



SHAPES

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

D6.3 – Improving In-Home and Community-based Care Pilot Activities Report

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Table of Acronyms and Abbreviations

Table 3 Acronyms and Abbreviations

Acronym	Full Term
Avg	Average
AI	Artificial Intelligence
API	Application Programming Interface
App	(mobile) Application
bpm	Beats per minute
CSF	Critical success factors
DPA	Data processing agreement
DPIA	Data protection impact assessment
DS	Digital solution
EIP on AHA	European Innovation Partnership on Active and Healthy Ageing
EQ-5D-5L	European Quality of Life 5 Dimensions 5 Level Version
EU	European Union
FICS	Function-Interactions-Content-Style
GDPR	General Data Protection Regulation
GSES	General Self-Efficacy Scale
HCP	Healthcare professional
HLM	Health literacy measure
HR	Heart rate
i.e.	id est
ISO	International Standards Organisation
KPI	Key Performance Indicator
M	mean
MAFEIP	Monitoring and Assessment Framework of the EIP
MAST	Model for Assessment of Telemedicine
max	maximum
med	median
min	minimum
NASSS	Non-adoption, Abandonment, Scale-up, Spread, and Sustainability
OBK	Oberbergischer Kreis
OSSS-3	Oslo Social Support Scale
PACT	People Activities Context Technology
PMB	Programme Management Board
PO	Primary Objective
POI	Point of Interest
PT	Pilot Theme
SD	Standard deviation
SHAPES	Smart and Healthy Ageing through People Engaging in supportive Systems

SO	Secondary Objective
SU	Service User
SUS	System Usability Scale
TAM	Technology Assessment Model
UC	Use Case
UC-PT	Use Case of Pilot Theme
UEQ-S	User Experience Questionnaire -Short
UX	User eXperience
WHO-QOL Bref	World Health Organization Quality of Life Bref
WP	Work Package

Keywords

Digital solutions, technology, active and healthy aging, older people, in-home and community-based care services, autonomy

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Executive Summary

This deliverable contains the work completed by Pilot Theme 2 of the SHAPES Pan-European Pilot Campaign. It presents the planning and outcomes of all activities and tasks that have been completed in Phases 1 to 5 of the pilot campaign for improving in-home and community-based care. The deliverable only presents the results which will be further discussed in D6.9.

The work described here is the result of collaboration and dedication of the whole of Pilot Theme 2, including the pilot site leaders 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 2.
2. Detailed description of the work undertaken in Phases 1 to 5 by the four use-cases being evaluated in this pilot theme.
3. An ethical requirements check.

1 Introduction

The Pilot Theme 2 “Improving In-Home and Community-based Care” has the approach to build a safe environment by providing an appropriate home setting for older individuals. This stretches from the arrangement of support up to reflecting the participants’ key health parameters, enabling access to information about the local community, protection against cognitive decline as well as assistance during the night.

The target group consists mainly of people 65+, mostly living on their own in the according reference site. Some use cases had additional requirements to consider such as cognitive impairments (UC-PT2-003) or a specific pilot environment i.e. the home-setting or nursing home (UC-PT2-004).

Pilot Theme 2 aims to reduce feelings of isolation and loneliness as well as insecurities in day-to-day life and during the night. Therefore, it focuses on the empowerment of older individuals to monitor their health and wellbeing status at home, get personalised recommendations and advice for exercises and activities and to provide assistance to increase the feeling of safety and wellbeing in order to support independent living of older individuals.

Such a safe and caring environment has been created and built by the technical support of wearables, sensors, tablets, robot and the combination of digital solutions for each research condition of each use case.

1.1 Rationale and purpose of the deliverable

The deliverable D6.3 “Improving In-Home and Community-based Care Pilot Activities Report” presents the key findings and results of the SHAPES Pilot Theme 2. It describes the pilot activities and preparatory work undertaken during each of the five phases of the pilot, which closely follow the methodology outlined in Deliverable D6.1. The D6.3 only presents the results, the discussion and implications of these results will be presented in D6.9.

Pilot Theme 2 is led by the GEWI - Institut für Gesundheitswirtschaft e.V. in Germany. Within this pilot theme there are multiple ‘use cases’ each deploying and evaluating different digital solutions according to the type of support required. Four use-cases are used to represent this pilot theme:

- UC-PT2-001 “Remote monitoring of key health parameters” (lead site: GEWI; replicating site: AIAS, 5th YPE)
- UC-PT2-002 “Supporting the interaction of the individual with the community” (lead site: GEWI; replicating site: AIAS, UP, CCS)
- UC-PT2-003 “Long Lasting Memories LLM CARE Health and Social Care Ecosystem for Cognitive and Physical training” (lead site: AUTH; replicating site: GEWI)
- UC-PT2-004a/b “Surveillance Rounds at Community Care” (a), “Night Surveillance Rounds in the Home-Setting” (b). (lead site: GEWI; replicating site: 5th YPE)

1.1.1 Deliverable Objectives

The high-level objectives of this interim Deliverable are to:

- Introduce the use cases in pilot theme 2 and describe all work completed on the pilot theme to date.
- Describe the methodology used to conduct Phases 1–5 at each of the pilot sites involved in PT2.
- Report on the key findings at each phase.

1.1.2 Key inputs and outputs

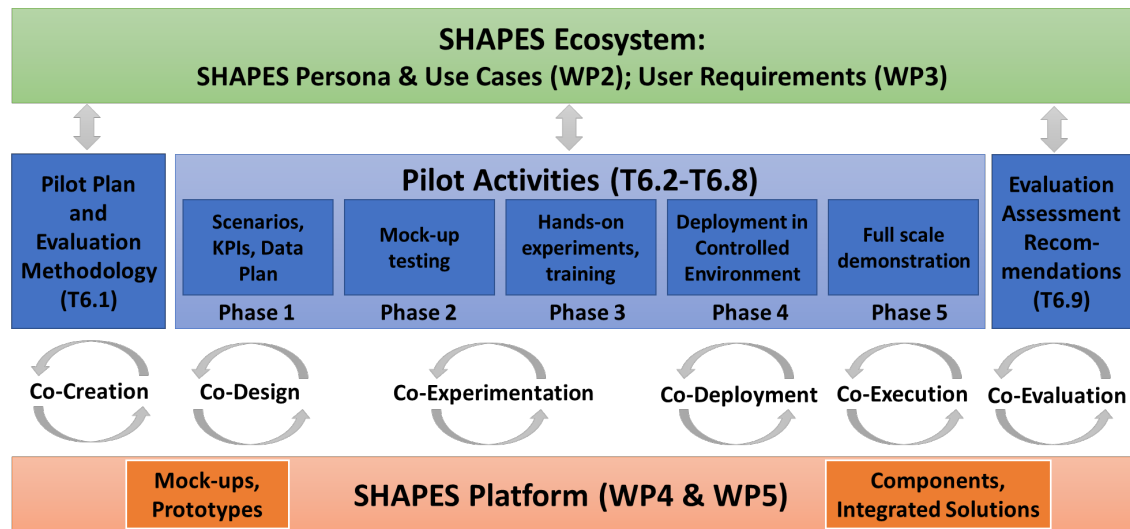


Figure 1: Overview of WP6.

The previous Figure 1 presents an overview of WP6 with its different phases 1-5, as well as any related tasks (T6.1-T6.9) and WPs that contribute to the pilot activities taking place in WP6.

This deliverable builds 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 to be developed in WP4 were co-designed, co-tested and co-validated. 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 are developed in WP2, as well as on the user requirements, which are 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 four use cases in their entirety. Main outcomes and key recommendations from each use case are then brought together in the Conclusion.

2 Use case PT2-001

2.1 Introduction

In the following, the initial ideas and according pilot activities of the UC-PT2-001 *Remote monitoring of key health parameters* are presented. The target group of this use case was composed of +65 year old persons living in their home-setting in the rural reference site “Oberbergischer Kreis” (OBK) in Germany. The use case target users were insufficiently informed about the realm of their capabilities, thus subject to suffer from isolation and associated risks such as loss of speech, vitality, and lack of general fitness. The individuals at stake were still rather agile but needed to be somewhat motivated and/or informed about the variety of physical and mental activities at their disposal or within their reach in order to keep exercising regularly and/or entertain social contacts.

The use case was based on the needs and life world of the persona “Helena” (7) who was described in more detail in D2.5. The 93-year old lady lived with her cats in her own house in a small village. Due to her arthritis and decreasing mental fitness she experienced declining health and wellbeing conditions.

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

- Improve the monitoring of the individual’s health and wellbeing status
- Identify associations between relevant health parameters and the individual’s perceived wellbeing.
- Improve older individual’s health and wellbeing outcomes and quality of life.

Additionally, the users’ trust and acceptance of the SHAPES Platform and Digital Solutions have been explored. This use case was led by the GEWI – Institut für Gesundheitswirtschaft e.V. and was replicated by AIAS and 5th YPE.

2.2 Description

Although health problems increase with age, old age does not inevitably stand for illness, limitations and the need of care. Individual lifestyles and personal resources, social integration and the level of access to medical and social care greatly impact the health status, quality of life and well-being of older individuals. Supporting older people

in living healthy and independent lives equally can reduce risk factors such as unhealthy lifestyles, to improve external health determinants and to strengthen accessible healthcare for (1).

2.3 Digital solutions used in this use case

In the course of the project, adaptations had to be made to this first planning of the use case scenario referring to the provision of features to be supported by SHAPES digital solutions. The previously intended inclusion of a urine analysis as well as the smart water bottle could not be realised, as no Open Call partner could be found to provide this technology. Therefore, these were not part of the testing and deployment of the digital solutions. Consequently, they were not considered in the NASSS Framework nor in the MOMENTUM. Instead, a liquid intake monitoring feature was included, allowing the end-users to take manual entries of their liquid intake. Since the data being collected was triangulated via other technologies, the UC itself only misses little information.

Several digital solutions are used by the participants (endusers) which are all integrated via the SHAPES Front-end App. These are accessed via a tablet provided by the GEWI - Institut für Gesundheitswirtschaft e.V. Additionally, participants receive a CE-marked activity wristband. The following digital solutions used in this use case are:

eCare (EDGE)

Remote monitoring platform which displays heart rate, steps, physical activity, sleep quality, sleep duration, sleep assessment, wellbeing assessment and survey data gathered manually or automatically, using connected devices like the activity wristband and the tablet, in home environment.

eHealthpass (GNO)

Health and Wellbeing App for the manual entry of fluid intake, COVID-19 symptom checker and provision of personal data (i.e. medical record, social history background) collected during registration process of the participant.

Sleep and activity analysis (TREE)

Analysis of sleep (quality and quantity) and activity measures based on the collected data from the activity wristband.

Validation (wellbeing assessment) and recommendation system (VICOM)

Validation of the collected data used for the recommendation module providing personalized feedback to the participants to improve their health and wellbeing status.

ELLIOT (University of Thessaly)

The intelligent nutrition assistant uses Artificial Intelligence (AI) for registering and administrating the nutrition intake of older individuals to prevent negative effects of malnutrition. Participants have a clear view on the nutrients consumed every day.

Logmeal4Shape (University of Barcelona)

An intelligent tool based on deep learning for food intake monitoring of older individuals. The algorithms allow to automatically recognize the food from an image and construct an objective and precise food diary of the older adults.

Researcher dashboard (GNO; EDGE; VICOM)

Browser-based dashboard to monitor participants' adherence to the intervention during the pilot period and verify the data captured by the different digital solutions supporting the use case.

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

To assess the COVID-19 response a symptom checker was included in the DS and used in the use case querying the main symptoms such as sign of a cold, shortness of breath, loss of taste or smell, coughing and fever.

2.3.2 Equipment and devices used (from third parties)

The following external devices are used in UC-PT2-001:

- Tablet: Samsung Galaxy S6L SM-P615;
- CE-marked devices: Xiaomi Mi Band 3 activity wristband.

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 used 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.

2.4 Data plan

The data plan for phases 4 and 5 for PT2-001 has been finalised and can be accessed on the SHAPES website ([Data plan UC PT2-001](#)).

2.4.1 Data capture methods to be used

Data capture methods used during this pilot are listed below:

Phase 2

- Semi-structured interview

Phase 3

- Semi-structured interview;
- User experience questionnaire-short version (UEQ-S).

Phase 4

- Participant error reporting log.

Phase 5

Excel file 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 (2);
 - EQ-5D-5L (3);
 - General Self-Efficacy Scale (4);
 - Oslo Social Support Scale (5);
 - Single item health literacy scale;
 - Participation questions;

- System Usability Scale (6);
- Technology acceptance questions (7);
- UEQ-S (8).

The SHAPES app (eCare and eHealthpass) to capture the following data:

- Health parameters:
 - heart rate;
 - step count;
 - fluid intake;
 - nutrition intake;
 - sleep parameters;
 - wellbeing assessment;
 - sleep assessment;
 - COVID-measures.
- Tracking data (i.e., user logs);
- Service user and healthcare professional interviews (Annex 1).

2.4.2 Planning of evaluation

MAST

The MAST framework (model for assessment of telemedicine) (9) was applied as it provides a structured approach for assessing the effectiveness and contribution of UC-PT2-001 to quality of care. In a multidisciplinary process, MAST summarises and evaluates information to the use of telemedicine related to the medical, social, economic and ethical issues.

For UC-PT2-001, three of the seven dimensions of MAST were identified to be of importance to consider. These were: Clinical effectiveness, Patient perspectives and Economic aspects. A further exploration and description of the reasons for inclusion will be provided in the evaluation report (D6.9). Table 4 gives an overview of the MAST evaluation.

Table 4: Data required for MAST evaluation of UC-PT2-001

MAST Domain	Topic	Outcome	Data required	Time point
Clinical Effectiveness	Physical health	heart rate, sleep quality and wellbeing		
	Mental health	OSSS-3 (social support) and life events		
	Effects on health-related quality of life	Health related quality of life and wellbeing	EQ-5D-5L scores; WHOQOL-BREF scores	Baseline, end of pilot, 3-month follow up
	Behavioural outcomes	Steps, fluid and nutrition intake, sleep duration		
Patient perspectives	Satisfaction and acceptance	User Experience	UEQ-S scores	End of pilot
		User acceptance	TAM score	End of pilot
	Understanding of information	Usability of application	SUS Scores	End of pilot
	Confidence (in the treatment)		1-item health literacy	
	Ability to use the application			
	Access & Accessibility			
	Empowerment	User engagement	Number of logins	During pilot
	Self-efficacy	Self-efficacy	SHAPES Participation questionnaire	During pilot
			GSES (Self-efficacy)	During pilot
Economic aspects	Amount of resources used when delivering the application and comparators	Cost of devices	Cost as per 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

MAFEIP

The MAFEIP tool (10) was not applied to evaluate UC-PT2-001 due to a small-scale deployment and a non-case controlled study design of the UC.

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

Momentum

Critical success factors (CSFs) and performance indicators offered by the Momentum blueprint (11) were determined in UC-PT2-001 (Annex 2). These factors should be considered when scaling up telemedicine and integrating it into healthcare delivery systems. Although the digital solutions supporting this use case do not deliver specific telemedicine services and no health care professional is involved, the aim is to increase the wellbeing of the individual, aiming to prevent the onset of a medical condition. The advantage of a rapid consideration in the planning of the pilot design predominates. Outcomes of the process are included in the annex (Annex 2) and details of each CFS are provided below.

CSF 1. Cultural readiness for the telemedicine service

In the region where this use case has been deployed, only limited sharing of clinical information between different health care providers is realised. Within one institution, information is shared with the patient. Progress and promoting of telemedicine are highly welcomed in the region.

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

The advantages of telemedicine are clearly seen and considered the best solution to address shortage of skilled healthcare professionals.

CSF 3. Ensure leadership through a champion

At the end of the project a clear leadership will be identified. The way towards deployment of the SHAPES digital solutions should be supported by influential persons.

CSF 4. Involvement of healthcare professionals and decision-makers

Healthcare professionals and decision-makers were partially involved in the development of the content of the project in Phases 1-3. As the deployment of this use case does not foresee any participation of health care professionals their input was not further sought in Phases 4 and 5 of the pilot. As the organisation of this use case is working together with decision makers from the reference site, those have been involved in the whole process of the project.

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

Patients have been involved in the development of the SHAPES digital solutions through the activities of all phases. The development was based on the patient needs and training for using the digital solutions was delivered.

CSF 6. Ensure that the technology is user-friendly

The project considered attentively the user-friendliness of the digital solutions. Potential users were asked about their opinion and experience interacting with the solution and all feedback was considered in the final development of the SHAPES digital solutions. The evaluation also included metrics like the System Usability Scale (SUS).

CSF 7. Pull together the resources needed for deployment

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

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

In general, health insurances have a vested interest in lowering costs i.e. their spendings, and direct more and more efforts and resources towards increasing prevention in Germany. Yet, first evaluations to identify primary clients for the SHAPES digital solutions still have to be completed.

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

It will be evaluated at the end of the project and included in D3.10.

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

Legal requirements in the German context have been reviewed to ensure that the use case was piloted within the relevant legislation. Since the digital solutions were not classified as a medical device, all relevant requirements were met.

Completion of a Data Protection Impact Assessment (DPIA) identified and minimised the risks associated with the pilot with input sought from other work packages and the SHAPES Data Protection Officer at GEWI. 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 are limited, the solution is being 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 with the monitoring protocol.

CSF 13. Identify and apply relevant legal and security guidelines

GDPR was applied. The digital solutions implemented all applicable security and privacy-related regulations.

CSF 14. Involve legal and security experts

Advice from legal experts and experts on data security matters was received from project partners (for example LAUREA, that has extensive expertise in this field). The technical partner VICOM was awarded the ISO 27001 certification for information security management.

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 the participants' privacy has been protected. The project underwent 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 delivery of high-quality, person-centred health and care digital solutions and services.

The pilot is being 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 works 24/7/365. In case of any bugs or issues the development and maintenance team fixes it. EDGE, GNOMON and VICOM are the owners of all the software that is used in the pilot. This means that there is no software dependencies with third parties, and that SHAPES partners are able to adapt source code at any point. The system logs all activities so any incident can be identified and solved quickly. In addition to the user manual, pilot hosts have access to the software developers of the different digital solutions so in case of doubts or questions we can answer them directly from EDGE, GNOMON, VICOM, TREE, ELLIOT and Logmeal4SHAPES.

CSF 18. Establish and maintain good procurement processes

The requirements applicable to the devices used in the pilot were previously defined and vendors that fulfil them were identified. The SHAPES project provides the servers that are needed to run the solution. Those servers meet the service level needed to run the pilot successfully.

NASSS

The NASSS framework (Nonadoption, Abandonment, Scale-up, Spread and Sustainability) (12) was used to increase the success of the technology of use case UC-PT2-001. It was conducted to detect risks, which might lead to project failure. The short version of the NASSS questionnaire was considered and completed by the pilot team (Annex 3). In three out of six domains uncertainties were identified and mitigation measures developed to ensure the success of the use case (Table 5).

Table 5: Uncertainties and mitigation measures identified using the NASSS framework (UC-PT2-001)

NASSS complexity domain	Uncertainties detected	Mitigation measures taken
Technology	<p>The technology is not fully developed and thus does not exist in a robust and definitive form yet. Significant uncertainties derive from the open call component:</p> <ul style="list-style-type: none"> ELLIOT and Logmeal4SHAPES: Enablers-ST2 Monitoring of nutrition intake 	<p>The technology to be developed is described and planned in detail in the UC. In the development process, the actual solution is closely aligned with the planned application and function of the technology. Mock-up-tests are performed with potential end-users to support the realisation process and constantly specify the technology.</p>
Technology	<p>Part of the technology are standard commercial devices (tablet, activity wristband) wherefore no significant uncertainties are expected in this respect. However, significant uncertainties remain due to the open call components of ELLIOT and Logmeal4SHAPES for monitoring nutrition.</p>	<p>In the contracts with the OC partner, the provision of the technology at a fixed time is stipulated and ensured by them.</p>
Technology	<p>Integration of digital solutions of the open call partners (ELLIOT and Logmeal4SHAPES) is pending as well as the functionality of the SHAPES Platform, which has not been defined to the use case leaders.</p>	<p>Functionality of platform is discussed in cross work package meetings; solutions of open call partners (ELLIOT and Logmeal4SHAPES) are tested in phases 3 and 4 (researcher and in controlled environment)</p>
Technology	<p>The technology to be developed has a high degree of interdependencies. Constant testing of the technology is needed to detect and rectify occurring</p>	<p>Actions to increase efficiency in the development phase involve the close collaboration with technical partners in biweekly meetings and constant</p>

	technical problems/issues (bugs and crashes).	testing and feedback loops to assure alignment.
The value proposition	The technology, which is a combination of different digital solutions, does not exist in a definite form and a realistic assessment of challenges of implementing at scale has not been conducted yet.	In a large-scale pilot campaign, the real-world value is assessed and an analysis of costs and benefits is considered.
The external context for the innovation	<p>The COVID-19 pandemic might affect the deployment of the UC in the home setting due to restrictive access to individuals' homes.</p> <p>Regulations regarding the COVID-19 pandemic have to be further evaluated.</p>	Internal discussions on potential regulatory issues and challenges and safety measures are applied, remote working is performed if feasible

2.5 Phase 1

2.5.1 PACT and FICS Scenario

Table 6: PACT (UC-PT2-001)

Code	UC-PT2-001	Version	0.3	Date	2021/03/22
Applicable SHAPES Persona	Helena (P7) lives alone in her own house, small village, daughter is the caregiver				
Applicable SHAPES use case	UC-PT2-001 Remote monitoring of key health parameters				
People Roles and/or actors of typical users involved in delivering and receiving the telemedicine intervention	<ul style="list-style-type: none"> Older individuals living at home by themselves, insufficiently informed about the realm of their capabilities thus subject to suffer from isolation and associated risks such as loss of speech, vitality, and lack of general fitness. The individuals at stake are still rather agile but need to be somewhat motivated and/or informed about the variety of physical and mental activities at their disposal or within their reach in order to keep exercising regularly and/or entertain social contacts. Older individuals are inclined to stay "in touch" with others from the community as well as with virtual assistants to maintain their mental and physical health. 				

	<ul style="list-style-type: none"> • It can happen that older individuals do not eat properly and do not drink enough. The consequences can be dehydration and can lead to weakness and falls. • Low to average e-literacy, low to average affinity to technology • Caregiver: relatives, average level of e-literacy and access to devices (smartphone, tablet, laptop)
Activities Activities to be performed by the actors in order to successfully provide and receive the telemedicine intervention <i>procedures for the professional and the patient; Parameters that determine the measures used in the intervention</i>	<p>Older people / care receiver</p> <ul style="list-style-type: none"> • Steps are be measured by using an activity wristband; data are used to set a realistic goal depending on the individual physical condition and to send reminders if the 50% of the individual's number-of-steps target has not yet been reached at lunchtime. • Exercises are tracked by the activity wristband. The collected data shows if minimum recommendations of aerobic physical activity have been delivered. Messages pop up to avoid long, uninterrupted periods of sitting and to start physical activities. • Fluid intake can be monitored by entering the daily liquid intake in an App. Based on these data, recommendations and reminders can be given to the individual to counteract forgetting to drink. • Sleep (duration and quality) can be recorded by the activity wristband. By surveying the older individual, it can be determined the individual optimum hours of sleep. Based on these data, tips and recommendations can be given regarding the ideal point to get up or fall asleep as well as to establish a good-night routine. • Nutrition is very complex to measure and requires a lot of discipline of the person. The component of a food diary entered via the tablet provides data if all nutrients are supplied in sufficient quantities. A summary of the day is shown in the form of a traffic light system and recommendation to eat more fruit and vegetables the next day. • Wellbeing and sleep is assessed additionally, to quantifiable health data, the perceived state of wellbeing and sleep can be selected at a scale of smileys. <p>Caregiver</p> <ul style="list-style-type: none"> • Overview about health data, wellbeing, traffic light system (nutrition), recommendations and reminders.

	<ul style="list-style-type: none"> • can see abnormalities from daily routines and expected health parameters. • has opportunity to take action reaching the recommend water intake, activities etc. • gets and gives support to older individuals in pursuing daily life.
Context <i>Social-medical relevance of the telemedicine intervention; privacy issues; risks for the patient; locations</i>	<ul style="list-style-type: none"> • The sensors are worn on the wrist (activity wristband) of the older individual. The gathered data are forwarded to a tablet (or smartphone). • The care receivers as well as the caregivers can review the recorded daily data. It is important that the care receiver can freely dispose of the transfer of his or her data. He/she must be able to set up a release option for the caregiver. This allows the care receiver to decide which data is passed on and when. • The aim of monitoring important health parameters of older individuals is to maintain/ improve health status thanks to preventive health and care measures. The care measures have to be done continuously. It occurs a lack of information if the care receiver is outside their home; does use other facilities and forgets food tracking. • Warranty of data privacy; contact details are only managed by pilot site (GEWI) • GDPR and ethics in line with WP8 • Data and servers must be located within the EU • German language • Location: HealthRegion CologneBonn (Oberbergischer Kreis), Germany
Scenario	<p>Helena is 93 years old and lives with her cats in her own house with garden. Helena has sometimes bad days in addition to arthritis. On those days she forgets to drink, falls, and has already started a fire while making tea. These dangerous situations scare her and her daughter. Additionally, she needs motivation and support to keep moving. She takes sleeping pills. Therefore, she is very happy to try the technical devices from the use case PT2-001.</p> <p>Once all the equipment has been installed and Helena has understood how to use it, Helena is curious to see if the technical devices can contribute to improving her general well-being and her feeling of safety and independence in everyday life.</p>

The activity wristband is very important device for her. As Helena is enthusiastic about the functions that it offers her. During the following nights, her sleeping pattern has been analysed. She presents the recorded results at the next GP's appointment so that the GP has the possibility to give her very individual recommendations. The GP suggests her to improve her evening routine and recognizes that her sleeping time is not optimal. Based on that, she could improve her sleeping patterns which led to reduction of sleeping pills. After a few weeks, she does not longer need sleeping pills to get a good night's sleep. This is a great relief for Helena as she has felt weak from the sleeping pills.

The activity wristband has also improved her mobility and agility. By counting the steps that she takes every day, she was motivated to reach her step goal and went more often on her walk daily in her neighbourhood. If she did not move sufficiently, the activity wristband reminded her by notification alert. Overall, this device helped her to establish better routines in her daily life and the tracking of the state of mind and sleep feedback day by day via App (smiley scale) showed that she had more happy days and restful nights, leading to improvements in her wellbeing. Moreover, Helena also did her exercises for her arthrosis more regularly as she got a reminder of her activity wristband as well for this purpose. Through this continuity, Helena's pain caused by the arthritis has improved. This gives her a better quality of life and she can do more activities with her grandchildren.

A good and varied diet is also very important for Helena's wellbeing. Monitoring nutrition intake can be very helpful, which can be recorded in a food diary. Helena can also use this App to have suitable meals suggested for her needs. In the beginning, it took Helena a lot of discipline to enter all her meals into the food diary, but Helena got used to it quickly and now entering her meals is part of her routine. Helena likes the food diary very much because she eats more balanced and the App suggests new recipes to her. She enjoys trying these recipes because Helena loves to cook.

	<p>Helena and her daughter are very happy that Helena's health can be monitored better. This leads to a general improvement in her well-being, as Helena knows more about her own personal circumstances and her independence is increased. The medical equipment Helena has been provided with help her to stay longer in her own home.</p>
<p>Technology</p> <p><i>Type of information / parameter that are relevant in monitoring the health status; type and frequency of accessibility of information; feedback modalities (communication)</i></p>	<p>Type of information / parameter that are relevant in monitoring the health status</p> <p>Care receiver</p> <ul style="list-style-type: none"> • Age (year of birth) • Gender (m/f/d) • Frailty in regard to movement (pre-existing diseases, sense of directions, balance) • Medication in regard to sleep (i.e. sleeping pills) • Internet access • Skills how to use devices • Parameters: steps, exercises, liquid intake, sleep, nutrition, wellbeing • Activities customized to interests and capabilities • Support of healthy nutrition and drinking regime <p>Recommendations for parameters:</p> <p>Steps:</p> <ul style="list-style-type: none"> • Healthy older adults: 2,000-9,000 steps/day • “special populations” (reduced mobility and/or endurance due to disability and/or chronic illness): 1,200-8,800 steps/day • at least moderate intensity in 10 minutes duration <p>Exercises:</p> <ul style="list-style-type: none"> • older adults: 75 min/ week vigorous intensity, 150 min/week moderate intensity • perform aerobic physical activity in appropriate combinations of both intensities (doing at least 10-minute intervals, i.e. at least 3 x 10 minutes/day or 5 x 30 minutes/week)

- older adults with poor mobility: to improve balance and prevent falls: physical activity 3+ days/week
- 2+ days of muscle strengthening exercises involving all major muscle groups
- If, for health reasons, the recommended amount of physical activity cannot be achieved, older people should be physically active as much as possible
- avoid long, uninterrupted periods of sitting

Liquid intake:

- standard recommendation: 8-10 cups of fluid/day
- heart failure patients: fluid restricted to 4-6 cups of fluid/day in addition to being on diuretics
- The German Society for Nutrition: 1.5L/day, summer: 2L/day
- Reminders are given if the person does not drink enough according to the following guidelines:
 - a glass of water immediately after waking up (stimulates digestion and circulation)
 - 3 hours into the day: drink at least 0.5L
 - 6 hours into the day: min. 0.75L
 - 9 hours into the day: min. 1 L
 - 12 hours into the day: min. 1.3 L
 - 15 hours into the day: min. 1.5L
 - Cap drinking 2 hours before bedtime in order not to interrupt the night's sleep

Sleep:

- Duration: 7-8 hours' sleep (max. 9; min. 5-6)
- By surveying the test persons in the first two weeks of the use case duration, it can be determined at how many hours of sleep their individual optimum lies, at which they feel maximally recovered and satisfied.
- On this basis, the App can give tips and recommendations as to when the person should ideally go to bed and when they should get up.
- If the test person is not sleeping well: avoid artificial "blue light" right before going to bed

- If the test person is not sleeping well: recommending drinking a small cup of soothing herbal tea.

→ Reminder "good night routine, i.e.
- Turn off TV at a fixed time (at least 30 minutes before bedtime)
- Drink a small cup of herbal tea
- Write a diary entry to remove recurring thoughts for the night
- Opening bedroom windows for a few minutes

Nutrition:

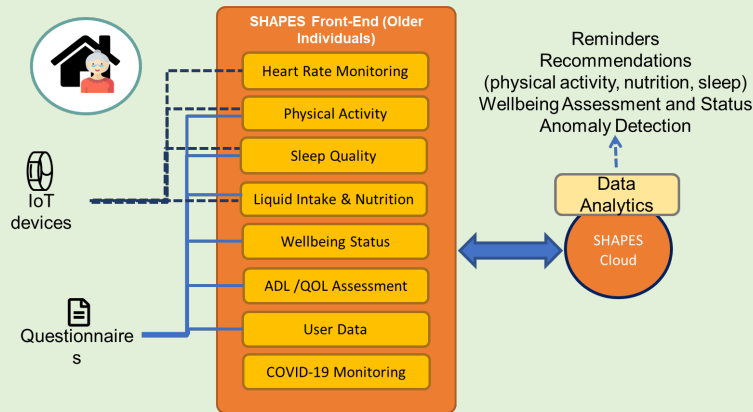
- Eat healthy:
- 2 cups of fruit (4 servings)
- 2.5 cups of vegetables (5 servings)
- 180 grams of grains
- 160 grams of meat and beans/day (red meat: 1–2 times/week, poultry: 2–3 times/week)
- salt intake: 5 grams (equivalent to a teaspoon) a day and reduce salt and high-sodium spices (i.e. soy sauce and fish sauce) when cooking food
- mix of wholegrains: wheat, maize and rice
legumes: lentils and beans
plenty of fresh fruit and vegetables, with some foods "from animal sources (i.e. meat, fish, eggs and milk)".
- prefer "unsaturated fats (i.e. in fish, avocado, nut, olive, soya, rape, sunflower and corn oil)" instead of "saturated fats (i.e. in fatty meats, butter, palm and coconut oil, cream, cheese, ghee and lard)"
- "Avoid industrially produced trans fats (i.e. found in processed food, fast food, snack food, fried food, frozen pizza, pies, cookies, margarines and spreads)".
- Increase steaming or boiling instead of frying food
- Increase "vegetables, fresh fruit and unsalted nuts as snacks, instead of soda, fruit juices, fruit concentrates, flavoured milk, yogurt drinks, cookies, cakes and chocolate".
- start a food diary

	<ul style="list-style-type: none"> • “Take nutritional supplements such as vitamin pills or drinks. They can help you meet your daily needs for certain foods. Ask your health-care professional for advice.” • If you lose weight quickly, have a hard time chewing or swallowing, or have stomach pain or swelling” - consult your doctor.” • Older people affected by malnutrition: oral food supplements + nutritional advice • Get vitamin D going outside in the sun for 30 minutes/day <p>Caregiver</p> <ul style="list-style-type: none"> • Access for documentation of food diary and drink • Internet access • Skills how to use devices <p>Type and frequency of accessibility of information</p> <ul style="list-style-type: none"> • continuous access to food diary • continuous updating of data provided by devices (at least three time per day) <p>Feedback modalities (communication)</p> <ul style="list-style-type: none"> • access to document intake of food and drink • function of barcode scanner as additional option to document food • possibility of daily reminder • alarm in case of strong abnormalities from daily routines and expected health parameters
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Table 7: FIC (UC-PT2-001)

Category	Details
Function and events	<p>This use case presents two actors – the older individual and an informal caregiver – personified in the SHAPES persona 7 Helena.</p> <p>The older individual (care recipient) wears a activity wristband (wearable) on the wrist to automatically capture heart rate, physical activity and sleep quality data. In addition, the care recipient is able to</p>

	<p>register its food and water intake information. Also, the care recipient is able to monitor COVID-19 symptoms. Hence, the functionalities accessible to the actors are:</p> <ul style="list-style-type: none"> • Authentication of the care recipient, provided by the SHAPES Platform, via the SHAPES Front-end App; • Heart Rate Monitoring – visualisation of the heart rate measurements; • Physical Activity Monitoring – visualisation of the physical activity data and of personalised reminders and recommendations; • Sleep Quality Monitoring – visualisation of the sleep quality data and of personalised reminders and recommendations; • Wellbeing Surveys – answer of simple questionnaires concerning health and wellbeing status and display of reminders; • Water and Food intake , where the users shall be able to view and log their daily meal plans and monitor the nutrition facts. In addition, the users shall be able to monitor the water intake; • With respect to COVID-19, the users are able to fill in the symptom checker, view educational material relevant to COVID-19 and perform video-consultations with the doctors.
Interactions and usability issues	<p>The SHAPES Front-end App has been designed to facilitate the users' interaction with the different digital solutions supporting the use case. In addition, the digital solutions have implemented intuitive, friendly and easy-to-use screens and navigation options to reduce any usability issues that may arise.</p> <p>Importantly, the personalised reminders and recommendations, provided by each digital solution concerning their specific functionalities, support the users' interaction with the digital solutions, encouraging the fulfilment of all tasks identified in the use case's research protocol and a dynamic engagement with the use case's objectives.</p>
Content and structure	<p>The following image represents the content and structure built to support this use case. It displays the type of data being collected by each device and the data transfer to the SHAPES cloud.</p>



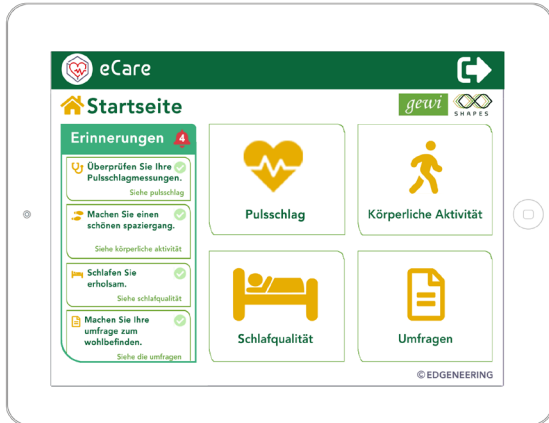
The SHAPES Front-end App delivers a single centralised access to the different digital solutions and their provided functionalities. It is displayed on the following picture, showing a tablet with 8 items on the screen.

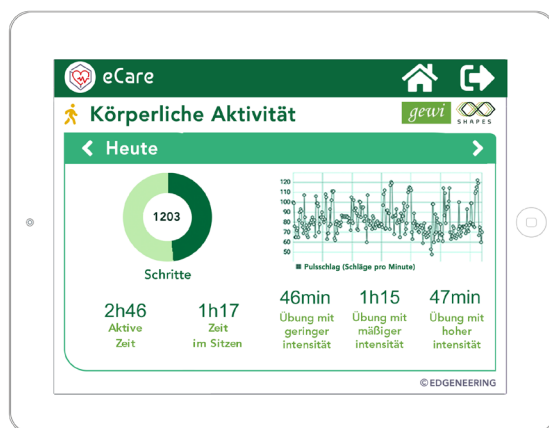
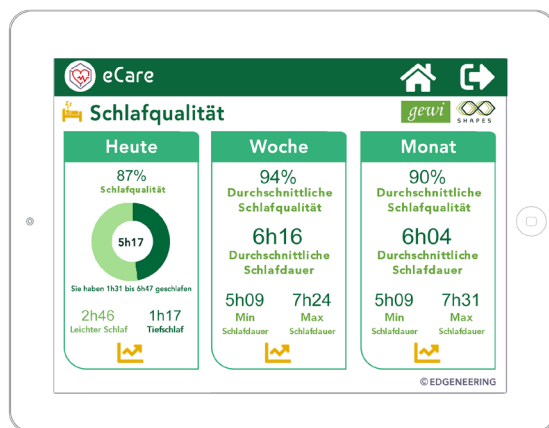
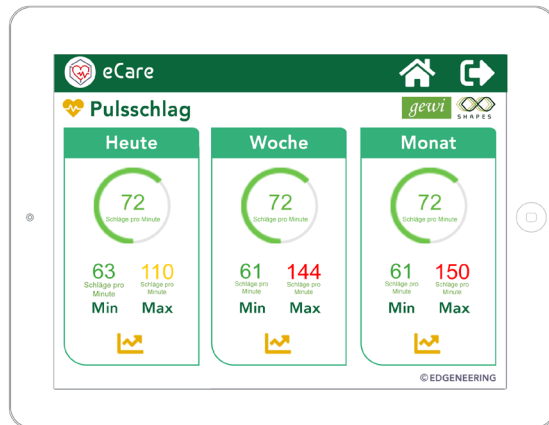


Each functionality is then provided by the respective digital solution, enabling the user to visualise all the relevant information concerning the specific functionality and to interact with the solutions by making entries, providing feedback and answering to questionnaires.

Overall, the use case addresses the following data and functionality:

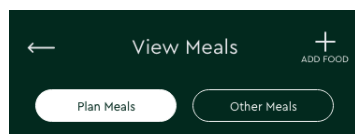
- heart rate measurements;
- step counts;
- physical activity measurements;
- sleep activity measurements;
- answers to questionnaires;
- reminders to specific tasks;
- recommendations for a healthier lifestyle;

	<ul style="list-style-type: none"> • Water and Food intake, where the users shall be able to view and log their daily meal plans and monitor the nutrition facts. In addition, the users shall be able to monitor the water intake; • With respect to COVID-19, the users are able to fill in the symptom checker, view educational material relevant to COVID-19 and perform video-consultations with the doctors. <p>Each measurement or data is timestamped.</p>
Style and aesthetics	<p>The technological solution supporting the use case adopted a “look and feel” inspired in the SHAPES project identity, namely its logo, colours and the use of photos. As a result, the digital solutions present the SHAPES logo and the logo of the partner organising the use case pilot; they also use green and golden tones and the national language of the use case pilot participants. Following the SHAPES UX guidelines (Deliverable D5.1), the digital solutions present a simple and straightforward language and a friendly, easy-to-use navigation scheme. The following images exemplify the style and aesthetics of the different digital solutions supporting the use case. They show the different surfaces used in the DSs to visualise the different health parameters:</p> 





Food Intake



Breakfast

Sofficini, frozen kind of roll stuffed with cheese ☒
100gr

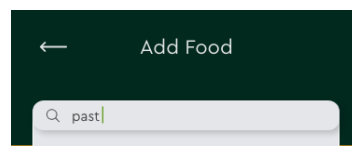
Almonds fresh ☒
50gr



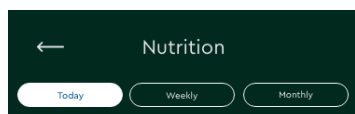
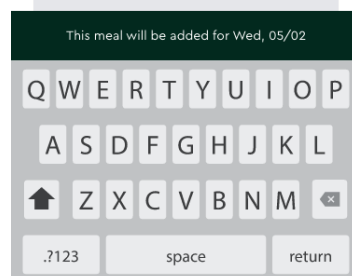
Lunch

Chicken while with skin cooked ☐
230gr

Salad ☐
200gr



ALMOND PASTE
FLAKY PASTRY OR PUFF PASTRY
FLAKY PASTRY ROLL
MILK, COW, SEMI-SKIMMED
PASTA OLIVE OIL
PASTA WITH MEAT



Nutrition

75%

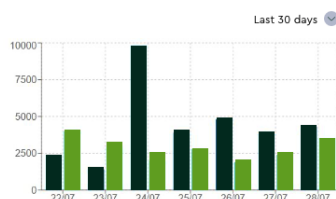
Mon, 22/07/2021

1850 Kcal

16g protein, 4g carbs
5,5g fat

min 965 kcal

max 2580 kcal



Water Intake

←

Log Value

Value

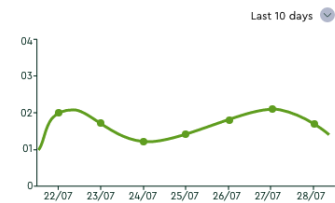
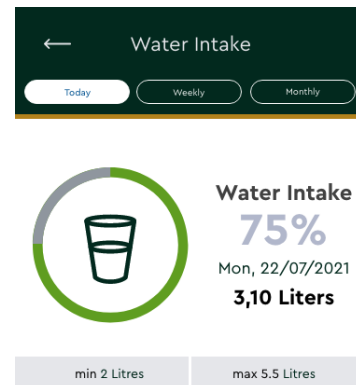
1,5

Litre

Date

21/10/2021 15:36

Save



COVID-19 related functionality provided by COVIDShield Digital Solution

1) Symptom Checker

Symptom Checker

Did you take any medicine

Aspirin

Mesulid

Depon

Panadol

Sleep sure

Paracetamol

PREVIOUS

50%

NEXT

Home

Calendar

Chat

Notification

Settings

Symptom Checker

100%

At the end of the questionnaire, please click SUBMIT the answers to the system

Submit →

Back

Home

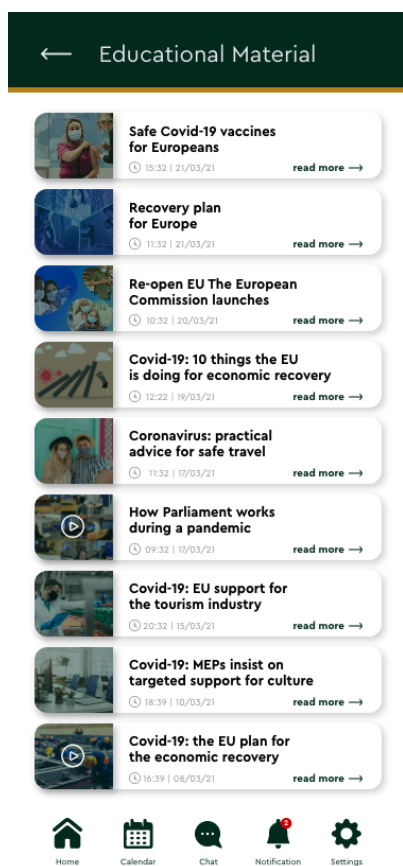
Calendar

Chat

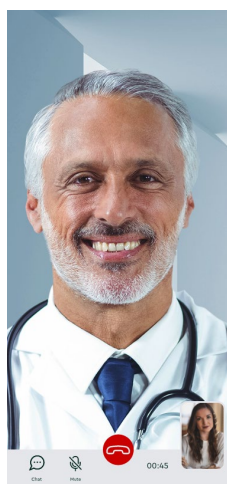
Notification

Settings

2) Educational Material



3) Video Consultation with a Healthcare Professional



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 monitoring the progress or lack of it towards achieving the objectives of each specific use case. The following KPIs have been selected to define the success of the pilot activities for UC-PT2-001.

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

Technical performance

3. There is no re-start of any of the components of the technology, except for the 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 User Experience Questionnaire (UEQ-S) was classified as 'Excellent', 'Good' or 'Above average' based on published benchmark data.
5. At least 60% of participants continued to login to use the app daily after two weeks of the pilot.
6. At least 60% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Other indicators (examples, to be defined in a measurable manner)

- Quality of live (WHOQOL-BREF, EQ-5D-5L);
- Technology acceptance;
- Sleep quality;
- Steps;
- Physical activity;
- Fluid intake.

2.5.2 Timeline of pilot activities

The original timeline of pilot activities was to conduct Phase 1 and 2 between May 2020 and January 2021, followed by Phase 3 from February until June 2021. The Phase 4 was planned to be conducted between August 2021 and April 2022.

The adapted timeline of pilot activities can be found in Figure 2. It shows that Phase 3 was shifted and extended to July 2021 until April 2022. This period was extended, with no impact on the next phases or the deliverable, due to the COVID-19 situation. Hands-on trainings were deployed in the home-setting of the participants and therefore conducted at a point in time when it was safer for all individuals involved to have in-person meetings. Phase 4 required in-person meetings as well, since further testing of the technical aspects needed at least one in-person meeting per participant. GEWI conducts Phases 1-5 and the replicating sites AIAS and 5thYPE conduct Phase 5.

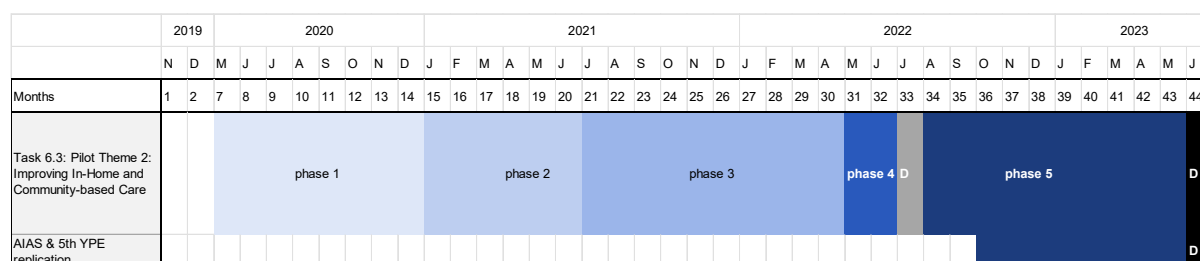


Figure 2: Timeline of pilot activities of UC-PT2-001

2.6 Phase 2: Testing of mock-ups and prototypes

2.6.1 Methodology of testing

In Phase 2, initial ideas of the technology of UC-PT2-001 were put in a visual representation, or mock-up prototypes. At that stage, no functionality was offered and the mock-up was primarily used to evaluate design and potential functions by developers and participants. The technology comprised the SHAPES Front-end App (EDGE), eCare App (EDGE) and the eHealthpass App (GNOMON).

The presentations were conducted remotely via videoconference. In the first part participants were informed about the background of the SHAPES project and the use case. The second part focused on visual images of the screens a user would encounter when using the App.

Participants

Phase 2 was conducted with six older people fulfilling the criteria to be 65 years and older.

Informed consent procedure

In a first step, participants obtained explanation to the background and purpose of the study and about the process of the mock-up. In addition, an information sheet was provided. With the agreement to participate, they received the consent form. Informed consent for all participants was taken with the following format of signatures collected where appropriate:

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

Data collection

Feedback was collected using a questionnaire (Annex 4) comprising a combination of open and closed questions. Throughout the presentation of the mock-ups feedback on design and layout was collected. The questions were a combination of open and closed questions to gather general and specific feedback about the presented design.

2.6.2 Results of testing

In summary, the overall perception of the use case was high and the interviewee did understand the context. Feedback on layout included comments on the display of icons, amount of notifications and access to data history. Regarding the interaction, participants mentioned their interest in motivational recommendations, the possibility of selecting their own personal notifications and recommendations as well as considering pre-existing conditions. In terms of IT-behaviour, they suggested to provide positive experience with technologies and to do an introduction of the technology in dialogue. Further, it was proposed to have the possibility to test the devices which were already planned for the next phase.

2.7 Phase 3: Hands-on Experiments

2.7.1 Methodology of hands-on experiments

Hands-on experiments were conducted as individual in-home visits in strict compliance with safety measures of the COVID-19 pandemic. On the previously scheduled date, a researcher visited the participants at home to collect feedback from

end-users and evaluate the performance of the digital solutions in the actual pilot setting.

Participants

Phase 3 hands-on experiments were conducted with two target users of the SHAPES App (i.e., ≥ 65 years' old; living at home in the reference site Oberbergischer Kreis, stable internet connection). Gender equality was sought but not achieved in the group of older person participants.

Eligible participants had been identified by GEWI during the process of recruitment for phases 4 and 5. A first screening was performed for potentially eligible participants. Informed consent for all participants was taken during the meeting (Annex 5 and 6).

Method

In the beginning, the participant was introduced to the SHAPES project and the digital solutions. For the older persons, technologies were presented as a functioning prototype with the eCare and eHealthPass digital solutions accessed via the SHAPES App, as well as the model of activity wristband (Xiaomi 3) device which are used in the use case. The researcher guided the participant through a series of steps and tasks to demonstrate the different functionalities of the App. Instructions were given with the support of a presentation projected on a laptop screen. Additionally, the participant received a user manual to support the handling of the digital solutions. The Apps were accessed by participants via an internet-enabled tablet device provided by GEWI. The activity wristband was also provided by GEWI. During the testing, the following tasks have been performed:

Demonstration to Older persons

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 fluid intake manually.

The pace of the session was determined by the participant. After the demonstrations, the participant has been encouraged to use the App and devices following the steps of the demonstration. Thereby, the researcher was still present in order to answer questions and troubleshoot any issues.

Feedback about the App has been collected as detailed below.

Collection of feedback

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 applied 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 researcher. Notes were taken by the researcher throughout the session.

After the hands-on experience, participants were asked to complete the User Experience Questionnaire (UEQ) to collect quantitative data about the impression of the participants about user experience. The UEQ assesses six aspects of user experience (attractiveness, perspicuity, efficiency, dependability, stimulation and novelty). There are eight items and respondents mark on a seven-stage scale between two terms in each item (i.e., attractive ○ ○ ○ ○ ○ ○ ○ unattractive).

At the end of the session, participants were interviewed by the researcher to collect their experiences in using the prototype. An interview schedule / topic guide 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 hands-on experience;
- f) Overall satisfaction.

Data analysis

Results of the UEQ 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, has been shared and discussed with the technical partners.

2.7.2 Results of the hands-on experiments

Recruitment

For the recruitment of participants, several actions have been applied to draw attention to the project. These entailed displaying articles in regional newspapers, using mailing lists and contacting relevant gatekeepers from the network by applying face-to-face recruitment. Interested people contacted the research team via mail, letter or phone. After a first screening, potentially eligible participants were contacted. Thereby, two participants were identified who were interested and willing to participate in the hands-on-training.


Participants

Two male participants (PT1 and PT2) were recruited to take part in the phase 3. They both fulfilled the eligible criteria of being residents of the reference site Oberbergischer Kreis and aged ≥ 65 years. Besides, they were tech-savvy and experienced in handling the devices.

Participants feedback

The Phase 3 hands-on experiments were conducted between 4th and 6th April 2022. Detailed service user feedback from each participant is presented in Table 8.

Table 8: user feedback from hands-on testing of UC-PT2-001

PT1		PT2	Ideas for adaptations: (5: high priority – 1: low priority)
Ease of use	Straightforward/ intuitive/ „normal tablet“	Pending on the App but overall confusing (different interfaces)	
	Easy to use	Barely structured	
		No continuous home-button (best to have the same as in eCare)	4-5 eHealthPass: integration of same home button as in eCare 

	Change from Front-End App to eHealthPass: inconvenient to pivot/ turn the screen/	Annoying that it is not sensitive to position (eHealthPass not in tablet version)	4 eHealthPass: adapt to tablet device (instead of smartphone device)
Design	Clear and normal display	Front-end and eCare Apps clear and easy to handle Would be nice to have all Apps in the same display	
	Text size quite big, no problems to read	Font in the pop-up “data is loaded” and in statistics “no date available” to small	5 eCare: please increase the font (maybe same size as “today”, “week”, “month”)
Utility	Progress of body weight would be interesting		1 eCare: statistics on body weight feasible?
		Does not see the usefulness of being forwarded from the Front-end to the statistics (would prefer being forwarded to the answers, i.e. sleep quality)	3 eCare: redirection from Front-end “sleep-quality” to the manual entry for “How well did you sleep?”
	Recommendation/ reminder for more fluid intake is desired	Bug: in heart rate statistics menu you can’t open the weekly/ monthly view; it brings you back to the eCare menu (pop up: eCare does not respond)	5 eCare: please remove bug in statistics
	COVID education material is not useful; no	COVID symptom checker does not seem to be useful,	

	convenient choice of material (only articles from EU-Commission and European centre for disease prevention and control (ECDC), mostly in English; only few links really COVID-19 related); information most probably gathered through radio or newspaper	might rather be a reminder	
	Is the password editable?	Fluid intake: Does not like to have “alcohol” as default Quantities need to be adapted (less than 250ml/ 150ml/4cl/2cl)	5 eHealthPass: - please adapt drop-down list for fluids (first non-alcoholic beverages, second alcoholic beverages) - please add more quantities (2cl, 4cl, 150ml)
Gender neutrality	Nothing noticed in this regard	Nothing noticed in this regard	
Quality of training	Training was understandable and simple	Training was understandable and in an appropriate time	
	Procedure was just as described as on the phone; nothing unexpected		
	Introduction like this seems mandatory before piloting		

Tasks	All task completed (easily)	All task completed (easily)	
<ul style="list-style-type: none"> • Enter your daily wellbeing • Enter quality of sleep • Enter the fluid intake for the day • Look into the COVID-19 education material 			

PT1

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

PT2

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

Figure 3: UEQ-S responses to the SHAPES App after hands-on experiments (UC-PT2-001)

Recommendation for technical partners

A meeting was held with all technical partners to present service user feedback to them. Thereby, it was collaboratively discussed how to best address and mitigate the content of the users' feedback collected during the hands-on testing. The detailed ideas for adaptations for each item of the user feedback is provided in Table 8. These referred to the navigation through the App, fixing bugs as well as changes in wording or design.

Conclusion

The hands-on training with target users was the second user engagement activity being conducted in preparation for the deployment of the UC-PT2-001 in phase 5. Thereby, participants were able to interact with the App, test its different functionalities and use all three components of the App (SHAPES front-end, eCare and eHealthpass), which were interlinked and presented to users as 'one' App for the first time. This way, potential navigation issues or inconsistencies could be detected at this early stage and were shared with the technical partners. In a process of collaboration and discussion, changes were jointly agreed on with the aim both taking into account the individual characteristics and features of each individual App and yet making the user experience as consistent as possible. Overall, the recommendations being elaborated within this activity supported that the different Apps work smoothly together and can be forwarded into the next phase 4. This phase provided the opportunity to then test the functionality of the App in a real-world environment.

2.8 Phase 4: Small Scale Live Demonstration

2.8.1 Recruitment of participants

In Phase 4, the digital solutions were tested by the end-user over a longer period. Hereby, focus was given to the technical functioning of the digital solutions (elimination of dead links or bugs related to the data transfer). The Phase 4 small-scale demonstrations have been conducted with 3 participants. Those were not intended to be representative of the target population with regards to the residence site. Apart from that, testing the digital solutions at home in a real-life environment has been achieved. Eligible participants have been recruited internally from the GEWI colleagues.

Inclusion criteria:

- Has stable self-reported Wi-Fi connection at home
- Self-reported moderate digital literacy
- Employee of gewi-Institut für Gesundheitswirtschaft e.V.

Exclusion criteria:

- none

Informed consent for all participants has been taken from each participant prior to the start of phase 4 (Annex 7 and 8).

2.8.2 Technical aspects & Logistics

For the small-scale live demonstrations, the same devices purchased for the hands-on training in phase 3 were used. These included an Android tablet device and a CE-marked Bluetooth enabled activity wristband. Specifications of the devices used were those defined in the study protocol for the large-scale pilot study.

Android tablet specifications

- Android version 10 and above
- Processor speed 1GHz or more
- Storage 4GB or above
- Support Wi-Fi

activity wristband specifications:

- Xiaomi Mi Band 3

The SHAPES App, that comprised the SHAPES Front-end App, eCare App and the eHealthpass App, has been installed on the tablets and was given to the participants to use at home along with one activity wristband. Researcher provided full training on how to use each device and handed out appropriate user manuals.

Participants were asked to use the devices to take daily readings of their heart rate and number of steps. The data from the activity wristband were automatically transferred to the SHAPES App via Bluetooth. Participants could access their data via the App and had the possibility to enter readings manually. In addition, participants were asked to enter their fluid intake, sleep and wellbeing assessment on a daily basis. For the purposes of phase 4, these data did not need to correspond to reality.

Participant's data was uploaded to a browser-based dashboard, which researchers could access to view the participants' data.

Participants were asked to take notes if any errors occurred. Errors may include:

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

The notes and experiences were shared with the pilot site researchers and the technical partners in order to determine the causes of any errors and define elimination and prevention actions. A summary of these outcomes are presented in chapter 2.8.5.

In the end, participants were asked in a short unstructured interview to share their experiences and suggest any amendments or additions they felt were needed also with respect to the user manual for the SHAPES App to allow adjustments to be implemented before the use in the large-scale pilot.

The pilot site researchers (and if necessary, the technical partners) were available during the live demonstrations to provide support where necessary. A log of all requests for support was kept and analysed after the demonstration. This process should inform the type of technical support potentially required during the run-in period

of the large-scale pilot, and supported the study team in making appropriate arrangements.

2.8.3 Roles and Responsibilities

The SHAPES pilot site researchers at GEWI were responsible for recruiting and collecting the consent of participants interested to take part in the live demonstration. GEWI provided training and was the single point of contact for the participants. Technical partners (EDGE, GNOMON, VICOM and TREE) were responsible for providing technical support (via GEWI) to the participants if needed.

2.8.4 Ethical considerations

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. Consent from 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 UC-PT2-001 did not meet the definition of ‘research’ and as such did not require specific local ethics board approval or DPIA documentation.

2.8.5 Outcome of the Small-Scale Live Demonstration

Phase 4 of the small-scale live demonstration took place from May to June for four weeks (between 9th May - 9th June 2023).

Participant

Two female and one male participants were recruited to participate in the Phase 4 small-scale live demonstration. Participants were family members or friends from the GEWI staff aged 64 – 67 years old and thus belonging to the reference group. No participant had prior connection to the SHAPES project nor viewed the SHAPES App prior to receiving training.

Outcomes referring to the technical functioning of the DS as main focus of Phase 4 are presented in Table 9. Additional feedback has been collected with respect to the layout and design, the ease of use, the utility and the user acceptance which is summarised afterwards.

Table 9: Outcome Phase 4 for UC-PT2-001

Outcome	User 6	User 7	User 8	Comments
Each participant wears the activity wristband as much of the time as possible.	yes	yes	yes	
>90% of data for heart rate and steps are transmitted to the SHAPES App.	Issues reported	Issues reported	Issues reported	<ul style="list-style-type: none"> Loading of data took long and sometimes failed, values were not displayed (as if data from the activity wristband were not being transferred to the App), the App frequently had to be restarted. Even though some tasks were done that day this was not displayed or displayed with a delay (i.e. 0/5 tasks were fulfilled)
Data flow from EDGE/GNOMON servers to the Datalake for VICOM/ TREE analysis is successful and the display on the researcher dashboard is working.	Issues reported	Issues reported	Issues reported	<ul style="list-style-type: none"> Data collected during the night is not continuously received by TREE Data collected during the day is partly received by TREE Transfer was further tested using a direct interface as the Symbiote connector was not yet stable to be used.
Number of errors noted by the participants.	4	2	1	<ul style="list-style-type: none"> Sometimes an error message appeared when updating the data Sometimes data were not displayed or only the daily readings (not the weekly overview) Sometimes data did not load or took much time

				<ul style="list-style-type: none"> • Sometimes the App shut down after some time when uploading the data
--	--	--	--	-------------------------------------------------------------------------------------------------------------------------

Layout and Design:

- The 6 items in the Front-end App gave a good overview (positive feedback for the visualization).
- Increase the font size to facilitate older people accessing their data

Ease of use:

- Users being less tech-savvy perceived the regular logging in and out as challenging which affected the use of the functionalities (liquid and food intake); this measure was taken for reasons of data protection
- eCare App:
 - straightforward and easy to use (without too much time effort).
- eHealthpass:
 - rotation of the screen (when entering the App) was perceived as confusing
 - handling the App was experienced as time consuming which hindered the actual use of the App; it was wished to make the handling of the App more straight forward (i.e. include less beverages to select from)
- Logmeal:
 - Challenges in starting the App, sometimes this process failed
 - not all terms were displayed in German language.
 - Manual entry of meals for the previous day is not possible but would be supportive.
 - Manual entry would be good as entering the meals by taking pictures does not work reliably.

Utility:

- the heart rate monitoring and sleep statistics were perceived as supportive.
- the formulation of the task („Go for a walk“) should be more motivating by giving a specific goal (i.e. „walk xy km in 30 minutes“).
- User liked having the step count and heart rate monitored, however getting feedback on the blood pressure would have been more informative for the person.

- Most of the participants perceived the monitoring of liquid intake as “fun”, “motivating” and “supportive” (“nice to see the amount over time”).

User Acceptance:

- One participant perceived using the DSs as too controlling (loss of QoL) and would not like to use it all the time (this is refereeing to any comparable devices not particularly the SHAPES DS).
- Another participant would like to use this App further

Recommendation for technical partners

The feedback received from the participants (previously presented) was shared with all technical partners in a joint meeting. Thereby, it was collaboratively discussed how to address and mitigate the content of the users’ feedback collected during Phase 4. Special focus was given to issues related to the technical functioning. The data transfer was further tested by using a direct interface as the Symbiote connector was not yet stable to be used. Thus a GEWI researcher continued wearing the activity wristband and using the App to collect data for the technical partners (TREE and VICOM) to perform their analysis and recommendations system.

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’s objective was to recruit 8 participants at the GEWI lead pilot site and 10 participants at the replicating sites AIAS and 5thYPE. The period of intervention was set for 2 months.

An overview of the intervention procedures serving as definition of the standard operating procedure was developed prior to the start of the pilot activities as part of the study protocol and can be found attached to this document (Annex 9).

2.9.1 Recruitment

GEWI

Several recruitment activities were conducted/performed to draw attention to the project. These entailed displaying articles in regional newspapers and newsletters, using mailing lists and contacting relevant gatekeepers from the network by applying face-to-face recruitment.

Interested people made contact via mail or phone. A first screening of the responses was performed for potentially eligible participants. As interested participants actively contacted the research team, no consent of contact was be provided.

First communication about the pilot has been conducted via phone from the research team to present all relevant information and answer questions from the potential participants. Afterwards, information sheets and consent forms (Annex 10 and 11) were sent out to eligible participants in case they still showed interest in the study.

Eligibility criteria

Inclusion criteria:

- person aged 65 years old or older at the time of recruitment
- living in the OBK
- living on their own
- self-reported capacity to wear the activity wristband and use the Apps installed on the tablet
- self-reported capacity to consent
- has daily access to internet

Exclusion criteria:

- none

Informed written consent was obtained in-person from all participants prior to the start of the pilot. Besides, all participants received a copy of the information sheet as well as a training in using the digital solutions as well as a manual summarising relevant steps. Following the training, the informed consent forms were scanned from the researcher and shared with the participants as acknowledgment of reception. The original informed consent was then safely stored in a locked cupboard, that was only accessible to GEWI staff.

AIAS

AIAS collaborated with the public company for Welfare services of the Municipality of Bologna (ASP Bologna) in order to involve them in a broader discussion on how public care services can benefit from e-Health systems such as those proposed by SHAPES. As target group for this specific use case, it was identified the older people using the sheltered flats service offered by ASP Bologna.

ASP Bologna did the first screening of the users, according to the inclusion criteria provided and introduced the project to the selected participants. Afterwards, a group meeting was organised where the AIAS Team presented the overall SHAPES project and the specific activity in which the participants were asked to participate. Any questions raised from participants were answered as well. Once all the relevant information was provided by the teams, we asked who was willing to participate in the pilot activities to fill up the consent form and provide us with all the necessary information in order to set up the technological devices.

Eligibility criteria

Inclusion criteria:

- person aged 65 years old or older at the time of recruitment
- living in the ASP Bologna facility (sheltered apartments or Residential centre)
- living on their own
- self-reported capacity to wear the activity wristband and use the Apps installed on the tablet
- self-reported capacity to consent

Exclusion criteria:

- Inability to give an autonomous informed consent.

Informed written consent was obtained in-person from all participants prior to the start of the pilot. Besides, all participants received a copy of the information sheet and a copy of the informed consent form. The original informed consent was then safely stored in a locked cupboard, that is only accessible to AIAS staff and in a specific folder in AIAS server.

5thYPE

The healthcare centre of Istiaia at Evia which is supervised by the 5th Health Regional Authority of Thessaly & Sterea, Greece (5thYPE), was chosen as test area to perform the study. The cardiologist doctor of the local Health Centre performed the recruitment of the participants with the relevant inclusion criteria. The doctor was responsible for the inclusion of the participants since their Health status and living conditions were well known because of their regular monitoring. In this way, the participants' chosen medical status was best fitted with the devices (wristband, tablet) delivered to them for better results (most of the participants had cardiac problems that were better tracked

by the devices). 1 out of the 5 wristbands was malfunctioning, therefore 4 persons were recruited in total.

Eligibility criteria

Inclusion criteria:

- Person aged 65 years old or older at the time of recruitment
- Living in the Istiaia area, Evia, Greece
- Their health status being monitored by the Health Centre of Istiaia
- Living on their own
- Self-reported capacity to wear the activity wristband and use the Apps installed on the tablet
- Self-reported capacity to consent
- Access to the Internet
- Having trouble accessing Health services either because of long distance or lack of means of transportation

Exclusion criteria:

- Inability to give an autonomous informed consent.
- Lacking regular contact with the doctor during the period of the study (i.e., being absent from the area)

Informed written consent was also obtained in-person from all participants prior to the start of the pilot. Besides, all participants received a copy of the information sheet and a copy of the informed consent form. This data is securely kept by 5thYPE.

2.9.2 Communication and dissemination of pilot activities

GEWI

All data being collected with the pilot study are respectively owned by the organisation conducting the study, namely GEWI, AIAS and 5thYPE. After completion of the study, all collected data was analysed, processed and presented in Deliverable D6.3 as one of the deliverables of the SHAPES Innovation Action. This report is available via the SHAPES website (www.shapes2020.eu). Participants were notified of the outcome of the study by the research team via mail or phone. Besides, GEWI aims at disseminating the findings of the pilot study at conferences and other events as well as in scientific papers and articles. GEWI also seeks to communicate the findings of

this study via social media (LinkedIn, Instagram, GEWI website), and in other, non-peer reviewed, media outlets. Participating SHAPES partners have the rights to use data from this study in their own analysis and dissemination plans. Therefore, appropriate Data Processing Agreements have been set up and signed by all partners to facilitate the sharing of pseudonymised data with specific SHAPES partners for specific purposes.

AIAS

AIAS, in line with GEWI's communication activities, aim to disseminate the findings of the replicating pilots at conferences and other events related to health care technologies.

5thYPE

5thYPE, in line with GEWI's communication activities, aim to disseminate the findings of the replicating pilots at conferences and other events related to health care technologies in both national and European levels.

2.9.3 Risk management

GEWI

All foreseeable data-related risks have been compiled into detailed risk assessment documents which form part of the Data Protection Impact Assessments for Phase 5. For each risk identified, a risk classification, root cause, name and consequences were assigned. Once identified, each risk was then analysed and scored from 1 (unlikely/minor)-4 (almost certain/critical) regarding their probability and impact. Subsequently, appropriate mitigation actions were assigned. These risks have been reviewed during the course of the deployment.

In addition, an ethics approval has been achieved for UC-001 of Pilot 2. This approval process additionally enabled all contributors to identify further risks as well as to find the appropriate mitigation actions.

Finally, an ethics workshop was conducted for UC-001 with all partners involved previous to the start of phase 5. This workshop allowed to jointly elaborate on potential risks and opportunities with respect to the ethical frameworks of SHAPES as well as to identify relevant mitigation actions.

AIAS

AIAS has applied the same actions as previously described by GEWI wherefore these will not be repeated here.

5thYPE

All the potential risks were identified and integrated in the relevant risk assessment document of the Data Protection Impact Assessment. There was a specific focus on potential COVID-19 risks because the age of the participants and their health status were considered critical. This work was well documented along with the relevant mitigation actions prior to the beginning of the study. These preparation processes assisted significantly coping with the case of one participant contracted COVID-19 and having to isolate from the study execution for one week.

Moreover, specific focus was given to risks related to technological issues that were also well documented in the Data Protection Impact Assessment. The assessment helped addressing the technological risks appeared like software misconfigurations, Greek language misinterpretations and lack of Internet connectivity.

The ethical approval was also obtained by all the participants thus leading to a better address of any potential risks.

2.9.4 Outcome of large-scale pilot activity

GEWI

Overview

The phase 5 large-scale pilot of the SHAPES UC-PT2-001 was conducted between October 2022 and February 2023 with 8 participants. 6 participants (75%) had already been using an activity wristband and were thus knowledgeable about their different health parameters.

During phase 5, challenges were encountered with respect to the data transfer to the SHAPES datalake. In this UC, there are different digital solutions provided by different SHAPES partners and OC partners to offer an integrated DS combining a number of health parameters that are most relevant to the individuals' wellbeing and health status. Thus, all collected data required data transfer and exchange interfaces to allow the integration of different features. Due to challenges with the Symbiote connector,

the data transfer and data analysis was pending, and much extra effort was given by all technical partners to improve the data flow. Due to these challenges, only some of the users were occasionally receiving analyses or recommendations based on part of their data.

Socio-demographics of the participants:

Table 10: Baseline characteristics GEWI (UC-PT2-001)

Variables	Number of participants	Value
Age (years)	8	M = 76 SD = 5,93
Male	8	number = 6 (75%)
Smoking status: yes	8	Number = 1
Country: Germany	8	100%
Marital status	8	Married: 6 Single: 1 Widowed: 1
Occupational status: retired	8	100%
Residence: own home	8	100%

Primary and secondary outcome

Primary outcome

The primary outcomes were to measure a predefined set of KPIs which have already been presented in chapter 0 as well as to evaluate the UC-PT2-001 use case using the MAST evaluation tool.

The following tables present the data used to determine the success of each KPI. Table 17 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 11: KPI 1 GEWI (UC-PT2-001)

Parameter	GEWI
Target number of participants	8
Number of participants recruited	8
Percentage recruited	100%

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

Table 12: KPI 2 GEWI (UC-PT2-001)

Parameter	GEWI
Number of participants at baseline	8
Number of withdrawals	0
Number of participants at end of study	8
Percentage retained	100%

KPI 1 and KPI 2 were successfully achieved with 100%, meaning that the recruitment and engagement initiatives of GEWI were successful, not only in identifying interested and willing participants, fitted to the effort at play, but also that the strategy to maintain contact and provide support throughout the pilot did have a positive impact on the absence of withdrawals, despite the length of the pilot.

Technical performance

KPI 3 There is no re-start* of any of the components of the technology, except for the activity wristband, for at least 90% of the days.

Table 13: KPI 3 GEWI (UC-PT2-001)

Parameter	Value
Number of participants without any re-start of any of the components of the technology	8
Total number of participants	8
Percentage of participants without re-starts	100%

*re-start refers to the deinstallation and re-installation of any of the components due to mal functioning. This does not include any update of a new version of the App.

KPI 3 was successfully achieved and no re-start of any of the components of the technology was needed. This shows that the DSs were functioning well during the pilot, meaning that the collaboration between the technical partners, the intensive test phase 4 and the continuous development process have had a positive impact on the deployment of the technical solution in Phase 5.

User engagement and acceptance

KPI 4 The overall user experience quality of the App as measured using the short version of the User Experience Questionnaire (UEQ-S) was classified as ‘Excellent’, ‘Good’ or ‘Above average’ based on published benchmark data.

Table 14: KPI 4 GEWI (UC-PT2-001)

Scale	Mean	Comparison to benchmark
Pragmatic quality	-0,28	In the range of the 25% worst results (bad)
Hedonic quality	0,38	50% of results better, 25% of results worse (below average)
Overall	0,05	In the range of the 25% worst results (bad)

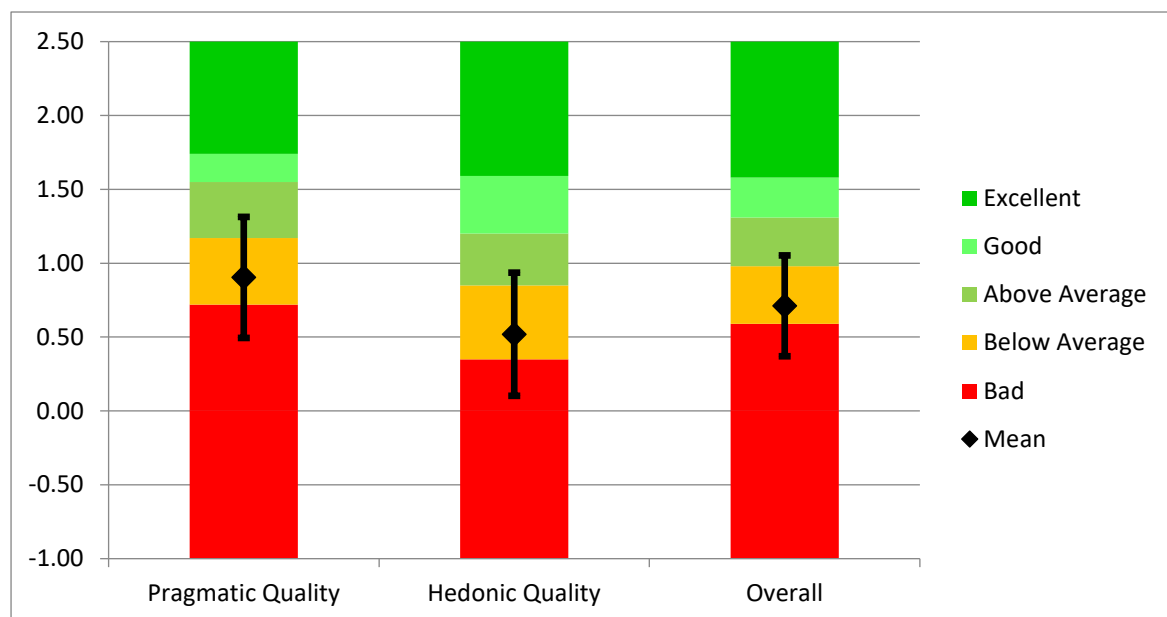


Figure 4: Mean UEQ-S and benchmark scores for the usability of the App GEWI (UC-PT2-001)

KPI 4 was not reached, as the overall user experience was rated as bad. It is noted that the main cause for the evaluation was the absence of analyses concerning the collected participants' health and wellbeing parameters. Participants tended to compare the provided DSs with their initial monitoring Apps (Apple or Garmin) and therefore had high expectations. It has to be noted that it was not in the scope of the pilot to provide DSs that were at the same technological readiness level as comparable commercial solutions. However, the personal user experiences strongly affected their perception and evaluation of the DSs.

KPI 5 At least 60% of participants continued to login to use the App daily after two weeks of the pilot.

Table 15: KPI 5 GEWI (UC-PT2-001)

Parameter	Value
Number of participants who logged in daily for at least 2 weeks after baseline	5
Total number of participants	8
Percentage using the App daily for at least two weeks	62,5%

Only participants are considered that took daily records for at least 14 days in a row. In order to make any manual entries, registration in the Front-end App must have taken place beforehand. Thereby the eCare App and the eHealthPass App were not considered separately.

KPI 5 was achieved and 62,5% of the participants continued using the App after two weeks of the pilot. This indicates that participants were able to handle and use the DSs on their own, and that it was possible for them to integrate it in their everyday life. It also indicates that participants recognise the positive effect that the App had in their daily living, bringing about additional self-awareness to their own health and wellbeing.

KPI 6 At least 60% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Table 16: KPI 6 GEWI (UC-PT2-001)

Parameter	Value
Number of participants at end of pilot	8
Number of participants scoring >68 in SUS	0 (M=54,06; SD=11,33; Med = 57,5; Min = 32,5; Max = 65)
Percentage of participants scoring > 68 in SUS	0%

In line with KPI 4, KPI 6 was not reached. Most participants were already knowledgeable of their health and wellbeing parameters, as they have already been using similar monitoring systems. Due to the absence of the analyses of their health and wellbeing parameters, the DSs seemed not to provide additional benefit to them and, as a result, the perceived usability ranked low. In this respect, it is noted that

participants tended to compare the DSs with their initial systems (Apple, Garmin), commercially available solutions, and therefore could recognise that the DSs did not attain the same level of readiness. This also affected their rating of the DSs' usability with an average value of 54,06 from 100 points.

Overview of KPI achievement

Table 17: Overview of KPI achievement GEWI (UC-PT2-001)

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	YES	Recruitment initiatives of GEWI were successful, related to the identification of interested and willing participants, who also fitted to the effort at play.
KPI 2	YES	Engagement initiatives of GEWI were successful, related to the strategy to maintain contact and provide support throughout the pilot. The positive impact reflected on the absence of withdrawals, despite the length of the pilot.
KPI 3	YES	No re-start of any of the components of the technology was needed. This corroborates that the DSs were performing well and that participants were able to engage with the DSs.
KPI 4	NO	The overall user experience was rated as bad, with the main concerns centered in the absence of analyses on the collected health and wellbeing parameters and in the comparison with existing commercial solutions that participants were very familiar with and expectations were high. It is noted that it was not in the scope of the pilot to provide DSs that were at the same technological readiness level as comparable commercial solutions. However, the personal preferences and previous experience of participants strongly affected their perception and evaluation of the DSs.
KPI 5	YES	Participants were able to handle and use the DSs on their own, and it was possible for them to integrate their use seamlessly in their everyday life.

KPI 6	NO	Participants were quite knowledgeable of their health and wellbeing parameters, as they have already been using monitoring systems. The expectations were then centred on the novelty of the analyses on the collected health and wellbeing parameters. Due to the absence of these analyses, participants considered that no additional benefit stemmed from the DSs, leading to a low perceived usability level. In addition, participants tended to compare the DSs with commercial solutions (Apple, Garmin) and they did not display the same level of readiness. This also affected their rating of the DSs' usability with an average value of 54,06 from 100 points.
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Evaluation of MAST

The MAST framework as already introduced in chapter 2.4.2 was used to evaluate the effectiveness and contribution of UC-PT2-001 to quality of care. The evaluated data/outcome are presented in the table below:

Table 18: MAST Evaluation GEWI UC-PT2-001

MAST Domain	Topic	Outcome	Baseline (mean/SD)	End of pilot (mean/SD)	Change in mean (SD)
Clinical Effectiveness	Physical health	Heart rate, steps, sleep and wellbeing assessment	These data were continuously collected during the pilot answer the research hypothesis as stated in the research protocol and will thus be further presented with respect to the secondary outcomes		
	Mental health	OSSS-3 (social support) and life events	M = 10,25 SD = 1,83 Med = 10,00 Min = 8,00 Max = 14,00 “moderate social support”	M = 10,5 SD = 1,31 Med = 10,00 Min = 9,00 Max = 13,00 “moderate social support”	0,25 (-0,52)
	Effects on health-related quality of life	EQ-5D-5L VAS scores	Health Status M = 84,50 SD = 12,73 Med = 85,00	Health Status M = 85,63 SD = 9,80 Med = 90,00	1,13 (-2,93)

			Min = 66,00 Max = 100,00	Min = 70,00 Max = 100,00	
		WHOQOL-BREF scores	Domain 1: M = 68,13 SD = 8,94 Med = 66,00 Min = 56,00 Max = 81,00 (1 missing value for all participants)	Domain 1: M = 69,00 SD = 7,86 Med = 66,00 Min = 63,00 Max = 81,00 (1 missing value for all participants)	0,87 (-1,08)
			Domain 2: M = 79,00 SD = 11,89 Med = 81,00 Min = 63,00 Max = 100,00	Domain 2: M = 75,13 SD = 8,08 Med = 75,00 Min = 63,00 Max = 81,00	-3,87 (-3,81)
			Domain 3: M = 68,00 SD = 7,91 Med = 69,00 Min = 56,00 Max = 75,00	Domain 3: M = 72,00 SD = 4,54 Med = 69,00 Min = 69,00 Max = 81,00	4 (-3,37)
			Domain 4: M = 86,88 SD = 11,74 Med = 91,00 Min = 63,00 Max = 100,00	Domain 4: M = 87,13 SD = 10,19 Med = 88,00 Min = 63,00 Max = 94,00	0,25 (-1,55)
	Behavioural outcomes	Steps, fluid and nutrition intake, sleep duration, wellbeing status	These data were continuously collected during the pilot to answer the research objectives and will thus be further presented with respect to the secondary outcomes		
Patient perspectives	Satisfaction and acceptance	User Experience (UEQ-S scores)	/	M = 0,05 SD = 1,01 (see KPI 4)	
		User acceptance (TAM score)	/	Ease of use: M = 4,38 SD = 2,20 Med = 5,5 Min = 1 Max = 6	

				Usefulness: M = 3,25 SD = 1,67 Med = 3 Min = 1 Max = 6	
				Future use: M = 4,00 SD = 1,85 Med = 4,5 Min = 1 Max = 6	
	Understand- ing of information Confidence (in the treatment) Ability to use the application Access & Accessibility	Usability of application (SUS Scores)	/	M = 54,06 SD = 11,33 Med = 57,5 Min = 32,5 Max = 65 (See KPI 6)	
		Usability of application (1- item health literacy)	M = 3,75 SD = 1,28 Med = 4,00 Min = 1,00 Max = 5,00	M = 4,00 SD = 0,93 Med = 4 Min = 2 Max = 5	0,25 (- 0,35)
	Empower- ment Self-efficacy	User engagement (Number of logins)	These data were continuously collected during the pilot to answer the research objectives and will thus be further presented with respect to the secondary outcomes.		
		Self-efficacy (SHAPES Participation questionnaire)		Participation in activities: M = 3,13 SD = 0,83 Med = 3 Min = 2 Max = 4	
				Effect of using DS on participation in activities: M = 3,5 SD = 0,53 Med = 3,5	

				Min = 3 Max = 4	
		Self-efficacy (GSES)	M = 33 SD = 4,38 Med = 33,50 Min = 25,00 Max = 39,00	M = 31,38 SD = 5,04 Med = 30 Min = 22 Max = 38	= -1,62 (0,66)
Economic aspects	Amount of resources used when delivering the application and comparators	Cost of devices	<ul style="list-style-type: none">• Tablet: 328,57€• Protective cover tablet: 13,99€• Activity wristband: 28,54€		
		Cost of using digital solutions and SHAPES platform	<ul style="list-style-type: none">• Electricity (charging the tablet): negligible (approx. 0,76 cents per charging)• Internet connection: negligible as most people already have internet access (Germany: 40€ per month)• Data analysis module + SHAPES data lake + personal efforts: n/a*• eCare App + server EDGE + personal efforts: n/a*• eHealthPass App + server Gnomon + personal efforts: n/a*• VICOM recommendation module + server + personal efforts: n/a*		
		Cost of staffing	<ul style="list-style-type: none">• Travel cost: 350€• Training Material (development and print): 290€ (5h à 50€ + 40€)• Training + end of study (preparation and deployment): 2000€ (40h à 50€)• User support via phone: 800€ (2h à 50€ per week for 8 weeks)		
*Not available as they were a customized solution and are not available at a commercial stage yet					

A summary of the baseline data results is provided. Any analysis and discussion of outcomes with respect to the impact will be part of the deliverables D6.9 and D6.10.

Considering the application of the WHOQOL-Bref questionnaire, the participants mostly perceived that their physical health (Domain 1; m = 68,13) and their social relationships (Domain 3; m = 68,00) below the norm of 73,5 and 71,5 (13). It has to be noted that for Domain 1, there is one missing value for all participants, which might

explain the slightly lower mean value. According to the OSSS-3, the participants perceived that they had moderate social support ($m = 10,25$) and on a scale from 0 to 100 (EQ-5D-5L VAS score) they indicated their health status at 84,50 on average. In contrast, participants rated their psychological wellbeing (Domain 2; $m = 79$) and their living environment (Domain 4; $m = 86,88$) clearly above the norm of 70,6 and 75,1 (13). This is further underpinned by the results from the GSES, where participants pinpointed their perceived self-efficacy with 33 out of 40 points. The average of 3,75 out of 5 (HLM) indicated that participants had a higher level of health literacy.

The results from the questionnaires reflect that participants consider themselves to be healthy and fit for their age, as well as health literate. As a result, they are a very demanding and challenging group to serve in the pilot.

Secondary outcomes

Besides, the pilot aimed at testing the capability of the SHAPES Platform and Digital Solutions to provide opportunities for maintaining or possibly even improving the health status of older individuals, primarily through the adoption and encouragement of preventive health and care measures.

Therefore, the following primary and secondary objectives were defined within the study protocol:

Primary objectives

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

Secondary objectives

- To investigate the capability of the novel system to improve the supervision of the individual health and wellbeing status (SO1).
- To investigate the association of the first (active / sedentary behaviour) and second level (active in activities of daily living / intermediate activity / exercise) of physical activity classification, sleep quality analysis, fluid intake and nutrition analysis with the individual perceived wellbeing (SO2).
- To investigate the capability of the novel system to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects (SO3).
- To explore user trust and acceptance of the novel system (SO4).

The objectives were assessed by using different methods such as notes during the introduction training and the interview at the end of the pilot, the different questionnaires as well as data collected by the DSs. A complete overview of the outcomes collected can be retrieved from the study protocol (Annex 9).

Table 19: Objectives GEWI UC-PT2-001

PO1
To investigate user engagement with the novel system (PO1).
At the beginning of the pilot, participants were instructed to use the App on a daily basis. According to the login files 62,5% of the users logged in daily for at least 2 weeks after baseline of the pilot. This has also been reported by most participants in the interviews.
For most users, it took some time to get familiarised with the DSs as not all components were found intuitive. However, they were motivated to test the DSs and have quickly started to explore them independently.
PO2
To investigate the user-perceived usefulness of the novel system (PO2).
According to the UEQ-S, the user perceived usefulness of the App was rated as bad. Mostly, this was caused by the challenges in receiving analyses and recommendations on the individuals' behaviour. As most of the users (75%) have already been using an activity wristband, they were already knowledgeable of their health parameters (such as steps and heart rate). Thus, only getting an overview of their data did not offer them additional information and was deemed of little additional benefit for their everyday life. It is thus noted that personal experience with DSs does affect the perceived usefulness of DSs and that analyses and recommendations on behaviour are praised by users.
In the TAM, most participants evaluated the DS as easy to use (M=4,38). However, this differed between the different components of the DS. Especially the handling and accessing of health data that was assessed automatically was perceived as clear and straightforward. With respect to the nutrition App, this was reported as "not user-friendly" and frustrating, as the meals proposed in the App did not fit the German context with its eating habits and routines. Also, entries could not be saved and selected again, which would have been supportive to facilitate the entry process. As nutrition intake is often related to a routine, 90% of users have expressed the need for such a recall function. Users almost never took pictures of their food as it was not recognized by the App, and mostly took manual entries instead, which was described as "time consuming" and "annoying". In line with this feedback, all users stopped entering their food intake after some time.
Besides, most users eventually experienced challenges in accessing the eHealthPass App directly from the Front-end App as the connection failed and they had to login again. What was introduced as a safety measure (regularly logging in

and out of the App) hampered the participants' engagement several times during the pilot to make manual entries of their food and liquid intake. Next to this feedback, the users raised the points that depending on their type of beverage, they were not able to select their actual volume from the drop-down list or missed some additional type of beverage to enter. Most users had difficulties in understanding the summary of their daily liquid intake and shared some ideas for improvement.

The usefulness of the App was rated with a medium score ($M=3,25$). Critique referred to the lack of analyses and recommendations on their data. It was also complained several times that the activity wristband did not assess any other activities apart from steps (such as cycling, mountain biking, skiing, working in the garden, exercising in the gym) and participants considered that the daily step count was not reflecting accurately the individuals' actual daily activity. Moreover, it was mentioned that occasionally it took some time until the individual's data was displayed/actualised. This strongly varied between the users and seemed to depend on their Wi-Fi connectivity at home, as well as their interaction with the DSs. Most users looked into the App a few times a day allowing the system to upload the data more regularly, whereas others opened it only once or twice a day whereby the amount of data was high (thousands of daily readings were registered from the activity wristband) and took a few minutes to upload. Part of the users also expressed their difficulties in trusting in the data being displayed in the App such as the information on sleep ($n=2$), nutrition intake ($n=7$) or number of steps ($n=1$) as for them it was not transparent how these were developed.

Apart from that, most participants described the information on their sleep (deep sleep, light sleep and sleep duration) as new and interesting.

Despite previous concerns, the participants valued the approach of having these different types of parameters joint in one App, as it is providing a good overview of their health and wellbeing status.

Most participants saw a great potential in the DS and would like to use it in the future ($M=4,00$) if they could receive analyses and recommendations on data and their feedback and suggestions for adjustments were integrated.

The SUS was rated below the benchmark of >68 ($M=54,06$). Due to the different surfaces of both components, the users expressed their impression of inconsistencies in the DS and that the integration of functionalities was lacking, mainly addressing again the absence of analyses and recommendations.

SO1

To investigate the capability of the novel system to improve the supervision of the individual health and wellbeing status (SO1).

As described before, most users were already aware of their different parameters and missing further analyses or recommendations on their data, as these would have been an "add on" for the supervision of their health and wellbeing status.

Compared to most of their initial tracking systems, the DS was not perceived as improving the supervision.

Besides, some users explained, that they are still fit and healthy and that their health and wellbeing is stable. This was also reflected by the data from the wellbeing assessment, that users were instructed to enter manually on a daily basis. However, it needs to be considered, that the users entered data differently, with some participants making several entries per day to test the DS and some having several missing. Nevertheless, the change in mean remained mostly stable. In this respect, one user further explained that they might perceive the DS as more supportive and needed at a later stage, if their health status really starts decreasing. Then the DS might show such development earlier and thus support the individual in recognising any changes.

SO2

To investigate the association of the first (active / sedentary behaviour) and second level (active in activities of daily living / intermediate activity / exercise) of physical activity classification, sleep quality analysis, liquid intake and nutrition analyses with the individual perceived wellbeing (SO2).

Due to technical challenges, including the transfer of data, neither the physical activity analysis nor the sleep quality analysis were available steadily enough to investigate their association with the individual perceived wellbeing.

SO3

To investigate the capability of the novel system to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects (SO3).

The main results of the harmonisation questionnaires and its change in mean have been presented as part of the MAST evaluation (Table 18). Due to the limited number of participants (n=8) within this pilot, the comparison of results from baseline to the end of pilot will not be performed per pilot site as drawing any conclusions from this would be misleading. Instead, some overall evaluation will be performed with data from all pilot sites as part of the D6.9/D6.10.

During the interviews, almost all participants mentioned that monitoring their different health and wellbeing parameters on a daily basis did arise awareness and was also motivating. Thereby, the interests in the type of parameters collected varied per user. Some users mentioned that seeing their daily steps motivated to still go for a walk in the afternoon if their target had not been reached yet or to pay more attention to their liquid intake. Any other behaviour change has not been reported by participants.

With respect to the life quality and wellbeing, some users reported that they felt satisfied when they reached their targets. It was also explained that they felt satisfied in the evening when knowing that they had been physically active. Apart from that, one user mentioned that being concerned with one's own health is a form of self-

care, which is also satisfying and therefore possibly increasing the quality of life of well.

SO4

To explore user trust and acceptance of the novel system (SO4).

The reaction towards the DS were differing. Participants, who have already been tracking their health meters, tended to compare the SHAPES DS to their own system. Their reaction was mainly critical as the developed DS was not at the same stage of readiness and did not provide the expected information.

As previously described, some users articulated difficulties in trusting in the collected data and analysis (nutrition intake, sleep, steps). However, most of them were interested in testing a new DS as it keeps them fit to get new input and to deal with new DS.

Data Collected by the eCare Platform in phase 5 UC-PT2-001 (GEWI)

Following the scope of the use case, the eCare Platform (eCare App and eCare researcher dashboard) allowed pilot participants and the GEWI researchers to visualise the participants' heart rate, step counts and self-assessments of wellbeing and sleep, on a daily, weekly and monthly basis. The eCare App provided also a list of daily tasks to ensure that participants remained aware of what was expected of them and could check as complete the tasks they were required to fulfil manually, including the delivery of the wellbeing and sleep self-assessments. Further, the eCare researcher dashboard allowed the GEWI researchers to monitor the participants' adherence to the research protocol (care plan) and verify their engagement during the pilot.

During the pilot timeframe, eCare collected a total of **373 665 measurements**, including heart rate measurements, step counts, sleep duration measurements and sleep and wellbeing self-assessments distributed as follows:

Table 20: Number of Measurements in eCare of UC-PT2-001 (GEWI)

Participant	# HR Measurements	# Step Counts	# Sleep Duration Measurements	# Sleep Assessments	# Wellbeing Assessments
1SU	35 612	8 470	95	110	105
2SU	27 968	9 275	78	70	58
3SU	24 121	7 735	77	77	68
4SU	52 948	11 424	103	81	73
5SU	28 885	6 248	83	84	84
6SU	35 351	12 806	64	60	56
7SU	51 853	16 897	80	117	92
8SU	34 934	7 215	74	68	66
Total	291 672	80 070	654	667	602

The table below provides the average value of each of the specific measurements collected per participant for the full duration of the pilot activity, providing a first insight to the participants' general health and wellbeing status.

Table 21: Average Measurements in eCare for the Participants of UC-PT2-001 (GEWI)

Participant	HR Measurements (Avg)	Sleep Hours (Avg)	Light Sleep Hours (Avg)	Deep Sleep Hours (Avg)	Sleep Feedback (Avg)	Wellbeing Feedback (Avg)
1SU	72 bpm	7h00m	4h48m	2h12m	4	4
2SU	73 bpm	6h42m	4h56m	1h48m	5	5
3SU	71 bpm	6h06m	4h12m	1h56m	3	3
4SU	74 bpm	7h24m	5h12m	2h12m	3	4
5SU	68 bpm	6h30m	4h48m	1h42m	4	4
6SU	71 bpm	6h36m	4h30m	2h06m	3	3
7SU	72 bpm	6h56m	4h24m	2h30m	4	4
8SU	70 bpm	5h42m	1h12m	4h30m	3	3

Not only were these measurements displayed to each one of the pilot participants, but they were visualised also by the GEWI research team in the eCare researcher dashboard as numbers, statistics, graphics and tables, exportable in a .csv file for additional analysis. The following figures illustrate the display in the eCare researcher dashboard of the measurements of heart rate, steps, sleep duration, and sleep and wellbeing self-assessments of each pilot participant for the duration of the pilot.

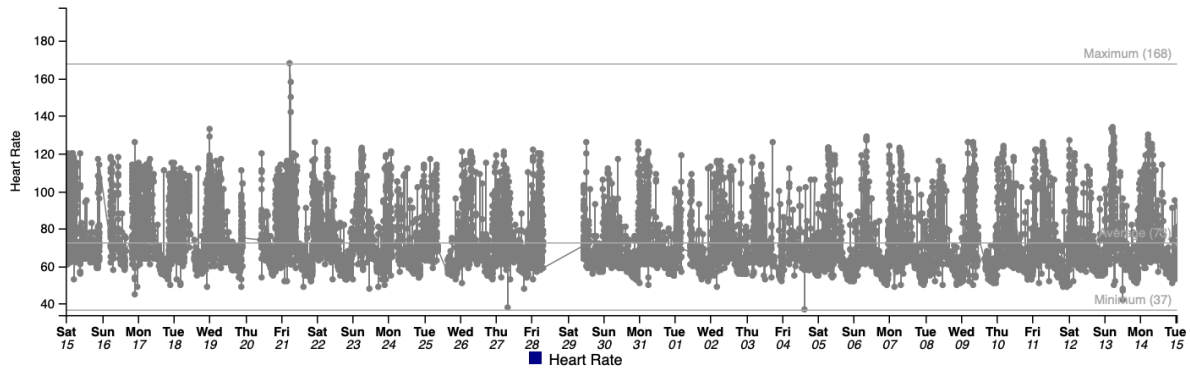


Figure 5: Heart Rate Measurements of Participant 1SU between October 15th and November 15th 2022

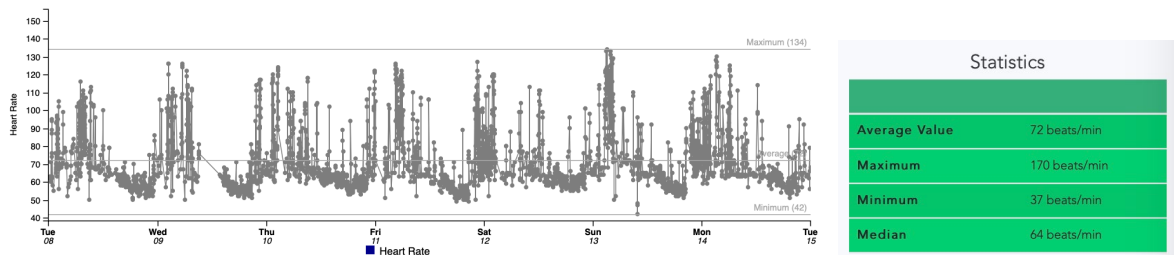


Figure 6: Heart Rate Measurements of Participant 1SU between November 8th and 15th 2022 and Heart Rate Statistics of Participant 1SU during the Phase 5 of UC-PT2-001 (GEWI)

Participant 1 registered a total of 175 683 steps in October 2022, 139 129 steps in November 2022 and 89 385 steps in December 2022, reflecting an average of 101 060 steps for the duration of the pilot.

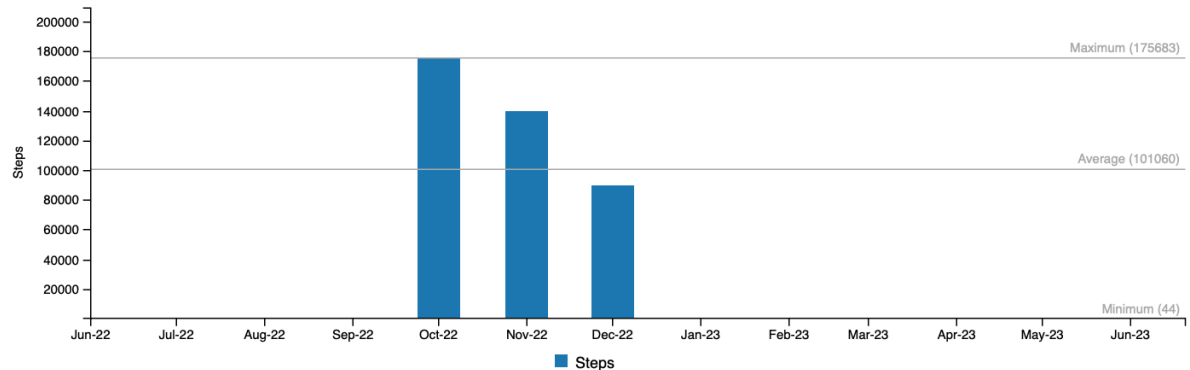


Figure 7: Steps of Participant 1SU during the Phase 5 of UC-PT2-001 (GEWI)

Participant 1SU registered a total of 199h30m of sleep in October 2022, 234h06m of sleep in November 2022 and 187h of sleep in December 2022, reflecting an average of 7h of sleep for the duration of the pilot.

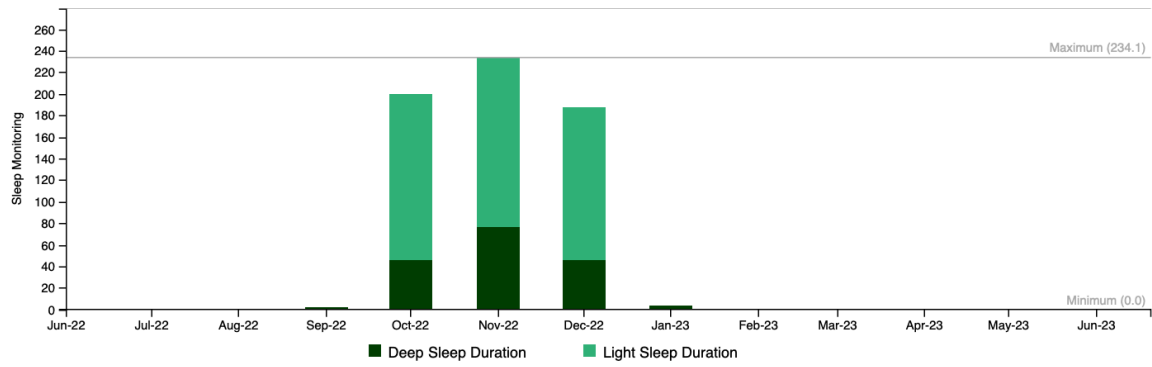


Figure 8: Sleep Hours of Participant 1SU during the Phase 5 of UC-PT2-001 (GEWI)

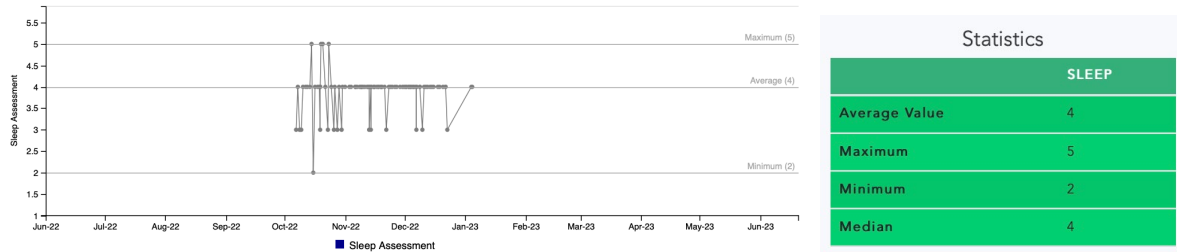


Figure 9: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 1SU during the Phase 5 of UC-PT2-001 (GEWI)

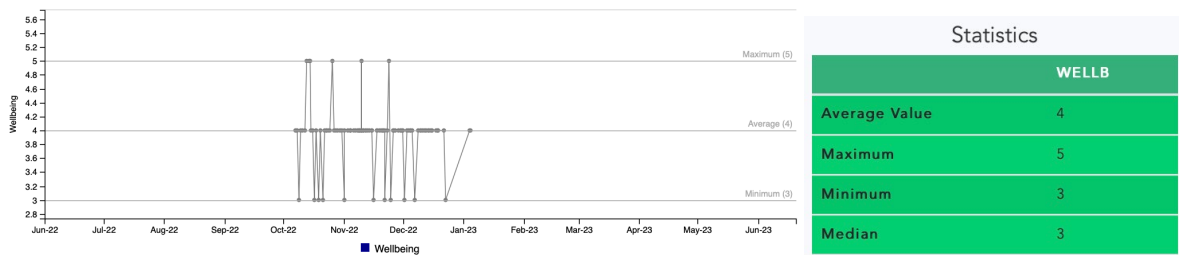


Figure 10: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 1SU during the Phase 5 of UC-PT2-001 (GEWI)

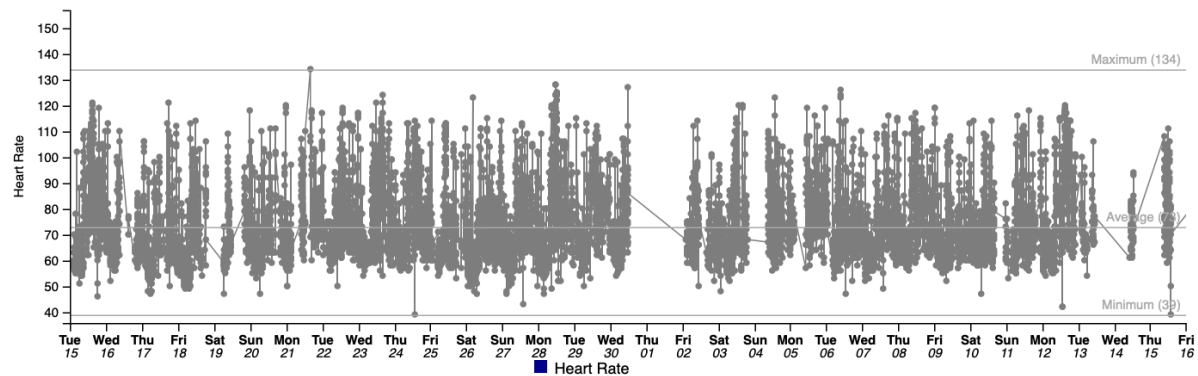


Figure 11: Heart Rate Measurements of Participant 2SU between November 15th and December 16th 2022

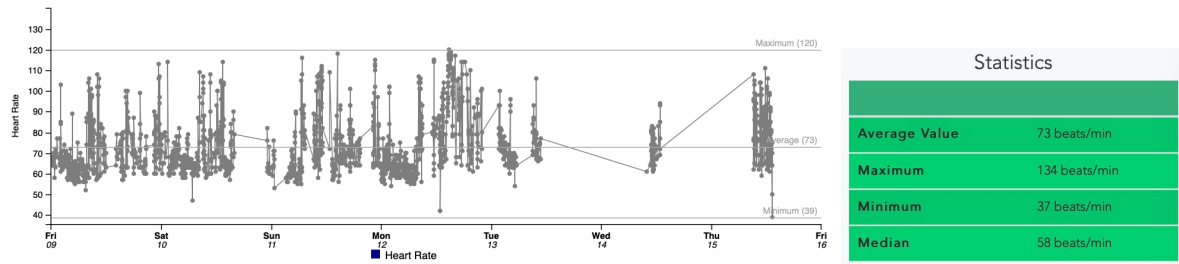


Figure 12: Heart Rate Measurements of Participant 2SU between December 9th and 15th 2022 and Heart Rate Statistics of Participant 2SU during the Phase 5 of UC-PT2-001 (GEWI)

Participant 2SU registered a total of 118 405 steps in October 2022, 119 027 steps in November 2022 and 68 092 steps in December 2022, reflecting an average of 101 841 steps for the duration of the pilot.

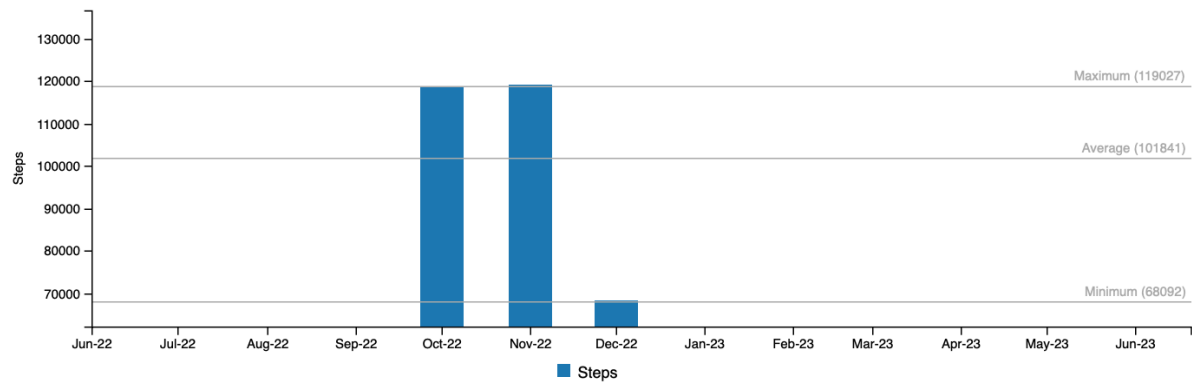


Figure 13: Steps of Participant 2SU during the Phase 5 of UC-PT2-001 (GEWI)

Participant 2SU registered a total of 119h18m of sleep in October 2022, 164h36m of sleep in November 2022 and 131h12m of sleep in December 2022, reflecting an average of 6h42m of sleep for the duration of the pilot.

