not applicable or don't know*	
The political and/or policy climate is adverse Current policies promote remote technologies and the reduction of health costs, particularly those related to an increasing ageing population.		x		
Professional bodies are opposed to the innovation or don't actively support it		x		

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Most professional bodies go after reduction of costs and improvement of health care. There is some concerns about the acceptance of technologies that reduce hospitalisations by private hospitals, as their business model is based on number of admissions and visits/contacts.				
Patient organisations and lobbying groups are opposed to the innovation or don't actively support it No.		x		
The regulatory context is adverse We need to check this.			x	
The commercial context is adverse Current trends see the value in technologies based on connectivity and data knowledge.		x		
Opportunities for learning from other (similar) organisations are limited There are many types of entities which provide care to people with chronic heart failure, as it is a disease which affects 1-2% of the population. There are many opportunities to learn from them and broaden the applicability of our solution.		x		
Introduction of the technology/innovation could be threatened by external changes that impact on the organisation		x		
The policy, regulatory and economic context for this innovation is likely to be turbulent over the next 3-5 years		x		
SUMMARY: There is significant complexity relating to the external context which is likely to affect the project's success		x		
	Yes	*No*		

THINGS TO EXPLORE OR DISCUSS: List the key things in each domain that you would like to look up or discuss with other team members or wider stakeholders

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The value proposition The time of the pilot has to be carefully re-evaluated in order to reach KPIs in terms of reduction of costs in use of health care resource. We need to re-evaluate the design of the pilot to maximise the outcome in can provide: control group? Longitudinal study to evaluate weight of intervention vs. life-style changes. Value for formal caregivers need to be further discussed.	**The technology** Many interdependencies will be developed. Bugs and crashes expected. Resources are allocated but constant check is needed to keep developing times.
The illness or condition	**The organisation**
The intended adopters The technology requires answering questions on a daily basis. As heart failure is a chronic disease, the technology is intended to be used for a long time. We need to re-evaluate the adequateness of questions to avoid drop-outs (older people/caregiver get tired of answering questions). The use by formal caregivers need to be further discussed.	**The external context** Regulatory context needs to be further evaluated.

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Annex 31 UC-PT3-001 NASSS-CAT (long version)

NASSS-CAT (PROJECT VERSION)

FOR MONITORING PROJECT COMPLEXITY OVER TIME

This version of the NASSS-CAT is intended to be used when you are setting up and running a specific project to implement a new technology in a health or care setting. You may be asked to complete it more than once as the project unfolds. Score one point for every 'agree' answer and add up the orange column. In the blue column, tick if you think this issue is going to get more complex in the next phase of the project. Note: this tool will only give you a semi-quantitative estimate because some aspects of a project will be more important than others.

	Not applicable or don't know	*Agree*	*Disagree*	*Likely to get more complex in next phase*
STRATEGIC COMPLEXITIES				
1. The vision and benefits for the project are not yet clear		x		
2. The fit between this technology and the organisation's mission and strategy is poor		x		
3. The business case for the work is unclear or contested	1			1
4. The scope of the project is unclear or contested		x		
5. The work will have major knock-ons for other key projects and business-as-usual operations	1			
6. Success criteria are not yet explicitly set out and agreed by key stakeholders		x		
7. The project's success could be threatened by external changes that impact on the organisation	1			
TOTAL STRATEGIC COMPLEXITY SCORE	3 /7			1 /7

Not applicable or don't know *Likely to get more complex in next phase*

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	Agree	Disagree		
TECHNICAL COMPLEXITIES				
1. The technology does not yet exist in a robust and dependable form	1			
2. The technology is unfamiliar to the project team		x		
3. The technology supply chain is not yet in place	1			
4. The technology cannot be installed until the system is upgraded (e.g. hardware, bandwidth)	1			
5. A key technology needs to be installed across multiple technical systems to achieve 'integration'	1			
6. Introducing the technology will require significant changes in care pathways and organisational routines		x		
7. Quality standards and regulatory requirements for using the technology in a health/care setting have not been fully defined (or key stakeholders don't know about them or accept them)	1			
TOTAL TECHNICAL COMPLEXITY SCORE	5 /7			/7

	Agree	Disagree	Not applicable or don't know	Likely to get more complex in next phase
OPERATIONAL COMPLEXITIES				
1. A schedule and resource plan have not yet been defined		x		
2. The pace of the project (time to achieve key goals and milestones) seems unachievable		x		
3. The budget is insufficient for the task or there is limited flexibility in how the budget can be used		x		
4. Resources (e.g. test facilities, equipment) may not be available when needed	1			
5. Evaluation measures and metrics have not yet been agreed	1			1
6. Accurate, timely and comprehensive data reporting will be difficult or impossible		x		

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7. New management tools and data sources will be needed to guide, monitor and evaluate the project	1			
TOTAL OPERATIONAL COMPLEXITY SCORE	3 /7			1 /7

	Agree	Disagree	Not applicable or don't know	Likely to get more complex in next phase
PEOPLE-RELATED COMPLEXITIES				
1. The people leading the project are inexperienced in this kind of work	1			
2. The people leading the project do not have adequate control over project staff (e.g. no direct reporting)		x		
3. There are not yet sufficient people with the right skills available to participate in the project.		x		
4. There are no key people who are wholly allocated to the work for the project		x		
5. Lines of responsibility for tasks and deliverables are not yet defined		x		
6. Team members have limited confidence in the technology or do not fully understand how to use it		x		
7. Team members have limited motivation and are not yet functioning well as a team		x		
TOTAL PEOPLE-RELATED COMPLEXITIES	1 /7			/7

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"POLITICAL" COMPLEXITIES				
1. The work does not have a senior sponsor in the organisation who recognises its importance and helps negotiate its progress		x		
2. The senior management team in the relevant department does not fully support the work		x		
3. Substantial work will be needed to bring people on board and develop a shared vision for the change		x		
4. People beyond the core team don't understand the project or have unrealistic expectations for it		x		
5. People beyond the project team don't support the project or are not aligned or have insufficient time		x		
6. The core team does not have the authority to make decisions		x		
7. The work will require cooperation across sectors (e.g. health / social care)	1			
TOTAL "POLITICAL" COMPLEXITY SCORE	1 /7			/7

Plot your scores on the radar charts below to get a quick visualisation of the different complexities as assessed by you. The one on the left is your assessment of current complexity (orange columns above); on the right is your assessment of emergent complexity (blue columns above). Compare your radar charts with those made by your colleagues. Do your charts look the same? If not, where are the discrepancies and what explains these?

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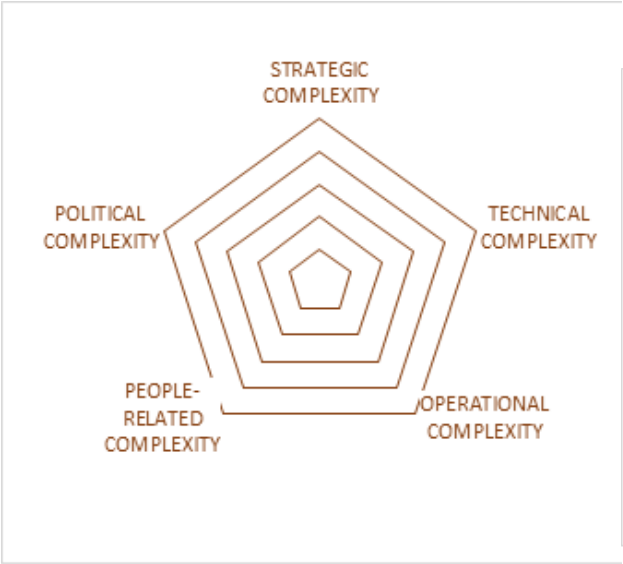
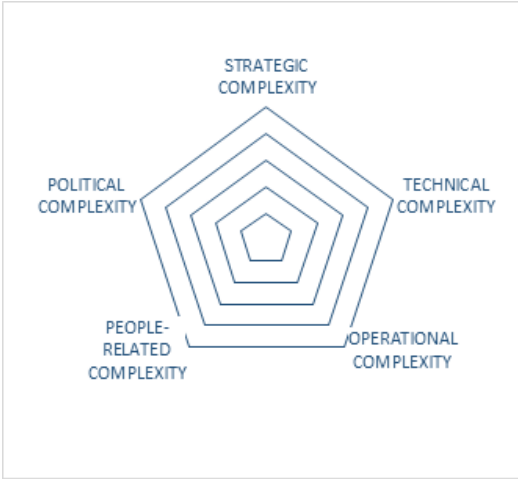
Assessment of current complexity



Assessment of emergent complexity (how things will unfold in the future)



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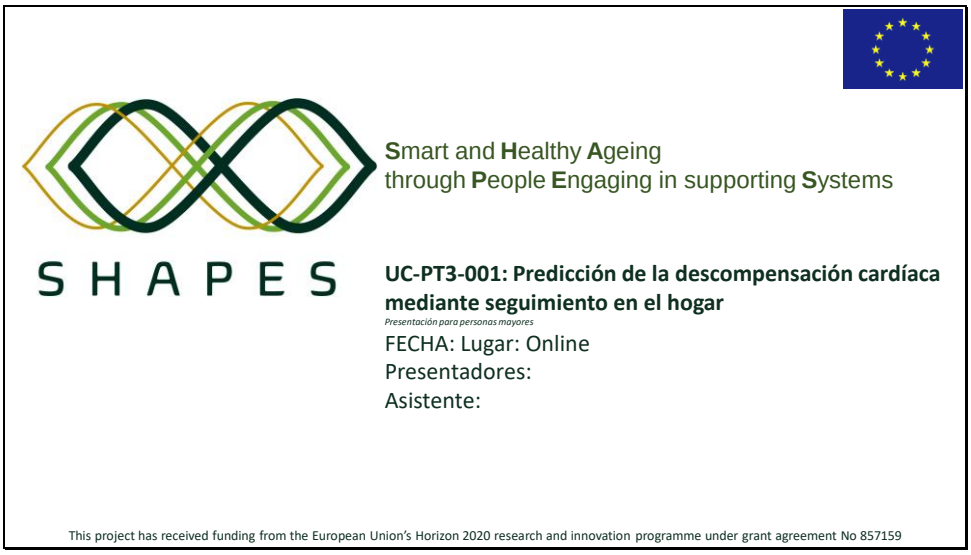
Annex 32 UC-PT3-001 Phase 2 Participant presentations

Slide 1



Slide 2

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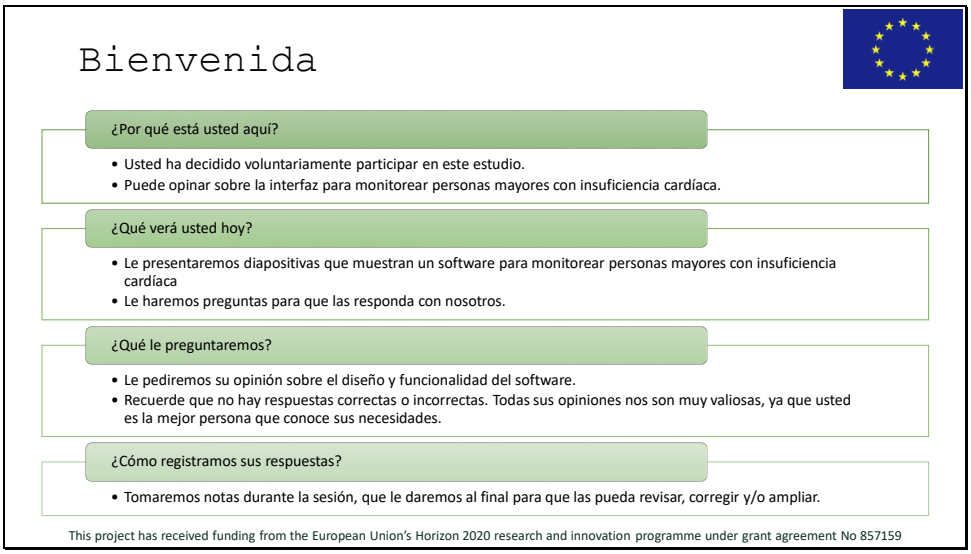
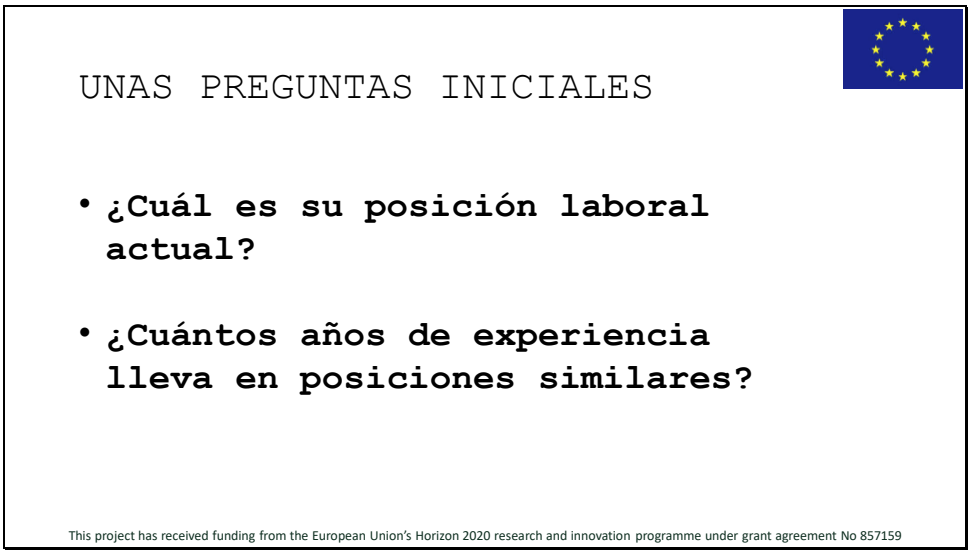
Slide 3

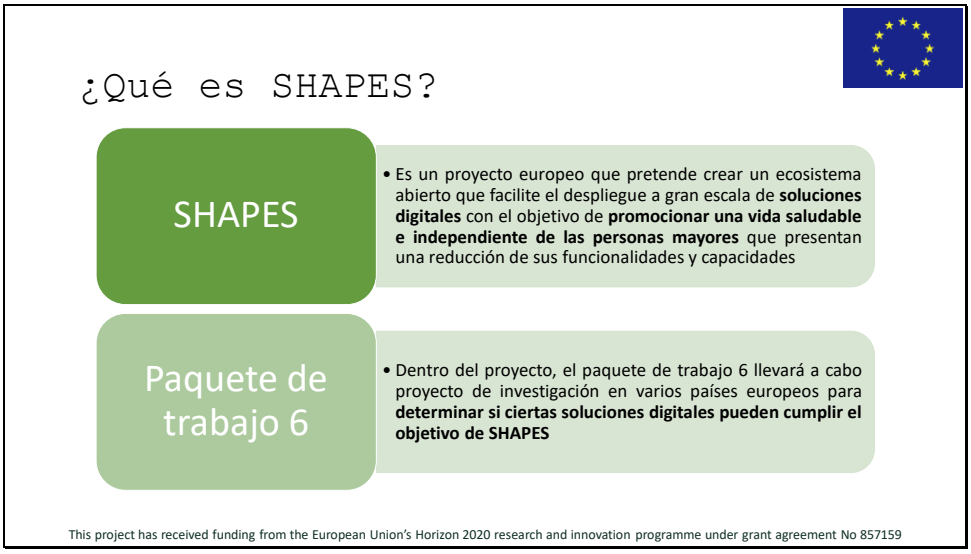


Slide 4

Slide 5



Slide 6



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Slide 7

El proyecto de investigación relacionado con esta sesión:
Predicción de la descompensación cardíaca mediante seguimiento en el hogar

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Slide 8

El proyecto de investigación relacionado con esta sesión:
Predicción de la descompensación cardíaca mediante seguimiento en el hogar

Clinika de Kay /
Clinica Humana lidera este proyecto de investigación en SHAPES

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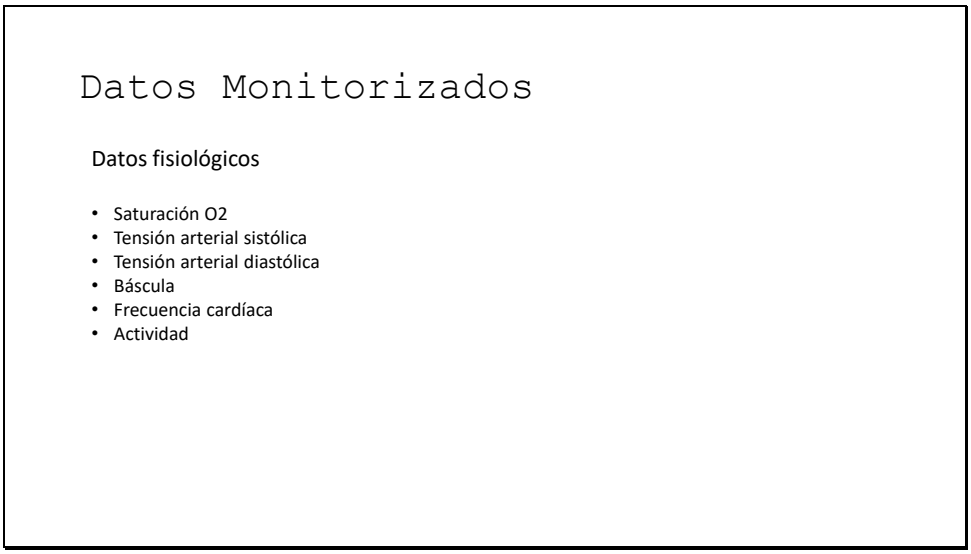
Slide 9

Slide 10

Slide 11



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Datos recogidos

Cuestionarios

- SET 1 preguntas (diarias)
  - Q1 ¿En los últimos 3 días, sus piernas están más, menos o igual de hinchadas? (Menos/Igual/Más)
  - Q2 Comparado con los últimos 3 días, usted se siente ¿Mejor, Igual, Peor?
  - Q3 ¿En los últimos 3 días, ha tomado alguna medicación no prescrita por el médico? (Sí/No)

- SET2 preguntas (se lanzan cuando en SET 1 las piernas están más hinchadas, se siente peor o ha tomado alguna medicación no prescrita o alguno de los datos fisiológicos está fuera del rango recomendado)
  - Q4 ¿Le falta más el aire al hacer actividades? (Sí/No)
  - Q5 ¿Le falta el aire o se ahoga cuando está estirado o en la cama? (Sí/No)
  - Q6 ¿Tose más o tiene más flemas? (Sí/No)
  - Q7 ¿Cree que su medicación le hace sentir mal? (Sí/No)
  - Q8 ¿Sigue la dieta y ejercicios que le han indicado sus médicos o enfermeros/as? (Sí/No)
  - Q9 ¿Orina menos, igual o más? (Menos/Igual/Más)
  - Q10 ¿Siente palpitaciones en el pecho o cuello? (Sí/No)
  - Q11 ¿Tiene somnolencia? (Sí/No)

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Datos recogidos

Coméntenos sobre la formulación de las preguntas. ¿Es la adecuada para personas mayores con insuficiencia cardíaca en estadio II-III? Tenga presente que las preguntas pueden repetirse en días seguidos.

De 100 personas, ¿cuántas en esta situación, o sus cuidadores, cree que:

- se cansarán de responde a las preguntas en pocos días?
- se cansarán de responder a las preguntas antes de 1 mes?
- se cansarán de responder a las preguntas entre 1 mes y 3 meses?
- se cansarán de responder a las preguntas entre 3 meses y 6 meses?
- se cansarán de responder a las preguntas entre 6 meses y 1 año?
- no se cansarán o estarán respondiendo más de 1 año?

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AVISOS

Avisos rojos:

- Falta de aire al hacer una actividad Q4 (Sí)
- Falta de aire al estar estirado o en la cama Q5 (Sí)
- Somnolencia Q11 (Sí)
- O2 sat < 90
- Frecuencia cardíaca <50 o >100
- Tensión arterial sistólica <85 o >180
- Tensión arterial diastólica <50 o >110
- VICOM predictor >66%
- 2 avisos cualesquiera en el SET 2 de preguntas
- Aumento de 2kg de peso en menos de 2 días y la respuesta a Q1 es "igual" o "más"

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AVISOS

Avisos naranjas:

- Toser más o más flemas Q6 (Sí)
- La medicación le hace sentir mal Q7 (Sí)
- Orina menos Q8 (menos)
- Siente palpitaciones en pecho o cuello Q10 (Sí)
- O2 sat en el rango entre 90 y 94
- Frecuencia cardíaca en el rango entre 50 y 55 o entre 90 y 100
- Tensión arterial sistólica: entre 85 y 95 o entre 150 y 180
- Tensión arterial diastólica entre 50 y 60 o entre 100 y 110
- VICOM predictor entre 33%y 66%
- Aumento de 2 kg de peso en 2 días
- Aumento de 2 kg de peso en 7 días y la respuesta a Q1 es “igual” o “más”

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AVISOS

Avisos amarillos:

- Sensación general de salud Q1 (Peor)
- Sin datos de O2 sat en 2 días
- Sin datos de TAS en 2 días
- Sin datos de TAD en 2 días
- Sin datos de peso en 2 días
- Sin datos de actividad en 2 días
- Sin “sesiones” de actividad en 3 días
- Sin datos en O2 sat, TAS, TAD y peso en 1 día
- No es posible la predicción con VICOM
- El paciente tiene nueva información sobre la medicación (hay que recogerlas y anotarlas)
- El paciente tiene nueva información sobre el uso de recursos de la salud (hay que recogerlas y anotarlas)
- El paciente tiene nueva información sobre analíticas (hay que recogerlas y anotarlas)
- Aumento de 2 kg de peso en 7 días
- No ha querido responder a Q8 (¿Sigue la dieta y ejercicios que le han indicado sus médicos o enfermeros/as? en tres días

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Avisos

Los avisos que hemos mostrado se implementarías por defecto.

¿Les gustaría personalizarlos por paciente?

1 (TOTALMENTE EN DESACUERDO) . . . . 2…. 3…. 4…. 5 (TOTALMENTE DE ACUERDO)

¿Qué tipo de avisos te gustaría personalizar para pacientes concretos?

¿Encontraría útil valores definidos para varios grupos? (por ejemplo, pacientes con IC & EPOC o pacientes con IC & Diabetes).

¿Qué grupos?

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Slide 18

PANEL DE CONTROL: HOME

Slide 19

PANEL DE CONTROL: HOME

¿Cree que necesitaría ver alguna información más en la página de inicio del panel de control?

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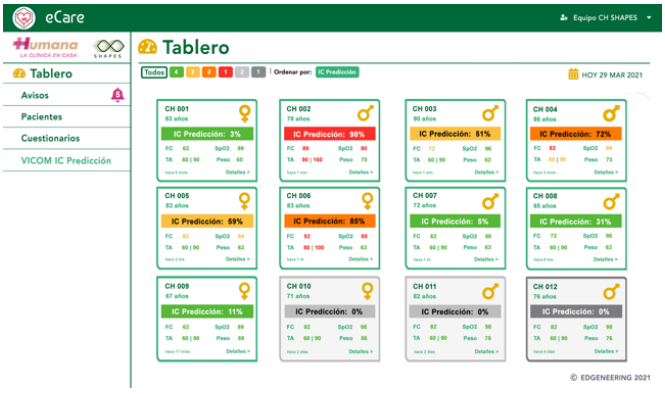
Slide 20

PANEL DE CONTROL: TABLERO



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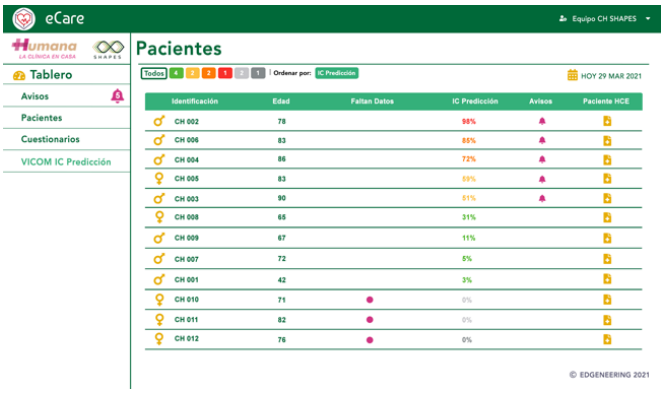
Slide 21

PANEL DE CONTROL: LISTA PACIENTES



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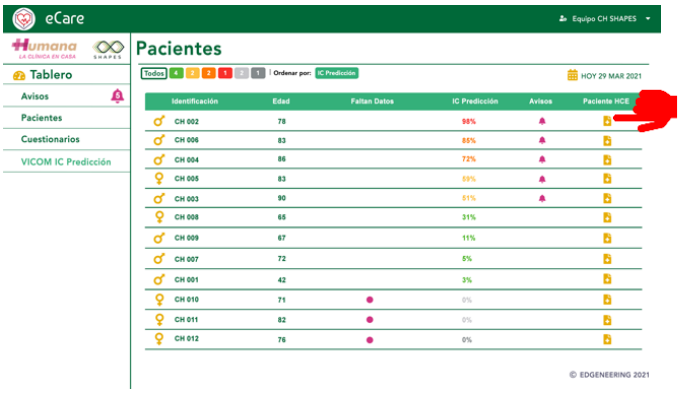
Slide 22

PANEL DE CONTROL: LISTA PACIENTES



Link a la Historia Clínica propia de Clínica Humana

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Slide 23

PANEL DE CONTROL: LISTA DE PACIENTES

¿Qué visualización prefiere, tablero o lista?

¿Alguna otra información que le gustaría ver en tablero/lista de pacientes?

¿Alguna otra información que le gustaría quitar de tablero/lista de pacientes?

Para poder ver alertas ¿cuántos días quieres representar en las tablas? ¿solo el último? ¿los dos últimos? ¿más?

¿Cada cuánto mirará el panel de control?

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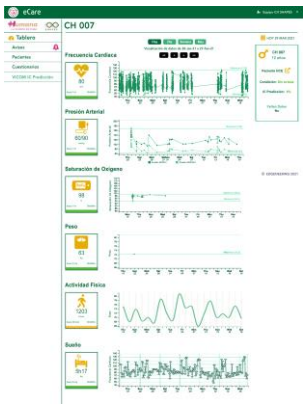
PANEL DE CONTROL: PACIENTE



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PANEL DE CONTROL: PACIENTE

ZOOM en la siguiente diapositiva

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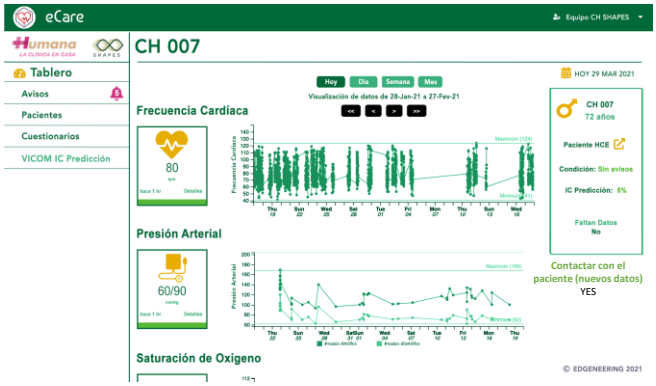
PANEL DE CONTROL: PACIENTE



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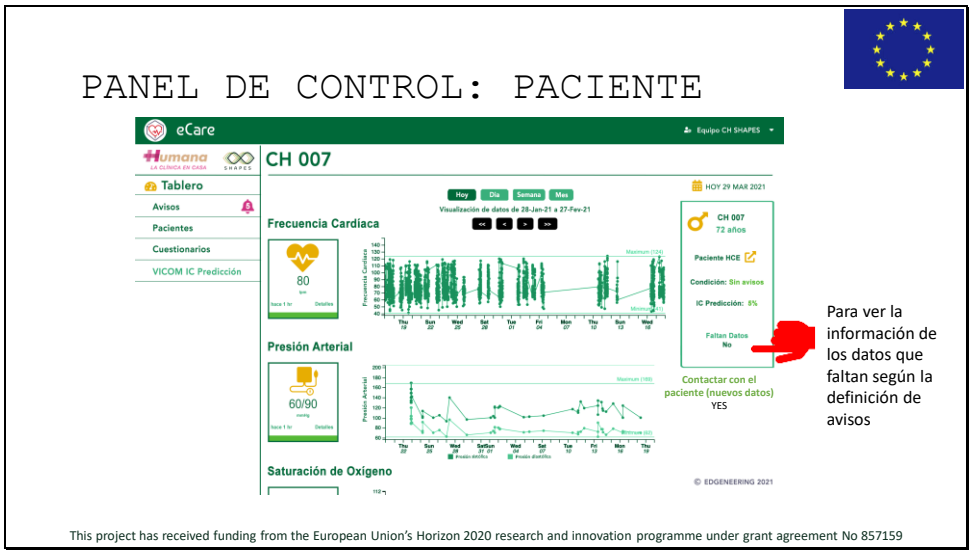

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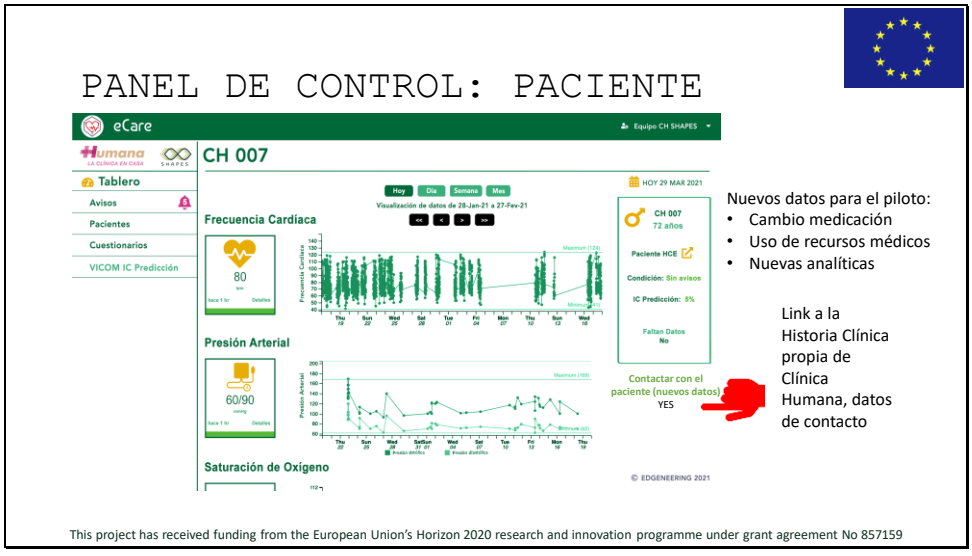

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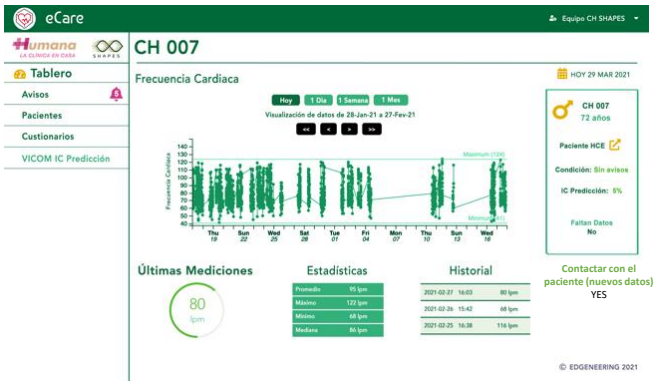
Slide 29

PANEL DE CONTROL: PACIENTE



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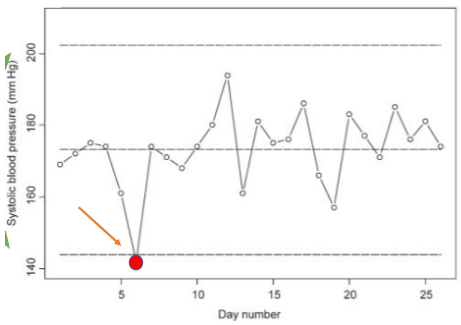
PANEL DE CONTROL: PACIENTE

Si el valor supera un umbral superior o inferior definido en un aviso, se marcará de otro color



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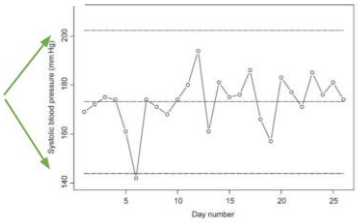
PANEL DE CONTROL: PACIENTE
Umbrales dinámicos

Los umbrales dinámicos producen umbrales que cambian con el tiempo. Cuando el valor está fuera de los límites el proceso se clasifica como fuera de control

Umbrales calculados con el proceso dinámico SPC



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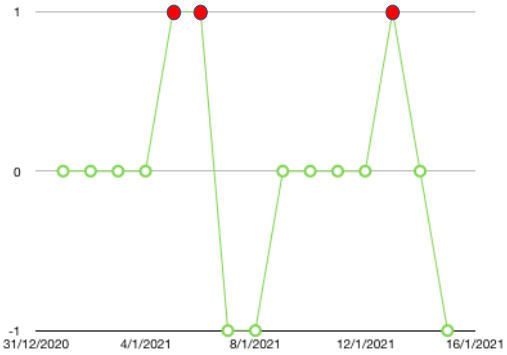
PANEL DE CONTROL: PACIENTE

Q1 ¿En los últimos 3 días, sus piernas están más, menos o igual de hinchadas?

Si el valor corresponde con un aviso, se marcará.



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PANEL DE CONTROL: TABLERO, PACIENTES y GRÁFICAS

¿Le gusta de forma general la forma y la distribución de los gráficos?

1 (TOTALMENTE EN DESACUERDO) . . . . 2…. 3…. 4…. 5 (TOTALMENTE DE ACUERDO)

¿Qué gráficos NO le parecen útiles?

¿En qué orden miraría las gráficas y datos? Describa el proceso de análsis.

¿Alguna otra información que le gustaría añadir/quitar de tablero/lista de pacientes?

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PANEL DE CONTROL: TABLERO, PACIENTES y GRÁFICAS

¿Usará la información de los umbrales dinámicos?

1 (TOTALMENTE EN DESACUERDO) . . . . 2…. 3…. 4…. 5 (TOTALMENTE DE ACUERDO)

Para poder ver alertas ¿cuántos días quieres representar en las tablas? ¿solo el último? ¿los dos últimos? ¿más?

¿Cada cuánto mirará el panel de control?

¿Le son útiles las representaciones para ver los avisos?

1 (TOTALMENTE EN DESACUERDO) . . . . 2…. 3…. 4…. 5 (TOTALMENTE DE ACUERDO)

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PANEL DE CONTROL: TABLERO, PACIENTES y GRÁFICAS

Otros comentarios

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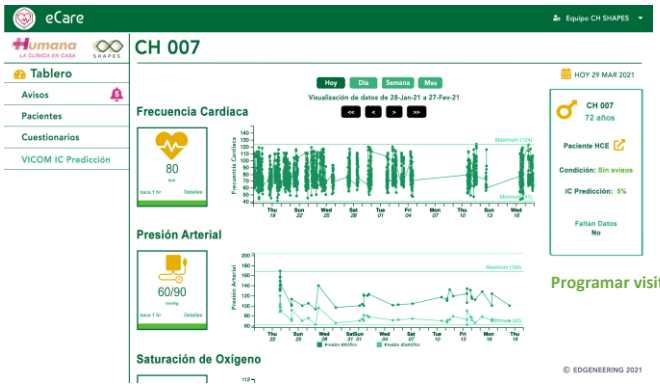
Intervención: programar visita



Cuando se crea conveniente programar una visita

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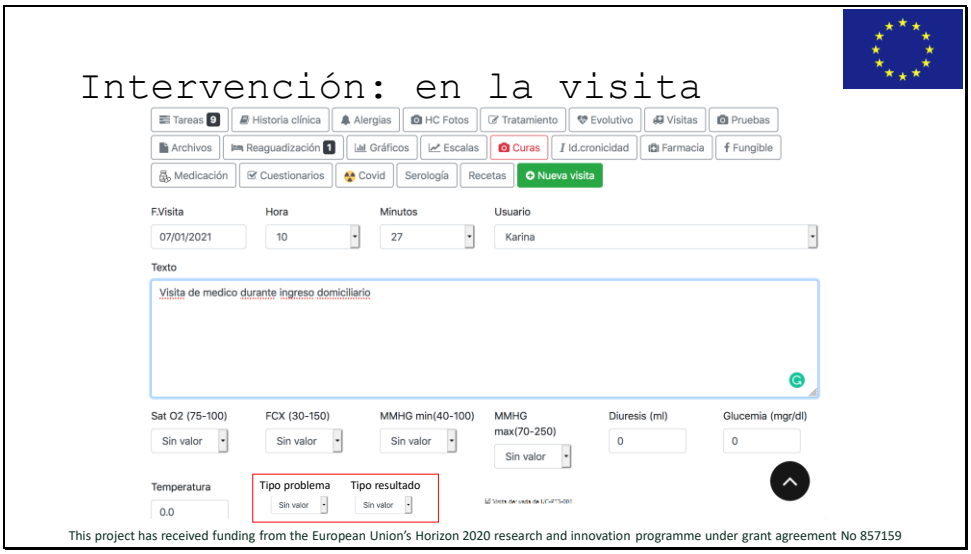
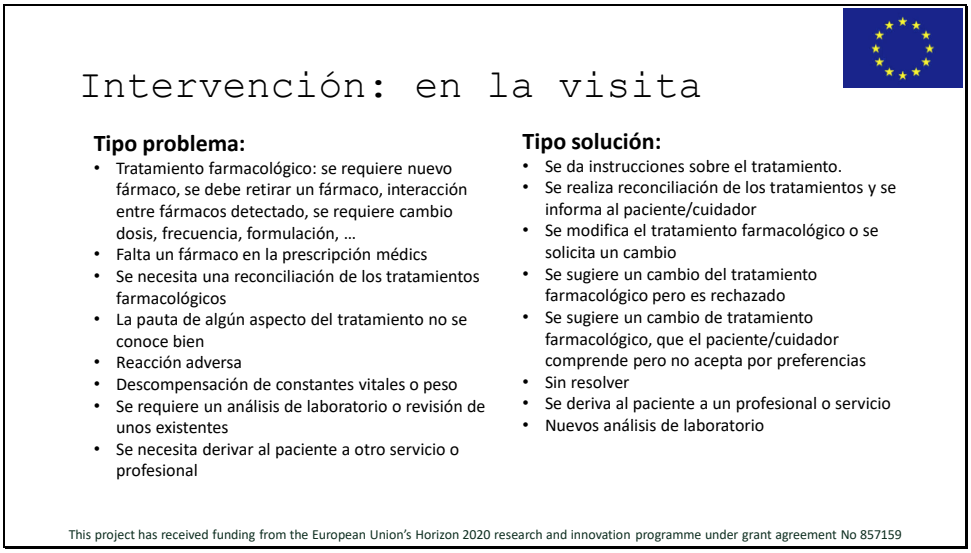


Slide 40



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Intervención: en la visita

¿Algún otro tipo de problema o solución?

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RECORDATORIOS

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RECORDATORIOS

Puede programar recordatorios para la persona mayor

1. Medicamentos
2. Citas con su equipo médico
3. Ejercicios
4. Y todo lo que quiera!

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RECORDATORIOS

- **¿Qué recordatorios puede programar?**
  - Con campos específicos
    - Medicamentos
    - Citas con el médico
  - Cualquier otro tipo de recordatorio se puede programar, de momento, con los campos básicos

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RECORDATORIOS

- **¿Cómo puede programar los recordatorios?**
  - **Interfaz web**
  - **Campos a rellenar**
    - Información básica: Tipo recordatorio, persona mayor, fecha y hora, alerta si la recepción no ha sido confirmada, ...
    - Información específica: Información específica del tipo de recordatorio

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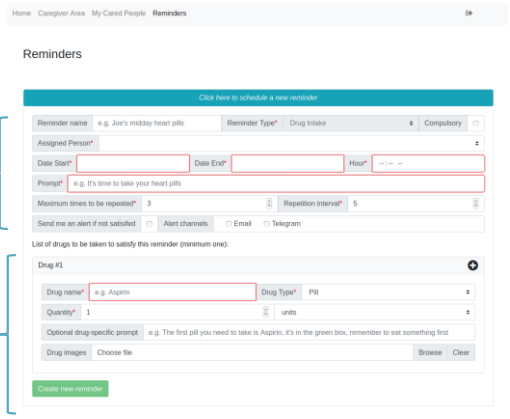
RECORDATORIOS

- Programación ejemplo con **medicamento**
  - Información básica
  - Información específica



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RECORDATORIOS

El **asistente envía el mensaje** escrito en "prompt" a la persona mayor, ARI lo menciona y sale escrito en la pantalla

La persona mayor puede **confirmar la recepción del mensaje** (eg. "ok", "hecho", "de acuerdo", ...) y el recordatorio se registra como satisfecho

En algunas situaciones, la persona mayor puede hacer **preguntas para clarificar**, que pueden ser respondidas si forman parte del modelo del recordatorio
Ejemplo:
- Recordatorio de cumpleaños: "De quién era el cumpleaños" [La respuesta es el nombre de la persona]
- Recordatorio de medicación: "Cuántas pastillas dijiste?" [La respuesta es la cantidad asignada a ese medicamento]

Si la persona mayor **no conforma la recepción del mensaje**, el asistente esperará el tiempo determinado para repetir el recordatorio, si el cuidador lo ha configurado de esta forma.

Si el máximo número de repeticiones es alcanzado sin respuesta, se envía un mensaje alerta al cuidador, si se ha habilitado esa función.

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SUGERENCIAS con recordatorio

- Las sugerencias pueden ser recordatorios donde el objetivo es motivar a la persona mayor a hacer alguna actividad
- Este tipo de sugerencias se programan igual que los recordatorios

1. Ejercicios
2. Recomendaciones de vida saludable
3. Educación sobre la enfermedad
4. Y todo lo que quieras!

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RECORDATORIOS y SUGERENCIAS

- Las sugerencias y recordatorios son técnicamente la misma funcionalidad
- Las sugerencias pueden ser cualquier actividad o información (consejo).

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RECORDATORIOS/SUGERENCIAS

¿Cree que a su persona mayor le gustaría tener recordatorios?

1(TOTALMENTE EN DESACUERDO)....2….3….4….5(TOTALMENTE DE ACUERDO)

¿Qué tipo de recordatorios cree que son más útiles? ¿Son recordatorios regulares o puntuales?

Medicamentos

1(TOTALMENTE EN DESACUERDO)....2….3….4….5(TOTALMENTE DE ACUERDO) – Regulares/Puntuales

Citas con el médico

1(TOTALMENTE EN DESACUERDO)....2….3….4….5(TOTALMENTE DE ACUERDO) – Regulares/Puntuales

¿Otro tipo de citas? (médico, enfermero, fisioterapeuta, …)

¿Otros tipos?

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RECORDATORIOS/SUGERENCIAS

¿Cuántos recordatorios regulares se le ocurren que podría programar al principio, por persona?

0-5 / 6-10 / 11-20 / >20

¿Cuántos recordatorios puntuales cree que podría poner cada semana, por persona?

0-5 / 6-10 / 11-20 / >20

¿Quieres recibir alertas si la persona mayor no confirma la recepción del mensaje del recordatorio?

SÍ/NO

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RECORDATORIOS/SUGERENCIAS

¿Cree que es útil darle consejos de salud?

1(TOTALMENTE EN DESACUERDO)....2….3….4….5(TOTALMENTE DE ACUERDO) – Regulares/Puntuales

¿Cuántos consejos de salud pondría por persona, por semana, de media? ¿Serían regulares o puntuales?

0-5 / 6-10 / 11-20 / >20

¿Cree que es útil darle información para educar a la persona mayor sobre la insuficiencia cardíaca?

1(TOTALMENTE EN DESACUERDO)....2….3….4….5(TOTALMENTE DE ACUERDO) – Regulares/Puntuales

¿Cuántas frases educativas de salud pondría por persona, por semana, de media? ¿Serían regulares o puntuales?

0-5 / 6-10 / 11-20 / >20

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Y PARA ACABAR…

- **Le dejamos las notas tomadas, para que las pueda leer, reflexionar y enviarnos comentarios si lo considera conveniente**

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¿QUIERE COMENTAR ALGO SOBRE EL PROCEDIMIENTO DE LA ENTREVISTA?

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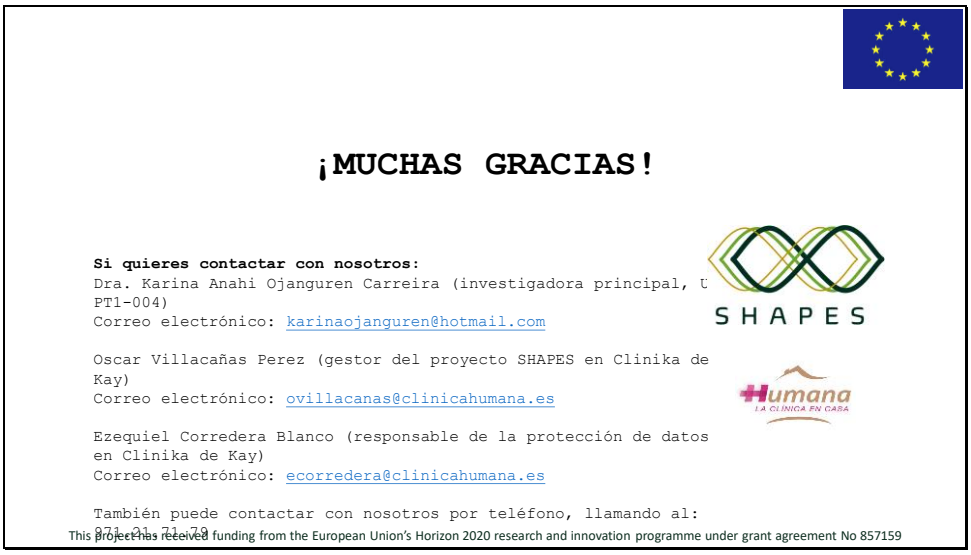
¡MUCHAS GRACIAS!
Si quieres contactar con nosotros:
Dra. Karina Anahi Ojanguren Carreira (investigadora principal, U
PT1-004)
Correo electrónico: karinaojanguren@hotmail.com
Oscar Villacañas Perez (gestor del proyecto SHAPES en Clinika de
Kay)
Correo electrónico: ovillacanas@clinicahumana.es
Ezequiel Corredera Blanco (responsable de la protección de datos
en Clinika de Kay)
Correo electrónico: ecorredera@clinicahumana.es
También puede contactar con nosotros por teléfono, llamando al:
871 21 21 79
SHAPES
Humana
LA CLINICA EN CASA
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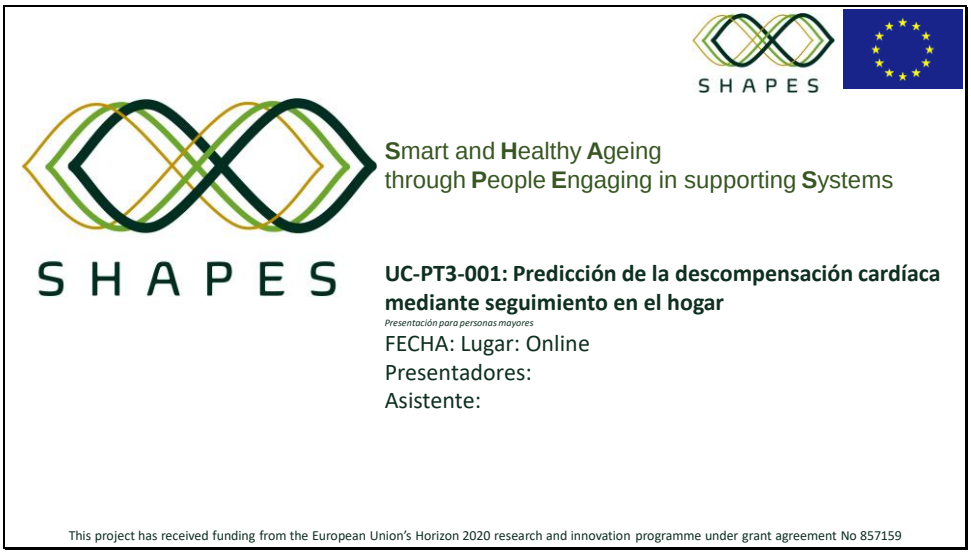
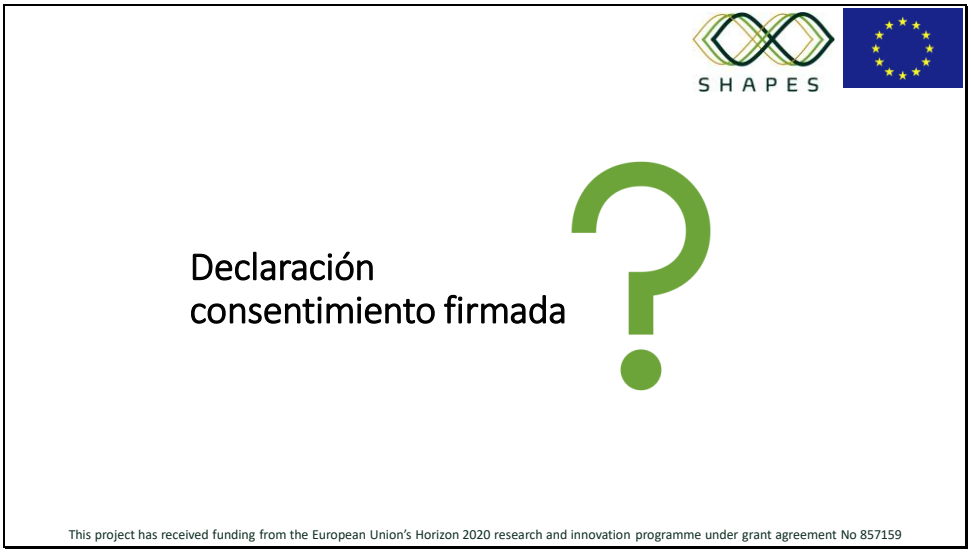
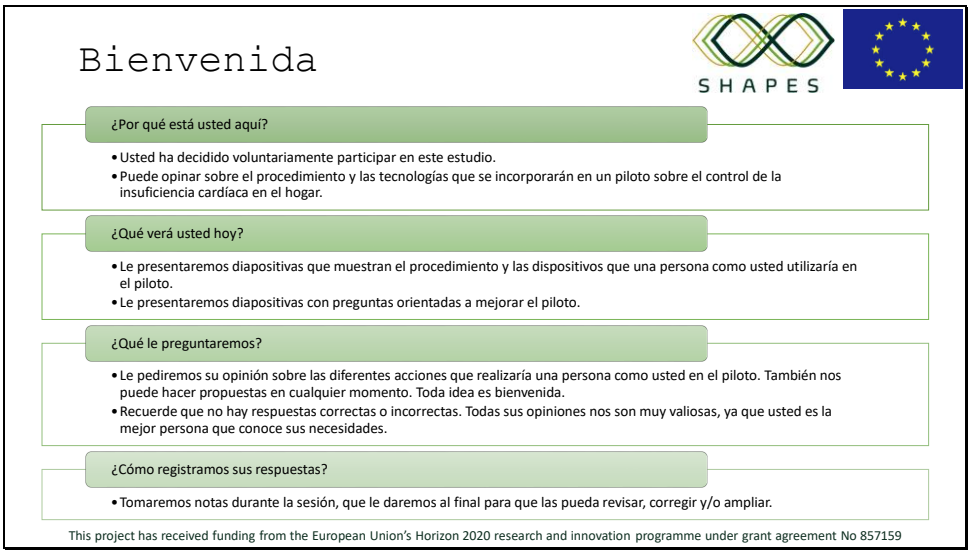
Slide 1



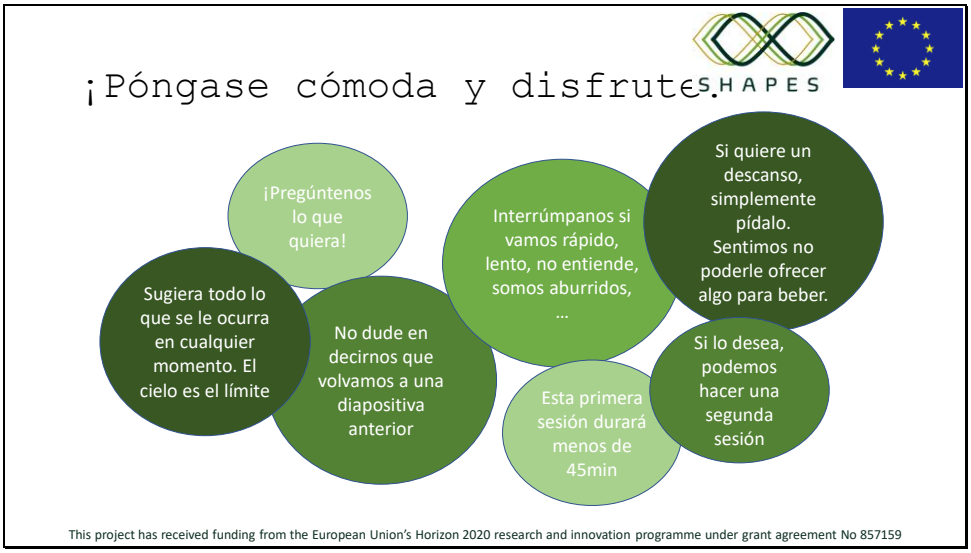
Slide 2



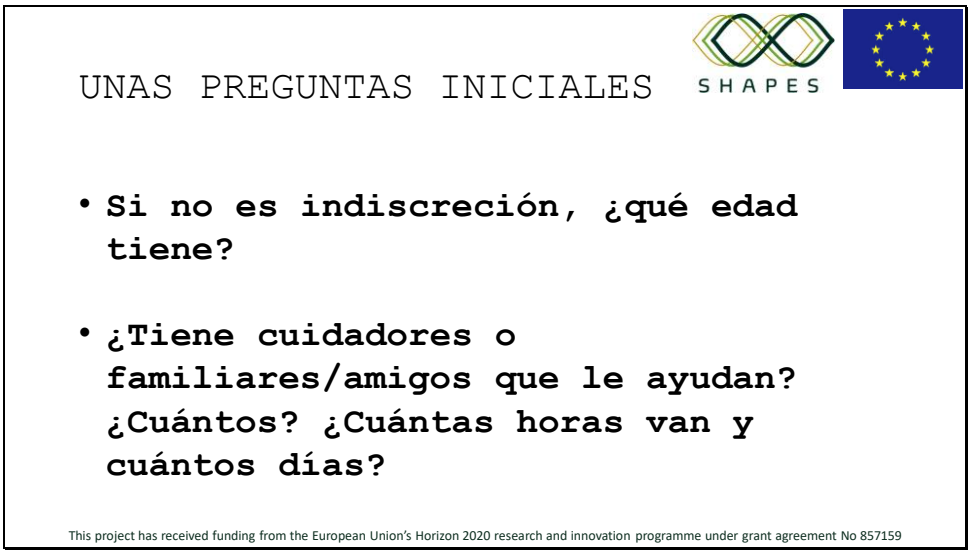
Slide 3



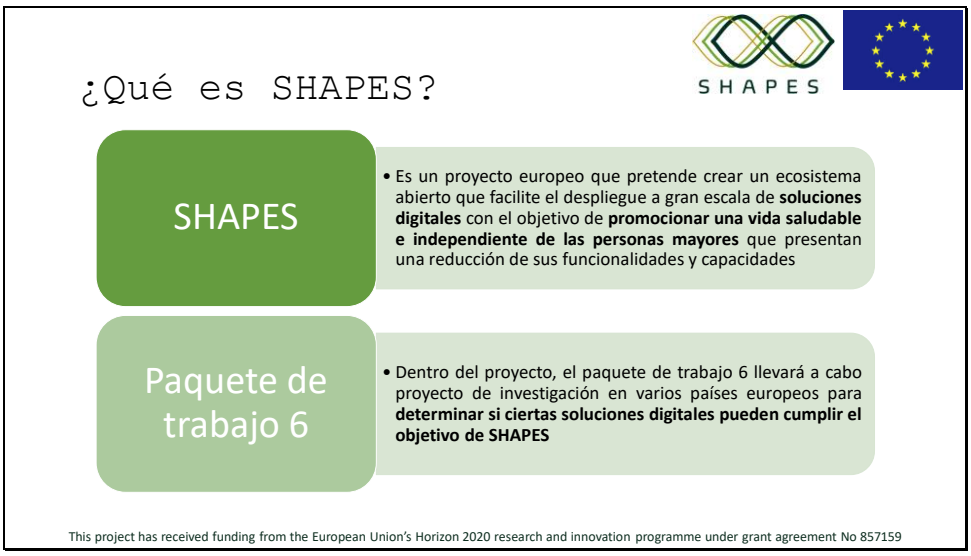
Slide 4



Slide 5



Slide 6



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Slide 7

El proyecto de investigación relacionado con esta sesión:
Predicción de la descompensación cardíaca mediante seguimiento en el hogar

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El proyecto de investigación relacionado con esta sesión:
Predicción de la descompensación cardíaca mediante seguimiento en el hogar

Clinika de Kay / Clinica Humana lidera este proyecto de investigación en SHAPES

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El proyecto de investigación relacionado con esta sesión: Predicción de la descompensación cardíaca mediante seguimiento en el hogar

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SHAPES

¿Cuál es su papel? ¿Qué tendría que hacer en el piloto si participase?

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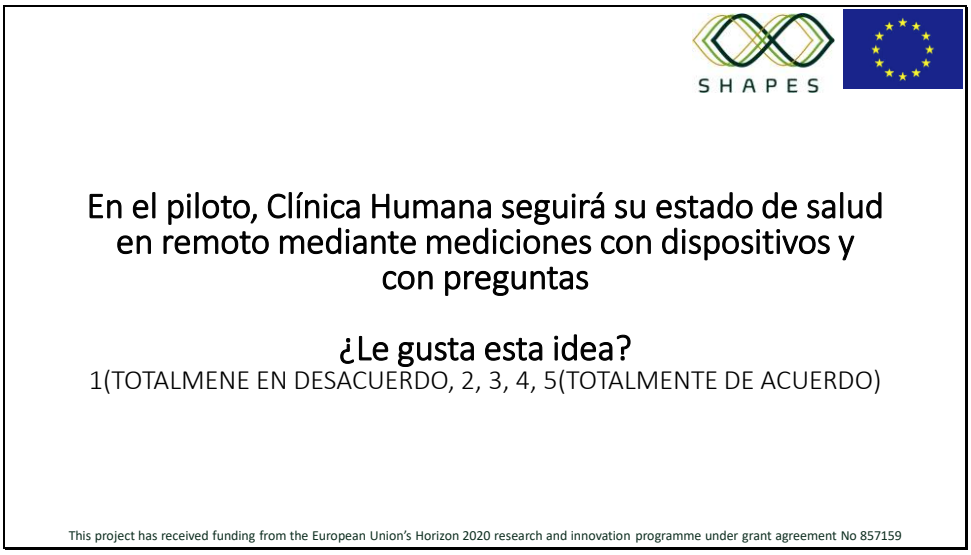
Slide 11



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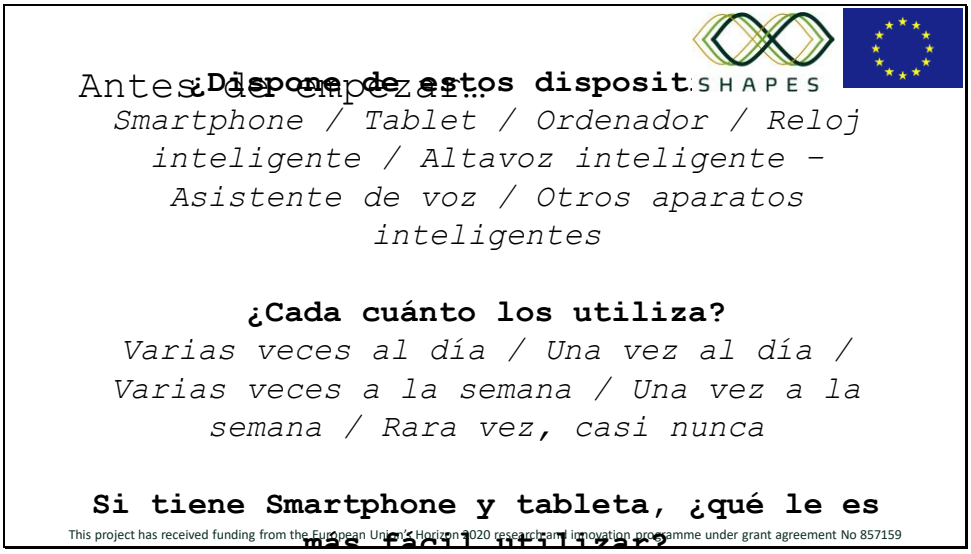

Slide 13

Antes de empezar…

Con los dispositivos que usa, ¿para qué los utiliza?

Con los dispositivos que usa más, ¿se siente cómoda al utilizarlos?

1(TOTALMENTE EN DESACUERDO), 2, 3, 4, 5(TOTALMETE DE ACUERDO)

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Slide 14

DISPOSITIVOS

Tensiómetro

Báscula

Pulsera de actividad

Pulsioxímetro

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DISPOSITIVOS




¿Conoce estos dispositivos?

¿Los ha utilizado alguna vez?

¿Los utiliza ahora regularmente? ¿Con qué frecuencia?

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DISPOSITIVOS



¿Estaría dispuesto a utilizar estos dispositivos al menos una vez al día?

Si utiliza alguno actualmente, ¿los usa usted solo o con ayuda de alguien?

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DISPOSITIVOS

¿Estaría dispuesto ha llevar el brazalete todo el día?

¿Estaría dispuesto ha llevar el brazalete también mientras duerme?

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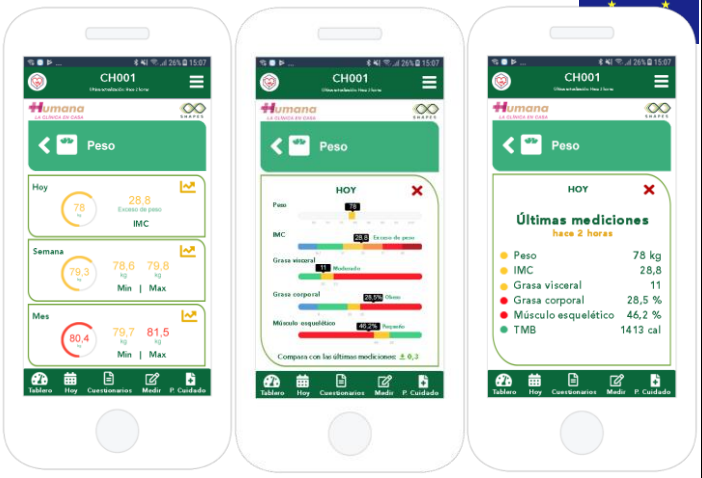
Slide 18

DISPOSITIVOS: Los datos se transferirán a su teléfono móvil y podrá verlos - PESO



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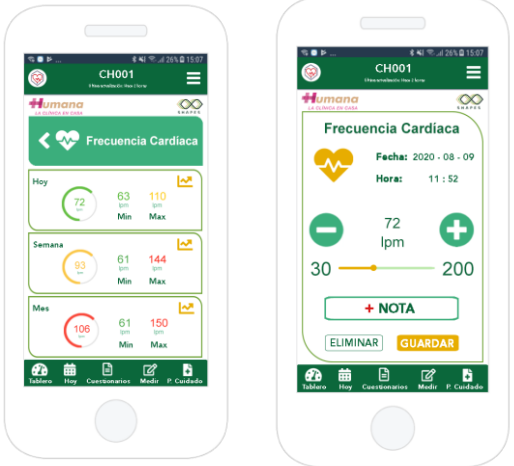
Slide 19

DISPOSITIVOS: Los datos se transferirán a su teléfono móvil y podrá verlos - FRECUENCIA CARDÍACA



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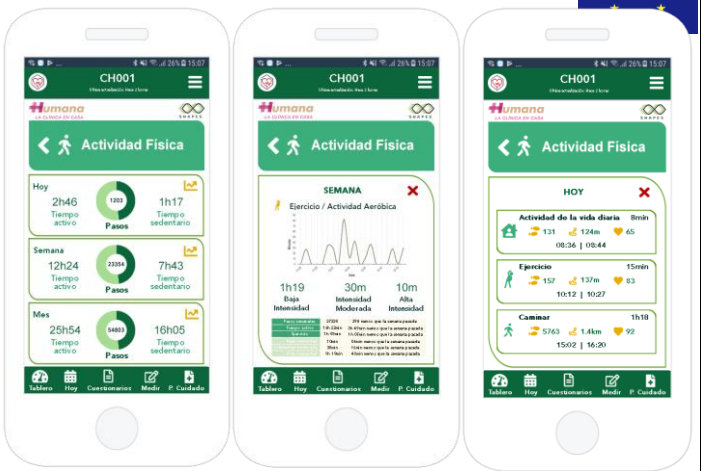
Slide 20

DISPOSITIVOS: Los datos se transferirán a su teléfono móvil y podrá verlos - ACTIVIDAD



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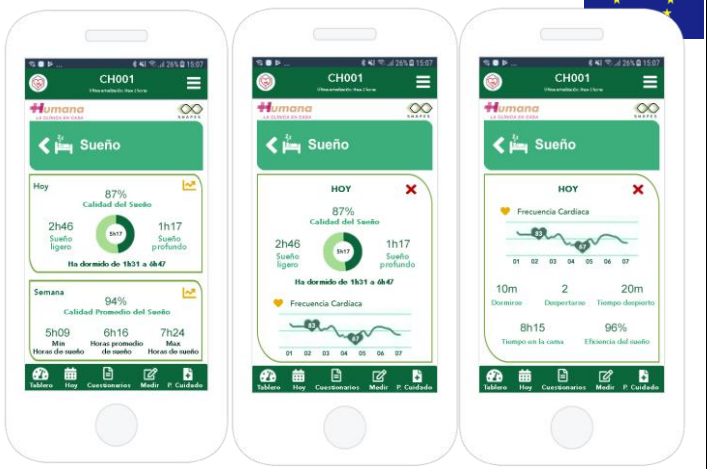
Slide 21

DISPOSITIVOS: Los datos se transferirán a su teléfono móvil y podrá verlos - SUEÑO



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DISPOSITIVOS

Siempre pude introducir los datos de forma manual

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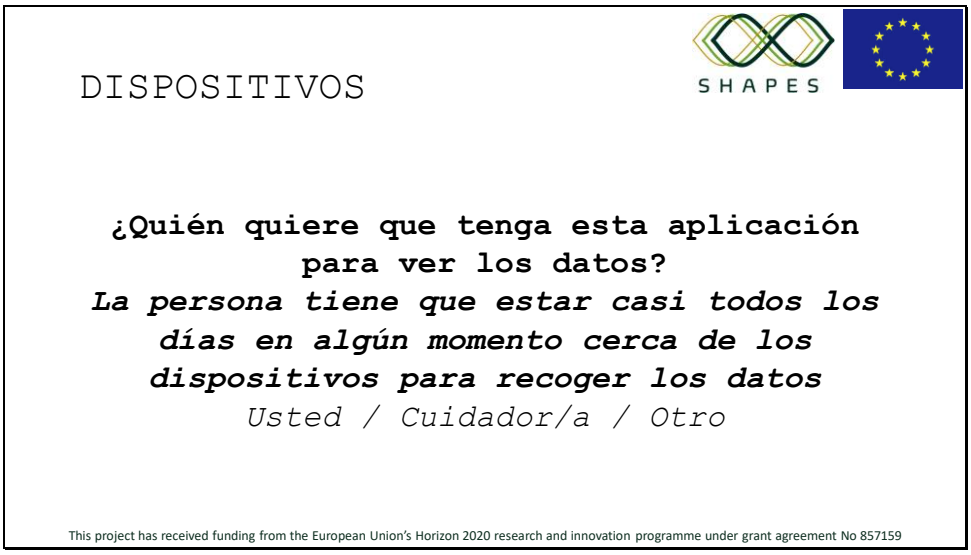

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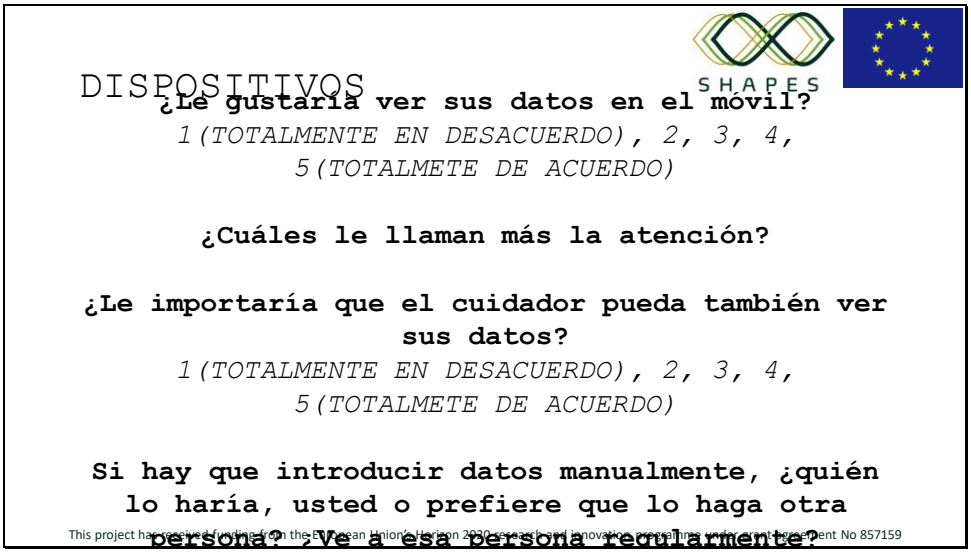

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DISPOSITIVOS

¿Le ha sido fácil entender las gráficas ?

1(TOTALMENTE EN DESACUERDO), 2, 3, 4, 5(TOTALMETE DE ACUERDO)

¿Los colores?

1(TOTALMENTE EN DESACUERDO), 2, 3, 4, 5(TOTALMETE DE ACUERDO)

¿Le interesa que se marquen los colores que indican un desvío de lo normal?

1(TOTALMENTE EN DESACUERDO), 2, 3, 4, 5(TOTALMETE DE ACUERDO)

¿El tamaño de la letra y los gráficos es el adecuado?

1(TOTALMENTE EN DESACUERDO), 2, 3, 4, 5(TOTALMETE DE ACUERDO)

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DISPOSITIVOS

¿La app móvil muestra demasiada / la justa / poca información?

Comentarios

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Preguntas de seguimiento

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PREGUNTAS: unas primeras cuestiones

¿Ha utilizado alguna vez un Chatbot o un Asistente Virtual?

SÍ / NO / Quizás, No lo sé

Si ha utilizado algún asistente virtual, seleccione la frase que mejor se ajuste

Divertido, entretenido / Aburrido / Útil / Inútil / Frustrante / Natural

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PREGUNTAS: unas primeras cuestiones

Si ha utilizado algún asistente virtual, ¿se acuerda de cuáles?

Alexa / Google Assistant / Cortana / Siri / (OTROS DESCRIBIR)

Si ha utilizado algún asistente virtual, ¿cómo ha sido la experiencia?

Muy mala / Mala / Indiferente / Buena / Muy buena

Breve explicación sobre sus experiencias

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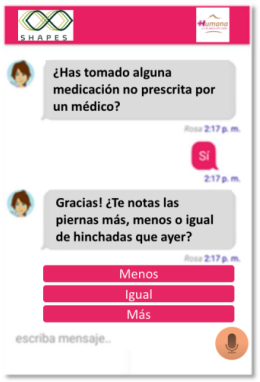
PREGUNTAS: CHATBOT



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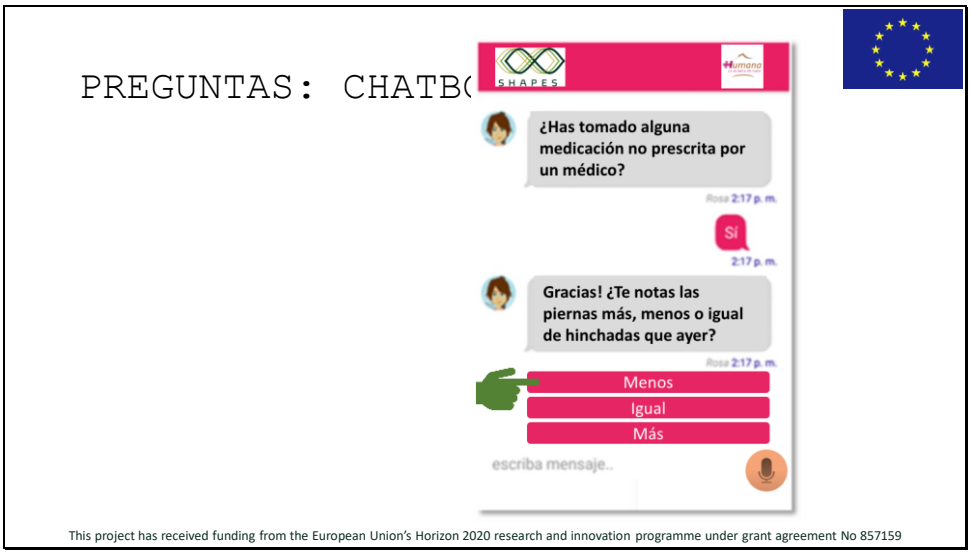

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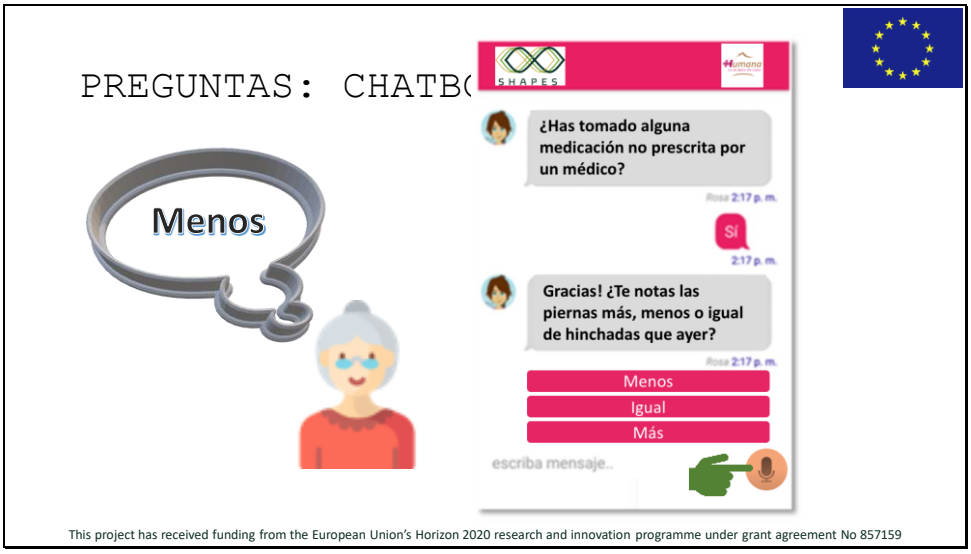
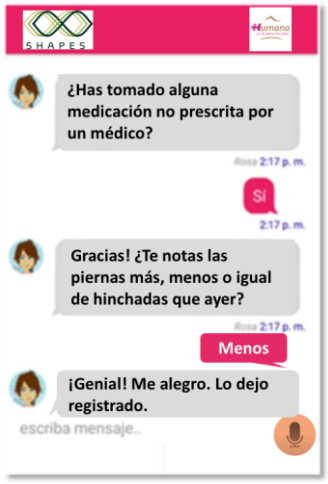


Slide 33

PREGUNTAS: CHATBO



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PREGUNTAS: CHATBOT

SHAPES

¿Utiliza WhatsApp o similar? ¿Con qué frecuencia?

Varias veces al día / Una vez al día / Varias veces a la semana / Una vez a la semana / Rara vez, casi nunca

En tal caso, ¿se siente cómoda?

1(TOTALMENTE EN DESACUERDO), 2, 3, 4, 5(TOTALMETE DE ACUERDO)

En tal caso, ¿cómo se comunica?

Texto, Voz, Ambos

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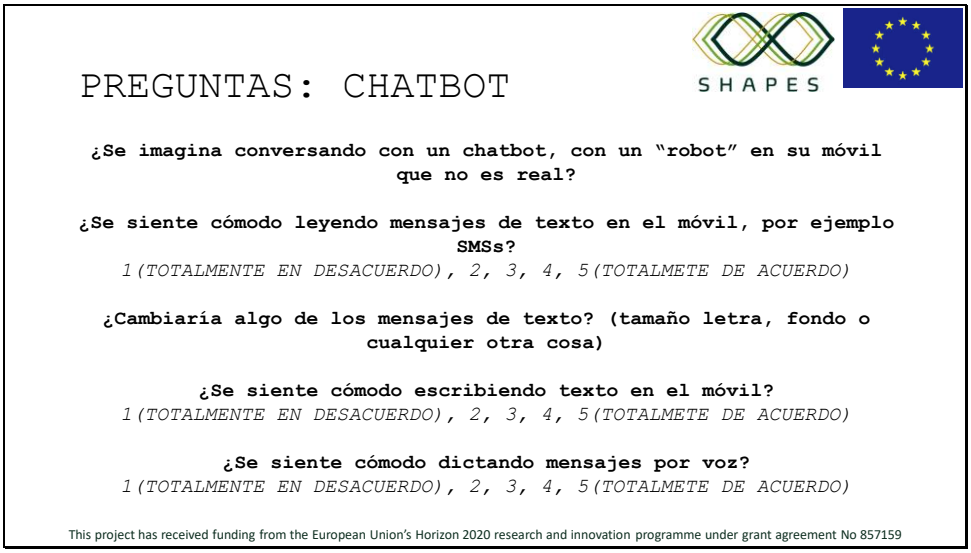

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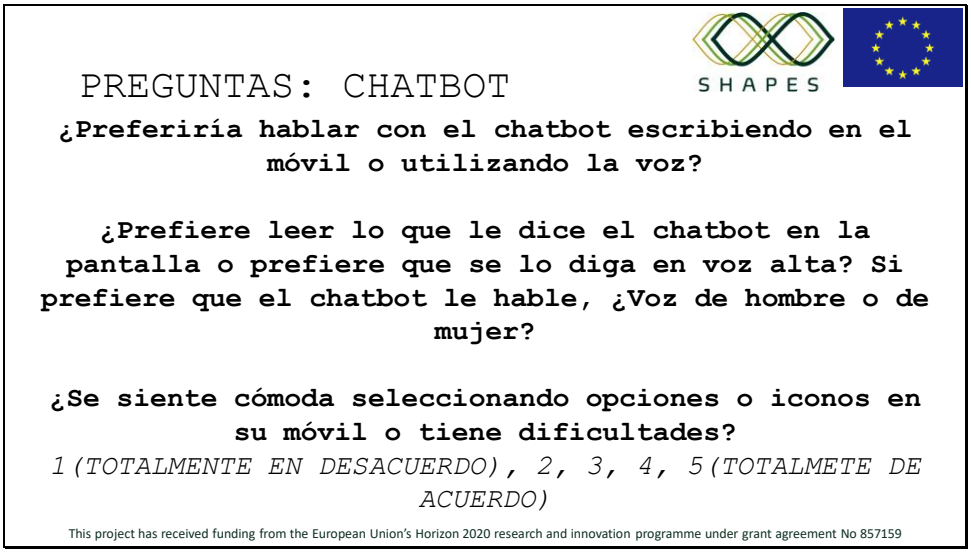

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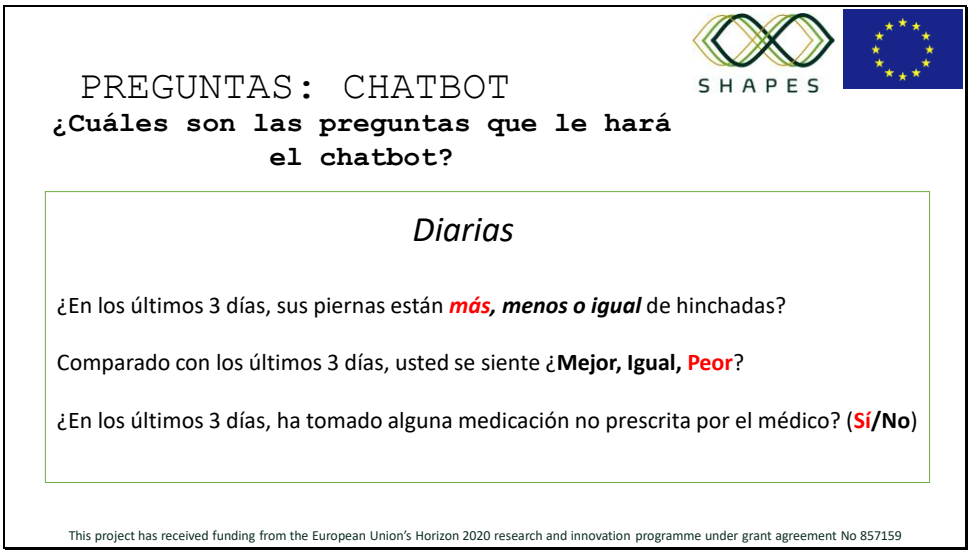

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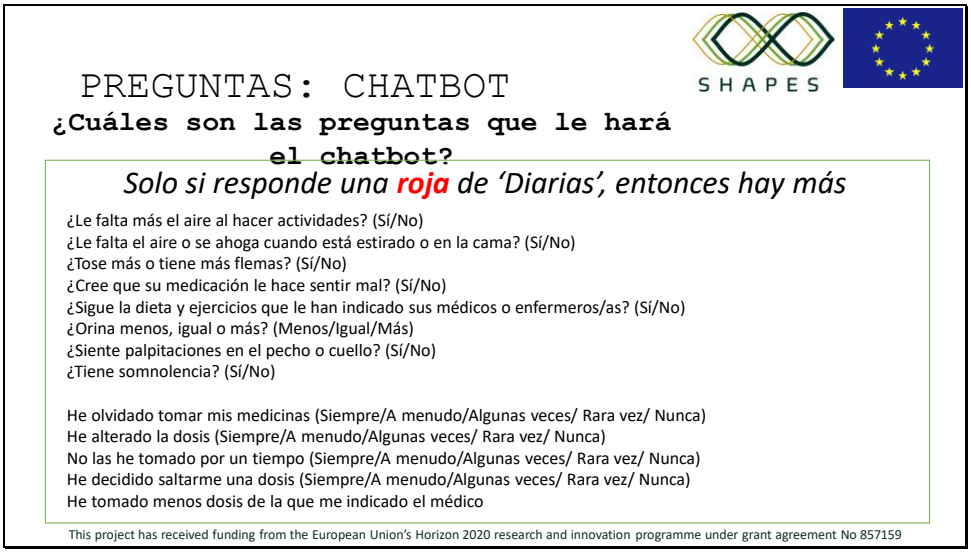

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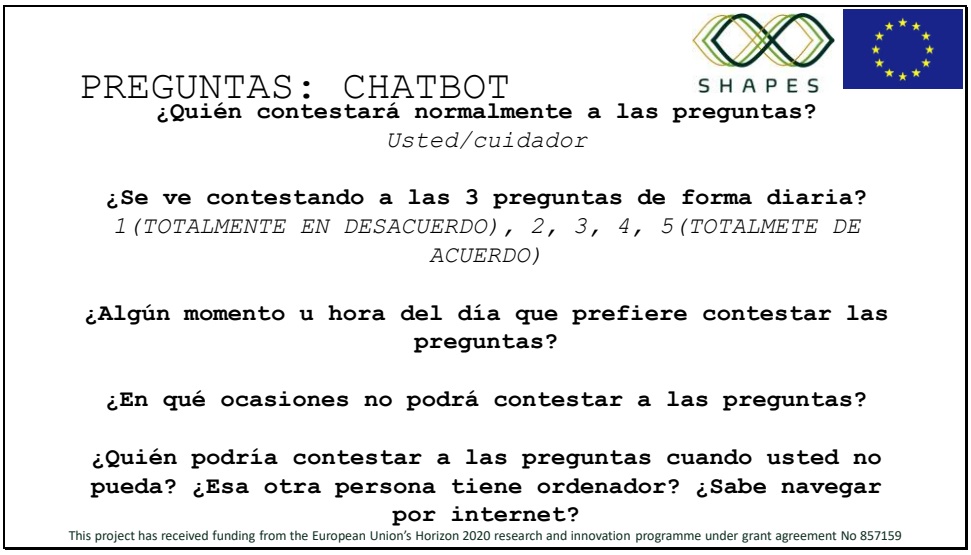

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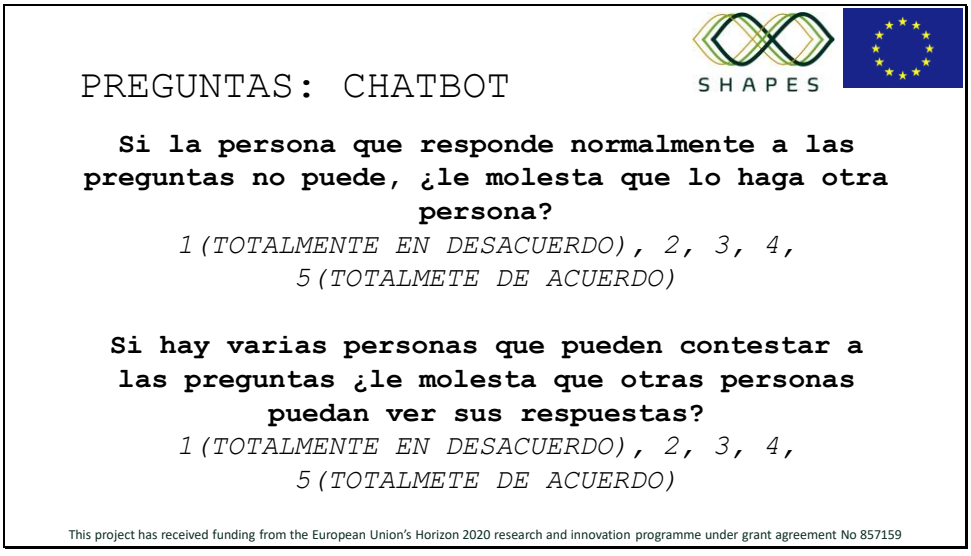

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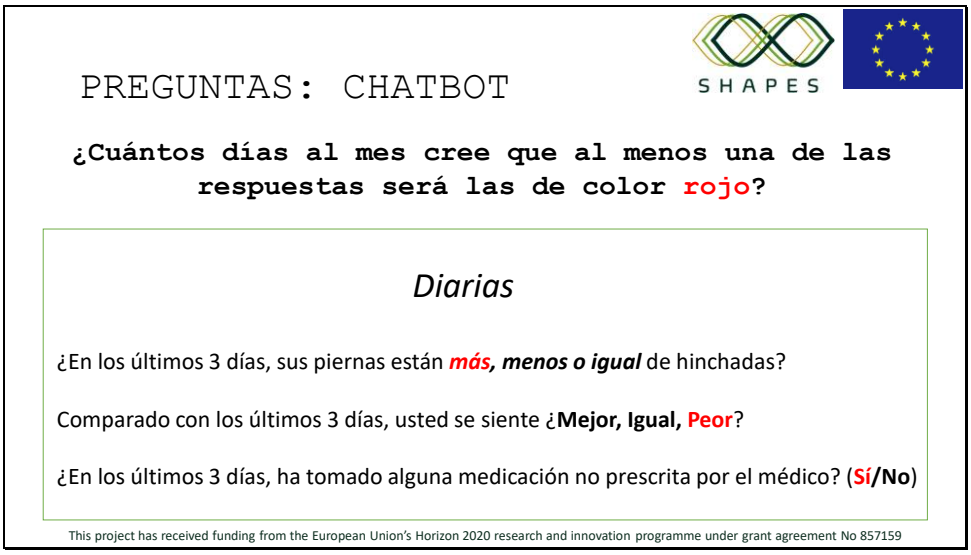

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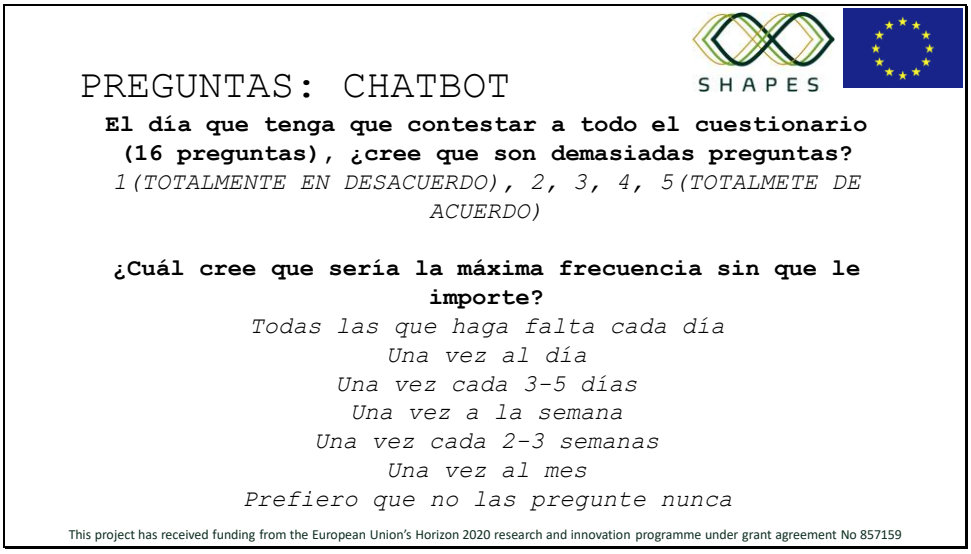

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PREGUNTAS: CHATBOT

¿Le gustaría que el chatbot le diera consejos de salud relacionados con la insuficiencia cardíaca?