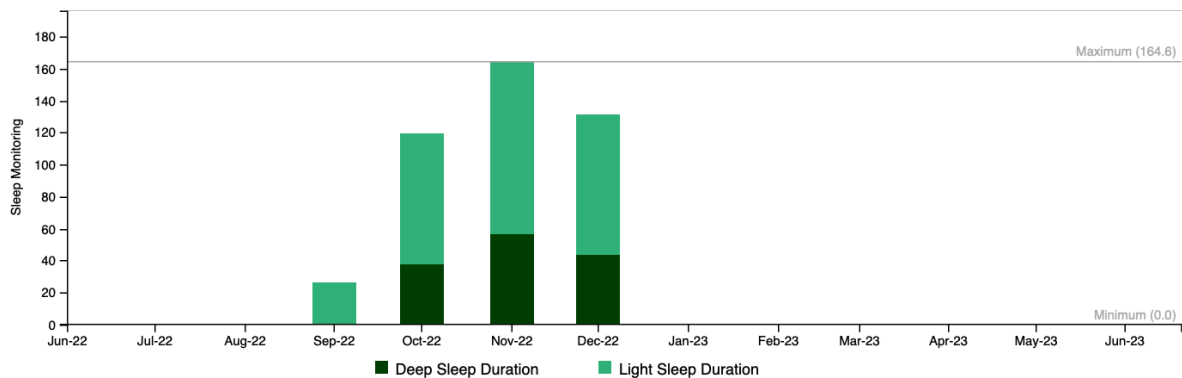


Figure 14: Sleep Hours of Participant 2SU during the Phase 5 of UC-PT2-001 (GEWI)

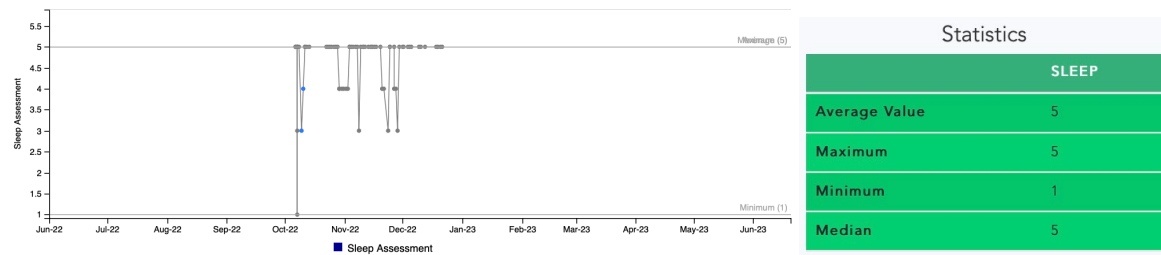


Figure 15: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 2SU during the Phase 5 of UC-PT2-001 (GEWI)

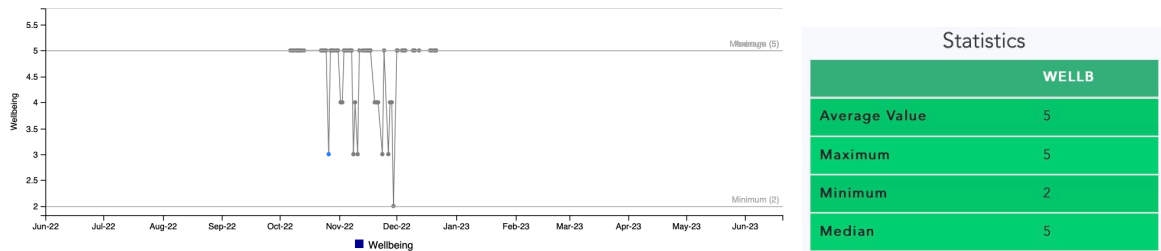


Figure 16: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 2SU during the Phase 5 of UC-PT2-001 (GEWI)

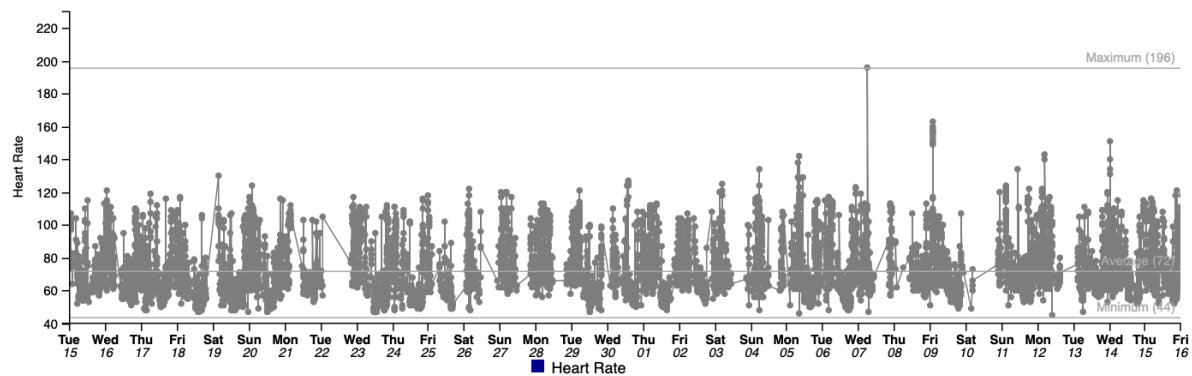


Figure 17: Heart Rate Measurements of Participant 3SU between November 15th and December 16th 2022

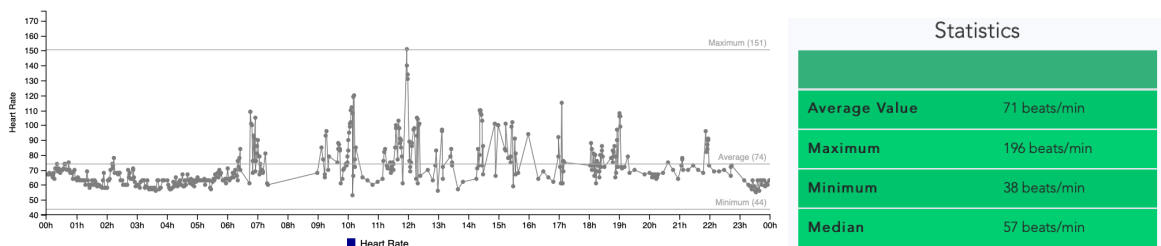


Figure 18: Heart Rate Measurements of Participant 3SU on December 14th 2022 and Heart Rate Statistics of Participant 3SU during the Phase 5 of UC-PT2-001 (GEWI)

Participant 3SU registered a total of 109 705 steps in October 2022, 126 434 steps in November 2022 and 100 420 steps in December 2022, reflecting an average of 67 325 steps for the duration of the pilot.

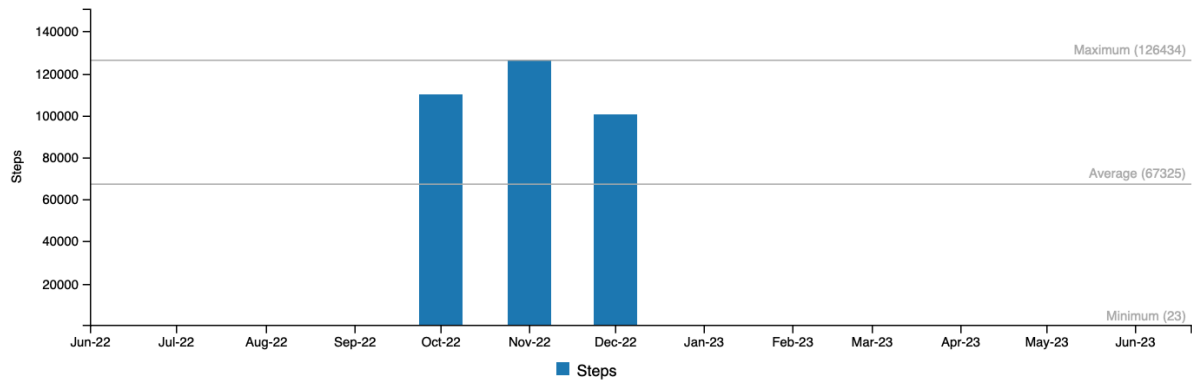


Figure 19: Steps of Participant 3SU during the Phase 5 of UC-PT2-001 (GEWI)

Participant 3SU registered a total of 127h36m of sleep in October 2022, 139h36m of sleep in November 2022 and 127h36m of sleep in December 2022, reflecting an average of 6h06m of sleep for the duration of the pilot.

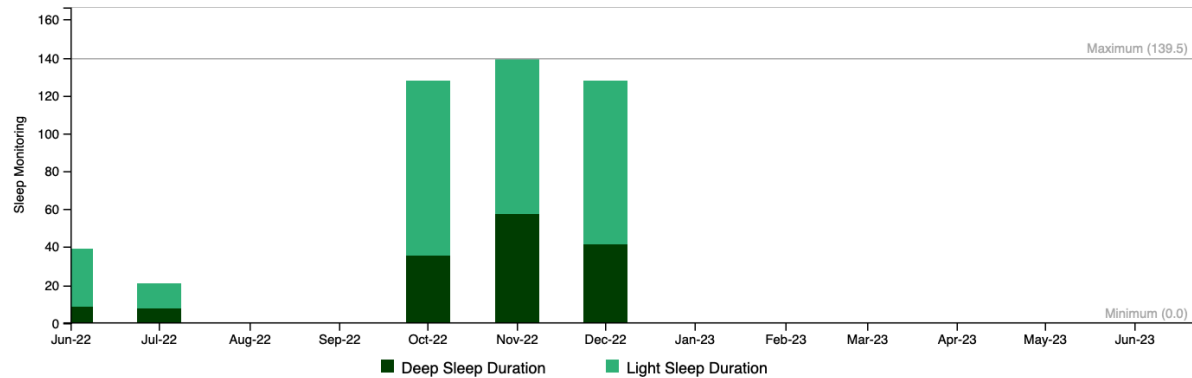


Figure 20: Sleep Hours of Participant 3SU during the Phase 5 of UC-PT2-001 (GEWI)

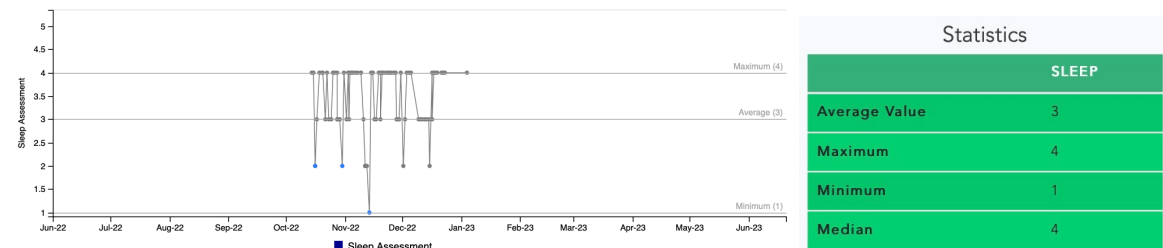


Figure 21: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 3SU during the Phase 5 of UC-PT2-001 (GEWI)

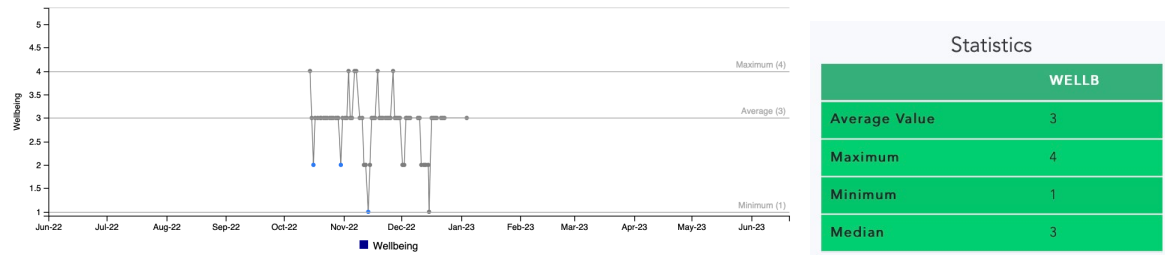


Figure 22: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 3SU during the Phase 5 of UC-PT2-001 (GEWI)

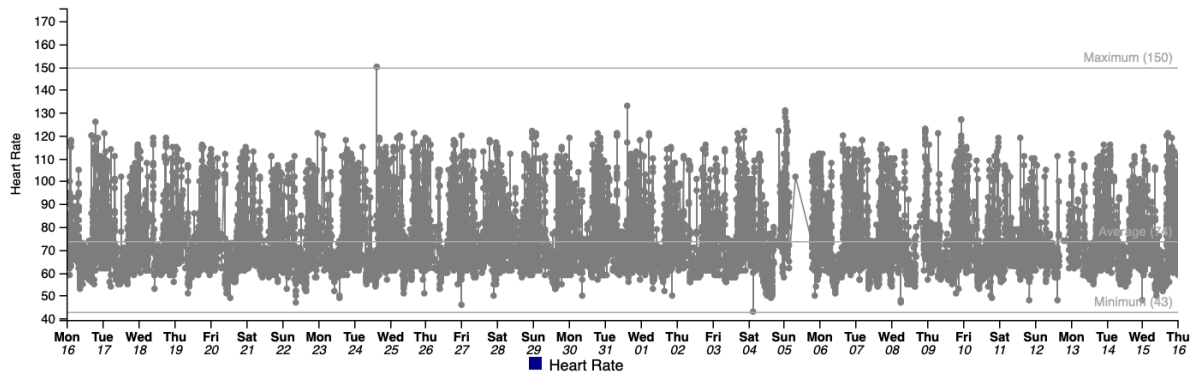


Figure 23: Heart Rate Measurements of Participant 4SU between January 16th and February 16th 2023

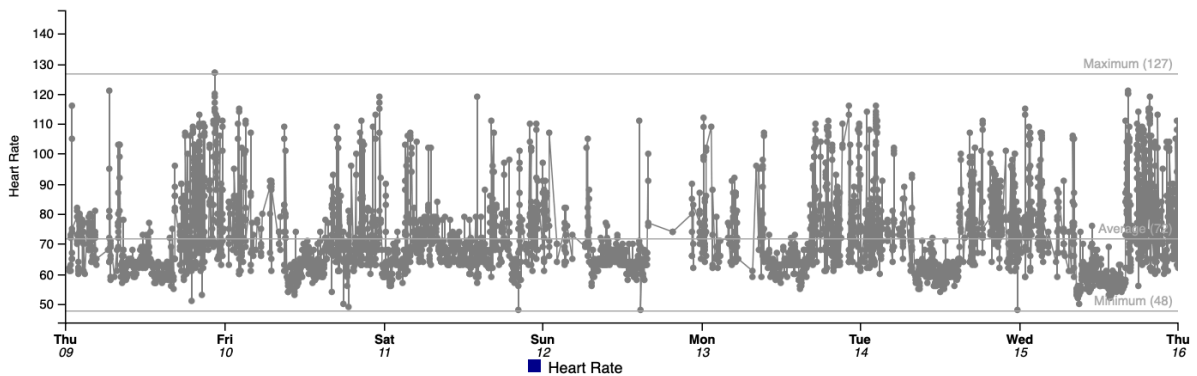


Figure 24: Heart Rate Measurements of Participant 4SU between February 9th and 16th 2023

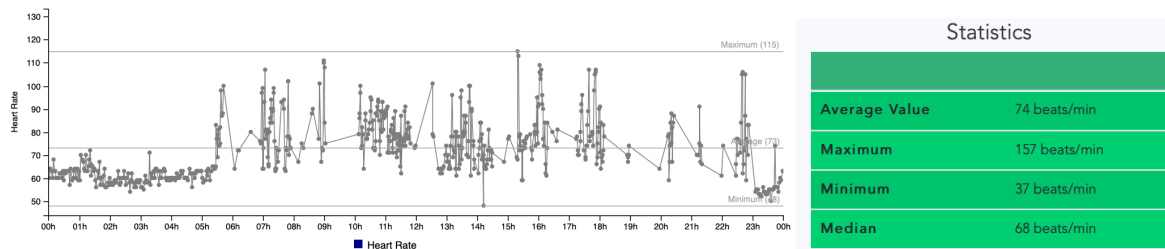


Figure 25: Heart Rate Measurements of Participant 4SU on February 15th 2023 and Heart Rate Statistics of Participant 4SU during the Phase 5 of UC-PT2-001 (GEWI)

Participant 4SU registered a total of 106 880 steps in November 2022, 88 821 steps in December 2022, 109 902 steps in January 2023, 84 946 steps in February 2023 and 18 327 steps in March 2023, reflecting an average of 68 150 steps for the duration of the pilot.

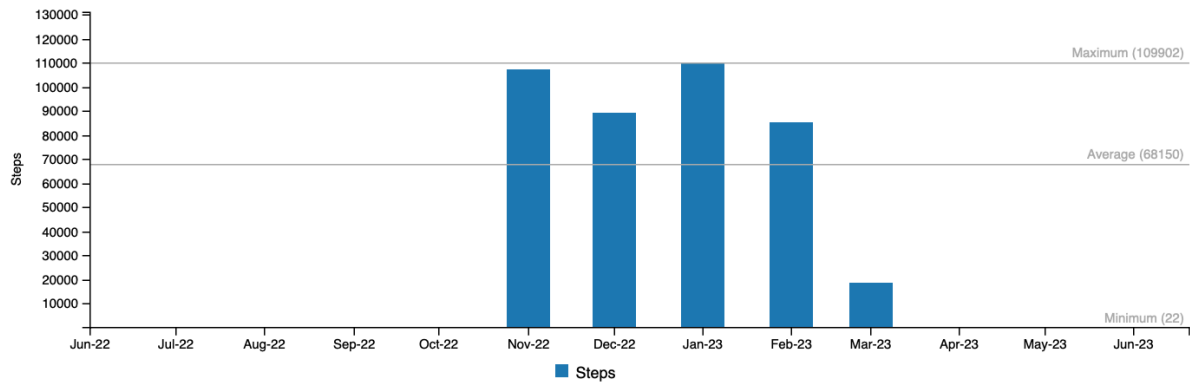


Figure 26: Steps of Participant 4SU during the Phase 5 of UC-PT2-001 (GEWI)

Participant 4SU registered a total of 145h06m of sleep in November 2022, 208h18m of sleep in December 2022, 195h36m of sleep in January 2023, 174h36m of sleep in February 2023 and 29h36m of sleep in March 2023, reflecting an average of 7h24m of sleep for the duration of the pilot.

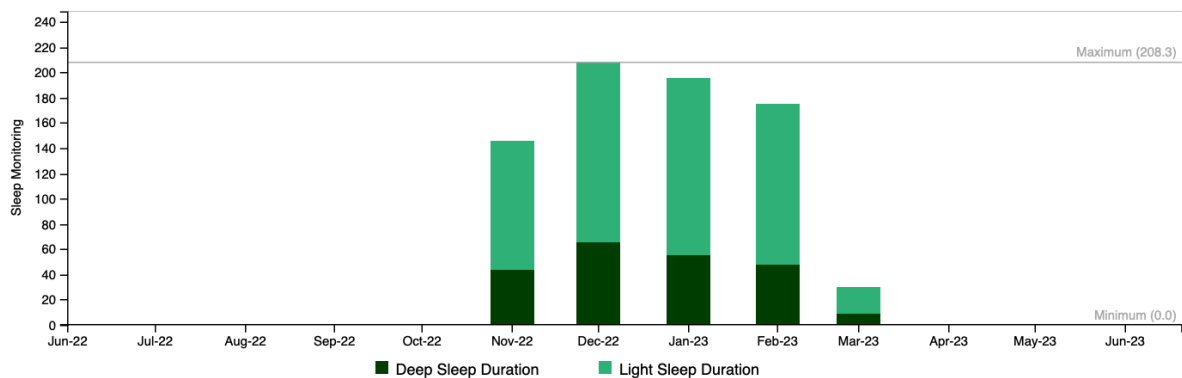


Figure 27: Sleep Hours of Participant 4SU during the Phase 5 of UC-PT2-001 (GEWI)

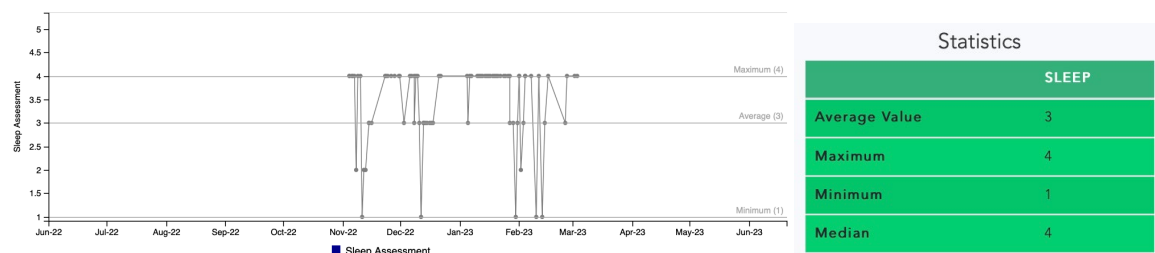


Figure 28: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 4SU during the Phase 5 of UC-PT2-001 (GEWI)

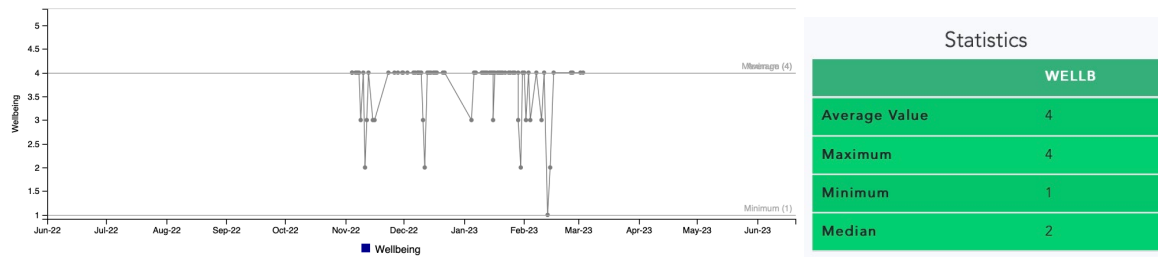


Figure 29: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 4SU during the Phase 5 of UC-PT2-001 (GEWI)

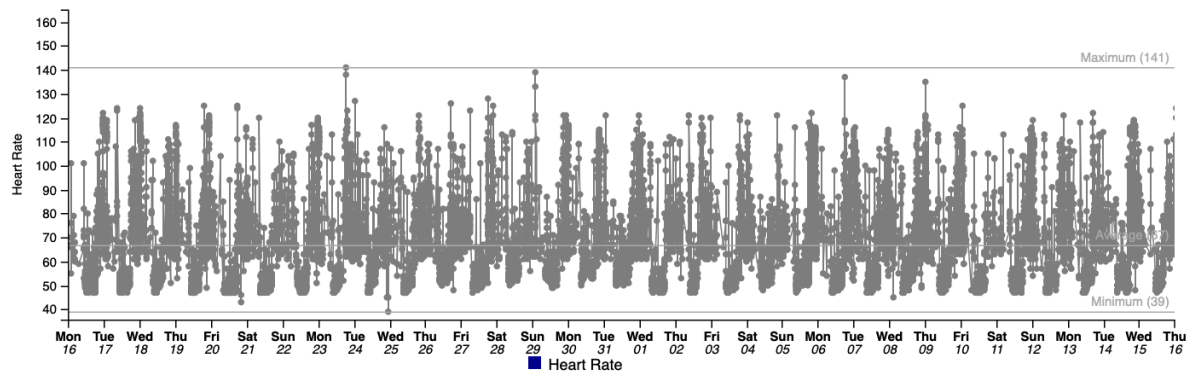


Figure 30: Heart Rate Measurements of Participant 5SU between January 16th and February 16th 2023

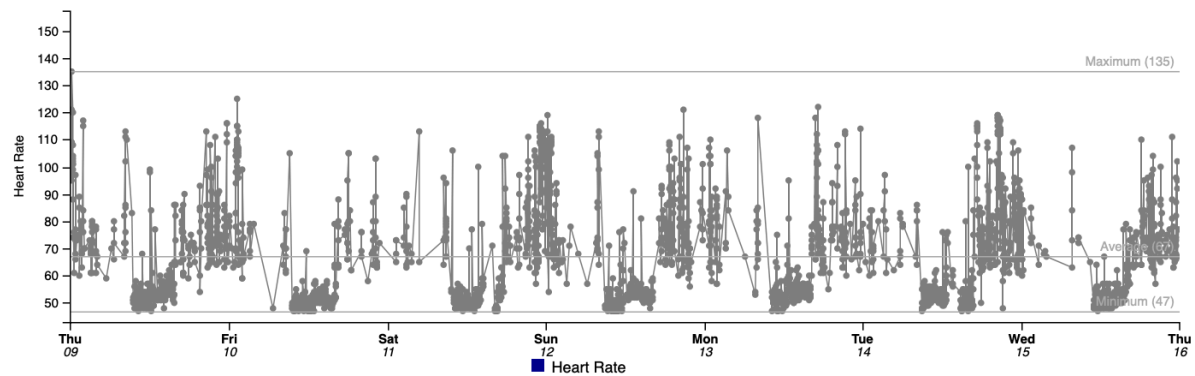


Figure 31: Heart Rate Measurements of Participant 5SU between February 9th and 16th 2023

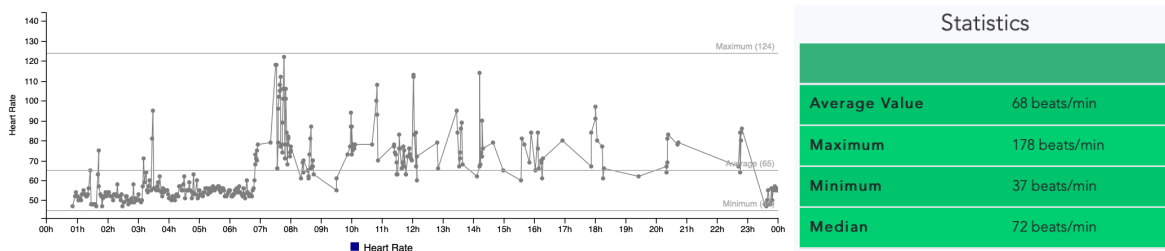


Figure 32: Heart Rate Measurements of Participant 5SU on February 14th 2023 and Heart Rate Statistics of Participant 5SU during the Phase 5 of UC-PT2-001 (GEWI)

Participant 5SU registered a total of 63 550 steps in December 2022, 128 688 steps in January 2023, 93 756 steps in February 2023 and 366 steps in March 2023, reflecting an average of 57 278 steps for the duration of the pilot.

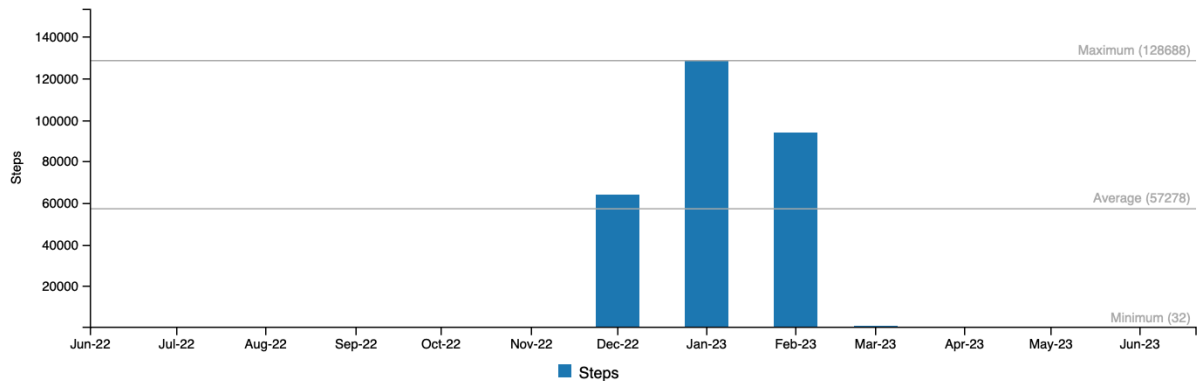


Figure 33: Steps of Participant 5SU during the Phase 5 of UC-PT2-001 (GEWI)

Participant 5SU registered a total of 120h12m of sleep in December 2022, 204h48m of sleep in January 2023, 183h12m of sleep in February 2023 and 23h of sleep in March 2023, reflecting an average of 6h30m of sleep for the duration of the pilot.

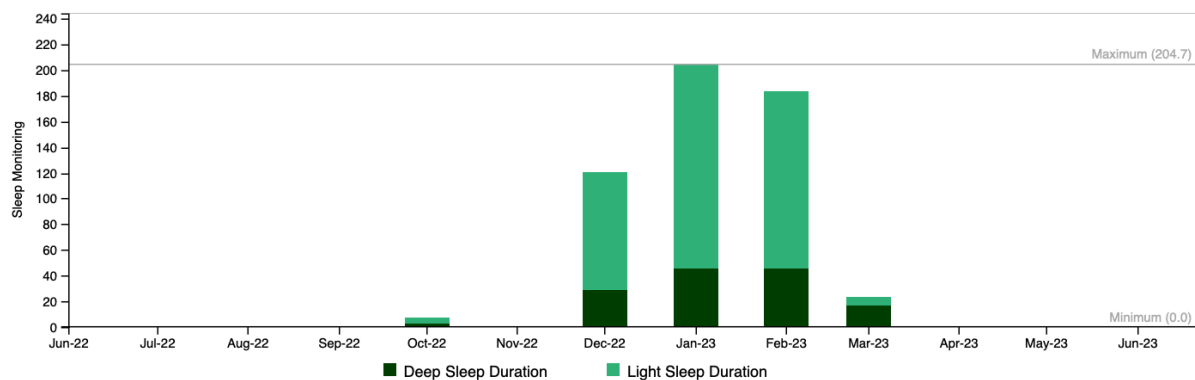
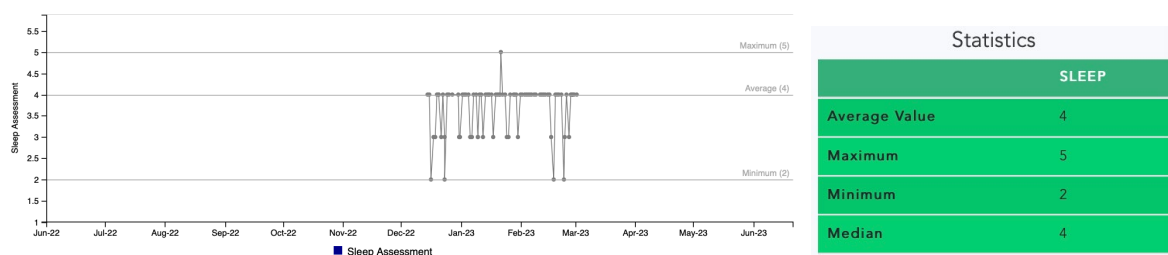


Figure 34: Sleep Hours of Participant 5SU during the Phase 5 of UC-PT2-001 (GEWI)



Statistics	
SLEEP	
Average Value	4
Maximum	5
Minimum	2
Median	4

Figure 35: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 5SU during the Phase 5 of UC-PT2-001 (GEWI)

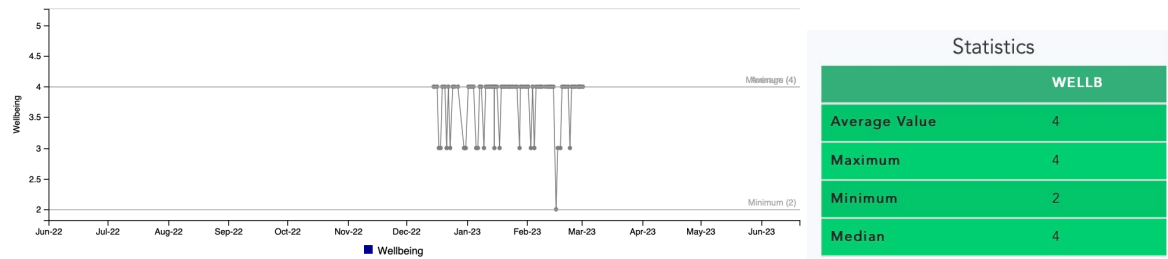


Figure 36: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 5SU during the Phase 5 of UC-PT2-001 (GEWI)

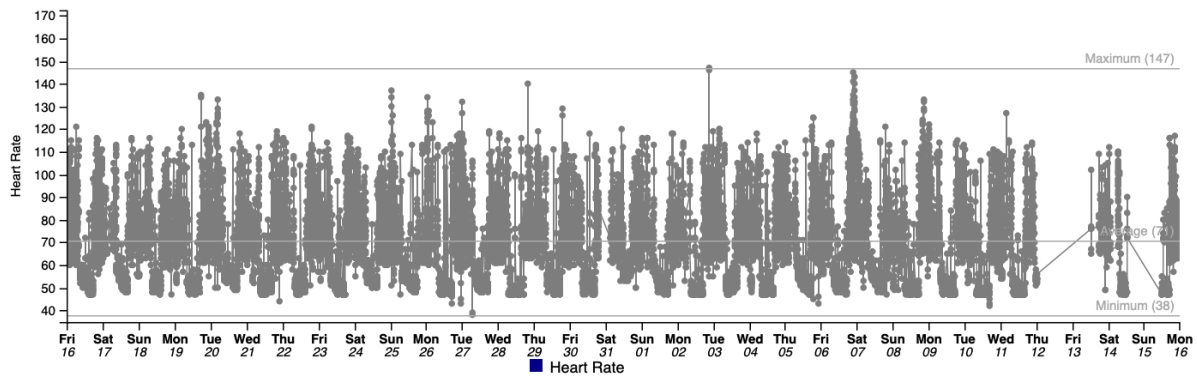


Figure 37: Heart Rate Measurements of Participant 6SU between December 16th 2022 and January 16th 2023

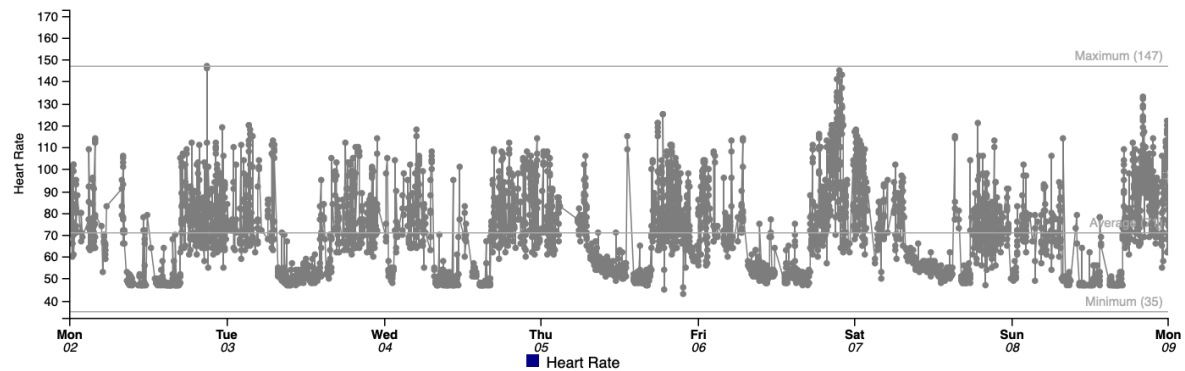


Figure 38: Heart Rate Measurements of Participant 6SU between January 2nd and 9th 2023

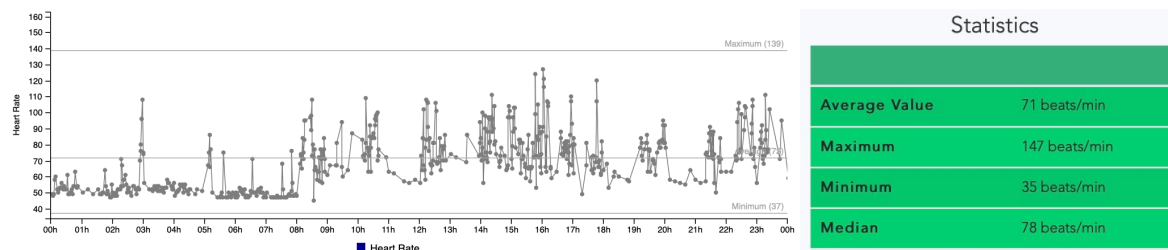


Figure 39: Heart Rate Measurements of Participant 6SU on February 8th 2023 and Heart Rate Statistics of Participant 6SU during the Phase 5 of UC-PT2-001 (GEWI)

Participant 6SU registered a total of 136 746 steps in December 2022, 162 281 steps in January 2023 and 182 027 steps in February 2023, reflecting an average of 160 351 steps for the duration of the pilot.

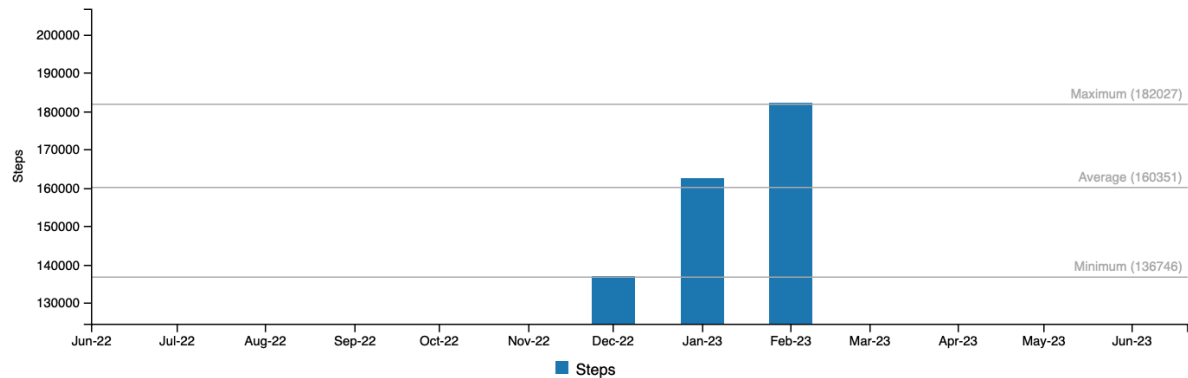


Figure 40: Steps of Participant 6SU during the Phase 5 of UC-PT2-001 (GEWI)

Participant 6SU registered a total of 125h24m of sleep in December 2022, 144h54m of sleep in January 2023 and 143h06m of sleep in February 2023, reflecting an average of 6h36m of sleep for the duration of the pilot.

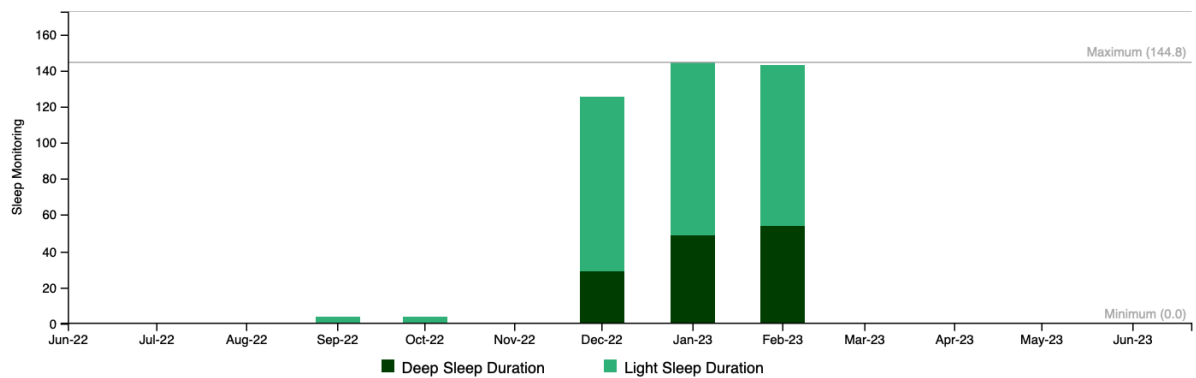


Figure 41: Sleep Hours of Participant 6SU during the Phase 5 of UC-PT2-001 (GEWI)

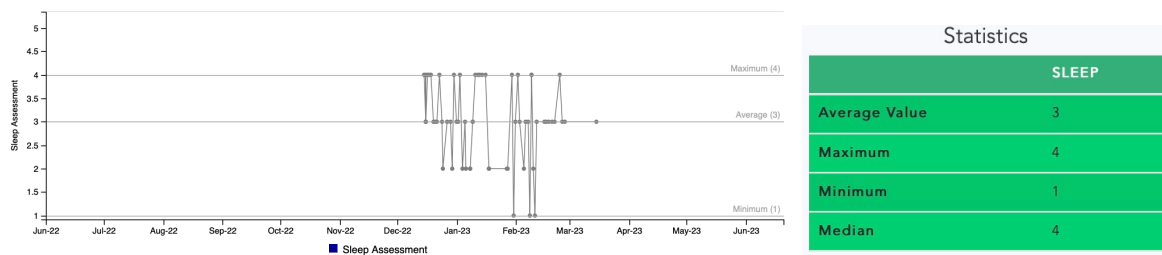


Figure 42: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 6SU during the Phase 5 of UC-PT2-001 (GEWI)

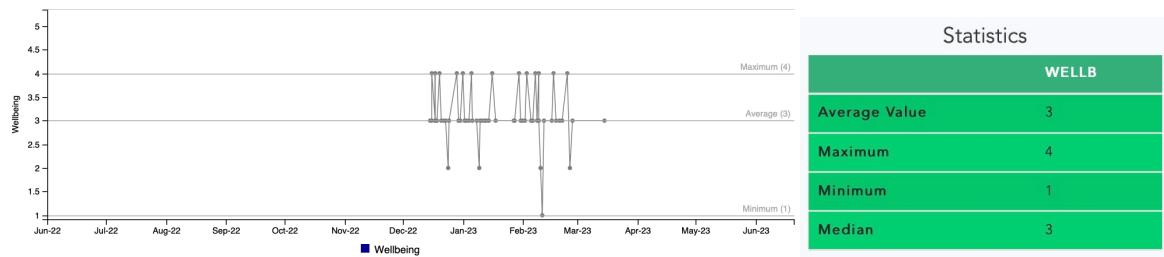


Figure 43: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 6SU during the Phase 5 of UC-PT2-001 (GEWI)

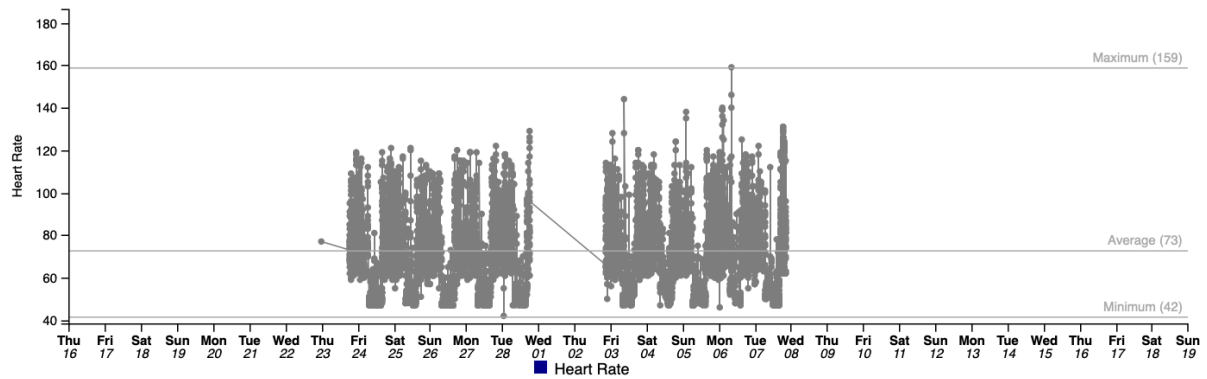


Figure 44: Heart Rate Measurements of Participant 7SU between February 16th and March 19th 2023

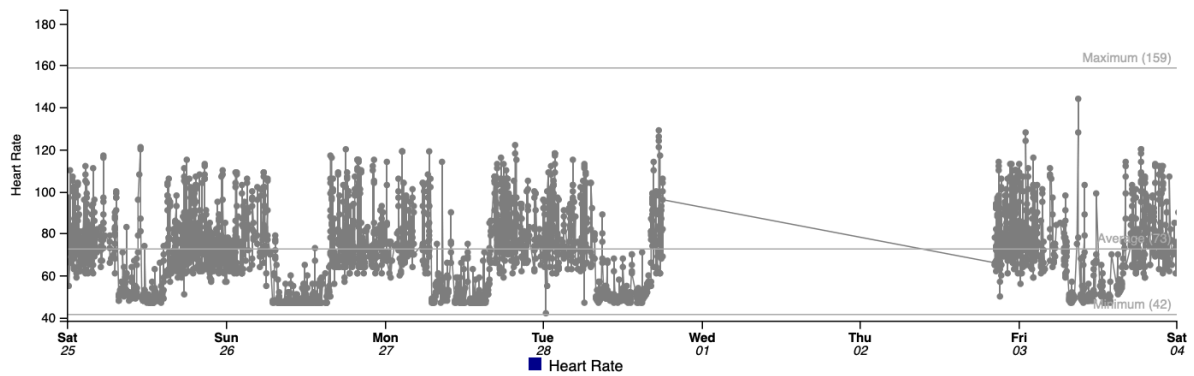


Figure 45: Heart Rate Measurements of Participant 7SU between February 25th and March 4th 2023

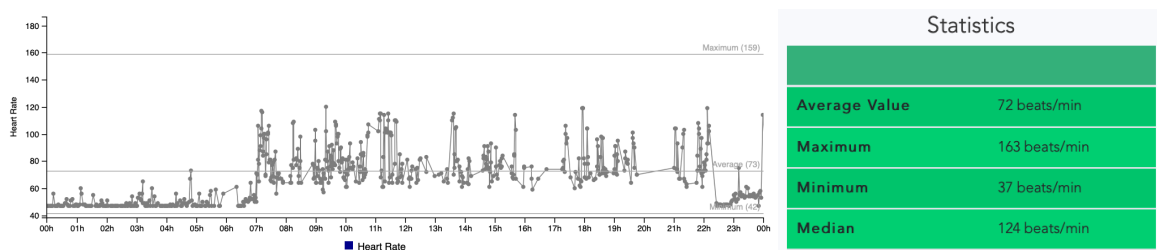


Figure 46: Heart Rate Measurements of Participant 7SU on February 27th 2023 and Heart Rate Statistics of Participant 7SU during the Phase 5 of UC-PT2-001 (GEWI)

Participant 7SU registered a total of 17 809 steps in November 2022, 282 611 steps in December 2022, 269 350 steps in January 2023, 57 620 steps in February 2023

and 33 261 steps in March 2023, reflecting an average of 110 112 steps for the duration of the pilot.

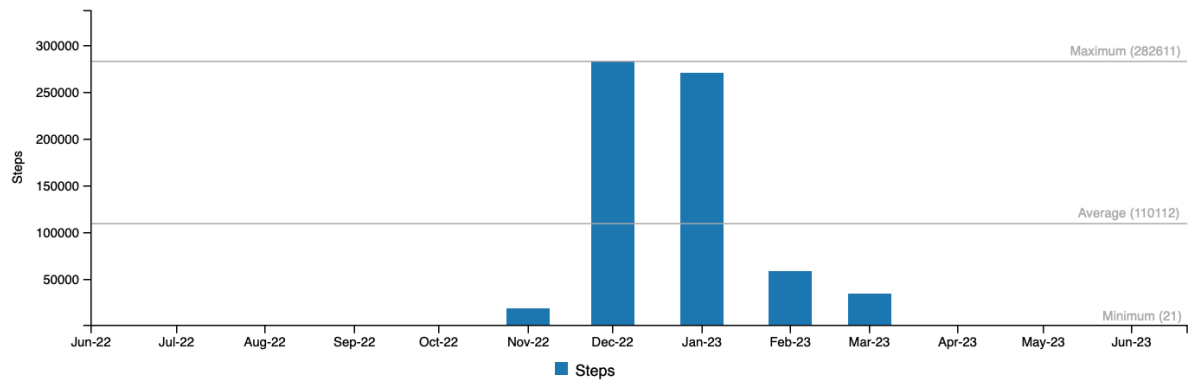


Figure 47: Steps of Participant 7SU during the Phase 5 of UC-PT2-001 (GEWI)

Participant 7SU registered a total of 15h42m of sleep in November 2022, 215h24m of sleep in December 2022, 222h18m of sleep in January 2023, 59h30m of sleep in February 2023 and 42h48m of sleep in March 2023, reflecting an average of 6h54m of sleep for the duration of the pilot.

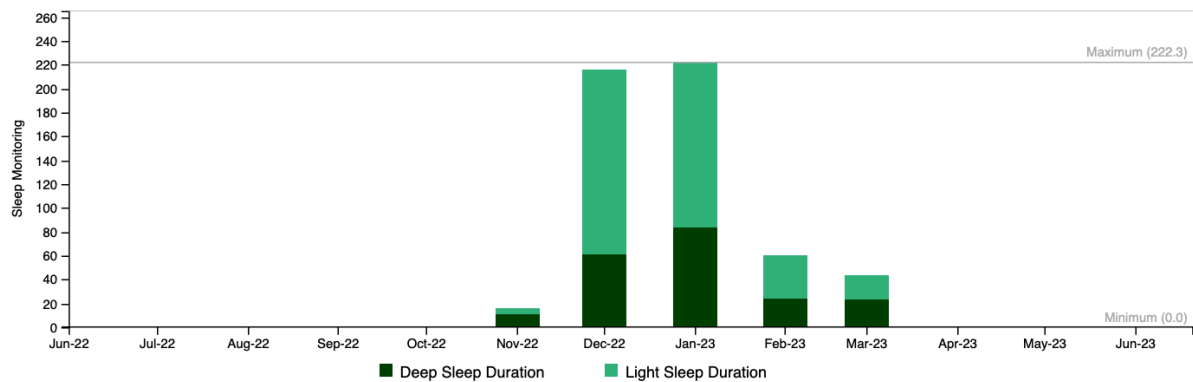


Figure 48: Sleep Hours of Participant 7SU during the Phase 5 of UC-PT2-001 (GEWI)

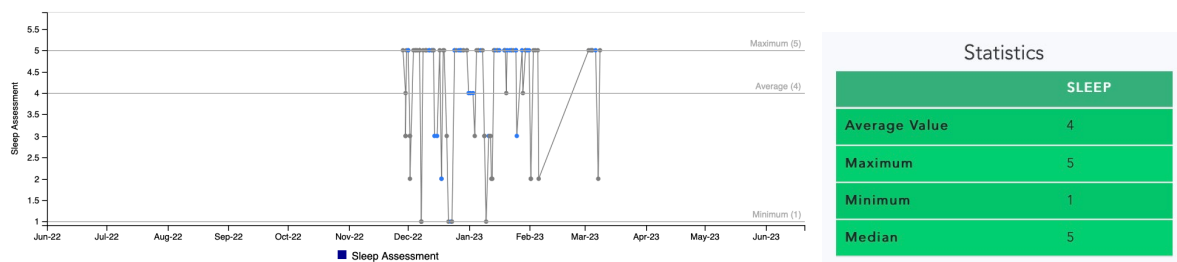


Figure 49: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 7SU during the Phase 5 of UC-PT2-001 (GEWI)

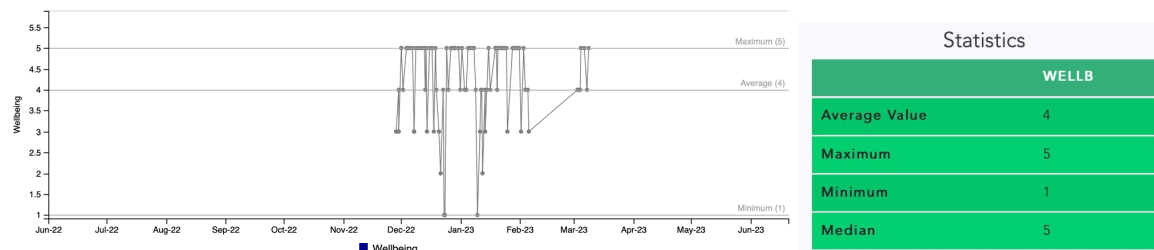


Figure 50: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 7SU during the Phase 5 of UC-PT2-001 (GEWI)

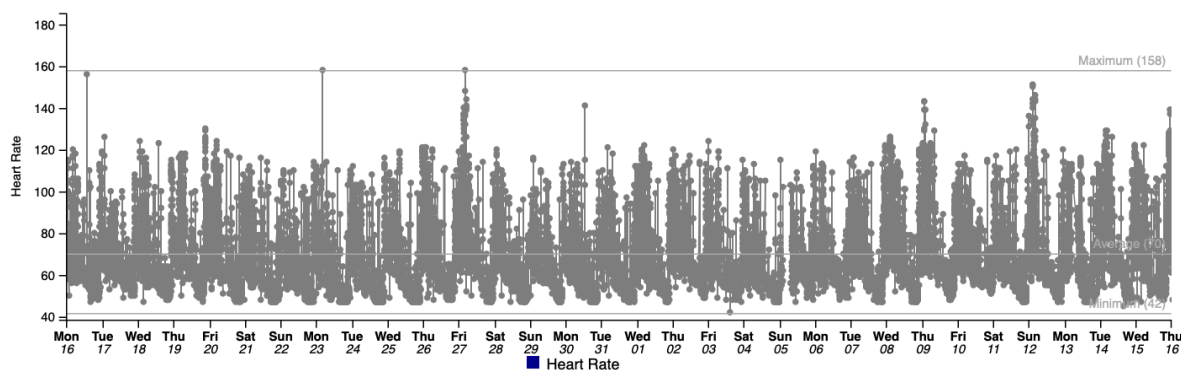


Figure 51: Heart Rate Measurements of Participant 8SU between January 16th and February 16th 2023

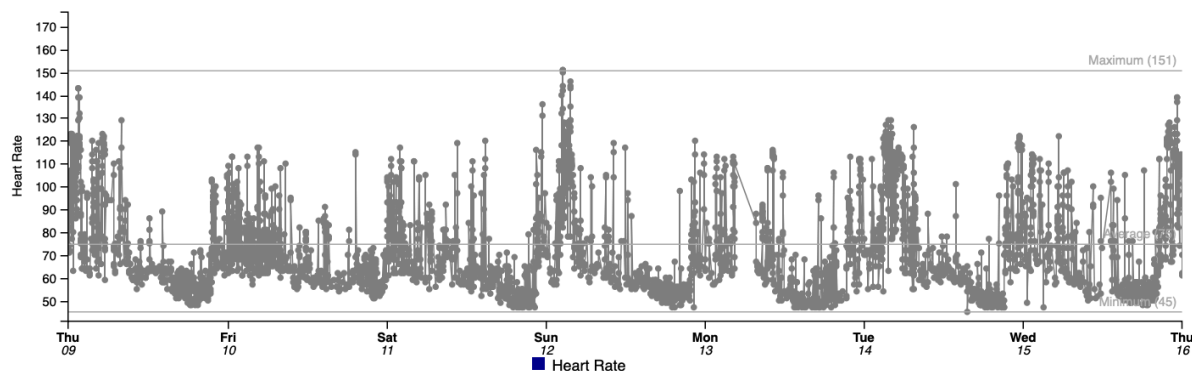


Figure 52: Heart Rate Measurements of Participant 8SU between February 9th and 16th 2023

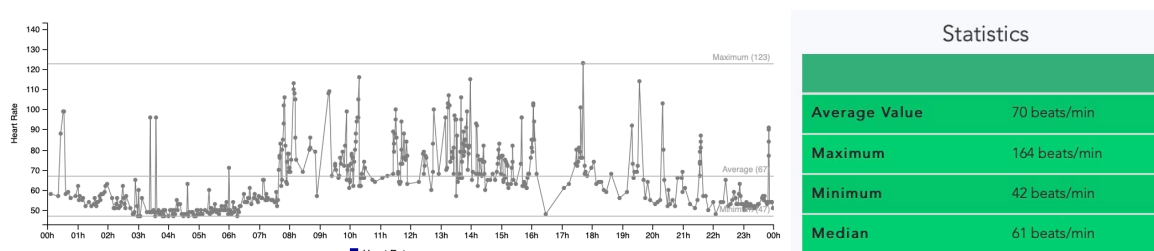


Figure 53: Heart Rate Measurements of Participant 8SU on February 21st 2023 and Heart Rate Statistics of Participant 8SU during the Phase 5 of UC-PT2-001 (GEWI)

Participant 8SU registered a total of 57 268 steps in December 2022, 100 928 steps in January 2023 and 109 430 steps in February 2023, reflecting an average of 53 551 steps for the duration of the pilot.

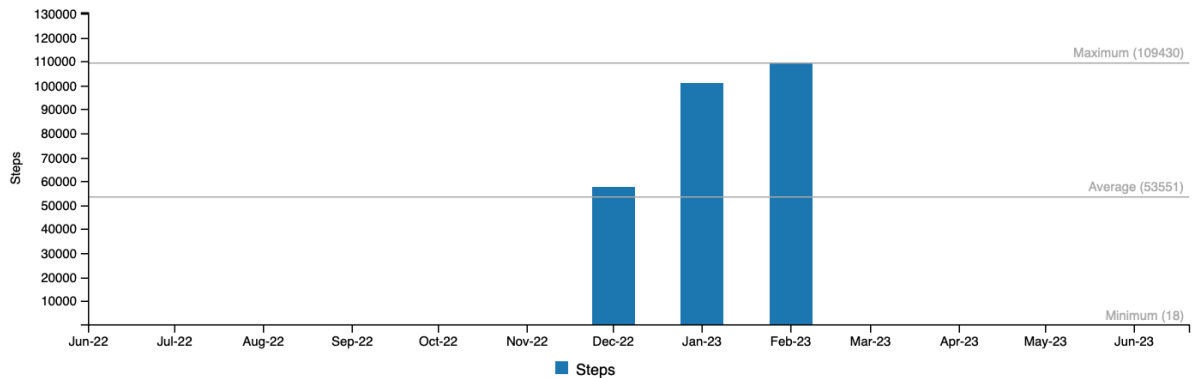


Figure 54: Steps of Participant 8SU during the Phase 5 of UC-PT2-001 (GEWI)

Participant 8SU registered a total of 104h30m of sleep in December 2022, 181h42m of sleep in January 2023 and 133h of sleep in February 2023, reflecting an average of 5h42m of sleep for the duration of the pilot.

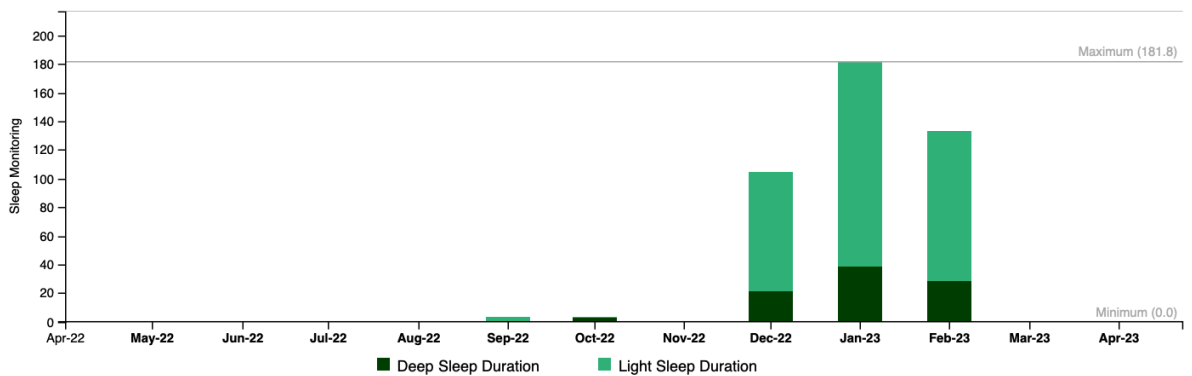


Figure 55: Sleep Hours of Participant 8SU during the Phase 5 of UC-PT2-001 (GEWI)

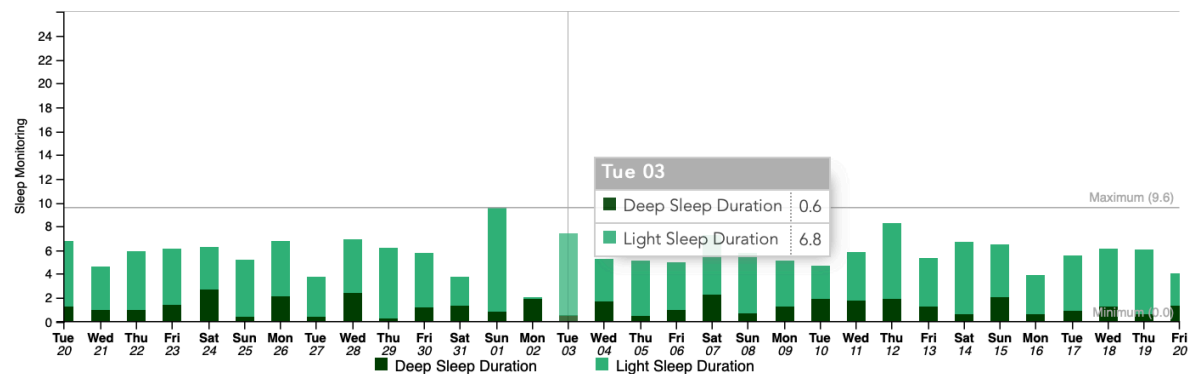


Figure 56: Sleep Hours of Participant 8SU between December 20th 2022 and January 20th 2023

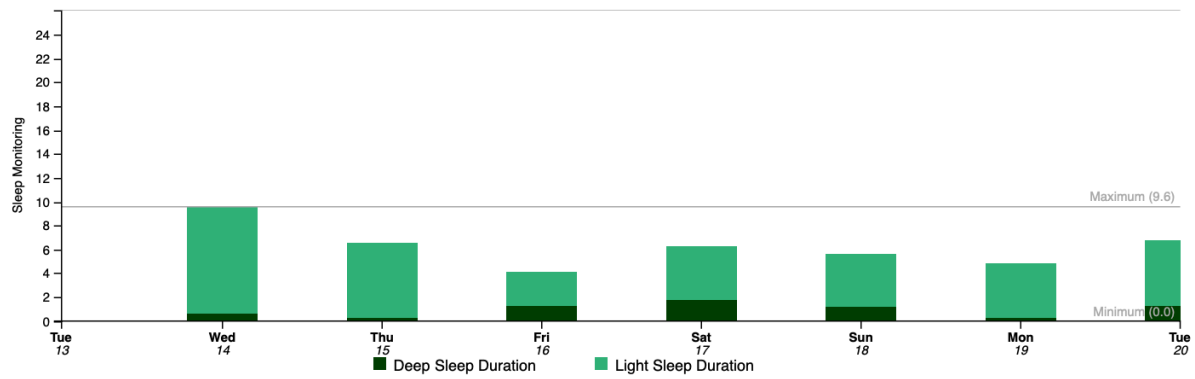


Figure 57: Sleep Hours of Participant 8SU between December 14th and 20th 2022

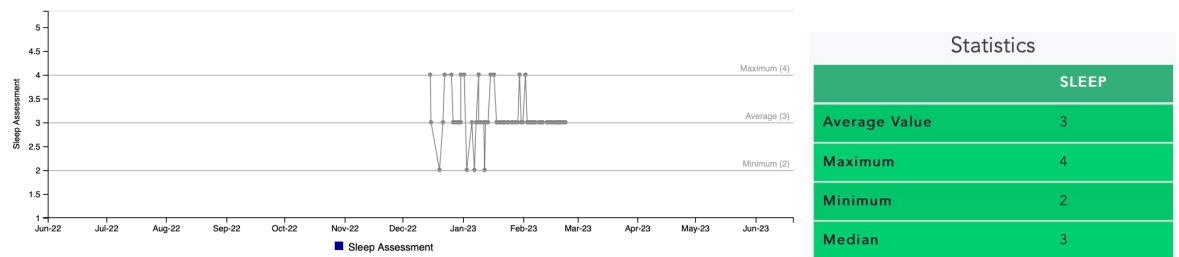


Figure 58: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 8SU during the Phase 5 of UC-PT2-001 (GEWI)

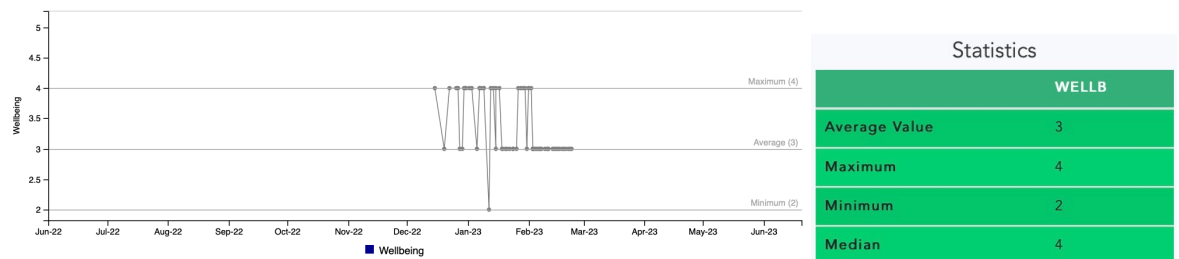


Figure 59: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 8SU during the Phase 5 of UC-PT2-001 (GEWI)

Recommendations for partners (from interviews)

A summary of the most prominent additional feedback is presented in the following. More detailed information and feedback has continuously been shared with the partners in the weekly/bi-weekly meetings.

eCare App:

- Users felt that, when entering a poorly rated self-assessment on wellbeing and sleep, it determined the value for the weekly wellbeing and sleep self-assessment overview. In fact, the weekly and monthly overview correspond to

the average response of each of the self-assessments entered in the previous 7 or 30 days, respectively.

- Users would have wished to view a detailed summary on their heart rate as only seeing the mean value does not offer them much information. Displaying the mean value of the heart rate was a way to render the heart rate information manageable for older individuals, since the activity wristband registers hundreds of heart rate measurements per day (up to 720 heart rate measurements may be registered every 24 hours).

eHealthPass:

- Order of the listed beverages should be changed with water being the placeholder.
- Additional beverages to be added to the list (ex. non-alcoholic beer).
- Graphical overview of daily liquid intake should provide information on the volume and the proportion of the type of beverage (coffee, tea...) per day (ex. with a bar graph).
- Volume of liquid intake should be possible to be entered manually as well.

Logmeal:

- Adding food in grams or pieces does not always make sense; user did not know what was meant by piece.
- Graphical summary of food intake should sum up the food intake would need to provide a summary of one week.
- Overview of individual nutritional values was too detailed for the layman.
- Entering single food items would be better instead of complete meals.
- Alphabetical listing of foods (also on the following letters) would support the selection process.
- Add a memory function to easily recall meals i.e. breakfast.
- Enter numbers manually, not by wheel as swiping is inconvenient for the target group.
- Adding entries of the previous day/hour should be possible.

AIAS

Overview

The replication pilot of the SHAPES UC-PT2-001 was conducted between November 2022 and January 2023 with 11 participants, 7 care receivers and 4 care professionals.

Socio-demographics of the participants:

Table 22: Baseline characteristics AIAS (UC-PT2-001)

Variables	Number of participants	Value
Age (years)	7 (+4 Professionals)	Mean = 76.8 SD = 7.5
Male	3	
Female	4 (+4 professionals)	
Smoking status	NA	NA
Country: ITALY	7	100%
Marital status	7	Single: 1 Widowed: 6
Occupational status: retired	7	100%
Residence:	6	Sheltered apartment: 6 Residential care centre: 1

Primary and secondary outcome

The primary outcomes were to measure a predefined set of KPIs which have already been presented in chapter 0 as well as to evaluate the UC-PT2-001 use case using the MAST evaluation tool.

The following tables present the data used to determine the success of each KPI. Table 17 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: KPI 1 AIAS (UC-PT2-001)

Parameter	AIAS
Target number of participants	5
Number of participants recruited	7 (users) +4 (professionals) =11
Percentage recruited	>100%

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

Table 24: KPI 2 AIAS (UC-PT2-001)

Parameter	AIAS
Number of participants at baseline	7
Number of withdrawals	1
Number of participants at end of study	6
Percentage retained	85,7%

KPI 1 and KPI 2 were successfully achieved, meaning that the recruitment and engagement initiatives of AIAS were successful, not only in identifying interested and willing participants, fitted to the effort at play, but also that the strategy to maintain contact and provide support throughout the pilot did make a positive impact on the low number of withdrawals, despite the length of the pilot.

Technical performance

KPI 3 There is no re-start* of any of the components of the technology, except for the activity wristband, for at least 90% of the days.

Table 25: KPI 3 AIAS (UC-PT2-001)

Parameter	Value
Number of participants without any re-start of any of the components of the technology	7
Total number of participants	7
Percentage of participants without re-starts	100%

*re-start refers to the deinstallation and re-installation of any of the components due to mal functioning. This does not include any update of a new version of the App.

KPI 3 was successfully achieved and no re-start of any of the components of the technology was needed. This shows, that the DSs were functioning well meaning that the collaboration between the technical partners, the intensive test phase 4 and the continuous development process have had a positive impact on the deployment of the technical solution in Phase 5.

User engagement and acceptance

KPI 4 The overall user experience quality of the App as measured using the short version of the User Experience Questionnaire (UEQ-S) was

classified as ‘Excellent’, ‘Good’ or ‘Above average’ based on published benchmark data.

Table 26: KPI4 AIAS (UC-PT2-001)

Scale	Mean	Comparison to benchmark
Pragmatic quality	Not assessed	Not assessed
Hedonic quality	Not assessed	Not assessed
Overall	Not assessed	Not assessed

The participants had difficulties in understanding and answering the UEQ-S questionnaires. To avoid frustration, the UEQ-S was not evaluated in paper format but rather addressed in the final focus group discussion (see Table 31).

KPI 5 At least 60% of participants continued to login to use the App daily after two weeks of the pilot.

Table 27: KPI 5 AIAS (UC-PT2-001)

Parameter	Value
Number of participants who logged in daily for at least 2 weeks after baseline	7
Total number of participants	7
Percentage using the App daily after two weeks	100%

KPI 5 was achieved and 100% of the participants continued using the App after two weeks of the pilot. This indicates that participants were able to handle and use the DSs on their own, and that it was possible for them to integrate it in their everyday life.

KPI 6 At least 60% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Table 28: KPI 5 AIAS (UC-PT2-001)

Parameter	Value
Number of participants at end of pilot	7
Number of participants scoring >68 in SUS	1
Percentage of participants scoring > 68 in SUS	14%

KPI 6 was not reached and only 14% scored >68 in the SUS questionnaires. This reflects that most participants perceived the usability of the DSs as low. Main concerns

were related to their perception that handling the DSs was not intuitive as well as challenges with respect to the functioning of some parts of the App (see Table 31).

Overview of KPI achievement

Table 29: Overview of KPI achievement AIAS (UC-PT2-001)

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	YES	Recruitment initiatives of AIAS were successful, related to the identification of interested and willing participants, who also fitted to the effort at play.
KPI 2	YES	Engagement initiatives of AIAS were successful, related to the strategy to maintain contact and provide support did make a positive impact on the absence of withdrawals, despite the length of the pilot.
KPI 3	YES	No re-start of any of the components of the technology was needed. This shows that the DSs were functioning well and participants were able to engage with the DSs.
KPI 4	Not assessed	Participants had difficulties in understanding and answering the UEQ-S questionnaires. To avoid frustration, topics of the UEQ-S were only addressed in the final focus group discussion.
KPI 5	YES	Participants were able to handle and use the DSs on their own, and that it was possible for them to integrate it in their everyday life.
KPI 6	NO	Participants perceived the usability of the DSs as low and indicated that handling was not intuitive and encountered challenges with respect to the functioning of some parts of the App.

Evaluation of MAST

The MAST framework as already introduced in chapter 2.4.2 was used to evaluate the effectiveness and contribution of UC-PT2-001 to quality of care. The evaluated data/outcome are presented in the table below:

Table 30: MAST Evaluation AIAS (UC-PT2-001)

MAST Domain	Topic	Outcome	Baseline (mean/SD)	End of pilot (mean/SD)	Change in mean (SD)
Clinical Effectiveness	Physical health	Heart rate, steps, sleep and wellbeing assessment	These data were continuously collected during the pilot to answer the research objectives and will thus be further presented with respect to the secondary outcomes.		
	Mental health	OSSS-3 (social support) and life events	Mean = 9.3 SD = 1.6 Med = 10 Min = 6 Max = 11 “Moderate Social Support”	Mean = 9.8 SD = 2.1 Med = 9.5 Min = 8 Max = 13 “Moderate Social Support” (1 missing value)	0.5 (0.5)
	Effects on health-related quality of life	EQ-5D-5L VAS score	Health Status: Mean = 68 SD = 26.5 Med = 70 Min = 30 Max = 100	Health Status: Mean = 61 SD = 23 Med = 60 Min = 40 Max = 95 (2 missing values)	-7 (-3.5)
		WHOQOL-BREF scores	Domain 1: Mean = 46.4 SD = 19.9 Med = 44 Min = 25 Max = 81 (1 missing value for all participants)	Domain 1: Mean = 59.5 SD = 28.6 Med = 56.5 Min = 25 Max = 100 (1 missing value for all participants)	13.1 (8.7)
			Domain 2: Mean = 64.4 SD = 22.5 Med = 69 Min = 19 Max = 88	Domain 2: Mean = 54.3 SD = 28.68 Med = 56.5 Min = 25 Max = 100 (1 missing values)	-10.1 (6.18)
			Domain 3: Mean = 72.3 SD = 25.5 Med = 81 Min = 25 Max = 100	Domain 3: Mean = 45.8 SD = 21.4 Med = 44 Min = 19 Max = 81 (1 missing values)	-26.5 (-4.1)
			Domain 4:	Domain 4:	-12.3 (12.6)

			Mean = 77 SD = 10.7 Med = 69 Min = 69 Max = 94	Mean = 64.7 SD = 23.3 Med = 69 Min = 25 Max = 94 (1 missing values)	
	Behavioural outcomes	Steps, fluid and nutrition intake, sleep duration, wellbeing status	These data were continuously collected during the pilot to answer the research objectives and will thus be further presented with respect to the secondary outcomes.		
Patient perspectives	Satisfaction and acceptance	User Experience (UEQ-S scores)	Not assessed	Not assessed	
		User acceptance (TAM score)	/	Usefulness: Mean = 2.7 SD=0.6 Med=3 Min=2 Max=3 (4 missing values)	
				Future use: Mean = 3 SD=0 Med=3 Min=3 Max=3 (5 missing values)	
	Understanding of information Confidence (in the treatment) Ability to use the application Access & Accessibility	Usability of application (SUS Scores)	/	Mean = 65.8 SD= 29.6 Med=50 Min= 47.5 Max= 100	
		Usability of application (1-item health literacy)	Mean = 4 SD= 1.4 Med= 4 Min= 1 Max= 5	Mean = 4 SD=1.4 Med=4 Min=3 Max=5 (5 missing values)	0 (0)
	Empowerment Self-efficacy	User engagement	These data were continuously collected during the pilot to answer the research objectives and will thus be further presented with respect to the secondary outcomes.		

		(Number of logins)			
		Self-efficacy (SHAPES Participation questionnaire)	/	Participation in activities: M = 3.7 SD = 1 Med = 4 Min = 2 Max = 5 (1 missing value)	
			/	Effect of using DS on participation in activities: M = 2.6 SD = 0.9 Med = 3 Min = 1 Max = 3 (1 missing value)	
		Self-efficacy (GSES)	Mean = 32.6 SD= 5.2 Med=32 Min=27 Max=39	Mean = 29.5 SD= 12.8 Med=33.5 Min=11 Max=40 (3 Missing values)	
Economic aspects	Amount of resources used when delivering the application and comparators	Cost of devices	<ul style="list-style-type: none"> • Tablet: 289,00 € (Mean) • Protective cover tablet: 20,99€ (Mean) • Activity wristband: 28,89 € (Mean) 		
		Cost of using digital solutions and SHAPES Platforms	See Table 18		
		Cost of staffing	See Table 18		

In the following the results of the baseline data is summarised. Any analysis and discussion of outcomes with respect to the impact will be part of the deliverables D6.9 and D6.10.

Considering the application of the WHOQOL-Bref questionnaire, the participants mostly perceived that their physical health (Domain 1; m = 46,4) and their psychological wellbeing (Domain 2; m = 64,4) below the norm of 73,5 and 70,6 (13).

It has to be noted that for Domain 1, there is one missing value for all participants, which might explain the lower mean value. According to the (EQ-5D-5L VAS score), they indicated their health status at 68 out of 100. In contrast, the participants rated their social relationships (Domain 3; $m = 72,3$) and their living environment (Domain 4; $m = 77$) slightly above the norm of 71,5 and 75,1 (13). This is further underpinned by the results from the OSSS-3, where the participants pinpointed that they had moderate social support ($m = 10,25$). In the GSES, the participants rated their perceived self-efficacy with 32,6 out of 40 points. The average of 4 out of 5 (HLM) indicate that the participants had a higher level of health literacy.

The results from the questionnaires reflect the general understanding of the participants, that they were rather healthy and fit for their age, even though their evaluation showed slightly lower values.

Secondary outcomes

Table 31: Objectives AIAS (UC-PT2-001)

PO1
To investigate user engagement with the novel system (PO1).
During the initial training, participants were instructed to use the App as much as possible, hopefully on a daily basis. According to the registrations, more than 70% of participants regularly logged almost every day. Other participants logged once a week on average.
The users were very motivated to use the system proposed. However, they were a bit disappointed after realising that the solutions were not completely intuitive and some functionalities they would like to have were not functioning properly.
PO2
To investigate the user-perceived usefulness of the novel system (PO2).
The users recognized the usefulness of the DS proposed but they found them not really easy to use. They found some of the functionalities not completely reliable, especially the food monitoring App. At the end, they did not use the system in its entirety but only some of the functionalities: this is reflected in the TAM and SUS score.
During the interviews, most of the users reported that if the system would have functioned well they probably would have the willingness to continue to use it, otherwise it is merely a source of frustration.
SO1
To investigate the capability of the novel system to improve the supervision of the individual health and wellbeing status (SO1).

Most users were mostly healthy, so the DS was not perceived as improving their supervision, also because they felt that the data collected were not completely reliable (especially data from the food monitoring App).

One of the users reported that he would have need other data to monitor that were not foreseen by the use case (i.e. blood glucose, blood pressure).

SO2

To investigate the association of the first (active / sedentary behaviour) and second level (active in activities of daily living / intermediate activity / exercise) of physical activity classification, sleep quality analysis, liquid intake and nutrition analysis with the individual perceived wellbeing (SO2).

Due to technical challenges, including the transfer of data, neither the physical activity analysis nor the sleep quality analysis were available steadily enough to investigate their association with the individual perceived wellbeing.

SO3

To investigate the capability of the novel system to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects (SO3).

The main results of the harmonisation questionnaires and its change in mean have been presented as part of the MAST evaluation (

Table 30). Due to the limited number of participants (n=7) within this pilot, the comparison of results from baseline to the end of pilot will not be performed per pilot site as drawing any conclusions from this would be misleading. Instead, some overall evaluation will be performed with data from all pilot sites as part of the D6.9 and D6.10.

The users' interviews highlighted a different perception of the usefulness of the DS, according to their health status, conditions and social interaction.

They affirmed that thanks to the involvement on this activity their awareness regarding the monitoring of their health status and wellbeing raised. They understand the importance to track health data, to have somebody that can access to the data collected but they also expressed the need to add more important health data in the system (this was outside of the use case's scope).

Data Collected by the eCare Platform in phase 5 UC-PT2-001 (AIAS)

During the pilot timeframe, eCare collected a total of **53 037 measurements**, including heart rate measurements, step counts, sleep duration measurements and sleep and wellbeing self-assessments distributed as follows:

Table 32: Number of Measurements in eCare of UC-PT2-001 (AIAS)

Participant	# HR Measurements	# Step Counts	# Sleep Duration Measurements	# Sleep Assessments	# Wellbeing Assessments
1SU	11 203	2 080	58	51	33
2SU	7 586	482	54	41	38
3SU	8 290	1 032	78	111	70
4SU	123	8 393	50	70	71
5SU	1 252	3 054	76	67	66
6SU	823	2 480	16	14	12
7SU	4 389	834	29	5	6
Total	33 666	18 355	361	359	296

The table below provides the average value of each of the specific measurements collected per participant for the full duration of the pilot activity, providing a first insight to the participants' general health and wellbeing status.

Table 33: Average Measurements in eCare for the Participants of UC-PT2-001 (AIAS)

Participant	HR Measurements (Avg)	Sleep Hours (Avg)	Light Sleep Hours (Avg)	Deep Sleep Hours (Avg)	Sleep Feedback (Avg)	Wellbeing Feedback (Avg)
1SU	74 bpm	5h54m	4h12m	1h42m	3	3
2SU	69 bpm	4h18m	3h36m	0h42m	4	3
3SU	63 bpm	3h36m	3h24m	0h12m	3	4
4SU	69 bpm	6h54m	4h06m	2h48m	5	5
5SU	70 bpm	6h30m	3h48m	2h42m	4	4
6SU	79 bpm	6h00m	4h36m	1h24m	4	4
7SU	71 bpm	6h30m	3h30h	3h00m	3	3

Not only were these measurements displayed to each one of the pilot participants, but they were visualised also by the AIAS research team in the eCare researcher dashboard as numbers, statistics, graphics and tables, exportable in a .csv file for additional analysis. The following figures illustrate the display in the eCare researcher dashboard of the measurements of heart rate, steps, sleep duration, and sleep and wellbeing self-assessments of each pilot participant for the duration of the pilot.

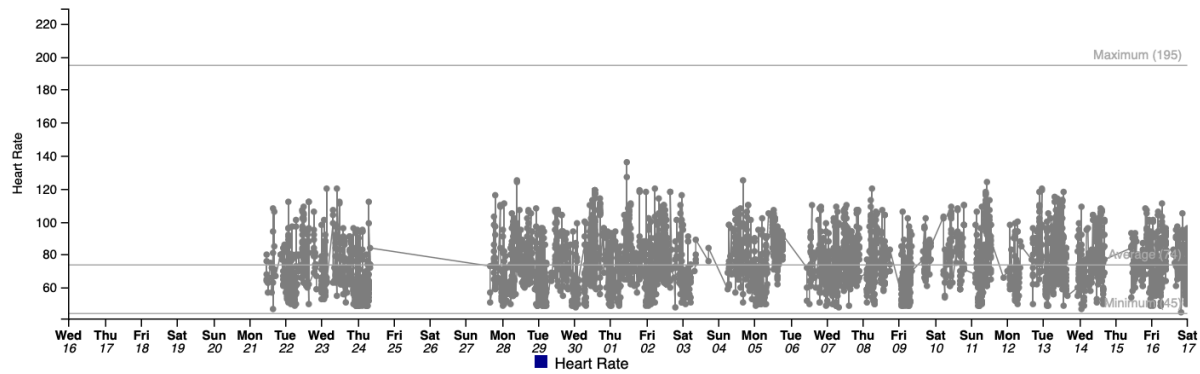


Figure 60: Heart Rate Measurements of Participant 1SU between November 16th and December 17th 2022

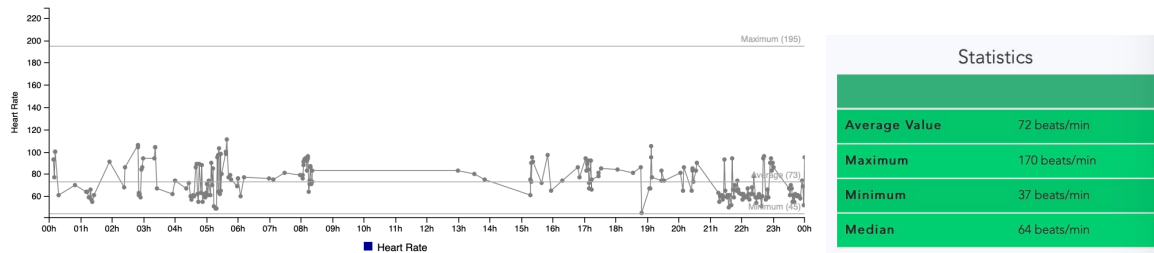


Figure 61: Heart Rate Measurements of Participant 1SU on December 17th 2022 and Heart Rate Statistics of Participant 1SU during the Phase 5 of UC-PT2-001 (AIAS)

Participant 1SU registered a total of 5 368 steps in November 2022, 30 295 steps in December 2022 and 27 669 steps in January 2023, reflecting an average of 21 111 steps for the duration of the pilot.

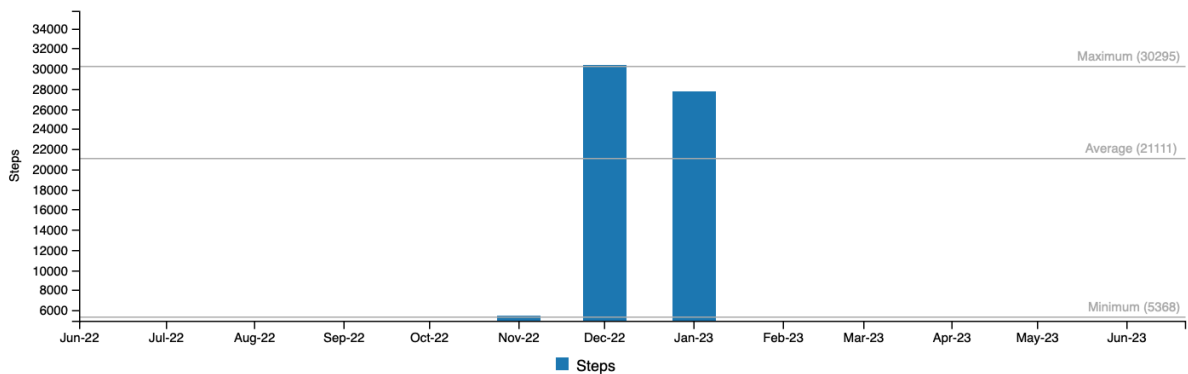


Figure 62: Steps of Participant 1SU during the Phase 5 of UC-PT2-001 (AIAS)

Participant 1SU registered a total of 40h12m of sleep in November 2022, 156h48m of sleep in December 2022 and 143h24m of sleep in January 2023, reflecting an average of 5h54m of sleep for the duration of the pilot.

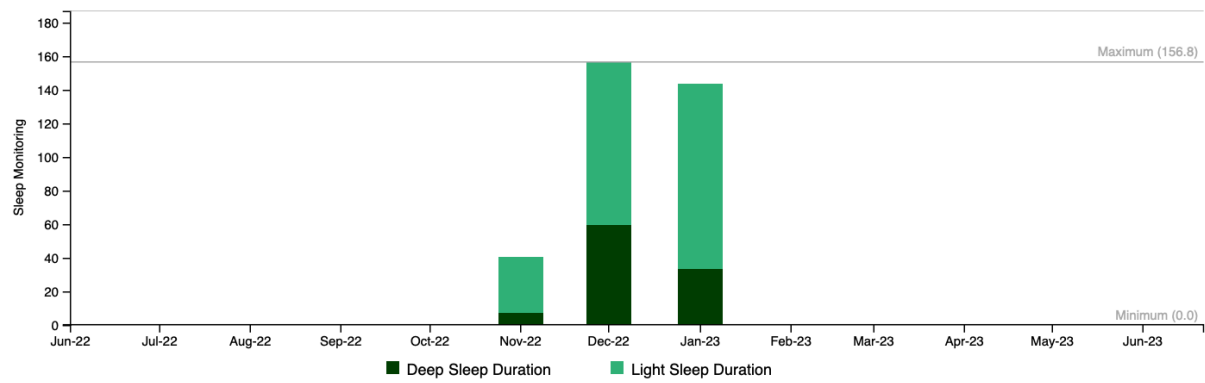


Figure 63: Sleep Hours of Participant 1SU during the Phase 5 of UC-PT2-001 (AIAS)

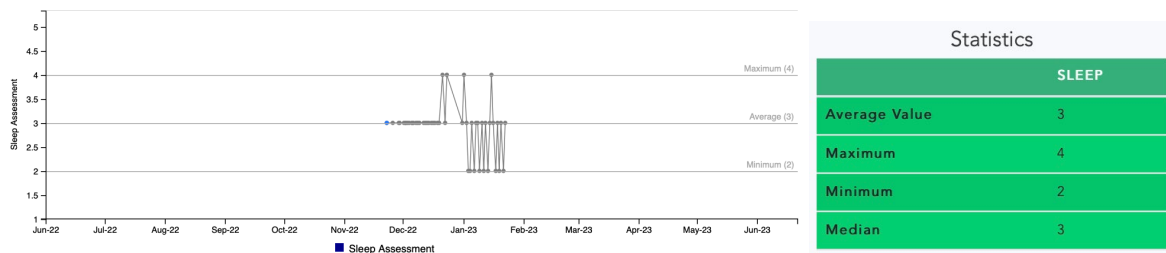


Figure 64: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 1SU during the Phase 5 of UC-PT2-001 (AIAS)

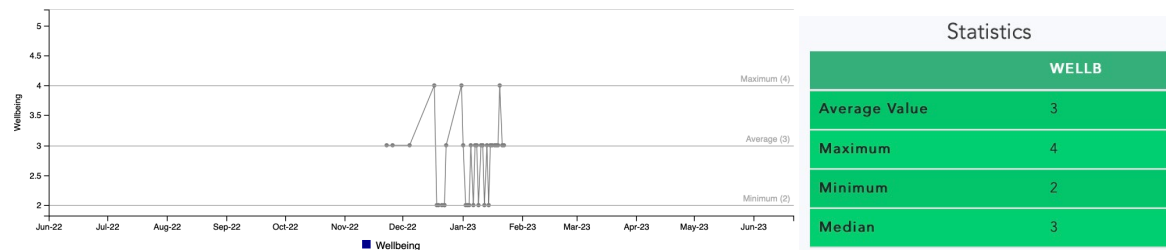


Figure 65: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 1SU during the Phase 5 of UC-PT2-001 (AIAS)

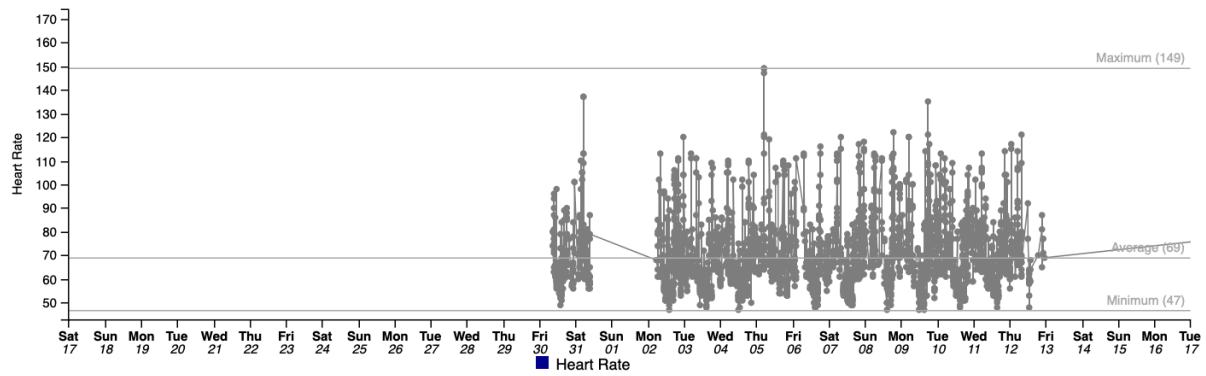


Figure 66: Heart Rate Measurements of Participant 2SU between December 17th 2022 and January 17th 2023

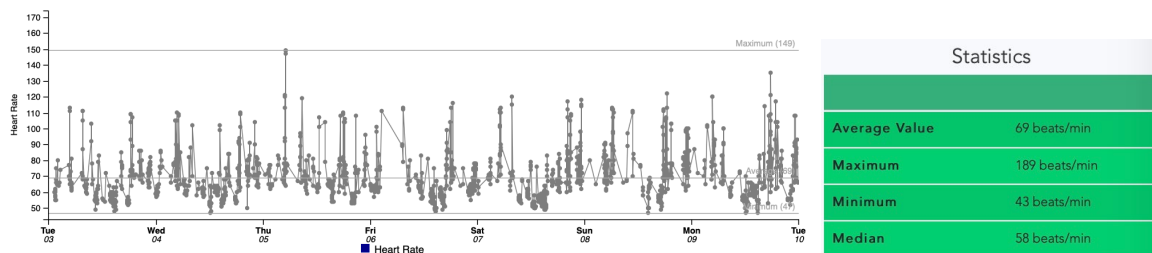


Figure 67: Heart Rate Measurements of Participant 2SU between January 3rd and 10th 2023 and Heart Rate Statistics of Participant 2SU during the Phase 5 of UC-PT2-001 (AIAS)

Participant 2SU registered a total of 2 796 steps in November 2022, 3 269 steps in December 2022 and 1 899 steps in January 2023, reflecting an average of 2 655 steps for the duration of the pilot.

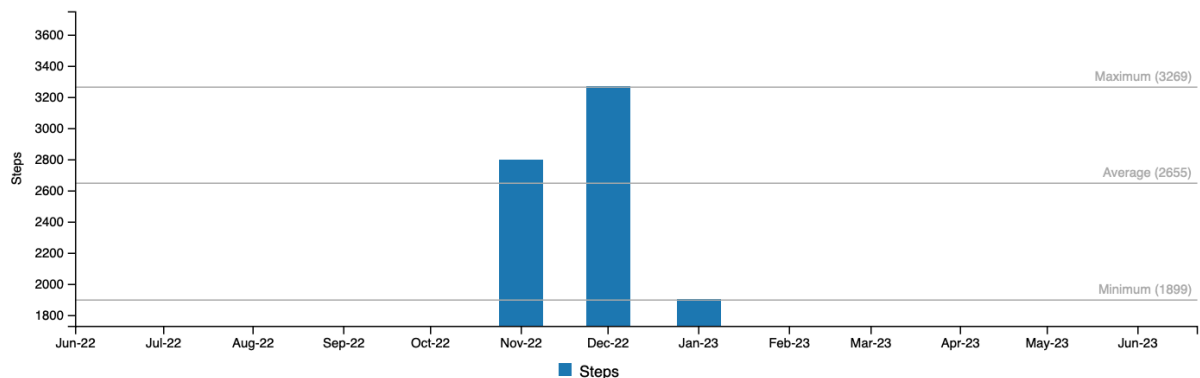


Figure 68: Steps of Participant 2SU during the Phase 5 of UC-PT2-001 (AIAS)

Participant 2SU registered a total of 35h36m of sleep in November 2022, 132h06m of sleep in December 2022 and 64h00m of sleep in January 2023, reflecting an average of 4h18m of sleep for the duration of the pilot.

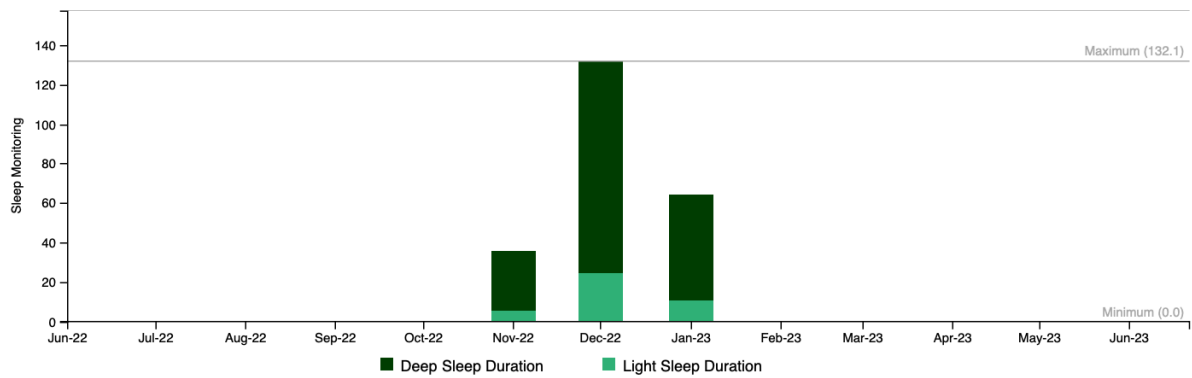


Figure 69: Sleep Hours of Participant 2SU during the Phase 5 of UC-PT2-001 (AIAS)

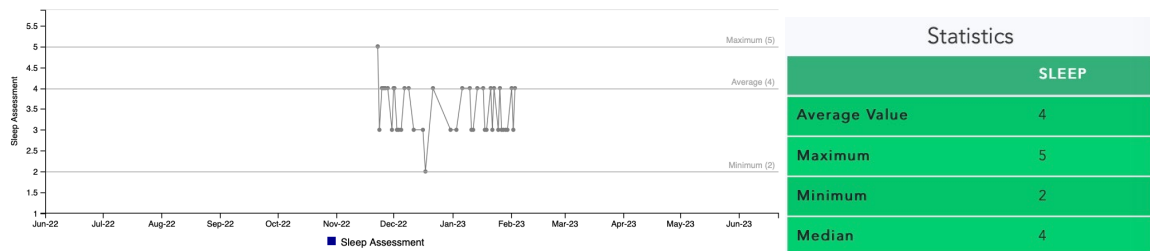


Figure 70: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 2SU during the Phase 5 of UC-PT2-001 (AIAS)

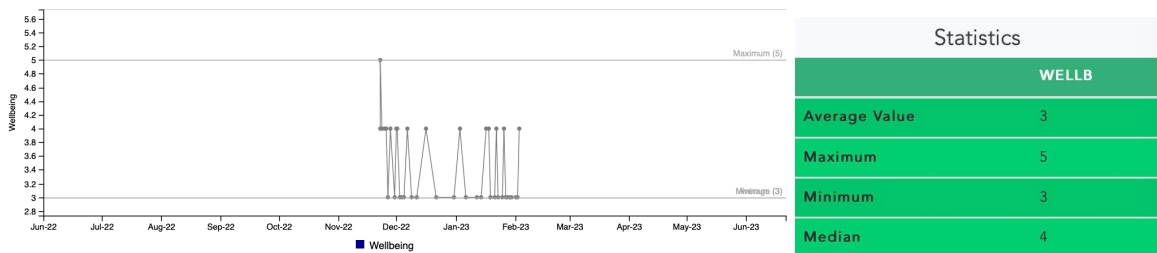


Figure 71: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 2SU during the Phase 5 of UC-PT2-001 (AIAS)

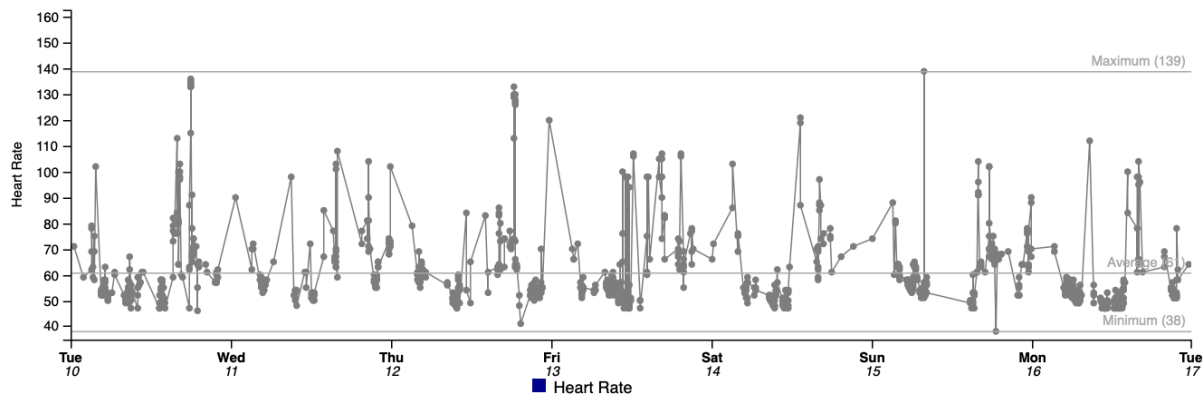


Figure 72: Heart Rate Measurements of Participant 3SU between January 10th and 17th 2023

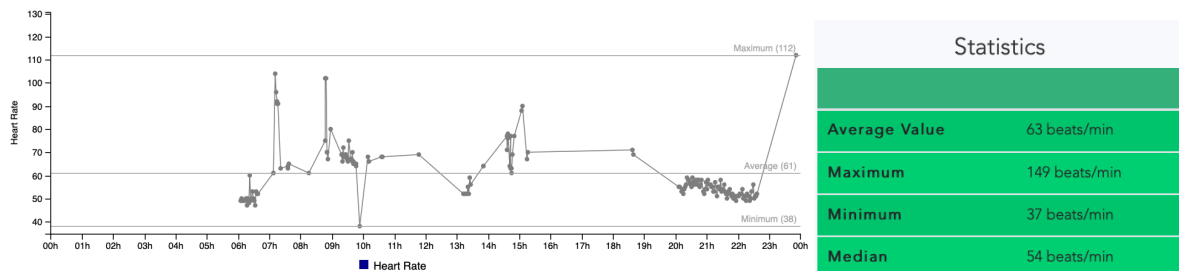


Figure 73: Heart Rate Measurements of Participant 3SU on January 16th 2023 and Heart Rate Statistics of Participant 3SU during the Phase 5 of UC-PT2-001 (AIAS)

Participant 3SU registered a total of 10 167 steps in November 2022, 12 452 steps in December 2022 and 20 446 steps in January 2023, reflecting an average of 11 908 steps for the duration of the pilot.

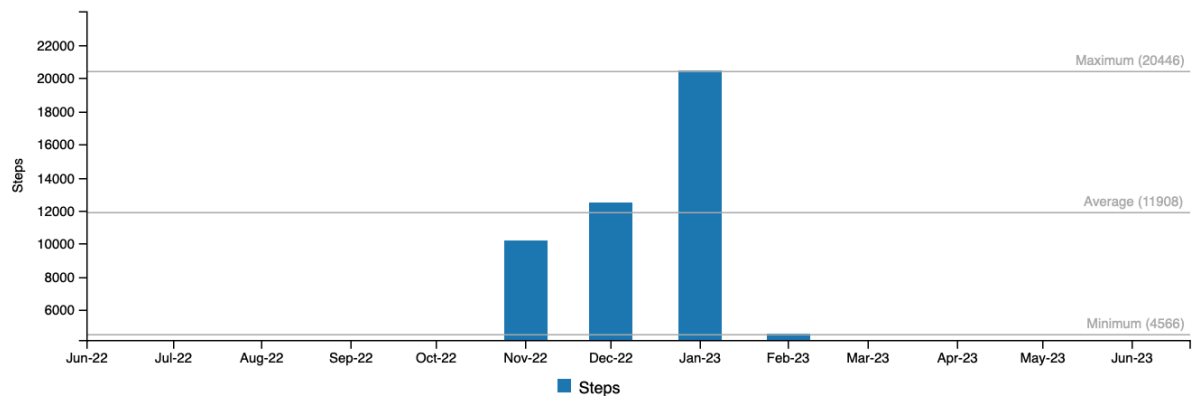


Figure 74: Steps of Participant 3SU during the Phase 5 of UC-PT2-001 (AIAS)

Participant 3SU registered a total of 35h48m of sleep in November 2022, 103h24m of sleep in December 2022, 112h54m in January 2023 and 31h30m of sleep in February 2023, reflecting an average of 3h36m of sleep for the duration of the pilot.

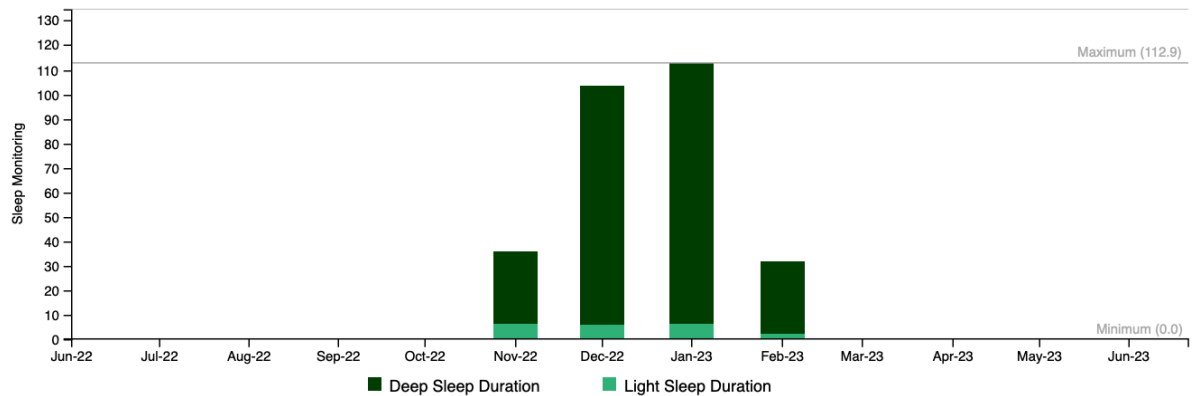


Figure 75: Sleep Hours of Participant 3SU during the Phase 5 of UC-PT2-001 (AIAS)

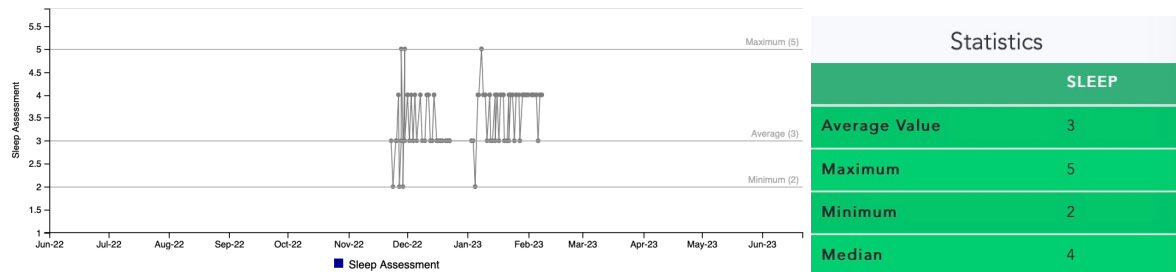


Figure 76: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 3SU during the Phase 5 of UC-PT2-001 (AIAS)

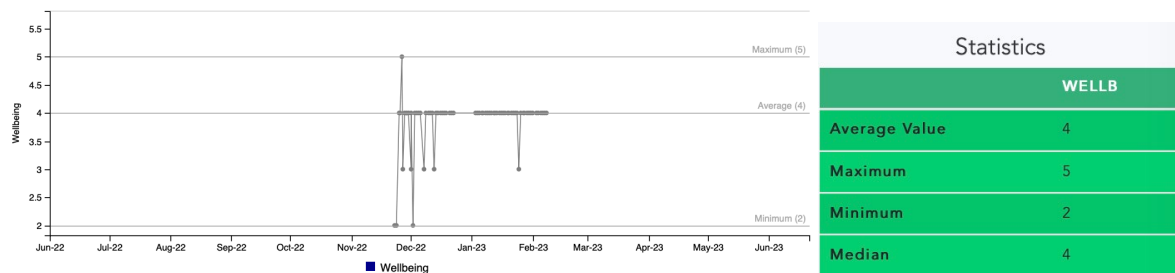


Figure 77: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 3SU during the Phase 5 of UC-PT2-001 (AIAS)

Participant 4SU did not activate the automatic capture of the heart rate in the activity wristband. As a result, it was only possible to register the heart rate measurements that participant 4SU performed manually in the activity wristband.

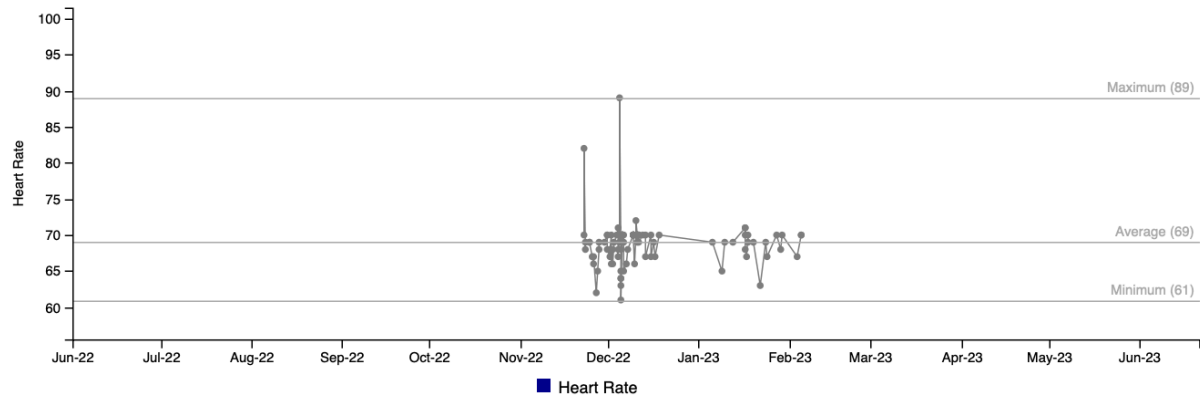


Figure 78: Heart Rate Measurements of Participant 4SU during the Phase 5 of UC-PT2-001 (AIAS)

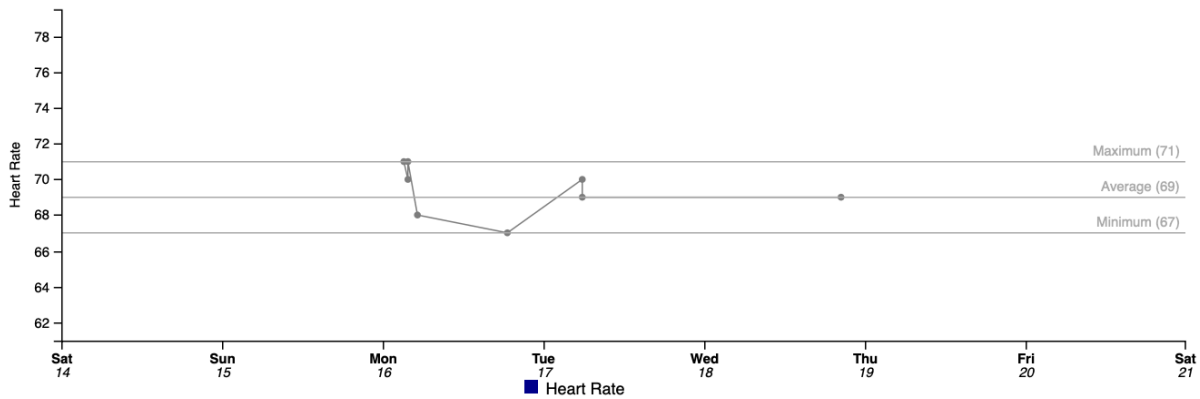


Figure 79: Heart Rate Measurements of Participant 4SU between January 14th and 21st 2023

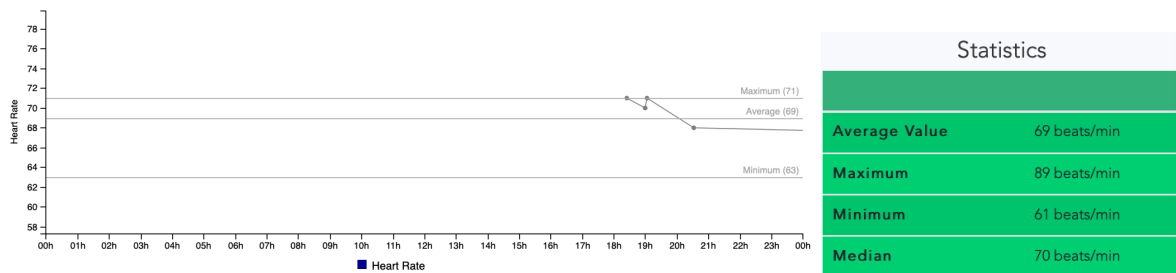


Figure 80: Heart Rate Measurements of Participant 4SU on January 16th 2023 and Heart Rate Statistics of Participant 4SU during the Phase 5 of UC-PT2-001 (AIAS)

Participant 4SU registered a total of 42 326 steps in November 2022, 83 378 steps in December 2022, 105 612 steps in January 2023 and 30 951 steps in February 2023, reflecting an average of 65 567 steps for the duration of the pilot.

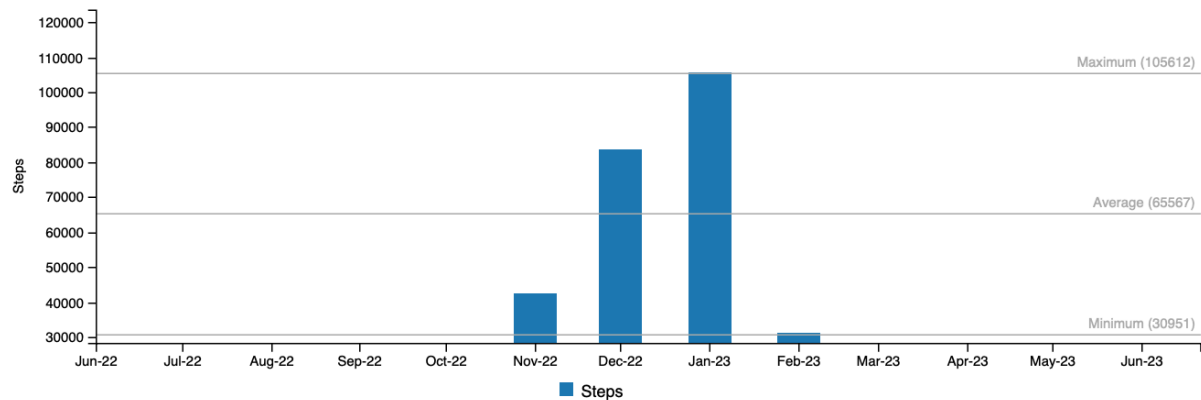


Figure 81: Steps of Participant 4SU during the Phase 5 of UC-PT2-001 (AIAS)

Participant 4SU registered a total of 51h18m of sleep in November 2022, 208h18m of sleep in December 2022, 59h06m of sleep in January 2023 and 27h12m of sleep in February 2023, reflecting an average of 6h54m of sleep for the duration of the pilot.