1(TOTALMENTE EN DESACUERDO), 2, 3, 4, 5(TOTALMETE DE ACUERDO)

¿Le gustaría que el chatbot le hiciera recordatorios?

1(TOTALMENTE EN DESACUERDO), 2, 3, 4, 5(TOTALMETE DE ACUERDO)

¿De qué tipo? Medicación, ejercicios, pesarse, tomar tensión, tomar el oxígeno en sangre, ponerse la pulsera de actividad

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PREGUNTAS: CHATBOT

Usted también puede decirle cosas al chatbot:

"Me han cambiado la medicación"
"He ido al médico"
"Tengo nuevas analíticas"

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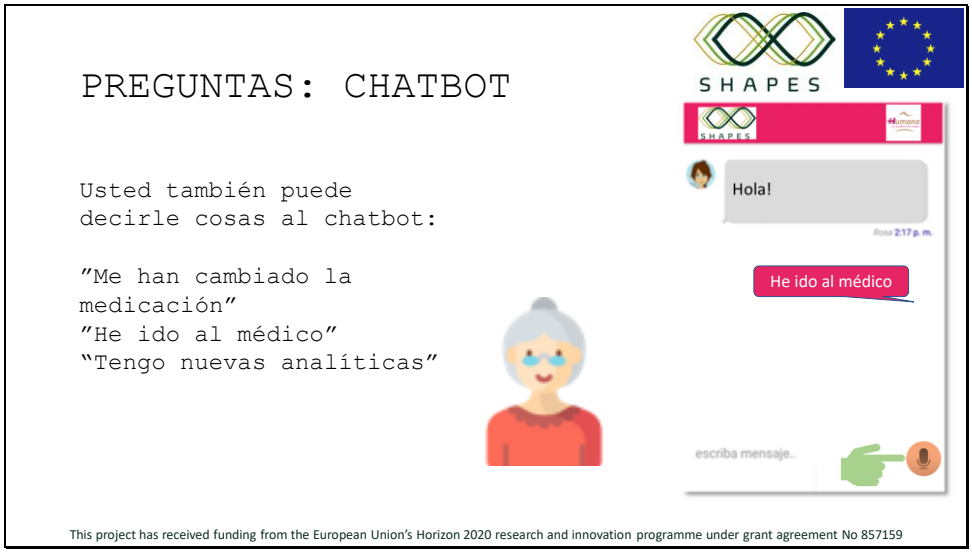
PREGUNTAS: CHATBOT
Usted también puede decirle cosas al chatbot:
”Me han cambiado la medicación”
”He ido al médico”
“Tengo nuevas analíticas”
SHAPES
Hola!
He ido al médico
escriba mensaje..
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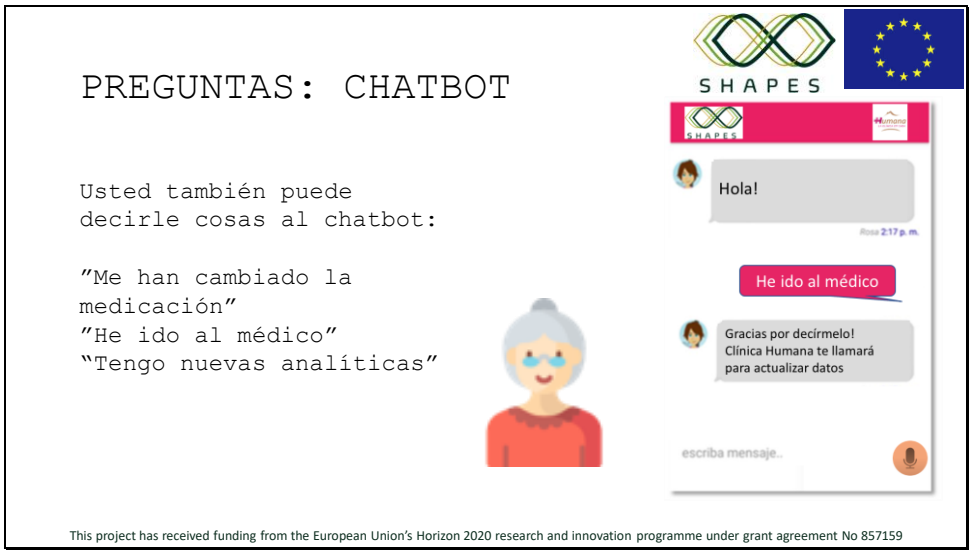
PREGUNTAS: CHATBOT
Usted también puede decirle cosas al chatbot:
”Me han cambiado la medicación”
”He ido al médico”
“Tengo nuevas analíticas”
SHAPES
Hola!
He ido al médico
Gracias por decírmelo! Clínica Humana te llamará para actualizar datos
escriba mensaje..
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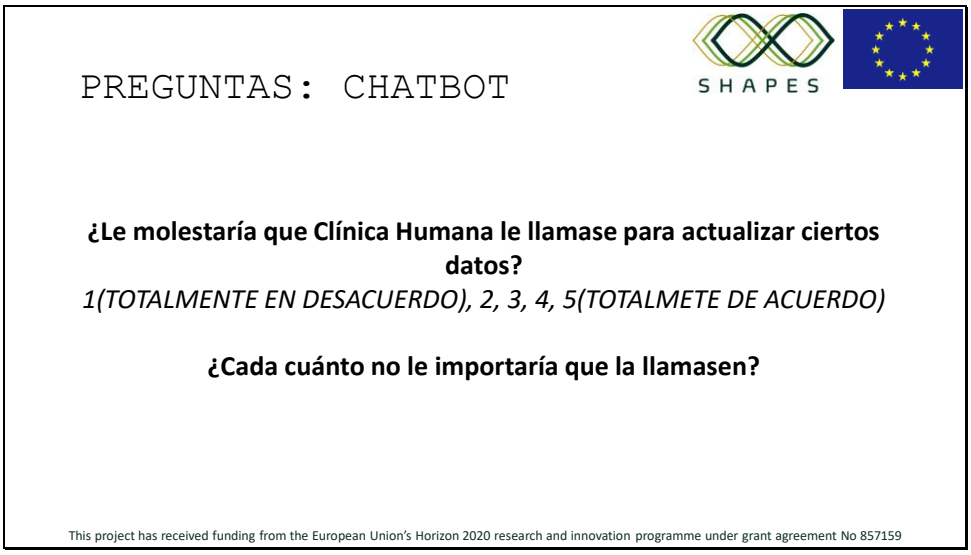

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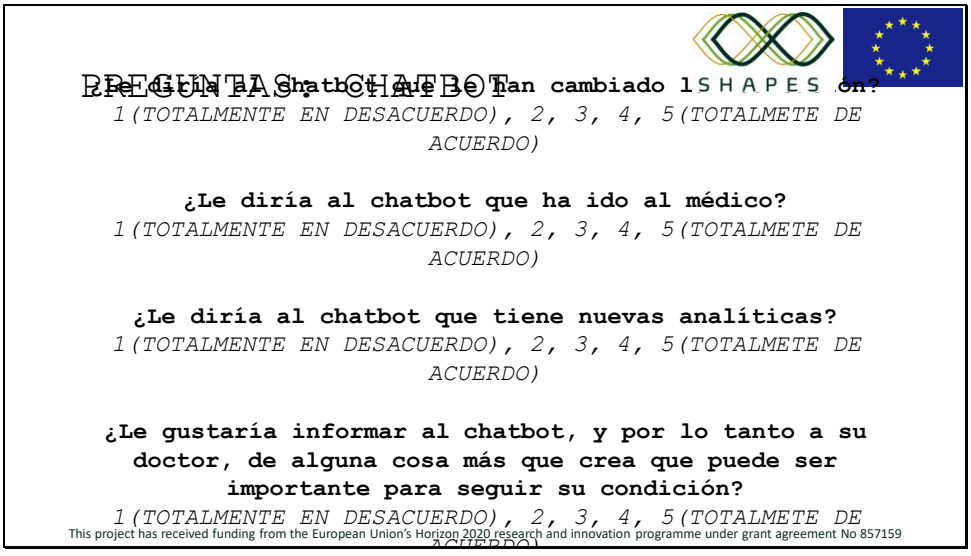

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PREGUNTAS: CHATBOT

Y si no le dice nada al chatbot sobre sus visitas médicas, analíticas o cambios de medicación, le hará una pregunta cada 1 o 2 semanas ☺

¿Quiere que le haga estas preguntas?
1(TOTALMENTE EN DESACUERDO), 2, 3, 4, 5(TOTALMETE DE ACUERDO)

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Muy bien, ¿pero como se accede a todo esto que le hemos mostrado?

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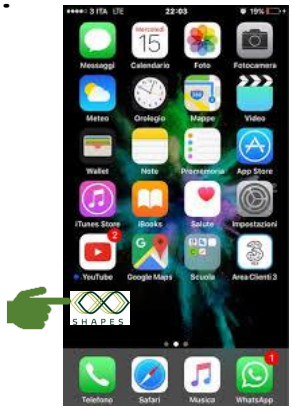
¿Cómo acceder a las aplicaciones?

Usted tendrá en su móvil una aplicación,



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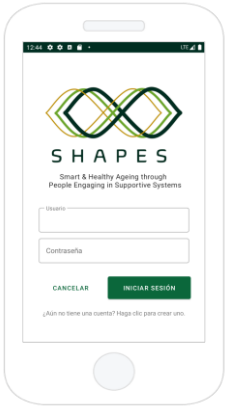
¿Cómo acceder a las aplicaciones?

…donde la primera vez tendrá que registrarse,



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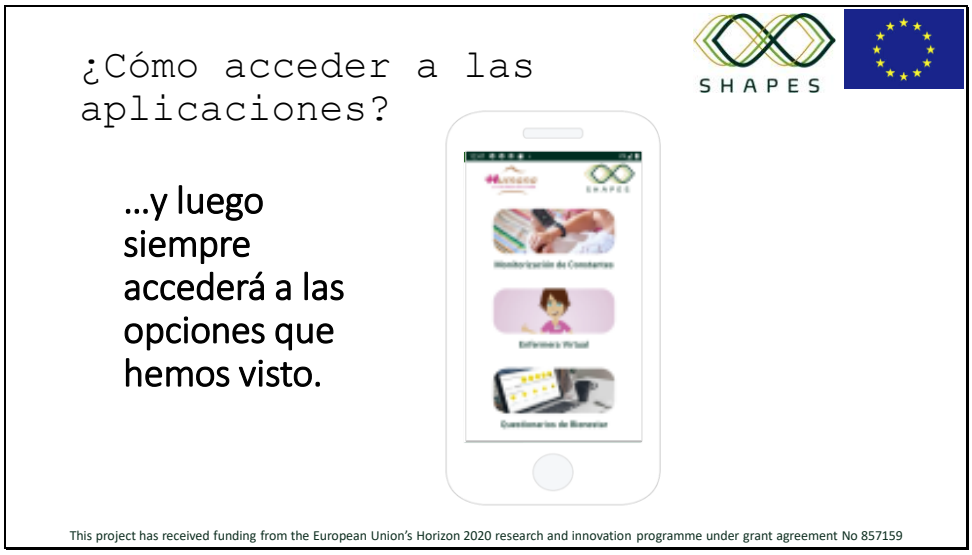
Slide 53



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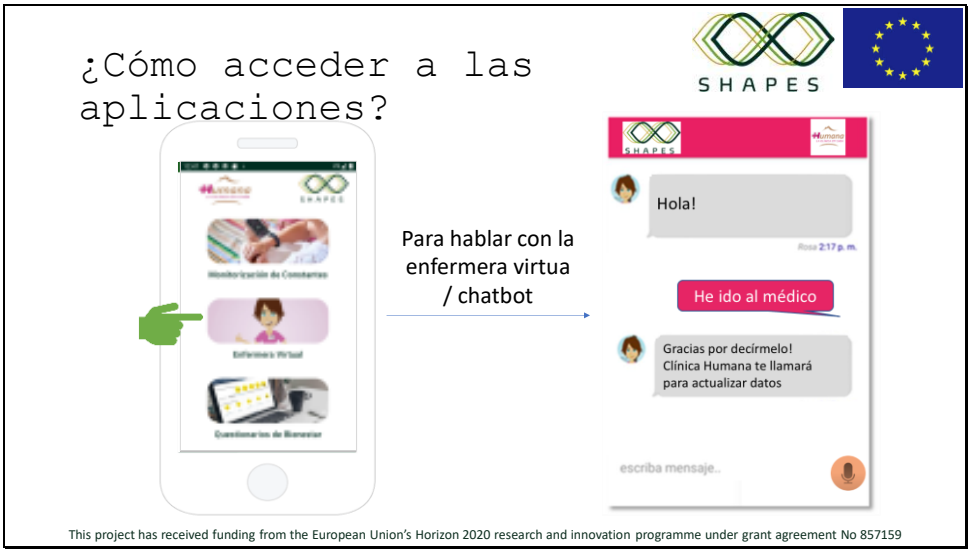
Slide 55

Slide 56



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Unas últimas pregunta

¿Sabe que son las notificaciones en el móvil?
Sí/No

¿Explíqueme qué hace cuando recibe una notificación?

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¿Alguna cosa que quiera añadir?

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CUESTIONARIO GENERAL

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CUESTIONARIO GENERAL

- **¿Le gustan las nuevas tecnologías?**

SÍ / NO / INDIFERENTE

- **¿Utilizas los siguientes métodos de comunicación por internet?**

Correo electrónico / Skype-Zoom-VideoLlamada / WhatsApp o equivalentes / Redes sociales como Facebook, Instagram / Forums de internet (poner posts)

- **¿Cómo te comunicas mejor con las nuevas tecnologías?**

Escribiendo mensajes / Tocando en la pantalla las opciones / Usando mi voz

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Y PARA ACABAR…

- **Le dejamos las notas tomadas, para que las pueda leer, reflexionar y enviarnos comentarios si lo considera conveniente**

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¿QUIERE COMENTAR ALGO SOBRE EL PROCEDIMIENTO DE LA ENTREVISTA?

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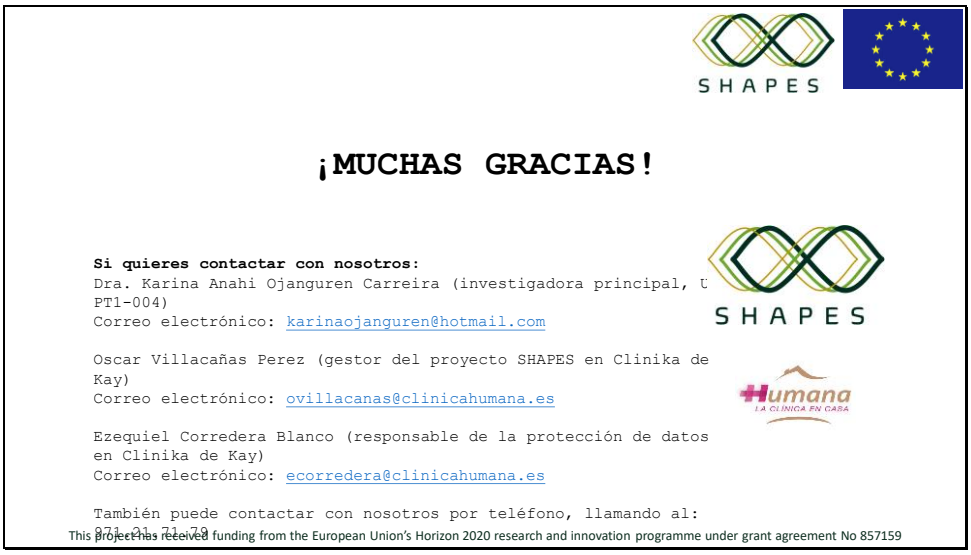
SHAPES
¡MUCHAS GRACIAS!
Si quieres contactar con nosotros:
Dra. Karina Anahi Ojanguren Carreira (investigadora principal, U
PT1-004)
Correo electrónico: karinaojanguren@hotmail.com
SHAPES
Oscar Villacañas Perez (gestor del proyecto SHAPES en Clinika de
Kay)
Correo electrónico: ovillacanas@clinicahumana.es
Humana
LA CLINICA EN CASA
Ezequiel Corredera Blanco (responsable de la protección de datos
en Clinika de Kay)
Correo electrónico: ecorredera@clinicahumana.es
También puede contactar con nosotros por teléfono, llamando al:
871 21 21 79
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Annex 33 UC-PT3-001 Phase 2 participant information sheets (older people, caregivers, and health professionals)

INFORMACIÓN PARA PARTICIPANTES DE SHAPES: persona mayor

Título del estudio: Campaña de proyectos pilotos paneuropeos en el proyecto SHAPES: participación del usuario y opinión de las soluciones digitales del piloto 3 (Optimización de la medicación), caso de uso 1 (Predicción de la descompensación cardíaca mediante seguimiento en el hogar)

Nos gustaría invitarle a participar en nuestro estudio, durante el cuál apreciaríamos conocer sus opiniones y comentarios sobre las funcionalidades y el diseño de soluciones digitales que están siendo desarrolladas para que los profesionales de la salud puedan hacer un seguimiento de personas mayores de 65 años con insuficiencia cardíaca. En concreto, nos gustaría conocer sus opiniones sobre los diferentes dispositivos (tales como tensiómetros) y aplicaciones de móviles que una persona de su perfil, o su cuidador, usaría en este escenario. Estos dispositivos y aplicaciones son los sistemas que recopilarían datos sobre su condición de insuficiencia cardíaca.

En este estudio pretendemos incluir al menos a 5 personas:

- 3 personas mayores de 65 años que tengan un alto grado de independencia, junto a sus cuidadores si da el caso
- 1 profesional de la salud
- 1 técnico informático como proveedor de asistencia técnica.

Usted ha sido identificado como una persona con el perfil adecuado para nuestro estudio, por lo que le hacemos llegar esta hoja informativa para leer y considerar si le gustaría participar.

Esta hoja informativa describe el estudio y su papel en este. Antes de que se decida en participar, es importante que entienda por qué se realiza el estudio y

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qué acciones le implican. Por favor, tome el tiempo que considere necesario para leer este documento y discutir cualquier aspecto con las personas que desee. Cualquier aspecto que no entienda, o si simplemente desea más información, por favor pregunte al investigador o a cualquiera de las personas de contacto detalladas al final de este documento, que le contactará una vez haya tenido tiempo de leer esta información.

Naturaleza voluntaria de la participación

La participación en este estudio es totalmente voluntaria. Puede abandonar el estudio en cualquier momento sin dar ninguna explicación y sin que tenga ninguna consecuencia negativa para usted.

Objeto y objetivos del estudio

Este estudio es parte de un proyecto de investigación mayor que tiene como objeto probar diferentes formas de uso de tecnologías que ayuden a las personas en sus hogares mientras envejecen.

El objetivo del estudio en el que usted ha sido invitado a participar es recoger opiniones y comentarios sobre una solución digital que permite a los profesionales de la salud realizar un seguimiento de pacientes con insuficiencia cardíaca de forma remota. Sus comentarios y opiniones serán de gran utilidad para hacer las funcionalidades útiles en un entorno real así como para investigar nuevas funcionalidades en las que no hayamos pensado y tengamos la capacidad de incorporarlas.

La versión final de la solución digital, será nuevamente compartida con los usuarios en tres ocasiones más:

- Una sesión presencial donde se podrá interaccionar con las funciones y volveremos a recoger opiniones para posibles mejoras.
- Un piloto donde se simulará la aplicación final en un entorno real controlado, donde volveremos a recoger opiniones para posibles mejoras.
- Un piloto donde se probará la solución digital en un entorno real.

¿Quién organiza y financia la investigación?

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Clinika de Kay SL, con marca Clínica Humana, organiza el estudio. Este es parte de un proyecto de investigación mayor llamado SHAPES (www.shapes2020.eu), que es financiado por el programa de investigación e innovación Horizon 2020 de la Unión Europea bajo el acuerdo de subvención No. 875159.

¿Qué implica su participación?

Si decide participar en este estudio, se le pedirá que tome parte en una entrevista a distancia mediante video-llamada a través de internet. En la video-llamada puede participar su cuidador. Por parte de Clinika de Kay, en la video-llamada participará un gestor del proyecto, que le hará la entrevista, y un auxiliar para tomar notas, ambos personal de Clinika de Kay. Si así lo desea, el auxiliar puede estar presencialmente con usted para ayudarle en cualquier aspecto durante la entrevista.

¿Qué pasará exactamente?

Toma de consentimiento

- Después de que haya tenido tiempo de leer la información contenida en este documento, puede contactar con cualquiera de los contactos de Clinika de Kay al final de este documento para cualquier aclaración.
- Si quiere participar en el estudio, rellene con su nombre, fecha y firme el consentimiento informado y devuélvalo a Clínika de Kay por correo electrónico a ovillacanas@clinicahumana.es o entréguelo en mano a cualquiera de los administradores de Clinika de Kay (Jose Eduardo Carrasco Alberti o la Dra. Karina Ojanguren Carreira).
- Si nos devuelve el consentimiento por correo electrónico, el mismo se utilizará para devolverle una copia del documento firmado por el gestor del proyecto SHAPES en Clinika de Kay, reconociendo la recepción del documento. Si nos devuelve el consentimiento en mano, asumimos que desea que Clinika de Kay comparta su dirección habitual y teléfono con los miembros de este estudio con el único fin de aportarle otra información requerida relacionada con este estudio, incluyendo una copia del consentimiento firmada por el gestor del proyecto SHAPES en Clinka de Kay.

Antes de la video-llamada

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- El gestor del proyecto SHAPES o uno de los administradores de Clinika de Kay se pondrá en contacto con usted para acordar un día y una hora para realizar la primera video-llamada.
- Un miembro de Clinika de Kay se pondrá en contacto con usted y comprobará que dispone de la tecnología necesaria para realizar la video-llamada y le explicará, si es necesario, cómo utilizarla.
- La persona de Clinika de Kay que se ponga en contacto con usted, le notificará el perfil de las personas que asistirán a la llamada en relación a la entrevista, pudiendo haber más de un usuario final. A este momento, puede opinar sobre la composición de los componentes y sugerir cambios para adaptarnos a sus necesidades y comodidad.

Durante la video-llamada

- Durante la video-llamada se le mostrará información sobre el estudio y el proyecto SHAPES.
- A continuación, para poner en contexto con la tecnología, se le hará una breve descripción del caso de uso en el que el presente estudio de investigación se enmarca.
- A continuación se le preguntará sobre su edad y si tiene cuidadores.
- A continuación, se le mostrarán unas diapositivas, figuras y textos descriptivos sobre diversas funcionalidades de la solución digital, como se utiliza en el piloto y las acciones que debería realizar una persona de su perfil.
- Después de cada grupo de diapositivas relacionadas con una funcionalidad concreta, el presentador le hará una serie de preguntas para recoger su opinión sobre la funcionalidad y su conocimiento sobre la situación en la que se aplica la funcionalidad. Algunas respuestas serán cerradas (por ejemplo, “¿le gusta que le hagan un cuestionario de seguimiento cada día? Sí, No, No estoy seguro”) y otras abiertas (por ejemplo, “¿qué tipo de recordatorios cree que necesita?”). En ningún caso está obligado a responder y siempre puede añadir comentarios aun siendo la respuesta cerrada.
- En todo caso, las preguntas no son un test o prueba, y no hay respuestas correctas o incorrectas. Nuestra intención es conocer su opinión honesta sobre lo que le mostramos.
- El presentador y/o un auxiliar tomarán notas durante la video-llamada.
- La video-llamada no debería durar más de 45 minutos. Trabajaremos a su ritmo y puede tomar los descansos que considere oportunos.
- Al final de la llamada le dejaremos una copia de los siguientes documentos:
    - Las diapositivas presentadas en la video-llamada con las notas tomadas por Clinika de Kay superpuestas. Puede revisar las diapositivas con sus notas para revisarlas, sugerir cambios o añadir más comentarios que nos puede hacer llegar en cualquier momento.

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Después de la video-llamada

- Puede modificar y completar las respuestas dadas durante la video-llamada en el documento aportado y hacérnoslas llegar.
- Si prefiere, en vez de entregarnos las aportaciones en el documento anterior, podemos realizar otra video-llamada para recoger sus opiniones surgidas. Para realizarlo de este modo, tiene que ponerse en contacto con nosotros.
- Al final del proceso se le entregará un resumen de los resultados de este estudio.
- Después de entregarle los resultados, el mail o dirección postal aportados se borrarán, o se desligará de este estudio de investigación si mantiene otras relaciones con Clinika de Kay

Datos recogidos durante este proyecto de investigación

- Los únicos datos personales que se recogerán de usted serán:
  - Su nombre para identificar el consentimiento informado
  - Su correo electrónico (opcional) para contactar con usted y enviarle información
  - Su dirección postal (opcional) para contactar con usted y enviarle información
  - Su teléfono (opcional) para contactar con usted
- Todos los documentos generados, se guardarán solamente en un servidor de Clinika de Kay, con acceso protegido con contraseña únicamente a las personas especificadas al final de este documento. El correo electrónico se guardará también en el servidor de correo de Clinika de Kay. Como copias de los documentos, solo existirán las que transfiramos a usted por correo electrónico y las que le proporcionemos en papel, si así nos lo ha solicitado.
- Si usted menciona cualquier dato durante la entrevista que le pudiera identificar, no se registrará en las notas o se registrará de forma anonimizada.
- Los resultados anonimizados pueden ser usados en futuras investigaciones y/o en actividades de comunicación (por ejemplo, como parte de otras investigaciones dentro del proyecto SHAPES, en artículos de revistas, congresos y conferencias).
- Sus datos personales serán destruidos una vez se le haya proporcionado los resultados de este estudio. Si usted tiene cualquier otro tipo de relación con Clinika de Kay, solo se desligarán sus datos personales en lo relacionado a este estudio.
- Puede pedir la destrucción de sus datos personales en cualquier momento.
- Los datos anonimizados se guardarán durante la duración del proyecto SHAPES (actualmente, sin contar con posibles extensiones, hasta octubre de 2023) y durante 5 (cinco) años después de la finalización del proyecto.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Posibles beneficios por participar

No existen beneficios directos a nivel individual por participar en este estudio, más allá del interés personal y la experiencia de participar en un estudio. Sin embargo, el beneficio indirecto de este estudio es que sus opiniones y puntos de vista serán usados para mejorar las funcionalidades de la solución digital. Su aportación también será valiosa para el uso de tecnologías en la ayuda de personas mayores con insuficiencia cardíaca en sus hogares. Personas de toda Europa se beneficiarán de su participación.

Posibles inconvenientes por participar

No prevemos que usted sufra ningún inconveniente por participar en este estudio.

Hallazgos incidentales

Los hallazgos incidentales son los descubrimientos que se pueden dar en el estudio sin que este haya sido diseñado para estos fines. En el presente estudio de investigación no se espera encontrar ningún tipo de hallazgo incidental.

Información de costes y compensación económica

La participación en este estudio no le incurrirá ningún coste siempre que la video-llamada entre en su plan de datos de internet. Si esto supone una barrera para usted, comuníquenoslo y aportaremos nuestra propia conexión a internet sin ningún coste para usted. Usted no recibirá ninguna compensación económica por su participación.

Información sobre los resultados del estudio

Los resultados de este estudio pueden ser utilizados en futuras investigaciones y/o en actividades de comunicación (por ejemplo, como parte de otras investigaciones dentro del proyecto SHAPES, en artículos de revistas, congresos y conferencias). Se le enviarán por correo electrónico o a su dirección postal los resultados del estudio.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Interrupción del estudio

Las personas de Clinika de Kay que intervienen en este estudio pueden interrumpirlo de forma permanente, sin finalizar, en cualquier momento. Sin embargo, actualmente, no existen razones para que este hecho ocurra. Si quiere salir del estudio, puede pedirlo en cualquier momento a cualquiera de los contactos que encontrará al final del documento. Siempre podremos seguir utilizando sus datos de forma anonimizada.

Más información

Puede pedir en cualquier momento más información a través de los contactos proporcionados al final de este documento

Datos de contacto del personal de Clinika de Kay asociado a este estudio

Dra. Karina Anahi Ojanguren Carreira (investigadora principal)

Correo electrónico: karinaojanguren@hotmail.com

Oscar Villacañas Perez (gestor del proyecto SHAPES)

Correo electrónico: ovillacanas@clinicahumana.es

Ezequiel Corredera Blanco (responsable de la protección de datos)

Correo electrónico: ecorredera@clinicahumana.es

También puede contactar con nosotros por teléfono, llamando al: 971.21.71.79 ☎

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INFORMACIÓN PARA PARTICIPANTES DE SHAPES: cuidador

Título del estudio: Campaña de proyectos pilotos paneuropeos en el proyecto SHAPES: participación del usuario y opinión de las soluciones digitales del piloto 3 (Optimización de la medicación), caso de uso 1 (Predicción de la descompensación cardíaca mediante seguimiento en el hogar)

Nos gustaría invitarle a participar en nuestro estudio, durante el cuál apreciaríamos conocer sus opiniones y comentarios sobre las funcionalidades y el diseño de soluciones digitales que están siendo desarrolladas para que los profesionales de la salud puedan hacer un seguimiento de personas mayores de 65 años con insuficiencia cardíaca. En concreto, nos gustaría conocer sus opiniones sobre los diferentes dispositivos (tales como tensiómetros) y aplicaciones de móviles que una persona mayor o su cuidador usarían en este escenario. Estos dispositivos y aplicaciones son los sistemas que recopilarían datos sobre la condición de insuficiencia cardíaca.

En este estudio pretendemos incluir al menos a 5 personas:

- 3 personas mayores de 65 años que tengan un alto grado de independencia, junto a sus cuidadores si da el caso
- 1 profesional de la salud
- 1 técnico informático como proveedor de asistencia técnica.

Usted ha sido identificado como una persona con el perfil adecuado para nuestro estudio, por lo que le hacemos llegar esta hoja informativa para leer y considerar si le gustaría participar.

Esta hoja informativa describe el estudio y su papel en este. Antes de que se decida en participar, es importante que entienda por qué se realiza el estudio y qué acciones le implican. Por favor, tome el tiempo que considere necesario para leer este documento y discutir cualquier aspecto con las personas que desee. Cualquier aspecto que no entienda, o si simplemente desea más información, por favor pregunte al investigador o a cualquiera de las personas de contacto detalladas al final de este documento, que le contactará una vez haya tenido tiempo de leer esta información.

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Naturaleza voluntaria de la participación

La participación en este estudio es totalmente voluntaria. Puede abandonar el estudio en cualquier momento sin dar ninguna explicación y sin que tenga ninguna consecuencia negativa para usted.

Objeto y objetivos del estudio

Este estudio es parte de un proyecto de investigación mayor que tiene como objeto probar diferentes formas de uso de tecnologías que ayuden a las personas en sus hogares mientras envejecen.

El objetivo del estudio en el que usted ha sido invitado a participar es recoger opiniones y comentarios sobre una solución digital que permite a los profesionales de la salud realizar un seguimiento de pacientes con insuficiencia cardíaca de forma remota. Sus comentarios y opiniones serán de gran utilidad para hacer las funcionalidades útiles en un entorno real así como para investigar nuevas funcionalidades en las que no hayamos pensado y tengamos la capacidad de incorporarlas.

La versión final de la solución digital, será nuevamente compartida con los usuarios en tres ocasiones más:

- Una sesión presencial donde se podrá interaccionar con las funciones y volveremos a recoger opiniones para posibles mejoras.
- Un piloto donde se simulará la aplicación final en un entorno real controlado, donde volveremos a recoger opiniones para posibles mejoras.
- Un piloto donde se probará la solución digital en un entorno real.

¿Quién organiza y financia la investigación?

Clinika de Kay SL, con marca Clínica Humana, organiza el estudio. Este es parte de un proyecto de investigación mayor llamado SHAPES (www.shapes2020.eu), que es financiado por el programa de investigación e innovación Horizon 2020 de la Unión Europea bajo el acuerdo de subvención No. 875159.

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¿Qué implica su participación?

Si decide participar en este estudio, se le pedirá que tome parte en una entrevista a distancia mediante video-llamada a través de internet. En la video-llamada participará la persona mayor que cuida. Por parte de Clinika de Kay, en la video-llamada participará un gestor del proyecto, que le hará la entrevista, y un auxiliar para tomar notas, ambos personal de Clinika de Kay. Si así lo desea, el auxiliar puede estar presencialmente con usted para ayudarle en cualquier aspecto durante la entrevista.

¿Qué pasará exactamente?

Toma de consentimiento

- Después de que haya tenido tiempo de leer la información contenida en este documento, puede contactar con cualquiera de los contactos de Clinika de Kay al final de este documento para cualquier aclaración.
- Si quiere participar en el estudio, rellene con su nombre, fecha y firme el consentimiento informado y devuélvalo a Clínika de Kay por correo electrónico a ovillacanas@clinicahumana.es o entréguelo en mano a cualquiera de los administradores de Clinika de Kay (Jose Eduardo Carrasco Alberti o la Dra. Karina Ojanguren Carreira).
- Si nos devuelve el consentimiento por correo electrónico, el mismo se utilizará para devolverle una copia del documento firmado por el gestor del proyecto SHAPES en Clinika de Kay, reconociendo la recepción del documento. Si nos devuelve el consentimiento en mano, asumimos que desea que Clinika de Kay comparta su dirección habitual y teléfono con los miembros de este estudio con el único fin de aportarle otra información requerida relacionada con este estudio, incluyendo una copia del consentimiento firmada por el gestor del proyecto SHAPES en Clinka de Kay.

Antes de la video-llamada

- El gestor del proyecto SHAPES o uno de los administradores de Clinika de Kay se pondrá en contacto con usted para acordar un día y una hora para realizar la primera video-llamada.
- Un miembro de Clinika de Kay se pondrá en contacto con usted y comprobará que dispone de la tecnología necesaria para realizar la video-llamada y le explicará, si es necesario, cómo utilizarla.
- La persona de Clinika de Kay que se ponga en contacto con usted, le

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notificará el perfil de las personas que asistirán a la llamada en relación a la entrevista, pudiendo haber más de un usuario final. A este momento, puede opinar sobre la composición de los componentes y sugerir cambios para adaptarnos a sus necesidades y comodidad.

Durante la video-llamada

- Durante la video-llamada se le mostrará información sobre el estudio y el proyecto SHAPES.
- A continuación, para poner en contexto con la tecnología, se le hará una breve descripción del caso de uso en el que el presente estudio de investigación se enmarca.
- A continuación se le preguntará sobre su dedicación y experiencia como cuidador.
- A continuación, se le mostrarán unas diapositivas, figuras y textos descriptivos sobre diversas funcionalidades de la solución digital, como se utiliza en el piloto y las acciones que debería realizar una persona de su perfil.
- Después de cada grupo de diapositivas relacionadas con una funcionalidad concreta, el presentador le hará una serie de preguntas para recoger su opinión sobre la funcionalidad y su conocimiento sobre la situación en la que se aplica la funcionalidad. Algunas respuestas serán cerradas (por ejemplo, “¿le gusta que le hagan un cuestionario de seguimiento cada día? Sí, No, No estoy seguro”) y otras abiertas (por ejemplo, “¿qué tipo de recordatorios cree que necesita?”). En ningún caso está obligado a responder y siempre puede añadir comentarios aun siendo la respuesta cerrada.
- En todo caso, las preguntas no son un test o prueba, y no hay respuestas correctas o incorrectas. Nuestra intención es conocer su opinión honesta sobre lo que le mostramos.
- El presentador y/o un auxiliar tomarán notas durante la video-llamada.
- La video-llamada no debería durar más de 45 minutos. Trabajaremos a su ritmo y puede tomar los descansos que considere oportunos.
- Al final de la llamada le dejaremos una copia de los siguientes documentos:
    - Las diapositivas presentadas en la video-llamada con las notas tomadas por Clinika de Kay superpuestas. Puede revisar las diapositivas con sus notas para revisarlas, sugerir cambios o añadir más comentarios que nos puede hacer llegar en cualquier momento.

Después de la video-llamada

- Puede modificar y completar las respuestas dadas durante la video-llamada en el documento aportado y hacérnoslas llegar.
- Si prefiere, en vez de entregarnos las aportaciones en el documento anterior, podemos realizar otra video-llamada para recoger sus opiniones

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surgidas. Para realizarlo de este modo, tiene que ponerse en contacto con nosotros.
- Al final del proceso se le entregará un resumen de los resultados de este estudio.
- Después de entregarle los resultados, el mail o dirección postal aportados se borrarán, o se desligará de este estudio de investigación si mantiene otras relaciones con Clinika de Kay

Datos recogidos durante este proyecto de investigación

- Los únicos datos personales que se recogerán de usted serán:
  - Su nombre para identificar el consentimiento informado
  - Su correo electrónico (opcional) para contactar con usted y enviarle información
  - Su dirección postal (opcional) para contactar con usted y enviarle información
  - Su teléfono (opcional) para contactar con usted
- Todos los documentos generados, se guardarán solamente en un servidor de Clinika de Kay, con acceso protegido con contraseña únicamente a las personas especificadas al final de este documento. El correo electrónico se guardará también en el servidor de correo de Clinika de Kay. Como copias de los documentos, solo existirán las que transfiramos a usted por correo electrónico y las que le proporcionemos en papel, si así nos lo ha solicitado.
- Si usted menciona cualquier dato durante la entrevista que le pudiera identificar, no se registrará en las notas o se registrará de forma anonimizada.
- Los resultados anonimizados pueden ser usados en futuras investigaciones y/o en actividades de comunicación (por ejemplo, como parte de otras investigaciones dentro del proyecto SHAPES, en artículos de revistas, congresos y conferencias).
- Sus datos personales serán destruidos una vez se le haya proporcionado los resultados de este estudio. Si usted tiene cualquier otro tipo de relación con Clinika de Kay, solo se desligarán sus datos personales en lo relacionado a este estudio.
- Puede pedir la destrucción de sus datos personales en cualquier momento.
- Los datos anonimizados se guardarán durante la duración del proyecto SHAPES (actualmente, sin contar con posibles extensiones, hasta octubre de 2023) y durante 5 (cinco) años después de la finalización del proyecto.

Posibles beneficios por participar

No existen beneficios directos a nivel individual por participar en este estudio, más allá del interés personal y la experiencia de participar en un estudio. Sin

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embargo, el beneficio indirecto de este estudio es que sus opiniones y puntos de vista serán usados para mejorar las funcionalidades de la solución digital. Su aportación también será valiosa para el uso de tecnologías en la ayuda de personas mayores con insuficiencia cardíaca en sus hogares. Personas de toda Europa se beneficiarán de su participación.

Posibles inconvenientes por participar

No prevemos que usted sufra ningún inconveniente por participar en este estudio.

Hallazgos incidentales

Los hallazgos incidentales son los descubrimientos que se pueden dar en el estudio sin que este haya sido diseñado para estos fines. En el presente estudio de investigación no se espera encontrar ningún tipo de hallazgo incidental.

Información de costes y compensación económica

La participación en este estudio no le incurrirá ningún coste siempre que la video-llamada entre en su plan de datos de internet. Si esto supone una barrera para usted, comuníquenoslo y aportaremos nuestra propia conexión a internet sin ningún coste para usted. Usted no recibirá ninguna compensación económica por su participación.

Información sobre los resultados del estudio

Los resultados de este estudio pueden ser utilizados en futuras investigaciones y/o en actividades de comunicación (por ejemplo, como parte de otras investigaciones dentro del proyecto SHAPES, en artículos de revistas, congresos y conferencias). Se le enviarán por correo electrónico o a su dirección postal los resultados del estudio.

Interrupción del estudio

Las personas de Clinika de Kay que intervienen en este estudio pueden interrumpirlo de forma permanente, sin finalizar, en cualquier momento. Sin

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embargo, actualmente, no existen razones para que este hecho ocurra. Si quiere salir del estudio, puede pedirlo en cualquier momento a cualquiera de los contactos que encontrará al final del documento. Siempre podremos seguir utilizando sus datos de forma anonimizada.

Más información

Puede pedir en cualquier momento más información a través de los contactos proporcionados al final de este documento

Datos de contacto del personal de Clinika de Kay asociado a este estudio

Dra. Karina Anahi Ojanguren Carreira (investigadora principal)

Correo electrónico: karinaojanguren@hotmail.com

Oscar Villacañas Perez (gestor del proyecto SHAPES)

Correo electrónico: ovillacanas@clinicahumana.es

Ezequiel Corredera Blanco (responsable de la protección de datos)

Correo electrónico: ecorredera@clinicahumana.es

También puede contactar con nosotros por teléfono, llamando al: 971.21.71.79 ☎

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

INFORMACIÓN PARA PARTICIPANTES DE SHAPES: profesional de la salud

Título del estudio: Campaña de proyectos pilotos paneuropeos en el proyecto SHAPES: participación del usuario y opinión de las soluciones digitales del piloto 3 (Optimización de la medicación), caso de uso 1 (Predicción de la descompensación cardíaca mediante seguimiento en el hogar)

Nos gustaría invitarle a participar en nuestro estudio, durante el cuál apreciaríamos conocer sus opiniones y comentarios sobre las funcionalidades y el diseño de soluciones digitales que están siendo desarrolladas para que los profesionales de la salud puedan hacer un seguimiento de personas mayores de 65 años con insuficiencia cardíaca. En concreto, nos gustaría conocer sus opiniones sobre los datos recogidos de las personas y los paneles de control que permiten su visualización, con el objetivo de que una persona como usted pueda analizarlos y establecer intervenciones tempranas.

En este estudio pretendemos incluir al menos a 5 personas:

- 3 personas mayores de 65 años que tengan un alto grado de independencia, junto a sus cuidadores si da el caso
- 1 profesional de la salud
- 1 técnico informático como proveedor de asistencia técnica.

Usted ha sido identificado como una persona con el perfil adecuado para nuestro estudio, por lo que le hacemos llegar esta hoja informativa para leer y considerar si le gustaría participar.

Esta hoja informativa describe el estudio y su papel en este. Antes de que se decida en participar, es importante que entienda por qué se realiza el estudio y qué acciones le implican. Por favor, tome el tiempo que considere necesario para leer este documento y discutir cualquier aspecto con las personas que desee. Cualquier aspecto que no entienda, o si simplemente desea más información, por favor pregunte al investigador o a cualquiera de las personas de contacto detalladas al final de este documento, que le contactará una vez haya tenido tiempo de leer esta información.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Naturaleza voluntaria de la participación

La participación en este estudio es totalmente voluntaria. Puede abandonar el estudio en cualquier momento sin dar ninguna explicación y sin que tenga ninguna consecuencia negativa para usted.

Objeto y objetivos del estudio

Este estudio es parte de un proyecto de investigación mayor que tiene como objeto probar diferentes formas de uso de tecnologías que ayuden a las personas en sus hogares mientras envejecen.

El objetivo del estudio en el que usted ha sido invitado a participar es recoger opiniones y comentarios sobre un sistema integrado de soluciones digitales que permiten hacer un seguimiento de personas mayores de 65 años con insuficiencia cardíaca. De personas con su perfil, nos interesa conocer si los datos recogidos y la forma de visualizarlos permiten un seguimiento efectivo y proporciona herramientas para permitir intervenciones tempranas.

Las soluciones digitales que componen el sistema de seguimiento serán nuevamente compartidas con los usuarios en tres ocasiones más:

- Una sesión presencial donde se podrá interaccionar con el robot y/o sus funciones y volveremos a recoger opiniones para posibles mejoras.
- Un piloto donde se simulará la aplicación final en un entorno real controlado, donde volveremos a recoger opiniones para posibles mejoras.
- Un piloto donde se probará la tecnología en un entorno real.

¿Qué implica su participación?

Si decide participar en este estudio, se le pedirá que tome parte en una entrevista a distancia mediante video-llamada a través de internet. Por parte de Clinika de Kay, en la video-llamada participará un gestor del proyecto, personal de Clinika de Kay, que le hará la entrevista.

¿Qué pasará exactamente?

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Toma de consentimiento

- Después de que haya tenido tiempo de leer la información contenida en este documento, puede contactar con cualquiera de los contactos de Clinika de Kay al final de este documento para cualquier aclaración.
- Si quiere participar en el estudio, rellene con su nombre, fecha y firme el consentimiento informado y devuélvalo a Clínika de Kay por correo electrónico a ovillacanas@clinicahumana.es o entréguelo en mano a cualquiera de los administradores de Clinika de Kay (Jose Eduardo Carrasco Alberti o la Dra. Karina Ojanguren Carreira).
- Si nos devuelve el consentimiento por correo electrónico, el mismo se utilizará para devolverle una copia del documento firmado por el gestor del proyecto SHAPES en Clinika de Kay, reconociendo la recepción del documento. Si nos devuelve el consentimiento en mano, asumimos que desea que Clinika de Kay comparta su dirección habitual y teléfono con los miembros de este estudio con el único fin de aportarle otra información requerida relacionada con este estudio, incluyendo una copia del consentimiento firmada por el gestor del proyecto SHAPES en Clinka de Kay.

Antes de la video-llamada

- El gestor del proyecto SHAPES o uno de los administradores de Clinika de Kay se pondrá en contacto con usted para acordar un día y una hora para realizar la primera video-llamada.
- Un miembro de Clinika de Kay se pondrá en contacto con usted y comprobará que dispone de la tecnología necesaria para realizar la video-llamada y le explicará, si es necesario, cómo utilizarla.
- La persona de Clinika de Kay que se ponga en contacto con usted, le notificará el perfil de las personas que asistirán a la llamada en relación a la entrevista, pudiendo haber más de un usuario final. A este momento, puede opinar sobre la composición de los componentes y sugerir cambios para adaptarnos a sus necesidades y comodidad.

Durante la video-llamada

- Durante la video-llamada se le mostrará información sobre el estudio y el proyecto SHAPES.
- A continuación, para poner en contexto con la tecnología, se le hará una breve descripción del caso de uso en el que el presente estudio de investigación se enmarca.
- A continuación se le preguntará sobre su dedicación y experiencia como

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profesional de la salud.

- A continuación, se le mostrarán unas diapositivas, figuras y textos descriptivos sobre diversas funcionalidades de la solución digital, como se utiliza en el piloto y las acciones que debería realizar una persona de su perfil.
- Después de cada grupo de diapositivas relacionadas con una funcionalidad concreta, el presentador le hará una serie de preguntas para recoger su opinión sobre la funcionalidad y su conocimiento sobre la situación en la que se aplica la funcionalidad. Algunas respuestas serán cerradas (por ejemplo, "¿puede hacer un seguimiento de forma diaria? Sí, No, No estoy seguro") y otras abiertas (por ejemplo, "¿qué tipo de recordatorios cree que necesitan las personas mayores?"). En ningún caso está obligado a responder y siempre puede añadir comentarios aun siendo la respuesta cerrada.
- En todo caso, las preguntas no son un test o prueba, y no hay respuestas correctas o incorrectas. Nuestra intención es conocer su opinión honesta sobre lo que le mostramos.
- El presentador tomará notas durante la video-llamada.
- La video-llamada no debería durar más de 90 minutos. Trabajaremos a su ritmo y puede tomar los descansos que considere oportunos.
- Al final de la llamada le dejaremos una copia de los siguientes documentos:
    - Las diapositivas presentadas en la video-llamada con las notas tomadas por Clinika de Kay superpuestas. Puede revisar las diapositivas con sus notas para revisarlas, sugerir cambios o añadir más comentarios que nos puede hacer llegar en cualquier momento.

Después de la video-llamada

- Puede modificar y completar las respuestas dadas durante la video-llamada en el documento aportado y hacérnoslas llegar.
- Si prefiere, en vez de entregarnos las aportaciones en el documento anterior, podemos realizar otra video-llamada para recoger sus opiniones surgidas. Para realizarlo de este modo, tiene que ponerse en contacto con nosotros.
- Al final del proceso se le entregará un resumen de los resultados de este estudio.
- Después de entregarle los resultados, el mail o dirección postal aportados se borrarán, o se desligará de este estudio de investigación si mantiene otras relaciones con Clinika de Kay

Datos recogidos durante este proyecto de investigación

- Los únicos datos personales que se recogerán de usted serán:
    - Su nombre para identificar el consentimiento informado
    - Su correo electrónico (opcional) para contactar con usted y enviarle

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información
    - Su dirección postal (opcional) para contactar con usted y enviarle información
    - Su teléfono (opcional) para contactar con usted
- Todos los documentos generados, se guardarán solamente en un servidor de Clinika de Kay, con acceso protegido con contraseña únicamente a las personas especificadas al final de este documento. El correo electrónico se guardará también en el servidor de correo de Clinika de Kay. Como copias de los documentos, solo existirán las que transfiramos a usted por correo electrónico y las que le proporcionemos en papel, si así nos lo ha solicitado.
- Si usted menciona cualquier dato durante la entrevista que le pudiera identificar, no se registrará en las notas o se registrará de forma anonimizada.
- Los resultados anonimizados pueden ser usados en futuras investigaciones y/o en actividades de comunicación (por ejemplo, como parte de otras investigaciones dentro del proyecto SHAPES, en artículos de revistas, congresos y conferencias).
- Sus datos personales serán destruidos una vez se le haya proporcionado los resultados de este estudio. Si usted tiene cualquier otro tipo de relación con Clinika de Kay, solo se desligarán sus datos personales en lo relacionado a este estudio.
- Puede pedir la destrucción de sus datos personales en cualquier momento.
- Los datos anonimizados se guardarán durante la duración del proyecto SHAPES (actualmente, sin contar con posibles extensiones, hasta octubre de 2023) y durante 5 (cinco) años después de la finalización del proyecto.

Posibles beneficios por participar

No existen beneficios directos a nivel individual por participar en este estudio, más allá del interés personal y la experiencia de participar en un estudio. Sin embargo, el beneficio indirecto de este estudio es que sus opiniones y puntos de vista serán usados para mejorar las funcionalidades de la solución digital. Su aportación también será valiosa para el uso de tecnologías en la ayuda de personas mayores con insuficiencia cardíaca en sus hogares. Personas de toda Europa se beneficiarán de su participación.

Posibles inconvenientes por participar

No prevemos que usted sufra ningún inconveniente por participar en este estudio.

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Hallazgos incidentales

Los hallazgos incidentales son los descubrimientos que se pueden dar en el estudio sin que este haya sido diseñado para estos fines. En el presente estudio de investigación no se espera encontrar ningún tipo de hallazgo incidental.

Información de costes y compensación económica

La participación en este estudio no le incurrirá ningún coste siempre que la video-llamada entre en su plan de datos de internet. Si esto supone una barrera para usted, comuníquenoslo y aportaremos nuestra propia conexión a internet sin ningún coste para usted. Usted no recibirá ninguna compensación económica por su participación.

Información sobre los resultados del estudio

Los resultados de este estudio pueden ser utilizados en futuras investigaciones y/o en actividades de comunicación (por ejemplo, como parte de otras investigaciones dentro del proyecto SHAPES, en artículos de revistas, congresos y conferencias). Se le enviarán por correo electrónico o a su dirección postal los resultados del estudio.

Interrupción del estudio

Las personas de Clinika de Kay que intervienen en este estudio pueden interrumpirlo de forma permanente, sin finalizar, en cualquier momento. Sin embargo, actualmente, no existen razones para que este hecho ocurra. Si quiere salir del estudio, puede pedirlo en cualquier momento a cualquiera de los contactos que encontrará al final del documento. Siempre podremos seguir utilizando sus datos de forma anonimizada.

Más información

Puede pedir en cualquier momento más información a través de los contactos proporcionados al final de este documento

Datos de contacto del personal de Clinika de Kay asociado a este estudio

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Dra. Karina Anahi Ojanguren Carreira (investigadora principal)

Correo electrónico: karinaojanguren@hotmail.com

Oscar Villacañas Perez (gestor del proyecto SHAPES)

Correo electrónico: ovillacanas@clinicahumana.es

Ezequiel Corredera Blanco (responsable de la protección de datos)

Correo electrónico: ecorredera@clinicahumana.es

También puede contactar con nosotros por teléfono, llamando al: 971.21.71.79 ☎

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Annex 34 UC-PT3-001 Phase 2 participant consent forms (older people, caregivers, and health professionals

DECLARACIÓN CONSENTIMIENTO PARA PARTICIPANTES DE SHAPES: personas mayores

Título del estudio: Campaña de proyectos pilotos paneuropeos en el proyecto SHAPES: participación del usuario y opinión de las soluciones digitales del piloto 3 (Optimización de la medicación), caso de uso 1 (Predicción de la descompensación cardíaca mediante seguimiento en el hogar)

Localización del estudio:

Clinika de Kay / Clínica Humana

Contactos:

Dra. Karina Anahi Ojanguren Carreira (investigadora principal)

Correo electrónico: karinaojanguren@hotmail.com

Oscar Villacañas Perez (gestor del proyecto SHAPES)

Correo electrónico: ovillacanas@clinicahumana.es

Ezequiel Corredera Blanco (responsable de la protección de datos)

Correo electrónico: ecorredera@clinicahumana.es

También puede contactar con nosotros por teléfono, llamando al: 971.21.71.79 ☎

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Declaración del participante

- He sido invitado a participar en el estudio arriba mencionado. El objetivo del estudio es la recopilación de opiniones y comentarios sobre el diseño y las funcionalidades de soluciones digitales orientadas al seguimiento de la condición de insuficiencia cardíaca en pacientes mayores de 65 años. En concreto, he sido invitado para opinar sobre el uso de dispositivos, aplicaciones móviles y sus respectivas funcionalidades incorporadas que permiten a un profesional de la salud hacer el seguimiento con los datos recogidos. También, he sido invitado para proponer nuevas funcionalidades que pudieran ser de utilidad para mejorar el seguimiento de la insuficiencia cardíaca. El estudio es una oportunidad para que los investigadores aseguren la utilidad de las funcionalidades a implementar en el piloto desde el punto de vista de las personas mayores con insuficiencia cardíaca.

- He leído y entendido la hoja informativa para el participante. La hoja informativa para el participante me ha aportado suficiente información sobre el estudio arriba mencionado, sus objetivos y su ejecución, sobre mis derechos y sobre los posibles beneficios e inconvenientes al participar.

- He tenido la oportunidad de preguntar sobre el estudio y las cuestiones han sido respondidas satisfactoriamente.

- Se me ha dado suficiente información sobre la recogida, procesamiento, transferencia/divulgación y borrado de mis respuestas durante el estudio. Entiendo que, a excepción de mi nombre, correo electrónico y, mi dirección postal y teléfono no se procesará ningún otro dato personal durante el estudio. Se me ha entregado el documento Política de Privacidad, donde se explica el proceso que se hace de mis datos personales, y la Declaración Nacional sobre Integridad Científica, cuyos principios sigue Clinika de Kay para este estudio.

- Al firmar esta declaración, confirmo que consiento de forma voluntaria participar en este estudio y que también autorizo el procesamiento de mis respuestas para los objetivos descritos en este documento.

- No he sido presionado o coaccionado para participar y he tenido suficiente tiempo para considerar mi participación en el estudio. Entiendo que mi participación es totalmente voluntaria y que soy libre en abandonar mi consentimiento en cualquier momento sin necesidad de aportar ninguna razón, justificación o aclaración.

- También tengo el derecho de pedir que borren todos los datos personales y cualquier dato que permita mi identificación según la ley de protección de datos (Ley Orgánica 3/2018, de Protección de Datos). Por cualquier conflicto

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que tenga con nosotros en relación a la protección de datos, puede dirigirse a la Agencia Española de Protección de Datos (AEPD), https://www.aepd.es/es.

A rellenar por el participante

Consentimiento participación en el estudio (por favor, complete los campos siguientes para confirmar su consentimiento)

Nombre:

Fecha:

Firma:

A rellenar por el gestor del proyecto SHAPES en Clinika de Kay

Recepción del consentimiento firmado (por favor, complete los campos siguientes para confirmar la recepción del consentimiento firmado por parte del participante)

Nombre:

Fecha:

Firma:

El original de este documento firmado por el participante será custodiado por Clinika de Kay. La hoja informativa para el participante y una copia de este documento firmado tanto por el participante como por el gestor del proyecto SHAPES en Clinika de Kay serán entregados al participante.

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DECLARACIÓN CONSENTIMIENTO PARA PARTICIPANTES DE SHAPES: cuidadores

Título del estudio: Campaña de proyectos pilotos paneuropeos en el proyecto SHAPES: participación del usuario y opinión de las soluciones digitales del piloto 3 (Optimización de la medicación), caso de uso 1 (Predicción de la descompensación cardíaca mediante seguimiento en el hogar)

Localización del estudio:

Clinika de Kay / Clínica Humana

Contactos:

Dra. Karina Anahi Ojanguren Carreira (investigadora principal)

Correo electrónico: karinaojanguren@hotmail.com

Oscar Villacañas Perez (gestor del proyecto SHAPES)

Correo electrónico: ovillacanas@clinicahumana.es

Ezequiel Corredera Blanco (responsable de la protección de datos)

Correo electrónico: ecorredera@clinicahumana.es

También puede contactar con nosotros por teléfono, llamando al: 971.21.71.79 ☎

Declaración del participante

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

- He sido invitado a participar en el estudio arriba mencionado. El objetivo del estudio es la recopilación de opiniones y comentarios sobre el diseño y las funcionalidades de soluciones digitales orientadas al seguimiento de la condición de insuficiencia cardíaca en pacientes mayores de 65 años. En concreto, he sido invitado para opinar sobre el uso de dispositivos, aplicaciones móviles y sus respectivas funcionalidades incorporadas que permiten a un profesional de la salud hacer el seguimiento con los datos recogidos. También, he sido invitado para proponer nuevas funcionalidades que pudieran ser de utilidad para mejorar el seguimiento de la insuficiencia cardíaca. El estudio es una oportunidad para que los investigadores aseguren la utilidad de las funcionalidades a implementar en el piloto desde el punto de vista de las personas mayores con insuficiencia cardíaca

- He leído y entendido la hoja informativa para el participante. La hoja informativa para el participante me ha aportado suficiente información sobre el estudio arriba mencionado, sus objetivos y su ejecución, sobre mis derechos y sobre los posibles beneficios e inconvenientes al participar.

- He tenido la oportunidad de preguntar sobre el estudio y las cuestiones han sido respondidas satisfactoriamente.

- Se me ha dado suficiente información sobre la recogida, procesamiento, transferencia/divulgación y borrado de mis respuestas durante el estudio. Entiendo que, a excepción de mi nombre, correo electrónico y, mi dirección postal y teléfono no se procesará ningún otro dato personal durante el estudio. Se me ha entregado el documento Política de Privacidad, donde se explica el proceso que se hace de mis datos personales, y la Declaración Nacional sobre Integridad Científica, cuyos principios sigue Clinika de Kay para este estudio.

- Al firmar esta declaración, confirmo que consiento de forma voluntaria participar en este estudio y que también autorizo el procesamiento de mis respuestas para los objetivos descritos en este documento.

- No he sido presionado o coaccionado para participar y he tenido suficiente tiempo para considerar mi participación en el estudio. Entiendo que mi participación es totalmente voluntaria y que soy libre en abandonar mi consentimiento en cualquier momento sin necesidad de aportar ninguna razón, justificación o aclaración.

- También tengo el derecho de pedir que borren todos los datos personales y cualquier dato que permita mi identificación según la ley de protección de datos (Ley Orgánica 3/2018, de Protección de Datos). Por cualquier conflicto que tenga con nosotros en relación a la protección de datos, puede dirigirse a la Agencia Española de Protección de Datos (AEPD), https://www.aepd.es/es.

A rellenar por el participante

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Consentimiento participación en el estudio (por favor, complete los campos siguientes para confirmar su consentimiento)

Nombre:	
Fecha:	
Firma:	

A rellenar por el gestor del proyecto SHAPES en Clinika de Kay

Recepción del consentimiento firmado (por favor, complete los campos siguientes para confirmar la recepción del consentimiento firmado por parte del participante)

Nombre:	
Fecha:	
Firma:	

El original de este documento firmado por el participante será custodiado por Clinika de Kay. La hoja informativa para el participante y una copia de este documento firmado tanto por el participante como por el gestor del proyecto SHAPES en Clinika de Kay serán entregados al participante.

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DECLARACIÓN CONSENTIMIENTO PARA PARTICIPANTES DE SHAPES: profesionales de la salud

Título del estudio: Campaña de proyectos pilotos paneuropeos en el proyecto SHAPES: participación del usuario y opinión de las soluciones digitales del piloto 3 (Optimización de la medicación), caso de uso 1 (Predicción de la descompensación cardíaca mediante seguimiento en el hogar)

Localización del estudio:

Clinika de Kay / Clínica Humana

Contactos:

Dra. Karina Anahi Ojanguren Carreira (investigadora principal)

Correo electrónico: karinaojanguren@hotmail.com

Oscar Villacañas Perez (gestor del proyecto SHAPES)

Correo electrónico: ovillacanas@clinicahumana.es

Ezequiel Corredera Blanco (responsable de la protección de datos)

Correo electrónico: ecorredera@clinicahumana.es

También puede contactar con nosotros por teléfono, llamando al: 971.21.71.79 ☎

Declaración del participante

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

- He sido invitado a participar en el estudio arriba mencionado. El objetivo del estudio es la recopilación de opiniones y comentarios sobre el diseño y las funcionalidades de soluciones digitales orientadas al seguimiento de la condición de insuficiencia cardíaca en pacientes mayores de 65 años. En concreto, he sido invitado para opinar sobre las funcionalidades incorporadas en varios paneles de control que permiten visualizar el estado de personas con insuficiencia cardíaca y, a partir de lo mostrado, decidir la necesidad de realizar una visita médica. También, he sido invitado para proponer nuevas funcionalidades que pudieran ser de utilidad al para mejorar la recopilación de datos y su visualización. El estudio es una oportunidad para que los investigadores aseguren la utilidad de las funcionalidades a implementar en el piloto desde el punto de vista de los profesionales de salud en centros proveedores de salud.

- He leído y entendido la hoja informativa para el participante. La hoja informativa para el participante me ha aportado suficiente información sobre el estudio arriba mencionado, sus objetivos y su ejecución, sobre mis derechos y sobre los posibles beneficios e inconvenientes al participar.

- He tenido la oportunidad de preguntar sobre el estudio y las cuestiones han sido respondidas satisfactoriamente.

- Se me ha dado suficiente información sobre la recogida, procesamiento, transferencia/divulgación y borrado de mis respuestas y datos personales durante el estudio. Entiendo que, a excepción de mi nombre, correo electrónico y, opcionalmente, mi dirección postal, no se procesará ningún otro dato personal durante el estudio. Se me ha entregado el documento Aviso de Privacidad, donde se explica el proceso que se hace de mis datos personales, y la Declaración Nacional sobre Integridad Científica, cuyos principios sigue Clinika de Kay para este estudio.

- Al firmar esta declaración, confirmo que consiento de forma voluntaria participar en este estudio y que también autorizo el procesamiento de mis respuestas para los objetivos descritos en este documento.

- No he sido presionado o coaccionado para participar y he tenido suficiente tiempo para considerar mi participación en el estudio. Entiendo que mi participación es totalmente voluntaria y que soy libre en abandonar mi consentimiento en cualquier momento sin necesidad de aportar ninguna razón, justificación o aclaración.

- También tengo el derecho de pedir que borren todos los datos personales y cualquier dato que permita mi identificación según la ley de protección de datos (Ley Orgánica 3/2018, de Protección de Datos). Por cualquier conflicto que tenga con nosotros en relación a la protección de datos, puede dirigirse a la Agencia Española de Protección de Datos (AEPD), https://www.aepd.es/es.

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A rellenar por el participante

Consentimiento participación en el estudio (por favor, complete los campos siguientes para confirmar su consentimiento)

Nombre:	
Fecha:	
Firma:	

A rellenar por el gestor del proyecto SHAPES en Clinika de Kay

Recepción del consentimiento firmado (por favor, complete los campos siguientes para confirmar la recepción del consentimiento firmado por parte del participante)

Nombre:	
Fecha:	
Firma:	

El original de este documento firmado por el participante será custodiado por Clinika de Kay. La hoja informativa para el participante y una copia de este documento firmado tanto por el participante como por el gestor del proyecto SHAPES en Clinika de Kay serán entregados al participante.

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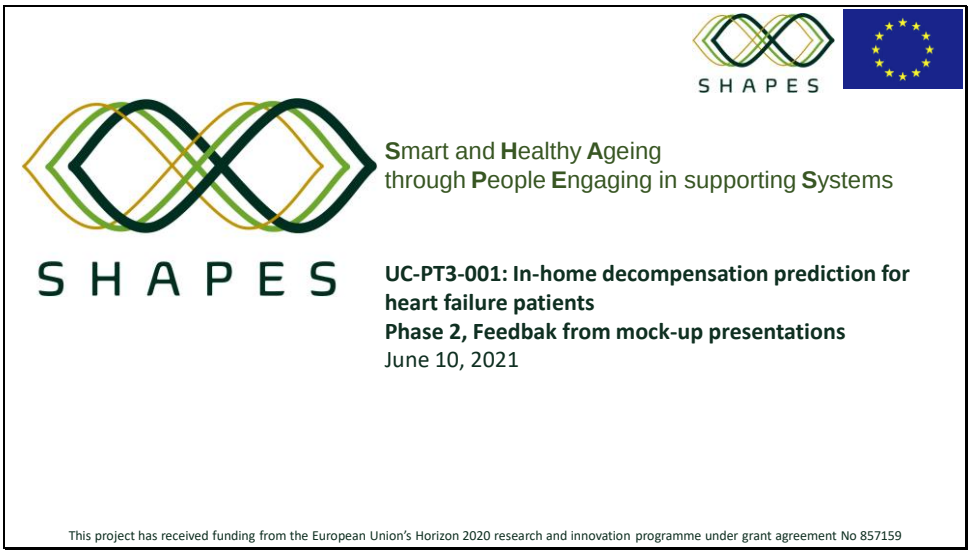
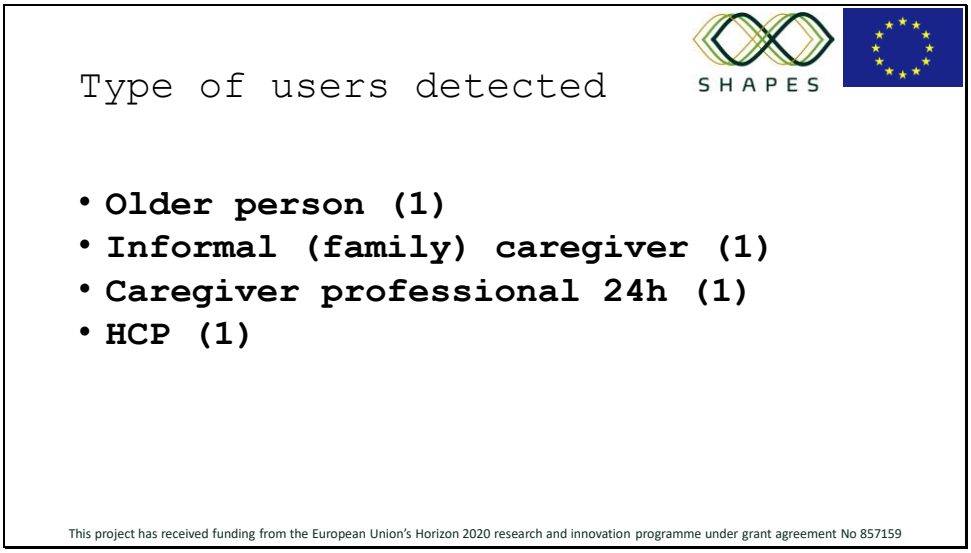
Annex 35 UC-PT3-001 Phase 2 feedback report

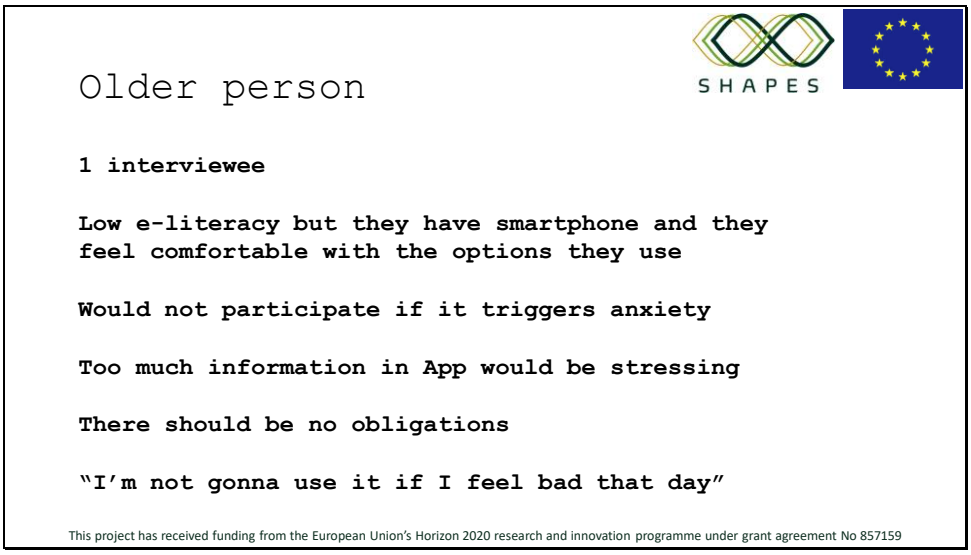
Slide 1



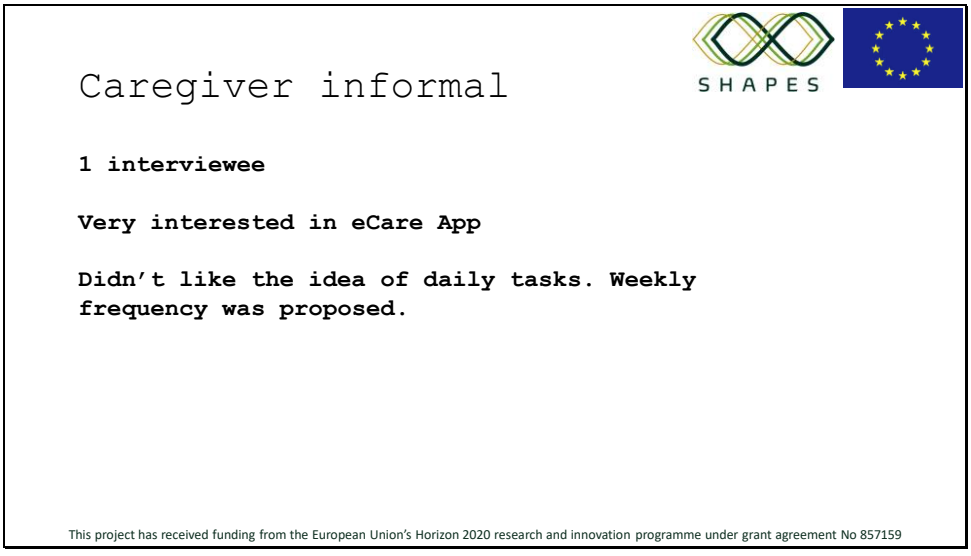
Slide 2



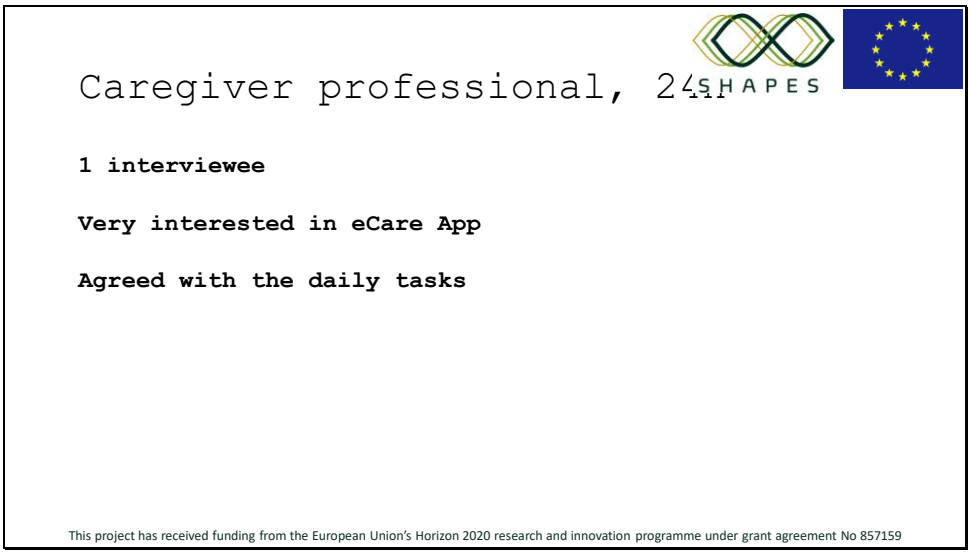
Slide 3



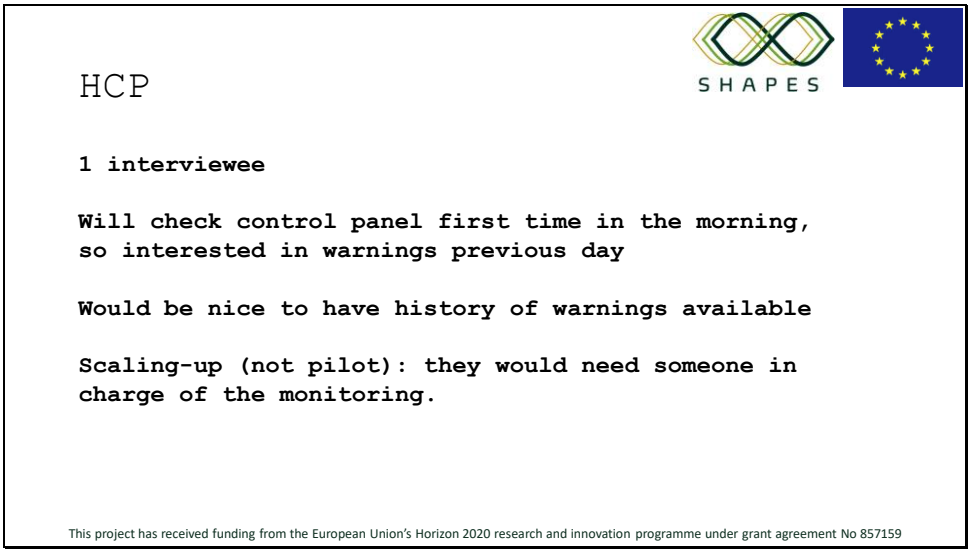
Slide 4



Slide 5



Slide 6



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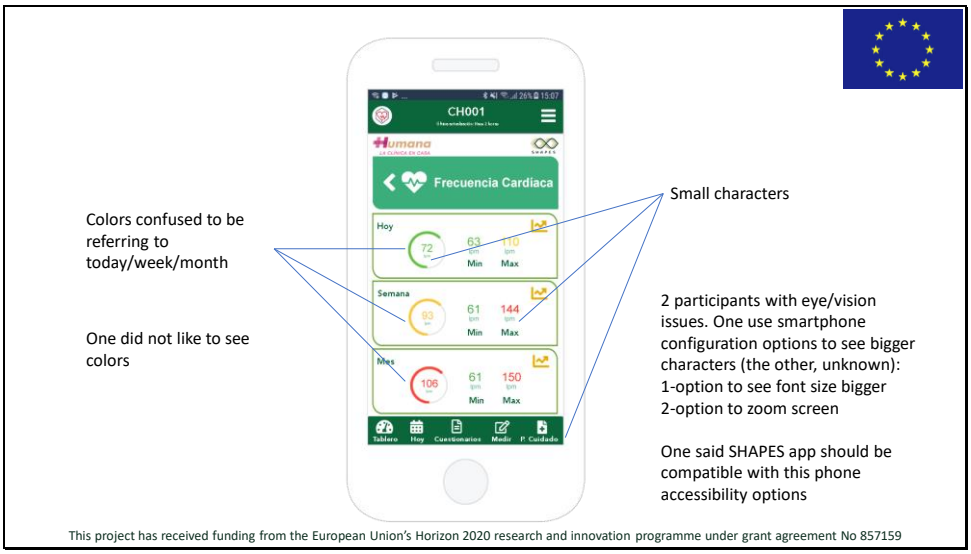
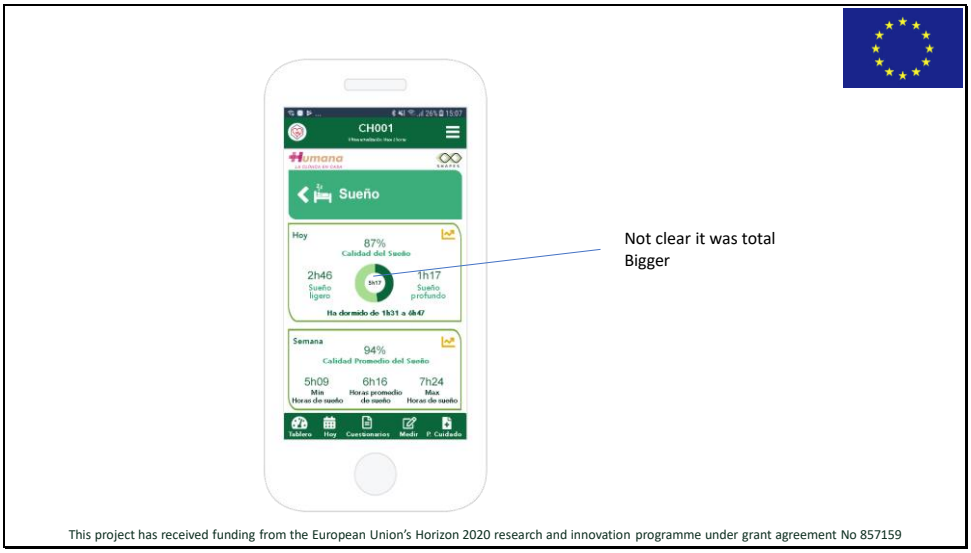
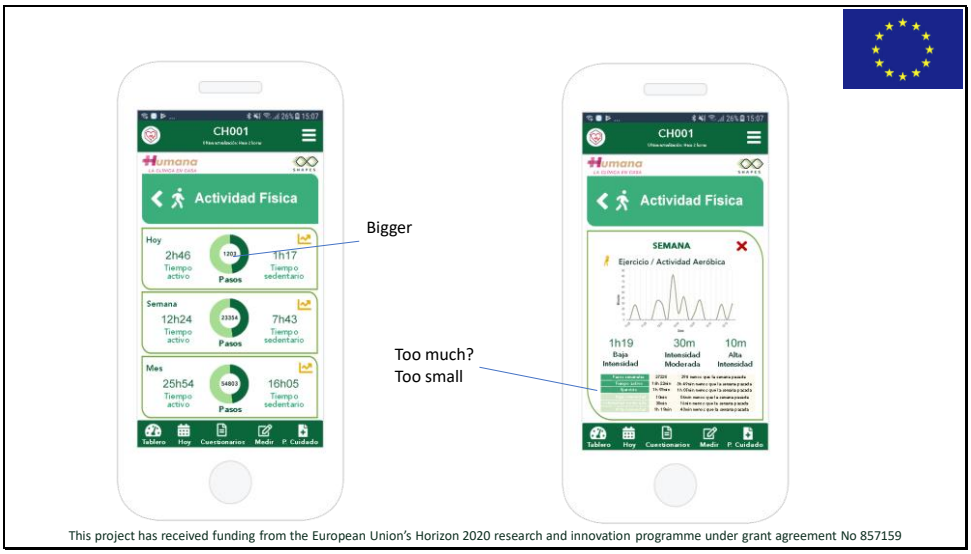
Slide 7



Slide 8



Slide 9



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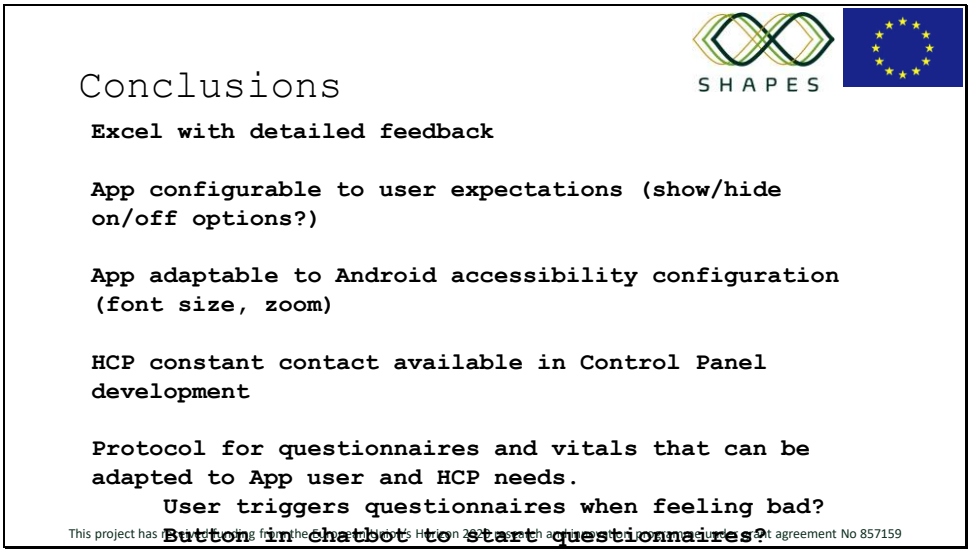
Slide 10



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Annex 36 UC-PT3-001 Phase 3 participant information sheet

INFORMACIÓN PARA PARTICIPANTES DE SHAPES: persona mayor

Título del estudio: Campaña de proyectos pilotos paneuropeos en el proyecto SHAPES: participación del usuario y opinión de las soluciones digitales del piloto 3 (Optimización de la medicación), caso de uso 1 (Predicción de la descompensación cardíaca mediante seguimiento en el hogar) – Fase 3

Nos gustaría invitarle a participar en nuestro estudio, durante el cuál apreciaríamos conocer sus opiniones y comentarios sobre las funcionalidades y el diseño de soluciones digitales que están siendo desarrolladas para que los profesionales de la salud puedan hacer un seguimiento de personas mayores de 65 años con insuficiencia cardíaca con el objetivo de hacer intervenciones tempranas. En concreto, nos gustaría conocer sus opiniones sobre los diferentes dispositivos (tales como tensiómetros) y aplicaciones móvil y ordenador que una persona de su perfil usarían en este escenario. Durante el estudio, se le pedirá que utilice, siempre ante nuestra presencia, las soluciones digitales. Ejemplos de estas actividades serían:

- Usar el tensiómetro para ver como los datos son transferidos a la aplicación
- Contestar unas preguntas a través de la aplicación

En este estudio pretendemos incluir al menos a 5 personas:

- 4 personas mayores de 65 años que tengan un alto grado de independencia y/o a sus cuidadores
- 1 profesional de la salud

Usted ha sido identificado como una persona con el perfil adecuado para nuestro estudio, por lo que le hacemos llegar esta hoja informativa para leer y considerar si le gustaría participar.