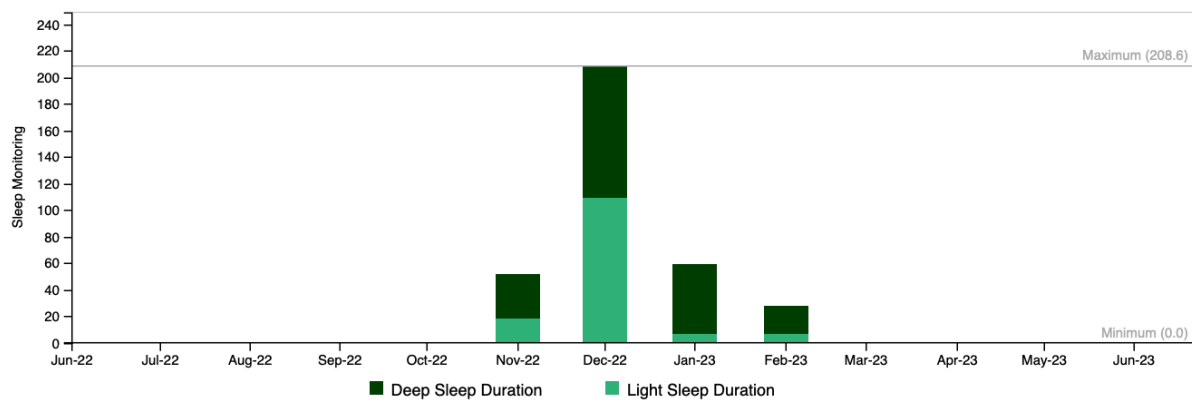


Figure 82: Sleep Hours of Participant 4SU during the Phase 5 of UC-PT2-001 (AIAS)

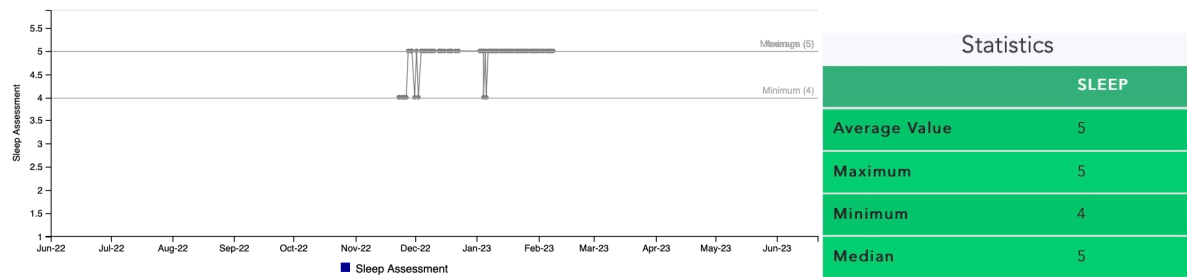


Figure 83: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 4SU during the Phase 5 of UC-PT2-001 (AIAS)

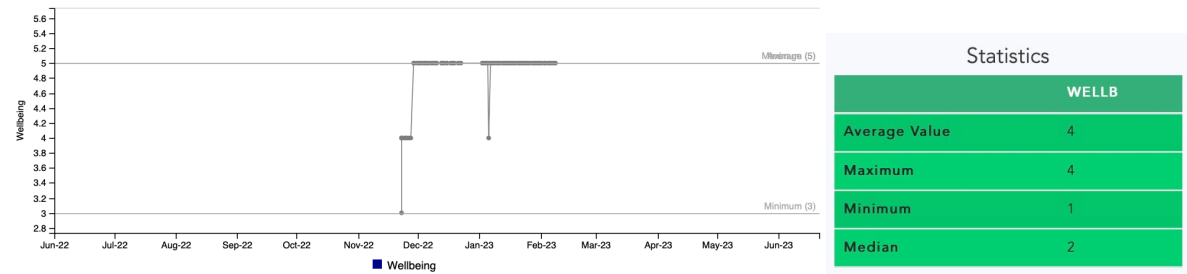


Figure 84: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 4SU during the Phase 5 of UC-PT2-001 (AIAS)

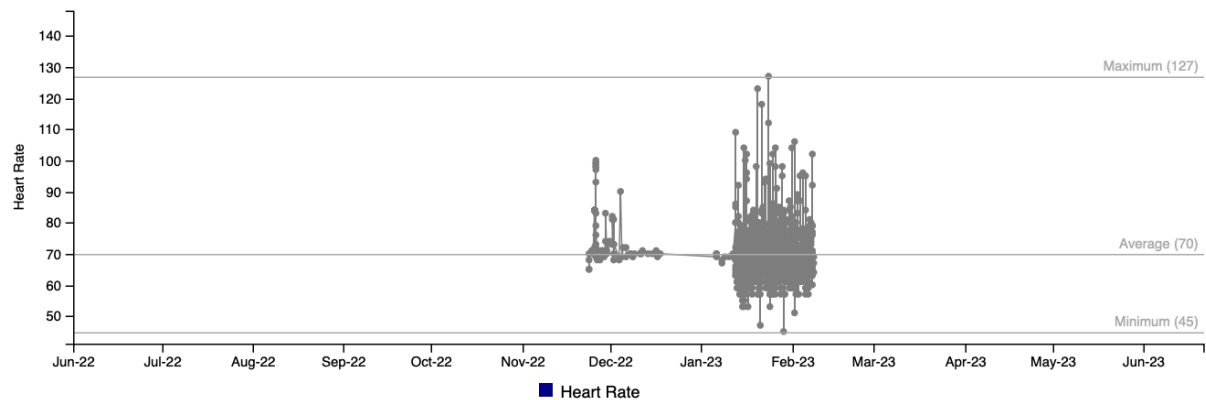


Figure 85: Heart Rate Measurements of Participant 5SU during the Phase 5 of UC-PT2-001 (AIAS)

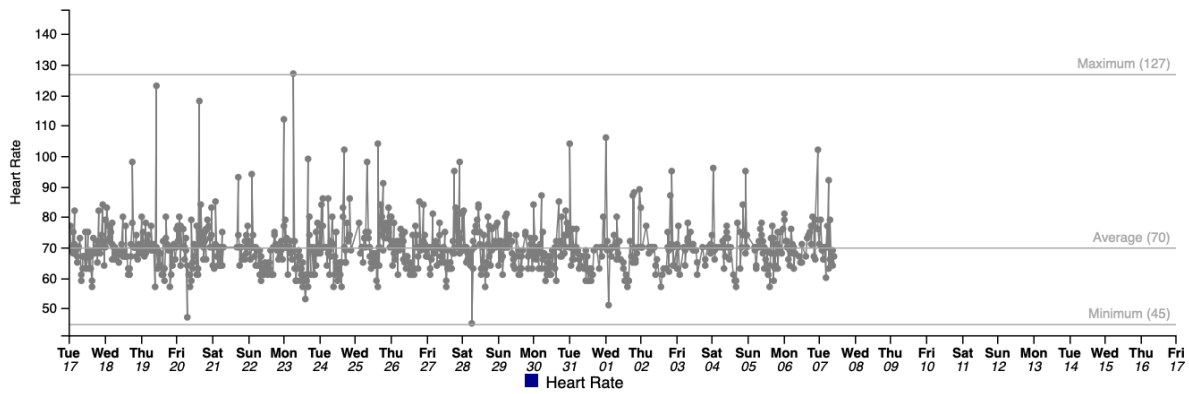


Figure 86: Heart Rate Measurements of Participant 5SU between January 17th and February 17th 2023

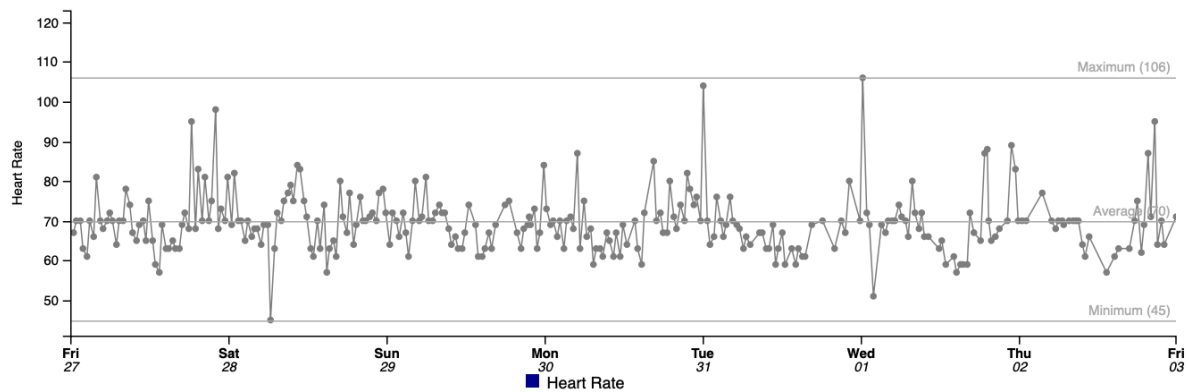


Figure 87: Heart Rate Measurements of Participant 5SU between January 27th and February 3rd 2023

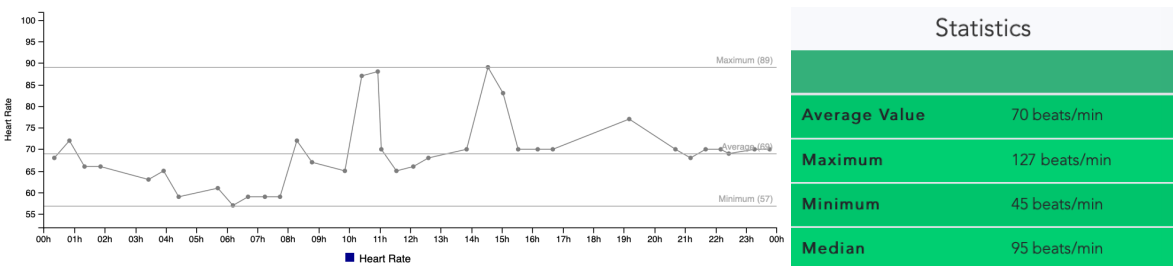


Figure 88: Heart Rate Measurements of Participant 5SU on February 2nd 2023 and Heart Rate Statistics of Participant 5SU during the Phase 5 of UC-PT2-001 (AIAS)

Participant 5SU registered a total of 4736 steps in November 2022, 21 856 steps in December 2022, 19 731 steps in January 2023 and 4 292 steps in February 2023, reflecting an average of 12 654 steps for the duration of the pilot.

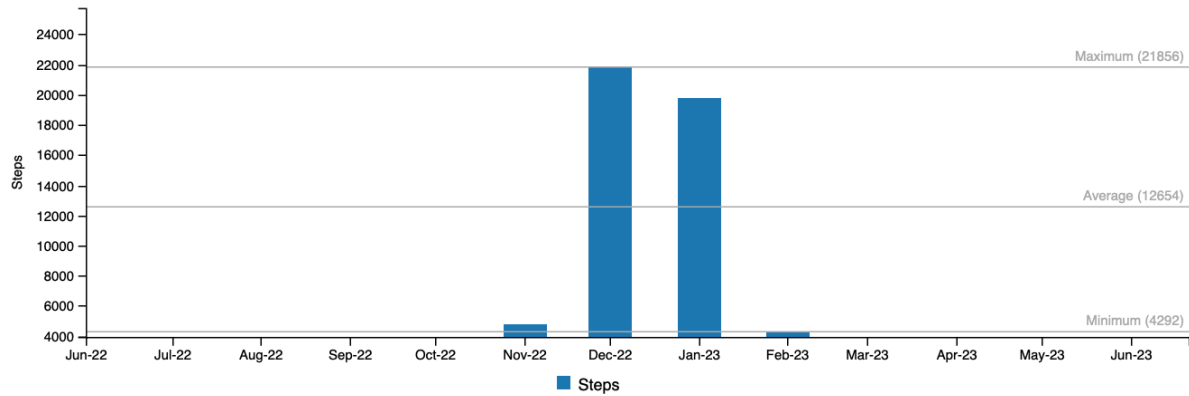


Figure 89: Steps of Participant 5SU during the Phase 5 of UC-PT2-001 (AIAS)

Participant 5SU registered a total of 49h12m of sleep in November 2022, 199h42m of sleep in December 2022, 193h12m of sleep in January 2023 and 53h48m of sleep in February 2023, reflecting an average of 6h30m of sleep for the duration of the pilot.

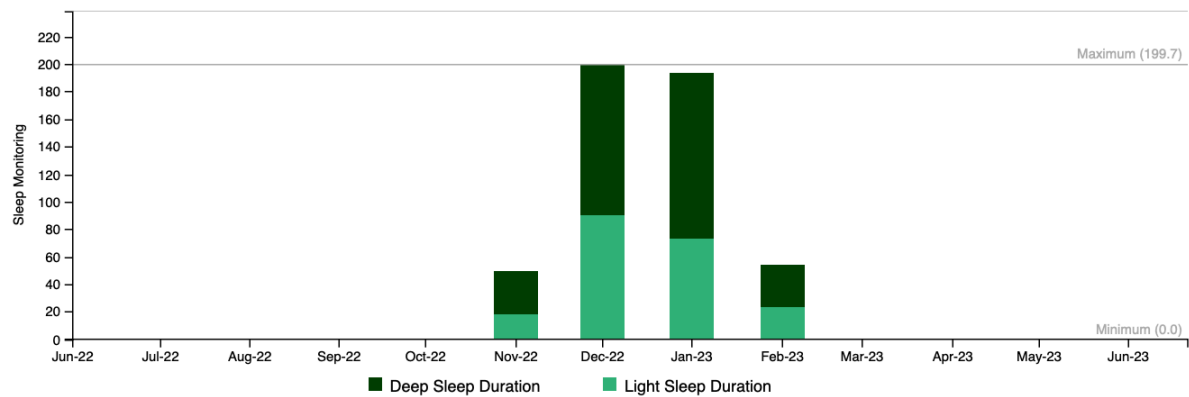


Figure 90: Sleep Hours of Participant 5SU during the Phase 5 of UC-PT2-001 (AIAS)

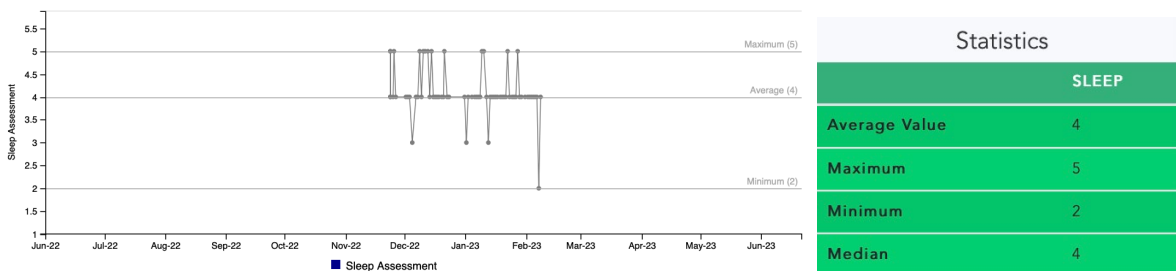


Figure 91: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 5SU during the Phase 5 of UC-PT2-001 (AIAS)

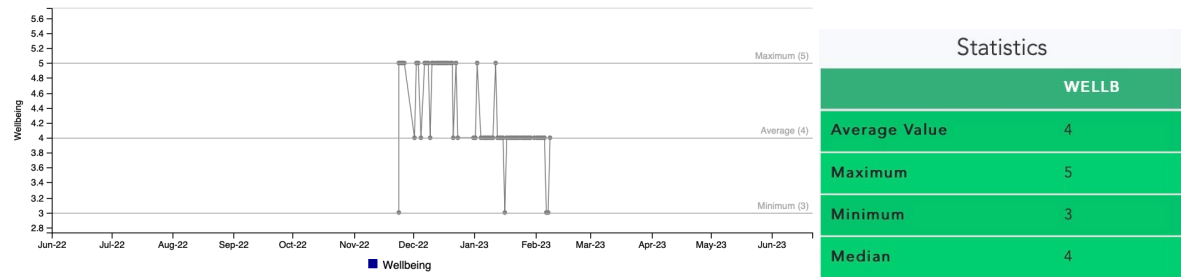


Figure 92: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 5SU during the Phase 5 of UC-PT2-001 (AIAS)

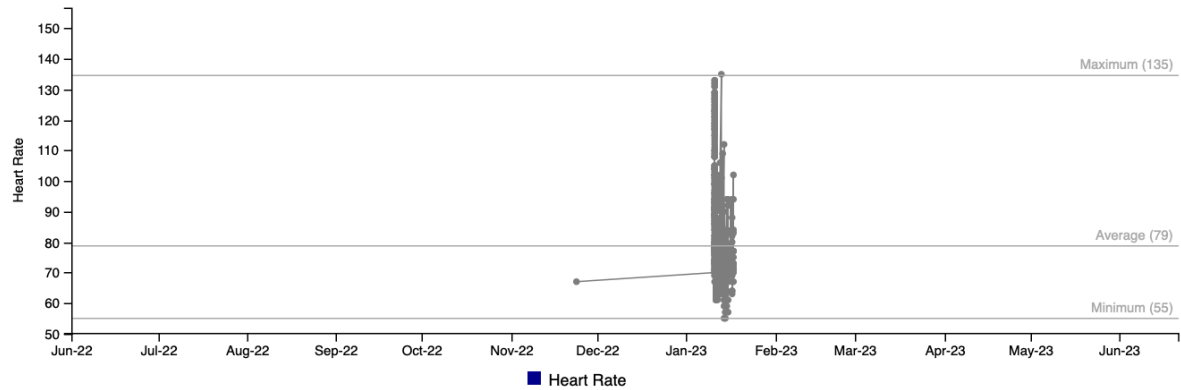


Figure 93: Heart Rate Measurements of Participant 6SU during the Phase 5 of UC-PT2-001 (AIAS)

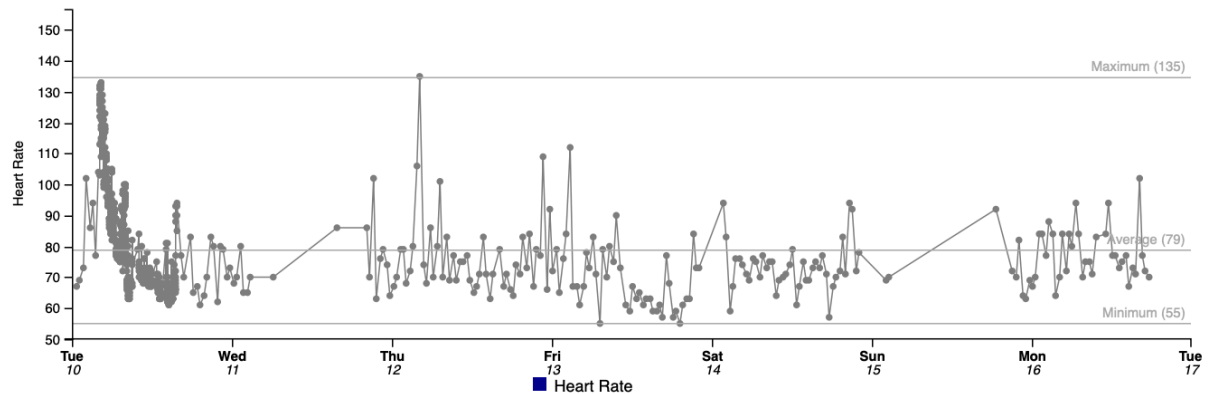


Figure 94: Heart Rate Measurements of Participant 6SU between January 10th and 17th 2023

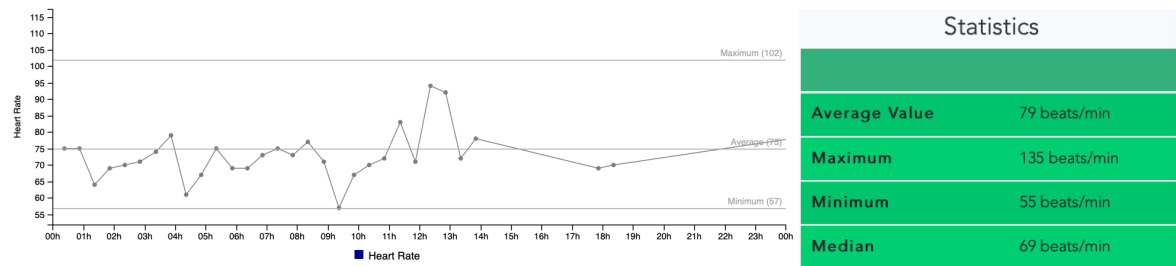


Figure 95: Heart Rate Measurements of Participant 6SU on January 15th 2023 and Heart Rate Statistics of Participant 6SU during the Phase 5 of UC-PT2-001 (AIAS)

Participant 6SU registered a total of 7 435 steps in November 2022, 65 371 steps in December 2022 and 31 058 steps in January 2023, reflecting an average of 34 621 steps for the duration of the pilot.

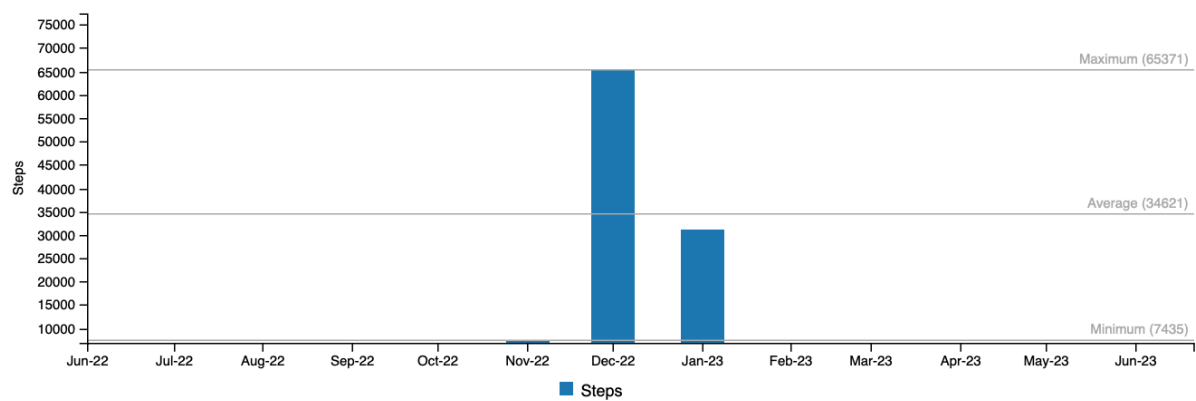


Figure 96: Steps of Participant 6SU during the Phase 5 of UC-PT2-001 (AIAS)

Participant 6SU registered a total of 7h30m of sleep in November 2022, 53h24m of sleep in December 2022 and 35h30m of sleep in January 2023, reflecting an average of 6h00m of sleep for the duration of the pilot.

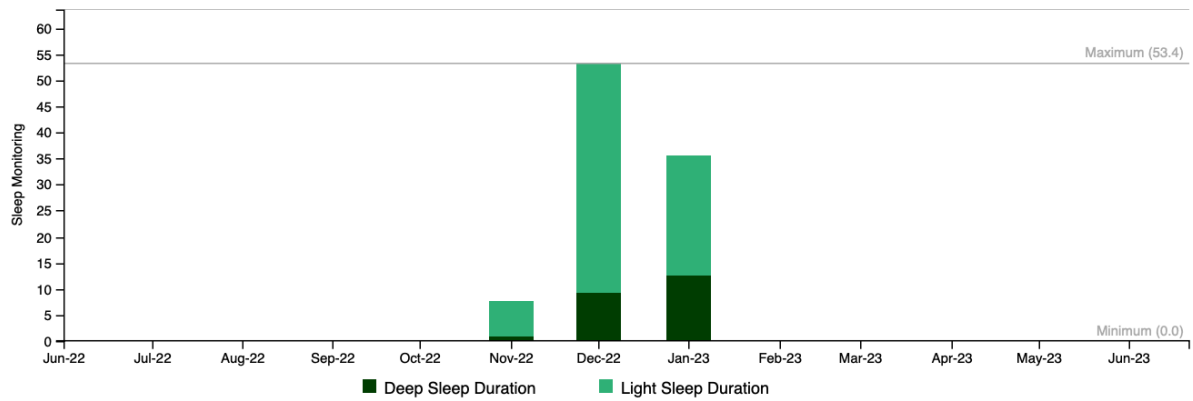


Figure 97: Sleep Hours of Participant 6SU during the Phase 5 of UC-PT2-001 (AIAS)

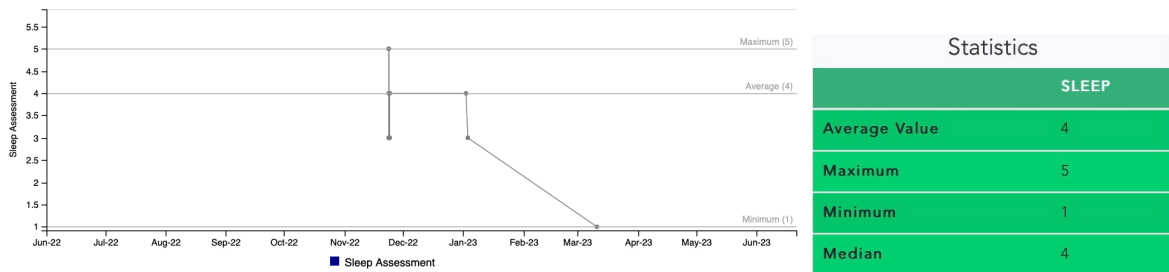


Figure 98: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 6SU during the Phase 5 of UC-PT2-001 (AIAS)

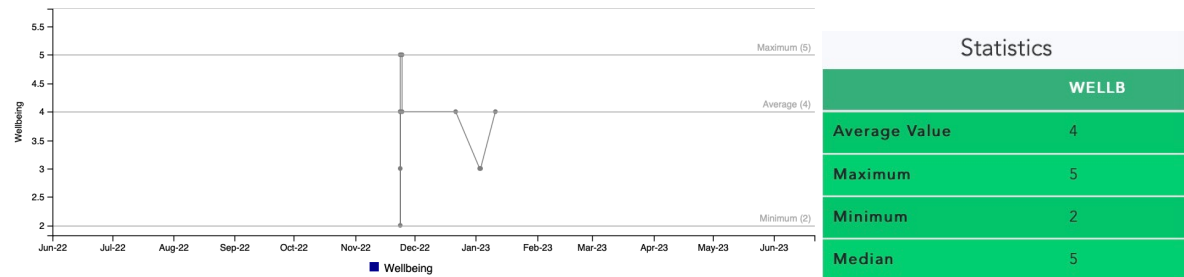


Figure 99: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 6SU during the Phase 5 of UC-PT2-001 (AIAS)

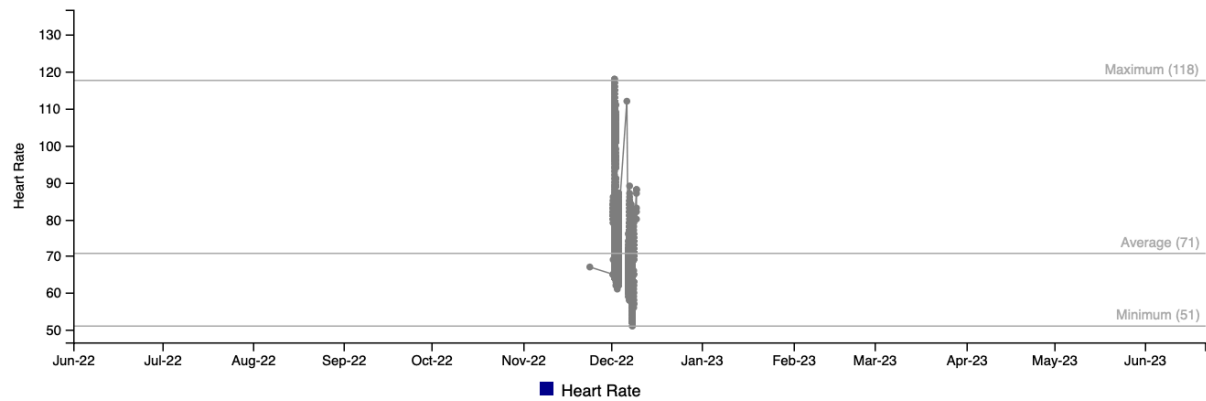


Figure 100: Heart Rate Measurements of Participant 7SU during the Phase 5 of UC-PT2-001 (AIAS)

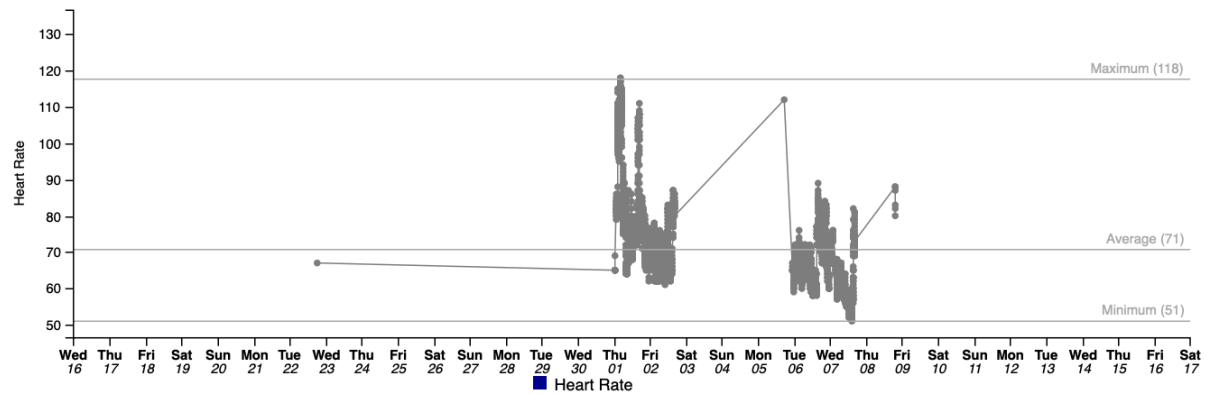


Figure 101: Heart Rate Measurements of Participant 7SU between November 16th and December 17th 2022

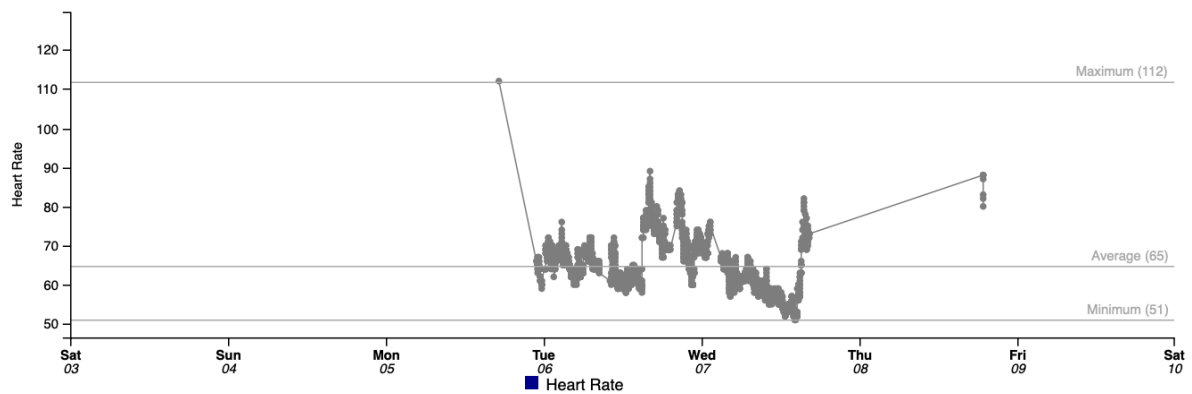


Figure 102: Heart Rate Measurements of Participant 7SU between December 3rd and 10th 2022

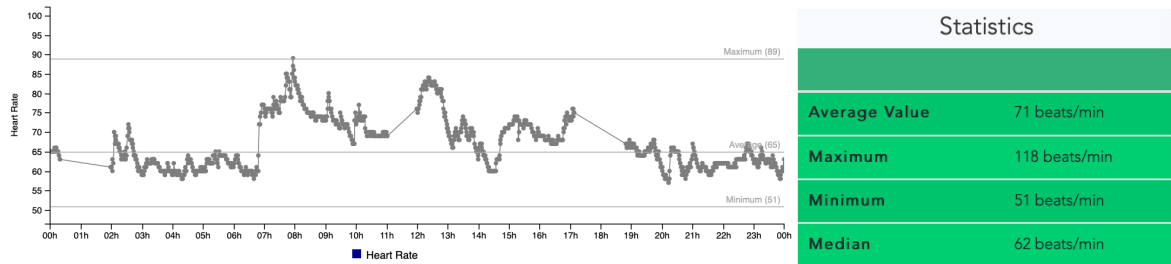


Figure 103: Heart Rate Measurements of Participant 7SU on December 7th 2022 and Heart Rate Statistics of Participant 7SU during the Phase 5 of UC-PT2-001 (AIAS)

Participant 7SU registered a total of 20 289 steps in November 2022 and 6481 steps in December 2022, reflecting an average of 13 385 steps for the duration of the pilot.

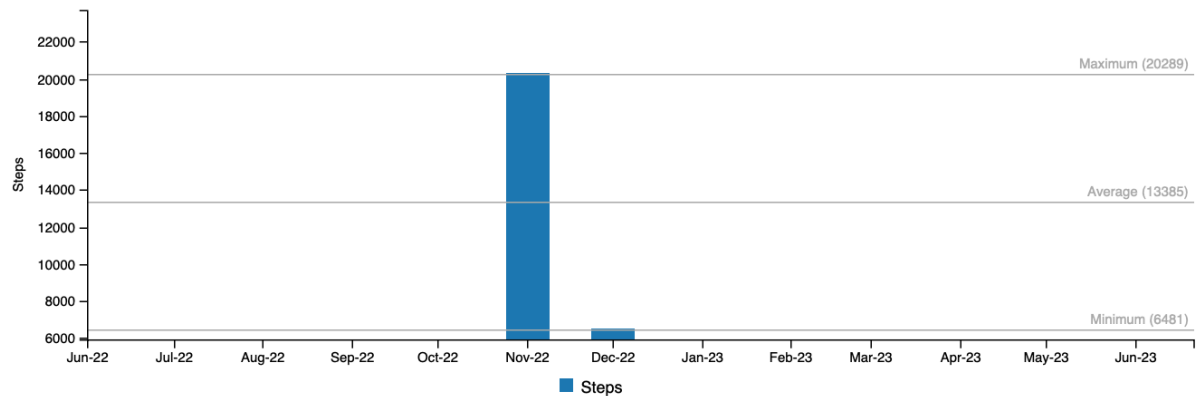


Figure 104: Steps of Participant 7SU during the Phase 5 of UC-PT2-001 (AIAS)

Participant 7SU registered a total of 55h30m of sleep in November 2022, 102h36m of sleep in December 2022 and 28h42m of sleep in January 2023, reflecting an average of 6h30m of sleep for the duration of the pilot.

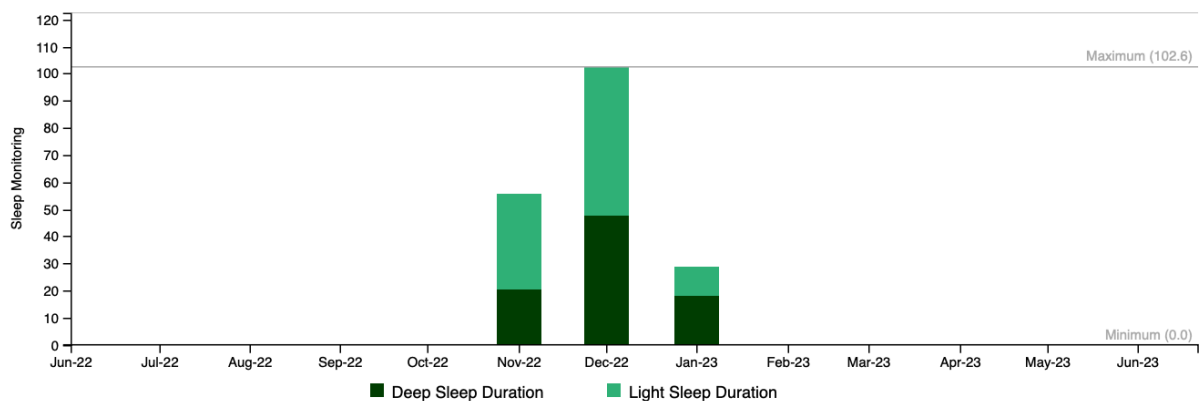


Figure 105: Sleep Hours of Participant 7SU during the Phase 5 of UC-PT2-001 (AIAS)

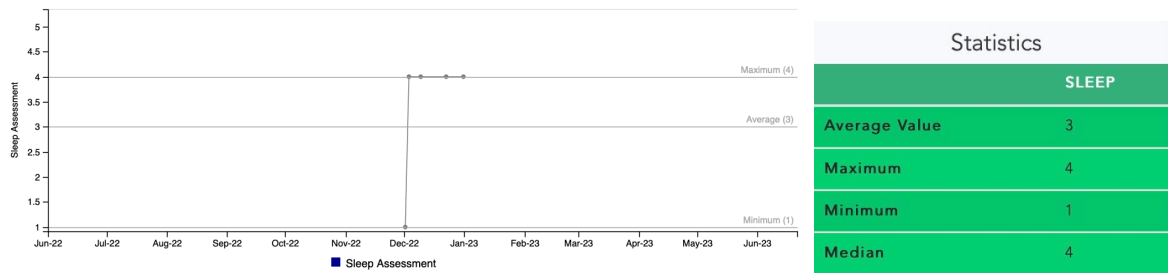


Figure 106: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 7SU during the Phase 5 of UC-PT2-001 (AIAS)

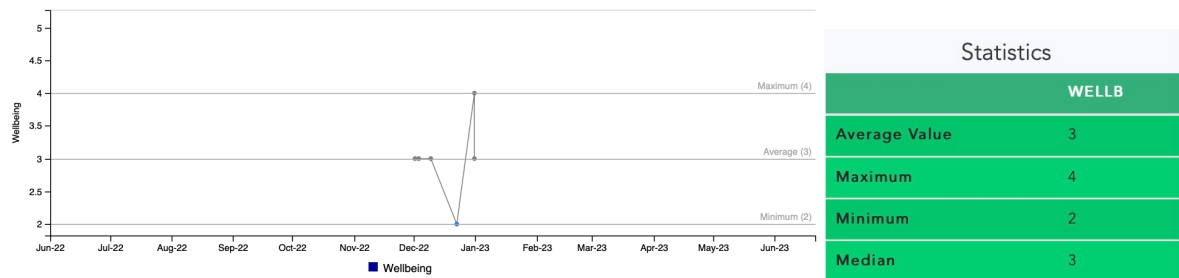


Figure 107: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 7SU during the Phase 5 of UC-PT2-001 (AIAS)

Recommendations for partners (from interviews)

AIAS researchers were constantly in contact with the technical partners, and we reported bugs and feedback continuously during the pilot period.

Main problem reported:

- Log-in system should be improved in order not to insert username and password many times in the same access.
- Reliability of data (sleep and steps, in particular)
- Food recognition App not functioning.
- Liquid intake App not very intuitive

5thYPE

Overview

The replicated pilot of the SHAPES UC-PT2-001 was conducted between start date 17th April 2023 and end date of 17th May 2023 with 4 participants and 1 Cardiologist.

Socio-demographics of the participants:

Table 34: Baseline characteristics 5thYPE (UC-PT2-001)

Variables	Number of participants	Value
Age (years)	4	M = 75,25 SD = 6,90
Male	4	number = 1 (25%)
Country: Greece	4	100%
Marital status	4	Married: 2 Widowed: 2
Occupational status: retired	4	Number = 3 (75%)
Occupational status: not employed	4	Number = 1 (25%)
Residence: own home	4	100%

Primary and secondary outcome

The primary outcomes were to measure a predefined set of KPIs which have already been presented in chapter 0 as well as to evaluate the UC-PT2-001 use case using the MAST evaluation tool.

The following tables present the data used to determine the success of each KPI. Table 41 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 35: KPI 1 5thYPE (UC-PT2-001)

Parameter	5thYPE
Target number of participants	4
Number of participants recruited	4
Percentage recruited	100%

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

Table 36: KPI 2 5thYPE (UC-PT2-001)

Parameter	5thYPE
Number of participants at baseline	4
Number of withdrawals	0

Number of participants at end of study	4
Percentage retained	100%

KPI 1 and KPI 2 were successfully achieved with 100%, meaning that the recruitment and engagement initiatives of 5thYPE were successful, not only in identifying interested and willing participants, fitted to the effort at play, but also that the strategy to maintain contact and provide support did make a positive impact on the absence of withdrawals, despite the length of the pilot.

Technical performance

KPI 3 There is no re-start* of any of the components of the technology, except for the activity wristband, for at least 90% of the days.

Table 37: KPI 3 5thYPE (UC-PT2-001)

Parameter	Value
Number of participants without any re-start of any of the components of the technology	2
Total number of participants	4
Percentage of participants without re-starts	50%

*re-start refers to the deinstallation and re-installation of any of the components due to mal functioning. This does not include any update of an new version of the App.

KPI 3 was not achieved as for 50% of participants, re-starting the DSs was done. For these participants, their data collected from their activity band was captured and visualised in the eCare App, allowing participants to be aware of their health and wellbeing status, but it was not uploaded to the eCare server and could not be displayed in the eCare researcher dashboard. It is noted that two participants in the pilot registered an absence of Internet connectivity in their area of residence. However, to eliminate any other potential reason, a re-start was forced for those participants.

User engagement and acceptance

KPI 4 The overall user experience quality of the App as measured using the short version of the User Experience Questionnaire (UEQ-S) was classified as ‘Excellent’, ‘Good’ or ‘Above average’ based on published benchmark data.

Table 38: KPI 4 5thYPE (UC-PT2-001)

Scale	Mean	Comparison to benchmark
Pragmatic quality	Not assessed	Not assessed
Hedonic quality	Not assessed	Not assessed
Overall	Not assessed	Not assessed

The number of questionnaires to be completed by the participants at the end of the pilot Due to the number of harmonisation questionnaires the exhaustion of the participants clearly exhausted the participants. To avoid frustration and prevent breaking the trust bond between the participants and their GP, the UEQ-S was not assessed in the end evaluation. Conclusions on the user experience were derived from the open interviews which are summarised in Table 43.

KPI 5 At least 60% of participants continued to login to use the App daily after two weeks of the pilot.*

Table 39: KPI 5 5thYPE (UC-PT2-001)

Parameter	Value
Number of participants who logged in daily for at least 2 weeks after baseline	4
Total number of participants	4
Percentage using the App daily for at least two weeks	100%

*Only considered the participants that took daily records for at least 14 days in a row. In order to make any manual entries, registration in the Front-end App must have taken place beforehand. Thereby, the eCare App and the eHealthPass App were not considered separately.

KPI 5 was achieved and 100% of the participants continued using the App after two weeks of the pilot. This indicates that participants were able to handle and use the DSs on their own, and that it was possible for them to integrate it in their everyday life.

KPI 6 At least 60% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Table 40: KPI 6 5thYPE (UC-PT2-001)

Parameter	Value
Number of participants at end of pilot	4
Number of participants scoring >68 in SUS	3
Percentage of participants scoring > 68 in SUS	75%

KPI 6 was achieved as 75% ranked the usability of the DSs >68 (m = 73,75). This reflects the participants' capability of handling and integrating the DSs in their everyday life. Furthermore, it gives an indication of the participants' willingness for future use, implying that the users recognise some positive effect of using the App for their daily living.

Overview of KPI achievement

Table 41: Overview of KPIs achievement 5thYPE (UC-PT2-001)

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	YES	Recruitment initiatives of 5 th YPE were successful, related to the identification of interested and willing participants, who also fitted to the effort at play.
KPI 2	YES	Engagement initiatives of 5 th YPE were successful, related to the strategy to maintain contact and provide support did make a positive impact on the absence of withdrawals, despite the length of the pilot.
KPI 3	NO	For 50% of participants, the DSs were re-started. For these participants, their data collected from their activity band was captured and visualised in the eCare App, allowing participants to be aware of their health and wellbeing status, but it was not uploaded to the eCare server and could not be displayed in the eCare researcher dashboard. It is noted that two participants in the pilot registered an absence of Internet connectivity in their area of residence. However, to eliminate any other potential reason, a re-start was forced for those participants.

KPI 4	Not assessed	UEQ-S was not assessed in paper format to avoid increased exhaustion, frustration and prevent breaking the trust bond between the participants and their GP. Instead, conclusions on the user experience were derived from the open interviews conducted during at the end of the pilot.
KPI 5	YES	Participants were able to handle and use the DSs on their own, and that it was possible for them to integrate it in their everyday life.
KPI 6	YES	75% of the participants ranked the usability of the DSs >68 (m = 73,75). This reflects the participants' capability of handling and integrating the DSs in their everyday life. Furthermore, it gives an indication of the participants' willingness for future use, implying that the users recognise some positive effect of using the App for their daily living.

Evaluation of MAST

The MAST framework as already introduced in chapter 2.4.2 was used to evaluate the effectiveness and contribution of UC-PT2-001 to quality of care. The evaluated data/outcome are presented in the table below:

Table 42: MAST Evaluation 5thYPE UC-PT2-001

MAST Domain	Topic	Outcome	Baseline (mean/SD)	End of pilot (mean/SD)	Change in mean (SD)
Clinical Effectiveness	Physical health	Heart rate, steps, sleep and wellbeing assessment	These data were continuously collected during the pilot to answer the research objectives and will thus be further presented with respect to the secondary outcomes.		
	Mental health	OSSS-3 (social support) and life events	M = 9,5 SD = 1,91 Med = 9 Min = 8 Max = 12 “moderate social support”	M = 9,5 SD = 1,91 Med = 9 Min = 8 Max = 12 “moderate social support”	0 (0)
	Effects on health-	EQ-5D-5L VAS scores	Health Status M = 86,25 SD = 11,09	Health Status M = 90,75 SD = 7,89	4,5 (-3,2)

	related quality of life		Med = 90 Min = 70 Max = 95	Med = 92,5 Min = 80 Max = 98	
		WHOQOL-BREF scores	Domain 1: M = 78,25 SD = 8,14 Med = 78 Min = 69 Max = 88	Domain 1: M = 78,25 SD = 10,69 Med = 81 Min = 63 Max = 88	0 (2,55)
			Domain 2: M = 76,75 SD = 15,13 Med = 81,5 Min = 56 Max = 88	Domain 2: M = 83,25 SD = 13,79 Med = 88 Min = 63 Max = 94	6,5 (-1,34)
			Domain 3: M = 57,75 SD = 19,52 Med = 62,5 Min = 31 Max = 75	Domain 3: M = 54,75 SD = 26,59 Med = 62,5 Min = 19 Max = 75	-3 (7,07)
			Domain 4: M = 70,25 SD = 10,69 Med = 72 Min = 56 Max = 81	Domain 4: M = 62,75 SD = 10,21 Med = 63 Min = 50 Max = 75	-7,5 (-0,48)
	Behavioural outcomes	Steps, fluid and nutrition intake, sleep duration, wellbeing status	These data were continuously collected during the pilot to answer the research objectives and will thus be further presented with respect to the secondary outcomes.		
Patient perspectives	Satisfaction and acceptance	User Experience (UEQ-S scores)	/	Not assessed	
		User acceptance (TAM score)	/	Usefulness: M = 4,25 SD = 0,5 Med = 4 Min = 4 Max = 5	

				Future use: M = 5 SD = 0 Med = 5 Min = 5 Max = 5	
	Understanding of information Confidence (in the treatment)	Usability of application (SUS Scores)	/	M = 73,75 SD = 5,95 Med = 73,75 Min = 67,5 Max = 80 (See KPI 6)	
	Ability to use the application Access & Accessibility	Usability of application (1-item health literacy)	M = 4,5 SD = 1 Med = 5 Min = 3 Max = 5	M = 4,5 SD = 1 Med = 5 Min = 3 Max = 5	0 (0)
	Empowerment Self-efficacy	Self-efficacy (SHAPES Participation questionnaire)	/	Participation in activities: M = 4 SD = 0 Med = 4 Min = 4 Max = 4	
				Effect of using DS on participation in activities: M = 4,25 SD = 0,96 Med = 4,5 Min = 3 Max = 5	
		Self-efficacy (GSES)	M = 29,75 SD = 6,18 Med = 31,5 Min = 21 Max = 35	M = 30,5 SD = 7,68 Med = 33,5 Min = 19 Max = 36	0,75 (1,5)

In the following the results of the baseline data is summarised. Any analysis and discussion of outcomes with respect to the impact will be part of the deliverables D6.9 and D6.10.

Considering the application of the WHOQOL-Bref questionnaire, the participants mostly perceived that their physical health (Domain 1; $m = 78,25$) and their psychological wellbeing (Domain 2; $m = 76,75$) clearly above the norm of 73,5 and 70,6 (13). This was further underpinned by the results from the EQ-5D-5L VAS score. On its scale from 0 to 100 they pinpointed their health status at 86,25 on average. In contrast, the participants rated and their social relationships (Domain 3; $m = 57,75$) and their living environment (Domain 4; $m = 70,25$) below the norm of 71,5 and 75,1 (13). According to the OSSS-3, the participants perceived that they had moderate social support ($m = 9,5$). In the GSES the participants indicated their perceived self-efficacy with 29,75 out of 40 points and the average of 4,5 out of 5 (HLM) showed that the participants had a high level of health literacy.

The results from the questionnaires reflect the general understanding of the participants, that they were healthy and fit for their age.

Secondary outcomes

Table 43: Objectives 5thYPE UC-PT2-001

PO1
To investigate user engagement with the novel system (PO1).
The participants faced in the beginning problems familiarising themselves with the daily usage of the devices (tablet, wristband) and especially with their regular charging. Some participants reported problems with internet and Bluetooth connectivity that forced them to reconnect. Moreover, they reported problem with the correct usage of Greek Characters that they were not shown to them correctly.
The study ended in a regular daily capture of their health data with all the participants using the devices every day apart from some features than needed user interaction.
PO2
To investigate the user-perceived usefulness of the novel system (PO2).
The execution of the study was very well accepted by the participants because it provided to them the sense of reassurance. Since a medical doctor was involved in the recruitment process, she also had access to the dashboard displaying the participants' data and could thus support the monitoring process. This further supported participants' feeling of safety by potentially detecting any changes related to their health parameters at an early stage and the option to receive medical treatment. Their opinions are reflected in their feedback.
SO1
To investigate the capability of the novel system to improve the supervision of the individual health and wellbeing status (SO1).

The ability of daily monitoring their health parameters by themselves (cardiac pulses, daily activities like sleep and steps), led the participants to have a whole view of their daily behaviour.

SO2

To investigate the association of the first (active / sedentary behaviour) and second level (active in activities of daily living / intermediate activity / exercise) of physical activity classification, sleep quality analysis, liquid intake and nutrition analysis with the individual perceived wellbeing (SO2).

There were technical challenges to be addressed first to address the association of the vital signs and the participant's perceived wellbeing. The lack of certain data that needed human interaction and input on a steady daily basis hindered this assessment.

SO3

To investigate the capability of the novel system to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects (SO3).

The participants' feedback along with the doctor's findings showed that the patients could capture and measure how effective or not their sleep quality was, and how they could adapt their physical activity in conformance with the doctor's guidelines. This led the participants to becoming active regulators in their medical treatment procedure.

The Figure below shows the menu of the Cardiologist Dashboard where the vital signals along with evaluations of feeling good and sleep quality of a participant are indicated:

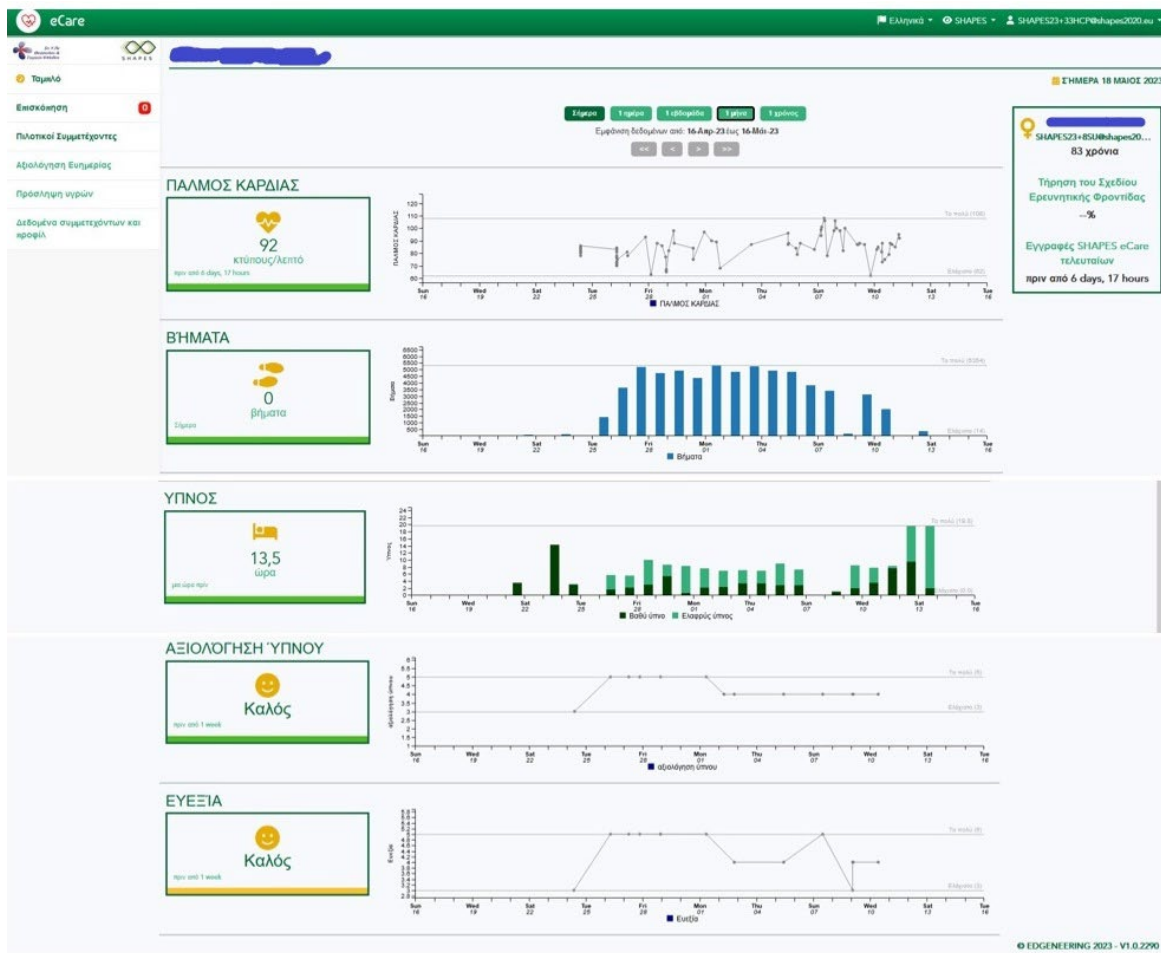


Figure 108: Cardiologist's dashboard as provided by the eCare platform in Greek Language.

Data Collected by the eCare Platform in phase 5 UC-PT2-001 (5th YPE)

During the pilot timeframe, eCare collected a total of **53 037 measurements**, including heart rate measurements, step counts, sleep duration measurements and sleep and wellbeing self-assessments distributed as follows:

Table 44: Number of Measurements in eCare of UC-PT2-001 (5th YPE)

Participant	# HR Measurements	# Step Counts	# Sleep Duration Measurements	# Sleep Assessments	# Wellbeing Assessments
8SU	94	2137	35	13	14
9SU	-	-	-	2	2
10SU	-	-	-	4	4
12SU	64	2176	16	1	4
Total	158	4313	51	20	24

It is noted that two participants in the pilot registered an absence of Internet connectivity in their area of residence. As a result, the data from their activity wristband were captured and visualised in the eCare App, allowing participants to be aware of their health and wellbeing status, but it was not uploaded to the eCare server and could not be displayed in the eCare researcher dashboard. This is the reason why, at the time of the writing of this report, there is no data available for the two participants concerning the measurements provided through the activity wristband.

The table below provides the average value of each of the specific measurements collected per participant for the full duration of the pilot activity, providing a first insight to the participants' general health and wellbeing status.

Table 45: Average Measurements in eCare for the Participants of UC-PT2-001 (5thYPE)

Participant	HR Measurements (Avg)	Sleep Hours (Avg)	Light Sleep Hours (Avg)	Deep Sleep Hours (Avg)	Sleep Feedback (Avg)	Wellbeing Feedback (Avg)
8SU	84 bpm	8h18m	4h30m	3h48m	4	4
9SU	-	-	-	-	4	3
10SU	-	-	-	-	5	3
12SU	74 bpm	7h30m	4h06m	3h24m	5	4

Not only were these measurements displayed to each one of the pilot participants, but they were visualised also by the 5thYPE research team in the eCare researcher dashboard as numbers, statistics, graphics and tables, exportable in a .csv file for additional analysis. The following figures illustrate the display in the eCare researcher dashboard of the measurements of heart rate, steps, sleep duration, and sleep and wellbeing self-assessments of pilot participants for the duration of the pilot.

Participant 8SU deactivated the automatic capture of the heart rate in the activity wristband early in the pilot. As a result, the heart rate measurements registered were performed manually by participant 8SU in the activity wristband.

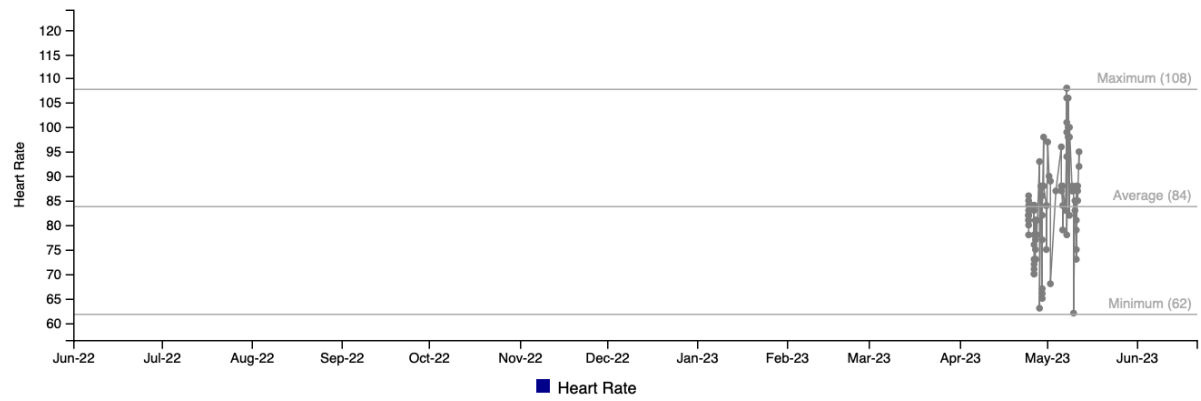


Figure 109: Heart Rate Measurements of Participant 8SU during the Phase 5 of UC-PT2-001 (5th YPE)

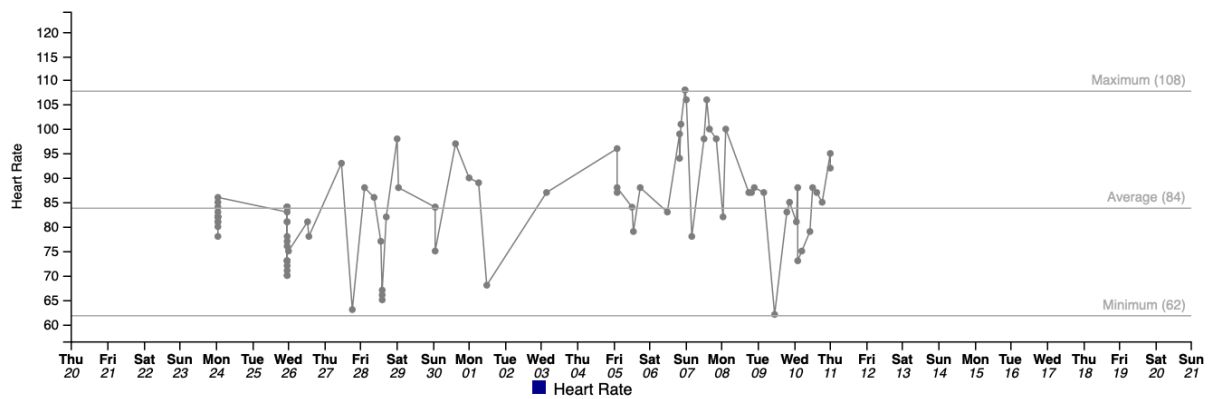


Figure 110: Heart Rate Measurements of Participant 8SU between April 20th and May 20th 2023

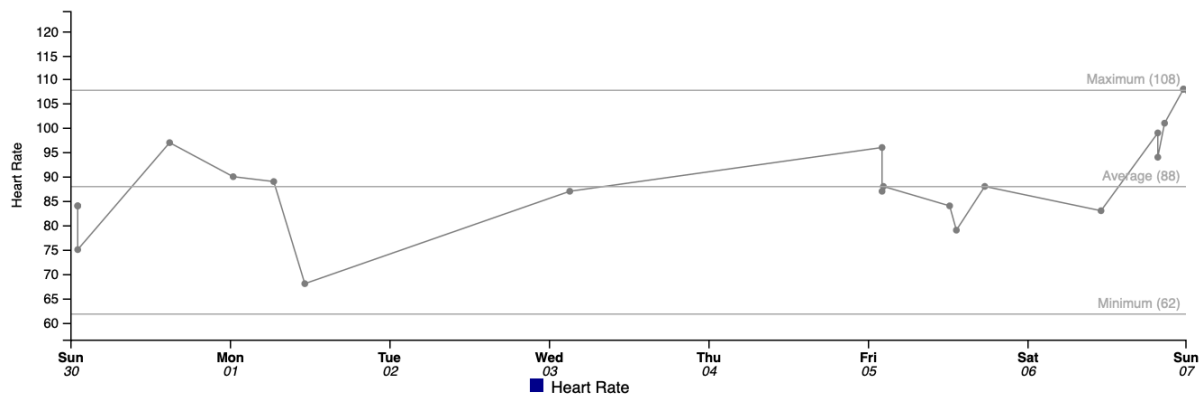


Figure 111: Heart Rate Measurements of Participant 8SU between April 30th and May 7th 2023

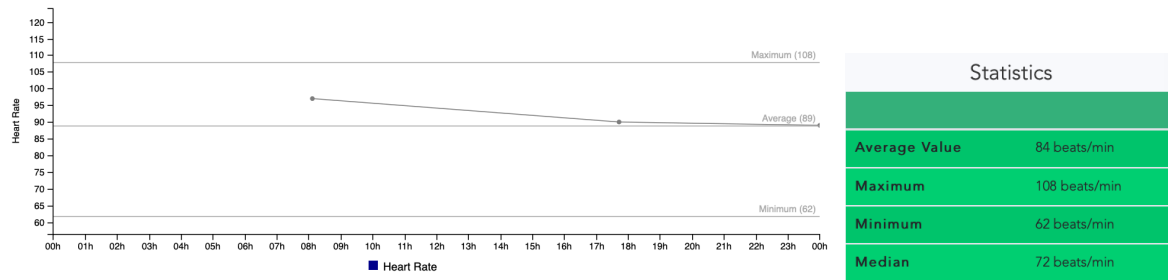


Figure 112: Heart Rate Measurements of Participant 8SU on December 17th 2022 and Heart Rate Statistics of Participant 8SU during the Phase 5 of UC-PT2-001 (5th YPE)

Participant 8SU registered a total of 23 420 steps in April 2023 and 42 480 steps in May 2023, reflecting an average of 22 136 steps for the duration of the pilot.

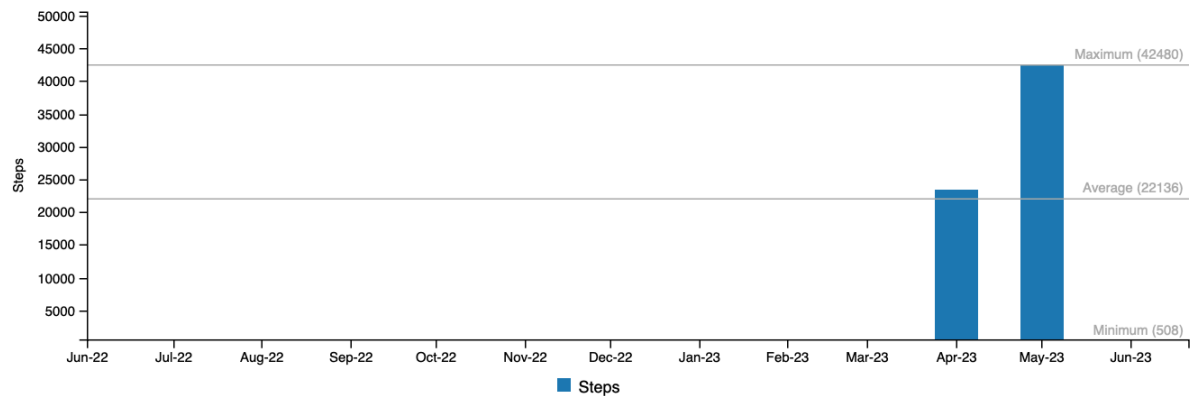


Figure 113: Steps of Participant 8SU during the Phase 5 of UC-PT2-001 (5th YPE)

Participant 8SU registered a total of 101h06m of sleep in April 2023 and 131h42m in May 2023, reflecting an average of 8h18m of sleep for the duration of the pilot.

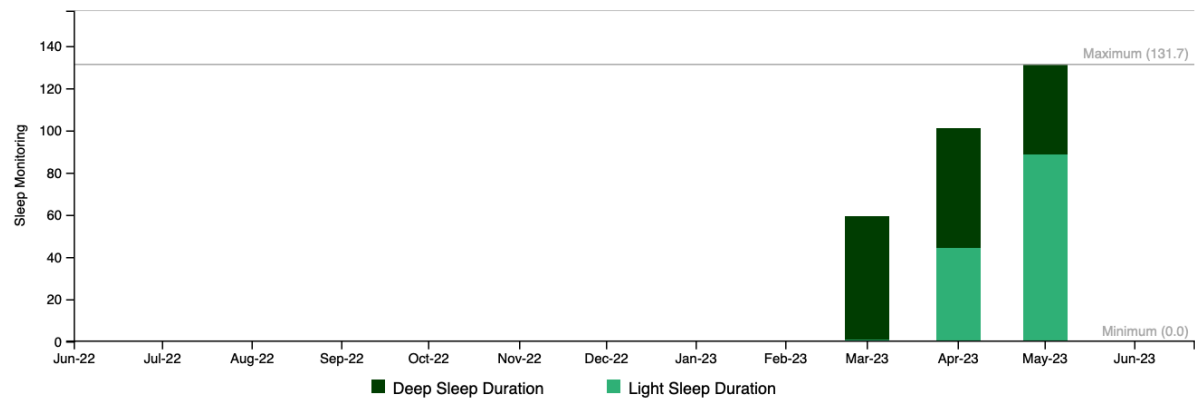


Figure 114: Sleep Hours of Participant 8SU during the Phase 5 of UC-PT2-001 (5th YPE)

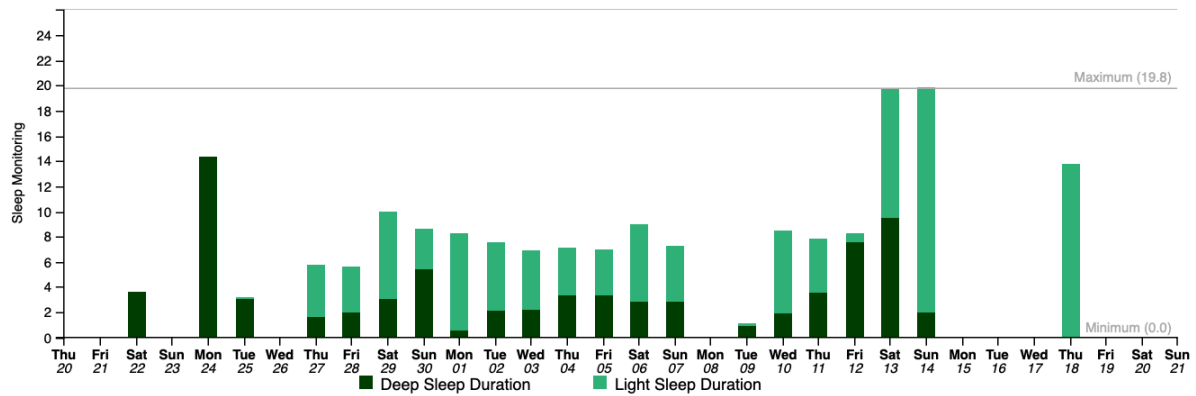


Figure 115: Sleep Hours of Participant 8SU between April 20th and May 21st 2023

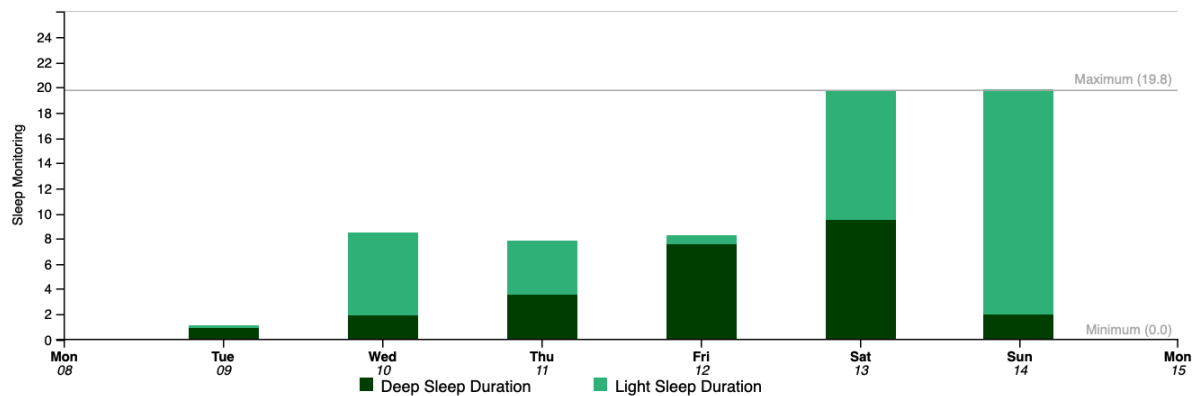


Figure 116: Sleep Hours of Participant 8SU between May 8th and May 15th 2023

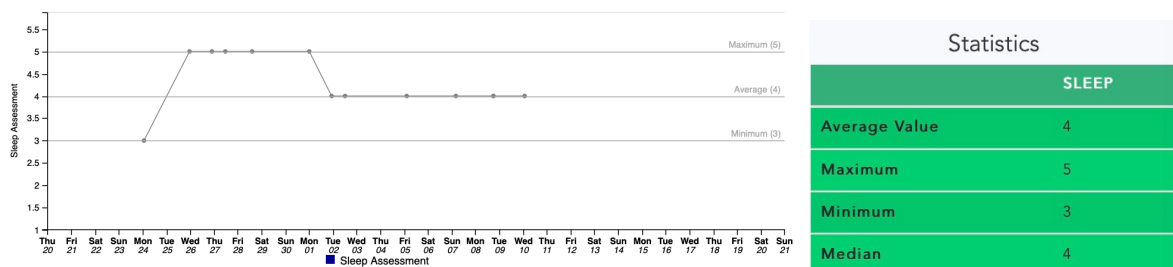
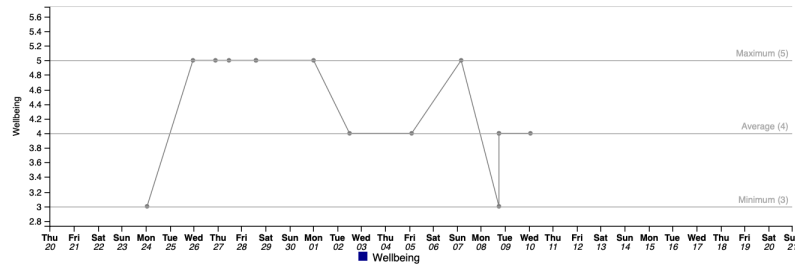
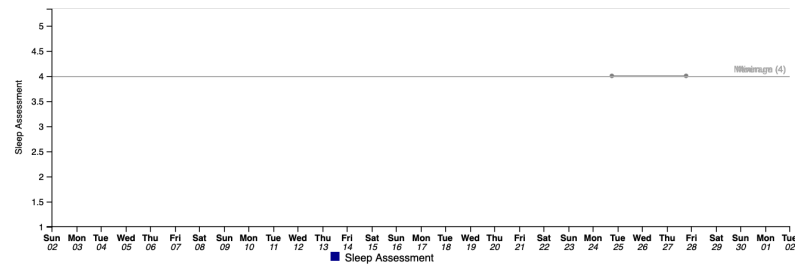


Figure 117: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 8SU during the Phase 5 of UC-PT2-001 (5th YPE)



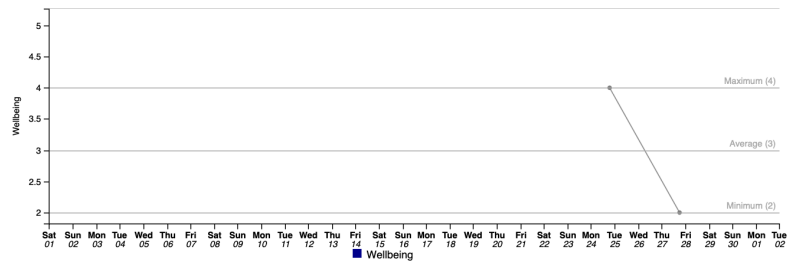
Statistics	
WELLB	
Average Value	4
Maximum	5
Minimum	3
Median	4

Figure 118: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 8SU during the Phase 5 of UC-PT2-001 (5th YPE)



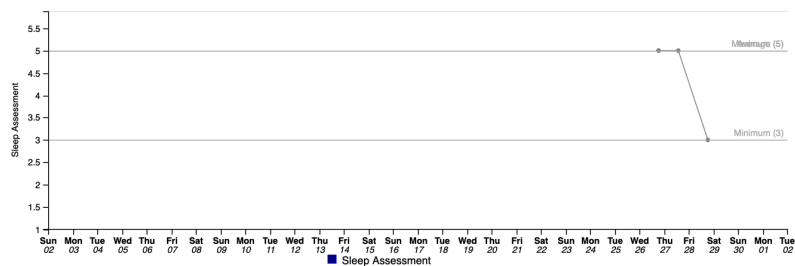
Statistics	
SLEEP	
Average Value	4
Maximum	4
Minimum	4
Median	4

Figure 119: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 9SU during the Phase 5 of UC-PT2-001 (5th YPE)



Statistics	
WELLB	
Average Value	3
Maximum	4
Minimum	2
Median	3

Figure 120: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 9SU during the Phase 5 of UC-PT2-001 (5th YPE)



Statistics	
SLEEP	
Average Value	5
Maximum	5
Minimum	3
Median	5

Figure 121: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 10SU during the Phase 5 of UC-PT2-001 (5th YPE)

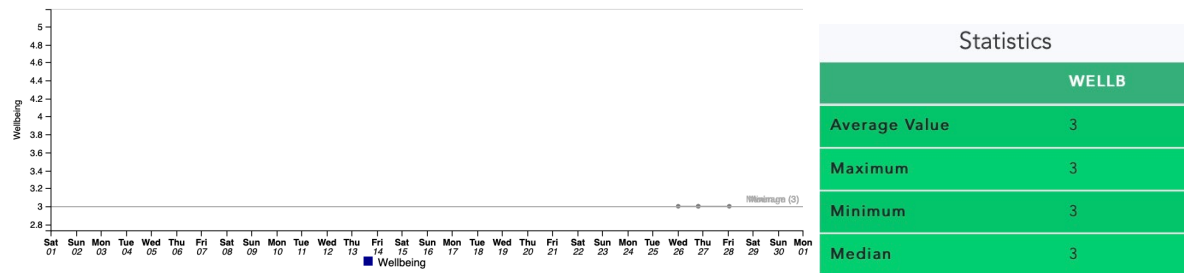


Figure 122: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 10SU during the Phase 5 of UC-PT2-001 (5th YPE)

Participant 12SU deactivated the automatic capture of the heart rate in the activity wristband early in the pilot. As a result, the heart rate measurements registered were performed manually by participant 12SU in the activity wristband.

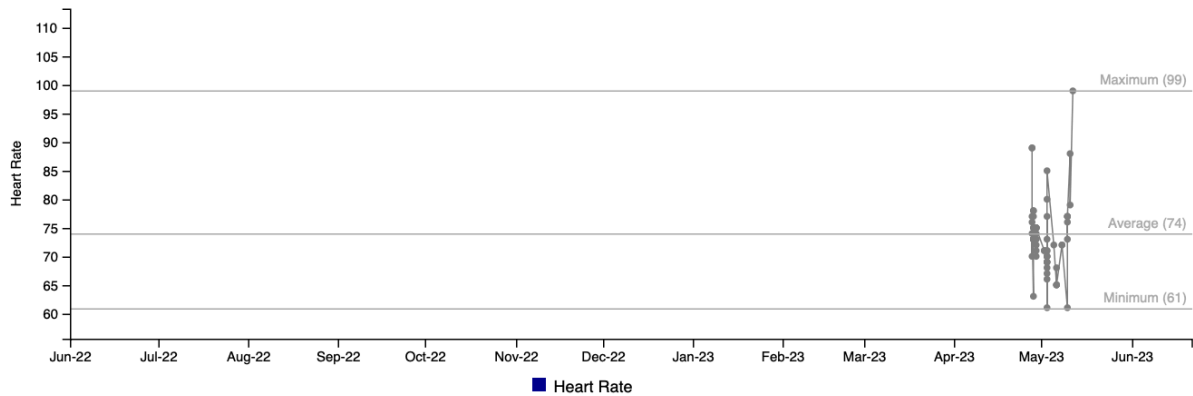


Figure 123: Heart Rate Measurements of Participant 12SU during the Phase 5 of UC-PT2-001 (5th YPE)

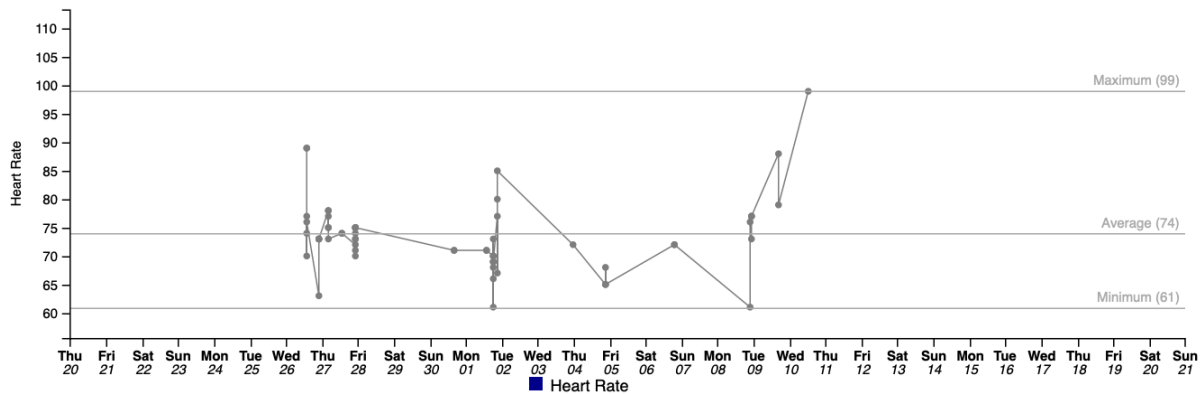


Figure 124: Heart Rate Measurements of Participant 12SU between April 20th and May 21th 2023

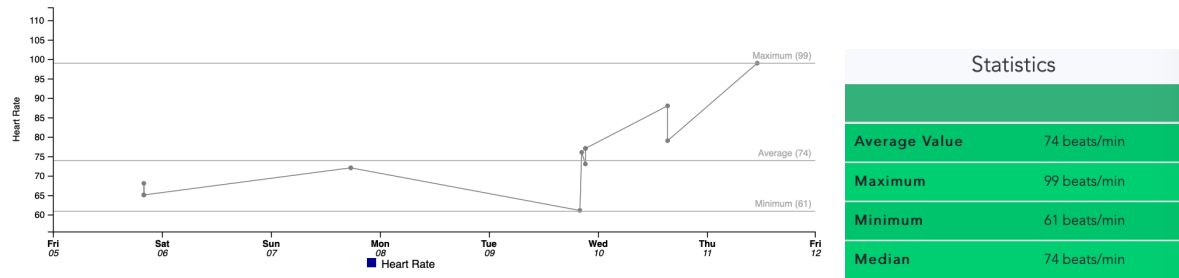


Figure 125: Heart Rate Measurements of Participant 12SU between May 5th and 12th 2023 and Heart Rate Statistics of Participant 12SU during the Phase 5 of UC-PT2-001 (5th YPE)

Participant 12SU registered a total of 25 922 steps in April 2023 and 37 629 steps in May 2023, reflecting an average of 31 776 steps for the duration of the pilot.

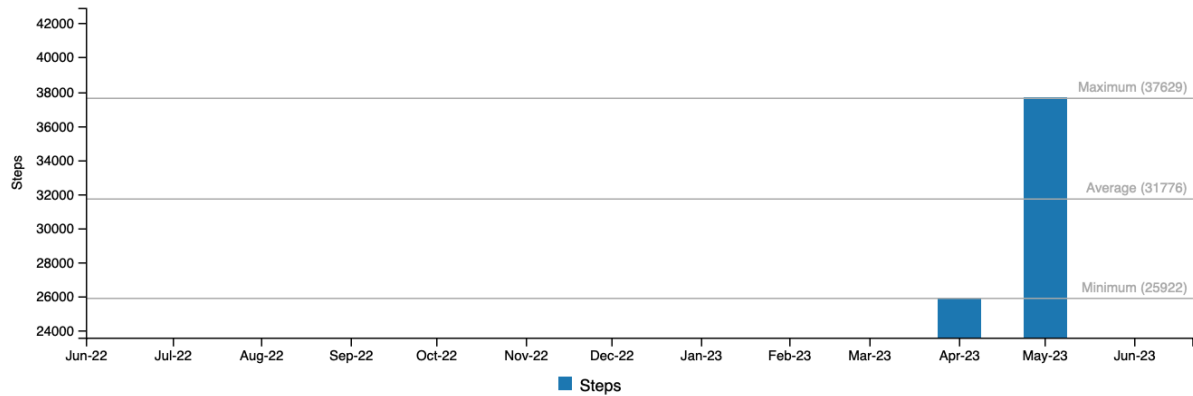


Figure 126: Steps of Participant 12SU during the Phase 5 of UC-PT2-001 (5th YPE)

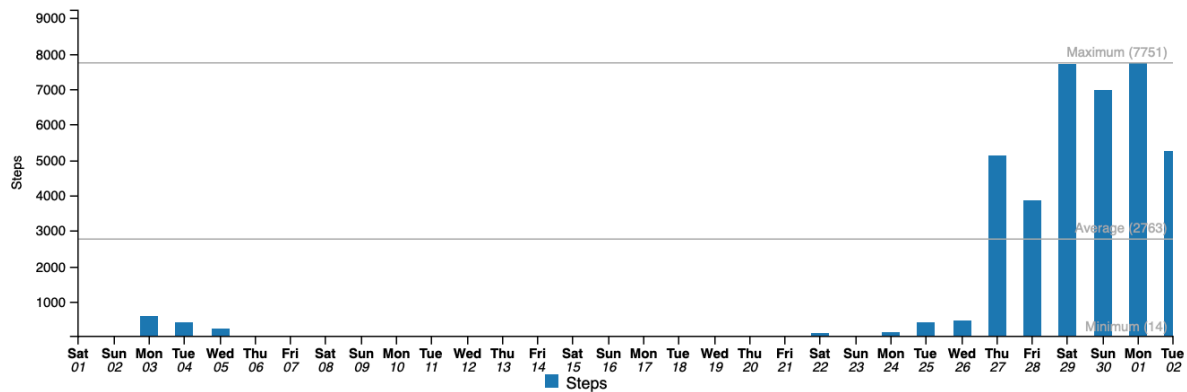


Figure 127: Steps of Participant 12SU between April 1st and May 2nd 2023

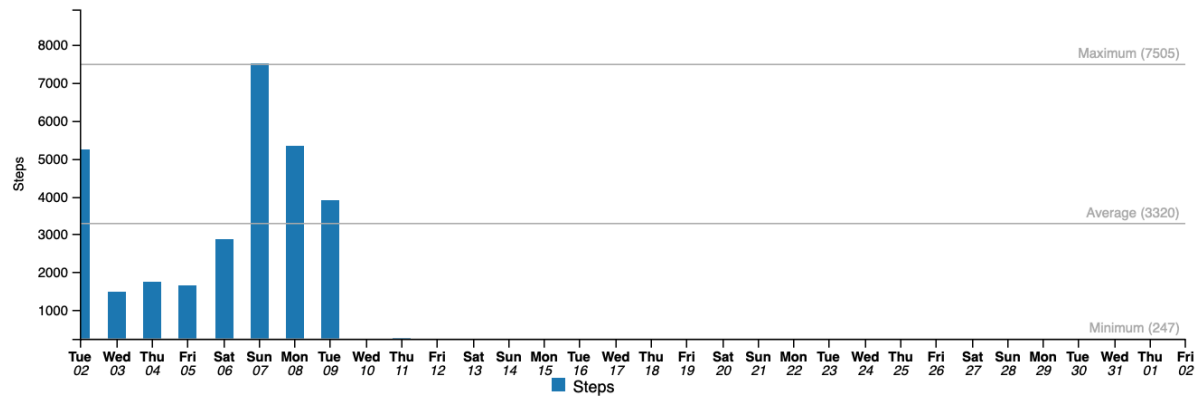


Figure 128: Steps of Participant 12SU between May 2nd and June 2nd 2023

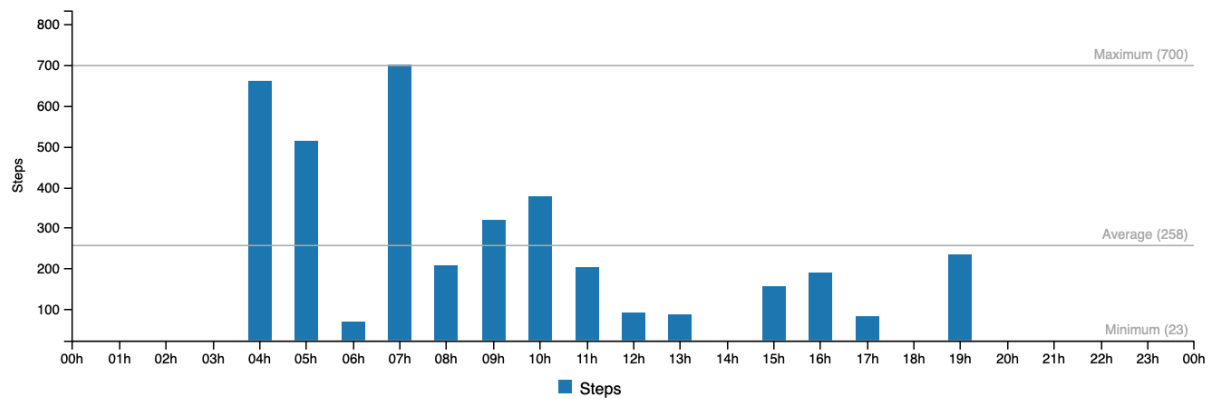


Figure 129: Steps of Participant 12SU on May 9th 2023

Participant 12SU registered a total of 40h12m of sleep in April 2023 and 80h18m of sleep in May 2023, reflecting an average of 7h30m of sleep for the duration of the pilot.

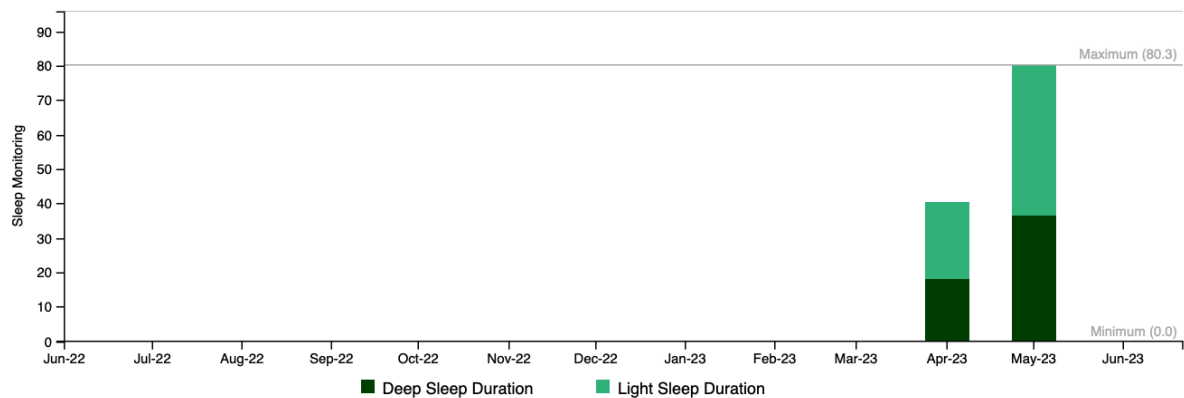


Figure 130: Sleep Hours of Participant 12SU during the Phase 5 of UC-PT2-001 (5th YPE)

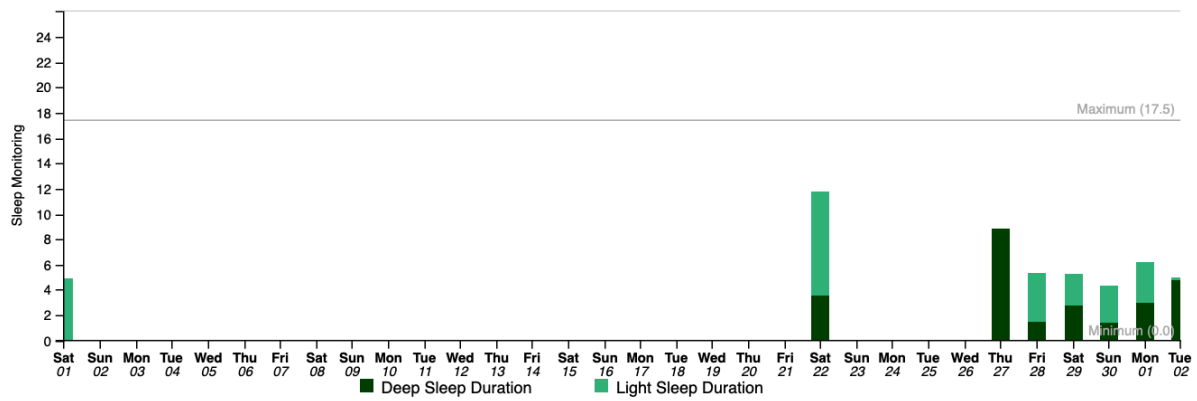


Figure 131: Sleep Hours of Participant 12SU between April 1st and May 2nd 2023

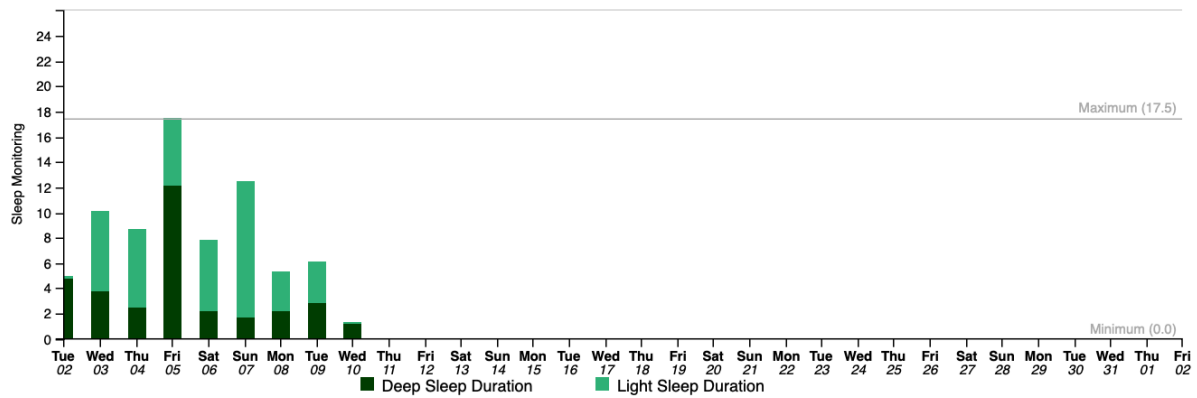


Figure 132: Sleep Hours of Participant 12SU between May 2nd and June 2nd 2023

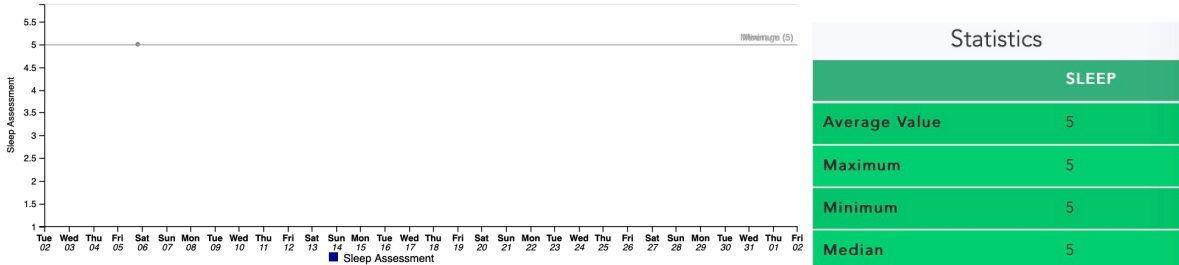


Figure 133: Sleep Assessment Reports and Sleep Assessment Statistics of Participant 12SU during the Phase 5 of UC-PT2-001 (5th YPE)

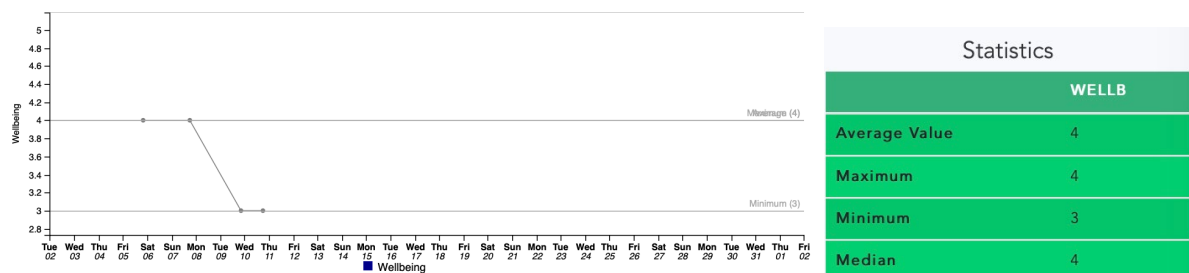


Figure 134: Wellbeing Assessment Reports and Wellbeing Assessment Statistics of Participant 12SU during the Phase 5 of UC-PT2-001 (5th YPE)

Recommendations for partners (from interviews)

5thYPE researchers were constantly in contact with the technical partners, and we reported bugs and feedback continuously during the pilot period.

Main problem reported:

- Log-in system should be improved in order not to insert username and password many times in the same access.
- Reliability of data (sleep and steps, in particular)
- Food recognition App not functioning.
- Liquid intake App not very intuitive

3 Use case 002

3.1 Introduction

In the following the pilot activities of PT2-002 *Supporting the interaction of the older individual with the community* are described. The target group of this use case was composed of 65+ year old persons living in their home-setting in the rural reference site “Oberbergischer Kreis” (OBK) in Germany and at least one caregiver (family, friends, formal caregiver). These target users are insufficiently informed about regional activities or integrated in society and thus at risk to suffer from loneliness and isolation. The individuals at stake need to be somewhat motivated and/or informed about the variety of regional activities or events in order to regularly entertain social contacts. If older individuals are already somewhat distanced from their community and take little to no part in day-to-day activities within the community, they don’t necessarily hear about new developments or opportunities for engagement, sports, educational or cultural events.

The use case was based on the needs and life world of the persona “Roisin” (5) who was described in more detail in D2.5. She was 84 years old and had recently moved from the village to the city to live with her daughter’s family. For Roisin it was completely new to live in a city and her daughter’s family was at work or school most of the day, she soon started to feel lonely and uncomfortable in the new surroundings.

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:

- Reduce the feeling of loneliness and thus improve the well-being of the older individuals
- Identify associations between the number of interactions, contacts and attendance of events and the feeling of loneliness.
- Improve or maintain the older individual’s wellbeing outcomes and quality of life.

Additionally, the users’ trust and acceptance of the SHAPES platform and Digital Solutions were explored. This use case is led by the GEWI – Institut für Gesundheitswirtschaft e.V. and was replicated by AIAS, CCS and UP.

3.2 Description

Although aging is inevitably related to decline, it does not necessarily imply illness and the need of care. Next to individual lifestyles, personal resources and the level of access to medical and social care, the aspect of social integration and its closely related feeling of loneliness has a strong impact on the health status, quality of life and well-being of older individuals. The causes leading to loneliness can be very different and they change with age. However, increasing evidence suggests that perceived social isolation or loneliness for longer periods of time is a relevant risk factor for physical and mental illness (14). Thus, chronically lonely people have a high risk of developing depression, are more susceptible to cardiovascular disease and possibly have an increased risk of cancer. Combating loneliness is therefore not only important for social cohesion, but it is also an active health precaution to support older people in living healthy and independent lives (15).

3.3 Digital solutions used in this use case

FinoT Platform (FINT)

A smart IoT-based living platform that leverages on the smart neighbourhood, smart community and smart city paradigms to deliver relevant information on weather, air quality, pollution, local public works, local transportation and local activities.

DigiRoom (OMN)

A web-based, no-install communication tool for i.e. the communication with their informal caregivers or family members/friends who are not close by/able to meet physically.

3.3.1 Digital solutions used for COVID-19 response

In UC-PT2-002 no digital solution for the COVID-19 response was in place.

3.3.2 Equipment and devices used (from third parties)

The following external devices were used in UC-PT2-002:

- Tablet: Samsung Galaxy S6L SM-P615

Further details on these devices are provided in section 3.8.2. The third party devices purchased for use in this use case were specifically identified by technical partners FINT (and OMN). The manufacturers of the devices used and the digital solution providers (FINT/OMN) 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.

3.4 Data plan

The data plan for phases 4 and 5 for PT2-002 has been finalised and can be accessed on the SHAPES website ([link](#)).

3.4.1 Data capture methods to be used

Data capture methods used during this pilot are listed below:

Phase 2

- Semi-structured interview

Phase 3

- User experience questionnaire-short version (UEQ-S)
- User Experience Questionnaire (UEQ)

Phase 4

- Participant error reporting log (to follow in final deliverable)

Phase 5

Excel file to capture the following data:

- Participant data (see Data Plan)
- Harmonised questionnaires (more details on harmonised data will be provided in Deliverable 6.9)
 - WHOQOL-BREF (2)
 - EQ-5D-5L (3)
 - General Self-Efficacy Scale (4)
 - Oslo Social Support Scale (5)

- Single item health literacy scale
- Participation questions
- System Usability Scale (6)
- Technology acceptance questions (7)
- UEQ-S (8)
- Flourish (16)
- Loneliness scale (17)

The SHAPES App (FINT) to capture the following data:

- Tracking data (i.e., user logs)
- Service user and healthcare professional interviews (schedule to follow in final deliverable)

3.4.2 Planning of evaluation

MAST

The MAST framework (model for assessment of telemedicine) (9) has been applied as it provides a structured approach for assessing the effectiveness and contribution of UC-PT2-002 to quality of care. In a multidisciplinary process, MAST summarises and evaluates information to the use of telemedicine related to the medical, social, economic and ethical issues.

For UC-PT2-002, three of the seven dimensions of MAST were identified/found to be of importance to consider:

- Clinical effectiveness
- Patient perspectives
- Economic aspects

A further exploration and description of the reasons for inclusion will be provided in the evaluation report (D6.9).

Table 46 shows a summary of the MAST evaluation.

Table 46: Data required for MAST evaluation of UC-PT2-002

MAST Domain	Topic	Outcome	Data required	Time point
Clinical Effectiveness	Mental health	OSSS-3 (social support) and life events		
	Effects on health-related quality of life	Health related quality of life and wellbeing	EQ-5D-5L scores; WHOQOL-BREF scores	Baseline, end of pilot, 3-month follow up
Patient perspectives	Satisfaction and acceptance	User Experience	UEQ-S scores	End of pilot
		User acceptance	TAM score	End of pilot
	Understanding of information	Usability of application	SUS Scores	End of pilot
	Confidence (in the treatment)		1-item health literacy	
	Ability to use the application			
	Access & Accessibility			
	Empowerment	User engagement	Number of logins	During pilot
	Self-efficacy	Self-efficacy	SHAPES Participation questionnaire	During pilot
			GSES (Self-efficacy)	During pilot
Economic aspects	Amount of resources	Cost of devices	Cost as per device	End of pilot

	used when delivering the application and comparators		purchasing invoice	
		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

MAFEIP

The MAFEIP tool (10) was not applied to evaluate UC-PT2-002 due to a small-scale deployment and a non-case controlled study design of the UC.

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

Momentum

Critical success factors (CSFs) and performance indicators offered by the Momentum blueprint (11) were determined in UC-PT2-002. These factors should be considered when scaling up telemedicine and integrating it into healthcare delivery systems. Although the digital solution of this use case does not count as telemedicine, and the aim is to increase wellbeing of the individual rather than medical conditions, the advantage of a rapid consideration during the pilot design predominates. Outcome of the process are included in the annex (Annex 12) and details of each CFS are provided below.

CSF 1. Cultural readiness for the telemedicine service

In the region where this use case has been deployed, only limited sharing of clinical information between different health care providers is realised. Within one institution, information is shared with the patient. Progress and promoting of telemedicine are highly welcomed in the region.

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

The advantages of telemedicine are clearly seen and considered the best solution to address shortage of skilled healthcare professionals.

CSF 3. Ensure leadership through a champion

At the end of the project a clear leadership will be identified. The way towards deployment of the SHAPES digital solutions should be supported by influential persons.

CSF 4. Involvement of healthcare professionals and decision-makers

Healthcare professionals and decision-makers were partially involved in the development of the content of the project in Phases 1-3. As the organisation of this use case is working together with decision makers from the reference site, those have been involved in the whole process of the project.

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

Patients have been involved in the development of the SHAPES digital solutions through the activities of all phases. The development was based on the patient needs and training for using the digital solutions was delivered.

CSF 6. Ensure that the technology is user-friendly

The project considered attentively the user-friendliness of the digital solutions. Potential users were asked about their opinion and experience interacting with the solution and all feedback was considered in the final development of the SHAPES digital solutions. The evaluation also included metrics like the System Usability Scale (SUS).

CSF 7. Pull together the resources needed for deployment

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

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

In general, health insurances have a vested interest in lowering costs i.e. their spendings, and direct more and more efforts and resources towards increasing prevention in Germany. Yet, first evaluations to identify primary clients for the SHAPES digital solutions still have to be completed.

CSF 9. Prepare and implement a business plan

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

CSF 10. Prepare and implement a change management plan

It will be evaluated at the end of the project and included in D3.10.

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

Legal requirements in the German context have been reviewed to ensure that the use case was piloted within the relevant legislation. Since the digital solutions were not classified as a medical device, all relevant requirements were met.

Completion of a Data Protection Impact Assessment (DPIA) identified and minimised the risks associated with the pilot with input sought from other work packages and the SHAPES Data Protection Officer at GEWI. 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 are limited, the solution is being 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 with the monitoring protocol.

CSF 13. Identify and apply relevant legal and security guidelines

GDPR was applied. The digital solutions implemented all applicable security and privacy-related regulations.

CSF 14. Involve legal and security experts

Advice from legal experts and experts on data security matters was received from project partners (for example LAUREA, that has extensive expertise in this field).

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 is protected. The project underwent 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 telemedicine services. The pilot is being designed to be in no need to cope with this requirement.

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

The IT system works 24/7/365. In case of any bugs or issues the development and maintenance team fixes it. FINOT and TREE are the owners of all the software that is used in the pilot. This means that there is no software dependencies with third parties, and that SHAPES partners are able to adapt source code at any point. The system logs all activities so any incident can be identified and solved quickly. In addition to the user manual, pilot hosts have access to the software developers of the different digital solutions so in case of doubts or questions we can answer them directly from FINOT and TREE.

CSF 18. Establish and maintain good procurement processes

The requirements applicable to the devices used in the pilot were previously defined and vendors that fulfil them were identified. The SHAPES project provides the servers that are needed to run the solution. Those servers meet the service level needed to run the pilot successfully.

NASSS

The NASSS framework (Nonadoption, Abandonment, Scale-up, Spread and Sustainability) (12) was used to increase the success of the technology of use case UC-PT2-002. It was conducted to detect risks, which might lead to project failure. The short version of the NASSS questionnaire was considered and completed by the pilot team (Annex 13). In four out of six domains uncertainties were identified and mitigation measures developed to ensure the success of the use case (Table 47).

Table 47: Uncertainties and mitigation measures identified using the NASSS framework (UC-PT2-002)

NASSS complexity domain	Uncertainties detected	Mitigation measures taken
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Illness or condition	Visual impairments or restricted mobility could reduce the interaction with the tablet and/or the access to participation.	A caregiver is assigned to each care receiver who discusses and supports the recommendations during the deployment of the use case.
Technology	The technology is not fully developed and thus does not exist in a robust and definitive form yet.	The technology to be developed is described and planned in detail in the UC. In the development process, the actual solution is closely aligned with the planned application and function of the technology. Mock-up-tests are performed with potential end-users to support the realisation process and constantly specify the technology. Besides, the solution is based on standard commercial devices wherefore the degree of complexity is expected to be manageable.
Technology	The functioning of the SHAPES Platform has not been defined to the use case leaders.	Functionality of platform is discussed in cross work package meetings. Solutions of open call partners are tested in phases 3 by researchers and in phase 4 in a small scale live demonstration.
Technology	The technology to be developed has a high degree of interdependencies. Constant testing of the technology is needed to detect and rectify occurring technical problems/issues (bugs and crashes).	Actions to increase efficiency in the development phase involve the close collaboration with technical partners in biweekly meetings and constant testing and feedback loops to assure alignment.
The value proposition	The technology does not exist in a definite form and a realistic assessment of challenges of implementing at	In a large-scale pilot campaign the real-world value are assessed and an analysis of costs and benefits is considered.

	scale has not been conducted yet.	
The external context for innovation	<p>The COVID-19 pandemic might affect the deployment of the UC, as recommending to attend public events might not be advisable for older individuals, identified as the most vulnerable groups.</p> <p>Regulations regarding the COVID-19 pandemic have to be further evaluated.</p>	<p>It is under discussion with the technology developer to send hygiene and safety measures for events or refer to the measures from the event organiser</p> <p>Internal discussions on potential regulatory issues and challenges and safety measures are applied, remote working are performed if feasible</p>

3.5 Phase 1

3.5.1 PACT and FICS Scenario

Table 48: PACT (UC-PT2-002)

Code	UC-PT2-002	Version	0.1	Date	2020/09/21
Applicable SHAPES Persona	Roisin (P5) lives together with daughters' family, suburb of a big city, daughter Ciara takes role of caregiver				
Applicable SHAPES use case	UC-PT2-002 Supporting the interaction of the individual with the community				
People	<ul style="list-style-type: none"> Older individuals who suffer from loneliness and are afraid to be a burden for the caregiver Older adults have the wish to be actively involved in social activities in community For these individuals it needs to be ensured that they have easy access to suitable opportunities and developments in the community Apart from access to social activities, language barriers and progressive diseases can also limit integration Low to average e-literacy, low to average affinity to technology Caregiver: relatives, average level of e-literacy and access to devices (smartphone, tablet, laptop) 				
Activities	Care receiver				

	<ul style="list-style-type: none"> • Cultural activities, such as live music, theatre visits, exhibitions and lectures bring variety to the everyday life of the ageing population. They can bring back memories through music and encourages animated discussions and exchanges between them. • Sports courses bring movement and activity into the everyday life of ageing individuals. These courses are an offer of the district and are tailored to the individual needs of ageing individuals. The offer includes swimming courses, dance courses, running groups and many more. • Basic knowledge such as news, weather forecast, navigation and public transport give you knowledge to plan activities. In addition, the older individuals are supported in participating in activities. Older individuals may be keen to take part in an activity but do not have the necessary mobility. This is where the platform helps, because it suggests transport options to the older individuals • <i>Information on counselling opportunities</i> <p>Caregiver</p> <ul style="list-style-type: none"> • the platform leads to a relief of the caregiver. They know that their relatives are not lonely and are well integrated into society
Context	<ul style="list-style-type: none"> • It is important to distinguish between the different individuals who use the platform. Some of them are very technically minded, can use the platform without any problems and are able to deal with the functions independently. Many other potential users do not do so. For them it is not possible to use the technical device (mobile phone or tablet) independently. They need support from informal caregivers throughout the entire process. • In case the ageing individual is not able to use the platform on his own, he is dependent on his relatives. The caregivers receive offers of activities for the care receiver. These can be events such as theatre performances or sports activities such as swimming lessons. The care receiver can now choose together with the caregiver the activities he/she would like to participate in. On the platform there is a link that you

can follow and then book a ticket easily and quickly. Then you can be forwarded to your calendar and note the event. In the best case, the ageing individual does not need any help with this and can take part in the process independently.

- The offers have been filtered beforehand according to **pre-set settings**. Among other things, the place of residence, age, physical fitness and of course the preferences and interests are stored. This enables the platform to automatically suggest activities based on the profile of the ageing individual.
- One way to maintain the self-determination of the care receiver as much as possible would be a **release option (approval)**. The care receiver can decide how much influence the informal caregiver gets. The care receiver can decide whether the caregiver has access to his or her calendar or has the option of booking events for the care receiver. The role of the caregiver is therefore quite flexible. The caregiver can hardly be involved in the interaction of the care receiver or be a big part of the use of the platform.
- Another question is how the **information is made available to the platform**. There is certainly information, such as the weather, transport possibilities or cinema programs, which are automatically updated. It would be a misfortune if there were no possibility to list unique offers in the Platform. For example, an action where you can bake biscuits during the advent season. To do this, a person in between is needed. This person receives a form from a provider and makes the information available to the platform. In this form different categories are queried. For example, the provider of an activity must indicate where it takes place, what physical fitness is required or whether the activity is easily accessible for people in wheelchairs. When this process is completed and the person uploaded the event, the offer is suggested to the care receivers who have matched the filter and they can decide whether they want to participate in the activity. In the case that the provider does not know the platform and does not put his activity online, it would be good if a person would be actively looking for events every fortnight or once a month and make this information available to the platform.

	<ul style="list-style-type: none"> • How many activities are proposed depends on many factors. How full is the person's calendar, how many interests or restrictions does he or she have, does he or she live in a rural or urban area? • For the informal caregiver the platform is a great relief. He/she can very easily support the care receiver to participate in activities that could be fun. He/she can very easily support the caregiver to participate in activities that could be fun. This requires good arrangements between the caregiver and care receiver. • <i>Warranty of data privacy; contact details are only managed by pilot site (GEWI)</i> • <i>GDPR and ethics in line with WP8</i> • <i>Data and servers must be located within the EU</i> • <i>German language</i> • <i>Location: HealthRegion CologneBonn (Oberbergischer Kreis), Germany</i>
Scenario	<p>Roisin moved to her daughter Ciara and her family in the suburbs of a large city. There she feels very alone, because the family members work or are at school during the day and in the evening, Roisin does not want to restrict them. But Roisin does not feel comfortable in her new surroundings. She has hardly any contact with community, but she would be very happy if she could have more social contact playing bingo or doing exercises for her knee.</p> <p>Roisin could use the platform very well and she would like to try it out. She has a medium affinity for technology, but also a low digital competence. That is why she asks her daughter Ciara to register with her on the platform. Ciara notices that her mother is not well, and she feels lonely, so she thinks it is a good idea. The registration process takes about 10 minutes. Roisin and Ciara are asked where Roisin lives, how she is physically fit, whether she has mobility problems, what topics she is interested in and what interests and hobbies she has. The platform creates a profile and activities are suggested to Roisin. Ciara shows Roisin how she can use the platform's functions. As Ciara has to work early the next morning, she wants to sleep, and they postpone the booking of events. The next morning Roisin opens the computer and receives basic information about the day, such as the weather and individually selected news topics. In addition, the ageing person gets a</p>

	<p>look at her calendar. This gives a good overview of the day. So far Roisin has only entered the birthdays of her family and a doctor's appointment next week. The platform remembers individual interests and can make offers tailored to the needs of each person. For example, the platform recognizes that good weather is to be expected during the day and suggests that the user take part in the senior citizens' walk in the afternoon. For the next few days, Roisin will propose a bingo-afternoon, a trip to a city museum, a visit to the cinema, a reading by an author and sports activities. Roisin is very happy and has the possibility to favours the session of bingo, the author's reading and a gymnastics course, so that she can later show the offers to Ciara. In the evening Ciara comes home from work and because Roisin favours the activity she wants to participate in, the booking process is very fast. Roisin is pleased with Ciara's support, because she doesn't dare to register for the courses on her own or book a ticket for an event. Roisin is looking forward to next week, as she has some nice activities planned.</p> <p>There is a bus stop directly in front of Roisin's flat. The platform suggests a route to Roisin, which allows her to arrive on time and with enough time to change buses for the bingo afternoon. She is very happy about this, because nobody can drive her by car at this time of day.</p> <p>After Roisin has taken part in an activity, she can evaluate the event. In this way, the platform can remember what Roisin liked and propose similar events to her in the near future.</p>
Technology	<p>Type of information / parameter that are relevant to offer a wide range of leisure activities</p> <p>Care receiver</p> <ul style="list-style-type: none"> • Age (year of birth) • Gender (m/f/d) • Internet access • Skills how to use devices • Parameters: Frequency of contact, • Activities customized to interests and capabilities • Place of residence • Initial survey about hobbies and preferred interests

Caregiver

- Internet access
- Skills how to use devices
- Training how to book tickets (i.e. events, tickets) for care receiver

Personnel administrator

- could be an external person or the caregiver/ informal caregiver
- the care receiver decides the influence of the administrator

Task/ Function:

- support older individuals in the process of using the platform
- Information transfer from events to the platform
- Intervene in case of conflicting acts (for example if the user wants to participate in two activities at the same time)

Type and frequency of accessibility of information

- continuous access to information about local community
- Daily provisions
- continuous updating of data provided by devices (at least three time per day)

Registration information

- Name
- Date of birth
- Place of residence
- Emergency contact
- physical or psychological limitations
- physical fitness
- interesting topics/news (Selection of politics, economy, sports, literature, music)
- Interest in culture (Selection of readings, museum visits, historical offers, exhibitions ...)

	<ul style="list-style-type: none"> • Interest in sport (Selection of ball sports, gymnastics, outdoor and indoor sports, dancing...) • available days/times • Area in which to find activities (Selection 2km, 5km, 10km) <p>feedback modalities (communication)</p> <ul style="list-style-type: none"> • Possibility to forward events of interest from care receiver to caregiver
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Table 49: FICS (UC-PT2-002)

Category	Detail
Function and events	<p>This use case presents two actors, namely Rosin an older person playing the role of the care receiver and Ciara playing the role of Rosin's daughter acting also as her caregiver.</p> <p>Both Rosin and Ciara use smart device (i.e., tablet or smart phone) that are used to access the App. Via this App both of them are able to register their profile, including their role, associate to each other (caregiver - care receiver mapping) and subsequently use the application to discover/view/book/manage the available upcoming events; in addition, the actual event attendees (care receiver and/or caregiver) are able to assess the event. Via the application the care receiver and the caregiver are able to also communicate to each other via text/audio/video media channels. Hence, the functionalities accessible to the actors are:</p> <ul style="list-style-type: none"> • Authentication of the care receiver and caregiver, provided by the SHAPES Platform, via the SHAPES Front-end App. • Register profile and event preferences information. • Care receiver are able to specify what type of actions the caregiver can carry out on her/his behalf. • View available recommended events (based on the registered preferences) • View detailed info per selected event.

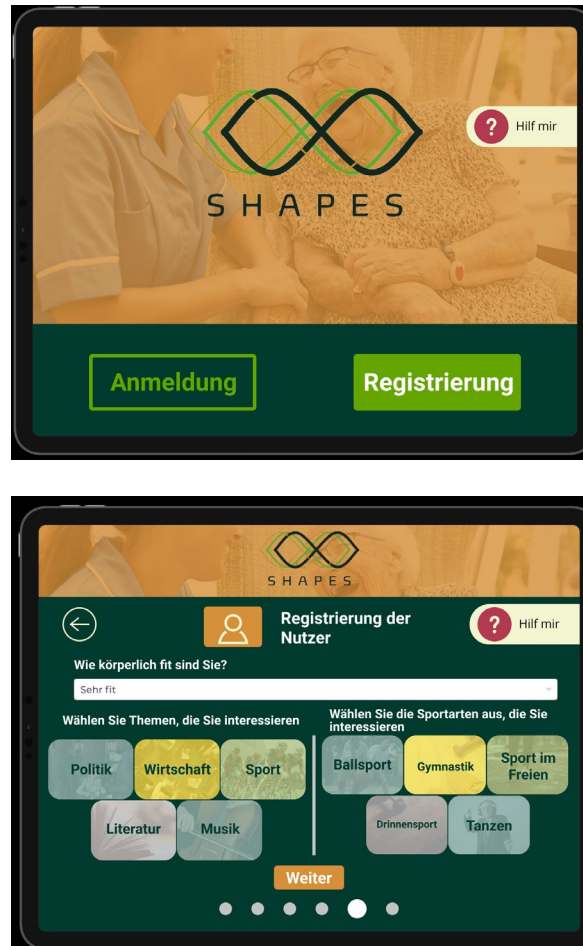
	<ul style="list-style-type: none"> • Book the desired events. • Manage the booked events. • Receive reminders for the upcoming booked events • Text, Audio and Video based communication amongst the care receiver and the caregiver. • Visualisation of the weather forecast measurements. • The caregiver are able to recommend events to the care receiver. • The caregiver are able to book on behalf of the care receiver events; this is possible only after the explicit consent of the care receiver. • The Event attendee (i.e., care receiver and/or caregiver) is able to assess the event.
Interactions and usability issues	<p>The SHAPES UC-PT2-002 App has been designed to facilitate the users' interaction with it and has implemented intuitive, friendly and easy-to-use screens and navigation options that should reduce any usability issues that may arise.</p> <p>Importantly, the personalised reminders and recommendations, provided for the available events support the users' interaction with the digital solution, encouraging the fulfilment of all the tasks identified in the use case's protocol and a dynamic engagement with the use case's objectives.</p>
Content and structure	<p>For this use case the following content is used:</p> <ul style="list-style-type: none"> • Care receiver user profile • Caregiver user profile • Event information • Event's assessment data • Weather Data • Event data <p>The content is structured in json objects to facilitate its programmatic processing and its exchange (where applicable) between SHAPES entities.</p> <p>The following table depicts the in more details each content's type data categories.</p>

Data Categories	Entries
User profile (Care receiver)	
Name	Socio-demographic
user id	Platform Access
Date of birth	Socio-demographic
Gender (m/f/d)	Socio-demographic
Internet access	Technology
Skills how to use devices	User skills
Place of residence	Socio-demographic
Frequency of contact	User preferences
Emergency contact	User preferences
Physical or psychological limitations	User preferences
Physical fitness	User preferences
Interesting topics/news (Selection of)	User preferences
Interest in culture (Selection of reading)	User preferences
Interest in sport (Selection of ball sports)	User preferences
Area in which to find activities (Selection of)	User preferences
Availability (days/times)	User preferences
Usage data with regard to care receiver	
Days used	Tracking of progress
Time/Duration of interactions	Tracking of progress
Number of interactions	Tracking of progress
Events registration completed	Tracking of progress
Events attended	Tracking of progress
Events attended history	Tracking of progress
Event assessment	
User Score	User evaluation
Comments	User evaluation
Precision	Algorithm's evaluation
Recall	Algorithm's evaluation
F1 Score	Algorithm's evaluation
Weather Data	
Temperature	Environmental conditions
Humidity	Environmental conditions
Precipitation	Environmental conditions
precipitationType	Environmental conditions
windSpeed	Environmental conditions
windDirection	Environmental conditions
solarRadiation	Environmental conditions
Event Data	
Event type	Event information
Event place	Event information
Event date	Event information
Event time	Event information
Event participation cost	Event information

Style and aesthetics

The technological solution developed for this use case adopts a SHAPES “look and feel” inspired by the project’s identity, namely its logo, colours and icons. As a result, the UC-PT2-002 digital solution presents the SHAPES logo and the logo of FINT, the partner organising the use case pilot; the solution also uses green and golden tones and the national language of the use case pilot participants.

Following the SHAPES UX guidelines (Deliverable D5.1) and Digital Solutions presentation (Deliverable D5.2), the UC-PT2-002 App presents a simple, straightforward, friendly and easy-to-use navigation scheme. The following images exemplify the style and aesthetics of the solution supporting the UC-PT2-002 use case. The following three screenshots demonstrate the above principles.



3.5.2 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 monitoring the progress or lack of it towards achieving the objectives of each specific use case. The following KPIs have been selected to define the success of the pilot activities for UC-PT2-002.

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 further development 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.

Technical performance

3. There is no re-start of any of the components of the technology 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 User Experience Questionnaire (UEQ-S) was classified as 'Excellent', 'Good' or 'Above average' based on published benchmark data.
5. At least 60% of participants continued to login to use the App daily after two weeks of the pilot.
6. At least 60% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Other indicators (examples, to be defined in a measurable manner)

- Booked events
- Participation in activities
- Quality of live (WHOQOL-BREF, EQ-5D-5L)
- Social support (OSSS-3)

3.5.3 Timeline of pilot activities

The original timeline of pilot activities was to conduct Phase 1 and 2 between May 2020 and January 2021, followed by Phase 3 from February until June 2021. The Phase 4 was planned to be conducted between August 2021 and April 2022.

The adapted timeline of pilot activities can be found in Figure 135. It shows that Phase 3 was shifted and extended to July 2021 until April 2022. This period was extended, with no impact on the next phases or the deliverable, due to the COVID-19 situation. Hands-on training were deployed in the home-setting of the participants and therefore the training was conducted at a point of time when it was safer for all involved to have in-person meetings. Phase 4 involved in-person meetings as well, since further testing of the technical aspects needed at least one in-person meeting per participant. GEWI conducted Phases 1-5 and the replicating sites AIAS, CCS and UP conducted Phase 5.

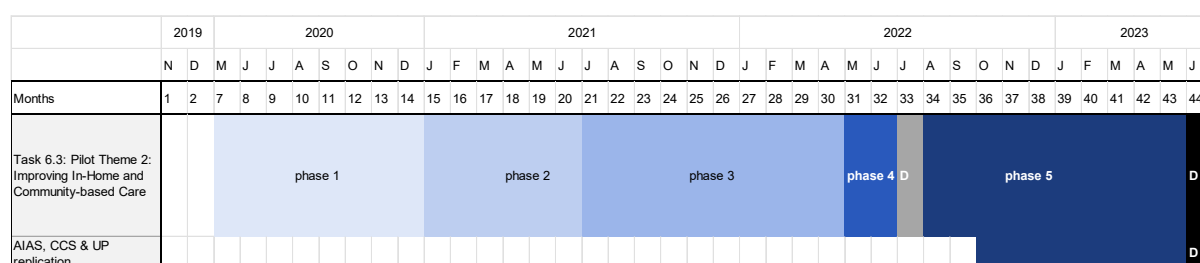


Figure 135: Timeline of pilot activities of UC-PT2-002

3.6 Phase 2: Testing of mock-ups and prototypes

3.6.1 Methodology of testing

In Phase 2 initial ideas of the technology of UC-PT2-002 were put in a visual representation, called mock-up. At that stage no functionality was offered and the mock-up was primarily used to evaluate design and potential functions by developers and participants. The presented technology is the SHAPES App developed by FINT.

The presentations were conducted remotely via videoconference. In the first part participants were informed about the background of the SHAPES project and the use case. The second part focused on visual images of the screens a user would encounter when using the App.

Participants

Phase 2 was conducted with six older people fulfilling the criteria to be 65 years and older and three informal (family) caregivers.

Informed consent procedure

In a first step participants obtained explanation to the background and purpose of the study and about the process of the mock-up. In addition an information sheet was provided. With the agreement to participate they received the consent form. Informed consent for all participants was taken with the following format of signatures collected where appropriate:

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

Data collection

Feedback was collected using a questionnaire (Annex 14) comprising a combination of open and closed questions. Throughout the presentation of the mock-up feedback on design and layout was collected. The questions were a combination of open and closed questions to gather general and specific feedback about the functionalities.

3.6.2 Results of testing

In summary the overall perception of the use case was high and the interviewee did understand the context. Feedback on the layout included comments on focusing on self-determination and defining access to certain information.

Regarding the interaction the participants requested a shared set-up during the registration process, getting access to see the care receivers preferences and to reconsider the neighbourhood assistance. In terms of IT-behaviour, the clear design of the mock-up and the well-designed process of events booking and payments procedure were mentioned. On the other hand no benefit was seen in the video function and chatbot option. Further it was proposed to have digital mediators as caregivers and to introduce the technology through dialogue.

3.7 Phase 3: Hands-on Experiments

3.7.1 Methodology of hands-on experiments

Hands-on experiments were conducted as individual in-home visits in strict compliance with safety measures of the COVID-19 pandemic. On the previously scheduled date, a researcher visited the participants at home to collect feedback from end-users and evaluate the performance of the digital solution in the actual pilot setting.

Participants

Phase 3 hands-on experiments were conducted with one target user of the SHAPES App (i.e., ≥ 65 years' old; living at home in the reference site Oberbergischer Kreis, stable internet connection).

Eligible participants have been identified by GEWI during the process of recruitment for phase 4 and 5. Therefore, several actions have been applied to draw attention to the project. These entailed displaying articles in regional newspapers, using mailing lists and contacting relevant gatekeepers from the network by applying face-to-face recruitment. Interested people contacted the research team via mail, letter or phone. A first screening was performed for potentially eligible participants. Informed consent for all participants was taken during the meeting (Annex 15 and 16).

Method

In the beginning, the participant was introduced to the SHAPES project and the digital solution. For the older persons, technologies were presented as a functioning prototype with the FINT digital solutions accessed via the SHAPES App. The researcher guided the participant through a series of steps and tasks to demonstrate the different functionalities of the App. Instructions were given with the support of a presentation projected on a laptop screen. Additionally, the participant received a user manual to support the handling of the digital solution. The App was accessed by participants via an internet-enabled tablet device provided by GEWI. During the testing, the following tasks have been performed:

Demonstration to Older persons

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 fluid intake manually

The pace of the session was determined by the participant. After the demonstrations, the participant has been encouraged to use the App and devices following the steps of the demonstration. Thereby, the researcher was still present in order to answer questions and troubleshoot any issues.

Feedback about the App has been collected as detailed below.

Collection of feedback

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

A concurrent 'think out loud' approach was applied 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. The participants were encouraged to verbalise their reactions, thoughts, feelings, and opinions about the prototype throughout their engagement with the researcher. Notes were taken by the researcher throughout the session.

After the hands-on experience, participants were asked to complete the User Experience Questionnaire (UEQ) to collect quantitative data about the impression of the participants about user experience. The UEQ assesses six aspects of user experience (attractiveness, perspicuity, efficiency, dependability, stimulation and novelty). There are eight items and respondents mark on a seven-stage scale between two terms in each item (i.e., attractive ○ ○ ○ ○ ○ ○ unattractive).

At the end of the session, participants were interviewed by the researcher to collect their experiences in using the prototype. An interview schedule / topic guide 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 hands-on experience
- f) Overall satisfaction

Data analysis

Results of the UEQ 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, has been shared and discussed with the technical partners.

3.7.2 Results of the hands-on experiments

Recruitment

For the recruitment of participants, several actions have been applied to draw attention to the project. These entailed displaying articles in regional newspapers, using mailing lists and contacting relevant gatekeepers from the network by applying face-to-face recruitment. Interested people contacted the research team via mail, letter or phone. After a first screening, potentially eligible participants were contacted. Thereby, one participant was identified who was interested and willing to participate in the hands-on-training.

Participant

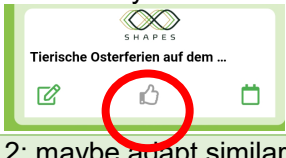
One female participant (PT1) was recruited to take part in the phase 3. She fulfilled the eligible criteria of being residents of the reference site Oberbergischer Kreis and aged ≥ 65 years. She was not tech-savvy and had very little experience in handling the digital devices.

Participants feedback

The Phase 3 hands-on experiment was conducted between 4th and 6th April 2022. Detailed service user feedback from the participant is presented in Table 50.

Table 50: user feedback from hands-on testing of UC-PT2-002

PT1		Should be adapted:
		(5: high priority – 1: low priority)
Ease of use	Difficult to memorize all the icons	
	Icons are not clear (calendar, paper basket)	5: clearer calendar-icon, bigger icon for paper basket

	<p>Different options to leave a menu are confusing</p> <ul style="list-style-type: none"> ➤ Within the recommended events you need to slide in the menu; within the calendar you need to click the arrow in the upper left corner; from the online source you need to click on the hardware arrow to get back to the App 	
	Voice assistant would be helpful	
	<p>Slide in the menu</p> <ul style="list-style-type: none"> ➤ Only available in the home and recommended events menu ➤ Challenging in terms of fine motor skills 	5: show the menu always (the thereby constantly provided home button could also solve the confusion of how to leave a menu)
Design	<p>Colours not clear: change from grey to green (thumbs up in caregiver view) hard to see</p>	<p>3: maybe increase the size of that icon and fill the form of the hand in green (only when event was chosen) additionally</p> 
	+Icon for adding an event not clear, would need description	2: maybe adapt similar to the button "learn more"
	Create event: to stay long on the date is not clear/ confusing with regard to the other actions	2: is there a way to skip this step and have it automatically done by using that +-icon?
Utility	<p>Might be useful</p> <p>Nice to have that calendar instead of one in paper form</p>	
Gender neutrality	neutrality	
Quality of training	<p>Training was fun and understandable</p> <p>Very helpful and required</p>	
Tasks	<p>Needed lot of support in all tasks</p> <ul style="list-style-type: none"> • Open calendar • Open and read recommended event • Add event to the calendar • Go back to home menu <p>Confused by how to leave the online source (and get back to the App)</p> <p>Within the calendar not clear how to get back</p> <p>Making the menu (at the side) visible was big challenge every time</p>	

PT1

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

Figure 136: UEQ-S responses to the SHAPES App after hands-on experiments (UC-PT2-002)

Recommendation for technical partners

A meeting was held with the technical partner to present service user feedback to them. Thereby, it was collaboratively discussed how to best address and mitigate the content of the users' feedback collected during the hands-on experiments. The detailed ideas for adaptations for each item of the user feedback is provided in Table 50. These referred to the navigation through the App, fixing bugs as well as changes in wording or design.

Conclusions

The hands-on training with a target user was the second user engagement activity being conducted in preparation for the deployment of the UC-PT2-002 in phase 5. Thereby, the participant was able to interact with the App, test its different functionalities and use all components of the App, which were interlinked and presented to the user within 'one' App for the first time. This way, potential navigation issues or inconsistencies could be detected at this early stage and were shared with the technical partner. In a process of collaboration and discussion, changes were jointly agreed on with the aim both taking into account the individual characteristics and features of the App and yet making the user experience as consistent and user-friendly as possible. Overall, the recommendations being elaborated within this activity supported that the App works smoothly and can be forwarded into the next phase 4. This phase provided the opportunity to then test the functionality of the App in a real-world environment.

3.8 Phase 4: Small Scale Live Demonstration

In UC-PT2-002 small scale demonstrations of the SHAPES platform and digital solutions of this use case were conducted during Phase 4 of the SHAPES pan-European pilot campaign at GEWI. The demonstration tested the methods and procedures which are to be used in the pilot at a larger scale among the target population. The aim is to identify factors such as issues with transfer of data or connectivity or other that may be relevant to the large scale pilot.

3.8.1 Recruitment of participants

The Phase 4 small-scale demonstration was 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. Eligible participants were recruited internally from the GEWI colleagues.

Inclusion criteria

- Has stable self-reported Wi-Fi connection at home
- Self-reported moderate digital literacy
- Employee of gewi-Institut für Gesundheitswirtschaft e.V.

Exclusion criteria

- none

Informed consent for all participants was taken from each participant (Annex 17 and 18).

3.8.2 Technical aspects & Logistics

The device purchased for the hands-on training in phase 3 were used for the small scale live demonstrations as well. These included an Android tablet device with the following specifications:

- Android version 10 and above
- Processor speed 1GHz or more
- Storage 4GB or above
- Support Wi-Fi

The SHAPES App, that is represented by the FINT App was installed on the tablet and given to the participants to use at home. Researchers provided full training on how to use the device and a user manual was provided.

Participants were asked to register and use the App on a daily basis to look into the recommended events. Those events that corresponded to the participants preferences should be entered in the calendar of the App. Participants could view their data via the App and had the ability to enter events in the calendar manually. For the purposes of phase 4, these data did not need to correspond to reality.

Participants were asked to take notes if any errors occurred. Errors may include:

- System crashes
- Error messages
- Dead links

The notes and experiences were shared with the pilot site researchers and the technical partners in order to determine the causes of any errors and define elimination and prevention actions. A summary of these outcomes will be presented in chapter 3.8.5.

In the end participants were asked in a short unstructured interview to share their experiences and suggest any amendments or additions they felt were needed also with respect to the user manual for the SHAPES App to allow adjustments to be implemented before the use in the large-scale pilot.

The pilot site researchers (and if necessary, the technical partners) were available during the live demonstrations to provide support where necessary. A log of all requests for support was kept and analysed after the demonstration. This process should inform the type of technical support potentially required during the run-in period of the large scale pilot, and supported the study team in making appropriate arrangements.

3.8.3 Roles and Responsibilities

The SHAPES pilot site researchers at GEWI were responsible for recruiting and consenting participants to take part in the live demonstration. GEWI provided training and was the single point of contact for the participants. The technical partner (FINT) was responsible for providing technical support (via GEWI) to the participants if needed.

3.8.4 Ethical considerations

An ethical self-assessment for phases 1–5 of this use case has been 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. Consent from 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 UC-PT2-002 did not meet the definition of ‘research’ and as such did not require specific local ethics board approval or DPIA documentation.

3.8.5 Outcome of the Small-Scale Live Demonstration

Participant

Two female participants were recruited to in the Phase 4 small-scale live demonstration. Participants were network members from GEWI aged 65+ years old and thus belonging to the reference group.

Outcomes referring to the technical functioning of the DS as main focus of Phase 4 is presented in Table 51. Additional feedback has been collected with respect to the layout and design, the ease of use and the utility which is summarised afterwards.

Table 51: Outcome Phase 4 UC-PT2-002

Outcome	User 6	User 7	Comments
Number of errors noted by participants	2	2	<ul style="list-style-type: none"> • Digiroom didn’t work • Login in the App didn’t work for 2 days

Layout and Design:

- font size was too small and should be increased to support older individuals using the App
- weather forecast was not targeted towards the region of the participant, which would be more relevant information
- the quotes of the day were perceived as confusing as they were not related to anything

Ease of use:

- User profile: the keyboard blocks parts of the fields hindering the entry of data to the user profile (removing the keyboard is not intuitive for the participants)
- calendar: using the calendar was perceived as very complicated as adding and deleting any events didn't work properly

Utility:

- physical/ psychological limitations: choice of conditions and allergies was perceived as too extend and not much contributing to the use of the App; adding limitations regarding activities of daily living was perceived as more useful and relevant with respect to the target of the App
- preferences: additional preferences should be offered such as: gardening, grandchildren, family, choir, board games; provided topics should be subdivided (i.e. music: rock, jazz, classic etc.)
- events: sometimes, there were no events displayed in the App, some of the some events had already taken place in the past; deleting past events would support the using the App

Recommendation for technical partners

The feedback received from the participants (previously presented) was shared with all technical partners in a joint meeting. Thereby, it was collaboratively discussed how to address and mitigate the content of the users' feedback collected during the Phase 4. Special focus was given to issues related to the technical functioning. The technical partners made adjustments to the App and GEWI researchers tested these adaptations and shared their feedback in the regular meetings.

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's objective was to recruit 5 participants at the GEWI lead pilot site and 10 participants at the replicating sites AIAS, CCS and UP. The period of intervention was set for 3 months.

An overview of the intervention procedures serving as definition of the standard operating procedure has been developed prior to the start of the pilot activities as part of the study protocol and can be found attached to this document (Annex 19).

3.9.1 Recruitment

GEWI

Several recruitment activities were conducted/performed to draw attention to the project. These entailed displaying articles in regional newspapers and newsletters, using mailing lists and contacting relevant gatekeepers from the network by applying face-to-face recruitment.

Interested people made contact via mail or phone. A first screening of the responses was performed for potentially eligible participants. As interested participants actively contacted the research team, no consent of contact was be provided.

First communication about the pilot has been conducted via phone from the research team to present all relevant information and answer questions from the potential participants. Afterwards information sheets and consent forms (Annex 20 and 21) were sent out to eligible participants in case they still showed interest in the study.

Eligibility criteria

Inclusion criteria:

- person aged 65 years old or older at the time of recruitment
- living in the OBK
- living on their own
- self-reported capacity to use the App installed on the tablet
- self-reported capacity to consent
- has daily access to internet (WIFI or other 3 or 4G internet connection)

Exclusion criteria:

- none

Informed written consent was obtained in-person from all participants prior to the start of the pilot. Besides, all participants received a copy of the information sheet as well as a training in using the digital solution as well as a manual summarising relevant steps. Following the training, the informed consent forms were scanned from the researcher and shared with the participants as acknowledgment of reception. The original informed consent was then safely stored in a locked cupboard, that was only accessible for GEWI staff.

AIAS

AIAS research team presented the SHAPES project and the opportunity to participate to pilots' activities to support the development of digital solution technologies, during various activities that the association is carrying with the local community of older people such as the so-called "Sportello digitale (Digital help desk)", a supporting desk where people have the possibility to learn how to use digital technologies and how to access to the increasing numbers of digital public services, and the "Salotto Digitale", group meetings where people are introduced to the opportunities and risks of the digital world.

We gave all the information regarding the pilot activities and our contacts for the consensus to participate. A group meeting with all the potential participants that expressed interest was organised. The overall SHAPES project and the specific activity in which we asked to collaborate has been deepened and any questions raised from participants were answered. Once all the relevant information were provided by the team, we asked to who was willing to participate at the pilot activities to fill up the consent form and provide us with all the necessary information in order to set up the technological devices.

Eligibility criteria

Inclusion criteria:

- person aged 65 years old or older at the time of recruitment
- living on their own
- self-reported capacity to use the Apps installed on the tablet
- self-reported capacity to consent

Exclusion criteria:

- Inability to give an autonomous informed consent.

Informed written consent was obtained in-person from all participants prior to the start of the pilot. Besides, all participants received a copy of the information sheet and a copy of the informed consent form. The original informed consent was then safely stored in a locked cupboard, that is only accessible for AIAS staff and in a specific folder in AIAS server.

CCS

CCS performed several recruitment activities to create awareness for the project and to find suitable pilot participants for the testing. The following steps were taken by CCS to recruit participants for the pilot activities:

- Invitation of older individuals to the information event “senior citizen café” through a newspaper advertisement;
- Newspaper advertisement in a free regional newspaper (“Wochenkurier”);
- Presentation to participants from other CCS projects (HoCare2.0, GATEKEEPER);
- Recruitment in the context of CCS public relations (CCS newsletter, LinkedIn, Xing, CCS website);
- Recruitment in the personal environment of CCS employees.
- Enquiry with the pilot participants who have already taken part in the CCS lead pilot site

Eligibility criteria

Inclusion criteria:

- person aged 65 years old or older at the time of recruitment
- living in Dresden and the surrounding area (radius < 50km)
- living on their own or with a partner (cohabitation, marriage)
- self-reported capacity to use the App installed on the tablet
- self-reported capacity to consent
- has daily access to internet at home

Exclusion criteria:

- Lack of digital skills to use a tablet/smartphone
- Lack of internet access

A written consent form was obtained from all participants before the pilot activities started. This was signed by each participant and the original was stored in a locked cupboard at CCS premises. Only CCS staff had access to the originals. A copy was given to each participant.

In addition, all participants received an information sheet on the pilot action, training on how to use the digital solution and a manual summarising the relevant steps. The documents were provided by GEWI, adapted and also used by CCS.

UP

At UP participants were recruited through social networks of the Olomouc University Palacky. The older individuals were dispersed across different regions (but not all regions) of the Czech Republic.

Eligibility criteria

Inclusion Criteria

Participants were included if:

- Living independently in the community;
- Being 65 years old or older at the time of recruitment;
- Presenting mild to no cognitive impairment;
- Having daily access to Internet (WIFI or other 3 or 4G internet connection);
- Having their own self-reported capacity to use the Apps installed on the tablet;
- Having self-reported capacity to consent;

Exclusion Criteria

Potential participants were excluded if they reported:

- Not having their own self-reported capacity to use the Apps installed on the tablet;
- Taking drugs that could impair cognition in the past 3 months;
- Not having daily access to Internet (WIFI or other 3 or 4G internet connection);

Written consent was obtained from all participants and signed by each participant prior to the pilot activities. The originals of the consents were stored securely on the premises of UP and only UP staff had access to them. Each participant received one copy.

All participants were thoroughly familiarised with the pilot project and trained to use the digital solution.

3.9.2 Communication and dissemination of pilot activities

GEWI

All data collected within the pilot study are respectively owned by the organisation conducting the study, namely GEWI, AIAS, CCS and UP. After completion of the study, all collected data was analysed, processed and presented in Deliverable D6.3 as one of the deliverables of the SHAPES Innovation Action. This report will be public for review and accessible via the SHAPES website (www.shapes2020.eu). Participants were notified of the outcome of the study by the research team via mail or phone. GEWI will aim to disseminate the findings of the pilot study at conferences and other events as well as in the scientific papers and articles. GEWI will also seek to communicate the findings of this study via social media (LinkedIn, Instagram, GEWI website), 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. Therefore, appropriate Data Processing Agreements have been set up and signed by all partners to facilitate the sharing of pseudonymised data with specific SHAPES partners for specific purposes.

AIAS

AIAS, in line with GEWI's communication activities, will aim at disseminating the findings of the replicating pilots at conferences and other events related to health care technologies for older people.

CCS

CCS will disseminate the results of the pilot activities through CCS public relations (CCS newsletter, CCS website, LinkedIn, Xing). In addition, CCS will try to present the results at other relevant events and conferences. The pilot participants will receive a separate and summarised report in national language on the project results. In order to be able to use the data of the overall study for communication and dissemination, a Data Processing Agreement was signed between CCS and GEWI.

UP

UP will aim at disseminating the findings of the replicating pilots at conferences and other events related to health care technologies for older people.

3.9.3 Risk management

GEWI, AIAS, CCS, UP

All foreseeable data-related risks have been compiled into detailed risk assessment documents which form part of the Data Protection Impact Assessments for Phase 5. For each risk identified, a risk classification, root cause, name and consequences were assigned. Once identified, each risk was then analysed and scored from 1 (unlikely/minor)-4 (almost certain/critical) regarding their probability and impact. Subsequently, appropriate mitigation actions were assigned. These risks have been reviewed during the course of the deployment.

Besides, ethical approval has been achieved for UC-002 of Pilot 2. This approval process additionally enabled all contributors to identify any further risks as well as to find appropriate mitigation actions.

Finally, an ethics workshop has been conducted for UC-002 with all partners involved previous to the start of phase 5. This workshop allowed to jointly elaborate on potential risks and opportunities with respect to the ethical frameworks of SHAPES as well as to identify any mitigation actions.

3.9.4 Outcome of large-scale pilot activity

GEWI

Overview

The phase 5 large-scale pilot of the SHAPES UC-PT2-002 was conducted between September 2022 and January 2023 with 4 participants and 1 external care giver. All participants agreed to be supported by the external care giver. The external care giver was located in Cologne, was female and 45 years old

Socio-demographics of the participants:

Table 52: Baseline characteristics GEWI UC-PT2-002

Variables	Number of participants	Value
Age (years)	4 care receiver; (+1 care giver (CG))*	M = 73,25 SD = 3,59
Male	4	number = 1 (25%)

Technological skills:	4	Advanced user: 2 Beginners: 2
Country: Germany	4	100%
Marital status	4	Married: 2 Widowed: 2
Occupational status: retired	4	100%
Residence: own home	4	100%
*as the care receiver is not part of the actual target group it is not included in the table above		

Primary and secondary outcome

Primary outcome

The primary outcomes were to measure a predefined set of KPIs which have already been presented in chapter 3.5.2 as well as to evaluate the UC-PT2-002 use case using the MAST evaluation tool.

The following tables present the data used to determine the success of each KPI. Table 59 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 53: KPI 1 GEWI (UC-PT2-002)

Parameter	GEWI
Target number of participants	5
Number of participants recruited	5
Percentage recruited	100%

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

Table 54: KPI 2 GEWI (UC-PT2-002)

Parameter	GEWI
Number of participants at baseline	5
Number of withdrawals	0
Number of participants at end of study	5
Percentage retained	100%

PI 1 and KPI 2 were successfully achieved with 100%, meaning that the recruitment and engagement initiatives of GEWI were successful, not only in identifying interested and willing participants, fitted to the effort at play, but also that the strategy to maintain contact and provide support did make a positive impact on the absence of withdrawals, despite the length of the pilot.

Technical performance

KPI 3 There is no re-start* of any of the components of the technology for at least 90% of the days.

Table 55: KPI 3 GEWI (UC-PT2-002)

Parameter	Value
Number of participants without any re-start of any of the components of the technology	4
Total number of participants	4
Percentage of participants without re-starts	100%

*re-start refers to the deinstallation and re-installation of any of the components due to mal functioning. This does not include any update of an new version of the App.

KPI 3 was successfully achieved and no re-start of any of the components of the technology was needed. This shows, that the DSs were functioning well meaning that the collaboration between the technical partners, the intensive test phase 4 and the continuous development process have had a positive impact on the deployment of the technical solution in Phase 5.

User engagement and acceptance

KPI 4 The overall user experience quality of the App as measured using the short version of the User Experience Questionnaire (UEQ-S) was classified as ‘Excellent’, ‘Good’ or ‘Above average’ based on published benchmark data.

Table 56: KPI 4 GEWI (UC-PT2-002)

Scale	Mean	Comparison to benchmark
Pragmatic quality	1,125	50% of results better, 25% of results worse (below average)
Hedonic quality	0,5	50% of results better, 25% of results worse (below average)

Overall	0,81	50% of results better, 25% of results worse (below average)
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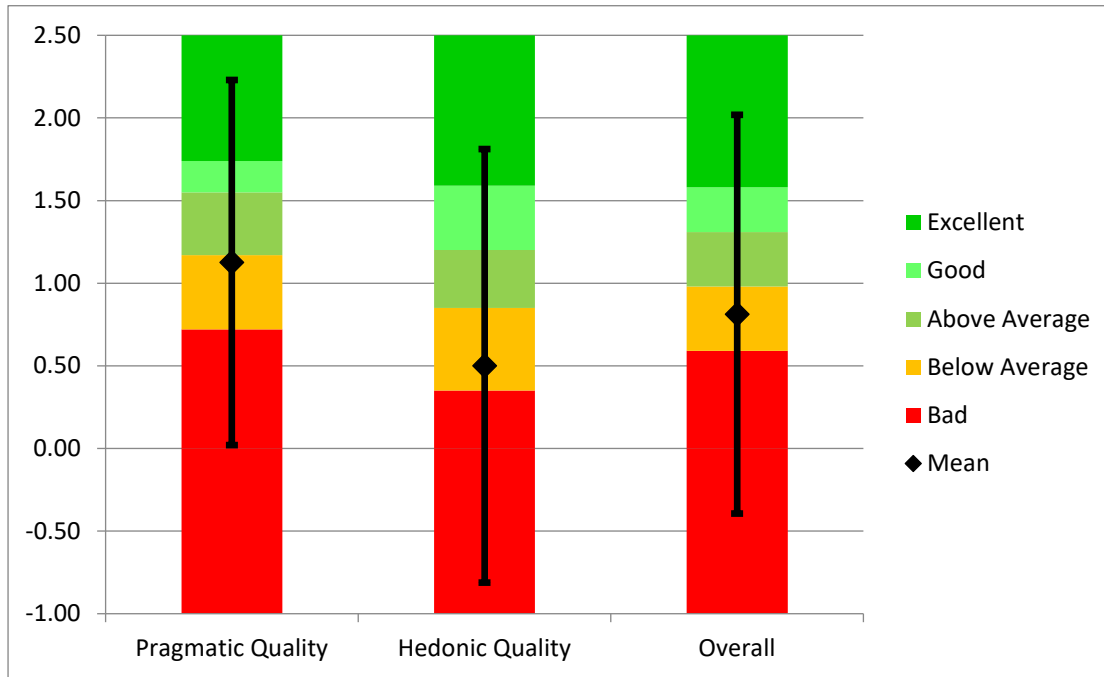


Figure 137: Mean UEQ-S and benchmark scores for the usability of the App GEWI (UC-PT2-002)

KPI 4 was not reached, as the overall user experience was rated as below average. Main concerns were related to the challenges in receiving recent events and activities. Despite high efforts, finding suitable regional websites was hardly possible, as most websites did not provide the requested RSS feed. According mitigation actions were taken, however only providing recent event to the participants was not possible at this stage. The DSs built on the quality and quantity of websites being integrated in the system. It has to be noted that the availability of websites fulfilling the requirements was not in the scope of the pilot.

KPI 5 At least 60% of participants continued to login to use the App daily after two weeks of the pilot.

Table 57: KPI 5 GEWI (UC-PT2-002)

Parameter	Value
Number of participants who logged in daily for at least 2 weeks after baseline	0
Total number of participants	4
Percentage using the App daily after two weeks	0%

The caregiver was not instructed to make daily use of the App is therefore not included in the table ahead.

KPI 5 was not achieved and none of the participants continued using the App after two weeks of the pilot on a daily base. This again was related to the lack of recent events, activities and news being available and accessible in the App. Such, using the App did offer only limited benefit for them and led to an infrequent use of it.

KPI 6 At least 60% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Table 58: KPI 6 GEWI (UC-PT2-002)

Parameter	Value
Number of participants at end of pilot	4
Number of participants scoring >68 in SUS	1
Percentage of participants scoring > 68 in SUS	25%

In line with KPI 4, KPI 6 was not reached as only 25% scored >68 in the SUS. Most participants reported that due to the limited availability of recent events, activities and news, the App was of less interest and use for them. It is noted that the availability of appropriate websites was outside the scope of the pilot. However, this also affected the participants' ranking of the DS's usability with an average value of 59,38 from 100 points.

Overview of KPI achievement

Table 59: Overview of KPI achievement GEWI (UC-PT2-002)

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	YES	Recruitment initiatives of GEWI were successful, related to the identification of interested and willing participants, who also fitted to the effort at play.
KPI 2	YES	Engagement initiatives of GEWI were successful, related to the strategy to maintain contact and provide support did make a positive impact on the absence of withdrawals, despite the length of the pilot.

KPI 3	YES	No re-start of any of the components of the technology was needed. This shows, that the DSs were functioning well and participants were able to engage with the DSs.
KPI 4	NO	The overall user experience was rated as below average. Main concerns were related to the challenges in receiving recent events and activities due to the limited availability of websites providing the requested RSS feed. It has to be noted that this was outside the scope of the pilot.
KPI 5	NO	None of the participants continued using the App after two weeks of the pilot on a daily base. This again was related to the lack of recent events, activities and news being available and accessible in the App. Such, using the App did offer only limited benefit for them and led to an infrequent use of it.
KPI 6	NO	Only 25% of the participants scored >68 in the SUS. Most participants reported that due to the limited availability of recent events, activities and news, the App was of less interest and use for them. It is to be noted that the availability of appropriate websites was outside the scope of the pilot. However, this also affected the participants' ranking of the DS's usability with an average value of 59,38 from 100 points.

Evaluation of MAST

The MAST framework as already introduced in chapter 3.4.2 was used to evaluate the effectiveness and contribution of UC-PT2-002 to quality of care. The evaluated data/outcome are presented in the table below:

Table 60: MAST Evaluation GEWI (UC-PT2-002)

MAST Domain	Topic	Outcome	Baseline (mean/SD)	End of pilot (mean/SD)	Chang in mean (SD)
Clinical Effectiveness	Mental health	OSSS-3 (social support) and life events	M = 11,5 SD = 1,00 Med = 11,00 Min = 11,00 Max = 13,00	M = 12,25 SD = 1,26 Med = 12,00 Min = 11,00 Max = 14,00	0,75 (0,26)

			“moderate social support”	“strong social support”	
	Effects on health-related quality of life	EQ-5D-5L scores	Health Status M = 82,50 SD = 9,57 Med = 85,00 Min = 70,00 Max = 90,00	Health Status M = 80,00 SD = 4,08 Med = 80,00 Min = 75,00 Max = 85,00	-2,5 (-5,49)
		WHOQOL-BREF scores	Domain 1 M = 81,50 SD = 11,50 Med = 81,5 Min = 69,00 Max = 94,00	Domain 1 M = 81,5 SD = 14,43 Med = 81,50 Min = 69,00 Max = 94,00	0 (2,93)
			Domain 2 M = 79,75 SD = 6,18 Med = 78,00 Min = 75,00 Max = 88,00	Domain 2 M = 78,00 SD = 3,46 Med = 78,00 Min = 75,00 Max = 81,00	-1,75 (-2,72)
			Domain 3 M = 59,5 SD = 14,84 Med = 59,50 Min = 44,00 Max = 75,00	Domain 3 M = 73,5 SD = 15,80 Med = 72,00 Min = 56,00 Max = 94,00	14 (0,96)
			Domain 4 M = 81,25 SD = 5,32 Med = 81,00 Min = 75,00 Max = 88,00	Domain 4 M = 81,5 SD = 11,50 Med = 81,50 Min = 69,00 Max = 94,00	0,25 (6,18)
	Patient perspectives	Satisfaction and acceptance	User Experience (UEQ-S scores)	/	M = 0,81 SD = 1,23
			User acceptance (TAM score)	/	Ease of use: M = 12,00 SD = 1,41 Med = 2,5 Min = 2 Max = 5
				Future use:	

				M = 14,00 SD = 1,00 Med = 3,0 Min = 3,0 Max = 5 Usefulness: M = 14,00 SD = 1,00 Med = 3 Min = 3 Max = 5	
	Understanding of information	Usability of application (SUS Scores)	/	M = 59,38 SD = 25,11 Med = 52,5 Min = 37,5 Max = 95	
	Confidence (in the treatment)				
	Ability to use the application	Usability of application (1-item health literacy)	M = 4,00 SD = 0,00 Med = 4 Min = 4 Max = 4	M = 4,00 SD = 0,82 Med = 4 Min = 3 Max = 5	0 (0,82)
	Access & Accessibility				
	Empowerment	User engagement (Number of logins)	This data has been continuously collected during the pilot to answer the research objectives and will thus be further presented with respect to the secondary outcomes.		
	Self-efficacy	Self-efficacy (SHAPES Participation questionnaire)	/	Participation in activities: M = 4,50 SD = 0,58 Med = 4,5 Min = 4 Max = 5	
				Effect of using DS on participation in activities: M = 3,75 SD = 0,50 Med = 4,0 Min = 3 Max = 4	

		Self-efficacy (GSES)	M = 32,25 SD = 1,50 Med = 33 Min = 30 Max = 33	M = 34,00 SD = 3,86 Med = 32,5 Min = 32 Max = 40	1,75 (2,36)
Economic aspects	Amount of resources used when delivering the application and comparators	Cost of devices	• Tablet: 328,57€ • Protective cover tablet: 13,99€		
		Cost of using digital solutions and SHAPES platform	• Electricity (charging the tablet): negligible (approx. 0,76 cents per charging) • Internet connection: negligible as most people already have internet access (Germany: 40€ per month) • Server Finot* • Server TREE*		
		Cost of staffing	• Travel cost: 160€ • Training Material (development and print): 285€ (5h à 50€ + 35€) • Training + end of study (preparation and deployment): 1500€ (30h à 50€) • User support via phone: 600€ (1h à 50€ per week for 12 weeks)		
* Not available as they were a customized solution and are not available at a commercial stage yet					

In the following the results of the baseline data is summarised. Any analysis and discussion of outcomes with respect to the impact will be part of the deliverables D6.9 and D6.10.

Considering the application of the WHOQOL-Bref questionnaire, the participants mostly perceived their physical health (Domain 1; m = 81,5), their psychological wellbeing (Domain 2; m = 79,75) and their living environment (Domain 4; m = 81,25) clearly above the norm of 73,5, 70,6 and 75,1 (13). This is further underpinned by the EQ-5D-5L VAS score. On its scale from 0 to 100 they indicated their health status at 82,50 on average. In contrast, they perceived their social relationships (Domain 3; m = 59,5) below the norm of 71,5 (13). According to the OSSS-3, the participants rated that they had moderate social support (m = 11,5). Following the results from the GSES, the participants pinpointed their perceived self-efficacy with 32,25 out of 40 points. The average of 4,0 out of 5 (HLM) indicate that the participants have a high level of health literacy.

The results from the questionnaires reflect the general understanding of the participants, that they were healthy and fit for their age.

Secondary outcomes

Besides, the pilot aimed at testing the capability of SHAPES platform and Digital Solutions to provide opportunities for supporting the interaction of the older individual with community.

Therefore the following primary and secondary objectives were defined within the study protocol:

Primary objectives

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

Secondary objectives

- To investigate the capability of the novel system to improve the feeling of loneliness and thus enhance the well-being of the older individuals (SO1)
- To investigate the capability of the novel system to inform older individuals about future events and activities, tailored to their preferences and/or to any of their psychophysical challenges (SO2).
- To investigate the association of number of interactions, contacts and attendance of events and the feeling of loneliness (SO3).
- To investigate the capability of the novel system to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects (SO4).
- To explore user trust and acceptance of the novel system (SO5).

Table 61: Objectives GEWI (UC-PT2-002)

PO1
To investigate user engagement with the novel system (PO1).
The user engagement with the novel system strongly varied between the different users. During the introduction training it was observed that those participants being more advanced in using technology (50%) were more confident in handling and navigating through the App. In the interviews it was reported by 2 participants, that they have used the DS almost on a daily basis but less during the course of the pilot whereas the others only rarely looked into the App. Reason for that were mainly referring to the challenges in having new and updated events and activities provided

by the App, strongly affecting the participants interest in using the DS. Half of the participant (n=2) also used the calendar function of the App for adding the event there. According to the user files, 2 of the booked events were actually attended which was also mentioned during the interviews. However, a final evaluation of these by awarding stars was not made.

The news were only screened eventually. Users explained, that some of the news articles provided were not accessible for free and asked for a membership. Besides, most users were also receiving a newspaper in paper format as they prefer to actually touch it. Thus, the news section was not of highest importance to them.

The video call feature Digiroom has not been tested during the pilot.

PO2

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

According to the UEQ-S the user experience quality of the App was rated as “below average”. Main feedback reported was targeting the challenges in receiving recent events and activities as most of those proposed in the App had already taken place in the past. Contrarily to the initial plan, expired events were not automatically deleted. The reason for this was the challenge of finding suitable regional websites that also provided an RSS feed. Since only one such website has been found, an alternative technical solution has been developed to have more websites being used from the DS. Nevertheless, the lack of websites with RSS feed entailed that events could no longer be deleted automatically after the date had expired. Manually deleting the expired events was perceived as annoying and frustrating by the users, due to the high number of events being displayed.

In the TAM, participants evaluation of the ease of use was varying (M= 3,0; Min=2; Max=5). Thereby, users with higher technological competences also delivered higher scores in the questionnaire. During the interview it was mentioned that the App was well structured. As a criticism, it was noted, that expired events were not deleted automatically which had to be done manually by the user. This was perceived as inconvenient. The automation of this process would much facilitate the handling of the App.

To further support the ease of use and attractiveness of the App, some more tailoring of information being displayed to the individual’s interests was suggested. This pre-selection by the systems was supposed to motivate the user to really screen the events section.

The usefulness of the App was rated with a medium score (M=3,50). As previously mentioned, the critique was referring to the lack of new and current information. In this respect it was stressed that the usefulness of the DS is strongly depending on the quality and variety of sources being included. However, the idea of providing information from different sources and platforms in one App is perceived as very beneficial and useful by the participants.

Additionally, it was suggested that synchronising the calendar from the App with the own mobile phone would further support the usefulness of the App. Such, the user could keep an overview of their schedule and furthermore receive reminders for any upcoming event.

Last but not least, some additional information regarding the accessibility, the transportation to the event or a map should be integrated in the App, to support individuals in interacting with society.

Part of the participants (n=3) saw a great potential in the DS and would like to use it in the future (M=3,5) if more updated and tailored events were included in the App.

The SUS was rated below the benchmark of >68 (M=59,38). Here again, the rating strongly varied between the participants. As there were no new events displayed, the participants shared their impression, that the DS was not working properly which further hindered their use.

SO1

To investigate the capability of the novel system to improve the feeling of loneliness and thus enhance the well-being of the older individuals (SO1)

Looking at the results collected from the ULS 6 questionnaires, the participants scores indicate little feelings of loneliness and isolation. Although the scores slightly improved from M=9,50 (SD=1,73) at baseline to M= 9,25 (SD=0,5) at the end of intervention (smaller score indicate less feelings of loneliness), this trend should not be overrated. In this respect, the small number of participants needs to be considered. Besides, it was mentioned, that using the App did not have much impact on the participant's interaction with society due to the lack of new information provided in the App. It was explained by most participants, that they already received news and information on regional events via different channels such as newspaper, WhatsApp groups or during regular meetings in their network.

The same trend of improvement was seen for the Flourishing scale with an change in mean of 0,25 (change in SD=-0,3), where higher scores indicate more psychological resources and strengths. This was further validated in the interviews as all study participants stated that they have already had a strong network of relatives and friends, were involved in volunteer activities and thus have already been interacting with others a lot.

Even though the participants themselves did not need any support in interacting with society, they found the basic idea of the App valuable and saw a great potential in it.

SO2

To investigate the capability of the novel system to inform older individuals about future events and activities, tailored to their preferences and/or to any of their psychophysical challenges (SO2).

The tailoring of information on events to the individuals' preferences was executed by the caregiver. In this respect the feedback has been shared, that only seeing the interests indicated in the App without knowing the user in person did not provide enough/profound information wherefore the recommendation of suitable activities was challenging. Besides, the participants articulated that automatically filtering the activities and events to the individual profile would have been beneficial for the selection of events and overall use of the App.

SO3

To investigate the association of number of interactions, contacts and attendance of events and the feeling of loneliness (SO3).

As previously explained, most of the activities and events displayed in the DS were expired wherefore the interaction with the App and the attendance of events was limited. Thus, no further conclusion can be drawn up to this stage.

However, most participants (N=3) could imagine that using such a App displaying current events could affect the feeling of loneliness

SO4

To investigate the capability of the novel system to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects (SO4).

The main results of the harmonisation questionnaires and its change in mean have been presented as part of the MAST evaluation (Table 60). Due to the limited number of participants (n=4) within this pilot the comparison of results from baseline to the end of pilot will not be performed per pilot site as drawing any conclusions from this would be misleading. Instead, some overall evaluation will be performed with data from all pilot sites as part of the upcoming D6.9 and D6.10.

As previously described, all participants have already been active and interacting with society a lot. However, it was mentioned in the interviews (n=2) that for people not being that active, using such a DS could indeed support them in participating in events. This could then affect their psychological health as they might be more satisfied.

SO5

To explore user trust and acceptance of the novel system (SO5).

The reaction towards the DS were differing. Some of the participants were especially focusing on the potential for people suffering from isolation or nursing staff caring for older people. Others clearly articulated, that they were not convinced and have had different expectations in the DS.

Recommendations for partners (from interviews)

The feedback from the users has been continuously collected throughout the pilot through observations, and notes taken during the direct or remote contact with the participants and the semi-structured interview at the end of the pilot.

- With respect to the target group of isolated people, a more personal and motivating wording as well as reminders would be more activating to attend events
- The DS would also be interesting for other target groups ex. nursing staff working in the ambulant setting, for them to propose any events to their patients. Besides, they could then support them.
- Additional information on regional support systems or other age related topics such as preventive medical check-ups, living will etc. would be interesting.

AIAS

Overview

The phase 5 large-scale pilot of the SHAPES UC-PT2-002 was conducted between September 2022 and January 2023 with 7 participants.

Socio-demographics of the participants:

Table 62: Baseline characteristics AIAS (UC-PT2-002)

Variables	Number of participants	Value (mean/SD)
Age (years)	7	72
Gender	7	Male = 3 Female =4
Technological skills	7	Advanced user: 7 Beginners:0
Country:	Italy	7
Marital status	7	Married: 4
Occupational Status: retired	7	7
Residence: own home	7	7

Primary and secondary outcome

The primary outcomes were to measure a predefined set of KPIs which have already been presented in chapter 3.5.2 as well as to evaluate the UC-PT2-002 use case using the MAST evaluation tool.

The following tables present the data used to determine the success of each KPI. Table 69 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 63: KPI 1 AIAS (UC-PT2-002)

Parameter	AIAS
Target number of participants	7
Number of participants recruited	7
Percentage recruited	100%

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

Table 64: KPI 2 AIAS (UC-PT2-002)

Parameter	AIAS
Number of participants at baseline	7
Number of withdrawals	0
Number of participants at end of study	7
Percentage retained	100%

KPI 1 and KPI 2 were successfully achieved with 100%, meaning that the recruitment and engagement initiatives of AIAS were successful, not only in identifying interested and willing participants, fitted to the effort at play, but also that the strategy to maintain contact and provide support did make a positive impact on the absence of withdrawals, despite the length of the pilot.

Technical performance

KPI 3 There is no re-start* of any of the components of the technology for at least 90% of the days.

Table 65: KPI 3 AIAS (UC-PT2-002)

Parameter	Value
Number of participants without any re-start of any of the components of the technology	7
Total number of participants	7
Percentage of participants without re-starts	100%

*re-start refers to the deinstallation and re-installation of any of the components due to mal functioning. This does not include any update of an new version of the App.

KPI 3 was successfully achieved and no re-start of any of the components of the technology was needed. This shows, that the DSs were functioning well meaning that the collaboration between the technical partners, the intensive test phase 4 and the continuous development process have had a positive impact on the deployment of the technical solution in Phase 5.

User engagement and acceptance

KPI 4 The overall user experience quality of the App as measured using the short version of the User Experience Questionnaire (UEQ-S) was classified as ‘Excellent’, ‘Good’ or ‘Above average’ based on published benchmark data.

Table 66: KPI 4 AIAS (UC-PT2-002)

Scale	Mean	Comparison to benchmark
Pragmatic quality	Not assessed	
Hedonic quality	Not assessed	
Overall	Not assessed	

The participants had difficulties in understanding and answering the UEQ-S questionnaires. To avoid frustration, the UEQ-S was not evaluated in paper format but rather addressed in the final focus group discussion (see Table 71).

KPI 5 At least 60% of participants continued to login to use the App daily after two weeks of the pilot.

Table 67: KPI 5 AIAS (UC-PT2-002)

Parameter	Value
Number of participants who logged in daily for at least 2 weeks after baseline	7
Total number of participants	7
Percentage using the App daily after two weeks	100%

KPI 5 was achieved and 100% of the participants continued using the App after two weeks of the pilot. This indicates that participants were able to handle and use the DSs on their own, and that it was possible for them to integrate it in their everyday life.

KPI 6 At least 60% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Table 68: KPI 5 AIAS (UC-PT2-002)

Parameter	Value
Number of participants at end of pilot	7
Number of participants scoring >68 in SUS	6
Percentage of participants scoring > 68 in SUS	86%

KPI 6 was achieved as 86% ranked the usability of the DSs >68 (m = 76,1). This reflects the participants' capability of handling and integrating the DSs in their everyday life. Furthermore, it gives an indication of the participants' willingness for future use, implying that the users recognise some positive effect of using the App for their daily living.

Overview of KPI achievement

Table 69: Overview of KPI achievement AIAS (UC-PT2-002)

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	YES	Recruitment initiatives of AIAS were successful, related to the identification of interested and willing participants, who also fitted to the effort at play.
KPI 2	YES	Engagement initiatives of AIAS were successful, related to the strategy to maintain contact and provide support did make a positive impact on the absence of withdrawals, despite the length of the pilot.
KPI 3	YES	No re-start of any of the components of the technology was needed. This shows that the DSs were functioning well and participants were able to engage with the DSs.
KPI 4	Not assessed	Participants had difficulties in understanding and answering the UEQ-S questionnaires. To avoid frustration, topics of the UEQ-S were only addressed in the final focus group discussion.

KPI 5	YES	Participants were able to handle and use the DSs on their own, and that it was possible for them to integrate it in their everyday life.
KPI 6	YES	86% of the participants ranked the usability of the DSs >68 (m = 76,1). This reflects the participants' capability of handling and integrating the DSs in their everyday life. Furthermore, it gives an indication of the participants' willingness for future use, implying that the users recognise some positive effect of using the App for their daily living.

Evaluation of MAST

The MAST framework as already introduced in chapter 2.4.2 was used to evaluate the effectiveness and contribution of UC-PT2-002 to quality of care. The evaluated data/outcome are presented in the table below:

Table 70: MAST Evaluation AIAS (UC-PT2-002)

MAST Domain	Topic	Outcome	Baseline (mean/SD)	End of pilot (mean/SD)	Chang in mean (SD)
Clinical Effectiveness	Mental health	OSSS-3 (social support) and life events	M = 9.6 SD = 0.8 Med = 9 Min = 9 Max = 11 Moderate Social support	M = 9.1 SD = 0.4 Med = 9 Min = 9 Max = 10 Moderate Social support	-0.5 (-0.4)
	Effects on health-related quality of life	EQ-5D-5L VAS Score	Health Status Not assessed	Health Status M = 75 SD = 16 Med = 80 Min = 40 Max = 85	
		WHOQOL-BREF scores	Domain 1 M = 71.4 SD = 17.9 Med = 81 Min = 38 Max = 88	Domain 1 M = 69 SD = 14.4 Med = 69 Min = 44 Max = 88	-2.4 (-3.5)

Patient perspectives			Domain 2 M = 64.3 SD = 13.8 Med = 69 Min = 50 Max = 81	Domain 2 M = 57.4 SD = 13.2 Med = 63 Min = 38 Max = 69	-6.9 (-0.6)
			Domain 3 M = 60.9 SD = 12.9 Med = 69 Min = 44 Max = 75	Domain 3 M = 53.6 SD = 11.2 Med = 56 Min = 44 Max = 75	-7.3 (-1.7)
			Domain 4 M = 68.9 SD = 10.1 Med = 69 Min = 50 Max = 81	Domain 4 M = 66.4 SD = 10.2 Med = 63 Min = 56 Max = 88	-2.5 (0.1)
	Satisfaction and acceptance	User Experience (UEQ-S scores)	/	n/a	
		User acceptance (TAM score)		Future use: M = 4.4 SD = 0.8 Med = 5 Min = 3 Max = 5	
				Usefulness: M = 3.7 SD = 1.5 Med = 4 Min = 1 Max = 5	
	Understanding of information	Usability of application (SUS Scores)	/	M = 76.1 SD = 8.1 Med = 72.5 Min = 47.5 Max = 100	
	Confidence (in the treatment)				
	Ability to use the application	Usability of application (1-item health literacy)	M = 3.7 SD = 1.1 Med = 4 Min = 2 Max = 5	M = 3.7 SD = 1 Med = 4 Min = 2 Max = 5	0 (-0.1)
	Access & Accessibility				

	Empowerment Self-efficacy	User engagemen t (Number of logins)	This data has been continuously collected during the pilot to answer the research objectives and will thus be further presented with respect to the secondary outcomes.		
		Self- efficacy (SHAPES Participatio n questionna ire)	/	Participation in activities: M = 3.7 SD = 0.5 Med = 4 Min = 3 Max = 4	
				Effect of using DS on participation in activities: M = 3.4 SD = 1 Med = 3 Min = 2 Max = 5	
		Self- efficacy (GSES)	M = 28.1 SD = 3 Med = 28 Min = 27 Max = 39	M = 25.1 SD = 4.5 Med = 25 Min =11 Max = 40	-3 (1.5)
Economic aspects	Amount of resources used when delivering the application and comparators	Cost of devices	• Tablet: 328,57€ • Protective cover tablet: 13,99€		
		Cost of using digital solutions and SHAPES platform	See Table 60		
		Cost of staffing	See Table 60		
* Not available as they were a customized solution and are not available at a commercial stage yet					

In the following the results of the baseline data is summarised. Any analysis and discussion of outcomes with respect to the impact will be part of the deliverables D6.9 and D6.10.

Considering the application of the WHOQOL-Bref questionnaire, the participants mostly perceived that their physical health (Domain 1; $m = 71,4$), their psychological wellbeing (Domain 2; $m = 64,3$), their social relationships (Domain 3; $m = 60,9$) and also their living environment (Domain 4; $m = 68,9$) were below the norm (Domain 1: 73,5; Domain 2: 70,6; Domain 3: 71,5; Domain 4: 75,1) (13). According to the OSSS-3, the participants perceived that they had moderate social support ($m = 9,6$) and in the GSES, the participants rated their perceived self-efficacy with 28,1 out of 40 points. The average of 3,7 out of 5 (HLM) indicated that the participants had a higher level of health literacy.

The results from the questionnaires reflect the general understanding of the participants, that they were rather healthy and fit for their age even though their evaluation showed slightly lower values.

Secondary outcomes

In line with GEWI's study protocol, the same objectives were examined and objectives collected by AIAS.

Table 71: Objectives AIAS (UC-PT2-002)

PO1
To investigate user engagement with the novel system (PO1).
Initially, the App aroused a lot of interest among the participants who started to use it consistently. Use declined over time due to some technical issues, which were resolved following the latest updates to the App.
It was appreciated by users that in order to test the App, in addition to their individual use of it, weekly meetings were organised between all the participants in the trial (7 users) and two AIAS Bologna staff members (one technical and one social/health). Thanks to these, it was possible to maintain a high level of engagement, discussing the various functions of the App, reflecting together on how to improve them, assisting in the event of technical problems and keeping track of the whole testing process. These meetings were also an opportunity for the participants to learn new functions of the technological tool at their disposal (tablet) and about other topics related to the App.
PO2
To investigate the user-perceived usefulness of the novel system (PO2).
Participants stated the idea is very nice and interesting, it should however be enriched a little bit with local news and information depending on the location.
If the information was more localized, it would help develop new interests with respect to what the area offers and would inform you how to access it. If news

were complementary to interests it would be a nice enrichment so that people would open the App not only for events but also for news, for example neighbourhood or all neighbourhoods

This application could be stimulating to get more involved and participate in more events.

SO1

To investigate the capability of the novel system to improve the feeling of loneliness and thus enhance the well-being of the older individuals (SO1)

Even if the participants were active people with a strong network and many interests, the weekly meetings helped a lot in improving their feeling of well-being. A small community was created and they started to meet and participate at social events together.

They stated that the App would have been more inspiring if it were more complete and intuitive but could be stimulating to get more involved and participate in more events.

SO2

To investigate the capability of the novel system to inform older individuals about future events and activities, tailored to their preferences and/or to any of their psychophysical challenges (SO2).

One of the most frequently expressed needs is a "filter" function to skim the events, finding those of a specific theme more quickly. It was also suggested to think of an initial interface where the thematic categories of events would appear, so that one could click on a specific category within which one could find all the events available for that theme (like a dashboard with boxes for each theme i.e. ballet, art, etc. instead of having to scroll through many events of mixed themes).

SO3

To investigate the association of number of interactions, contacts and attendance of events and the feeling of loneliness (SO3).

Most of the activities and events displayed in the DS were not completely focussed on the personal interests of the participants.

However, most participants could imagine that using such a App displaying current events could increase their participations at events.

SO4

To investigate the capability of the novel system to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects (SO4).

The main results of the harmonisation questionnaires and its change in mean have been presented as part of the MAST evaluation (Table 70). Due to the limited number of participants (n=7) within this pilot the comparison of results from baseline to the end of pilot will not be performed per pilot site as drawing any conclusions

from this would be misleading. Instead, some overall evaluation will be performed with data from all pilot sites as part of the D6.9 and D6.10.

The weekly meeting however, were really appreciated by the participants and we continue with them also after pilot end.

SO5

To explore user trust and acceptance of the novel system (SO5).

The users' interviews highlighted how the DS have a great potential but it needs to be improved in some aspect related to accessibility and usability.

Recommendations for partners (from interviews)

AIAS was constantly in contact with the technical partner, and reported bugs and feedback continuously during the pilot period.

Main feedback collected reported:

- It could be useful to have a place to write notes and also save interesting sites.
- mobility information could be included in the App (i.e. How to get to the event, transport, parking, etc.)
- Accompany writings with icons to make everything clearer.
- Comments were also made on the layout of the interface, which was considered to be out of proportion in some parts (on the main screen, for example, a request was made to reduce the size of the weather to give more space to the news, which was considered to be of greater relevance.)

CCS

Overview

The phase 5 large-scale pilot of the SHAPES UC-PT2-002 was conducted between February 2023 and April 2023 with 4 participants. The main time of the test phase had to be used to ensure the functionality of the App with the technology partner. Neither messages nor events were displayed. When these functions were possible, only a few events were displayed. This problem could not be solved until the end.

Socio-demographics of the participants

Table 72: Baseline characteristics CCS (UC-PT2-002)

Variables	Number of participants	Value
Age (years)	4 care receiver; (+2 care giver (CG))*	Average age care receiver = 72 Average age care giver = 37
Male	3	50%
Female	3	50% (including 2 female care giver)
Technological skills:	6	Advanced user: 6 (including CG)
Country: Germany	6	100%
Marital status	6	Married: 4 Divorced: 1 Widowed: 1
Occupational status	4 retired 2 employed full-time	100 % care receiver 100 % care giver
Residence: own home	6	100%

Primary and secondary outcome

The following tables present the data used to determine the success of each KPI. Table 79 provides an overview of the success of the pilot with regards to KPIs.

User engagement and acceptance Recruitment and retention

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

Table 73: KPI 1 CCS (UC-PT2-002)

Parameter	CCS
Target number of participants	6
Number of participants recruited	6
Percentage recruited	100%

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

Table 74: KPI 2 CCS (UC-PT2-002)

Parameter	CCS
Number of participants at baseline	6
Number of withdrawals	0
Number of participants at end of study	6
Percentage retained	100%

KPI 1 and KPI 2 were successfully achieved with 100%, meaning that the recruitment and engagement initiatives of CCS were successful, not only in identifying interested and willing participants, fitted to the effort at play, but also that the strategy to maintain contact and provide support did make a positive impact on the absence of withdrawals, despite the length of the pilot.

Technical performance

KPI 3 There is no re-start* of any of the components of the technology for at least 90% of the days.

Table 75: KPI 3 CCS (UC-PT2-002)

Parameter	Value
Number of participants without any re-start of any of the components of the technology	5
Total number of participants	6
Percentage of participants without re-starts	83,3%

*re-start refers to the deinstallation and re-installation of any of the components due to mal functioning. This does not include any update of an new version of the App.

to mal functioning. This does not include any update of an new version of the App.

KPI 3 was not achieved as for 83,3% of participants, re-starting the DSs was needed due to mal functioning of the App and challenges in receiving recent events, activities and news. To eliminate any technical reasons leading to this issue, a re-start was forced for one participants.

KPI 4 The overall user experience quality of the App as measured using the short version of the User Experience Questionnaire (UEQ-S) was classified as ‘Excellent’, ‘Good’ or ‘Above average’ based on published benchmark data.

Table 76: KPI 4 CCS (UC-PT2-002)

Scale	Mean	Comparison to benchmark
Attractiveness	-1,28	Bad; In the range of the 25% worst results.
Pragmatic quality	-1,28	Bad; In the range of the 25% worst results.
Hedonic quality	-1,04	Bad; In the range of the 25% worst results.
Overall	-1,2	Bad; In the range of the 25% worst results.

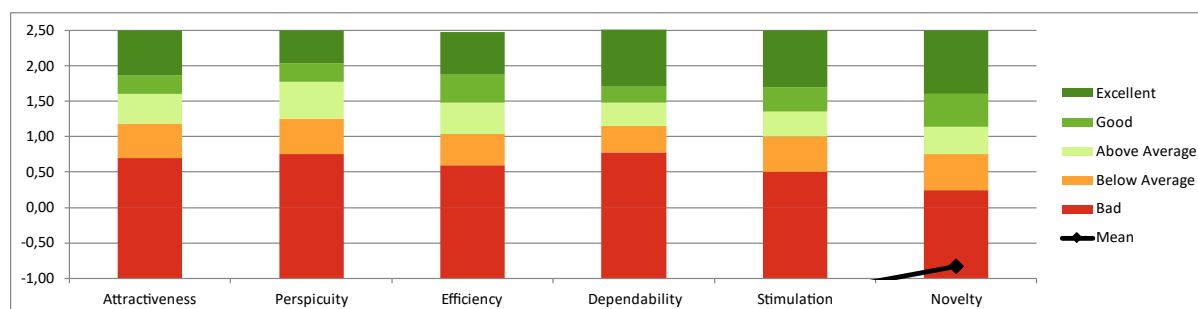


Figure 138: Mean UEQ and benchmark scores for the usability of the App CCS (UC-PT2-002)

KPI 4 was not reached, as the overall user experience was rated as bad. Main concerns were related to the challenges in receiving recent events and activities. Besides, user had difficulties in handling and using the App as it was not perceived as intuitive for them.

KPI 5 At least 60% of participants continued to login to use the App daily after two weeks of the pilot.

Table 77: KPI 5 CCS (UC-PT2-002)

Parameter	Value
Number of participants who logged in daily for at least 2 weeks after baseline	0
Total number of participants	6
Percentage using the App daily after two weeks	0%

KPI 5 was not achieved and none of the participants continued using the App after two weeks of the pilot on a daily base. This again was related to the lack of recent events, activities and news being available and accessible in the App. Furthermore, this

reflects that the participants encountered challenges in handling the App and that it was hard for them to integrate it in their everyday life.

KPI 6 At least 60% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Table 78: KPI 6 CCS (UC-PT2-002)

Parameter	Value
Number of participants at end of pilot	6
Number of participants scoring >68 in SUS	0
Percentage of participants scoring > 68 in SUS	0%

In line with KPI 4, KPI 6 was not reached as none of the participants scored >68 in the SUS. Most of them reported that due to the limited availability of recent events, activities and news, the App was of less interest and use for them. Besides, they encountered challenges in handling the App impeding the use of it and the integration in their everyday life.

Overview of KPI achievement

Table 79: Overview of KPI achievement CCS (UC-PT2-002)

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	YES	Recruitment initiatives of CCS were successful, related to the identification of interested and willing participants, who also fitted to the effort at play
KPI 2	YES	Engagement initiatives of CCS were successful, related to the strategy to maintain contact and provide support did make a positive impact on the absence of withdrawals, despite the length of the pilot.
KPI 3	NO	For one participant, re-starting the DSs was needed due to mal functioning of the App and challenges in receiving recent events, activities and news. To eliminate any technical reasons leading to this issue, a re-start was forced for 1 participant.

KPI 4	NO	Overall user experience was rated as bad. Main concerns were related to the challenges in receiving recent events and activities. Besides, user had difficulties in handling and using the App as it was not perceived as intuitive for them.
KPI 5	NO	None of the participants continued using the App after two weeks of the pilot on a daily base, due to the lack of recent events, activities and news being available and accessible in the App. Furthermore, this reflects that the participants encountered challenges in handling the App and that it was hard for them to integrate it in their everyday life.
KPI 6	NO	None of the participants scored >68 in the SUS. Most of them reported that due to the limited availability of recent events, activities and news, the App was of less interest and use for them. Besides, they encountered challenges in handling the App impeding the use of it and the integration in their everyday life.

Evaluation of MAST

The MAST framework as already introduced in chapter 2.4.2 was used to evaluate the effectiveness and contribution of UC-PT2-002 to quality of care. The evaluated data/outcome for CCS are presented in the table below:

Table 80: MAST Evaluation CCS (UC-PT2-002)

MAST Domain	Topic	Outcome	Baseline (mean/SD)	End of pilot (mean/SD)	Chang in mean
Clinical Effectiveness	Mental health	OSSS-3 (social support) and life events	M = 12,3 SD = 0,47 Med = 12 Min = 12,00 Max = 13,00 “strong social support”	M = 12,3 SD = 0,47 Med = 12 Min = 12,00 Max = 13,00 “strong social support”	No change

	Effects on health-related quality of life	EQ-5D-5L - VAS	Health Status M = 93,3 SD = 4,71 Med = 90 Min = 90 Max = 100	Health Status M = 93,3 SD = 4,71 Med = 90 Min = 90 Max = 100	No change
		WHOQOL-BREF scores	Domain 1 M = 88,83 SD = 4,83 Med = 88,0 Min = 81 Max = 94	Domain 1 M = 88,83 SD = 4,83 Med = 88,0 Min = 81 Max = 94	No change
			Domain 2 M = 92 SD = 3,10 Med = 94,0 Min = 88 Max = 94	Domain 2 M = 92 SD = 3,10 Med = 94,0 Min = 88 Max = 94	No change
			Domain 3 M = 81 SD = 0 Med = 81 Min = 81 Max = 81	Domain 3 M = 81 SD = 0 Med = 81 Min = 81 Max = 81	No change
			Domain 4 M = 85,67 SD = 3,61 Med = 88 Min = 81 Max = 88	Domain 4 M = 85,67 SD = 3,61 Med = 88 Min = 81 Max = 88	No change
Patient perspectives	Satisfaction and acceptance	User Experience (UEQ-S scores)	/	M = -1,2 SD = 0,11	
		User acceptance (TAM score)	/	Ease of use: M = 2 SD = 0 Med = 2 Min = 2 Max = 2	

				Future use: M = 1 SD = 0 Med = Min = 1 Max = 1	
				Usefulness: M = 2 SD = 0 Med = 2 Min = 2 Max = 2	
	Understanding of information Confidence (in the treatment) Ability to use the application Access & Accessibility	Usability of application (SUS Scores)	/	M = 18,8 SD = 1,79 Med = 15 Min = 15 Max = 17,5	
		Usability of application (1-item health literacy)	M = 4,00 SD = 0 Med = 4,00 Min = 4,00 Max = 4,00	M = 4,00 SD = 0 Med = 4,00 Min = 4,00 Max = 4,00	No change
	Empowerment Self-efficacy	User engagement (Number of logins)	This data has been continuously collected during the pilot to answer the research objectives and will thus be further presented with respect to the secondary outcomes.		
		Self-efficacy (SHAPES Participation questionnaire)	/	/	
		Self-efficacy (GSES)	M = 38 SD = 0 Med = 38 Min = 38 Max = 38	M = 38 SD = 0 Med = 38 Min = 38 Max = 38	No change
Economic aspects	Amount of resources used when delivering the application and comparators	Cost of devices	<ul style="list-style-type: none"> Tablet: 269,99€ + 19% VAT Protective cover tablet: 13,99€ + 19% VAT 		
		Cost of using digital solutions and SHAPES platform	See Table 60		
		Cost of staffing	See Table 60		

In the following the results of the baseline data is summarised. Any analysis and discussion of outcomes with respect to the impact will be part of the deliverables D6.9 and D6.10.

Considering the application of the WHOQOL-Bref questionnaire, the participants mostly perceived their physical health (Domain 1; $m = 88,83$), their psychological wellbeing (Domain 2; $m = 92$), their social relationships (Domain 3; $m = 81,00$) and living environment (Domain 4; $m = 85,67$) clearly above the norm (13). This is further underpinned by the results of the EQ-5D-5L VAS score. On its scale from 0 to 100 they indicated their health status at 93,30 on average. According to the OSSS-3, the participants perceived that they had strong social support ($m = 12, 3$) and in the GSES, they pinpointed their perceived self-efficacy with 38 out of 40 points. The average of 4 out of 5 (HLM) indicated that the participants have a high level of health literacy.

The results from the questionnaires reflect the general understanding of the participants, that they were healthy and fit for their age.

Recommendations for partners (from interviews)

Overall, the participants' assessment of the technical solution (event App) was very negative:

- System Usability Scale (SUS): The average SUS - Score was 15,8 which shows that the usability was evaluated very poor
- UEQ: The results show that the participants' responses tended to be negative, i.e. the solution was rated as rather complicated and incomprehensible. Table 6 provides an overview about the items:

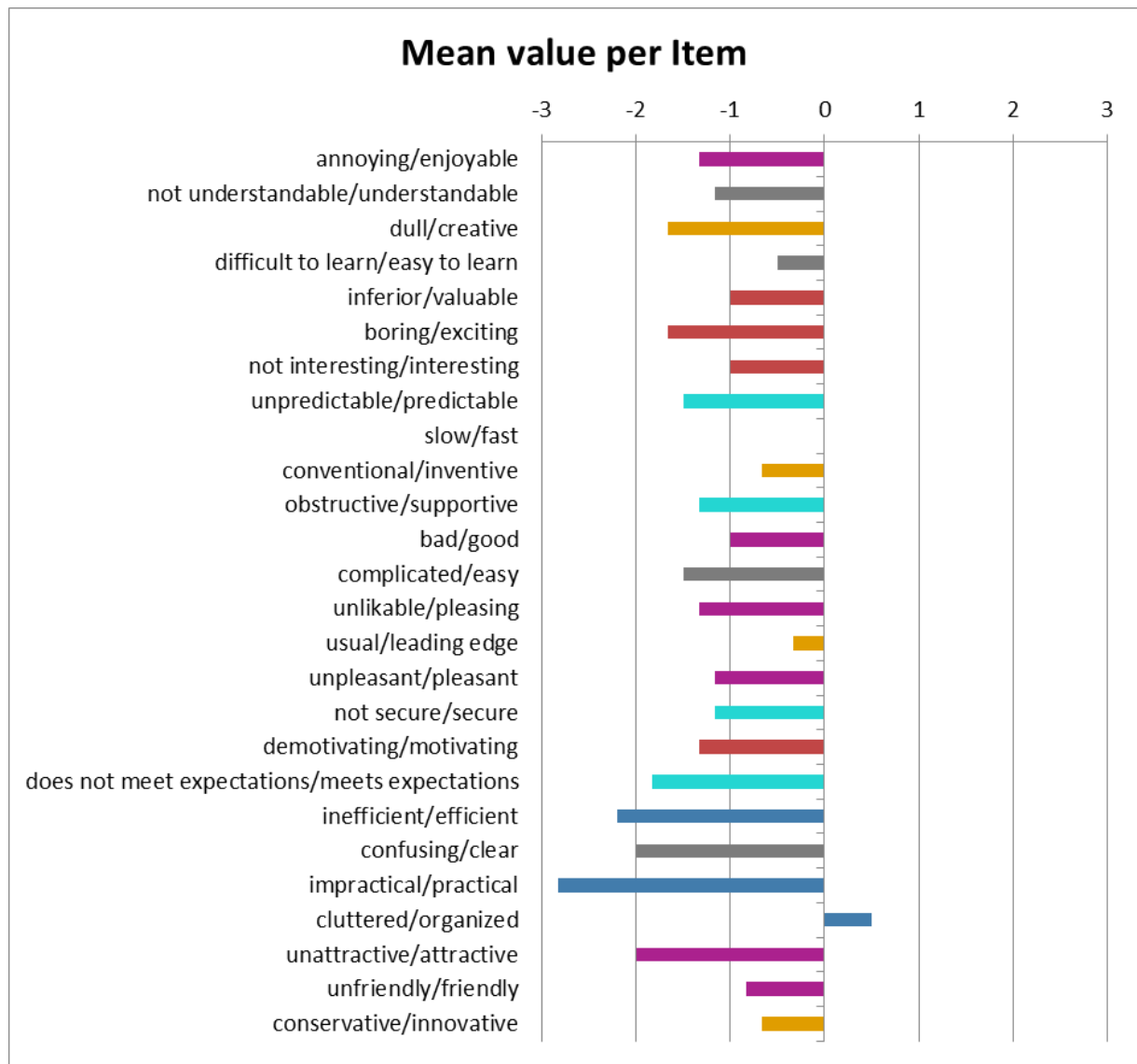


Figure 139: UEQ Result of CCS participants

- Technology Acceptance Model (TAM): Currently, the participants do not see any benefit in the application, although the basic idea is not bad. None of the participants would use the technology in the future, as there are enough sites to find out about events and news is displayed anyway.

The App is very difficult to use without prior training and even with training it was very difficult for the participants. The App is not intuitive to use because of the following things:

- Login data cannot be saved

- Menu is hard to find (only by swiping on the screen)
- Manual entries in the calendar are only possible by long "pressing" the date (if nothing happens when clicking, the users think the App does not work)
- Calendar is very hard to find
- Symbols are very small (numbers in the calendar)

The application is not very user-friendly. Overall, the layout and design is not very appealing for the test users. In addition, many events are not displayed and the news are duplicated. If the events are filtered by interest, only 1-4 events are displayed. They are the same for several days. The App does not have to be used every day, as news and weather are also displayed on the smartphone or tablet. Overall, the test users do not see any added value in the application at this stage. The application should be revised by the developer. For example, more functions should be added:

- Synchronisation with the calendar on the smartphone;
- Reminders in the form of push notifications;
- Event recommendations as push notification;
- When certain events are viewed, automatic recommendations for similar events should be given;
- There should be the possibility for people to use the App even if they don't have a caregiver who can recommend events.

UP

Overview

The phase 5 large-scale pilot of the SHAPES UC-PT2-002 was conducted between February and May 2023 with 6 participants – one caregiver and 5 older people. Much of the time was used to ensure the functionality of the application with the technology partner. At first, only events from Prague were displayed (which was very far for all participants) and it was not possible to use the App to make phone calls. These shortcomings were then eliminated, and the App at least displayed news from the regions of the older people and events from more distant cities from the participants. The problem with events could not be solved until the end.

Socio-demographics of the participants:

Table 81: Baseline characteristics UP (UC-PT2-002)

Variables	Number of participants	Value (mean/SD)
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Age (years)	5	72,8 (6,76)
male	5	Number = 0 (0%)
Country: Czech republic	5	100 %
Technological skills:	5	Advanced user: 3 Beginners: 2
Marital status	5	Married: 2 Widowed: 2 Divorced: 1
Occupational status: retired	5	100%
Residence:	own home: 4 caregivers home: 1	80% 20%

Primary and secondary outcome

The primary outcomes were to measure a predefined set of KPIs which have already been presented in chapter 3.5.2 as well as to evaluate the UC-PT2-002 use case using the MAST evaluation tool.

The following tables present the data used to determine the success of each KPI. Table 88 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 82: KPI 1 UP (UC-PT2-002)

Parameter	UP
Target number of participants	5
Number of participants recruited	5
Percentage recruited	100%

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

Table 83: KPI 2 UP (UC-PT2-002)

Parameter	UP
Number of participants at baseline	5
Number of withdrawals	0
Number of participants at end of study	5
Percentage retained	100%

KPI 1 and KPI 2 were successfully achieved with 100%, meaning that the recruitment and engagement initiatives of UP were successful, not only in identifying interested and willing participants, fitted to the effort at play, but also that the strategy to maintain contact and provide support did make a positive impact on the absence of withdrawals, despite the length of the pilot.

Technical performance

KPI 3 There is no re-start* of any of the components of the technology for at least 90% of the days.

Table 84: KPI 3 UP (UC-PT2-002)

Parameter	Value
Number of participants without any re-start of any of the components of the technology	2
Total number of participants	5
Percentage of participants without re-starts	40%

*re-start refers to the deinstallation and re-installation of any of the components due to mal functioning. This does not include any update of an new version of the App.

KPI 3 was not achieved as for 60% of participants, re-starting the DSs was needed due to mal functioning of the App and challenges in receiving recent events, activities and news. To eliminate any technical reasons leading to this issue, a re-start was forced for 60% participants.

User engagement and acceptance

KPI 4 The overall user experience quality of the App as measured using the short version of the User Experience Questionnaire (UEQ-S) was classified as ‘Excellent’, ‘Good’ or ‘Above average’ based on published benchmark data.

Table 85: KPI 4 UP (UC-PT2-002)

Scale	Mean	Comparison to benchmark
Pragmatic quality	-2	Bad; In the range of the 25% worst results.
Hedonic quality	-2,75	Bad; In the range of the 25% worst results.

Overall	-1,93	Bad; In the range of the 25% worst results.
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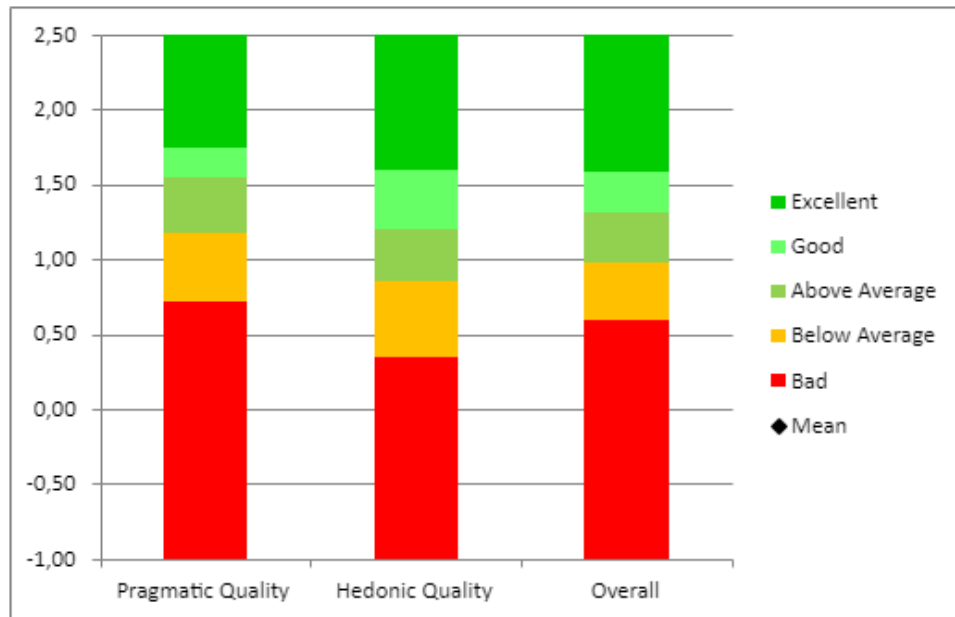


Figure 140: Mean UEQ-S and benchmark scores for the usability of the App UP (UC-PT2-002)

KPI 4 was not reached, as the overall user experience was rated as bad. Main concerns were related to the challenges in receiving recent events and activities from the participants' region. Despite high efforts, finding suitable regional websites was hardly possible, as the participants live in small village and rural areas where little events take place. However, the DSs built on the availability of high-quality websites providing regional events that can be integrated in the system. It has to be noted that the availability of websites was not in the scope of the pilot.

KPI 5 At least 60% of participants continued to login to use the App daily after two weeks of the pilot.

Table 86: KPI 5 UP (UC-PT2-002)

Parameter	Value
Number of participants who logged in daily for at least 2 weeks after baseline	3
Total number of participants	5
Percentage using the App daily after two weeks	60%

KPI 5 was achieved and 60% of the participants continued using the App after two weeks of the pilot. This indicates that participants were able to handle and use the DSs on their own, and that it was possible for them to integrate it in their everyday life.

KPI 6 At least 60% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Table 87: KPI 6 UP (UC-PT2-002)

Parameter	Value
Number of participants at end of pilot	5
Number of participants scoring >68 in SUS	0
Percentage of participants scoring > 68 in SUS	0%

In line with KPI 4, KPI 6 was not reached as none of the participants scored >68 in the SUS. Most of them reported that due to the limited availability of regional events, activities and news, the App was of less interest and use for them. It is noted that the availability of appropriate websites was outside the scope of the pilot. However, this also affected the participants' ranking of the DS's usability with an average value of 48,2 from 100 points.

Overview of KPI achievement

Table 88: Overview of KPI achievements UP (UC-PT2-002)

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	YES	Recruitment initiatives of UP were successful, related to the identification of interested and willing participants, who also fitted to the effort at play.
KPI 2	YES	Engagement initiatives of UP were successful, related to the strategy to maintain contact and provide support did make a positive impact on the absence of withdrawals, despite the length of the pilot.
KPI 3	NO	For 60% of participants, re-starting the DSs was needed due to mal functioning of the App and challenges in receiving recent events, activities and news. To eliminate any

		technical reasons leading to this issue, a re-start was forced for 60% participants.
KPI 4	NO	Overall user experience was rated as bad, due to challenges in receiving recent events and activities from the participants' region. Despite high efforts, finding suitable regional websites was hardly possible, as the participants live in small village and rural areas where little events take place. However, the DSs built on the availability of high-quality websites providing regional events that can be integrated in the system. It has to be noted that the availability of websites was not in the scope of the pilot.
KPI 5	YES	Participants were able to handle and use the DSs on their own, and that it was possible for them to integrate it in their everyday life.
KPI 6	NO	None of the participants scored >68 in the SUS, due to the limited availability of regional events, activities and news, the App was of less interest and use for them. It is noted that the availability of appropriate websites was outside the scope of the pilot. However, this also affected the participants' ranking of the DS's usability with an average value of 48,2 from 100 points.

Evaluation of MAST

The MAST framework as already introduced in chapter 2.4.2 was used to evaluate the effectiveness and contribution of UC-PT2-001 to quality of care. The evaluated data/outcome are presented in the table below:

Table 89: MAST Evaluation UP (UC-PT2-002)

MAST Domain	Topic	Outcome	Baseline (mean/SD)	End of pilot (mean/SD)	Change in mean (SD)
Clinical Effectiveness	Mental health	OSSS-3 (social support) and life events	M = 6,8 SD = 1,79 Med = 7,00 Min = 5,00 Max = 9,00 "poor social support"	M = 7,8 SD = 1,79 Med = 9,00 Min = 5,00 Max = 9,00 "poor social support"	1 (0)

	Effects on health-related quality of life	EQ-5D-5L scores	Health Status M = 86,2 SD = 4,60 Med = 88 Min = 78 Max = 89	Health Status M = 85,6 SD = 11,9 Med = 89 Min = 69 Max = 97	0,6 (-7,3)
		WHOQOL-BREF scores	Domain 1 M = 59 SD = 17,79 Med = 63 Min = 38 Max = 81	Domain 1 M = 72,2 SD = 8,64 Med = 69 Min = 63 Max = 88	13,2 (-9,15)
			Domain 2 M = 75 SD = 18,67 Med = 81 Min = 44 Max = 94	Domain 2 M = 70,8 SD = 18 Med = 75 Min = 44 Max = 94	-4,2 (-0,67)
			Domain 3 M = 66,2 SD = 20,57 Med = 56 Min = 44 Max = 94	Domain 3 M = 73 SD = 20,5 Med = 75 Min = 44 Max = 94	6,8 (-0,07)
			Domain 4 M = 70,20 SD = 2,68 Med = 69 Min = 69 Max = 75,00	Domain 4 M = 88,8 SD = 7,39 Med = 91 Min = 75 Max = 94	18,6 (4,71)
Patient perspectives	Satisfaction and acceptance	User Experience (UEQ-S scores)	/	M = -0,15 SD = 0,487 Med = -0,125 Min = -0,875 Max = 0,5	
		User acceptance (TAM score)	/	Ease of use: M = 12,00 SD = 1,41 Med = 2,5 Min = 2 Max = 5	

				Future use: M = 14,00 SD = 1,00 Med = 3,0 Min = 3,0 Max = 5	
				Usefulness: M = 14,00 SD = 1,00 Med = 3 Min = 3 Max = 5	
	Understanding of information Confidence (in the treatment) Ability to use the application Access & Accessibility	Usability of application (SUS Scores)	/	M = 48,2 SD = 2,95 Med = 50 Min = 45 Max = 51	
		Usability of application (1-item health literacy)	M = 4,00 SD = 0,71 Med = 4 Min = 3 Max = 5	M = 3,8 SD = 0,447 Med = 4 Min = 3 Max = 4	-0,2 (-0,26)
	Empowerment Self-efficacy	User engagement (Number of logins)	This data has been continuously collected during the pilot to answer the research objectives and will thus be further presented with respect to the secondary outcomes.		
		Self-efficacy (SHAPES Participation questionnaire)	Participation in activities: M = 4,2 SD = 0,837 Med = 4 Min = 3 Max = 5	Participation in activities: M = 4,4 SD = 0,894 Med = 5 Min = 3 Max = 5	0,2 (-0,06)
				Effect of using DS on participation in activities: M = 3,2 SD = 0,447 Med = 3 Min = 3 Max = 4	

		Self-efficacy (GSES)	M = 32,25 SD = 1,50 Med = 33 Min = 30 Max = 33	M = 34,00 SD = 3,86 Med = 32,5 Min = 32 Max = 40	1,75 (2,36)
Economic aspects	Amount of resources used when delivering the application and comparators	Cost of devices	<ul style="list-style-type: none"> • Tablet: 328,57€ • Touch pen: 39,96€ • Protective cover tablet: 13,99€ 		
		Cost of using digital solutions and SHAPES platform	See Table 60		
		Cost of staffing	See Table 60		

In the following the results of the baseline data is summarised. Any analysis and discussion of outcomes with respect to the impact will be part of the deliverables D6.9 and D6.10.

Considering the application of the WHOQOL-Bref questionnaire, the participants mostly perceived their physical health (Domain 1; m = 59), their social relationships (Domain 3; m = 66,2) and their living environment (Domain 4; m = 70,2) below the respective norm of 73,5; 71,5 and 75,1 (13). This is further underpinned by the OSSS-3, where the participants indicated that they had poor social support (m = 6,8). According to the EQ-5D-5L VAS score, they pinpointed their health status on a scale from 0 to 100 at 86,2 on average. In contrast, they perceived their psychological wellbeing (Domain 2; m = 75) above the norm of 70,6 (13). Following the results from the GSES, the participants ranked their perceived self-efficacy at 32,25 out of 40 points. The average of 4,0 out of 5 (HLM) indicated that the participants had a high level of health literacy.

The results from the questionnaires reflect the general understanding of the participants, that they were rather healthy and fit for their age, as well as health literate.

Recommendations for partners (from interviews)

Participants were generally dissatisfied with the App, due to prevailing technical difficulties as well as a number of shortcomings of the App, see below:

- System Usability Scale (SUS): The average SUS - Score was 48,2 (SD 2,95) which shows that the usability was evaluated very poor.

- Results of the scale User Experience Questionnaire (shortened; UEQ-S) show that the participants' responses were more negative, i.e. the solution was rated as rather annoying than enjoyable or confusing than clear. Table 84 provides an overview about the items:

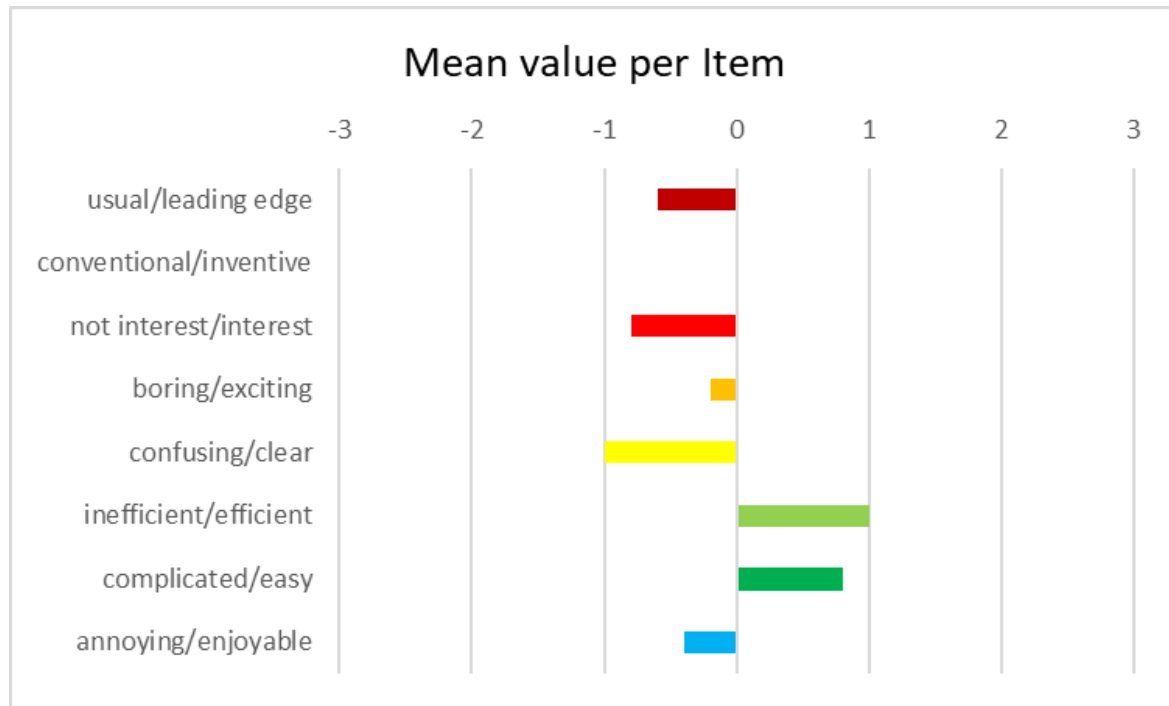


Figure 141: UEQ Result of UP participants

Technology Acceptance Model (TAM): The participants think, the technology is easy to use, but 3 participants (from 5 of them) do not see its usefulness. Only one participant would use the technology in the future, as all of them rather use the phone for calling, their own calendar and television or websites when they are looking for news and events.

Most of participants used the technology alone at home and did not need any technical help.

Technical issues:

The overall impression of the application was affected by technical challenges. Two of the participants' names were not displayed correctly for a long time after logging in (the names of these two participants were confused and the error could not be corrected). Four of the five participants were shown messages from another region

most of the time, which also gave a poor impression. In the ongoing phone calls with the caregiver and in the final interview, were sentences such as:

“I need news from my region.”

“I like to read the news, but the offers are from Třebíč and the Vysočina region.”

“I watch the news (it is from Třebíč, the weather is from Těšetice, I prefer Olomouc) I have the weather on my mobile phone directly from where I live. It shows me the same quote all the time. It would need a change.”

“It doesn't work as it should.”

“The news from my region doesn't work.”

Negative feedback:

It was very difficult to get event websites from the regions of need because most of the older individuals live in small villages where there are not so many events and the local websites do not work so well. Many events in small villages are also known to people through printed sources, bulletin boards or radio. Then the second thing is how older individuals can get to the planned event. Often they depend on their family members because public transportation is not sufficient or is already too exhausting for older individuals. That is why it was decided to add news from the participants' region to the App, which was also problematic (see above).

When using App, the saving of the events was for some of participants complicated: “I find entering events confusing, impractical to enter time on the clock.”

Some of the participants rated the App as redundant:

“Google news are also personalized and are therefore in the end more convenient than the messages in the App. I prefer video calls via WhatsApp, no need to make an appointment.”

“We only use the phone to call each other by mutual agreement. Otherwise, the application cannot be used.”

“I watch the messages and make phone calls. The App is not important to me, I have contact with my surroundings without using it.”

“I use the App, but it is redundant, a browser for messages and a phone for calls would be enough.”

One participant did not want to read so many negative messages, so she did not use the App much.

The application could be improved as follows:

- Easier to add the events
- Making phone calls without prior planning
- Figure out how to download surrounding events more easily into the App

Positive feedback:

One participant saw the App as enriching. The application helped him to not be afraid to try other Apps on the tablet, i.e. Google, Netflix. “I am glad for this opportunity, the tablet has improved my access to information.” Another participant was glad for the possibility to have one own tablet: “Thanks to the tablet I have learned to use the news on Google.”

Participants rated positively during the experiment:

- Learn to use the tablet
- Learn to use other applications
- Access to information

4 Use case 003

4.1 Introduction

Cognitive skills are considered key elements in the daily functioning of older adults. Although, for some of these cognitive skills (i.e. memory, problem-solving activities or speed processing), decline is inevitable in the process of ageing (18); (19); (20); (21). This kind of decline undermines older adults' ability to maintain an independent lifestyle (22); (23). However, technology assisted solutions may facilitate older adults continued independent living(24). In this vein, the Lab of Medical Physics and Digital Innovation of the Aristotle University of Thessaloniki (AUTH) developed a service which is addressed to adults and integrates both physical and cognitive training through web service technologies (25); (26) aiming at improving their health condition, and thus their quality of life.

The Integrated Healthcare System Long Lasting Memories Care (LLM Care) is a successful example of commercializing the “Long Lasting Memories” research program (<http://www.longlastingmemories.eu/>), which was built on the broad foundations of long-term research (pan-European and initially funded by the European Commission under the coordination of Greece). LLM Care is an innovative social care service provided by the Lab of Medical Physics and Digital Innovation of the School of Medicine in the Aristotle University of Thessaloniki (AUTH). Specifically, LLM Care is a certified ICT platform that combines state-of-the-art cognitive exercise with physical activity in an advanced assisted living environment and offers an integrated solution for cognitive and physical health, providing effective protection against cognitive decline and, thereby, actively improving the quality of life.

This service is a non-pharmaceutical intervention against cognitive deterioration, which is scientifically substantiated by publications in international and European conferences and journals. The combination of physical and cognitive exercise reduces the risk of diseases and prolongs the time of independent and autonomous living. It also provides a comprehensive solution that has a direct impact on improving the quality of life of individuals, including older people or other vulnerable groups, intellectual disabilities and Down syndrome, women with breast cancer, Parkinson's disease patients, etc.(27).

4.2 Description

“LLM Care Health and Social Care Ecosystem for Cognitive and Physical training” is one of the use cases that are being deployed within Pilot Theme 2. Through this use case, the integrated home-based social and health care service is provided by addressing the maintenance of cognitive and physical condition along with the promotion of independent living and healthy ageing of older adults. The target group of this use case is older adults with or without neurodegenerative diseases, mild cognitive impairment and mild dementia, chronic and mental disorders (i.e., schizophrenia), and difficulties in the production or comprehension of speech (i.e., tracheostomy, aphasia, stroke, and brain injuries). The Integrated Health and Social Care System Long Lasting Memories Care—LLM Care acts as an umbrella for the digital technologies of Talk & Play, Talk & Play Marketplace, NewSum and MYONABLER@VR.

4.3 Digital solutions used in this use case

4.3.1 The Long-Lasting Memories Care—LLM Care

The Long Lasting Memories Care—LLM Care (28) is an integrated ICT platform that combines cognitive training exercises (29) with physical activity (30), providing evidence-based interventions in order to improve both cognitive functions and overall physical condition (31), as well as quality of life. The combination of cognitive and physical training provides an effective protection against age-related cognitive decline, thus improving the overall quality of life through the enhancement of physical condition and mental health, while preventing deterioration and social exclusion (32). LLM Care is considered a non-pharmaceutical intervention against cognitive deterioration that provides vital training to people belonging to vulnerable groups in order to improve their mental abilities while simultaneously boosting their physical wellbeing through daily monitoring. It has been recognized as an innovative ecosystem and was awarded a Transnational “Reference Point 2 **” within the EIP on AHA (31); (33) due to its excellence in developing, adopting, and scaling up of innovative practices on active and healthy ageing.

LLM Care incorporates two interoperable components, physical and cognitive training. The physical training component, FitForAll, is an exergaming platform (Figure 142) that was developed by the research group of Medical Physics and Digital Innovation Laboratory of Aristotle University of Thessaloniki within the European project “Long-Lasting Memories (LLM)” (28). FitForAll is addressed to older adults as well as

individuals belonging to other vulnerable groups with the aim to promote a healthier and more independent living. It is based on new technologies and offers essential physical training within an engaging game environment through the incorporation of different gaming exercises (exergames) including aerobic, muscle flexibility, endurance, and balance training. More specifically, physical training is based on exercise protocols that have been proven to strengthen the body and enhance aerobic capacity, flexibility, and balance (34) while the adjustment of the difficulty level according to individuals' performance is provided aiming at achieving the optimum exercise performance.



Figure 142: LLM Care physical and cognitive training.

The cognitive training component (Figure 142) is the specialized software BrainHQ that was designed and developed by Posit Science (29) in order to support cognitive game-based exercises in a fully personalized and adaptable cognitive training environment. Provision of personalized training, where each exercise is automatically adjusted to the beneficiary's level of competence, has been proven to accelerate and promote visual as well as auditory processing by improving memory, thinking, observation, and concentration (35). BrainHQ is an online interactive environment that incorporates empowering cognitive techniques and includes six categories with more than 29 exercises with a hundred levels of difficulty, which focus on attention, memory, brain speed, people skills, navigation, and intelligence. It is addressed to older adults, as well as individuals belonging to other vulnerable groups aiming at a healthier and more independent living.

4.3.2 Talk & Play Desktop-Based Application

Talk & Play is a desktop application addressed to people with difficulties in the production or comprehension of speech (i.e., tracheostomy, aphasia, stroke, and brain injuries) with the aim to ensure sufficient communication and enhanced independence during their leisure time, while offering in-home cognitive training with the support of their caregivers (36). Three categories of activities are provided: (a) Communication,

(b) Games, and (c) Entertainment (Figure 143). In the context of the SHAPES Pilot Campaign, Talk & Play was exploited among older adults and was available in Greek, English, and German.



Figure 143: Talk & Play application interface

In addition to that, the Talk & Play Marketplace was provided as an expansion of the Talk & Play App acting as an online platform addressed both to formal and informal caregivers, providing them the opportunity to access, create, share, and download material and resources used in the Talk & Play App (Figure 144). More specifically, free access to a variety of communication and game resources was provided, based on the crowdsourcing paradigm that promotes the generation of information, co-production of services, and creation of new solutions and public policies (37). Caregivers were able to explore and evaluate the content of Communication and Games categories and resources, as well as download the existing material and upload their own.

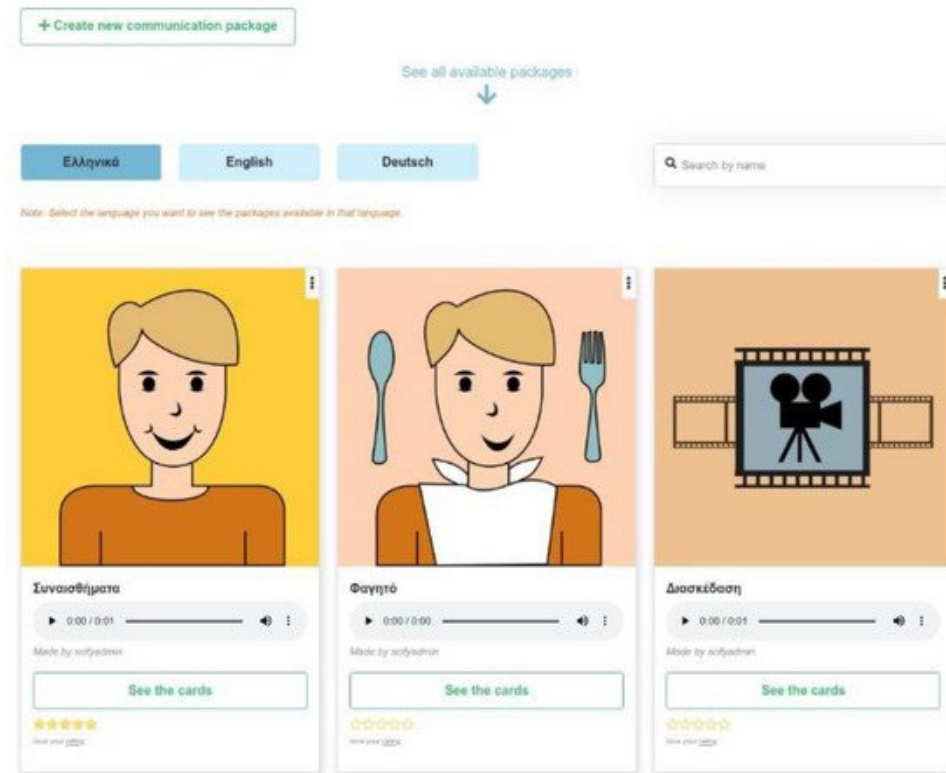


Figure 144: Talk & Play Marketplace interface.

4.3.3 NewSum App

NewSum (38); (39) is a mobile application that enables news summarization based on Natural Language Processing (NLP) and Artificial Intelligence (AI). The NewSum App exploits state-of-the-art, language-agnostic methods of NLP to automatically develop news's summaries from a variety of news resources. Essentially, articles that refer to the same news's field are grouped in specific categories and concise summaries are created, without allowing the duplication of repeated information (40). NewSum provides a simple User Interface (UI) design, and its exploitation does not require a high level of digital skills and affinity to technology by users (Figure 145). Therefore, it can be exploited as a useful news summarization mobile App appropriate for older adults with little to no experience with technology and mobile Apps. In the context of the SHAPES Pilot Campaign, NewSum was available in Greek and English.