Esta hoja informativa describe el estudio y su papel en este. Antes de que se decida en participar, es importante que entienda por qué se realiza el estudio y qué acciones le implican. Por favor, tome el tiempo que considere necesario para leer este documento y discutir cualquier aspecto con las personas que desee. Cualquier aspecto que no entienda, o si simplemente desea más información, por favor pregunte al investigador o cualquiera de las personas de contacto detalladas al final de este documento, que le contactará una vez haya tenido tiempo de leer esta información.

Naturaleza voluntaria de la participación

La participación en este estudio es totalmente voluntaria. Puede abandonar el estudio en cualquier momento sin dar ninguna explicación y sin que tenga ninguna consecuencia negativa para usted.

Objeto y objetivos del estudio

Este estudio es parte de un proyecto de investigación mayor que tiene como objeto probar diferentes formas de uso de tecnologías que ayuden a las personas en sus hogares mientras envejecen.

El objetivo del estudio en el que usted ha sido invitado a participar es recoger opiniones y comentarios sobre si las soluciones digitales que le enseñaremos se son útiles para usted y fáciles de usar. Sus comentarios y opiniones serán de gran utilidad para hacer las funcionalidades útiles en un entorno real así como para investigar nuevas funcionalidades en las que no hayamos pensado y tengamos la capacidad de incorporarlas.

Las versiones finales de las soluciones digitales serán nuevamente compartidas con otros participantes en dos ocasiones más:

- Un piloto donde se simulará la aplicación final en un entorno real controlado, donde volveremos a recoger opiniones para posibles mejoras.
- Un piloto donde se probará la tecnología en un entorno real.

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¿Quién organiza y financia la investigación?
Clinika de Kay SL, con marca Clínica Humana, organiza el estudio. Este es parte de un proyecto de investigación mayor llamado SHAPES (www.shapes2020.eu), que es financiado por el programa de investigación e innovación Horizon 2020 de la Unión Europea bajo el acuerdo de subvención No. 875159.

¿Qué implica su participación?
Si decide participar en este estudio, se le pedirá que tome parte en una sesión práctica con un gestor del proyecto SHAPES en Clinika de Kay. En la sesión, le enseñaremos cómo se utilizan las tecnologías, le invitaremos a probarlas y le formularemos algunas preguntas para conocer su opinión. Únicamente si usted acepta, grabaremos cómo utiliza las soluciones digitales, sin registrar su cara en ningún momento.

¿Qué pasará exactamente?

Toma de consentimiento

- Después de que haya tenido tiempo de leer la información contenida en este documento, puede contactar con cualquiera de los contactos de Clinika de Kay al final de este documento para cualquier aclaración.
- Si quiere participar en el estudio, rellene con su nombre, fecha y firme el consentimiento informado y devuélvalo a Clínika de Kay por correo electrónico a ovillacanas@clinicahumana.es o entréguelo en mano a cualquiera de los administradores de Clinika de Kay (Jose Eduardo Carrasco Alberti o la Dra. Karina Ojanguren Carreira).
- Si nos devuelve el consentimiento por correo electrónico, el mismo se utilizará para devolverle una copia del documento firmado por el gestor del proyecto SHAPES en Clinika de Kay, reconociendo la recepción del documento. Si nos devuelve el consentimiento en mano, asumimos que desea que Clinika de Kay comparta su dirección habitual y teléfono con los miembros de este estudio con el único fin de aportarle otra información requerida relacionada con este estudio.

Durante la sesión

- Se le hará una demostración de uso de las soluciones digitales
- Usted utilizará las soluciones digitales siguiendo nuestras indicaciones y siempre en presencia nuestra. No es una prueba, nos puede hacer cualquier pregunta, consulta o darnos su opinión en cualquier momento. Si acepta, grabaremos en video cómo utiliza las soluciones digitales, sin registrar en ningún momento su cara.
- Usted completará un cuestionario (UEQ-S).
- Le haremos una entrevista para conocer sus opiniones sobre las soluciones digitales. Le proporcionamos de forma adjunto un guion sobre esta entrevista.
- En todo caso, las preguntas no son un test o prueba, y no hay respuestas correctas o incorrectas. Nuestra intención es conocer su opinión honesta sobre lo que le mostramos.
- El presentador tomará notas durante la sesión.
- La sesión durará 2h. Iremos a su ritmo. Puede tomar las pausas que considere oportunas.

Después de la sesión

- Le entregaremos un resumen sobre sus opiniones recogidas.
- Puede modificar y completar las respuestas dadas y hacérnoslas llegar.
- Al final del proceso se le entregará un resumen de los resultados de este estudio.
- Después de entregarle los resultados, el mail, dirección postal y teléfono aportados se borrarán, o se desligará de este estudio de investigación si mantiene otras relaciones con Clinika de Kay

Datos recogidos durante este proyecto de investigación

- Los datos personales que se recogerás de usted serán:
    - Su nombre para identificar el consentimiento informado
    - Su correo electrónico (opcional) para contactar con usted y enviarle información
    - Su dirección postal (opcional) para contactar con usted y enviarle información
    - Su teléfono (opcional) para contactar con usted

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- Sus opiniones y respuestas a los cuestionarios
- Opcional: grabaciones en video sobre cómo utiliza las soluciones digitales sin que se registre su cara

- Todos los documentos generados, se guardarán solamente en un servidor de Clinika de Kay, con acceso protegido con contraseña únicamente a las personas especificadas al final de este documento. El correo electrónico se guardará también en el servidor de correo de Clinika de Kay. Como copias de los documentos, solo existirán las que transfiramos a usted por correo electrónico y las que le proporcionemos en papel, si así nos lo ha solicitado.
- Si usted menciona cualquier dato durante la entrevista que le pudiera identificar, no se registrará en las notas o se registrará de forma anonimizada.
- Los resultados anonimizados pueden ser usados en futuras investigaciones y/o en actividades de comunicación (por ejemplo, como parte de otras investigaciones dentro del proyecto SHAPES, en artículos de revistas, congresos y conferencias).
- Sus datos personales serán destruidos una vez se le haya proporcionado los resultados de este estudio. Si usted tiene cualquier otro tipo de relación con Clinika de Kay, solo se desligarán sus datos personales en lo relacionado a este estudio.
- Puede pedir la destrucción de sus datos personales en cualquier momento.
- Los datos anonimizados se guardarán durante la duración del proyecto SHAPES (actualmente, sin contar con posibles extensiones, hasta octubre de 2023) y durante 5 (cinco) años después de la finalización del proyecto.

Posibles beneficios por participar

No existen beneficios directos a nivel individual por participar en este estudio, más allá del interés personal y la experiencia de participar en un estudio. Sin embargo, el beneficio indirecto de este estudio es que sus opiniones y puntos de vista serán usados para mejorar las funcionalidades del robot. Su aportación también será valiosa para el uso de tecnologías en la ayuda de personas mayores en sus hogares mientras envejecen. Personas de toda Europa se beneficiarán de su participación.

Posibles inconvenientes por participar

No prevemos que usted sufra ningún inconveniente por participar en este estudio.

Hallazgos incidentales

Los hallazgos incidentales son los descubrimientos que se pueden dar en el estudio sin que este haya sido diseñado para estos fines. En el presente estudio de investigación no se esperan encontrar ningún tipo de hallazgo incidental.

Información de costes y compensación económica

La participación en este estudio no le incurrirá ningún coste siempre que la video-llamada entre en su plan de datos de internet. Si esto supone una barrera para usted, comuníquenoslo y aportaremos nuestra propia conexión a internet sin ningún coste para usted. Usted no recibirá ninguna compensación económica por su participación.

Información sobre los resultados del estudio

Los resultados de este estudio pueden ser utilizados en futuras investigaciones y/o en actividades de comunicación (por ejemplo, como parte de otras investigaciones dentro del proyecto SHAPES, en artículos de revistas, congresos y conferencias). Se le enviarán por correo electrónico o a su dirección postal los resultados del estudio.

Interrupción del estudio

Las personas de Clinika de Kay que intervienen en este estudio pueden interrumpirlo de forma permanente, sin finalizar, en cualquier momento. Sin embargo, actualmente, no existen razones para que este hecho ocurra. Si quiere salir del estudio, puede pedirlo en cualquier momento a cualquiera de los contactos al final del documento. Siempre podremos seguir utilizando sus datos anonimizados.

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Más información
Puede pedir en cualquier momento más información a los contactos del final de este documento

Datos de contacto del personal de Clinika de Kay asociado a este estudio

Dra. Karina Anahi Ojanguren Carreira (investigadora principal)
Correo electrónico: karinaojanguren@hotmail.com

Oscar Villacañas Perez (gestor del proyecto SHAPES)
Correo electrónico: ovillacanas@clinicahumana.es

Jose Eduardo Carretero Alberti (responsable de la protección de datos)
Correo electrónico: clinikadekay@gmail.com

También puede contactar con nosotros por teléfono, llamando al: 971.21.71.79

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Annex 37 UC-PT3-001 Phase 3 participant consent form

DECLARACIÓN CONSENTIMIENTO PARA PARTICIPANTES DE SHAPES:

Título del estudio: Campaña de proyectos pilotos paneuropeos en el proyecto SHAPES: participación del usuario y opinión de las soluciones digitales del piloto 3 (Optimización de la medicación), caso de uso 1 (Predicción de la descompensación cardíaca mediante seguimiento en el hogar) – Fase 3

Localización del estudio:

Clinika de Kay / Clínica Humana

Contactos:

Dra. Karina Anahi Ojanguren Carreira (directora médica)

Correo electrónico: karinaojanguren@hotmail.com

Oscar Villacañas Perez (gestor del proyecto SHAPES)

Correo electrónico: ovillacanas@clinicahumana.es

José Eduardo Carretero Alberti (responsable de la protección de datos)

Correo electrónico: clinikadekay@gmail.com

También puede contactar con nosotros por teléfono, llamando al: 971.21.71.79

Declaración del participante

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- He sido invitado a participar en el estudio arriba mencionado. El objetivo del estudio es la recopilación de opiniones y comentarios sobre la utilidad, el uso, el diseño y las funcionalidades de soluciones digitales orientadas al seguimiento de la condición de insuficiencia cardíaca en pacientes mayores de 65 años. Durante el estudio se me hará una demostración de las soluciones digitales y tendré oportunidad de utilizarlas. También, he sido invitado para proponer nuevas funcionalidades que pudieran ser de utilidad para mejorar el seguimiento de la insuficiencia cardíaca. El estudio es una oportunidad para que los investigadores aseguren la utilidad de las funcionalidades a implementar en el piloto desde el punto de vista de las personas mayores con insuficiencia cardíaca.

- He leído y entendido la hoja informativa para el participante. La hoja informativa para el participante me ha aportado suficiente información sobre el estudio arriba mencionado, sus objetivos y su ejecución, sobre mis derechos y sobre los posibles beneficios e inconvenientes al participar.

- He tenido la oportunidad de preguntar sobre el estudio y las cuestiones han sido respondidas satisfactoriamente.

- Se me ha dado suficiente información sobre la recogida, procesamiento, transferencia/divulgación y borrado de mis respuestas durante el estudio. Entiendo que, a excepción de mi nombre y datos para ponerse en contacto conmigo (correo electrónico y/o dirección postal y/o teléfono) no se procesará ningún otro dato que me identifique durante el estudio. Si acepto, se realizarán grabaciones de video cuando esté utilizando las soluciones digitales, donde no aparecerá mi cara. Esta aceptación es totalmente opcional, voluntaria y no influye en participar en este estudio. La aceptación voluntaria la marca al final de este documento.

- Se me ha entregado el documento Política de Privacidad, donde se explica el proceso que se hace de mis datos personales, y la Declaración Nacional sobre Integridad Científica, cuyos principios sigue Clinika de Kay para este estudio.

- Al firmar esta declaración, confirmo que consiento de forma voluntaria participar en este estudio y que también autorizo el procesamiento de mis respuestas para los objetivos descritos en este documento.

- No he sido presionado o coaccionado para participar y he tenido suficiente tiempo para considerar mi participación en el estudio. Entiendo que mi participación es totalmente voluntaria y que soy libre en abandonar mi consentimiento en cualquier momento sin necesidad de aportar ninguna razón, justificación o aclaración.

- También tengo el derecho de pedir que borren todos los datos personales y cualquier dato que permita mi identificación según la ley de protección de datos (Ley Orgánica 3/2018, de Protección de Datos). Por cualquier conflicto que tenga con nosotros en relación a la protección de datos, puede dirigirse a la Agencia Española de Protección de Datos (AEPD), https://www.aepd.es/es.

A rellenar por el participante

Consentimiento participación en el estudio (por favor, complete los campos siguientes para confirmar su consentimiento)

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Nombre:	
Fecha:	
Firma:	

Acepto que se me grabe, exceptuando mi cara, mientras utilizo la app, el panel de control y/o los dispositivos médicos. (Marque el "Sí", en caso de aceptar)	Sí ☐ No ☐

A rellenar por el gestor del proyecto SHAPES en Clinika de Kay

Recepción del consentimiento firmado (por favor, complete los campos siguientes para confirmar la recepción del consentimiento firmado por parte del participante)

Nombre:	
Fecha:	
Firma:	

El original de este documento firmado por el participante será custodiado por Clinika de Kay. La hoja informativa para el participante y una copia de este documento firmado tanto por el participante como por el gestor del proyecto SHAPES en Clinika de Kay serán entregados al participante.

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Annex 38 UC-PT3-001 Phase 3 Interview schedule

Interview schedule

SHAPES Pan-European Pilot Campaign: User engagement and feedback on digital solutions for pilot theme 3 (Medicine control and optimisation), use case 1 (In-home decompensation prediction for heart failure patients) – phase 3

This interview will explore your views about the app. We are interested in hearing your thoughts, feelings and honest opinions about the app so please speak freely. There are no right or wrong answers and any feedback you have will be used to help improve the app and make it more accessible to people in your age group.

Topic/Theme	Interview question
Ease of use	• Were you able to easily use the app/dashboards/devices? • Tell me about any concerns you had while using the app/dashboards/devices? • How intuitive do you think the app/dashboards/devices are? • What do you think might prevent you from using this app/dashboard/devices?
Design	• Do you think the app/dasboards are nice to look at? • Are the colours used in the app/dashboards appealing? • Was there any sections of the app/dashboards that you could not read/see clearly?
Utility	• Do you think the app/dashboards are suitable for your needs? • Which of the features in the app/dashboards do you think are most relevant to you? • What other features would be useful for you?
Gender neutrality	• Do you think the app/dashboards are in any way too masculine or feminine? • Do you think the app/dashboards would appeal more to men or women, or to both about the same?

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Quality of training	• Was there any information missing in the demostration that would have been useful to know when you were using the app/dashboards? • Would you need any further support to use this app/dashboard/devices?
Overall satisfaction	• What is your overall impression of the app/dashboards? • How would people in your age group respond to being asked to use this app/dashboards? • What feature of the app/dashboards did you like the most? • How often would you use this app/dashboards? • Did it meet your expectations? • Is there anything you would improve?

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Annex 39 UC-PT3-001 Phase 4 Participant information sheet (older people and caregivers)

FULL D'INFORMACIÓ A LA PERSONA MAJOR PER A LA REALITZACIÓ DE PROJECTES D'INVESTIGACIÓ.

HIP: v1.0; 7 de gener del 2022

TÍTOL DE L'ESTUDI: Aplicació digital i plataforma SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) com suport en el control i la optimització de la medicació en persones majors amb insuficiència cardíaca. Estudi de viabilitat, no aleatoritzat, en escenari real per a l'avaluació de la participació d'usuari i la percepció de la seva utilitat. UC-PT3-001-CH.

CODI DEL PROTOCOL: UC-PT3-001-CH

PROMOTOR: Clinika de Kay, SL

INVESTIGADOR PRINCIPAL: *Dra. Karina Anahi Ojanguren Carreira*

CÀRREC, UNITAT, CENTRE: Directora mèdica, GRUP HUMANA (Clinika de Kay SL, Hospitalización a Domicilio SL)

TELÈFON: +34 971 21 71 79

CORREU ELECTRÒNIC: research@clinicahumana.es

INTRODUCCIÓ

Aquest document és per informar-vos sobre un estudi en el qual se us convida a participar. L'estudi l'ha aprovat el Comitè d'Ètica de la Investigació de les Illes Balears, d'acord amb la legislació vigent, i es du a terme amb respecte als principis enunciats en la declaració d'Hèlsinki i en les normes de bona pràctica clínica.

La nostra intenció és tan sols que rebeu la informació correcta i suficient perquè pugueu avaluar i jutjar si voleu participar-hi o no. Per a això, llegiu aquest full informatiu amb atenció i us aclarirem els dubtes que us puguin sorgir després de l'explicació. A més, podeu consultar amb les persones que considereu oportú. Si teniu cap dubte dirigiu-vos a la Dra. Karina Anahi Ojanguren Carreira a través de les dades de contacte que surten al principi d'aquest document.

DESCRIPCIÓ GENERAL

L'estudi en el què vostè està convidat a participar consisteix en fer servir unes eines digitals (les eines SHAPES) que ajuden en el control de la insuficiència cardíaca. Les eines no substitueixen ni modifiquen els tractaments mèdics i farmacològics. L'objectiu principal de l'estudi és avaluar si les eines SHAPES són fàcils d'utilitzar i es perceben com a útils pels usuaris. Hi ha dos tipus de participants a l'estudi, persones majors de 60 anys i, opcionalment, un dels seus cuidadors i metges del Grup Humana.

Vostè, en la condició de persona major, podrà fer servir l'aplicació mòbil SHAPES per enregistrar i veure l'històric de les següents dades: tensió arterial, freqüència cardíaca, saturació d'oxigen en sang, pes, composició massa corporal, nombre de passes, intensitat activitat física, hores i qualitat del son. Les dades les pot mesurar amb els següents aparells, que li proporcionarem específicament per l'estudi: un tensiòmetre, un pulsioxímetre, una bàscula i un braçalet d'activitat. També, amb l'aplicació mòbil SHAPES pot respondre a qüestionaris relacionats amb la seva salut, la presa de medicaments i sobre l'existència de nova informació rellevant, com ara resultats d'anàlisis de sang o orina, hospitalitzacions i altres usos de serveis mèdics i canvis en la medicació. Sense ser obligatori, dins de l'estudi se li recomanarà que proporcioni dades

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de tensió, freqüència cardíaca, saturació d'oxigen i pes una vegada al dia i que porti el braçalet d'activitat sempre. També, podria rebre recordatoris per respondre els qüestionaris o recomanacions de vida saludable. Vostè tindrà llibertat per seguir o no les recomanacions i contestar els qüestionaris en altres moments. Si ho prefereix, l'ús de l'aplicació mòbil la pot delegar al seu cuidador.

Al principi de l'estudi, en entrevistes personals, es recolliran dades clíniques seves, per a què el metge participant de l'estudi pugui conèixer el seu perfil com a pacient.

Totes les dades, excepte les d'activitat física i del son, també seran visibles per un metge, que forma part de l'equip mèdic del GRUP HUMANA. El metge pot contactar amb vostè si ho considera necessari, tant per fer-li una avaluació com per actualitzar les dades. Aquests contactes o visites en cap cas alteraran els serveis que el GRUP HUMANA li ofereix de forma regular fora d'aquest estudi.

Al final de l'estudi, es faran qüestionaris per avaluar la usabilitat, la utilitat i l'acceptació de les eines SHAPES. Al final de l'estudi, es realitzarà una entrevista a tots els participants per recollir la seva opinió. Finalment, als 3 mesos d'acabar l'estudi us farem uns qüestionaris de seguiment.

Nombre de participants i durada: L'objectiu de l'estudi es reclutar 10 persones majors i 1 o 2 metges del GRUP HUMANA. Un màxim de 3 persones majors i cuidadors podran opcionalment provar l'aplicació mòbil SHAPES durant una setmana abans de l'estudi, que servirà de test per provar tècnicament les solucions i on els usuaris podran proporcionar opinions per a la seva millora. Posteriorment, el total de participants faran ús de les eines SHAPES i dels dispositius durant 3 mesos.

Obligacions dels participants: Vostè ha de tenir 60 anys o més i haver estat diagnosticat amb insuficiència cardíaca. Per informe mèdic o segons criteri de la investigadora principal durant el reclutament, vostè ha de trobar-se a l'inici de l'estudi en un estadi II o III de la malaltia. L'usuari de de l'aplicació mòbil SHAPES (vostè o el seu cuidador) ha de tenir internet estable en algun moment del dia de forma regular.

Vostè rebrà formació i recomanacions d'ús de les eines SHAPES i dispositius associats per part dels investigadors a l'inici de l'estudi, però el seu compliment no és obligatori perquè l'objectiu de l'estudi és la seva avaluació en un entorn real. Les recomanacions per a vostè o el seus cuidadors són:

- Ús tensiòmetre, pulsioxímetre i bàscula un cop al dia.
- Respondre el qüestionari de seguiment un cop al dia.
- Portar el braçalet d'activitat constantment.

ALTRA INFORMACIÓ RELLEVANT

Qualsevol nova informació referent als dispositius o aplicació SHAPES utilitzats en l'estudi i que pugui afectar la vostra disposició per participar-hi, que es descobreixi durant la vostra participació, us la comunicarà la Dra. Karina Ojanguren el més aviat possible.

Si vostè decideix retirar el consentiment per participar en aquest estudi, no s'afegirà cap dada nova a la base de dades i podreu exigir que es destrueixin totes les vostres dades sempre hi quan no hagin estat anonimitzades.

També heu de saber que us poden retirar de l'estudi en cas que els responsables de l'estudi ho considerin oportú, ja sigui per motius de seguretat, per qualsevol esdeveniment advers que es produeixi o perquè considerin que no compliu amb els procediments establerts. En qualsevol dels casos, rebreu una explicació adequada del motiu que ha ocasionat la vostra retirada de l'estudi.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

En signar el full de consentiment adjunt es compromet a complir amb els procediments de l'estudi que se us han exposat.

BENEFICIS I RISCS DERIVATS DE LA VOSTRA PARTICIPACIÓ EN L'ESTUDI

No existeixen beneficis directes a nivell individual per participat en aquest estudi, més enllà de l'interès personal i l'experiència de participar en un estudi d'investigació. Encara que la intenció final de les eines SHAPES és millorar la qualitat de vida de les persones majors, i a l'estudi es recullen dades per fer una primera avaluació en aquest aspecte, l'objectiu principal de l'estudi és avaluar l'acceptació de l'eina entre els participants, un estudi que es considera necessari avaluar abans de fer un altre estudi focalitzat en els resultats mèdics.

Així, vostè podrà experimentar una millora de la seva qualitat de vida derivada d'un millor control de la insuficiència cardíaca, però també podria no experimentar cap millora. Tot i que es preveu improbable, podrien experimentar un empitjorament de la seva salut, per causes relacionades o no a l'estudi. La persona major pot abandonar l'estudi en qualsevol moment.

En relació als cuidadors, no s'espera que obtinguin cap benefici, més enllà de la satisfacció de poder fer un seguiment diari de la persona al seu càrrec.

ASSEGURANÇA

El GRUP HUMANA compta amb les assegurances de Responsabilitat Civil General que cobreixen els participants d'aquest estudi. Compta amb la pòlissa d'assegurança 560.005.411, a nom de Clinika de Kay SL amb la companyia AGRUPACIÓN MUTUAL ASEGURADORA, i la pòlissa d'assegurança 0961370001257 a nom de Hospitalización a Domicilio SL, amb la companyia MAPFRE SEGUROS DE EMPRESA. Aquestes dues pòlisses s'ajusten a la legislació vigent i cobreixen tots els perjudicis que puguin produir-se en relació amb la vostra participació en l'estudi.

CONFIDENCIALITAT

Responsable del tractament: *Dra. Karina Anahi Ojanguren Carreira, Cerr Anselm Turmeda 8, bajos, 07010, Palma, Illes Balears, +34 971 21 71 79, karinaojanguren@hotmail.com*

Responsable del tractament de dades: *José Eduardo Carretero Alberti, Cerr Anselm Turmeda 8, bajos, 07010, Palma, Illes Balears, +34 971 21 71 79, clinikadekay@gmail.com*

Finalitat de la recollida de dades: Investigació de la participació d'usuari i la utilitat de les eines SHAPES; Investigació sobre correlacions de paràmetres mèdics i d'estils de vida amb el control de la insuficiència cardíaca; Validació retrospectiva d'un predictor de descompensació cardíaca.

Destinataris de la informació: A més de Clinika de Kay, els següents col·laboradors tindran accés a algunes dades:

- Dades pseudoanonimitzades durant la intervenció (associades a un codi, on només Clinika de Kay pot relacionar aquest codi amb les seves dades identificadores).
    - EDGENEERING: per habilitar la visualització de dades mèdiques i d'activitat física i son. Contacte: Rua Abranches Ferrão, nº 10 - 11C 1600-001 Lisboa Portugal. Tel. +351 930 617 003. E-mail: edge@edgeneering.eu.
    - TREE TECHNOLOGY SA: dades del braçalet d'activitat per computar intensitat d'activitat física i paràmetres del son. Contacte: Camino de las

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Huertas 18, planta 1, 28223 Pozuelo de Alarcón, Madrid (Espanya) Tel. +34 902 286 386 · +34 910 059 088.

- Dades de-identificades (sense codi associat)
  - VICOMTECH: dades dels dispositius mèdics i respostes a qüestionaris per validar un predictor de descompensació cardíaca. Contacte: Parque Científico y Tecnológico de Gipuzkoa, Paseo Mikeletegi 57, 20009 Donostia / San Sebastián (Espanya) Tel. +(34) 943 309 230.
  - TREE TECHNOLOGY SA: dades mèdiques, d'activitat física, de son i d'ús de recursos sanitaris per investigar sobre correlacions. Contacte: Camino de las Huertas 18, planta 1, 28223 Pozuelo de Alarcón, Madrid (Espanya) Tel. +34 902 286 386 · +34 910 059 088.
  - Consorci SHAPES: qüestionaris estandarditzats (realitzats al principi, final i als 3 mesos de la intervenció) i dades sociodemogràfiques. Clinika de Kay col·labora amb el consorci europeu SHAPES per a la investigació d'eines digitals adreçades a les persones majors. Coordinador: National University Ireland Maynooth, Co. Kildare, Irlanda, shapes.info@mu.ie
- Dades anonimitzades (agregades)
  - Northern Health and Social Care Trust, per realitzar anàlisis amb altres estudis semblants amb pacients que pateixen diverses condicions. Contacte: Research Office Governance Department Bush House Bush Road Antrim BT41 2QB 028 9442 4653; frances.johnston@northerntrust.hscni.net
  - Comunitat científica: els qüestionaris estandarditzats i les dades sociodemogràfiques seran accessibles a la comunitat científica. Executor, coordinador SHAPES: National University Ireland Maynooth, Co. Kildare, Irlanda, shapes.info@mu.ie

Termini màxim de conservació de les dades: Al final del projecte SHAPES (Octubre 2023), les dades es de-identificaran i es conservaran a Clinika de Kay durant 5 anys. Després d'aquest període, es conservaran a Clinika de Kay de forma anònima i agregada i indefinidament. En el cas dels qüestionaris estandarditzats i dades socio-demogràfiques, les dades es conservaran de forma anònima i agregada, indefinidament a la plataforma SHAPES per fer-les accessibles a la comunitat científica.

El tractament, la comunicació i la cessió de les dades de caràcter personal de tots els subjectes participants s'ajusta al que disposa la Llei orgànica 3/2018, de 5 de desembre, de protecció de dades de caràcter personal i garantia dels drets digitals.

D'acord amb el que estableix la legislació esmentada, podeu exercir els drets d'accés, rectificació, supressió, oposició, limitació del tractament de dades, i fins i tot a traslladar les vostres dades a un tercer autoritzat (portabilitat); per a això heu de dirigir-vos a l'investigador principal responsable de tractament en les adreces següents:

- Investigadora principal: *Dra. Karina Anahi Ojanguren Carreira, Cerr Anselm Turmeda 8, bajos, 07010, Palma, Illes Balears, +34 971 21 71 79, karinaojanguren@hotmail.com*
- Responsable del tractament de dades*: José Eduardo Carretero Alberti, Cerr Anselm Turmeda 8, bajos, 07010, Palma, Illes Balears, +34 971 21 71 79, clinikadekay@gmail.com*

Les vostres dades es tractaran informàticament i s'incorporaran a un sistema automatitzat de dades de caràcter personal que compleix amb totes les mesures de seguretat d'accés restringit amb l'objectiu descrit en aquest document.

Per garantir la confidencialitat de la informació obtinguda,

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1. *codificació o pseudoanonimització*: durant l'estudi, les vostres dades estaran identificats mitjançant un codi i només el metge de l'estudi i col·laboradors dins del GRUP HUMANA poden relacionar aquestes dades amb vós i amb la vostra història clínica. Per tant, la vostra identitat no es revelarà a ningú, excepte en cas d'urgència mèdica, requeriment de l'Administració sanitària o requeriment legal.
2. *de*-identificació: a l'octubre 2023, el codi es dissociarà de les vostres dades.
3. *anonimització*: a partir d'octubre 2028, les vostres dades s'agregaran i es dissociaran irreversiblement de les vostres dades personals, de tal manera que serà impossible identificar a qui pertanyen posteriorment.

Només es transmetran a tercers i a altres països les dades imprescindibles necessàries per poder realitzar l'estudi, i que en cap cas contindran informació que us pugui identificar directament, com ara nom i cognoms, inicials, adreça, núm. de la seguretat social, etc. En el cas que es produís aquesta cessió, serà per a les mateixes finalitats de l'estudi descrit i garantint la confidencialitat com a mínim amb el nivell de protecció de la legislació vigent al nostre país.

L'accés a la vostra informació personal quedarà restringit al metge de l'estudi i col·laboradors dins del GRUP HUMANA, als metges participants de l'estudi (dades personals mèdiques però no identificables), autoritats sanitàries, al Comitè d'Ètica de la Investigació de les Illes Balears i personal autoritzat, quan ho hagin de menester per comprovar les dades i procediments de l'estudi, però sempre mantenint-ne la confidencialitat d'acord amb la legislació vigent.

Igualment, se us informa que podreu realitzar qualsevol consulta sobre aquest tractament davant la Delegació de Protecció de Dades de Clinika de Kay SL, que té la seu al carrer *Illes Balears nº7, escala A, pis 3B, Palma, 07014, Illes Balears, Espanya,* i el correu electrònic de contacte n'és *clinikadekay@gmail.com.*

En qualsevol cas, podeu adreçar-vos a l'Agència Espanyola de Protecció de Dades per a qualsevol reclamació derivada del tractament de les vostres dades personals.

COMPENSACIÓ ECONÒMICA

La vostra participació en l'estudi no us suposarà cap despesa, més enllà de l'ús del seu pla de dades d'internet. Vostè no rebrà cap compensació per participar en aquest estudi.

Els metges participants en l'estudi no rebran cap compensació econòmica. Els metges participants poden tenir el seu sou subvencionat per la comissió europea com a participants del projecte SHAPES (subvenció número 857159).

El sou de la investigadora principal de l'estudi, la Dra. Karina Anahi Ojanguren Carreira, està subvencionat per la comissió europea com a participant del projecte SHAPES (subvenció número 857159). La Dra. Karina Anahi Ojanguren Carreira és propietària tant de CLINIKA DE KAY SL com de HOSPITALIZACIÓN A DOMICILIO SL i, en conseqüència, de l'eina que proporciona els qüestionaris dins de l'aplicació mòbil SHAPES i de l'aplicació web per la visualització als metges.

PARTICIPACIÓ VOLUNTÀRIA

Heu de saber que la vostra participació en aquest estudi és voluntària i que podeu decidir no participar-hi o canviar la vostra decisió i retirar el consentiment en qualsevol moment, sense donar cap tipus d'explicació, així com sol·licitar la destrucció de les dades, sempre i quan no hagin estat anonimitzades, sense que per això s'alteri la relació amb el vostre metge o el tractament que heu de rebre.

AGRAÏMENT

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Sigui quina sigui la vostra decisió, tant el promotor com l'equip investigador us volen agrair el temps i l'atenció. Esteu contribuint a conèixer millor la vostra malaltia i a tractar-la, la qual cosa en el futur pot beneficiar multitud de persones.

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Annex 40 UC-PT3-001 Phase 4 Participant consent form (older people and caregivers)

CONSENTIMENT INFORMAT PER A LA REALITZACIÓ DE PROJECTES D'INVESTIGACIÓ – Persona major

V1.0 , 7 de gener del 2022

TÍTOL DE L'ESTUDI:

Aplicació digital i plataforma SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) com suport en el control i la optimització de la medicació en persones majors amb insuficiència cardíaca. Estudi de viabilitat, no aleatoritzat, en escenari real per a l'avaluació de la participació d'usuari i la percepció de la seva utilitat. UC-PT3-001-CH.

CODI DEL PROMOTOR: UC-PT3-001-CH

PROMOTOR: Clinika de Kay SL

INVESTIGADOR PRINCIPAL ***Dra. Karina Anahi Ojanguren Carreira, Directora mèdica, GRUP HUMANA, +34 971 21 71 79, karinaojanguren@hotmail.com***

CENTRE: GRUP HUMANA (Clinika de Kay SL, Hospitalización a Domicilio SL)

.....*(nom i llinatges)*

☐ He llegit el full d'informació que se m'ha lliurat.

☐ He pogut fer preguntes sobre l'estudi.

☐ He rebut prou informació sobre l'estudi.

☐ He parlat amb Esperança Lladó Pascual.

☐ Comprenc que la meva participació és voluntària.

☐ Comprenc que puc retirar-me de l'estudi:

- Quan vulgui.
- Sense haver de donar explicacions.
- Sense que això repercuteixi en les meves cures mèdiques.

☐ Comprenc que si decidesc retirar-me de l'estudi els resultats obtinguts fins a aquell moment es poden continuar utilitzant, a no ser que expressament indiqui la destrucció de totes les meves dades des de l'inici de l'estudi i sempre que no hagin estat anonimitzades.

En el cas que els resultats de la investigació proporcionin dades que em puguin interessar a mi o als meus familiars: (*indicau una de les caselles*)

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☐ En vull ser informat.

☐ No en vull ser informat, però accept que el meu metge contacti amb els meus familiars si els resultats els poden afectar.

☐ Comprenc que tenc els drets d'accés, rectificació, supressió, oposició, limitació del tractament de dades i, fins i tot, a traslladar les meves dades a un tercer autoritzat (portabilitat), d'acord amb el que disposa la Llei orgànica 3/2018, de 5 de desembre, de protecció de dades de caràcter personal i garantia dels drets digitals.

☐ Prest lliurement la meva conformitat per participar en l'estudi i don el meu consentiment per a l'accés i la utilització de les meves dades en les condicions que es detallen en el full d'informació al pacient/cuidador.

☐ Prest lliurement la meva conformitat per a què ..... (*nom cuidador*) pugui fer servir l'aplicació mòbil SHAPES per visualitzar les meves dades personals recollides del dispositius i respondre els qüestionaris en el meu nom (Opcional).

☐ Prest lliurement la meva conformitat per participar en el pre-estudi on es recolliran dades personals a través dels dispositius i qüestionaris per comprovar el funcionament tècnic de les eines SHAPES (Opcional).

En acabar la investigació, les meves dades poden ser:

☐ destruïdes

☐ de-identificada en octubre de 2023 i anonimitzada (agregació) en octubre de 2028.

[Rúbrica del persona major] [Rúbrica de l'investigador]

Nom: Nom:
Data: Data:

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Annex 41 UC-PT3-001 Phase 4 Participant information sheet (Health professionals)

FULL D'INFORMACIÓ AL PROFESSIONAL DE LA SALUT PER A LA REALITZACIÓ DE PROJECTES D'INVESTIGACIÓ.

HIPro: v1.0; 7 de gener del 2022

TÍTOL DE L'ESTUDI: Aplicació digital i plataforma SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) com suport en el control i la optimització de la medicació en persones majors amb insuficiència cardíaca. Estudi de viabilitat, no aleatoritzat, en escenari real per a l'avaluació de la participació d'usuari i la percepció de la seva utilitat. UC-PT3-001-CH.

CODI DEL PROTOCOL: UC-PT3-001-CH

PROMOTOR: Clinika de Kay, SL

INVESTIGADOR PRINCIPAL: *Dra. Karina Anahi Ojanguren Carreira*

CÀRREC, UNITAT, CENTRE: Directora mèdica, GRUP HUMANA (Clinika de Kay SL, Hospitalización a Domicilio SL)

TELÈFON: +34 971 21 71 79
CORREU ELECTRÒNIC: research@clinicahumana.es

INTRODUCCIÓ

Aquest document és per informar-vos sobre un estudi en el qual se us convida a participar. L'estudi l'ha aprovat el Comitè d'Ètica de la Investigació de les Illes Balears, d'acord amb la legislació vigent, i es du a terme amb respecte als principis enunciats en la declaració d'Hèlsinki i en les normes de bona pràctica clínica.

La nostra intenció és tan sols que rebeu la informació correcta i suficient perquè pugueu avaluar i jutjar si voleu participar-hi o no. Per a això, llegiu aquest full informatiu amb atenció i us aclarirem els dubtes que us puguin sorgir després de l'explicació. A més, podeu consultar amb les persones que considereu oportú. Si teniu cap dubte dirigiu-vos a la Dra. Karina Anahi Ojanguren Carreira a través de les dades de contacte que surten al principi d'aquest document.

DESCRIPCIÓ GENERAL

L'estudi en el què vostè està convidat a participar consisteix en fer servir unes eines digitals (les eines SHAPES) que ajuden en el control de pacients amb insuficiència cardíaca. Les eines no substitueixen ni modifiquen els tractaments mèdics i farmacològics. L'objectiu principal de l'estudi és avaluar si les eines SHAPES són fàcils d'usar i es perceben com a útils pels usuaris. Hi ha dos tipus de participants a l'estudi,

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persones majors de 60 anys i, opcionalment, un dels seus cuidadors i metges del Grup Humana.

Les persones majors podran fer servir l'aplicació mòbil SHAPES per poder enregistrar i veure l'històric de les següents dades: tensió arterial, freqüència cardíaca, saturació d'oxigen en sang, pes, composició massa corporal, nombre de passes, intensitat activitat física, hores i qualitat del son. També, amb l'aplicació mòbil SHAPES podran respondre a qüestionaris relacionats amb la seva salut, la presa de medicaments i sobre l'existència de nova informació rellevant, com ara resultats d'anàlisis de sang o orina, hospitalitzacions i altres usos de serveis mèdics i canvis en la medicació.

Vostè, com a professional sanitari participant veurà cada dia les dades enregistrades de cada persona major amb les aplicacions web SHAPES. Les aplicacions mostren l'històric dels enregistraments i mostra les dades en diferents colors (indicadors) segons els seus valors. Segons el que visualitzi, vostè decidirà segons el seu criteri si contacta o visita a la persona major (contacte derivat de l'estudi), de forma independent al seguiment que se li fa com a usuari del GRUP HUMANA. Aquests contactes derivats de l'estudi, així com les intervencions derivades, es registraran per avaluar l'impacte. Vostè també serà responsable d'actualitzar la informació a través de l'aplicació en referència a resultats d'anàlisis de sang o orina, hospitalitzacions i altres usos de serveis mèdics i canvis en la medicació.

Al final de l'estudi, es faran qüestionaris per avaluar la usabilitat, la utilitat i l'acceptació de les eines SHAPES. Al final de l'estudi, es realitzarà una entrevista a tots els participants per recollir la seva opinió.

Nombre de participants i durada: L'objectiu de l'estudi es reclutar 10 persones majors i 1 o 2 metges del GRUP HUMANA. Un màxim de 3 persones majors i cuidadors podran opcionalment provar l'aplicació mòbil SHAPES durant una setmana abans de l'estudi, que servirà de test per provar tècnicament les solucions i on els usuaris podran proporcionar opinions per a la seva millora. Posteriorment, el total de participants faran ús de les eines SHAPES i dels dispositius durant 3 mesos. Finalment, aproximadament als 3 mesos d'acabar, es realitzaran qüestionaris de seguiment.

Obligacions dels participants: Vostè ha de ser un metge titulat.

Les recomanacions per els metges participants són:

- Avaluar l'estat de les persones majors de l'estudi a través de les aplicacions web SHAPES un cop al dia durant els dies laborables. En cas de considerar que aquesta periodicitat d'avaluació no és adient, ho ha de comunicar a la gestora del projecte, Esperança Lladó Pascual per avaluar la continuïtat del projecte.

ALTRA INFORMACIÓ RELLEVANT

Si vostè decideix retirar el consentiment per participar en aquest estudi, no s'afegirà cap dada nova a la base de dades i podreu exigir que es destrueixin totes les vostres dades sempre hi quan no hagin estat anonimitzades.

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També heu de saber que us poden retirar de l'estudi en cas que els responsables de l'estudi ho considerin oportú, ja sigui per motius de seguretat, per qualsevol esdeveniment advers que es produeixi o perquè considerin que no compliu amb els procediments establerts. En qualsevol dels casos, rebreu una explicació adequada del motiu que ha ocasionat la vostra retirada de l'estudi.

En signar el full de consentiment adjunt es compromet a complir amb els procediments de l'estudi que se us han exposat.

BENEFICIS I RISCS DERIVATS DE LA VOSTRA PARTICIPACIÓ EN L'ESTUDI

No existeixen beneficis directes a nivell individual per participat en aquest estudi, més enllà de l'interès personal i l'experiència de participar en un estudi d'investigació. Encara que la intenció final de les eines SHAPES és millorar la qualitat de vida de les persones majors, i a l'estudi es recullen dades per fer una primera avaluació en aquest aspecte, l'objectiu principal de l'estudi és avaluar l'acceptació de l'eina entre els participants, un estudi que es considera necessari avaluar abans de fer un altre estudi focalitzat en els resultats mèdics.

En relació als metges participants, no s'espera que obtinguin cap benefici, més enllà de la satisfacció de poder fer un seguiment diari dels pacients.

ASSEGURANÇA

El GRUP HUMANA compta amb les assegurances de Responsabilitat Civil General que cobreixen els participants d'aquest estudi. Compta amb la pòlissa d'assegurança 560.005.411, a nom de Clinika de Kay SL amb la companyia AGRUPACIÓN MUTUAL ASEGURADORA, i la pòlissa d'assegurança 0961370001257 a nom de Hospitalización a Domicilio SL, amb la companyia MAPFRE SEGUROS DE EMPRESA. Aquestes dues pòlisses s'ajusten a la legislació vigent i cobreixen tots els perjudicis que puguin produir-se en relació amb la vostra participació en l'estudi.

CONFIDENCIALITAT

Responsable del tractament: *Dra. Karina Anahi Ojanguren Carreira, Cerr Anselm Turmeda 8, bajos, 07010, Palma, Illes Balears, +34 971 21 71 79, karinaojanguren@hotmail.com*

Responsable del tractament de dades: *José Eduardo Carretero Alberti, Cerr Anselm Turmeda 8, bajos, 07010, Palma, Illes Balears, +34 971 21 71 79, clinikadekay@gmail.com*

Finalitat de la recollida de dades: Investigació de la participació d'usuari i la utilitat de les eines SHAPES; Investigació sobre correlacions de paràmetres mèdics i d'estils de vida amb el control de la insuficiència cardíaca; Validació retrospectiva d'un predictor de descompensació cardíaca.

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Destinataris de la informació: A més de Clinika de Kay, els següents col·laboradors tindran accés a algunes dades:

- Dades de-identificades (sese codi associat)
  - Consorci SHAPES: qüestionaris estandarditzats (realitzats al final de la intervenció). Clinika de Kay col·labora amb el consorci europeu SHAPES per a la investigació d'eines digitals adreçades a les persones majors. Coordinador: National University Ireland Maynooth, Co. Kildare, Irlanda, shapes.info@mu.ie
- Dades anonimitzades (agregades)
  - Northern Health and Social Care Trust, per realitzar anàlisis amb altres estudis semblants amb pacients que pateixen diverses condicions. Contacte: Research Office Governance Department Bush House Bush Road Antrim BT41 2QB 028 9442 4653; frances.johnston@northerntrust.hscni.net
  - Comunitat científica: els qüestionaris estandarditzats seran accessibles a la comunitat científica. Executor, coordinador SHAPES: National University Ireland Maynooth, Co. Kildare, Irlanda, shapes.info@mu.ie

Termini màxim de conservació de les dades: Al final del projecte SHAPES (Octubre 2023), les dades de-identificades es conservaran a Clinika de Kay durant 5 anys. Després d'aquest període, es conservaran a Clinika de Kay de forma anònima i agregada. En el cas dels qüestionaris estandarditzats les dades es conservaran de forma anònima i agregada a la plataforma SHAPES per fer-los accessibles a la comunitat científica.

El tractament, la comunicació i la cessió de les dades de caràcter personal de tots els subjectes participants s'ajusta al que disposa la Llei orgànica 3/2018, de 5 de desembre, de protecció de dades de caràcter personal i garantia dels drets digitals.

D'acord amb el que estableix la legislació esmentada, podeu exercir els drets d'accés, rectificació, supressió, oposició, limitació del tractament de dades, i fins i tot a traslladar les vostres dades a un tercer autoritzat (portabilitat); per a això heu de dirigir-vos a l'investigador principal responsable de tractament en les adreces següents:

- Investigadora principal: *Dra. Karina Anahi Ojanguren Carreira, Cerr Anselm Turmeda 8, bajos, 07010, Palma, Illes Balears, +34 971 21 71 79, karinaojanguren@hotmail.com*
- *Responsable del tractament de dades: José Eduardo Carretero Alberti, Cerr Anselm Turmeda 8, bajos, 07010, Palma, Illes Balears, +34 971 21 71 79, clinikadekay@gmail.com*

Les vostres dades es tractaran informàticament i s'incorporaran a un sistema automatitzat de dades de caràcter personal que compleix amb totes les mesures de seguretat d'accés restringit a l'objectiu descrit en aquest document.

Per garantir la confidencialitat de la informació obtinguda,

1) *codificació o pseudoanonimització*: durant l'estudi, les vostres dades estaran identificats mitjançant un codi i només l'investigador principal i col·laboradors dins del GRUP HUMANA poden relacionar aquestes dades amb vós. Per tant, la vostra

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identitat no es revelarà a ningú, excepte en cas de requeriment de l'Administració sanitària o requeriment legal.

2) *de*-identificació: a l'octubre 2023, el codi es dissociarà de les vostres dades.
3) *anonimització*: a partir d'octubre 2028, les vostres dades s'agregaran i es dissociaran irreversiblement de les vostres dades personals, de tal manera que serà impossible identificar a qui pertanyen posteriorment.

Només es transmetran a tercers i a altres països les dades imprescindibles necessàries per poder realitzar l'estudi, i que en cap cas contindran informació que us pugui identificar directament, com ara nom i cognoms, inicials, adreça, etc. En el cas que es produís aquesta cessió, serà per a les mateixes finalitats de l'estudi descrit i garantint la confidencialitat com a mínim amb el nivell de protecció de la legislació vigent al nostre país.

L'accés a la vostra informació personal quedarà restringit als col·laboradors dins del GRUP HUMANA, als metges participants de l'estudi (dades personals mèdiques però no identificables), autoritats sanitàries, al Comitè d'Ètica de la Investigació de les Illes Balears i personal autoritzat, quan ho hagin de menester per comprovar les dades i procediments de l'estudi, però sempre mantenint-ne la confidencialitat d'acord amb la legislació vigent.

Igualment, se us informa que podreu realitzar qualsevol consulta sobre aquest tractament davant la Delegació de Protecció de Dades de Clinika de Kay SL, que té la seu al carrer *Illes Balears nº7, escala A, pis 3B, Palma, 07014, Illes Balears, Espanya*, i el correu electrònic de contacte n'és *clinikadekay@gmail.com.*

En qualsevol cas, podeu adreçar-vos a l'Agència Espanyola de Protecció de Dades per a qualsevol reclamació derivada del tractament de les vostres dades personals.

COMPENSACIÓ ECONÒMICA

Vostè, com a metge participant en l'estudi no rebran cap compensació econòmica. Els metges participants poden tenir el seu sou subvencionat per la comissió europea com a participants del projecte SHAPES (subvenció número 857159).

El sou de la investigadora principal de l'estudi, la Dra. Karina Anahi Ojanguren Carreira, està subvencionat per la comissió europea com a participant del projecte SHAPES (subvenció número 857159). La Dra. Karina Anahi Ojanguren Carreira és propietària tant de CLINIKA DE KAY SL com de HOSPITALIZACIÓN A DOMICILIO SL i, en conseqüència, de l'eina que proporciona els qüestionaris dins de l'aplicació mòbil SHAPES i de l'aplicació web per la visualització als metges.

La participació de persones majors a aquest estudi no els suposarà cap despesa així com tampoc rebran cap compensació econòmica.

PARTICIPACIÓ VOLUNTÀRIA

Heu de saber que la vostra participació en aquest estudi és voluntària i que podeu decidir no participar-hi o canviar la vostra decisió i retirar el consentiment en qualsevol moment,

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sense donar cap tipus d'explicació, així com sol·licitar la destrucció de les dades, sempre i quan no hagin estat anonimitzades, sense que per això s'alteri la relació amb el vostre metge o el tractament que heu de rebre.

AGRAÏMENT

Sigui quina sigui la vostra decisió, tant el promotor com l'equip investigador us volen agrair el temps i l'atenció. Esteu contribuint a conèixer millor la insuficiència cardíaca i a tractar-la, la qual cosa en el futur pot beneficiar multitud de persones.

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Annex 42 UC-PT3-001 Phase 4 Participant consent form (Health professionals)

CONSENTIMENT INFORMAT PER A LA REALITZACIÓ DE PROJECTES D'INVESTIGACIÓ - Professional

V1.0 , 7 de gener del 2022

TÍTOL DE L'ESTUDI: Aplicació digital i plataforma SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) com suport en el control i la optimització de la medicació en persones majors amb insuficiència cardíaca. Estudi de viabilitat, no aleatoritzat, en escenari real per a l'avaluació de la participació d'usuari i la percepció de la seva utilitat.UC-PT3-001-CH.

CODI DEL PROMOTOR: UC-PT3-001-CH

PROMOTOR: Clinika de Kay SL

INVESTIGADOR PRINCIPAL ***Dra. Karina Anahi Ojanguren Carreira, Directora mèdica, GRUP HUMANA, +34 971 21 71 79, karinaojanguren@hotmail.com***

CENTRE: GRUP HUMANA (Clinika de Kay SL, Hospitalización a Domicilio SL)

.....*(nom i llinatges)*

☐ He llegit el full d'informació que se m'ha lliurat.

☐ He pogut fer preguntes sobre l'estudi.

☐ He rebut prou informació sobre l'estudi.

☐ He parlat amb Esperança Lladó Pascual.

☐ Comprenc que la meva participació és voluntària.

☐ Comprenc que puc retirar-me de l'estudi:

- Quan vulgui.
- Sense haver de donar explicacions.
- Sense que això repercuteixi en la meva activitat laboral.

☐ Comprenc que si decidesc retirar-me de l'estudi els resultats obtinguts fins a aquell moment es poden continuar utilitzant, a no ser que expressament indiqui la destrucció de totes les meves dades des de l'inici de l'estudi i sempre que no hagin estat anonimitzades.

☐ Comprenc que tenc els drets d'accés, rectificació, supressió, oposició, limitació del tractament de dades i, fins i tot, a traslladar les meves dades a un tercer autoritzat

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(portabilitat), d'acord amb el que disposa la Llei orgànica 3/2018, de 5 de desembre, de protecció de dades de caràcter personal i garantia dels drets digitals.

☐ Prest lliurement la meva conformitat per participar en l'estudi i don el meu consentiment per a l'accés i la utilització de les meves dades en les condicions que es detallen en el full d'informació al participant professional de la salut.

☐ Prest lliurement la meva conformitat per participar en el pre-estudi on es recolliran dades personals a través dels dispositius i qüestionaris per comprovar el funcionament tècnic de les eines SHAPES (opcional).

En acabar la investigació, les meves dades poden ser:

☐ destruïdes

☐ de-identificada en octubre de 2023 i anonimitzada (agregació) en octubre de 2028.

[Rúbrica del participant professional de la salut] [Rúbrica de l'investigador]

Nom: Nom:
Data: Data:

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Annex 43 UC-PT3-001 USER MANUALS

SHAPES PT3-001

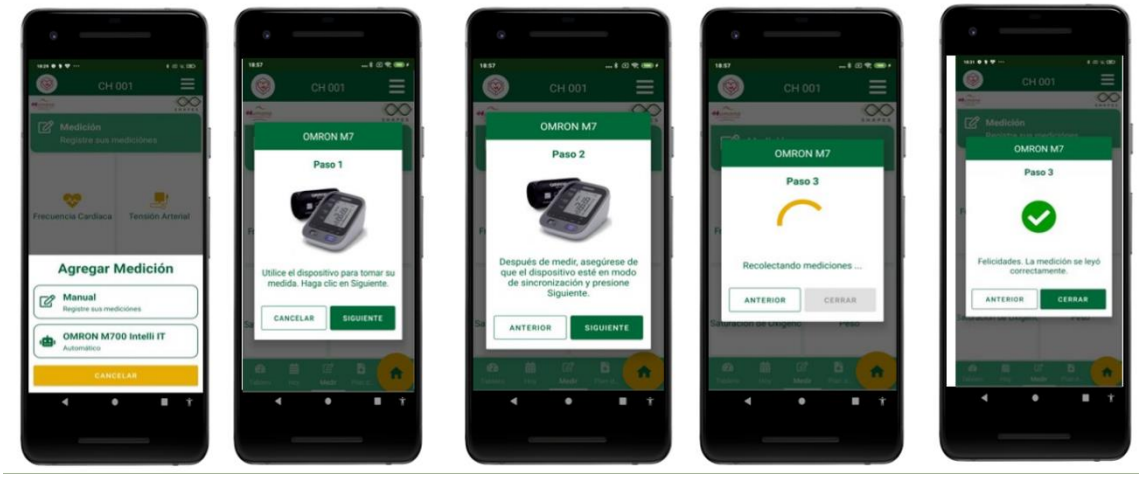
INSTRUCCIONES PARTICIPANTE (PERSONA MAYOR - CUIDADOR)

MATERIAL:

- Aplicación móvil
- Dispositivos médicos (tensiómetro, pulsioxímetro y báscula)
- Pulsera de actividad

DESCRIPCIÓN DE RUTINA DIARIA:

1. Cada mañana el usuario se tomará las constantes:
    a. Tensión arterial: Los pasos a seguir son:
        i. Colocar el tensiómetro
        ii. Asegurarnos de que el usuario es el correcto (1)
        iii. Pulsar el botón para empezar la medición
        iv. Esperar a que aparezca la tensión arterial
        v. Ir a la aplicación y elegir “Agregar medición OMRON M700 Intelli IT”



    b. Saturación de oxígeno: Los pasos a seguir son:
        i. Pulsar el botón del pulsioxímetro
        ii. Colocar el pulsioxímetro en el dedo
        iii. Esperar a que se estabilice la saturación de oxígeno

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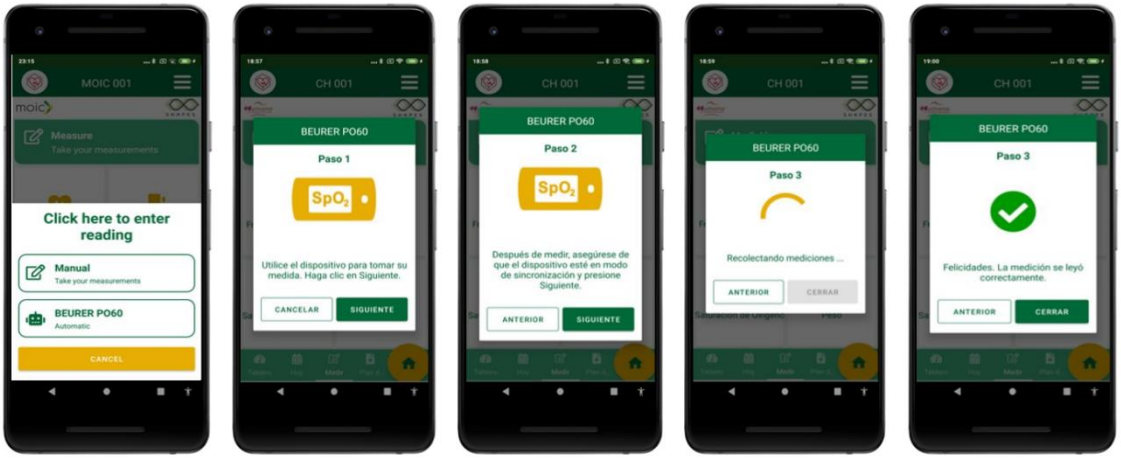
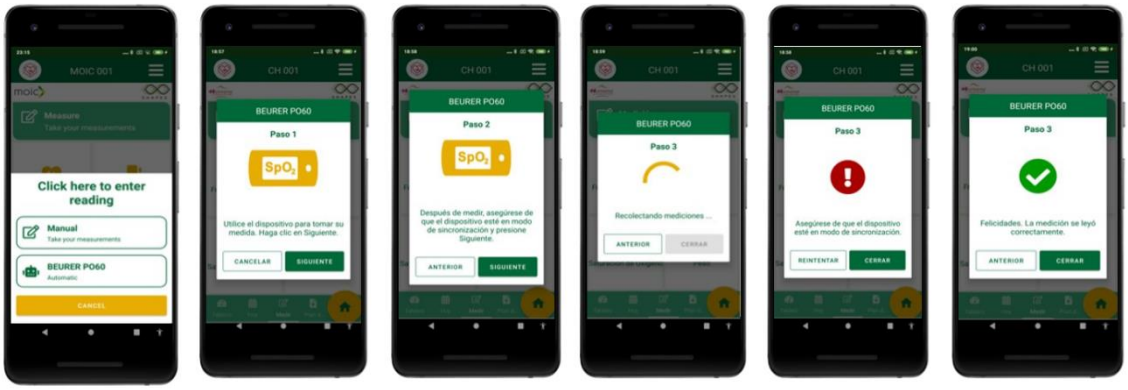
iv. Retirar el dedo y esperar que aparezca SYNC en la pantalla
v. Ir a la aplicación y elegir “Agregar medición BEURER P060”



Si no funciona, pulsar “reintentar”:



2. Cada mañana el usuario se pesará. Los pasos a seguir son:
    a. Pulsar el botón ON/OFF
    b. Confirmar que nos encontramos en el usuario 1 (MUY IMPORTANTE)
    c. Subir a la báscula y esperar que aparezca el peso y resto de datos
    d. Ir a la aplicación y elegir “Agregar medición OMRON VIVA”

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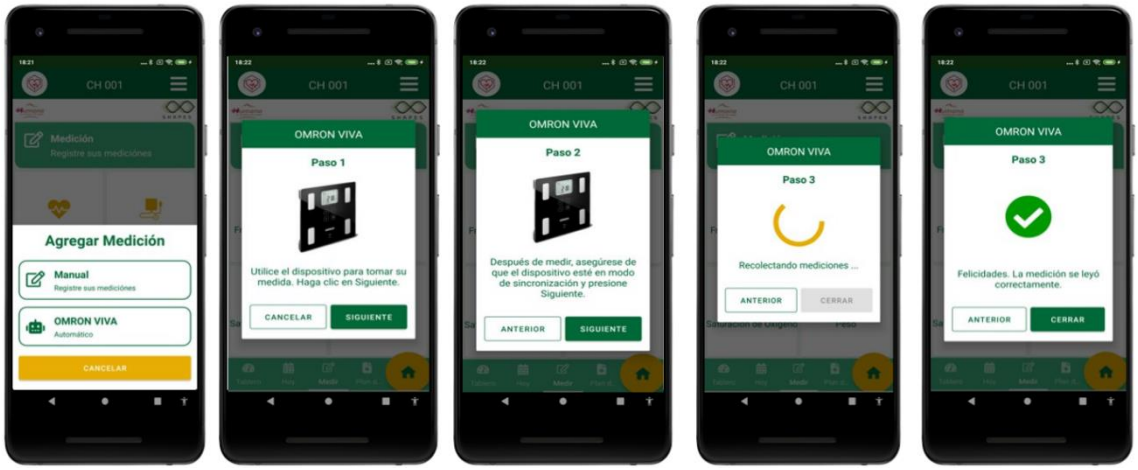

3. El usuario llevará la pulsera de actividad durante el máximo tiempo posible, incluso durante la noche, siempre que no esté en contacto con agua. El registro de actividad física y sueño se hará de forma automática y el usuario podrá ver estos datos en la aplicación móvil.
4. El usuario recibirá notificaciones al dispositivo móvil a modo de recordatoria para realizar los cuestionarios de forma periódica:
    a. Cuestionario de seguimiento: 1 vez al día
    b. Cuestionario de adherencia a la medicación: 1 vez a la semana
    c. Cuestionario “Dar nueva información”: Siempre que el usuario tenga nueva información sobre cambio de medicación, contacto con un sanitario o ingreso, resultado de analítica.

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SHAPES PT3-001

INSTRUCCIONES PARTICIPANTE (SANITARIO)

LINKS A LAS HERRAMIENTAS DIGITALES:

Dashboard Clínica Humana: https://test.clinicahumana.es/shapes

Dashboard eCare: https://shapes.edgeneering.eu/login

DESCRIPCIÓN:

Cada mañana el sanitario accederá primero a la Dashboard de eCare y luego a la Dashboard de Clínica Humana con su usuario y contraseña.

A continuación, se explica detalladamente la rutina sugerida para poder llevar a cabo la fase 5 de manera exitosa.

Dashboard eCare:

1. Accederá a la página principal (Ilustración 1) dónde podrá ver las alertas de los pacientes por prioridad de atención (según color).

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Ilustración 1. Alertas (página principal) eCare Dashboard

2. Accederá al Tablero (Ilustración 2) donde podrá ver el estado de cada uno de los pacientes, sus constantes y tendrá la opción de ver más detalles.

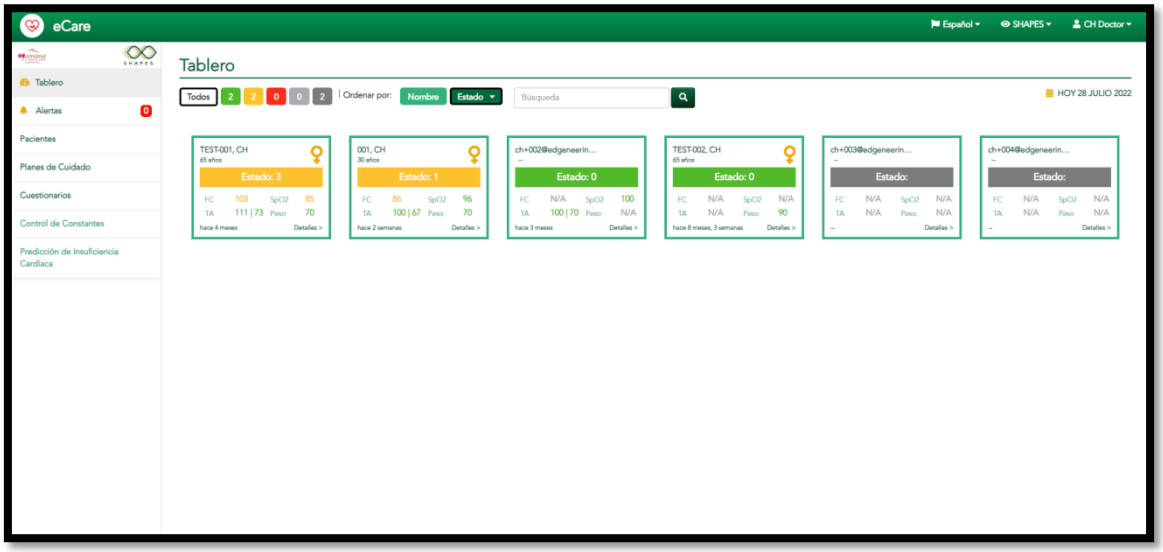

Ilustración 2. Tablero de eCare Dashboard

3. Accederá al apartado de Pacientes donde podrá ver en detalle las constantes vitales y el peso, así como un histórico de cada uno.

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Ilustración 3. Sección Pacientes eCare Dashboard

4. Además, el sanitario podrá entrar en el plan de cuidado de cada paciente para personalizarlo y que éste le aparezca al paciente en la aplicación móvil.

Ilustración 4. Planes de cuidado eCare Dashboard

La sección Cuestionarios se utilizará en la fase 5 de este proyecto por parte del "Researcher". Las secciones Control de constantes (TREE) y Predicción de insuficiencia cardíaca (VICOM) se encuentran deshabilitadas y solamente serán visibles al finalizar el proyecto para no intervenir en el criterio médico.

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Dashboard Clínica Humana:

1. Accederá a la página principal de la Dashboard de CH (Ilustración 5) donde podrá visualizar un resumen de todas las alarmas para todos los pacientes. Clicando en cada grupo de alarmas podrá ver el detalle de las mismas.

Ilustración 5. Página principal Dasbboard CH

2. Seguidamente accederá a Listado donde verá el listado de pacientes y su información:
    a. Nombre: Clicando encima del usuario podrá actualizar la información del paciente.
    b. P1: Podrá ver los datos médicos del paciente.
    c. P2: Podrá ver los resultados de analíticas.
    d. P3: Podrá ver las respuestas a los cuestionarios:
        i. Chatbot 1: Cuestionario de seguimiento (se espera que los pacientes respondan de forma diaria)
        ii. Chatbot 2: Cuestionario de adherencia a la medicación (se espera que los pacientes respondan de forma semanal)
        iii. Chatbot 3: Nueva información (se espera que los pacientes aporten nueva información sobre visitas sanitarias, hospitalizaciones, resultados de analíticas o cambio de medicación, en el momento que tengan nueva información).

Predictor de descompensación cardíaca (VICOMTECH)

En caso de que alguno de los pacientes experimente alguno de los siguientes eventos (admisión en hospital, visita a urgencias, tratamiento farmacológico en el hogar o defunción) el sanitario deberá rellenar el formulario en formato Excel en línea “Outcomes HF Pred”.

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En la primera hoja de este documento se explica cómo rellenar el documento (Ilustración 6) y en la segunda hoja el sanitario podrá rellenar los datos para cada paciente (Ilustración 7).

Esta información se enviará a VICOMTECH al final del proyecto para comparar los eventos de descompensación de cada paciente con los resultados predictivos del algoritmo de descompensación cardíaca.

OUTCOMES HF Pred								
Incident type	Description	Observations	Data to gather					
			Identifier (SHAPES ID)	Start date	End date	Incidence	Treatment	Related_HF
Admission	The patient is admitted to hospital.	Both the beginning and the end of the entry shall be indicated, and that it was an admission.	Patient identifier	The date in which the patient is admitted	The date the patient is discharged.	"hospital_admission"	None	yes / no
Emergency Department (ED)	The patient attends the emergency department.	If admitted after a visit to the emergency department, a new "admission" label will be created at the time of admission. Both the beginning and the end of the entry shall be indicated, and that it was an ED visit.	Patient identifier	The date in which the patient has visited the ED	The date the patient is discharged (usually the same day).	"ED"	None	yes / no
Home treatment	The patient is treated remotely with medication.	"home treatment", generating a new instance. In this way, each medication (instance) will have its start date, end date, incidence type, and the medication with which it has been treated remotely. If the treatment is not related to HF, the treatment would be "other". The "Treatment" variable is gathered as "oral_diuretics", "intravenous_diuretics" or "other". This can be extended if any other medication type is already used and known in the pilots, but discussed	Patient identifier	The date in which the patient has started with this medication.	The date the patient has ended with this medication.	"home_treatment"	"oral_diuretics", "intravenous_diuretics " or "other"	yes / no
Death	When the patient dies.	-	Patient identifier	Date of death.	None	"death"	None	yes / no
*To estimate if it would be a readmission (the variable "is_readmission"), only the incidents with the tag "Related_HF" in yes will be used.								

Ilustración 6. Instrucciones "Outcomes HF Pred"

OUTCOMES HF Pred								
Incident type	Description	Observations	Data to gather					
			Identifier	Start date	End date	Incidence	Treatment	Related_HF

Ilustración 7. Plantilla "Outcomes HF Pred"

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Annex 44 UC-PT3-001 Phase 5 Participant information sheets (older people and caregivers; Healthcare professionals)

FULL D'INFORMACIÓ A LA PERSONA MAJOR/CUIDADOR PER A LA REALITZACIÓ DE PROJECTES D'INVESTIGACIÓ.

HIP: v1.0; 7 de gener del 2022

TÍTOL DE L'ESTUDI: Aplicació digital i plataforma SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) com suport en el control i la optimització de la medicació en persones majors amb insuficiència cardíaca. Estudi de viabilitat, no aleatoritzat, en escenari real per a l'avaluació de la participació d'usuari i la percepció de la seva utilitat. UC-PT3-001-CH.

CODI DEL PROTOCOL: UC-PT3-001-CH

PROMOTOR: Clinika de Kay, SL

INVESTIGADOR PRINCIPAL: *Dra. Karina Anahi Ojanguren Carreira*

CÀRREC, UNITAT, CENTRE: Directora mèdica, GRUP HUMANA (Clinika de Kay SL, Hospitalización a Domicilio SL)

TELÈFON: +34 971 21 71 79
CORREU ELECTRÒNIC: research@clinicahumana.es

INTRODUCCIÓ

Aquest document és per informar-vos sobre un estudi en el qual se us convida a participar. L'estudi l'ha aprovat el Comitè d'Ètica de la Investigació de les Illes Balears, d'acord amb la legislació vigent, i es du a terme amb respecte als principis enunciats en la declaració d'Hèlsinki i en les normes de bona pràctica clínica.

La nostra intenció és tan sols que rebeu la informació correcta i suficient perquè pugueu avaluar i jutjar si voleu participar-hi o no. Per a això, llegiu aquest full informatiu amb atenció i us aclarirem els dubtes que us puguin sorgir després de l'explicació. A més, podeu consultar amb les persones que considereu oportú. Si teniu cap dubte dirigiu-vos a la Dra. Karina Anahi Ojanguren Carreira a través de les dades de contacte que surten al principi d'aquest document.

DESCRIPCIÓ GENERAL

L'estudi en el què vostè està convidat a participar consisteix en fer servir unes eines digitals (les eines SHAPES) que ajuden en el control de la insuficiència cardíaca. Les eines no substitueixen ni modifiquen els tractaments mèdics i farmacològics. L'objectiu principal de l'estudi és avaluar si les eines SHAPES són fàcils d'utilitzar i es perceben

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com a útils pels usuaris. Hi ha dos tipus de participants a l'estudi, persones majors de 60 anys i, opcionalment, un dels seus cuidadors i metges del Grup Humana.

Vostè, en la condició de persona major, podrà fer servir l'aplicació mòbil SHAPES per enregistrar i veure l'històric de les següents dades: tensió arterial, freqüència cardíaca, saturació d'oxigen en sang, pes, composició massa corporal, nombre de passes, intensitat activitat física, hores i qualitat del son. Les dades les pot mesurar amb els següents aparells, que li proporcionarem específicament per l'estudi: un tensiòmetre, un pulsioxímetre, una bàscula i un braçalet d'activitat. També, amb l'aplicació mòbil SHAPES pot respondre a qüestionaris relacionats amb la seva salut, la presa de medicaments i sobre l'existència de nova informació rellevant, com ara resultats d'anàlisis de sang o orina, hospitalitzacions i altres usos de serveis mèdics i canvis en la medicació. Sense ser obligatori, dins de l'estudi se li recomanarà que proporcioni dades de tensió, freqüència cardíaca, saturació d'oxigen i pes una vegada al dia i que porti el braçalet d'activitat sempre. També, podria rebre recordatoris per respondre els qüestionaris o recomanacions de vida saludable. Vostè tindrà llibertat per seguir o no les recomanacions i contestar els qüestionaris en altres moments. Si ho prefereix, l'ús de l'aplicació mòbil la pot delegar al seu cuidador.

Al principi de l'estudi, en entrevistes personals, es recolliran dades clíniques seves, per a què el metge participant de l'estudi pugui conèixer el seu perfil com a pacient.

Totes les dades, excepte les d'activitat física i del son, també seran visibles per un metge, que forma part de l'equip mèdic del GRUP HUMANA. El metge pot contactar amb vostè si ho considera necessari, tant per fer-li una avaluació com per actualitzar les dades. Aquests contactes o visites en cap cas alteraran els serveis que el GRUP HUMANA li ofereix de forma regular fora d'aquest estudi.

Al final de l'estudi, es faran qüestionaris per avaluar la usabilitat, la utilitat i l'acceptació de les eines SHAPES. Al final de l'estudi, es realitzarà una entrevista a tots els participants per recollir la seva opinió. Finalment, als 3 mesos d'acabar l'estudi us farem uns qüestionaris de seguiment.

Nombre de participants i durada: L'objectiu de l'estudi es reclutar 10 persones majors i 1 o 2 metges del GRUP HUMANA. Un màxim de 3 persones majors i cuidadors podran opcionalment provar l'aplicació mòbil SHAPES durant una setmana abans de l'estudi, que servirà de test per provar tècnicament les solucions i on els usuaris podran proporcionar opinions per a la seva millora. Posteriorment, el total de participants faran ús de les eines SHAPES i dels dispositius durant 3 mesos.

Obligacions dels participants: Vostè ha de tenir 60 anys o més i haver estat diagnosticat amb insuficiència cardíaca. Per informe mèdic o segons criteri de la investigadora principal durant el reclutament, vostè ha de trobar-se a l'inici de l'estudi en un estadi II o III de la malaltia. L'usuari de de l'aplicació mòbil SHAPES (vostè o el seu cuidador) ha de tenir internet estable en algun moment del dia de forma regular.

Vostè rebrà formació i recomanacions d'ús de les eines SHAPES i dispositius associats per part dels investigadors a l'inici de l'estudi, però el seu compliment no és obligatori perquè l'objectiu de l'estudi és la seva avaluació en un entorn real. Les recomanacions per a vostè o el seus cuidadors són:

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- Ús tensiòmetre, pulsioxímetre i bàscula un cop al dia.
- Respondre el qüestionari de seguiment un cop al dia.
- Portar el braçalet d'activitat constantment.

ALTRA INFORMACIÓ RELLEVANT

Qualsevol nova informació referent als dispositius o aplicació SHAPES utilitzats en l'estudi i que pugui afectar la vostra disposició per participar-hi, que es descobreixi durant la vostra participació, us la comunicarà la Dra. Karina Ojanguren el més aviat possible.

Si vostè decideix retirar el consentiment per participar en aquest estudi, no s'afegirà cap dada nova a la base de dades i podreu exigir que es destrueixin totes les vostres dades sempre hi quan no hagin estat anonimitzades.

També heu de saber que us poden retirar de l'estudi en cas que els responsables de l'estudi ho considerin oportú, ja sigui per motius de seguretat, per qualsevol esdeveniment advers que es produeixi o perquè considerin que no compliu amb els procediments establerts. En qualsevol dels casos, rebreu una explicació adequada del motiu que ha ocasionat la vostra retirada de l'estudi.

En signar el full de consentiment adjunt es compromet a complir amb els procediments de l'estudi que se us han exposat.

BENEFICIS I RISCS DERIVATS DE LA VOSTRA PARTICIPACIÓ EN L'ESTUDI

No existeixen beneficis directes a nivell individual per participat en aquest estudi, més enllà de l'interès personal i l'experiència de participar en un estudi d'investigació. Encara que la intenció final de les eines SHAPES és millorar la qualitat de vida de les persones majors, i a l'estudi es recullen dades per fer una primera avaluació en aquest aspecte, l'objectiu principal de l'estudi és avaluar l'acceptació de l'eina entre els participants, un estudi que es considera necessari avaluar abans de fer un altre estudi focalitzat en els resultats mèdics.

Així, vostè podrà experimentar una millora de la seva qualitat de vida derivada d'un millor control de la insuficiència cardíaca, però també podria no experimentar cap millora. Tot i que es preveu improbable, podrien experimentar un empitjorament de la seva salut, per causes relacionades o no a l'estudi. La persona major pot abandonar l'estudi en qualsevol moment.

En relació als cuidadors, no s'espera que obtinguin cap benefici, més enllà de la satisfacció de poder fer un seguiment diari de la persona al seu càrrec.

ASSEGURANÇA

El GRUP HUMANA compta amb les assegurances de Responsabilitat Civil General que cobreixen els participants d'aquest estudi. Compta amb la pòlissa d'assegurança 560.005.411, a nom de Clinika de Kay SL amb la companyia AGRUPACIÓN MUTUAL ASEGURADORA, i la pòlissa d'assegurança 0961370001257 a nom de Hospitalización a Domicilio SL, amb la companyia MAPFRE SEGUROS DE EMPRESA. Aquestes dues

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pòlisses s'ajusten a la legislació vigent i cobreixen tots els perjudicis que puguin produir-se en relació amb la vostra participació en l'estudi.

CONFIDENCIALITAT

Responsable del tractament: *Dra. Karina Anahi Ojanguren Carreira, Cerr Anselm Turmeda 8, bajos, 07010, Palma, Illes Balears, +34 971 21 71 79, karinaojanguren@hotmail.com*

Responsable del tractament de dades: *José Eduardo Carretero Alberti, Cerr Anselm Turmeda 8, bajos, 07010, Palma, Illes Balears, +34 971 21 71 79, clinikadekay@gmail.com*

Finalitat de la recollida de dades: Investigació de la participació d'usuari i la utilitat de les eines SHAPES; Investigació sobre correlacions de paràmetres mèdics i d'estils de vida amb el control de la insuficiència cardíaca; Validació retrospectiva d'un predictor de descompensació cardíaca.

Destinataris de la informació: A més de Clinika de Kay, els següents col·laboradors tindran accés a algunes dades:

- Dades pseudoanonimitzades durant la intervenció (associades a un codi, on només Clinika de Kay pot relacionar aquest codi amb les seves dades identificadores).
    - EDGENEERING: per habilitar la visualització de dades mèdiques i d'activitat física i son. Contacte: Rua Abranches Ferrão, nº 10 - 11C 1600-001 Lisboa Portugal. Tel. +351 930 617 003. E-mail: edge@edgeneering.eu.
    - TREE TECHNOLOGY SA: dades del braçalet d'activitat per computar intensitat d'activitat física i paràmetres del son. Contacte: Camino de las Huertas 18, planta 1, 28223 Pozuelo de Alarcón, Madrid (Espanya) Tel. +34 902 286 386 · +34 910 059 088.
- Dades de-identificades (sense codi associat)
    - VICOMTECH: dades dels dispositius mèdics i respostes a qüestionaris per validar un predictor de descompensació cardíaca. Contacte: Parque Científico y Tecnológico de Gipuzkoa, Paseo Mikeletegi 57, 20009 Donostia / San Sebastián (Espanya) Tel. +(34) 943 309 230.
    - TREE TECHNOLOGY SA: dades mèdiques, d'activitat física, de son i d'ús de recursos sanitaris per investigar sobre correlacions. Contacte: Camino de las Huertas 18, planta 1, 28223 Pozuelo de Alarcón, Madrid (Espanya) Tel. +34 902 286 386 · +34 910 059 088.
    - Consorci SHAPES: qüestionaris estandarditzats (realitzats al principi, final i als 3 mesos de la intervenció) i dades sociodemogràfiques. Clinika de Kay col·labora amb el consorci europeu SHAPES per a la investigació d'eines digitals adreçades a les persones majors. Coordinador: National University Ireland Maynooth, Co. Kildare, Irlanda, shapes.info@mu.ie
- Dades anonimitzades (agregades)
    - Northern Health and Social Care Trust, per realitzar anàlisis amb altres estudis semblants amb pacients que pateixen diverses condicions. Contacte: Research Office Governance Department Bush House Bush

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Road Antrim BT41 2QB 028 9442 4653; frances.johnston@northerntrust.hscni.net

- Comunitat científica: els qüestionaris estandarditzats i les dades sociodemogràfiques seran accessibles a la comunitat científica. Executor, coordinador SHAPES: National University Ireland Maynooth, Co. Kildare, Irlanda, shapes.info@mu.ie

Termini màxim de conservació de les dades: Al final del projecte SHAPES (Octubre 2023), les dades es de-identificaran i es conservaran a Clinika de Kay durant 5 anys. Després d'aquest període, es conservaran a Clinika de Kay de forma anònima i agregada i indefinidament. En el cas dels qüestionaris estandarditzats i dades socio-demogràfiques, les dades es conservaran de forma anònima i agregada, indefinidament a la plataforma SHAPES per fer-les accessibles a la comunitat científica.

El tractament, la comunicació i la cessió de les dades de caràcter personal de tots els subjectes participants s'ajusta al que disposa la Llei orgànica 3/2018, de 5 de desembre, de protecció de dades de caràcter personal i garantia dels drets digitals.

D'acord amb el que estableix la legislació esmentada, podeu exercir els drets d'accés, rectificació, supressió, oposició, limitació del tractament de dades, i fins i tot a traslladar les vostres dades a un tercer autoritzat (portabilitat); per a això heu de dirigir-vos a l'investigador principal responsable de tractament en les adreces següents:

- Investigadora principal: *Dra. Karina Anahi Ojanguren Carreira, Cerr Anselm Turmeda 8, bajos, 07010, Palma, Illes Balears, +34 971 21 71 79, karinaojanguren@hotmail.com*
- Responsable del tractament de dades*: José Eduardo Carretero Alberti, Cerr Anselm Turmeda 8, bajos, 07010, Palma, Illes Balears, +34 971 21 71 79, clinikadekay@gmail.com*

Les vostres dades es tractaran informàticament i s'incorporaran a un sistema automatitzat de dades de caràcter personal que compleix amb totes les mesures de seguretat d'accés restringit amb l'objectiu descrit en aquest document.

Per garantir la confidencialitat de la informació obtinguda,

4) *codificació o pseudoanonimització*: durant l'estudi, les vostres dades estaran identificats mitjançant un codi i només el metge de l'estudi i col·laboradors dins del GRUP HUMANA poden relacionar aquestes dades amb vós i amb la vostra història clínica. Per tant, la vostra identitat no es revelarà a ningú, excepte en cas d'urgència mèdica, requeriment de l'Administració sanitària o requeriment legal.
5) *de*-identificació: a l'octubre 2023, el codi es dissociarà de les vostres dades.
6) *anonimització*: a partir d'octubre 2028, les vostres dades s'agregaran i es dissociaran irreversiblement de les vostres dades personals, de tal manera que serà impossible identificar a qui pertanyen posteriorment.

Només es transmetran a tercers i a altres països les dades imprescindibles necessàries per poder realitzar l'estudi, i que en cap cas contindran informació que us pugui identificar directament, com ara nom i cognoms, inicials, adreça, núm. de la seguretat social, etc. En el cas que es produís aquesta cessió, serà per a les mateixes finalitats de l'estudi descrit i

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garantint la confidencialitat com a mínim amb el nivell de protecció de la legislació vigent al nostre país.

L'accés a la vostra informació personal quedarà restringit al metge de l'estudi i col·laboradors dins del GRUP HUMANA, als metges participants de l'estudi (dades personals mèdiques però no identificables), autoritats sanitàries, al Comitè d'Ètica de la Investigació de les Illes Balears i personal autoritzat, quan ho hagin de menester per comprovar les dades i procediments de l'estudi, però sempre mantenint-ne la confidencialitat d'acord amb la legislació vigent.

Igualment, se us informa que podreu realitzar qualsevol consulta sobre aquest tractament davant la Delegació de Protecció de Dades de Clinika de Kay SL, que té la seu al carrer *Illes Balears nº7, escala A, pis 3B, Palma, 07014, Illes Balears, Espanya*, i el correu electrònic de contacte n'és *clinikadekay@gmail.com.*

En qualsevol cas, podeu adreçar-vos a l'Agència Espanyola de Protecció de Dades per a qualsevol reclamació derivada del tractament de les vostres dades personals.

COMPENSACIÓ ECONÒMICA

La vostra participació en l'estudi no us suposarà cap despesa, més enllà de l'ús del seu pla de dades d'internet. Vostè no rebrà cap compensació per participar en aquest estudi.

Els metges participants en l'estudi no rebran cap compensació econòmica. Els metges participants poden tenir el seu sou subvencionat per la comissió europea com a participants del projecte SHAPES (subvenció número 857159).

El sou de la investigadora principal de l'estudi, la Dra. Karina Anahi Ojanguren Carreira, està subvencionat per la comissió europea com a participant del projecte SHAPES (subvenció número 857159). La Dra. Karina Anahi Ojanguren Carreira és propietària tant de CLINIKA DE KAY SL com de HOSPITALIZACIÓN A DOMICILIO SL i, en conseqüència, de l'eina que proporciona els qüestionaris dins de l'aplicació mòbil SHAPES i de l'aplicació web per la visualització als metges.

PARTICIPACIÓ VOLUNTÀRIA

Heu de saber que la vostra participació en aquest estudi és voluntària i que podeu decidir no participar-hi o canviar la vostra decisió i retirar el consentiment en qualsevol moment, sense donar cap tipus d'explicació, així com sol·licitar la destrucció de les dades, sempre i quan no hagin estat anonimitzades, sense que per això s'alteri la relació amb el vostre metge o el tractament que heu de rebre.

AGRAÏMENT

Sigui quina sigui la vostra decisió, tant el promotor com l'equip investigador us volen agrair el temps i l'atenció. Esteu contribuint a conèixer millor la vostra malaltia i a tractar-la, la qual cosa en el futur pot beneficiar multitud de persones.

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FULL D'INFORMACIÓ AL PROFESSIONAL DE LA SALUT PER A LA REALITZACIÓ DE PROJECTES D'INVESTIGACIÓ.

HIPro: v1.0; 7 de gener del 2022

TÍTOL DE L'ESTUDI: Aplicació digital i plataforma SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) com suport en el control i la optimització de la medicació en persones majors amb insuficiència cardíaca. Estudi de viabilitat, no aleatoritzat, en escenari real per a l'avaluació de la participació d'usuari i la percepció de la seva utilitat. UC-PT3-001-CH.

CODI DEL PROTOCOL: UC-PT3-001-CH

PROMOTOR: Clinika de Kay, SL

INVESTIGADOR PRINCIPAL: *Dra. Karina Anahi Ojanguren Carreira*

CÀRREC, UNITAT, CENTRE: Directora mèdica, GRUP HUMANA (Clinika de Kay SL, Hospitalización a Domicilio SL)

TELÈFON: +34 971 21 71 79
CORREU ELECTRÒNIC: research@clinicahumana.es

INTRODUCCIÓ

Aquest document és per informar-vos sobre un estudi en el qual se us convida a participar. L'estudi l'ha aprovat el Comitè d'Ètica de la Investigació de les Illes Balears, d'acord amb la legislació vigent, i es du a terme amb respecte als principis enunciats en la declaració d'Hèlsinki i en les normes de bona pràctica clínica.

La nostra intenció és tan sols que rebeu la informació correcta i suficient perquè pugueu avaluar i jutjar si voleu participar-hi o no. Per a això, llegiu aquest full informatiu amb atenció i us aclarirem els dubtes que us puguin sorgir després de l'explicació. A més, podeu consultar amb les persones que considereu oportú. Si teniu cap dubte dirigiu-vos a la Dra. Karina Anahi Ojanguren Carreira a través de les dades de contacte que surten al principi d'aquest document.

DESCRIPCIÓ GENERAL

L'estudi en el què vostè està convidat a participar consisteix en fer servir unes eines digitals (les eines SHAPES) que ajuden en el control de pacients amb insuficiència cardíaca. Les eines no substitueixen ni modifiquen els tractaments mèdics i farmacològics. L'objectiu principal de l'estudi és avaluar si les eines SHAPES són fàcils d'usar i es perceben com a útils pels usuaris. Hi ha dos tipus de participants a l'estudi, persones majors de 60 anys i, opcionalment, un dels seus cuidadors i metges del Grup Humana.

Les persones majors podran fer servir l'aplicació mòbil SHAPES per poder enregistrar i veure l'històric de les següents dades: tensió arterial, freqüència cardíaca, saturació d'oxigen en sang, pes, composició massa corporal, nombre de passes, intensitat activitat

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física, hores i qualitat del son. També, amb l'aplicació mòbil SHAPES podran respondre a qüestionaris relacionats amb la seva salut, la presa de medicaments i sobre l'existència de nova informació rellevant, com ara resultats d'anàlisis de sang o orina, hospitalitzacions i altres usos de serveis mèdics i canvis en la medicació.

Vostè, com a professional sanitari participant veurà cada dia les dades enregistrades de cada persona major amb les aplicacions web SHAPES. Les aplicacions mostren l'històric dels enregistraments i mostra les dades en diferents colors (indicadors) segons els seus valors. Segons el que visualitzi, vostè decidirà segons el seu criteri si contacta o visita a la persona major (contacte derivat de l'estudi), de forma independent al seguiment que se li fa com a usuari del GRUP HUMANA. Aquests contactes derivats de l'estudi, així com les intervencions derivades, es registraran per avaluar l'impacte. Vostè també serà responsable d'actualitzar la informació a través de l'aplicació en referència a resultats d'anàlisis de sang o orina, hospitalitzacions i altres usos de serveis mèdics i canvis en la medicació.

Al final de l'estudi, es faran qüestionaris per avaluar la usabilitat, la utilitat i l'acceptació de les eines SHAPES. Al final de l'estudi, es realitzarà una entrevista a tots els participants per recollir la seva opinió.

Nombre de participants i durada: L'objectiu de l'estudi es reclutar 10 persones majors i 1 o 2 metges del GRUP HUMANA. Un màxim de 3 persones majors i cuidadors podran opcionalment provar l'aplicació mòbil SHAPES durant una setmana abans de l'estudi, que servirà de test per provar tècnicament les solucions i on els usuaris podran proporcionar opinions per a la seva millora. Posteriorment, el total de participants faran ús de les eines SHAPES i dels dispositius durant 3 mesos. Finalment, aproximadament als 3 mesos d'acabar, es realitzaran qüestionaris de seguiment.

Obligacions dels participants: Vostè ha de ser un metge titulat.

Les recomanacions per els metges participants són:

- Avaluar l'estat de les persones majors de l'estudi a través de les aplicacions web SHAPES un cop al dia durant els dies laborables. En cas de considerar que aquesta periodicitat d'avaluació no és adient, ho ha de comunicar a la gestora del projecte, Esperança Lladó Pascual per avaluar la continuïtat del projecte.

ALTRA INFORMACIÓ RELLEVANT

Si vostè decideix retirar el consentiment per participar en aquest estudi, no s'afegirà cap dada nova a la base de dades i podreu exigir que es destrueixin totes les vostres dades sempre hi quan no hagin estat anonimitzades.

També heu de saber que us poden retirar de l'estudi en cas que els responsables de l'estudi ho considerin oportú, ja sigui per motius de seguretat, per qualsevol esdeveniment advers que es produeixi o perquè considerin que no compliu amb els procediments establerts. En qualsevol dels casos, rebreu una explicació adequada del motiu que ha ocasionat la vostra retirada de l'estudi.

En signar el full de consentiment adjunt es compromet a complir amb els procediments de l'estudi que se us han exposat.

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BENEFICIS I RISCS DERIVATS DE LA VOSTRA PARTICIPACIÓ EN L'ESTUDI

No existeixen beneficis directes a nivell individual per participat en aquest estudi, més enllà de l'interès personal i l'experiència de participar en un estudi d'investigació. Encara que la intenció final de les eines SHAPES és millorar la qualitat de vida de les persones majors, i a l'estudi es recullen dades per fer una primera avaluació en aquest aspecte, l'objectiu principal de l'estudi és avaluar l'acceptació de l'eina entre els participants, un estudi que es considera necessari avaluar abans de fer un altre estudi focalitzat en els resultats mèdics.

En relació als metges participants, no s'espera que obtinguin cap benefici, més enllà de la satisfacció de poder fer un seguiment diari dels pacients.

ASSEGURANÇA

El GRUP HUMANA compta amb les assegurances de Responsabilitat Civil General que cobreixen els participants d'aquest estudi. Compta amb la pòlissa d'assegurança 560.005.411, a nom de Clinika de Kay SL amb la companyia AGRUPACIÓN MUTUAL ASEGURADORA, i la pòlissa d'assegurança 0961370001257 a nom de Hospitalización a Domicilio SL, amb la companyia MAPFRE SEGUROS DE EMPRESA. Aquestes dues pòlisses s'ajusten a la legislació vigent i cobreixen tots els perjudicis que puguin produir-se en relació amb la vostra participació en l'estudi.

CONFIDENCIALITAT

Responsable del tractament: *Dra. Karina Anahi Ojanguren Carreira, Cerr Anselm Turmeda 8, bajos, 07010, Palma, Illes Balears, +34 971 21 71 79, karinaojanguren@hotmail.com*

Responsable del tractament de dades: *José Eduardo Carretero Alberti, Cerr Anselm Turmeda 8, bajos, 07010, Palma, Illes Balears, +34 971 21 71 79, clinikadekay@gmail.com*

Finalitat de la recollida de dades: Investigació de la participació d'usuari i la utilitat de les eines SHAPES; Investigació sobre correlacions de paràmetres mèdics i d'estils de vida amb el control de la insuficiència cardíaca; Validació retrospectiva d'un predictor de descompensació cardíaca.

Destinataris de la informació: A més de Clinika de Kay, els següents col·laboradors tindran accés a algunes dades:

- Dades de-identificades (sese codi associat)
    - Consorci SHAPES: qüestionaris estandarditzats (realitzats al final de la intervenció). Clinika de Kay col·labora amb el consorci europeu SHAPES per a la investigació d'eines digitals adreçades a les persones majors. Coordinador: National University Ireland Maynooth, Co. Kildare, Irlanda, shapes.info@mu.ie
- Dades anonimitzades (agregades)
    - Northern Health and Social Care Trust, per realitzar anàlisis amb altres estudis semblants amb pacients que pateixen diverses condicions.

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Contacte: Research Office Governance Department Bush House Bush Road Antrim BT41 2QB 028 9442 4653; frances.johnston@northerntrust.hscni.net

- Comunitat científica: els qüestionaris estandarditzats seran accessibles a la comunitat científica. Executor, coordinador SHAPES: National University Ireland Maynooth, Co. Kildare, Irlanda, shapes.info@mu.ie

Termini màxim de conservació de les dades: Al final del projecte SHAPES (Octubre 2023), les dades de-identificades es conservaran a Clinika de Kay durant 5 anys. Després d'aquest període, es conservaran a Clinika de Kay de forma anònima i agregada. En el cas dels qüestionaris estandarditzats les dades es conservaran de forma anònima i agregada a la plataforma SHAPES per fer-los accessibles a la comunitat científica.

El tractament, la comunicació i la cessió de les dades de caràcter personal de tots els subjectes participants s'ajusta al que disposa la Llei orgànica 3/2018, de 5 de desembre, de protecció de dades de caràcter personal i garantia dels drets digitals.

D'acord amb el que estableix la legislació esmentada, podeu exercir els drets d'accés, rectificació, supressió, oposició, limitació del tractament de dades, i fins i tot a traslladar les vostres dades a un tercer autoritzat (portabilitat); per a això heu de dirigir-vos a l'investigador principal responsable de tractament en les adreces següents:

- Investigadora principal: *Dra. Karina Anahi Ojanguren Carreira, Cerr Anselm Turmeda 8, bajos, 07010, Palma, Illes Balears, +34 971 21 71 79, karinaojanguren@hotmail.com*
- *Responsable del tractament de dades: José Eduardo Carretero Alberti, Cerr Anselm Turmeda 8, bajos, 07010, Palma, Illes Balears, +34 971 21 71 79, clinikadekay@gmail.com*

Les vostres dades es tractaran informàticament i s'incorporaran a un sistema automatitzat de dades de caràcter personal que compleix amb totes les mesures de seguretat d'accés restringit a l'objectiu descrit en aquest document.

Per garantir la confidencialitat de la informació obtinguda,

7) *codificació o pseudoanonimització*: durant l'estudi, les vostres dades estaran identificats mitjançant un codi i només l'investigador principal i col·laboradors dins del GRUP HUMANA poden relacionar aquestes dades amb vós. Per tant, la vostra identitat no es revelarà a ningú, excepte en cas de requeriment de l'Administració sanitària o requeriment legal.
8) *de*-identificació: a l'octubre 2023, el codi es dissociarà de les vostres dades.
9) *anonimització*: a partir d'octubre 2028, les vostres dades s'agregaran i es dissociaran irreversiblement de les vostres dades personals, de tal manera que serà impossible identificar a qui pertanyen posteriorment.

Només es transmetran a tercers i a altres països les dades imprescindibles necessàries per poder realitzar l'estudi, i que en cap cas contindran informació que us pugui identificar directament, com ara nom i cognoms, inicials, adreça, etc. En el cas que es produís aquesta cessió, serà per a les mateixes finalitats de l'estudi descrit i garantint la confidencialitat com a mínim amb el nivell de protecció de la legislació vigent al nostre país.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

L'accés a la vostra informació personal quedarà restringit als col·laboradors dins del GRUP HUMANA, als metges participants de l'estudi (dades personals mèdiques però no identificables), autoritats sanitàries, al Comitè d'Ètica de la Investigació de les Illes Balears i personal autoritzat, quan ho hagin de menester per comprovar les dades i procediments de l'estudi, però sempre mantenint-ne la confidencialitat d'acord amb la legislació vigent.

Igualment, se us informa que podreu realitzar qualsevol consulta sobre aquest tractament davant la Delegació de Protecció de Dades de Clinika de Kay SL, que té la seu al carrer *Illes Balears nº7, escala A, pis 3B, Palma, 07014, Illes Balears, Espanya*, i el correu electrònic de contacte n'és *clinikadekay@gmail.com.*

En qualsevol cas, podeu adreçar-vos a l'Agència Espanyola de Protecció de Dades per a qualsevol reclamació derivada del tractament de les vostres dades personals.

COMPENSACIÓ ECONÒMICA

Vostè, com a metge participant en l'estudi no rebran cap compensació econòmica. Els metges participants poden tenir el seu sou subvencionat per la comissió europea com a participants del projecte SHAPES (subvenció número 857159).

El sou de la investigadora principal de l'estudi, la Dra. Karina Anahi Ojanguren Carreira, està subvencionat per la comissió europea com a participant del projecte SHAPES (subvenció número 857159). La Dra. Karina Anahi Ojanguren Carreira és propietària tant de CLINIKA DE KAY SL com de HOSPITALIZACIÓN A DOMICILIO SL i, en conseqüència, de l'eina que proporciona els qüestionaris dins de l'aplicació mòbil SHAPES i de l'aplicació web per la visualització als metges.

La participació de persones majors a aquest estudi no els suposarà cap despesa així com tampoc rebran cap compensació econòmica.

PARTICIPACIÓ VOLUNTÀRIA

Heu de saber que la vostra participació en aquest estudi és voluntària i que podeu decidir no participar-hi o canviar la vostra decisió i retirar el consentiment en qualsevol moment, sense donar cap tipus d'explicació, així com sol·licitar la destrucció de les dades, sempre i quan no hagin estat anonimitzades, sense que per això s'alteri la relació amb el vostre metge o el tractament que heu de rebre.

AGRAÏMENT

Sigui quina sigui la vostra decisió, tant el promotor com l'equip investigador us volen agrair el temps i l'atenció. Esteu contribuint a conèixer millor la insuficiència cardíaca i a tractar-la, la qual cosa en el futur pot beneficiar multitud de persones.

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Annex 45 UC-PT3-001 Phase 5 Participant consent forms (older people and caregivers; Healthcare professionals)

CONSENTIMENT INFORMAT PER A LA REALITZACIÓ DE PROJECTES D'INVESTIGACIÓ - Cuidador

V1.0 , 7 de gener del 2022

TÍTOL DE L'ESTUDI: Aplicació digital i plataforma SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) com suport en el control i la optimització de la medicació en persones majors amb insuficiència cardíaca. Estudi de viabilitat, no aleatoritzat, en escenari real per a l'avaluació de la participació d'usuari i la percepció de la seva utilitat. UC-PT3-001-CH.

CODI DEL PROMOTOR: UC-PT3-001-CH

PROMOTOR: Clinika de Kay SL

INVESTIGADOR PRINCIPAL ***Dra. Karina Anahi Ojanguren Carreira, Directora mèdica, GRUP HUMANA, +34 971 21 71 79, karinaojanguren@hotmail.com***

CENTRE: GRUP HUMANA (Clinika de Kay SL, Hospitalización a Domicilio SL)

.....*(nom i llinatges)*

☐ He llegit el full d'informació que se m'ha lliurat.

☐ He pogut fer preguntes sobre l'estudi.

☐ He rebut prou informació sobre l'estudi.

☐ He parlat amb Esperança Lladó Pascual.

☐ Comprenc que la meva participació és voluntària.

☐ Comprenc que puc retirar-me de l'estudi:

- Quan vulgui.
- Sense haver de donar explicacions.

☐ Comprenc que si decidesc retirar-me de l'estudi els resultats obtinguts fins a aquell moment es poden continuar utilitzant, a no ser que expressament indiqui la destrucció de totes les meves dades des de l'inici de l'estudi i sempre que no hagin estat anonimitzades.

☐ Comprenc que tenc els drets d'accés, rectificació, supressió, oposició, limitació del tractament de dades i, fins i tot, a traslladar les meves dades a un tercer autoritzat (portabilitat), d'acord amb el que disposa la Llei orgànica 3/2018, de 5 de desembre, de protecció de dades de caràcter personal i garantia dels drets digitals.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

☐ Prest lliurement la meva conformitat per participar en l'estudi i don el meu consentiment per a l'accés i la utilització de les meves dades en les condicions que es detallen en el full d'informació a la persona major/cuidador.

☐ Prest lliurement la meva conformitat per participar en el pre-estudi on es recolliran dades personals a través dels dispositius i qüestionaris per comprovar el funcionament tècnic de les eines SHAPES (opcional).

En acabar la investigació, les meves dades poden ser:

☐ destruïdes

☐ de-identificada en octubre de 2023 i anonimitzada (agregació) en octubre de 2028.

[Rúbrica del cuidador] [Rúbrica de l'investigador]

Nom: Nom:
Data: Data:

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

CONSENTIMENT INFORMAT PER A LA REALITZACIÓ DE PROJECTES D'INVESTIGACIÓ – Persona major

V1.0 , 7 de gener del 2022

TÍTOL DE L'ESTUDI: Aplicació digital i plataforma SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) com suport en el control i la optimització de la medicació en persones majors amb insuficiència cardíaca. Estudi de viabilitat, no aleatoritzat, en escenari real per a l'avaluació de la participació d'usuari i la percepció de la seva utilitat. UC-PT3-001-CH.

CODI DEL PROMOTOR: UC-PT3-001-CH

PROMOTOR: Clinika de Kay SL

INVESTIGADOR PRINCIPAL ***Dra. Karina Anahi Ojanguren Carreira, Directora mèdica, GRUP HUMANA, +34 971 21 71 79, karinaojanguren@hotmail.com***

CENTRE: GRUP HUMANA (Clinika de Kay SL, Hospitalización a Domicilio SL)

.....*(nom i llinatges)*

☐ He llegit el full d'informació que se m'ha lliurat.

☐ He pogut fer preguntes sobre l'estudi.

☐ He rebut prou informació sobre l'estudi.

☐ He parlat amb Esperança Lladó Pascual.

☐ Comprenc que la meva participació és voluntària.

☐ Comprenc que puc retirar-me de l'estudi:

- Quan vulgui.
- Sense haver de donar explicacions.
- Sense que això repercuteixi en les meves cures mèdiques.

☐ Comprenc que si decidesc retirar-me de l'estudi els resultats obtinguts fins a aquell moment es poden continuar utilitzant, a no ser que expressament indiqui la destrucció de totes les meves dades des de l'inici de l'estudi i sempre que no hagin estat anonimitzades.

En el cas que els resultats de la investigació proporcionin dades que em puguin interessar a mi o als meus familiars: (*indicau una de les caselles*)

☐ En vull ser informat.

☐ No en vull ser informat, però accept que el meu metge contacti amb els meus familiars si els resultats els poden afectar.

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☐ Comprenc que tenc els drets d'accés, rectificació, supressió, oposició, limitació del tractament de dades i, fins i tot, a traslladar les meves dades a un tercer autoritzat (portabilitat), d'acord amb el que disposa la Llei orgànica 3/2018, de 5 de desembre, de protecció de dades de caràcter personal i garantia dels drets digitals.

☐ Prest lliurement la meva conformitat per participar en l'estudi i don el meu consentiment per a l'accés i la utilització de les meves dades en les condicions que es detallen en el full d'informació al pacient/cuidador.

☐ Prest lliurement la meva conformitat per a què ..... (*nom cuidador*) pugui fer servir l'aplicació mòbil SHAPES per visualitzar les meves dades personals recollides del dispositius i respondre els qüestionaris en el meu nom (Opcional).

☐ Prest lliurement la meva conformitat per participar en el pre-estudi on es recolliran dades personals a través dels dispositius i qüestionaris per comprovar el funcionament tècnic de les eines SHAPES (Opcional).

En acabar la investigació, les meves dades poden ser:

☐ destruïdes

☐ de-identificada en octubre de 2023 i anonimitzada (agregació) en octubre de 2028.

[Rúbrica del persona major] [Rúbrica de l'investigador]

Nom: Nom:
Data: Data:

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

CONSENTIMENT INFORMAT PER A LA REALITZACIÓ DE PROJECTES D'INVESTIGACIÓ - Professional

V1.0 , 7 de gener del 2022

TÍTOL DE L'ESTUDI: Aplicació digital i plataforma SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) com suport en el control i la optimització de la medicació en persones majors amb insuficiència cardíaca. Estudi de viabilitat, no aleatoritzat, en escenari real per a l'avaluació de la participació d'usuari i la percepció de la seva utilitat.UC-PT3-001-CH.

CODI DEL PROMOTOR: UC-PT3-001-CH

PROMOTOR: Clinika de Kay SL

INVESTIGADOR PRINCIPAL ***Dra. Karina Anahi Ojanguren Carreira, Directora mèdica, GRUP HUMANA, +34 971 21 71 79, karinaojanguren@hotmail.com***

CENTRE: GRUP HUMANA (Clinika de Kay SL, Hospitalización a Domicilio SL)

.....*(nom i llinatges)*

☐ He llegit el full d'informació que se m'ha lliurat.

☐ He pogut fer preguntes sobre l'estudi.

☐ He rebut prou informació sobre l'estudi.

☐ He parlat amb Esperança Lladó Pascual.

☐ Comprenc que la meva participació és voluntària.

☐ Comprenc que puc retirar-me de l'estudi:

- Quan vulgui.
- Sense haver de donar explicacions.
- Sense que això repercuteixi en la meva activitat laboral.

☐ Comprenc que si decidesc retirar-me de l'estudi els resultats obtinguts fins a aquell moment es poden continuar utilitzant, a no ser que expressament indiqui la destrucció de totes les meves dades des de l'inici de l'estudi i sempre que no hagin estat anonimitzades.

☐ Comprenc que tenc els drets d'accés, rectificació, supressió, oposició, limitació del tractament de dades i, fins i tot, a traslladar les meves dades a un tercer autoritzat (portabilitat), d'acord amb el que disposa la Llei orgànica 3/2018, de 5 de desembre, de protecció de dades de caràcter personal i garantia dels drets digitals.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

☐ Prest lliurement la meva conformitat per participar en l'estudi i don el meu consentiment per a l'accés i la utilització de les meves dades en les condicions que es detallen en el full d'informació al participant professional de la salut.

☐ Prest lliurement la meva conformitat per participar en el pre-estudi on es recolliran dades personals a través dels dispositius i qüestionaris per comprovar el funcionament tècnic de les eines SHAPES (opcional).

En acabar la investigació, les meves dades poden ser:

☐ destruïdes

☐ de-identificada en octubre de 2023 i anonimitzada (agregació) en octubre de 2028.

[Rúbrica del participant professional de la salut] [Rúbrica de l'investigador]

Nom: Nom:
Data: Data:

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Annex 46 UC-PT3-001c MOMENTUM blueprint

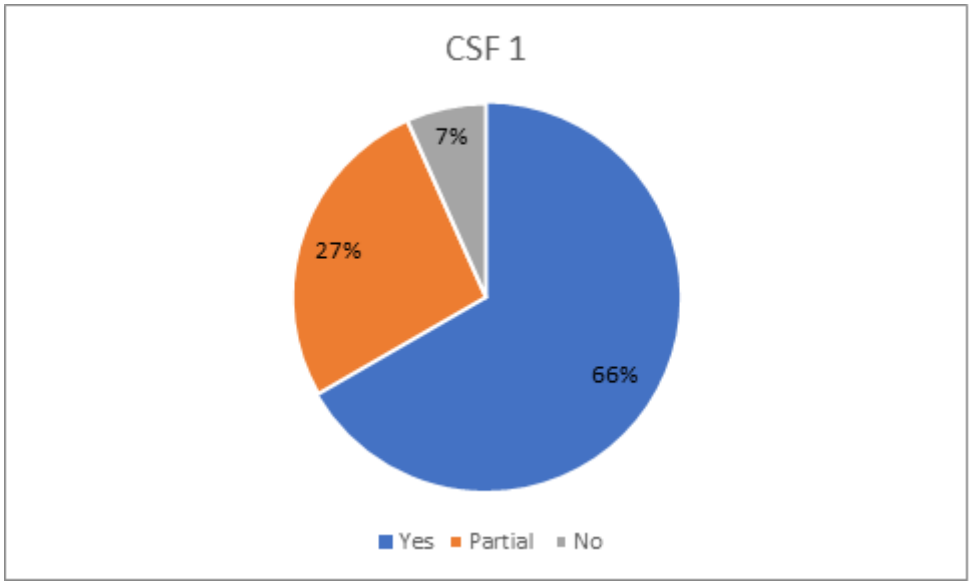
Momentum summary – HF use case

1. Ensure that there is cultural readiness for the telemedicine service. (Cultural readiness in a healthcare system or organisation has three components:

. A set of beliefs and perceptions that influence establishment of priorities

. Attitudes and norms that affect behaviour including decisions, ideas and practices that determine how a person, organisation, society will respond to the environment.

· Values and current needs that determine whether telemedicine will be viewed positively or negatively)



In comparison with previous years it seems that the cultural readiness has increased. This is probably due to the COVID-19 pademic together with new generation of physicians that would like to use modern technologies in their practise. So we can conclude that the cultural readiness exist.

2. Come to a consensus on the advantages of telemedicine in meeting compelling need(s)

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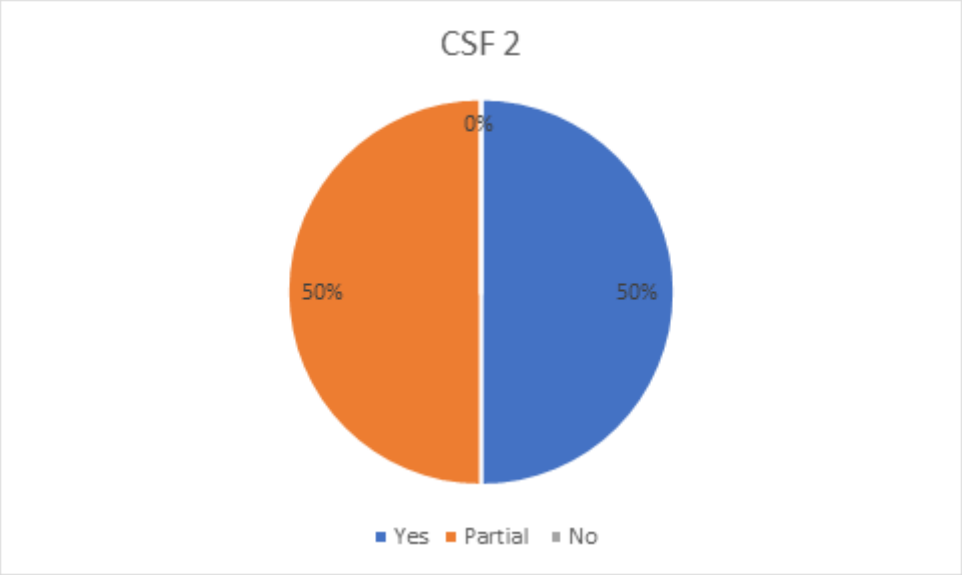
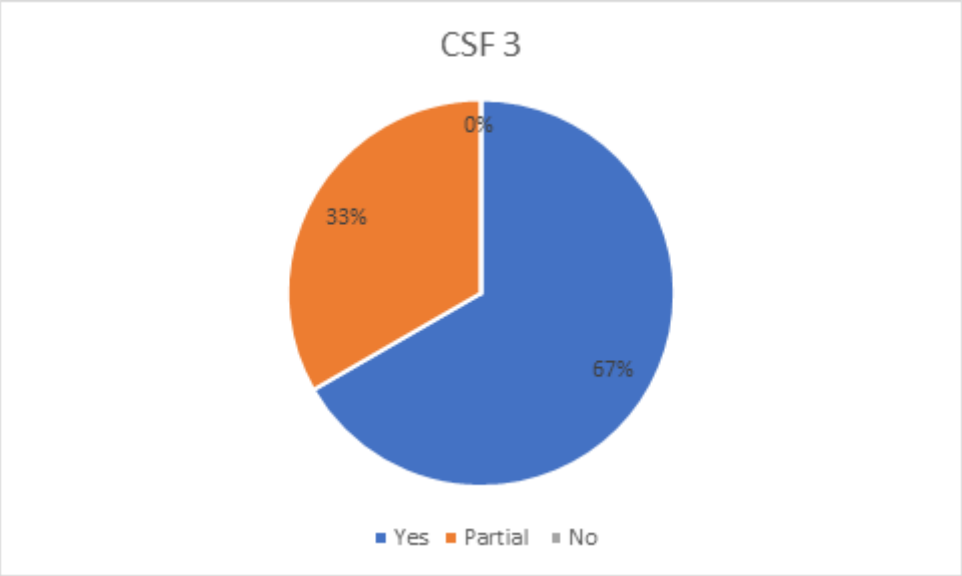


The consensus in the matter of meeting contemporary compelling needs is still not existent, however, this might change in the near future based on increasing the education of all important stakeholders.

3. Ensure leadership through a champion (A champion is a person who is committed to the telemedicine idea or initiative or service.)



Majority of telemedicine users believes that there is an existent leadership covered by the person of a Champion. One third of the people believes that at least partially such a leadership exists.

4. Involve healthcare professionals and decision-makers (two aspects of the new telemedicine system or service are to be considered:

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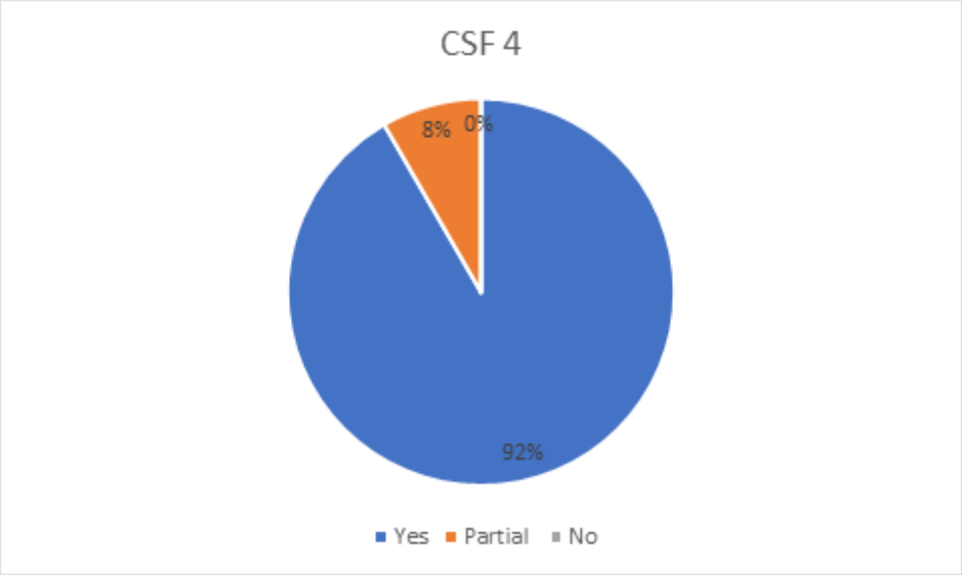
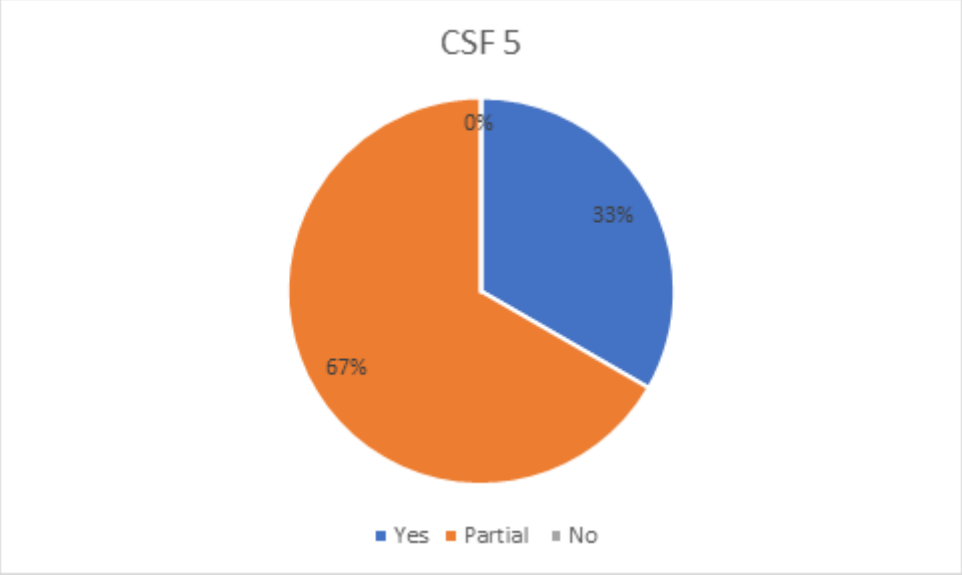
. the organisation, workflow and work structure, and

. the economic components)



All the relevant stakeholders are involved within the planning, design and implementation phases.

5. Put the patient at the centre of the service (Telemedicine services can benefit patients in two ways: through patient involvement in their own healthcare, and through the advantages it brings to their families, and their informal or formal carers.)



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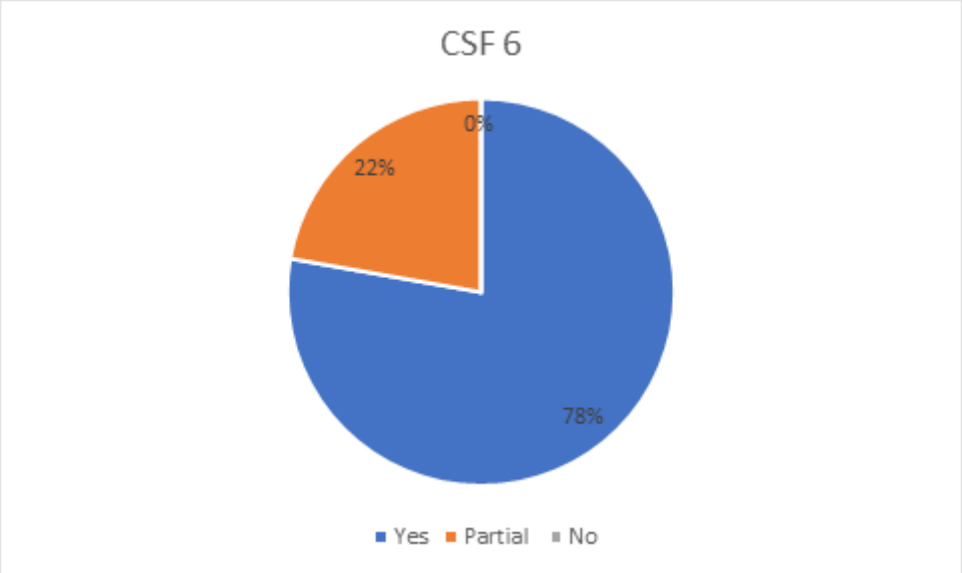
Formal carers are usually well involved in the whole telemedicine service. Nevertheless, involvement of the informal carers can be still increased. Some of the reasons why the informal carers are not yet involved are not fully in the control of the telemedicine service creators or operators. These are mainly economic and education reasons. The change of the informal carer's attitude are steadily changing, however, this is a longterm issue.

6. Ensure that the technology is user-friendly (User-friendliness is a combination of attributes from both the technical and human dimensions.)



User experience is being steadily improved by the team consisting of both IT experts and psychologist. Design is based on the good practices and is supported by experiments on focus groups created by the real users. Therefore, this area of interest is well covered and possible issues can be resolved immediately based on the user feedback.

7. Pull together the resources needed for deployment (There are essentially four major types of resources that need to be made available:

· Financing

· People

· Information

· Time.)

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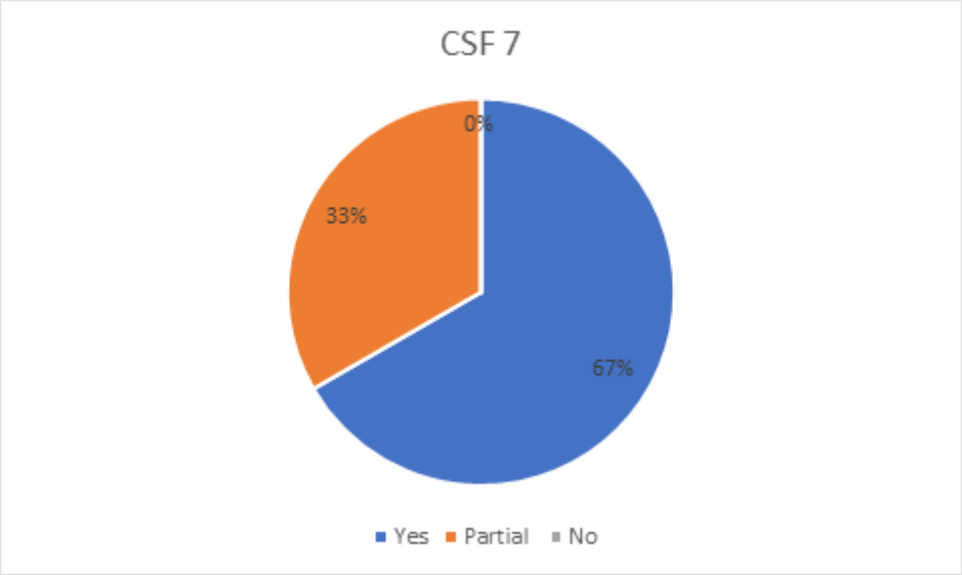
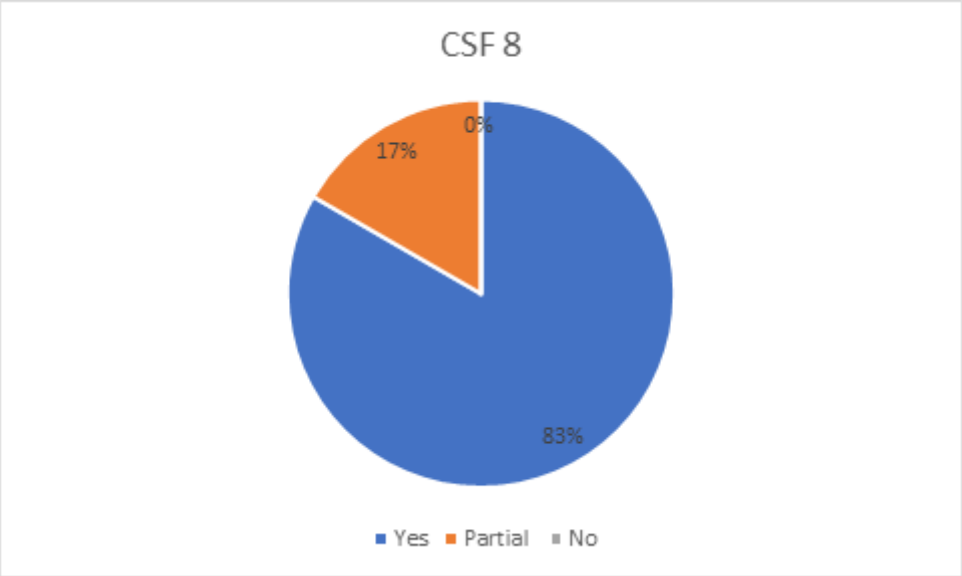


Participant's were quite optimistic. This is possibly due to their involvement only in their specific parts of the project. In general, such projects are extremely challenging in all of the abovementioned aspects. Especially experienced IT experts willing to be employed in the government sector are extremely difficult to find. Consequently, the existing IT teams suffer by overload. This is probably the major bottleneck of such project. A possible solution could be motivating of future IT experts via internships in the telemedicine IT team.

8. Address the needs of the primary client(s) (The primary client is the initial main partner in implementing the telemedicine service or in designing the telemedicine tool.)



User centric approach is applied in all stages of the development process, therefore, consensus is very positive in this aspect.

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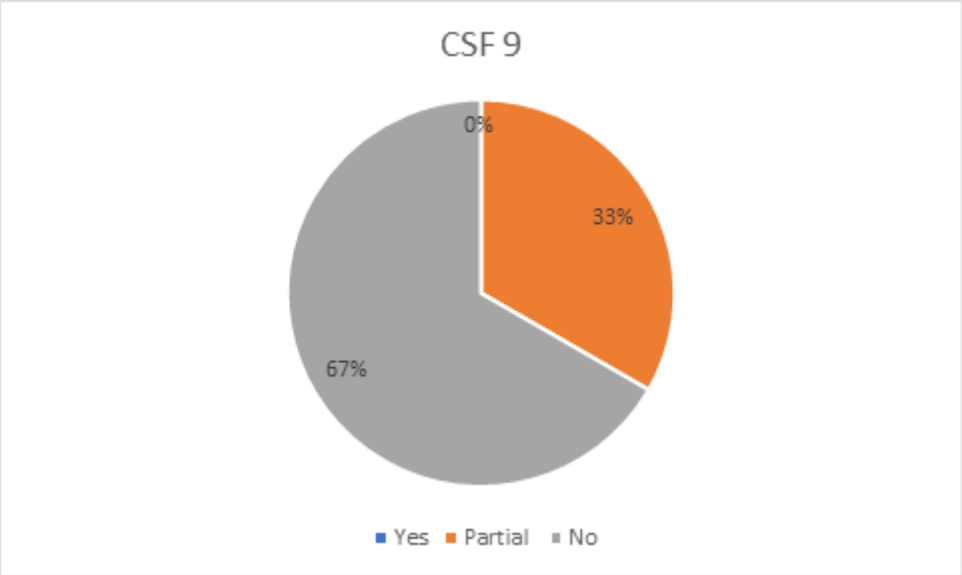
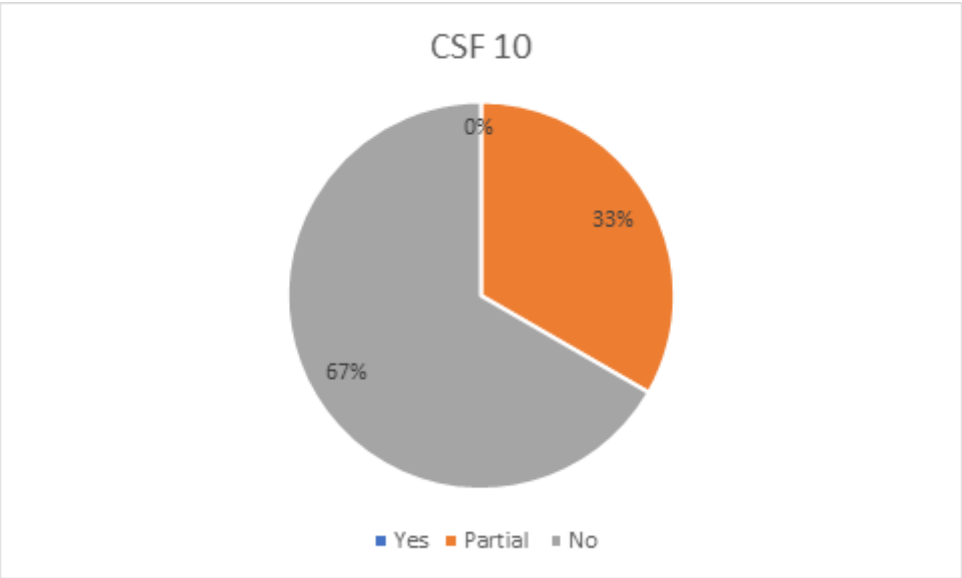
9. Prepare and implement a business plan (A business plan is a written document which results from the careful analysis of available data.)



Implementation of a business plan was not envisaged in this stage of a project. Moreover, a state owned hospital is not elligible to sell any hardware or software solutions, therefore, it is not important to create any business plan. This task should be addressed to the different stakeholders of the healthcare system, especially the insurance companies.

10. Prepare and implement a change management plan (A change management plan enables healthcare professionals to understand these changes and accept innovation in their daily work.)



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A change management plan is still in progress. And the workflow for regular updates is being tested.

11. Assess the conditions under which the service is legal

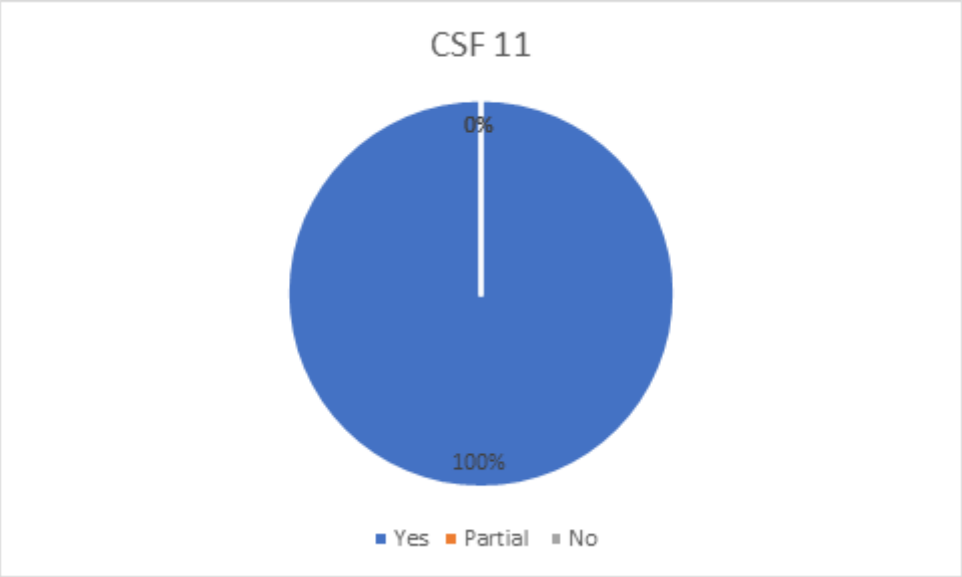
(Four aspects are to be considered:

. The telemedicine service is regarded by the authorities as an appropriate way to offer healthcare services.

· The telemedicine service is regarded as legal by carrying out a legal risk assessment.

· The telemedicine service is covered by law or if it is not inhibited by law or by bodies with competence in the telemedicine field.

· The telemedicine service is in accordance with general requirements for best practice in medicine.)



There is a single minded consensus, that the legal issues of the system are well covered by the experts in the fields of the general and medical law.

12. Guarantee that the technology has the potential for scale-up (Telemedicine doers have to take into account what actions are needed to make the leap from pilot to large-scale deployment in both technological and commercial terms. The potential for scale-up can be achieved by using either standard technologies or technologies that are similar and yet are produced/offered by a range of suppliers.)

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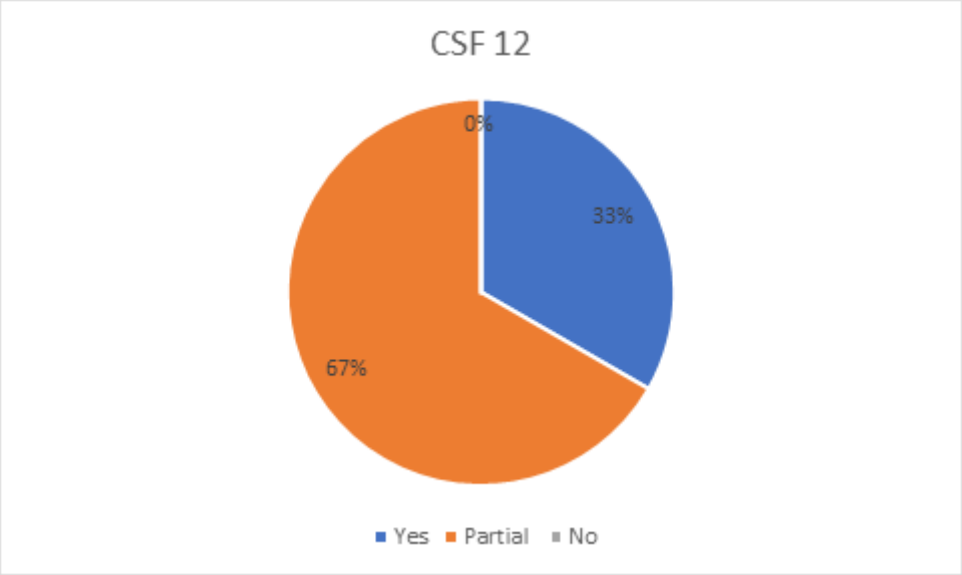
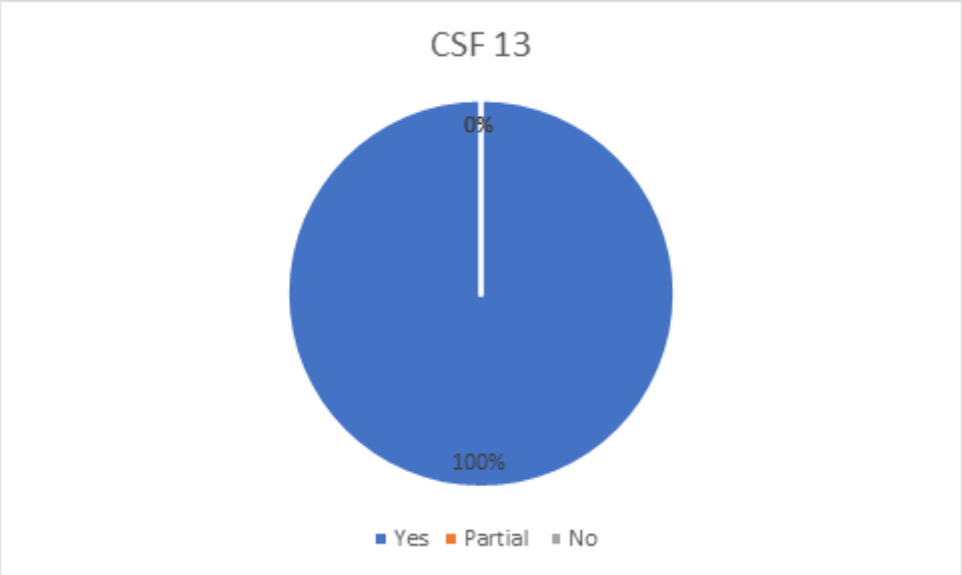


Scale-up of the telemedicine solution relies in the majority on the interest of insurance companies. Nevertheless, landscape is prepared for the implementation of telemedicine solutions and should be part of the local policies, strategies and action plans.

13. Identify and apply relevant legal and security guidelines (This critical success factor reminds telemedicine doers to look for useful relevant guidelines on legal and security matters.)



During the COVID-19 pandemic government institutes involved in the cybersecurity issued several guidelines related to the realm of telemedicine and the requirements mentioned there are implemented in the telemedicine solution.

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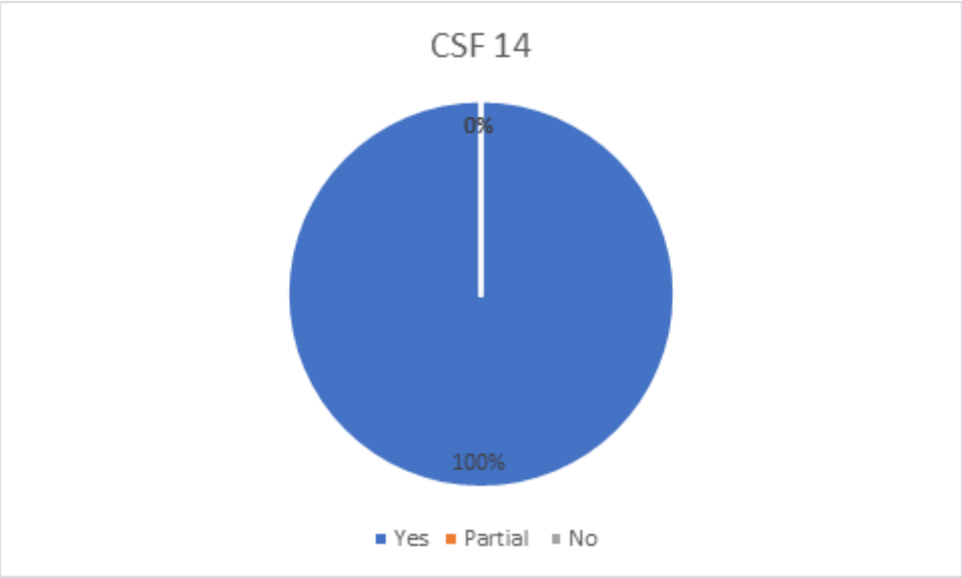
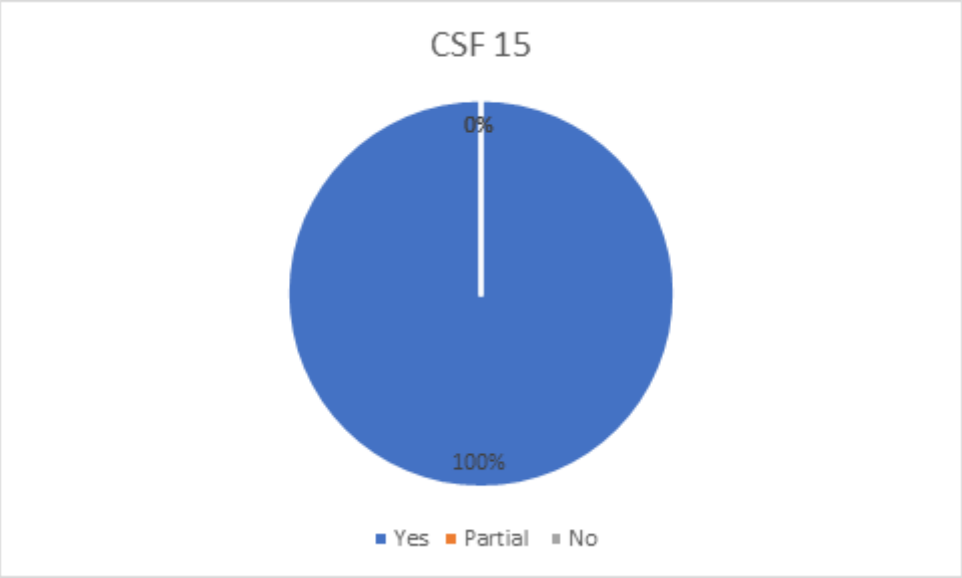
14. Involve legal and security experts (This critical success factor incorporates involving and asking advice from legal and security experts when needed, to minimise the risk of experiencing legal and security problems when deploying a telemedicine service.)



Lawyers and cybersecurity experts are involved through the whole development process and are prepared to consult the issues when needed.

15. Ensure that telemedicine doers and users are privacy aware (Privacy awareness is related to privacy by design. It is therefore important to make sure that everyone who is involved maintains a high degree of privacy awareness and knows the regulations – esp. GDPR and acts in accordance with them.



Telemedicine system designers are well aware about the constraints of GDPR and related privacy issues and are preparing the telemedicine system in concordance with the requirements. However, we cannot be 100 % sure that the users are also as experienced.

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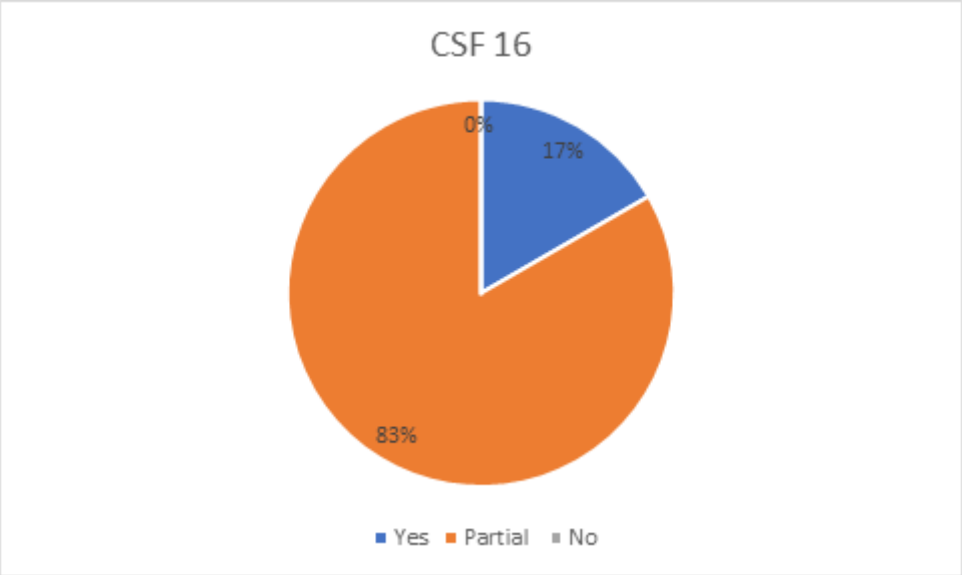
Creators will make all of the relevant information available directly from the application, so the important things can be easily find and understood, especially for the ageing and challenged people. Future improvements in this area are expected as this topic is steadily changing and evolving.

16: Ensure that the appropriate information technology infrastructure and eHealth infrastructure are in place (Ensuring that the appropriate IT infrastructures and eHealth infrastructures are available so that the telemedicine implementation can rely on these infrastructures from the initial deployment to the last stage of the scale-up phase.)



Physical infrastructure is already available and prepared for a scale-up process. Currently the readiness of physical infrastructure is not as challenging as the human resources issues in the field of ICT.

17. Put into place the technology and processes needed to monitor the service (Service monitoring includes all activities needed to govern IT, such as maintenance plans, security issues, service continuity, a help desk, and access management.)

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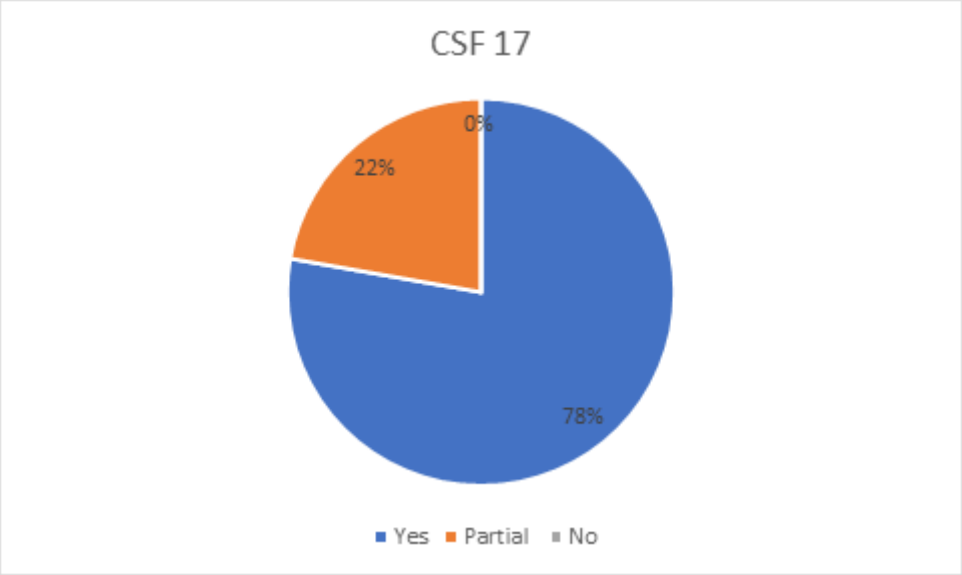
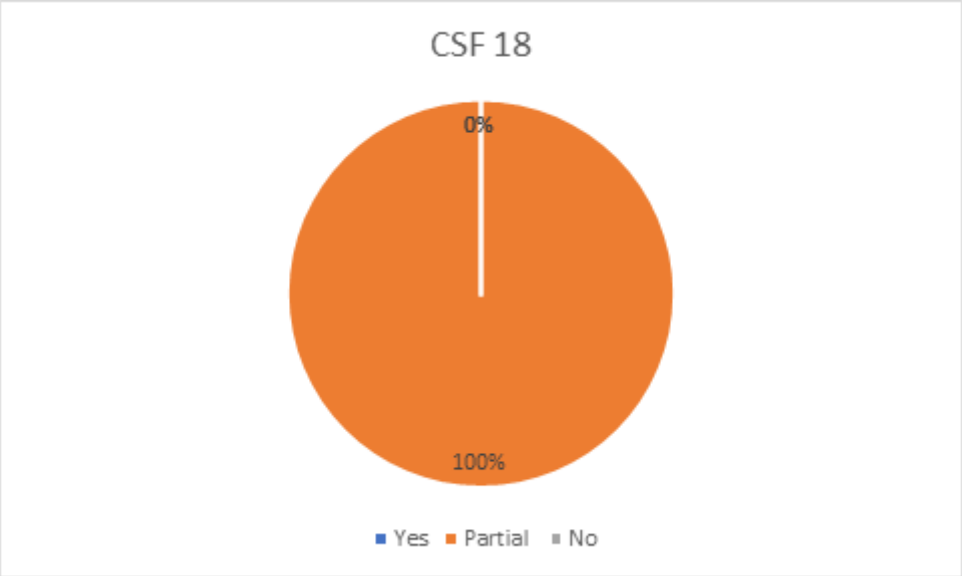


Monitoring services are still in the phase of preparation as the majority of human resources are currently focused for the development of the telemedicine solution. It is expected that the situation will change as soon as the development of main parts of the system will be finished.

18. Establish and maintain good procurement processes (Good procurement processes involve two main focus areas: content and process. With regard to content, any product or service that is contracted out may be delivered with a wide range of quality variability. With regard to process, it is important to have a formal method of procurement for the purchase.)



Procurement processes for the public organization, like the university hospitals, are well defined by the Czech law. Though, they are defined and human resources needed for their implementation already allocated, sometimes these processes can be rigid and slow.

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Nevertheless, they are mandatory for our organization. No major changes in their current state of implementation are expected in the near future.

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Annex 47 UC-PT3-001c NASSS-CAT (long version)

NASSS-CAT (LONG VERSION)

ASSESSING AND HANDLING COMPLEXITY IN TECHNOLOGY PROJECTS

Introduction

This evidence-based guide has been developed from a systematic literature review and extensive primary research. It is designed to help you reflect on your ideas and goals for a **technology-supported change project** in health or social care and work towards a project plan. A high proportion of such projects fail, but there are ways of improving the chances that your project will succeed.

Technology projects are characterised by **complexity** – i.e. they have multiple interacting components that cannot be tightly controlled. Complex projects are unpredictable and risky, hence less likely to succeed than simple ones. This guide will help you to identify the different areas of complexity (that is, the uncertainties, interdependencies and possible unintended consequences) in your project and think of ways to reduce or manage these (e.g. by making some aspects simpler or mitigating risks)

How to use this guide

We recommend that you start using this guide as early as possible and keep revisiting it as your project unfolds. It will only take you a few minutes to skim through it and gain an initial orientation, but working carefully through the detail of the guide will take much longer. There is no 'right' way to use the guide; it is intended to prompt conversations and help you bring together different areas of expertise (such as clinical, technical and business development).

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For example, you could assign different parts of the guide to different people to fill in in detail, then reconvene and compare your responses. You may wish to employ a facilitator to run a workshop with the project team.

Structure of this guide

PART 1 of this guide is divided into 6 domains, each in two parts:

- **A free-text box for you to present this domain in your own words**. This will help surface the issues, technologies, people and activities relevant to *your* project and how they seem to fit together. Make it flow like a story (i.e. write in sentences rather than using tables or bullet points), so as to capture the messiness (non-linearity) of the project. Telling a brief story will allow you to draw out the 'plot' of what's happened so far and identify interdependencies and tricky issues that may contribute to the project's success or failure (or something in between).
- **Some questions to help you estimate key areas of complexity** (most of which should have come up in your narrative). The more red boxes you tick, the more complex this domain is (though the boxes don't carry equal weight, so adding up the ticks won't give you a quantitative score). The top-level questions are quite broad, but if a question is particularly relevant to your proposed project, you can 'drill down' with the more detailed questions. Ideally, you should be able to back up your answers with evidence, such as published figures or research, or data you have collected yourself (for example from interviews or focus groups). Some questions will not apply to your project, so tick 'not applicable' for these. If a question seems relevant but you're not sure how to answer it, tick 'don't know' – and perhaps discuss this one with colleagues later. Can you distinguish the things you don't *yet* know (but could find out) from the things that are unknowable (inherently uncertain), which you have to handle with creativity and judgement as the project unfolds?

Note: [1] No single individual will be able to answer all the questions but you should find that if you involve a range of people across your organisation, you will be able to address all the domains. For each domain, we've suggested who might be best placed to answer the questions. [2] The tick-box questions will give an artificially structured and linear perspective. Bear in mind that complex change is an inherently messy and unpredictable process, but the box-ticking may help you find a 'way in' to your narrative.

PART 2 is designed to help your team handle the different kinds of complexity in your project. It consists of prompts to help you plan and manage an implementation project and think about how to

- **Reduce complexity** where possible (e.g. by limiting the scope of the project)

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- **Respond to complexity** where it can't be reduced (e.g. by bringing staff together to make sense of a situation, strengthening relationships, or collecting and analysing real-time data)

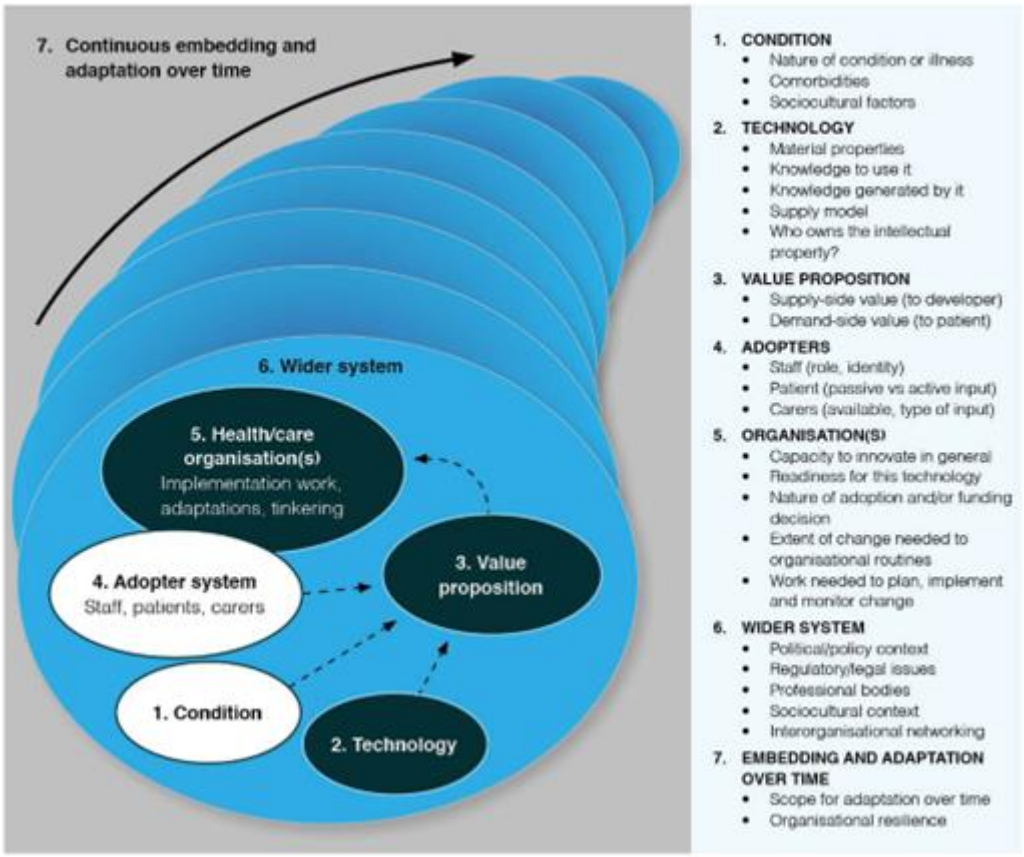

Diagram: The NASSS framework (© Greenhalgh at al J Med Internet Research 2017; 19 (11): e367)

PART 1: ANALYSING COMPLEXITY IN YOUR PROJECT

1. THE ILLNESS OR CONDITION

[a clinician, social worker or researcher might be the best person to complete this section]

Briefly describe the condition(s) for which the innovation or technology has been designed (e.g. heart failure, mental health, social isolation). In some situations, there won't be a specific illness or condition.

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The following questions should help you summarise whether the condition or illness is straightforward, well-understood, follows a predictable course and has predictable implications for care. This isn't about whether the illness is serious*, but whether you can predict what will happen next. For suggestions for responding to complexity in this domain, see page 13.*

IDENTIFYING COMPLEXITIES IN THE ILLNESS OR CONDITION:	*Agree*	*Disagree*	*Not applicable or don't know*
There are significant uncertainties about the illness or condition *Additional detail – e.g.* • *The condition is not clearly defined, or too little is known about it to inform planning* • *The population affected by the condition is not well-defined* • *The condition affects people in different ways, so a 'one size fits all' solution is unlikely to work* • *People with the condition are likely to be under the care of multiple professionals and/or in more than one care pathway*		X	
Many people with the condition have other co-existing illnesses or impairments that could affect their ability to benefit from the technology or service		X	

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e.g. • *Physical or mental co-morbidities* • *Cognitive impairment*			
Many people with the condition have social or cultural factors that could affect their ability to benefit from the technology or service. *e.g.* • *Poverty* • *Social exclusion e.g. drug use, homeless* • *Religious restrictions or expectations on how they manage their illness* • *Low health literacy (limited ability to understand health issues and how to handle them)* • *Low system literacy (limited understanding of how services work and how to navigate them)* • *Low digital literacy (limited ability to use, or learn to use, new IT products)* • *Unable to understand the language used by professional staff*		X	
The population with the condition, and/or how the condition is treated, is likely to change significantly over the next 3-5 years	X		
SUMMARY: The illness or condition has significant complexity which is likely to affect the project's success	*Yes* ☐	*No* ☒	

2. THE TECHNOLOGY (or other innovation)

[the technology developer might be the best person to complete this section]

Describe the technology/ies or other innovation. It might be an app, a device, a tool, a protocol or pathway, an algorithm, a model, a piece of hardware – or some combination of these.

Highlight what is new apart from the technology (e.g. new way of working). An innovation can be old technology (e.g. telephone) used in a new way.

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The questions below will help you decide if the technology (and how it works to support care) is straightforward, well-understood and will have a predictable effect. For suggestions for responding to complexity in this domain, see page 13.

IDENTIFYING COMPLEXITIES IN THE TECHNOLOGY OR OTHER INNOVATION:	*Agree*	*Disagree*	*Not applicable or don't know*
There are significant uncertainties about what the technology is *e.g.* • *The technology is difficult to define (e.g. connects with hidden infrastructure, supplier does not disclose full details)* • *The technology does not yet exist in a robust and definitive form*		X	
There are significant uncertainties about where the technology will come from *e.g.* • *The technology supply chain is not yet in place* • *The technology is not easily substitutable (i.e. if the supplier withdrew, it would not be obtainable elsewhere)*		X	
There are significant uncertainties about the technology's performance and dependability *e.g.* • *Data collection and transmission (where relevant) are not yet accurate or reliable* • *There are significant privacy or security concerns*	X		
There are significant uncertainties about the technology's usability and acceptability *e.g.* • *It is not possible for people to try out the technology on a small scale before adopting it* • *The data or knowledge generated by the technology is not well understood or trusted* • *There is not yet evidence from prototyping that intended users find the technology easy to use without human support (e.g. clinician, carer or help desk)* • *There is not yet evidence from prototyping that the technology is acceptable to its intended users (e.g. that it generates data that are well-understood and trusted, and which reflect how their condition is normally managed)*	X		
There are significant technical interdependencies *e.g.* • *A key technology needs to be installed across multiple technical systems so as to achieve 'integration'* • *The technology cannot be installed until the organisation's IT system is upgraded or changed (e.g. new hardware, better bandwidth)* • *The technology would require individual users to upgrade their device(s) or home IT system* • *The technology overlaps (unproductively) with an existing technology that performs the same or a similar function*	X		
The technology is likely to require major changes to organisational tasks and routines	X		

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e.g. • *Implementing the technology means some staff will have to do their jobs in a different way and/or interact with different people* • *Implementing the technology will require new or different steps in the overall care pathway (e.g. new administrative processes)*				
The technology (and/or the service model it supports) is likely to change significantly within the next 3-5 years *e.g.* • *The technology has limited potential to be adapted to take account of future clinical developments and other changes* • *The technology supply model may not be sustainable (e.g. the client-supplier relationship is weak, or there are questions about the company's reputation)*	X			
SUMMARY: The technology has significant complexity which is likely to affect the project's success	*Yes* ☒	*No* ☐		

3. THE VALUE PROPOSITION (costs and benefits of the technology) [the technology developer and business lead for the organisation might complete this section]

Describe the value (financial or otherwise) that the new technology and care model might generate.
For commercial stakeholders, this may be return on investment. For patients, it may be cure, comfort, or quality of life. For healthcare organisations, it may be improvements in quality of care,
efficiency (saving time, freeing up staff), safety (including reduced risk of litigation), or inclusivity.

The following questions address what kind of value the technology might generate for different groups of people. For suggestions for responding to complexity in this domain, see page 14.

IDENTIFYING COMPLEXITIES IN THE VALUE PROPOSITION:	*Agree*	*Disagree*	*Not applicable or don't know*	
The commercial value of the technology is uncertain *e.g.* • *If the technology does not yet exist in a definitive form, the case for investing in its [further] technical development is weak*		X		

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• *The technology does not have a plausible business case, including up-front investment, a well-defined customer base and market drivers, consideration of competing products and realistic assessment of challenges of implementing at scale in a public-sector health or care environment*			
The value to the patient or client is uncertain *e.g.* • *There are no high-quality studies (e.g. randomised controlled trials) to demonstrate the technology's efficacy for this patient/client group* • *The technology's benefits have not been shown to outweigh its potential harms* • *The technology's efficacy and safety were not measured in terms of an outcome that matters to patients*		X	
The value to the clinician or other staff member is uncertain *e.g.* • *The technology may create work (or other hassles) for the front-line staff* • *The technology's benefits have not been shown to outweigh the hassle of using it*		X	
The value to the healthcare system is uncertain *e.g.* • *The technology (or the technology-supported care model) is not considered to have any overall advantage over existing practice* • *The technology has not yet been shown to be effective and cost-effective in terms of how much benefit it will bring for a given financial outlay* • *There are safety concerns about the technology or care model* • *This technology-supported care model has not yet been successfully implemented in a similar context to the one being contemplated* • *There are concerns that the technology, whilst improving care for some patients, could widen inequalities* • *Regulatory and other approvals for the technology are not yet in place*		X	
The value to this particular healthcare organisation is uncertain *e.g.* • *The technology will require new technical infrastructure before it can be introduced to this organisation (see Technology domain)* • *The technology will require extensive changes to organisational routines and pathways (see Technology and Organisation domains)* • *Aspects of the local procurement processes make it hard to commission this technology (see Organisation domain)*		X	
The technology could generate a negative value (i.e. costs are likely to outweigh benefits) for some stakeholders. *e.g.* • *Potential loss of income* • *Destabilising a provider* • *Hidden or knock-on costs*	X		
The value proposition is likely to change significantly over the next 3-5 years. *e.g.* • *A new, better technology is on the horizon* • *The market for the technology will change significantly* *A key regulatory decision could be made or reversed)*	X		
SUMMARY: The value proposition has significant complexity which is likely to affect the project's success			

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	Yes ☒	*No* ☐	

4. THE INTENDED ADOPTERS OF THE INNOVATION/TECHNOLOGY

[this section should be completed by, or on behalf of, everyone who might use the technology]

Describe the intended users of the technology or other innovation. Consider: patients/lay people,
professionals, administrative and support staff. Are there people who will be impacted indirectly
(e.g. clinicians may be the main users but admin staff may need to adapt their procedures)?

The following questions will help you summarise whether people directly involved with the technology understand what it is for, think it is worth trying, feel able to use it and are motivated to give it a go, and also what the indirect knock-ons may be for others. For suggestions for responding to complexity in this domain, see page 14.

IDENTIFYING COMPLEXITIES IN THE INTENDED ADOPTERS:	*Agree*	*Disagree*	*Not applicable or don't know*	
There is uncertainty about whether and how patients/carers or citizens will adopt the technology *e.g.* • *The technology would require substantial input from the patient or their immediate carer* • *Some patients will view the technology in a negative way (e.g. not appropriate for their home, or reminding them of an illness they'd prefer to forget about)* • *Quite a few people in the intended user group may be unable or unwilling to learn to use the technology*	X			
There is uncertainty about whether and how front-line staff will adopt the technology *e.g.* • *Some staff members question the value proposition for the technology (e.g. they feel that adopting it would jeopardise the quality or safety of patient care, or they believe it is more time-consuming than existing practice)* • *The technology would require staff to do their jobs differently, and perhaps take on a new, unwanted, role and identity (e.g. 'data entry person')* • *Some individuals or teams do not have the resources, time, space or support to learn to use the technology* • *Staff have not been trained or supported to be creative and flexible when implementing technologies*	X			
There is uncertainty about the implications for people who might be indirectly affected by the technology	X			

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e.g. • *The technology would require input from others (e.g. relatives, care home staff), who may be unable or unwilling to learn to use it* • *The technology would make someone else's job obsolete or more difficult*				
There will be significant changes to individual users' perceptions of the technology over the next 3-5 years *e.g.* • *Key staff groups are likely to change their views on the technology* • *Patients or their lay carers are likely to change their views on the technology*	X			
SUMMARY: There is significant complexity relating to the intended adopters which is likely to affect the project's success	*Yes* ☒	*No* ☐		

5. THE ORGANISATION(S) IMPLEMENTING THE TECHNOLOGY

[this section is best completed by people who know the organisation and the challenges it faces e.g. board member, human resources lead, staff representative]

Briefly describe the organisation(s) involved in the project (for example, digital agency, healthcare provider, social care provider). What kind of organisation is it? How is it structured – and what is it like to work there? What is its track record of taking up new technologies? How well-resourced is it (in terms of both staff and funding)? Is there much enthusiasm for this particular technology? You may need to complete this section separately for the main and partner/ impacted organisations (and use the highest complexity score in your planning, since the initiative will only be as strong as its weakest link).