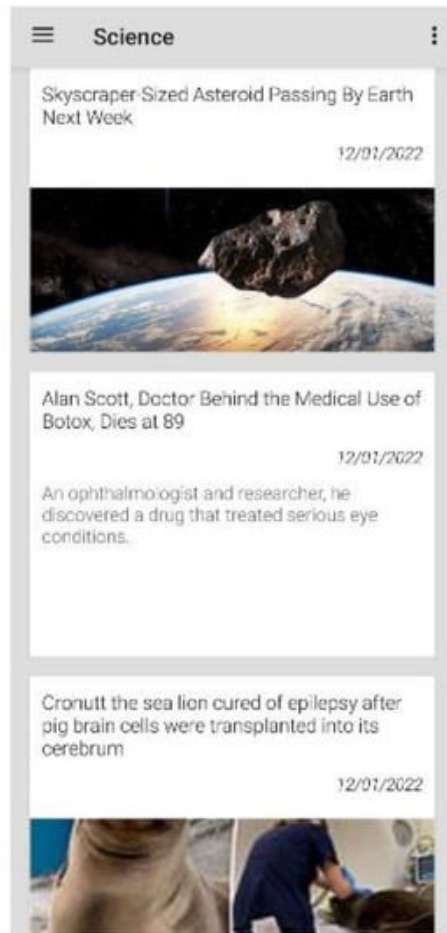


Figure 145: NewSum application interface

4.4 Data plan

The data plan for phases 4 and 5 for PT2-003 has been finalised and can be accessed on the SHAPES website ([Data plan UC-PT2-003](#)).

4.4.1 Data capture methods to be used

Phase 2

- Open-ended questions
- System Usability Scale (SUS)

Phase 3

- USE Questionnaire: Usefulness, Satisfaction, and Ease of use
- System Usability Scale (SUS)
- User Experience Questionnaire (UEQ)

Phase 4

- Participant error reporting log (to follow in final deliverable)

Phase 5

Baseline demographics

- Participant's ID
- Age
- Marital status
- Gender
- Education
- Digital literacy

Data stored in the physical training system FitForAll during intervention

- Number of total sessions
- Number of total games played
- Number of total metric values
- Number of total iterations
- Total days trained
- Number of total games/sessions
- Number of total games skipped/session
- Total duration of play time
- Number of total iterations/sessions
- Number of total metrics/sessions
- Number of total points/sessions
- Heart rate
- Blood pressure

Physical assessment (pre- and post- intervention)

- Risk of falls (Personal Risk Factors Fall Prevention Checklist)
- Physical status (Senior Fitness Test (Fullerton))

- Balance (Berg Balance Scale; Tinetti Test)
- Static balance (Stork Balance test (1 leg)
- Weight/Height² (Body Mass Index)
- Balance while walking (10m Walk Test)
- Short physical status (Short Physical Performance Battery Protocol)
- Aerobic capacity (6-min walk test)

Data stored in the cognitive training system BrainHQ

- Days trained
- Time/Duration of interactions
- Number of interactions
- Levels completed
- Percentile overview
- Level of BrainAQ (overall gains from training with BrainHQ)
- Stars earned

Cognitive assessment (pre- and post-intervention)

- Montreal Cognitive Assessment (MoCA)
- Mini Mental Examination
- Trail Making Test A, B
- Digit Symbol Substitution Test (DSST)
- Verbal Fluency
- STROOP/"Name that colour" test

Data stored in the Talk & Play App

- Number of total sessions
- Number of total games played
- Number of total metric values
- Number of total games/sessions
- Total duration of play time
- Topics/news items visited per news category (for NewSum)
- Communication Card Categories visited/ contributed to (for Talk and Play and Talk and Play Marketplace)
- Game categories played/contributed to (for Talk and Play and Talk and Play Marketplace)

Data stored in the Talk & Play Marketplace

- Number of games created by professionals
- Number of games (created by professionals) played by end-users
- Number of downloads per game / communication pack

Data stored in the NewSum App

- Topics/news items visited per news category (for NewSum)

Psychosocial assessment

- Beck Anxiety Inventory (BAI)
- Geriatric Depression Scale-15 (GDS-15)
- Friendship Scale Assessment
- WHOQOL-BREF
- 1-item health literacy
- EQ-5D-VAS
- Oslo Social Support Scale (OSSS-3) with Life Events Scale
- Self-efficacy (GSES)
- Participation questions (x2)

Usability & Technology Acceptance measures

- System Usability Scale (SUS)
- Technology Acceptance Model (TAM)

4.4.2 Planning of evaluation

MAST

The MAST framework (model for assessment of telemedicine) (9) was applied as it provides a structured approach for assessing the effectiveness and contribution of UC-PT2-003 to quality of care. In a multidisciplinary process, MAST summarises and evaluates information to the use of telemedicine related to the medical, social, economic and ethical issues.

For UC-PT2-003, two of the seven dimensions of MAST were identified to be of importance to consider. These were: Clinical effectiveness and Patient perspectives.

A further exploration and description of the reasons for inclusion will be provided in the evaluation report (D6.9). Table 90 shows a summary of the MAST evaluation.

1. Health problem and characteristics of the application
2. Safety
3. Clinical effectiveness
4. Patient's perspective
5. Economic aspects
6. Organisational aspects
7. Sociocultural, ethical, and legal aspects

Table 90: Data required for MAST evaluation of UC-PT2-003

MAST Domain	Topic	Outcome	Data required	Time point
Clinical Effectiveness	Physical health	Physical condition	Risk of falls (Personal Risk Factors Fall Prevention Checklist)	Baseline
			Physical status (Senior Fitness Test (Fullerton)	Post-intervention
			Balance (Berg Balance Scale; Tinetti Test)	
			Static balance (Stork Balance test (1 leg)	
			Weight/Height ² (Body Mass Index)	
			Balance while walking (10m Walk Test)	
			Short physical status (Short Physical Performance Battery Protocol)	
			Aerobic capacity (6-min walk test)	
	Quality of life	Health related quality of life	Beck Anxiety Inventory (BAI)	Baseline
			Geriatric Depression Scale-15 (GDS-15)	Post-intervention

		and wellbeing	<p>Friendship Scale Assessment</p> <p>WHOQOL-BREF</p> <p>1-item health literacy</p> <p>EQ-5D-VAS</p> <p>Oslo Social Support Scale (OSSS-3) with Life Events Scale</p> <p>Self-efficacy (GSES)</p> <p>Participation questions (x2)</p>	
	Cognitive health	Cognitive condition	<p>Montreal Cognitive Assessment (MoCA)</p> <p>Mini Mental Examination</p> <p>Trail Making Test A, B</p> <p>Digit Symbol Substitution Test (DSST)</p> <p>Verbal Fluency</p> <p>STROOP/"Name that colour" test</p>	<p>Baseline</p> <p>Post-intervention</p>
Patient perspectives	Satisfaction and acceptance	User Experience	System Usability Scale (SUS)	Post-intervention
		User acceptance	Technology Acceptance Model (TAM)	Post-intervention
	Understanding of information	Usability of application	<p>System Usability Scale (SUS)</p> <p>1-item health literacy</p>	Post-intervention
	Confidence (in the treatment)			

	Ability to use the application			
	Access & Accessibility			
	Perceived impact	User engagement	Interviews	Post-intervention

MAFEIP

The MAFEIP tool (10) was not applied to evaluate UC-PT2-003 due to a small-scale deployment (N=13) of the UC.

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

Momentum

Critical success factors (CSFs) and performance indicators offered by the Momentum blueprint (11) were determined in UC-PT2-003. These factors should be considered when scaling up telemedicine and integrating it into healthcare delivery systems. Although the digital solution of this use case does not count as telemedicine and no healthcare professionals are involved, the aim is to increase the cognitive and physical health of older individuals and, therefore, their quality of life. Outcomes of the process are included in the annex (Annex 22) and details of each CFS are provided below.

CSF 1. Cultural readiness for the telemedicine service

The digital solutions being used in this UC are not considered telemedicine neither medical device. To this end, no clinical data and information are to be exchanged between different health care providers.

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

The digital solutions being replicated in this UC are not considered telemedicine neither medical device. Therefore, the advantages of telemedicine are not directly explored.

CSF 3. Ensure leadership through a champion

Engaging key stakeholders, including healthcare providers, researchers, project managers, IT personnel, and older people, is essential for successful telemedicine implementation. Facilitators should promote open communication, solicit feedback, and address concerns to ensure a collaborative approach.

CSF 4. Involvement of healthcare professionals and decision-makers

The deployment of this use case does not foresee any participation of healthcare professionals. As the organisation of this use case is working together with decision makers from the reference site, those have been involved in the process of the project.

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

Older adults are involved in the development of this digital solution through upcoming activities of the next phases. The development is based on the older adults' needs and appropriate training for using the digital solutions is planned.

CSF 6. Ensure that the technology is user-friendly

The project considered attentively the user-friendliness of the digital solutions. Potential users were asked about their opinion and experience interacting with the solution and all feedback was considered in the final development of the SHAPES digital solutions. The evaluation also included metrics like the System Usability Scale (SUS).

CSF 7. Pull together the resources needed for deployment

The resources required for the deployment of the digital solutions in this UC are provided to SHAPES funding and internal resources already allocated. The technical partners of the use case provided all IT competences.

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

Older adults in this UC were considered primary clients. Their personalized needs and requirements were explored through all phases (Mock-up, Hands-on training, Small-scale pilot). Based on the results and feedback collected in these phases, the UC leader and technical partners proceeded in essential improvements of the DS and the UC to meet older adults' needs and preferences and ensure smooth pilot activities.

CSF 9. Prepare and implement a business plan

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

CSF 10. Prepare and implement a change management plan

It will be evaluated at the end of the project.

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

Legal requirements in the Greek context have been reviewed to ensure that the use case was piloted within the relevant legislation. Since the digital solution was not classified a medical device, all relevant requirements were met.

Completion of a Data Protection Impact Assessment (DPIA) identifies and minimises any risks associated with the pilot with input sought from other work packages and the SHAPES Data Protection Officer at AUTH. Data processing agreements are 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 are limited, the solution is being designed with the intention to scale it to a pan-European level. The use of human resources is evaluated during the pilot, with a proper analysis of resources needed in relationship with the monitoring protocol.

CSF 13. Identify and apply relevant legal and security guidelines

GDPR was applied. The digital solutions implemented all applicable security and privacy-related regulations.

CSF 14. Involve legal and security experts

Advice from legal experts and experts on data security matters was received from project partners (for example LAUREA, that has extensive expertise in this field). AUTH acting both as technical partner was awarded the ISO 9001 certification for Software Design, Development and Production. Design & Implementation of Education/Training programmes

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 older adults' privacy has been protected. The project underwent a full ethical evaluation before permission is 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 telemedicine services. The pilot is being 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 works 24/7. In case of any bugs or issues the development and maintenance team fixes it. AUTH and SciFY 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. The system logs all activities so any incident can be identified and solved quickly.

CSF 18. Establish and maintain good procurement processes

applicable to the devices used in the pilot were previously defined and vendors that fulfil them were identified. The SHAPES project provides the servers that are needed to run the solution. Those servers meet the service level needed to run the pilot successfully.

NASSS

The NASSS framework (Nonadoption, Abandonment, Scale-up, Spread and Sustainability) (12) was used to increase the success of the technology of use case UC-PT2-003. It was conducted to detect risks, which might lead to project failure. The short version of the NASSS questionnaire was considered and completed by the pilot team (Annex 23). In one out of six domains uncertainties were identified and mitigation measures developed to ensure the success of the use case (

Table 91).

Table 91: Uncertainties and mitigation measures identified using the NASSS framework

NASSS complexity domain	Uncertainties detected	Mitigation measures taken
The external context for the innovation	Overall, no significant external conditions that could complicate the adoption and spread of the innovation are foreseen as the DS of this UC have already been developed, launched and exploited by healthcare organisations in the public and private sector. However, regulations regarding the COVID-19 pandemic have to be further evaluated.	Internal discussions on potential regulatory issues and challenges and safety measures are applied, remote working is performed if feasible

4.5 Phase 1

4.5.1 PACT and FICS Scenario

Table 92: Scenario AUTH UC-PT2-003

Code	UC-PT2-003	Version	0.1	Date	2020/09/03
Applicable SHAPES Persona	Isabella – a divorced 75 years old woman diagnosed with Alzheimer’s disease				
Applicable SHAPES use case	UC-PT2-003 LLM CARE Healthcare System for Cognitive and Physical training				
People Roles and/or actors of typical users involved in delivering and receiving the	1. Older people 65+ <ul style="list-style-type: none"> with or without neurodegenerative disease (i.e., dementia, Alzheimer’s and Parkinson’s disease) with Mild Cognitive Impairment with chronic and mental disorders (Schizophrenia) with disabilities (older people who have communication issues due to movement impairments or difficulties in 				

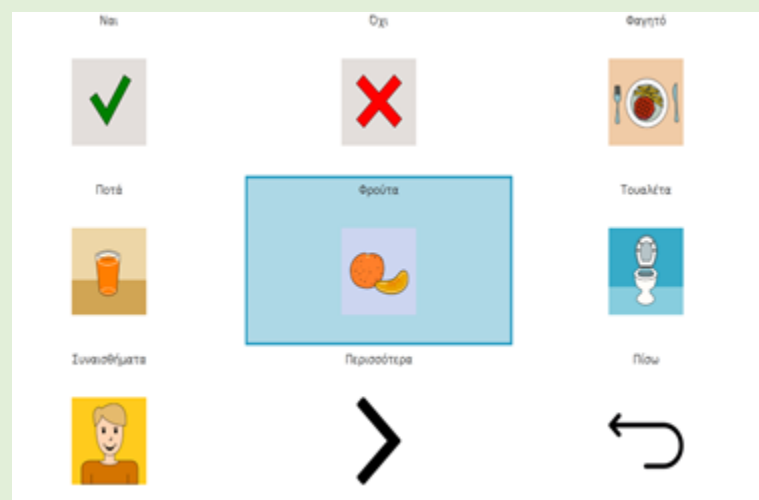
telemedicine intervention	<p>speech (i.e., tracheostomy combined with mobility limitations, or with kinetic disabilities with not enough exercise during ergotherapy)</p> <p>2. Caregivers (formal or informal) who facilitate the training session.</p>
<p>Activities</p> <p>Activities to be performed by the actors in order to successfully provide and receive the telemedicine intervention <i>procedures for the professional and the patient; Parameters that determine the measures used in the intervention</i></p>	<p>Older people 65+</p> <p>Phase 1:</p> <p>1. Cognitive training: BrainHQ, Talk and Play, NewSum</p> <p>BrainHQ</p> <ol style="list-style-type: none"> 1. User logs in the BrainHQ platform (https://www.brainhq.com/). 2. User selects the training mode, personalized training or selection of preferred exercises: <ol style="list-style-type: none"> a. Personalized training: User selects the "Start Personal Trainer" button to begin the training. Personalized training includes a daily training session for the user based on his/her unique preferences and performance. b. Selection of preferred exercises: It is recommended that the user spend 10 minutes (1-2 exercises) in each category (Memory, Brain Speed, Attention, People Skills, Intelligence, or Navigation). 3. The user can monitor his/her progress in the "Progress" tab where multiple information with regard to the performance is provided. In specific, the user can track: <ol style="list-style-type: none"> a. The days trained b. The duration of the training c. The levels completed d. The percentile overview of each category e. Stars Earned: Each time the user completes an exercise level, the total of the earned stars gained in the exercise is presented. f. The level of BrainAQ: BrainAQ represents user's overall gains from training with BrainHQ. When joining BrainHQ, the user's quotient starts at zero. Each time a new training level is completed, the BrainAQ ticks upward. As user's performance improves, the BrainAQ increases likewise, reflecting the cognitive gains from training.

The recommended duration of the cognitive training with BrainHQ is **3-4** times a week for 30 minutes per time (approximately 90 minutes per week).

Talk and Play

1. User opens the application and double-clicks on the default user, or on the custom user that was created for them.
2. User selects one of the following available actions: “Communication”, “Entertainment”, and “Games”
 - a. User selects **Communication** action button:

User selects the desired word by pressing the button, when the cursor is at the relevant word box, as shown in the image.



- b. User selects **Entertainment** action button:

If the caregiver has set a folder from which audio and video files are streamed, the user can select either to listen audio files, or watch videos.

- c. User selects **Games** action button:

User accesses the created games from the following categories: “Reaction”, “Time Sequence”, and “Find Similarities”.

- User selects the “**Reaction**” category. A game is presented aiming to train the user that when he/she

	<p>presses a button, a particular reaction is presented on the screen.</p> <ul style="list-style-type: none"> • User selects the “Time Sequence” category. A game is presented aiming to train the user to set the images in the correct time order. • User selects the “Find Similarities” category. A game is presented aiming to train the user to click on the most similar shape, after being given a certain shape. <p>3. The user clicks the “Back” button and exits the application.</p>
	<p>NewSum</p> <p>User opens the NewSum App on their Android phone/tablet.</p> <ol style="list-style-type: none"> 1. If the user opens the App for the first time, a series of introductory steps is presented, in order to configure the application: <ol style="list-style-type: none"> a) User selects the language of his/her preference, from a list of available languages. This is the language both of the content and interface. b) User selects the news categories he/she would like to see in the application, from a list of available news categories. c) User selects a “favourite” news category, from a list of available news categories. This category is shown as default, every time the application opens. 2. User sets his/her preferences and a list of news from the default category is presented. 3. User opens the main menu on the left of the screen and selects a category from a list of news categories. 4. User opens the menu on the right of the screen and performs the following actions: <ol style="list-style-type: none"> a) Selects to see either all news or top news b) Selects to see the “Settings” page. From this page, the user can set the following options: <ul style="list-style-type: none"> • App language • Favourite category • News sources that are used to collect news • Download images only when the App is connected in Wi-Fi or not 5. User clicks on a single news card in order to view the news page. 6. User accesses the list of news sources that were used in order to create the news summarization.

	<ol style="list-style-type: none"> 7. User rates the summarization by clicking on the “rating” (star) button. 8. User selects to share the news by clicking on the “share” button. <p>Phase 2: Physical training (FitForAll)</p> <ol style="list-style-type: none"> 1. User logs in to the FitForAll platform 2. User is guided by an intuitive interface to connect the controller devices. Once connection is established, the user is transferred to the training session environment. 3. User stands in front of the desktop computer or laptop in a 1.5 m distance from the motion detection device. 4. Auxiliary interfaces offer instructions about the physical tasks to be performed. After reading the instructions, there are two options to initiate the physical training; the caregiver can press the start button, or the user can rise his/her hand in order to activate the motion detection device. <p>A short count-down prepares the user before each physical task. During the physical training the user is able to pause or skip a game at any time by simply touching the screen. Each session has a specific difficulty level. This comprises of two components: the physical exercise intensity component (i.e., more repetitions per exercise), which is the dominant one and the gameplay difficulty (i.e., avoid obstacles during the golf game). Apart from the option of creating/modifying interventions, FitForAll incorporates a default intervention protocol, tailored to older people, which consists of four difficulty levels.</p> <p>The recommended training duration for the physical activity is 3-5 sessions per week.</p> <p>Caregiver</p> <p>Phase 1:</p> <p style="text-align: center;">2. Cognitive training: BrainHQ, Talk and Play, NewSum</p> <p>Brain HQ</p> <p>A caregiver monitors the user’s performance during the cognitive training session and facilitates the user where it is needed.</p> <p>Talk and Play</p>
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1. The caregiver opens the application and selects the “Default User Preferences” option, in order to customize the interface of the application user
 - a. The caregiver changes the name and photo of the user.
 - b. The caregiver sets the default keyboard button for the application navigation.
 - c. The caregiver sets the navigation cursor’s speed and selects whether the application should play sounds and show texts.
 - d. The caregiver saves the user configuration and goes back to the main screen.
 - e. The caregiver exports the saved configuration to a file so that it can be loaded in another instance of the application.



2. The caregiver can select to add a new communication word, edit an existing communication word, and delete an existing communication word, via the “Communication” options tab:



3. The caregiver can set a folder from which music and video files are streamed, via the “Entertainment” tab:



The caregiver can see the existing games and add/remove game cards from the “Games” tab:

4. The caregiver can see all created users and the custom users in the main screen.
5. The caregiver can delete a user.
6. The caregiver can load a previously saved configuration file.

NewSum

The caregiver can set up the application for the first time, to define the language and news sources of his/her preferences. Activities described above, in the “Older people 65+” section.

<p>Context</p> <p><i>Social-medical relevance of the telemedicine intervention; privacy issues; risks for the patient; locations</i></p>	<ul style="list-style-type: none"> • Combination of state-of-the-art cognitive training with physical activity in an advanced assistive living environment • Non- pharmaceutical intervention • Effective prevention of cognitive decline [1] • 24/7 availability: convenient access • Cognitive training systems can be used anywhere with internet connection. Physical training system requires a motion detection device, which is also portable. • Data repository: accessibility of data stored • Secure platform ensuring user's data privacy • Graded difficulty levels • Adaptable and personalized protocol • No risks foreseen <p>[1] Bamidis, PD., Fissler, P., Papageorgiou, SG., Zilidou, V., Konstantinidis, El., Billis, AS., Romanopoulou, E., Karagianni, M., Beratis, I., Tsapanou, A., Tsilikopoulou, G.: Gains in cognition through combined cognitive and physical training: the role of training dosage and severity of neurocognitive disorder. <i>Frontiers in Aging Neuroscience</i>, 7, 152 (2015).</p>
<p>Scenario</p>	<p>Isabella is a 75-year-old lady, who lives in a small town in Spain. She is divorced and lives alone in a two-room apartment. She was diagnosed with Alzheimer's disease two years ago and her illness is in the early to middle stage. Once she got the results of her diagnosis, she started receiving medication and was told to have a check-up every three years. Isabella is already experiencing some health issues regarding the deterioration of her memory. Lately, she started losing her personal belongings and, in particular, she once misplaced her purse and could not find it for a week. The most embarrassing situation happened when she went downtown and could not find her way home, while another time she met with an old friend of hers and could not remember her name. In addition, she recently switched off the electricity by accident in the whole house and the heating was off for two days. Due to these incidents, Isabella started keeping a notebook with the most important information, in order for her to remember where she puts her stuff.</p> <p>Isabella's son, Marco (46), who lives nearby with his family, visits her every day, does the chores and brings her food. He has a part-time job in a factory and, therefore, he is often tired, worried and frustrated. He started experiencing mood swings, since Isabella started asking repeatedly the same</p>

questions. Indeed, there were a couple of times that he raised his voice at her, but he felt ashamed and guilty for his impulsiveness. Marco often worries about his mum, especially when he cannot be with her as he is afraid that she might get lost. They also have the help of a field nurse, but only twice a week for a few hours.

It is important for Isabella to maintain her dignity and self-sufficiency, keep herself socially active and stay in home care as long as possible. She is also worried about Marco and wants him to better cope with the caregiving situation. Three months ago, Marco came across the daughter of Mrs. Eleni, an 82-year-old lady, who lives next to Isabella and informed him that her mother started participating in a cognitive and physical training intervention called Integrated Healthcare System Long Lasting Memories Care (LLM Care) that is conducted in the Open Care Center for older adults in their neighborhood. Specifically, LLM Care is a certified ICT platform that combines state-of-the-art cognitive exercise with physical activity in an advanced assisted living environment and offers an integrated solution for cognitive and physical health, providing effective protection against cognitive decline and, thereby, actively improving the quality of life. Therefore, Marco considered it a great opportunity for his mother and suggested she join the team as well.

Isabella was positive about her son's suggestion and joined promptly the training program in the Open Care Center for older adults. In particular, she attends the training intervention 3-4 times per week, where she interacts for one hour with the cognitive training program BrainHQ and for, one more hour with the physical training program FitForAll, another 30 minutes with the cognitive exercises from the Talk & Play App, and half an hour more browsing news from the Newsum mobile App. Specifically, BrainHQ includes six categories with more than 29 effective exercises and hundreds of graded difficulty levels that focus on attention, memory, brain speed, people skills, navigation and intelligence. Every exercise is dynamically adapted to the skill level of each trainee in order to produce true cognitive improvements. Isabella finds the software easy and user-friendly and enjoys the fact that she can interact autonomously with several cognitive exercises. Indeed, Isabella considers very important that she is able to choose among the personalized trainer feature that continually measures her performance and serves up the

	<p>exercises that are right for her and the design of her own program, choosing exercises and workouts that meet her personal interests, mood, and schedule. In addition, FitForAll incorporates exercise protocols that enhance aerobic capacity, flexibility, balance and strengthening of muscles. Difficulty adjustment is also provided, based on Isabella's performance and, thus, she feels confident that she achieves the optimal function training.</p> <p>Moreover, Talk & Play includes variations of card games in three game categories (Stimulus/reaction, Find similarities, and Time sequence). With Talk & Play, Isabella is able to train her memory and cognitive state while having fun.</p> <p>Additionally, by reading the news from various news categories with the Newsum mobile App on the tablet that is available in the Open Care Center, Isabella quickly catches up with the outside world while getting informed.</p> <p>Isabella is really excited about this venture because many older adults, who suffer from similar health issues, join the LLM Care training program in the Open Care Centre and, therefore, she has the chance to socialize with peers, along with their trainers. Indeed, after 4 weeks of joining the training intervention, Marco has already observed improvements in his mother's cognitive abilities (concentration, observation, and memory) as well as in her physical condition (gait, balance and flexibility). He is really glad that technology keeps his mother busy and focused and considers that the program provides a meaningful workout both to Isabella's brain and body that could potentially offer a greater quality of life.</p>
Technology <i>Type of information/parameter that are relevant in monitoring the health status; type and frequency of accessibility of information;</i>	Cognitive training (BrainHQ, TALK and PLAY, NewSum) BrainHQ Baseline demographics <ul style="list-style-type: none"> – Participant's ID – Age – Gender – Marital status – Education – Digital literacy

*feedback
modalities
(communication)*

Data stored in the cognitive training system during intervention

- Days trained
- Time/Duration of interactions
- Number of interactions
- Levels complete
- Percentile overview
- Level of BrainAQ (overall gains from training with BrainHQ)
- Stars earned

Cognitive assessment (pre- and post-intervention)

- Montreal Cognitive Assessment (MoCA)
- Mini Mental Examination
- Trail Making Test A, B
- Digit Symbol Substitution Test (DSST)
- Verbal Fluency
- STROOP/"Name that colour" test

Psychosocial assessment

- Beck Anxiety Inventory (BAI)
- Geriatric Depression Scale-15 (GDS-15)
- Friendship Scale Assessment
- WHOQOL-BREF
- 1-item health literacy
- EQ-5D-VAS
- Oslo Social Support Scale (OSSS-3) with Life Events Scale
- Self-efficacy (GSES)
- Participation questions (x2)

Technology interaction (pre- and post-intervention)

Usability

- System Usability Scale (SUS)

Technology Acceptance

A Technology acceptance model (TAM)

Talk and Play

	<p>Baseline demographics</p> <ul style="list-style-type: none"> – Participant's ID – Age – Gender – Native language – Education – Digital literacy <p>Data retrieved during intervention</p> <ul style="list-style-type: none"> – Module used – Days trained (per module) – Duration of interactions (per module) <p>Psychosocial assessment</p> <ul style="list-style-type: none"> – Beck Anxiety Inventory (BAI) – Geriatric Depression Scale-15 (GDS-15) – Friendship Scale Assessment – WHOQOL-BREF – 1-item health literacy – EQ-5D-VAS – Oslo Social Support Scale (OSSS-3) with Life Events Scale – Self-efficacy (GSES) – Participation questions (x2) <p>Technology (pre- and post-intervention)</p> <p><i>Usability</i></p> <ul style="list-style-type: none"> – System Usability Scale (SUS) <p><i>Technology Acceptance</i></p> <p>A technology acceptance model (TAM)</p>
	<p>NewSum</p> <p>Baseline demographics</p> <ul style="list-style-type: none"> – Participant's ID – Age – Gender

	<ul style="list-style-type: none"> - Marital status - Education - Digital literacy <p>Data retrieved during intervention</p> <ul style="list-style-type: none"> - Module used - Days trained (per module) - Duration of interactions (per module) <p>Psychosocial assessment</p> <ul style="list-style-type: none"> - Beck Anxiety Inventory (BAI) - Geriatric Depression Scale-15 (GDS-15) - Friendship Scale Assessment - WHOQOL-BREF - 1-item health literacy - EQ-5D-VAS - Oslo Social Support Scale (OSSS-3) with Life Events Scale - Self-efficacy (GSES) - Participation questions (x2) <p>Technology (pre- and post-intervention)</p> <p><i>Usability</i></p> <ul style="list-style-type: none"> - System Usability Scale (SUS) <p><i>Technology Acceptance</i></p> <p>A technology acceptance model (TAM)</p>
	<p>Physical training (FitForAll)</p> <ul style="list-style-type: none"> • Baseline demographics <ul style="list-style-type: none"> - Participant's ID - Age - Gender - Marital status - Education - Digital literacy <p>Data stored in the physical training system during intervention</p> <ul style="list-style-type: none"> • Affective/Emotional state

	<ul style="list-style-type: none"> • Number of total sessions • Number of total games played • Number of total metric values • Number of total iterations • Total days trained • Number of total games/sessions • Number of total games skipped/session • Total duration of play time • Number of total iterations/sessions • Number of total metrics/sessions • Number of total points/sessions <p>Physical assessment (pre- and post- intervention)</p> <ul style="list-style-type: none"> • Risk of falls (Personal Risk Factors Fall Prevention Checklist) • Physical status (Senior Fitness Test (Fullerton) • Balance (Berg Balance Scale; Tinetti Test) • Static balance (Stork Balance test (1 leg) • Weight/Height² (Body Mass Index) • Balance while walking (10m Walk Test) • Short physical status (Short Physical Performance Battery Protocol) • Aerobic capacity (6-min walk test) <p>Technology (pre- and post-intervention)</p> <p><i>Usability</i></p> <p>System Usability Scale (SUS)</p> <p><i>Acceptance</i></p> <p>A senior technology acceptance model (TAM)</p>
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4.5.2 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 monitoring the progress or lack of it towards achieving the objectives of each specific use case. The following KPIs have been selected to define the success of the pilot activities for UC-PT2-003.

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 further development or deployment.

AUTH – LLM Care Intervention

Recruitment and retention

- At least 80% of the recruited participants successfully participated in all sixteen (16) training sessions of the piloting.

Cognitive status

- At least 70% of recruited participants maintained or improved their cognitive status.

Physical status

- At least 70% of recruited participants maintained or improved their physical status.

Quality of life, wellbeing and social support

- At least 70% of recruited participants maintained or improved their quality of life and different psychosocial aspects.

Usability and technology acceptance

- At least 80% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

AUTH – NewSum Intervention

Recruitment and retention

- At least 80% of the recruited participants successfully remained engaged for one month.

Quality of life, wellbeing and social support

- At least 70% of recruited participants maintained or improved their quality of life and different psychosocial aspects.

Usability and technology acceptance

- At least 80% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

4.5.3 Timeline of pilot activities

For the different replicating sites

The original timeline of pilot activities was to conduct Phase 1 and 2 between May 2020 and January 2021, followed by Phase 3 from February until June 2021. The Phase 4 was planned to be conducted between August 2021 and April 2022.

The adapted timeline of pilot activities can be found in Figure 146. It shows that Phase 3 was shifted and extended to July 2021 until April 2022. This period was extended, with no impact on the next phases or the deliverable, due to the COVID-19 situation. Mock-up session was conducted virtually, while hands-on training was deployed in the Thessaloniki Action for Health & Wellbeing Living Lab in the premises of the Lab of Medical Physics and Digital Innovation of the AUTH. Phase 4 involved in-person meetings as well, since further testing of the technical aspects needed at least one in-person meeting per participant. Phase 5 was conducted from September to March.

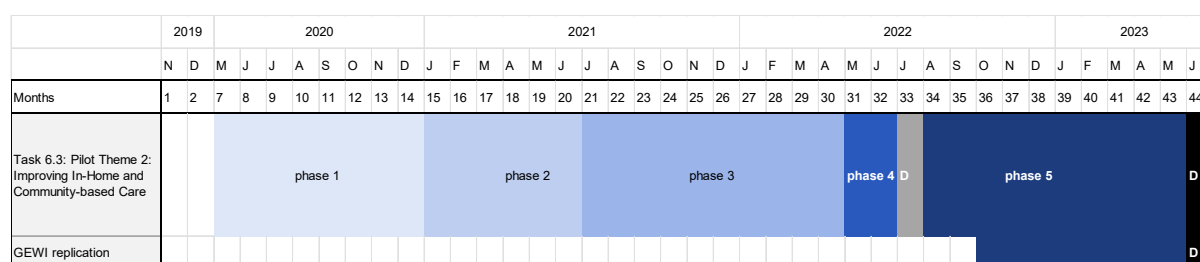


Figure 146: Timeline of pilot activities of UC-PT2-003

4.6 Phase 2: Testing of mock-ups and prototypes

4.6.1 Methodology of testing

The aim of the mock-ups was to validate the digital solutions deployed in UC-PT2-003 and provide technical partners the opportunity to integrate user feedback at an early stage of the technological development process. In particular, the digital solutions for UC-PT2-003 underwent a co-design and user-testing process to optimise their usability and acceptability amongst end-users and receive feedback on the design and functionality of the digital solutions respectively.



It is important to mention that UC-PT2-003 comprises four different DS; a) the Integrated Health and Social Care System Long Lasting Memories LLM Care, b) Talk and Play Desktop App, c) NewSum & d) Talk and Play Marketplace. However, validation and feedback were sought on the design and development of Talk & Play Marketplace, which is addressed to formal and informal caregivers, due to the fact that the rest of DS have already been widely explored amongst the relevant target group and have been scientifically validated through evidence-based studies.

The mock-ups were conducted virtually using the Zoom platform. Participants included two formal caregivers, two informal caregivers, three moderators and two technical partners. Eligible individuals were provided with a consent form and a brief information section, where the background and purpose of the study were further explained along with what participants could expect to happen in case they agree to participate in the session.

A PowerPoint presentation was shown to participants, where they were introduced with brief background information about the SHAPES project and its scope along with an overview of the purpose of UC-PT2-003 and the included digital solutions. Mock-ups of the DS, in particular visual images of all the types of screens participants are likely to encounter when using the App, were then presented to them. Technical partners were asking questions on the design and layout of the mock-ups during participants' interaction with the mock-up of Talk and Play Marketplace. These questions were predefined and comprised a combination of open and closed questions designed to obtain both general and specific feedback about the mock ups.

4.6.2 Results of testing

The mock-up sessions were held virtually and recorded, capturing participants' audio responses. After the conduction of the session participants were given an online form, where quantitative standardized measurements regarding technology usability and acceptance along with open-ended questions focusing on the DS functionalities, were included.

Specifically, participants had the opportunity to express their feedback and opinions on Talk and Play and Talk and Play Marketplace. The feedback was referring to the following aspects:

- User Interface: The user interface was attractive, practical and easy to navigate through. The colours and layout were visually appealing, making the interaction with the DS pleasant.

- **Variety of Exercises:** The range of cognitive exercises provided was adequate. However, it would be helpful to have more difficulty levels or adjustable settings that could be in line with the participants' needs.
- **Creation of content:** This potential allows professionals to develop their own content and adjust it to the participants' needs.

Findings and related feedback, including any recommendations shared by the participants, were presented and sent out to technical partners, in order to proceed with further amendments of the DS.

4.7 Phase 3: Hands-on Experiments

4.7.1 Methodology of hands-on experiments

Hands-on experiments were performed in Phase 3 of the SHAPES Pilot Campaign for UC-PT2-003, in order to collect feedback from end-users and evaluate the functionalities and usability of the DS in the actual pilot setting. End-users had the opportunity to fully exploit the UC's DS that have been designed and developed during previous phases. In order to ensure that essential feedback was gathered, mixed methods of evaluation were carried out. The aim of the hands-on experiments was to train end-users to use the final version of the DS that is deployed in the piloting of UC-PT2-003, provide end-users with the opportunity to challenge the DS functionalities as well as provide feedback and proposed amendments of the DS before phases 4 and 5.

Hands-on experiments were conducted face-to-face, following all necessary safety guidelines and protocols regarding COVID-19. Three older adults (≥ 65 years) were invited to the premises of the Medical Physics and Digital Innovation Lab. Specifically, an initial presentation of the project was conducted, in order to familiarise them with the aim and scope of the SHAPES project. Afterwards, the AUTH team facilitated a hands-on session, where older adults had the opportunity to exploit the different digital solutions, following a structured scenario with specific steps to be followed. This was to ensure that all participants were guided in the same exercises and exposed in specific duration, in order to harmonise the process and, therefore, gain valuable feedback.

A concurrent 'think out loud' approach was used to collect reactions to the DS and identify any areas that 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 were recorded to capture feedback accurately. Evaluation and feedback were also gathered after the digital solutions' exploitation through opened-ended questions as well as standardised questionnaires. The quantitative evaluation included the USE Questionnaire: Usefulness, Satisfaction, and Ease of use, the User Experience Questionnaire (UEQ) and the System Usability Scale (SUS).

4.7.2 Results of the hands-on experiments

Results of the USE, UEQ & SUS measuring user friendliness, system usability and acceptance, user satisfaction and open-ended questions focused on each digital solution functionalities and features, were compared against published benchmark data and findings reported alongside interview data in a feedback report. Findings and related feedback, including any recommendations by participants, were presented and sent out to technical partners, in order to proceed with further amendments of the DS and be prepared for the piloting activities.

4.8 Phase 4: Small Scale Live Demonstration

Small-scale demonstrations of the digital solutions of the UC-PT2-003 were conducted during Phase 4 of the SHAPES pan-European pilot campaign only at AUTH premises. The aim of the demonstration was to test the methods and digital solutions which were to be tested in the following large-scale pilot activities as well as identify potential challenges and issues before the onset of Phase 5.

4.8.1 Recruitment of participants

Participants' recruitment has been actualized within the network of the Living Lab Thess-AHALL ecosystem: municipalities and public entities, hospitals, rehabilitation centers and nursing homes as well as a great number of individuals/beneficiaries. Both direct and indirect recruitment strategies have been implied, where members of the AUTH research team were responsible for the identification, approach and selection of participants, who are eligible for participating in the study based on the inclusion criteria. The AUTH research team screened potentially eligible participants and recruited those eligible according to the inclusion criteria. Information sheets and consent forms have been distributed among all participants to inform them about the scope of the study. All participants' questions as well as any misunderstandings have

been clarified and adequately addressed, while participants have been informed that they could withdraw from the pilot activity at any time.

Sample Size

Three participants were recruited to perform Phase 4 being representatives of the target population.

Inclusion criteria

Table 93: Inclusion criteria UC-PT2-003

Criteria	Group 1	Group 2	Group 3	Group 4
Older adults 65+ with or without neurodegenerative diseases, mild cognitive impairment and mild dementia, chronic and mental disorders (i.e., Schizophrenia)	√	√		
Older adults 65+ with difficulties in production or comprehension of speech (i.e., tracheostomy, aphasia, stroke, brain injuries etc.)			√	
Healthcare professionals or/and formal caregivers				√
Time commitment to the training protocol	√	√	√	√
Good hearing and sight	√	√	√	√
No signs of any significant mobility difficulties	√	√	√	√
Consent form	√	√	√	√

Exclusion criteria

1. Diagnosis of severe neurological or psychiatric disorders
2. Drug abuse
3. Concurrent participation in another study

4.8.2 Technical aspects & Logistics

No specific technical arrangements were needed for the small-scale demonstrations in AUTH, as all software and hardware were already set and run on its premises.

4.8.3 Roles and Responsibilities

During this phase, UC leader AUTH and replicating site GEWI, prepared the Phase 5 replication of the PT2-003. GEWI team received all the necessary equipment in its premises and proceeded with all the necessary technical arrangements and settings. AUTH team was GEWI contact person for any technical issues, which were communicated to the technical team, and was also responsible for providing technical support to replicating site if needed. Moreover, AUTH team prepared the study documentation, namely the research protocol and training manuals to be shared with the replicating site.

The SHAPES pilot site researchers at AUTH were responsible for recruiting and collecting participants consent to participate in the live demonstration. In addition, AUTH provided was the single point of contact for the participants providing both training and technical support where needed.

4.8.4 Ethical considerations

Data Protection Impact Assessment (DPIA), Data Processing Agreement (DPA) and Data Sharing Agreement (DSA) have been developed by the AUTH team, approved by the AUTH DPO and were submitted for approval along with the bioethics documents in the Ethics Committee of the Aristotle University of Thessaloniki.

A folder containing hard originals and copies of documents related to the use case, including consent forms and filled questionnaires, has been retained in a locked office pedestal located at the Lab of Medical Physics and Digital Innovation, School of Medicine, Aristotle University of Thessaloniki (University Campus, Thessaloniki, Greece). An electronic copy of the documents along with the participants list (linking the participants' name to their pseudonymised SHAPES ID) has been retained by approved AUTH staff working on the SHAPES study and stored securely on AUTH servers protected by the AUTH firewall. Only AUTH staff who are approved to work on the SHAPES project had access to identifiable pseudonymized documents. Appropriate agreements have been put in place to facilitate the processing of pseudonymised data by other SHAPES partners which are explicitly described in DPA and DSA documents.

4.8.5 Outcome of the Small-Scale Live Demonstration

The small-scale pilot activities in AUTH took place during January - February 2023 in which all digital solutions of UC-PT2-003 were demonstrated and tested with three (3) older adults. Specifically, participants were invited to attend four (4) different sessions to interact with the digital solutions and participate in a focus group sharing their experience, views and any potential recommendations for the pilot activities.

Outcomes that were evaluated are presented in Table 94.

Table 94: Outcome of the Small-Scale Live Demonstration.

Outcome	Measurement	Instrument
Digital solutions performance	Technical information about ARI performance during sessions.	Log files and remote monitoring of digital solutions sessions
Technical aspects	Analysis of the different functionalities of digital solutions.	Focus group
Adverse events	Participants were asked about the occurrence of any adverse event or system errors.	Focus group
Trust and technology acceptance	Scale Score.	Technology acceptance questions
System Usability Scale (SUS)	Scale Score.	SUS
Affinity to technology	Participants were asked about their affinity and use of technology.	Focus group
Participants' perceptions	Participants' perceptions regarding the acceptability and adequacy of the intervention program, structure of the training program, resources used, experience on the digital solutions used and aspects related to UC were discussed in the focus group.	Focus group

Overall, the participants' experience was highly positive. The participants expressed genuine enthusiasm and satisfaction with the technologies they interacted with expressing that they appreciated the opportunity to explore and engage with novel digital solutions, which allowed them to enhance their daily living and potentially

improve their quality of life. The participants found the technologies intuitive and user-friendly, enabling them to quickly grasp the functionalities and navigate through different features. They particularly enjoyed the interactive interfaces, which made the experience more engaging and enjoyable.

Based on their feedback and observations, we have identified some potential recommendations to further improve the user experience for older individuals. Specifically, participants commented on incorporating personalized settings and customization options in all the digital solutions that would enable them to tailor digital solutions to their specific needs and preferences. The AUTH team shared these recommendations with all technical partners and discussed proceeding with minor adaptations that could be adopted to respond to participants' feedback.

Technical challenges

During Phase 4 AUTH team encountered unexpected technical challenges during the small-scale testing of the Open Call digital solution, namely MYONABLER@VR, which hindered its ability to proceed with the intended pilot activities.

The complexity of the technology and its unique requirements posed difficulties in achieving the desired functionality and performance with the target population, older adults 65+ with or without neurodegenerative diseases, mild cognitive impairment and mild dementia, chronic and mental disorders (i.e., Schizophrenia). This realisation emerged during thorough testing with participants, which highlighted technical constraints that rendered the existing hardware unsuitable to support the intended scope and requirements of the pilot. Indicating the physical capabilities (i.e. muscle condition) of older adults as the main barrier for properly operating with the MYONABLER@VR application, is further advocated by the fact that preliminary tests of the application and the sensor were conducted with success by both CERTH and AUTH employees (i.e. adults between 30s and 50s), in a meeting held prior to the kick-start of the pilot activities. In particular, these tests verified that the application was functional when operated by younger users and even by users who suffer from osteoarthritis of the knee. Also the connection with the Symbiote platform was verified, allowing each user to create a personal account in Symbiote, from within the MYONABLER@VR application, and use it to store the data resulting from his/her interaction with the application. This data consists of information about the date when an exercise was last performed and whether it was successfully completed, as well as information about the raw EMG data collected for each completed exercise. Acquiring new and alternative hardware emerged as solution, but testing and configuration procedures, which are essential for mitigating risks and ensuring optimal piloting

performance, required additional time and resources. Despite the extensive efforts and resources invested in the development process, technical partners were unable to resolve these issues within the expected timeline that prevented the planned pilot activities from taking place.

The same challenges have also affected the replication conducted by GEWI. Therefore, MYONABLER VR was not included in the use case replication.

4.9 Phase 5: Large-scale pilot activity

Large-scale pilot activities were conducted in the [Thessaloniki Action for HeAlth & Wellbeing Living Lab – Thess-AHALL Living Lab](#) that operates since 2014 under the auspices of the Lab of Medical Physics and Digital Innovation, School of Medicine of Aristotle University of Thessaloniki. The lab fosters initiatives encouraging regional development and healthcare systems sustainability by the provision of novel technologies and innovation being a core member of the European Network of Living Labs (ENoLL), and the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) where Thess-AHALL is a three-star awarded reference site. Thess-AHALL was selected as AUTH pilot site as it is actively engaged with older people, vulnerable populations and other relevant community stakeholders, actively pursuing co-creation and co-design of technological solutions to improve health and social conditions and facilitate independent living. Staffed by an interdisciplinary team and researchers (psychologists, technologists, physicians etc.) the Thess-AHALL envisages to facilitate the ultimate aim of speeding up innovation, collaboration, development, and testing of more accurate services, which is achieved by the early involvement of users as co-creators.

Planned pilot activities were conducted in the e-home infrastructure that consists of a room that resembles a real house kitchen and living room. The room is equipped with home appliances and furniture so as to better resemble an older adult's home. There are also monitoring devices installed (i.e., 3D depth sensor camera, fisheye camera).

The primary objective of this UC was to explore whether the LLM Care Ecosystem and all the integrated digital solutions potentially promote the improvement of older adults' cognitive and physical status and, therefore, their quality of life.

Primary objectives

- To validate the capability of the proposed Digital Solutions to enhance older adults' cognitive condition (PO1).

- To validate the capability of the proposed Digital Solutions to enhance older adults' physical condition (PO2).
- To validate the capability of the proposed Digital Solutions to enhance older adults' psychosocial condition (PO3).

Secondary objectives

- To explore usability and technology acceptance of the proposed Digital Solutions (SO1).
- To collect demographics data from participants (SO2).

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).
- To validate the capability of the SHAPES Platform and Digital Solutions to improve the older individuals' health outcomes and quality of life (TO2).
- To validate the capability of the SHAPES Platform and Digital Solutions to gain the older individuals' trust and acceptance (TO3).
- To validate the capability of the SHAPES Platform and Digital Solutions to gain the care professionals' trust and acceptance (TO4).

4.9.1 Recruitment

AUTH

Participants' recruitment has been actualized within the network of the Living Lab Thess-AHALL ecosystem: municipalities and public entities, hospitals, rehabilitation centers and nursing homes as well as a great number of individuals/beneficiaries. Both direct and indirect recruitment strategies have been implied, where members of the AUTH research team were responsible for the identification, approach and selection of participants, who are eligible for participating in the study based on the inclusion criteria. The AUTH research team screened potentially eligible participants and

recruited those eligible according to the inclusion criteria. Information sheets and consent forms have been distributed among all participants, in order to inform them about the scope of the study. All participants' questions as well as any misunderstandings that may arise have been clarified and adequately addressed. Participants have been informed that they could withdraw from the pilot activity at any time.

Four (4) different groups of participants formed (see inclusion criteria below) to interact with the digital solutions of UC-PT2-003. Group 1 assigned to interact with the LLM Care cognitive and physical training system, Group 2 with the NewSum App, Group 3 with the Talk and Play and Group 4 with the Talk & Play Marketplace.

Inclusion criteria

Table 95: Inclusion criteria GEWI (UC-PT2-003)

Criteria	Group 1	Group 2	Group 3	Group 4
Older adults 65+ with or without neurodegenerative diseases, mild cognitive impairment and mild dementia, chronic and mental disorders (i.e., Schizophrenia)	√	√		
Older adults 65+ with difficulties in production or comprehension of speech (i.e., tracheostomy, aphasia, stroke, brain injuries etc.)			√	
Healthcare professionals or/and formal caregivers				√
Time commitment to the training protocol	√	√	√	√
Good hearing and sight	√	√	√	√
No signs of any significant mobility difficulties	√	√	√	√
Consent form	√	√	√	√

Exclusion criteria

1. Diagnosis of severe neurological or psychiatric disorders
2. Drug abuse
3. Concurrent participation in another study

GEWI

Several recruitment activities were conducted/performed to draw attention to the project. These entailed displaying articles in regional newspapers and newsletters, using mailing lists and contacting relevant gatekeepers from the network by applying face-to-face recruitment.

Interested people made contact via mail or phone. A first screening of the responses was performed for potentially eligible participants. As interested participants actively contacted the research team, no consent for contact was be provided.

First communication about the pilot has been conducted via phone from the research team to present all relevant information and answer questions from the potential participants. Afterwards information sheets and consent forms were sent out to eligible participants in case they still showed interest in the study.

As previously presented, the UC-PT2-003 involved 4 different Groups of participants. Since the NewSum application (participants group 2) appeared to be only available in the Greek language, this DS has not further been included in the replication from GEWI.

For the replication of UC-PT2-003 the recruitment of participants was challenging, wherefore several attempts were made to find suitable candidates. Challenges were particularly related to the recruitment of people for the Talk&Play App (Group 3) and Talk&Play Marketplace (Group 4). Several rehab clinics (n=2) and speech therapy practices (n=2) have been contacted, that were located in the reference site and were treating people with difficulties in the production and comprehension of speech. Those were contacted by phone, were introduced to the SHAEPS project and the pilot and asked to support the recruitment process. Following the call, some information material was shared by mail to hand out to patients of their institution. However, due to their intense workload and lack in staffing due to illness, they did not have the capacity to support finding eligible participants of this target group. Thus, it was not possible to recruit any participants from Group 3 and 4 to test the Talk&Play App and Talk&Play Marketplace.

As the pilot activities included the deployment of a cognitive and physical training integrating various technical devices and digital solutions, it was conducted in an external room form a partnering organisation (care facility) which was located in the reference site. This allowed the researcher to support and instruct the participants during the training if needed. Due to the number and duration of the training sessions

and even more importantly the long distances to travel to the training's location given the rural nature of the region, it was difficult to find suitable participants. Again, several attempts were made, and different professional and private networks mobilized to find potential participants.

4.9.2 Communication and dissemination of pilot activities

AUTH, GEWI

Once the study was completed, all data were analysed, tabulated and used to prepare this final report, available as one of the agreed deliverables of the SHAPES Innovation Action — Deliverable D6.3. This deliverable (and all other agreed deliverables) will be available to the public for review and accessible via the SHAPES website (www.shapes2020.eu). AUTH and GEWI will seek to disseminate the findings from this study at conferences and in the scientific papers and articles. AUTH will also seek to communicate the findings of this study via social media and in other non-peer-reviewed media channels. Participating SHAPES partners will have the right to use this study anonymised data in their analysis and dissemination plans. As detailed under 'Access to Data', Data Processing Agreements are in place to facilitate sharing pseudonymised data with specific SHAPES partners for specific purposes.

4.9.3 Risk management

AUTH, GEWI

All foreseeable data-related risks have been compiled into detailed risk assessment documents which form part of the Data Protection Impact Assessments for Phase 5. For each risk identified, a risk classification, root cause, name and consequences were assigned. Once identified, each risk was then analysed and scored from 1 (unlikely/minor)-4 (almost certain/critical) regarding their probability and impact. Subsequently, appropriate mitigation actions were assigned. These risks have been reviewed during the course of the deployment. Besides, ethical approval has been achieved for UC-003 of Pilot 2. This approval process additionally enabled all contributors to identify any further risks as well as to find appropriate mitigation actions. Finally, an ethics workshop has been conducted for UC-003 with all partners involved previous to the start of Phase 5. This workshop allowed to jointly elaborate on potential risks and opportunities with respect to the ethical frameworks of SHAPES as well as to identify any mitigation actions.

4.9.4 Outcome of large-scale pilot activity

AUTH Outcomes (Variables)

O1: Days trained in the LLM Care cognitive training system (PO1)

O2: Time/Duration of interactions in the LLM Care cognitive training system (PO1)

O3: Number of interactions in the LLM Care cognitive training system (PO1)

O4: Levels completed in the LLM Care cognitive training system (PO1)

O5: Percentile overview in the LLM Care cognitive training system (PO1)

O6: Level of BrainHQ (overall gains from training with BrainHQ) from the LLM Care cognitive training system (PO1)

O7: Stars earned in the LLM Care cognitive training system (PO1)

O8: The following questionnaires: Montreal Cognitive Assessment (MoCA), Mini Mental Examination, Trail Making Test A, B, Logical Memory (LM), Verbal Fluency, STROOP/"Name that color" test (PO1)

O9: Number of total sessions in the LLM Care physical training system (PO2)

O10: Number of total games played in the LLM Care physical training system (PO2)

O11: Number of total metric values in the LLM Care physical training system (PO2)

O12: Number of total iterations in the LLM Care physical training system (PO2)

O13: Total days trained in the LLM Care physical training system (PO2)

O14: Number of total games/session in the LLM Care physical training system (PO2)

O15: Number of total games skipped/session in the LLM Care physical training system (PO2)

O16: Total duration of play time in the LLM Care physical training system (PO2)

O17: Number of total iterations/session in the LLM Care physical training system (PO2)

O18: Number of total metrics/session in the LLM Care physical training system (PO2)

O19: Number of total points/session in the LLM Care physical training system (PO2)

O20: Heart rate in the LLM Care physical training system (PO2)

O21: Blood pressure in the LLM Care physical training system (PO2)

O22: The following assessments: Personal Risk Factors Fall Prevention Checklist, Senior Fitness Test (Fullerton), Berg Balance Scale, Stork Balance test (1 leg), Body Mass Index, 10m Walk Test, Short Physical Performance Battery Protocol, 6-min walk test (6 MWT) (PO2)

O23: The following questionnaires: Beck Anxiety Inventory (BAI), Geriatric Depression Scale-15 (GDS-15), SF12, Friendship Scale Assessment, WHOQOL-BREF, 1-item health literacy, EQ-5D-VAS, Oslo Social Support Scale (OSSS-3) with Life Events Scale, Self-efficacy (GSES), Participation questions (x2) (PO3, TO1, TO2)

In relation to the secondary objectives:

O24: The following questionnaires: System Usability Scale (SUS), Technology Acceptance Model (TAM) (SO1, TO1, TO3, TO4)

O25: The following demographics data: participant's ID, age, gender (m/f), marital status, education, digital literacy (SO2)

GEWI

As GEWI has intended to follow the same execution of the pilot as further described in the study protocol, the outcomes previously presented equally apply to the replication of UC-003 by GEWI.

4.9.5 Results of the Large-Scale Pilot Activity

AUTH

The large-scale pilot activities of Group 1 and Group 2 in AUTH were conducted during March and May 2023. In particular, a total of 8 older adults participated in Group 1

engaging in 16 sessions 3 times per week and interacting with the LLM Care cognitive and physical training, during a 2-month period. Group 2 participants exploited the NewSum App in their homes 3 times per week for 20 minutes each (10-12 sessions in total).

However, AUTH team has encountered significant recruitment difficulties, which have hampered its ability to proceed with the intended Group 3 and Group 4 pilot activities in the planned timeline. Talk & Play is addressed to older adults 65+ with difficulties in production or comprehension of speech (i.e., tracheostomy, aphasia, stroke, brain injuries etc.) making recruitment even more demanding. Due to the fact that potential participants did not meet the required inclusion criteria has further narrowed down the options and prolonged the recruitment process. With the aim to ensure that the selected participants will have the right background to contribute effectively to the pilot activities AUTH plans to seek alternative approaches to attract qualified participants and conduct the pilots. Outcomes will be included in the D6.9.

GEWI

Prior to the start of Phase 5 all the necessary hardware and technical equipment were purchased by GEWI partners and placed in their premises. AUTH technical team helped GEWI partners to install and test LLM Care cognitive and physical training system, namely BrainHQ and FitForAll. AUTH technical team helped GEWI partners to install and test LLM Care cognitive and physical training system, namely BrainHQ and FitForAll, while monitoring and responding to any doubt or technical issue that partners had.

The large-scale pilot activities in GEWI were conducted during February and May 2023 with a total of 5 older adults. Due to the challenges encountered during the recruitment of eligible participants (see 4.9.1), appropriate mitigation actions were taken. Thus, the training was opened to residents of the care facility as for them, participating in the training on a regular base was feasible. Following, 2 participants have been recruited to take part in 16 training sessions 2 times per week during a 2-month period. However, during the pre-assessment evaluation it became clear that their cognitive and physical level of impairment had strong implications for the deployment of the training and according to adjustment was undertaken regarding the course of the training. Due to these challenges in conducting the training according to the study protocol, 3 further participants were recruited only using the cognitive training component in their home setting. Participants could train as often as they wished, however at least 3 times a week for 16 sessions.

To this end, results of both AUTH and GEWI participants' interaction with LLM Care are presented below.

4.9.5.1 Group 1: LLM Care Intervention

AUTH

Overview

Baseline: AUTH research team performed a series of cognitive and physical assessments to evaluate the cognitive and physical condition of each participant. In addition, demographics data and psychometric self-administrative tests have been fulfilled by participants to explore their quality of life. In case a participant was not capable of independently performing the tests, a research member assisted him/her during the process.

Intervention period: Participants were engaged in 16 sessions 3 times per week and interacting with the LLM Care cognitive and physical training, during a 2-month period. Both cognitive and physical training systems had a duration of 60 minutes. All sessions were conducted under the supervision of a healthcare professional trained in the use of LLM Care on the premises of the Thessaloniki Active and Healthy Ageing Living Lab (Thess-AHALL).

End of intervention: The same baseline assessments have been performed to re-evaluate and detect any improvements in participants' cognitive and physical condition as well as their quality of life. In addition, usability & technology acceptance measures have been also performed to evaluate participants' interaction with the proposed digital solutions.

Demographics

Table 96 presents the demographics data for the participants in both AUTH and GEWI premises.

Table 96: Participants' Demographics

Demographics		
	AUTH (N=8)	GEWI (N=5)
Age	M= 71.6 ±4.27	M= 82,4 ± 7,09
Gender	100% Females	40% female, 60% male

Level of education	12.5% Lower Secondary Certificate 12.5% Primary School Certificate 50% Vocational training Institute Certificate 25% Bachelor's degree	Reported between 4 and 8 years of secondary school*
Marital status	87.5% Widows 12.5 Married	40% widowed 60% married
Level of Digital Literacy	50% Basic Users 50% Intermediate Users	M= 3,20 ± 1,79

Primary and secondary outcome

Primary outcome

The primary outcomes were to measure a predefined set of KPIs which have already been presented in chapter 4.5.2. The following tables 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 recruited participants successfully participated in all sixteen (16) training sessions of the piloting.

Table 97: KPI 1 AUTH (UC-PT2-003)

Parameter	AUTH
Target number of total training sessions	16
Number of total training sessions	16
Percentage of participants participating in 16 sessions	100%

KPI 1 was successfully achieved with 100%, meaning that engagement initiatives of AUTH were successful, related to the strategy to provide support and maintain contact, which had a positive impact on the absence of withdrawals, despite the number and length of training sessions.

Cognitive status

KPI 2 At least 70% of recruited participants maintained or improved their cognitive status.

Table 98: KPI 2 AUTH (UC-PT2-003)

Parameter	Value
Percentage per cognitive screening test indicating participants that maintained or improved their cognitive status	MoCA – 100%
	MMSE – 75%
	Trail Making A – 50%
	Trail Making A Errors – 100%
	Trail Making B – 62.5%
	Trail Making B Errors – 88.9%
	Phonological Verbal Fluency – 62.5%
	Semantic Verbal Fluency – 75%
	STROOP 1 – 75%
	STROOP 2 - 75%
	STROOP 3 – 87.5%
	Symbol Digital Modalities Test (SDMT) – 65.5%
Average percentage of cognitive status	76.2%

Participants' cognitive function was evaluated with standardized psychometric assessments, specifically, the Montreal Cognitive Assessment (MoCA), Mini-Mental State Examination (MMSE), Trail Making A and B, Phonological and Semantic Verbal Fluency, STROOP and Symbol Digital Modalities Test (SDMT). Pre and post evaluation scores were analysed, demonstrating notable enhancements in participants' cognitive status, as indicated by increased mean scores across all assessments.

Physical status

KPI 3 At least 70% of recruited participants maintained or improved their physical status.

Table 99: KPI 3 AUTH (UC-PT2-003)

Parameter	Value
Percentage per physical test indicating participants that maintained or improved their physical status	Personal Risk Factors – 87.5%
	Chair Stand test in 30 seconds – 75%
	Arm Curl Test in 30 seconds – 100%
	2-minute Step tests – 75%
	Chair Sit and Reach Test – 75%
	Back Stratch Test – 50%
	8- Foot Up-and-Go Test – 63%
	Berg Balance Scale – 100%
	Tinetti Test – 100%
	Stork Balance test (1 leg) – 63%
	Self-selected Velocity – 88%
	Fast Velocity – 75%
	Actual Velocity - average Self-Selected Velocity – 88%
	Actual Velocity - average Fast Velocity – 75%
Average percentage of physical status	79.2%

Additionally, participants’ physical status was evaluated through the Personal Risk Factors Fall Prevention Checklist, Senior Fitness Test (Fullerton), Berg Balance Scale, Tinetti Test, Stork Balance test (1 leg), Body Mass Index and 10m Walk Test. Following the pre- and post-evaluation, participants’ physical condition was improved as reflected by higher mean scores in the post evaluation.

Quality of life, wellbeing and social support

KPI 4 At least 70% of recruited participants maintained or improved their quality of life and different psychosocial aspects.

Table 100: KPI 4 AUTH (UC-PT2-003)

Parameter	Value
Percentage per QoL test indicating participants that maintained or improved their psychosocial status	WHOQOL-Bref – 77%
	Health related quality of life EQ-5D–5L – 88%
	General Self- Efficacy GSE – 100%
	Social Function OSSS-3 – 50%
	Beck Anxiety Inventory (BAI) – 63%
	Geriatric Depression Scale – 88%
	Friendship Scale – 50%
Average percentage of psychosocial status	73.2%

Participants’ quality of life, wellbeing and social inclusion was evaluated with standardized psychometric assessments, namely the WHOQOL-Bref, Health related quality of life EQ-5D–5L, General Self-efficacy GSE, Social Function OSSS-3, Beck Anxiety Inventory (BAI), Geriatric Depression Scale and Friendship Scale. Following the results of the pre- and post-evaluations, scores demonstrated that 100% of the participants showed improvement in their psychosocial aspects, as reflected by higher mean scores in all the assessments.

Usability and technology acceptance

KPI 5 At least 80% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Table 101: KPI 5 AUTH (UC-PT2-003)

Parameter	Value
Percentage of participants scoring > 68 in SUS	87.5%

The overall user experience quality was measured through the System Usability Scale (SUS) and Technology Acceptance Model (TAM) after the completion of the piloting. According to the SUS scores, scores above 80 are considered excellent. Participants scored an average rating of 84.7 for the LLM Care, which indicates a high level of perceived usability.

Overview of KPI achievement

Table 102: Overview of KPI achievement AUTH (UC-PT2-003)

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	YES	Engagement initiatives of AUTH were successful, related to the strategy to provide support and maintain contact, which had a positive impact on the absence of withdrawals, despite the number and length of training sessions.
KPI 2	YES	Pre and post evaluation scores were analysed, demonstrating notable enhancements in participants' cognitive status, as indicated by increased mean scores across all assessments.
KPI 3	YES	Pre- and post-evaluation measures indicated that the participants' physical condition was improved as reflected by higher mean scores in the post evaluation.
KPI 4	YES	The results of the pre and post evaluations, scores demonstrated that 100% of the participants showed improvement in their psychosocial aspects, as reflected by higher mean scores in all the assessments.
KPI 5	YES	Participants scored an average rating of 84.7 for the LLM Care, which indicates a high level of perceived usability.

Evaluation of data and outcomes from the evaluation assessments

Additionally, data and outcomes from the different evaluation assessments are part of the primary outcomes and are thus summarised below. The allocation of the different assessments to the different domains of the MAST evaluation has been presented in chapter 4.4.2. To facilitate the reader in capturing the information, the data is presented in single tables.

Table 103: LLM Care training data of AUTH participants.

Cognitive training - BrainHQ	
	AUTH

Days trained	16
Levels completed	151.5±18.03
Stars earned	409.125±77.23

Physical training- FitForAll	
	AUTH
Days trained	16
Number of total games per session	315.75±20.64
Iterations	6,201.25±798.30
Number of total sessions	16

System Usability Assessment and Technology Acceptance Model

Data collected in AUTH regarding usability indicate that SUS was 84.7 ± 11.8 and TAM scores $M = 6.41 \pm 0.09$, highlighting a very high level of technology acceptance and self-reported system usability.

Table 104: LLM Care Usability and Technology Acceptance of AUTH participants.

Usability and Technology Acceptance	
Assessments	Post-intervention
System Usability Scale (SUS)	$M = 84.7 \pm 11.8$
Technology Acceptance Model (TAM)	$M = 19.3 \pm 1.6$

Quality of Life, Social Support, Cognitive and Physical Function

Data collected during the pre-and post-assessments of participants' quality of life, cognitive and physical functioning are presented below.

Table 105: Participants' psychosocial status AUTH

Psychosocial status		
Psychosocial assessments	Pre-intervention	Post-intervention
WHOQOL- Bref	$M = 61 \pm 6.9$	$M = 67.3 \pm 9.2$
Health related quality of life - EQ - 5D – 5L	<u>MOBILITY</u> 100% - I have no problems in walking about	<u>MOBILITY</u> 100% - I have no problems in walking about

	<p><u>SELF CARE</u></p> <p>100% - I have no problems washing or dressing myself</p> <p><u>USUAL ACTIVITIES</u></p> <p>100% - I have no problems doing my usual activities</p> <p><u>PAIN/DISCOMFORT</u></p> <p>50% - I have no pain or discomfort</p> <p>37.5% - I have moderate pain or discomfort</p> <p>12.5% - I have extreme pain or discomfort</p> <p><u>ANXIETY/DEPRESSION</u></p> <p>50% - I am extremely anxious or depressed</p> <p>37.5% - I am moderately anxious or depressed</p> <p>12.5% - I am not anxious or depressed</p>	<p><u>SELF CARE</u></p> <p>100% - I have no problems washing or dressing myself</p> <p><u>USUAL ACTIVITIES</u></p> <p>100% - I have no problems doing my usual activities</p> <p><u>PAIN/DISCOMFORT</u></p> <p>50% - I have no pain or discomfort</p> <p>50% - I have moderate pain or discomfort</p> <p><u>ANXIETY/DEPRESSION</u></p> <p>25% - I am extremely anxious or depressed</p> <p>37.5% - I am moderately anxious or depressed</p> <p>37.5% - I am not anxious or depressed</p>
Health related quality of life (EQ - VAS)	$M=71.9 \pm 13$	$M=83.8 \pm 9.9$
General Self-efficacy GSE	$M=30 \pm 4.8$	$M=34.5 \pm 3.9$
Social Function OSSS-3	$M= 8.6 \pm 2.1$	$M= 8.5 \pm 1.5$
1-item Health Literacy	<p>25% - Extremely Confident</p> <p>50% - Quite a bit</p> <p>12.5 - Somewhat</p>	<p>28.6% - Extremely Confident</p> <p>28.6% - Quite a bit</p> <p>14.3 - Somewhat</p>

	12.5 - Not at all	14.3 - A little bit 14.3 - Not at all
Beck Anxiety Inventory (BAI)	$M=5.5 \pm 3$	$M=4.2 \pm 3.5$
Geriatric Depression Scale	$M= 7 \pm 3.1$	$M= 3.5 \pm 3.6$
Friendship Scale	$M=20.7 \pm 3.5$	$M=21.6 \pm 3.1$
Did you experience any of these life events [In the last 6 months/ since the last time we spoke]?	62.5% - No 37.5 - Yes	62.5% - Yes 37.5 - No
Did you get emotional support from anybody in relation to the event?	66.7% - Yes, a lot of support 33.3% - No support	80% - Yes, a lot of support 20% - Yes, some support
From whom did you get emotional support?	100% - Children 50% - Brother/sister 50% - Friend 50% - Other relative	60% - Children 20% - Brother/sister 20% - Friend 20% - Other: the LLM Care program
I participate enough in activities that are important to me	62.5% - Strongly Agree 37.5% - Agree	87.5% - Strongly Agree 12.5% - Agree
Using the LLM Care makes participating in the activities that are important to me:	37.5% - Much easier 37.5% - A little easier 12.5% - About the same 12.5% - A little more difficult	75% - Much easier 12.5% - A little easier 12.5% - About the same

Table 106: Participants' cognitive assessment AUTH (results presented as mean \pm sd).

Cognitive function

Cognitive assessments	Pre-intervention	Post-intervention
MoCA	$M= 26.4 \pm 1.5$	$M= 28.4 \pm 1$
MMSE	$M=28.2 \pm 1.3$	$M=29.1 \pm 0.3$
TMT A – Time (sec)	$M=52.2 \pm 11.8$	$M=57.6 \pm 23.1$
TMT A – Errors	-	-
TMT B – Time (sec)	$M= 125.6 \pm 44.8$	$M= 114.1 \pm 46.6$
TMT B – Errors	$M=0.9 \pm 1.45$	$M=0.5 \pm 0.75$
Verbal Fluency Phonological	$M=33.2 \pm 9.9$	$M=37.3 \pm 14.8$
Verbal Fluency Semantic	$M= 39.5 \pm 10.1$	$M= 47.5 \pm 9.8$
Stroop 1 (Black and white)	$M=94.9 \pm 15$	$M=95.6 \pm 21.8$
Stroop 2 (Coloured Boxes)	$M=70 \pm 13.2$	$M=74.2 \pm 23.4$
Stroop 3 (Coloured Words)	$M=36.9 \pm 10.1$	$M=42.6 \pm 12.9$
Symbol Digital Modalities Test (SDMT)	$M=36.2 \pm 11.3$	$M=36.9 \pm 10.8$

Table 107: Participants' physical assessment AUTH (results presented as mean \pm sd).

Physical function		
Physical assessments	Pre-intervention	Post-intervention
Personal Risk Factors	$M= 1.5 \pm 1.7$	$M= 0.75 \pm 0.7$
Chair Stand test in 30 sec.	$M=12 \pm 3.1$	$M=12.6 \pm 3.3$
Arm Curl Test in 30 sec.	$M=16.2 \pm 4.4$	$M=19.9 \pm 3.9$
2-minute Step tests (number of steps)	$M= 83.8 \pm 11.8$	$M= 93.6 \pm 3.3$
Chair Sit and Reach Test (in cm)	$M= -4.75 \pm 44.8$	$M= 9.1 \pm 9.8$
Back Stretch Test (in cm)	$M=-7.8 \pm 12.3$	$M=-4.6 \pm 16.5$

8- Foot Up-and-Go Test (in sec)	$M=5.6 \pm 1$	$M=6 \pm 1.2$
Berg Balance Scale	$M= 52.8 \pm 2.7$	$M= 54.9 \pm 1.3$
Tinetti Test	$M=27.6 \pm 0.5$	$M=28 \pm 0$
Stork Balance Stand test	$M=23.4 \pm 26.5$	$M=31.7 \pm 40.2$
Body Mass Index	$M=27 \pm 4.2$	$M=27.1 \pm 5.3$
Self-selected Velocity average time (in sec)	$M=4.7 \pm 0.5$	$M=4.4 \pm 0.6$
Fast Velocity average time (in sec)	$M=3.6 \pm 0.6$	$M=3.4 \pm 0.7$
Actual Velocity - average Self-Selected Velocity (in m/s)	$M=1.3 \pm 0.1$	$M=1.4 \pm 0.2$
Actual Velocity - average Fast Velocity (in m/s)	$M=1.7 \pm 0.2$	$M=1.8 \pm 0.3$

GEWI

Overview

Baseline: GEWI research team performed a series of cognitive and physical assessments (N=2) to evaluate the condition of each participant. As previously mentioned, the participants were partially cognitively impaired therefore the pre-assessment procedure had to be adjusted and not all tests could be performed. In addition, demographics data and psychometric self-administrative tests have been fulfilled by participants to explore their quality of life. In case a participant was not capable of independently performing the tests, a research member assisted him/her during the process.

Participants testing the cognitive training component in their home-setting, no physical assessments (N=3) were performed. The other procedures remained the same.

Intervention period: Participants were engaged in 16 sessions 2 times per week and interacting with the LLM Care cognitive and physical training, during a 2-month period. As the participants felt more secure and thus reached better scores, both participated simultaneously in the trainings sessions and took turns when performing the tasks. This further allowed them to have some regular breaks to recover. Due to the level of impairment of the participants it was not possible to perform the cognitive and physical

training component for 60 minutes each. However, during the course of the training, the duration and number of tasks performed increased. All sessions were conducted under the supervision of a researcher who was trained in the use of LLM Care prior to being the pilot.

Participants (N=3) tested the cognitive training component in their home-setting, performed the training at least 3 times a week for 16 sessions. They carried out the training on their own after being introduced to the programme and receiving a user manual. In addition, they were encouraged to contact the researcher with any questions or concerns. The researcher made contact about once a week by phone to remotely accompany the users during the pilot.

End of intervention: It was intended to perform the same baseline assessments to re-evaluate and detect any improvements in participants' cognitive and physical condition as well as their quality of life. Again, executing all assessments was not feasible therefore the evaluation was adapted to the individual's constitutional state. Participants in the home-setting were exhausted from the number of questionnaires and assessments and thus rejected participating in the post-evaluation. This was accepted by the researcher since voluntary participation in the study was a major premise with regards to the ethical considerations.

Primary and secondary outcome

Primary outcome

The primary outcomes were to measure a predefined set of KPIs which have already been presented in chapter 4.5.2. The following tables present the data used to determine the success of each KPI. Table 113 provides an overview of the success of the pilot with regards to KPIs. The post-intervention assessments were only evaluated with a limited number of participants due to the reasons previously described. The number of participants considered for the evaluation has been indicated in the tables.

Recruitment and retention

KPI 1 At least 80% of the recruited participants successfully participated in all sixteen (16) training sessions of the piloting.

Table 108: KPI 1 GEWI (UC-PT2-003)

Parameter	GEWI
Target number of total training sessions	16

Average number of total training sessions	11
Number of participants considered for the evaluation of the KPI	5
Percentage of participants participating in 16 sessions	0%

Participants taking part in the cognitive and physical training component had 16 training sessions. However, due to their level of cognitive impairment, they were not capable of performing each training components for 1h. Thus the KPI 1 was not achieved. Participants in the home-setting were instructed to perform the training for 16 sessions à 1h, which was also challenging for them to incorporate in their everyday life.

Cognitive status

KPI 2 At least 70% of recruited participants maintained or improved their cognitive status.

Table 109: KPI 2 GEWI (UC-PT2-003)

Parameter	Value
Percentage per cognitive screening test indicating participants that maintained or improved their cognitive status	MoCA – 100%
	MMSE – 100%
	Trail Making A – not applicable*
	Trail Making A Errors – not applicable*
	Trail Making B – not applicable*
	Trail Making B Errors – not applicable*
	Phonological Verbal Fluency – not assessed
	Semantic Verbal Fluency – not assessed
	STROOP 1 – 100%
	STROOP 2 - 100%
	STROOP 3 – 100%

	Symbol Digital Modalities Test (SDMT) – not assessed
Number of participants considered for the evaluation of the KPI	1
Average percentage of cognitive status	100%

*not applicable as the participant couldn't finish in the required time

The participant's cognitive functioning was evaluated with standardized psychometric assessments. Pre- and post-evaluation scores were analysed, demonstrating maintenance or even small improvements in the participant's cognitive status, as indicated by remaining or increased mean scores across most of the assessments. However, during the post-evaluation, the participant was familiar with the researcher, therefore clearly less insecure and performed the assessments more successfully. At this stage of cognitive decline, the aspect of confidentiality is of increased importance and might have influenced the participant's performance as well.

Physical status

KPI 3 At least 70% of recruited participants maintained or improved their physical status.

Table 110: KPI 3 GEWI (UC-PT2-003)

Parameter	Value
Percentage per physical test indicating participants that maintained or improved their physical status	Personal Risk Factors – not assessed
	Chair Stand test in 30 seconds – 0%
	Arm Curl Test in 30 seconds – 50%
	2-minute Step tests – 50%
	Chair Sit and Reach Test – 100%
	Back Stretch Test – 100%
	8- Foot Up-and-Go Test – 100%
	Berg Balance Scale – 100%

	<p>Tinetti Test – 100%</p> <p>Stork Balance test (1 leg) – not assessed</p> <p>Self-selected Velocity – not assessed</p> <p>Fast Velocity – not assessed</p> <p>Actual Velocity – not assessed</p> <p>Actual Velocity – not assessed</p>
Number of participants considered for the evaluation of the KPI	2
Average percentage of physical status	75%

Additionally, participants' physical status was evaluated. Following the pre- and post-evaluation, participants' physical condition was maintained or even slightly improved in part of the assessments. This is as reflected by improved scores in the post-evaluation. However, again the participants were familiar with the researcher, therefore clearly less insecure and performed the assessments more successfully. At this stage of cognitive decline, the aspect of confidentiality is of increased importance and might have influenced the participant's physical performance as well.

Quality of life, wellbeing and social support

KPI 4 At least 70% of recruited participants maintained or improved their quality of life and different psychosocial aspects.

Table 111: KPI 4 GEWI (UC-PT2-003)

Parameter	Value
Percentage per QoL test indicating participants that maintained or improved their psychosocial status	WHOQOL-Bref – 100%
	Health related quality of life EQ-5D–5L – 100%
	General Self- Efficacy GSES – 100%
	Social Function OSSS-3 – 100%
	Beck Anxiety Inventory (BAI) – 100%

	Geriatric Depression Scale – 100%
	Friendship Scale – 100%
Number of participants considered for the evaluation of the KPI	5
Average percentage of psychosocial status	100%

Participants quality of life, wellbeing and social inclusion was evaluated with standardized psychometric assessments. Following the results of the pre- and post-evaluations, scores demonstrated that 100% of the participants showed maintained or improved scores in their psychosocial aspects, as reflected by equal or higher mean scores in all the assessments.

Usability and technology acceptance

KPI 5 At least 80% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Table 112: KPI 5 GEWI (UC-PT2-003)

Parameter	Value
Number of participants considered for the evaluation of the KPI	5
Percentage of participants scoring > 68 in SUS	20%

The overall user experience quality was measured through the System Usability Scale (SUS) and Technology Acceptance Model (TAM) after the completion of the piloting. According to the SUS scores, scores above 80 are considered excellent. Participants

scored an average rating of 48.5 indicating a poor level of perceived usability. However, for participants conducting both training components and being accompanied by the researcher, the average rating was higher (51.25) meaning the usability is ok. Their main concern with respect to usability was referring to the level of adapting the programme to their needs, differing due to their level of cognitive impairment. For participants testing the DS in the home setting the rating was differing a lot resulting in a mean value of 46.66 (min=12.5; max=77.5) indicating a poor level of perceived usability. The LLM Care training was not initially developed to be deployed in the home-setting. Due to the challenges in the recruitment (see 4.9.5) this mitigation action was taken to allow more participants to test the cognitive training component. At the same time, this meant that no supervision of and support for the cognitive training could be offered.

Overview of KPI achievement

Table 113: Overview of KPI achievement GEWI (UC-PT2-003)

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	NO	Participants taking part in the cognitive and physical training component had 16 training sessions. However, due to their level of cognitive impairment, they were not capable of performing each training components for 1h. Thus the KPI 1 was considered as not achieved. Participants in the home-setting were instructed to perform the training for 16 sessions à 1h, which was also challenging for them to incorporate in their everyday life.
KPI 2	YES	Pre- and post-evaluation scores were analysed, demonstrating maintenance or even small improvements in the participant's cognitive status, as indicated by remaining or increased mean scores across most of the assessments. However, during the post-evaluation, the participant was familiar with the researcher, therefore clearly less insecure and performed the assessments more successfully. At this stage of cognitive decline, the aspect of confidentiality is of increased importance and might have influenced the participant's performance as well.

KPI 3	YES	Participants' physical condition was maintained or even slightly improved in part of the assessments, which is reflected by improved scores in the post-evaluation. Again the participants were familiar with the researcher, therefore clearly less insecure and performed the assessments more successfully. At this stage of cognitive decline, the aspect of confidentiality is of increased importance and might have influenced the participant's physical performance as well.
KPI 4	YES	100% of the participants maintained or improved their scores of the psychosocial assessments, as reflected by equal or higher mean scores in all the assessments.
KPI 5	NO	Scores from the SUS indicating a poor level of perceived usability (average rating of 48.5). Rankings differed between those participants conducting both training components (average rating 51.25) and those testing the DS in the home setting (average rating of 46.66). Main concerns were referring to the level of adapting the programme to their needs, differing due to their level of cognitive impairment. It is to be noted that the LLM Care training was neither developed to be used by people with medium levels of cognitive decline not to be deployed in the home-setting. Thus, the training was not capable of addressing the specific needs of this target group and this setting, which however were outside the scope of the pilot.

Evaluation of data and outcomes from the evaluation assessments

Additionally, data and outcomes from the different evaluation assessments are part of the primary outcomes and are thus summarised below. The allocation of the different assessments to the different domains of the MAST evaluation has been presented in chapter 4.4.2. To facilitate the reader in capturing the information, the data is presented in single tables.

In addition, usability & technology acceptance measures have been also performed with all participants (n=4) to evaluate participants' interaction with the proposed digital solutions.

Table 114: LLM Care training data of GEWI participants.

Cognitive training - BrainHQ	
	GEWI
Days trained	11.5±2.64
Levels completed	143.75±94.51
Stars earned	367.5±323.4

Physical training- FitForAll	
	GEWI
Days trained	16
Number of total games per session	144±8.49
Iterations	14261±64.05
Number of total sessions	16

System Usability Assessment and Technology Acceptance Model

Data collected in GEWI regarding usability indicate that SUS was $M = 48,50 \pm 24,53$ and TAM scores $M = 10,6 \pm 2,61$ highlighting a very high level of technology acceptance and self-reported system usability.

Table 115: LLM Care Usability and Technology Acceptance of GEWI participants.

Usability and Technology Acceptance	
Assessments	Post-intervention
System Usability Scale (SUS)	$M = 48,5 \pm 24,53$
Technology Acceptance Model (TAM)	$M = 10,6 \pm 2,61$

Quality of Life, Social Support, Cognitive and Physical Function

Table 116: Participants' psychosocial assessment GEWI (results presented as mean±sd).

Psychosocial status		
	Pre-intervention	Post-intervention
Psychosocial assessments		
WHOQOL-Bref	$M = 81 \pm 12,53$	$M = 81 \pm 12,53$

Health related quality of life - EQ - 5D – 5L	<u>MOBILITY</u>	<u>MOBILITY</u>
	40% - I have no problems in walking about	40% - I have no problems in walking about
	40% - I have slight problems in walking about	40% - I have slight problems in walking about
	20% - I have moderate problems in walking about	20% - I have moderate problems in walking about
	<u>SELCARE</u>	<u>SELCARE</u>
	80% - I have no problems washing or dressing myself	80% - I have no problems washing or dressing myself
	20% - I have slight problems washing or dressing myself	20% - I have slight problems washing or dressing myself
	<u>USUAL ACTIVITIES</u>	<u>USUAL ACTIVITIES</u>
	40% - I have no problems doing my usual activities	40% - I have no problems doing my usual activities
	20% - I have slight problems doing my usual activities	20% - I have slight problems doing my usual activities
	20% - I have moderate problems doing my usual activities	20% - I have moderate problems doing my usual activities
	20% - I am unable to do my usual activities	20% - I am unable to do my usual activities
	<u>PAIN/DISCOMFORT</u>	<u>PAIN/DISCOMFORT</u>
	40% - I have no pain or discomfort	40% - I have no pain or discomfort

	20% - I have slight pain or discomfort	20% - I have slight pain or discomfort
	40% - I have moderate pain or discomfort	40% - I have moderate pain or discomfort
	<u>ANXIETY/DEPRESSION</u>	<u>ANXIETY/DEPRESSION</u>
	60% - I am not anxious or depressed	60% - I am not anxious or depressed
	20% - I am slightly anxious or depressed	20% - I am slightly anxious or depressed
	20% - I am moderately anxious or depressed	20% - I am moderately anxious or depressed
Health related quality of life (EQ - VAS)	M=83 ± 13,04	M=83 ± 13,04
Self-efficacy GSE	M=33,4 ± 6,47	M=33,4 ± 6,47
Social Function OSSS-3	M=11,6 ± 2,61	M=11,6 ± 2,61
Health Literacy	M=3,2 ± 1,79	M=3,2 ± 1,79
Beck Anxiety Inventory (BAI)	M=0 ± 0	M=0 ± 0
Geriatric Depression Scale	M=2 ± 1,58	M=2 ± 1,58
Friendship Scale	M=20 ± 3,08	M=20 ± 3,08
Did you experience any of these life events [In the last 6 months/ since the last time we spoke]?	20% =yes 80% not assessed	20% =yes 80% not assessed
Did you get emotional support from anybody in relation to the event?	20% - Yes, some support 80% - not assessed	66.7% - Yes, some support 80% - not assessed
From whom did you get emotional support?	20% - Children 80% - not assessed	20% - Children 80% - not assessed
I participate enough in activities that are important to me		M=4,4 ± 1,34
Using the LLM Care makes participating in the activities that are important to me:		M=3,40 ± 0,55

Due to the high number of assessments and questionnaires as well as the cognitive constitution of part of the participants, most of them did not agree to conduct the assessments again. Thus, scores presented below are referring to one single participant. Compared to the baseline score, almost all slightly improved. In relation to the mean value, the results achieved are nevertheless below average, which can be attributed to the cognitive impairment of the participant.

Table 117: Participants' cognitive assessment GEWI (results presented as mean \pm sd).

Cognitive function		
	Pre-intervention	Post-intervention
Cognitive assessments		
MoCA	M=18,8 \pm 8,41	15
MMSE	M=23,8 \pm 5,17	23
TMT A – Time (sec)	M=59,88 \pm 36,88	110
TMT A – Errors	M=0,5 \pm 0,58	1
TMT B – Time (sec)	M=83,84 \pm 16,00	/
TMT B – Errors	M=1,67 \pm 2,08	/
Verbal Fluency Phonological	M=9,5 \pm 7,78	/
Verbal Fluency Semantic	M=20 \pm 11,31	/
Stroop 1 (Black and white)	M=99 \pm 14,18	95
Stroop 2 (Coloured Boxes)	M=70 \pm 21,79	62
Stroop 3 (Coloured Words)	M=30,33 \pm 11,01	27
Symbol Digital Modalities Test (SDMT)	M=26 \pm 13,56	not assessed

The physical assessments were only performed with participants completing the whole training (n=2). Due to their cognitive and physical constitution, not all assessments could be conducted.

Table 118: Participants' physical assessment GEWI (results presented as mean \pm sd).

Physical function		
	Pre-intervention	Post-intervention
Physical assessments		
Personal Risk Factors	not assessed	not assessed
Chair Stand test in 30 sec.	M=9 \pm 2,83	M=8 \pm 2,82
Arm Curl Test in 30 sec.	M=8 \pm 4,24	M=9,5 \pm 7,01
2-minute Step tests (number of steps)	M=50 \pm 28,28	M=47,5 \pm 24,75
Chair Sit and Reach Test (in cm)	M= 4 \pm 5,66	M=4 \pm 5,66
Back Stretch Test (in cm)	M=-21 \pm 17,62	M=-19,5 \pm 18,65

8- Foot Up-and-Go Test (in sec)	M=11,82 ± 6,68	M=10,92 ± 6,4
Berg Balance Scale	M=52 ± 5,66	M=52 ± 5,66
Tinetti Test	M=24 ± 5,66	M=24 ± 5,66
Stork Balance Stand test	not assessed	not assessed
Body Mass Index	not assessed	not assessed
Self-selected Velocity average time (in sec)	not assessed	not assessed
Fast Velocity average time (in sec)	not assessed	not assessed
Actual Velocity - average Self-Selected Velocity (in m/s)	not assessed	not assessed
Actual Velocity - average Fast Velocity (in m/s)	not assessed	not assessed

4.9.5.2 Group 2: NewSum Intervention

Demographics

Table 119 presents the demographics data from the participants in AUTH premises.

Table 119: Participants' Demographics

Demographics	
	AUTH (N=5)
Age	M= 71.8 ±6.7
Gender	60% Females 40% Males
Level of education	60% bachelor's degree 40% Primary school certificate
Marital status	80% Married 20% Widow/er
Level of Digital Literacy	100% Basic Users

Primary and secondary outcome

Primary outcome

The primary outcomes were to measure a predefined set of KPIs which have already been presented in chapter 4.5.2. The following tables present the data used to determine the success of each KPI. Table 123 provides an overview of the success of the pilot with regards to KPIs.

Recruitment and retention

KPI 1 At least 80% of the recruited participants successfully remained engaged for one month.

Table 120: KPI 1 AUTH NewSum(UC-PT2-003)

Parameter	AUTH
Target number of participants that successfully remained engaged for one month.	5
Number of participants that successfully remained engaged for one month.	5
Percentage of participants that successfully remained engaged for one month.	100%

KPI 1 was successfully achieved with 100%, meaning that engagement initiatives of AUTH were successful, related to the strategy to provide support and maintain contact, which had a positive impact on the absence of withdrawals, despite the length of the pilot.

Quality of life, wellbeing and social support

KPI 2 At least 70% of recruited participants maintained or improved their quality of life and different psychosocial aspects.

Table 121: KPI 2 AUTH NewSum (UC-PT2-003)

Parameter	Value
Percentage per QoL test indicating participants that maintained or improved their psychosocial status	WHOQOL-Bref – 60%
	Health related quality of life EQ-5D–5L – 60%
	General Self- Efficacy GSE – 60%
	Social Function OSSS-3 – 80%
	Friendship Scale – 100%
Average percentage of psychosocial status	72%

Participants quality of life, wellbeing and social inclusion was evaluated with standardized psychometric assessments, namely the WHOQOL-Bref, Health related quality of life EQ-5D–5L, General Self-efficacy GSE, Social Function OSSS-3 and Friendship Scale. Following the results of the pre- and post-evaluations, scores demonstrated that participants showed improvement in their psychosocial aspects, as reflected by higher mean scores in all the assessments.

Usability and technology acceptance

KPI 3 At least 80% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Table 122: KPI 3 AUTH NewSum (UC-PT2-003)

Parameter	Value
Percentage of participants scoring > 68 in SUS	75%

The overall user experience quality was measured through the System Usability Scale (SUS) and Technology Acceptance Model (TAM) after the completion of the piloting. According to the SUS scores, scores above 80 are considered excellent. Participants scored a relatively high level of usability for the NewSum, with a mean score of 80.5.

Overview of KPI achievement

Table 123: Overview of KPI achievement AUTH NewSum (UC-PT2-003)

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	Yes	Engagement initiatives of AUTH were successful, related to the strategy to provide support and maintain contact, which had a positive impact on the absence of withdrawals, despite the length of the pilot.
KPI 2	Yes	Results of the pre- and post-evaluation indicated that participants showed improvement in their psychosocial aspects, as reflected by higher mean scores in all the assessments.

KPI 3	Yes	The overall user experience quality was scored with a mean score of 80.5, indicating a relatively high level of usability.
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Evaluation of data and outcomes from the evaluation assessments

Additionally, data and outcomes from the different evaluation assessments are part of the primary outcomes and are thus summarised below. The allocation of the different assessments to the different domains of the MAST evaluation has been presented in chapter 4.4.2. To facilitate the reader in capturing the information, the data is presented in single tables.

Data collected in AUTH regarding usability indicate that SUS was 84.7 ± 11.8 and TAM scores $M = 6.41 \pm 0.09$, highlighting a very high level of technology acceptance and self-reported system usability.

Table 124: NewSum Usability and Technology Acceptance of AUTH participants.

Usability and Technology Acceptance	
Assessments	Post-intervention
System Usability Scale (SUS)	$M = 80.5 \pm 22.1$
Technology Acceptance Model (TAM)	$M = 16 \pm 2.2$

Quality of Life and Social Support

Data collected in AUTH during the pre-and post-assessments of participants' quality of life are presented below.

Table 125: Participants' psychosocial status AUTH

Psychosocial status		
Psychosocial assessments	Pre-intervention	Post-intervention
WHOQOL- Bref	$M = 66.8 \pm 6$	$M = 67.7 \pm 4.6$
Health related quality of life - EQ - 5D – 5L	<u>MOBILITY</u> 80% - I have no problems in walking about	<u>MOBILITY</u> 80% - I have no problems in walking about

	<p>20% - I have moderate problems in walking about</p> <p><u>SELF CARE</u></p> <p>100% - I have no problems washing or dressing myself</p> <p><u>USUAL ACTIVITIES</u></p> <p>80% - I have no problems doing my usual activities</p> <p>20% - I have moderate problems doing my usual activities</p> <p><u>PAIN/DISCOMFORT</u></p> <p>60% - I have moderate pain or discomfort</p> <p>40% - I have no pain or discomfort</p> <p><u>ANXIETY/DEPRESSION</u></p> <p>60% - I am moderately anxious or depressed</p> <p>40% - I am not anxious or depressed</p>	<p>20% - I have moderate problems in walking about</p> <p><u>SELF CARE</u></p> <p>80% - I have no problems washing or dressing myself</p> <p>20% - I have moderate problems washing or dressing myself</p> <p><u>USUAL ACTIVITIES</u></p> <p>100% - I have no problems doing my usual activities</p> <p><u>PAIN/DISCOMFORT</u></p> <p>40% - I have no pain or discomfort</p> <p>40% - I have moderate pain or discomfort</p> <p>20% - I have extreme pain or discomfort</p> <p><u>ANXIETY/DEPRESSION</u></p> <p>40% - I am not anxious or depressed</p> <p>40% - I am extremely anxious or depressed</p> <p>20% - I am moderately anxious or depressed</p>
Health related quality of life (EQ - VAS)	$M=76 \pm 18.8$	$M=76 \pm 15.2$
General Self-efficacy GSE	$M=27.8 \pm 3.5$	$M=30 \pm 2.1$

Social Function OSSS-3	$M=10 \pm 1.2$	$M=10.6 \pm 3.1$
1-item Health Literacy	40% - Quite a bit 20% - Not at all 20% - A little bit 20% - Somewhat	40% - Quite a bit 20% - Not at all 20% - A little bit 20% - Somewhat
Friendship Scale	$M=20.8 \pm 2.9$	$M=17.2 \pm 9.9$
Did you experience any of these life events [In the last 6 months/since the last time we spoke]?	60% - No 40% - Yes	60% - No 40% - Yes
Did you get emotional support from anybody in relation to the event?	50% - Yes, some support 50% - No support	50% - Yes, some support 50% - No support
From whom did you get emotional support?	50% - Children 50% - Brother/sister	50% - Children 50% - Other
I participate enough in activities that are important to me	60% - Agree 40% - Neither Agree nor Disagree	75% - Agree 25% - Neither Agree nor Disagree
Using the NewSum application makes participating in the activities that are important to me:	60% - About the same 20% - A little easier 20% - Much easier	50% - A little easier 50% - About the same

Interviews results

A summary of older adults' experiences and the overall feedback gained at the end of the LLM Care intervention, resulting from the final interviews (individual or group interviews) conducted in AUTH is presented in Table 126. In particular, a focus group was conducted in AUTH, where participants had the opportunity to discuss and share their thoughts and perceptions with other participants and the AUTH research team. Experiences and information discussed among participants are categorized in seven (7) discrete categories: i) technology adoption and barriers, ii) user experience and ease of use, iii) communication and social connections, iv) health and well-being, v)

willingness to pay the DS and vi) Digital solution provision and vii) recommendations for improvement.

Table 126: Older adults' experiences and overall feedback collected in AUTH

Thematic	Feedback
Technology Adoption and Barriers	A notable observation was the participants' new experience with using tablets, as several individuals mentioned that they had never utilized this technology before. The program introduced them to a novel and empowering digital tool, which opened up new avenues of engagement and interaction. This highlights the program's capacity to not only deliver its core objectives but also equip participants with valuable digital skills, fostering their technological literacy. Participants' positive response to this aspect of the program underscores its ability to introduce innovative approaches and enhance participants' digital capabilities.
User Experience and Ease of Use	The program was considered straightforward and user-friendly by all participants. Their feedback expressed a strong inclination to continue incorporating the program into their routine, even after the conclusion of the intervention, with a minimum frequency of two sessions per week in their own homes. This reflects their high level of satisfaction and enthusiasm toward the program's content and delivery. Notably, participants were satisfied with the physical and cognitive exercises, recognizing the significant positive impact these components had on their overall well-being. The program's ease of use and its effectiveness in fostering improvement were also acknowledged, highlighting its ability to provide accessible and valuable interventions to enhance participants' physical and cognitive abilities.
Communication and Social Connections	The program significantly enhanced participants' communication abilities, facilitating more effective interactions with others. Participants exhibited strong motivation through actively engaging with the program and contributing to research initiatives. This profound sense of purpose highlights the program's empowering nature,

	fostering increased social inclusion and a sense of value as contributors to research endeavours.
Health and Well-being	The LLM Care program elicited an overwhelmingly positive response from the participants, demonstrating its efficacy in fostering social inclusion and active participation. Notably, it exerted a substantial positive impact on their overall well-being and significantly enhanced their overall quality of life. Moreover, participants reported a notable enhancement in their well-being when engaging in the intervention, while their families expressed satisfaction observing their active involvement in the program. A subset of participants reported a reduction in their dependency on sleep medication, indicating an improvement in their sleep quality. These findings highlight the program's effectiveness in delivering tangible and holistic benefits to the participants.
Willingness to pay the DS	Participants consistently expressed their with the program's affordability, citing no challenges or concerns related to payment. In fact, they advocated for government funding to ensure widespread accessibility to all older individuals who possess an interest in the program, thereby safeguarding its long-term sustainability.
Digital solution provision	Participants highlighted the significance of making the program freely available to promote equitable access and maximize its reach among the target demographic. This feedback further emphasizes participants' recognition of the program's value and their desire for inclusive support from governmental sources to facilitate its continued operation and benefit a larger population.
Recommendations for Improvement	The team involved in the program received high praise from participants. Participants' feedback consistently emphasized the importance of sustaining and continuing the provision of the program. This positive sentiment reflects the program's remarkable ability to deliver a seamless and impactful experience.

Table 127: Older adults' experiences and overall feedback collected in GEWI

Thematic	Feedback
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Technology Adoption and Barriers

Cognitive and physical training:

During the cognitive and physical training, some initial challenges were faced with respect to connecting all devices properly. Users had to get used to the new digital devices as they hadn't used any kind of touch screen before.

Cognitive training:

Participants only conducting the cognitive training in their home-setting reported that by training in the personal trainer mode, there were always the same exercises proposed. Other exercises with the focus on "memory" or "people skills" were not entering the predefined set but had to be selected and started manually. Some of the exercises were only available in English whereas for others it was no problem to have them explained in German.

User Experience and Ease of Use

Cognitive and physical training:

For users participating in the cognitive and physical training, the training was a regular activity and perceived as contrast to their monotonous daily routine. They mentioned that the physical training was not too demanding. As one of the participants could not find their glasses anymore, following the exercises on the screen was difficult. The researcher thus accompanied the exercises verbally and physically by performing the movements as well. For the cognitive training, only some certain exercises were conducted with the users to avoid being overwhelming. Since both participants were new to using any kind of digital devices, they needed to get familiarised to using a touch screen first. After some time of getting used to the devices, the setting and the researcher it was possible to increase the number and level of exercises. Performing the exercises on the tablet was closely accompanied and supported by the researcher.

Cognitive training:

For participants with higher level of digital competence, the DS was easy to use. It was reported that the explanation of the exercises was not always straight forward therefore

	<p>it took some time for them to understand what to do. Their criticism was targeted at the analysis of their results. All of them stated that seeing their results and receiving some feedback on the performance would have been beneficial and motivating. The analysis or overview of the scores was not perceived as easily accessible. Some type of visualization in a graph would have been supportive for them.</p> <p>Especially users with slight to moderate cognitive impairments had difficulties in performing the different tasks. For this target group, it would be necessary to have a warm-up phase and not start with the highest level of their previous training immediately.</p>
Communication and Social Connections	<p><u>Cognitive and physical training:</u></p> <p>Participants clearly valued having a person spending time with them and listen to them. This was one major aspect for them why they perceived the training beneficial, not so much the concrete physical and cognitive exercises.</p> <p><u>Physical training:</u></p> <p>Nothing reported.</p>
Health and Well-being	<p><u>Cognitive and physical training:</u></p> <p>The physical training was not perceived as having an effect on their health and wellbeing, as it was not really demanding. With respect to the cognitive training, the same participant was reporting that it was challenging but also slightly helped them to concentrate in everyday life.</p> <p>However, more benefit was seen in having regular activities in everyday life.</p> <p><u>Cognitive training:</u></p> <p>Overall, participants saw potential in the DS to support the cognitive fitness level. Any concrete effect was not experienced during the pilot.</p>
Recommendations for Improvement	<ul style="list-style-type: none"> • Tailor the programme to the individuals needs by asking a few questions prior to the start <ul style="list-style-type: none"> ○ cognitive level ○ type of impairment (i.e. red-green weakness, hearing impairment)

- alternative exercises for people with any type of impairment
- for people with early stages of dementia:
 - warm-up phase would be relevant to avoid any type of overload
 - staying in one level for longer in order to manifest achievements
 - only change one parameter increasing the difficulty at once
- analysis of the individual's performance after each training session:
 - use of a bar- and/or line chart displaying the achievements over time
 - comparison of scores per exerciser and over all exercises performed that session

5 Use case 004a

5.1 Introduction

In the following the pilot activities of PT2-004a *Night Surveillance rounds at Community Care* are described. The target group of this use case was composed of 65+ year old persons living in a nursing home and the caregivers working in these facilities in the rural reference site “Oberbergischer Kreis” (OBK) in Germany. No other criteria, than age and residence, or specific needs had to be fulfilled by the target group. This use case uses a robot, that can help to “patrol” hallways and detect if anything is wrong providing a function of night-time surveillance.

The main objectives of this use case were to investigate user engagement with the SHAPES digital solution and to validate the capability to:

- Support residence in nursing homes
- Support caregivers in nursing homes
- Improve older individual’s life quality of life, wellbeing and psychosocial aspects

Additionally, the users’ trust and acceptance of the SHAPES digital solution was explored. This use case was led by the GEWI – Institut für Gesundheitswirtschaft e.V. and was not replicated.

5.2 Description

Nursing homes are often constrained to bring residents to their rooms quite early for evening retreat. The long evening shifts are often carried-out with a great reduction of staff. KOMPAL can help to “patrol” hallways and detect if anything is wrong providing a function of night-time surveillance. The connected cameras can help to facilitate to see if a resident is unexpectedly leaving his room, identify him, using the VICOMTECH recognition module – as can be common for disoriented patients – in the middle of the night, and be connected to alarms on corridor and main doors. If KOMPAL is inside a resident’s room, he can also help to monitor how the patient is doing, detect a fall, and make it easier for them to alert in case of emergency. KOMPAL can also be connected to various sensors and detect for sudden changes in temperature or the appearance of smoke.

5.3 Digital solutions used in this use case

Kompai Robot (KOMPAI)

Robot that provides several different functionalities such as: fall detection, walking assistance, entertainment, measuring the body temperature and UV-disinfection.

5.3.1 Digital solutions used for COVID-19 response

To assess the COVID-19 response the robot does provide two different features:

- UV-disinfection through five lamps installed on a trailer
- Measuring the body temperature and send an alert if the temperature is too high

5.4 Data plan

The data plan for phases 4 and 5 for PT2-004a has been finalised and can be accessed on the SHAPES website ([Data plan UC-PT2-004a](#)).

5.4.1 Data capture methods to be used

Data capture methods used during this pilot are listed below:

Phase 2

- Semi-structured interview

Phase 5

- Excel file to capture the following data:
 - Participant data (see Data Plan)
 - Harmonised questionnaires (more details on harmonised data will be provided in Deliverable 6.9)
 - WHOQOL-BREF (2)
 - EQ-5D-5L (3)
 - General Self-Efficacy Scale (4)
 - Oslo Social Support Scale (5)
 - Single item health literacy scale

- Participation questions
- System Usability Scale (6)
- Technology acceptance questions (7)
- UEQ-S (8)

5.4.2 Planning of evaluation

MAST

The MAST framework (model for assessment of telemedicine) (9) was applied as it provides a structured approach for assessing the effectiveness and contribution of UC-PT2-004a/b to quality of care. In a multidisciplinary process, MAST summarises and evaluates information to the use of telemedicine related to the medical, social, economic and ethical issues.

For UC-PT2-004a/b, four of the seven dimensions of MAST were identified to be of importance. These were: Safety, Clinical Effectiveness, Patient perspectives and Economic aspects. A further exploration and description of the reasons for inclusion will be provided in the evaluation report (D6.9). Table 128 shows a summary of the MAST evaluation.

Table 128: Data required for MAST evaluation of UC-PT2-004a/b

MAST Domain	Topic	Outcome	Data required	Time point
Safety	Clinical safety	Frequency (of collision)	Protocol of collisions	During the pilot
Clinical Effectiveness	Mental health Clinical Effectiveness	Social support	OSSS-3 and life events scale	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
Patient perspectives	Satisfaction and acceptance	User experience	UEQ-S scores	End of pilot
		User acceptance	TAM score	End of pilot

	Understanding of information	Usability of technology	SUS scale	End of pilot
	Ability to use technology			
	Self-efficacy	Self-efficacy	General self-efficacy scale	Baseline and end of pilot
Economic aspects	Amount and costs of resources used	Cost of device	Cost as per device purchasing invoice	End of pilot

MAFEIP

The MAFEIP tool (10) was not applied to evaluate UC-PT2-004a/b due to a small-scale deployment and the non-case controlled study design of this UC.

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

Momentum

Critical success factors (CSFs) and performance indicators offered by the Momentum blueprint (11) were determined in UC-PT2-004a/b. These factors should be considered when scaling up telemedicine and integrating it into healthcare delivery systems. Although the digital solution of this use case does not count as telemedicine in particular and the aim is to increase wellbeing and a feeling of safety of the individual rather than medical conditions, the advantage of a rapid consideration during the pilot design predominates. Outcome of the process are included in the annex (Annex 24) and details of each CSF are provided below.

CSF 1. Cultural readiness for the telemedicine service

In the region where this use case has been deployed, only limited sharing of clinical information between different health care providers is realised. Within one institution information are shared with the patient. Progress and promoting of telemedicine is highly welcomed in the region.

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

The advantages of telemedicine are clearly seen and considered the best solution to address shortage of skilled health professionals. UC-PT2-004a in particular does not aim to meet any needs within the medical area.

CSF 3. Ensure leadership through a champion

At the end of the project a clear leadership will be identified. The way towards deployment of the SHAPES digital solutions should be supported by influential persons.

CSF 4. Involvement of healthcare professionals and decision-makers

Healthcare professionals and decision-makers were partially involved in the development of the content of the project in Phases 1-3. As the organisation of this use case is working together with decision makers from the reference site, those have been involved in the process of the project.

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

Patients were involved in the development of this digital solution through activities of all phases. The development was based on the patient needs and a training for using the digital solution is planned.

CSF 6. Ensure that the technology is user-friendly

The project considered attentively the user-friendliness of the digital solutions. Potential users were asked about their opinion and experience interacting with the solution and all feedback was considered in the final development of the SHAPES digital solutions. The evaluation also included metrics like the System Usability Scale (SUS).

CSF 7. Pull together the resources needed for deployment

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

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

In general, health insurances have a vested interest in lowering costs i.e. their spendings, and direct more and more efforts and resources towards increasing prevention in. Yet, first evaluations to identify primary clients for this digital solution still have to be completed.

CSF 9. Prepare and implement a business plan

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

CSF 10. Prepare and implement a change management plan

It will be evaluated after the end of the project.

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

Legal requirements in the German context have been reviewed to ensure that the use case was piloted within the relevant legislation. Since the digital solutions were not classified as a medical device, all relevant requirements were met.

Completion of a Data Protection Impact Assessment (DPIA) identified and minimised the risks associated with the pilot with input sought from other work packages and the SHAPES Data Protection Officer at GEWI. 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 are limited, the solution is being 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 with the monitoring protocol.

CSF 13. Identify and apply relevant legal and security guidelines

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

CSF 14. Involve legal and security experts

Advice from legal experts and experts on data security matters was received from project partners (for example LAUREA, that has extensive expertise in this field)

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 the participants' privacy has been protected. The project underwent 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 telemedicine services.

The pilot is being 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 works 24/7/365. In case of any bugs or issues the development and maintenance team fixes it. KOMPAL and VICOM are the owners of all the software that is used in the pilot. This means that there is no software dependencies with third parties, and that SHAPES partners are able to adapt source code at any point. The system logs all activities so any incident can be identified and solved quickly. In addition to the user manual, pilot hosts have access to the software developers of the different digital solutions so in case of doubts or questions we can answer them directly from KOMPAL and VICOM.

CSF 18. Establish and maintain good procurement processes

The requirements applicable to the devices used in the pilot were previously defined and vendors that fulfil them were identified. The SHAPES project provides the servers that are needed to run the solution. Those servers meet the service level needed to run the pilot successfully.

NASSS

The NASSS framework (Nonadoption, Abandonment, Scale-up, Spread and Sustainability) (12) was used to increase the success of the technology of use cases UC-PT2-004a/b. As these use cases are going to be conducted with the same technology (a robot) and only the settings differ, one NASSS framework was performed to cover both use cases. It was conducted to detect risks, which might lead to project failure. The short version of the NASSS questionnaire was considered and

completed by the pilot team (Annex 25). In four out of six domains uncertainties were identified and mitigation measures developed to ensure the success of the use case.

Table 129: Uncertainties and mitigation measures identified using the NASSS framework (UC-PT2-004a/b)

NASSS complexity domain	Uncertainties detected	Mitigation measures taken
Technology	The technology is not fully developed and thus does not exist in a robust and definitive form yet. Significant uncertainties derive from different functionalities, merged in one robot.	The technology developed is described and planned in detail in the UC. In the development process, the actual solution is closely aligned with the planned application and function of the technology. Mock-up-tests are performed with potential end-users to support the realisation process and constantly specify the technology.
Technology	The technology to be developed has a high degree of interdependencies. Constant testing of the technology is needed to detect and rectify occurring technical problems/issues (bugs and crashes).	Actions to increase efficiency in the development phase involve the close collaboration with technical partners in biweekly meetings and constant testing and feedback loops to assure alignment.
The value proposition	The technology, which is intended to support informal and formal caregivers, does not exist in a definite form and a realistic assessment of costs and effectiveness at scale has not been conducted yet.	In a large-scale pilot campaign the real-world value is assessed and an analysis of costs and benefits is considered.
The intended adaptors	Although intended users are involved in the development of the use case, having a robot in the own living environment can be a major change for some people.	Pre-deployment procedures are in place. The robot is demonstrated by presentation first and in a second step, training sessions for using the robot are performed.