The following questions will help you assess whether the organisation is capable and ready to take on the innovation, and whether the work involved has been understood and planned for. For suggestions for responding to complexity in this domain, see page 15.

IDENTIFYING COMPLEXITIES IN THE ORGANISATION(S):	*Agree*	*Disagree*	*Not applicable or don't know*	
The organisation's capacity to take on technological innovations is limited *e.g.* • *Leadership is weak and the organisation's mission and values are unclear*	X			

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• *Internal relations, especially between managers and clinicians, are poor* • *The structure is top-down and hierarchical, so individual departments are discouraged from horizon-scanning for new products and ideas, and have limited scope to introduce innovations* • *The organisation has a poor track record of introducing any kind of change* • *There are no slack resources (people or money) to channel into innovative projects* • *It is not a learning organisation: staff are not encouraged to meet and talk about new ideas and projects, there are few or no measures in place to capture data and monitor progress, and risk-taking is discouraged* • *Digital maturity is low*			
The organisation is not ready for this particular innovation *e.g.* • *The fit between the organisation's mission and the innovation is poor* • *Key people (especially senior management) oppose the innovation or are unconvinced of its value* • *The business case is weak or questioned (see Value Proposition domain)* • *The implications (e.g. work required) of introducing, implementing and evaluating the technology have not been adequately assessed (or have been questioned)* • *Money is needed but a budget line has not been allocated*	*X*		
Organisational routines and processes will need to change very considerably to accommodate the technology *e.g.* • *Different kinds of staff (e.g. new hires) will need to be involved in the process or pathway once the technology has been introduced* • *A new (or radically revised) process or pathway will need to be developed* • *The core process or pathway will need to link differently with other key processes and pathways in the organisation*	*X*		
Procurement processes are in place that make it harder to commission this technology *e.g.* • *The provider is not on the procurement framework* • *Existing contracts need to expire first* • *Aspects of the procurement process are not yet clear (e.g. Who will fund this? Who will be liable for costs? Is there an identified budget? It is capital or revenue ? Is the funding recurrent? Are there issues with timing/accruals of funding?)*	*X*		
The work needed to introduce and routinise the innovation has been underestimated and/or inadequately resourced *e.g.* • *Work to bring people on board and develop a shared, organisation-wide vision for the change* • *Work to develop, implement and mainstream new care pathways and processes* • *Work to coordinate the project across more than one organisation or sector* • *Work to evaluate and monitor the change*	*X*		
The organisation(s) involved are likely to have significant restructurings or changes in leadership, mission or strategy over the next 3-5 years	*X*		
SUMMARY: There is significant complexity relating to one or more participating organisations which is likely to affect the project's success	*Yes* ☒	*No* ☐	

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6. THE EXTERNAL CONTEXT FOR INNOVATION
[this section might be completed by a 'horizon-scanner' who looks beyond the organisation]

Describe the national and local context for your technology or programme (e.g. legal obligations,
policy, professional bodies views on best practice, related national initiatives). Think about the
key influences on the project beyond the organisation(s) you identified in the previous section.

The following questions will help you summarise whether there are external conditions (such as the state of policy, public/ professional opinion, expected external events such as political climate change) likely to complicate the adoption and mainstreaming of the innovation. *For suggestions for responding to complexity in this domain, see page 17.*

IDENTIFYING COMPLEXITIES IN THE EXTERNAL CONTEXT:	*Agree*	*Disagree*	*Not applicable or don't know*
The political and/or policy climate is adverse *e.g.* • *External political or economic changes impacting on the organisation could threaten the introduction of the innovation* • *Current policy priorities conflict with this initiative*	X		
Professional organisations are opposed to the innovation or don't actively support it *e.g.* • *There are concerns about quality or safety of care* • *There are concerns about confidentiality and wider information governance* • *There are concerns about professional workload* • *Priorities are elsewhere*	X		
Patient organisations and lobbying groups are opposed to the innovation or don't actively support it *e.g.* • *There are concerns about quality or safety of care* • *There are concerns about privacy and/or what will happen to the data* • *Priorities are elsewhere*		X	
The regulatory context is adverse		X	

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e.g. • *Quality standards and regulatory requirements for using the technology in a health or care setting have not been fully defined* • *Key stakeholders do not know about or accept these standards and requirements*			
The commercial context is adverse *e.g.* • *The technology industry views the innovation (or similar products) negatively* • *The technology does not use industry-standard components* • *There is lack of support for timely updates to the technology to support ongoing work as intended*	X		
Opportunities for learning from other (similar) organisations are limited *Additional detail* • *No other similar organisations are yet using the technology* • *Inter-organisational knowledge exchange networks are weak*		X	
Introduction of the technology/innovation could be threatened by external changes that impact on the organisation	X		
The policy, regulatory and economic context for this innovation is likely to be turbulent over the next 3-5 years *e.g.* • *Change of government* • *New policy priorities* • *Economic recession* • *New regulatory framework* • *Withdrawal of industry commitment*	X		
SUMMARY: There is significant complexity relating to the external context which is likely to affect the project's success	*Yes* ☒	*No* ☐	

EMERGENCE OVER TIME

[this section pulls together the bottom row of each of the previous domains]

Summarise the main changes which, if they happen, could affect the project over the next 3-5 years. Which of these do you think is most significant? What are the key uncertainties?

For suggestions for responding to complexity in this domain, see page 18.

ESTIMATING WHAT THE FUTURE HOLDS:	*Agree*	*Disagree*	*Not applicable or don't know*

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The population with the condition, and/or how the condition is treated, is likely to change significantly over the next 3-5 years	X			
The technology (and/or the service model it supports) is likely to change significantly over the next 3-5 years	X			
The value proposition for the technology is likely to change significantly over the next 3-5 years	X			
There will be significant changes to individual users' perceptions of the technology over the next 3-5 years	X			
The organisation(s) involved are likely to have significant restructurings or changes in leadership, mission or strategy over the next 3-5 years.	X			
The policy, regulatory and economic context for this innovation is likely to be turbulent over the next 3-5 years	X			

PART 2: ACTION PLANNING AND PROJECT MAGAGEMENT

Taking account all your responses to Part 1, this section prompts you and your team to **plan your implementation project** and consider measures to **reduce or respond to complexity** in the different NASSS domains. Below, we offer some ideas and resources to get you started. The resources and links have been selected for a UK setting but could easily be adapted for other countries.

Planning your implementation project

Skim this section first – but then go on to look at the different complexities and ideas for responding to them. You may end up deciding not to go ahead with the project at all.

Project management in a highly predictable environment is fairly straightforward, but under conditions of complexity, things can't be fully predicted or laid out in advance. You need to set a broad goal, take action on several fronts simultaneously (making sure you attend to the human and political aspects of the project as well as the technical and financial aspects), while periodically reviewing progress and adjusting your strategy.

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For large, ambitious projects, we recommend the Project Initiation Routemap, a guide by the UK government for planning complex projects in the public sector. The Routemap emphasises three linked strategic tasks:

- Assess the complexity and context of the delivery environment (see NASSS questions above, especially Domain 2 'The Technology' and Domain 5 'The Organisation'), and consider how you could respond to this complexity (see suggestions below);
- Assess the capacity and capability of organisations and teams to deliver the project (in particular, sponsor, senior management buy-in and support, dedicated delivery team);
- Work to strengthen and align context and capability (e.g. align requirements, governance, execution strategy, organisation design and development, procurement, risk management, asset management).

See also the NESTA DIY toolkit for bringing ideas to life (designed for social care providers) – a structured way to get from the initial idea for a new technology to a well-designed project to get it up and running in a service.

Due diligence. Before investing in a technology, make sure the company selling it is legal and solvent, that the technology has the requisite regulatory approvals, that personal data is handled sensitively and respectfully, and that any associated risks have been considered. There are numerous due diligence checklists available – see these for example:

UK government digital service standards – a 14-point checklist when planning a service that involves digital technology. Linked to these are UK government technology and digital standards.

How to do due diligence for health care technologies – introductory blog from private company SecureDocs.

Digital Assessment Questionnaire from NHS Digital, a self-assessment checklist for apps and similar technologies.

Medical devices – software applications – Advice from the UK government on when software applications are considered to be a medical device and how they are regulated.

NHS Health and Social Care Data Security Standards (including a full due diligence checklist for suppliers).

UK government code of conduct for data-driven health and care technology – Principles and advice for machine learning applications that use NHS data.

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Commercialising new technologies. If you are developing a new technology and you think it has commercial potential, you will need to systematically demonstrate to investors how it will generate value. Try this resource:

Guidance and Impact tracking System (GAITS) – a web-based project and portfolio management platform designed to support commercialisation of new health technologies, developed by the US consultancy firm CIMIT.

Adoption Readiness Level tool by Liverpool City Region's e-health cluster – a self-assessment tool for tech developers that considers five domains (market, human, systems integration, finance/procurement, motivation).

Responding to complexity in the illness or condition

Your first step in developing technological solutions for an illness or condition is to understand the full range and depth of what the illness *is* and how it affects people.

Find out more about the illness. For example, find the prevalence, likely progression, and current 'best practice' care model. This will allow you to estimate how many users a product is likely to have, how long they can/will use it for, and how this fits with current care. Remember, there will be 'mild' and 'severe' forms of the illness, different age groups, ethnicities, genders and so on. Once you understand how the illness is patterned, this could inform work to 'personalise' the technology for different sub-groups (see 'Responding to complexity in the intended users' below). To learn about the illness, use different data sources, e.g. from national and regional databases, academic and grey literature, health and care practitioners, patient organisations, patients. For example:

NHS Choices – a searchable database of illnesses, including diagnosis, treatment and likely course

NICE guidelines - evidence-based recommendations in a variety of conditions, procedures and technologies across health and social care developed by independent committees

Cochrane library – a database of high-quality systematic reviews of treatments

Healthtalk – a database of patients' accounts of what it's like to live with different illnesses

Macmillan – a website for people with cancer, with detailed information on prevalence, treatment and prognosis. There are similar patient-facing websites for most conditions. Explore them!

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Responding to complexity in the technology(ies)

Don't make the mistake of treating a new technology as a plug-and-play solution. You need to ask a lot of questions about it before you can be sure it's the right tool for the job. New technologies often look appealing and promising until we consider all aspects of the innovation process.

Find out more about the technology and assess its quality and implications. If you are not the creator of the technology, familiarise yourself with all relevant aspects of it or ask an expert. Look at it; play with it; do a 'walk through' the imagined use case. Will this product really help with what you are planning to achieve? Could a different technology (perhaps one that is already tried and tested) do a similar job with less hassle?

NHS apps library – a searchable database of quality-assured smartphone health apps

Publicly available 'curated' databases of apps – for example:

- Psyberguide for mental health apps
- ORCHA, an independent organisation that evaluates apps

Find out more about where the technology will come from and associated challenges. Ideally the building blocks for your chosen technology e.g. coding platform, devices etc can be accessed or purchased easily (no long waiting periods or unreliable supply chains). Ideally, the technology should not depend on a single vendor/device/coding language etc, but work (or have the potential to work with or easily change to) others as well. They will have been tested extensively so you don't have to worry about these components being dependable. Conflicts of interest and claims to intellectual property (IP) should be sorted out before the project begins. It should be clear who will fund the technology, what it will cost and which costs are covered (set up, maintenance, updates etc).

Identify and address the key points where technical complexity will impact on success. Find out about any unknowns and dependencies as soon as possible, and develop a plan to deal with them, including alternatives or workarounds. Reduce unnecessary technical integration. Integration between multiple systems makes everything more complex. Ask whether it is really necessary or if there are ways to avoid or delay this, especially during initial testing. But bear in mind that some forms of technical integration (e.g. to make a new piece of software accessible from within a patient's existing electronic record) may make the technology *simpler* for a clinician to use.

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Consider how the technology will disrupt the system. Map possible disruptions and take steps to avoid or mitigate them. Can you modify the technology to make it less disruptive? Can you reduce knock-ons by adjusting other systems or processes? What measures might you put in place (e.g. small-scale pilot running in parallel with the old service, on-the-job training, help desk) to deal with the disruption until systems and processes have evolved to accommodate the new technology? We pick up this important point again under 'the organisation' below.

Responding to complexity in the value proposition

This project is only going to work if all stakeholders gain something of value from it.

Consider how to increase the technology's appeal to investors. If the technology is at an early stage of development, what is its likely upstream value as viewed by investors (especially the business case for generating profits, further spin-offs, and highly qualified jobs), drug and device regulators (preliminary evidence of efficacy and safety), and financial regulators (auditable business processes and governance)? Can the technology be 'de-risked' by removing costly but inessential features? See the Guidance and Impact tracking System (GAITS) resource linked above.

Consider how to increase the technology's value to patients or citizens. If a technology is meant to be used by patients or lay people, its potential benefits must be weighed against its costs (and the person's willingness and ability to contribute to these), the work needed to use it (and whether the person or their carer is able and willing to do that work), and the desirability of medicalisation and surveillance. Can the design be improved to make the technology more appealing? Can the data be visualised in a way patients or carers can engage with?

See links above under 'Responding to complexity in the illness'

Getting the most out of PROMS – A guide to using patient-reported outcome measures to assess whether an intervention or technology is actually improving outcomes that are valued by patients

A guide to PROMs methodology from NHS Digital (using hip and knee replacement as an example)

Identify evidence of effectiveness and cost-effectiveness. If the technology is at a more advanced stage of development, there may be research evidence comparing its effectiveness (does it work?) and cost-

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effectiveness (is it good value for money?) with 'usual care' and measuring an outcome that is important to patients. Try these resources:

NICE Evidence Standards for digital health technologies – These cover both effectiveness and economic impact.

Consider real-world value issues. Is there a realistic assessment of the challenges of implementing this innovation at scale in a particular public-sector health or care environment? Even when something has been shown to be cost-effective, it may not be locally affordable or a funding priority.

The NICE Evidence Standards website linked above offers a budget impact guide and budget impact template for local cost planning.

Responding to complexity in the intended adopters of the technology

This project is only going to work if the people you want to use the technology are able and willing to do so.

Address acceptability, accessibility and usability for patients and citizens. If the technology requires input from a patient, carer or other lay person, will they find the product aesthetically pleasing and easy to use? Does the technology make sense, for example, in the context of how patients and carers already do things, their routines and existing tools they use to support their work? Remember, everyone is different. Some people have limited vision or dexterity; some people find instructions hard to understand. Can you make the product more accessible? Is it worth building design changes in now or planning to do so in the future (e.g. after proof of concept testing)? If the technology includes several components, can users select what is most relevant for them? These resources may help:

How to do research on user needs in the 'discovery phase' of technology design – a website from the UK government.

International Design Foundation – a US site offering tips and resources for making websites and apps more accessible.

How to design websites for older people – a guide from the Alzheimers Society.

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Address staff motivation and concerns. Assess the level of enthusiasm for the technology from different staff groups, and also how motivated teams are to take on the new technology. Have any of them had experience of using this technology elsewhere? Listen to staff concerns – which may be legitimate – and to their ideas for increasing the project's success. This resource may help:

Higher Education England Digital Capabilities Framework for assessing the digital capability of staff.

Modify staff roles and provide training. Develop new roles and job descriptions where needed, perhaps by adapting ones already in use elsewhere. Set learning objectives (some of which will be about building confidence to make judgements, not about mechanically following protocol). Design and develop training courses. Remember: using a technology usually needs on-the-job and team-based training, not just sitting in classrooms. Allocate sufficient budget for this work, and consider issues such as backfill.

Promote social learning. One way to become confident in using a technology is to shadow someone in the same role who is already an enthusiast for it ('champion') and confident in using it ('super user'). Learning in this way not only develops skills but also helps people develop a positive attitude and identity.

Support collective sensemaking and communities of practice. People need to make sense of new technologies – sometimes by coming together to complain about them initially! Surfacing one's irritation with a technology may be the first step to coming to terms with it. Both staff and patients may benefit from being in 'communities of practice' (groups or networks of people who share an interest in something and are trying to get better at it). Online communities of patients, for example, are often good sources of knowledge and wisdom about how to manage a condition. Try to get these communities on board if introducing a patient-facing technology.

The Kings Fund guide to engaging NHS staff may provide some practical ways of achieving the above.

Responding to complexity in the organisation

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The project is only going to work if the organisation has the capacity to take on innovations and if there is good 'innovation-system fit'. The tips below may help if you are trying to support an organisation to implement a new, technology-supported care model.

Assess the organisation's capacity to innovate. An innovative organisation has strong leadership, good clinician-managerial relations, a devolved management structure, slack resources (money and/or staff) that can be channelled into new projects, good lines of communication and an ethos where it's OK to take risks and learn from failures. If an organisation appears to lack these essential prerequisites for innovation, consider whether you need to strengthen its capacity before pressing ahead. Here are some questions to help you assess capacity to innovate:

- Is there a culture that supports innovation and change (e.g. are staff trusted to introduce new ideas)?
- Does the organization have systems and processes in place that support innovation and change e.g. effective information and communication systems, opportunities for networking and learning across departments/teams?
- Do the senior management team actively seek opportunities for improvement and encourage ideas and feedback from patients, the public and staff?
- Are the organisation's leaders helping to create a facilitative context through providing motivation and support, creating a vision and reinforcing the change process?
- Is there a distributed and devolved style of management?
- Is there a history of introducing successful change in comparable projects at a local level?
- Are there mechanisms in place to support learning and evaluation and to embed changes in routine practice e.g. regular team meetings, audit and feedback processes, professional development opportunities and performance review systems?

Assess innovation-system fit. Even when an organisation is capable of running a successful project to implement a new technology, it might be the wrong technology to introduce in this organisation right now. Has the organisation successfully adopted similar technologies in the past? Are its strategic priorities aligned with the use of the proposed technology? Or are other projects more pressing?

Assess the implications of the technology for the organisation. Careful mapping out of tasks and processes is necessary to surface how the technology or other innovation is likely to change these. The pathway in which the technology is used directly (e.g. clinical care) may have indirect knock-ons for other processes and pathways (e.g. booking, correspondence, billing). You need to estimate costs (both initial and recurrent), and consider how money will need to flow across the system. Before signing off on a project, boards generally want to know how much will it cost up-front, what the likely savings will be, and when these savings will occur. These resources may help:

Process mapping guide from NHS Improvement. Ideas and tools for mapping the steps in a care pathway. A full list of additional service improvement and redesign tools from NHS Improvement is available here.

Using costing information to support better outcomes – a guide from NHS Improvement.

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Assess the level of 'political' backing for the innovation. For an organisational-level adoption decision to be approved, it needs support from both top management (a 'senior sponsor') and the rank-and-file. Supporters of the change must outnumber opponents and be more strategically placed. People with 'wrecking power' can block progress and may need to be brought on board (or worked around). To assess all this, use the NASSS-CAT PROJECT tool and also:

Stakeholder analysis guide from NHS Improvement. This guide will help you construct a table or chart listing all the stakeholders who will need to accept (and, in many cases, start to use) the technology. Consider each key stakeholder's perspective (and their potential wrecking power).

Consider inter-organisational relationships. Costs and benefits of technology projects are hard to predict, and savings may accrue elsewhere in the system. When there is no pre-existing contractual relationship between organisations, it can be hard to reach a satisfactory arrangement for how to manage these uncertainties.

Think how (and by whom) success will be evaluated. If this project is going to happen, you will need to monitor how well the change is going. You will almost certainly need both quantitative metrics (to answer the "how many…?" and "are we on track…?" questions) and also qualitative measures (to answer the "how do people feel about this…?" questions). Evaluation is everyone's job, and data are often best collected by people doing the job. Extensive data collection can be time-consuming and slow the project down (i.e. the perfect may be the enemy of the good).

Evaluation: what to consider – A guide by the Health Foundation. This basic guide includes qualitative and quantitative approaches.

The 'rainbow framework' for evaluation and monitoring by Michael Quinn Patton. It takes you through 7 colour-coded steps, namely Manage (e.g. define stakeholders, secure funding), Define (set a scope for the evaluation), Frame (intended users of the evaluation, what they will use it for, what success will look like), Describe (sample, measures/metrics, data sources, analytic approaches), Understand Causes (deeper analysis to produce explanatory models), Synthesise (combining results), and Report & Support Use (publishing and disseminating).

Evaluation Works and Evidence Works toolkits to guide commissioning decisions, produced by West of England Academic Health Sciences Network and their partners.

Allocate funding. Studies of 'failed' technology projects often identify inadequate funding as a leading cause. You will probably need substantial set-up funding and possibly a recurrent budget line (for things like licences and IT support). Budget adequately for staff to learn and adjust as the transition occurs (see 'Responding to complexity in the intended adopters' above).

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Manage the transition. Good change management involves a combination of 'hard' and 'soft' approaches. As well as setting goals and milestones and using agreed metrics to monitor progress, you also need to create opportunities for staff to come together and talk about the technology and new care model. As noted above, collective sensemaking, training (especially on-the-job training for both individuals and teams) and social learning from champions and super-users is crucial for building capacity. Use creative tools such as flip-charts and post-it exercises to surface people's interpretations and concerns. Invite them to come up with creative ideas and solutions to any problems they identify. Allocate sufficient budget for this work, and consider issues such as backfill. This guide may help:

Leading large-scale change: a practical guide from NHS England.

Responding to complexity in the external environment

Plans for technology-supported change locally are unlikely to work out if there is a major mis-match with national policy or the prevailing political, economic or professional environment.

Try to align your project with current policy priorities. If the technology is actively supported in policy, it will be easier to introduce. If priorities are elsewhere, it may be worth trying to 'rebrand' the work to fit these.

Address regulatory issues and challenges. Consider which regulations (from which regulatory bodies) are relevant to the introduction of this technology. Are all approvals already in place? If not, who do you need to work with to make progress in this regard? See 'Due diligence' section on page 12.

Get the professions on board. If clinicians or social workers believe that the technology compromises the care of their patients or clients, or if they view it as demeaning to their role or a threat to their professional jurisdiction or income, their professional bodies may oppose it. Early dialogue with such bodies may avert such a situation.

Establish inter-organisational networks or collaboratives. Complex, organisation-wide change is a lot easier if change agents in one organisation can network with their opposite numbers in comparable organisations – for example in quality improvement collaboratives or learning sets. Here's a resource for that:

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Improvement collaboratives in health care – A guide from the Health Foundation.

Keep a close eye on the outer context. External shocks to an organisation (such as economic turbulence) make change precarious. Whist such shocks are often hard to predict, it is a good idea to see what's on the horizon. The following questions may help you:

- Does the new technology and the proposed changes to services align with the strategic priorities for the wider health system e.g. in terms of current health policy, national priorities for action and improvement?
- Are there incentives in the wider health system that reinforce the proposed change e.g. pay for performance schemes, regulatory requirements etc.?
- Are there existing inter-organisational networks (e.g. specialised clinical networks) that will be helpful in terms of supporting the proposed changes?
- How much stability/instability is there in the wider health system – and how might this likely influence the implementation project?

Responding to emergent complexity (new complexities that develop over time)

The point about emergent change is it's difficult if not impossible to predict. So this domain is really about how you might build resilience in your staff and your organisation to enable them to respond to things that come up in the future.

Acknowledge unpredictability. Have you left open the possibility that the project might unfold in one of several different ways? Can you flesh out these different possible futures and talk them through with your stakeholders?

Recognise and support self-organisation. Front-line teams will 'tinker' – that is, try to adapt the technology and the work process to make them work better locally. Are you able to capture data to evaluate and support these efforts?

Facilitate interdependencies. Have you identified the key interdependencies in the project? Is there anything you can do to strengthen existing interdependencies or develop and strengthen new ones?

Maintain space for experimentation and sensemaking. As complex projects unfold, staff will need to tinker more, and also talk about what's happening. Encourage them to admit ignorance, explore paradoxes, exchange different viewpoints (there's no need for them to agree on a single version of the 'truth'!) and reflect collectively.

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Develop adaptive capability in staff and teams. Train your staff to be creative and to adapt to change as it happens. They will sometimes need to make judgements in the light of incomplete or ambiguous data.

Attend to human relationships. Dealing with emergent problems requires give-and-take. It's sometimes a matter of muddling through. This will happen more easily if people know, like and trust each other.

Harness conflict productively. There is rarely a single, right way of addressing a complex problem, so view conflicting perspectives as the raw ingredients for producing multifaceted solutions.

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Annex 48 UC-PT3-001c/COPD Phase 2 Consent form (target users)

INFORMOVANÝ SOUHLAS

Název projektu:

SHAPES - Smart and Healthy Ageing through People Engaging in Supportive Systems - Pan-European Pilot Campaign: User engagement and feedback on digital solutions for pilot theme 3 — medicines control and optimisation.

Oblast výzkumu:

Ověření přínosu digitálních technologií v oblasti poskytování telemedicínských služeb v domácím prostředí prostřednictvím telemedicínské platformy FNOL v rámci mezinárodního projektu Smart and Healthy Ageing through People Engaging in Supportive Systems (SHAPES).

Místo testování:

Fakultní nemocnice Olomouc (FNOL) – I.Interní klinika kardiologická

Kontakt:

- Michal Štýbnar (FNOL) Michal.Stybnar@fnol.cz, tel. 588 443 713
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Prohlášení účastníka

- Byl jsem pozván k účasti na výše uvedené studii. Účelem této studie je shromáždit zpětnou vazbu o designu a uspořádání aplikace ve zdravotnictví (aplikace), která je vyvíjena pro chronicky nemocné pacienty FNOL. Studie je příležitostí pro výzkumný tým FNOL, aby se ujistili, že aplikace je praktická a použitelná z pohledu uživatele.
- Byl jsem seznámen s účelem testování a byly mi poskytnuty dostatečné informace o výše uvedené studii, jejím účelu a provedení, o mých právech a možných výhodách a nevýhodách účasti.
- Měl jsem příležitost klást otázky týkající se studie a nechal jsem si na tyto otázky uspokojivě odpovědět.
- Během studie jsem dostal (a) dostatečné informace o shromažďování, zpracování, přenosu / zveřejnění a vymazání svých odpovědí. Beru na vědomí, že kromě mého jména, kontaktních údajů a videozáznamů získaných během studie nebudou během této studie zpracovávány žádné další osobní údaje.
- Podepsáním tohoto formuláře potvrzuji, že dobrovolně souhlasím s účastí v této studii a že také uděluji souhlas se zpracováním mých odpovědí pro účely popsané v tomto dokumentu.
- Nebyl jsem pod tlakem ani přesvědčen k účasti a měl jsem dostatek času na zvážení své účasti ve studii. Beru na vědomí, že moje účast je zcela dobrovolná a že mohu svůj souhlas kdykoli odvolat, a to bez udání důvodu.
- Mám také právo požádat o odstranění mých identifikovatelných osobních údajů v souladu s nařízením o ochraně údajů.

Já, níže podepsaný/á, souhlasím s účastí na testování nových funkcí a nové podoby mobilní a webové aplikace (dále jen „aplikace“) Fakultní nemocnice Olomouc, IČ: 00098892, sídlem I.P.Pavlova 185/6, Olomouc (dále jen „společnost“), souhlasím s tím, aby byla ze strany společnosti, jakožto výhradního správce a zpracovatele osobních údajů, zaznamenána, shromažďována a zpracována moje aktivita testujícího uživatele při práci s aplikací včetně audiovizuálního záznamu mé osoby při takovém testování, ze kterého budou patrné mé reakce na funkcionality aplikace a způsoby práce s aplikací.

Audiovizuální záznam a další záznam mé práce s aplikací smí být ze strany společnosti použit výhradně pro její interní neveřejné potřeby za účelem zjištění správnosti návrhu aplikace a její případné úpravy a nesmí být zpřístupněn třetímu subjektu. Tento můj souhlas je společnosti poskytnut pouze po nezbytně

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nutnou dobu, po kterou bude pracovat na vývoji aplikace v rámci projektu SHAPES.

Vyplní účastník studie:

Souhlas (pro potvrzení vašeho souhlasu vyplňte níže uvedené podrobnosti)

Jméno:	
Datum:	
Podpis:	

Vyplní zadavatel studie

Vyplněním níže uvedených údajů potvrďte přijetí podepsaného souhlasu účastníka studie

Jméno:	
Datum:	
Podpis:	

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Annex 49 UC-PT3-001c/COPD Phase 2 Feedback report

Overview of feedback

Using the feedback collected during the presentations and interviews with participants, the Phase 2 mock-ups of the SHAPES FNOL component of the PT3-001c and PT3-COPD use case user app were assessed using the ISO Standards for multimedia design (ISO 14915). General feedback is provided first followed by specific feedback and recommendations for each mock-up screen. Recommendations for the technical partners are provided for each screen.

Suitability for the communication objective *(i.e., suitability of the presentation of the information for achieving the goals of the providers and visitors).*

In middle-aged and older users, we may encounter the so-called fear-of-computer syndrome. That is, fears that the individual will not be able to master working with a computer. Therapeutic advice that helps people with this syndrome is very well applicable to the general population of older users (without a diagnosed syndrome). An important point is, that on the one hand, a clearly designed application, but we should not forget the motivating conversation with the user. For older users who are concerned about working with the tablet, it is advisable to introduce the application and motivate them in person (not just by a brochure or leaflet). This introductory interview can have a major impact on the future use of the application.

Positive feedback	• Create screens with a small number of elements.
	• Direct the user's attention to only one task at a time.
	• Use a contrast sans-serif font.
	• Use simple design.
	• Show important information (doctor's reports, etc.) with a priority.
Negative feedback	• Do not use icons (or limit their use), respondents often do not understand icons.

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• The colors used in the application should be justified and in order. Using color coding with no reason is not recommended, as this confuses users.

Suitability for perception and understanding (i.e., is the information transmitted easy to understand and can be easily recorded?)

The clearer and more comprehensible the application, the higher the willingness of users to use the application. This is in line with the Technological Acceptance Model; the assumption that people make more use of technologies for which they perceive benefits and are easily accessible for control (UX, UI). The application should suitably combine a pleasant appearance, ease of use, trustworthiness and thus bring an overall positive experience with the application.

Positive feedback	• Use one-click confirmation (not double-click).
	• Use the familiar hospital logo and match the application to the colors that users have associated with this logo (greater credibility).
	• Create space for the user's "errors", typos, incorrectly selected surgeries, etc. - these user errors must be taken into account by the application and be able to respond to them correctly.
Negative feedback	• Do not use complex gestures to control (do not use a slider or double-click) the application.
	• Beware of clickable elements too close to each other (seniors have trouble hitting them).
	• Test the application properly before its release, when the application is launched to the public, do not change it.

Suitability for exploration *(i.e., is the participant able to find the desired information or complete his task without any previous knowledge or experience regarding the presentation or structure of the information offered).*

In majority of cases the application consists of several predefined scenarios which should guide the user through the whole process and avoid too much of „blind“ exploration. However, also for such a case the application consists of several navigation elements that can be accessed by ease. Nevertheless, the alternate routes should not be confusing.

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Positive feedback	• Wizards are useful tools to guide the users through the measurement process.
Negative feedback	• Alternative paths to the destination may confuse users, pay increased attention whether they are justified.

Suitability for user motivation *(i.e., a participant must be encouraged to act. By focusing on the needs of the participants, an appealing presentation and goal-oriented guidance, the participant can be motivated).*

The application should be designed in such a way that patients gain better control over their health condition, thus increasing user adherence, improving health status and thus reducing healthcare costs. Immediate feedback on the deviation in health (fluctuations in weight, pressure, etc.) supports early intervention (dietary adjustment, change of drugs, new exercise regimen, etc.).

Positive feedback	• Create a connection with something that users already know and like to use (e.g. e-prescription). • Present the application as an "extended hand of a doctor", the application complements the contact with the doctor (does not replace it). • The application should include doctor's feedback for the tasks completed by the patient (it can also be added automatically); then users will understand the application as meaningful
Negative feedback	• Lower confidence of older respondents in the electronic data form (deeper trust in paper notes). • When introducing the application to the public, attention should be paid to possible misinformation, some users expressed uncertainty as to why such an application is being created ("is there a risk of healthcare collapse?").

UC-PT3-001c and UC-PT3-COPD: Phase 2 feedback report for technical partners

The Phase 2 mock-up User Experience testing with recruited participants was conducted on 29th March and 11th April 2021. Tests were conducted personally on-site while following elevated pandemic precautions.

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With the written permission of the respondents, all sessions were recorded including audio, video and respondent's interaction with the prototype. Detailed feedback was summarized based on these recordings.

UX testing goals

The user needs / experience testing was conducted to validate design assumptions and to facilitate better specification of design principles which are used in the mobile app. We decided to conduct very specific research due the following factors:

- Expected user demographic – older people with limited digital skills
- Non-trivial set of functions required for long term monitoring of chronically ill users
- The ability to compare research results in controlled manner with feedback which will be collected in pilot run of the app

The results of the testing are used as input for

- Design of first version of mobile app
- Validation of design after the pilot run of the app
- As a source of input for our design guidelines for future patient related apps

Participants

Ten participants consented to take part in the study. They included three male and seven female participants. The breakdown of participant type was as follows:

Six target users (TU1 – TU6) who were recruited via University hospital Olomouc (FNOL). All of them except one were already retired. The youngest patient with the heart failure was recruited due to his experience with the previous version of the application so it can be compared, whether any improvement of the UX design were perceived from his perspective.

Rest of the target users were aged over 60 years' and had diagnosed heart failure. Only the youngest participant was experienced with use of mobile applications. Rest of the participants did not used mobile applications before, however, they all reported some elementary knowledge with the internet browsing.

Four healthcare professionals (HCP1 – HCP4) were recruited via contacts on cardiology department.

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Two HCPs were physicians with specializations in cardiology two HCPs were nurses. One of the medical doctors was a male. All of the HCP users were rather confident in using their smartphones or tablets as they regularly use them.

Selection of screens and key scenarios

The prototypes used in testing, as well as selection of the test scenarios was based on our pre-existing experience with operation of older telemedicine app.

The most acute problems are validated in scenarios 1, 2 and 3. Issues addressed in these scenarios were most common issues, that user have had in the previous app.

Scenario 4 is one of the key scenarios in remote monitoring of older / chronically ill patients, as it provides means to continually monitor patient health indicators, as well as his medication intake and treatment adherence.

Scenarios 5, 6 and 7 are focused on activities which facilitate user ability so “self-service” most often task and achieve their practical goals thought the app, rather than contacting hospital / doctor via classical means (phone calls, visits). Both phone calls and visits have been historically used by patients for very basic tasks, which can be easily solved on-line but in asynchronous manner, thus reducing workload on hospital staff and facilities.

First round of testing - Wireframes

First day of the testing was focused on the clickable wireframe prototype representing the future shape of the application. These wireframes provided basic layout and several active links connecting between some of the windows to demonstrate how the final application would respond.

In order to test the application’s UX several use case scenarios were tested, they were as follows:

- Access to measurement tab, acquisition of selected measurements
- Access to medication tab, including medication request
- Consultation request

Fig. 1 depicts the first prototype of the graphical user interface of the telemedicine application developed by FNOL. For the first prototype it was decided that the design should be landscape oriented and should be designed exclusively for the use with tablets, as the larger screen would allow to accent the needs of the older users in an easy manner.

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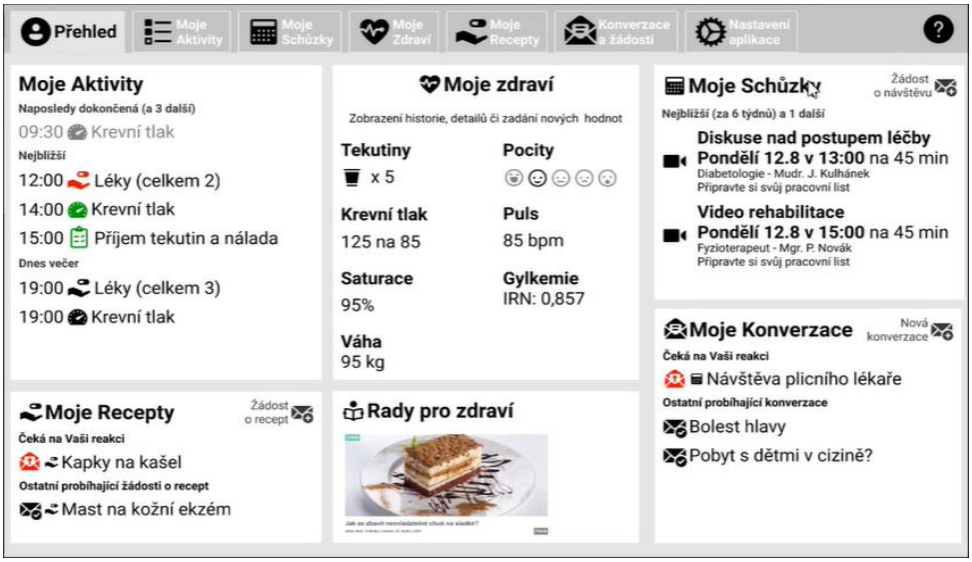

Fig. 1 First version of the wireframe prototype

The user comments, responses and observed behaviours were analysed and grouped by similar topics. Based on these inputs we generated following improvement recommendations:

Acquiring measurements:

- Today's measurements should be in the form of a checklist. Colour differentiation should not be its only attribute.
- During the routine usage of the measuring function the users would like to skip some of the wizard steps.
- Button for the second step should be described by different wording. Instead of „checked/in order", it should be used more descriptive „Blood pressure meter working correctly".
- Wizard can be implemented also by video instructions. The devices where video instructions are most helpful will be identified through practical usage in pilot project.
- It should be possible to initiate measurement or wizard directly from the notification.

Medication list:

- List should be visualised similarly to the today's measurements agenda.

Medication request:

- Instead of a text field it should be possible to choose by a multiselect from the list of available medications. The last item could be „other – please specify".
- Note for a physician can be omitted.
- The last screen should inform how the ePrescription will be delivered to the patient.

Request for a consultation:

- Multistep dialogue can help the patients to focus on each specific item of the form.
- It is not necessary to give a subject name to the consult, only the reason could be selected from a list.
- It is expected that within the calendar there will be a list of available free time slots as it is typical for the majority of covid-19 test and vaccination reservation systems. This improvement can be fully implemented only after proper update in HMS scheduling capabilities.

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- Upon the completion of the video consultation request, better information how the patient will be notified whether the doctor has accepted it and which time slot he has chosen should be provided.
- It is confusing whether the ordering system is designed for personal or on-line (videoconferencing) visits. But for first generation of the system, only video conference visits will be supported.
- Test users were not sure which side should initiate the call.

Navigation through the application:

- Test users were not able to return to the home screen as they usually ignored the tabs in the headings.

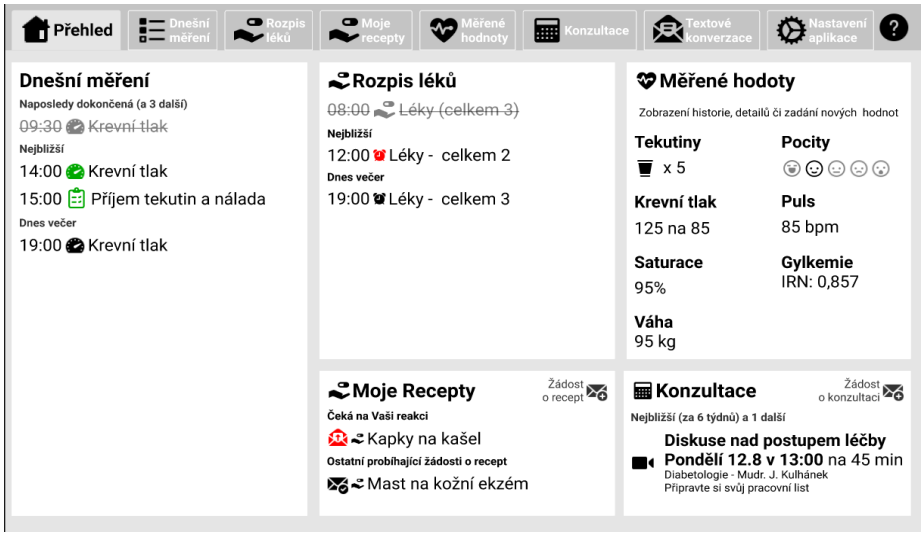

Fig. 2 Second version of the wireframe prototype based on the feedback collected from users

Second round of testing Hi-Resolution design prototypes

Second round of the testing was focused on the usage of the Hi-Resolution application prototypes. Following pages contains summary of test findings and resulting recommendations:

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SCENARIO 1 – USER LOGIN

a) **Suitability for the communication objective**

The upper bar is redundant, contributes to cognitive overload.

b) **Suitability for perception and understanding**

There is no explicit information that the application is product of the University Hospital Olomouc.

Design does not use the colors from the University Hospital Olomouc design manual.

c) **Suitability for exploration**

The login button is not pronounced.

d) **Suitability for user motivation**

Missing "more info about application" click button.

All participants perceive the application as beneficial and practically usable.

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Recommendations

4. The user's first contact with the application must inspire confidence, a visible display of the official hospital logo in the format in which users are accustomed to will help to achieve that.
5. Minimization of non-login graphics (cleaner path to the destination).
6. Highlight the login button, its colour and style should prompt the user for action.
7. Do not use a negative description (e.g. “troubleshooting”) the first time the user contacts the application.

SCENARIO 2 – CLARITY OF MAIN DASHBOARD

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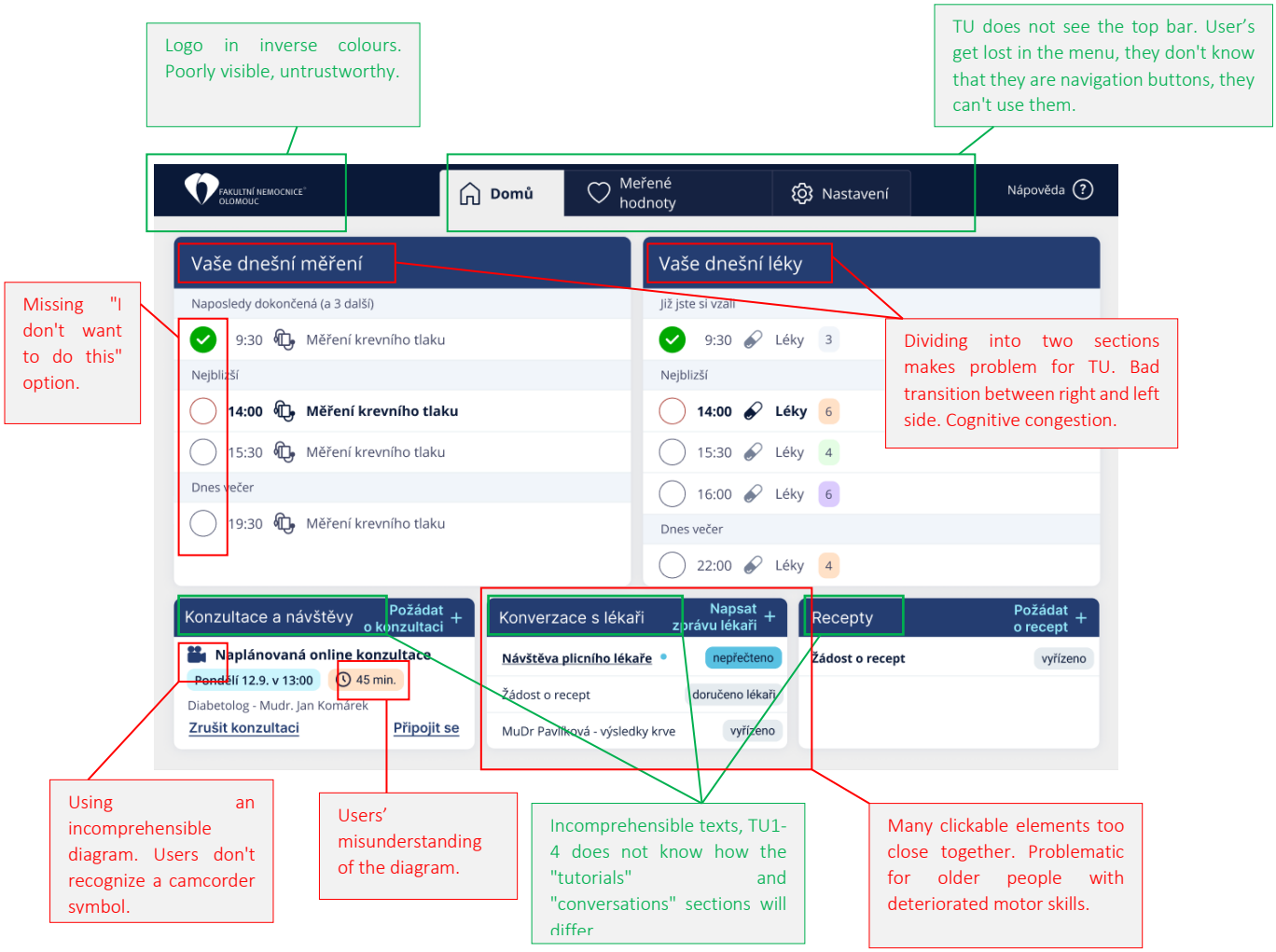

a) **Suitability for the communication objective**

Users have no problem reading texts. The use of sans-serif fonts has proven to be easier to read.

Font contrast is sufficient.

b) **Suitability for perception and understanding**

The controls are convenient for all users and do not cause them any problems.

Users appreciate one-click control (no complicated gestures, sliders and double-clicks).

In the lower part of the screen there are too many clickable elements in close proximity to each other. More concentration for a

c) **Suitability for exploration**

It was difficult for users to distinguish in which part they can solve a given task (order a doctor, write a doctor, order medication). The individual categories melted together.

The user states: "Will I really contact the doctor? Or the nurse? "

d) **Suitability for user motivation**

The most positively evaluated function of the application from the user's perspective is a statement of medication and prescription requests.

Users are embarrassed by the on-line connection with the doctor, in 3 cases they states that they would miss "something".

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	precise click is needed.
	None of the users understood the clock and time icon (no one could tell how long the consultation would take).

Recommendations

1. Distinct button to return "home" as a safe point.
2. Do not divide the attention into several sections, always focus on a single one.
3. Visible navigation bar for switching between sections.
4. Clickable elements at a greater distance from each other (deteriorated motor skills of seniors).
5. Text is preferred over again (the icons were incomprehensible for some users)
6. Test button texts to make them understandable to all users.
7. Tasks that users have to complete has to be in a single section; do not split attention.
8. Consistently separate individual types of requests (messages from prescription requests)

Button Texts

We revealed that users did not understand the texts on the buttons. Therefore, we created 3 variants of the button descriptions and verified them on a group of 30 respondents (average age 48 years) with an outcome that even a small change in the texts will cause completely different expectations.

We recommend not to use the action labels on the buttons. Text "I want to contact a doctor" was incorrectly evaluated by users in 8 cases as an immediate connection („I click on the button and call immediately“) with a medical staff.

Feedback: Application appearance

Users expressed feelings of congestion while on the home screen, as they would appreciate greater clarity and structure.
"If not so many things went on that screen. If it would be individual, if it weren't so complex."
"If there was less information. That it wouldn't confuse you from the beginning."

Feedback: motivation for use

Users evaluate the possibility of using a medical application positively. *"It happens to old people that they suddenly cannot remember something. I'm talking about something and suddenly I don't know. I have everything written on several papers, and who's supposed to look for them all the time. And so I think that if someone can use the Internet, it will be beneficial for them.“* In three adjectives, TUs would call the application *"useful"*, *"fast"* and *"targeted"*. According to TUs, the application has the

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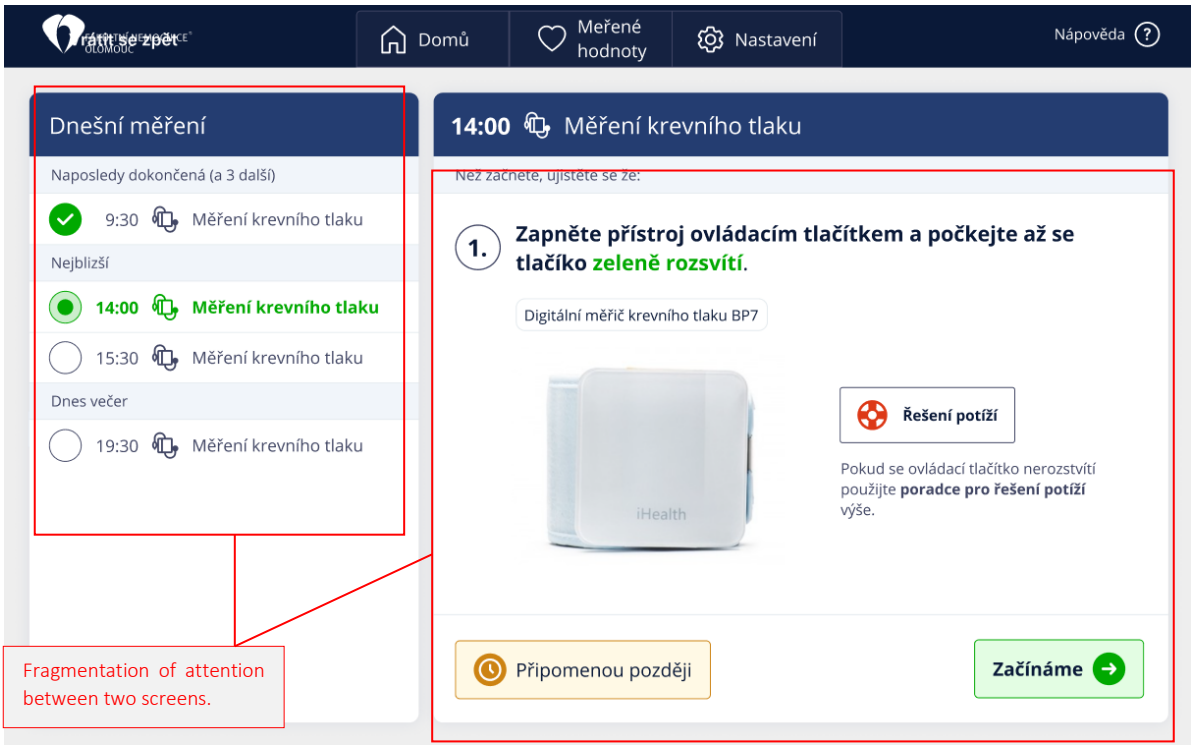
highest importance for the chronically ill, as they do not have to visit the doctor so often. TU also evaluates the application positively in the context of the current pandemic. They are afraid to leave their homes, they neglect preventive care. However, the application has a potential to replace their visits of health centres.

"Like I'm at the physician's office every day and I don't have to go anywhere."

"We are really affraid these days. I'm in touch with other people from the senior's club and I know they're afraid to go out."

SCENARIO 3 – USING BLOOD PRESSURE MONITOR



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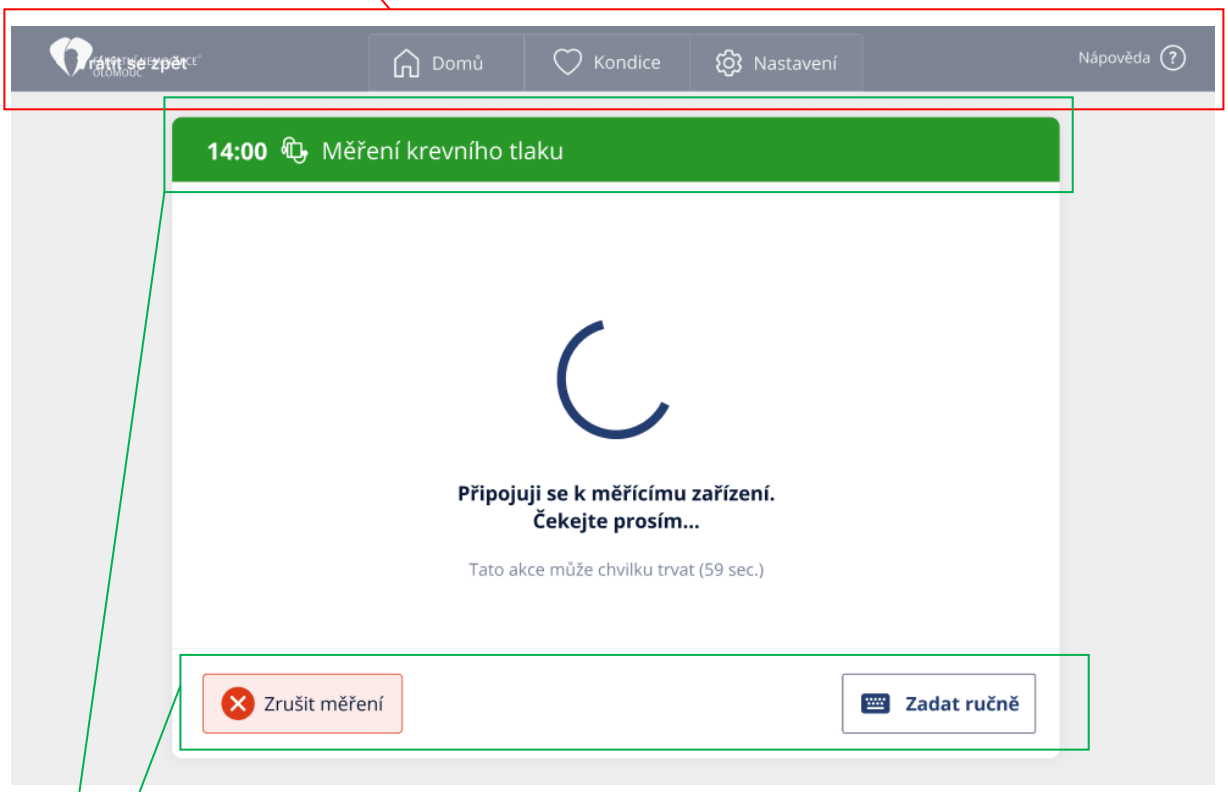
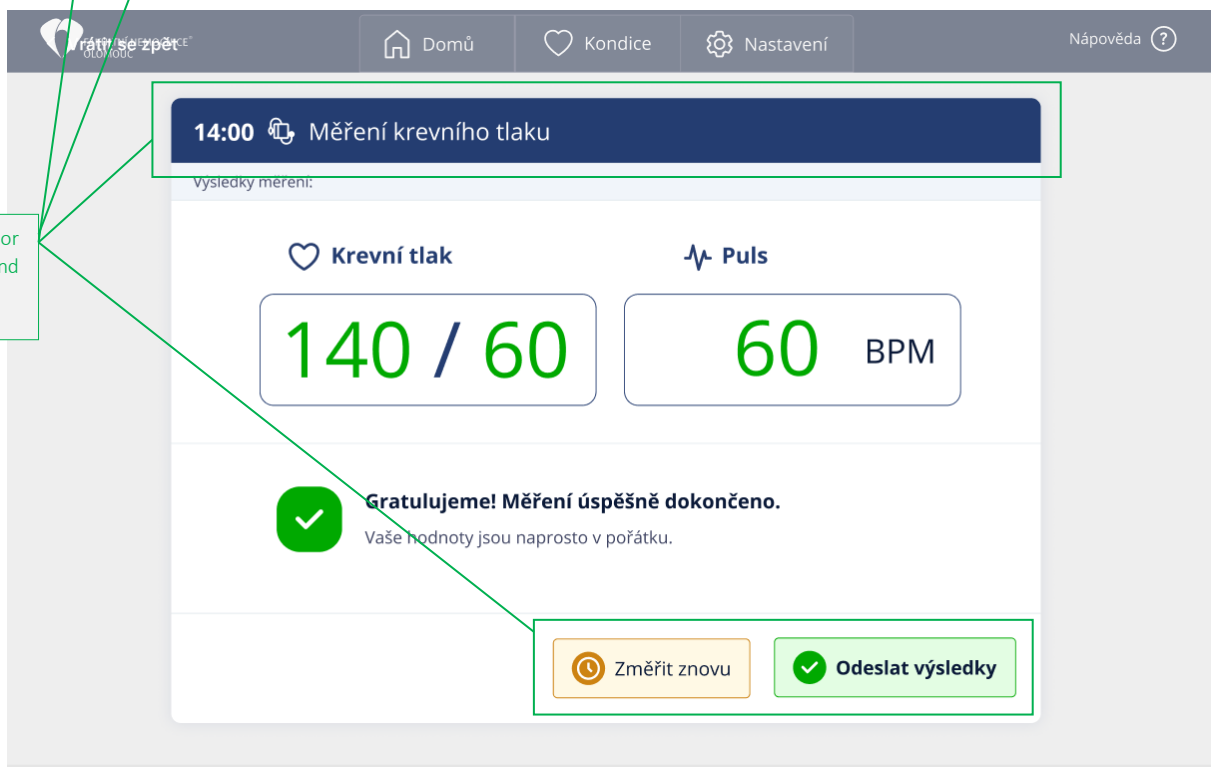
Poorly visible top navigation bar. TUs do not use it, they cannot return to the main screen.



Inconsistent color structure and button layout.



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a) **Suitability for the communication objective**	b) **Suitability for perception and understanding**	c) **Suitability for exploration**	d) **Suitability for user motivation**
Text clearly visible and readable. Dividing into two screens (overwhelming the senses), increasing uncertainty where to look and where to interact, causes problems.	Clear and understandable. After learning the routine measurement the number of steps will become annoying.	None of the users had trouble measuring the pressure according to the procedure.	TUs want to know who will respond to their results, when and how. TUs want feedback on the measurement results. TUs would welcome the history of measurement, motivational.

Recommendations

1. Unify color badges and coding.
2. To give users a feedback on the measurement results, if this is not technically possible, at least reassuring what is happening with the results and whether someone is checking them (or that someone will respond if something is wrong).
3. Highlight (place elsewhere) the navigation bar. Users cannot return to the main menu.
4. A reminder in the notification should give the possibility to dirtectly start the measurement, start the wizard or postpone the task.

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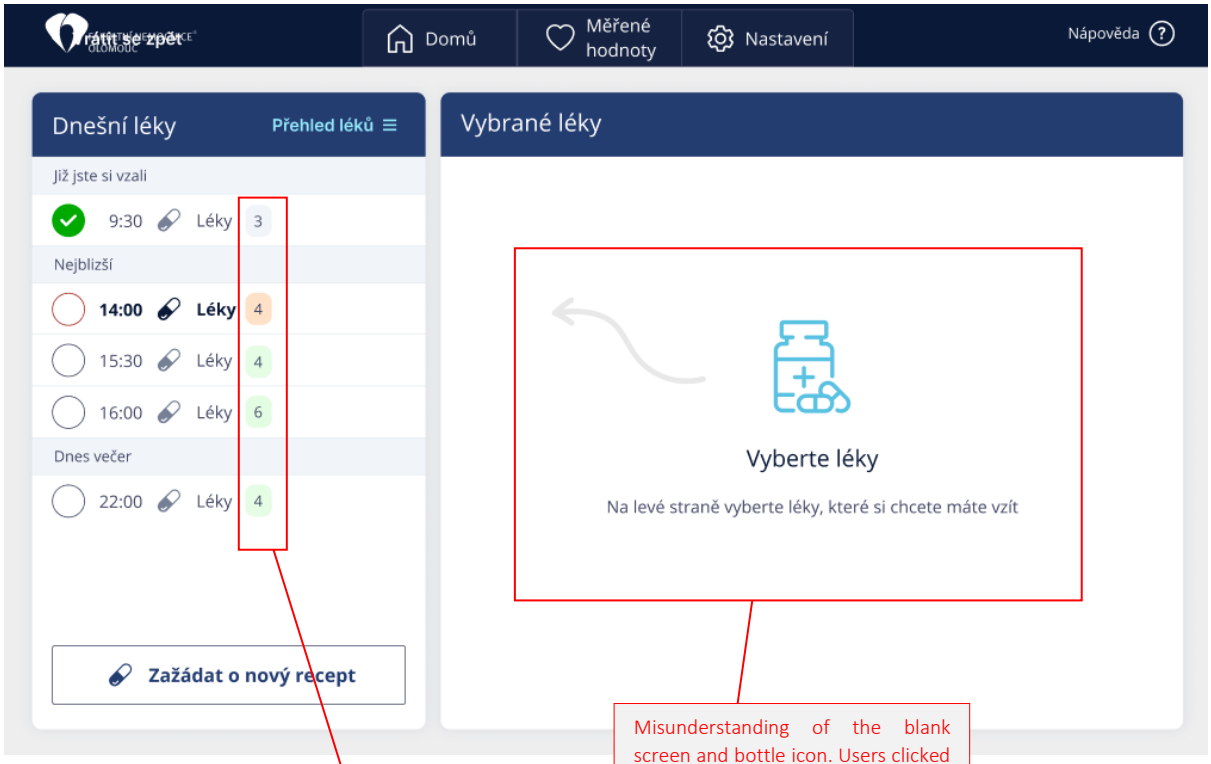
SCENARIO 4 – MEDICATION



TUs do not know what the number means. They cannot work with the interface. They don't how to continue.

Misunderstanding of the blank screen and bottle icon. Users clicked on the drug bottle to select. Nobody understood that the action is to be performed on the left side of the screen

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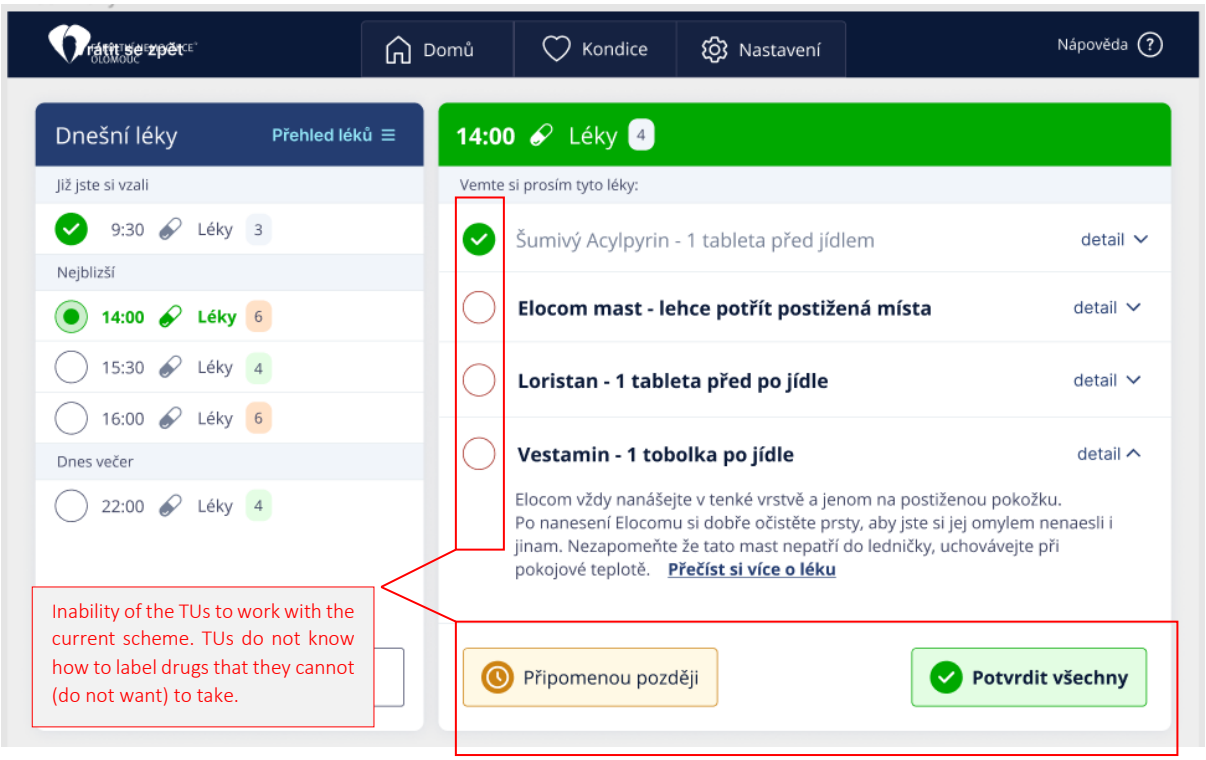

a) **Suitability for the communication objective**
Text visible and readable.

Dividing into two screens (overwhelming the senses), increasing uncertainty as to where to look and where to interact, causes problems.

TUs do not understand why the numbers next to drug names always have a different color (is there a reason for that?).

b) **Suitability for perception and understanding**
TUs did not understand the fill drawings on empty lists, they wanted to click on these „icons“.

The text "drugs" is too general, TUs do not understand the meaning of this feature functionality.

c) **Suitability for exploration**

TUs are having trouble postponing the action for later.

It makes a problem to take some of the medication and postpone some other until later.

The confirmation button is missing, TUs do not know how to abort the action.

d) **Suitability for user motivation**

2 TUs expressed concerns about the drug listings in electronic form, they have greater trust in paper notes.

The most difficult task for TUs.

Recommendations

1. Delete anything that resembles a button (icons, graphics).
2. The screen should not be divided into two parts (TUs are confused).

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3. Medicines should be listed by its specific name (not by the superior word “medicines”).
4. Agenda should be processed as a checklist with red and green circles – options “take the medicine”, “will not take the medicine”.
5. If the user does not want to take the medicine, he should be informed about the risk, or be able to open a window with the option "write to the doctor" and explain the reason.

Recommendations for the application development

At first glance, seniors should see what is actually "wanted to be done". If they are to take measurements, they should see that on the first page and the input should be fast for them ("I have three minutes in the morning and it's done"). Test the application properly before its release, do not introduce changes after its release. Seniors will learn the procedures and any post-hoc intervention in the learned procedure will make them uncertain.

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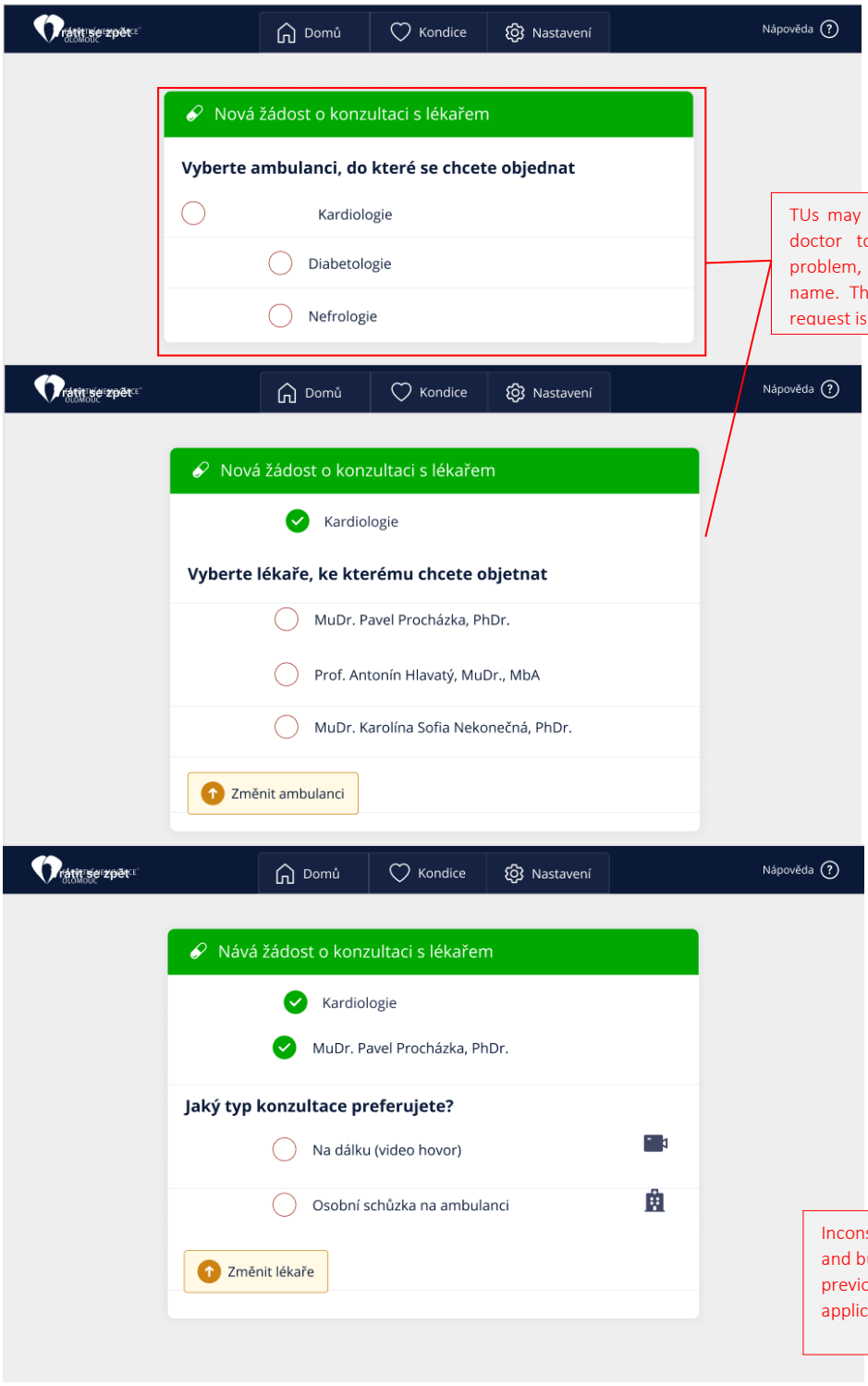
SCENARIO 5 – REQUEST FOR ONLINE VISIT

The target group (older people) had a worse operational memory, so planning an online meeting was divided into several sub-steps (6 consecutive steps), where it was practically impossible to make a mistake. The screens are intuitive and instructive.



TUs may not always be sure which doctor to visit with the specific problem, or what is the doctor's name. The possibility of a general request is missing.

Inconsistent design of colors and buttons in relation to the previous parts of the application.

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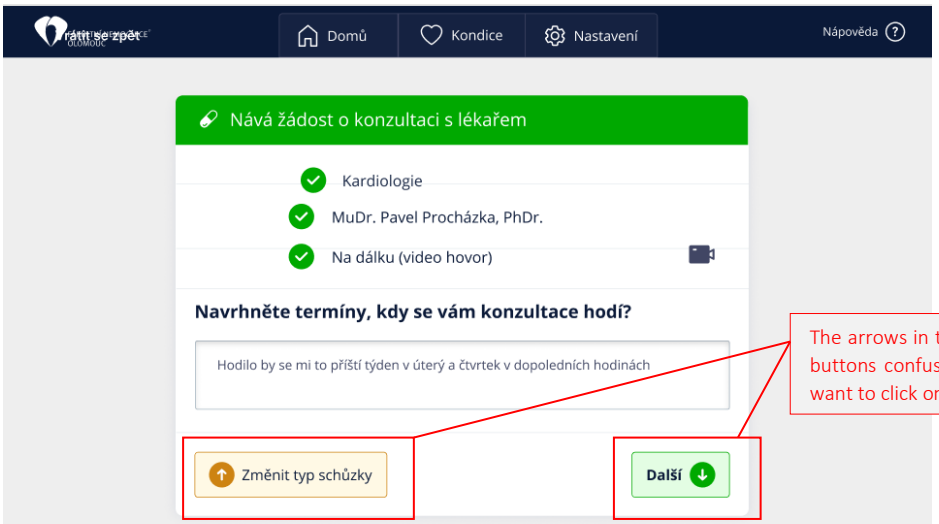
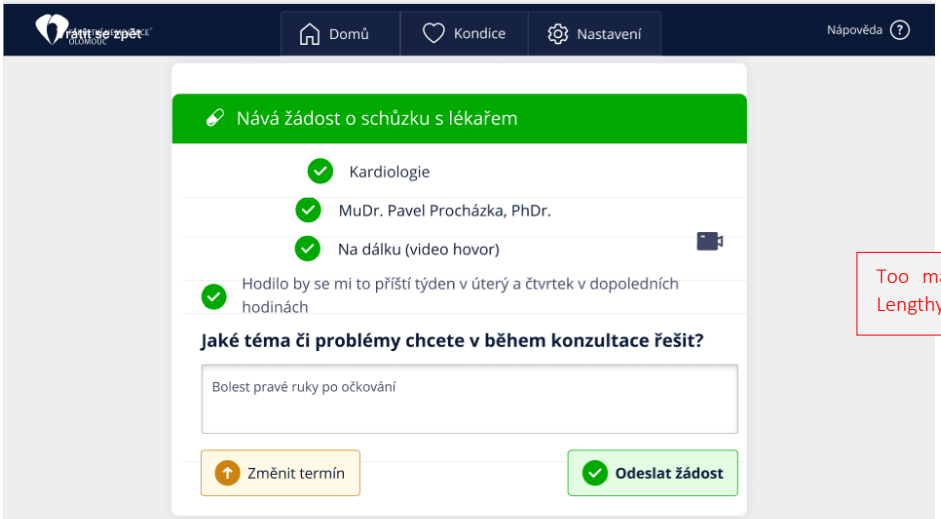
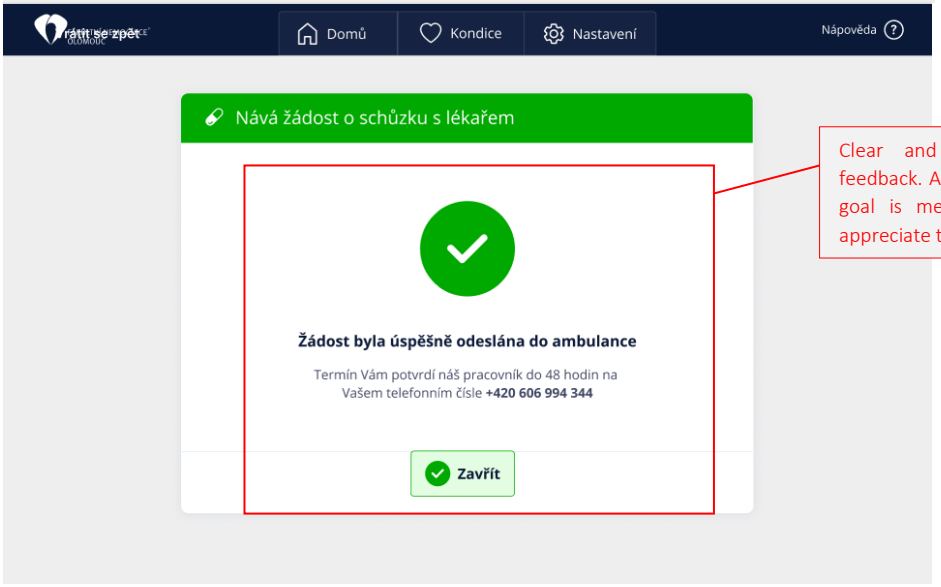


The arrows in the conversion buttons confuse TUs as they want to click on them.



Too many steps in a row. Lengthy and frustrating.



Clear and understandable feedback. Assurance that the goal is met in order. TUs appreciate that.

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a) **Suitability for the communication objective**	b) **Suitability for perception and understanding**	c) **Suitability for exploration**	d) **Suitability for user motivation**
Readable, understandable. The use of new icons in the conversion buttons (arrows) confused TUs and they wanted to click on them.	Users showed uncertainty in the choice of specific physician/physician's office. Fear of making a mistake (wrong choice of physician), uncertainty.	Understandable but tedious. The users felt frustrated and tired.	TU3 says he would rather call. On the contrary, TU2 and TU4 are stating that it is good that they do not have to disturb anyone by a phone and that their doctor will read their request when he has time to do that.

Recommendations

1. Unify the "fulfilled" and "negative" buttons across the entire application. E. g. finished tasks in the green colour, waiting tasks in red colour, neutral in grey colour.

2. The application should be tolerant of user errors (e. g. when the user improperly evaluates the type of surgery or physician, it should be redirected correctly).

3. The application should be easy for beginners, but should not bother experienced users (many steps before I reach the goal).

Feedback

The division of the meeting request into 6 steps is instructive and understandable, users do not have a problem with ordering, but they evaluate that feature to be too time consuming. The disadvantage is also that this part of the application differs in its structure from other schemes used within the application, and that consequently confuses the user.

Too many windows to write in increases the uncertainty of older users. The task is demanding on the graphomotor skills of older users.

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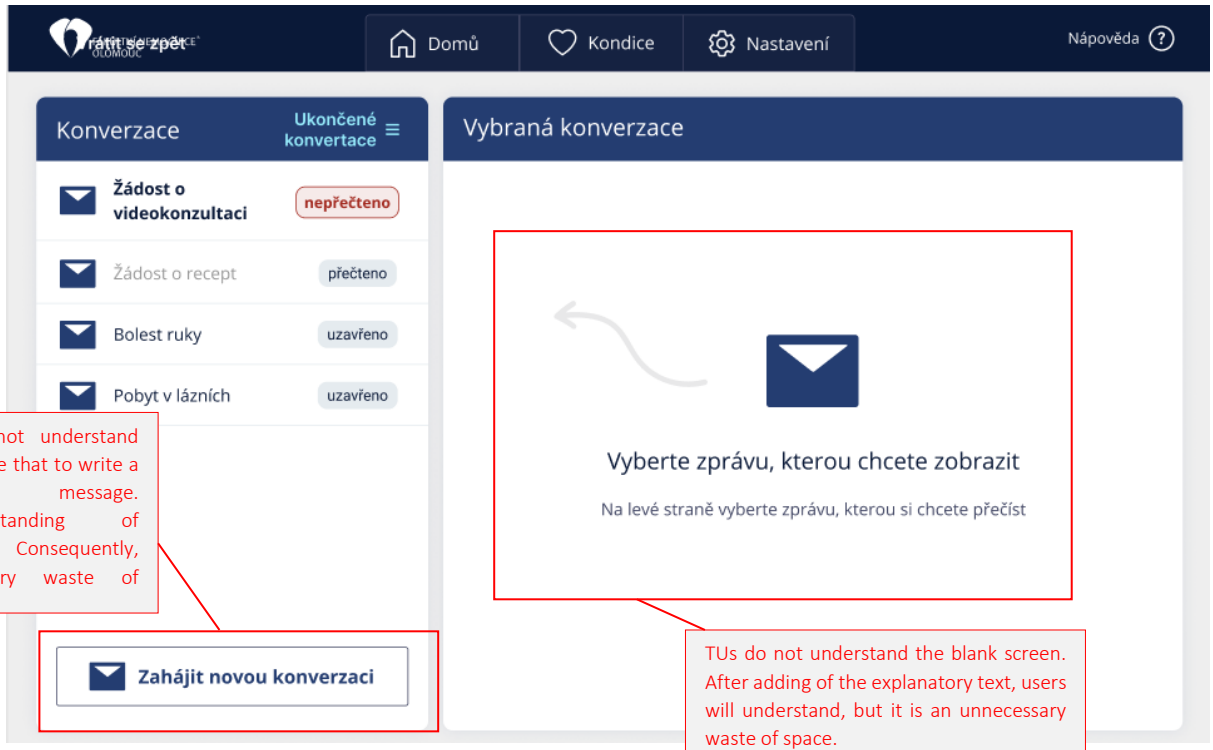
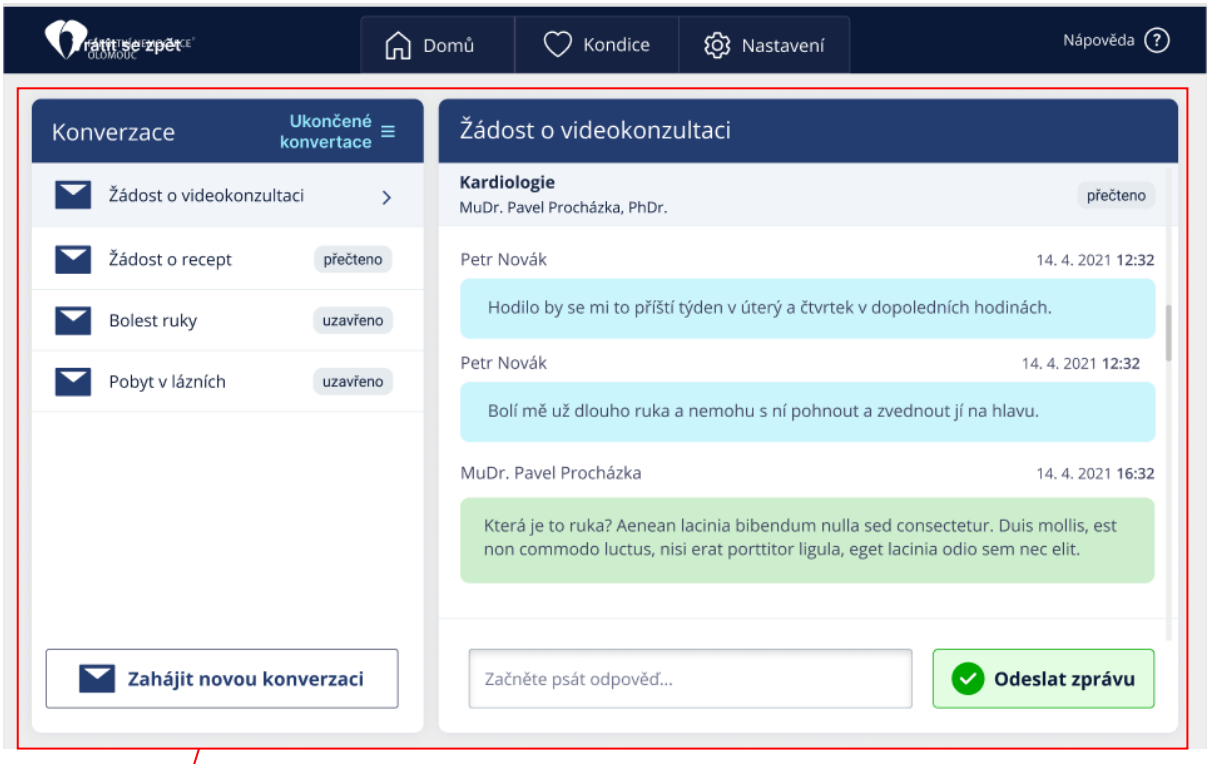
SCENARIO 6 – NEW MESSAGE TO DOCTOR



TUs do not understand how to use that to write a new message. Misunderstanding of meaning. Consequently, unnecessary waste of

TUs do not understand the blank screen. After adding of the explanatory text, users will understand, but it is an unnecessary waste of space.



Lots of information, inability to orient and navigate in individual parts of the screen.

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a) **Suitability for the communication objective**	b) **Suitability for perception and understanding**	c) **Suitability for exploration**	d) **Suitability for user motivation**
Texts are readable. Interface is too colourful.	Users did not understand the fill drawings on empty lists, they wasted a lot of time examining them.	Difficult orientation, too much information. Users are unable to start a new conversation with the doctor. Difficult movement between the individual parts. Inability to return to the main page.	In two cases, misunderstanding the use of the option to write a message to the doctor. In one case, an expression of uncertainty to whom the report will be send (physician or nurse?)