The intended adaptors	The value of the technology might be questioned by some staff members of nursing homes. Insecurity regarding the safety of patients or a higher time-consumption might be possible.	Pre-deployment procedures are in place. The robot is demonstrated by presentation first and in a second step, training sessions for using the robot are performed. Questions and concerns are addressed properly.
The external context for innovation	The COVID-19 pandemic might affect the deployment of the UC, as nursing homes have restrictions on external visitors.	Internal discussions on potential regulatory issues and challenges and safety measures are applied.

5.5 Phase 1

5.5.1 PACT and FICS Scenario

Table 130: PACT (UC-PT2-004a)

Code	UC-PT2-004a	Version	0.1	Date	2020/10/09
Applicable SHAPES use case	UC-PT2-004a Night Surveillance Rounds at Community-Care				
People <i>Roles and/or actors of typical users involved in delivering and receiving the intervention</i>	<ul style="list-style-type: none"> Care receiver needs support during the night, i.e. guidance to the bathroom or help in case of accident Caregiver has not always opportunity to pay attention to the specific needs of an older individual during the night. 				
Activities Support provided by the KOMPAĬ robot and VICOM technology	KOMPAĬ-3 Care receiver <ul style="list-style-type: none"> Security: KOMPAĬ recognizes risk factors and can do warning signals as well as emergency messages. In case of a fall it can sound the alarm and inform care personnel Health parameters: KOMPAĬ can collect, store and provide medical data and parameters available online in a cloud. The robot is able to reach medical personnel in an emergency. The robot ensures that important key 				

	<p>parameters are available when an emergency doctor arrives</p> <ul style="list-style-type: none"> • Social connectivity: If older people are often alone, they may feel lonely. KOMPAI allows them to either talk to the robot itself or to have the older person call family or friends. In this way the ageing person can easily make phone calls with stored contacts without having to use a mobile phone. • Security risk: VICOM technologies also make it possible to monitor other security risks, such as smoke or unlocked doors <p>Caregiver</p> <ul style="list-style-type: none"> • the robot is a great relief. They know that when they are not on site, the aging person can get help and can be connected with the community • during the night shift, the robot has a control function. The robot is located in the corridor and monitors whether residents leave their room due to confusion. This happens more often, especially when older people suddenly find themselves in a strange environment • thanks to VICOMTECH recognition module, it is possible to identify the person
Context	<ul style="list-style-type: none"> • If the basic settings for the robot have been made, the user does not need to be technically affine. The user hardly needs any technical knowledge to use the robot in everyday life, because many wishes can be expressed verbally. For example, the user can command the robot to call someone. This is very easy for the ageing society to understand. • it has to be differentiated whether in a nursing home the individual residents are provided with a robot or one per floor. • for the caregivers it is good to know that the residents are not lonely in their rooms. Through the robot they can establish contact with the outside world. In addition, it is possible for the residents to keep themselves busy by playing games or listening to music etc. • It is also important to question the requirements for using the robot. What is the nature of the ground? Can the robot be used on carpet, parquet, street and garden? Is there a solution in case the house is not built

	<p>at ground level and several floors are occupied? What is the minimum door size? etc.</p> <ul style="list-style-type: none"> - Guarantee of data protection; contact details are only be managed by the pilot website (GEWI) - GDPR and ethics in line with WP8 - Data and servers must be located within the EU - German language - Location: HealthRegion KölnBonn (Oberbergischer Kreis), Germany
<p>Technology</p> <p>Type of information / parameter that are relevant in monitoring the health status; type and frequency of accessibility of information; feedback modalities (communication)</p>	<p>Type of information / parameter that are relevant to offer a wide range of leisure activities</p> <p>Care receiver</p> <ul style="list-style-type: none"> • Age (year of birth) • Gender (m/f/d) • Internet access • Skills how to use devices • Parameters: Frequency of contact, reminder, emergency contacts, smoke detection, health parameter – access to the cloud, • Place of residence <p>Caregiver</p> <ul style="list-style-type: none"> • Internet access • Skills how to use devices • Access to the health parameters (if requested by the care receiver) <p>Registration information</p> <ul style="list-style-type: none"> • Name • Date of birth • Place of residence • Emergency contact • Physical or psychological limitations • Number of flatmates • Nature of the soil: Type of material, level, barriers, change of floor (from carpet to tiles), size of doors, type of door blades, • Language of the robot

- Parameters to be monitored by the robot: to be determined (i.e. heart rate, additional technical solutions? Wearable? Sensor at the bars (wireless)?)

Features easy to implement: robot + wearable

- Face identification of the residents

Feedback modalities (communication)

- There should be a feedback possibility between the robot and the user. This could be, for example, the possibility to rate the game just played in the format of smileys. Or it is possible to rate the frequency of interaction with the robot. This way the interaction between the robot and the user can be improved.

Relief in everyday life

- Caregiver: “KOMPAĬ, go to Maria’s room and remind her to take her medicine. Ask her if she has already taken the medicine.”
- Robot moves to the person.
- Robot: “Hello, how are you? Have you taken your medicine yet?”
- Care receiver: “I am not sure.”
- Robot: “Check in your tin to see if it is still in there.”
- Care receiver: “Oh, thanks KOMPAĬ. No I have not taken the medicine yet, but I will do it right away!”
- Caregiver: “KOMPAĬ, can you accompany Maria from her room to the dining room?”
- The robot moves into Maria’s room.
- Robot: “Hello Maria, can I come in?”
- Mrs Schmidt: “Yes, what is it?”
- Robot: “Dinner is about to be served, I would like to accompany you to the dining room.”

Night surveillance:

- The robot patrols the corridors of the nursing home. A resident opens her door in the middle of the night and steps out into the corridor. The robot registers the movement, turns on the flashlight and recognises the person.

	<ul style="list-style-type: none"> • <i>Robot: “Good evening, Maria. Can I help you?”</i> • <i>Care receiver: “Hello KOMPAĬ, I feel confused. Can you take me back to my room?”</i> • Robot accompanies Care receiver back to her/him room.
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Table 131: FICS (UC-PT2-004a)

Category	Details
Function and events <i>Functionality of the intended system which is capable to realise actor’s activities</i>	<p>The robot offers the following functions to the older individuals and their caregivers in the community care setting:</p> <ul style="list-style-type: none"> • <u>Rounds or tours: announcements, surveillance, animation:</u> A tour is defined by a title and a launch time. It is a route from POIs to POIs (Points of Interest) to which the robot must go to take action. They can be: <ul style="list-style-type: none"> ○ Announcements: information given by hand beforehand by a caregiver ○ Monitoring: movement detection (ambulation of people), temperature controls, air quality control, doors open ... The idea is to patrol to detect possible anomalies and if so (fall, people outside their room at night, ...), send a screenshot to the guard to warn him. ○ Activities: broadcasting videos, music, audio stories, cooking recipes, etc. • <u>Entertainment (individual or collective)</u> • <u>to play games</u> • <u>see the weather,</u> • <u>see individual horoscope,</u> • <u>talk to family via video calls,</u> • <u>watch photos or videos,</u> • <u>listen to music or audio stories.</u> • <u>Given the current COVID-19 pandemic,</u> • <u>The robot can perform UV-C disinfection round for area disinfection (Room, living room, corridor, ...)</u> • <u>the robot can offer someone to disinfect their hands (on-board gel dispenser)</u> • <u>Measure the body temperature and send an alert if COVID-19 suspicion</u>
Interactions and usability issues	In this use case, we expect to have two users:

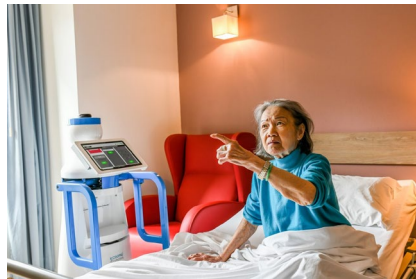
<p><i>User-system or system-component interactions meditating actor's activities; Types of the interactions, i.e. unidirectional data streaming service or reliable messaging service</i></p>	<ul style="list-style-type: none"> • Older person • A health professional <p>There are 2 user interfaces: one for the older person and one for the healthcare professional. The healthcare professional have access to the following data on the dashboard:</p> <ul style="list-style-type: none"> • The person to alert in case of a problem, • The duration of each round, the number of km covered and the events encountered during each round • Alerts • Activity measurements • Temperature measurements • Areas disinfected <p>The older person has access to the following data:</p> <ul style="list-style-type: none"> • Possible actions he/she can perform with the robot: entertainment options, making a call... • Launching the "walking assistance" function from the touch screen. • Temperature measurements by speech and touch screen <p>The health care professional is able to add new announcements for the information tour, as well as songs, group/individual games or photos.</p>
<p>Content and structure</p> <p><i>Variables of the interaction</i></p>	<p>The interface of the older person are the Kumpaï robot, as well as its touch screen integrated at the back (under Windows) and a removable Android tablet connected to the touch screen of the robot via Teamviewer that the person can have on him to have access to the embedded applications. For interaction, speech as well as the touch screen interface is used.</p>

Style and aesthetics

Look and feel of the system



Surveillance

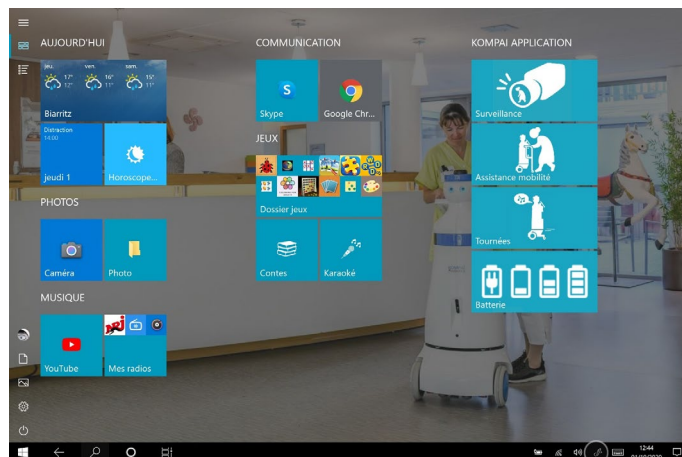


Entertainment





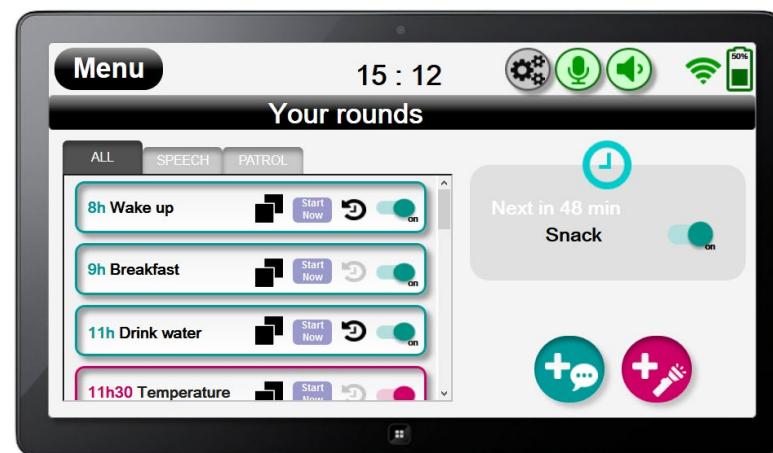
Disinfection option



Main interface



Route monitoring interface



Route setting

5.5.2 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 monitoring the progress or lack of it towards achieving the objectives of each specific use case. The following KPIs have been selected to define the success of the pilot activities for UC-PT2-004a.

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 further development or deployment.

Recruitment and retention

1. The recruited participants remained enrolled in the pilot until the end of the study.

Technical performance

2. There is no re-start of any of the components of the technology for at least 90% of the days.

User engagement and acceptance

3. The overall user experience quality of the App as measured using the short version of the User Experience Questionnaire (UEQ-S) was classified as 'Good' or 'Above average' based on published benchmark data.
4. At least 50% of the older people interacts with the robot 50% of the days.
5. At least one care provider/caregiver scored one of the following functionalities above average rating (>68) in the System Usability Scale (SUS).

Other indicators (examples, to be defined in a measurable manner)

- Older people: sentiment of safety during the night (questionnaire)
- Caregivers: Safety of the older people answered with robot during the night surveillance round (questionnaire)
- Caregivers: number of times round is used
- Caregivers/family: number of alerts
- Caregiver/family: number of times remote navigation is used
- Older people: type of interaction with robot and duration
- Older people: Type of games played (number)
- Older people: number of times the physical activity is used
- Caregiver/Family: number of suggestions/reminders programmed at each day
- Caregiver/HCP: number of times remote control of cameras is used
- Caregiver/HCP: number of times remote navigation is used

The presentations were conducted remotely via videoconference. In the first part participants were informed about the background of the SHAPES project and the use case. The second part focused on visual images of the screens a user would encounter when using the robot.

Participants

Phase 2 was conducted with six older people fulfilling the criteria to be 65 years and older. Further assessment was gained through members of the World Federation of the Deafblind (WFDB).

Informed consent procedure

In a first step participants obtained explanation to the background and purpose of the study and about the process of the mock-up. In addition an information sheet was provided. With the agreement to participate they received the consent form. Informed consent for all participants was taken with the following format of signatures collected where appropriate:

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

Data collection

Feedback was collected using a questionnaire (Annex 26) which included a combination of open and closed questions. Throughout the presentation of the mock-up feedback on design and layout was collected. The questions were a combination of open and closed questions to gather general and specific feedback about the functionalities.

5.6.2 Results of testing

The overall perception of the use case was high and the interviewee did understand the context. The use of the robot for nursing homes is clearly evaluated positively. Especially the patrolling rounds and entertainment function in common areas were emphasized. The support for disoriented people was rated to be very beneficial. In terms of IT-behaviour or the handling of robots interviewees were concerned about complications and technical errors which they might not be able to solve. Further it

was discussed if the robot would lead to an overall added value since other alternatives (i.e. smart homes) already exist.

5.7 Phase 3: Hands-on Experiments

5.7.1 Methodology

Phase 3 was conducted for UC-PT2-004a and b simultaneously. Activities are presented in the following:

In the beginning of phase 3, the technical partners from KOMPAL visited Germany to train the GEWI researchers in programming and using the robot. After the GEWI team had been introduced to the robot, the different functionalities were explained and tested. Thus, a mapping of GEWI premises was conducted and patrolling rounds were created. The developed rounds were further used to test the entertainment function of the robot (playing music and launching announcements) as well as the surveillance module to detect any falls.

Additionally, the UV-disinfection module was installed and tested by using the trailer to disinfect a room. Again, researchers were trained before conducting the tests on their own.

As part of phase 3, the robot was also presented in a nursing home in the reference site OBK. Participants of the demonstration were the head of the nursing staff and two nurses from the nursing home. Apart from that several representatives of the regional project "Kompetenz digital" took part in the meeting. Since these have already offered support in the use of technical devices for older people as part of their regional project, they were invited to act as multipliers to connect with people living at home in the OBK.

After a short introduction to the SHAPES project, a live demonstration of the robot took place by launching an entertainment round. Thereby, the robot was following the predefined round and played some music. Besides, the sensor was demonstrated and tested by the audience, detecting whether the person is wearing a mask and whether the mask is worn properly.

Even though the robot was still blocking a few times, all participants were interested in and open-minded towards the new DS. Some remarks were shared by the nurses addressing the blocking of the robot. It was mentioned that the robot would need to navigate independently without the nursing staff intervening on a regular basis to provide some support for their work. Besides, representatives of "Kompetenz digital"

shared additional ideas on smart technologies to add to the robot or Apps to install on the tablet as they saw potential for some further developments.

Since the technical partners from KOMPAL were involved in the demonstration of the robot in the nursing home as well as the previous tests in GEWI premises, they could experience any technical challenges first hand. Thereby, it was collaboratively discussed how to address and mitigate the challenges encountered.

5.8 Phase 4: Small Scale Live Demonstration

All pre-study testing has taken place in the premises of the GEWI institute. This testing phase lasted until the start of the pilot. This way of performing phase 4 was considered due to pragmatic reasons as this avoided transportation of the robot and potential damage to the material.

In phase 4, several tests were conducted by the GEWI team and/or remotely by the KOMPAL team in GEWI premises. Thereby, the following functionalities of the robot were tested:

- fall detection module
- automatic launch of rounds
- UV-disinfection module
- start and conduction of entertainment and surveillance rounds
- sensor for measuring the temperature
- sensor detecting if a mask is worn

Several rounds were tested and any technical challenges reported to KOMPAL. Due to the narrow corridors of the GEWI premises the robot blocked several times and was struggling to complete its predefined round. This was addressed with the technical partners who further improved the navigation of the robot. Thereby, the safety distanced detected by the sensors was lowered allowing the robot to navigate more smoothly through the narrow corridors and bottlenecks. Besides, the fall detection module was further improved to detect any fall more reliably.

5.9 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's objective

was to recruit 1 nursing home at the GEWI lead pilot site that was willing to test the robot for 1 months.

An overview of the intervention procedures serving as definition of the standard operating procedure had been developed prior to the start of the pilot activities as part of the study protocol and can be found attached to this document (Annex 27).

5.9.1 Recruitment

Several recruitment activities were conducted to draw attention to the project. These entailed displaying articles in regional newspapers and newsletters, using mailing lists and contacting relevant gatekeepers from the network by applying face-to-face recruitment.

For the UC-PT2-004a, receiving ethical approval from the ethical committee provided some challenges. The concerns mainly targeted the free participation as well as the insurance matters in case of any technical or non-technical problem. After setting up appropriate mitigation actions, the ethics committee finally approved the deployment of the robot in the nursing home setting.

A second challenge that was faced for the pilot of UC-PT2-004a was finding a suitable nursing home that was willing and had the capacity to test the robot in their premises. Due to several COVID-19 outbreaks and a severe lack in staffing the pilot phase had to be postponed several times ending in a final withdrawal of the initially contacted nursing home.

After contacting relevant gatekeepers from the network once again, a nursing home was identified that spontaneously agreed on testing the robot in their premises. First communication about the pilot has been conducted via phone from the research team to present all relevant information and answer questions from the head of the nursing home. Afterwards information sheets and consent forms (Annex 28 and 29) were shared and additional preparations coordinated.

Eligibility criteria

Inclusion criteria:

- person aged 65 years old or older at the time of recruitment
- living in a nursing home in the OBK
- self-reported capacity to use the App installed on the tablet

- self-reported capacity to consent

Exclusion criteria:

- none

Due to the challenges in finding a suitable nursing home, the reference site OBK was slightly extended to the Siegerland, which is the neighbouring region of the OBK and therefore dealing with the same challenges of on rural area with an aging population.

5.9.2 Communication and dissemination of the pilot activities

All data being collected with the pilot study are owned by GEWI. After completion of the study, all collected data was analysed, processed and presented in Deliverable D6.3 as one of the deliverables of the SHAPES Innovation Action. This report will be public for review and accessible via the SHAPES website (www.shapes2020.eu). Participants were notified of the outcome of the study by the research team via mail or phone. GEWI will aim to disseminate the findings of the pilot study at conferences and other events as well as in the scientific papers and articles. GEWI will also seek to communicate the findings of this study via social media (LinkedIn, Instagram, GEWI website), 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. Therefore, appropriate Data Processing Agreements have been set up and signed by all partners to facilitate the sharing of pseudonymised data with specific SHAPES partners for specific purposes.

5.9.3 Risk management

All potential data-related risks have been addressed/targeted in detailed risk assessment documents which form part of the Data Protection Impact Assessments for Phase 5. For each risk identified, a risk classification, root cause, name and consequences were assigned. Once identified, each risk was then analysed and scored from 1 (unlikely/minor)-4 (almost certain/critical) regarding their probability and impact. Subsequently, appropriate mitigation actions were assigned. These risks have been reviewed during the course of the deployment.

Ethical approval was achieved for UC-004a of Pilot 2. This approval process additionally enabled all contributors to identify any further risks and to identify appropriate mitigation actions.

Finally, an ALTAI tool (Assessment List for Trustworthy Artificial Intelligence) has been filled in by the technical partner to address potential risks that might occur by the use of AI. The tools supported the elaboration on potential risks and opportunities with respect to the ethical frameworks of SHAPES as well as the identification of mitigation actions were needed.

5.9.4 Outcome of large-scale activity

Overview

The phase 5 large-scale pilot of the SHAPES UC-PT2-004a was conducted from 20th April until 5th May 2023 in a nursing home. The initially planned pilot duration of 4 week had to be adjusted to a two-week deployment due to the challenges in the recruitment process, previously elaborated.

Before the actual start of the pilot, the pre-deployment procedure had started in the nursing home. This procedure included a power point presentation of the robot and its functionalities and a brain storming session how to adapt it to the most suitable work routine most suitably. The first planning was performed with the head of the nursing staff as this person had the required expertise and overview of all activities and regulations within the nursing home. Afterwards, an inspection of the selected station took place for the researcher to get an impression of the setting and make first contact the nursing staff. Although some of them seemed sceptical about having a robot support them, they were all open towards the pilot and some were even enthusiastic to test it.

The transportation and installation of the robot was done by the research team supported by a technical partner from KOMPAI, to ensure a correct/professional set up of the robot. Therefore, the initial ideas with respect to the detailed entertainment rounds, announcements and surveillance rounds were proposed to the nursing staff and adjustments made where needed.

After the installation of the robot was finalized, an introduction workshop took place with the nursing staff of the day shift (n=4) and a user manual was handed out with the most important instructions on how to use the robot. The participants of the workshop reported the most important information to the night shift as they were not able to take part in the workshop. Due to reasons of feasibility (the high workload, the short duration of the pilot), the nursing staff was not further introduced to the programming of the robot (creating rounds, adding announcements, making adjustments to the surveillance rounds).

All employees were encouraged to contact the researcher for any technical issues or doubts about the use of the novel system during the entire period of the pilot. It was agreed for researchers to contact the nursing staff every second day via phone and offer direct support on site if needed.

The robot was programmed to do surveillance rounds during the night (5 per night) and entertainment rounds during the day (2 per day). During the night, the night shift could follow the robot's rounds via a tablet by directly connecting to the robot via Splashtop. During the day, the robot made announcements regarding the date, time, the weather or menu of the day as well as reproduced some proverbs. In between the announcements, a YouTube playlist was played. Due to the absolute necessity of following some safety measures and the limited time of introducing the nursing staff to the DS, the disinfection module was only tested once by the researchers.

Due to the extremely high workload, and the continuously shifting working team (morning shift, late shift and night shift) assessing all the questions from the questionnaires was not feasible and would have strongly affected the workflow. To avoid any lack in care for the residents, more work and stress for the nursing staff and potential withdrawal from the pilot, appropriate mitigation actions were taken and filling in the questionnaires was not forced. On site observation were included to collect additional information with respect to the primary research objectives of investigating the user engagement and user-perceived usefulness. A short interview was conducted in the end of the pilot with two nurses and one employee of the social service as well as the head of the nursing home. Some feedback with respect to their experiences in using the robot has been collected among the night shift via phone (n=2).

Primary and secondary outcome

Primary Objectives

The primary outcomes were to measure a predefined set of KPIs which have already been presented in chapter 5.5.2 as well as to evaluate the UC-PT2-004a use case using the MAST evaluation tool.

The following tables present the data used to determine the success of each KPI. Table 134 provides an overview of the success of the pilot with regards to KPIs.

Recruitment and retention

KPI 1 The recruited nursing home remained enrolled in the pilot until the end of the study.

Table 132: KPI 1 GEWI (UC-PT2-004a)

Parameter	GEWI
Number of participants at baseline	1 nursing home
Number of withdrawals	0
Number of participants at end of study	1
Percentage retained	100%

KPI 1 was successfully achieved with 100%, meaning that the recruitment and engagement initiatives of GEWI were successful, not only in identifying an interested and willing nursing home, fitted to the effort at play, but also that the strategy to maintain contact and provide support did make a positive impact on the absence of withdrawals.

Technical performance

KPI 2 There is no re-start of any of the components of the technology, for at least 90% of the days.

Table 133: KPI 2 GEWI (UC-PT2-004a)

Parameter	Value
Number of days with re-starts of any of the components of the technology	0
Total number of days	15
Percentage of days without re-starts	100%

KPI 2 was successfully achieved and no re-start of any of the components of the technology was needed. This shows, that the DSs were functioning well meaning that the collaboration between the technical partners, the intensive test phase 4 and the continuous development process have had a positive impact on the deployment of the technical solution in Phase 5.

User engagement and acceptance

KPI 3 The overall user experience quality of the App as measured using the short version of the User Experience Questionnaire (UEQ-S) was

classified as ‘Good’ or ‘Above average’ based on published benchmark data.

As previously described, assessing the UEQ-S was not appropriate due to extremely high workload and thus omitted. Mitigation actions were taken by including on site observations and conducting a short interview at the end of the pilot with two nurses and one employee of the social service as well as the head of the nursing home (see Table 136)

KPI 4 At least 50% of the older people interacts with the robot 50% of the days.

No interaction was measured by using the games. From the interviews it was identified that a playlist was used via YouTube and the participants enjoyed to sing together.

KPI 5 At least one care provider/caregiver scored one of the following functionalities above average rating (>68) in the System Usability Scale (SUS).

As previously described, assessing the SUS was not appropriate due to extremely high workload and thus omitted. Mitigation actions were taken by including on site observations and conducting a short interview at the end of the pilot with two nurses and one employee of the social service as well as the head of the nursing home (see Table 136).

Overview of KPI achievement

Table 134: Overview of KPI achievement GEWI (UC-PT2-004a)

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	YES	Engagement initiatives of GEWI were successful, related to the strategy to maintain contact and provide support did make a positive impact on the absence of withdrawals, despite the length of the pilot.
KPI 2	YES	No re-start of any of the components of the technology was needed. This shows, that the DSs were functioning well and participants were able to engage with the DSs.
KPI 3	Not assessed	Assessing the UEQ-S was not appropriate due to extremely high workload and thus omitted.

		Mitigation actions were taken by including on site observations and conducting a short interview at the end of the pilot with two nurses and one employee of the social service as well as the head of the nursing home.
KPI 4	NO	No interaction was measured by using the games. From the interviews it was identified that a playlist was used via YouTube and the participants enjoyed to sing together.
KPI 5	Not assessed	Assessing the SUS was not appropriate due to extremely high workload and thus omitted. Mitigation actions were taken by including on site observations and conducting a short interview at the end of the pilot with two nurses and one employee of the social service as well as the head of the nursing home.

Evaluation of MAST

The MAST framework as already introduced in chapter 5.4.2 was used to evaluate the effectiveness and contribution of UC-PT2-004 to quality of care. The evaluated data/outcome are presented in the table below:

Table 135: MAST Evaluation GEWI (UC-PT2-004a)

MAST Domain	Topic	Outcome	Baseline (mean/SD)	End of pilot (mean/SD)
Safety	Clinical safety	Frequency of collision (Protocol of collisions)	/	None reported
Clinical Effectiveness	Mental health	OSSS-3 and life events scale	Not assessed	Not assessed
	Effects on health related quality of life	EQ-5D-5L scores	Not assessed	Not assessed
Patient perspectives	Satisfaction and acceptance	UEQ-S scores	/	Not assessed
		TAM score	/	Not assessed
	Understanding of information	SUS scale	/	Not assessed
	Ability to use technology			

	Self-efficacy	General self-efficacy scale	Not assessed	Not assessed
Economic aspects	Amount and costs of resources used	Cost of device	Rental solution (1 month):	
			<ul style="list-style-type: none">• 1100€ per month including basic robot + installation & training (Europe) + site support	
		Cost of using digital solutions and SHAPES platform	<ul style="list-style-type: none">• Electricity (charging the tablet): negligible (approx. 0,76 cents per charging)• Internet connection: negligible as most people already have internet access (Germany: 40€ per month)• Data analysis module KOMPAI*	
		Cost of staffing	<ul style="list-style-type: none">• Travel cost: 550€• Training Material (development and print): 390€ (7h à 50€ + 40€)• Training + end of study (preparation and deployment): 2000€ (40h à 50€)• User support via phone: 200€ (2h à 50€ per week for 2 weeks)	
*Not available as they were customized solution and not available at a commercial stage yet				

As previously described, assessing the various harmonisation questionnaires was not appropriate due to extremely high workload and thus omitted. Mitigation actions were taken by including on site observations and conducting a short interview at the end of the pilot with two nurses and one employee of the social service as well as the head of the nursing home. The outcomes are summarised in Table 136.

Secondary Objectives

Besides, the pilot aimed at testing the capability of SHAPES platform and Digital Solutions to provide opportunities for supporting in reducing the workload of employees in nursing homes and create a feeling of safety for the residents

Therefore the following primary and secondary objectives were defined within the study protocol:

Primary objectives

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

Secondary objectives

- To investigate the capability of the digital solutions to support caregivers in nursing homes:
 - Night surveillance, UV disinfection, measurement of body temperature (SO1).
- To investigate the capability of the digital solutions to support residents in nursing homes:
 - Entertainment (games, announcements) (SO2a).
 - Feeling of safety during night (Night surveillance) (SO2b)
- To investigate the capability of the novel system to improve older individual's quality of life, wellbeing and psychological and psychosocial aspects (SO3).
- To explore user trust and acceptance of the novel system (SO4).

Table 136: Objectives GEWI (UC-PT2-004a)

PO1
To investigate user engagement with the novel system (PO1).
As previously described, there were several automatic rounds launched during the pilot such as the night surveillance round (n=148) and the entertainment rounds (n=67). The high number of rounds imply that the robot was stopped on its rounds several times due to navigation errors (n=133) or blockages through obstacles (n=138) before it was manually told to continue the round. On average, the robot drove 1506,5 m (24104m in total) and was used 429 min a day (Min=224; Max=710). Most of the time it was running in patrol mode for the night surveillance.
PO2
To investigate the user-perceived usefulness of the novel system (PO2).
As already described, the entertainment and surveillance rounds were automatically launched several times a day. After some first days of the pilot, the entertainment round was adjusted by shortening the round, changing the start time of the robot,

decreasing the frequency of announcements as well as changing the background music. These adjustments were made due to feedback received from the nursing staff and to further improve fitting into the working routines as an important aspect with respect to the perceived usefulness.

During the interview in the end of the pilot, it was mentioned, that it was interesting to test such a device and that a robot as technical device is impressive however, it would be more suitable for younger people, being more used to digital devices. The programmed and automatic rounds were hoped to be more situation-specific such as the announcements deployed. As it was not possible to preschedule specific announcement for specific days or times, these adjustments had to be done manually by the nursing staff. Due to the high workload and deployment period of only 2 weeks, this manual handling of the robot was not focused during the workshop and not used by the nursing staff.

Overall, the staff saw some potential and mentioned several times, that such technology will be important for the future however at this stage, the system was still not reliable enough and needs some further development.

SO1

To investigate the capability of the digital solutions to support nursing staff in nursing homes: Night surveillance, UV disinfection, measurement of body temperature (SO1)

Within the interview as well as the study support via phone, the nursing staff reported that the robot got stuck every day and night and needed support either from the staff or the research team via remote control, which they mostly managed fine. As such, regular support was needed during the pilot, also from the research staff. Besides, it was reported that during the night surveillance round the robot often detected false falls (49 in total) mainly referring from people sitting in a wheelchair or an armchair with their feet up. For each fall a percentage was given reflecting the accuracy of the detection. The benchmark for the identification as a fall was set rather low (50% accuracy) to avoid not detecting a real fall by simultaneously increasing the probability of a false detection. For real falls, the calculated percentage was close to 100%. Furthermore, the recognition of falls was rather late and the robot did not seem to grasp the complete angle.

Apart from that, the night shift reported, that the robot seemed to have problems with the light during the night as this was dimmed and that the WIFI connection mostly was not strong enough to continuously connect to the robot via the tablet. Integrating an external 4G sim card to the tablet slightly improved the monitoring of rounds. Thereby, seeing what is happening on the corridors was described as supportive from the night shift.

Highly acclaimed by the nursing staff was the disinfection module, which was tested once under supervision. In this respect it has been noticed by the staff that the room

smells much better and very nice therefore they would have liked to use that more often.

Overall, the robot was not perceived as obstructive at night nor during day but also of limited benefit as the DS was not yet reliable.

SO2

To investigate the capability of the digital solutions to support residents in nursing homes: Entertainment (games, announcements) (SO2a) and feeling of safety during night (Night surveillance) (SO2b)

As reported by the nursing staff and the employee of the social service, most of the residents were too cognitively impaired to be able to play any games on the tablet for their entertainment. Such would have needed close support by the nursing staff or employees of the social service. It was further explained, that older people at this stage of cognitive impairment need something haptic like a board game with dices, something they know and potentially remember what to do. Interacting with a tablet and playing online games is just not possible for most of them and thus not used.

With respect to the announcements, it was observed that some of the residents also started answering or talking to the robot. Thus, the nursing staff mentioned, that having a chatbot included in the robot would be good as it would support the interaction and also help residents to get used to it more easily. It was reported by the nursing staff as well as the residents, that the announcements were always the same with too little variety which was perceived as annoying.

Apart from that, YouTube has been used once by the nursing staff to play old songs which was much enjoyed by the residents as they even joined in.

SO3

To investigate the capability of the novel system to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects (SO3).

As previously described, it was not possible to assess the harmonisation questionnaires among the residents nor the nursing staff. From the observations and the interviews it was retrieved that especially the entertainment function provides potential to support and maybe even improve the individuals wellbeing. In the daily routines of a nursing the residents especially those in need of care and support experience regular timeslots of waiting when the nursing staff is involved in looking after all residents. Especially, during these times, some entertainment and activation of the residents would be very beneficial for the individual and could affect their quality of life.

SO4

To explore user trust and acceptance of the novel system (SO4)

The reaction towards the robot were very diverse and emotionally intense reaching from open and interested to dismissive and upset. In the beginning the robot was shortly introduced and presented during a morning session among all residents of

the nursing home. Also their reactions were diverse, with older people, being reserved or much against it and others being very open, interested and willing to talk to it.

As reported by the nursing staff, some of the residents of the ward were afraid of the robot, especially those that were more cognitively impaired. On the other hand, their relatives were very interested, took photos and asked questions when seeing the robot.

Among part of the employees (social service), the concern was articulated that robots could take away their jobs in the future which strongly influenced their attitude towards it. However, this concern was not shared by all.

The interviewed nursing staff themselves were perceived as generally interested and mentioned the potential they saw in robotics as integral part of the future. This will be supported by the fact that people will be more familiar with technology then, both the residents and the nursing staff, allowing a more intuitive and competent use of such digital solution.

The overall opinion of the head of the nursing home was positive, as it was a pilot with the aim to see what works and what doesn't. She also sees a high potential for the future to target the shortages in the care delivery.

Recommendations for partners (from interviews)

- Option to program differing announcements for different days/daytimes to allow more tailoring (i.e. Quizzquestion and then the answer after a short pause)
- Music in the background was too slow and smooth
- A chatbot function would have supported the interaction with the robot and facilitate the resident in making contact to the robot

6 Use case 004b

6.1 Introduction

In the following the pilot activities of PT2-004b *Night Surveillance rounds in the Home-Setting* are described. The target group of this use case was composed of 65+ year old persons living at home by themselves and are often cared for by an outpatient nursing service or informal caregivers during the day. During the night, however, they are often on their own. The study was planned to take place in the home of a person from the target group who lived in the rural reference site “Oberbergischer Kreis” (OBK) in Germany. No other criteria, than age and residence, or specific needs need to be fulfilled by the target group. This use case uses a robot, that can help to “patrol” hallways and detect if anything is wrong providing a function of night-time surveillance. The main objectives of this use case were to investigate user engagement with the SHAPES digital solution and to validate the capability to:

- Support older individuals through night surveillance and entertainment functions
- Improve older individual’s life quality of life, wellbeing and psychosocial aspects

Additionally, the users’ trust and acceptance of the SHAPES digital solution was explored. This use case is led by the GEWI – Institut für Gesundheitswirtschaft e.V. and was replicated by 5thYPE in Greece.

6.2 Description

Older individuals living at home by themselves are often cared for by an outpatient nursing service or informal caregivers during the day. During the night, however, they are often on their own.

A robot can help detect alarming signals providing a night-time surveillance service. If the robot is inside the older individual’s bedroom, it can also help monitoring how the person is sleeping, detect a fall, and make it easier for the older individual to alert someone in case of emergency. The robot can also be connected to various sensors and detect sudden changes in room temperature or i.e. the appearance of smoke. The connected cameras can facilitate observing whether the older individual is unexpectedly leaving the bedroom or even the apartment/house and could alert a predefined person. The robot can also assist the older individual in his/her necessary movements at night, such as going to the bathroom. Due to the integrated hand bar

the older individual can hold on to the robot and safely be guided to the bathroom and back to bed.

6.3 Digital solutions used in this use case

Kompai Robot (KOMPAL)

Robot that provides different functionalities such as: fall detection, walking assistance and entertainment.

6.3.1 Digital solutions used for COVID-19 response

There is no digital solutions for the COVID-19 response in UC-PT2-004b.

6.4 Data plan

The data plan for phases 4 and 5 for PT2-004b has been finalised and can be accessed on the SHAPES website ([Data plan UC-PT2-004b](#)).

6.4.1 Data capture methods to be used

As this UC is using the same technology as UC-PT2-004a, the technology is providing almost all the same functions and only the setting (home vs. nursing home) differs, the data capture methods and the evaluation tools are identical. Hence, please see the data capture methods and the planning of evaluation in chapter 5.4.1 and 5.4.2.

6.4.2 Planning of evaluation

See above.

6.5 Phase 1

6.5.1 PACT and FICS Scenario

Table 137: PACT (UC-PT2-004b)

Code	UC-PT2-004b	Version	0.1	Date	2020/10/06
Applicable SHAPES Persona	Helena (P7) lives alone in her own house, small village, daughter is the caregiver				
Applicable SHAPES use case	UC-PT2-004b Night Surveillance Rounds in the Home-Setting				
People	<ul style="list-style-type: none"> Ageing individuals want to stay in their familiar domestic environment. Older individuals living at home by themselves are often cared for by an outpatient nursing service or informal caregivers during the day. During the night, however, they are often on their own. During the night there are many risks for the older individuals. They may have problems orientating themselves, finding the bathroom alone at night and there is an increased risk of falling. If the older person falls, they may not be able to get help on their own and may have to stay on the floor until they are helped the next morning by a nurse or informal caregiver During the day there is a regular caregiver to take care of the ageing person. However, he/she is often alone and may feel lonely, isolated and dependent on the caregiver Low e-literacy, low to average affinity to technology caregiver: in addition to an ambulant nursing service, relatives take care of the person to be cared for 				
Activities	Care receiver <ul style="list-style-type: none"> Security: KOMPAÏ recognizes risk factors and can do warning signals as well as emergency massages. In case of a fall it can sound the alarm and inform an emergency contact, such as relatives or the emergency doctor Health parameters: KOMPAÏ can collect, store and provide medical data and parameters available online in a cloud. The robot is able to reach medical personnel in an emergency. The robot ensures that important key parameters are available when an emergency doctor arrives. 				

	<ul style="list-style-type: none"> • Independence: For people who are dependent on caregivers for home care, it is difficult to cope with everyday life on their own. They can suffer from disorientation and confusion. KOMPAÏ can help them to go about their everyday life alone and provides cognitive support. KOMPAÏ can also serve as a reminder. • Social connectivity: If older individuals are often alone, they may feel lonely. KOMPAÏ allows them to either talk to the robot itself or to have the ageing person call family or friends. In this way the ageing person can easily make phone calls with stored contacts without having to use a mobile phone. • Security risk: VICOM technologies also make it possible to monitor other security risks, such as smoke or unlocked doors • For the Caregiver, the robot is a great relief. They know that when they are not on site, the aging person can get help and can be connected with the community
Context	<ul style="list-style-type: none"> • If the basic settings for the robot have been made, the user does not need to be technically affine. The user hardly needs any technical knowledge to use the robot in everyday life, because many wishes can be expressed verbally. For example, the user can command the robot to call his/her daughter. This is very easy for the older society to understand. • To protect the privacy of the care receiver, data protection rules and sharing options have to be integrated into the system. The caregiver has to decide what the attention frequency of the robot is, so that the robot only listens when explicitly called. The care receiver must also be allowed to decide how much health-related data is available to the emergency doctor and relatives. • The role of the caregiver can be very different. In most cases, however, it exists because the older person lives in their domestic context but needs the robot. This means that the care receiver is likely to have cognitive and/or physical problems, which makes the presence of a caregiver necessary. On the one hand the caregiver can be a relative. For them the robot is a great relief. On the other hand, the caregiver can also be a nurse. In this case, the robot is also helpful, as medical data can be easily stored and retrieved. For this to work, the care receiver must be able to decide who has access to its data.

	<ul style="list-style-type: none"> It is also important to question the requirements for using the robot. What are the floor conditions? Can the robot be used on carpet, parquet, street and garden? Is there a solution in case the house is not built at ground level and several floors are occupied? What is the minimum door size? etc. - Guarantee of data protection; contact details are only managed by the pilot website (GEWI) - GDPR and ethics in line with WP8 - Data and servers must be located within the EU - German language - Location: HealthRegion KölnBonn (Oberbergischer Kreis), Germany
Scenario	<p>Helena lives in a small village with garden and her cats. Nearby lives her daughter and takes care of her almost daily. Her state of health is fluctuating. Besides arthrosis she sometimes has bad days. Then she falls down, forgets to drink enough or generally feels very weak. In order to relieve her daughter and to prevent bad events, Helena is considering going into a nursing home. But she feels uncomfortable leaving her familiar surroundings and is sad to have to give up her favourite furniture and cats.</p> <p>Helena is very happy that she has the opportunity to use the robot and her daughter is relieved. Two weeks later the robot arrived, and Helena and her daughter have to make some initial basic adjustments. The language of the robot contact details, and much more must be entered in a first 15 minute registration process. Helena is slowly getting used to the robot. She is relieved that she can support herself on it, because her arthrosis often causes her pain. Helena also likes the call function. She has adjusted that the robot does not follow her automatically, but that she simply has to call him once and he comes to her. At first Helena felt strange talking to a robot. She has few technical skills and in the small village where she lives she has never seen anything like it.</p> <p>After Helena fell down more often, her daughter could not sleep well at night because she was very worried. The robot makes Helena's nightly situation easier. She takes pills in the evening to help her sleep, and these can have the side effect of confusing her at night when she wakes up and wants to go to the toilet. She is grateful that she can hold the robot as a walking aid. The robot also gives her light, and she can move around her</p>


	<p>house alone at night. For Helena it was good that the robot can reach someone in an emergency. Helena fell down once and could no longer help herself. Last time she had to wait several hours on the floor until she was found. Now she could command the robot to call her emergency contact. If it should happen again that Helena should fall down, she would call KOMPAÏ to her. First, she tries to straighten up with his help and if that doesn't work, KOMPAÏ calls her daughter. She could help her in this case. But if her daughter does not answer the phone and Helena needs medical help, KOMPAÏ calls the emergency doctor. So Helena gets help quickly when she needs it. In this case KOMPAÏ saves important health parameters of Helena. For example, blood test results can be called up. So Helena's treatment would be much faster and more effective.</p> <p>Another feature that Helena likes very much is the entertainment aspect. She feels very lonely in her house and her cats are not always there and are very old. She can make a video call with her family members or friends. She can talk to the robot. Additionally, Helena can command the robot to play her favourite poems or music. Helena also uses the game function a lot. For her the online games are a completely new and very entertaining way to pass the time.</p>
Technology	<p>Type of information / parameter that are relevant to use devices</p> <p>Care receiver</p> <ul style="list-style-type: none"> • Age (year of birth) • Gender (m/f/d) • Internet access • Skills how to use devices • Parameters: Frequency of contact, reminder, emergency contacts, smoke detection, health parameter – access to the cloud, • Place of residence <p>Caregiver</p> <ul style="list-style-type: none"> • Internet access • Skills how to use devices • Access to the health parameters (if requested by the care receiver)

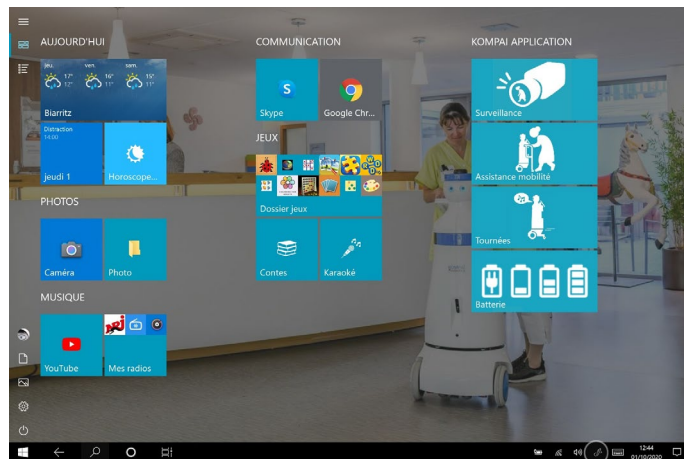
	<p>Registration information</p> <ul style="list-style-type: none"> • Name • Date of birth • Place of residence • Emergency contact • physical or psychological limitations • Number of flatmates • Pets ownership • Nature of the soil: Type of material, level, barriers, change of floor (from carpet to tiles), size of doors, type of door blades, • Language of the robot • Parameters to be monitored by the robot: Water supply, movement... <p>Feedback modalities (communication)</p> <ul style="list-style-type: none"> • There should be a feedback possibility between the router and the user. This could be, for example, the possibility to rate the game just played in the format of smileys. Or it is possible to rate the frequency of interaction with the robot. This way the interaction between the robot and the user can be improved.
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Table 138: FICS (UC-PT2-004b)

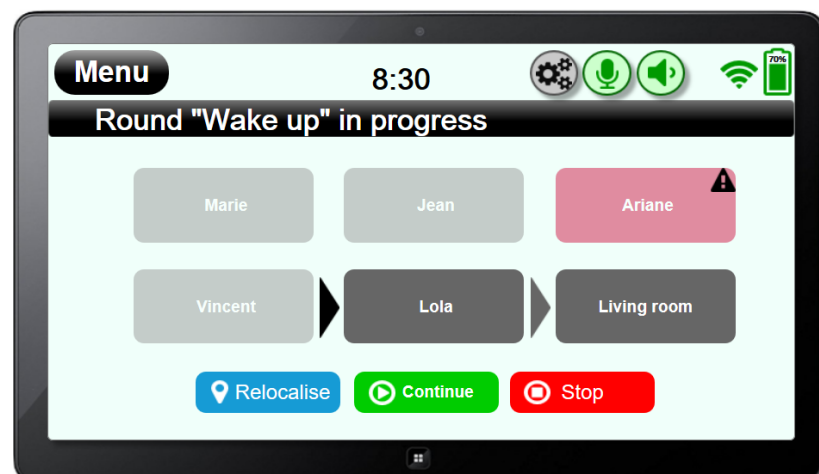
Category	Detail
<p>Function and events</p> <p><i>Functionality of the intended system which is capable to realise actor's activities</i></p>	<p>The robot offers the following functions to the Helena and her daughter in the home care setting:</p> <ul style="list-style-type: none"> • Rounds or tours: surveillance, animation: A tour is defined by a title and a launch time. It is a route from POIs to POIs (Points of Interest) to which the robot must go to take action. They can be: <ul style="list-style-type: none"> ○ Monitoring: movement detection (ambulation of people), temperature controls, air quality control, doors open ... The idea is to patrol to detect possible anomalies and if so (fall, Helena outside her room late at night, ...), send a screenshot to the her daughter to warn him. ○ Activities: broadcasting videos, music, audio stories, cooking recipes, etc. • Entertainment <ul style="list-style-type: none"> ○ to play games

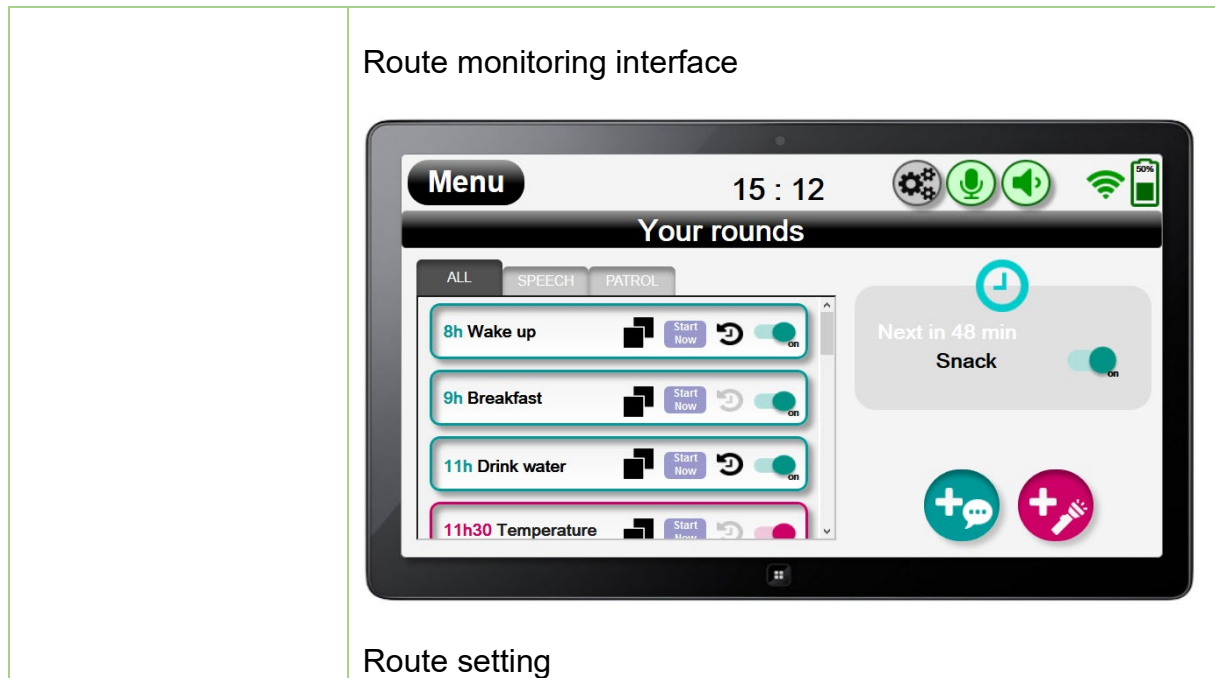
	<ul style="list-style-type: none"> ○ see the weather, ○ see individual horoscope, ○ talk to her daughter, her doctor or somebody else via visio, ○ watch photos or videos, ○ listen to music or audio stories. ● Mobility assistance to Helena <ul style="list-style-type: none"> ○ Free Mode : allows Helena to go where she wants with the help of the robot ○ Guided Mode : The robot takes Helena from a starting point to an ending point by following a trajectory established thanks to a map ○ Exercise mode : to be used in the presence of her daughter to do walking exercises (prescribed by her doctor). ● The robot can light the way to Helena to go from one location to another during the night ● Given the current COVID-19 pandemic, <ul style="list-style-type: none"> ○ the robot can offer Helena or someone visiting her to disinfect their hands (on-board gel dispenser) ○ Measure the body temperature of Helena and send an alert if COVID-19 suspicion
<p>Interactions and usability issues</p> <p><i>User-system or system-component interactions</i></p> <p><i>meditating actor's activities; Types of the interactions, i.e. unidirectional data streaming service or reliable messaging service</i></p>	<p>In this use case, we expect to have 3 users:</p> <ul style="list-style-type: none"> ● Helena ● Her daughter ● Caregivers <p>There are 2 user interfaces: one for Helena and one for the healthcare professional. The healthcare professional have access to the following data on the dashboard:</p> <ul style="list-style-type: none"> ● The person to alert in case of a problem (her daughter), ● The duration of each round, the number of km covered and the events encountered during each round ● Alerts ● Activity measurements ● Temperature measurements <p>Helena has access to the following data:</p>

	<ul style="list-style-type: none"> • Possible actions she can perform with the robot: entertainment options, making a call... • Launching the "walking assistance" function from the touch screen. • Temperature measurements by speech and touch screen <p>The health care professional or her daughter is able to add new songs, games or photos.</p>
Content and structure <i>Variables of the interaction</i>	<p>The interface of Helena is the Kompaï robot, as well as its touch screen integrated at the back (under Windows) and a removable Android tablet connected to the touch screen of the robot via Teamviewer that Helena or her daughter can have on her to have access to the embedded applications. For interaction, speech as well as the touch screen interfaces are used.</p>
Style and aesthetics <i>Look and feel of the system</i>	



Main interface





6.5.2 Key performance indicators

As the KPIs of this UC-PT2-004b are the same as for UC-PT2-004a, please see the listing in chapter 5.5.2.

6.5.3 Timeline of pilot activities

The original timeline of pilot activities was to conduct Phase 1 and 2 between May 2020 and January 2021, followed by Phase 3 from February until June 2021. Phase 4 was planned to be conducted between August 2021 and April 2022.

The adapted timeline of pilot activities can be found in Figure 148. It shows that Phase 3 was shifted and extended to July 2021 until April 2022. This period was extended, with no impact on the next phases or the deliverable, due to the COVID-19 situation. During that phase testing of the functionalities were done by GEWI employees in the premises of GEWI. This procedure was chosen to avoid in-person meetings and keep everyone safe on the one hand and on the other hand out of pragmatic reasons. Transport of the robot requires huge effort and is not without risk for the material and technical components of the robot. Phase 4 involved further testing of the technical aspects and was conducted in the same environment as Phase 3. GEWI conducted Phases 1-4 and the replicating site 5thYPE conduct Phase 5.

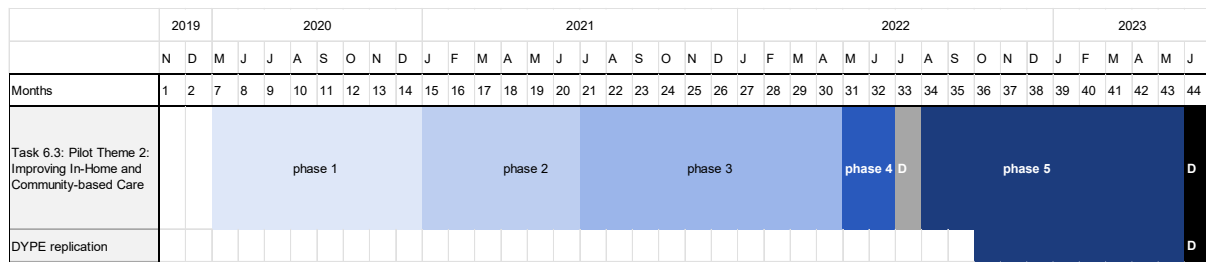


Figure 148: Timeline of pilot activities of UC-PT2-004b

6.6 Phase 2: Testing of mock-ups and prototypes

6.6.1 Methodology of testing

In Phase 2 initial ideas of the technology of UC-PT2-004b were put in a visual representation, called mock-up. At that stage no functionality was offered, and the mock-up was primarily used to evaluate design and potential functions by developers and participants. The presented technology was the SHAPES robot Kompai (KOMPAI).

The presentations were conducted remotely via videoconference. In the first part participants were informed about the background of the SHAPES project and the use case. The second part focused on visual images of the screens a user would encounter when using the robot.

6.6.2 Results of testing

The overall perception of the use case was high and the interviewee understood the context. The use of the robot in the home-setting was seen critically. It was questioned how much added value a night surveillance would have and whether patrolling made sense in that environment. Especially the limited space in an apartment and other criteria such as stairs would make the application unable to be implemented. In terms of IT-behaviour or the handling of robots interviewees were concerned about complications and technical errors which they might not be able to solve. Further it was discussed if the robot would lead to an overall added value since other alternatives (i.e. smart homes) already exist.



6.7 Phase 3: Hands-on Experiments

6.7.1 Methodology

As already described, Phase 3 was conducted for UC-PT2-004a and b simultaneously. Please refer to the detailed description of all activities and tests in Phase 3 in chapter 5.7.1.

6.8 Phase 4: Small Scale Live Demonstration

As already described in chapter 5.8, all pre-study testing has taken place in the premises of the GEWI institute. This testing phase lasts until the start of the pilot. This way of performing phase 4 was considered due to pragmatic reasons as this avoided transportation of the robot and potential damage to the material.

In phase 4, several tests were conducted by the GEWI team and/or remotely by the KOMPAI team in GEWI premises. Thereby, the following functionalities of the robot were tested:

- fall detection module
- automatic launch of rounds
- start and conduction of surveillance rounds
- activating and use of the chatbot
- navigating the robot by voice command

Complementary to any tests conducted for UC-PT2-004a (see chapter 5.8) a chatbot has been developed in collaboration with the technical partner from VICOM. This feature was used to navigate the robot in the home-setting by voice command. Several tests have been performed by the GEWI researcher and the technical Team from VICOM to test the activation, understanding and responding of the chatbot. Instructions that the chatbot was trained on were related to reliably understand and differ between different points of interests (POIs) (i.e. kitchen, bathroom, bed room) and respond accordingly. Then the chatbot was incorporated in the system of the robot. Corresponding tests were performed by KOMPAI and additional meetings arranged with VICOM to address any challenges encountered. This included to reposition the microphone of the robot to improve the chatbot's understanding of the voice layer.

In the end, it was possible to send the robot to a predefined position on the created map by giving some simple instructions.

6.9 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's objective was to recruit 1 older person living at home at the GEWI lead pilot site and 1 at the replication site from 5thYPE that was willing to test the robot for 1 months.

An overview of the intervention procedures serving as definition of the standard operating procedure was developed prior to the start of the pilot activities as part of the study protocol and can be found in the annex (Annex 30).

6.9.1 Recruitment

GEWI

Several recruitment activities were conducted/performed to draw attention to the project. These entailed displaying articles in regional newspapers and newsletters, using mailing lists and contacting relevant gatekeepers from the network and applying face-to-face recruitment.

Also for the UC-PT2-004b, finding a suitable participant that was willing to test the robot in their home and whose premises were of adequate size entailed challenges. After several loops of contacting gatekeepers and people from the reference site, a potential candidate was found, however, they finally decided against participation at short notice. Despite another attempt, no suitable participant was found, which is why the UC-004b could not be implemented at GEWI.

5thYPE

5thYPE's recruitment process for UC-PT2-004b was based upon the trust and familiarity that has been built, over the last years, between our team's medical doctor and her patients. The familiarity factor also played an important role between the potential participant and at least one member of 5thYPE's technical team, so that technical support visits could be facilitated when needed. From the potential participants fitting these criteria, that were contacted, two (2) expressed a high level of willingness. Both participant's houses were of adequate size, however:

- one was on the ground floor, and had narrow corridors and minor levels on the floor that would prohibit the Nari robot to move around,
- the other was on the first floor, and all of the main rooms shared a large, open, common space with no levels / steps on the floor, that could make the surveillance rounds of the Nari robot easier.

The latter was chosen for executing UC-PT2-004b.

6.9.2 Eligibility criteria

5thYPE

- people older than 65 years old or older at the time of recruitment
- living at home by themselves
- self-reported capacity to consent

6.9.3 Communication and dissemination of pilot activities

5thYPE

The 5thYPE replicator created a live demo at its premises upon the reception of the KOMPAL's robot. In this demo, the potential of robot capabilities was demonstrated. The demo was photographed and recorded in video and by using this material the replication of PT2-004b was disseminated via press releases to national newspapers, healthcare websites. Indicatively, we list here some of the websites – newspapers

- <http://sertnews.gr>
- lamianow.gr
- tinealarissa.gr

Furthermore, the Head of the 5th Regional Health Authority of Thessaly & Sterea (5thYPE) presented the Nari robot in local radio stations (www.mixcloud.com), and local TV channels where also the video of the demo was shown (see from 42nd minute and after in the video from the TV station's website digitalstar.gr). Additionally, the CIO of 5thYPE presented the PT2-004b on a TV channel broadcast located at Athens. Also, we aim at disseminating the findings of the replicating pilots at conferences and other events related to health care technologies in both National and European Levels in collaboration with GEWI.

Pictures from the dissemination activities are given below.



The picture is taken from the Greek news on TV. It displays three men testing the robot.



The picture is taken from the Greek news on TV. It displays a person talking.



The picture displays four men posing around the robot.



The picture displays four men posing around the robot.

6.9.4 Risk management

5thYPE

All the potential risks were identified and integrated in the relevant risk assessment document of the Data Protection Impact Assessment. There was a specific focus on potential COVID-19 risks because the age and health of the participant was considered critical. This work was well documented along with the relevant mitigation actions prior to the beginning of the study

Specific focus was given to risks related to technological issues and robot movement conditions that were also well documented in the Data Protection Impact Assessment. The assessment helped addressing the technological risks, like software misconfigurations, Greek language misinterpretations and voice recognition and lack of Internet connectivity.

The ethical approval was also obtained by the participant thus leading to better addressing the potential risks appeared.

6.9.5 Outcome of large-scale pilot activity

5thYPE

Overview

The phase 5 large-scale pilot of the SHAPES UC-PT2-004b was conducted between 4th March 2023 and 18th March 2023 participant living at home on their own.

Socio-demographics of the participants:

Table 139: Baseline characteristics 5thYPE UC-004b

Variables	Number of participants	Value
Age (years)	1	77
Male	1	number = 1 (100%)
Country: Greece	1	100%
Marital status	1	Widowed: 1
Occupational status: retired	1	100%
Residence: own home	1	100%

Primary and secondary outcome

Primary Objectives

The primary outcomes were to measure a predefined set of KPIs which have already been presented in chapter 5.5.2 as well as to evaluate the UC-PT2-004b use case using the MAST evaluation tool.

The following tables present the data used to determine the success of each KPI. Table 145 provides an overview of the success of the pilot with regards to KPIs.

Recruitment and retention

KPI 1 The recruited participant remained enrolled in the pilot until the end of the study.

Table 140: KPI 1 5thYPE (UC-PT2-004b)

Parameter	5thYPE
Number of participants at baseline	1
Number of withdrawals	0
Number of participants at end of study	1
Percentage retained	100%

KPI 1 was successfully achieved with 100%, meaning that the recruitment and engagement initiatives of 5thYPE were successful, not only in identifying interested and willing participants, fitted to the effort at play, but also that the strategy to maintain contact and provide support did make a positive impact on the absence of withdrawals.

Technical performance

KPI 2 There is no re-start* of any of the components of the technology, for at least 90% of the days.

Table 141: KPI 2 5thYPE (UC-PT2-004b)

Parameter	Value
Number of days with re-starts of any of the components of the technology	0
Total number of days	15
Percentage of days without re-starts	100%

*re-start refers to the deinstallation and re-installation of any of the components due to mal functioning. This does not include any update of a new version of the App.

KPI 2 was successfully achieved and no re-start of any of the components of the technology was needed. This shows, that the DSs were functioning well meaning that the collaboration between the technical partners, the intensive test phase 4 and the continuous development process have had a positive impact on the deployment of the technical solution in Phase 5.

User engagement and acceptance

KPI 3 The overall user experience quality of the App as measured using the short version of the User Experience Questionnaire (UEQ-S) was classified as ‘Good’ or ‘Above average’ based on published benchmark data.

Table 142: KPI 3 5thYPE (UC-PT2-004b)

Scale	Mean	Comparison to benchmark
Pragmatic quality	1,250	Above average
Hedonic quality	3,000	Excellent
Overall	2,125	Excellent

As only one participant has been involved no mean UEQ-S and benchmark scores have been visualised.

KPI 3 was successfully achieved and the perceived quality of the robot was evaluated as excellent. This highlights the novelty and potential of the robot that has been deployed in the pilot.

KPI 4 At least 50% of the older people interact with the robot 50% of the days.

Table 143: KPI 4 5thYPE (UC-PT2-004b)

Parameter	Value
Number of days of interaction with the robot	9
Total number of day	15
Percentage of days with interaction	60%

KPI 4 was successfully achieved and the participant interacted with the robot 60% of days. This indicates that the participant was able to handle and use the robot, and that it was possible for him to integrate it in their everyday life.

KPI 5 At least one care provider/caregiver scored one of the following functionalities above average rating (>68) in the System Usability Scale (SUS).

Table 144: KPI 5 5thYPE (UC-PT2-004b)

Parameter	Value
Number of care provider/caregiver involved	0
Number of care provider scoring >68 in SUS	Not applicable
Percentage of participants scoring > 68 in SUS	Not applicable

No caregiver/care provider was involved in the replication of UC-PT2-004b as focus was given to the interaction of the older individual with the DS. Thus KPI 5 was not applicable.

Overview of KPI achievement

Table 145: Overview of KPI achievement 5thYPE (UC-PT2-004b)

Key performance indicator	Achieved during large-scale pilot activity (yes/no)	Comments
KPI 1	YES	Engagement initiatives of 5 th YPE were successful, related to the strategy to maintain contact and provide support did make a positive impact on the absence of withdrawals, despite the length of the pilot.
KPI 2	YES	No re-start of any of the components of the technology was needed. This shows, that the DSs were functioning well and participants were able to engage with the DSs.
KPI 3	YES	The perceived quality of the robot was evaluated as excellent, especially highlighting the novelty and potential of the robot that has been deployed in the pilot.
KPI 4	YES	Participant interacted with the robot 60% of days, indicating that he was able to handle and use the robot, and that it was possible for him to integrate it in their everyday life.
KPI 5	Not applicable	No caregiver/care provider was involved in the replication of UC-PT2-004b as focus was given to the interaction of the older individual with the DS. Thus KPI 5 was not applicable.

Evaluation of MAST

The MAST framework as already introduced in chapter 6.4.26.4.2 was used to evaluate the effectiveness and contribution of UC-PT2-004 to quality of care. The evaluated data are presented in the table below. As only one participant has been involved in the replication, only the single score is displayed (no mean, SD, median, min, max).

Table 146: MAST Evaluation 5thYPE (UC-PT2-004b)

MAST Domain	Topic	Outcome	Baseline (only one value)	End of pilot (only one value)	Change
Safety	Clinical safety	Frequency of collision (Protocol of collisions)	/	None reported	
Clinical Effectiveness	Mental health	OSSS-3 and life events scale	10 “moderate social support”	10 “moderate social support”	none
	Effects on health related quality of life	EQ-5D-5L VAS scores	Health Status: 85	Health Status: 85	none
Patient perspectives	Satisfaction and acceptance	TAM score	/	Usefulness: 3 Future Use: 4	
	Understanding of information	SUS scale	/	52,5	
	Ability to use technology				
	Self-efficacy	General self-efficacy scale	32	34	2
Economic aspects	Amount and costs of resources used	Cost of device (Cost as per device purchasing invoice)	See Table 135		
		Cost of utilities	See Table 135		

In the following the results of the baseline data is summarised. Any analysis and discussion of outcomes with respect to the impact will be part of the deliverables D6.9 and D6.10.

Considering the application of the EQ-5D-5LVAS score, the participant indicated his health status on a scale from 0 to 100 at 85. According to the OSSS-3, the participant perceived that he had moderate social support ($m = 10$) and pinpointed in the GSES his perceived self-efficacy with 32 out of 40 points.

The results from the questionnaires reflect the general understanding of the participants, that they were healthy and fit for their age.

Secondary outcomes

Besides, the pilot aimed at testing the capability of SHAPES digital solutions to provide opportunities for supporting older individuals living at home by themselves, especially during the night time.

Therefore the following primary and secondary objectives were defined within the study protocol:

Primary objectives

- To investigate user engagement with the digital solutions (PO1).
- To investigate the user-perceived usefulness of the digital solutions (PO2).

Secondary objectives

- To investigate the capability of the digital solutions to support older individuals:
 - Night surveillance and walking assistance (SO1).
- To investigate the capability of the digital solutions to support older individuals:
 - Entertainment (games, reminders) (SO2).
- To investigate the capability of the novel system to improve older individual's quality of life, wellbeing and psychological and psychosocial aspects (SO3).
- To explore user trust and acceptance of the novel system (SO4).

Table 147: Objectives 5thYPE UC-PT2-004b

PO1
To investigate user engagement with the novel system (PO1).
The robot was configured to execute night surveillance rounds 3 times every night after midnight (two between midnight and 4am and one very early in the morning), and day surveillance rounds every Saturday (around noon). The fall detection feature, was tested successfully by the technical member of 5thYPE (before the first day of the pilot execution), however the robot – after the first test round kept on

detecting one of the two sofas as a fallen person, therefore it was disabled to avoid false fall detections.

The robot detected the presence of the participant 14 times, out of which it was told (voice instructed) to go to different POIs 8 times (2 to the kitchen, 1 to the bathroom, 1 to the living room and 4 unsuccessful). The remaining 6 times that the robot detected the presence of the participant, no other interaction took place.

In the 4 unsuccessful ones the participant instructed the robot to go to a specific POI but it did not execute (responding “I am sorry, I did not understand”). The participant did not pursue any other means of instructing the robot, and upon time completion the robot returned to its docking station.

8 times the robot detected an obstacle and stopped the surveillance round; this was attributed mainly to passing closely to certain pieces of furniture (sofa, coffee table). However, upon time of completion the robot returned to its docking station.

Lastly, 1 time the robot alerted that its battery level was very low, due to unsuccessful homing to the charging station. The technical team (5thYPE) had to visit the participant’s home to manually drive and install the robot onto the station.

PO2

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

The participant reported at the interview that the robot performed adequately, despite the few times it didn’t deliver. He found the interaction with the robot very interesting and fun. Knowing that the robot made its surveillance rounds every night made him feel safer; the walking feature however was reported to be of a greater interest for much larger spaces and distances and for people with mobility difficulties. Besides the surveillance, 5thYPE technical team had set up the WhatsApp messaging application in the robot’s on-board tablet, with the participant’s contacts of his grandchildren. The participant initiated a call with his grandson (a university student in another city), which he found joyful, however he had to stand up in front of the robot to initiate the call. He mentioned that he would like to initiate the WhatsApp calls just as he does when he tells the robot where to go, with voice commands. Overall, the participant found this technology to be important and useful, as long as it is further developed to eliminate any functional issues.

SO1

To investigate the capability of the digital solutions to support older individuals: Night surveillance and walk assistance (SO1)

The night surveillance and walk assistance features were welcomed by the participant, although as mentioned above it appears as those features could have a greater positive impact in a nursing home rather than an individual’s private home. Narrow spaces and furniture account for this reason, as well as carpets that had to be removed before engaging the robot in the home set-up pilot execution.

The robot also failed to execute some voice commands. 5thYPE's technical team found that this was attributed to the internet speed connection. Installing a portable 4G router slightly improved the robot's ability to respond to the voice commands, however, a robust and broadband internet connection is a prerequisite for the whole cycle of language processing to complete successfully.

Overall, the robot was not perceived as obstructive at night, nor during day but also of limited benefit as the solution was not yet reliable.

SO2

To investigate the capability of the digital solutions to support older individuals: Entertainment (games, reminder) (SO2)

The music and weather announcements, although perceived as fun features by the participant, were not of a great interest for him, therefore it was not implemented during the execution of the pilot. The WhatsApp feature was very interesting for the participant.

Overall, the robot was not perceived as obstructive at night, nor during day but also of limited benefit as the solution was not yet reliable.

SO3

To investigate the capability of the novel system to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects (SO3).

The music and weather announcements, although perceived as fun features by the participant, were not of a great interest for him, therefore it was not implemented during the execution of the pilot. The WhatsApp feature was very interesting for the participant, and as already mentioned it would be extremely useful if he could invoke calls with his persons of interest simply by using voice commands (i.e. call Mark). The fact that he had to stand in front of the robot, to manually initiate a WhatsApp call my tapping into the on-board tablet, was perceived as more complicated.

SO4

To explore user trust and acceptance of the novel system (SO4)

Overall the participant demonstrated a quite positive attitude towards the solution. Distinctly he mentioned that *"there were times I checked upon my new child to see if she was OK. So, I would ask Nari how she was feeling, if she needed anything, etc."*

Recommendations

- It was found that a measure to overcome the potential immobilization of the robot due to proximity issues that were perceived as obstacles, was to re-design the route by adding more intermediate destinations between start and final destination (POI). Special attendance should be given to those

intermediate stops during the entry and exit of a corridor or door, to ensure that the robot could enter (exit) vertically (in a straight line) and not at an angle.

- The voice control / execution feature requires a broadband internet connection to secure that the communication channel between the robot and the Adilib solution could perform seamlessly without problems.

7 Conclusion

This deliverable, “D6.3 - Improving In-Home and Community-based Care Pilot Activities Report”, outlines the methods, key findings and results of all use cases in SHAPES Pilot Theme 2. The discussion and implications of these results will be presented in D6.9.

Within Pilot Theme 2, all use-cases (UC-PT2-001, UC-PT2-002, UC-PT2-003, UC-PT2-004a+b) followed the multi-phase methodology designed for WP6 “Pan-European piloting campaign” and successfully completed all phases. All feedback and outputs that were collected during Phases 1–3 were used to facilitate the deployment of the digital solutions in the following Phases 4 and 5.

In Phase 1, all necessary preparatory work was conducted as a prerequisite for the effective planning of the pilots. Within continuous loops of reviewing and adapting relevant steps and mandatory aspects (i.e. data plans), (technical) challenges were encountered and resolved at an early stage of the pilot campaign. Thus, these were not affecting the process and timescales of the different use cases within Pilot Theme 2. Due to the involvement of potential end-users, carers and health professionals in Phases 2 and 3, the user-facing components of the digital solutions were adapted according to the needs and feedback received from the target group. The users’ reactions towards the digital solutions were generally interested in these innovations and provided insight into how end-users may engage with the digital solutions during the pilot. In Phase 4, the digital solutions were tested by the end-user over a longer period. Hereby, focus was given to the technical functioning of the digital solutions (elimination of dead links or bugs related to the data transfer). This stage of early testing was strongly impacted by the COVID-19 pandemic. Thus, the user involvement was only possible to a limited extent. Basic bugs were identified and jointly addressed with the technical partners. While data collection was in place at the user end, data transfer to the SHAPES platform was pending as the Symbiote connector was not yet stable to be used. A direct interface was used to further test the data transfer. In the subsequent Phase 5, a higher number of end-users were involved to test the DS in a real world setting. As previously elaborated, the focus was given to the evaluation of user engagement and user-perceived usefulness.

In UC-PT2-001, all piloting partners (GEWI, AIAS and 5thYPE) succeeded in recruiting their intended number of participants, whereby in total 19 participants tested the developed DSs for the remote monitoring of key health parameters. The results from the questionnaires assessed among the target group reflected the general

understanding, that the participants were healthy and fit for their age, as well as health literate. The level of technological competence was differing between the users.

Challenges encountered during all pilots of UC-PT2-001 were deriving from the absence of analyses of the participants' health and wellbeing parameters, leading to the predominant perception, that the DSs seemed not to provide much additional benefit. As a result, the perceived usability of the DSs (collected within the SUS and UEQ-S) was mostly scored below the intended bench marks. In this respect, it seemed that people with higher technological skills and experiences in handling technology also had higher expectations towards the DSs which impacted their overall evaluation of the DSs. In conclusion, the needs, wishes and expectations of older people seems to depend on their health literacy and technological competencies.

In UC-PT2-002, all piloting partners (GEWI, AIAS, CCS and UP) succeeded in recruiting their intended number of participants, whereby in total 23 participants tested the developed DSs for supporting the interaction of the older individual with the community. The results from the questionnaires assessed among the target group reflected the general understanding, that the participants were healthy and fit for their age.

Challenges encountered during all pilots of UC-PT2-002 were deriving from the lack of recent and regional events and activities provided in the App, leading to the predominant perception, that the DSs was not that interesting and beneficial for most of the participants' daily lives. As a result, the actual use as well as the perceived usability of the App (evaluated by KPI 5, the SUS and the UEQ-S) was mostly low and scores below the intended bench marks. Thus, the usability as well as the actual use of the App strongly depends on the quality and quantity of websites integrated in the system and thus displayed in the App. However, it needs to be noted, that the availability of appropriate websites was outside the scope of this pilot.

In UC-PT2-003, different target groups were addressed. With respect to the LLM Care cognitive and physical training (Group 1) and NewSum (Group 2), the piloting partners (AUTH and GEWI) successfully recruited their intended number of participants, whereby in total 18 participants tested the developed DSs. The results from the questionnaires assessed among the target group reflected the general understanding, that AUTH's participants were healthy and fit for their age whereas part of GEWI's participants were cognitively impaired (n=3).

AUTH demonstrated that the LLMCare cognitive and physical training had a positive impact on older people's cognitive and physical conditions as all KPIs and pilot objectives were achieved.

Due to challenges in GEWI's recruitment process, older people already showing clear signs of cognitive decline were offered to participate in the training which was adapted

accordingly. Observations showed that also this target group was motivated and willing to participate and benefited from the regularity of training sessions and the attention they received during the training session. However, it became clear that the capacity to perform exercises and participate in training sessions strongly differs among people with cognitive impairment and those without. Nevertheless, a great potential is seen that those can also benefit from an accompanied digital training that is adjusted to their needs.

Participants testing the LLMCare cognitive training component in the home-setting needed a high level of technological competencies to be able to perform the training on their own. If the training was intended to be independently used in the home-setting, some further adjustments would be needed (such as the provision of easily accessible analysis of the training achievements).

In UC-PT2-004, the robot a was successfully deployed in a nursing home in Germany as well as in a home-setting in Greece. Due to challenges in the recruitment process piloting the robot in a home-setting in Germany was not possible.

Overall, the reaction towards the robot was mostly interested and open but some people were also generally opposed to this type of technology and refused to interact with it.

Challenges encountered were related to the reliability of the robot when performing entertainment or surveillance rounds including the fall detection module. Despite, these technical challenges, an immensely high potential was seen in the DS especially for the future of the nursing home setting. In this respect, the early involvement and training of the nursing staff was observed as prerequisite for future use and the acceptance among the nursing staff as well as the residents of the nursing home.

Lessons learned from the pilots within Pilot Theme 2 are presented below:

In UCs with several technical solutions, interfaces and partners involved, have encountered more challenges in Phase 5 and thus required extra efforts by all partners involved. A relevant finding for any future project thus is: the more digital solutions and interfaces included in a DS, the higher its susceptibility to malfunctioning and thus the more testing and personal efforts are needed. At the same time, these were also perceived as offering the greatest potential by the end-users, who generally evaluated the combination and linking of multiple functions in one DS as attractive.

With respect to the recruitment of participants, this process was challenging especially for those partners and organisations that did not have any direct contact to the target group. Partners with direct contact (for example via the university hospital that their institution was affiliated to) reported less challenges in finding eligible participants.

Particularly for the German context, most of the recruited participants were either interested in health and innovative technology or already suffering from some impairment and thus with a vested interest in participating in the pilots. Therefore, the end-users included in the pilots potentially had higher technical skills as well as knowledge and awareness about their health and were possibly not representative of the general age group. Due to these differences in competences of older people, the expectations and needs regarding the DS varied and might require different approaches, functionalities or support.

Overall, older individuals were still very interested in innovations and technological devices and most of them were either capable or eager to learn to handle the solution. Most of the participants saw a great potential in the developed DS, which confirmed the relevance of addressing the needs that were identified within the SHAPES project and thus legitimised SHAPES approaches and objectives.

8 Ethical requirements check

Table 148: 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)	GEWI and all replicating partners of PT2 are committed to and have applied non-discriminatory selection criteria as well as language. GEWI and all contributing partners recognize the crucial importance of defending the dignity, integrity and privacy of participating individuals. This pilot intends to further promote the fundamental rights of older adults as well as their informal and formal carers.
Biomedical Ethics and Ethics of Care (3.2)	Ethical committees were consulted, and green light was sought prior to Phase 5 of the use cases. The use of webcams was explicitly mentioned, the functions of the robot and/or the voice-assistance Nari were detailed in the consent forms submitted to the individuals. The robot was placed in a nursing home offering a dedicated spot where non-consenting individuals would not be confronted to the robot. Feedback from participating individuals was included in this deliverable.
Convention on the Rights of Persons with Disabilities and supported decision-making (3.3)	<p>The will and preferences of older people and persons with disabilities were respected and prioritized at all stages. They were involved in the different phases of the use cases, their feedback was taken into account.</p> <p>Anonymity and confidentiality of data has been guaranteed at all stages.</p> <p>Ethical self-assessments were conducted to discover and minimize potential risks by developing according mitigation actions.</p>
Capabilities approach (3.4)	Capabilities of the end-users have been respected and considered at all stages of the process. This especially refers to the planning and performing of assessments.
Sustainable Development and CSR (4.1)	<p>PT2 aims to contribute to the following sustainable development goals:</p> <ul style="list-style-type: none"> - SDG1 End poverty: PT2 contributes to promoting access to innovative health and

	<p>care services without out-of-pocket payments</p> <ul style="list-style-type: none"> - SGD3 Good Health and Wellbeing: PT2, as SHAPES as a whole, is dedicated to this goal; better health and wellbeing outcomes are the pilot's KPI in terms of prevention, health promotion and quality of life improvement (cf. data on nutrition, sleep, mental and physical exercises, wellbeing) - SDG4 Good Education: PT2 is contributing to increasing the health competencies of all stakeholders involved (older adults, formal and informal carers) by conveying information and feedback on personal health and wellbeing data. - SDG5 Gender Equality: PT2 enforced gender equality in the design of its use cases, including all genders. - SDG9 Industry, Innovation and Infrastructure: PT2 incorporated innovative solutions provided by open call partners, hence stimulated innovation, promoted data analytics; SHAPES partners involved in PT2 further developed IT infrastructure capabilities for integrated health and care solutions - SDG10 Reduced Inequalities: PT2 recognised in its different use cases the differences of needs within the group of adults 65+ and addressed them accordingly in order to level the playing field for all age groups - SGD11 Sustainable cities and communities: PT2 was set in the Oberbergischer Kreis and its immediate surroundings. The rural setting of PT2 is particularly welcoming to solutions reducing CO2 emissions (less individual car drives). With their focus on health promotion, the PT2-use cases intended, among other, to avoid the development of chronic diseases (i.e. diabetes, CVD) particularly time, mobility and resource consuming.
Customer logic approach (4.2)	Potential end-users have been involved in the development process to incorporate their feedback addressing usability and interface design of the DS.
Artificial intelligence (4.3)	ALTAI tool (Assessment List for Trustworthy Artificial Intelligence) has been conducted in

	cooperation with the technical partner to address potential risks that might occur by the use of AI.
Digital transformation (4.4)	All project activities contribute to improving the overall quality of the development and assessment process of the SHAPES platform and digital solutions.
Privacy and data protection (5)	A detailed plan of measures and data being collected has been set up prior to the deployment phases to ensure data protection and user privacy. GDPR aspects have been considered and were outlined in the ethics applications for each UC. Ethical approval was received for all UCs.
Cyber security and resilience (6)	The database is stored safely on a firewall protected server.
Digital inclusion (7.1)	It was planned to reach and involve people with low levels of digital literacy
The moral division of labour (7.2)	Not applicable
Caregivers and welfare technology (7.3)	Caregivers have been considered and involved in cases when the end-users are in need of support for handling their health and wellbeing condition or any type of digital device due to digital literacy issues.
Movement of caregivers across Europe (7.4)	Not applicable

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Annex

Annex 1: Interview guide

Questions on the perceived impact

The following topics pick up the perceived impact of the digital solution on the participant's everyday life.

1. Use of the SHAPES digital solutions:

- How have you perceived the use and integration of the digital solutions in your everyday life?
- How has it impacted your everyday life?
 - i. Health-literacy
 - ii. Self-management of health condition
 - iii. Support for active and healthy ageing
 - iv. Improving quality of life
 - v. Supporting extended living at home
- What impact did it have on your behaviour related to health?
- What has your experience been like when using the digital solutions?
- What is your family's/friends'/neighbours'/formal and informal caregivers'/interpreters'/assistants' opinion/perspective about/on using the DS?

2. Perceived usefulness:

- How have you perceived the usefulness of the digital solutions?
- How did it support you? What did it support you with?

3. Strength and weaknesses

- What did you like about the SHAPES digital solutions?
- What did you like least about the SHAPES digital solutions?

4. Willingness of use of SHAPES

Willingness of future use is assessed in the TAM but no additional information on potential conditions is included yet

- Under what conditions would you be willing to continue using the digital solutions beyond the end of this pilot?

5. Health cost data

- If this innovation was available to use in the future, how much would you be willing to pay for it per month?
 - i. < 5€

- ii. 5-10€
- iii. 11-20€
- iv. 21-50€
- v. 51-100€
- vi. > 100€
- vii. I would not be willing to pay for it

- Who should pay for the DS?
 - i. Individual end-user
 - ii. Health insurance (private)
 - iii. Health insurance (public)
 - iv. Government-funded
 - v. Other:

- Ability to pay (if not already assessed as part of the sociodemographics):

“A household may have different sources of income and more than one household member may contribute to it. Thinking of your household’s total monthly income, is your household able to make ends meet?”

- How did using the digital solution impact your:
 - i. medicine intake?
 - ii. intake of non-prescription medicine/ over the counter drugs?
 - iii. visits at the doctor/hospital?
 - iv. number/frequency of therapy sessions?
 - v. Relationship with your doctor / caregiver / medical staff / assistants / interpreters / support person etc.

6. Additional feedback:

- Do you have any further thoughts/experience/impressions you would like to share with us?

Annex 2: Momentum outcomes UC-PT2-001

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.

GEWI
Not applicable as no healthcare professionals are involved in the UC

- In my organisation/region patients and providers (healthcare professionals) are ready to use ICT (e.g., computers, tablets, mobile phones).

GEWI
In general, an critical attitude towards using ICTs and the collection of personal data might exist among that age group. However, early involvement of potential users, open communication with step by step explanations/support and high standards of data security will be applied to lower and counteract a potential risk.

- In my organisation/region financial and other incentives are aligned with the service to be deployed.

GEWI
To do

- In my organisation/region an underpinning culture embraces technology.

GEWI
No

- In my organisation/region an underpinning culture welcomes and even promotes

change, innovation and shows openness to new ideas.

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GEWI

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.

GEWI

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.

GEWI

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.

GEWI

To do.

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.

GEWI

No, as they are not involved in the deployment of the UC

- Healthcare professionals have been involved in the development of the process and time schedule for this project.

GEWI
No, as they are not involved in the deployment of the UC

- Decision-makers have been involved in the development of the content of this project.

GEWI
No, as they are not involved in the deployment of the UC

- Decision-makers have been involved in the development of the process and time schedule for this project.

GEWI
No, as they are not involved in the deployment of the UC

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

- In this project¹⁷ the patients have been sufficiently involved in the development of the telemedicine solution.

GEWI
Plan to do so (phase 2-4)

- In this project telemedicine service is based on the patient's needs.

GEWI
YES, clear objective in increasing quality of life and wellbeing

- 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.

GEWI
Planned to do so. To be developed in following phases.

7.2.4 CSF 6. Ensure that the technology is user-friendly

- The telemedicine technology used in our project is user-friendly for patients.

GEWI
It is the objective and great effort is done within the SHAPES consortium to define requirements to fulfil this. Besides that, regular feedback loops with end users are planned in phases 2-4 and feedback will be considered.

- The telemedicine technology used in our project is user-friendly for health professionals.

GEWI
No, as they are not involved in the deployment of the UC

- The telemedicine technology used in our project does not need an extended training process prior to using it.

GEWI
We expect minimum training. To be defined in mock-up sessions.

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.

GEWI
YES, from SHAPES and internal resources already allocated.

- In my region/organisation the IT competences needed for deployment of the telemedicine solution are available.

GEWI
YES. VICOM, EDGE and Gnomon provide IT competences.

- In my region/organisation enough time for the training needed in order to implement the telemedicine solution is available.

GEWI

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YES

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

- The telemedicine solution addresses the needs of the primary clients.

GEWI

To be evaluated.

- The telemedicine solution is sufficiently adapted to the needs of the primary users.

GEWI

YES, although details have still to be developed further. (patients as end-user)

- The telemedicine solution addresses the needs of the health sector.

GEWI

To be evaluated.

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.

GEWI

To do (D7.3 SHAPES Business Plan WP7)

- business plan for the project has been implemented.

GEWI

To do after the project end.

- The business plan has been approved by the relevant management level.

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.

GEWI
To do after the project end.

- A change management plan for the project has been implemented.

GEWI
To do after the project end.

- A change management plan has been approved by the relevant management level.

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.

GEWI
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	GEWI	
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.	

- In our region/organisation we are ready for large-scale deployment of the technology.

GEWI
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.

GEWI
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.

GEWI
Yes

- The project is carried out in accordance with the relevant guidelines on security matters.

VICOM	GEWI
YES. GDPR will be applied. The system provided implements all security and privacy related regulations.	Yes

7.4.2 CSF 14. Involve legal and security experts

- We have received advice on the project from legal experts.

VICOM	GEWI
YES. VICOM awarded the ISO 27001 certification for information security management.	To do

- We have received advice on the project from experts on data security matters.

VICOM	GEWI
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YES. VICOM awarded the ISO 27001 certification for information security management.	To do (within SHAPES consortium)
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- In this project we are not experiencing any data security problems.

VICOM	GEWI
No.	TBD

I have confidence in the legality of this project.

VICOM	GEWI
YES. It's a H2020 project with partners with extensive expertise in this field (LAUREA for example)	Yes

- I have confidence in the security of this project.

VICOM	GEWI
YES. It's a H2020 project with partners with extensive expertise in this field (HMU and VICOM for example)	Yes

7.4.3 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.

VICOM	GEWI
YES	Yes

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	GEWI
YES. SHAPES is developing a technology	To do

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platform for pan-european distribution of telemedicine services. The pilot is being designed to cope with this requirement as well.	
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- We have ensured that the eHealth infrastructures needed are in place for deployment and large-scale implementation.

VICOM	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

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	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

- We have set up a system to solve any incident that may occur during the service.

VICOM	GEWI
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YES. The system logs all activities so any incident can be identified and solved quickly.	To do
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We have a system which supports the end-users in resolving any doubts that they might experience with the telemedicine solution.

VICOM	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.	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	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

We have clear agreements regarding the service level provided by our vendors.

VICOM	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

Annex 3: NASSS questionnaire UC-PT2-001

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:

Pilot 2 – Improving in-home and community based care

UC-PT2-001 Remote monitoring of key health parameters (steps, exercise, water intake, sleep, nutrition)

The aim of this use case is the remote monitoring of important health parameters of older individuals with the aim of maintaining or possibly even improving their health status thanks to preventive health and care measures. Wearables, sensors and other devices can enable individuals to remain independent for longer through the provision of specific tips and recommendations. Also, it should be possible to thereby showcase the so-called “feel-good effect” i.e. the power of knowing everything is – relatively speaking – in order. It is expected that recording a stable (good) health status will make older individuals feel safer and thus more secure in pursuing daily activities such as moving around the house or outdoors, engaging with family, friends and the community or committing to further hobbies.

Dear technical partners, please feel free to comment.

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 This use case focuses on the monitoring of key health parameters and its influences on the overall empowerment about your day-to-day behaviour regarding nutrition, drinks, steps, exercises and sleep. It does not consider any particular disease or medication. The use case is open for a lot of potential participants, personal conditions will be asked at the beginning of starting the pilot.		X	
Many people with the condition have other co-existing illnesses or impairments that could affect their ability to benefit from this solution People have no special condition in the use but could have impairments which then can affect their ability to benefit from monitoring of certain parameters.		X	
Many people with the condition have social or cultural factors that could affect their ability to benefit from the technology or service		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 condition has significant complexity which is likely to affect the project's success	Yes <input type="checkbox"/>		No <input checked="" type="checkbox"/>

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) This use case consists of many SHAPES solution: eCare (EDGE), eHealthpass (GNO), Chatbot (CH Rosa), routine detection & activity intensity level classification (TREE), recommendation systems and wellbeing assessment (VICOM), Covidshield (GNO). Although some parameters and some details of the solution still have to be developed in more in-depth, there are building a good framework of the use case. Significant uncertainties arise from component of the open call: <ul style="list-style-type: none"> SHAPES-OC1- Enablers-ST2 Monitoring of nutrition intake 	X		
There are significant uncertainties in where the technology will come from (e.g. supply chain issues, substitutability) Standard devices are already selected: tablet, fitness tracker Significant uncertainties will remain due to the open call: Monitoring of nutrition intake	X		
There are significant uncertainties about the technology's performance and dependability (e.g. bugs, crashing, cutting out) Some devices are still missing due to open call. At this point of the project, the missing components can be considered and taken into in the planning, but some uncertainties will stay until the final of the open call and the integration of new partner's solution.	X		
There are significant uncertainties about the technology's usability and acceptability (e.g. key people don't trust the data it provides) As the data are prepared to be presented in the most user-friendly way and are displayed on a dashboard (in "almost" real time), people are in the position to asses their own data.		X	
There are significant technical interdependencies Yes, but this is necessary to reach the aim of this use case – so they are considered.	X		
The technology is likely to require major changes to organisational tasks and routines Implementing the technology does not involve additional staff. Implementation of the technology does not intervene with any steps in the care pathway		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	Yes <input checked="" type="checkbox"/>		No <input type="checkbox"/>

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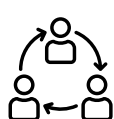
3. THE VALUE PROPOSITION



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 In this use case are involved different kinds of digital solution and technical components; the commercial value of this combo is not (exactly) known.	X		
The value to the intended users (e.g. patients, clinicians) is uncertain The value for the intended user is defined: "Remote monitoring of key health parameters".		X	
The value to the healthcare system (e.g. from efficacy and cost-effectiveness studies) is uncertain The use case aims to supports the empowerment and self-efficiency of the person in regard to the own health conditions and has no direct value to the healthcare system which e.g. could lead to remarkable cost-effectiveness. It focuses on the impact of wellbeing without help of healthcare professionals (so far).			X
The value to this particular healthcare organisation, given the current situation locally, is uncertain The use case will be deployed in home-setting, there is not particular health organisation involved.			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.		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	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	

4. THE INTENDED ADOPTERS

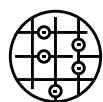


Think about who is intended to use the technology and what changes it will bring for them.

	Agree	Disagree	Not applicable or don't know
There is uncertainty about whether and how patients/citizens will adopt the technology [if applicable] The participant will get support on site or remote. The apps will be as most user-friendly as possible.		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 This has not been considered yet.			X

There will be significant changes to individual users' perceptions of the technology over the next 3-5 years Maybe due to the pandemic the e-literacy of older individuals evolved in general.			X
SUMMARY: There is significant complexity relating to intended adopters which is likely to affect the project's success	Yes <input type="checkbox"/>		No <input type="checkbox"/>

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 There is no (additional) organisation as participating site involved in this use case. This use case will be deployed in home-setting.			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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	

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 The office of social affairs in pilot site supports the activities of SHAPES.		X	
Professional bodies are opposed to the innovation or don't actively support it Professional bodies are not involved in this use case.		X	
Patient organisations and lobbying groups are opposed to the innovation or don't actively support it The team of the senior and care counselling of the office of social affairs supported us already in WP3 (finding interview partners) and is keen to see at some day the deployment of the use case.		X	
The regulatory context is adverse Due to pandemic the deployment of the use case in the home-setting is not advisable.	X		
The commercial context is adverse		X	
Opportunities for learning from other (similar) organisations are limited		X	

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Introduction of the technology/innovation could be threatened by external changes that impact on the organisation Depending on the course of the pandemic	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	Yes <input type="checkbox"/>	No <input type="checkbox"/>	

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

<p>The illness or condition</p> <p>Empowerment for monitoring of own key health parameters</p>	<p>The technology</p> <p>Complexity of integration existing SHAPES solutions with new components of the open call. Planning with and without new components is necessary if there are no applicants in the open call.</p>	<p>The value proposition</p> <p>Should be more considered in the further development (KPI)</p>
<p>The intended adopters</p> <p>The participant of the use case has to handle four devices and several digital solutions. User-friendliness of the apps and good training material are important.</p>	<p>The organisation</p> <p>No involvement of another organisation (besides SHAPES partners)</p>	<p>The external context</p> <p>Deployment of use case in home-setting is strongly dependent on the course of the pandemic.</p>

Annex 4: Questionnaire for Mock-up sessions UC-PT2-001

Questionnaire for Mock-ups of UC-PT2-001

Welcome of participant

1. **General information about SHAPES**
2. **Information about use case and its intention, presentation of use case scenario**
3. **Mock-up**

Participant should be actively made aware that she/he can ask questions or add comments at any time during mock-up session.

Interviewer should collect any impressions and conversation which occurs besides the questionnaire.

An open atmosphere should be created, and the participants should be motivated to explain thoughts and opinions.

Presentation of SHAPES digital solutions (mock-up)

UNDERSTANDING	
What do you see?	
What do you think that you can do on this screen/slide? ...and how would you do it (press button, talk, typing,)?	
Is the visualization appealing to you?	
What do you like? What don't you like? Is there anything missing (e.g. information, button, function)?	
LAYOUT	
What is the general idea of this slide/screen?	
Can you read all information? Are contrast sufficient?	
What would make it easier to understand provided information?	
Do you feel overwhelmed?	
What do you think about the pictures/ diagrams or icons?	
INTERACTION	
Are you able to find information for specific parameters/ topics?	

Are you aware that you can add own information to the digital solution?	
What functions are comprehensible to you? Which ones are not?	
What would you do to get information about specific health parameter (e.g. your sleep quality)?	
What do you think you could do on this site?	
Where can you click?	
Do you think you could act accordingly?	
How many recommendations a day would be fair?	
Do you like to see any other information?	
FEEDBACK	
After seeing all the slides/screens – what do you think?	
What kind of training would you need to deploy the use case?	
Can you imagine providing your personal data to the digital solution?	
Which information/ functions are most interesting/ helpful to you?	
Which functions are useless for you/ would you not need? And why?	
IT-BEHAVIOUR	
Which devices do you use regularly?	
Tell me about apps that you like to use daily.	
How intuitive are the solutions to you? Do you get any support?	
Are you interested in technology? Thinking of the special devices needed (e.g. Smartwatch): Would you wear it? Which problems may appear with it? If it is available in the future, would you buy it for yourself?	

Annex 5: Consent form phase 3 UC-PT2-001

EINVERSTÄNDNISERKLÄRUNG FÜR TEILNEHMENDE (Zielbenutzer:in)

Titel der Studie: SHAPES Pan-Europäische Pilotkampagne: Nutzerbeteiligung und Feedback zu digitalen Lösungen für Pilotthema 2 - Optimale Anpassung des Wohnumfeldes für eine höhere Unabhängigkeit & verbesserte Lebensqualität

Ort der Studie:

Bei Ihnen zu Hause

Kontakt:

...

Erklärung des Teilnehmenden

Ich bin eingeladen worden, an der oben genannten Studie teilzunehmen. Der Zweck der Studie ist es, Feedback zur Anwendung und Nutzerfreundlichkeit einer Gesundheitsanwendung (einer App) zu sammeln. Die App wird für Menschen ab 65 Jahren entwickelt, die zu Hause leben. Die Studie gibt uns die Gelegenheit sicherzustellen, dass die App aus der Perspektive älterer Menschen praktisch und benutzbar ist.

- Ich habe das SHAPES-Teilnehmerinformationsblatt gelesen und verstanden. Es hat mich ausreichend über die oben genannte Studie, ihren Zweck und die Durchführung der Studie, über meine Rechte und über die möglichen Vor- und Nachteile einer Teilnahme informiert.
 - Ich hatte die Möglichkeit, Fragen zur Studie zu stellen und habe diese Fragen zufriedenstellend beantwortet bekommen.
 - Ich bin ausreichend über die Erhebung, Verarbeitung, Weitergabe und Löschung meiner Antworten während der Studie informiert worden. Mir ist bekannt, dass außer meines Namens und meiner Kontaktdaten keine weiteren personenbezogenen Daten im Rahmen dieser Studie verarbeitet werden.
 - Mit meiner Unterschrift bestätige ich, dass ich freiwillig an dieser Studie
- This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159



teilnehme und dass ich auch der Verarbeitung meiner Antworten zu den in diesem Dokument beschriebenen Zwecken und Zielen zustimme.

- Ich wurde nicht unter Druck gesetzt oder zur Teilnahme überredet und ich hatte genügend Zeit, mir meine Teilnahme an der Studie zu überlegen. Mir ist bewusst, dass meine Teilnahme völlig freiwillig ist und dass es mir freisteht, meine Einwilligung jederzeit und ohne Angabe von Gründen zurückzuziehen.
- Ich habe auch das Recht, die Löschung meiner identifizierbaren persönlichen Daten in Übereinstimmung mit den Datenschutzbestimmungen zu verlangen.

Optional

Ich bin damit einverstanden, von gewi bezüglich der Teilnahme an zukünftigen Projekten im Zusammenhang mit dieser Studie kontaktiert zu werden, die innerhalb dieses und nächstes Jahres anfallen

Ja Nein
(bitte ankreuzen)

Auszufüllen vom Teilnehmenden

Bitte füllen Sie die folgenden Angaben aus, um Ihre Zustimmung zu bestätigen:

Name:	
Datum:	
Unterschrift:	

Annex 6: Information sheet phase 3 UC-PT2-001

SHAPES-TEILNEHMERINFORMATIONSBLATT: Zielbenutzer:in

Titel der Studie: SHAPES Pan-Europäische Pilotkampagne: Nutzerbeteiligung und Feedback zu digitalen Lösungen für das Pilotthema 2 - Optimale Anpassung des Wohnumfelds für eine höhere Unabhängigkeit & verbesserte Lebensqualität

Wir möchten Sie einladen, an unserer Studie teilzunehmen, bei der wir gerne Ihr Feedback zur Funktionsweise einer Gesundheitsanwendung (einer App) erfragen möchten. Die App wird für Menschen ab 65 Jahren entwickelt, die zu Hause leben. Ihr Feedback gibt uns die Gelegenheit sicherzustellen, dass die App aus der Perspektive älterer Menschen praktisch und benutzbar ist. Wir beabsichtigen, mindestens zwei Personen in diese Studie einzubeziehen.

Sie wurden als geeignet für die Teilnahme an unserer Studie identifiziert und haben daher dieses Informationsblatt erhalten. Es beschreibt die Studie und Ihre Rolle darin. Zunächst ist es wichtig, dass Sie verstehen, warum die Studie durchgeführt wird und was die Teilnahme für Sie bedeutet. Bitte lesen Sie dieses Informationsblatt gründlich, bevor Sie entscheiden, ob Sie an der Studie teilnehmen möchten. Wenn Sie Fragen haben oder sich noch weitere Informationen wünschen, wenden Sie sich gerne an unsere Ansprechpartnerinnen ...

Freiwilligkeit der Teilnahme

Die Teilnahme an dieser Studie ist freiwillig. Sie können jederzeit ohne Angabe von Gründen von der Studie zurücktreten, ohne dass dies negative Folgen für Sie hat.

Zweck und Ziele der Studie

Diese Studie ist Bestandteil eines größeren Forschungsprojekts, das darauf abzielt, verschiedene Möglichkeiten des Einsatzes von Technologie zur Unterstützung älterer Menschen in ihrem häuslichen Umfeld zu testen.

Das Ziel der Studie besteht darin, dass Sie die verschiedenen Funktionen der App für uns testen. Außerdem werden Sie ermutigt, Ihre ersten Reaktionen, Gedanken, Gefühle und Meinungen zur Nutzung der App mit uns zu teilen und Verbesserungsvorschläge zu äußern. Anhand dieses Feedbacks werden wir weitere Anpassungen vornehmen, um die App benutzerfreundlicher für ältere Menschen zu gestalten.

Die fertige App wird dann in einer größeren Studie eingesetzt, um herauszufinden, ob sie Menschen darin unterstützen kann, wichtige Gesundheitsparameter und Aktivitäten von zu Hause aus zu verwalten und

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somit ihre Lebensqualität und Gesundheitsergebnisse zu verbessern.

Wer organisiert und finanziert die Forschung?

Das Institut für Gesundheitswirtschaft e.V. (gewi) organisiert diese Studie. Sie ist Teil eines größeren Forschungsprogramms mit dem Namen SHAPES-Projekt, das von der Europäischen Union im Rahmen des Programms Horizon 2020 (Grant Agreement no 857159) finanziert wird.

Was wird die Teilnahme beinhalten?

Wenn Sie zustimmen, an dieser Studie teilzunehmen, werden Sie mit einem Fitnessarmband und einem Tablet ausgestattet, auf dem die App bereits installiert ist. Zudem werden Sie in einer ca. 2-stündigen Trainingseinheit von einer wissenschaftlichen Mitarbeiterin in die Nutzung der Geräte eingeführt. Diese findet bei Ihnen zu Hause statt.

Was genau wird passieren?

Nachdem Sie Zeit hatten, dieses Informationsblatt zu lesen, wird die wiss. Mitarbeiterin mit Ihnen in Kontakt treten, um die weitere Teilnahme zu besprechen. Wenn Sie mit der Teilnahme einverstanden sind, werden Sie gebeten eine Einverständniserklärung zu unterschreiben.

Im nächsten Schritt wird der Termin für die Trainingseinheit vereinbart.

Diese gestaltet sich wie folgt:

- Die wiss. Mitarbeiterin wird das Fitnessarmband und die App präsentieren und dabei auf die einzelnen Funktionen eingehen.
- Ihnen wird gezeigt, wie Sie selber die App benutzen können.
- Eine Anleitung wird während der Trainingseinheit auf einem Laptopbildschirm angezeigt.
- Im zweiten Schritt werden Ihnen kleine Aufgaben gestellt, die mit der Anwendung der App zu tun haben. Damit wollen wir herausfinden, an welchen Stellen es Schwierigkeiten **mit der App** gibt.
- Sie werden ermutigt "laut" zu denken und Ihre ersten Ideen und Reaktionen während der Präsentation und den Aufgaben mitzuteilen. Hierbei gibt es keine richtigen oder falschen Antworten. Wir sind interessiert an Ihrer ehrlichen Meinung und Ihrer Einschätzung zu dem, was wir Ihnen zeigen.
- Die wiss. Mitarbeiterin macht sich während der Trainingseinheit Notizen, die für die spätere Auswertung benötigt werden.
- Die Einheit wird etwa zwei Stunden dauern. Wir werden in einem von

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Ihnen festgelegten Tempo arbeiten und können jederzeit eine Pause einlegen.

- Im Anschluss an die Aufgabenstellung wird Ihnen die wiss. Mitarbeiterin Fragen zu Ihrer Einschätzung mit dem Umgang der App stellen. Sie können uns an der Stelle ausführlich mitteilen, was Ihnen gefallen hat, was Ihnen nicht gefallen hat oder was Sie selber an der App verändern würden.

Erhebung und Verarbeitung von Informationen nach der Trainingseinheit

- Außer Ihrem Namen und Ihren Kontaktdaten werden keine weiteren personenbezogenen Daten erhoben.
- Anonymisierte Ergebnisse können in weiteren Forschungs- und/oder Kommunikationsaktivitäten verwendet werden (z. B. im Rahmen weiterer Forschung im SHAPES-Projekt, in Zeitschriftenartikeln, Workshops und Konferenzen).
- Ihre persönlichen Kontaktdaten werden von den Forschenden vernichtet, sobald Sie eine Zusammenfassung der Ergebnisse dieser Studie erhalten haben.
- Anonymisierte Rohdaten werden für die Dauer des SHAPES-Projekts und für fünf Jahre nach dessen Beendigung gespeichert.

Mögliche Vorteile einer Teilnahme

Es gibt keinen direkten Nutzen für Sie als Einzelperson für die Teilnahme an dieser Studie, abgesehen vom persönlichen Interesse und der Erfahrung, an einer Studie teilzunehmen. Der indirekte Nutzen dieser Studie besteht jedoch darin, dass Sie uns Ihre Ansichten und Meinungen mitteilen können und so zu dem Design und der Funktionsweise der App beitragen. Ihr Input wird Kenntnisse darüber liefern, wie Technologien eingesetzt werden können, um Menschen im Alter in ihrem häuslichen Umfeld zu unterstützen. Menschen aus ganz Europa werden von Ihrer Teilnahme profitieren.

Mögliche Nachteile der Studienteilnahme

Wir sehen keine Unannehmlichkeiten oder Nachteile für Sie, wenn Sie an dieser Studie teilnehmen.

Finanzielle Informationen

Die Teilnahme an dieser Studie ist für Sie mit keinen Kosten verbunden. Sie erhalten keine Bezahlung für Ihre Teilnahme.

Information über die Studienergebnisse

Die Ergebnisse dieser Studie können in weiteren Forschungs- und/oder

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Kommunikationsaktivitäten verwendet werden (z. B. im Rahmen weiterer Forschung im SHAPES-Projekt, in Zeitschriftenartikeln, Workshops und Konferenzen). Eine Zusammenfassung der Ergebnisse wird Ihnen zur Verfügung gestellt.

Beendigung der Studie

Die Forscher, die die Studie durchführen, können die Studie beenden. Derzeit gibt es hierfür jedoch keinerlei Gründe oder Anlässe. Außerdem steht es Ihnen jederzeit frei, Ihre Teilnahme an der Studie zu beenden. Wenden Sie sich in diesem Fall bitte an die Forschenden. Ihre anonymisierten Daten können weiterhin in die Studie einbezogen werden.

Weitere Informationen

Weitere Informationen im Zusammenhang mit der Studie können Sie bei den folgenden am SHAPES-Projekt beteiligten Personen erfragen:

...

Annex 7: Consent form Phase 4 UC-PT2-001

EINVERSTÄNDNISERKLÄRUNG FÜR STUDIENTEILNEHMER:INNEN

Titel der Studie: SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) Pan-Europäische Pilotkampagne: Digitale Lösung zur Messung wichtiger Gesundheitsparameter. Eine nicht-randomisierte Machbarkeitsstudie in der realen Welt zur Bewertung der Benutzerfreundlichkeit und des von den Benutzern:innen wahrgenommenen Nutzens.

Entwickler (Auftraggeber): gewi – Institut für Gesundheitswirtschaft e.V. (Karolingerring 31, 50678 Köln)

Erklärung von: _____ (Name)

- Ich wurde eingeladen, an der oben genannten Studie teilzunehmen. Der Zweck der Studie ist es, mittels Fitnessarmband und Gesundheitsanwendung (einer App) wichtige Gesundheitsparameter zu messen. Die App wurde für Menschen ab 65 Jahren entwickelt wird, die zu Hause leben. Die Studie ist eine Gelegenheit für die wissenschaftlichen Mitarbeitenden, um sicherzustellen, dass die App und das Fitnessarmband aus technischer Perspektive funktionieren.
- Ich habe das Informationsblatt für Studienteilnehmer:innen gelesen und verstanden. Das Informationsblatt hat mich ausreichend über die oben genannte Studie, ihren Zweck und die Durchführung der Studie, über meine Rechte und über die möglichen Vor- und Nachteile einer Teilnahme informiert.
- Ich hatte die Möglichkeit, Fragen zur Studie zu stellen und habe diese Fragen zufriedenstellend beantwortet bekommen.
- Ich bin ausreichend über die Erhebung, Verarbeitung, Weitergabe/Weitergabe und Löschung meiner Antworten während der Studie informiert worden. Mir ist bekannt, dass außer meines Namens und meiner Kontaktdaten keine weiteren personenbezogenen Daten im Rahmen dieser Studie verarbeitet werden.

- Mit meiner Unterschrift bestätige ich, dass ich freiwillig an dieser Studie teilnehme und dass ich auch der Verarbeitung meiner Antworten zu den in diesem Dokument beschriebenen Zwecken zustimme.
- Ich wurde nicht unter Druck gesetzt oder zur Teilnahme überredet und ich hatte genügend Zeit, mir meine Teilnahme an der Studie zu überlegen. Mir ist bewusst, dass meine Teilnahme völlig freiwillig ist und dass es mir freisteht, meine Einwilligung jederzeit und ohne Angabe von Gründen zurückzuziehen.
- Ich habe auch das Recht, die Löschung meiner identifizierbaren persönlichen Daten in Übereinstimmung mit den Datenschutzbestimmungen zu verlangen.