Recommendations

1. Simplify the navigation, give the user clear points to understand where he actually is.

2. Switching between left and right side increases user uncertainty. It gives the impression that something is wrong.

3. Keep graphics to a minimum to avoid distraction.

4. Use same colours consistently throughout the application, colour expresses the current state.

5. Use of a logical hierarchic structure, navigate in paths with predefined goals

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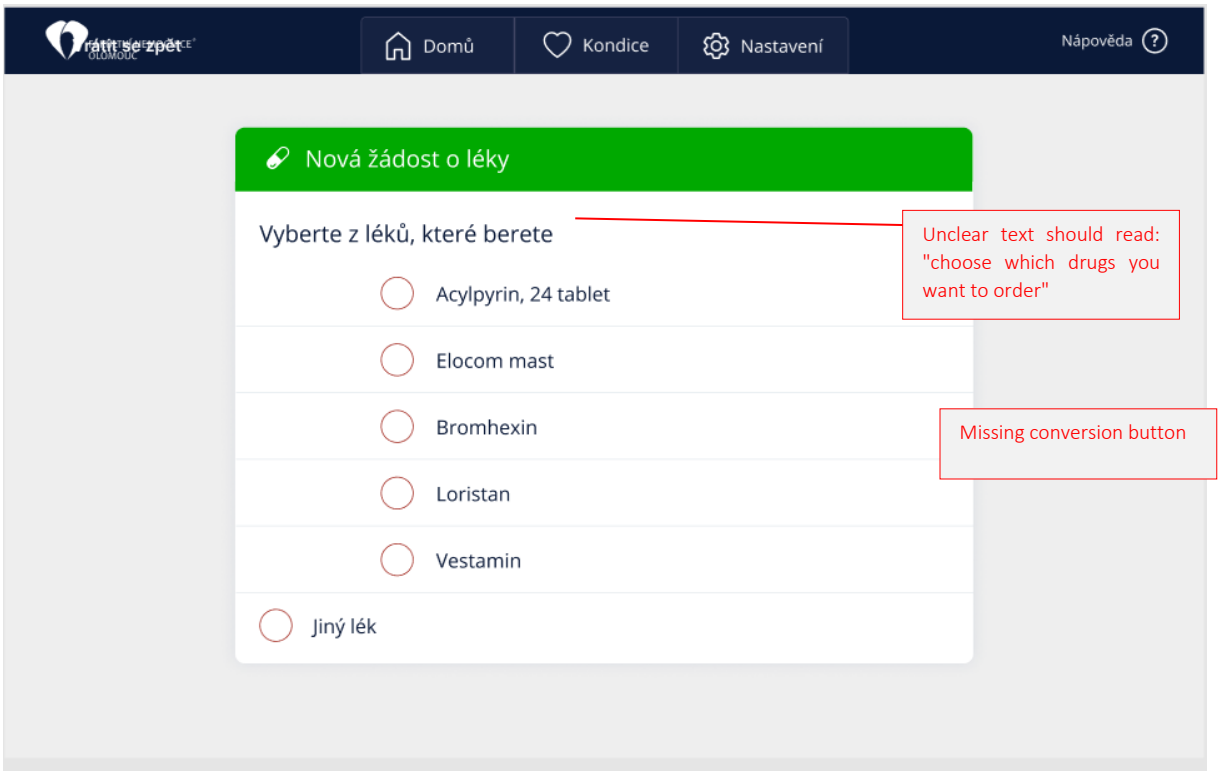
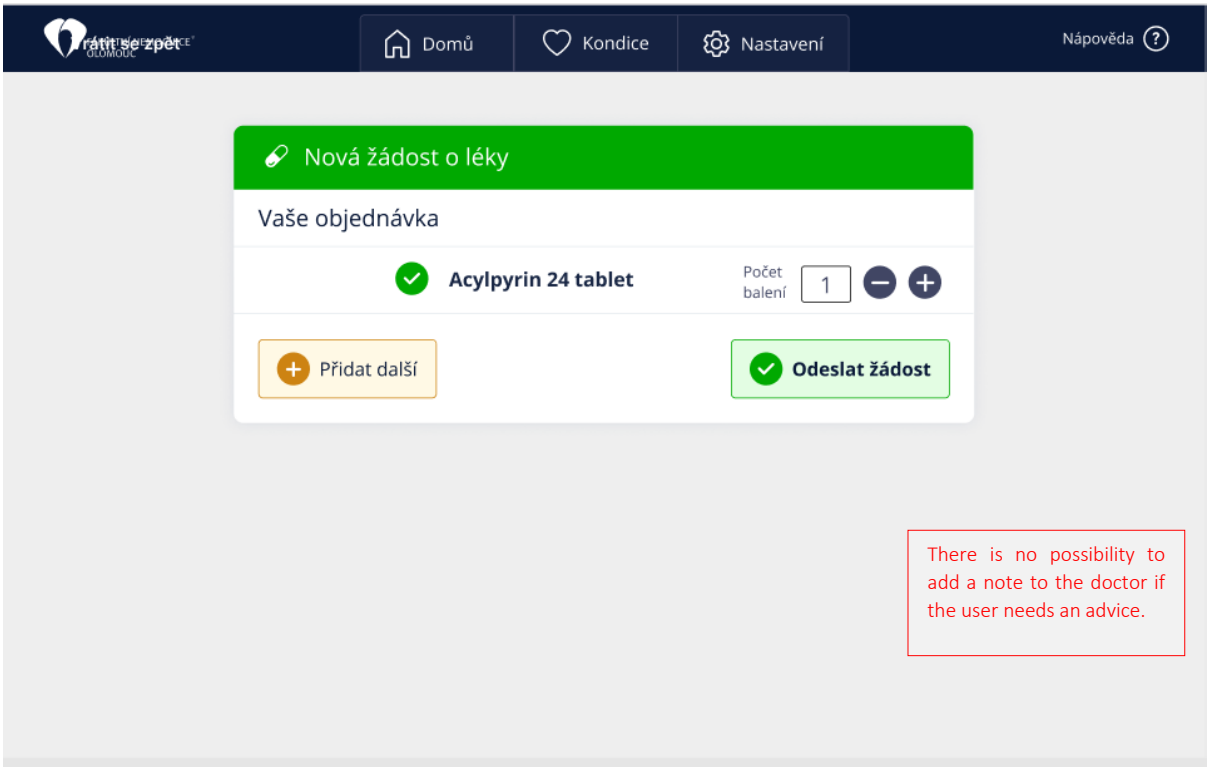
SCENARIO 7 – PRESCRIPTION REQUEST





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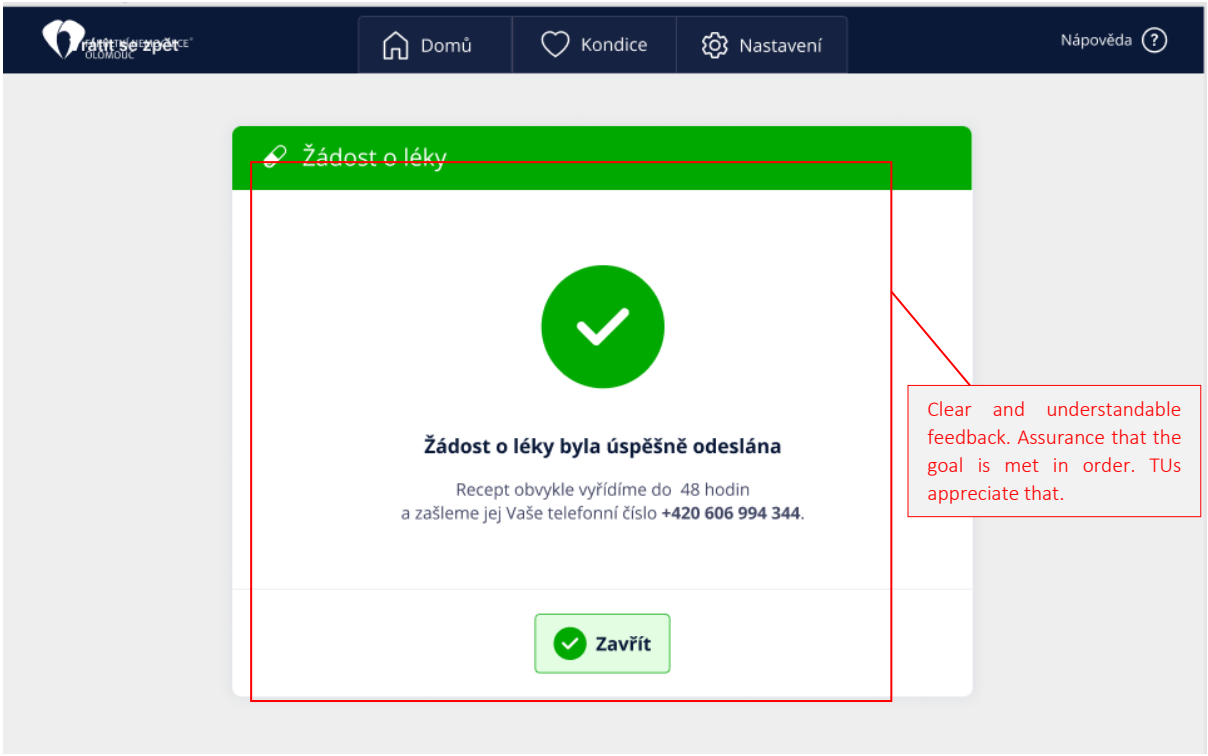

a) **Suitability for the communication objective**	b) **Suitability for perception and understanding**	c) **Suitability for exploration**	d) **Suitability for user motivation**
Everything is clear.	Users understand the purpose of this page.	Conversion button for prescription request is missing.	Every TU is used to work with the e-prescription, they perceive that as very advantageous.

Recommendations

1. A good whisper for adding a drug that is not already in the list

2. The whisperer should be tolerant of errors and typos

3. The whisperer should work quickly

Feedback:

Ordering drugs through the application is not used by a user who already has experience with the application. He prefers to call, so he can "greet the doctor". "I always call the doctor and say, 'Girls, how are you?'

Other senior women mentioned the possibility of ordering through the application as a great help for them. They don't want to bother the doctor with their call. They have the impression

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that often their message will be useless. They both state that they are used to work with e-recipes. They perceive them as a great help, they like them.

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Summary

Feedback: What could prevent the use of the application?

TUs are not afraid of the sensitive data misuse (none of TU expressed concerns). When explicitly asked, if they are worried about data leaks, they say they trust the hospital.
They perceive the application as trustworthy. They are not afraid of data misuse. They really like the idea of accessing their data to third parties (children, grandchildren), they are not afraid of any misuse.

An older woman is thinking about why the application is actually created. She states: *“And why is such an application being created? Are there few doctors? Is there a risk of disaster? Is more sick and doctors can't catch up? Is it a preparation so the system will not to collapse? ”.*

Even such ideas have to be considered to prevent spread of any disinformation and conspiracies.

2 TUs demonstrated less trust in technology and virtual data. One TU stated that even if he had the data saved within the tablet, he would still believe more in the notes written on a paper where the his drugs are listed.

"I'd rather meet the doctor in person. On the one hand it's wonderful that I don't have to go anywhere, but on the other hand it's somewhat strange. Something is missing."
"Favorite doctor, it's like a pastor. That is the greatest truth. People wouldn't believe it through a tablet equally."

Recommendation for the application development

Communicate the application towards older people as an "extended hand of a doctor". It does not replace contact with a doctor, but should complement him appropriately.

Deepen trust in technology. But most likely, older people will still have a "backup" plan within their calendars and paper notes. Maybe it will be suppressed later.

The older people people partially want to maintain some level of contact with the doctor. But they got relatively easy used to the e-prescription system, so it is possible that they could similarly master the telemedicine application as well.

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Annex 50 UC-PT3-001c/COPD Phase 3 Participant information sheet

SHAPES INFORMAČNÍ LIST PRO ÚČASTNÍKY

Název studie: SHAPES Pan-European Pilot Campaign („Pan-evropská pilotní kampaň SHAPES“): Praktický test a zpětná vazba k digitálním řešením pro pilotní téma 3 - kontrola a optimalizace medikace.

Rádi bychom Vás pozvali k účasti na naší studii, během níž bychom si rádi vyslechli vaši zpětnou vazbu k návrhu a uspořádání zdravotnické aplikace, která je vyvíjena pro osoby starší 60 let, které trpí srdečním selháním nebo chronickou plicní obstrukční chorobou. Studie je pro nás příležitostí ujistit se, že aplikace je praktická a použitelná z pohledu starších osob. Naším cílem je zapojit do této studie nejméně pět osob, včetně starších osob s chronickou nemocí a zdravotníků.

Byl/a jste identifikován/a jako vhodný/á účastník/ce naší studie a obdržel/a jste tento informační list, který si můžete přečíst a zvážit, zda se chcete zúčastnit.

Tento informační list popisuje studii a Vaši roli v ní. Než se rozhodnete, je důležité, abyste pochopil/a, proč se studie provádí a co pro Vás bude znamenat. Věnujte prosím čas přečtení těchto informací a případně je prodiskutujte s ostatními. Pokud Vám něco není jasné nebo pokud byste chtěl/a získat více informací, kontaktujte Ladislava Stankeho, Ladislav.Stanke@fnol.cz, který Vás bude kontaktovat zpět.

Dobrovolnost účasti

Účast v této studii je dobrovolná. Ze studie můžete kdykoli odstoupit bez udání důvodu a bez jakýchkoli negativních důsledků.

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Účel a cíle studie

Tato studie je jednou z částí rozsáhlejšího výzkumného projektu, jehož cílem je otestovat různé způsoby využití technologií, které pomáhají stárnoucím lidem bezpečně fungovat v jejich domovech a zůstat aktivní.

Účelem studie je ukázat aplikaci jejím cílovým uživatelům (tj. starším osobám se srdečním selháním a chronickou plicní obstrukční chorobou) a umožnit jim vyzkoušet různé funkce aplikace. Účastníci budou vyzváni, aby se podělili o své první reakce, myšlenky, pocity a názory na to, jaké to je aplikaci používat, a aby nabídli návrhy, jak by ji bylo možné vylepšit. Na základě této zpětné vazby provedeme změny, aby byla aplikace pro starší osoby uživatelsky přívětivější.

Hotová aplikace pak bude použita v reálné studii, která má zjistit, zda může pomoci lidem sledovat a řídit jejich zdravotní stav z domova a zlepšit kvalitu jejich života a zdravotní výsledky.

Kdo výzkum organizuje a financuje?

Tuto studii organizuje Fakultní nemocnice Olomouc a Národní telemedicínské centrum. Je součástí rozsáhlejšího výzkumného programu nazvaného projekt SHAPES, který je financován Evropskou unií v rámci programu Horizont 2020 (grantová dohoda č. 857159).

Co bude účast zahrnovat?

Pokud budete souhlasit s účastí v této studii, budete požádán/a, abyste se zúčastnil/a osobního rozhovoru s našimi výzkumníky v kanceláři Národního telemedicínského centra ve Fakultní nemocnici Olomouc.

Co se bude dít během rozhovoru?

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Informovaný souhlas

- Po přečtení tohoto informačního listu se s Vámi spojíme, abychom projednali Vaši účast.
- Pokud budete souhlasit s účastí, budete na začátku rozhovoru požádáni o podepsání informovaného souhlasu s účastí na studii a vrátíte jej spolu s kontaktními údaji výzkumníkovi.

Před rozhovorem

- Výzkumník Vám zavolá nebo pošle e-mail, aby s vámi domluvil vhodný čas pro schůzku a předá Vám adresu.

Během rozhovoru

- Během rozhovoru Vám budou nejprve poskytnuty informace o studii a širším pojetí projektu SHAPES.
- Poté Vám bude na tabletu výzkumníka ukázána testovaná aplikace.
- Výzkumný pracovník vás provede řadou kroků a úkolů, aby vám ukázal různé funkce, které aplikace umí, a vysvětlil, jak ji používat.
- Pokyny budou během hovoru prezentovány na obrazovce tabletu a budou také vytištěny v školicí příručce.
- Během této části hovoru budete požádáni, abyste "přemýšleli nahlas" a vyjádřili své první reakce a myšlenky týkající se aplikace. Zajímá nás zejména, co nefunguje (spíše než slyšet pouze pozitivní zpětnou vazbu).
- Výzkumník Vám dá čas se dostatečně seznámit s aplikací.
- Poté dostanete jednoduchý úkol, který musíte splnit bez pomoci. Nejedná se o testování, ale výzkumníci budou spíše sledovat, zda se v aplikaci nevyskytnou nějaké překážky nebo problémy.
- Nakonec Vám výzkumník položí několik otázek o vašich zkušenostech s používáním aplikace. To je Vaše příležitost sdělit nám podrobněji, co se Vám na aplikaci líbí, nelíbí a co byste změnili.
- Nejedná se o test a neexistují správné a špatné odpovědi. Zajímá nás Váš upřímný názor a zpětná vazba na to, co Vám ukazujeme.
- Výzkumník si možná bude během hovoru dělat poznámky, případně pořizovat nahrávky.
- Hovor by neměl trvat déle než jednu hodinu. Budeme pracovat tempem, které si určíte, a kdykoli během hovoru si můžete udělat přestávku.

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Sběr a zpracování informací po rozhovoru

- Kromě Vašeho jména, kontaktních údajů a nahrávek získaných během rozhovoru nebudou shromažďovány žádné další osobní údaje.
- Všechny nahrávky získané během rozhovoru budou přeneseny do počítače chráněného heslem, ke kterému budou mít přístup pouze místní výzkumní pracovníci.
- Nahrávky můžeme přepsat a při tomto procesu anonymizujeme veškeré identifikovatelné údaje. Nahrávky budou po použití zničeny.
- Anonymizovaná zjištění mohou být použita v dalším výzkumu a/nebo komunikačních aktivitách (např. v rámci dalšího výzkumu v projektu SHAPES, v článcích v časopisech, na seminářích a konferencích).
- Vaše osobní kontaktní údaje budou výzkumníky zničeny poté, co Vám bude poskytnut souhrn zjištění této studie.
- Anonymizované nezpracované údaje budou uchovávány po dobu trvání projektu SHAPES a pět let po jeho skončení.

Možné výhody účasti

Kromě osobního zájmu a zkušenosti s účastí ve studii nemáte z účasti v této studii žádné přímé výhody. Nepřímým přínosem této studie však je, že Vaše názory a stanoviska budou použity ke zlepšení vzhledu a fungování aplikace. Vaše podněty budou také sloužit jako informace o tom, jak budeme využívat technologie na pomoc lidem v jejich domovech, když zestárnou. Z Vaší účasti budou mít prospěch lidé z celé Evropy.

Možné nevýhody účasti

Nepředpokládáme, že by Vám účast v této studii přinesla nějaké nepříjemnosti nebo nevýhody.

Finanční informace

Účast v této studii pro Vás nebude znamenat žádné náklady. Za svou účast neobdržíte žádnou platbu.

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Informování o výsledcích studie

Zjištění této studie mohou být použita v dalším výzkumu a/nebo komunikačních aktivitách (např. v rámci dalšího výzkumu v projektu SHAPES, v článcích v časopisech, na seminářích a konferencích). Souhrn zjištění Vám bude v případě zájmu zpřístupněn.

Ukončení studie

Výzkumní pracovníci provádějící studii mohou studii ukončit, v současné době však neexistují žádné předvídatelné důvody, proč by tato studie měla být ukončena. Pokud byste chtěli svou účast kdykoli odvolat, můžete tak učinit. V takovém případě se prosím obraťte na výzkumného pracovníka. Vaše anonymizované údaje můžeme i nadále použít.

Další informace

Další informace týkající se studie si můžete vyžádat od následujících osob zapojených do projektu SHAPES.

Kontakty

Národní telemedicínské centrum Fakultní nemocnice Olomouc

Ladislav Stanke (výzkumný pracovník)

E-mail: Ladislav.Stanke@fnol.cz; Telefon: 583 443 713

Michal Štýbnar (koordinační pracovník)

E-mail: Michal.Stybnar@fnol.cz; Telefon: 583 443 713

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Annex 51 UC-PT3-001c/COPD Phase 3 Participant consent form

INFORMOVANÝ SOUHLAS

Název projektu:

SHAPES - Smart and Healthy Ageing through People Engaging in Supportive Systems - Pan-European Pilot Campaign: Hands-on experiments and feedback on digital solutions for pilot theme 3 — medicines control and optimisation.

Oblast výzkumu:

Ověření přínosu digitálních technologií v oblasti poskytování telemedicínských služeb v domácím prostředí prostřednictvím telemedicínské platformy FNOL v rámci mezinárodního projektu Smart and Healthy Ageing through People Engaging in Supportive Systems (SHAPES).

Místo testování:

Fakultní nemocnice Olomouc (FNOL) – I.Interní klinika kardiologická

Kontakt:

- Michal Štýbnar (FNOL) Michal.Stybnar@fnol.cz, tel. 588 443 713

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- Ladislav Stanke (FNOL) Ladislav.Stanke@fnol.cz, tel. 588 443 713

Prohlášení účastníka

- Byl jsem pozván k účasti na výše uvedené studii. Účelem této studie je shromáždit zpětnou vazbu a otestovat aplikaci ve zdravotnictví (aplikace), která je vyvíjena pro chronicky nemocné pacienty FNOL. Studie je příležitostí pro výzkumný tým FNOL, aby se ujistili, že aplikace je praktická a použitelná z pohledu uživatele.
- Byl jsem seznámen s účelem testování a byly mi poskytnuty dostatečné informace o výše uvedené studii, jejím účelu a provedení, o mých právech a možných výhodách a nevýhodách účasti.
- Měl jsem příležitost klást otázky týkající se studie a nechal jsem si na tyto otázky uspokojivě odpovědět.
- Během studie jsem dostal (a) dostatečné informace o shromažďování, zpracování, přenosu / zveřejnění a vymazání svých odpovědí. Beru na vědomí, že kromě mého jména, kontaktních údajů a videozáznamů získaných během studie nebudou během této studie zpracovávány žádné další osobní údaje.
- Podepsáním tohoto formuláře potvrzuji, že dobrovolně souhlasím s účastí v této studii a že také uděluji souhlas se zpracováním mých odpovědí pro účely popsané v tomto dokumentu.
- Nebyl jsem pod tlakem ani přesvědčen k účasti a měl jsem dostatek času na zvážení své účasti ve studii. Beru na vědomí, že moje účast je zcela dobrovolná a že mohu svůj souhlas kdykoli odvolat, a to bez udání důvodu.
- Mám také právo požádat o odstranění mých identifikovatelných osobních údajů v souladu s nařízením o ochraně údajů.

Já, níže podepsaný/á, souhlasím s účastí na testování nových funkcí a nové podoby mobilní a webové aplikace (dále jen „aplikace“) Fakultní nemocnice Olomouc, IČ: 00098892, sídlem I.P.Pavlova 185/6, Olomouc (dále jen „společnost“), souhlasím s tím, aby byla ze strany společnosti, jakožto

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výhradního správce a zpracovatele osobních údajů, zaznamenána, shromažďována a zpracována moje aktivita testujícího uživatele při práci s aplikací včetně audiovizuálního záznamu mé osoby při takovém testování, ze kterého budou patrné mé reakce na funkcionality aplikace a způsoby práce s aplikací.

Audiovizuální záznam a další záznam mé práce s aplikací smí být ze strany společnosti použit výhradně pro její interní neveřejné potřeby za účelem zjištění správnosti návrhu aplikace a její případné úpravy a nesmí být zpřístupněn třetímu subjektu. Tento můj souhlas je společnosti poskytnut pouze po nezbytně nutnou dobu, po kterou bude pracovat na vývoji aplikace v rámci projektu SHAPES.

Vyplní účastník studie:

Souhlas (pro potvrzení vašeho souhlasu vyplňte níže uvedené podrobnosti)

Jméno:	
Datum:	
Podpis:	

Vyplní zadavatel studie

Vyplněním níže uvedených údajů potvrďte přijetí podepsaného souhlasu účastníka studie

Jméno:	
Datum:	

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Podpis:	

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Annex 52 UC-PT3-001c/COPD Phase 3 User training manual

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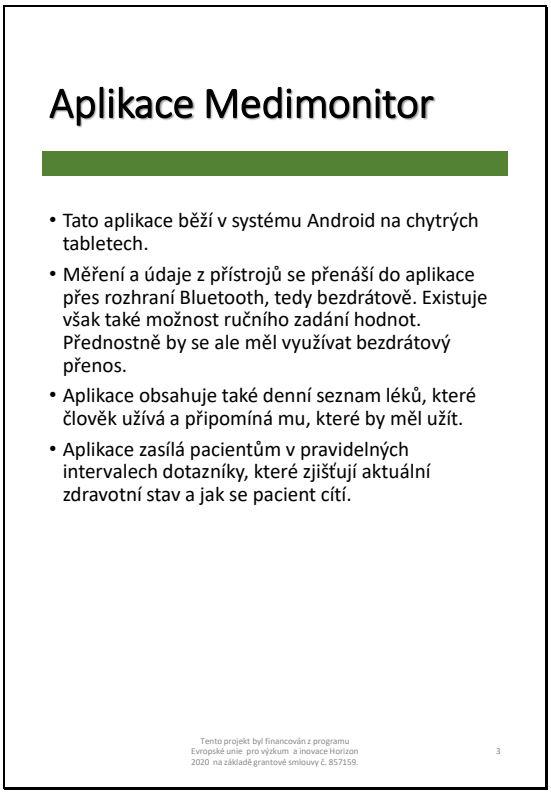

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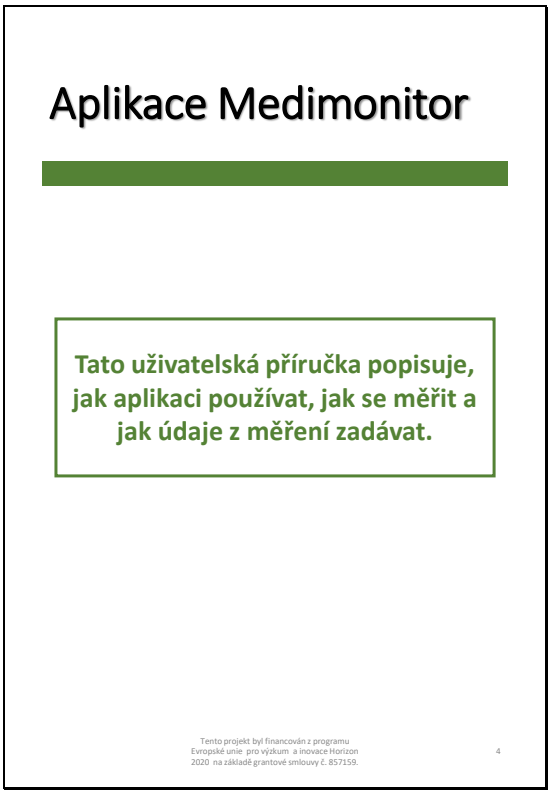

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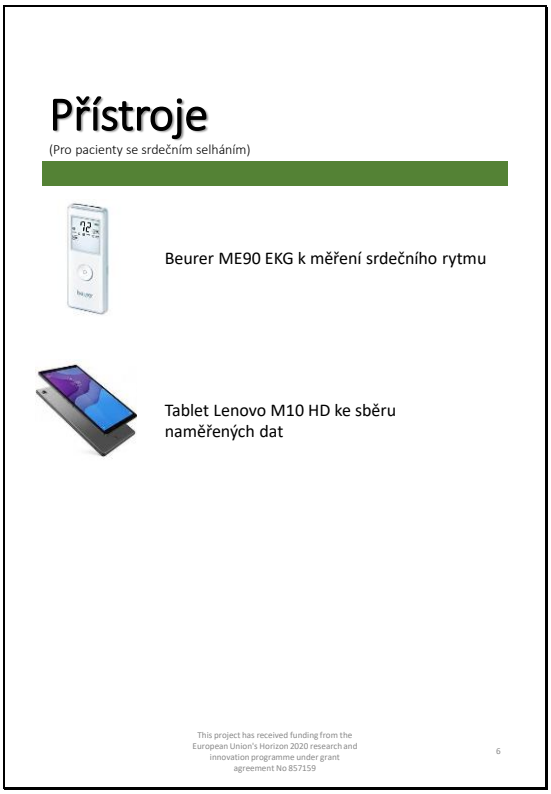
Přístroje
(Pro pacienty se srdečním selháním)
Beurer ME90 EKG k měření srdečního rytmu
Tablet Lenovo M10 HD ke sběru naměřených dat
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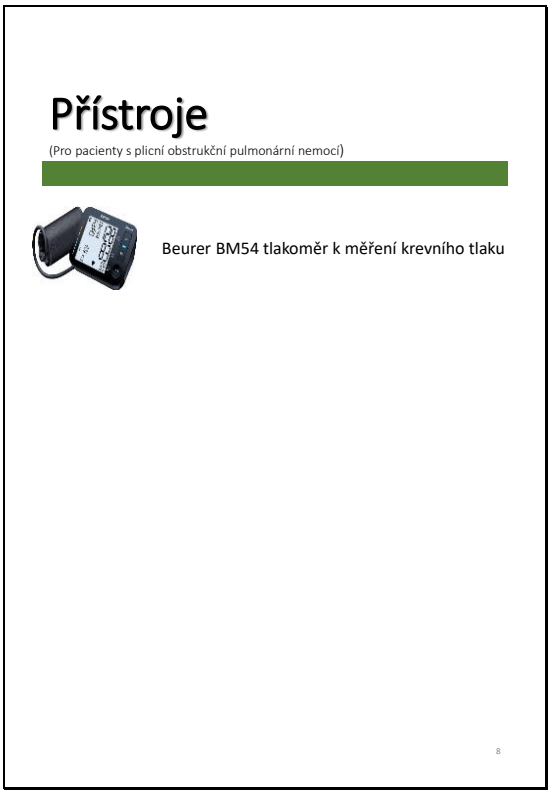

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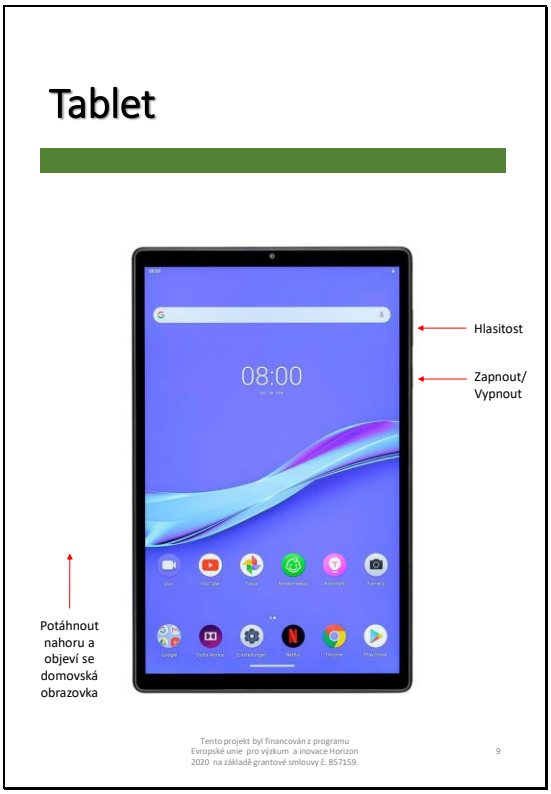

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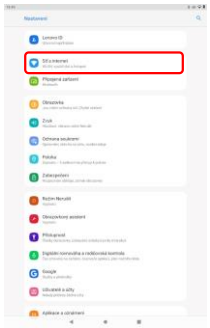
Připojení k Wi-Fi

1. Na domovské obrazovce klikněte na ikonu **Nastavení**
2. V nastavení klikněte na **Síť a internet**
3. Klikněte na **WLAN** a vyberte si z dostupných sítí
4. Vraťte se na domovskou obrazovku



Tento projekt byl financován z programu Evropské unie pro výzkum a inovace Horizon 2020 na základě grantové smlouvy č. 857159.

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Využívání aplikace pro měření vašeho zdraví

Během pilotního období v projektu SHAPES budete požádáni, abyste sledovali svou váhu, saturaci, krevní tlak, počet kroků a měření srdečního rytmu.

Tato aplikace Vaše měření ukládá a můžete je případně diskutovat i se svými poskytovateli zdravotní péče.

Pokud se během testování nebudete cítit dobře nebo budete mít jakékoliv obavy ohledně vašich naměřených hodnot, je důležité, aby jste kontaktovali svého lékaře, praktického lékaře nebo sestru.

Tato příručka obsahuje základní pokyny jak manipulovat s přístroji a aplikací. Další pokyny a informace naleznete v dodaných uživatelských příručkách, případně na vyžádání.

Tento projekt byl financován z programu Evropské unie pro výzkum a inovace Horizon 2020 na základě grantové smlouvy č. 857159.

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Aplikace

1. Na domovské obrazovce klikněte na ikonu **Konzultace FNOL**
2. Přihlaste se pomocí svých přihlašovacích údajů

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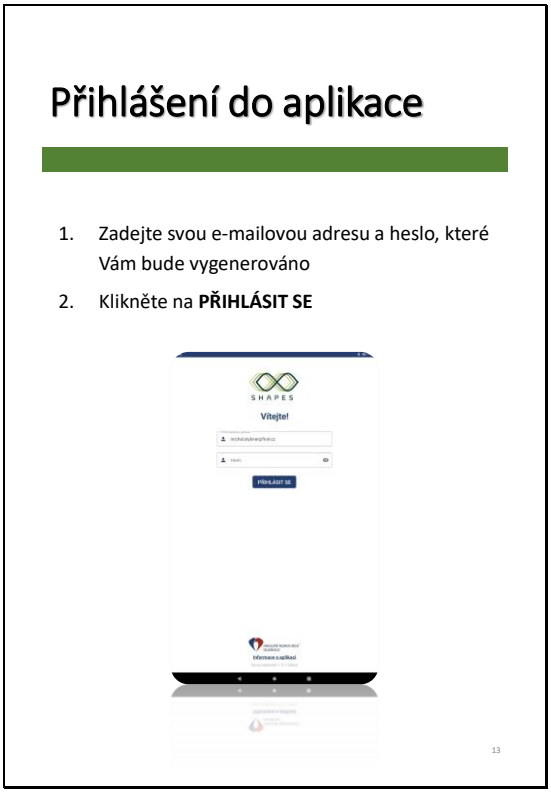

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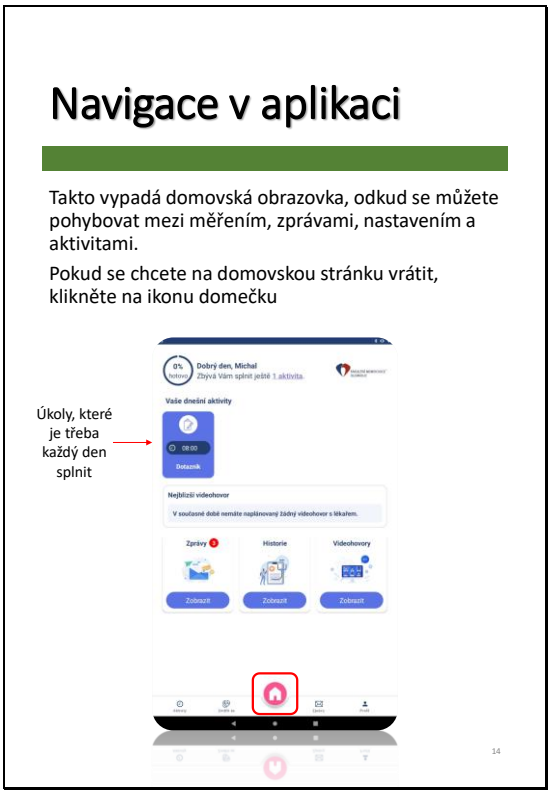

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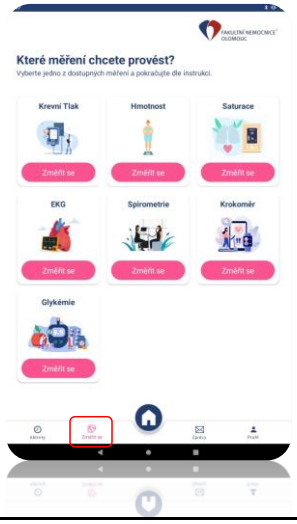
Navigace v aplikaci – Změřit se

Pokud kliknete na ikonu **ZMĚŘIT SE**, umožní vám to změřit se i mimo stanovené úkoly, pokud se např. během dne nebudete cítit dobře.



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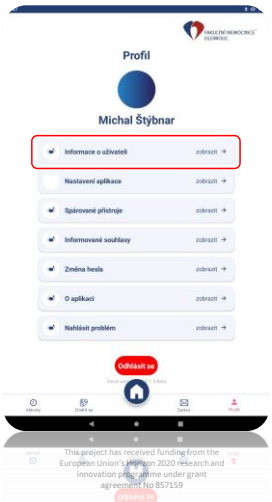
Navigace v aplikaci - Profil

V podzáložce **Informace o uživateli** naleznete informace o vás a přiřazené ambulance.



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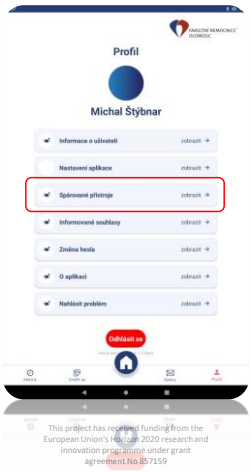
Navigace v aplikaci - Profil

V podzáložce **Spárované přístroje** máte seznam přístrojů, které jsou s tímto tabletem spárované a tudíž je můžete využívat k měření.



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Navigace v aplikaci - Profil
Podzáložka **Změna hesla** je pro vás, pokud si budete chtít změnit/aktualizovat heslo. Stačí na ni kliknout a přesměruje vás to na internetový prohlížeč, kde změnu hesla provedete.
Profil
Michal Štýbnar
Informace o uživateli
Nastavení aplikace
Spárované přístroje
Informované souhlasy
Změna hesla
O aplikaci
Nahlásit problém
Odhlásit se
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Navigace v aplikaci - Profil

Podzáložka **O aplikaci** obsahuje aktuální verzi aplikace, telefon, e-mail, adresu a webovou stránku.

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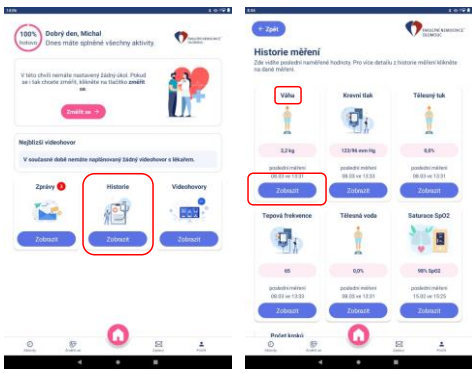
Navigace v aplikaci – Historie

Pokud kliknete na ikonu **HISTORIE**, otevře se vám historie vašich měření. Po kliknutí na jednotlivé měření (např. Váha) a kliknutím na tlačítko **DATA DO GRAFU** se vám ukáže i graf.



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Hmotnost

Zařízení

Beurer BM54

Co můžeme pomocí váhy změřit?

- Váha měří celkovou tělesnou hmotnost, kterou je důležité pravidelně sledovat při zdravotních stavech, jako je například srdeční selhání.
- Tyto chytré váhy měří také BMI index, tělesný tuk, kosterní svaly a procenta vody v těle.

Jak často se mám vážit?

- Pro tuto studii by jste se měli zvážit vždy jednou denně po ránu.

Tento projekt byl financován z programu Evropské unie pro výzkum a inovace Horizon 2020 na základě grantové smlouvy č. 857159.

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Hmotnost

Informace o monitorování vaší váhy

Udržování ideální váhy může pomoct lépe zvládat symptomy dlouhodobých onemocnění a může pomoci předejít dalším zdravotním problémům.

!Náhlé zvýšení tělesné hmotnosti u pacientů se srdečním selháním!

Pokud náhle přiberete během 2-5 dnů, může to být způsobené zadržováním tekutin. Přibráním 1-2 kilogramů může vaše tělo zadržovat až 1 litr tekutin navíc. Dalším příznakem, kterého si můžete všimnout, mohou být otoky v oblasti kotníků, chodidel nebo břicha. Pokud máte pocit, že je toto vás případ, požádejte o pomoc svého lékaře/sestru.

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Měření hmotnosti

Pro změření vaší hmotnosti klikněte na dlaždici Hmotnost na hlavní domovské stránce a nebo na změřit se a dlaždice **Hmotnost**.
Měření lze provádět dvěma způsoby. Buď pomocí přístroje a nebo zadáním hodnot ručně.

Měření hmotnosti pomocí přístroje

1. Klikněte na tlačítko **Pomocí přístroje**
2. Klikněte na tlačítko **zapnout a spojit se s přístrojem**
3. Začne probíhat připojování, vydržte chvíli
4. Jakmile se **váha sama rozsvítí**, stoupněte na ni a zvažte se
5. Po naměření hodnot a **zkontrolování naměřených hodnot** v tabletu dejte uložit měření
6. Klikněte na **uložit měření a OK**

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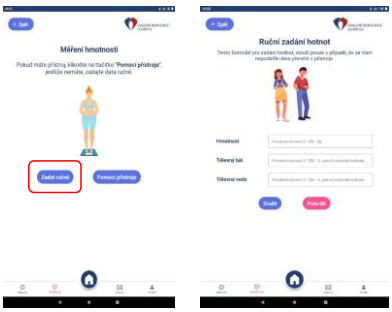
Měření hmotnosti

Měření hmotnosti zadáním hodnot ručně

1. Klikněte na tlačítko **Zadat ručně**
2. Stoupněte na váhu a zvažte se
3. Napište hodnoty hmotnosti, tělesného tuku a tělesné vody



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Saturace

Zařízení

Beurer PO60 Bluetooth pulzní oxymetr

Co můžeme oxymetrem změřit?

- Toto zařízení měří hladinu nasycení krevního hemoglobinu kyslíkem.
- Hodnota saturace je zaznamenána v procentech (%).

Jak často se budete měřit?

- Pro tuto studii se budete měřit vždy jedenkrát denně po ránu.

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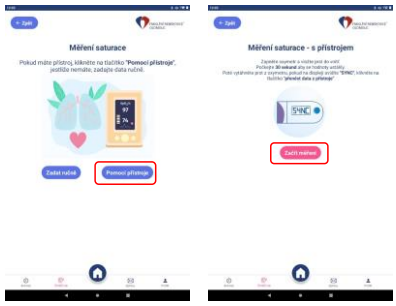
Měření saturace

Měření saturace pomocí přístroje

1. Klikněte na dlaždici **Saturace**
2. Klikněte na tlačítko **Pomocí přístroje**
3. Zapněte oxymetr a vložte prst dovnitř
4. Klikněte na tlačítko **Začít měření**
5. Počkejte 30 s, aby se hodnoty ustálily
6. Vytáhněte prst z oxymetru
7. Jakmile se na displeji objeví **SYNC**, klikněte na tlačítko přenést z přístroje



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Měření saturace

8. Jakmile uvidíte na tabletu naměřené hodnoty, klikněte na **Uložit** a poté **OK**

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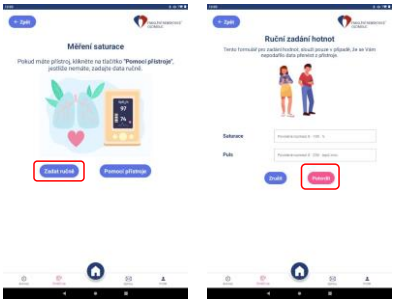
Měření saturace

Měření saturace zadáním hodnot ručně

1. Klikněte na dlaždici **Saturace**
2. Klikněte na **Zadat ručně**
3. Zadejte hodnoty do řádku saturace a hodnoty do řádku puls
4. Klikněte na tlačítko **Potvrdit**



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Krevní tlak

Zařízení

Tlakoměr Beurer BM54

Co můžeme tlakoměrem změřit?

- Toto zařízení měří krevní tlak, což je tlak, při kterém je vaše krev pumpována tepnami.
- Naměřená hodnota krevního tlaku obsahuje dvě čísla. První se udává systolický tlak a druhé jako diastolický tlak.
- Většinou se tato čísla vyobrazují jako zlomek (např. 120/80).
- Krevní tlak se měří v jednotkách mmHg.

Jak často se mám tlakoměrem měřit?

- Pro tuto studii se budete měřit vždy jedenkrát denně po ránu.

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Krevní tlak

Informace o monitorování krevního tlaku

Vysoký krevní tlak může zatížit vaše srdce a přispět k rozvoji mnoha srdečních onemocnění.

U většiny pacientů je cílový krevní tlak pod 140/80 mmHg.

Kdy se budete měřit?

V rámci této studie se budete měřit každý den, vždy po ránu.

! Pokud máte o svůj krevní tlak obavy a nebo se necítíte dobře, obraťte se na svého lékaře, praktického lékaře a nebo zdravotní sestru !

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Měření krevního tlaku

Měření krevního tlaku pomocí přístroje

1. Nasaďte si manžetu tlakoměru na paži tak, aby hadička směřovala dolů a utáhněte (viz. Obrázek str. 34)
2. V aplikaci klikněte na dlaždici **Krevní tlak**
3. Poté klikněte na tlačítko **Pomocí přístroje**
4. Na tlakoměru zmáčkněte **tlačítko pro zapínání** a změřte se (viz. Obrázek str. 35)
5. Tlakoměr je velmi citlivý. Proto prosím u měření nemluvte a nadměrně se nehýbejte
6. Po naměření hodnot zmáčkněte **ještě jednou tlačítko pro zapnutí**
7. Rozsvítí se vám **modrá kontrolka** (viz. Obrázek str. 35)
8. Jakmile se rozsvítí kontrolka, na tabletu klikněte na tlačítko **Přenést data z přístroje**
9. Až uvidíte na tabletu naměřené hodnoty, klikněte na tlačítka **Dokončit a OK**

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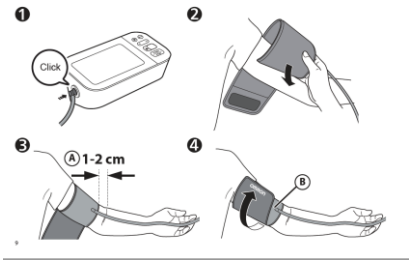
Měření krevního tlaku



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Měření krevního tlaku

Měření krevního tlaku zadáním hodnot ručně

1. Na tabletu klikněte na dlaždici **Krevní tlak**
2. Nasaďte si manžetu tlakoměru (viz Obrázek str. 35)
3. Změřte se
4. Na tabletu po naměření hodnot zmáčkněte tlačítko **Zadat ručně**
5. Zadejte systolický a diastolický tlak
6. Poté klikněte na tlačítko **Potvrdit**

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Spánek

Zařízení

BodiMetrics Circul pulzní oxymetr 

Co můžeme pulzním oxymetrem změřit?

- Toto zařízení monitoruje nasycení kyslíku v krvi, sleduje spánek, včetně spO2 a fází spánku (lehký, hluboký a REM) a výskytu apnoe.

Jak často se budu oxymetrem měřit?

- Pro tuto studii se budete měřit každou noc po celou dobu spánku.

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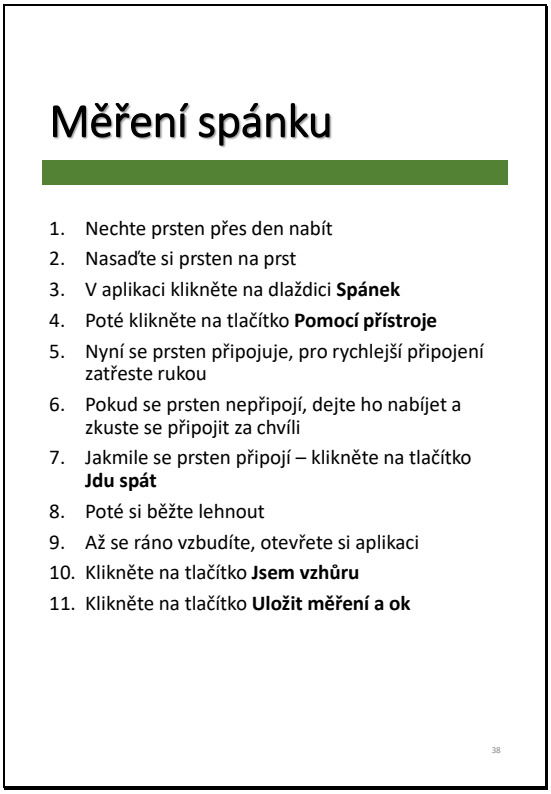

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Spirometr

Zařízení

Spirobank spirometr

Co můžeme spirometrem změřit?

- Spirometrem se měří tzv. spirometrie, tedy vitální funkce plic (slouží jako základní vyšetření k diagnostice chorob plic).

Jak často se budu spirometrem měřit?

- Pro tuto studii se budete měřit každý den.

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Měření spirometrie

1. Klikněte na dlaždici **Spirometrie**
2. Klikněte na tlačítko **Pomocí přístroje**
3. Klikněte na tlačítko **Připojit se k přístroji**
4. Vyčkejte až se přístroj připojí
5. **Mimo přístroj** proveďte **NÁDECH** a následně **do přístroje usilovně VYDECHNĚTE** a znovu se **usilovně NADECHNĚTE přes přístroj**
6. Následně dejte uložit měření a ok

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Inhalace

Zařízení

- FindAir chytrý inhalátor

Jak chytrý inhalátor funguje?

- Inhalátor sbírá data o používání léků podávaných inhalačně skrze senzor, který je k inhalátoru připojen.

Jak často budu inhalátor používat?

- Pro tuto studii budete inhalovat každý den.

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Měření inhalace

1. Klikněte na dlaždici **Inhalace**
2. Vezměte svůj chytrý inhalátor
3. Nyní klikněte na tlačítko **Pomocí přístroje**
4. Klikněte na tlačítko **Připojit se k přístroji** a vyčkejte až se přístroj připojí
5. Jakmile se přístroj připojí, proveďte inhalaci
6. Pro dokončení klikněte na ulož měření a ok

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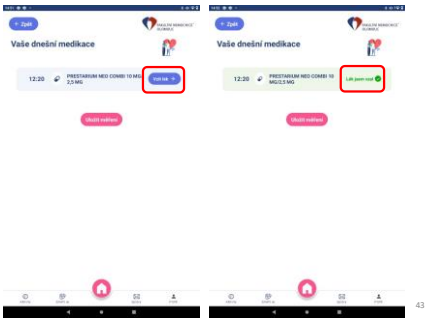
Medikace

Součástí studie je v tabletu pro vás nachystána i připomínka medikace.

1. V dlaždici **Vzít lék/Medikace** najdete výčet Vašich předepsaných léků, jaké množství v jaký čas je máte brát.
2. Jakmile si v daný čas lék vezmete, stačí kliknout u příslušného názvu léku na tlačítko **Vzít lék**
3. Poté se vám objeví zeleně **Lék jsem vzal**



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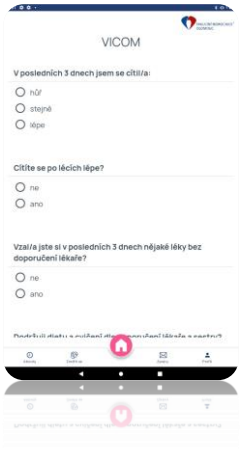
Dotazník

V rámci studie Vám bude každý den zasílán dotazník VICOM, který budete vyplňovat.

Dotazník se týká vašeho momentálního zdravotního stavu, čili jak se dnes cítíte.



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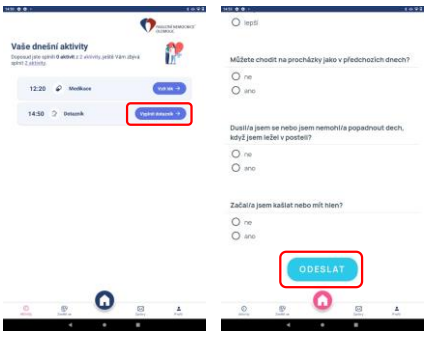
Dotazník

1. Kliknete na dlaždici **Dotazník/Vyplnit dotazník**
2. Otevře se vám dotazník
3. Zaškrtněte vždy příslušné políčko u otázky podle toho, jak se dnes cítíte
4. Po vyplnění všech otázek kliknete na tlačítko **Odeslat**



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Annex 53 UC-PT3-001c Phase 4 Participant information sheet

INFORMOVANÝ SOUHLAS PACIENTA

Já, níže podepsaný/á, souhlasím s účastí na projektu SHAPES, jehož popis, jakožto i účel a rizika jsou popsány v dalším textu Vašeho informovaného souhlasu. Lékař, který je součástí řešitelského týmu usoudil, že splňujete požadavky pro účast v uvedeném projektu.

Název projektu:

Monitoring pacientů se srdečním selháním (řešeno v rámci projektu SHAPES)

Oblast monitorace:

Ověření přínosu digitálních technologií v oblasti monitorace pacientů v domácím prostředí

Hlavní řešitel: RNDr. et RNDr. Ing. Ladislav Stanke, Ph.D.

Spoluřešitelé: MUDr. Renáta Aiglová, Ph.D., MUDr. Jakub Flašík, Mgr. Michal Štýbnar

Pracoviště řešitel a spoluřešitelů: Národní telemedicínské centrum (NTMC), Fakultní nemocnice Olomouc (FNOL), I. Interní klinika, Fakultní nemocnice Olomouc

Rizika projektu:

Riziko poškození pacienta nelze nikdy zcela vyloučit, nicméně v prezentovaném případě je minimalizováno na velice nízkou úroveň. Tablet i použité přístroje, které

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přijdou do kontaktu s pacientem, jsou komerčně dodávané přístroje, které mají označení CE, nebo FDA approved. Případná rizika by vyplývala zejména z využití nevhodných zdrojů pro dobíjení baterií, kde by hrozilo případné poškození baterií, které může v některých případech vést k jejich zahřátí či až zahoření, což je riziko většiny bateriových přístrojů. Nicméně tato rizika jsou jednotlivými výrobci rovněž minimalizována s využitím ochranných obvodů detekujících možná přetížení, kontrolujících teplotu apod. U uživatele, který postupuje dle návodu, případně instrukcí a využívá správné napájecí zdroje (pro daný přístroj určené) je toto riziko ještě nižší.

Projekt SHAPES (The Smart & Healthy Ageing through People Engaging in Supportive Systems) tak nepředstavuje žádná rizika pro Váš zdravotní stav a nemůže přispět k jeho zhoršení. Projekt je založen na měření biomedicínských signálů, konkrétně jde o EKG, krevní tlak, hmotnost, saturaci krve kyslíkem a počet ušlých kroků za den. Měření probíhá s pomocí přístrojů k tomu určených, které budou zapůjčeny z pracoviště řešitele.

Pokud běžně nevyužíváte žádné informační a komunikační technologie, jako je počítač, tablet, chytrý telefon apod., tak Vám může na počátku trvat, než získáte plnou jistotu v ovládání všech přístrojů a tabletu s poskytnutým programovým prostředím. Nicméně není nutné se této fáze obávat, jelikož personál je ochoten Vám v případě nejasností či nejistoty s čímkoliv poradit.

V případě dodržení instrukcí k jednotlivým zapůjčeným přístrojům není známo, že by se jednalo o přístroje, které by Vás mohly jakkoli ohrozit.

Samotný monitoring probíhá s využitím tabletu, na kterém je nainstalována telemedicínská aplikace (Medimonitor) – u některých pacientů, kteří nejsou zvyklí pracovat s ICT technologiemi může trvat déle se naučit aplikaci ovládat, byť bylo pracováno s využitím znalostí a dobrých praxí v oblastech uživatelské zkušenosti (UX – user experience) a přístupnosti, které by měly zmíněné riziko minimalizovat.

Za účelem komunikace je využíváno wi-fi sítě, která patří pacientovi. V tomto ohledu není možné vždy zaručit stabilitu a dostupnost sítě. Pro krátkodobé výpadky jsou data ukládána v tabletu. Při poruše komunikace mezi jednotlivými přístroji a tabletem je možné některé hodnoty (netýká se např. EKG záznamu) zadat ručně.

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Účel a popis projektu:

- Ověření možnosti telemedicínského monitoringu v místě bydliště pacienta pomocí vybraných přístrojů.

- Ověření schopností telemedicínské aplikace vyvinuté ve FNOL (Medimonitor) pro komunikaci s jednotlivými přístroji, agregaci a odeslání dat na server FNOL.

- Ověření možnosti zobrazování varování na základě detekce překročení prahů měřených hodnot (bude probíhat prospektivně)

- Ověření možnosti nalezení algoritmu (případně vytrénování neuronové sítě) pro včasnou detekci blížící se dekompenzace na základě naměřených dat (tato část proběhne retrospektivně po náběru všech dat z přístrojů zapůjčených pacientům).

V rámci projektu bude testována možnost vzdálené monitorace pacientů s chronickým srdečním selháním. Za tímto účelem je pacientům zapůjčena sada přístrojů zakoupených z prostředků mezinárodního projektu SHAPES, na kterém NTMC (Národní telemedicínské centrum) FNOL aktuálně participuje. Konkrétně se jedná o váhu, mobilní EKG, chytré hodinky (použity za účelem využití pedometru pro měření počtu ušlých kroků během každého dne, kdy bude monitorace probíhat), tlakoměr a oxymetr. Každý z těchto přístrojů je schopen pomocí Bluetooth odeslat naměřená data do tabletu (v případě selhání datového přenosu je možné hodnoty zadat i manuálně), který budou mít pacienti rovněž k dispozici. Cílovou skupinou projektu je stárnoucí populace, přičemž hlavním cílem projektu je podporovat aktivní stárnutí s využitím moderních digitálních technologií. V předložené studii se konkrétně jedná o skupinu seniorních pacientů se srdečním selháním. Mezi dílčí cíle projektu patří ověření přínosu telemedicínské aplikace FNOL (Medimonitor) pro akvizici, agregaci a odesílání dat naměřených pomocí přístrojů u pacienta na server FNOL. Pseudonymizovaná (pozměněná takovým způsobem, aby neobsahovala konkrétní jména pacientů) data jsou dále využita jako vstupy pro připravované algoritmy, případně neuronové sítě, které mají za cíl prevenci dekompenzace jejich stavu.

Postupy používané v rámci projektu:

- Odběry krve pro kvantifikaci markerů relevantních pro diagnózu a pro titraci medikace.

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- Administrace dotazníků (prezentovány osobně i elektronicky na zapůjčeném tabletu).

- Měření pomocí zapůjčených zařízení (váha, mobilní EKG, chytré hodinky, tlakoměr a oxymetr) – 1 denně dle instrukcí lékaře a výzkumného týmu).

- Využívání telemedicínské aplikace (pro akvizici, agregaci a odesílání naměřených dat, vedení videokonzultací).

- Statistická analýza výsledků.

- Hledání algoritmů, učení neuronových sítí pro predikci dekompenzací.

Prospěšnost projektu:

Pro zlepšení námi vyvíjených digitálních technologií a služeb z oblasti elektronického zdravotnictví je pro nás cenná zpětná vazba od uživatelů-pacientů tak abychom mohli naše služby dále zdokonalovat směrem k uživatelské přívětivosti, proto jste žádáni, abyste otestovali naši telemedicínskou aplikaci, včetně její schopnosti propojení s dalšími zařízeními, které byly popsány výše. Vámi naměřené hodnoty mohou rovněž pomoci lépe pochopit průběh Vašeho onemocnění. Tyto hodnoty budou dále důkladně analyzovány s využitím pokročilých algoritmů či neuronových sítí.

Kdo se může studie zúčastnit:

Do studie se můžete přihlásit, pakliže jste byly diagnostikováni se srdečním selháním a jste starší 60 let.

Kdo se nemůže studie zúčastnit:

Vzhledem k povaze projektu se nemohou zapojit pacienti s kognitivními poruchami (např. Alzheimerova choroba) a pacienti, kteří nemají v místě bydliště připojení k internetu (bezdrátovou wi-fi síť pro připojení zapůjčeného tabletu), které umožní přenos naměřených hodnot na servery FNOL.

Povinnosti pacienta:

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Jako pacient zapojený do výše popsaného projektu máte povinnost sdělovat lékařskému a vědeckému personálu všechny informace o svém zdravotním stavu a žádné informace nezamlčovat.

Prohlašuji tímto, že jsem pročetl/a všechny výše uvedené informace týkající se popsaného projektu – a těmto jsem porozuměl/a.

Byl/a jsem dostatečně informován/a o cílech, průběhu, účelu a rizicích vyplývajících z účasti na projektu. Jsem si vědom/a, že kdykoli v průběhu i po ukončení mojí účasti na projektu je lékař odpovědný za poskytnutí doplňujících informací o jakékoliv případné zdravotní újmě související s mojí účastí v projektu nebo informací, které mohou ovlivnit moji ochotu v projektu setrvat.

Souhlasím se svou účastí v projektu SHAPES.

Jsem si vědom/a toho, že odstoupení nebo vyřazení z projektu SHAPES, ať už z jakéhokoli důvodu, žádným způsobem neovlivní kvalitu zdravotní péče, která mi bude poskytována. Podpisem tohoto informovaného souhlasu se nevzdávám žádného ze svých zákonných práv.

Kdykoliv mohu uplatnit svá práva u svého ošetřujícího lékaře a požádat v souladu se zákonem o přístup k záznamům a případně je opravit, pokud jsou nepřesné. Projekt SHAPES je prováděn v souladu s právními předpisy České republiky.

Budu-li chtít získat jakékoliv doplňující informace o projektu SHAPES, mohu se obrátit na svého lékaře. Obdržím jeden originálně podepsaný stejnopis tohoto dokumentu.

Po ukončení monitorace je pacient povinen vrátit tablet a všechny zapůjčené přístroje pracovníkovi, který mu je vydal.

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Jméno a příjmení pacienta Podpis pacienta

(Hůlkovým písmem)

_____
_____

Datum:_____ (mes-dd-rrrr)

Jméno a příjmení informujícího lékaře Podpis lékaře

(Hůlkovým písmem)

_____
_____

Datum: _____ (mes-dd-rrrr)

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Annex 54 UC-PT3-001c Phase 4 Participant consent form

Souhlas se zpracováním osobních údajů

Subjekt údajů:

Jméno a příjmení: …….

Datum narození: ……

Správce:

Fakultní nemocnice Olomouc

se sídlem: I.P.Pavlova 185/6, 779 00 Olomouc

zastoupna: prof. MUDr. Romanem Havlíkem, Ph.D.

(“Zpracovatel”)

SHAPES

Maynooth University

Maynooth,

Co. Kildare,

Irsko.

(“Správce”)

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Účely zpracování:

Vaše osobní údaje budou zpracovávány pro účely uskutečnění sběru dat pro mezinárodní projekt SHAPES (dále jen „projekt SHAPES“), v rámci kterého bude testována možnost vzdálené monitorace pacientů s chronickým srdečním selháním.

Rozsah zpracovaných osobních údajů:

Vaše osobní údaje budou zpracovány v následujícím rozsahu: jméno, příjmení, datum narození,……. Vaše osobní údaje budou zpracovávány pouze v rozsahu nezbytném pro naplnění účelu a v souladu s ním.

Právní základ:

Vaše osobní údaje budou zpracovány na základě písemného souhlasu, který může být kdykoli odvolán písemně nebo e-mailem prostřednictvím výše uvedených kontaktních údajů a to v souladu s příslušnými právními normami o ochraně osobních údajů, zejména v souladu s Nařízením Evropského parlamentu a Rady (EU) 2016/679 ze dne 27. dubna 2016 o ochraně fyzických osob v souvislosti se zpracováním osobních údajů a o volném pohybu těchto údajů a o zrušení směrnice 95/46/ES (obecné nařízení o ochraně osobních údajů, či GDPR). Odvoláním souhlasu není dotčena zákonnost předchozího zpracování.

Poskytnutí osobních údajů je zcela dobrovolné. S odmítnutím udělení souhlasu nejsou spojeny žádné negativní důsledky. Zpracování osobních údajů je však nezbytné pro Vaše zařazení do projektu SHAPES a bez udělení souhlasu není účast na projektu SHAPES možná.

Příjemci:

Správce SHAPE nebude znát Vaši totožnost, jelikož mu budou data předávána v pseudoanonymizované podobě. K Vašim osobním údajům bude mít přístup pouze Váš lékař a vědecký tým Fakultní nemocnice Olomouc. Osobní údaje mohou být také zpřístupněny kontrolním a jiným orgánům při výkonu jejich kontrolní nebo jiné úřední činnosti.

Předávání osobních údajů do třetí země:

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Vaše osobní údaje nebudou předávány do třetích zemí.

Doba uchování:

Pokud nebude Váš souhlas se zpracováním osobních údajů odvolán, budou osobní údaje uchovávány a využívány po dobu provádění projektu SHAPES, případně v nezbytném rozsahu i po jejím skončení s ohledem na ochranu oprávněných zájmů správce.

Práva subjektu údajů:

Jako subjekt údajů máte právo na přístup k osobním údajům, právo na jejich opravu nebo výmaz (pokud bude odvolán souhlas nebo uplyne doba uchování), popřípadě na omezení zpracování a na přenositelnost osobních údajů k jinému správci. Máte rovněž právo požadovat po Správci informace o způsobu, rozsahu a účelu zpracování osobních údajů a Správce má povinnost Vám tyto informace sdělit neprodleně, nejpozději do 1 měsíce od obdržení žádosti. Veškeré žádosti budou podávány prostřednictvím výše uvedených kontaktních údajů. Dále máte právo obrátit se kdykoliv se svým podnětem nebo stížností na Úřad pro ochranu osobních údajů (www.uoou.cz).

Souhlas:

Prohlašuji, že jsem byl/a řádně informován/a o výše uvedeném zpracování osobních údajů, jsem si vědom/a svých práv a svobodně s tímto zpracováním souhlasím.

Datum: ……..

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Podpis: _____¬_____

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Annex 55 UC-PT3-001c/COPD Phase 4 User training manual

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O projektu SHAPES

- **SHAPES** je evropský projekt, který zkoumá, jak mohou technologie pomoci starším lidem v českých komunitách a umožnit jim žít zdravěji a déle ve vlastních domovech.
- V celé Evropě se provádí výzkumné studie za účelem zjištění zda technologie (např. mobilní aplikace nebo chytré senzory a roboti) mohou pomoci lidem starším 60 let v sedmi klíčových oblastech zájmu.
- V České republice zkoumáme, jak můžeme pomocí mobilní aplikace (Medimonitor) podpořit měření s využitím přístrojů a užívání léků z pohodlí domova.

SHAPES

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Aplikace Medimonitor

- Tato aplikace běží v systému Android na chytrých tabletech.
- Měření a údaje z přístrojů se přenáší do aplikace přes rozhraní Bluetooth, tedy bezdrátově. Existuje však také možnost ručního zadání hodnot. Přednostně by se ale měl využívat bezdrátový přenos.
- Aplikace obsahuje také denní seznam léků, které člověk užívá a připomíná mu, které by měl užít.
- Aplikace zasílá pacientům v pravidelných intervalech dotazníky, které zjišťují aktuální zdravotní stav a jak se pacient cítí.

Tento projekt byl financován z programu Evropské unie pro výzkum a inovace Horizon 2020 na základě grantové smlouvy č. 857159.

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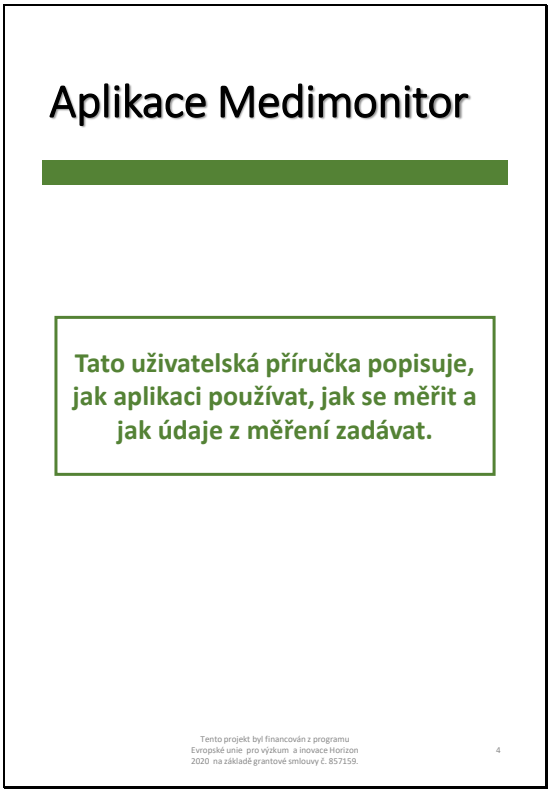

Slide 5

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Přístroje

(Pro pacienty se srdečním selháním)

Beurer BF600 váha k měření hmotnosti

Beurer PO60 pulzní oxymetr k měření saturace

Beurer BM54 tlakoměr k měření krevního tlaku

Xiaomi MI Band 6 k měření kroků

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Přístroje

(Pro pacienty se srdečním selháním)

Beurer ME90 EKG k měření srdečního rytmu

Tablet Lenovo M10 HD ke sběru naměřených dat

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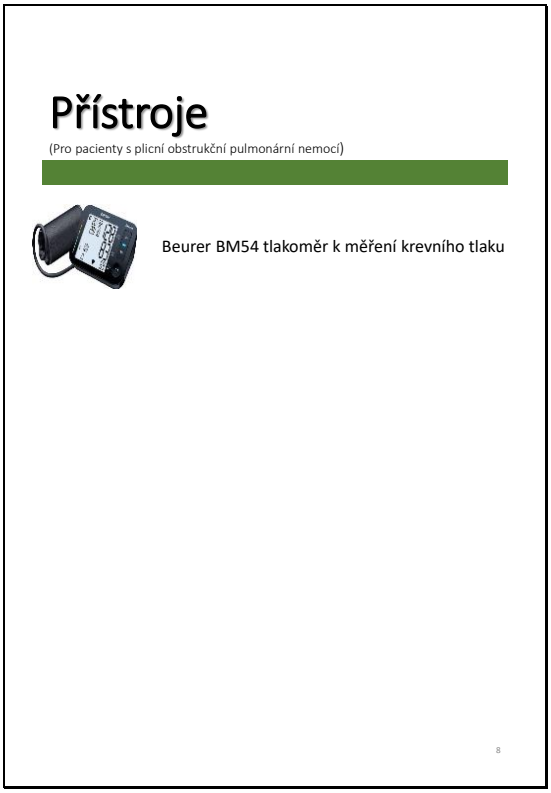

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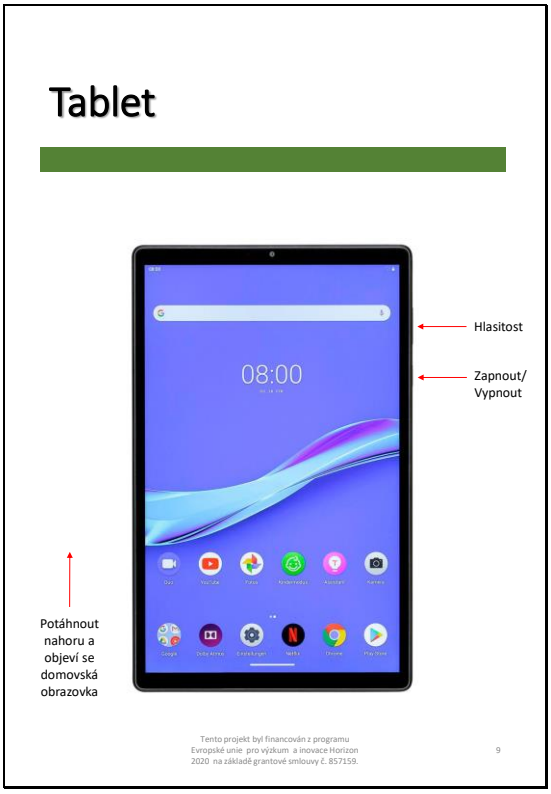

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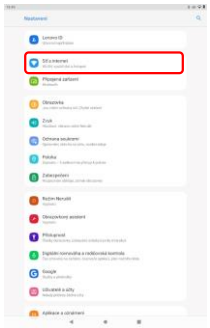
Připojení k Wi-Fi

1. Na domovské obrazovce klikněte na ikonu **Nastavení**
2. V nastavení klikněte na **Síť a internet**
3. Klikněte na **WLAN** a vyberte si z dostupných sítí
4. Vraťte se na domovskou obrazovku



Tento projekt byl financován z programu Evropské unie pro výzkum a inovace Horizon 2020 na základě grantové smlouvy č. 857159.

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Využívání aplikace pro měření vašeho zdraví

Během pilotního období v projektu SHAPES budete požádáni, abyste sledovali svou váhu, saturaci, krevní tlak, počet kroků a měření srdečního rytmu.

Tato aplikace Vaše měření ukládá a můžete je případně diskutovat i se svými poskytovateli zdravotní péče.

Pokud se během testování nebudete cítit dobře nebo budete mít jakékoliv obavy ohledně vašich naměřených hodnot, je důležité, aby jste kontaktovali svého lékaře, praktického lékaře nebo sestru.

Tato příručka obsahuje základní pokyny jak manipulovat s přístroji a aplikací. Další pokyny a informace naleznete v dodaných uživatelských příručkách, případně na vyžádání.

Tento projekt byl financován z programu Evropské unie pro výzkum a inovace Horizon 2020 na základě grantové smlouvy č. 857159.

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Aplikace

1. Na domovské obrazovce klikněte na ikonu **Konzultace FNOL**
2. Přihlaste se pomocí svých přihlašovacích údajů

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Přihlášení do aplikace

1. Zadejte svou e-mailovou adresu a heslo, které Vám bude vygenerováno
2. Klikněte na **PŘIHLÁSIT SE**

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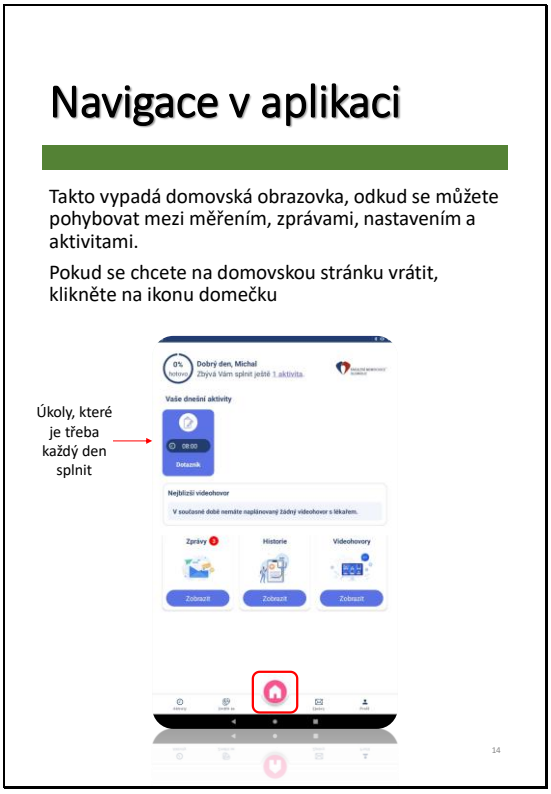

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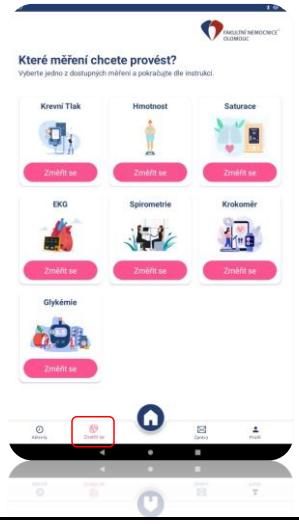
Navigace v aplikaci – Změřit se

Pokud kliknete na ikonu **ZMĚŘIT SE**, umožní vám to změřit se i mimo stanovené úkoly, pokud se např. během dne nebudete cítit dobře.



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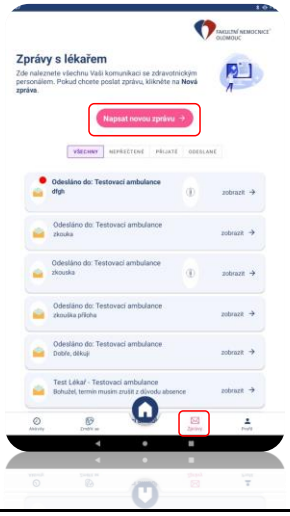
Navigace v aplikaci - Zprávy

V záložce **ZPRÁVY** můžete komunikovat s vaším lékařem nebo jiným odborníkem. Pro napsání nové zprávy stačí kliknout na tlačítko Napsat novou zprávu.



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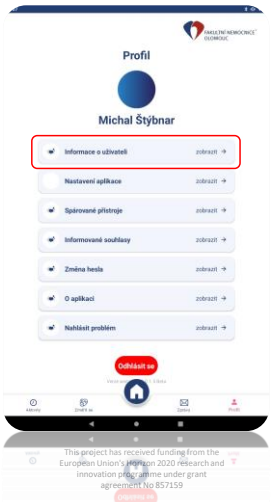
Navigace v aplikaci - Profil

V podzáložce **Informace o uživateli** naleznete informace o vás a přiřazené ambulance.



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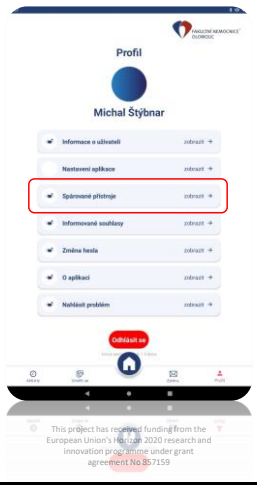
Navigace v aplikaci - Profil

V podzáložce **Spárované přístroje** máte seznam přístrojů, které jsou s tímto tabletem spárované a tudíž je můžete využívat k měření.



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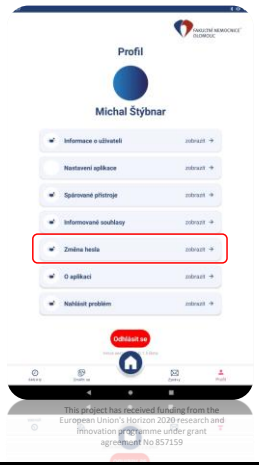
Navigace v aplikaci - Profil

Podzáložka **Změna hesla** je pro vás, pokud si budete chtít změnit/aktualizovat heslo. Stačí na ni kliknout a přesměruje vás to na internetový prohlížeč, kde změnu hesla provedete.



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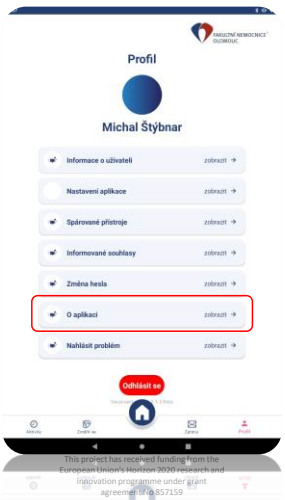
Navigace v aplikaci - Profil

Podzáložka **O aplikaci** obsahuje aktuální verzi aplikace, telefon, e-mail, adresu a webovou stránku.



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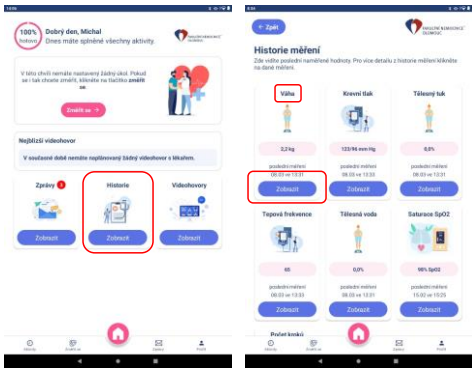
Navigace v aplikaci – Historie

Pokud kliknete na ikonu **HISTORIE**, otevře se vám historie vašich měření. Po kliknutí na jednotlivé měření (např. Váha) a kliknutím na tlačítko **DATA DO GRAFU** se vám ukáže i graf.



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Hmotnost

Zařízení

Beurer BM54

Co můžeme pomocí váhy změřit?

- Váha měří celkovou tělesnou hmotnost, kterou je důležité pravidelně sledovat při zdravotních stavech, jako je například srdeční selhání.
- Tyto chytré váhy měří také BMI index, tělesný tuk, kosterní svaly a procenta vody v těle.

Jak často se mám vážit?

- Pro tuto studii by jste se měli zvážit vždy jednou denně po ránu.

Tento projekt byl financován z programu Evropské unie pro výzkum a inovace Horizon 2020 na základě grantové smlouvy č. 857159.

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Hmotnost

Informace o monitorování vaší váhy

Udržování ideální váhy může pomoct lépe zvládat symptomy dlouhodobých onemocnění a může pomoci předejít dalším zdravotním problémům.

!Náhlé zvýšení tělesné hmotnosti u pacientů se srdečním selháním!

Pokud náhle přiberete během 2-5 dnů, může to být způsobené zadržováním tekutin. Přibráním 1-2 kilogramů může vaše tělo zadržovat až 1 litr tekutin navíc. Dalším příznakem, kterého si můžete všimnout, mohou být otoky v oblasti kotníků, chodidel nebo břicha. Pokud máte pocit, že je toto vás případ, požádejte o pomoc svého lékaře/sestru.

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Měření hmotnosti

Pro změření vaší hmotnosti klikněte na dlaždici Hmotnost na hlavní domovské stránce a nebo na změřit se a dlaždice **Hmotnost**.
Měření lze provádět dvěma způsoby. Buď pomocí přístroje a nebo zadáním hodnot ručně.

Měření hmotnosti pomocí přístroje

1. Klikněte na tlačítko **Pomocí přístroje**
2. Klikněte na tlačítko **zapnout a spojit se s přístrojem**
3. Začne probíhat připojování, vydržte chvíli
4. Jakmile se **váha sama rozsvítí**, stoupněte na ni a zvažte se
5. Po naměření hodnot a **zkontrolování naměřených hodnot** v tabletu dejte uložit měření
6. Klikněte na **uložit měření a OK**

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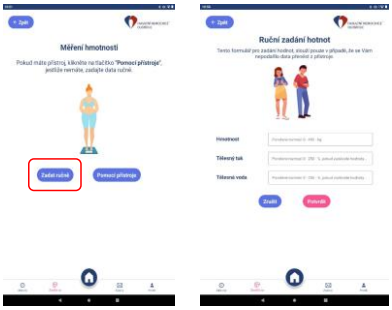
Měření hmotnosti

Měření hmotnosti zadáním hodnot ručně

1. Klikněte na tlačítko **Zadat ručně**
2. Stoupněte na váhu a zvažte se
3. Napište hodnoty hmotnosti, tělesného tuku a tělesné vody



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Saturace

Zařízení

Beurer PO60 Bluetooth pulzní oxymetr

Co můžeme oxymetrem změřit?

- Toto zařízení měří hladinu nasycení krevního hemoglobinu kyslíkem.
- Hodnota saturace je zaznamenána v procentech (%).

Jak často se budete měřit?

- Pro tuto studii se budete měřit vždy jedenkrát denně po ránu.

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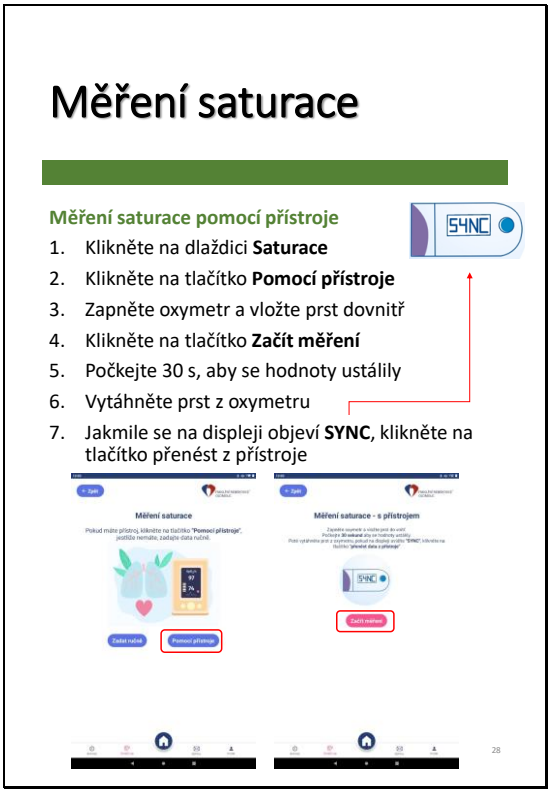

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Měření saturace

8. Jakmile uvidíte na tabletu naměřené hodnoty, klikněte na **Uložit** a poté **OK**

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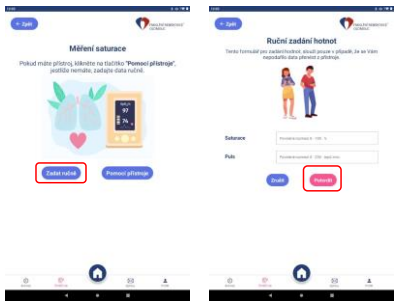
Měření saturace

Měření saturace zadáním hodnot ručně

1. Klikněte na dlaždici **Saturace**
2. Klikněte na **Zadat ručně**
3. Zadejte hodnoty do řádku saturace a hodnoty do řádku puls
4. Klikněte na tlačítko **Potvrdit**



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Krevní tlak

Zařízení

Tlakoměr Beurer BM54

Co můžeme tlakoměrem změřit?

- Toto zařízení měří krevní tlak, což je tlak, při kterém je vaše krev pumpována tepnami.
- Naměřená hodnota krevního tlaku obsahuje dvě čísla. První se udává systolický tlak a druhé jako diastolický tlak.
- Většinou se tato čísla vyobrazují jako zlomek (např. 120/80).
- Krevní tlak se měří v jednotkách mmHg.

Jak často se mám tlakoměrem měřit?

- Pro tuto studii se budete měřit vždy jedenkrát denně po ránu.

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Krevní tlak

Informace o monitorování krevního tlaku

Vysoký krevní tlak může zatížit vaše srdce a přispět k rozvoji mnoha srdečních onemocnění.

U většiny pacientů je cílový krevní tlak pod 140/80 mmHg.

Kdy se budete měřit?

V rámci této studie se budete měřit každý den, vždy po ránu.

! Pokud máte o svůj krevní tlak obavy a nebo se necítíte dobře, obraťte se na svého lékaře, praktického lékaře a nebo zdravotní sestru !

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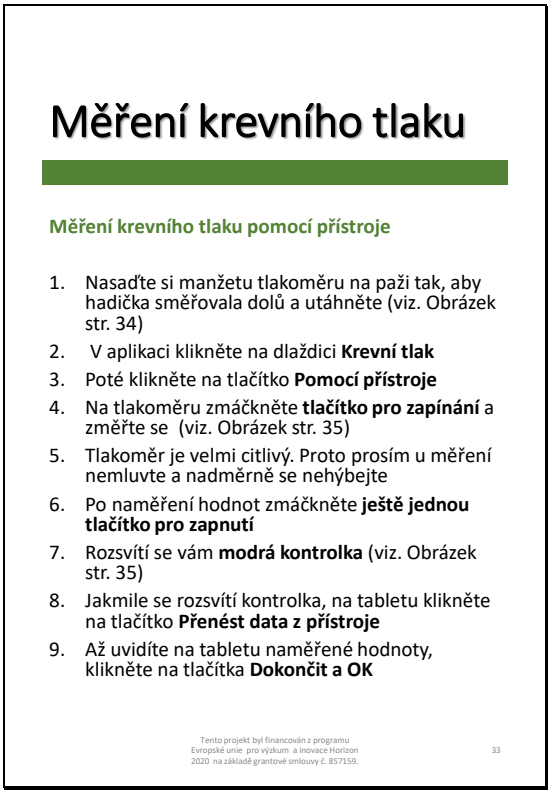

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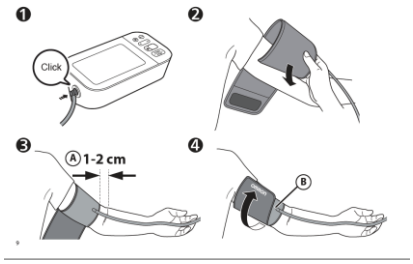
Měření krevního tlaku



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Měření krevního tlaku

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Měření krevního tlaku

Měření krevního tlaku zadáním hodnot ručně

1. Na tabletu klikněte na dlaždici **Krevní tlak**
2. Nasaďte si manžetu tlakoměru (viz Obrázek str. 35)
3. Změřte se
4. Na tabletu po naměření hodnot zmáčkněte tlačítko **Zadat ručně**
5. Zadejte systolický a diastolický tlak
6. Poté klikněte na tlačítko **Potvrdit**

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Spánek

Zařízení

BodiMetrics Circul pulzní oxymetr

Co můžeme pulzním oxymetrem změřit?

- Toto zařízení monitoruje nasycení kyslíku v krvi, sleduje spánek, včetně spO2 a fází spánku (lehký, hluboký a REM) a výskytu apnoe.

Jak často se budu oxymetrem měřit?

- Pro tuto studii se budete měřit každou noc po celou dobu spánku.

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Měření spánku

1. Nechte prsten přes den nabít
2. Nasaďte si prsten na prst
3. V aplikaci klikněte na dlaždici **Spánek**
4. Poté klikněte na tlačítko **Pomocí přístroje**
5. Nyní se prsten připojuje, pro rychlejší připojení zatřeste rukou
6. Pokud se prsten nepřipojí, dejte ho nabíjet a zkuste se připojit za chvíli
7. Jakmile se prsten připojí – klikněte na tlačítko **Jdu spát**
8. Poté si běžte lehnout
9. Až se ráno vzbudíte, otevřete si aplikaci
10. Klikněte na tlačítko **Jsem vzhůru**
11. Klikněte na tlačítko **Uložit měření a ok**

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Spirometr

Zařízení

Spirobank spirometr

Co můžeme spirometrem změřit?

- Spirometrem se měří tzv. spirometrie, tedy vitální funkce plic (slouží jako základní vyšetření k diagnostice chorob plic).

Jak často se budu spirometrem měřit?

- Pro tuto studii se budete měřit každý den.

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Měření spirometrie

1. Klikněte na dlaždici **Spirometrie**
2. Klikněte na tlačítko **Pomocí přístroje**
3. Klikněte na tlačítko **Připojit se k přístroji**
4. Vyčkejte až se přístroj připojí
5. **Mimo přístroj** proveďte **NÁDECH** a následně **do přístroje usilovně VYDECHNĚTE** a znovu se **usilovně NADECHNĚTE přes přístroj**
6. Následně dejte uložit měření a ok

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Inhalace

Zařízení

- FindAir chytrý inhalátor

Jak chytrý inhalátor funguje?

- Inhalátor sbírá data o používání léků podávaných inhalačně skrze senzor, který je k inhalátoru připojen.

Jak často budu inhalátor používat?

- Pro tuto studii budete inhalovat každý den.

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Měření inhalace

1. Klikněte na dlaždici **Inhalace**
2. Vezměte svůj chytrý inhalátor
3. Nyní klikněte na tlačítko **Pomocí přístroje**
4. Klikněte na tlačítko **Připojit se k přístroji** a vyčkejte až se přístroj připojí
5. Jakmile se přístroj připojí, proveďte inhalaci
6. Pro dokončení klikněte na ulož měření a ok

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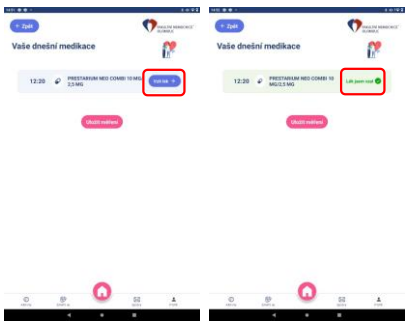
Medikace

Součástí studie je v tabletu pro vás nachystána i připomínka medikace.

1. V dlaždici **Vzít lék/Medikace** najdete výčet Vašich předepsaných léků, jaké množství v jaký čas je máte brát.
2. Jakmile si v daný čas lék vezmete, stačí kliknout u příslušného názvu léku na tlačítko **Vzít lék**
3. Poté se vám objeví zeleně **Lék jsem vzal**



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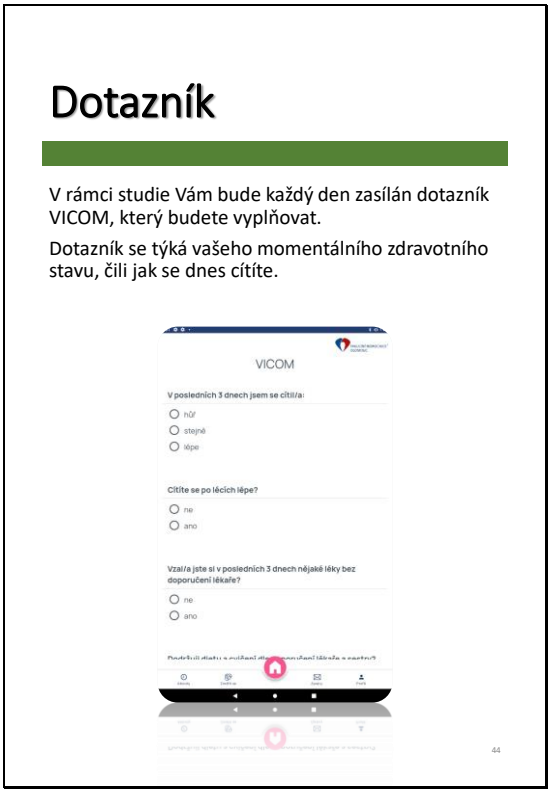

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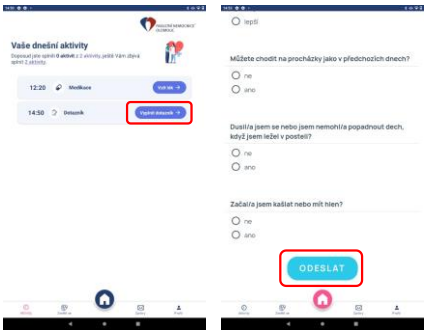
Dotazník

1. Kliknete na dlaždici **Dotazník/Vyplnit dotazník**
2. Otevře se vám dotazník
3. Zaškrtněte vždy příslušné políčko u otázky podle toho, jak se dnes cítíte
4. Po vyplnění všech otázek kliknete na tlačítko **Odeslat**



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Annex 56 UC-PT001/COPD Ethicial self-assessment

ETHICAL SELF-ASSESSMENT FOR THE PILOTS IN PHASES 1-5

This template is based on the ethics self-assessment template of Horizon 2020 projects. (https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf).

The template is modified for the purposes of SHAPES pilots, including also new ethical topics identified in WP11 requirements and in WP8 work. On the other hand a few points (Human foetuses, Human cells/tissues, Dual use etc.) of the original EU Ethical Self-assessment template are left out because they are not relevant for SHAPES pilots.

Ethics self-assessment should be completed for each SHAPES piloting activities as follows:

- each organization collecting any data and/or collaborating with end-users in phases 1-3 will provide its own ethical self-assessment.
- each organization responsible for small scale and/or large scale pilots in phases 4-5 will provide its own ethical self-assessment.
- if the organization is a pilot host both during the phases 1-3 and 4-5, it can provide a joint ethical self-assessment covering all the phases 1-5.

Fill in the template and upload it to WP8 Teams/Pilot - Ethical self-assessments https://teams.microsoft.com/_#/files/WP8?threadId=19%3Abcea934935c74da5bd02c31abcea4e95%40thread.skype&ctx=channel&context=Pilots%2520-%2520ethical%2520self-assessments&rootfolder=%252Fsites%252FSHAPESProject%252FShared%2520Documents%252FWP8%252FPilots%2520-%2520ethical%2520self-assessments

Pilot identification	UC – PT3– 001C Advanced telemonitoring of patients with heart failure in home environment
Form completed by (name & partner)	Ladislav Stanke
Date	November 2nd, 2020

HUMANS AND PERSONAL DATA	
Does your pilot involve human participants? (if yes, see steps 1,2, 3 below)	☐ yes ☒ no
Does your research involve personal data collection and/or processing? (if yes, see steps 4,5,6,7,8 below) ☐ ☒ Secondary use of personal data? yes no ☐ ☒	☐ yes ☒ no

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Tracking or observing of participants? yes no [ ] [X] Processing of health, biometric orgenetic data? yes no	

1 Human dignity
-Always respect human dignity and the intrinsic value of the individuals.
-The methods and tools to be used in co-creation with the older persons are to be chosen carefully by considering person's capability to function, so that there will be no burden for, e.g., vulnerable participants, or any risk for stigmatisation. All direct costs for participants are to be covered by the project.
(-See Ethical Requirements GE8-GE9 in D8.4.)

2 Research/pilot plan and ethics approvals
-A written research/pilot plan must be provided and available on request, including details of the recruitment, types of vulnerability and diseases, inclusion and exclusion criteria and informed consent procedures. If people unable to provide consent will be involved, the procedures for obtaining approval from the legal representative must be described in detail. In addition, the plan must demonstrate appropriate efforts to ensure fully informed understanding of the implications of participation.
-Ethics approvals by local authorities must be acquired and kept on file in WP6 TEAMS/archives (e.g., when involving vulnerable persons and persons unable to give consent) before the work begins.
-This also applies in the situation with Covid-19 pandemic.

3 Consents and agreements with end-users
-The pilot organizations should collect participants' consent forms and provide an information sheet specifying the nature of the research and pilot, including also the processing of personal data as part of the research and/or on the SHAPES platform.

Pilot phases 1-3:
-The main principle is that consent from each participant is to be acquired before the person is involved in the research. However if you are only collecting feedback e.g. in short brain storming sessions – and without any personal data - this is not necessary.
-Avoid any collection of personal data if possible in these phases 1-3.
-The template for the consent, information sheet and privacy policy are attached and available in Teams WP8. The final documents have to be written in the participant's language. Edited & translated templates are to be uploaded to WP6 Teams.
-The researcher/pilot organisation will keep the signed consent forms on file in a safe place until the end of the project (after final review/or time defined in national legislation) and destroy them after that.

Pilot phases 4-5:
-Consent from each participant using SHAPES services is to be acquired before the use of the SHAPES begins, as well as agreements regarding the various digital services. The former includes also consent for the use of person's data on big data analytics.
-The consent (and agreements) will be collected on the SHAPES platform. (See Ethical Requirements GE37 and ET13 in D8.4.)
- If consent functionalities are not yet ready in the beginning of the phase 4/5, they will be collected manually. Template will be co-created (WP8+WP6 pilots) before these phases of pilots will start.

4 Privacy and data protection descriptions
-Researchers should provide details regarding the procedures of the personal data collection, minimization, anonymization & pseudonymisation, storage, protection, retention, transfer and destruction or re-use of data, as well as those regarding data safety procedures, justification for the processing of special categories of personal data, data subjects rights, data transfers to third countries and tracking and observing methods.
-In case of further processing of previously collected personal data, an explicit confirmation that the beneficiary has lawful basis for the data processing and that the appropriate technical and organisational

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measures are in place to safeguard the rights of the data subjects must to be confirmed (secondary use of personal data).

Pilots in phases 1-3:
-We recommend not to process any real personal data. However if this is needed, contact Data Protection Manager for further guidelines.

Pilots in phases 4-5:
-Personal Data Processing Descriptions are to be provided an uploaded to WP6 Teams before the pilot begins. Note that the use of secondary data has to be reported already in M12 by using Personal Data Processing Descriptions template that can be found in WP8 Teams.
-The SHAPES functionalities regarding data minimization, anonymization etc. are documented in various SHAPES deliverables.
-(See Ethical Requirements GE23-GE46, ET4-ET20, PE6, ME9-ME13 in D8.4.)

5 Tracking and observing of participants
-Researchers should provide details of the methods used for tracking, surveillance or observation of participants, details of the methods used for profiling, risk assessment for the data processing activities, how will harm be prevented and the rights of the research participants safeguarded and details on the procedures for informing the research participants about profiling, and its possible consequences and the protection measures.

Pilots in phases 1-3:
-We recommend not to perform such activities. However if this is needed, contact Data Protection Manager for further guidelines.

Pilots in phases 4-5:
-This is related e.g. to the facial recognition and home environment monitoring as part of the SHAPES platform. Issue will be analyzed as part of ethics risk assessment in D8.4. and DPIA.
(-See Ethical requirement GE57 in D8.4)

6 Legal compliance with local legislation related to health, genetic & biometrics data and GDPR
-The beneficiary must check if special derogations pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data have been established under the national legislation of the country where the research takes place and submit a declaration of compliance with respective national legal framework(s).

Pilots in phases 1-3:
-We recommend not to collect any health data. However if this is needed, contact Data Protection Manager for further guidelines.

Pilots in phases 4-5:
-Find out if there is local legislation on the topic.
-If yes, acquire approvals needed and provide compliance check before pilot begins (in that work utilize your Data Processing Descriptions and Data Lifecycle Management Plan.). Upload the documents in WP6 Teams.
(-See updated Ethical Requirement ME2 in D8.4).

7 The Data Protection Officer and Data Owners
-Each pilot in phases 1-5 should nominate Data Owner before the collection of data begins.
-For phases 4-5 also Data protection Officer is needed. She/he typically comes from the same organization as Data Owner (and can be a same person as well). Name of the organization (and the name of the person) is to be confirmed in M12.
(-See Ethical Requirements ME12-ME13 in D8.4.)

8 Privacy and Data Protection Impact Assessment
-The DPIA regarding the phase 5 is to be performed by each pilot in collaboration with SHAPES Data Protection Manager 2 months before the pilot phase 5 begins. DPIA will also be verified during the pilot phase 5.
(-See Ethical Requirement M10 in D8.4).

THIRD COUNTRIES	

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Does your research involve non-EU countries?	X yes ☐ no
Do you plan to import any material from non-EU countries into the EU?	X yes ☐ no
Do you plan to export any material from the EU to non-EU countries?	X yes ☐ no
If yes: The researchers should provide a risk-benefit analysis, the details of the activities and compliance checks with the EU and local legislations before the collaboration begins. Analysis is to be provided to Ethics Manager and Data Protection Manager.	
INCIDENTIAL AND/OR SENSITIVE FINDINGS	
Does your research involve a risk of incidental findings?	☐ yes X no
If yes, Research plans that may involve a risk of incidental findings must be accepted either by the organisation's own board of ethics (e.g., at universities), or if the organisation does not have such, then at the SHAPES EAB before the research begins. The plan for incidental findings must be sent to the WP8 internal review team for comments. If incidental findings are identified in the context of SHAPES activities, they must be immediately reported to the relevant authority or to the responsible organisational role, as well as to SHAPES Ethics Manager. Pilots in phases 1-3: Acquire approvals before the research if there is a risk for incidental findings. Pilots in phases 4-5: Incidental findings on the SHAPES platform during the pilots have been taken into account in the ethical requirements, see Ethical Requirement M6 in D8.4.	
DATA MANAGEMENT (all data, not only personal data)	
All the pilots are responsible to define their data sets and provide input to WP6 Data Lifecycle Management Plan. (see D8.13) Pilots in phases 1-3: Data Sets are to be identified before the pilot begins. Pilots in phases 4-5: First version of the Data Lifecycle Management plan needs to be ready before pilots phase 4 begins.	

Summary of the deadlines for the phases 1-3 and 4-5.

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Activity	Phases 1-3	Phases 4-5
Human dignity	Choose methods and tools of co-creation carefully.	Choose methods and tools of co-creation carefully.
Research plans and approvals	Provide/acquire before the research begins	Provide/acquire before the pilot begins
Consents	Collect before person's participation	Collect before person begins to use SHAPES
Privacy and Data protection descriptions, including also secondary use of personal data.	*We recommend not to collect real personal data. Contact Data Protection Manager if this is needed.*	Provide before the pilot begins. The secondary use of personal data is to be reported by the end of M12.
Tracking and observing of participants	*We recommend not to perform such activities. Contact Data Protection Manager if this is needed.*	*This information is/will be available on SHAPES technical documents, Personal Data Descriptions, on DPIA and Ethical Risk assessments.*
Legal compliance with local legislation on GDPR	*We recommend not to collect real personal data. Contact Data Protection Manager if this is needed.*	Acquire approvals and provide compliance before the pilot begins.
Data Protection Officer and Data Owners	Nominate Data owner before the collection of data begins.	Nominate the Data Protection Officer (or at least the organization) by the end of M12.
Privacy and Data Protection Impact assessments	N/A	Provide DPIA 2 months before the pilot in phase 5 begins.
Third countries	Provide information before the collaboration/ processing of personal data begins.	Provide information before the collaboration/ processing of personal data begins.
Incidental findings	Acquire approvals before the research if there is a risk for incidental findings.	*The procedures regarding the incidental findings on the SHAPES platform will be defined as part of the Ethical Requirement ME6.*
Data Management	Data sets are to be identified before the pilot begins.	Provide first version of Data Lifecycle Management Plan before the phase 4 begins.

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Annex 57 UC-PT3-001c Phase 5 Participant information sheet

SHAPES INFORMAČNÍ LIST PRO ÚČASTNÍKY

Kontakty:

Národní telemedicínské centrum Fakultní nemocnice Olomouc (NTMC FNOL)

Ladislav Stanke (výzkumný pracovník)

E-mail: Ladislav.Stanke@fnol.cz; Telefon: 583 443 713

Michal Štýbnar (koordinační pracovník)

E-mail: Michal.Stybnar@fnol.cz; Telefon: 583 443 713

Název studie: SHAPES Pan-European Pilot Campaign („Pan-evropská pilotní kampaň SHAPES“): SHAPES pilot zaměřený na pacienty se srdečním selháním pro pilotní téma 3 - kontrola a optimalizace medikace.

Rádi bychom Vás pozvali k účasti na pilotní studii, během níž bude probíhat pilotní ověření digitálního řešení vyvinutého v rámci mezinárodního projektu SHAPES v podobě zdravotnické aplikace a propojených zdravotnických přístrojů, které je vyvíjené pro osoby starší 60 let, které trpí srdečním selháním. Studie je pro nás příležitostí zjistit, zda může toto digitální řešení pomoci lidem sledovat a řídit jejich zdravotní stav z domova a zlepšit kvalitu jejich života a zdravotní výsledky. Naším cílem je zapojit do této studie nejméně dvacet pět starších osob s chronickou nemocí.

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Byl/a jste identifikován/a jako vhodný/á účastník/ce našeho pilotu a obdržel/a jste tento informační list, který si můžete přečíst a zvážit, zda se chcete zúčastnit.

Tento informační list popisuje pilotní studii a Vaši roli v ní. Než se rozhodnete, je důležité, abyste pochopil/a, proč se pilot provádí a co pro Vás bude znamenat. Věnujte prosím čas přečtení těchto informací a případně je prodiskutujte s blízkými či výzkumníky. Pokud Vám něco není jasné nebo pokud byste chtěl/a získat více informací, kontaktujte výzkumné pracovníky uvedené výše, kteří Vás budou kontaktovat zpět.

Dobrovolnost účasti

Účast v této studii je dobrovolná. Ze studie můžete kdykoli odstoupit bez udání důvodu a bez jakýchkoli negativních důsledků. Pokud ze studie odstoupíte nebo odvoláte svůj souhlas, budou všechny Vaše osobní údaje shromážděné pro účely výzkumu odstraněny. Případně můžete povolit, aby osobní údaje shromážděné před odstoupením byly do výzkumu zahrnuty. V případě, že budete s účastí na pilotní studii souhlasit, budete požádáni o podepsání informovaného souhlasu s účastí ve studii. Během pilotního projektu Vám budou k dispozici výše uvedení pracovníci Fakultní nemocnice Olomouc (FNOL), kteří Vám budou při používání technologie pomáhat a řešit případné problémy.

Účel a cíle studie

Tato studie je jednou z částí rozsáhlejšího výzkumného projektu s názvem SHAPES, jehož cílem je otestovat různé způsoby využití technologií, které pomáhají stárnoucím lidem bezpečně fungovat v jejich domovech a zůstat aktivní.

Hlavním cílem této pilotní akce je zjistit, jak účastníci používají digitální řešení a technologii SHAPES.

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Mezi další cíle pilotu patří:

- pomoci lidem monitorovat jejich zdravotní stav, životní funkce a užívání léků, a tím podpořit bezpečnější a efektivnější užívání léků v domácnosti
- snížit pravděpodobnost dekompenzace pacienta pravidelným monitorováním vybraných biomedicínských signálů, které mohou upozornit na bezprostřední ohrožení zdravotního stavu pacienta
- vyvinout technologii pro předvídání zhoršení srdečního selhání a posoudit sběr dat, který je k tomu zapotřebí
- posoudit, zda je používání technologie SHAPES spojeno se změnou neplánované zdravotní péče
- zlepšit kvalitu života účastníků a současně snížit potřebu pravidelných návštěv pacienta v nemocnici
- prozkoumat důvěru a přijetí technologie SHAPES
- zjistit, zda používání technologie SHAPES může prodloužit nezávislý a soběstačný život

Kdo výzkum organizuje a financuje?

Tuto studii organizuje Fakultní nemocnice Olomouc a Národní telemedicínské centrum. Je součástí rozsáhlejšího výzkumného programu nazvaného projekt SHAPES, který je financován Evropskou unií v rámci programu Horizont 2020 (grantová dohoda č. 857159). Projekt SHAPES sdružuje přední výzkumné skupiny, společnosti a odborníky z celé Evropy. Konsorcium projektu SHAPES tvoří 36 partnerů ze 14 evropských zemí. Podobné pilotní projekty probíhají v celé Evropě.

Co bude účast zahrnovat?

Pokud budete souhlasit s účastí v této studii, budete požádán/a, abyste se zúčastnil/a osobního rozhovoru s našimi výzkumníky ve Fakultní nemocnici Olomouc, kde Vám budou poskytnuty veškeré informace o této pilotní studii a budou Vám zapůjčeny přítroje, které jsou součástí digitálního řešení SHAPES.

Co se bude dít během účasti ve studii?

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Potenciální účastníci budou vytipováni lékařským personálem FNOL a budou pozváni na schůzku s ošetřujícím lékařem a výzkumnými pracovníky organizující pilotní studii. Na schůzce bude položeno několik otázek, abychom se ujistili, že jsou vytipovaní účastníci způsobilí, a budou požádáni o písemný informovaný souhlas s účastí v pilotním projektu a dále souhlas se zpracováním osobních údajů.

Účastníkům budou poskytnuta zařízení s označením CE a technologií Bluetooth, a to konkrétně diagnostická váha Beurer BF600, oxymetr Beurer PO60, tlakoměr Beurer BM54, EKG Beurer ME90, pedometr Xiaomi Mi Band 6, tablet Lenovo Tab M10. Zapůjčený tablet bude obsahovat staženou aplikaci SHAPES. Všechny přístroje budou řádně vydezinfikovány před předáním.

Před zahájením pilotního projektu budou účastníci proškoleni výše uvedenými pracovníky Fakultní nemocnice Olomouc, případně příslušným lékařem nebo zdravotní sestrou a bude jim poskytnut čas na to, aby si technologii dostatečně vyzkoušeli. Budou také požádáni o vyplnění několika dotazníků a poskytnutí některých základních informací. Tyto informace budou zahrnovat kontaktní údaje, případně kontaktní osobu a její údaje, věk, bydlení, rodinný stav, profesní status, vzdělání, stupeň soběstačnosti, anamnézu, zdravotní stav, laboratorní výsledky a využívání zdrojů zdravotní péče za 3 měsíce před pilotním projektem a během pilotního projektu. Některé z těchto informací budou se souhlasem získány z lékařských záznamů. Dotazníky se budou týkat kvality života, soběstačnosti, sociální podpory, zdravotní gramotnosti, aktivit denního života, užívání léků a přesvědčení o lécích.

Během 12týdenního pilotního projektu budou účastníci vyzváni, aby si pomocí přístrojů denně měřili svou hmotnost (včetně indexu tělesné hmotnosti, tělesného tuku), krevní tlak, srdeční frekvenci, saturaci kyslíkem, EKG a denní aktivitu. Tyto údaje jsou elektronicky přenášeny do aplikace SHAPES prostřednictvím Bluetooth. Účastníci si mohou prostřednictvím aplikace prohlížet své údaje a v případě potřeby mají možnost zadávat hodnoty ručně, napsat vzkaz lékařskému personálu, případně si domluvit videohovor. Účastníci budou také vyzváni k vyplnění denního dotazníku obsahujícího otázky o jejich zdravotním stavu a

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týdenního dotazníku o užívání léků. Lékový režim účastníka bude výzkumníky nahrán do aplikace a bude k dispozici k nahlédnutí jednak jako komplexní seznam všech léků, jednak jako denní seznam, který bude sloužit jako připomínka toho, co je třeba ten den užít. Účastníci budou prostřednictvím aplikace každý týden dotazováni, zda v jejich léčbě v daném týdnu došlo k nějakým změnám, aby mohl být jejich lékový režim odpovídajícím způsobem aktualizován. Pokud účastníci uvedou, že došlo ke změně jejich medikace, budou aktualizovány informace v aplikaci.

Výzkumníci budou účastníky kontaktovat telefonicky, pokud nebudou 3 po sobě jdoucí dny přijata žádná data, a každý měsíc (pokud to bude nutné), aby účastníkům pomohli s používáním technologie a odstranili případné problémy. V případě technickým potíží bude využita funkcionalita vzdálené podpory, kdy mohou výzkumníci na dálku pomoci účastníkům studie. Během pilotního projektu budou získané údaje použity k vývoji technologie, která pomůže předvídat zhoršení srdečního selhání, aby v budoucnu mohla být na základě těchto údajů předvídáno zhoršení zdravotního stavu. Během pilotního projektu bude sledováno skutečné používání aplikace SHAPES, aby se otestovala její použitelnost a zjistilo se, zda je zapotřebí další úprava či podpora. Po skončení 12týdenního pilotního období budou výzkumní pracovníci zasílat k vyplnění další sadu dotazníků, které budou podobné těm, které byly vyplňovány na začátku studie, a budou zahrnovat otázky týkající se rodinného stavu, profesního statusu a podpory, která je využívána v každodenním životě. Dotazníky administrované v této fázi budou více zaměřeny na to, co si účastníci myslí o technologii, a některé ze stejných dotazníků administrovaných dříve budou položeny znovu.

Tři měsíce po ukončení pilotního projektu budou účastníci požádáni o vyplnění následných dotazníků, přičemž se bude jednat o dotazníky, které byly již dříve administrovány.

Údaje účastníků, naměřené fyziologické hodnoty a výstupy z analýz budou nahrány do výzkumného panelu v prohlížeči výzkumného a lékařského personálu FNOL. Výzkumní pracovníci, lékaři a zdravotní sestry budou moci prohlížet klinické údaje a údaje z dotazníků každého účastníka a podle potřeby spravovat medikační režimy účastníků,

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případně účastníky kontaktovat a pozvat na kontrolní prohlídku.

Shromážděné informace o účastnících budou bezpečně a důvěrně uloženy na serverech Fakultní nemocnice Olomouc. Totožnost účastníků budou moci zjistit pouze osoby, které tvoří výzkumný tým na projektu SHAPES složený ze zaměstnanců Fakultní nemocnice Olomouc. Všichni ostatní partneři projektu SHAPES obdrží kód a nebudou moci pomocí tohoto kódu účastníky osobně identifikovat. Identifikovatelné informace budou uloženy do konce října 2023, po tomto datu budou informace deidentifikovány a uloženy po dobu dalších 5 let ve FNOL. Soubor deidentifikovaných údajů může být sdílen s ostatními členy konsorcia SHAPES, pokud je uzavřena příslušná dohoda o sdílení údajů. Anonymní agregovaný soubor údajů bude uložen na dobu neurčitou pro budoucí využití výzkumnými pracovníky.

Schéma studie je znázorněno níže.

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Pozvání

Lidé, kteří byli identifikování jako vhodní pro zařazení do studie obdrží pozvánku. Informace ohledně studie jsou poskytnuty stejně jako příležitost položit doplňující dotazy.

Souhlas

Lidé, kteří souhlasí s účastí ve studii jsou požádání, aby si přečetli a podepsali informované souhlasy, pokud jsou skutečně rozhodnuti o své účasti. Tímto se z nich stávají účastníci studie.

Zaškolení a trénink v zacházení s tabletem a přístroji

Účastníkům jsou předány tablety a přístroje. Zaměstnanci Fakultní nemocnice Olomouc (FNOL) provedou úvodní zaškolení účastníků. Účastníci dostanou čas všechny přístroje otestovat a podat zaměstnancům FNOL doplňující dotazy ohledně jejich správného ovládání.

Sběr počátečních hodnot o zdravotním stavu účastníků studie

Výzkumníci prověří zdravotní stav účastníků z doby **před** jejich zapojením do studie. Tyto informace získají na základě předložených dotazníků a kontroly zdravotních záznamů jednotlivých účastníků.

Domácí používání aplikace a přístrojů

Účastníci jsou požádáni, aby využívali aplikaci SHAPES a přístroje pro monitoring srdečního selhání v domácích podmínkách po dobu **tří měsíců**. Výzkumníci kontaktují účastníky po několika dnech, aby zjistili, zdali je potřeba jakákoliv podpora z jejich strany směrem k účastníkům studie, dále pokud budou chybět data z několika posledních dní. Účastníci naopak oznámí výzkumníkům změny ve své medikaci. Další kontakt je navázán z jedné či druhé strany dle potřeby.

Sběr informací na konci pilotní studie

Na konci studie výzkumníci prověří zdravotní stav účastníků **po** skončení studie, zdali došlo k jakýmkoli změnám oproti počátečnímu stavu. Informace jsou získány pomocí dotazníků a kontroly zdravotních záznamů jednotlivých účastníků.

Návazný rozhovor

Po skončení pilotní studie mohou být někteří účastníci požádáni o osobní rozhovor ohledně jejich zkušeností během doby studie. K tomu může dojít bezprostředně po dokončení studie, popřípadě až za několik týdnů. Všichni účastníci také obdrží několik dotazníků týkajících se jejich zdravotního stavu a jejich zapojení do studie.

Dotazníky po konci studie

Tři měsíce po skončení pilotní studie výzkumníci budou sbírat návazné informace pomocí dotazníkového šetření. Poté bude studie ukončena.

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Možné výhody účasti

Pilotní projekt může účastníkům pomoci zvýšit schopnost účinně sledovat a řídit svůj zdravotní stav.

V budoucnu může být tato technologie využívána v celé Evropě jako asistence starším lidem při sledování svého zdravotního stavu.

Do budoucna může tato studie usnadnit lékařům sledování osob na dálku a využívat algoritmy umělé inteligence k předvídání zhoršení zdravotního stavu. Tato funkce však nebude v této studii zkoumána.

Možné nevýhody účasti

Nepředpokládáme, že by účast v této studii účastníkům přinesla nějaké nepříjemnosti nebo nevýhody kromě pravidelného používání tabletu a přístrojů a případného kontaktu s výzkumnými pracovníky.

Náhodné zjištění

Ačkoli je to velmi nepravděpodobné, účastníci mohou při monitorování, které provádějí, zjistit případné zdravotní potíže. Ty by měly být nezávisle konzultovány se zdravotnickým pracovníkem.

Finanční informace

Účast v této studii nebude znamenat žádné náklady. Za účast také nebude vyplácena žádná platba. Tento projekt je financován z programu Evropské unie pro výzkum a inovace Horizon 2020 na základě grantové dohody č. 857159.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Informování o výsledcích studie

Výsledky této studie mohou být použity v dalším výzkumu, komunikačních aktivitách (např. v rámci dalšího výzkumu v projektu SHAPES, v článcích v časopisech, na seminářích a konferencích) a zprávách pro kontrolní orgány. Souhrn zjištění bude zpřístupněn po dokončení všech analýz. Nikde nebude možné identifikovat účastníky.

Ukončení studie

Výzkumní pracovníci provádějící studii mohou z jakéhokoli důvodu ukončit studii dříve, než bylo plánováno, aby ochránili bezpečnost účastníků nebo bezpečnost údajů účastníků.

Na konci 12týdenního pilotního projektu budou propůjčená zařízení (váha, EKG, monitor krevního tlaku, pulzní oxymetr, pedometr a tablet) účastníky vrácena a přístup k aplikaci SHAPES bude ukončen.

Další informace

Další informace týkající se studie si můžete vyžádat od následujících osob zapojených do projektu SHAPES.

Kontakty

Národní telemedicínské centrum Fakultní nemocnice Olomouc

Ladislav Stanke (výzkumný pracovník)

E-mail: Ladislav.Stanke@fnol.cz; Telefon: 583 443 713

Michal Štýbnar (koordinační pracovník)

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

E-mail: Michal.Stybnar@fnol.cz; Telefon: 583 443 713

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Annex 58 UC-PT3-001c Phase 5 Participant consent form

INFORMOVANÝ SOUHLAS PACIENTA

Já, níže podepsaný/á, souhlasím s účastí na projektu SHAPES, jehož popis, jakožto i účel a rizika jsou popsány v dalším textu Vašeho informovaného souhlasu. Lékař, který je součástí řešitelského týmu usoudil, že splňujete požadavky pro účast v uvedeném projektu.

Název projektu:

Monitoring pacientů se srdečním selháním (řešeno v rámci projektu SHAPES)

Oblast monitorace:

Ověření přínosu digitálních technologií v oblasti monitorace pacientů v domácím prostředí

Hlavní řešitel: RNDr. et RNDr. Ing. Ladislav Stanke, Ph.D.

Spoluřešitelé: MUDr. Renáta Aiglová, Ph.D., MUDr. Jakub Flašík, Mgr. Michal Štýbnar

Pracoviště řešitel a spoluřešitelů: Národní telemedicínské centrum (NTMC), Fakultní nemocnice Olomouc (FNOL), I. Interní klinika, Fakultní nemocnice Olomouc

Rizika projektu:

Riziko poškození pacienta nelze nikdy zcela vyloučit, nicméně v prezentovaném případě je minimalizováno na velice nízkou úroveň. Tablet i použité přístroje, které přijdou do kontaktu s pacientem, jsou komerčně dodávané přístroje, které mají označení CE, nebo FDA approved. Případná rizika by vyplývala zejména z využití nevhodných zdrojů pro dobíjení baterií, kde by hrozilo případné poškození baterií, které může v některých případech vést k jejich zahřátí či až zahoření, což je riziko

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většiny bateriových přístrojů. Nicméně tato rizika jsou jednotlivými výrobci rovněž minimalizována s využitím ochranných obvodů detekujících možná přetížení, kontrolujících teplotu apod. U uživatele, který postupuje dle návodu, případně instrukcí a využívá správné napájecí zdroje (pro daný přístroj určené) je toto riziko ještě nižší.

Projekt SHAPES (The Smart & Healthy Ageing through People Engaging in Supportive Systems) tak nepředstavuje žádná rizika pro Váš zdravotní stav a nemůže přispět k jeho zhoršení. Projekt je založen na měření biomedicínských signálů, konkrétně jde o EKG, krevní tlak, hmotnost, saturaci krve kyslíkem a počet ušlých kroků za den. Měření probíhá s pomocí přístrojů k tomu určených, které budou zapůjčeny z pracoviště řešitele.

Pokud běžně nevyužíváte žádné informační a komunikační technologie, jako je počítač, tablet, chytrý telefon apod., tak Vám může na počátku trvat, než získáte plnou jistotu v ovládání všech přístrojů a tabletu s poskytnutým programovým prostředím. Nicméně není nutné se této fáze obávat, jelikož personál je ochoten Vám v případě nejasností či nejistoty s čímkoliv poradit.

V případě dodržení instrukcí k jednotlivým zapůjčeným přístrojům není známo, že by se jednalo o přístroje, které by Vás mohly jakkoli ohrozit.

Samotný monitoring probíhá s využitím tabletu, na kterém je nainstalována telemedicínská aplikace (Medimonitor) – u některých pacientů, kteří nejsou zvyklí pracovat s ICT technologiemi může trvat déle se naučit aplikaci ovládat, byť bylo pracováno s využitím znalostí a dobrých praxí v oblastech uživatelské zkušenosti (UX – user experience) a přístupnosti, které by měly zmíněné riziko minimalizovat.

Za účelem komunikace je využíváno wi-fi sítě, která patří pacientovi. V tomto ohledu není možné vždy zaručit stabilitu a dostupnost sítě. Pro krátkodobé výpadky jsou data ukládána v tabletu. Při poruše komunikace mezi jednotlivými přístroji a tabletem je možné některé hodnoty (netýká se např. EKG záznamu) zadat ručně.

Účel a popis projektu:

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- Ověření možnosti telemedicínského monitoringu v místě bydliště pacienta pomocí vybraných přístrojů.

- Ověření schopností telemedicínské aplikace vyvinuté ve FNOL (Medimonitor) pro komunikaci s jednotlivými přístroji, agregaci a odeslání dat na server FNOL.

- Ověření možnosti zobrazování varování na základě detekce překročení prahů měřených hodnot (bude probíhat prospektivně)

- Ověření možnosti nalezení algoritmu (případně vytrénování neuronové sítě) pro včasnou detekci blížící se dekompenzace na základě naměřených dat (tato část proběhne retrospektivně po náběru všech dat z přístrojů zapůjčených pacientům).

V rámci projektu bude testována možnost vzdálené monitorace pacientů s chronickým srdečním selháním. Za tímto účelem je pacientům zapůjčena sada přístrojů zakoupených z prostředků mezinárodního projektu SHAPES, na kterém NTMC (Národní telemedicínské centrum) FNOL aktuálně participuje. Konkrétně se jedná o váhu, mobilní EKG, chytré hodinky (použity za účelem využití pedometru pro měření počtu ušlých kroků během každého dne, kdy bude monitorace probíhat), tlakoměr a oxymetr. Každý z těchto přístrojů je schopen pomocí Bluetooth odeslat naměřená data do tabletu (v případě selhání datového přenosu je možné hodnoty zadat i manuálně), který budou mít pacienti rovněž k dispozici. Cílovou skupinou projektu je stárnoucí populace, přičemž hlavním cílem projektu je podporovat aktivní stárnutí s využitím moderních digitálních technologií. V předložené studii se konkrétně jedná o skupinu seniorních pacientů se srdečním selháním. Mezi dílčí cíle projektu patří ověření přínosu telemedicínské aplikace FNOL (Medimonitor) pro akvizici, agregaci a odesílání dat naměřených pomocí přístrojů u pacienta na server FNOL. Pseudonymizovaná (pozměněná takovým způsobem, aby neobsahovala konkrétní jména pacientů) data jsou dále využita jako vstupy pro připravované algoritmy, případně neuronové sítě, které mají za cíl prevenci dekompenzace jejich stavu.

Postupy používané v rámci projektu:

- Odběry krve pro kvantifikaci markerů relevantních pro diagnózu a pro titraci medikace.

- Administrace dotazníků (prezentovány osobně i elektronicky na zapůjčeném tabletu).

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- Měření pomocí zapůjčených zařízení (váha, mobilní EKG, chytré hodinky, tlakoměr a oxymetr) – 1 denně dle instrukcí lékaře a výzkumného týmu).

- Využívání telemedicínské aplikace (pro akvizici, agregaci a odesílání naměřených dat, vedení videokonzultací).

- Statistická analýza výsledků.

- Hledání algoritmů, učení neuronových sítí pro predikci dekompenzací.

Prospěšnost projektu:

Pro zlepšení námi vyvíjených digitálních technologií a služeb z oblasti elektronického zdravotnictví je pro nás cenná zpětná vazba od uživatelů-pacientů tak abychom mohli naše služby dále zdokonalovat směrem k uživatelské přívětivosti, proto jste žádáni, abyste otestovali naši telemedicínskou aplikaci, včetně její schopnosti propojení s dalšími zařízeními, které byly popsány výše. Vámi naměřené hodnoty mohou rovněž pomoci lépe pochopit průběh Vašeho onemocnění. Tyto hodnoty budou dále důkladně analyzovány s využitím pokročilých algoritmů či neuronových sítí.

Kdo se může studie zúčastnit:

Do studie se můžete přihlásit, pakliže jste byly diagnostikováni se srdečním selháním a jste starší 60 let.

Kdo se nemůže studie zúčastnit:

Vzhledem k povaze projektu se nemohou zapojit pacienti s kognitivními poruchami (např. Alzheimerova choroba) a pacienti, kteří nemají v místě bydliště připojení k internetu (bezdrátovou wi-fi síť pro připojení zapůjčeného tabletu), které umožní přenos naměřených hodnot na servery FNOL.

Povinnosti pacienta:

Jako pacient zapojený do výše popsaného projektu máte povinnost sdělovat lékařskému a vědeckému personálu všechny informace o svém zdravotním stavu a žádné informace nezamlčovat.

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Prohlašuji tímto, že jsem pročetl/a všechny výše uvedené informace týkající se popsaného projektu – a těmto jsem porozuměl/a.

Byl/a jsem dostatečně informován/a o cílech, průběhu, účelu a rizicích vyplývajících z účasti na projektu. Jsem si vědom/a, že kdykoli v průběhu i po ukončení mojí účasti na projektu je lékař odpovědný za poskytnutí doplňujících informací o jakékoliv případné zdravotní újmě související s mojí účastí v projektu nebo informací, které mohou ovlivnit moji ochotu v projektu setrvat.

Souhlasím se svou účastí v projektu SHAPES.

Jsem si vědom/a toho, že odstoupení nebo vyřazení z projektu SHAPES, ať už z jakéhokoli důvodu, žádným způsobem neovlivní kvalitu zdravotní péče, která mi bude poskytována. Podpisem tohoto informovaného souhlasu se nevzdávám žádného ze svých zákonných práv.

Kdykoliv mohu uplatnit svá práva u svého ošetřujícího lékaře a požádat v souladu se zákonem o přístup k záznamům a případně je opravit, pokud jsou nepřesné. Projekt SHAPES je prováděn v souladu s právními předpisy České republiky.

Budu-li chtít získat jakékoliv doplňující informace o projektu SHAPES, mohu se obrátit na svého lékaře. Obdržím jeden originálně podepsaný stejnopis tohoto dokumentu.

Po ukončení monitorace je pacient povinen vrátit tablet a všechny zapůjčené přístroje pracovníkovi, který mu je vydal.

Jméno a příjmení pacienta Podpis pacienta

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(Hůlkovým písmem)

_____
_____

Datum:_____ (mes-dd-rrrr)

Jméno a příjmení informujícího lékaře Podpis lékaře

(Hůlkovým písmem)

_____
_____

Datum: _____ (mes-dd-rrrr)

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Annex 59 UC-PT3-001c Phase 5 privacy notice

Souhlas se zpracováním osobních údajů

Subjekt údajů:

Jméno a příjmení: **……**

Datum narození: ……

Správce:

Fakultní nemocnice Olomouc

se sídlem: I.P.Pavlova 185/6, 779 00 Olomouc

zastoupna: prof. MUDr. Romanem Havlíkem, Ph.D.

(“**Zpracovatel**”)

SHAPES

Maynooth University

Maynooth,

Co. Kildare,

Irsko.

(“**Správce**”)

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Účely zpracování:

Vaše osobní údaje budou zpracovávány pro účely uskutečnění sběru dat pro mezinárodní projekt SHAPES (dále jen „projekt **SHAPES**“), v rámci kterého bude testována možnost vzdálené monitorace pacientů s chronickým srdečním selháním.

Rozsah zpracovaných osobních údajů:

Vaše osobní údaje budou zpracovány v následujícím rozsahu: jméno, příjmení, datum narození,……. Vaše osobní údaje budou zpracovávány pouze v rozsahu nezbytném pro naplnění účelu a v souladu s ním.

Právní základ:

Vaše osobní údaje budou zpracovány na základě písemného souhlasu, který může být kdykoli odvolán písemně nebo e-mailem prostřednictvím výše uvedených kontaktních údajů a to v souladu s příslušnými právními normami o ochraně osobních údajů, zejména v souladu s Nařízením Evropského parlamentu a Rady (EU) 2016/679 ze dne 27. dubna 2016 o ochraně fyzických osob v souvislosti se zpracováním osobních údajů a o volném pohybu těchto údajů a o zrušení směrnice 95/46/ES (obecné nařízení o ochraně osobních údajů, či GDPR). Odvoláním souhlasu není dotčena zákonnost předchozího zpracování.

Poskytnutí osobních údajů je zcela dobrovolné. S odmítnutím udělení souhlasu nejsou spojeny žádné negativní důsledky. Zpracování osobních údajů je však nezbytné pro Vaše zařazení do projektu SHAPES a bez udělení souhlasu není účast na projektu SHAPES možná.

Příjemci:

Správce SHAPE nebude znát Vaši totožnost, jelikož mu budou data předávána v pseudoanonymizované podobě. K Vašim osobním údajům bude mít přístup pouze Váš lékař a vědecký tým Fakultní nemocnice Olomouc. Osobní údaje mohou být také zpřístupněny kontrolním a jiným orgánům při výkonu jejich kontrolní nebo jiné úřední činnosti.

Předávání osobních údajů do třetí země:

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Vaše osobní údaje nebudou předávány do třetích zemí.

Doba uchování:

Pokud nebude Váš souhlas se zpracováním osobních údajů odvolán, budou osobní údaje uchovávány a využívány po dobu provádění projektu SHAPES, případně v nezbytném rozsahu i po jejím skončení s ohledem na ochranu oprávněných zájmů správce.

Práva subjektu údajů:

Jako subjekt údajů máte právo na přístup k osobním údajům, právo na jejich opravu nebo výmaz (pokud bude odvolán souhlas nebo uplyne doba uchování), popřípadě na omezení zpracování a na přenositelnost osobních údajů k jinému správci. Máte rovněž právo požadovat po Správci informace o způsobu, rozsahu a účelu zpracování osobních údajů a Správce má povinnost Vám tyto informace sdělit neprodleně, nejpozději do 1 měsíce od obdržení žádosti. Veškeré žádosti budou podávány prostřednictvím výše uvedených kontaktních údajů. Dále máte právo obrátit se kdykoliv se svým podnětem nebo stížností na Úřad pro ochranu osobních údajů (www.uoou.cz).

Souhlas:

Prohlašuji, že jsem byl/a řádně informován/a o výše uvedeném zpracování osobních údajů, jsem si vědom/a svých práv a svobodně s tímto zpracováním souhlasím.

Datum: ……..

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Podpis: _____

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Annex 60 UC-PT3-COPD MOMENTUM blueprint summary

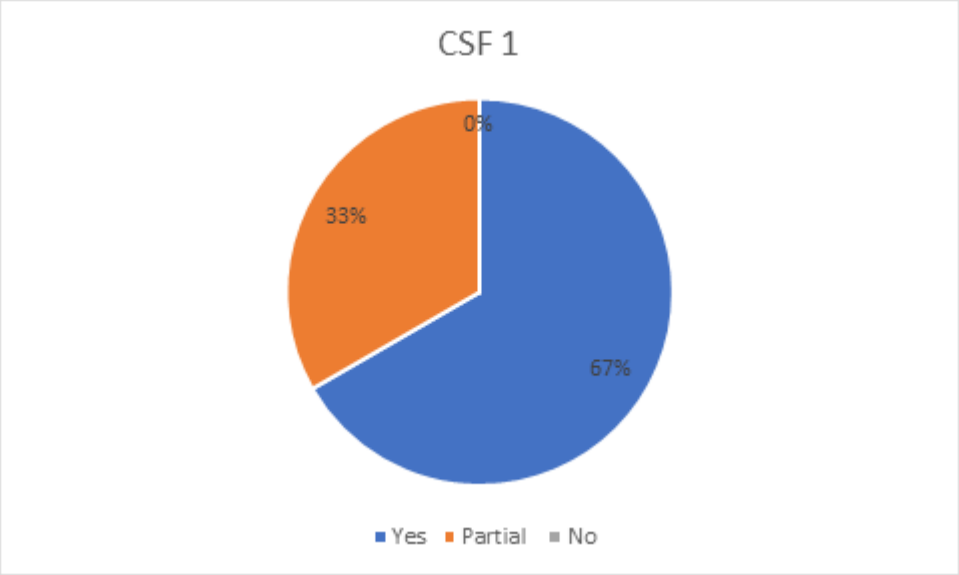
Momentum summary – COPD use case

1. Ensure that there is cultural readiness for the telemedicine service. (Cultural readiness in a healthcare system or organisation has three components:

. A set of beliefs and perceptions that influence establishment of priorities

. Attitudes and norms that affect behaviour including decisions, ideas and practices that determine how a person, organisation, society will respond to the environment.

· Values and current needs that determine whether telemedicine will be viewed positively or negatively)



In comparison with previous years it seems that the cultural readiness has increased. This is probably due to the COVID-19 pademic together with new generation of physicians that would like to use modern technologies in their practise. So we can conclude that the cultural readiness exist.

2. Come to a consensus on the advantages of telemedicine in meeting compelling need(s)

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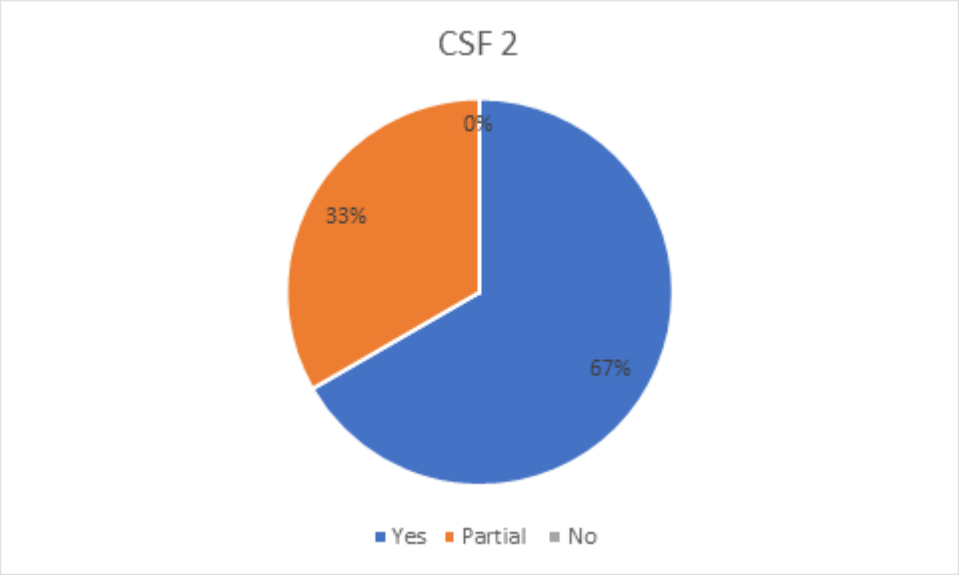
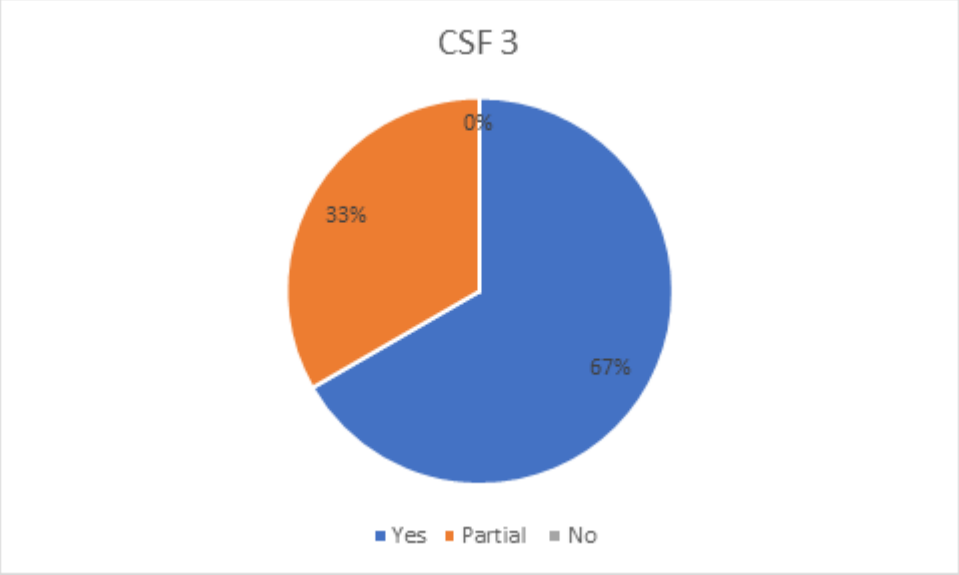


The consensus in this matter is slightly above the one observed in the HF case. This is probably due to the novel of some of the hardware and sofware tools available for the COPD use case.

3. Ensure leadership through a champion (A champion is a person who is committed to the telemedicine idea or initiative or service.)



Majority of telemedicine users believes that there is an existent leadership covered by the person of a Champion. One third of the people believes that at least partially such a leadership exists.

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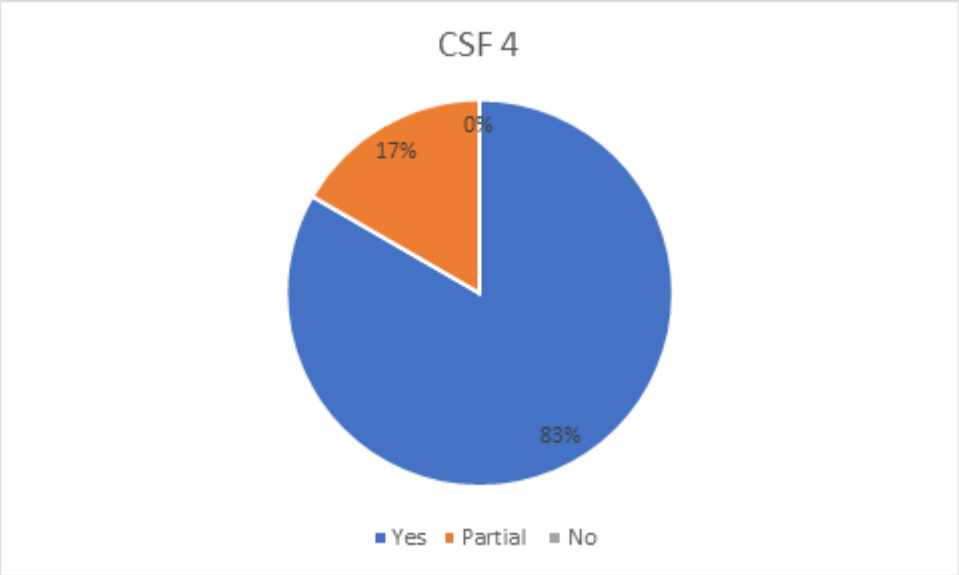
4. Involve healthcare professionals and decision-makers (two aspects of the new telemedicine system or service are to be considered:

. the organisation, workflow and work structure, and

. the economic components)



All the relevant stakeholders are involved within the planning, design and implementation phases.

5. Put the patient at the centre of the service (Telemedicine services can benefit patients in two ways: through patient involvement in

their own healthcare, and through the advantages it brings to their families, and their informal or formal carers.)

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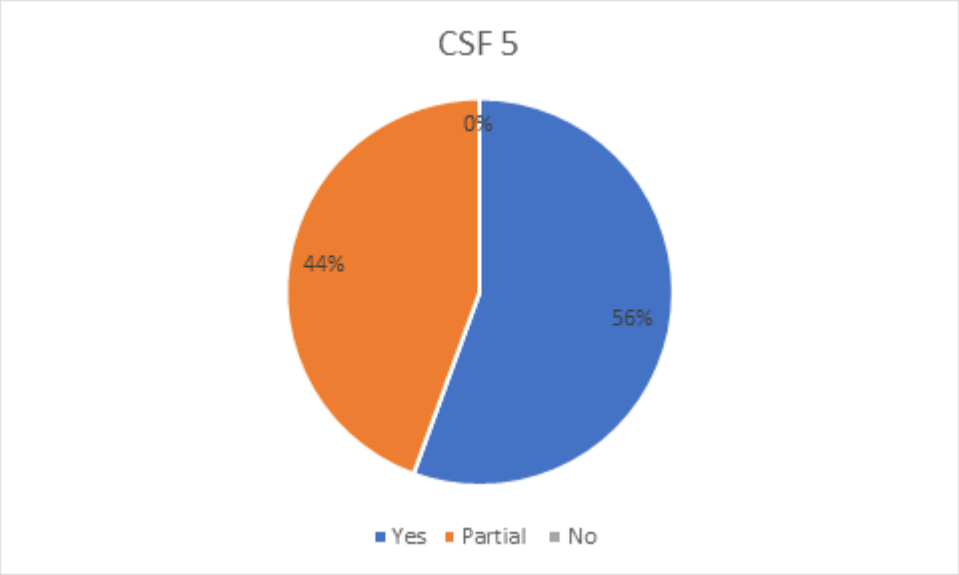

Formal carers are usually well involved in the whole telemedicine service. Nevertheless, involvement of the informal carers can be still increased. Some of the reasons why the informal carers are not yet involved are not fully in the control of the telemedicine service creators or operators. These are mainly economic and education reasons. The change of the informal carer's attitude are steadily changing, however, this is a longterm issue. Nevertheless, the results are somewhat more positive than in comparison with the HF use case.

6. Ensure that the technology is user-friendly (User-friendliness is a combination of attributes from both the technical and human

dimensions.)

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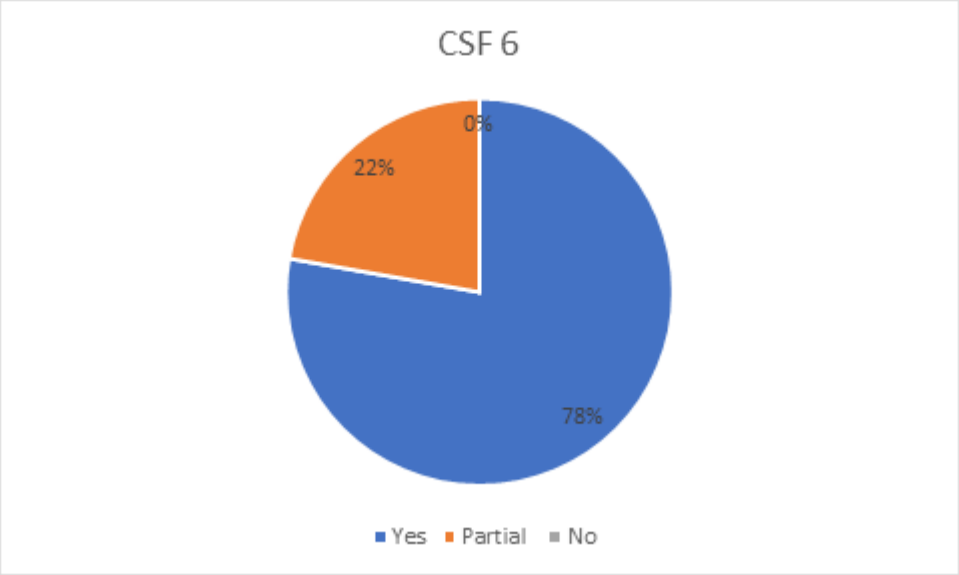

User experience is being steadily improved by the team consisting of both IT experts and psychologist. Design is based on the good practices and is supported by experiments on focus groups created by the real users. Therefore, this area of interest is well covered and possible issues can be resolved immediately based on the user feedback.

7. Pull together the resources needed for deployment (There are essentially four major types of resources that need to be made available:

· Financing

· People

· Information

· Time.)

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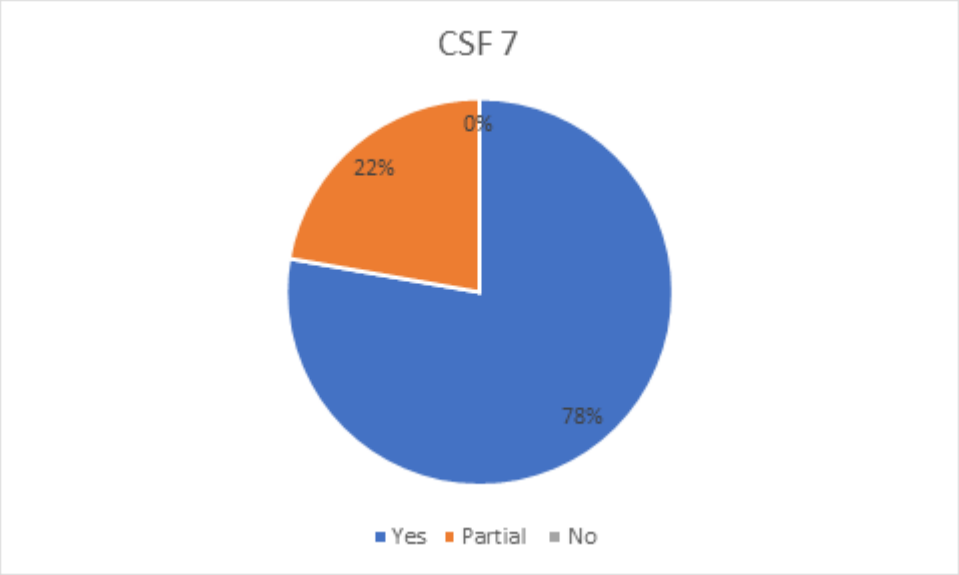
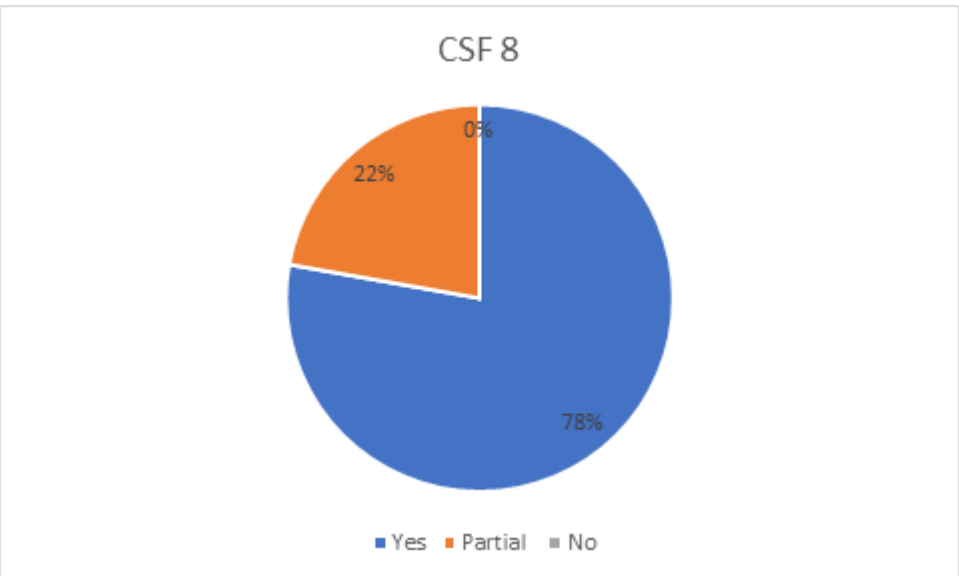


Participant's were quite optimistic. This is possibly due to their involvement only in their specific parts of the project. In general, such projects are extremely challenging in all of the abovementioned aspects. Especially experienced IT experts willing to be employed in the government sector are extremely difficult to find. Consequently, the existing IT teams suffer by overload. This is probably the major bottleneck of such project. A possible solution could be motivating of future IT experts via internships in the telemedicine IT team.

8. Address the needs of the primary client(s) (The primary client is the initial main partner in implementing the telemedicine service or in designing the telemedicine tool.)



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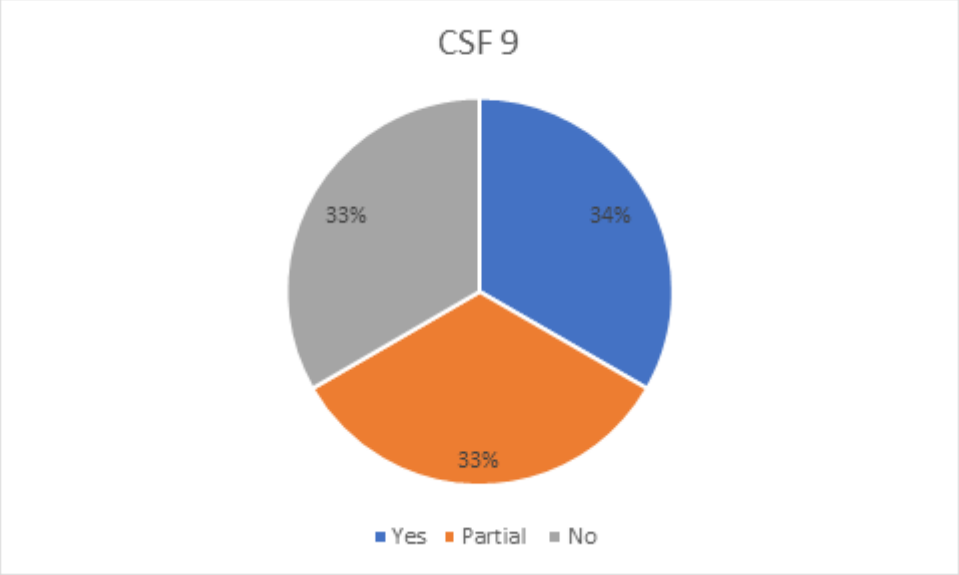
User centric approach is applied in all stages of the development process, therefore, consensus is very positive in this aspect.

9. Prepare and implement a business plan (A business plan is a written document which results from the careful analysis of available data.)



Implementation of a business plan was not envisaged in this stage of a project. Moreover, a state owned hospital is not elligible to sell any hardware or software solutions, therefore, it is not important to create any business plan. This task should be addressed to the different stakeholders of the healthcare system, especially the insurance companies.

10. Prepare and implement a change management plan (A change management plan enables healthcare professionals to understand these changes and accept innovation in their daily work.)

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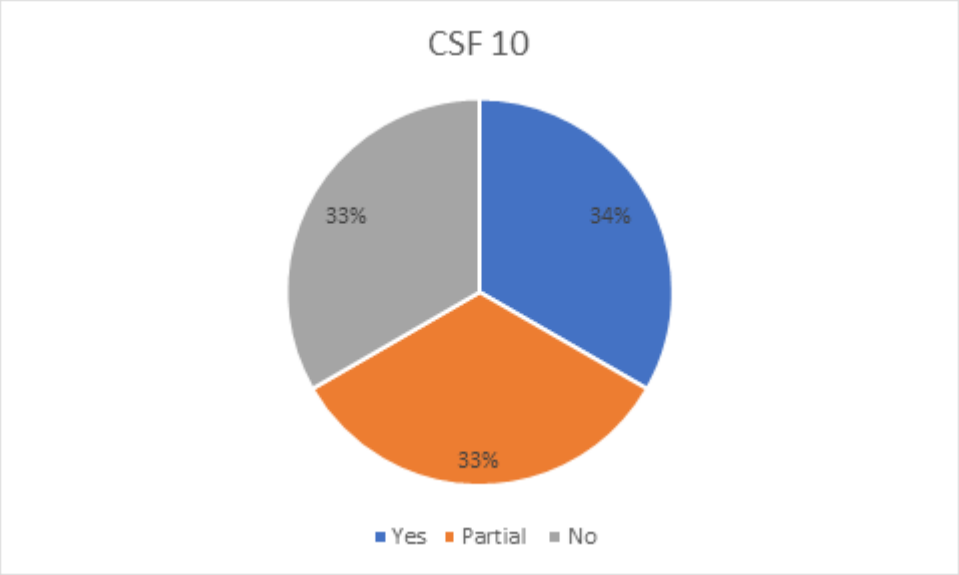

A change management plan is still in progress. And the workflow for regular updates is being tested.

11. Assess the conditions under which the service is legal

(Four aspects are to be considered:

. The telemedicine service is regarded by the authorities as an appropriate way to offer healthcare services.

· The telemedicine service is regarded as legal by carrying out a legal risk assessment.

· The telemedicine service is covered by law or if it is not inhibited by law or by bodies with competence in the telemedicine field.

· The telemedicine service is in accordance with general requirements for best practice in medicine.)

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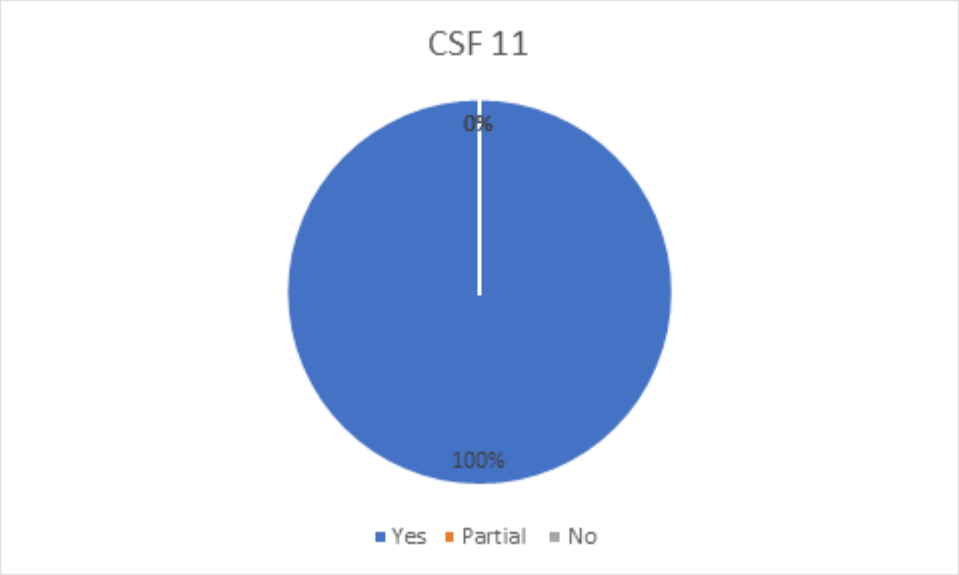
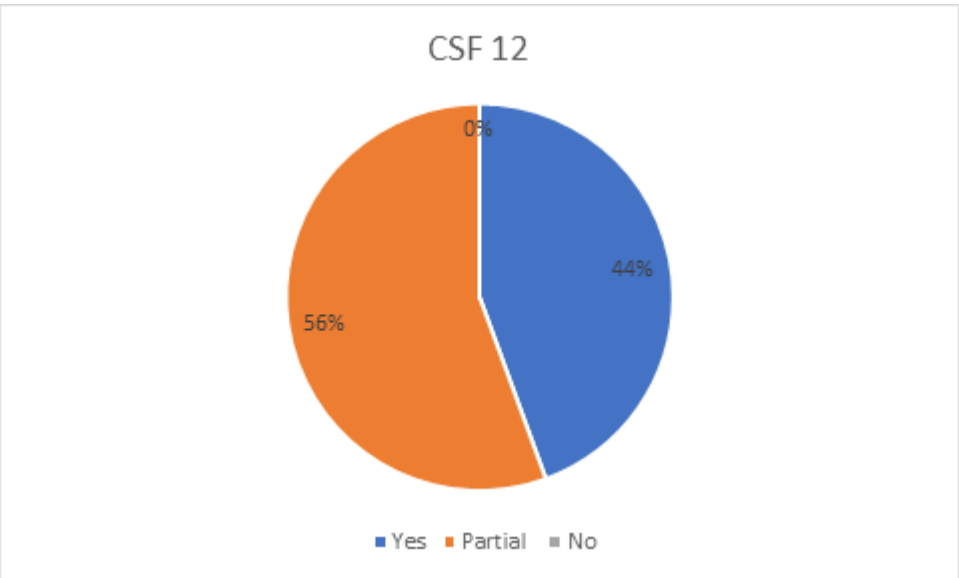


There is a single minded consensus, that the legal issues of the system are well covered by the experts in the fields of the general and medical law.

12. Guarantee that the technology has the potential for scale-up (Telemedicine doers have to take into account what actions are needed to make the leap from pilot to large-scale deployment in both technological and commercial terms. The potential for scale-up can be achieved by using either standard technologies or technologies that are similar and yet are produced/offered by a range of suppliers.)



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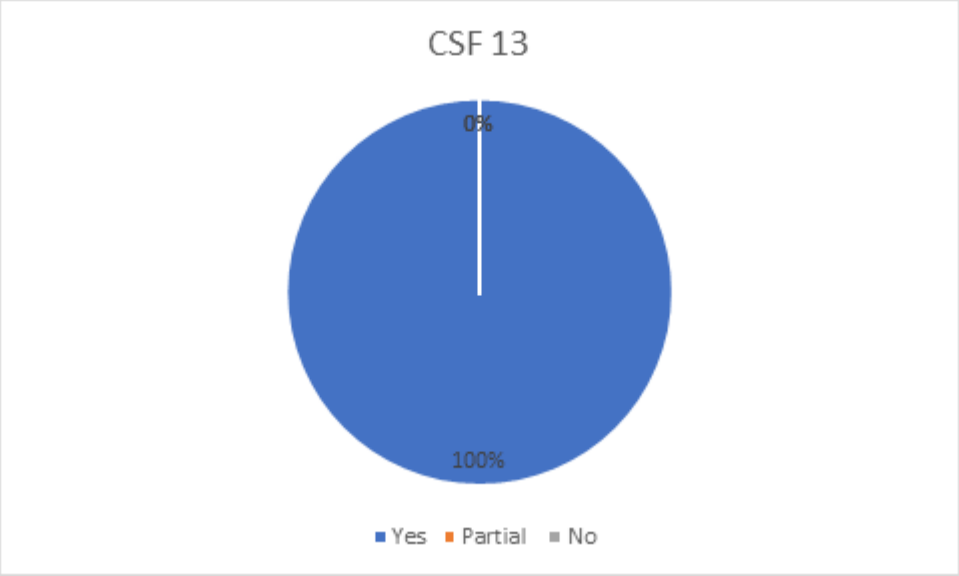
Scale-up of the telemedicine solution relies in the majority on the interest of insurance companies. Nevertheless, landscape is prepared for the implementation of telemedicine solutions and should be part of the local policies, strategies and action plans.

13. Identify and apply relevant legal and security guidelines (This critical success factor reminds telemedicine doers to look for useful relevant guidelines on legal and security matters.)



During the COVID-19 pandemic government institutes involved in the cybersecurity issued several guidelines related to the realm of telemedicine and the requirements mentioned there are implemented in the telemedicine solution.

14. Involve legal and security experts (This critical success factor incorporates involving and asking advice from legal and security

experts when needed, to minimise the risk of experiencing legal and security problems when deploying a telemedicine service.)

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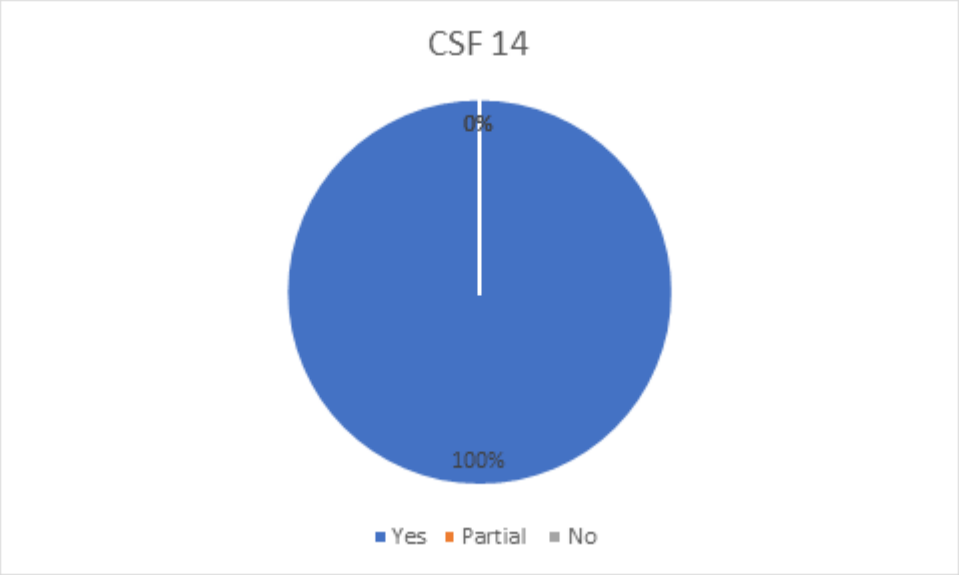
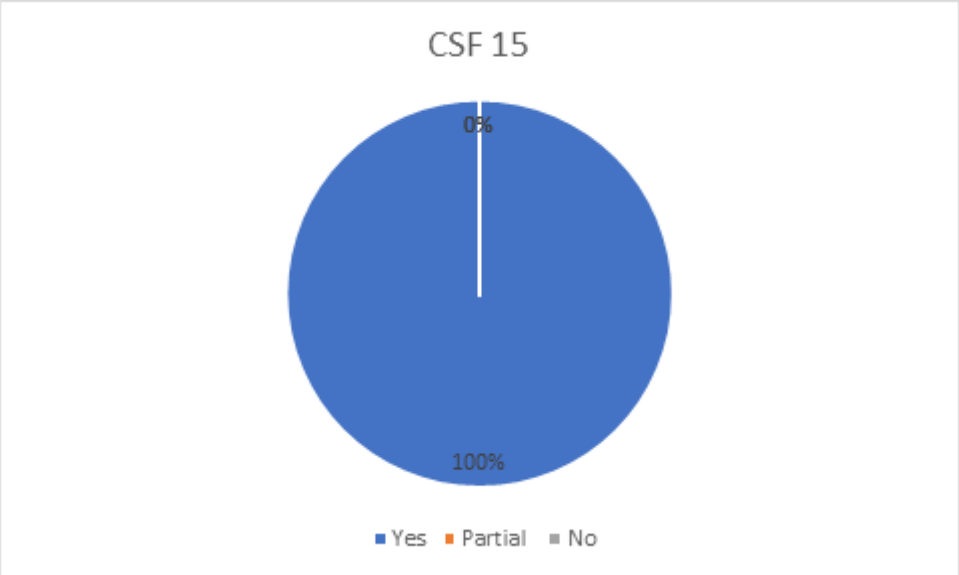


Lawyers and cybersecurity experts are involved through the whole development process and are prepared to consult the issues when needed.

15. Ensure that telemedicine doers and users are privacy aware (Privacy awareness is related to privacy by design. It is therefore important to make sure that everyone who is involved maintains a high degree of privacy awareness and knows the regulations – esp. GDPR and acts in accordance with them.



Telemedicine system designers are well aware about the constraints of GDPR and related privacy issues and are preparing the telemedicine system in concordance with the requirements. However, we cannot be 100 % sure that the users are also as experienced. Creators will make all of the relevant information available directly from the application, so the important things can be easily find and understood, especially for the ageing and

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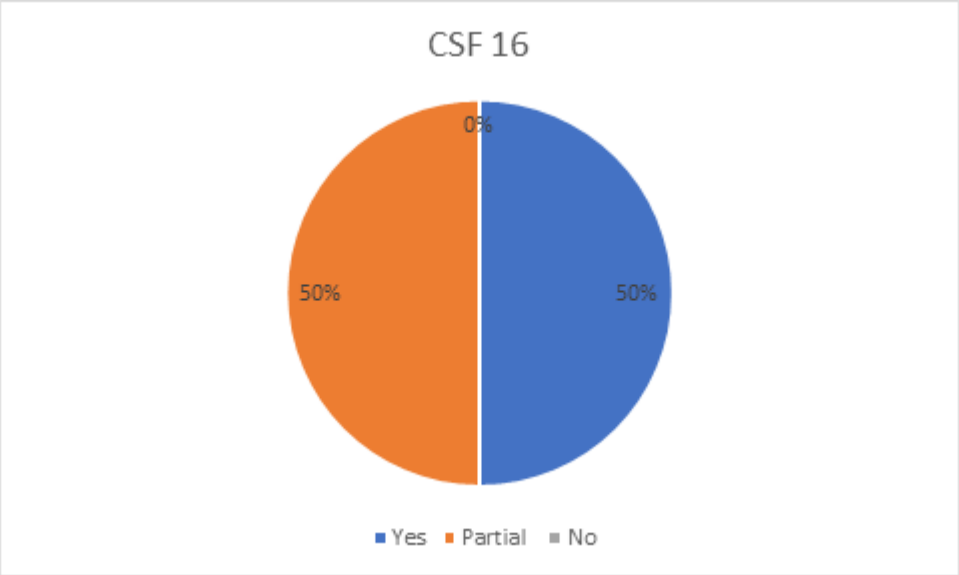
challenged people. Future improvements in this area are expected as this topic is steadily changing and evolving.

16: Ensure that the appropriate information technology infrastructure and eHealth infrastructure are in place (Ensuring that the appropriate IT infrastructures and eHealth infrastructures are available so that the telemedicine implementation can rely on these infrastructures from the initial deployment to the last stage of the scale-up phase.)



Physical infrastructure is already available and prepared for a scale-up process. Currently the readiness of physical infrastructure is not as challenging as the human resources issues in the field of ICT.

17. Put into place the technology and processes needed to monitor

the service (Service monitoring includes all activities needed to govern IT, such as maintenance plans, security issues, service continuity, a help desk, and access management.)