Auszufüllen vom Teilnehmenden

Bitte füllen Sie die folgenden Angaben aus, um Ihre Zustimmung zu bestätigen:

Name:	
Datum:	
Unterschrift:	

Annex 8: Information sheet phase 4 UC-PT2-001

INFORMATIONSBLETT FÜR STUDIENTEILNEHMER:INNEN

Titel der Studie: SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) Pan-Europäische Pilotkampagne: Digitale App und Plattform zur Messung wichtiger Gesundheitsparameter. Eine nicht-randomisierte Machbarkeitsstudie in der realen Welt zur Bewertung der Benutzerfreundlichkeit und des von den Benutzern:innen wahrgenommenen Nutzens

Entwickler/ Sponsor: gewi – Institut für Gesundheitswirtschaft e.V.

...

Wir möchten Sie einladen, an unserer Studie teilzunehmen, bei der Sie die Funktionalität einer Gesundheits-App und eines Fitnessarmbands (digitale Lösung) testen sollen. Die App wurde für Menschen ab 65 Jahren entwickelt, die zu Hause leben. Die Studie bietet uns die Möglichkeit, die digitale Lösung in einer realen Umgebung zu testen und etwaige Probleme mit Verbindung und der Datenübertragung zu ermitteln. Es wird auch geprüft, ob Änderungen an den Prozessen, der Logistik oder der Dokumentation vorgenommen werden müssen, die im groß angelegten Pilotprojekt verwendet werden sollen.

Wir möchten, dass Sie korrekte und ausreichende Informationen erhalten, damit Sie beurteilen können, ob Sie teilnehmen möchten oder nicht. Bitte lesen Sie daher dieses Informationsblatt sorgfältig durch, und wir werden etwaige Zweifel nach der Erläuterung klären. Außerdem können Sie sich mit Personen beraten, die Sie für geeignet halten. Wenn Sie Fragen haben, wenden Sie sich bitte an ... (Studienleitung) unter den am Anfang dieses Dokumentes angegebenen Kontaktdaten.

Freiwillige Teilnahme

Die Teilnahme an dieser Studie ist freiwillig. Sie können jederzeit die Teilnahme ohne Angabe von Gründen und ohne negative Folgen für Sie beenden.

Zweck und Ziele der Studie

Diese Studie ist Teil eines größeren Forschungsprojekts, in dem verschiedene Möglichkeiten des Einsatzes von Technologie zur Unterstützung älterer Menschen in ihrem Zuhause getestet werden sollen. Ziel dieser Studie ist es, die Lösung in einer realen Umgebung zu testen. Die App und das Fitnessarmband werden vier Wochen lang verwendet, und wir werden Informationen darüber sammeln, wie gut sie funktionieren, sowohl aus der Sicht des/der Benutzers:in als auch der Systeminfrastruktur der Lösung, wo die Forscher die von der App übertragenen Informationen einsehen.

Was ist mit der Teilnahme verbunden?

Sie erhalten ein Tablet Gerät, auf dem die App installiert ist, und ein Fitnessarmband. Zu Beginn der Studie erhalten Sie von der Studienleitung eine Schulung und ein Benutzerhandbuch für die Verwendung der App.

Sie werden gebeten täglich Daten zu **Schlafqualität, Wohlbefinden, Flüssigkeitszufuhr und Ernährung** in der SHAPES-App zu erfassen und das **Fitnessarmband dauerhaft** zu tragen. Die Daten vom Fitnessarmband werden per Bluetooth an die App übertragen. In der App können

Sie alle Ihre Daten sehen und auch manuell Werte eintragen. Für den Zweck dieser Studie verwenden Sie fiktive Daten, die Sie in der App eintragen.

Datenverarbeitung

Ihre Daten werden von der App drahtlos auf die gesicherten Server der technischen Partner hochgeladen. Die Daten werden dann sicher über direkte Verbindungen mit den Partnern zur Analyse geteilt. Die umgewandelten Daten werden sicher an die Server des technischen Partners zurückgeschickt und über ein browserbasiertes Dashboard angezeigt, damit die Forscher Ihren Verlauf während der Studie verfolgen können. Sie werden keinen Zugriff auf die umgewandelten Daten oder das Dashboard haben.

Zudem ist auf dem Gerät, das Sie vom gewi- Institut für Gesundheitswirtschaft e.V. im Rahmen der Studie erhalten, eine App installiert (Anydesk), die es im Falle von technischen Problemen den Wissenschaftlerinnen ermöglicht, aus der Distanz auf das Gerät zuzugreifen und potenzielle Probleme zu beheben. Das Vorgehen ist abgesichert durch doppeltes Einverständnisverfahren Ihrerseits. Es werden dabei keine persönlichen Daten gespeichert.

Nur das Forscherinnen-Team des gewi Instituts wird Sie identifizieren können. Allen anderen SHAPES Partnern wird ein Code zur Verfügung gestellt, mit dem es nicht möglich ist Sie persönlich zu identifizieren. Ihre Informationen werden bis zum Start der nächsten Phase des Projekts gespeichert (dieser ist für September 2022 geplant). Ihre Daten werden dann von allen Servern gelöscht.

Vorteile und Risiken, die sich aus Ihrer Teilnahme an der Studie ergeben

Auf individueller Ebene bringt die Teilnahme an dieser Studie keinen direkten Nutzen, abgesehen von dem persönlichen Interesse und der Erfahrung durch die Teilnahme an einer Forschungsstudie. Obwohl das Ziel von SHAPES letztlich darin besteht, die Lebensqualität älterer Menschen zu verbessern, und die Studie Daten sammelt, um eine Bewertung in dieser Hinsicht vorzunehmen, besteht das Hauptziel der Studie darin, die Akzeptanz der digitalen Hilfsmittel bei den Teilnehmern:innen zu bewerten.

Das dauerhafte Tragen des Fitnessarmbands kann zu Beginn gewöhnungsbedürftig sein. Es werden keine Risiken vorhergesehen.

Wirtschaftlicher Ausgleich

Für Ihre Teilnahme an der Studie entstehen Ihnen keine Kosten, außer der Nutzung Ihres Internets. Für die Teilnahme an dieser Studie erhalten Sie keine Vergütung.

Verwendung der Studienergebnisse

Die Ergebnisse dieser Studie können für weitere Forschungs- und/oder Kommunikationsaktivitäten genutzt werden (z. B. im Rahmen der weiteren Forschung im SHAPES-Projekt, in Zeitschriftenartikeln, Workshops und Konferenzen). Eine Zusammenfassung der Ergebnisse wird Ihnen zur Verfügung gestellt.

Beendigung der Studie

Die Forscherinnen, die die Studie durchführen, können die Studie beenden, jedoch gibt es derzeit keine vorhersehbaren Gründe, warum diese Studie beendet werden sollte. Es steht Ihnen jederzeit frei, Ihre Teilnahme zurückzuziehen. In diesem Fall wenden Sie sich bitte an die Studienleitung. Wir dürfen dann Ihre anonymisierten Daten weiterhin verwenden.

Annex 9: Study protocol phase 5 UC-PT2-001

Title of the project

Smart and Healthy Ageing through People Engaging in Supportive Systems (SHAPES) digital app and platform for remote monitoring of key health parameters of older individuals. A non-randomized, feasibility study in real world for the evaluation of user engagement and user-perceived usefulness. (UC-PT2-001-GEWI).



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

1. Summary of the pilot study

The intervention being piloted in this study is a novel system of supporting older individuals (>65 years old) living at home by themselves through unobtrusively capturing relevant health parameters (wellbeing, steps, heart rate, activities, sleep, fluid intake, nutrition) through wearables and other devices to display their individual health status and to give personal recommendations. This allows the older individual to reflect on own health conditions and to improve the overall wellbeing and the quality of life in the long run. This pilot is a feasibility study in order to have a first evaluation of the engagement and user-perceived usefulness of the novel system in a real-world environment. The project is designed as a non-randomised, single-armed, cross-sectional interventional pilot study with an optional qualitative interview component. To expand the impact, an equivalent study will be carried out in Italy (AIAS) and Greece (5th YPE). This project is undertaken within the European project SHAPES (www.shapes2020.eu), which evaluates several digital solutions addressed to older individuals. Data collected in this project will be anonymised and shared with SHAPES consortium for a pan-European evaluation of digital solutions.

The target group in this study is composed of +65 year old individuals living in their home-setting in the reference site “Oberbergischer Kreis” in Germany. Participants will be asked to use the SHAPES app on the tablet provided by the gewi - Institut für Gesundheitswirtschaft e.V. Additionally, participants will receive a CE-marked activity wristband (Xiaomi Mi Band 3) and will be encouraged to take daily readings of their health parameters (wellbeing, steps, heart rate, activities, sleep, fluid intake, nutrition) and wear the wristband at all times. The collected data can be viewed via the app (feature provided by the SHAPES partner EDGENEERING’s eCare software and GNOMON’s eHealthpass software), which collects the readings either via Bluetooth or manually inserted by the older person. Furthermore, the participants receive personalised recommendations based on the results of the monitored key health parameters as well as the individual goals set up during the registration process.

2. Introduction

People who are aged 65 years and older account for almost a fifth of the population of the European Union. The number of people in this age group is projected to reach 151 million in 2060¹. Conversely, the proportion of EU citizens who describe themselves as being in 'good' or 'very good' health is falling and varies considerably between member states (ranges between 43.4% and 82.8%). In addition, 'poor health' is more often reported from older people compared to younger people. Naturally, being in 'good health' is not only of value to the individual (better quality of life, improved wellbeing, greater social participation), but it is also important for societal and economic growth². Thus, there is an imperative to keep people healthy and active as they age.

Although health problems and complaints increase with age, old age does not inevitably stand for illness, limitations and the need of care. Individual lifestyles and personal resources, social integration and the level of access to medical and social care greatly impact the health status, quality of life and well-being of older individuals. Supporting older people in living healthy and independent lives equally entails to reduce risk factors such as unhealthy lifestyles, to improve external health determinants and to strengthen accessible healthcare for all².

Innovative systems such as information and communication technologies (ICT/eHealth) offer great opportunities to support and enhance independence for older adults and may be related to health, cognitive functioning, independence maintenance, and social inclusion in advanced age³. With the right choice of eHealth technology, older people can be enabled to monitor and reflect on their own health and wellbeing. Thus, changes in their condition can be potentially detected at an early stage and according actions can be taken - resulting in better and longer health, independence and quality of life.

Health literacy and individual involvement will be key elements in the successful introduction of eHealth into the health and social care system. Citizens, including older individuals, must be seen as custodians of their own health⁴, thus emerging technologies need to be user-friendly and empowering. Developments in ICT (eHealth) for the in-home care services, including ways of monitoring wellbeing and providing a secure home environment, and key emerging technologies on robotics and sensors open up the concept of 'Ambient Intelligence' and offer the potential for different environments (i.e., at home, in the street, during transportation,) to embed intelligence that helps with everyday life. To date, initiatives to achieve traction in this area have been modest, with experiments involving advanced ICT services supporting health and care through small-scale, localised initiatives.

The Smart & Healthy Ageing through People Engaging in Supportive Systems (SHAPES) Innovation Action (www.shapes2020.eu), a European project in which gewi - Institut für Gesundheitswirtschaft e.V. is a member, intends to build, pilot and deploy a large-scale, EU-standardised open platform. The integration of a broad range of technological, organisational, clinical, educational and societal solutions seeks to facilitate long-term healthy and active ageing and the maintenance of a high-quality standard of life. Mediated by technology, in-home and local community environments interact with health and care networks contributing to the reduction of costs, hospitalisations and institutional care.

SHAPES intends to build an interoperable Platform integrating smart digital solutions to collect and analyse older individuals' health, environmental and lifestyle information,

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identify their needs and provide personalised solutions that uphold the individuals' data protection and trust. Standardisation, interoperability and scalability of the SHAPES Platform aims to increase efficiency gains in health and care delivery across Europe, bringing improved quality of life to older individuals, their families, caregivers and care service providers. SHAPES large-scale piloting campaign will engage +2k older individuals in 15 pilot sites in 10 EU Member States, including six European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) Reference Sites, and involve hundreds of key stakeholders. SHAPES multidisciplinary approach to large-scale piloting is reflected across seven themes that, together, provide a clear understanding of the reality of European health and care systems and enable the validation of cost-efficient, interoperable and reliable innovations capable of effectively supporting healthy and independent living of older individuals within and outside the home. These seven themes are as follows:

- Pilot Theme 1: Smart Living Environment for Active Ageing at Home
- Pilot Theme 2: Improving In-Home and Community-based Care Services
- Pilot Theme 3: Medicine Control and Optimisation
- Pilot Theme 4: Psycho-social and Cognitive Stimulation Promoting Wellbeing
- Pilot Theme 5: Caring for Older Individuals with Neurodegenerative Diseases
- Pilot Theme 6: Physical Rehabilitation at Home
- Pilot Theme 7: Cross-border Health Data Exchange Supporting Mobility and Accessibility for Older Individuals

The Oberbergische Kreis in Germany is EIP on AHA (European Innovation Partnership on Active and Healthy Ageing) reference site for this pilot study. The gewi - Institut für Gesundheitswirtschaft e.V. is leading Pilot Theme 2 of the SHAPES pilot: 'Improving In-Home and Community-based Care Services', wherein the SHAPES platform and selected digital solutions will be used to provide an appropriate home setting for older individuals and to promote and maintain an individual's autonomy at home. Digital solutions and smart home devices are deployed to obtain a person-aware environment and to infer the individual's wellbeing based on relevant activities. Smart healthcare devices and wearables are integrated to frequently monitor the individual's health parameters and health condition. Within this pilot theme there are multiple 'use cases' each deploying and evaluating different digital solutions in several European countries according to the type of support required. Four use cases will be used to evaluate this pilot theme. The project in this document describes the piloting of the use case led by gewi - Institut für Gesundheitswirtschaft e.V. and carried out in "Oberbergischer Kreis", Germany.

The use case of this project study focuses on older persons living at home by themselves, insufficiently informed about the realm of their capabilities thus subject to suffer from isolation and associated risks such as loss of speech, vitality, and lack of general fitness. The individuals at stake are still rather agile but need to be somewhat motivated and/or informed about the variety of physical and mental activities at their disposal or within their reach in order to keep exercising regularly and/or entertain social contacts. The use of wearables and other devices can enable these individuals to self-monitor important health parameters, reflect on their own health and wellbeing status and adapt healthier lifestyles through the provision of specific tips and personalised recommendations. Thereby, the health outcomes and quality of life of the target population can be maintained or possibly even improved, enabling them to remain independent for longer. Also, it should be possible to showcase the so-called "feel-good effect" i.e. the power of knowing everything is – relatively speaking – in

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order. It is expected that recording a stable (good) health status will make older individuals feel safer and thus more secure in pursuing daily activities such as moving around the house or outdoors, engaging with family, friends and the community or committing to further hobbies.

The SHAPES platform along with selected digital solutions belonging to partners of the SHAPES consortium (eCare from EDGENEERING, eHealthPass from gnomon and nutrition app from Elliot) can become eHealth tools for the self-management of relevant health parameters that are particularly designed for older persons. In the presented project, the main objective is to evaluate whether users engage with such a system and if it is useful for them (self-perceived usefulness).

3. Literature

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4. Hypothesis and objectives

Hypothesis: This study will test the hypothesis that the SHAPES platform and Digital Solutions (novel system) are capable of providing opportunities for maintaining or possibly even improving the health status of older individuals thanks to preventive health and care measures.

Objectives

Primary objectives

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

Secondary objectives

- To investigate the capability of the novel system to improve the supervision of the individual health and wellbeing status (SO1).
- To investigate the association of the first (active / sedentary behaviour) and second level (active in activities of daily living / intermediate activity / exercise) of physical activity classification, sleep quality analysis, fluid intake and nutrition analysis with the individual perceived wellbeing (SO2).
- To investigate the capability of the novel system to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects (SO3).
- To explore user trust and acceptance of the novel system (SO4).

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 (TO1).
- To validate the capability of the SHAPES Platform and Digital Solutions to improve the older individuals' health and wellbeing outcomes and quality of life (TO2).
- To validate the capability of the SHAPES Platform and Digital Solutions to gain the older individuals' trust and acceptance (TO3).

Outcomes

In relation to at least one primary objective (related objectives in brackets):

- O1. Timestamps of login into the novel system via the dashboard function (PO1).
- O2. Notes taken during the introduction training and the unstructured interview at the end of the use of the novel system (PO1, PO2).
- O3. Short version of User Experience Questionnaire (UEQ-S)⁵ (PO2, SO4, TO3).
- O4. Social technological measures: Technology Acceptance Model (TAM) questionnaire⁶, System Usability Scale (SUS)⁷. (PO2, SO4, TO3).

In relation to the secondary and tertiary objectives (related objectives in brackets):

- O5: Steps: Personal daily steps, accumulated daily steps, number of steps (SO2)
- O6: Fluid intake: fluid intake (manually entered in app ml/l) (SO2)
- O7: Wellbeing: How do feel today? Likert Scale (SO1, SO2, SO3, TO2).

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- O8. Physical activity: Exercise (light/moderate/vigorous); High Intensity Aerobic Exercise Weekly (min./week); Medium Intensity Aerobic Exercise Weekly (min/week); Balance Exercise Weekly (times/week); Muscle-Strengthening Weekly (times/week); heart rate; TREE Analytics: Time sedentary (h and min); Time active (h and min); Time active in ADL (h and min); Time active aerobic activity (h and min); Time aerobic low (h and min); Time aerobic moderate (h and min); Time aerobic vigorous (h and min) (SO2).
- O9. Sleep parameters: sleep duration (in h), sleep question (how well did you sleep question); day naps (number and duration); Sleeping medicine (times/week); TREE Analytics: Sleep Quality Indicator (in %); Bedtime (datetime); time to fall asleep (datetime); Wake up time (datetime); Rise time (datetime); sleep time (hours); Time in bed (hours); Awake interruptions (times); Get out bed interruptions (times); Latency time (minutes) (SO2).
- O10. Nutrition: Picture of the meal via LogMeal/Elliot app (SO2).
- O11. Covid-19 measures: Do you have signs of a cold (4 categories); Shortness of breath (4 categories), loss of taste or smell (4 categories); cough (4 categories); fever (in °C); (TO2).
- O12. Psychosocial measures: WHOQOL-BREF⁸; EQ-5D-5L⁹; GSES (Self-efficacy)¹⁰; OSSS-3 (social support) and life events¹¹; 1-item health literacy; SHAPES Participation questionnaire (SO3, TO1, TO2).

In order to relate objectives to socio-demographics of app users:

- O13. Number of years of formal education; date of birth; 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
- O14. Health Status data: Weight (in kg), Smoking Status (Yes/No; number of cigarettes per day), Alcohol Use (Yes/No; number of glasses per day), Allergies (chosen from predefined categories), Number of medical conditions + optional question "which ones" (manual entry), Reduced mobility/endurance + optional question "why/to what extend" (manual entry)

In order enable login process in the novel system:

- O15. Participants ID (non-identifiable) and password.

In order to contact participants (data only kept at gewi - Institut für Gesundheitswirtschaft e.V.)

- O16. Name, Native Language

For technical reasons:

- O17. Model, manufacturer and serial number of devices (technical).

Table 1: Outcomes collected in the study. Novel system user is any participant who uses any component of the technology at any time. 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 are always done with the support of a researcher.

Outcome code	Outcome	Addressed to	Conducted by	Time of collection	Objective
O1, O2	Use of features in novel systems	Older person	Automatic and Researcher	I, E	PO1, PO2
O3	UEQ – S	Older person	Self-complete	E	PO2, SO4, TO3
O4	TAM, SUS	Older person	Self-complete	E	PO2, SO4, TO3
O5, O6, O7, O8, O9, O10	Data from devices	Older person	App user (Automatic or self-complete via app)	I	SO1, SO2, SO3, TO2
O11	Covid-19 measures	Older person	Researcher (baseline) and App user/self-complete (during pilot via app)	B, I	TO2
O12	WHOQOL-BREF, EQ-5D&VAS, GSES, OSSS-3 and life events, 1-item health literacy, SHAPES Participation Questionnaire	Older person	Self-complete	B, E, F	SO3, TO1, TO2
O13	Socio-demographic data: Number of years of formal education; date of birth; gender; marital status; country.	Older person	Researcher	B	Socio-demographic analysis
O13	Socio-demographic data: marital status; occupational status; caregiver status; help from family; professional help, neighbourhood environment; residence type; co-living with someone Literature measure	Older person	Researcher	B, E, F	Socio-demographic analysis
O14	Health Status data	Older person	App user	B	
O15	User and password	Older person	Self-complete	B	Login
O16	Contact details	Older person	Researcher	R	Contact
O17	Device technical data	NA	Researcher	B, I	Technical

References

Outcomes which are not referenced have been designed in the project definition of the use case.

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5. Methodology: Materials and methods

Study design: non-randomised, single-armed, cross-sectional interventional pilot study with an optional qualitative interview component. Period of intervention: 2 months.

Participants - Target users: people older than 65 living at home in the reference site OBK.

Eligibility: 1) person aged 65 years old or older at the time of recruitment; 2) living in the OBK 3) living on their own 4) self-reported capacity to wear the activity wristband and use the apps installed on the tablet; 5) self-reported capacity to consent; 6) has daily access to internet;

Sample size: 8 target users for pilot / 10 target users for replicating sites. This study is a feasibility study. Therefore, the focus is on qualitatively exploring the engagement and perceived usefulness of the digital solution of individual users. Only a small number of participants is required to achieve these study objectives. The sample sizes were defined on a feasibility-basis in order to be as representative as possible within the scope of available resources.

Materials

Tablet: Samsung Galaxy S6L SM-P615

CE-marked devices: Xiaomi Mi Band 3 activity wristband.

Software from SHAPES partners: SHAPES platform (SHAPES consortium); eCare (EDGEENGINEERING); eHealthPass (gnomon); SHAPES app and web (combination of components from eCare, gnomon and Nutrition App (LogMeal/Elliott)); Sleep quality and Physical intensity level (TREE TECHNOLOGY).

Other software: Excel, Libreoffice; Questionnaires: Those listed in outcomes.

Methods: Data integrity of non-CE software

Data integrity on eCare has already being performed. Integrity of recommendations send out based on the collected wellbeing data will be tested with a series of fake historic data.

Methods: Recruitment of older persons

Recruitment activities: Several actions will be displayed to draw attention to the project. These entail displaying articles in regional newspapers, using mailing lists and contacting relevant gatekeeper from the network by applying face to face recruitment.

Screening: Interested people can make contact via mail, letter or phone. A first screening of the responses will be performed for potentially eligible participants. As interested participants actively contact the research team, no consent of contact will be provided.

Invitation: First communication about the pilot will be conducted via phone from the research team to present all relevant information and answer questions from the potential participants.

Information sheets: Information sheets and consent forms will be sent out to eligible participants in case they still show interest.

Methods: Informed consent (all types of participants): Informed consent (duplicate) will be obtained remotely or in-person with the following format of signatures collected where appropriate: handwritten; typewritten; scanned; an electronic representation of a handwritten signature. The principal investigator of this study will countersign both documents and one will be delivered to the participants as acknowledgment of reception.

Methods: Test in a controlled environment: 3-5 older person participants will be invited to participate in a pre-study pilot for 1 month. It will consist of *intervention procedures* described below but only collect data necessary to check the functioning in the deployment (O1, O5-O11, O15 data). During the procedure the researcher will take notes to record relevant observations. At the end there is the option for a non-structured interview with all participants in order to collect additional feedback (O2).

Methods: Intervention procedures

All participants: At baseline, a face-to-face session with the researcher will take place at the participant's home. Participants will register in the SHAPES platform, devices and links will be provided and a training session will be given. Written reference material (guidelines and FAQs) will be provided. The first week of the pilot will be considered a run-in period. Participants will be contacted after the end of the run-in period to resolve doubts and concerns. Participants will be encouraged to contact the researcher for any technical issue or doubt about the use of the novel system during the entire period of the pilot.

App users: during the pilot, the participant will be asked to record O5, O6, O7, O8, O9, O10 and O11 data via the SHAPES app. O5, O8 and O9 data will be collected with the CE-marked Xiaomi Mi Band 3, which will be encouraged to wear at all times. The data is always transferred to the SHAPES App automatically via Bluetooth. O6, O7, O10 and O11 have to be recorded manually in the app. O1, O2 and O3 data (tracking data of the novel system use) will be automatically collected.

Methods: End of intervention (Within 14 days after the end of the intervention; For collected data, see Table 1): These data will be collected in face-to-face, one-to-one interviews or through forms to fill individually with the presence of a researcher for resolving doubts.

Methods: Follow-up study procedures (3-month follow-up, +/- 7 days; For collected data, see Table 1): These data will be collected in face-to-face, one-to-one interviews or through forms to fill individually with the presence of a researcher for resolving doubts.

Data collection tools: O1, O5, O6, O7, O8, O9, O10 (LogMeal version) and O11 data will be automatically stored in the database of the novel system. O10 (ELLIOT version) data will remain in the app/on the device. For authentication, users will register username and password (O15) in the SHAPES platform. The other data collection will be documented in an excel file. Paper questionnaires will be digitalised into the excel file.

Adverse incidents: In the very unlikely case that a participant spontaneously reports an adverse incident, all participants will be told to stop the participation in the pilot temporarily until further notice. gewi - Institut für Gesundheitswirtschaft e.V. will consult the cause and effects of the incident within the SHAPES consortium to define the way to proceed. In case of a product recall regarding the devices, the participant will be notified and requested not to use the device. Arrangements will be made to replace the device.

Protocol deviations: This pilot is examining the real-world use of the SHAPES app and associated devices. Therefore, if participants do not enter data as requested, this will not be documented as a protocol deviation, rather this will give insight into the usability of the solution. An interview (O2) will be done to find out reasons for the lack of engagement. They will not be penalised and will be analysed in terms of usability of the novel system.

Data management: Data processed in this pilot will be subject to the General Data Protection Regulation (GDPR) (679/2016) about personal data protection and warranties on digital rights, in agreement with the GDPR. gewi - Institut für Gesundheitswirtschaft e.V. will be the data controller for all data collected during this pilot. Data Processing Agreements will be put in place between gewi - Institut für Gesundheitswirtschaft e.V. and each SHAPES partner who processes data (EDGEENGINEERING, VICOMTECH, TREE TECHNOLOGY, Elliot, LogMeal, National University of Ireland Maynooth). During data collection and intervention, data processing will be pseudonymised. In analysis period, data processed by partners will be de-identified.

The data collected for this study will be stored securely, and kept contemporaneous and accurate. If a participant withdraws from the study, clarification sought as to what data may need to be erased. This data will be identified and erased without delay. Personal data will be kept in a form that permits identification until October 2023.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159



Personal data will be de-identified at the end of the SHAPES Innovation Action (Oct 2023), kept this way for five years and then aggregated (anonymisation). Anonymised aggregated data will be offered to the scientific community through the SHAPES consortium.

Personal data processing is described in the following project documents: Data Protection Impact Assessment, the Personal Data Processing Descriptions and the Risk Assessment.

Data analysis: Demographic characteristics will be summarised and reported to describe the sample population. Analysis related to SO4 will be carried out by TREE TECHNOLOGY. gewi - Institut für Gesundheitswirtschaft e.V. will analyse all data pertaining to the outcomes linked to the remaining primary and secondary objectives of the pilot (data from AIAS' and 5th YPE's study may be included). Quantitative and qualitative data analysis methods will be employed and findings reported. De-identified data pertaining to the tertiary outcomes that align with other pilots in the SHAPES pan-European piloting campaign (harmonised O3, O4 and O12 questionnaires and socio-demographic O13 data) will be analysed by the SHAPES coordinators at National University Ireland Maynooth.

Statistical methods: Where appropriate, descriptive statistics will be reported for all quantitative data, the mean and standard deviation (SD) will be reported where data are approximately normally distributed, and the median and interquartile range (IQR) reported where data are non-normally distributed. Differences in outcomes measured at baseline and at the end-of-pilot will be compared using paired t-test or Wilcoxon Signed Rank test (or appropriate alternative), depending on the distribution of the data. Confidence intervals and effect size will be calculated and reported to provide an estimation of the size and direction of intervention effect.

Missing data: Every effort will be made to reduce the potential for missing data, however, if missing data occurs it will be coded as 999 (participant declined to answer), 998 (administration error or failure), 997 (equipment error or failure), 996 (unknown after human check), 995 (other reason) or empty *NULL* (unknown, automatic).

6. Workplan

Research team:

- ..., head of gewi - Institut für Gesundheitswirtschaft e.V.
- ..., scientific researcher at gewi - Institut für Gesundheitswirtschaft e.V.
- ..., project manager at gewi - Institut für Gesundheitswirtschaft e.V.
- AIAS and 5th YPE (replicating site; an equivalent study will be carried out by AIAS and 5th YPE)
- National University Ireland Maynooth: Coordinator SHAPES project (Coord-SHAPES)

Technical team: for technical incidences, technical departments at VICOMTECH, TREE TECHNOLOGY, EDGENEERING, GNOMON, ELLIOT and LogMeal.

Centre where the study is carried out: older person participants will use app and devices at home. Researcher will be staff from gewi - Institut für Gesundheitswirtschaft e.V.

Sponsor: gewi - Institut für Gesundheitswirtschaft e.V.

Stages and tasks

1. Data integrity tests

Scheduled period: January-April 2022

Team members and tasks: gewi - Institut für Gesundheitswirtschaft e.V., EDGEENERING and GNOMON will perform data integrity tests on the app and the dashboards.

2. Recruitment & collection of informed consent

Scheduled period: February-April 2022

Team members and tasks: Researcher at gewi - Institut für Gesundheitswirtschaft e.V. will be in charge of the recruitment process. They will confirm eligibility, will countersigned consent and deliver 1 consent form to participants.

3. Test in a controlled environment

Scheduled period: May 2022

Intervention time length: 1 month per older person participant (3-5 older persons)

Team members and tasks: Researcher will deliver devices, install apps and organise training sessions with selected participants at their home. During the session, researcher will take notes and collect incidences, if any, and will communicate them to the technical team if necessary. Researcher will interview participants at the end of the 1-month period for collecting feedback.

4. Pilot study

Scheduled period: August(warm-up)/ September-October 2022

Intervention time length: 2 months per older person

Baseline:

Team members and tasks: Researcher will carry out face-to-face, one-to-one interviews and collection of data in excel file.

Intervention period:

Team members and tasks: On first day, researcher will deliver devices to participants who were not involved in the *controlled environment test*. They will give the training session and will provide reference material to the participants who were not involved in the *controlled environment test*. Researcher will organise a (remote) session with participants on day 7 to resolve doubts. Researcher will be the reference contact point of participants for any technical issue or doubt and will contact the Technical Team if necessary.

End of intervention interview:

Team members and tasks: Researcher will carry out face-to-face, one-to-one interviews and collection of data in excel file. In the end they will withdraw devices.

Follow-up, 3 months after end of intervention (+/- 7days):

Team members and tasks: Researcher will carry out face-to-face, one-to-one interviews and collection of data in the excel file.

5. Data analysis

Scheduled period: November-January 2022

Team members and tasks: Researcher and TREE TECHNOLOGY will perform statistical analysis, the latter with de-identified data. Analysis will be extended with de-identified data coming from AIAS' and 5th YPE's study.

Data will be kept pseudonymised at gewi - Institut für Gesundheitswirtschaft e.V. until October 2023. After this year, gewi - Institut für Gesundheitswirtschaft e.V. will de-identify data and will be kept in this form for 5 years more, when individual data will be deleted and an anonymous, aggregated dataset will be stored indefinitely.

6. SHAPES data analysis

Scheduled period: December 2022-October 2023

gewi - Institut für Gesundheitswirtschaft e.V. will de-identify O3, O4, O12 and O13 data and transfer them to Coord-SHAPES for analysis together with data coming from other use cases in SHAPES (responsible: Coord-SHAPES). After analysis and always before October 2023, individual data will be deleted and an anonymous, aggregated dataset will be stored indefinitely for sharing with the scientific community.

	Jan 2022	Feb 2022	Mar 2022	Apr 2022	May 2022	Jun 2022	Jul 2022	Aug 2022	Sep 2022	Oct 2022	Nov 2022	Dez 2022	Jan 2023	...	Oct 2023
Data integrity															
Recruitment															
Test controlled environment					3-5 older person participants										
Study								Baseline → Intervention (2 month) → 3-month follow-up							
Data analysis											UC-PT2-001 + all PT2 studies (with anonymous, aggregated data)				
SHAPES data analysis											De-identified data transferred to SHAPES platform				

7. Ethical considerations

Research ethics approval

Approval to conduct the pilot will be sought from a Research Ethics Committee (Ethik Kommission der Ärztekammer Nordrhein) before the start of the recruitment process. This protocol and all other relevant documents will be submitted. Prior to submission to the REC, this protocol will be reviewed and approved for submission by colleagues within the SHAPES consortium.

Protocol amendments

Any substantial amendments that require review by Ethik Kommission der Ärztekammer Nordrhein will not be implemented until the Ethik Kommission der Ärztekammer Nordrhein grants a favourable opinion for the trial, and all correspondence with the Ethik Kommission der Ärztekammer Nordrhein will be retained in the Trial Master File.

Consent

All participants will be asked to provide voluntary, informed consent for their participation in the pilot. The consent form will include the following explicit consents:

- All participants till reaching objectives: participation in the tests *under controlled environment*.

Declaration of interests

Research collaborators are employees of VICOMTECH and TREE TECHNOLOGY, proprietaries of “Sleep quality and Physical intensity level and Vitals control” technologies, respectively.

Access to data

gewi - Institut für Gesundheitswirtschaft e.V. will be the data controllers and as such will have access to the full dataset. Data Processing Agreements will be in place to facilitate the sharing of pseudonymised data with specific SHAPES partners for specific purposes during the undertaking of the pilot. For process of data regarding

analysis Data Processing Agreements will be in place to facilitate the sharing of de-identified data. De-identified data will be offered to the scientific community through the SHAPES platform.

Ancillary and post-trial care

At the end of the pilot the devices provided to participants will be removed and access to the SHAPES app will be stopped.

Dissemination policy

Any data that arise from the pilot study will be owned by the sponsor gewi - Institut für Gesundheitswirtschaft e.V. On completion of the study, all data will be 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 outcome of the study. gewi - Institut für Gesundheitswirtschaft e.V. 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. gewi - Institut für Gesundheitswirtschaft e.V. 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 will be in place to facilitate the sharing of pseudonymised or de-identified data with specific SHAPES partners for specific purposes. De-identified data will also be shared with the scientific community through the SHAPES platform.

Annex 10: Consent form Phase 5 UC-PT2-001

Patienteninformation/ Einwilligungserklärung

SHAPES Pan-Europäische Pilotkampagne: Digitale App und Plattform zur Messung wichtiger Gesundheitsparameter. Eine nicht-randomisierte Machbarkeitsstudie in der realen Welt zur Bewertung der Benutzerfreundlichkeit und des von den Benutzern:innen wahrgenommenen Nutzens

Sehr geehrte Teilnehmerin, sehr geehrter Teilnehmer,

wir möchten Sie fragen, ob Sie an einer wissenschaftlichen Studie teilnehmen möchten.

Sie haben Interesse an einer übersichtlichen Darstellung Ihrer persönlichen Gesundheitsfaktoren? Durch diese Studie soll erprobt werden, inwieweit die digitale Lösung ältere Menschen darin unterstützen kann, über die Messung und Verwaltung wichtiger Gesundheitsfaktoren, den aktuellen Gesundheitszustand und das Wohlbefinden zu erhalten oder zu verbessern. Dafür sollen die folgenden digitalen Lösungen getestet werden:

- Fitnessarmband (Xiaomi Mi Band 3) (Geräte mit Bluetooth-Verbindung)
- App für android Tablet (Samsung Galaxy S6L SM-P615) (Daten von dem Fitnessarmband werden in die App übertragen und können abgelesen werden)
- Webanwendung (Forscher:innen können dieselben Daten ablesen)

Bisher hat es sich als schwierig erwiesen, neue digitale Lösungen im Bereich Pflege und Versorgung von älteren Menschen einzuführen. Verschiedene Hindernisse haben dazu geführt, dass ein großflächiger Einsatz nicht umsetzbar war. In dieser Studie sollen Sie als Anwender:in daher beteiligt werden und Ihre Einschätzung und Erlebnisse mit den digitalen Lösungen werden als Hauptergebnisse ausgewertet.

Als Nebenziele soll geklärt werden, wie sich die digitalen Lösungen auf die Überwachung relevanter Gesundheitsparameter, die Lebensqualität und das Wohlbefinden älterer Menschen sowie die Akzeptanz und das Vertrauen in die digitalen Lösungen auswirken. Darüber hinaus werden die gesammelten Daten genutzt, um Zusammenhänge zwischen körperlicher Aktivität, Schlafqualität, Flüssigkeits- und Nahrungsaufnahme mit dem Wohlbefinden zu untersuchen. Als drittrangiges Ziel ist die Bewertung der Daten im Zusammenhang der Pilotkampagne SHAPES geplant. Dabei soll die Auswirkung von digitalen Lösungen auf ältere Menschen aus unterschiedlichen ländlichen und städtischen Regionen Europas bewertet werden.

Es werden insgesamt 8 ältere Menschen an der Studie in Deutschland teilnehmen.

Das gewi-Institut für Gesundheitswirtschaft e.V. übernimmt keine Haftung im Falle von auftretenden technischen Problemen oder Ausfällen und damit einhergehenden Folgen.

Die Studie soll insgesamt 8 Wochen dauern und im November/Dezember 2022 starten. Im Rahmen der Studie sollen folgende Daten von Ihnen mittels Interviews und Fragebögen erfasst und ausgewertet werden:

Fragebögen/ Daten	Zeitpunkt
Sozio-demographische Daten: Geburtsjahr, Geschlecht, Familienstand, Jahre in Ausbildung, Land	Zu Beginn der Studie (November/Dezember 2022)
Gesundheitsfragebogen (WHOQoL-BREF), Gesundheitsfragebogen (EQ-5D-5L), Selbstwirksamkeit (GSE), Soziale Unterstützung (OSSS-3), SHAPES Frage zur Teilhabe, SHAPES Frage zur Gesundheitskompetenz	Zu Beginn, am Ende und 3 Monate nach Ende der Studie
Sozio-demographische Daten: beruflicher Status, Status als Pflegeperson, Hilfe von der Familie, Art des Wohnsitzes, Zusammenleben mit jemandem	
Frage zur Technologie Akzeptanz (TAM)	Ende der Studie (Dezember/Januar 2022)
Anwender Erfahrungen (UEQ-S)	
Fragen zur System-Gebrauchlichkeit (SUS)	

Zusätzlich werden Sie gebeten die folgende App und Geräte zu benutzen:

Tabelle 1: Informationen zu App und Geräten (* Ausfüllen der Fragebögen ist nicht verpflichtend und kann jederzeit ausgeführt werden)

	Gerät	Funktion	Zeitpunkt
Nichtmedizinische App/ Geräte	SHAPES-App	<ul style="list-style-type: none"> die App ist auf dem Tablet installiert, dass Sie für studienzwecke vom gewi – Institut für Gesundheitswirtschaft e.V. erhalten. eigene Daten (die von dem Fitnessarmband erfasst werden) können abgelesen werden 	Frage zur Schlafqualität und dem Wohlbefinden: täglich Flüssigkeits- und Nahrungsaufnahme: täglich Aktualisierung des Symptom-Checkers (Covid): nach Bedarf*
	CE-gekennzeichnetes Fitnessarmband	<ul style="list-style-type: none"> Körperliche Aktivität: Schritte pro Minute; Schlafparameter: Schlaflatenzindex, Schlafdauerindex, Effizienzindex, Störungsindex 	Immer tragen; kein weiterer Aufwand

Am ersten Tag der Studie findet zum Kennenlernen und zur Schulung ein persönlicher Termin mit der Studienleitung statt. Die erste Woche wird als Einführungsphase betrachtet und Sie werden ermutigt, sich bei Problemen oder Zweifeln an die Studienleitung zu wenden.

Die genannten studienbedingten Maßnahmen erfordern einen zusätzlichen Zeitaufwand von ca. 10 Minuten pro Tag.

Die Teilnahme an dieser Studie ist freiwillig. Sie werden nur dann einbezogen, wenn Sie dazu schriftlich Ihre Einwilligung erklären. Sofern Sie nicht an der Studie teilnehmen oder später aus ihr ausscheiden möchten, entstehen Ihnen dadurch keine Nachteile. Sie können jederzeit, auch ohne Angabe von Gründen, Ihre Einwilligung mündlich oder schriftlich widerrufen.

Die Studie wurde der zuständigen Ethikkommission vorgelegt. Sie hat keine Einwände erhoben.

Mögliche Risiken, Beschwerden und Begleiterscheinungen

Da im Rahmen unserer Studie nur Daten erhoben werden, sind mit der Teilnahme keine medizinischen Risiken verbunden.

Das Ausfüllen der Fragebögen und die Dateneingabe in die SHAPES-App ist mit einem geringen Zeitaufwand verbunden und erfordert für diese Zeit Ihre Aufmerksamkeit. Das dauerhafte Tragen des Fitnessarmbandes kann eine gewisse Zeit zur Gewöhnung benötigen und könnte am Anfang noch als unbequem empfunden werden.

Möglicher Nutzen aus Ihrer Teilnahme an der Studie

Sie werden durch Ihre Teilnahme an dieser Studie keinen Nutzen für Ihre Gesundheit haben. Die Ergebnisse dieser Studie können dazu beitragen, wie Technologien eingesetzt werden können, um Menschen im Alter in ihrem häuslichen Umfeld zu unterstützen und ihre Lebensqualität zu verbessern.

Datenschutz

- Rechtsgrundlage für die Datenverarbeitung ist Ihre freiwillige Einwilligung (Art. 6 Abs. 1 Buchst. c) DSGVO).
- Der Verantwortliche für die Datenverarbeitung ist: gewi – Institut für Gesundheitswirtschaft e.V. (Karolingerring 31, 50678 Köln)

Ihre Daten werden zu jeder Zeit vertraulich behandelt. Die Daten, die mit der App erfasst werden, werden in pseudonymisierter Form an den Initiator der Studie gewi – Institut für Gesundheitswirtschaft e.V. (Karolingerring 31, 50678 Köln) bzw. von ihm beauftragte Stellen weitergeleitet. Die Daten werden wissenschaftlich ausgewertet und zur Ermittlung von Zusammenhängen zwischen körperlicher Aktivität, Schlafqualität, Flüssigkeits- und Nahrungsaufnahme mit dem Wohlbefinden verwendet. Zugriff auf die personenbezogenen Daten haben nur zuständige Personen im jeweiligen Studienzentrum.

Pseudonymisieren bedeutet, dass die personenbezogenen Daten wie der Name und das Geburtsdatum ohne Einbeziehung einer Liste nicht mehr einer konkreten Person zugeordnet werden können. Die personenbezogenen Daten werden durch einen Nummern- und/oder Buchstabencode ersetzt; die Angabe des Geburtsdatums wird auf das Geburtsjahr beschränkt. Im Studienzentrum ist eine Liste hinterlegt, auf der die Namen den Nummern- und/oder Buchstabencodes zugeordnet sind. Diese Liste wird im Studienzentrum gesondert aufbewahrt und unterliegt dort technischen und organisatorischen Maßnahmen, die gewährleisten, dass die personenbezogenen Daten Ihnen durch unbefugte Personen nicht zugeordnet werden können. Eine Entschlüsselung erfolgt nur in folgenden Situationen: in dem unwahrscheinlichen Fall, dass ein Angriff auf die IT-Systeme von SHAPES oder gewi-Institut ausgeübt wird, werden wir Sie persönlich kontaktieren.

Die Daten werden bis Oktober 2023 aufbewahrt. Sie sind gegen unbefugten Zugriff gesichert. Sie werden gelöscht, wenn sie nicht mehr benötigt werden, um die wissenschaftliche Auswertung und Analysen durchzuführen. Spätestens nach fünf Jahren nach Ende der Pan-europäischen Pilotkampagne werden sie gelöscht.

Sind mit der Datenverarbeitung Risiken verbunden?

Bei jeder Erhebung, Speicherung, Nutzung und Übermittlung von Daten bestehen Vertraulichkeitsrisiken (z.B. die Möglichkeit, die betreffende Person zu identifizieren). Diese Risiken lassen sich nicht völlig ausschließen und steigen, je mehr Daten miteinander verknüpft werden können. Der Initiator der Studie versichert Ihnen, alles nach dem Stand der Technik Mögliche zum Schutz Ihrer Privatsphäre zu tun und Daten nur an Stellen weiterzugeben, die ein geeignetes Datenschutzkonzept vorweisen können. Medizinische Risiken sind mit der Datenverarbeitung nicht verbunden.

Der Nummern- und/oder Buchstabencode (das Pseudonym) kann nur innerhalb der EU in den Studienzentren entschlüsselt werden, um die pseudonymisierten Daten Ihnen zuzuordnen (siehe oben). Es bestehen außerdem folgende Schutzmaßnahmen: verbindliche interne Datenschutzvorschriften gemäß Artikel 47 DSGVO und der Angemessenheitsbeschluss von der Europäischen Kommission. Sie können eine Kopie dieser Garantien erhalten und unter folgender

Adresse

abrufen:

https://ec.europa.eu/info/sites/default/files/file_import/data_protection_de_0.pdf

Können Sie Ihre Einwilligung widerrufen?

Sie können Ihre jeweilige Einwilligung jederzeit ohne Angabe von Gründen schriftlich oder mündlich widerrufen, ohne dass Ihnen daraus ein Nachteil entsteht. Wenn Sie Ihre Einwilligung widerrufen, werden keine weiteren Daten mehr erhoben. Die bis zum Widerruf erfolgte Datenverarbeitung bleibt jedoch rechtmäßig.

Sie können im Fall des Widerrufs auch die Löschung Ihrer Daten verlangen.

Welche weiteren Rechte haben Sie bezogen auf den Datenschutz?

Sie haben das Recht, vom Verantwortlichen Auskunft über die von Ihnen gespeicherten personenbezogenen Daten (einschließlich der kostenlosen Überlassung einer Kopie der Daten) zu verlangen. Ebenfalls können Sie die Berichtigung unzutreffender Daten sowie gegebenenfalls eine Übertragung der von Ihnen zur Verfügung gestellten Daten und die Einschränkung ihrer Verarbeitung verlangen.

Bitte wenden Sie sich im Regelfall an das Studienzentrum, denn allein das Studienzentrum kann aufgrund des Pseudonymisierungsprozesses vollumfänglich auf Ihre Daten zugreifen bzw. entsprechende Auskünfte geben. Der Initiator der Studie kann vor diesem Hintergrund nur sehr begrenzt helfen.

Bei Anliegen zur Datenverarbeitung und zur Einhaltung der datenschutzrechtlichen Anforderungen können Sie sich auch an folgende Datenschutzbeauftragte wenden:

- a) Datenschutzbeauftragter des Studienzentrums: ... (gewi – Institut für Gesundheitswirtschaft e.V., Karolingerring 31, 50678 Köln)

Sie haben ein Beschwerderecht bei jeder Aufsichtsbehörde für den Datenschutz. Eine Liste der Aufsichtsbehörden in Deutschland finden Sie unter:

https://www.bfdi.bund.de/DE/Infothek/Anschriften_Links/anschriften_links-node.html

Zuständige Beauftragte für das Land Nordrhein-Westfalen:

Frau Bettina Gayk

Postfach 20 04 44, 40102 Düsseldorf

Tel.: 0211 384 240

E-Mail: poststelle@ldi.nrw.de

Ansprechpartner:innen für Fragen zur Studie

Wenn Sie Fragen zu dieser Studie haben, wenden Sie sich bitte an:

gewi – Institut für Gesundheitswirtschaft e.V

...

Karolingerring 31, 50678 Köln

...

ODER

Studienarzt

Dr. med Christian Franchy

Facharzt für Innere und Allgemeinmedizin

Hämostaseologie

Ernährungsmedizin DGEM

Lehrbeauftragter des Schwerpunkts Allgemeinmedizin
der Medizinischen Fakultät der Universität zu Köln

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Tel.: 02266 1853

Fax: 02266-4407355

Einwilligungserklärung

SHAPES Pan-Europäische Pilotkampagne: Digitale App und Plattform zur Messung wichtiger Gesundheitsparameter. Eine nicht-randomisierte Machbarkeitsstudie in der realen Welt zur Bewertung der Benutzerfreundlichkeit und des von den Benutzern:innen wahrgenommenen Nutzens.

Name des/der Teilnehmers:in in Druckbuchstaben:.....

- Ich bin von Herrn / Frau (Studienleitung) _____ über Wesen, Bedeutung und Tragweite der Studie sowie die sich für mich daraus ergebenden Anforderungen aufgeklärt worden. Ich habe darüber hinaus den Text des Informationsblattes und dieser Einwilligungserklärung gelesen.
- Ich hatte ausreichend Zeit, Fragen zu stellen und mich zu entscheiden. Aufgetretene Fragen wurden mir vom Studienleitung beantwortet.
- Ich weiß, dass ich meine freiwillige Mitwirkung jederzeit beenden kann, ohne dass mir daraus Nachteile entstehen.

Ich erkläre mich bereit, an der Studie teilzunehmen.

1. Ich willige ein, dass personenbezogene Daten über mich, insbesondere soziodemographische (s. Tabelle auf S.3), wie in der Informationsblatt beschrieben, erhoben und in Papierform sowie auf elektronischen Datenträgern bei dem gewi- Institut für Gesundheitswirtschaft e.V. aufgezeichnet werden.

Soweit erforderlich, dürfen die erhobenen Daten pseudonymisiert (verschlüsselt) weitergegeben werden:

- a) im Falle unerwünschter Ereignisse: an die jeweils zuständige Ethik-Kommission und zuständigen Behörden sowie von dieser an die Europäische Datenbank.

2. Ich bin darüber aufgeklärt worden, dass ich meine Einwilligung jederzeit widerrufen kann. Im Falle des Widerrufs werden keine weiteren Daten mehr erhoben. Ich kann in diesem Fall die Löschung der Daten verlangen.

3. Ich willige ein, dass die Daten nach Beendigung oder Abbruch der klinischen Prüfung mindestens 5 Jahre aufbewahrt werden.

Ich willige in die Verarbeitung der genannten Daten ein.

Ein Exemplar des Informationsblatts und der Einwilligungserklärung habe ich erhalten. Ein Exemplar verbleibt im Prüfbüro.

Unterschrift des Teilnehmers/der Teilnehmerin

(Name und Vorname in Druckschrift)

(Datum)

(Unterschrift)

Erklärung und Unterschrift des aufklärenden Arztes/der aufklärenden Ärztin

Ich habe das Aufklärungsgespräch geführt und die Einwilligung eingeholt.

(Name und Vorname in Druckschrift)

(Datum)

(Unterschrift)

Annex 11: Information sheet Phase 5 UC-PT2-001

INFORMATIONSBLETT: Studienteilnehmer:in

Titel der Studie: SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) Pan-Europäische Pilotkampagne: Digitale App und Plattform zur Messung wichtiger Gesundheitsparameter. Eine nicht-randomisierte Machbarkeitsstudie in der realen Welt zur Bewertung der Benutzerfreundlichkeit und des von den Benutzern:innen wahrgenommenen Nutzens

Entwickler/ Sponsor: gewi – Institut für Gesundheitswirtschaft e.V.
Studienleitung (Deutschland): ...

Mit diesem Dokument möchten wir Sie über eine Studie informieren, an der Sie teilnehmen können. Die Studie wurde von der Ethik-Kommission der Ärztekammer Nordrhein genehmigt und ist in Übereinstimmung mit den Grundsätzen der Deklaration von Helsinki und den Standards der guten klinischen Praxis.

Wir möchten lediglich, dass Sie korrekte und ausreichende Informationen erhalten, damit Sie beurteilen können, ob Sie teilnehmen möchten oder nicht. Bitte lesen Sie daher dieses Informationsblatt sorgfältig durch, und wir werden etwaige Zweifel nach der Erläuterung klären. Außerdem können Sie sich mit Personen beraten, die Sie für geeignet halten. Wenn Sie Fragen haben, wenden Sie sich bitte an ... (Studienleitung) unter den am Anfang dieses Dokumentes angegebenen Kontaktdaten.

Allgemeine Beschreibung

In der Studie, an der Sie teilnehmen können, geht es um die Verwendung digitaler Hilfsmittel, zur Messung und Verwaltung wichtiger Gesundheitsparameter, mit dem Ziel, hierdurch Ihren aktuellen Gesundheitszustand und Ihr Wohlbefinden zu erhalten oder zu verbessern. Die Hilfsmittel bestehen aus einem Fitnessarmband und einer Gesundheits-App (SHAPES-App), die für eine selbständige Nutzung im eigenen zu Hause, also ohne ärztliche Betreuung, entwickelt wurden. Die Hilfsmittel ersetzen oder verändern keine medizinische und pharmakologische Behandlung. Das gewi-Institut für Gesundheitswirtschaft e.V. übernimmt keine Haftung im Falle von auftretenden technischen Problemen oder Ausfällen und damit einhergehenden Folgen. Das Hauptziel der Studie besteht darin, zu beurteilen, ob die digitalen Hilfsmittel einfach anwendbar sind und von Ihnen, als Studienteilnehmer:in als nützlich empfunden werden. Als Voraussetzung zur Studienteilnahme müssen Sie im Oberbergischen Kreis wohnen und über 65 Jahre alt sein.

Sie können die SHAPES-App nutzen, um folgende Daten aufzeichnen und sich anzeigen zu lassen: Herzfrequenz, Anzahl der Schritte, Intensität der körperlichen Aktivität, Stunden und Qualität des Schlafes. Diese Daten werden mit einem Fitnessarmband gemessen, das Ihnen speziell für die Studie zur Verfügung gestellt wird. Zudem können Sie die SHAPES-App nutzen, um Ihre Flüssigkeitszufuhr und Ernährung zu protokollieren oder sich über relevante Neuigkeiten zur Corona Pandemie zu informieren.

Im Rahmen der Studie wird Ihnen empfohlen, täglich Daten zur Flüssigkeitszufuhr und

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Ernährung in die SHAPES-App einzutragen und das Fitnessarmband dauerhaft zu tragen, ohne jedoch dass Sie dazu verpflichtet sind. Ebenso werden Sie gebeten, einmal pro Tag die Fragen nach Ihrem Wohlbefinden und Ihrer Schlafqualität zu beantworten. Sie können auch Empfehlungen erhalten, die Sie z.B. an mehr Bewegung oder mehr Flüssigkeitszufuhr erinnern. Es steht Ihnen frei, die Empfehlungen zu befolgen oder nicht.

Zu Beginn der Studie werden in einem persönlichen Gespräch Ihre gesundheitsbezogenen Daten erhoben, damit die Empfehlungen an Ihre körperliche Leistungsfähigkeit angepasst werden können.

Alle Daten, mit Ausnahme von körperlicher Aktivität und Schlaf, werden auch für die Studienleitung sichtbar sein. Die Studienleitung kann sich mit Ihnen in Verbindung setzen, wenn sie es für notwendig hält, sowohl um eine Beurteilung vorzunehmen als auch um die Daten zu aktualisieren.

Am Ende der Studie wird mittels Fragebögen die Benutzerfreundlichkeit, der Nutzen und die Akzeptanz der SHAPES-Anwendungen bewertet. Alle Studienteilnehmer:innen werden befragt. Weitere drei Monate nach Beendigung der Studie wird eine Nachbefragung durchgeführt.

Anzahl der Teilnehmer:innen und Dauer: Ziel der Studie ist es, 8 ältere Personen zu rekrutieren. Die SHAPES-App wird auf einem Tablet installiert sein und in Kombination mit dem Fitnessarmband über einen Zeitraum von zwei Monaten bewertet.

Pflichten der Teilnehmer:in: Sie müssen mindestens 65 Jahre alt sein und im Oberbergischen Kreis wohnen. Sie müssen regelmäßig und zu einer bestimmten Tageszeit über einen stabilen Internetzugang verfügen.

Zu Beginn der Studie erhalten Sie von der Studienleitung eine Schulung und Empfehlungen zur Verwendung der SHAPES-App und des Fitnessarmbands. Die Einhaltung ist jedoch nicht verpflichtend, da das Ziel der Studie darin besteht, die Bewertung im tatsächlichen Alltag zu erproben. Die Empfehlungen für Sie lauten:

- Tragen Sie einmal täglich Daten zu Ihrer Flüssigkeitszufuhr und Ernährung in die App ein.
- Beantworten Sie die Fragen zu Wohlbefinden und Schlafqualität.
- Tragen Sie das Fitnessarmband ständig.

Andere relevante Informationen

Alle neuen Informationen, über die SHAPES-Geräte oder die in der Studie verwendete App, die sich auf Ihre Bereitschaft zur Teilnahme auswirken könnten und die während Ihrer Teilnahme bekannt werden, werden Ihnen von der Studienleitung ... so schnell wie möglich mitgeteilt.

Wenn Sie sich entscheiden, Ihre Zustimmung zur Teilnahme an dieser Studie zurückzuziehen, werden keine weiteren Daten von Ihnen aufgenommen, und Sie können verlangen, dass alle Ihre Daten gelöscht werden, sofern sie nicht anonymisiert wurden.

Es wird hiermit auch darüber aufgeklärt, dass Sie von der Studie ausgeschlossen werden können, sollte die Studienleitung dies für angemessen halten. Sei es aus Sicherheitsgründen, wie bspw. Auftreten eines unerwünschten Ereignisses oder weil die festgelegten Verfahren

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nicht eingehalten wurden. In jedem Fall würden Sie eine angemessene Begründung erhalten.

Mit Ihrer Unterschrift auf der beigefügten Einverständniserklärung erklären Sie sich bereit, die Ihnen erläuterten Studienabläufe einzuhalten.

Vorteile und Risiken, die sich aus Ihrer Teilnahme an der Studie ergeben

Auf individueller Ebene bringt die Teilnahme an dieser Studie keinen direkten Nutzen, abgesehen von dem persönlichen Interesse und der Erfahrung durch die Teilnahme an einer Forschungsstudie. Obwohl das Ziel von SHAPES letztlich darin besteht, die Lebensqualität älterer Menschen zu verbessern, und die Studie Daten sammelt, um eine Bewertung in dieser Hinsicht vorzunehmen, besteht das Hauptziel der Studie darin, die Akzeptanz der digitalen Hilfsmittel bei den Teilnehmern:innen zu bewerten.

Es kann also sein, dass sich Ihre Lebensqualität durch die bessere Verwaltung wichtiger Gesundheitsparameter verbessert, es kann aber auch sein, dass Sie keine Verbesserung erfahren. Obwohl es unwahrscheinlich ist, kann sich Ihr Gesundheitszustand aus Gründen, die mit der Studie zusammenhängen oder nicht, verbessern.

Vertraulichkeit

Verantwortlich für die Durchführung der Studie und die Datenübermittlung: *gewi- Institut für Gesundheitswirtschaft e.V., ..., Karolingerring 31, 50678 Köln.*

Zweck der Datenerhebung: Untersuchung der Anwenderbeteiligung und der Nützlichkeit der SHAPES-Hilfsmittel; Untersuchung der Zusammenhänge zwischen den erfassten Gesundheitsparametern und dem allgemeinen Wohlbefinden; Überprüfung des potentiellen Einflusses der gegebenen Empfehlungen auf den Lebensstil.

Empfänger der Daten: Neben dem gewi- Institut haben die folgenden Partner Zugang zu einem Teil der Daten:

- Pseudonymisierte Daten während des Studie (verbunden mit einem Code, wobei nur gewi Institut diesen Code mit den identifizierenden Daten in Verbindung bringen kann).
 - EDGENEERING: Visualisierung der gesundheitsbezogenen Daten und Daten zur körperlichen Aktivität.
 - Kontakt: Rua Abranches Ferrão, nº 10 - 11C 1600-001 Lisboa Portugal. Tel. +351 930 617 003. E-mail: edge@edgeneering.eu.
 - TREE TECHNOLOGY SA: Visualisierung der Daten vom Fitnessarmband und Berechnung der körperlichen Aktivitätsintensität und Schlafparameter.
 - Kontakt: Camino de las Huertas 18, planta 1, 28223 Pozuelo de Alarcón, Madrid (Espanya) Tel. +34 902 286 386 · +34 910 059 088.
 - De-identifizierbare Daten (kein zugehöriger Code)
 - VICOMTECH: Daten von Fitnessarmband und Fragebogenantworten zur Erstellung personalisierter Empfehlungen.
 - Kontakt: Parque Científico y Tecnológico de Gipuzkoa, Paseo Mikeletegi 57, 20009 Donostia / San Sebastián (Espanya) Tel. +(34) 943 309 230.
 - TREE TECHNOLOGY SA: gesundheitsbezogene Daten, körperliche Aktivität,
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Schlaf und Wohlbefinden, zur Untersuchung von Korrelationen.

- Kontakt: Camino de las Huertas 18, planta 1, 28223 Pozuelo de Alarcón, Madrid (España) Tel. +34 902 286 386 · +34 910 059 088.
- SHAPES Konsortium: standardisierte Fragebögen (werden am Ende der Studie durchgeführt) und soziodemographische Daten. Das gewi Institut arbeitet mit dem europäischen SHAPE Konsortium zusammen, um digitale Hilfsmittel für ältere Menschen zu erforschen.
 - Koordinator: National University Ireland, Maynooth, Co. Kildare, Ireland, shapes.info@mu.ie

Maximale Dauer der Datenspeicherung: nach Abschluss des SHAPES-Projektes (Oktober 2023) werden die de-identifizierbaren Daten für 5 Jahre im gewi-Institut aufbewahrt. Nach Ablauf dieser Frist werden sie in anonymer und aggregierter Form aufbewahrt. Im Falle von standardisierten Fragebögen werden die Daten anonym gespeichert und in aggregierter Form auf der SHAPES Plattform für wissenschaftliche Zwecke verfügbar sein.

Auf dem Gerät, das Sie vom gewi- Institut für Gesundheitswirtschaft e.V. im Rahmen der Studie erhalten, ist zudem eine App installiert (Anydesk), die es im Falle von technischen Problemen den Wissenschaftlerinnen ermöglicht, aus der Distanz auf das Gerät zuzugreifen und potenzielle Probleme zu beheben. Das Vorgehen ist abgesichert durch doppeltes Einverständnisverfahren Ihrerseits. Es werden dabei keine persönlichen Daten gespeichert.

Die Verarbeitung, Übermittlung und Überlassung der personenbezogenen Daten aller teilnehmenden Personen erfolgt in Übereinstimmung mit den Bestimmungen der Datenschutzvorschriften gemäß Artikel 47 DSGVO und des Angemessenheitsbeschlusses von der Europäischen Kommission.

Gemäß den oben genannten Rechtsvorschriften können Sie Ihr Recht auf Auskunft, Berichtigung, Löschung, Widerspruch, Einschränkung der Datenverarbeitung und sogar auf Übermittlung Ihrer Daten an einen befugten Dritten (Übertragbarkeit) ausüben; dazu müssen Sie sich an die für die Verarbeitung verantwortliche Hauptprüferin (Studienleitung; s. Beginn des Dokuments) wenden.

Ihre Daten werden elektronisch verarbeitet und in ein automatisiertes System personenbezogener Daten aufgenommen, das alle Sicherheitsmaßnahmen für einen beschränkten Zugang zu dem in diesem Dokument beschriebenen Zweck erfüllt.

Gewährleistung der Vertraulichkeit der erhaltenen Informationen.

- 1) Kodierung und Pseudoanonymisierung: Während der Studie werden Ihre Daten durch einen Code identifiziert, und nur die Studienleitung und Mitarbeiter:innen des gewi-Instituts können diese Daten mit Ihnen in Verbindung bringen. Daher wird Ihre Identität niemandem bekannt gegeben, es sei denn, es besteht eine gesetzliche Verpflichtung.
- 2) De-Identifizierung: Im Oktober 2023 wird die Codierung von Ihren Daten getrennt.
- 3) Anonymisierung: Ab Oktober 2023 werden Ihre Daten aggregiert und unwiderruflich von Ihren persönlichen Daten getrennt, so dass es unmöglich sein wird, zu einem späteren Zeitpunkt einen Zusammenhang festzustellen.

Es werden nur die für die Durchführung der Studie erforderlichen Daten an Dritte und an

andere Länder weitergegeben. Es werden in keinem Fall Informationen enthalten sein, die Sie direkt identifizieren könnten, wie Vor- und Nachname, Initialen, Adresse usw. Sollte diese Weitergabe erfolgen, so geschieht dies zu gleichen Zwecken wie die oben beschriebene Studie, wobei die Vertraulichkeit mindestens auf dem Niveau des geltenden Rechts gewährleistet ist.

Der Zugang zu Ihren persönlichen Daten (persönliche gesundheitsbezogenen Daten, die jedoch nicht identifizierbar sind) ist auf die Mitarbeiter:innen des gewi-Instituts beschränkt. Dies erfolgt jedoch nur bei Erfordernis und wenn die Berechtigung vorliegt. In jedem Fall bleibt die Vertraulichkeit gemäß den geltenden Rechtsvorschriften gewahrt. Sie können sich immer an die deutsche Datenschutzbehörde wenden, wenn Sie sich über die Verarbeitung Ihrer persönlichen Daten beschweren möchten.

Wirtschaftlicher Ausgleich

Für Ihre Teilnahme an der Studie entstehen Ihnen keine Kosten, außer der Nutzung Ihres Internets. Für die Teilnahme an dieser Studie erhalten Sie keine Vergütung.

Freiwillige Teilnahme

Sie sollten wissen, dass Ihre Teilnahme an dieser Studie freiwillig ist und dass Sie sich jederzeit gegen eine Teilnahme entscheiden oder Ihre Entscheidung ändern und Ihre Zustimmung zurückziehen können, ohne irgendeine Erklärung abzugeben. Sie können die Löschung der Daten verlangen, sofern diese nicht anonymisiert wurden.

Danksagung

Wie auch immer Ihre Entscheidung ausfällt, sowohl der Projektträger als auch das Forschungsteam möchten Ihnen für Ihre Zeit und Aufmerksamkeit danken. Sie tragen zu einem besseren Verständnis von Zusammenhängen zwischen relevanten Gesundheitsparametern und dem allgemeinen Wohlbefinden bei, wovon viele Menschen in Zukunft profitieren können.

Annex 12: Momentum outcomes UC-PT2-002

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.

GEWI

Not applicable as no healthcare professionals are involved in the UC/ as the UC is not piloted in a clinical setting thus there is no clinical information involved

- In my organisation/region patients and providers (healthcare professionals) are ready to use ICT (e.g., computers, tablets, mobile phones).

GEWI

In general, an critical attitude towards using ICTs and the collection of personal data might exist among that age group. However, early involvement of potential users, open communication with step by step explanations/support and high standards of data security will be applied to lower and counteract a potential risk.

- In my organisation/region financial and other incentives are aligned with the service to be deployed.

GEWI

To do

- In my organisation/region an underpinning culture embraces technology.

GEWI
No

- In my organisation/region an underpinning culture welcomes and even promotes

change, innovation and shows openness to new ideas.

GEWI
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.

GEWI
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.

GEWI
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.

GEWI
To do.

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.

GEWI
No, as they are not involved in the deployment of the UC

- Healthcare professionals have been involved in the development of the process and time schedule for this project.

GEWI
No, as they are not involved in the deployment of the UC

- Decision-makers have been involved in the development of the content of this project.

GEWI
No, as they are not involved in the deployment of the UC

- Decision-makers have been involved in the development of the process and time schedule for this project.

GEWI
No, as they are not involved in the deployment of the UC

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

- In this project¹⁷ the patients have been sufficiently involved in the development of the telemedicine solution.

GEWI

Plan to do so (phase 2-4)

- In this project telemedicine service is based on the patient's needs.

GEWI

YES, clear objective in increasing quality of life and wellbeing

- 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.

GEWI

Planned to do so. To be developed in following phases.

7.2.4 CSF 6. Ensure that the technology is user-friendly

- The telemedicine technology used in our project is user-friendly for patients.

GEWI

It is the objective and great effort is done within the SHAPES consortium to define requirements to fulfil this. Besides that, regular feedback loops with end users are planned in phases 2-4 and feedback will be considered.

- The telemedicine technology used in our project is user-friendly for health professionals.

GEWI

No, as they are not involved in the deployment of the UC

- The telemedicine technology used in our project does not need an extended training

process prior to using it.

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GEWI
We expect minimum training. To be defined in mock-up sessions.

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.

GEWI
YES, from SHAPES and internal resources already allocated.

- In my region/organisation the IT competences needed for deployment of the telemedicine solution are available.

GEWI
YES. FINT and TREE provide IT competences.

- In my region/organisation enough time for the training needed in order to implement the telemedicine solution is available.

GEWI
YES

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

- The telemedicine solution addresses the needs of the primary clients.

GEWI
To be evaluated.

- The telemedicine solution is sufficiently adapted to the needs of the primary users.

GEWI
YES, although details have still to be developed further. (patients as end-user)

- The telemedicine solution addresses the needs of the health sector.

GEWI
To be evaluated.

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.

GEWI
To do (D7.3 SHAPES Business Plan WP7)

- A business plan for the project has been implemented.

GEWI
To do after the project end.

- The business plan has been approved by the relevant management level.

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.

GEWI
To do after the project end.

- A change management plan for the project has been implemented.

GEWI
To do after the project end.

- A change management plan has been approved by the relevant management level.

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.

GEWI
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.

GEWI
To evaluate after the pilot.
In fact the project is developing a platform intended to scale the telemedicine service to a pan-european level.

- In our region/organisation we are ready for large-scale deployment of the technology.

GEWI
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.

GEWI
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.

GEWI
Yes

- The project is carried out in accordance with the relevant guidelines on security matters.

GEWI
YES. GDPR will be applied. The system provided implements all security and privacy related regulations.

7.4.2 CSF 14. Involve legal and security experts

- We have received advice on the project from legal experts.

GEWI
To do

- We have received advice on the project from experts on data security matters.

GEWI
To do (within SHAPES consortium)

- In this project we are not experiencing any data security problems.

GEWI
TBD

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- I have confidence in the legality of this project.

GEWI
Yes

- I have confidence in the security of this project.

GEWI
Yes

7.4.3 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.

GEWI
Yes

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.

GEWI
YES. SHAPES is developing a technology platform for pan-european distribution of telemedicine services.

- We have ensured that the eHealth infrastructures needed are in place for deployment and large-scale implementation.

GEWI
To do/ no infrastructure is needed

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.

GEWI
To do

- We have set up a system to solve any incident that may occur during the service.

GEWI
To do

We have a system which supports the end-users in resolving any doubts that they

might experience with the telemedicine solution.

GEWI
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.

GEWI
Yes. The requirements we need from the devices that will be used in the pilot have been already defined and vendors that fulfil them have been identified.

We have clear agreements regarding the service level provided by our vendors.

GEWI
Yes. The SHAPES project provides the servers that are needed to run the digital solution service. Those servers meet the service level needed to run the pilot successfully.

Annex 13: NASSS questionnaire UC-PT2-002

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: UC-PT2-002.....

The causes leading to loneliness can be very different and they change with age.

Unfortunately, however, all people who suffer from loneliness for longer periods of time have one thing in common: their health, both physical and mental, suffers.

This use case aims therefore to support the interaction of the older individual with the community. If older individuals are already somewhat distanced from their community and they don't take part in day to day activities within the community, they also don't necessarily hear about new developments or opportunities for engagement, sports, educational or cultural events.

It needs to be ensured that they have easy access to suitable opportunities and developments in the community, such as specialized transport services, and are actively informed about e.g. weather conditions that allow for exercise outdoors but also activities such as readings, bingo, exhibitions and other opportunities to engage in activities taking place in local communities.

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 This use case focuses on the interaction with the community as well as to simplify the access of local information (e.g. weather, transportation, events). The use case is open for a lot of potential participants, personal conditions will be asked at the beginning of starting the pilot.		X	
Many people with the condition have other co-existing illnesses or impairments that could affect their ability to benefit from this solution Older individual could have "regular" general impairments (e.g. in terms of reading or mobility) which could reduce to the interaction with the tablet or independent access to events. In this use case, each care receiver will assign a care giver who discuss and supports the recommendations during the deployment of the use case.	X		
Many people with the condition have social or cultural factors that could affect their ability to benefit from the technology or service			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 condition has significant complexity which is likely to affect the project's success	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	

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) This use case consists of many SHAPES solution: FINoT (FINT), DigiRoom (OMN), safe digital assistant (VICOM), Newsum (SciFy), Data analytics (TREE), access earth (AELTD). Although some parameters and some details of the solution still have to be developed in more in-depth, there are building a good framework of the use case. Significant uncertainties arise from component of the open call: <ul style="list-style-type: none"> SHAPES-OC1- Enablers-ST6 Social support in local community 	X		
There are significant uncertainties in where the technology will come from (e.g. supply chain issues, substitutability) This is use case contains only one device (standard tablet).		X	
There are significant uncertainties about the technology's performance and dependability (e.g. bugs, crashing, cutting out) The utilized SHAPES solution are already developed. The integration of the component of the open call as well as the final architecture of the SHAPES platform are pending.	X		
There are significant uncertainties about the technology's usability and acceptability (e.g. key people don't trust the data it provides) Participants have the possibility to look at the information that were provided during the registration process at any time. Detailed information about the usability of the technology will be given in trainings at the begging of the pilot.		X	
There are significant technical interdependencies All digital solutions used in this use case will have interdependencies because there are all build together the opportunity to support the interaction of the community. As there are so many ways to be part of interaction, there will be most likely a solution if one of them fails.	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	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	

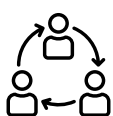
3. THE VALUE PROPOSITION



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	X		
The value to the intended users (e.g. patients, clinicians) is uncertain		X	
The personal value of participants as care receiver and care giver (e.g. family member, health care professional) are defined.			
The value to the healthcare system (e.g. from efficacy and cost-effectiveness studies) is uncertain			X
The use case aims to support the interaction of the older individual with the local community to counteract feeling of loneliness. The scenario does not have a direct connection with the healthcare system.			
The value to this particular healthcare organisation, given the current situation locally, is uncertain			X
There is no healthcare organisation involved. Only if the care giver will be in the role of a health care professional.			
The technology could generate a negative value (costs are likely to outweigh benefits) for some stakeholders		X	
The use case will merge a lot of public information provided for free from the pilot site (events, weather, transportation) within the different digital solutions.			
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	Yes <input type="checkbox"/>	No <input type="checkbox"/>	

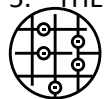
4. THE INTENDED ADOPTERS



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	
The participant will get support on site or remote. The apps will be as most user-friendly as possible			
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	
The consideration of the roles of potential care giver or overall "event administrator" is an ongoing process.			
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	Yes <input type="checkbox"/>	No <input type="checkbox"/>	

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
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 <input type="checkbox"/>	No <input type="checkbox"/>	

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		X	
The office of social affairs in pilot site supports the activities of SHAPES.		X	
Professional bodies are opposed to the innovation or don't actively support it		X	
Professional bodies are not involved in this use case (until now).		X	
Patient organisations and lobbying groups are opposed to the innovation or don't actively support it		X	
The team of the senior and care counselling of the office of social affairs supported us already in WP2 (finding interview partners) and is keen to see at some day the deployment of the use case.		X	
The regulatory context is adverse	X		
Due to pandemic the deployment of the use case, it is not advisable to recommend older individuals to attend public events.	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		
Depending on the course of the pandemic	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

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

<p>The illness or condition</p>	<p>The technology</p>	<p>The value proposition</p>
<p>The intended adopters</p>	<p>The organisation</p>	<p>The external context Deployment of use case in home-setting is strongly dependent on the course of the pandemic.</p>

Annex 14: Questionnaire for Mock-up sessions UC-PT2-002

Questionnaire for Mock-ups of UC-PT2-002

Welcome of participant

2. **General information about SHAPES**
3. **Information about use case and its intention, presentation of use case scenario**
4. **Mock-up**

Participant should be actively made aware that she/he can ask questions or add comments at any time during mock-up session.

Interviewer should collect any impressions and conversation which occurs besides the questionnaire.

An open atmosphere should be created, and the participants should be motivated to explain thoughts and opinions.

Presentation of SHAPES digital solutions (mock-up)

UNDERSTANDING	
What do you see?	
What do you think that you can do on this screen/slide? ...and how would you do it (press button, talk, typing,)?	
Is the visualization appealing to you?	
What do you like? What don't you like? Is there anything missing (e.g. information, button, function)?	
LAYOUT	
What is the general idea of this slide/screen?	
Can you read all information? Are contrast sufficient?	
What would make it easier to understand provided information?	
Do you feel overwhelmed?	
What do you think about the pictures/ diagrams or icons?	
INTERACTION (digital solutions)	
Are you able to find information for specific topics?	

Are you aware that you can add own information/ preferences to the digital solution?	
What functions are comprehensible to you? Which ones are not?	
What would you do to get more information about events (calendar, weather, transportation etc.)? What do you think you could do on this site? Where can you click? Do you think you could act accordingly?	
How many recommendations a day would be fair?	
Do you like to see any other information?	
INTERACTION (between care receiver & caregiver)	
Payment proceedings: Do you feel comfortable with payment process?	
Shared decision making: Do you like the idea of a joint process to book a ticket for an event?	
FEEDBACK	
After seeing all the slides/screens – what do you think?	
What kind of training would you need to deploy the use case?	
Can you imagine providing your personal data to the digital solution?	
Which information/ functions are most interesting/ helpful to you?	
Which functions are useless for you/ would you not need? And why?	
IT-BEHAVIOUR	
Which devices do you use regularly?	
Tell me about apps that you like to use daily.	
How intuitive are the solutions to you? Do you get any support?	
Are you interested in technology? Thinking of the special devices needed (e.g. Smartwatch): Would you wear it? Which problems may appear with it? If it is available in the future, would you buy it for yourself?	

Annex 15: Consent form phase 3 UC-PT2-002

EINVERSTÄNDNISERKLÄRUNG FÜR TEILNEHMENDE (Zielbenutzer:in)

Titel der Studie: SHAPES Pan-Europäische Pilotkampagne: Nutzerbeteiligung und Feedback zu digitalen Lösungen für Pilotthema 2 - Optimale Anpassung des Wohnumfeldes für eine höhere Unabhängigkeit & verbesserte Lebensqualität

Ort der Studie:

Bei Ihnen zu Hause

Kontakt

...

Erklärung des Teilnehmenden

Ich bin eingeladen worden, an der oben genannten Studie teilzunehmen. Der Zweck der Studie ist es, Feedback zur Anwendung und Nutzerfreundlichkeit einer App, die die Motivation zur Teilnahme an Aktivitäten fördern soll, zu sammeln. Die App wird für Menschen ab 65 Jahren entwickelt, die zu Hause leben. Die Studie gibt uns die Gelegenheit sicherzustellen, dass die App aus der Perspektive älterer Menschen praktisch und benutzbar ist.

- Ich habe das SHAPES-Teilnehmerinformationsblatt gelesen und verstanden. Es hat mich ausreichend über die oben genannte Studie, ihren Zweck und die Durchführung der Studie, über meine Rechte und über die möglichen Vor- und Nachteile einer Teilnahme informiert.
- Ich hatte die Möglichkeit, Fragen zur Studie zu stellen und habe diese Fragen zufriedenstellend beantwortet bekommen.
- Ich bin ausreichend über die Erhebung, Verarbeitung, Weitergabe und Löschung meiner Antworten während der Studie informiert worden. Mir ist bekannt, dass außer meines Namens und meiner Kontaktdaten keine weiteren personenbezogenen Daten im Rahmen dieser Studie verarbeitet werden.

- Mit meiner Unterschrift bestätige ich, dass ich freiwillig an dieser Studie teilnehme und dass ich auch der Verarbeitung meiner Antworten zu den in diesem Dokument beschriebenen Zwecken und Zielen zustimme.
- Ich wurde nicht unter Druck gesetzt oder zur Teilnahme überredet und ich hatte genügend Zeit, mir meine Teilnahme an der Studie zu überlegen. Mir ist bewusst, dass meine Teilnahme völlig freiwillig ist und dass es mir freisteht, meine Einwilligung jederzeit und ohne Angabe von Gründen zurückzuziehen.
- Ich habe auch das Recht, die Löschung meiner identifizierbaren persönlichen Daten in Übereinstimmung mit den Datenschutzbestimmungen zu verlangen.

Optional

Ich bin damit einverstanden, von gewi bezüglich der Teilnahme an zukünftigen Projekten im Zusammenhang mit dieser Studie kontaktiert zu werden, die innerhalb dieses und nächstes Jahres anfallen

Ja Nein
(bitte ankreuzen)

Auszufüllen vom Teilnehmenden

Bitte füllen Sie die folgenden Angaben aus, um Ihre Zustimmung zu bestätigen:

Name:	
Datum:	
Unterschrift:	

Annex 16: Information sheet phase 3 UC-PT2-002

SHAPES-TEILNEHMERINFORMATIONSBLATT: Zielbenutzer:in

Titel der Studie: SHAPES Pan-Europäische Pilotkampagne: Nutzerbeteiligung und Feedback zu digitalen Lösungen für das Pilotthema 2 - Optimale Anpassung des Wohnumfelds für eine höhere Unabhängigkeit & verbesserte Lebensqualität

Wir möchten Sie einladen, an unserer Studie teilzunehmen, bei der wir gerne Ihr Feedback zur Funktionsweise einer App, die die Motivation zur Teilnahme an Aktivitäten fördern soll, erfragen möchten. Die App wird für Menschen ab 65 Jahren entwickelt, die zu Hause leben. Ihr Feedback gibt uns die Gelegenheit sicherzustellen, dass die App aus der Perspektive älterer Menschen praktisch und benutzbar ist. Wir beabsichtigen, mindestens zwei Personen in diese Studie einzubeziehen.

Sie wurden als geeignet für die Teilnahme an unserer Studie identifiziert und haben daher dieses Informationsblatt erhalten. Es beschreibt die Studie und Ihre Rolle darin. Zunächst ist es wichtig, dass Sie verstehen, warum die Studie durchgeführt wird und was die Teilnahme für Sie bedeutet. Bitte lesen Sie dieses Informationsblatt gründlich, bevor Sie entscheiden, ob Sie an der Studie teilnehmen möchten. Wenn Sie Fragen haben oder sich noch weitere Informationen wünschen, wenden Sie sich gerne an unsere Ansprechpartnerinnen ...

Freiwilligkeit der Teilnahme

Die Teilnahme an dieser Studie ist freiwillig. Sie können jederzeit ohne Angabe von Gründen von der Studie zurücktreten, ohne dass dies negative Folgen für Sie hat.

Zweck und Ziele der Studie

Diese Studie ist Bestandteil eines größeren Forschungsprojekts, das darauf abzielt, verschiedene Möglichkeiten des Einsatzes von Technologie zur Unterstützung älterer Menschen in ihrem häuslichen Umfeld zu testen.

Das Ziel der Studie besteht darin, dass Sie die verschiedenen Funktionen der App für uns testen. Außerdem werden Sie ermutigt, Ihre ersten Reaktionen, Gedanken, Gefühle und Meinungen zur Nutzung der App mit uns zu teilen und Verbesserungsvorschläge zu äußern. Anhand dieses Feedbacks werden wir weitere Anpassungen vornehmen, um die App benutzerfreundlicher für ältere Menschen zu gestalten.

Die fertige App wird dann in einer größeren Studie eingesetzt, um

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herauszufinden, ob sie Menschen darin unterstützen kann, wichtige Gesundheitsparameter und Aktivitäten von zu Hause aus zu verwalten und somit ihre Lebensqualität und Gesundheitsergebnisse zu verbessern.

Wer organisiert und finanziert die Forschung?

Das Institut für Gesundheitswirtschaft e.V. (gewi) organisiert diese Studie. Sie ist Teil eines größeren Forschungsprogramms mit dem Namen SHAPES-Projekt, das von der Europäischen Union im Rahmen des Programms Horizon 2020 (Grant Agreement no 857159) finanziert wird.

Was wird die Teilnahme beinhalten?

Wenn Sie zustimmen, an dieser Studie teilzunehmen, wird Ihnen ein Tablet zur Verfügung gestellt, auf dem die App bereits installiert ist. Zudem werden Sie in einer ca. 2-stündigen Trainingseinheit von einer wissenschaftlichen Mitarbeiterin in die Nutzung der App eingeführt. Diese findet bei Ihnen zu Hause statt.

Was genau wird passieren?

Nachdem Sie Zeit hatten, dieses Informationsblatt zu lesen, wird die wiss. Mitarbeiterin mit Ihnen in Kontakt treten, um die weitere Teilnahme zu besprechen. Wenn Sie mit der Teilnahme einverstanden sind, werden Sie gebeten eine Einverständniserklärung zu unterschreiben.

(Im nächsten Schritt wird der Termin für die Trainingseinheit vereinbart.)

Die Trainingseinheit gestaltet sich wie folgt:

- Die wiss. Mitarbeiterin wird die App präsentieren und dabei auf die einzelnen Funktionen eingehen.
- Ihnen wird gezeigt, wie Sie selber die App benutzen können.
- Eine Anleitung wird während der Trainingseinheit auf einem Laptopbildschirm angezeigt.
- Im zweiten Schritt werden Ihnen kleine Aufgaben gestellt, die mit der Anwendung der App zu tun haben. Damit wollen wir herausfinden, an welchen Stellen es Schwierigkeiten **mit der App** gibt.
- Sie werden ermutigt "laut" zu denken und Ihre ersten Ideen und Reaktionen während der Präsentation und den Aufgaben mitzuteilen. Hierbei gibt es keine richtigen oder falschen Antworten. Wir sind interessiert an Ihrer ehrlichen Meinung und Ihrer Einschätzung zu dem, was wir Ihnen zeigen.
- Die wiss. Mitarbeiterin macht sich während der Trainingseinheit Notizen,

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die für die spätere Auswertung benötigt werden.

- Die Einheit wird etwa zwei Stunden dauern. Wir werden in einem von Ihnen festgelegten Tempo arbeiten und können jederzeit eine Pause einlegen.
- Im Anschluss an die Aufgabenstellung wird Ihnen die wiss. Mitarbeiterin Fragen zu Ihrer Einschätzung mit dem Umgang der App stellen. Sie können uns an der Stelle ausführlich mitteilen, was Ihnen gefallen hat, was Ihnen nicht gefallen hat oder was Sie selber an der App verändern würden.

Erhebung und Verarbeitung von Informationen nach der Trainingseinheit

- Außer Ihrem Namen und Ihren Kontaktdaten werden keine weiteren personenbezogenen Daten erhoben.
- Anonymisierte Ergebnisse können in weiteren Forschungs- und/oder Kommunikationsaktivitäten verwendet werden (z. B. im Rahmen weiterer Forschung im SHAPES-Projekt, in Zeitschriftenartikeln, Workshops und Konferenzen).
- Ihre persönlichen Kontaktdaten werden von den Forschenden vernichtet, sobald Sie eine Zusammenfassung der Ergebnisse dieser Studie erhalten haben.
- Anonymisierte Rohdaten werden für die Dauer des SHAPES-Projekts und für fünf Jahre nach dessen Beendigung gespeichert.

Mögliche Vorteile einer Teilnahme

Es gibt keinen direkten Nutzen für Sie als Einzelperson für die Teilnahme an dieser Studie, abgesehen vom persönlichen Interesse und der Erfahrung, an einer Studie teilzunehmen. Der indirekte Nutzen dieser Studie besteht jedoch darin, dass Sie uns Ihre Ansichten und Meinungen mitteilen können und so zu dem Design und der Funktionsweise der App beitragen. Ihr Input wird Kenntnisse darüber liefern, wie Technologien eingesetzt werden können, um Menschen im Alter in ihrem häuslichen Umfeld zu unterstützen. Menschen aus ganz Europa werden von Ihrer Teilnahme profitieren.

Mögliche Nachteile der Studienteilnahme

Wir sehen keine Unannehmlichkeiten oder Nachteile für Sie, wenn Sie an dieser Studie teilnehmen.

Finanzielle Informationen

Die Teilnahme an dieser Studie ist für Sie mit keinen Kosten verbunden. Sie erhalten keine Bezahlung für Ihre Teilnahme.

Information über die Studienergebnisse

Die Ergebnisse dieser Studie können in weiteren Forschungs- und/oder Kommunikationsaktivitäten verwendet werden (z. B. im Rahmen weiterer Forschung im SHAPES-Projekt, in Zeitschriftenartikeln, Workshops und Konferenzen). Eine Zusammenfassung der Ergebnisse wird Ihnen zur Verfügung gestellt.

Beendigung der Studie

Die Forscher, die die Studie durchführen, können die Studie beenden. Derzeit gibt es hierfür jedoch keinerlei Gründe oder Anlässe. Außerdem steht es Ihnen jederzeit frei, Ihre Teilnahme an der Studie zu beenden. Wenden Sie sich in diesem Fall bitte an die Forschenden. Ihre anonymisierten Daten können weiterhin in die Studie einbezogen werden.

Weitere Informationen

Weitere Informationen im Zusammenhang mit der Studie können Sie bei den folgenden am SHAPES-Projekt beteiligten Personen erfragen:

...

Annex 17: Consent form phase 4 UC-PT2-002

EINVERSTÄNDNISERKLÄRUNG FÜR STUDIENTEILNEHMER:INNEN

Titel der Studie: SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) Pan-Europäische Pilotkampagne: Digitale App und Plattform zur Förderung der Interaktion zwischen dem Individuum und der Gesellschaft. Eine nicht-randomisierte Machbarkeitsstudie in der realen Welt zur Bewertung der Benutzerfreundlichkeit und des von den Benutzern:innen wahrgenommenen Nutzens.

Entwickler (Auftraggeber): gewi – Institut für Gesundheitswirtschaft e.V. (Karolingerring 31, 50678 Köln)

Studienleitung: ...

Erklärung von: _____ (Name)

- Ich wurde eingeladen, an der oben genannten Studie teilzunehmen. Der Zweck der Studie ist es, die Funktionalität einer App zu testen. Die App hat das Ziel die Motivation zur Teilnahme an Aktivitäten vor Ort zu fördern und wurde für Menschen ab 65 Jahren entwickelt wird, die zu Hause leben. Die Studie ist eine Gelegenheit für die wissenschaftlichen Mitarbeitenden, um sicherzustellen, dass die App aus technischer Perspektive funktioniert.
- Ich habe das Informationsblatt für Studienteilnehmer:innen gelesen und verstanden. Das Informationsblatt hat mich ausreichend über die oben genannte Studie, ihren Zweck und die Durchführung der Studie, über meine Rechte und über die möglichen Vor- und Nachteile einer Teilnahme informiert.
- Ich hatte die Möglichkeit, Fragen zur Studie zu stellen und habe diese Fragen zufriedenstellend beantwortet bekommen.
- Ich bin ausreichend über die Erhebung, Verarbeitung, Weitergabe/Weitergabe und Löschung meiner Antworten während der Studie informiert worden. Mir ist bekannt, dass außer meines Namens

und meiner Kontaktdaten keine weiteren personenbezogenen Daten im Rahmen dieser Studie verarbeitet werden.

- Mit meiner Unterschrift bestätige ich, dass ich freiwillig an dieser Studie teilnehme und dass ich auch der Verarbeitung meiner Antworten zu den in diesem Dokument beschriebenen Zwecken zustimme.
- Ich wurde nicht unter Druck gesetzt oder zur Teilnahme überredet und ich hatte genügend Zeit, mir meine Teilnahme an der Studie zu überlegen. Mir ist bewusst, dass meine Teilnahme völlig freiwillig ist und dass es mir freisteht, meine Einwilligung jederzeit und ohne Angabe von Gründen zurückzuziehen.
- Ich habe auch das Recht, die Löschung meiner identifizierbaren persönlichen Daten in Übereinstimmung mit den Datenschutzbestimmungen zu verlangen.

Auszufüllen vom Teilnehmenden

Bitte füllen Sie die folgenden Angaben aus, um Ihre Zustimmung zu bestätigen:

Name:	
Datum:	
Unterschrift:	

Annex 18: Information sheet phase 4 UC-PT2-002

INFORMATIONSBLETT FÜR STUDIENTEILNEHMER:INNEN

Titel der Studie: SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) Pan-Europäische Pilotkampagne: Digitale App und Plattform zur Förderung der Interaktion zwischen dem Individuum und der Gesellschaft. Eine nicht-randomisierte Machbarkeitsstudie in der realen Welt zur Bewertung der Benutzerfreundlichkeit und des von den Benutzern:innen wahrgenommenen Nutzens

Entwickler/ Sponsor: gewi – Institut für Gesundheitswirtschaft e.V.

Studienleitung...

Institutsleiterin: ...

Wir möchten Sie einladen, an unserer Studie teilzunehmen, bei der Sie die Funktionalität einer App testen sollen. Die App besteht aus einer Onlineplattform und wurde für Menschen ab 65 Jahren entwickelt, die zu Hause leben. Das Ziel dieser Technologie besteht darin die Motivation zur Teilnahme an Aktivitäten vor Ort zu fördern und damit das Risiko von Einsamkeit und Isolation zu verringern. Die Studie bietet uns die Möglichkeit, die digitale Lösung in einer realen Umgebung zu testen und etwaige Probleme mit Verbindung und der Datenübertragung zu ermitteln. Es wird auch geprüft, ob Änderungen an den Prozessen, der Logistik oder der Dokumentation vorgenommen werden müssen, die im groß angelegten Pilotprojekt verwendet werden sollen.

Wir möchten, dass Sie korrekte und ausreichende Informationen erhalten, damit Sie beurteilen können, ob Sie teilnehmen möchten oder nicht. Bitte lesen Sie daher dieses Informationsblatt sorgfältig durch, und wir werden etwaige Zweifel nach der Erläuterung klären. Außerdem können Sie sich mit Personen beraten, die Sie für geeignet halten. Wenn Sie Fragen haben, wenden Sie sich bitte an ... (Studienleitung) unter den am Anfang dieses Dokumentes angegebenen Kontaktdaten.

Freiwillige Teilnahme

Die Teilnahme an dieser Studie ist freiwillig. Sie können jederzeit die Teilnahme ohne Angabe von Gründen und ohne negative Folgen für Sie beenden.

Zweck und Ziele der Studie

Diese Studie ist Teil eines größeren Forschungsprojekts, in dem verschiedene Möglichkeiten des Einsatzes von Technologie zur Unterstützung älterer Menschen in ihrem Zuhause getestet werden sollen. Ziel dieser Studie ist es, die Lösung in einer realen Umgebung zu testen. Die App wird vier Wochen lang verwendet, und wir werden Informationen darüber sammeln, wie gut sie funktioniert, sowohl aus der Sicht des/der Benutzers:in als auch der Systeminfrastruktur der Lösung.

Was ist mit der Teilnahme verbunden?

Sie erhalten ein Tablet Gerät, auf dem die App installiert ist. Zu Beginn der Studie erhalten Sie von der Studienleitung eine Schulung und ein Benutzerhandbuch für die Verwendung der App.

Sie werden gebeten sich in der App zu registrieren, diese einmal täglich zu nutzen und in die

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empfohlenen Veranstaltungen zu schauen. Sollte eine Veranstaltung Ihren Interessen entsprechen, tragen Sie diese bitte im Kalender der App ein.

Für den Zweck dieser Studie verwenden Sie fiktive Daten, die Sie in der App eintragen werden. Zum Abschluss der vier Wochen werden Sie gebeten drei verschiedene Fragebögen zur Anwendung der App zu beantworten.

Datenverarbeitung

Ihre Daten werden von der App drahtlos auf die gesicherten Server der technischen Partner hochgeladen. Die Daten werden dann sicher über direkte Verbindungen mit den Partnern zur Analyse geteilt.

Auf dem Gerät, das Sie vom gewi- Institut für Gesundheitswirtschaft e.V. im Rahmen der Studie erhalten, ist zudem eine App installiert (Anydesk), die es im Falle von technischen Problemen den Wissenschaftlerinnen ermöglicht, aus der Distanz auf das Gerät zuzugreifen und potenzielle Probleme zu beheben. Das Vorgehen ist abgesichert durch doppeltes Einverständnisverfahren Ihrerseits. Es werden dabei keine persönlichen Daten gespeichert.

Nur das Forscherinnen-Team des gewi Instituts wird Sie identifizieren können. Allen anderen SHAPES Partnern wird ein Code zur Verfügung gestellt, mit dem es nicht möglich ist Sie persönlich zu identifizieren. Ihre Informationen werden bis zum Start der nächsten Phase des Projekts gespeichert (dieser ist für September 2022 geplant). Ihre Daten werden dann von allen Servern gelöscht.

Vorteile und Risiken, die sich aus Ihrer Teilnahme an der Studie ergeben

Auf individueller Ebene bringt die Teilnahme an dieser Studie keinen direkten Nutzen, abgesehen von dem persönlichen Interesse und der Erfahrung durch die Teilnahme an einer Forschungsstudie. Obwohl das Ziel von SHAPES letztlich darin besteht, die Lebensqualität älterer Menschen zu verbessern, und die Studie Daten sammelt, um eine Bewertung in dieser Hinsicht vorzunehmen, besteht das Hauptziel der Studie darin, die Akzeptanz der digitalen Hilfsmittel bei den Teilnehmern:innen zu bewerten.

Es werden keine Risiken vorhergesehen.

Wirtschaftlicher Ausgleich

Für Ihre Teilnahme an der Studie entstehen Ihnen keine Kosten, außer der Nutzung Ihres Internets. Für die Teilnahme an dieser Studie erhalten Sie keine Vergütung.

Verwendung der Studienergebnisse

Die Ergebnisse dieser Studie können für weitere Forschungs- und/oder Kommunikationsaktivitäten genutzt werden (z. B. im Rahmen der weiteren Forschung im SHAPES-Projekt, in Zeitschriftenartikeln, Workshops und Konferenzen). Eine Zusammenfassung der Ergebnisse wird Ihnen zur Verfügung gestellt.

Beendigung der Studie

Die Forscherinnen, die die Studie durchführen, können die Studie beenden, jedoch gibt es derzeit keine vorhersehbaren Gründe, warum diese Studie beendet werden sollte. Es steht Ihnen jederzeit frei, Ihre Teilnahme zurückzuziehen. In diesem Fall wenden Sie sich bitte an die Studienleitung. Wir dürfen dann Ihre anonymisierten Daten weiterhin verwenden.

Annex 19: Study protocol phase 5 UC-PT2-002

Title of the project

Smart and Healthy Ageing through People Engaging in Supportive Systems (SHAPES) digital app and platform for supporting the interaction of the older individual with the community. A non-randomized, feasibility study in real world for the evaluation of user engagement and user-perceived usefulness. (UC-PT2-002-GEWI).



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159



8. Summary of the pilot study

The intervention being piloted in this study is a novel system of supporting older individuals (>65 years old) living at home by themselves who are at risk of isolation/loneliness to interact with the community through the use of a digital online forum that provides relevant information (weather, events, sports activities, excursions) and also enables remote support by a caregiver. This facilitates the older individual to participate in regional activities by providing tailored information and recommendations on events and enables their interaction with and integration in society. The pilot is a feasibility study in order to have a first evaluation of the engagement and user-perceived usefulness of the novel system in a real-world environment. The project is designed as a non-randomised, single-armed, cross-sectional interventional pilot study with an optional qualitative interview component. To expand the impact, an equivalent study will be carried out in Italy (AIAS), the Czech Republic (UP/OUŠHI) and in a second German reference site (CCS). This project is undertaken within the European project SHAPES (www.shapes2020.eu), which evaluates several digital solutions addressed to older individuals. Data collected in this project will be anonymised and shared with SHAPES consortium for a pan-European evaluation of digital solutions.

There are two types of participants: 1) older persons and 2) caregiver.

The target group in this study is composed of +65 year old individuals living in their home-setting in the reference site “Oberbergischer Kreis” in Germany and their caregiver (family, friends, formal caregiver). Caregivers will use the app to support the older person in handling the platform, to make events available for the platform and to be available for problems or questions. All participants will be asked to engage with the SHAPES app on the tablet provided by the gewi - Institut für Gesundheitswirtschaft e.V. Older people will be encouraged to use it on a daily base; caregivers once a week. The app proposes events, activities or information to the older person that match with the selected interests from the user profile and the user’s place of residence. These can be viewed, saved and added to the calendar via the app (feature provided by the SHAPES partner FINT). Furthermore, the participants can receive personalised recommendations on events from their caregiver or interact with other app users (all types) via the chatroom (DigiRoom provided by OMN).

9. Introduction

People who are aged 65 years and older account for almost a fifth of the population of the European Union. The number of people in this age group is projected to reach 151 million in 2060¹. Conversely, the proportion of EU citizens who describe themselves as being in 'good' or 'very good' health is falling and varies considerably between member states (ranges between 43.4% and 82.8%). In addition, 'poor health' is more often reported from older people compared to younger people. Naturally, being in 'good health' is not only of value to the individual (better quality of life, improved wellbeing, greater social participation), but it is also important for societal and economic growth². Thus, there is an imperative to keep people healthy and active as they age.

Although health problems and complaints increase with age, old age does not inevitably stand for illness, limitations and the need of care. Next to individual lifestyles, personal resources and the level of access to medical and social care, the aspect of social integration and its closely related feeling of loneliness has a strong impact on the health status, quality of life and well-being of older individuals. The causes leading to loneliness can be very different and they change with age. However, increasing evidence suggests that perceived social isolation or loneliness for longer periods of time is a relevant risk factor for physical and mental illness³. Thus, chronically lonely people have a high risk of developing depression, are more susceptible to cardiovascular disease and possibly have an increased risk of cancer. Combating loneliness is therefore not only important for social cohesion, but it is also an active health precaution to support older people in living healthy and independent lives⁴.

Innovative systems such as information and communication technologies (ICT/eHealth) offer great opportunities to support and enhance independence for older adults and may be related to health, cognitive functioning, independence maintenance, or even social inclusion in advanced age⁵. With the right choice of eHealth technology, older people can be enabled to interact with and participate in society. Thus, the risk of loneliness and isolation can be potentially reduced resulting in better and longer health, independence and quality of life.

Health literacy and individual involvement will be key elements in the successful introduction of eHealth into the health and social care system. Citizens, including older individuals, must be seen as custodians of their own health⁶, thus emerging technologies need to be user-friendly and empowering. Developments in ICT (eHealth) for the in-home care services and key emerging technologies on robotics and sensors open up the concept of 'Ambient Intelligence' and offer the potential for different environments (i.e., at home, in the street, during transportation) to embed intelligence that helps with everyday life. To date, initiatives to achieve traction in this area have been modest, with experiments involving advanced ICT services supporting health and care through small-scale, localised initiatives.

The Smart & Healthy Ageing through People Engaging in Supportive Systems (SHAPES) Innovation Action (www.shapes2020.eu), a European project in which gewi - Institut für Gesundheitswirtschaft e.V. is a member, intends to build, pilot and deploy a large-scale, EU-standardised open platform. The integration of a broad range of technological, organisational, clinical, educational and societal solutions seeks to facilitate long-term healthy and active ageing and the maintenance of a high-quality standard of life. Mediated by technology, in-home and local community environments

interact with health and care networks contributing to the reduction of costs, hospitalisations and institutional care.

SHAPES intends to build an interoperable Platform integrating smart digital solutions to collect and analyse older individuals' health, environmental and lifestyle information, identify their needs and provide personalised solutions that uphold the individuals' data protection and trust. Standardisation, interoperability and scalability of the SHAPES Platform aims to increase efficiency gains in health and care delivery across Europe, bringing improved quality of life to older individuals, their families, caregivers and care service providers. SHAPES large-scale piloting campaign will engage +2k older individuals in 15 pilot sites in 10 EU Member States, including six European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) Reference Sites, and involve hundreds of key stakeholders. SHAPES multidisciplinary approach to large-scale piloting is reflected across seven themes that, together, provide a clear understanding of the reality of European health and care systems and enable the validation of cost-efficient, interoperable and reliable innovations capable of effectively supporting healthy and independent living of older individuals within and outside the home. These seven themes are as follows:

- Pilot Theme 1: Smart Living Environment for Active Ageing at Home
- Pilot Theme 2: Improving In-Home and Community-based Care Services
- Pilot Theme 3: Medicine Control and Optimisation
- Pilot Theme 4: Psycho-social and Cognitive Stimulation Promoting Wellbeing
- Pilot Theme 5: Caring for Older Individuals with Neurodegenerative Diseases
- Pilot Theme 6: Physical Rehabilitation at Home
- Pilot Theme 7: Cross-border Health Data Exchange Supporting Mobility and Accessibility for Older Individuals

The Oberbergische Kreis in Germany is EIP on AHA (European Innovation Partnership on Active and Healthy Ageing) reference site for this pilot study. The gewi - Institut für Gesundheitswirtschaft e.V. is leading Pilot Theme 2 of the SHAPES pilot: 'Improving In-Home and Community-based Care Services', wherein the SHAPES platform and selected digital solutions will be used to provide an appropriate home setting and an person-aware environment for older individuals, to promote and maintain an individual's autonomy at home and to infer the individual's wellbeing based on relevant activities. Within this pilot theme there are multiple 'use cases' each deploying and evaluating different digital solutions in several European countries according to the type of support required. Four use cases will be used to evaluate this pilot theme. The project in this document describes the piloting of the use case led by gewi - Institut für Gesundheitswirtschaft e.V. and carried out in "Oberbergischer Kreis", Germany.

The use case of this project study focuses on older persons living at home by themselves, insufficiently informed about regional activities or integrated in society and thus at risk to suffer from loneliness and isolation. The individuals at stake need to be somewhat motivated and/or informed about the variety of regional activities or events in order to regularly entertain social contacts. If older individuals are already somewhat distanced from their community and they don't take part in day to day activities within the community, they also don't necessarily hear about new developments or opportunities for engagement, sports, educational or cultural events. The use of the digital platform thereby offers the older individual easy access to suitable opportunities and developments in the community and actively informs them about e.g. weather

conditions that allow for exercise outdoors but also activities such as readings, bingo, exhibitions and other opportunities to engage in activities taking place in local communities. Based on an initial survey, activities that align with the hobbies and interests of the older individual can be suggested. The older individual is reminded of activities that are taking place and informed on how to get there and what to bring. Also relevant news items are included in the platform. Thus, older individuals are enabled to interact with the community resulting in a reduced risk of loneliness and isolation. This equally entails to maintain or possibly even improve the wellbeing and quality of life of the target population, supporting them to remain independent for longer.

The SHAPES platform along with selected digital solutions belonging to partners of the SHAPES consortium (FINT and OMN) can become eHealth tools for interacting with community that are particularly designed for older persons. In the presented project, the main objective is to evaluate whether users engage with such a system and if it is useful for them (self-perceived usefulness).

10. Literature

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11. Hypothesis and objectives

Hypothesis: This study will test the hypothesis that the SHAPES platform and Digital Solutions (novel system) are capable of providing opportunities for supporting the interaction of the older individual with community.

Objectives

Primary objectives

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

Secondary objectives

- To investigate the capability of the novel system to improve the feeling of loneliness and thus enhance the well-being of the older individuals (SO1)
- To investigate the capability of the novel system to inform older individuals about future events and activities, tailored to their preferences and/or to any of their psychophysical challenges (SO2).
- To investigate the association of number of interactions, contacts and attendance of events and the feeling of loneliness (SO3).
- To investigate the capability of the novel system to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects (SO4).
- To explore user trust and acceptance of the novel system (SO5).

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 at risk of isolation (TO1).
- To validate the capability of the SHAPES Platform and Digital Solutions to improve the older individuals' interaction and engagement outcomes and quality of life (TO2).
- To validate the capability of the SHAPES Platform and Digital Solutions to gain the older individuals' trust and acceptance (TO3).
- To validate the capability of the SHAPES Platform and Digital Solutions to gain the caregivers' trust and acceptance (TO4).

Outcomes

In relation to at least one primary objective (related objectives in brackets):

- O1. Timestamps of login into the novel system (PO1).
- O2. Notes taken during the introduction training and the unstructured interview at the end of the use of the novel system (PO1, PO2).
- O3. Short version of User Experience Questionnaire (UEQ-S)⁷ (PO2, SO5, TO3, TO4).

- O4. Social technological measures: Technology Acceptance Model (TAM) questionnaire⁸, System Usability Scale (SUS)⁹. (PO2, SO5, TO3, TO4).

In relation to the secondary and tertiary objectives (related objectives in brackets):

- O5: Behavioural information: time; duration of interactions; frequency of contact (SO3)
- O6: Social: selection of interests (drop down menu) (SO2)
- O7. Location: place of residence in the OBK (city and federal state to enter manually) (SO2)
- O8. Internet access: How is your connectivity? (3 categories (slow, medium, fast)) (PO1, SO3)
- O9. user skills: how technically proficient are you? (3 categories (beginner, advanced, expert)) (PO1, SO3)
- O10. Health Status data: physical fitness (3 item scale (high/low/no answer)) (SO2).
- O11. Emergency contact: (name, relation) (SO3)
- O12. Psychosocial measures: WHOQOL-BREF¹⁰; EQ-5D-5L¹¹; GSES (Self-efficacy)¹²; OSSS-3 (social support) and life events¹³; 1-item health literacy; SHAPES Participation questionnaire; ULS-6 Loneliness Scale¹⁴, Flourishing Skala-Deutsch (FS-D)¹⁵ (TO1, TO2, SO4).

In order to relate objectives to socio-demographics of app users:

- O13. Number of years of formal education; date of birth; 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.

In order enable login process in the novel system:

- O14. Participants ID (non-identifiable) and password.

In order to contact participants (data only kept at gewi - Institut für Gesundheitswirtschaft e.V.)

- O15. Name, Native Language

For technical reasons:

- O16. Model, manufacturer and serial number of devices (technical).

Table 1: Outcomes collected in the study. Novel system user is any participant who uses any component of the technology at any time. 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 and caregivers are always done with the support of a researcher.

Outcome code	Outcome	Addressed to	Conducted by	Time of collection	Objective
O1, O2	Use of features in novel systems	Novel system users	Automatic and Researcher	I, E	PO1,PO2
O3	UEQ – S	Novel system users	Self-complete	E	PO2, SO5, TO3, TO4
O4	TAM, SUS	Novel system users	Self-complete	E	PO2, SO5, TO3, TO4
O5, O6, O7, O8, O9, O10, O11	Data from devices	Older person	App user (Automatic or self-complete via app)	I	PO1, SO2, SO3, TO2
O12	WHOQOL-BREF, EQ-5D&VAS, GSES, OSSS-3 and life events, 1-item health literacy, SHAPES Participation Questionnaire, ULS-6, FS-D	Older person	Self-complete	B, E, F	SO4, TO1, TO2
O13	Socio-demographic data: Number of years of formal education; date of birth; gender; marital status; country.	Novel system user	Researcher	B	Socio-demographic analysis
O13	Socio-demographic data: marital status; occupational status; caregiver status; help from family; professional help, neighbourhood environment; residence type; co-living with someone Literature measure	Novel system user	Researcher	B, E, F	Socio-demographic analysis
O14	User and password	Novel system user	Self-complete	B	Login
O15	Contact details	Novel system user	Researcher	R	Contact
O16	Device technical data	NA	Researcher	B, I	Technical

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Outcomes which are not referenced have been designed in the project definition of the use case.