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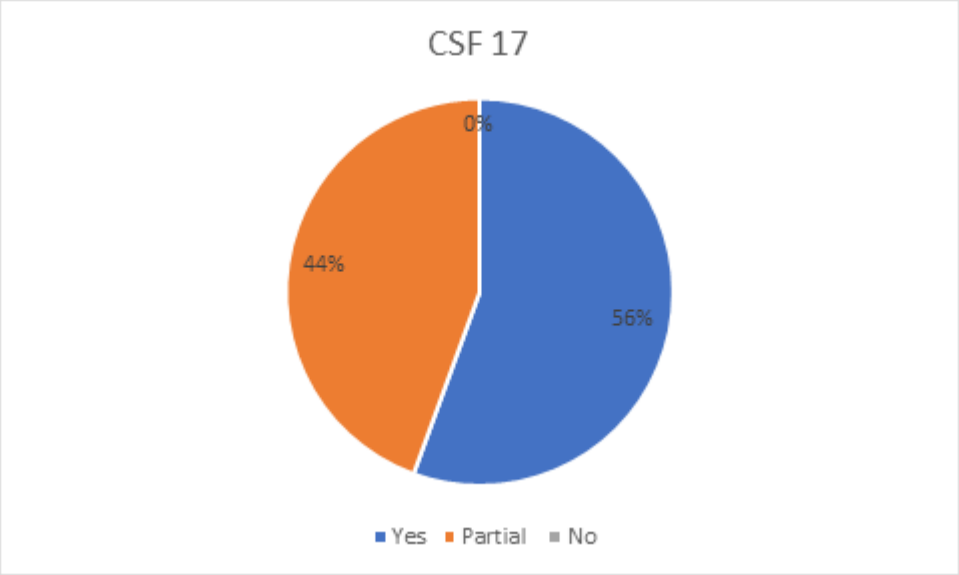
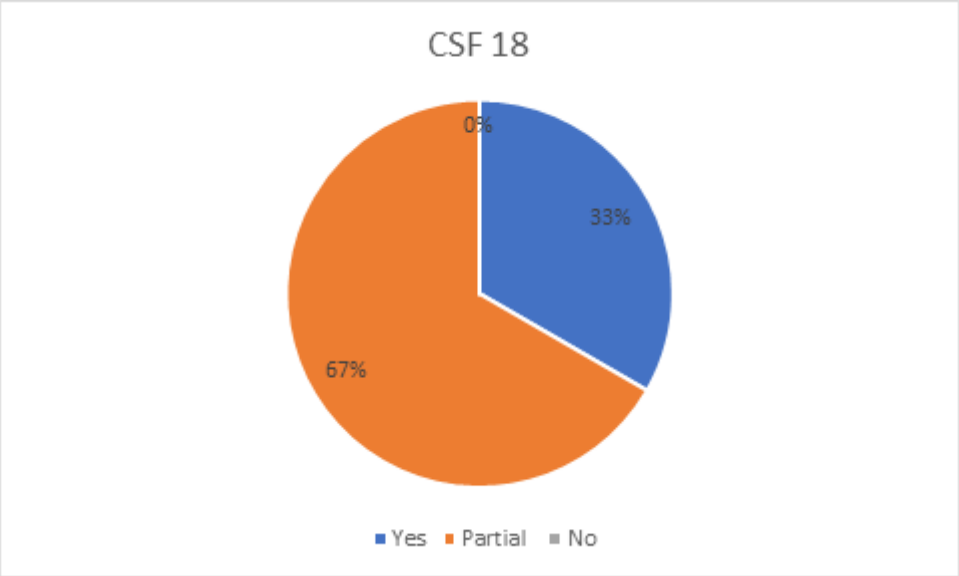


Monitoring services are still in the phase of preparation as the majority of human resources are currently focused for the development of the telemedicine solution. It is expected that the situation will change as soon as the development of main parts of the system will be finished.

18. Establish and maintain good procurement processes (Good procurement processes involve two main focus areas: content and process. With regard to content, any product or service that is contracted out may be delivered with a wide range of quality variability. With regard to process, it is important to have a formal method of procurement for the purchase.)



Procurement processes for the public organization, like the university hospitals, are well defined by the Czech law. Though, they are defined and human resources needed for their implementation already allocated, sometimes these processes can be rigid and slow.

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Nevertheless, they are mandatory for our organization. No major changes in their current state of implementation are expected in the near future.

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Annex 61 UC-PT3-COPD NASSS-CAT (long version)

NASSS-CAT (LONG VERSION)

Assessing and handling complexity in technology proJECTs

Introduction

This evidence-based guide has been developed from a systematic literature review and extensive primary research. It is designed to help you reflect on your ideas and goals for a **technology-supported change project** in health or social care and work towards a project plan. A high proportion of such projects fail, but there are ways of improving the chances that your project will succeed.

Technology projects are characterised by **complexity** – i.e. they have multiple interacting components that cannot be tightly controlled. Complex projects are unpredictable and risky, hence less likely to succeed than simple ones. This guide will help you to identify the different areas of complexity (that is, the uncertainties, interdependencies and possible unintended consequences) in your project and think of ways to reduce or manage these (e.g. by making some aspects simpler or mitigating risks)

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How to use this guide

We recommend that you start using this guide as early as possible and keep revisiting it as your project unfolds. It will only take you a few minutes to skim through it and gain an initial orientation, but working carefully through the detail of the guide will take much longer. There is no 'right' way to use the guide; it is intended to prompt conversations and help you bring together different areas of expertise (such as clinical, technical and business development). For example, you could assign different parts of the guide to different people to fill in in detail, then reconvene and compare your responses. You may wish to employ a facilitator to run a workshop with the project team.

Structure of this guide

PART 1 of this guide is divided into 6 domains, each in two parts:

- **A free-text box for you to present this domain in your own words**. This will help surface the issues, technologies, people and activities relevant to *your* project and how they seem to fit together. Make it flow like a story (i.e. write in sentences rather than using tables or bullet points), so as to capture the messiness (non-linearity) of the project. Telling a brief story will allow you to draw out the 'plot' of what's happened so far and identify interdependencies and tricky issues that may contribute to the project's success or failure (or something in between).
- **Some questions to help you estimate key areas of complexity** (most of which should have come up in your narrative). The more red boxes you tick, the more complex this domain is (though the boxes don't carry equal weight, so adding up the ticks won't give you a quantitative score). The top-level questions are quite broad, but if a question is particularly relevant to your proposed project, you can 'drill down' with the more detailed questions. Ideally, you should be able to back up your answers with evidence, such as published figures or research, or data you have collected yourself (for example from interviews or focus groups). Some questions will not apply to your project, so tick 'not applicable' for these. If a question seems relevant but you're not sure how to answer it, tick 'don't know' – and perhaps discuss this one with colleagues later. Can you distinguish the things you don't *yet* know (but could find out) from the things that are unknowable (inherently uncertain), which you have to handle with creativity and judgement as the project unfolds?

  Note: [1] No single individual will be able to answer all the questions but you should find that if you involve a range of people across your organisation, you will be able to address all the domains. For each domain, we've suggested who might be best placed to answer the questions. [2] The tick-box questions will give an artificially structured and linear perspective. Bear in mind that complex change is an inherently messy and unpredictable process, but the box-ticking may help you find a 'way in' to your narrative.

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PART 2 is designed to help your team handle the different kinds of complexity in your project. It consists of prompts to help you plan and manage an implementation project and think about how to

- **Reduce complexity** where possible (e.g. by limiting the scope of the project)
- **Respond to complexity** where it can't be reduced (e.g. by bringing staff together to make sense of a situation, strengthening relationships, or collecting and analysing real-time data)

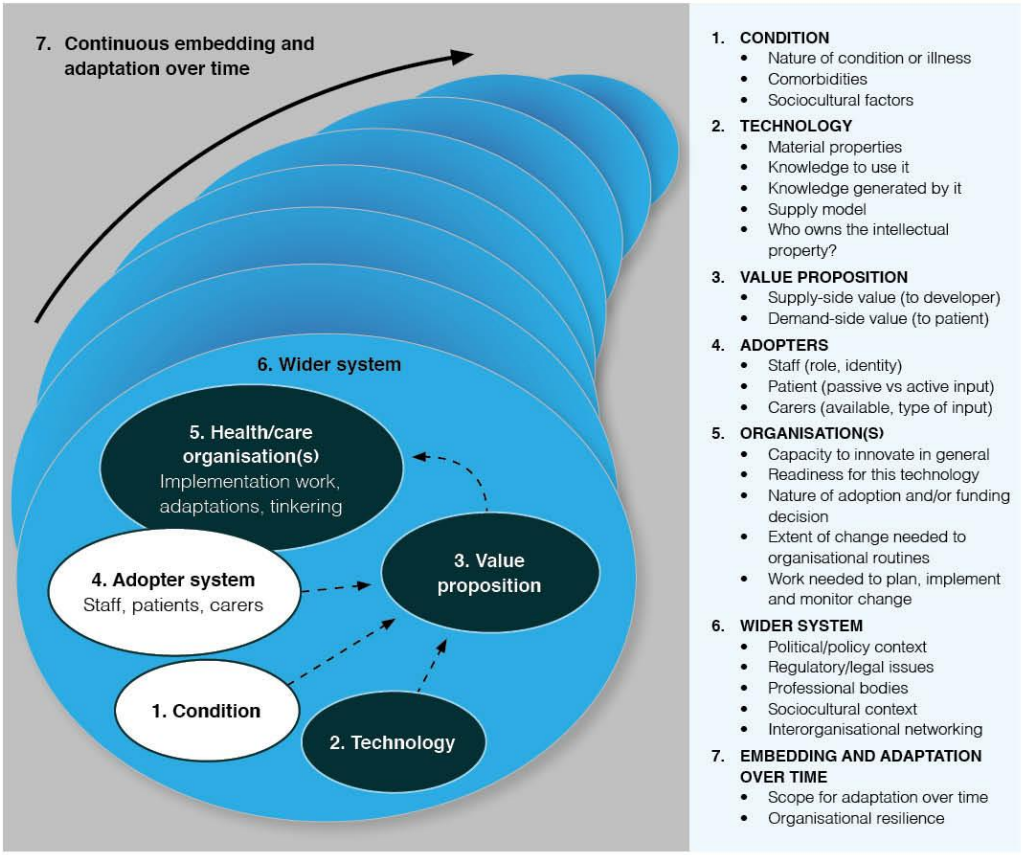

Diagram: The NASSS framework (© Greenhalgh at al J Med Internet Research 2017; 19 (11): e367)

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PART 1: ANALYSING COMPLEXITY IN YOUR PROJECT

THE ILLNESS OR CONDITION
[a clinician, social worker or researcher might be the best person to complete this section]

Briefly describe the condition(s) for which the innovation or technology has been designed (e.g. heart failure, mental health, social isolation). In some situations, there won't be a specific illness or condition.

The following questions should help you summarise whether the condition or illness is straightforward, well-understood, follows a predictable course and has predictable implications for care. This isn't about whether the illness is serious*, but whether you can predict what will happen next. For suggestions for responding to complexity in this domain, see page 980.*

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IDENTIFYING COMPLEXITIES IN THE ILLNESS OR CONDITION:	*Agree*	*Disagree*	*Not applicable or don't know*
There are significant uncertainties about the illness or condition *Additional detail – e.g.* ➢ *The condition is not clearly defined, or too little is known about it to inform planning* ➢ *The population affected by the condition is not well-defined* ➢ *The condition affects people in different ways, so a 'one size fits all' solution is unlikely to work* ➢ *People with the condition are likely to be under the care of multiple professionals and/or in more than one care pathway*		*X*	
Many people with the condition have other co-existing illnesses or impairments that could affect their ability to benefit from the technology or service *e.g.* ➢ *Physical or mental co-morbidities* ➢ *Cognitive impairment*		*X*	
Many people with the condition have social or cultural factors that could affect their ability to benefit from the technology or service. *e.g.* ➢ *Poverty* ➢ *Social exclusion e.g. drug use, homeless* ➢ *Religious restrictions or expectations on how they manage their illness* ➢ *Low health literacy (limited ability to understand health issues and how to handle them)* ➢ *Low system literacy (limited understanding of how services work and how to navigate them)* ➢ *Low digital literacy (limited ability to use, or learn to use, new IT products)* ➢ *Unable to understand the language used by professional staff*		*X*	
The population with the condition, and/or how the condition is treated, is likely to change significantly over the next 3-5 years	*X*		
SUMMARY: The illness or condition has significant complexity which is likely to affect the project's success			

Yes ☐ *No* ☒

THE TECHNOLOGY (or other innovation)
[the technology developer might be the best person to complete this section]

Describe the technology/ies or other innovation. It might be an app, a device, a tool, a protocol
or pathway, an algorithm, a model, a piece of hardware – or some combination of these.

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Highlight what is new apart from the technology (e.g. new way of working). An innovation can be old technology (e.g. telephone) used in a new way.

The questions below will help you decide if the technology (and how it works to support care) is straightforward, well-understood and will have a predictable effect. For suggestions for responding to complexity in this domain, see page 13.

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IDENTIFYING COMPLEXITIES IN THE TECHNOLOGY OR OTHER INNOVATION:	Agree	Disagree	Not applicable or don't know
There are significant uncertainties about what the technology is e.g. The technology is difficult to define (e.g. connects with hidden infrastructure, supplier does not disclose full details) The technology does not yet exist in a robust and definitive form		X	
There are significant uncertainties about where the technology will come from e.g. The technology supply chain is not yet in place The technology is not easily substitutable (i.e. if the supplier withdrew, it would not be obtainable elsewhere)		X	
There are significant uncertainties about the technology's performance and dependability e.g. Data collection and transmission (where relevant) are not yet accurate or reliable There are significant privacy or security concerns	X		
There are significant uncertainties about the technology's usability and acceptability e.g. It is not possible for people to try out the technology on a small scale before adopting it The data or knowledge generated by the technology is not well understood or trusted	X		

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There is not yet evidence from prototyping that intended users find the technology easy to use without human support (e.g. clinician, carer or help desk)	
There is not yet evidence from prototyping that the technology is acceptable to its intended users (e.g. that it generates data that are well-understood and trusted, and which reflect how their condition is normally managed)	
There are significant technical interdependencies	X
e.g.	
A key technology needs to be installed across multiple technical systems so as to achieve 'integration'	
The technology cannot be installed until the organisation's IT system is upgraded or changed (e.g. new hardware, better bandwidth)	
The technology would require individual users to upgrade their device(s) or home IT system	
The technology overlaps (unproductively) with an existing technology that performs the same or a similar function	
The technology is likely to require major changes to organisational tasks and routines	X
e.g.	
Implementing the technology means some staff will have to do their jobs in a different way and/or interact with different people	
Implementing the technology will require new or different steps in the overall care pathway (e.g. new administrative processes)	
The technology (and/or the service model it supports) is likely to change significantly within the next 3-5 years	X
e.g.	
The technology has limited potential to be adapted to take account of future clinical developments and other changes	
The technology supply model may not be sustainable (e.g. the client-supplier relationship is weak, or there are questions about the company's reputation)	

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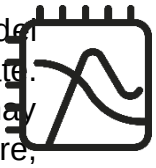
SUMMARY: The technology has significant complexity which is likely to affect the project's success

Yes ☒ No ☐

THE VALUE PROPOSITION (costs and benefits of the technology) [the technology developer and business lead for the organisation might complete this section]



Describe the value (financial or otherwise) that the new technology and care model might generate.
For commercial stakeholders, this may be return on investment. For patients, it may be cure, comfort, or quality of life. For healthcare organisations, it may be improvements in quality of care, efficiency (saving time, freeing up staff), safety (including reduced risk of litigation), or inclusivity.

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The following questions address what kind of value the technology might generate for different groups of people. For suggestions for responding to complexity in this domain, see page 14.

IDENTIFYING COMPLEXITIES IN THE VALUE PROPOSITION:	Agree	Disagree	Not applicable or don't know
The commercial value of the technology is uncertain e.g. If the technology does not yet exist in a definitive form, the case for investing in its [further] technical development is weak The technology does not have a plausible business case, including up-front investment, a well-defined customer base and market drivers, consideration of competing products and realistic assessment of challenges of implementing at scale in a public-sector health or care environment		X	
The value to the patient or client is uncertain e.g.		X	

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There are no high-quality studies (e.g. randomised controlled trials) to demonstrate the technology's efficacy for this patient/client group	
The technology's benefits have not been shown to outweigh its potential harms	
The technology's efficacy and safety were not measured in terms of an outcome that matters to patients	
The value to the clinician or other staff member is uncertain	X
e.g.	
The technology may create work (or other hassles) for the front-line staff	
The technology's benefits have not been shown to outweigh the hassle of using it	
The value to the healthcare system is uncertain	X
e.g.	
The technology (or the technology-supported care model) is not considered to have any overall advantage over existing practice	
The technology has not yet been shown to be effective and cost-effective in terms of how much benefit it will bring for a given financial outlay	
There are safety concerns about the technology or care model	
This technology-supported care model has not yet been successfully implemented in a similar context to the one being contemplated	
There are concerns that the technology, whilst improving care for some patients, could widen inequalities	
Regulatory and other approvals for the technology are not yet in place	
The value to this particular healthcare organisation is uncertain	X
e.g.	
The technology will require new technical infrastructure before it can be introduced to this organisation (see Technology domain)	

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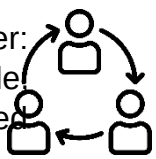
The technology will require extensive changes to organisational routines and pathways (see Technology and Organisation domains)	
Aspects of the local procurement processes make it hard to commission this technology (see Organisation domain)	
The technology could generate a negative value (i.e. costs are likely to outweigh benefits) for some stakeholders.	X
e.g.	
Potential loss of income	
Destabilising a provider	
Hidden or knock-on costs	
The value proposition is likely to change significantly over the next 3-5 years.	X
e.g.	
A new, better technology is on the horizon	
The market for the technology will change significantly	
A key regulatory decision could be made or reversed)	
SUMMARY: The value proposition has significant complexity which is likely to affect the project's success	

Yes ☒ No ☐

THE INTENDED ADOPTERS OF THE INNOVATION/TECHNOLOGY [this section should be completed by, or on behalf of, everyone who might use the technology]

Describe the intended users of the technology or other innovation. Consider: patients/lay people, professionals, administrative and support staff. Are there people who will be impacted indirectly (e.g. clinicians may be the main users but admin staff may need to adapt their procedures)?



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The following questions will help you summarise whether people directly involved with the technology understand what it is for, think it is worth trying, feel able to use it and are motivated to give it a go, and also what the indirect knock-ons may be for others. For suggestions for responding to complexity in this domain, see page 14.

IDENTIFYING COMPLEXITIES IN THE INTENDED ADOPTERS:	Agree	Disagree	Not applicable or don't know
There is uncertainty about whether and how patients/carers or citizens will adopt the technology e.g. The technology would require substantial input from the patient or their immediate carer	X		

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Some patients will view the technology in a negative way (e.g. not appropriate for their home, or reminding them of an illness they'd prefer to forget about)	
Quite a few people in the intended user group may be unable or unwilling to learn to use the technology	
There is uncertainty about whether and how front-line staff will adopt the technology	X
e.g.	
Some staff members question the value proposition for the technology (e.g. they feel that adopting it would jeopardise the quality or safety of patient care, or they believe it is more time-consuming than existing practice)	
The technology would require staff to do their jobs differently, and perhaps take on a new, unwanted, role and identity (e.g. 'data entry person')	
Some individuals or teams do not have the resources, time, space or support to learn to use the technology	
Staff have not been trained or supported to be creative and flexible when implementing technologies	
There is uncertainty about the implications for people who might be indirectly affected by the technology	X
e.g.	
The technology would require input from others (e.g. relatives, care home staff), who may be unable or unwilling to learn to use it	
The technology would make someone else's job obsolete or more difficult	
There will be significant changes to individual users' perceptions of the technology over the next 3-5 years	X
e.g.	
Key staff groups are likely to change their views on the technology	
Patients or their lay carers are likely to change their views on the technology	

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SUMMARY: There is significant complexity relating to the intended adopters which is likely to affect the project's success

Yes ☒ No ☐

THE ORGANISATION(S) IMPLEMENTING THE TECHNOLOGY
[this section is best completed by people who know the organisation and the challenges it faces e.g. board member, human resources lead, staff representative]

Briefly describe the organisation(s) involved in the project (for example, digital agency, healthcare provider, social care provider). What kind of organisation is it? How is it structured – and what is it like to work there? What is its track record of taking up new technologies? How well-resourced is it

(in terms of both staff and funding)? Is there much enthusiasm for this particular technology?
You may need to complete this section separately for the main and partner/ impacted organisations (and use the highest complexity score in your planning, since the initiative will only be as strong as its weakest link).

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The following questions will help you assess whether the organisation is capable and ready to take on the innovation, and whether the work involved has been understood and planned for. For suggestions for responding to complexity in this domain, see page 15.

IDENTIFYING COMPLEXITIES IN THE ORGANISATION(S):	Agree	Disagree	Not applicable or don't know
The organisation's capacity to take on technological innovations is limited	X		
e.g.			
Leadership is weak and the organisation's mission and values are unclear			
Internal relations, especially between managers and clinicians, are poor			
The structure is top-down and hierarchical, so individual departments are discouraged from horizon-scanning for new products and ideas, and have limited scope to introduce innovations			
The organisation has a poor track record of introducing any kind of change			

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There are no slack resources (people or money) to channel into innovative projects		
It is not a learning organisation: staff are not encouraged to meet and talk about new ideas and projects, there are few or no measures in place to capture data and monitor progress, and risk-taking is discouraged		
Digital maturity is low		
The organisation is not ready for this particular innovation	X	
e.g.		
The fit between the organisation's mission and the innovation is poor		
Key people (especially senior management) oppose the innovation or are unconvinced of its value		
The business case is weak or questioned (see Value Proposition domain)		
The implications (e.g. work required) of introducing, implementing and evaluating the technology have not been adequately assessed (or have been questioned)		
Money is needed but a budget line has not been allocated		
Organisational routines and processes will need to change very considerably to accommodate the technology	X	
e.g.		
Different kinds of staff (e.g. new hires) will need to be involved in the process or pathway once the technology has been introduced		
A new (or radically revised) process or pathway will need to be developed		
The core process or pathway will need to link differently with other key processes and pathways in the organisation		
Procurement processes are in place that make it harder to commission this technology	X	
e.g.		

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The provider is not on the procurement framework	
Existing contracts need to expire first	
Aspects of the procurement process are not yet clear (e.g. Who will fund this? Who will be liable for costs? Is there an identified budget? It is capital or revenue ? Is the funding recurrent? Are there issues with timing/accruals of funding?)	
The work needed to introduce and routinise the innovation has been underestimated and/or inadequately resourced	X
e.g.	
Work to bring people on board and develop a shared, organisation-wide vision for the change	
Work to develop, implement and mainstream new care pathways and processes	
Work to coordinate the project across more than one organisation or sector	
Work to evaluate and monitor the change	
The organisation(s) involved are likely to have significant restructurings or changes in leadership, mission or strategy over the next 3-5 years	X
SUMMARY: There is significant complexity relating to one or more participating organisations which is likely to affect the project's success	Yes ☒ No ☐

THE EXTERNAL CONTEXT FOR INNOVATION
[this section might be completed by a 'horizon-scanner' who looks beyond the organisation]

Describe the national and local context for your technology or programme (e.g. legal obligations,
policy, professional bodies views on best practice, related national initiatives). Think

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about the key influences on the project beyond the organisation(s) you identified in the previous section.

The following questions will help you summarise whether there are external conditions (such as the state of policy, public/ professional opinion, expected external events such as political climate change) likely to complicate the adoption and mainstreaming of the innovation. For suggestions for responding to complexity in this domain, see page 17.

IDENTIFYING COMPLEXITIES IN THE EXTERNAL CONTEXT: Not applicabl

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	Agree	Disagree	Agree or don't know
The political and/or policy climate is adverse	X		
e.g.			
External political or economic changes impacting on the organisation could threaten the introduction of the innovation			
Current policy priorities conflict with this initiative			
Professional organisations are opposed to the innovation or don't actively support it	X		
e.g.			
There are concerns about quality or safety of care			
There are concerns about confidentiality and wider information governance			
There are concerns about professional workload			
Priorities are elsewhere			
Patient organisations and lobbying groups are opposed to the innovation or don't actively support it		X	
e.g.			
There are concerns about quality or safety of care			
There are concerns about privacy and/or what will happen to the data			
Priorities are elsewhere			
The regulatory context is adverse		X	
e.g.			
Quality standards and regulatory requirements for using the technology in a health or care setting have not been fully defined			

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Key stakeholders do not know about or accept these standards and requirements		
The commercial context is adverse	X	
e.g.		
The technology industry views the innovation (or similar products) negatively		
The technology does not use industry-standard components		
There is lack of support for timely updates to the technology to support ongoing work as intended		
Opportunities for learning from other (similar) organisations are limited		X
Additional detail		
No other similar organisations are yet using the technology		
Inter-organisational knowledge exchange networks are weak		
Introduction of the technology/innovation could be threatened by external changes that impact on the organisation	X	
The policy, regulatory and economic context for this innovation is likely to be turbulent over the next 3-5 years	X	
e.g.		
Change of government		
New policy priorities		
Economic recession		
New regulatory framework		
Withdrawal of industry commitment		
SUMMARY: There is significant complexity relating to the external context which is likely to affect the project's success		

Yes ☒ No ☐

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EMERGENCE OVER TIME

[this section pulls together the bottom row of each of the previous domains]

Summarise the main changes which, if they happen, could affect the project over next
3-5 years. Which of these do you think is most significant? What are the key uncertainties?

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For suggestions for responding to complexity in this domain, see page 18.

ESTIMATING WHAT THE FUTURE HOLDS:	Agree	Disagree	Not applicable or don't know
The population with the condition, and/or how the condition is treated, is likely to change significantly over the next 3-5 years	X		
The technology (and/or the service model it supports) is likely to change significantly over the next 3-5 years	X		
The value proposition for the technology is likely to change significantly over the next 3-5 years	X		
There will be significant changes to individual users' perceptions of the technology over the next 3-5 years	X		
The organisation(s) involved are likely to have significant restructurings or changes in leadership, mission or strategy over the next 3-5 years.	X		
The policy, regulatory and economic context for this innovation is likely to be turbulent over the next 3-5 years	X		

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PART 2: ACTION PLANNING AND PROJECT MAGAGEMENT

Taking account all your responses to Part 1, this section prompts you and your team to plan your implementation project and consider measures to reduce or respond to complexity in the different NASSS domains. Below, we offer some ideas and resources to get you started. The resources and links have been selected for a UK setting but could easily be adapted for other countries.

Planning your implementation project

Skim this section first – but then go on to look at the different complexities and ideas for responding to them. You may end up deciding not to go ahead with the project at all.

Project management in a highly predictable environment is fairly straightforward, but under conditions of complexity, things can't be fully predicted or laid out in advance. You need to set a broad goal, take action on several fronts simultaneously (making sure you attend to the human and political aspects of the project as well as the technical and financial aspects), while periodically reviewing progress and adjusting your strategy.

For large, ambitious projects, we recommend the Project Initiation Routemap, a guide by the UK government for planning complex projects in the public sector. The Routemap emphasises three linked strategic tasks:

Assess the complexity and context of the delivery environment (see NASSS questions above, especially Domain 2 'The Technology' and Domain 5 'The Organisation'), and consider how you could respond to this complexity (see suggestions below);

Assess the capacity and capability of organisations and teams to deliver the project (in particular, sponsor, senior management buy-in and support, dedicated delivery team);

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Work to strengthen and align context and capability (e.g. align requirements, governance, execution strategy, organisation design and development, procurement, risk management, asset management).

See also the NESTA DIY toolkit for bringing ideas to life (designed for social care providers) – a structured way to get from the initial idea for a new technology to a well-designed project to get it up and running in a service.

Due diligence. Before investing in a technology, make sure the company selling it is legal and solvent, that the technology has the requisite regulatory approvals, that personal data is handled sensitively and respectfully, and that any associated risks have been considered. There are numerous due diligence checklists available – see these for example:

UK government digital service standards – a 14-point checklist when planning a service that involves digital technology. Linked to these are UK government technology and digital standards.

How to do due diligence for health care technologies – introductory blog from private company SecureDocs.

Digital Assessment Questionnaire from NHS Digital, a self-assessment checklist for apps and similar technologies.

Medical devices – software applications – Advice from the UK government on when software applications are considered to be a medical device and how they are regulated.

NHS Health and Social Care Data Security Standards (including a full due diligence checklist for suppliers).

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UK government code of conduct for data-driven health and care technology – Principles and advice for machine learning applications that use NHS data.

Commercialising new technologies. If you are developing a new technology and you think it has commercial potential, you will need to systematically demonstrate to investors how it will generate value. Try this resource:

Guidance and Impact tracking System (GAITS) – a web-based project and portfolio management platform designed to support commercialisation of new health technologies, developed by the US consultancy firm CIMIT.

Adoption Readiness Level tool by Liverpool City Region's e-health cluster – a self-assessment tool for tech developers that considers five domains (market, human, systems integration, finance/procurement, motivation).

Responding to complexity in the illness or condition

Your first step in developing technological solutions for an illness or condition is to understand the full range and depth of what the illness is and how it affects people.

Find out more about the illness. For example, find the prevalence, likely progression, and current 'best practice' care model. This will allow you to estimate how many users a product is likely to have, how long they can/will use it for, and how this fits with current care. Remember, there will be 'mild' and 'severe' forms of the illness, different age groups, ethnicities, genders and so on. Once you understand how the illness is patterned, this could inform work to 'personalise' the technology for different sub-groups (see 'Responding to complexity in the intended users' below). To learn about the illness, use different data sources, e.g. from national and regional databases, academic and grey literature, health and care practitioners, patient organisations, patients. For example:

NHS Choices – a searchable database of illnesses, including diagnosis, treatment and likely course

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NICE guidelines - evidence-based recommendations in a variety of conditions, procedures and technologies across health and social care developed by independent committees

Cochrane library – a database of high-quality systematic reviews of treatments

Healthtalk – a database of patients' accounts of what it's like to live with different illnesses

Macmillan – a website for people with cancer, with detailed information on prevalence, treatment and prognosis. There are similar patient-facing websites for most conditions. Explore them!

Responding to complexity in the technology(ies)

Don't make the mistake of treating a new technology as a plug-and-play solution. You need to ask a lot of questions about it before you can be sure it's the right tool for the job. New technologies often look appealing and promising until we consider all aspects of the innovation process.

Find out more about the technology and assess its quality and implications. If you are not the creator of the technology, familiarise yourself with all relevant aspects of it or ask an expert. Look at it; play with it; do a 'walk through' the imagined use case. Will this product really help with what you are planning to achieve? Could a different technology (perhaps one that is already tried and tested) do a similar job with less hassle?

NHS apps library – a searchable database of quality-assured smartphone health apps

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Publicly available 'curated' databases of apps – for example:

Psyberguide for mental health apps

ORCHA, an independent organisation that evaluates apps

Find out more about where the technology will come from and associated challenges. Ideally the building blocks for your chosen technology e.g. coding platform, devices etc can be accessed or purchased easily (no long waiting periods or unreliable supply chains). Ideally, the technology should not depend on a single vendor/device/coding language etc, but work (or have the potential to work with or easily change to) others as well. They will have been tested extensively so you don't have to worry about these components being dependable. Conflicts of interest and claims to intellectual property (IP) should be sorted out before the project begins. It should be clear who will fund the technology, what it will cost and which costs are covered (set up, maintenance, updates etc).

Identify and address the key points where technical complexity will impact on success. Find out about any unknowns and dependencies as soon as possible, and develop a plan to deal with them, including alternatives or workarounds. Reduce unnecessary technical integration. Integration between multiple systems makes everything more complex. Ask whether it is really necessary or if there are ways to avoid or delay this, especially during initial testing. But bear in mind that some forms of technical integration (e.g. to make a new piece of software accessible from within a patient's existing electronic record) may make the technology simpler for a clinician to use.

Consider how the technology will disrupt the system. Map possible disruptions and take steps to avoid or mitigate them. Can you modify the technology to make it less disruptive? Can you reduce knock-ons by adjusting other systems or processes? What measures might you put in place (e.g. small-scale pilot running in parallel with the old service, on-the-job training, help desk) to deal with the disruption until systems and processes have evolved to accommodate the new technology? We pick up this important point again under 'the organisation' below.

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Responding to complexity in the value proposition

This project is only going to work if all stakeholders gain something of value from it.

Consider how to increase the technology's appeal to investors. If the technology is at an early stage of development, what is its likely upstream value as viewed by investors (especially the business case for generating profits, further spin-offs, and highly qualified jobs), drug and device regulators (preliminary evidence of efficacy and safety), and financial regulators (auditable business processes and governance)? Can the technology be 'de-risked' by removing costly but inessential features? See the Guidance and Impact tracking System (GAITS) resource linked above.

Consider how to increase the technology's value to patients or citizens. If a technology is meant to be used by patients or lay people, its potential benefits must be weighed against its costs (and the person's willingness and ability to contribute to these), the work needed to use it (and whether the person or their carer is able and willing to do that work), and the desirability of medicalisation and surveillance. Can the design be improved to make the technology more appealing? Can the data be visualised in a way patients or carers can engage with?

See links above under 'Responding to complexity in the illness'

Getting the most out of PROMS – A guide to using patient-reported outcome measures to assess whether an intervention or technology is actually improving outcomes that are valued by patients

A guide to PROMs methodology from NHS Digital (using hip and knee replacement as an example)

Identify evidence of effectiveness and cost-effectiveness. If the technology is at a more advanced stage of development, there may be research evidence comparing its effectiveness (does it work?) and cost-effectiveness (is it good value for money?) with

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'usual care' and measuring an outcome that is important to patients. Try these resources:

NICE Evidence Standards for digital health technologies – These cover both effectiveness and economic impact.

Consider real-world value issues. Is there a realistic assessment of the challenges of implementing this innovation at scale in a particular public-sector health or care environment? Even when something has been shown to be cost-effective, it may not be locally affordable or a funding priority.

The NICE Evidence Standards website linked above offers a budget impact guide and budget impact template for local cost planning.

Responding to complexity in the intended adopters of the technology

This project is only going to work if the people you want to use the technology are able and willing to do so.

Address acceptability, accessibility and usability for patients and citizens. If the technology requires input from a patient, carer or other lay person, will they find the product aesthetically pleasing and easy to use? Does the technology make sense, for example, in the context of how patients and carers already do things, their routines and existing tools they use to support their work? Remember, everyone is different. Some people have limited vision or dexterity; some people find instructions hard to understand. Can you make the product more accessible? Is it worth building design changes in now or planning to do so in the future (e.g. after proof of concept testing)? If the technology includes several components, can users select what is most relevant for them? These resources may help:

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How to do research on user needs in the 'discovery phase' of technology design – a website from the UK government.

International Design Foundation – a US site offering tips and resources for making websites and apps more accessible.

How to design websites for older people – a guide from the Alzheimers Society.

Address staff motivation and concerns. Assess the level of enthusiasm for the technology from different staff groups, and also how motivated teams are to take on the new technology. Have any of them had experience of using this technology elsewhere? Listen to staff concerns – which may be legitimate – and to their ideas for increasing the project's success. This resource may help:

Higher Education England Digital Capabilities Framework for assessing the digital capability of staff.

Modify staff roles and provide training. Develop new roles and job descriptions where needed, perhaps by adapting ones already in use elsewhere. Set learning objectives (some of which will be about building confidence to make judgements, not about mechanically following protocol). Design and develop training courses. Remember: using a technology usually needs on-the-job and team-based training, not just sitting in classrooms. Allocate sufficient budget for this work, and consider issues such as backfill.

Promote social learning. One way to become confident in using a technology is to shadow someone in the same role who is already an enthusiast for it ('champion') and confident in using it ('super user'). Learning in this way not only develops skills but also helps people develop a positive attitude and identity.

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Support collective sensemaking and communities of practice. People need to make sense of new technologies – sometimes by coming together to complain about them initially! Surfacing one's irritation with a technology may be the first step to coming to terms with it. Both staff and patients may benefit from being in 'communities of practice' (groups or networks of people who share an interest in something and are trying to get better at it). Online communities of patients, for example, are often good sources of knowledge and wisdom about how to manage a condition. Try to get these communities on board if introducing a patient-facing technology.

The Kings Fund guide to engaging NHS staff may provide some practical ways of achieving the above.

Responding to complexity in the organisation

The project is only going to work if the organisation has the capacity to take on innovations and if there is good 'innovation-system fit'. The tips below may help if you are trying to support an organisation to implement a new, technology-supported care model.

Assess the organisation's capacity to innovate. An innovative organisation has strong leadership, good clinician-managerial relations, a devolved management structure, slack resources (money and/or staff) that can be channelled into new projects, good lines of communication and an ethos where it's OK to take risks and learn from failures. If an organisation appears to lack these essential prerequisites for innovation, consider whether you need to strengthen its capacity before pressing ahead. Here are some questions to help you assess capacity to innovate:

Is there a culture that supports innovation and change (e.g. are staff trusted to introduce new ideas)?

Does the organization have systems and processes in place that support innovation and change e.g. effective information and communication systems, opportunities for networking and learning across departments/teams?

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Do the senior management team actively seek opportunities for improvement and encourage ideas and feedback from patients, the public and staff?

Are the organisation's leaders helping to create a facilitative context through providing motivation and support, creating a vision and reinforcing the change process?

Is there a distributed and devolved style of management?

Is there a history of introducing successful change in comparable projects at a local level?

Are there mechanisms in place to support learning and evaluation and to embed changes in routine practice e.g. regular team meetings, audit and feedback processes, professional development opportunities and performance review systems?

Assess innovation-system fit. Even when an organisation is capable of running a successful project to implement a new technology, it might be the wrong technology to introduce in this organisation right now. Has the organisation successfully adopted similar technologies in the past? Are its strategic priorities aligned with the use of the proposed technology? Or are other projects more pressing?

Assess the implications of the technology for the organisation. Careful mapping out of tasks and processes is necessary to surface how the technology or other innovation is likely to change these. The pathway in which the technology is used directly (e.g. clinical care) may have indirect knock-ons for other processes and pathways (e.g. booking, correspondence, billing). You need to estimate costs (both initial and recurrent), and consider how money will need to flow across the system. Before signing off on a project, boards generally want to know how much will it cost up-front, what the likely savings will be, and when these savings will occur. These resources may help:

Process mapping guide from NHS Improvement. Ideas and tools for mapping the steps in a care pathway. A full list of additional service improvement and redesign tools from NHS Improvement is available here.

Using costing information to support better outcomes – a guide from NHS Improvement.

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Assess the level of 'political' backing for the innovation. For an organisational-level adoption decision to be approved, it needs support from both top management (a 'senior sponsor') and the rank-and-file. Supporters of the change must outnumber opponents and be more strategically placed. People with 'wrecking power' can block progress and may need to be brought on board (or worked around). To assess all this, use the NASSS-CAT PROJECT tool and also:

Stakeholder analysis guide from NHS Improvement. This guide will help you construct a table or chart listing all the stakeholders who will need to accept (and, in many cases, start to use) the technology. Consider each key stakeholder's perspective (and their potential wrecking power).

Consider inter-organisational relationships. Costs and benefits of technology projects are hard to predict, and savings may accrue elsewhere in the system. When there is no pre-existing contractual relationship between organisations, it can be hard to reach a satisfactory arrangement for how to manage these uncertainties.

Think how (and by whom) success will be evaluated. If this project is going to happen, you will need to monitor how well the change is going. You will almost certainly need both quantitative metrics (to answer the "how many…?" and "are we on track…?" questions) and also qualitative measures (to answer the "how do people feel about this…?" questions). Evaluation is everyone's job, and data are often best collected by people doing the job. Extensive data collection can be time-consuming and slow the project down (i.e. the perfect may be the enemy of the good).

Evaluation: what to consider – A guide by the Health Foundation. This basic guide includes qualitative and quantitative approaches.

The 'rainbow framework' for evaluation and monitoring by Michael Quinn Patton. It takes you through 7 colour-coded steps, namely Manage (e.g. define stakeholders, secure funding), Define (set a scope for the evaluation), Frame (intended users of the evaluation, what they will use it for, what success will look like), Describe (sample, measures/metrics, data sources, analytic approaches), Understand Causes (deeper analysis to produce explanatory models), Synthesise (combining results), and Report & Support Use (publishing and disseminating).

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Evaluation Works and Evidence Works toolkits to guide commissioning decisions, produced by West of England Academic Health Sciences Network and their partners.

Allocate funding. Studies of 'failed' technology projects often identify inadequate funding as a leading cause. You will probably need substantial set-up funding and possibly a recurrent budget line (for things like licences and IT support). Budget adequately for staff to learn and adjust as the transition occurs (see 'Responding to complexity in the intended adopters' above).

Manage the transition. Good change management involves a combination of 'hard' and 'soft' approaches. As well as setting goals and milestones and using agreed metrics to monitor progress, you also need to create opportunities for staff to come together and talk about the technology and new care model. As noted above, collective sensemaking, training (especially on-the-job training for both individuals and teams) and social learning from champions and super-users is crucial for building capacity. Use creative tools such as flip-charts and post-it exercises to surface people's interpretations and concerns. Invite them to come up with creative ideas and solutions to any problems they identify. Allocate sufficient budget for this work, and consider issues such as backfill. This guide may help:

Leading large-scale change: a practical guide from NHS England.

Responding to complexity in the external environment

Plans for technology-supported change locally are unlikely to work out if there is a major mis-match with national policy or the prevailing political, economic or professional environment.

Try to align your project with current policy priorities. If the technology is actively supported in policy, it will be easier to introduce. If priorities are elsewhere, it may be worth trying to 'rebrand' the work to fit these.

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Address regulatory issues and challenges. Consider which regulations (from which regulatory bodies) are relevant to the introduction of this technology. Are all approvals already in place? If not, who do you need to work with to make progress in this regard? See 'Due diligence' section on page 979.

Get the professions on board. If clinicians or social workers believe that the technology compromises the care of their patients or clients, or if they view it as demeaning to their role or a threat to their professional jurisdiction or income, their professional bodies may oppose it. Early dialogue with such bodies may avert such a situation.

Establish inter-organisational networks or collaboratives. Complex, organisation-wide change is a lot easier if change agents in one organisation can network with their opposite numbers in comparable organisations – for example in quality improvement collaboratives or learning sets. Here's a resource for that:

Improvement collaboratives in health care – A guide from the Health Foundation.

Keep a close eye on the outer context. External shocks to an organisation (such as economic turbulence) make change precarious. Whist such shocks are often hard to predict, it is a good idea to see what's on the horizon. The following questions may help you:

Does the new technology and the proposed changes to services align with the strategic priorities for the wider health system e.g. in terms of current health policy, national priorities for action and improvement?

Are there incentives in the wider health system that reinforce the proposed change e.g. pay for performance schemes, regulatory requirements etc.?

Are there existing inter-organisational networks (e.g. specialised clinical networks) that will be helpful in terms of supporting the proposed changes?

How much stability/instability is there in the wider health system – and how might this likely influence the implementation project?

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Responding to emergent complexity (new complexities that develop over time)

The point about emergent change is it's difficult if not impossible to predict. So this domain is really about how you might build resilience in your staff and your organisation to enable them to respond to things that come up in the future.

Acknowledge unpredictability. Have you left open the possibility that the project might unfold in one of several different ways? Can you flesh out these different possible futures and talk them through with your stakeholders?

Recognise and support self-organisation. Front-line teams will 'tinker' – that is, try to adapt the technology and the work process to make them work better locally. Are you able to capture data to evaluate and support these efforts?

Facilitate interdependencies. Have you identified the key interdependencies in the project? Is there anything you can do to strengthen existing interdependencies or develop and strengthen new ones?

Maintain space for experimentation and sensemaking. As complex projects unfold, staff will need to tinker more, and also talk about what's happening. Encourage them to admit ignorance, explore paradoxes, exchange different viewpoints (there's no need for them to agree on a single version of the 'truth'!) and reflect collectively.

Develop adaptive capability in staff and teams. Train your staff to be creative and to adapt to change as it happens. They will sometimes need to make judgements in the light of incomplete or ambiguous data.

Attend to human relationships. Dealing with emergent problems requires give-and-take. It's sometimes a matter of muddling through. This will happen more easily if people know, like and trust each other.

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Harness conflict productively. There is rarely a single, right way of addressing a complex problem, so view conflicting perspectives as the raw ingredients for producing multifaceted solutions.

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Annex 62 UC-PT3-COPD Phase 4 Participant information sheet and consent

INFORMOVANÝ SOUHLAS PACIENTA

Já, níže podepsaný/á, souhlasím s účastí na projektu SHAPES, jehož popis, jakožto i účel a rizika jsou popsány v dalším textu Vašeho informovaného souhlasu. Lékař, který je součástí řešitelského týmu usoudil, že splňujete požadavky pro účast v uvedeném projektu.

Název projektu:

Monitoring pacientů s chronickou obstrukční plicní nemocí - CHOPN (řešeno v rámci projektu SHAPES)

Oblast monitorace:

Ověření přínosu digitálních technologií v oblasti monitorace pacientů v domácím prostředí

Hlavní řešitel: RNDr. et RNDr. Ing. Ladislav Stanke, Ph.D.

Spoluřešitelé: MUDr. Samuel Genzor, Ph.D., MUDr. Jan Mizera, Mgr. Michal Štýbnar

Pracoviště řešitel a spoluřešitelů: Národní telemedicínské centrum (NTMC), Fakultní nemocnice Olomouc (FNOL), Klinika plicních nemocí a tuberkulózy, Fakultní nemocnice Olomouc

Rizika projektu:

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Riziko poškození pacienta nelze nikdy zcela vyloučit, nicméně v prezentovaném případě je minimalizováno na velice nízkou úroveň. Tablet i použité přístroje, které přijdou do kontaktu s pacientem, jsou komerčně dodávané přístroje, které mají označení CE, nebo FDA approved. Případná rizika by u dodaných přístrojů vyplývala zejména z využití nevhodných zdrojů pro dobíjení baterií, kde by hrozilo případné poškození baterií, které může v některých případech vést k jejich zahřátí či až zahoření, což je riziko většiny bateriových přístrojů. Nicméně tato rizika jsou jednotlivými výrobci rovněž minimalizována s využitím ochranných obvodů detekujících možná přetížení, kontrolujících teplotu apod. U uživatele, který postupuje dle návodu, případně instrukcí a využívá správné napájecí zdroje (pro daný přístroj určené) je toto riziko ještě nižší.

Projekt SHAPES (The Smart & Healthy Ageing through People Engaging in Supportive Systems) tak nepředstavuje žádná rizika pro Váš zdravotní stav a nemůže přispět k jeho zhoršení. Projekt je založen na měření biomedicínských signálů, konkrétně jde o spirometrii, měření krevního tlaku, saturace krve kyslíkem a monitoring adherence (využívání inhalátoru). Měření probíhá s pomocí přístrojů k tomu určených, které budou zapůjčeny z pracoviště řešitele.

Pokud běžně nevyužíváte žádné informační a komunikační technologie, jako je počítač, tablet, chytrý telefon apod., tak Vám může na počátku trvat, než získáte plnou jistotu v ovládání všech přístrojů a tabletu s poskytnutým programovým prostředím. Nicméně není nutné se této fáze obávat, jelikož personál je ochoten Vám v případě nejasností či nejistoty s čímkoliv poradit.

V případě dodržení instrukcí k jednotlivým zapůjčeným přístrojům není známo, že by se jednalo o přístroje, které by Vás mohly jakkoli ohrozit.

Samotný monitoring probíhá s využitím tabletu, na kterém je nainstalována telemedicínská aplikace (Medimonitor) – u některých pacientů, kteří nejsou zvyklí pracovat s ICT technologiemi může trvat déle se naučit aplikaci ovládat, byť bylo pracováno s využitím znalostí a dobrých praxí v oblastech uživatelské zkušenosti (UX – user experience) a přístupnosti, které by měly zmíněné riziko minimalizovat.

Za účelem komunikace je využíváno wi-fi sítě, která patří pacientovi. V tomto ohledu není možné vždy zaručit stabilitu a dostupnost sítě. Pro krátkodobé výpadky jsou data

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ukládána v tabletu. Při poruše komunikace mezi jednotlivými přístroji a tabletem je možné některé hodnoty zadat ručně.

Účel a popis projektu:

- Ověření možnosti telemedicínského monitoringu v místě bydliště pacienta pomocí vybraných přístrojů.

- Ověření schopností telemedicínské aplikace vyvinuté ve FNOL (Medimonitor) pro komunikaci s jednotlivými přístroji, agregaci a odeslání dat na server FNOL.

- Ověření možnosti zobrazování varování na základě detekce překročení prahů měřených hodnot (bude probíhat prospektivně)

- Ověření možnosti nalezení algoritmu (případně vytrénování neuronové sítě) pro včasnou detekci blížící se exacerbace na základě naměřených dat (tato část proběhne retrospektivně po náběru všech dat z přístrojů zapůjčených pacientům).

V rámci projektu bude testována možnost vzdálené monitorace pacientů s chronickou obstrukční plicní nemocí. Za tímto účelem je pacientům zapůjčena sada přístrojů zakoupených z prostředků mezinárodního projektu SHAPES, na kterém NTMC (Národní telemedicínské centrum) FNOL aktuálně participuje. Konkrétně se jedná o spirometr, tlakoměr, oxymetr a nástavec na inhalátor. Každý z těchto přístrojů je schopen pomocí Bluetooth odeslat naměřená data do tabletu (v případě selhání datového přenosu je možné hodnoty zadat i manuálně), který budou mít pacienti rovněž k dispozici. Cílovou skupinou projektu je stárnoucí populace, přičemž hlavním cílem projektu je podporovat aktivní stárnutí s využitím moderních digitálních technologií. V předložené studii se konkrétně jedná o skupinu seniorních pacientů s chronickou plicní obstrukční nemocí. Mezi dílčí cíle projektu patří ověření přínosu telemedicínské aplikace FNOL (Medimonitor) pro akvizici, agregaci a odesílání dat naměřených pomocí přístrojů u pacienta na server FNOL. Pseudonymizovaná (pozměněná takovým způsobem, aby neobsahovala konkrétní jména pacientů) data jsou dále využita jako vstupy pro připravované algoritmy, případně neuronové sítě, které mají za cíl prevenci dekompenzace jejich stavu.

Postupy používané v rámci projektu:

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- Odběry krve pro kvantifikaci markerů relevantních pro diagnózu a pro titraci medikace.

- Administrace dotazníků (prezentovány osobně i elektronicky na zapůjčeném tabletu).

- Měření pomocí zapůjčených zařízení:
    - Monitoring adherence (detekce používání inhalátoru) je rovněž automatický, je ovšem nutné mít poblíž tablet pro přenos dat.
    - Měření biomedicínských signálů pomocí spirometru, tlakoměru a oxymetru (SpO_2 senzoru), přičemž spirometrie a měření tlaku se provádí jednou denně, saturace kyslíkem se měří pomocí oxymetru v podobě prstenu kontinuálně během doby spánku a potom jednou ráno před užitím medikace společně s měřením ostatních veličin. Při měření je opět poblíž tablet.

- Využívání telemedicínské aplikace (pro akvizici, agregaci a odesílání naměřených dat, vedení videokonzultací).

- Statistická analýza výsledků.

- Hledání algoritmů, učení neuronových sítí pro predikci exacerbací.

Prospěšnost projektu:

Pro zlepšení námi vyvíjených digitálních technologií a služeb z oblasti elektronického zdravotnictví je pro nás cenná zpětná vazba od uživatelů-pacientů tak abychom mohli naše služby dále zdokonalovat směrem k uživatelské přívětivosti, proto jste žádáni, abyste otestovali naši telemedicínskou aplikaci, včetně její schopnosti propojení s dalšími zařízeními, které byly popsány výše. Vámi naměřené hodnoty mohou rovněž pomoci lépe pochopit průběh Vašeho onemocnění. Tyto hodnoty budou dále důkladně analyzovány s využitím pokročilých algoritmů či neuronových sítí.

Kdo se může studie zúčastnit:

Do studie se můžete přihlásit, pakliže jste byly diagnostikováni s chronickou plicní obstrukční nemocí a jste starší 60 let.

Kdo se nemůže studie zúčastnit:

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Vzhledem k povaze projektu se nemohou zapojit pacienti s kognitivními poruchami (např. Alzheimerova choroba) a pacienti, kteří nemají v místě bydliště připojení k internetu (bezdrátovou wi-fi síť pro připojení zapůjčeného tabletu), které umožní přenos naměřených hodnot na servery FNOL.

Povinnosti pacienta:

Jako pacient zapojený do výše popsaného projektu máte povinnost sdělovat lékařskému a vědeckému personálu všechny informace o svém zdravotním stavu a žádné informace nezamlčovat.

Prohlašuji tímto, že jsem pročetl/a všechny výše uvedené informace týkající se popsaného projektu – a těmto jsem porozuměl/a.

Byl/a jsem dostatečně informován/a o cílech, průběhu, účelu a rizicích vyplývajících z účasti na projektu. Jsem si vědom/a, že kdykoli v průběhu i po ukončení mojí účasti na projektu je lékař odpovědný za poskytnutí doplňujících informací o jakékoliv případné zdravotní újmě související s mojí účastí v projektu nebo informací, které mohou ovlivnit moji ochotu v projektu setrvat.

Souhlasím se svou účastí v projektu SHAPES.

Jsem si vědom/a toho, že odstoupení nebo vyřazení z projektu SHAPES, ať už z jakéhokoli důvodu, žádným způsobem neovlivní kvalitu zdravotní péče, která mi bude poskytována. Podpisem tohoto informovaného souhlasu se nevzdávám žádného ze svých zákonných práv.

Kdykoliv mohu uplatnit svá práva u svého ošetřujícího lékaře a požádat v souladu se zákonem o přístup k záznamům a případně je opravit, pokud jsou nepřesné. Projekt SHAPES je prováděn v souladu s právními předpisy České republiky.

Budu-li chtít získat jakékoliv doplňující informace o projektu SHAPES, mohu se obrátit na svého lékaře. Obdržím jeden originálně podepsaný stejnopis tohoto dokumentu.

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Po ukončení monitorace je pacient povinen vrátit tablet a všechny zapůjčené přístroje pracovníkovi, který mu je vydal.

Jméno a příjmení pacienta Podpis pacienta

(Hůlkovým písmem)

_____
_____

Datum:_____ (mes-dd-rrrr)

Jméno a příjmení informujícího lékaře Podpis lékaře

(Hůlkovým písmem)

_____
_____

Datum: _____ (mes-dd-rrrr)

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Annex 63 UC-PT3-COPD Phase 5 Participant information sheet

SHAPES INFORMAČNÍ LIST PRO ÚČASTNÍKY

Kontakty:

Národní telemedicínské centrum Fakultní nemocnice Olomouc (NTMC FNOL)

Ladislav Stanke (výzkumný pracovník)

E-mail: Ladislav.Stanke@fnol.cz; Telefon: 583 443 713

Michal Štýbnar (koordinační pracovník)

E-mail: Michal.Stybnar@fnol.cz; Telefon: 583 443 713

Název studie: SHAPES Pan-European Pilot Campaign („Pan-evropská pilotní kampaň SHAPES“): SHAPES pilot zaměřený na pacienty s chronickou obstrukční plicní nemocí pro pilotní téma 3 - kontrola a optimalizace medikace.

Rádi bychom Vás pozvali k účasti na pilotní studii, během níž bude probíhat pilotní ověření digitálního řešení vyvinutého v rámci mezinárodního projektu SHAPES v podobě zdravotnické aplikace a propojených zdravotnických přístrojů, které je vyvíjené pro osoby starší 60 let, které trpí chronickou obstrukční plicní nemocí. Studie je pro nás příležitostí zjistit, zda může toto digitální řešení pomoci lidem sledovat a řídit jejich zdravotní stav z domova a zlepšit kvalitu jejich života a zdravotní výsledky. Naším cílem je zapojit do této studie nejméně dvacet pět starších osob s chronickou nemocí.

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Byl/a jste identifikován/a jako vhodný/á účastník/ce našeho pilotu a obdržel/a jste tento informační list, který si můžete přečíst a zvážit, zda se chcete zúčastnit.

Tento informační list popisuje pilotní studii a Vaši roli v ní. Než se rozhodnete, je důležité, abyste pochopil/a, proč se pilot provádí a co pro Vás bude znamenat. Věnujte prosím čas přečtení těchto informací a případně je prodiskutujte s blízkými či výzkumníky. Pokud Vám něco není jasné nebo pokud byste chtěl/a získat více informací, kontaktujte výzkumné pracovníky uvedené výše, kteří Vás budou kontaktovat zpět.

Dobrovolnost účasti

Účast v této studii je dobrovolná. Ze studie můžete kdykoli odstoupit bez udání důvodu a bez jakýchkoli negativních důsledků. Pokud ze studie odstoupíte nebo odvoláte svůj souhlas, budou všechny Vaše osobní údaje shromážděné pro účely výzkumu odstraněny. Případně můžete povolit, aby osobní údaje shromážděné před odstoupením byly do výzkumu zahrnuty. V případě, že budete s účastí na pilotní studii souhlasit, budete požádáni o podepsání informovaného souhlasu s účastí ve studii. Během pilotního projektu Vám budou k dispozici výše uvedení pracovníci Fakultní nemocnice Olomouc (FNOL), kteří Vám budou při používání technologie pomáhat a řešit případné problémy.

Účel a cíle studie

Tato studie je jednou z částí rozsáhlejšího výzkumného projektu s názvem SHAPES, jehož cílem je otestovat různé způsoby využití technologií, které pomáhají stárnoucím lidem bezpečně fungovat v jejich domovech a zůstat aktivní.

Hlavním cílem této pilotní akce je zjistit, jak účastníci používají digitální řešení a technologii SHAPES.

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Mezi další cíle pilotu patří:

- pomoci lidem monitorovat jejich zdravotní stav, životní funkce a užívání léků, a tím podpořit bezpečnější a efektivnější užívání léků v domácnosti
- snížit pravděpodobnost dekompenzace pacienta pravidelným monitorováním vybraných biomedicínských signálů, které mohou upozornit na bezprostřední ohrožení zdravotního stavu pacienta
- vyvinout technologii pro předvídání zhoršení chronické obstrukční plicní nemoci a posoudit sběr dat, který je k tomu zapotřebí
- posoudit, zda je používání technologie SHAPES spojeno se změnou neplánované zdravotní péče
- zlepšit kvalitu života účastníků a současně snížit potřebu pravidelných návštěv pacienta v nemocnici
- prozkoumat důvěru a přijetí technologie SHAPES
- zjistit, zda používání technologie SHAPES může prodloužit nezávislý a soběstačný život

Kdo výzkum organizuje a financuje?

Tuto studii organizuje Fakultní nemocnice Olomouc a Národní telemedicínské centrum. Je součástí rozsáhlejšího výzkumného programu nazvaného projekt SHAPES, který je financován Evropskou unií v rámci programu Horizont 2020 (grantová dohoda č. 857159). Projekt SHAPES sdružuje přední výzkumné skupiny, společnosti a odborníky z celé Evropy. Konsorcium projektu SHAPES tvoří 36 partnerů ze 14 evropských zemí. Podobné pilotní projekty probíhají v celé Evropě.

Co bude účast zahrnovat?

Pokud budete souhlasit s účastí v této studii, budete požádán/a, abyste se zúčastnil/a osobního rozhovoru s našimi výzkumníky ve Fakultní nemocnici Olomouc, kde Vám budou poskytnuty veškeré informace o této pilotní studii a budou Vám zapůjčeny přítroje, které jsou součástí digitálního řešení SHAPES.

Co se bude dít během účasti ve studii?

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Potenciální účastníci budou vytipováni lékařským personálem FNOL a budou pozváni na schůzku s ošetřujícím lékařem a výzkumnými pracovníky organizující pilotní studii. Na schůzce bude položeno několik otázek, abychom se ujistili, že jsou vytipovaní účastníci způsobilí, a budou požádáni o písemný informovaný souhlas s účastí v pilotním projektu a dále souhlas se zpracováním osobních údajů.

Účastníkům budou poskytnuta zařízení s označením CE a technologií Bluetooth, a to konkrétně oximetr Circul, tlakoměr Beurer BM54, spirometr MIR, chytrý inhalátor FindAir, tablet Lenovo Tab M10. Zapůjčený tablet bude obsahovat staženou aplikaci SHAPES. Všechny přístroje budou řádně vydezinfikovány před předáním.

Před zahájením pilotního projektu budou účastníci proškoleni výše uvedenými pracovníky Fakultní nemocnice Olomouc, případně příslušným lékařem nebo zdravotní sestrou a bude jim poskytnut čas na to, aby si technologii dostatečně vyzkoušeli. Budou také požádáni o vyplnění několika dotazníků a poskytnutí některých základních informací. Tyto informace budou zahrnovat kontaktní údaje, případně kontaktní osobu a její údaje, věk, bydlení, rodinný stav, profesní status, vzdělání, stupeň soběstačnosti, anamnézu, zdravotní stav, laboratorní výsledky a využívání zdrojů zdravotní péče za 3 měsíce před pilotním projektem a během pilotního projektu. Některé z těchto informací budou se souhlasem získány z lékařských záznamů. Dotazníky se budou týkat kvality života, soběstačnosti, sociální podpory, zdravotní gramotnosti, aktivit denního života, užívání léků a přesvědčení o lécích.

Během 12týdenního pilotního projektu budou účastníci vyzváni, aby si pomocí přístrojů denně měřili svůj krevní tlak, srdeční frekvenci, saturaci kyslíkem, spirometrii a použití inhalátoru. Tyto údaje jsou elektronicky přenášeny do aplikace SHAPES prostřednictvím Bluetooth. Účastníci si mohou prostřednictvím aplikace prohlížet své údaje a v případě potřeby mají možnost zadávat hodnoty ručně, napsat vzkaz lékařskému personálu, případně si domluvit videohovor. Účastníci budou také vyzváni k vyplnění denního dotazníku obsahujícího otázky o jejich zdravotním stavu a týdenního dotazníku o užívání léků. Lékový režim účastníka bude výzkumníky nahrán do aplikace a bude k dispozici k nahlédnutí jednak

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jako komplexní seznam všech léků, jednak jako denní seznam, který bude sloužit jako připomínka toho, co je třeba v konkrétní den užít. Účastníci budou prostřednictvím aplikace každý týden dotazováni, zda v jejich léčbě v daném týdnu došlo k nějakým změnám, aby mohl být jejich lékový režim odpovídajícím způsobem aktualizován. Pokud účastníci uvedou, že došlo ke změně jejich medikace, budou aktualizovány informace v aplikaci.

Výzkumníci budou účastníky kontaktovat telefonicky, pokud nebudou 3 po sobě jdoucí dny přijata žádná data, a každý měsíc (pokud to bude nutné), aby účastníkům pomohli s používáním technologie a odstranili případné problémy. V případě technických potíží bude využita funkcionalita vzdálené podpory, kdy mohou výzkumníci na dálku pomoci účastníkům studie. Během pilotního projektu budou získané údaje použity k vývoji technologie, která pomůže předvídat zhoršení chronické obstrukční plicní nemoci, aby v budoucnu mohlo být na základě těchto údajů předvídáno zhoršení zdravotního stavu. Během pilotního projektu bude sledováno skutečné používání aplikace SHAPES, aby se otestovala její použitelnost a zjistilo se, zda je zapotřebí další úprava či podpora. Po skončení 12týdenního pilotního období budou výzkumní pracovníci zasílat k vyplnění další sadu dotazníků, které budou podobné těm, které byly vyplňovány na začátku studie, a budou zahrnovat otázky týkající se rodinného stavu, profesního statusu a podpory, která je využívána v každodenním životě. Dotazníky administrované v této fázi budou více zaměřeny na to, co si účastníci myslí o technologii, a některé ze stejných dotazníků administrovaných dříve budou položeny znovu.

Tři měsíce po ukončení pilotního projektu budou účastníci požádáni o vyplnění následných dotazníků, přičemž se bude jednat o dotazníky, které byly již dříve administrovány.

Údaje účastníků, naměřené fyziologické hodnoty a výstupy z analýz budou nahrány do výzkumného panelu v prohlížeči výzkumného a lékařského personálu FNOL. Výzkumní pracovníci, lékaři a zdravotní sestry budou moci prohlížet klinické údaje a údaje z dotazníků každého účastníka a podle potřeby spravovat medikační režimy účastníků, případně účastníky kontaktovat a pozvat na kontrolní prohlídku.

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Shromážděné informace o účastnících budou bezpečně a důvěrně uloženy na serverech Fakultní nemocnice Olomouc. Totožnost účastníků budou moci zjistit pouze osoby, které tvoří výzkumný tým na projektu SHAPES složený ze zaměstnanců Fakultní nemocnice Olomouc. Všichni ostatní partneři projektu SHAPES obdrží kód a nebudou moci pomocí tohoto kódu účastníky osobně identifikovat. Identifikovatelné informace budou uloženy do konce října 2023, po tomto datu budou informace deidentifikovány a uloženy po dobu dalších 5 let ve FNOL. Soubor deidentifikovaných údajů může být sdílen s ostatními členy konsorcia SHAPES, pokud je uzavřena příslušná dohoda o sdílení údajů. Anonymní agregovaný soubor údajů bude uložen na dobu neurčitou pro budoucí využití výzkumnými pracovníky.

Schéma studie je znázorněno níže.

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Pozvání

Lidé, kteří byli identifikování jako vhodní pro zařazení do studie obdrží pozvánku. Informace ohledně studie jsou poskytnuty stejně jako příležitost položit doplňující dotazy.

Souhlas

Lidé, kteří souhlasí s účastí ve studii jsou požádání, aby si přečetli a podepsali informované souhlasy, pokud jsou skutečně rozhodnuti o své účasti. Tímto se z nich stávají účastníci studie.

Zaškolení a trénink v zacházení s tabletem a přístroji

Účastníkům jsou předány tablety a přístroje. Zaměstnanci Fakultní nemocnice Olomouc (FNOL) provedou úvodní zaškolení účastníků. Účastníci dostanou čas všechny přístroje otestovat a podat zaměstnancům FNOL doplňující dotazy ohledně jejich správného ovládání.

Sběr počátečních hodnot o zdravotním stavu účastníků studie

Výzkumníci prověří zdravotní stav účastníků z doby **před** jejich zapojením do studie. Tyto informace získají na základě předložených dotazníků a kontroly zdravotních záznamů jednotlivých účastníků.

Domácí používání aplikace a přístrojů

Účastníci jsou požádáni, aby využívali aplikaci SHAPES a přístroje pro monitoring chronické obstrukční plicní nemoci v domácích podmínkách po dobu **tří měsíců**. Výzkumníci kontaktují účastníky po několika dnech, aby zjistili, zdali je potřeba jakákoliv podpora z jejich strany směrem k účastníkům studie, dále pokud budou chybět data z několika posledních dní. Účastníci naopak oznámí výzkumníkům změny ve své medikaci. Další kontakt je navázán z jedné či druhé strany dle potřeby.

Sběr informací na konci pilotní studie

Na konci studie výzkumníci prověří zdravotní stav účastníků **po** skončení studie, zdali došlo k jakýmkoli změnám oproti počátečnímu stavu. Informace jsou získány pomocí dotazníků a kontroly zdravotních záznamů jednotlivých účastníků.

Návazný rozhovor

Po skončení pilotní studie mohou být někteří účastníci požádáni o osobní rozhovor ohledně jejich zkušeností během doby studie. K tomu může dojít bezprostředně po dokončení studie, popřípadě až za několik týdnů. Všichni účastníci také obdrží několik dotazníků týkajících se jejich zdravotního stavu a jejich zapojení do studie.

Dotazníky po konci studie

Tři měsíce po skončení pilotní studie výzkumníci budou sbírat návazné informace pomocí dotazníkového šetření. Poté bude studie ukončena.

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Možné výhody účasti

Pilotní projekt může účastníkům pomoci zvýšit schopnost účinně sledovat a řídit svůj zdravotní stav.

V budoucnu může být tato technologie využívána v celé Evropě jako asistence starším lidem při sledování svého zdravotního stavu.

Do budoucna může tato studie usnadnit lékařům sledování osob na dálku a využívat algoritmy umělé inteligence k předvídání zhoršení zdravotního stavu. Tato funkce však nebude v této studii zkoumána.

Možné nevýhody účasti

Nepředpokládáme, že by účast v této studii účastníkům přinesla nějaké nepříjemnosti nebo nevýhody kromě pravidelného používání tabletu a přístrojů a případného kontaktu s výzkumnými pracovníky.

Náhodné zjištění

Ačkoli je to velmi nepravděpodobné, účastníci mohou při monitorování, které provádějí, zjistit případné zdravotní potíže. Ty by měly být nezávisle konzultovány se zdravotnickým pracovníkem.

Finanční informace

Účast v této studii nebude znamenat žádné náklady. Za účast také nebude vyplácena žádná platba. Tento projekt je financován z programu Evropské unie pro výzkum a inovace Horizon 2020 na základě grantové dohody č. 857159.

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Informování o výsledcích studie

Výsledky této studie mohou být použity v dalším výzkumu, komunikačních aktivitách (např. v rámci dalšího výzkumu v projektu SHAPES, v článcích v časopisech, na seminářích a konferencích) a zprávách pro kontrolní orgány. Souhrn zjištění bude zpřístupněn po dokončení všech analýz. Nikde nebude možné identifikovat účastníky.

Ukončení studie

Výzkumní pracovníci provádějící studii mohou z jakéhokoli důvodu ukončit studii dříve, než bylo plánováno, aby ochránili bezpečnost účastníků nebo bezpečnost údajů účastníků.

Na konci 12týdenního pilotního projektu budou propůjčená zařízení (monitor krevního tlaku, pulzní oxymetr, spirometr, chytrý inhalátor a tablet) účastníky vrácena a přístup k aplikaci SHAPES bude ukončen.

Další informace

Další informace týkající se studie si můžete vyžádat od následujících osob zapojených do projektu SHAPES.

Kontakty

Národní telemedicínské centrum Fakultní nemocnice Olomouc

Ladislav Stanke (výzkumný pracovník)

E-mail: Ladislav.Stanke@fnol.cz; Telefon: 583 443 713

Michal Štýbnar (koordinační pracovník)

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Annex 64 UC-PT3-COPD Phase 5 Participant consent form

INFORMOVANÝ SOUHLAS PACIENTA

Já, níže podepsaný/á, souhlasím s účastí na projektu SHAPES, jehož popis, jakožto i účel a rizika jsou popsány v dalším textu Vašeho informovaného souhlasu. Lékař, který je součástí řešitelského týmu usoudil, že splňujete požadavky pro účast v uvedeném projektu.

Název projektu:

Monitoring pacientů s chronickou obstrukční plicní nemocí - CHOPN (řešeno v rámci projektu SHAPES)

Oblast monitorace:

Ověření přínosu digitálních technologií v oblasti monitorace pacientů v domácím prostředí

Hlavní řešitel: RNDr. et RNDr. Ing. Ladislav Stanke, Ph.D.

Spoluřešitelé: MUDr. Samuel Genzor, Ph.D., MUDr. Jan Mizera, Mgr. Michal Štýbnar

Pracoviště řešitel a spoluřešitelů: Národní telemedicínské centrum (NTMC), Fakultní nemocnice Olomouc (FNOL), Klinika plicních nemocí a tuberkulózy, Fakultní nemocnice Olomouc

Rizika projektu:

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Riziko poškození pacienta nelze nikdy zcela vyloučit, nicméně v prezentovaném případě je minimalizováno na velice nízkou úroveň. Tablet i použité přístroje, které přijdou do kontaktu s pacientem, jsou komerčně dodávané přístroje, které mají označení CE, nebo FDA approved. Případná rizika by u dodaných přístrojů vyplývala zejména z využití nevhodných zdrojů pro dobíjení baterií, kde by hrozilo případné poškození baterií, které může v některých případech vést k jejich zahřátí či až zahoření, což je riziko většiny bateriových přístrojů. Nicméně tato rizika jsou jednotlivými výrobci rovněž minimalizována s využitím ochranných obvodů detekujících možná přetížení, kontrolujících teplotu apod. U uživatele, který postupuje dle návodu, případně instrukcí a využívá správné napájecí zdroje (pro daný přístroj určené) je toto riziko ještě nižší.

Projekt SHAPES (The Smart & Healthy Ageing through People Engaging in Supportive Systems) tak nepředstavuje žádná rizika pro Váš zdravotní stav a nemůže přispět k jeho zhoršení. Projekt je založen na měření biomedicínských signálů, konkrétně jde o spirometrii, měření krevního tlaku, saturace krve kyslíkem a monitoring adherence (využívání inhalátoru). Měření probíhá s pomocí přístrojů k tomu určených, které budou zapůjčeny z pracoviště řešitele.

Pokud běžně nevyužíváte žádné informační a komunikační technologie, jako je počítač, tablet, chytrý telefon apod., tak Vám může na počátku trvat, než získáte plnou jistotu v ovládání všech přístrojů a tabletu s poskytnutým programovým prostředím. Nicméně není nutné se této fáze obávat, jelikož personál je ochoten Vám v případě nejasností či nejistoty s čímkoliv poradit.

V případě dodržení instrukcí k jednotlivým zapůjčeným přístrojům není známo, že by se jednalo o přístroje, které by Vás mohly jakkoli ohrozit.

Samotný monitoring probíhá s využitím tabletu, na kterém je nainstalována telemedicínská aplikace (Medimonitor) – u některých pacientů, kteří nejsou zvyklí pracovat s ICT technologiemi může trvat déle se naučit aplikaci ovládat, byť bylo pracováno s využitím znalostí a dobrých praxí v oblastech uživatelské zkušenosti (UX – user experience) a přístupnosti, které by měly zmíněné riziko minimalizovat.

Za účelem komunikace je využíváno wi-fi sítě, která patří pacientovi. V tomto ohledu není možné vždy zaručit stabilitu a dostupnost sítě. Pro krátkodobé výpadky jsou data

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ukládána v tabletu. Při poruše komunikace mezi jednotlivými přístroji a tabletem je možné některé hodnoty zadat ručně.

Účel a popis projektu:

- Ověření možnosti telemedicínského monitoringu v místě bydliště pacienta pomocí vybraných přístrojů.

- Ověření schopností telemedicínské aplikace vyvinuté ve FNOL (Medimonitor) pro komunikaci s jednotlivými přístroji, agregaci a odeslání dat na server FNOL.

- Ověření možnosti zobrazování varování na základě detekce překročení prahů měřených hodnot (bude probíhat prospektivně)

- Ověření možnosti nalezení algoritmu (případně vytrénování neuronové sítě) pro včasnou detekci blížící se exacerbace na základě naměřených dat (tato část proběhne retrospektivně po náběru všech dat z přístrojů zapůjčených pacientům).

V rámci projektu bude testována možnost vzdálené monitorace pacientů s chronickou obstrukční plicní nemocí. Za tímto účelem je pacientům zapůjčena sada přístrojů zakoupených z prostředků mezinárodního projektu SHAPES, na kterém NTMC (Národní telemedicínské centrum) FNOL aktuálně participuje. Konkrétně se jedná o spirometr, tlakoměr, oxymetr a nástavec na inhalátor. Každý z těchto přístrojů je schopen pomocí Bluetooth odeslat naměřená data do tabletu (v případě selhání datového přenosu je možné hodnoty zadat i manuálně), který budou mít pacienti rovněž k dispozici. Cílovou skupinou projektu je stárnoucí populace, přičemž hlavním cílem projektu je podporovat aktivní stárnutí s využitím moderních digitálních technologií. V předložené studii se konkrétně jedná o skupinu seniorních pacientů s chronickou plicní obstrukční nemocí. Mezi dílčí cíle projektu patří ověření přínosu telemedicínské aplikace FNOL (Medimonitor) pro akvizici, agregaci a odesílání dat naměřených pomocí přístrojů u pacienta na server FNOL. Pseudonymizovaná (pozměněná takovým způsobem, aby neobsahovala konkrétní jména pacientů) data jsou dále využita jako vstupy pro připravované algoritmy, případně neuronové sítě, které mají za cíl prevenci dekompenzace jejich stavu.

Postupy používané v rámci projektu:

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- Odběry krve pro kvantifikaci markerů relevantních pro diagnózu a pro titraci medikace.

- Administrace dotazníků (prezentovány osobně i elektronicky na zapůjčeném tabletu).

- Měření pomocí zapůjčených zařízení:
    - Monitoring adherence (detekce používání inhalátoru) je rovněž automatický, je ovšem nutné mít poblíž tablet pro přenos dat.
    - Měření biomedicínských signálů pomocí spirometru, tlakoměru a oxymetru (SpO_2 senzoru), přičemž spirometrie a měření tlaku se provádí jednou denně, saturace kyslíkem se měří pomocí oxymetru v podobě prstenu kontinuálně během doby spánku a potom jednou ráno před užitím medikace společně s měřením ostatních veličin. Při měření je opět poblíž tablet.

- Využívání telemedicínské aplikace (pro akvizici, agregaci a odesílání naměřených dat, vedení videokonzultací).

- Statistická analýza výsledků.

- Hledání algoritmů, učení neuronových sítí pro predikci exacerbací.

Prospěšnost projektu:

Pro zlepšení námi vyvíjených digitálních technologií a služeb z oblasti elektronického zdravotnictví je pro nás cenná zpětná vazba od uživatelů-pacientů tak abychom mohli naše služby dále zdokonalovat směrem k uživatelské přívětivosti, proto jste žádáni, abyste otestovali naši telemedicínskou aplikaci, včetně její schopnosti propojení s dalšími zařízeními, které byly popsány výše. Vámi naměřené hodnoty mohou rovněž pomoci lépe pochopit průběh Vašeho onemocnění. Tyto hodnoty budou dále důkladně analyzovány s využitím pokročilých algoritmů či neuronových sítí.

Kdo se může studie zúčastnit:

Do studie se můžete přihlásit, pakliže jste byly diagnostikováni s chronickou plicní obstrukční nemocí a jste starší 60 let.

Kdo se nemůže studie zúčastnit:

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Vzhledem k povaze projektu se nemohou zapojit pacienti s kognitivními poruchami (např. Alzheimerova choroba) a pacienti, kteří nemají v místě bydliště připojení k internetu (bezdrátovou wi-fi síť pro připojení zapůjčeného tabletu), které umožní přenos naměřených hodnot na servery FNOL.

Povinnosti pacienta:

Jako pacient zapojený do výše popsaného projektu máte povinnost sdělovat lékařskému a vědeckému personálu všechny informace o svém zdravotním stavu a žádné informace nezamlčovat.

Prohlašuji tímto, že jsem pročetl/a všechny výše uvedené informace týkající se popsaného projektu – a těmto jsem porozuměl/a.

Byl/a jsem dostatečně informován/a o cílech, průběhu, účelu a rizicích vyplývajících z účasti na projektu. Jsem si vědom/a, že kdykoli v průběhu i po ukončení mojí účasti na projektu je lékař odpovědný za poskytnutí doplňujících informací o jakékoliv případné zdravotní újmě související s mojí účastí v projektu nebo informací, které mohou ovlivnit moji ochotu v projektu setrvat.

Souhlasím se svou účastí v projektu SHAPES.

Jsem si vědom/a toho, že odstoupení nebo vyřazení z projektu SHAPES, ať už z jakéhokoli důvodu, žádným způsobem neovlivní kvalitu zdravotní péče, která mi bude poskytována. Podpisem tohoto informovaného souhlasu se nevzdávám žádného ze svých zákonných práv.

Kdykoliv mohu uplatnit svá práva u svého ošetřujícího lékaře a požádat v souladu se zákonem o přístup k záznamům a případně je opravit, pokud jsou nepřesné. Projekt SHAPES je prováděn v souladu s právními předpisy České republiky.

Budu-li chtít získat jakékoliv doplňující informace o projektu SHAPES, mohu se obrátit na svého lékaře. Obdržím jeden originálně podepsaný stejnopis tohoto dokumentu.

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Po ukončení monitorace je pacient povinen vrátit tablet a všechny zapůjčené přístroje pracovníkovi, který mu je vydal.

Jméno a příjmení pacienta Podpis pacienta

(Hůlkovým písmem)

_____
_____

Datum:_____ (mes-dd-rrrr)

Jméno a příjmení informujícího lékaře Podpis lékaře

(Hůlkovým písmem)

_____
_____

Datum: _____ (mes-dd-rrrr)

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Souhlas se zpracováním osobních údajů

Subjekt údajů:

Jméno a příjmení: **……**

Datum narození: ……

Správce:

Fakultní nemocnice Olomouc

se sídlem: I.P.Pavlova 185/6, 779 00 Olomouc

zastoupena: prof. MUDr. Romanem Havlíkem, Ph.D.

(“**Zpracovatel**”)

SHAPES (The Smart & Healthy Ageing through People Engaging in Supportive Systems)

Maynooth University

Maynooth,

Co. Kildare,

Irsko.

zastoupena: Ray O‘Neill

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(“**Správce**”)

Účely zpracování:

Vaše osobní údaje budou zpracovávány pro účely uskutečnění sběru dat pro mezinárodní projekt SHAPES (dále jen „projekt **SHAPES**“), v rámci kterého bude testována možnost vzdálené monitorace pacientů s chronickým srdečním selháním.

Rozsah zpracovaných osobních údajů:

Vaše osobní údaje budou zpracovány v následujícím rozsahu: jméno, příjmení, datum narození,……. Vaše osobní údaje budou zpracovávány pouze v rozsahu nezbytném pro naplnění účelu a v souladu s ním.

Právní základ:

Vaše osobní údaje budou zpracovány na základě písemného souhlasu, který může být kdykoli odvolán písemně nebo e-mailem prostřednictvím výše uvedených kontaktních údajů a to v souladu s příslušnými právními normami o ochraně osobních údajů, zejména v souladu s Nařízením Evropského parlamentu a Rady (EU) 2016/679 ze dne 27. dubna 2016 o ochraně fyzických osob v souvislosti se zpracováním osobních údajů a o volném pohybu těchto údajů a o zrušení směrnice 95/46/ES (obecné nařízení o ochraně osobních údajů, či GDPR). Odvoláním souhlasu není dotčena zákonnost předchozího zpracování.

Poskytnutí osobních údajů je zcela dobrovolné. S odmítnutím udělení souhlasu nejsou spojeny žádné negativní důsledky. Zpracování osobních údajů je však nezbytné pro Vaše zařazení do projektu SHAPES a bez udělení souhlasu není účast na projektu SHAPES možná.

Příjemci:

Správce SHAPES nebude znát Vaši totožnost, jelikož mu budou data předávána v pseudoanonymizované podobě. K Vašim osobním údajům bude mít přístup pouze Váš lékař a vědecký tým Fakultní nemocnice Olomouc. Osobní údaje mohou být také

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zpřístupněny kontrolním a jiným orgánům při výkonu jejich kontrolní nebo jiné úřední činnosti.

Předávání osobních údajů do třetí země:

Vaše osobní údaje nebudou předávány do třetích zemí.

Doba uchování:

Pokud nebude Váš souhlas se zpracováním osobních údajů odvolán, budou osobní údaje uchovávány a využívány po dobu provádění projektu SHAPES, případně v nezbytném rozsahu i po jejím skončení s ohledem na ochranu oprávněných zájmů správce.

Práva subjektu údajů:

Jako subjekt údajů máte právo na přístup k osobním údajům, právo na jejich opravu nebo výmaz (pokud bude odvolán souhlas nebo uplyne doba uchování), popřípadě na omezení zpracování a na přenositelnost osobních údajů k jinému správci. Máte rovněž právo požadovat po Správci informace o způsobu, rozsahu a účelu zpracování osobních údajů a Správce má povinnost Vám tyto informace sdělit neprodleně, nejpozději do 1 měsíce od obdržení žádosti. Veškeré žádosti budou podávány prostřednictvím výše uvedených kontaktních údajů. Dále máte právo obrátit se kdykoliv se svým podnětem nebo stížností na Úřad pro ochranu osobních údajů (www.uoou.cz).

Souhlas:

Prohlašuji, že jsem byl/a řádně informován/a o výše uvedeném zpracování osobních údajů, jsem si vědom/a svých práv a svobodně s tímto zpracováním souhlasím.

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Datum: ……..

Podpis: _____

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