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12. Methodology: Materials and methods

Study design: non-randomised, single-armed, cross-sectional interventional pilot study with an optional qualitative interview component. Period of intervention: 3 months.

Participants - Target users: people older than 65 living at home in the reference site OBK by themselves, at the perceived risk of isolation/ loneliness.

Eligibility: 1) person aged 65 years old or older at the time of recruitment; 2) living in the OBK 3) living on their own 4) self-reported capacity to use the apps installed on the tablet; 5) self-reported capacity to consent; 6) has daily access to internet (WIFI or other 3 or 4G internet connection).

Participants – Caregiver: contact person of the older individual. They will commit to use the caregiver app at least once a week.

Sample size: 5 target users and their caregiver. Caregivers can also be assigned to several care receivers. These sample sizes were selected pragmatically to be as representative as possible within the scope of resources available.

Materials

Tablet: Samsung Galaxy S6L SM-P615

Software from SHAPES partners: FINT (FINoT platform & programmable cloud platform); OMN (DigiRoom)

Other software: Excel, Word; Questionnaires: Those listed in outcomes.

Methods: Data integrity of non-CE software

Data integrity on the FINoT platform will be performed. Integrity of recommendations of events based on the user's selection of interests will be tested with a series of fake historic data. Tests will pass if all data is correctly processed according to indicator rules.

Methods: Recruitment (all types of participants)

Recruitment activities: Several actions will be displayed to draw attention to the project. These entail displaying articles in regional newspapers, using mailing lists and contacting relevant gatekeeper from the network by applying face to face recruitment.

Screening: Interested people can make contact via mail, letter or phone. A first screening of the responses will be performed for potentially eligible participants. As interested participants actively contact the research team, no consent of contact will be provided.

Invitation: First communication about the pilot will be conducted via phone from the research team to present all relevant information and answer questions from the potential participants. Participants will also select a caregiver and make the first contact. In a next step, caregiver are encouraged to also get into contact with the research team themselves.

Information sheets: Information sheets and consent forms will be sent out to eligible participants and their caregiver in case they still show interest.

Methods: Informed consent (all types of participants): Informed consent (duplicate) will be obtained remotely or in-person with the following format of signatures collected where appropriate: handwritten; typewritten; scanned; an electronic representation of a handwritten signature. The principal investigator of this study will countersign both documents and one will be delivered to the participants as acknowledgment of reception.

Methods: Test in a controlled environment: 2 older person participants and their caregiver will be invited to participate in a pre-study of 1 month. It will consist of *intervention procedures* described below but only collect data necessary to check the functioning in the deployment (O1, O5-O11, O14 data). During the procedure the researcher will take notes to record relevant observations. At the end there is the

option for a non-structured interview with all participants in order to collect additional feedback (O2).

Methods: Intervention procedures

All participants: At baseline, a face-to-face session with the researcher will take place at the participant's home. Participants will register in the SHAPES platform, devices and links will be provided and a training session will be given. Written reference material (guidelines and FAQs) will be provided. The first week of the pilot will be considered a run-in period. Participants will be contacted after the end of the run-in period to resolve doubts and concerns. Participants will be encouraged to contact the researcher for any technical issue or doubt about the use of the novel system during the entire period of the pilot.

App users: during the pilot, the participant will be asked to record O5, O6, O7, O8, O9, O10 and O11 data via the FInoT app. These (O6-O11) have to be recorded manually in the app. O1 and O5 data (tracking data of the novel system use) will be automatically collected.

Methods: End of intervention (Within 14 days after the end of the intervention; For collected data, see Table 1): These data will be collected in face-to-face, one-to-one interviews or through forms to fill individually with the presence of a researcher for resolving doubts.

Methods: Follow-up study procedures (3-month follow-up, +/- 7days; For collected data, see Table 1): These data will be collected in face-to-face, one-to-one interviews or through forms to fill individually with the presence of a researcher for resolving doubts.

Data collection tools: O1, O5, O6, O7, O8, O9, O10 and O11 data will be automatically stored in the database of the novel system. For authentication, users will register username and password (O14) in the SHAPES app. The other data collection will be documented in an excel file. Paper questionnaires will be digitalised into the excel file.

Protocol deviations: This pilot is examining the real-world use of the SHAPES app and associated devices. Therefore, if participants do not enter data as requested, this will not be documented as a protocol deviation, rather this will give insight into the usability of the solution. An interview (O2) will be done to find out reasons for the lack of engagement. They will not be penalised and will be analysed in terms of usability of the novel system.

Data management: Data processed in this pilot will be subject to the General Data Protection Regulation (GDPR) (679/2016) about personal data protection and warranties on digital rights, in agreement with the GDPR. gewi - Institut für Gesundheitswirtschaft e.V. will be the data controller for all data collected during this pilot. Data Processing Agreements will be put in place between gewi - Institut für Gesundheitswirtschaft e.V. and each SHAPES partner who processes data (FINT, OMN, TREE TECHNOLOGY, National University of Ireland Maynooth). During data collection and intervention, data processing will be pseudonymised. In analysis period, data processed by partners will be de-identified.

The data collected for this study will be stored securely, and kept contemporaneous and accurate. If a participant withdraws from the study, clarification sought as to what data may need to be erased. This data will be identified and erased without delay. Personal data will be kept in a form that permits identification until October 2023. Personal data will be de-identified at the end of the SHAPES Innovation Action (Oct 2023), kept this way for five years and then aggregated (anonymisation). Anonymised aggregated data will be offered to the scientific community through the SHAPES consortium.

Personal data processing is described in the following project documents: Data Protection Impact Assessment, the Personal Data Processing Descriptions and the Risk Assessment.

Data analysis: Demographic characteristics will be summarised and reported to describe the sample population. Analysis related to SO4 will be carried out by TREE

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159



TECHNOLOGY. gewi - Institut für Gesundheitswirtschaft e.V. will analyse all data pertaining to the outcomes linked to the remaining primary and secondary objectives of the pilot (data from AIAS', CCS' and UP's study may be included). Quantitative and qualitative data analysis methods will be employed and findings reported. De-identified data pertaining to the tertiary outcomes that align with other pilots in the SHAPES pan-European piloting campaign (harmonised O3, O4 and O12 questionnaires and socio-demographic O13 data) will be analysed by the SHAPES coordinators at National University Ireland Maynooth.

Statistical methods: Where appropriate, descriptive statistics will be reported for all quantitative data, the mean and standard deviation (SD) will be reported where data are approximately normally distributed, and the median and interquartile range (IQR) reported where data are non-normally distributed. Differences in outcomes measured at baseline and at the end-of-pilot will be compared using paired t-test or Wilcoxon Signed Rank test (or appropriate alternative), depending on the distribution of the data. Confidence intervals and effect size will be calculated and reported to provide an estimation of the size and direction of intervention effect.

Missing data: Every effort will be made to reduce the potential for missing data, however, if missing data occurs it will be coded as 999 (participant declined to answer), 998 (administration error or failure), 997 (equipment error or failure), 996 (unknown after human check), 995 (other reason) or empty *NULL* (unknown, automatic).

13. Workplan

Research team:

- ..., head of gewi - Institut für Gesundheitswirtschaft e.V.
- ..., scientific researcher at gewi - Institut für Gesundheitswirtschaft e.V.
- ..., project manager at gewi - Institut für Gesundheitswirtschaft e.V.
- AIAS, CCS and UP (replicating site; an equivalent study will be carried out by AIAS, CCS and UP)
- National University Ireland Maynooth: Coordinator SHAPES project (Coord-SHAPES)

Technical team: for technical incidences, technical departments at FINT, OMN and TREE TECHNOLOGY.

Centre where the study is carried out: older person participants and caregivers will use app and devices at home. Researcher will be staff from gewi - Institut für Gesundheitswirtschaft e.V.

Sponsor: gewi - Institut für Gesundheitswirtschaft e.V.

Stages and tasks

1. Data integrity tests

Scheduled period: March-April 2022

Team members and tasks: gewi - Institut für Gesundheitswirtschaft e.V., FINT and TREE will perform data integrity tests on the app.

2. Recruitment & collection of informed consent

Scheduled period: February-April 2022

Team members and tasks: Researcher at gewi - Institut für Gesundheitswirtschaft e.V. will be in charge of the recruitment process. They will confirm eligibility, will countersigned consent and deliver 1 consent form to participants.

3. Test in a controlled environment

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Scheduled period: May 2022

Intervention time length: 1 month per older person participant and their caregiver (2 older persons and caregiver)

Team members and tasks: Researcher will deliver devices, install apps and organise training sessions with selected participants at their home. During the session, researcher will take notes and collect incidences, if any, and will communicate them to the technical team if necessary. Researcher will interview participants at the end of the 1-month period for collecting feedback.

4. Pilot study

Scheduled period: July-September 2022

Intervention time length: 3 months per older person

Baseline:

Team members and tasks: Researcher will carry out face-to-face, one-to-one interviews and collection of data in excel file.

Intervention period:

Team members and tasks: On first day, researcher will deliver devices to participants who were not involved in the *controlled environment test*. They will give the training session and will provide reference material to the participants who were not involved in the *controlled environment test*. Researcher will organise a (remote) session with participants on day 7 to resolve doubts. Researcher will be the reference contact point of participants for any technical issue or doubt and will contact the Technical Team if necessary.

End of intervention interview:

Team members and tasks: Researcher will carry out face-to-face, one-to-one interviews and collection of data in excel file. In the end they will withdraw devices.

Follow-up, 3 months after end of intervention (+/- 7days):

Team members and tasks: Researcher will carry out face-to-face, one-to-one interviews and collection of data in excel file.

5. Data analysis

Scheduled period: October-December 2022

Team members and tasks: Researcher and TREE TECHNOLOGY will perform statistical analysis, the latter with de-identified data. Analysis will be extended with de-identified data coming from AIAS', CCS' and UP's study.

Data will be kept pseudonymised at gewi - Institut für Gesundheitswirtschaft e.V. until October 2023. After this year, gewi - Institut für Gesundheitswirtschaft e.V. will de-identify data and will be kept in this form for 5 years more, when individual data will be deleted and an anonymous, aggregated dataset will be stored indefinitely.

6. SHAPES data analysis

Scheduled period: December 2022-October 2023

gewi - Institut für Gesundheitswirtschaft e.V. will de-identify O3, O4, O12 and O13 data and transfer them to Coord-SHAPES for analysis together with data coming from other use cases in SHAPES (responsible: Coord-SHAPES). After analysis and always before October 2023, individual data will be deleted and an anonymous, aggregated dataset will be stored indefinitely for sharing with the scientific community.

	Jan 2022	Feb 2022	Mar 2022	Apr 2022	May 2022	Jun 2022	Jul 2022	Aug 2022	Sep 2022	Oct 2022	Nov 2022	Dez 2022	Jan 2023	...	Oct 2023
Data integrity															
Recruitment															
Test controlled environment					2 older person & caregiver										
Study							Baseline → Intervention (3 months) → 3-month follow-up								
Data analysis											UC-PT2-002 + all PT2 studies (with anonymous, aggregated data)				
SHAPES data analysis											De-identified data transferred to SHAPES platform				

14. Ethical considerations

Research ethics approval

Approval to conduct the pilot will be sought from a Research Ethics Committee (Ethik Kommission der Ärztekammer Nordrhein) before the start of the recruitment process. This protocol and all other relevant documents will be submitted. Prior to submission to the REC, this protocol will be reviewed and approved for submission by colleagues within the SHAPES consortium.

Protocol amendments

Any substantial amendments that require review by Ethik Kommission der Ärztekammer Nordrhein will not be implemented until the Ethik Kommission der Ärztekammer Nordrhein grants a favourable opinion for the trial, and all correspondence with the Ethik Kommission der Ärztekammer Nordrhein will be retained in the Trial Master File.

Consent

All participants will be asked to provide voluntary, informed consent for their participation in the pilot. The consent form will include the following explicit consents:

- All participants till reaching objectives: participation in the tests *under controlled environment*.

Declaration of interests

gewi - Institut für Gesundheitswirtschaft e.V., sponsor of the study, is proprietary of the SHAPES App.

Research collaborators are employees of FINT, OMN and TREE TECHNOLOGY, FINT is proprietary of the FINoT platform.

Access to data

gewi - Institut für Gesundheitswirtschaft e.V. will be the data controllers and as such will have access to the full dataset. Data Processing Agreements will be in place to facilitate the sharing of pseudonymised data with specific SHAPES partners for

specific purposes during the undertaking of the pilot. For process of data regarding analysis Data Processing Agreements will be in place to facilitate the sharing of de-identified data. De-identified data will be offered to the scientific community through the SHAPES platform.

Ancillary and post-trial care

At the end of the pilot the devices provided to participants will be removed and access to the SHAPES app will be stopped.

Dissemination policy

Any data that arise from the pilot study will be owned by the sponsor gewi - Institut für Gesundheitswirtschaft e.V. On completion of the study, all data will be analysed and tabulated and used to prepare a final report, available as one of the agreed deliverables of the SHAPES Innovation Action — Deliverable D6.3. 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 outcome of the study. gewi - Institut für Gesundheitswirtschaft e.V. 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. gewi - Institut für Gesundheitswirtschaft e.V. 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 will be in place to facilitate the sharing of pseudonymised or de-identified data with specific SHAPES partners for specific purposes. De-identified data will also be shared with the scientific community through the SHAPES platform.

Annex 20: Consent form Phase 5 UC-PT2-002

Einwilligungserklärung

SHAPES Pan-Europäische Pilotkampagne: Digitale App und Plattform zur Förderung der Interaktion zwischen dem Individuum und der Gesellschaft. Eine nicht-randomisierte Machbarkeitsstudie in der realen Welt zur Bewertung der Benutzerfreundlichkeit und des von den Benutzern:innen wahrgenommenen Nutzens

Sehr geehrte Studieninteressantin, sehr geehrter Studieninteressent,

wir möchten Sie fragen, ob Sie an einer wissenschaftlichen Studie teilnehmen möchten.

Fühlen Sie sich manchmal einsam, isoliert oder wünschen sich mehr Interaktion mit Ihren Mitmenschen in Ihrer Umgebung? Durch diese Studie soll erprobt werden, inwiefern mit Hilfe der digitalen Lösung die Interaktion zwischen dem Individuum und der Gesellschaft gefördert werden kann. Dafür soll die folgende digitale Lösung getestet werden:

- SHAPES-App für android Tablet (Samsung Galaxy S6L SM-P615)

Bisher hat es sich als schwierig erwiesen, neue digitale Lösungen im Bereich Pflege und Versorgung von älteren Menschen einzuführen. Verschiedene Hindernisse haben dazu geführt, dass ein großflächiger Einsatz nicht umsetzbar war. In dieser Studie sollen Sie als Anwender:in daher beteiligt werden und Ihre Einschätzung und Erlebnisse mit den digitalen Lösungen werden als Hauptergebnisse ausgewertet.

Als Nebenziele soll geklärt werden, wie sich die digitalen Lösungen auf das Gefühl von Einsamkeit und Isolation auswirken, die Lebensqualität und das Wohlbefinden älterer Menschen sowie die Akzeptanz und das Vertrauen in die digitalen Lösungen. Darüber hinaus werden die gesammelten Daten genutzt, um Zusammenhänge zwischen der Anzahl der Interaktionen und Teilnahme an Veranstaltungen mit dem Gefühl von Einsamkeit zu untersuchen. Als drittrangiges Ziel ist die Bewertung der Daten im Zusammenhang der Pilotkampagne SHAPES geplant. Dabei soll die Auswirkung von digitalen Lösungen auf ältere Menschen aus unterschiedlichen ländlichen und städtischen Regionen Europas bewertet werden.

Es werden insgesamt 4 ältere Menschen und eine Betreuungsperson an der Studie teilnehmen. Das gewi-Institut für Gesundheitswirtschaft e.V. übernimmt keine Haftung im Falle von auftretenden technischen Problemen oder Ausfällen und damit einhergehenden Folgen.

Die Studie soll insgesamt 12 Wochen dauern und im September 2022 starten. Im Rahmen der Studie sollen folgende Daten von Ihnen mittels Interviews und Fragebögen erfasst und ausgewertet werden:

Fragebögen/ Daten	Zeitpunkt
Sozio-demographische Daten: Geburtsjahr, Geschlecht, Familienstand, Jahre in Ausbildung, Land	Zu Beginn der Studie (September 2022)
Gesundheitsfragebogen (WHOQoL-BREF), Gesundheitsfragebogen (EQ-5D-5L), Selbstwirksamkeit (GSE), Soziale Unterstützung (OSSS-3), SHAPES Frage zur Teilhabe, SHAPES Frage zur Gesundheitskompetenz, Einsamkeitsskala (ULS-6), Skala zum psychischen Wohlbefinden (FS-D)	Zu Beginn, am Ende und 3 Monate nach Ende der Studie
Sozio-demographische Daten: beruflicher Status, Status als Pflegeperson, Hilfe von der Familie, Art des Wohnsitzes, Zusammenleben mit jemandem	
Frage zur Technologie Akzeptanz (TAM)	Ende der Studie (November 2022)
Anwender Erfahrungen (UEQ-S)	
Fragen zur System-Gebrauchlichkeit (SUS)	
Unstrukturiertes Interview zur Erfassung, inwieweit mittels der App die Interaktion zwischen dem Individuum und der Gesellschaft gefördert werden konnte	

Zusätzlich werden Sie gebeten die folgende App und Geräte zu benutzen:

Tabelle 2: Informationen zu App und Geräten

	Gerät	Funktion	Zeitpunkt
Nichtmedizinische App/	SHAPES-App	<ul style="list-style-type: none"> die App ist auf dem Tablet installiert, das Sie für studienzwecke vom gewi – Institut für Gesundheitswirtschaft e.V. erhalten. 	Fragen zum persönlichen Profil: einmalig zu Beginn der Studie

Am ersten Tag der Studie findet zum Kennenlernen und zur Schulung ein persönlicher Termin mit der Studienleitung statt. Die erste Woche wird als Einführungsphase betrachtet und Sie werden ermutigt, sich bei Problemen oder Zweifeln an die Studienleitung zu wenden.

Die genannten studienbedingten Maßnahmen erfordern einen zusätzlichen Zeitaufwand von ca. 10 Minuten pro Tag.

Die Teilnahme an dieser Studie ist freiwillig. Sie werden nur dann einbezogen, wenn Sie dazu schriftlich Ihre Einwilligung erklären. Sofern Sie nicht an der Studie teilnehmen oder später aus ihr ausscheiden möchten, entstehen Ihnen dadurch keine Nachteile. Sie können jederzeit, auch ohne Angabe von Gründen, Ihre Einwilligung mündlich oder schriftlich widerrufen.

Die Studie wurde der zuständigen Ethikkommission vorgelegt. Sie hat keine Einwände erhoben.

Mögliche Risiken, Beschwerden und Begleitterscheinungen

Da im Rahmen unserer Studie nur Daten erhoben werden, sind mit der Teilnahme keine medizinischen Risiken verbunden.

Die ergänzende Datenerhebung über Fragebögen und Interviews sowie die einmalige Dateneingabe in die SHAPES-App ist lediglich mit einem Zeitaufwand von ca. 10 Minuten verbunden und erfordert für diese Zeit Ihre Aufmerksamkeit.

Möglicher Nutzen aus Ihrer Teilnahme an der Studie

Sie werden durch Ihre Teilnahme an dieser Studie keinen Nutzen für Ihre Gesundheit haben. Die Ergebnisse dieser Studie können Kenntnisse darüber liefern, wie Technologien eingesetzt werden können, um Menschen im Alter in ihrem häuslichen Umfeld zu unterstützen.

Datenschutz

- Rechtsgrundlage für die Datenverarbeitung ist Ihre freiwillige Einwilligung (Art. 6 Nr. 1 lit. a) DSGVO und Art. 9 Nr. 2 lit a) DSGVO).
- Der Verantwortliche für die Datenverarbeitung ist: gewi – Institut für Gesundheitswirtschaft e.V. (Karolingerring 31, 50678 Köln)

Ihre Daten werden zu jeder Zeit vertraulich behandelt. Während der unstrukturierten Interviews werden die wissenschaftlichen Mitarbeiter:innen Notizen machen und diese anschließend in digitaler Form aufbereiten. Alle Daten, die mittels der Interviews sowie der Fragebögen erfasst werden, werden in pseudonymisierter Form vom Initiator der Studie, gewi – Institut für Gesundheitswirtschaft e.V. (Karolingerring 31, 50678 Köln), sicher verwahrt. Die Daten, die über die App erfasst werden, werden in pseudonymisierter Form an den Initiator der Studie weitergeleitet. Zugriff auf die personenbezogenen Daten haben nur zuständige Personen im jeweiligen Studienzentrum.

Pseudonymisieren bedeutet, dass keine Angaben, mit denen Sie direkt identifiziert werden können (z.B. Name, Kontaktinformationen, Geburtsdatum etc.) verwendet werden, sondern nur ein Nummern- und/oder Buchstabencode. Ihre Studienleitung erstellt eine Pseudonymisierungsliste, die im Studienzentrum gesondert aufbewahrt wird und dort technischen und organisatorischen Maßnahmen unterliegt, die gewährleisten, dass die personenbezogenen Daten Ihnen durch unbefugte Personen nicht zugeordnet werden können. Eine Entschlüsselung erfolgt nur in folgenden Situationen: in dem

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unwahrscheinlichen Fall, dass ein Angriff auf die IT-Systeme von SHAPES oder gewi-Institut ausgeübt wird, werden wir Sie persönlich kontaktieren.

Die Daten werden bis Oktober 2023 aufbewahrt. Sie sind gegen unbefugten Zugriff gesichert. Sie werden gelöscht, wenn sie nicht mehr benötigt werden, um die wissenschaftliche Auswertung und Analysen durchzuführen. Spätestens nach fünf Jahren nach Ende der Pan-europäischen Pilotkampagne werden sie gelöscht.

Sind mit der Datenverarbeitung Risiken verbunden?

Bei jeder Erhebung, Speicherung, Nutzung und Übermittlung von Daten bestehen Vertraulichkeitsrisiken (z.B. die Möglichkeit, die betreffende Person zu identifizieren). Diese Risiken lassen sich nicht völlig ausschließen und steigen, je mehr Daten miteinander verknüpft werden können. Der Initiator der Studie versichert Ihnen, alles nach dem Stand der Technik Mögliche zum Schutz Ihrer Privatsphäre zu tun und Daten nur an Stellen weiterzugeben, die ein geeignetes Datenschutzkonzept vorweisen können. Medizinische Risiken sind mit der Datenverarbeitung nicht verbunden.

Der Nummern- und/oder Buchstabencode (das Pseudonym) kann nur innerhalb der EU in den Studienzentren entschlüsselt werden, um die pseudonymisierten Daten Ihnen zuzuordnen (siehe oben). Es bestehen außerdem folgende Schutzmaßnahmen: verbindliche interne Datenschutzvorschriften gemäß Artikel 47 DSGVO und der Angemessenheitsbeschluss von der Europäischen Kommission. Sie können eine Kopie dieser Garantien erhalten und unter folgender Adresse abrufen: https://ec.europa.eu/info/sites/default/files/file_import/data_protection_de_0.pdf

Können Sie Ihre Einwilligung widerrufen?

Sie können Ihre jeweilige Einwilligung jederzeit ohne Angabe von Gründen schriftlich oder mündlich widerrufen, ohne dass Ihnen daraus ein Nachteil entsteht. Wenn Sie Ihre Einwilligung widerrufen, werden keine weiteren Daten mehr erhoben. Die bis zum Widerruf erfolgte Datenverarbeitung bleibt jedoch rechtmäßig.

Sie können im Fall des Widerrufs auch die Löschung Ihrer Daten verlangen.

Welche weiteren Rechte haben Sie bezogen auf den Datenschutz?

Sie haben das Recht, vom Verantwortlichen Auskunft über die von Ihnen gespeicherten personenbezogenen Daten (einschließlich der kostenlosen Überlassung einer Kopie der Daten) zu verlangen. Ebenfalls können Sie die Berichtigung unzutreffender Daten sowie gegebenenfalls eine Übertragung der von Ihnen zur Verfügung gestellten Daten und die Einschränkung ihrer Verarbeitung verlangen.

Bitte wenden Sie sich im Regelfall an das Studienzentrum, denn allein das Studienzentrum kann aufgrund des Pseudonymisierungsprozesses vollumfänglich auf Ihre Daten zugreifen bzw. entsprechende Auskünfte geben. Der Initiator der Studie kann vor diesem Hintergrund nur sehr begrenzt helfen.

Bei Anliegen zur Datenverarbeitung und zur Einhaltung der datenschutzrechtlichen Anforderungen können Sie sich auch an folgende Datenschutzbeauftragte wenden:

- b) Datenschutzbeauftragter des Studienzentrums: ... (gewi – Institut für Gesundheitswirtschaft e.V., Karolingerring 31, 50678 Köln)

Sie haben ein Beschwerderecht bei jeder Aufsichtsbehörde für den Datenschutz. Eine Liste der Aufsichtsbehörden in Deutschland finden Sie unter:

https://www.bfdi.bund.de/DE/Infothek/Anschriften_Links/anschriften_links-node.html

Zuständige Beauftragte für das Land Nordrhein-Westfalen:

Frau Bettina Gayk

Postfach 20 04 44, 40102 Düsseldorf

Tel.: 0211 384 240

E-Mail: poststelle@ldi.nrw.de

Ansprechpartner:innen für Fragen zur Studie

Wenn Sie Fragen zu dieser Studie haben, wenden Sie sich bitte an:

gewi – Institut für Gesundheitswirtschaft e.V

...

Karolingerring 31, 50678 Köln

...

ODER

Studienarzt

Dr. med Christian Franchy

Facharzt für Innere und Allgemeinmedizin

Hämostaseologie

Ernährungsmedizin DGEM

Lehrbeauftragter des Schwerpunkts Allgemeinmedizin

der Medizinischen Fakultät der Universität zu Köln

Im Otto-Lob-Winkel 2

51789 Lindlar

Tel.: 02266 1853

Fax: 02266-4407355

Einwilligungserklärung

SHAPES Pan-Europäische Pilotkampagne: Digitale App und Plattform zur Förderung der Interaktion zwischen dem Individuum und der Gesellschaft. Eine nicht-randomisierte Machbarkeitsstudie in der realen Welt zur Bewertung der Benutzerfreundlichkeit und des von den Benutzern:innen wahrgenommenen Nutzens.

Name des/der Teilnehmer:in in Druckbuchstaben:.....

- Ich bin von Herrn / Frau (Studienleitung) _____ über Wesen, Bedeutung und Tragweite der Studie sowie die sich für mich daraus ergebenden Anforderungen aufgeklärt worden. Ich habe darüber hinaus den Text des Informationsblattes und dieser Einwilligungserklärung gelesen.
- Ich hatte ausreichend Zeit, Fragen zu stellen und mich zu entscheiden. Aufgetretene Fragen wurden mir von der Studienleitung beantwortet.
- Ich weiß, dass ich meine freiwillige Mitwirkung jederzeit beenden kann, ohne dass mir daraus Nachteile entstehen.

Ich erkläre mich bereit, an der Studie teilzunehmen.

1. Ich willige ein, dass personenbezogene Daten über mich, insbesondere soziodemographische Daten und (s. Tabelle auf S.3), wie in der Informationsblatt beschrieben, erhoben und in Papierform sowie auf elektronischen Datenträgern bei dem gewi- Institut für Gesundheitswirtschaft e.V. aufgezeichnet werden.

Soweit erforderlich, dürfen die erhobenen Daten pseudonymisiert (verschlüsselt) weitergegeben werden:

b) im Falle unerwünschter Ereignisse: an die jeweils zuständige Ethik-Kommission und zuständigen Behörden sowie von dieser an die Europäische Datenbank.

2. Ich bin darüber aufgeklärt worden, dass ich meine Einwilligung jederzeit widerrufen kann. Im Falle des Widerrufs werden keine weiteren Daten mehr erhoben. Ich kann in diesem Fall die Löschung der Daten verlangen.

3. Ich willige ein, dass die Daten nach Beendigung oder Abbruch der klinischen Prüfung mindestens 5 Jahre aufbewahrt werden.

Ich willige in die Verarbeitung der genannten Daten ein.

Ein Exemplar des Informationsblatts und der Einwilligungserklärung habe ich erhalten. Ein Exemplar verbleibt im Prüfbüro.

Unterschrift des Teilnehmers/der Teilnehmerin

(Name und Vorname in Druckschrift)

(Datum)

(Unterschrift)

Erklärung und Unterschrift des aufklärenden Arztes/der aufklärenden Ärztin

Ich habe das Aufklärungsgespräch geführt und die Einwilligung eingeholt.

(Name und Vorname in Druckschrift)

(Datum)

(Unterschrift)

Annex 21: Information sheet Phase 5 UC-PT2-002

INFORMATIONSBLETT FÜR STUDIENINTERESSIERTE

Titel der Studie: SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) Pan-Europäische Pilotkampagne: Digitale App und Plattform zur Förderung der Interaktion zwischen dem Individuum und der Gesellschaft. Eine nicht-randomisierte Machbarkeitsstudie in der realen Welt zur Bewertung der Benutzerfreundlichkeit und des von den Benutzern:innen wahrgenommenen Nutzens.

Entwickler/ Sponsor: gewi – Institut für Gesundheitswirtschaft e.V.
Studienleitung (Deutschland): ...

Sehr geehrte Studieninteressentin, sehr geehrter Studieninteressent,

Mit diesem Dokument möchten wir Sie über eine Studie informieren, an der Sie teilnehmen können. Die Ethik-Kommission hat das Forschungsvorhaben gemäß § 15 der Berufsordnung für die nordrheinischen Ärztinnen und Ärzte beraten und wird gegebenenfalls keine berufsethischen oder berufsrechtlichen Bedenken erheben. Die Studie ist in Übereinstimmung mit den Grundsätzen der Deklaration von Helsinki und den Standards der guten klinischen Praxis.

Wir möchten lediglich, dass Sie korrekte und ausreichende Informationen erhalten, damit Sie beurteilen können, ob Sie teilnehmen möchten oder nicht. Bitte lesen Sie daher dieses Informationsblatt sorgfältig durch, und wir werden etwaige Fragen nach der Erläuterung klären. Außerdem können Sie sich mit Personen beraten, die Sie für geeignet halten. Wenn Sie Fragen haben, wenden Sie sich bitte an ... (Studienleitung) unter den am Anfang dieses Dokumentes angegebenen Kontaktdaten.

Allgemeine Beschreibung

In der Studie, an der Sie teilnehmen können, geht es um die Verwendung digitaler Hilfsmittel, um die Motivation zur Teilnahme an Aktivitäten vor Ort im Oberbergischen Kreis zu fördern mit dem Ziel, hierdurch das Risiko von Einsamkeit und Isolation zu reduzieren und eine bessere und längere Gesundheit, Unabhängigkeit und Lebensqualität zu erreichen. Das Hilfsmittel besteht aus einer Onlineplattform, das in Form einer App (SHAPES-App) genutzt wird. Es wurde für eine selbständige Nutzung im eigenen zu Hause entwickelt. Das gewi-Institut für Gesundheitswirtschaft e.V. übernimmt keine Haftung im Falle von auftretenden technischen Problemen oder Ausfällen und damit einhergehenden Folgen. Das Hauptziel der Studie besteht darin, zu beurteilen, ob die digitalen Hilfsmittel einfach anwendbar sind und von Ihnen, als Studienteilnehmer:in als nützlich empfunden werden. Als Voraussetzung zur Studienteilnahme müssen Sie im Oberbergischen Kreis wohnen und über 65 Jahre alt sein.

Sie können die SHAPES-App nutzen, um relevante Informationen zum Wetter, zu Veranstaltungen und Aktivitäten oder zu regionalen Nachrichten zu erhalten. Auch können

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Sie von einer formellen (oder informellen) Betreuungsperson (Betreuungsperson im Rahmen der Studie/ Freund:in, Nachbarn:in, Familienangehörigen; Pflegefachkraft) Unterstützung im Umgang mit der App bekommen. Basierend auf den zu Beginn in die App eingetragenen Nutzerinformationen (Wohnort, Fitnesslevel und Interessen) bekommen Sie zudem angepasste Aktivitäten- und Veranstaltungsvorschläge von der Betreuungsperson in der App angezeigt. Darüber hinaus haben Sie über einen online Chatraum die Möglichkeit, sich mit anderen Appnutzern auszutauschen.

Im Rahmen der Studie wird Ihnen empfohlen, die App täglich zu nutzen und sich über regionale Veranstaltungen, Events und Aktivitäten zu informieren, ohne jedoch dass Sie dazu verpflichtet sind. Ebenso werden Sie Empfehlungen für Veranstaltungen von der Betreuungsperson erhalten. Es steht Ihnen frei, die Empfehlungen zu befolgen oder nicht.

Am Ende der Studie wird mittels Fragebögen die Benutzerfreundlichkeit, der Nutzen und die Akzeptanz der SHAPES-Anwendungen bewertet. Alle Studienteilnehmer:innen werden befragt. Weitere drei Monate nach Beendigung der Studie wird eine Nachbefragung durchgeführt.

Anzahl der Teilnehmer:innen und Dauer: Ziel der Studie ist es, 4 ältere Personen und eine Betreuungsperson zu rekrutieren. Die SHAPES-App wird auf einem Tablet installiert sein und über einen Zeitraum von drei Monaten bewertet.

Pflichten der Teilnehmer:in: Sie müssen mindestens 65 Jahre alt sein und im Oberbergischen Kreis wohnen. Sie müssen regelmäßig und zu einer bestimmten Tageszeit über einen stabilen Internetzugang verfügen.

Zu Beginn der Studie erhalten Sie von den Studienmitarbeiter:innen eine Schulung und Empfehlungen zur Verwendung der SHAPES-App. Die Einhaltung ist jedoch nicht verpflichtend, da das Ziel der Studie darin besteht, die Bewertung im tatsächlichen Alltag zu erproben. Die Empfehlungen für Sie lauten:

- Nutzen Sie einmal täglich die App.
- Bewerten Sie die Ihnen vorgeschlagenen Veranstaltungen.

Andere relevante Informationen

Alle neuen Informationen, über die SHAPES-Geräte oder die in der Studie verwendete App, die sich auf Ihre Bereitschaft zur Teilnahme auswirken könnten und die während Ihrer Teilnahme bekannt werden, werden Ihnen von der Studienleitung so schnell wie möglich mitgeteilt.

Wenn Sie sich entscheiden, Ihre Zustimmung zur Teilnahme an dieser Studie zurückzuziehen, werden keine weiteren Daten von Ihnen aufgenommen, und Sie können verlangen, dass alle Ihre Daten gelöscht werden, sofern sie nicht anonymisiert wurden.

Es wird hiermit auch darüber aufgeklärt, dass Sie von der Studie ausgeschlossen werden können, sollte die Studienleitung dies für angemessen halten. Sei es aus Sicherheitsgründen, wie bspw. Auftreten eines unerwünschten Ereignisses oder weil die festgelegten Verfahren nicht eingehalten wurden. In jedem Fall würden Sie eine angemessene Begründung erhalten.

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Mit Ihrer Unterschrift auf der beigefügten Einwilligungserklärung erklären Sie sich bereit, die Ihnen erläuterten Studienabläufe einzuhalten.

Vorteile und Risiken, die sich aus Ihrer Teilnahme an der Studie ergeben

Auf individueller Ebene bringt die Teilnahme an dieser Studie keinen direkten Nutzen, abgesehen von dem persönlichen Interesse und der Erfahrung durch die Teilnahme an einer Forschungsstudie. Obwohl das Ziel von SHAPES letztlich darin besteht, die Lebensqualität älterer Menschen zu verbessern, und die Studie Daten sammelt, um eine Bewertung in dieser Hinsicht vorzunehmen, besteht das Hauptziel der Studie darin, die Akzeptanz der digitalen Hilfsmittel bei den Teilnehmern:innen zu bewerten.

Es kann also sein, dass sich Ihre Lebensqualität durch die gesteigerte Interaktion und Einbindung in die Gesellschaft verbessert, es kann aber auch sein, dass Sie keine Verbesserung erfahren. Obwohl es unwahrscheinlich ist, kann sich Ihr Gesundheitszustand aus Gründen, die mit der Studie zusammenhängen oder nicht, verbessern.

Vertraulichkeit

Verantwortlich für die Durchführung der Studie und die Datenübermittlung: *gewi- Institut für Gesundheitswirtschaft e.V., ... , Karolingerring 31, 50678 Köln.*

Zweck der Datenerhebung: Untersuchung der Anwenderbeteiligung und der Nützlichkeit der SHAPES-Hilfsmittel; Untersuchung der Zusammenhänge zwischen einer gesteigerten Interaktion und Einbindung in die Gesellschaft und dem allgemeinen Wohlbefinden; Überprüfung des potentiellen Einflusses der vorgeschlagenen Veranstaltungen und Events auf die empfundene Einsamkeit.

Empfänger der Daten: Neben dem gewi- Institut haben die folgenden Partner Zugang zu einem Teil der Daten:

- Pseudonymisierte Daten während des Studie (verbunden mit einem Code, wobei nur gewi Institut diesen Code mit den identifizierenden Daten in Verbindung bringen kann).
 - o FINT: Visualisierung der personenbezogenen Daten
- De-identifizierbare Daten (kein zugehöriger Code)
 - o TREE TECHNOLOGY SA: Analyse der Auswahl von Veranstaltungen und Interessen
 - Kontakt: Camino de las Huertas 18, planta 1, 28223 Pozuelo de Alarcón, Madrid (Espanya) Tel. +34 902 286 386 · +34 910 059 088.
 - o SHAPES Konsortium: standardisierte Fragebögen (werden am Anfang und Ende der Studie durchgeführt) und soziodemographische Daten. Das gewi Institut arbeitet mit dem europäischen SHAPE Konsortium zusammen, um digitale Hilfsmittel für ältere Menschen zu erforschen.
 - Koordinator: National University Ireland, Maynooth, Co. Kildare, Ireland, shapes.info@mu.ie

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Die Verarbeitung, Übermittlung und Überlassung der personenbezogenen Daten aller teilnehmenden Personen erfolgt in Übereinstimmung mit den Bestimmungen der Datenschutzvorschriften gemäß Artikel 47 DSGVO und des Angemessenheitsbeschlusses von der Europäischen Kommission.

Gemäß den oben genannten Rechtsvorschriften können Sie Ihr Recht auf Auskunft, Berichtigung, Löschung, Widerspruch, Einschränkung der Datenverarbeitung und sogar auf Übermittlung Ihrer Daten an einen befugten Dritten (Übertragbarkeit) ausüben; dazu müssen Sie sich an die für die Verarbeitung verantwortliche Hauptprüferin (Studienleitung: s. Beginn des Dokuments) wenden.

Ihre Daten werden elektronisch verarbeitet und in ein automatisiertes System personenbezogener Daten aufgenommen, das alle Sicherheitsmaßnahmen für einen beschränkten Zugang zu dem in diesem Dokument beschriebenen Zweck erfüllt.

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- 5) De-Identifizierung: Im Oktober 2023 wird die Codierung von Ihren Daten getrennt.
- 6) Anonymisierung: Ab Oktober 2023 werden Ihre Daten aggregiert und unwiderruflich von Ihren persönlichen Daten getrennt, so dass es unmöglich sein wird, zu einem späteren Zeitpunkt einen Zusammenhang festzustellen.

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Der Zugang zu Ihren persönlichen Daten (persönliche gesundheitsbezogenen Daten, die jedoch nicht identifizierbar sind) ist auf die Mitarbeiter:innen des gewi-Instituts beschränkt. Dies erfolgt jedoch nur bei Erfordernis und wenn die Berechtigung vorliegt. In jedem Fall

bleibt die Vertraulichkeit gemäß den geltenden Rechtsvorschriften gewahrt. Sie können sich immer an die deutsche Datenschutzbehörde wenden, wenn Sie sich über die Verarbeitung Ihrer persönlichen Daten beschweren möchten.

Wirtschaftlicher Ausgleich

Für Ihre Teilnahme an der Studie entstehen Ihnen keine Kosten, außer der Nutzung Ihres Internets. Für die Teilnahme an dieser Studie erhalten Sie keine Vergütung.

Freiwillige Teilnahme

Sie sollten wissen, dass Ihre Teilnahme an dieser Studie freiwillig ist und dass Sie sich jederzeit gegen eine Teilnahme entscheiden oder Ihre Entscheidung ändern und Ihre Zustimmung zurückziehen können, ohne irgendeine Erklärung abzugeben. Sie können die Löschung der Daten verlangen, sofern diese nicht anonymisiert wurden.

Danksagung

Wie auch immer Ihre Entscheidung ausfällt, sowohl der Projektträger als auch das Forschungsteam möchten Ihnen für Ihre Zeit und Aufmerksamkeit danken. Sie tragen zu einem besseren Verständnis von Zusammenhängen zwischen der individuellen Interaktion mit und Einbindung in die Gesellschaft, dem Risiko von Einsamkeit und Isolation und dem allgemeinen Wohlbefinden bei, wovon viele Menschen in Zukunft profitieren können.

Annex 22: Momentum outcomes UC-PT2-003

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.

AUTH
Not applicable as no healthcare professionals are involved in the UC

- In my organisation/region patients and providers (healthcare professionals) are ready to use ICT (e.g., computers, tablets, mobile phones).

AUTH
The readiness of patients and healthcare professionals to embrace ICT (Information and Communication Technology) in our organization/region is highly advantageous. By utilizing computers, tablets, and mobile phones, we can enhance communication, streamline administrative tasks, improve access to information, and promote efficient healthcare delivery, ultimately benefiting both patients and providers.

- In my organisation/region financial and other incentives are aligned with the service to be deployed.

AUTH
Yes

- In my organisation/region an underpinning culture embraces technology.

AUTH
Yes

- In my organisation/region an underpinning culture welcomes and even promotes change, innovation and shows openness to new ideas.

AUTH
Yes, openness to new ideas is often accompanied by a focus on continuous learning and development. Providing opportunities for training, upskilling, and knowledge-sharing can empower older people to stay in line with the latest technological trends and contribute to innovative solutions.

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.

AUTH
Yes. The widespread agreement on the current telemedicine solution in our region/organization reflects its effectiveness in addressing a pressing need, ensuring accessible healthcare, enabling remote consultations, and enhancing patient-provider communication, resulting in improved healthcare outcomes.

- The current telemedicine solution is the best available solution for meeting a compelling need.

AUTH
Not applicable. The DS is not a telemedicine solution.

7.2 People

7.2.1 CSF 3. Ensure leadership through a champion

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- 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.

AUTH

The deployment of this use case does not foresee any participation of healthcare professionals. As the organisation of this use case is working together with decision makers from the reference site, those have been involved in the process of the project.

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.

AUTH

No, as they are not involved in the deployment of the UC.

- Healthcare professionals have been involved in the development of the process and time schedule for this project.

AUTH

No, as they are not involved in the deployment of the UC.

- Decision-makers have been involved in the development of the content of this project.

AUTH

No, as they are not involved in the deployment of the UC

- Decision-makers have been involved in the development of the process and time schedule for this project.

AUTH

No, as they are not involved in the deployment of the UC

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

- In this project¹⁷ the patients have been sufficiently involved in the development of the telemedicine solution.

AUTH

Plan to do so (phase 2-5)

- In this project telemedicine service is based on the patient's needs.

AUTH

YES, clear objective in increasing quality of life and wellbeing

- 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.

AUTH

Planned to do so. To be developed in following phases. Adequate information and training are provided to patients, empowering them to effectively utilize the proposed digital solution, maximize its benefits, and achieve optimal outcomes in their healthcare journey.

7.2.4 CSF 6. Ensure that the technology is user-friendly

- The telemedicine technology used in our project is user-friendly for patients.

AUTH

It is the objective and great effort is done within the SHAPES consortium to define requirements to fulfil this. Besides that, regular feedback loops through participatory approached have been adopted to gain feedback from end users are planned in phases 2-4, in order to efficiently conduct phase 5.

- The telemedicine technology used in our project is user-friendly for health professionals.

AUTH

Yes, as they can help facilitate the process for older people.

- The telemedicine technology used in our project does not need an extended training process prior to using it.

AUTH

We expect minimum training. To be defined in mock-up sessions.

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.

AUTH

YES, from SHAPES and internal resources already allocated.

- In my region/organisation the IT competences needed for deployment of the telemedicine solution are available.

AUTH

YES. AUTH and SciFY digital solutions providers ensure IT competences.

- In my region/organisation enough time for the training needed in order to implement the telemedicine solution is available.

AUTH

YES

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

- The telemedicine solution addresses the needs of the primary clients.

AUTH
To be evaluated.

- The telemedicine solution is sufficiently adapted to the needs of the primary users.

AUTH
YES, the digital solution has been extensively tailored and customized to cater to the specific requirements and preferences of the primary users, ensuring a seamless user experience and meeting their healthcare needs effectively and efficiently.

- The telemedicine solution addresses the needs of the health sector.

AUTH
To be evaluated.

7.3.3 CSF 9. Prepare and implement a business plan

- A business plan for the project has been developed.

AUTH
To do (D7.3 SHAPES Business Plan WP7)

- A business plan for the project has been implemented.

AUTH
To do after the project ends.

- The business plan has been approved by the relevant management level.

AUTH

To do after the project ends.

7.3.4 CSF 10. Prepare and implement a change management plan

- A change management plan for the project has been developed.

AUTH

To do after the project ends.

- A change management plan for the project has been implemented.

AUTH

To do after the project ends.

- A change management plan has been approved by the relevant management level.

AUTH

To do after the project ends.

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.

AUTH

Yes

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.

AUTH

Yes, the digital solutions have been fully exploited in phases 1-4, where continuous feedback from end-users was derived. This helped the research team to smoothly

deploy phase 5, where participants had the opportunity to engage and interact with the DS.

- In our region/organisation we are ready for large-scale deployment of the technology.

AUTH

Yes, the DS is fully developed and ready to be deployed.

- The project will supply the documentation needed to ensure that there is a basis for large-scale deployment of the project.

AUTH

Yes

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.

AUTH

Yes

- The project is carried out in accordance with the relevant guidelines on security matters.

AUTH

YES. The DS is in line with GDPR regulations.

7.4.2 CSF 14. Involve legal and security experts

- We have received advice on the project from legal experts.

AUTH

Yes, AUTH acting both as technical partner was awarded the ISO 9001 certification for Software Design, Development and Production. Design & Implementation of Education/Training programmes. Advice and feedback from legal experts and experts on data security matters along with the DPO will be considered.

- We have received advice on the project from experts on data security matters.

AUTH

Yes, AUTH acting both as technical partner was awarded the ISO 9001 certification for Software Design, Development and Production. Design & Implementation of Education/Training programmes. Advice and feedback from legal experts and experts on data security matters along with the DPO will be considered.

- In this project we are not experiencing any data security problems.

AUTH & SciFY	AUTH
NO	NO

- I have confidence in the legality of this project.

AUTH & SciFY	AUTH
YES. It's a H2020 project with partners with extensive expertise in this field (LAUREA for example)	Yes

- I have confidence in the security of this project.

AUTH & SciFY	AUTH
YES. It's a H2020 project with partners with extensive expertise in this field (LAUREA for example)	Yes

7.4.3 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.

AUTH & SciFY	AUTH
YES	Yes

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.

AUTH & SciFY	AUTH
YES. To support the deployment and large-scale implementation of the digital solution, we have diligently established the necessary IT infrastructures, including robust networks, hardware, and software systems, ensuring a reliable and scalable framework.	To do

- We have ensured that the eHealth infrastructures needed are in place for deployment and large-scale implementation.

AUTH & SciFY	AUTH
YES.	YES

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.

AUTH & SciFY	AUTH
YES. The system will work 24/365. In case of any bugs or issues the development and maintenance team will fix it. AUTH and SciFY 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.	Yes

- We have set up a system to solve any incident that may occur during the service.

AUTH & SciFY	AUTH
YES. The system logs all activities so any incident can be identified and solved quickly.	Yes

We have a system which supports the end-users in resolving any doubts that they

might experience with the telemedicine solution.

AUTH & SciFY	AUTH
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 consolidate our technical team.	Yes

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.

AUTH & SciFY	AUTH
NOT APPLICABLE	NOT APPLICABLE

We have clear agreements regarding the service level provided by our vendors.

AUTH & SciFY	AUTH
NOT APPLICABLE	NOT APPLICABLE

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.

Annex 23: NASSS questionnaire UC-PT2-003

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: UC-PT2-003.....

The causes leading to loneliness can be very different and they change with age. Unfortunately, however, all people who suffer from loneliness for longer periods of time have one thing in common: their health, both physical and mental, suffers. This use case aims therefore to support the interaction of the older individual with the community. If older individuals are already somewhat distanced from their community and they don't take part in day to day activities within the community, they also don't necessarily hear about new developments or opportunities for engagement, sports, educational or cultural events. It needs to be ensured that they have easy access to suitable opportunities and developments in the community, such as specialized transport services, and are actively informed about e.g. weather conditions that allow for exercise outdoors but also activities such as readings, bingo, exhibitions and other opportunities to engage in activities taking place in local communities.

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 This use case focuses on the improvement of participants' cognitive, physical and psychosocial condition. Participants are involved from the early stages of the process to design, develop and deploy the pilot activities, taking into account their unique needs, preferences through constant feedback iterations.		X	
Many people with the condition have other co-existing illnesses or impairments that could affect their ability to benefit from this solution Older individuals may experience common impairments such as difficulties in reading or limited mobility, which can hinder their interaction with tablets or independent access to events. In this scenario, each care receiver will be assigned a caregiver who will engage in discussions and provide support throughout the implementation of the use case.	X		

Many people with the condition have social or cultural factors that could affect their ability to benefit from the technology or service		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 condition has significant complexity which is likely to affect the project's success	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	

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) This use case consists of many SHAPES solutions: LLM Care (AUTH), NewSum (SciFY), Talk and Play (SciFY), Talk and Play Marketplace (SciFY). All of the DS are fully developed and are properly functioning.		X	
There are significant uncertainties in where the technology will come from (e.g. supply chain issues, substitutability) This is use case contains a desktop computer and a motion sensor.		X	
There are significant uncertainties about the technology's performance and dependability (e.g. bugs, crashing, cutting out) The DS of this UC are already developed. The integration with ASAPA and Symbiote components has been completed.		X	
There are significant uncertainties about the technology's usability and acceptability (e.g. key people don't trust the data it provides) Participants had the opportunity to evaluate the DS in terms of usability and technology acceptance during phases 2-5. Participants' viewpoints indicate that the DS of the UC do not foresee any uncertainties on these matters.		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 The DS are constantly evolving in the context of current technological trends.		X	
SUMMARY: The technology has significant complexity which is likely to affect the project's success	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	

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. The digital solution presents significant potential for improved efficiency, increased older adults' satisfaction, and expanded access to healthcare, indicating a clear and promising commercial value for the organization.		X	
The value to the intended users (e.g. patients, clinicians) is uncertain		X	

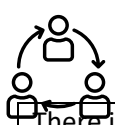
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159



The personal value of participants as care receiver and care giver (e.g. family member, health care professional) are defined.			
The value to the healthcare system (e.g. from efficacy and cost-effectiveness studies) is uncertain The use case aims to support the interaction of older adults both with a cognitive and physical training system to improve their quality of life. Therefore, this use case does not have a direct connection with the healthcare system.			X
The value to this particular healthcare organisation, given the current situation locally, is uncertain There is no healthcare organisation involved. Only if the caregiver will be in the role of a healthcare professional.			X
The technology could generate a negative value (costs are likely to outweigh benefits) for some stakeholders Proper planning, cost analysis, and stakeholder engagement can mitigate such risks and ensure that the overall value of the technology outweighs any potential drawbacks, resulting in a net positive impact		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	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	

4. THE INTENDED ADOPTERS

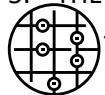
Think about who is intended to use the technology and what changes it will bring for



them.

	Agree	Disagree	Not applicable or don't know
There is uncertainty about whether and how patients/citizens will adopt the technology [if applicable] The DS provided in this UC are user-friendly and targeted to older people.		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 No uncertainties are foreseen, as the DS are already developed and deployed, therefore all implications are clearly indicated and defined prior to the pilot conduction.	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	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	

5. THE ORGANISATION(S) IMPLEMENTING THE TECHNOLOGY



Some organisations are better at taking up innovations than others. What about yours?

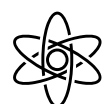
	Agree	Disagree	Not applicable or don't know
The organisation's capacity to take on technological innovations is limited		X	
The organisation is not ready for this particular innovation		X	
The organisation would find it hard to commission/purchase the innovation		X	

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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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	

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 A supportive political and policy environment can facilitate the adoption and implementation of the digital solution, enabling regulatory frameworks and incentives that promote its usage and positive impact on healthcare delivery and outcomes.		X	
Professional bodies are opposed to the innovation or don't actively support it A wide network of healthcare professionals and caregivers from the public and private sector: regional Health Districts of the Ministry of Health, Region of Central Macedonia, the National Intermunicipal Network of Healthy Cities - Health Promotion and other municipal structures for the open care of older adults across Greece (public hospitals, nursing homes in Greece and Cyprus) are constantly directly or indirectly involved in the replication of LLM Care.		X	
Patient organisations and lobbying groups are opposed to the innovation or don't actively support it The actual strength of LLM Care lies in its wide network of collaborators within the Quadruple Helix (Academia & Universities, Industry & Business, Government & Public sector, Civil Society) by joining forces under a common societal challenge: to foster digital transformation in the active and healthy ageing field, involving all key actors of the local & transnational ecosystem and introducing assistive technologies to improve older adults' health and quality of life. Therefore, policy makers and patient organisations are embracing innovation through the adoption and exploitation of the DS.		X	
The regulatory context is adverse. The regulatory framework provides necessary guidelines, ensures patient safety, and fosters the responsible use of digital solution, creating a supportive environment for its implementation and advancement in healthcare practices.		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	
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	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	

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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

The illness or condition	The technology	The value proposition
The intended adopters	The organisation	The external context

Annex 24: Momentum outcomes UC-PT2-004

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.

GEWI

Not applicable as no healthcare professionals are involved in the UC

- In my organisation/region patients and providers (healthcare professionals) are ready to use ICT (e.g., computers, tablets, mobile phones).

GEWI

In general, an critical attitude towards using ICTs and the collection of personal data might exist among that age group. However, early involvement of potential users, open communication with step by step explanations/support and high standards of data security will be applied to lower and counteract a potential risk.

- In my organisation/region financial and other incentives are aligned with the service to be deployed.

GEWI

To do

- In my organisation/region an underpinning culture embraces technology.

GEWI

No

- In my organisation/region an underpinning culture welcomes and even promotes

change, innovation and shows openness to new ideas.

GEWI

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.

GEWI

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.

GEWI

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.

GEWI

To do.

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.

GEWI
No, as they are not involved in the deployment of the UC

- Healthcare professionals have been involved in the development of the process and time schedule for this project.

GEWI
No, as they are not involved in the deployment of the UC

- Decision-makers have been involved in the development of the content of this project.

GEWI
No, as they are not involved in the deployment of the UC

- Decision-makers have been involved in the development of the process and time schedule for this project.

GEWI
No, as they are not involved in the deployment of the UC

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

- In this project¹⁷ the patients have been sufficiently involved in the development of the telemedicine solution.

GEWI

Plan to do so (phase 2-4)

- In this project telemedicine service is based on the patient's needs.

GEWI

YES, clear objective in increasing quality of life and wellbeing

- 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.

GEWI

Planned to do so. To be developed in following phases.

7.2.4 CSF 6. Ensure that the technology is user-friendly

- The telemedicine technology used in our project is user-friendly for patients.

GEWI

It is the objective and great effort is done within the SHAPES consortium to define requirements to fulfil this. Besides that, regular feedback loops with end users are planned in phases 2-4 and feedback will be considered.

- The telemedicine technology used in our project is user-friendly for health professionals.

GEWI

No, as they are not involved in the deployment of the UC

- The telemedicine technology used in our project does not need an extended training

process prior to using it.

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GEWI
We expect minimum training. To be defined in mock-up sessions.

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.

GEWI
YES, from SHAPES and internal resources already allocated.

- In my region/organisation the IT competences needed for deployment of the telemedicine solution are available.

GEWI
YES. KOMPAI and VICOM provide IT competences.

- In my region/organisation enough time for the training needed in order to implement the telemedicine solution is available.

GEWI
YES

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

- The telemedicine solution addresses the needs of the primary clients.

GEWI
To be evaluated.

- The telemedicine solution is sufficiently adapted to the needs of the primary users.

GEWI
YES, although details have still to be developed further. (patients as end-user)

- The telemedicine solution addresses the needs of the health sector.

GEWI
To be evaluated.

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.

GEWI
To do (D7.3 SHAPES Business Plan WP7)

- A business plan for the project has been implemented.

GEWI
To do after the project end.

- The business plan has been approved by the relevant management level.

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.

GEWI
To do after the project end.

- A change management plan for the project has been implemented.

GEWI
To do after the project end.

- A change management plan has been approved by the relevant management level.

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.

GEWI
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.

GEWI
To evaluate after the pilot.

- In our region/organisation we are ready for large-scale deployment of the technology.

GEWI
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.

GEWI

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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.

GEWI

Yes

- The project is carried out in accordance with the relevant guidelines on security matters.

GEWI

YES. GDPR will be applied. The system provided implements all security and privacy related regulations.

7.4.2 CSF 14. Involve legal and security experts

- We have received advice on the project from legal experts.

GEWI

To do

- We have received advice on the project from experts on data security matters.

GEWI

To do (within SHAPES consortium)

- In this project we are not experiencing any data security problems.

GEWI

TBD

- I have confidence in the legality of this project.

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GEWI

YES. It's a H2020 project with partners with extensive expertise in this field (LAUREA for example)

- I have confidence in the security of this project.

GEWI

YES. It's a H2020 project with partners with extensive expertise in this field (HMU for example)

7.4.3 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.

GEWI

Yes

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.

GEWI

To do

- We have ensured that the eHealth infrastructures needed are in place for deployment and large-scale implementation.

GEWI

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.

GEWI

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The system will work smoothly. In case of any bugs or issues the development and maintenance team will fix it. KOMPAL and VICOM are the owners of all the hard- and software that is used in the pilot. This means that we don't have any software dependencies with third parties.

- We have set up a system to solve any incident that may occur during the service.

GEWI

To do

We have a system which supports the end-users in resolving any doubts that they

might experience with the telemedicine solution.

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 KOMPAL and VICOM.

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.

GEWI

To do

We have clear agreements regarding the service level provided by our vendors.

GEWI

To do

Annex 25: NASSS questionnaire UC-PT2-004

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: **PT2-004a/b**

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 This use case focuses on the night surveillance by the functionality fall detecting. The use case is open for a lot of potential participants, personal conditions will be asked at the beginning of starting the pilot.		x	
Many people with the condition have other co-existing illnesses or impairments that could affect their ability to benefit from this solution People targeted in the use case have no special condition.		x	
Many people with the condition have social or cultural factors that could affect their ability to benefit from the technology or service		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 condition has significant complexity which is likely to affect the project's success	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	

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) This use case consists of a robot with different functionalities provided by different partners (Kompai, TREE, Vicom). The development is in progress and the functionalities (software) of the robot do not exist in a definitive form yet.	x		
There are significant uncertainties in where the technology will come from (e.g. supply chain issues, substitutability)		x	

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The robot (hardware) is already produced and has been tested in another environment (with other functionalities).			
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) The technical solution in form of a robot might be new to the end-users, however, these are involved in the development from an early stage on to give feedback which is assumed to enhance the acceptability.		x	
There are significant technical interdependencies All digital solutions used in this use case will have interdependencies in order to provide the different functionalities needed.	x		
The technology is likely to require major changes to organisational tasks and routines Implemented in a nursing home: Implementing the technology does not involve additional staff. A pre-deployment procedure requiring some time effort is needed to implement the technology in the setting once. However, this spending will be outweighed by the reduction of personal workload in the daily care pathway afterwards.		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	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	

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 The customer base for this technology is well defined.		x	
The value to the intended users (e.g. patients, clinicians) is uncertain The value for the intended user is defined: "Support in night-time surveillance"		x	
The value to the healthcare system (e.g. from efficacy and cost-effectiveness studies) is uncertain The technology is intended to support caregivers in formal care and informal care settings. So far 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.	x		
The value to this particular healthcare organisation, given the current situation locally, is uncertain Implementation in a nursing home will not require new technical infrastructure nor extensive changes to organisational routines and pathways		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.		x	

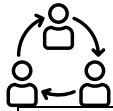
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The value proposition is likely to change significantly over the next 3-5 years			x
SUMMARY: The value proposition has significant complexity which is likely to affect the project's success	Yes <input type="checkbox"/>	No <input type="checkbox"/>	

4. 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] Having a robot in the personal living environment can be a major change for people. The technology would require substantial input from the participant or their immediate carer (starting the robot and the required application)	x		
There is uncertainty about whether and how front-line staff will adopt the technology Some staff members of the nursing home might 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)	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	Yes <input type="checkbox"/>	No <input type="checkbox"/>	

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 Does only require a one-time spending of efforts		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 <input type="checkbox"/>	No <input type="checkbox"/>	

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 The office of social affairs in pilot site supports the activities of SHAPES.		x	
Professional bodies are opposed to the innovation or don't actively support it Professional bodies are not involved in this use case.		x	
Patient organisations and lobbying groups are opposed to the innovation or don't actively support it The team of the senior and care counselling of the office of social affairs supported us already in WP3 (finding interview partners) and is keen to see at some day the deployment of the use case.		x	
The regulatory context is adverse Standards and requirements for implementing this use case in a nursing home are given by the nursing home itself. Researchers will comply with the procedures and measures (f.ex. Covid-19) of the nursing home during the implementation.		x	
The commercial context is adverse		x	
Opportunities for learning from other (similar) organisations are limited The robot is in use in a nursing home in France. An exchange of experiences might be helpful.		x	
Introduction of the technology/innovation could be threatened by external changes that impact on the organisation Depending on the course of the pandemic	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	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	

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

<p>The illness or condition</p>	<p>The technology</p>	<p>The value proposition</p>
<p>The intended adopters</p>	<p>The organisation</p>	<p>The external context</p>

Annex 26: Questionnaire for Mock-up sessions UC-PT2-004a,b

Questionnaire for Mock-ups of UC-PT2-004a,b

Welcome of participant

3. **General information about SHAPES**
4. **Information about use case and its intention, presentation of use case scenario**
5. **Mock-up**

Participant should be actively made aware that she/he can ask questions or add comments at any time during mock-up session.

Interviewer should collect any impressions and conversation which occurs besides the questionnaire.

An open atmosphere should be created, and the participants should be motivated to explain thoughts and opinions.

Presentation of SHAPES digital solutions (mock-up)

Questions for users:	
What is your overall opinion on the robot : 1. its design in humanoid form ? 2. its size, 3. its color, 4. would you prefer it to have arms?	
Can you imagine to use it in your daily life?	
Do you think you will use all the features we have presented?	
Are there any features you would have liked to have in addition to the ones we presented?	
Do you feel safer with the round surveillance function?	
What is the most relevant function for you?	
What can make it easier to integrate the robot in your daily life? What training would you need?	

Can you imagine in which situations the robot will be useful for you?	
If the robot is available in the future (not to expensive), would you buy it for yourself?	
Would you recommend it to someone ?	
Do you see any barriers in using the robot at your place?	
If you cannot talk to the robot but type in the tablet what you want to do, would that be a barrier for you? / Would you like to speak to the robot?	
Can you imagine speaking to the robot and interacting with him (e.g. playing cards, doing a workout, etc.)?	
Questions for caregivers:	
Do you think that the robot can free you from non-value added tasks like night surveillance?	
Do you think that the robot's settings are within the reach of the caregivers?	
What barriers can appear for the user, what do you think? Can you imagine, how to solve these?	
What do you like? What do you not like?	
What training will be useful for you to get to know the functions of the robot and the remote function?	
Which functions do you think are useful, which not? Are there any functions missing?	
Will you be available to get a call at night/ during the day from the robot?	
Can you imagine integrating the robot in the daily life in the nursing home?	
Questions for family members	
How do you find the robot in terms of appearance, design, size?	
If you have to choose a robot to accompany a member of your family at home, what are your selection criteria?	
What do you think about the functions proposed by the robot?	
Does the night surveillance provided by the robot bring you a feeling of tranquillity towards your patient?	
If you are called upon to follow up someone in your family at home and	

according to their degree of dependence, which function(s) would be the most relevant for you?	
Would you recommend it to someone else?	

Annex 27: Study protocol phase 5 UC-PT2-004a

Title of the project

Smart and Healthy Ageing through People Engaging in Supportive Systems (SHAPES) Night Surveillance Rounds at Community Care. A non-randomized, feasibility study in real world for the evaluation of user engagement and user-perceived usefulness. (UC-PT2-004a-GEWI)



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Summary

The intervention being piloted in this study is a novel system of supporting older individuals (>65 years old) living in a nursing home and the caregivers working in these facilities. This pilot is a feasibility study in order to have a first evaluation of the engagement and user-perceived usefulness of the novel system, which is a robot, in a real-world environment. The project is designed as a non-randomised, single-armed, cross-sectional interventional pilot study with an optional qualitative interview component. This project is undertaken within the European project SHAPES (www.shapes2020.eu), which evaluates several digital solutions addressed to older individuals. Data collected in this project will be anonymised and shared with SHAPES consortium for a pan-European evaluation of digital solutions.

Professional caregivers and residents of a nursing home in the reference site "Oberbergischer Kreis" in Germany will be asked to accept and interact with the robot within the public rooms of the nursing home. Professional caregivers will receive a presentation and training session on how to use the robot and residents will get information on how to interact with the robot. Professional caregivers will be encouraged to deploy the robot on a daily basis and use as many functions as possible. Main focus will be given to the patrolling of the robot especially during night time and its fall detection to reduce the workload of the nursing staff and to give the residents a feeling of safety. In addition, the robot can be used during the day to measure the body temperature, room disinfection and general entertainment of the residents. This should lead to a reduction in loneliness and boredom and thus improve their quality of life and well-being. At the same time, the reduction of the workload for the professional caregivers, should improve their working conditions.

1. Introduction

People who are aged 65 years and older account for almost a fifth of the population of the European Union. The number of people in this age group is projected to reach 151 million in 2060¹. Conversely, the proportion of EU citizens who describe themselves as being in ‘good’ or ‘very good’ health is falling and varies considerably between member states (ranges between 43.4% and 83.8%).

As age increases, however, so does the prevalence of people living with long term conditions as well and subsequently more people will be in need of long-term care. The analysis of the “2021 Long-term care report” even estimate a rising number of people potentially in need of long-term care (LTC) from 30.8 million in 2019 to 38.1 million in 2050 (1). Expenditures for LTC in the EU are projected to increase from 1.7% of GDP in 2019 to 2.5% of GDP in 2050 and are thus among the fastest rising social expenditures. Besides that the existing problems in LTC like poor working conditions, stressful working environments and working unlimited hours were just exacerbated by the Covid-19 pandemic (1). This is also reflected in reduction of staff and especially in understaffed evening and night shifts. Hence, nursing homes are often constrained to bring residents to their rooms quite early for evening retreat and still need to compensate a high workload, that often comes with a negative impact on carers’ physical and mental health (1).

One way to react on this could be the use of new technologies, that offer support for the employees and also enhance the living situation of the residents. With the right eHealth technology (that are user-friendly and empowering), changes in the caregivers workload and care-receivers quality of living can be potentially maintain on a moderate level early-on. Health literacy and individual involvement will be key elements in the successful introduction of eHealth into the health and social care system. Developments in ICT-based home care, including ways of monitoring wellbeing and providing a secure home environment, and key emerging technologies on robotics and sensors open up the concept of ‘Ambient Intelligence’ and offer the potential for different environments (i.e., at home, in the street, during transportation,) to embed intelligence that helps with everyday life. To date, initiatives to achieve traction in this area have been modest, with experiments involving advanced ICT services supporting health and care through small-scale, localised initiatives.

The Smart & Healthy Ageing through People Engaging in Supportive Systems (SHAPES) Innovation Action (www.shapes2020.eu), a European project in which gewi - Institut für Gesundheitswirtschaft e.V. is a member, intends to build, pilot and deploy a large-scale, EU-standardised open platform. The integration of a broad range of technological, organisational, clinical, educational and societal solutions seeks to facilitate long-term healthy and active ageing and the maintenance of a high-quality standard of life. Mediated by technology, in-home and local community environments interact with health and care networks contributing to the reduction of costs, hospitalisations and institutional care.

SHAPES intends to build an interoperable Platform integrating smart digital solutions to collect and analyse older individuals’ health, environmental and lifestyle information, identify their needs and provide personalised solutions that uphold the individuals’ data protection and trust. Standardisation, interoperability and scalability of the SHAPES Platform aims to increase efficiency gains in health and care delivery across Europe, bringing improved quality of life to older individuals, their families, caregivers and care service providers. SHAPES large-scale piloting campaign will engage +2k

older individuals in 15 pilot sites in 10 EU Member States, including six European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) Reference Sites, and involve hundreds of key stakeholders. SHAPES multidisciplinary approach to large-scale piloting is reflected across seven themes that, together, provide a clear understanding of the reality of European health and care systems and enable the validation of cost-efficient, interoperable and reliable innovations capable of effectively supporting healthy and independent living of older individuals within and outside the home. These seven themes are as follows:

- Pilot Theme 1: Smart Living Environment for Active Ageing at Home
- Pilot Theme 2: Improving In-Home and Community-based Care Services
- Pilot Theme 3: Medicine Control and Optimisation
- Pilot Theme 4: Psycho-social and Cognitive Stimulation Promoting Wellbeing
- Pilot Theme 5: Caring for Older Individuals with Neurodegenerative Diseases
- Pilot Theme 6: Physical Rehabilitation at Home
- Pilot Theme 7: Cross-border Health Data Exchange Supporting Mobility and Accessibility for Older Individuals

The Oberbergische Kreis in Germany is EIP on AHA (European Innovation Partnership on Active and Healthy Ageing) reference site for this pilot study. The gewi - Institut für Gesundheitswirtschaft e.V. is leading Pilot Theme 2 of the SHAPES pilot: 'Improving In-Home and Community-based Care Services', wherein the SHAPES platform and selected digital solutions will be used to provide an appropriate home setting and an person-aware environment for older individuals, to promote and maintain an individual's autonomy at home and to infer the individual's wellbeing based on relevant activities. Within this pilot theme there are multiple 'use cases' each deploying and evaluating different digital solutions in several European countries according to the type of support required. Four use cases will be used to evaluate this pilot theme. The project in this document describes the piloting of the use case led by gewi - Institut für Gesundheitswirtschaft e.V. and carried out in "Oberbergischer Kreis", Germany.

The use case of this project study focuses on older persons living in a nursing home and the caregivers working in these facilities. A high quality of life (QOL) of residents living in a nursing home is not only important for themselves but also for their families, providers and policy makers (2). It was shown that social contacts, security and a variety of stimuli constitute some of the central aspects of subjective quality of life (3). Yet, moving to a nursing home often results in diminishing contacts and a feeling of loneliness (4). Often this cannot be compensated by the caregivers due to the high workload. In the context of rising numbers of people in need of LTC and the foreseen nursing crisis there is a need for intervention that improve quality of life of residents and the working environment of caregivers simultaneously at best.

Digital solutions belonging to partners of the SHAPES consortium (the robot from Kompai and analytic software from Vicom) can become eHealth tools for supporting different situations in nursing homes. In the presented project, the main objective is to evaluate whether users engage with such a system and if it is useful for them (self-perceived usefulness).

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2. Hypothesis and objectives

Hypothesis: This study will test the hypothesis that the SHAPES digital solutions are capable of providing opportunities for supporting in reducing the workload of employees in nursing homes and create a feeling of safety for the residents.

Objectives

Primary objectives

- To investigate user engagement with the digital solutions (PO1).
- To investigate the user-perceived usefulness of the digital solutions (PO2).

Secondary objectives

- To investigate the capability of the digital solutions to support caregivers in nursing homes:
 - Night surveillance, UV disinfection, measurement of body temperature (SO1).
- To investigate the capability of the digital solutions to support residents in nursing homes:
 - Entertainment (games, announcements) (SO2a).
 - Feeling of safety during night (Night surveillance) (SO2b)
- To investigate the capability of the novel system to improve older individual's quality of life, wellbeing and psychological and psychosocial aspects (SO3).
- To explore user trust and acceptance of the novel system (SO4).

Tertiary objectives

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

- To validate the capability of the SHAPES Digital Solutions to support and extend healthy and independent living for older individuals (TO1).
- To validate the capability of the SHAPES Digital Solutions to improve the older individuals' health and wellbeing outcomes and quality of life (TO2).
- To validate the capability of the SHAPES Digital Solutions to gain the older individuals' trust and acceptance (TO3).
- To validate the capability of the SHAPES Digital Solutions to contribute for the reduction of the workload of the formal care givers (TO4).

Outcomes

In relation to at least one primary objective (related objectives in brackets):

- O1. Timestamps of login into the novel system (PO1).
- O2. Technology Acceptance Model (TAM) questionnaire (PO2, SO4, TO3)(5)
- O3. Short version of User Experience Questionnaire (UEQ-S) (PO2, SO4, TO3)(6).
- O4. Notes taken at an unstructured interview at the end of the use of the novel system (PO1, PO2, SO1, SO2a+b, TO4).

In relation to the secondary and tertiary objectives (related objectives in brackets):

- O5. The following questionnaires: WHOQOL-BREF (7), EQ-5D-5L(8), GSES(9), OSSS-3(10), SHAPES participation questions (SO3, TO1, TO2).
- O6. System Usability Scale (SUS) (SO4, TO3)(11).

In order to relate objectives to socio-demographics of app users:

- O7. Number of years of formal education; date of birth; 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.
- O8. SHAPES health literature measure.

In order to contact participants (data only kept at gewi Institut)

- O9. Name, telephone number, address

Table 1: Outcomes collected in the study. Novel system user is any participant who uses any component of the technology at any time. 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.

Outcome code	Outcome	Addressed to	Conducted by	Time of collection	Objective
O1	Use of features in novel systems	Novel system users	Automatic	I	PO1
O2	TAM	Novel system users	Self-complete	E	PO2, SO4, TO3
O3	UEQ – S	Novel system users	Self-complete	E	PO2, SO4, TO3
O4	Unstructured interview	Novel system users	Researcher	E	PO1, PO2, SO1, SO2, TO4
O5	WHOQOL-BREF, EQ-5D-5L, GSES, OSSS-3, SHAPES Participation Questionnaire	Older person	Self-complete	B, E, F	SO3, TO1, TO2
O6	SUS	Novel system users	Self-complete	E	SO4, TO3
O7	Socio-demographic data: Number of years of formal education; date of birth; gender; marital status; country.	Older person / Caregiver (App user)	Researcher	B	Socio-demographic analysis
O7, O8	Socio-demographic data: marital status; occupational status; caregiver status; help from family; professional help, neighbourhood environment; residence type; co-living with someone Literature measure	Older person / Caregiver (App user)	Researcher	B, E, F	Socio-demographic analysis
O9	Contact details	Novel system user	Researcher	R	Contact

References

Outcomes which are not referenced have been designed in the project definition of the use case.

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9. The General Self [Internet]. [zitiert 19. Mai 2022]. Verfügbar unter: <http://userpage.fu-berlin.de/~health/engscal.htm>
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3. Methodology: Materials and methods

Study design: non-randomised, single-armed, cross-sectional interventional pilot study with an optional qualitative interview component. Period of intervention: 1 months.

Participants - Target users: people older than 65 years living in a nursing home. *Eligibility:* 1) person aged 65 years old or older at the time of recruitment; 2) living in the OBK in a nursing home; 3) self-reported capacity to consent

Sample size: 1 nursing home. These sample size was selected pragmatically to be as representative as possible within the scope of resources available.

Materials

CE-marked devices: Kompai robot.

Other software: Excel, Libreoffice; Questionnaires: Those listed in outcomes.

Methods: Recruitment of older persons and caregivers

Recruitment activities: Several actions will be displayed to draw attention to the project. These entail displaying articles in regional newspapers, using mailing lists and contacting relevant gatekeeper from the network by applying face to face recruitment.

Screening: Interested nursing homes can make contact via mail, letter or phone. A first screening of the responses will be performed for potentially eligible participants.

Invitation: First communication about the pilot will be conducted via phone from the research team to present all relevant information and answer questions from the potential participants.

Information sheets: Information sheets and consent forms will be sent out to eligible participants in case they still show interest.

Methods: Informed consent (all types of participants): Informed consent (duplicate) will be obtained in-person or remotely with the following format of signatures collected where appropriate: handwritten; typewritten; scanned; an electronic representation of a handwritten signature. The principal investigator of this study will countersigned both documents and one will be delivered to the participants as acknowledgment of reception.

Methods: Test in a controlled environment: Pre-study testing will take place in the premises of the gewi institute. This testing phase will last until the start of the pilot and is considered out of pragmatical reasons. Transportation of the robot and potential damage to the material will be avoided this way.

Methods: Baseline procedures: Within four weeks before start of the pilot the pre-deployment procedure will start in the nursing home. This procedure includes a power point presentation of the robot and its functionalities, a Q&A for the employees and residents, a workshop with the robot and the deployment with training session.

Methods: Intervention procedures

All participants: On the first day, the robot will be set up in the target environment. A researcher will be present for the day to provide further training sessions for the employees. All participants will be encouraged to contact the researcher for any technical issue or doubt about the use of the novel system during the entire period of the pilot. If needed, additional training sessions will be provided by the researcher.

Methods: End of intervention (Within 14 days after the end of the intervention; For collected data, see Table 1): These data will be collected in face-to-face, one-to-one interviews or through forms to fill individually with the presence of a researcher for resolving doubts.

Methods: Follow-up study procedures (3-month follow-up, +/- 7days; For collected data, see Table 1): These data will be collected in face-to-face, one-to-one interviews or through forms to fill individually with the presence of a researcher for resolving doubts.

Protocol deviations: This pilot is examining the real-world use of the SHAPES app and associated devices. Therefore, if participants do not use the solution as requested,

this will not be documented as a protocol deviation, rather this will give insight into the usability of the solution. An interview (O6) will be done to find out reasons for the lack of engagement. They will not be penalised and will be analysed in terms of integration of the novel system into the current care pathway. If replacement is not possible, the study will only include analysis on older person/caregiver self-management.

Data management: Data processed in this pilot will be subject to the General Data Protection Regulation (GDPR) (679/2016) about personal data protection and warranties on digital rights, in agreement with the GDPR. gewi - Institut für Gesundheitswirtschaft e.V. will be the data controller for all data collected during this pilot. Data Processing Agreements will be put in place between gewi and each SHAPES partner who processes data (VICOMTECH, TREE TECHNOLOGY, National University of Ireland Maynooth). During data collection and intervention, data processing will be pseudonymised. In analysis period, data processed by partners will be de-identified.

The data collected for this study will be stored securely, and kept contemporaneous and accurate. If a participant withdraws from the study, clarification sought as to what data may need to be erased. This data will be identified and erased without delay. Personal data will be kept in a form that permits identification until October 2023. Personal data will be de-identified at the end of the SHAPES Innovation Action (Oct 2023), kept this way for five years and then aggregated (anonymisation). Anonymised aggregated data will be offered to the scientific community through the SHAPES consortium.

Personal data processing is described in the following project documents: Data Protection Impact Assessment, the Personal Data Processing Descriptions and the Risk Assessment.

Data analysis: Demographic characteristics will be summarised and reported to describe the sample population.

Quantitative and qualitative data analysis methods will be employed and findings reported. De-identified data pertaining to the tertiary outcomes that align with other pilots in the SHAPES pan-European piloting campaign (harmonised O5, O7 and O8 questionnaires and socio-demographic data) will be analysed by the SHAPES coordinators at National University Ireland Maynooth.

Statistical methods: Where appropriate, descriptive statistics will be reported for all quantitative data, the mean and standard deviation (SD) will be reported where data are approximately normally distributed, and the median and interquartile range (IQR) reported where data are non-normally distributed. Differences in outcomes measured at baseline and at the end-of-pilot will be compared using paired t-test or Wilcoxon Signed Rank test (or appropriate alternative), depending on the distribution of the data. Confidence intervals and effect size will be calculated and reported to provide an estimation of the size and direction of intervention effect.

Missing data: Every effort will be made to reduce the potential for missing data, however, if missing data occurs it will be coded as 999 (participant declined to answer), 998 (administration error or failure), 997 (equipment error or failure), 996 (unknown after human check), 995 (other reason) or empty *NULL* (unknown, automatic).

4. Workplan

Research team:

- ..., head of gewi - Institut für Gesundheitswirtschaft e.V.
- ..., scientific researcher at gewi - Institut für Gesundheitswirtschaft e.V.
- ..., project manager at gewi - Institut für Gesundheitswirtschaft e.V.
- National University Ireland Maynooth: Coordinator SHAPES project (Coord-SHAPES)

Technical team: for technical incidences, technical departments at Kompai, VICOMTECH and TREE TECHNOLOGY

Centre where the study is carried out: nursing home in the reference site. Researcher will be staff from gewi - Institut für Gesundheitswirtschaft e.V.

Sponsor: gewi - Institut für Gesundheitswirtschaft e.V.

Stages and tasks

1. Recruitment & collection of informed consent

Scheduled period: February-April 2022

Team members and tasks: Researcher at gewi - Institut für Gesundheitswirtschaft e.V. will be in charge of the recruitment process. They will confirm eligibility, will countersigned consent and deliver 1 consent form to participants.

2. Test in a controlled environment

Scheduled period: May/June 2022

Intervention time length: 1 month

Team members and tasks: Researcher will perform all testing activities. They will collect incidences, if any, and will communicate them to the technical team if necessary.

3. Pilot study

Scheduled period: September 2022

Intervention time length: 1 months

Baseline:

Team members and tasks: Researcher will carry out pre-deployment procedure in the nursing home.

Intervention period:

Team members and tasks: On the first day, the robot will be set up in the target environment. On the basis of an informal inhouse screening, the living area with the most interested residents and caregivers on new technologies will be identified. Only the users who gave their consent will be part of the study. They will be instructed regarding the use of the robot and the nature of the data to be collected.

The direct interaction with the robot relates to body temperature measurement that can be actively and freely decided by the residents. The entertainment function of the robot (announcing the menu, playing music) can be adapted to the situational needs of the residents. With respect to the (night) surveillance of the robot, an individual approach is planned in case of concerns or refusal to participate in the study by the residents. An open and step-by-step dialogue will take place in order to understand the residents' concerns and to have the chance to address them by mutual agreement. For example, predefined routes and times could be agreed upon and designated when the robot will be used for patrolling. The residents' decisions are always accepted and respected. If no agreement can be found with any resident, the study will be piloted in a different nursing home. Only users who provided their consent will be part of the study. They will be instructed regarding the use of the robot and the nature of the data to be collected. A researcher will be present on the first day to provide further training sessions and will be the reference contact point of users (only those who explicitly

accepted the consent form) for any technical issue or doubt and will contact the Technical Team if necessary.

End of intervention interview:

Team members and tasks: Researcher will carry out face-to-face, one-to-one interviews and collection of data in excel file.

Follow-up, 3 months after end of intervention (+/- 7days):

Team members and tasks: Researcher will carry out face-to-face, one-to-one interviews and collection of data in the excel file.

5. Data analysis

Scheduled period: October-November 2022

Team members and tasks: Researcher will perform statistical analysis. Data will be kept pseudonymised at gewi until October 2023. After this year, gewi will de-identify data and will be kept in this form for 5 years more, when individual data will be deleted and an anonymous, aggregated dataset will be stored indefinitely.

	Jan 2022	Feb 2022	Mar 2022	Apr 2022	May 2022	Jun 2022	Jul 2022	Aug 2022	Sep 2022	Oct 2022	Nov 2022	...	Oct 2023
Recruitment													
Test controlled environment					Conducted by researcher								
Study									Baseline → Intervention (1 months) → 3-month follow-up				
Data analysis										UC-PT2-004a			
SHAPES data analysis												De-identified data transferred to SHAPES platform	

5. Ethical considerations

Research ethics approval

Approval to conduct the pilot will be sought from a Research Ethics Committee (Ethik Kommission der Ärztekammer Nordrhein) before the start of the recruitment process. This protocol and all other relevant documents will be submitted. Prior to submission to the REC, this protocol will be reviewed and approved for submission by colleagues within the SHAPES consortium.

Protocol amendments

Any substantial amendments that require review by Ethik Kommission der Ärztekammer Nordrhein will not be implemented until the Ethik Kommission der Ärztekammer Nordrhein grants a favourable opinion for the trial, and all correspondence with the Ethik Kommission der Ärztekammer Nordrhein will be retained in the Trial Master File.

Consent

All participants will be asked to provide voluntary, informed consent for their participation in the pilot.

Access to data

gewi - Institut für Gesundheitswirtschaft e.V. will be the data controllers and as such will have access to the full dataset. Data Processing Agreements will be in place to facilitate the sharing of pseudonymised data with specific SHAPES partners for specific purposes during the undertaking of the pilot. For process of data regarding analysis Data Processing Agreements will be in place to facilitate the sharing of de-identified data. De-identified data will be offered to the scientific community through the SHAPES platform.

Ancillary and post-trial care

At the end of the pilot the robot provided to participants will be removed.

Dissemination policy

Any data that arise from the pilot study will be owned by the sponsor gewi - Institut für Gesundheitswirtschaft e.V. On completion of the study, all data will be analysed and tabulated and used to prepare a final report, available as one of the agreed deliverables of the SHAPES Innovation Action — Deliverable D6.3. 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 outcome of the study. gewi - Institut 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. gewi - Institut 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 will be in place to facilitate the sharing of pseudonymised or de-identified data with specific SHAPES partners for specific purposes. De-identified data will also be shared with the scientific community through the SHAPES platform.

Annex 28: Consent form Phase 5 UC-PT2-004a

Einwilligungserklärung

SHAPES Pan-Europäische Pilotkampagne: Unterstützung durch einen Pflegeroboter im Pflegeheim. Eine nicht-randomisierte Machbarkeitsstudie in der realen Welt zur Bewertung der Benutzerfreundlichkeit und des von den Benutzern:innen wahrgenommenen Nutzens

Sehr geehrte Mitarbeitende des Hauses obere Hengsbach,
wir möchten Sie fragen, ob Sie an einer wissenschaftlichen Studie teilnehmen möchten.

Sie haben Interesse an neuartiger Technik und würden gerne die Funktionen eines Pflegeroboters kennenlernen? Durch diese Studie soll erprobt werden, inwieweit ein Pflegeroboter ältere Menschen und das Personal in einem Pflegeheim unterstützen kann. Dabei werden die folgenden Ziele verfolgt:

- Unterhaltung der älteren Personen im Alltag
- Sicherheitsempfinden der älteren Personen in der Nacht
- Entlastung des Personals insbesondere in der Nacht

Dafür soll der folgende Roboter getestet werden:



Bisher hat es sich als schwierig erwiesen, neue digitale Lösungen im Bereich Pflege und Versorgung von älteren Menschen einzuführen. Verschiedene Hindernisse haben dazu geführt, dass ein großflächiger Einsatz nicht umsetzbar war. In dieser Studie sollen Sie als Anwender:in daher beteiligt werden und Ihre Einschätzung und Erlebnisse mit der neuen Technik werden als Hauptergebnisse ausgewertet.

Als Nebenziele soll geklärt werden, wie sich die neue Technik auf die Unterstützung und Unterhaltung älterer Menschen im Pflegeheim sowie die Akzeptanz und das Vertrauen in einen Pflegeroboter auswirken. Darüber hinaus wird untersucht, ob sich der Umgang mit dem Roboter auch auf das Wohlbefinden auswirkt. Als drittrangiges Ziel ist die Bewertung der Daten im Zusammenhang mit der Pilotkampagne SHAPES geplant. Dabei soll die Auswirkung

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von digitalen Lösungen auf ältere Menschen aus unterschiedlichen ländlichen und städtischen Regionen Europas bewertet werden.

Es wird ein Pflegeheim an der Studie in Deutschland teilnehmen.

Das gewi-Institut für Gesundheitswirtschaft e.V. übernimmt keine Haftung im Falle von auftretenden technischen Problemen oder Ausfällen und damit einhergehenden Folgen.

Die Studie soll insgesamt 2 Wochen dauern und im April 2023 starten. Am Ende der Studie sollen folgende Daten von Ihnen mittels Interviews und Fragebögen erfasst und ausgewertet werden:

Fragebögen/ Daten	Zeitpunkt
Frage zur Technologie Akzeptanz (TAM)	Ende der Studie (Mai 2023)
Anwender Erfahrungen (UEQ-S)	
Fragen zur System-Gebrauchlichkeit (SUS)	
Unstrukturiertes Interview zur Erfassung, inwieweit der Roboter zur Reduktion der Arbeitsbelastung beigetragen hat	

Vor Studienbeginn findet zum Kennenlernen und zur Schulung ein Seminar mit der Studienleitung statt. Ihnen werden alle Funktionen des Roboters erklärt und Sie erhalten ausreichend Zeit, sich mit der Technik vertraut zu machen und Fragen zu stellen.

Die Teilnahme an dieser Studie ist freiwillig. Sie werden nur dann einbezogen, wenn Sie dazu schriftlich Ihre Einwilligung erklären. Sofern Sie nicht an der Studie teilnehmen oder später aus ihr ausscheiden möchten, entstehen Ihnen dadurch keine Nachteile. Sie können jederzeit, auch ohne Angabe von Gründen, Ihre Einwilligung mündlich oder schriftlich widerrufen.

Die Studie wurde der zuständigen Ethikkommission vorgelegt. Sie hat keine Einwände erhoben.

Mögliche Risiken, Beschwerden und Begleiterscheinungen

Der tägliche Umgang mit dem Roboter ist mit keinen Risiken oder medizinischen Begleiterscheinungen verbunden. Mittels integrierter Sicherheitsmaßnahmen, wie einem Anti-Kollisionssensor werden Unfälle vermieden. Die ergänzende Datenerhebung über Fragebögen und Interviews ist lediglich mit einem Zeitaufwand von ca. 30 Minuten verbunden und erfordert für diese Zeit Ihre Aufmerksamkeit.

Möglicher Nutzen aus Ihrer Teilnahme an der Studie

Sie werden durch Ihre Teilnahme an dieser Studie keinen Nutzen für Ihre Gesundheit haben. Die Ergebnisse dieser Studie können dazu beitragen, wie Technologien eingesetzt werden können, um Menschen im Alter zu unterstützen und ihre Lebensqualität zu verbessern.

Datenschutz

- Rechtsgrundlage für die Datenverarbeitung ist Ihre freiwillige Einwilligung (Art. 6 Nr. 1 lit. a) DSGVO und Art. 9 Nr. 2 lit a) DSGVO).
- Der Verantwortliche für die Datenverarbeitung ist: gewi – Institut für Gesundheitswirtschaft e.V. (Karolingerring 31, 50678 Köln)

Ihre Daten werden zu jeder Zeit vertraulich behandelt. Während der unstrukturierten Interviews werden die wissenschaftlichen Mitarbeiter:innen Notizen machen und diese anschließend in digitaler Form aufbereiten. Alle Daten, die mittels der Interviews sowie der Fragebögen erfasst werden, werden in pseudonymisierter Form vom Initiator der Studie, gewi – Institut für Gesundheitswirtschaft e.V. (Karolingerring 31, 50678 Köln), sicher verwahrt. Die Daten werden wissenschaftlich ausgewertet und zur Ermittlung von Zusammenhängen zwischen einer Unterstützung des Roboters und des allgemeinen Wohlbefinden sowie auf die Steigerung des Gefühls der Sicherheit bei den Bewohnern:innen verwendet. Zugriff auf die personenbezogenen Daten haben nur zuständige Personen im jeweiligen Studienzentrum.

Pseudonymisieren bedeutet, dass keine Angaben, mit denen Sie direkt identifiziert werden können (z.B. Name, Kontaktinformationen, Geburtsdatum etc.) verwendet werden, sondern nur ein Nummern- und/oder Buchstabencode. Ihre Studienleitung erstellt eine Pseudonymisierungsliste, die im Studienzentrum gesondert aufbewahrt wird und dort technischen und organisatorischen Maßnahmen unterliegt, die gewährleisten, dass die personenbezogenen Daten Ihnen durch unbefugte Personen nicht zugeordnet werden können. Eine Entschlüsselung erfolgt nur in folgenden Situationen: in dem unwahrscheinlichen Fall, dass ein Angriff auf die IT-Systeme von SHAPES oder gewi-Institut ausgeübt wird, werden wir Sie persönlich kontaktieren.

Die Daten werden bis Oktober 2023 aufbewahrt. Sie sind gegen unbefugten Zugriff gesichert. Sie werden gelöscht, wenn sie nicht mehr benötigt werden, um die wissenschaftliche Auswertung und Analysen durchzuführen. Spätestens nach fünf Jahren nach Ende der Pan-europäischen Pilotkampagne werden sie gelöscht.

Sind mit der Datenverarbeitung Risiken verbunden?

Bei jeder Erhebung, Speicherung, Nutzung und Übermittlung von Daten bestehen Vertraulichkeitsrisiken (z.B. die Möglichkeit, die betreffende Person zu identifizieren). Diese Risiken lassen sich nicht völlig ausschließen und steigen, je mehr Daten miteinander verknüpft werden können. Der Initiator der Studie versichert Ihnen, alles nach dem Stand der Technik Mögliche zum Schutz Ihrer Privatsphäre zu tun und Daten nur an Stellen weiterzugeben, die ein geeignetes Datenschutzkonzept vorweisen können. Medizinische Risiken sind mit der Datenverarbeitung nicht verbunden.

Der Nummern- und/oder Buchstabencode (das Pseudonym) kann nur innerhalb der EU in den Studienzentren entschlüsselt werden, um die pseudonymisierten Daten Ihnen zuzuordnen (siehe oben). Es bestehen außerdem folgende Schutzmaßnahmen: verbindliche interne Datenschutzvorschriften gemäß Artikel 47 DSGVO und der Angemessenheitsbeschluss von der Europäischen Kommission. Sie können eine Kopie dieser Garantien erhalten und unter folgender Adresse abrufen:
https://ec.europa.eu/info/sites/default/files/file_import/data_protection_de_0.pdf

Können Sie Ihre Einwilligung widerrufen?

Sie können Ihre jeweilige Einwilligung jederzeit ohne Angabe von Gründen schriftlich oder mündlich widerrufen, ohne dass Ihnen daraus ein Nachteil entsteht. Wenn Sie Ihre Einwilligung widerrufen, werden keine weiteren Daten mehr erhoben. Die bis zum Widerruf erfolgte Datenverarbeitung bleibt jedoch rechtmäßig.

Sie können im Fall des Widerrufs auch die Löschung Ihrer Daten verlangen.

Welche weiteren Rechte haben Sie bezogen auf den Datenschutz?

Sie haben das Recht, vom Verantwortlichen Auskunft über die von Ihnen gespeicherten personenbezogenen Daten (einschließlich der kostenlosen Überlassung einer Kopie der Daten) zu verlangen. Ebenfalls können Sie die Berichtigung unzutreffender Daten sowie gegebenenfalls eine Übertragung der von Ihnen zur Verfügung gestellten Daten und die Einschränkung ihrer Verarbeitung verlangen.

Bitte wenden Sie sich im Regelfall an das Studienzentrum, denn allein das Studienzentrum kann aufgrund des Pseudonymisierungsprozesses vollumfänglich auf Ihre Daten zugreifen bzw. entsprechende Auskünfte geben. Der Initiator der Studie kann vor diesem Hintergrund nur sehr begrenzt helfen.

Bei Anliegen zur Datenverarbeitung und zur Einhaltung der datenschutzrechtlichen Anforderungen können Sie sich auch an folgende Datenschutzbeauftragte wenden:

- c) Datenschutzbeauftragter des Studienzentrums: ... (gewi – Institut für Gesundheitswirtschaft e.V., Karolingerring 31, 50678 Köln)

Sie haben ein Beschwerderecht bei jeder Aufsichtsbehörde für den Datenschutz. Eine Liste der Aufsichtsbehörden in Deutschland finden Sie unter:

https://www.bfdi.bund.de/DE/Infothek/Anschriften_Links/anschriften_links-node.html

Zuständige Beauftragte für das Land Nordrhein-Westfalen:

Frau Bettina Gayk

Postfach 20 04 44, 40102 Düsseldorf

Tel.: 0211 384 240

E-Mail: poststelle@ldi.nrw.de

Ansprechpartner:innen für Fragen zur Studie

Wenn Sie Fragen zu dieser Studie haben, wenden Sie sich bitte an:

gewi – Institut für Gesundheitswirtschaft e.V

...

Karolingerring 31, 50678 Köln

ODER

Studienarzt

Dr. med Christian Franchy

Facharzt für Innere und Allgemeinmedizin

Hämostaseologie

Ernährungsmedizin DGEM

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Einwilligungserklärung

SHAPES Pan-Europäische Pilotkampagne: Unterstützung durch einen Pflegeroboter im Pflegeheim. Eine nicht-randomisierte Machbarkeitsstudie in der realen Welt zur Bewertung der Benutzerfreundlichkeit und des von den Benutzern:innen wahrgenommenen Nutzens.

Name des/der Teilnehmers:in in Druckbuchstaben:

Einrichtungsleitung:.....

Pflegedienstleitung:.....

Ich bin von Herrn / Frau (Studienleitung), ... , über Wesen, Bedeutung und Tragweite der Studie sowie die sich für mich daraus ergebenden Anforderungen aufgeklärt worden. Ich habe darüber hinaus den Text des Informationsblattes und dieser Einwilligungserklärung gelesen.

- Ich hatte ausreichend Zeit, Fragen zu stellen und mich zu entscheiden. Aufgetretene Fragen wurden mir vom Studienleitung beantwortet.
- Ich weiß, dass ich meine freiwillige Mitwirkung jederzeit beenden kann, ohne dass mir daraus Nachteile entstehen.

Ich erkläre mich bereit, an der Studie teilzunehmen.

1. Ich willige ein, dass personenbezogene Daten über mich, insbesondere soziodemographische (s. Tabelle auf S.3), wie in der Informationsblatt beschrieben, erhoben und in Papierform sowie auf elektronischen Datenträgern bei dem gewi- Institut für Gesundheitswirtschaft e.V. aufgezeichnet werden.

Soweit erforderlich, dürfen die erhobenen Daten pseudonymisiert (verschlüsselt) weitergegeben werden:

- c) im Falle unerwünschter Ereignisse: an die jeweils zuständige Ethik-Kommission und zuständigen Behörden sowie von dieser an die Europäische Datenbank.**

2. Ich bin darüber aufgeklärt worden, dass ich meine Einwilligung jederzeit widerrufen kann. Im Falle des Widerrufs werden keine weiteren Daten mehr erhoben. Ich kann in diesem Fall die Löschung der Daten verlangen.

3. Ich willige ein, dass die Daten nach Beendigung oder Abbruch der klinischen Prüfung mindestens 5 Jahre aufbewahrt werden.

Ich willige in die Verarbeitung der genannten Daten ein.

Ein Exemplar des Informationsblatts und der Einwilligungserklärung habe ich erhalten. Ein Exemplar verbleibt im Prüfbüro.

Unterschrift des Teilnehmers/der Teilnehmerin

Einrichtungsleitung:

(Name und Vorname in Druckschrift)

(Datum)

(Unterschrift)

Pflegedienstleitung:

(Name und Vorname in Druckschrift)

(Datum)

(Unterschrift)

Annex 29: Information sheet Phase 5 UC-PT2-004a

INFORMATIONSBLETT FÜR PFLEGEFACHKRÄFTE

Titel der Studie: SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) Pan-Europäische Pilotkampagne: Unterstützung durch einen Pflegeroboter im Pflegeheim. Eine nicht-randomisierte Machbarkeitsstudie in der realen Welt zur Bewertung der Benutzerfreundlichkeit und des von den Benutzern:innen wahrgenommenen Nutzens.

Entwickler/ Sponsor: gewi – Institut für Gesundheitswirtschaft e.V.
Studienleitung (Deutschland): ...

Sehr geehrte Pflegefachkraft,

Mit diesem Dokument möchten wir Sie über eine Studie informieren, an der Sie teilnehmen können. Die Ethik-Kommission hat das Forschungsvorhaben gemäß § 15 der Berufsordnung für die nordrheinischen Ärztinnen und Ärzte beraten und wird gegebenenfalls keine berufsethischen oder berufsrechtlichen Bedenken erheben. Die Studie ist in Übereinstimmung mit den Grundsätzen der Deklaration von Helsinki und den Standards der guten klinischen Praxis.

Wir möchten lediglich, dass Sie korrekte und ausreichende Informationen erhalten, damit Sie beurteilen können, ob Sie teilnehmen möchten oder nicht. Bitte lesen Sie daher dieses Informationsblatt sorgfältig durch, und wir werden etwaige Fragen nach der Erläuterung klären. Außerdem können Sie sich mit Personen beraten, die Sie für geeignet halten. Wenn Sie Fragen haben, wenden Sie sich bitte an ... (Studienleitung) unter den am Anfang dieses Dokumentes angegebenen Kontaktdaten.

Allgemeine Beschreibung

In der Studie, an der Sie teilnehmen können, geht es um den Einsatz eines Pflegeroboters in den öffentlichen Räumlichkeiten Ihres Pflegeheims. Der SHAPES-Roboter wird von Ihnen als Pflegefachkraft bedient und hat unterschiedliche Funktionen. Insbesondere kann er in der Nacht auf den Fluren umherfahren und im Falle eines Sturzes eines/r Bewohners:in, dabei helfen, schnell Hilfe anzufordern. Dies soll den Bewohnenden ein höheres Sicherheitsempfinden vermitteln und auch eine Unterstützung für Sie als Pflegefachkraft bieten. Der Roboter wurde speziell für den Einsatz in Pflegeheimen entwickelt. Das gewi-Institut für Gesundheitswirtschaft e.V. übernimmt keine Haftung im Falle von auftretenden technischen Problemen oder Ausfällen und damit einhergehenden Folgen. Das Hauptziel der Studie besteht darin, zu beurteilen, ob der Roboter einfach anwendbar und von Ihnen als nützlich empfunden wird.

Der Roboter kann am Tage auch für die Körpertemperaturmessung, die Raum-Desinfektion und zur allgemeinen Unterhaltung eingesetzt werden. Im Rahmen der Studie wird empfohlen, den Roboter täglich zu nutzen, ohne jedoch dass Sie dazu verpflichtet sind.

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Am Ende der Studie wird mittels Fragebögen die Benutzerfreundlichkeit, der Nutzen und die Akzeptanz des Roboters bewertet. Dazu werden Sie als Pflegefachkraft wie auch die Bewohnenden des Pflegeheims befragt werden. Weitere drei Monate nach Beendigung der Studie wird eine Nachbefragung durchgeführt.

Anzahl der Teilnehmer:innen und Dauer: Ziel der Studie ist es, ein Pflegeheim zu rekrutieren. Der Roboter wird in den Räumlichkeiten installiert und über einen Zeitraum von zwei Wochen bewertet.

Zu Beginn der Studie erhalten Sie von der Studienleitung eine Schulung und Empfehlungen zur Verwendung des Roboters. Die Einhaltung ist jedoch nicht verpflichtend, da das Ziel der Studie darin besteht, die Bewertung im tatsächlichen Alltag zu erproben. Die Empfehlung für Sie lautet:

- Nutzen Sie den Roboter täglich.

Andere relevante Informationen

Alle neuen Informationen, über den Roboter, die sich auf Ihre Bereitschaft zur Teilnahme auswirken könnten und die während Ihrer Teilnahme bekannt werden, werden Ihnen von der Studienleitung so schnell wie möglich mitgeteilt.

Wenn Sie sich entscheiden, Ihre Zustimmung zur Teilnahme an dieser Studie zurückzuziehen, können Sie verlangen, dass alle Ihre Daten gelöscht werden, sofern sie nicht anonymisiert wurden.

Es wird hiermit auch darüber aufgeklärt, dass Sie von der Studie ausgeschlossen werden können, sollte die Studienleitung dies für angemessen halten. Sei es aus Sicherheitsgründen, wie bspw. Auftreten eines unerwünschten Ereignisses oder weil die festgelegten Verfahren nicht eingehalten wurden. In jedem Fall würden Sie eine angemessene Begründung erhalten.

Mit Ihrer Unterschrift auf der beigefügten Einverständniserklärung erklären Sie sich bereit, die Ihnen erläuterten Studienabläufe einzuhalten.

Vorteile und Risiken, die sich aus Ihrer Teilnahme an der Studie ergeben

Auf individueller Ebene bringt die Teilnahme an dieser Studie keinen direkten Nutzen, abgesehen von dem persönlichen Interesse und der Erfahrung durch die Teilnahme an einer Forschungsstudie. Obwohl das Ziel von SHAPES letztlich darin besteht, die Lebensqualität älterer Menschen zu verbessern, und die Studie Daten sammelt, um eine Bewertung in dieser Hinsicht vorzunehmen, besteht das Hauptziel der Studie darin, die Akzeptanz des Roboters bei den Teilnehmern:innen zu bewerten.

Vertraulichkeit

Verantwortlich für die Durchführung der Studie und die Datenübermittlung: *gewi- Institut für Gesundheitswirtschaft e.V., ..., Karolingerring 31, 50678 Köln.*

Zweck der Datenerhebung: Untersuchung der Anwenderbeteiligung und der Nützlichkeit des SHAPES-Roboters; Untersuchung der Zusammenhänge zwischen einer Unterstützung des Roboters und der Reduktion der Arbeitsbelastung des Pflegepersonals sowie des allgemeinen Wohlbefindens; Überprüfung des potentiellen Einflusses des Roboters auf das Sicherheitsempfinden der Bewohnern:innen.

Empfänger der Daten: Neben dem gewi- Institut haben die folgenden Partner Zugang zu einem Teil der Daten:

- Pseudonymisierte Daten während der Studie (verbunden mit einem Code, wobei nur das gewi- Institut für Gesundheitswirtschaft e.V. diesen Code mit den identifizierenden Daten in Verbindung bringen kann).
- De-identifizierbare Daten (kein zugehöriger Code)
 - o Kompai:
 - Kontakt: 97 Allée Théodore Monod 64210 Bidart (Frankreich) Tel. +33607538608
 - o Vicom: Bereitstellung des Sprachassistenten und Analyse der Daten
 - Kontakt: Parque Científico y Tecnológico de Gipuzkoa, Paseo Mikeletegi 57, 20009 Donostia / San Sebastián (Spanien) Tel. +34 943 30 92 30
 - o TREE TECHNOLOGY SA: Analyse der Bildvektoren für die Sturzerkennung
 - Kontakt: Camino de las Huertas 18, planta 1, 28223 Pozuelo de Alarcón, Madrid (Espanya) Tel. +34 902 286 386 · +34 910 059 088.
 - o SHAPES Konsortium: standardisierte Fragebögen (werden am Anfang und Ende der Studie durchgeführt) und soziodemographische Daten. Das gewi Institut arbeitet mit dem europäischen SHAPE Konsortium zusammen, um digitale Hilfsmittel für ältere Menschen zu erforschen.
 - Koordinator: National University Ireland, Maynooth, Co. Kildare, Ireland, shapes.info@mu.ie

Maximale Dauer der Datenspeicherung: nach Abschluss des SHAPES-Projektes (Oktober 2023) werden die de-identifizierbaren Daten für 5 Jahre im gewi-Institut aufbewahrt. Nach Ablauf dieser Frist werden sie in anonymer und aggregierter Form aufbewahrt. Im Falle von standardisierten Fragebögen werden die Daten anonym gespeichert und in aggregierter Form auf der SHAPES Plattform für wissenschaftliche Zwecke verfügbar sein.

Die Verarbeitung, Übermittlung und Überlassung der personenbezogenen Daten aller teilnehmenden Personen erfolgt in Übereinstimmung mit den Bestimmungen der Datenschutzvorschriften gemäß Artikel 47 DSGVO und des Angemessenheitsbeschlusses von der Europäischen Kommission.

Gemäß den oben genannten Rechtsvorschriften können Sie Ihr Recht auf Auskunft, Berichtigung, Löschung, Widerspruch, Einschränkung der Datenverarbeitung und sogar auf Übermittlung Ihrer Daten an einen befugten Dritten (Übertragbarkeit) ausüben; dazu müssen Sie sich an die für die Verarbeitung verantwortliche Hauptprüferin (Studienleitung: s. Beginn des Dokuments) wenden.

Ihre Daten werden elektronisch verarbeitet und in ein automatisiertes System personenbezogener Daten aufgenommen, das alle Sicherheitsmaßnahmen für einen

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beschränkten Zugang zu dem in diesem Dokument beschriebenen Zweck erfüllt.

Gewährleistung der Vertraulichkeit der erhaltenen Informationen.

- 7) Kodierung und Pseudonymisierung: Während der Studie werden Ihre Daten durch einen Code identifiziert, und nur die Studienleitung und Mitarbeiter:innen des gewi-Instituts können diese Daten mit Ihnen in Verbindung bringen. Daher wird Ihre Identität niemandem bekannt gegeben, es sei denn, es besteht eine gesetzliche Verpflichtung.
- 8) De-Identifizierung: Im Oktober 2023 wird die Codierung von Ihren Daten getrennt.
- 9) Anonymisierung: Ab Oktober 2023 werden Ihre Daten aggregiert und unwiderruflich von Ihren persönlichen Daten getrennt, so dass es unmöglich sein wird, zu einem späteren Zeitpunkt einen Zusammenhang festzustellen.

Es werden nur die für die Durchführung der Studie erforderlichen Daten an Dritte und an andere Länder weitergegeben. Es werden in keinem Fall Informationen enthalten sein, die Sie direkt identifizieren könnten, wie Vor- und Nachname, Initialen, Adresse usw. Sollte diese Weitergabe erfolgen, so geschieht dies zu gleichen Zwecken wie die oben beschriebene Studie, wobei die Vertraulichkeit mindestens auf dem Niveau des geltenden Rechts gewährleistet ist.

Der Zugang zu Ihren persönlichen Daten (persönliche gesundheitsbezogenen Daten, die jedoch nicht identifizierbar sind) ist auf die Mitarbeiter:innen des gewi-Instituts beschränkt. Dies erfolgt jedoch nur bei Erfordernis und wenn die Berechtigung vorliegt. In jedem Fall bleibt die Vertraulichkeit gemäß den geltenden Rechtsvorschriften gewahrt. Sie können sich immer an die deutsche Datenschutzbehörde wenden, wenn Sie sich über die Verarbeitung Ihrer persönlichen Daten beschweren möchten.

Wirtschaftlicher Ausgleich

Für Ihre Teilnahme an der Studie entstehen Ihnen keine Kosten, außer der Nutzung Ihres Internets. Für die Teilnahme an dieser Studie erhalten Sie keine Vergütung.

Freiwillige Teilnahme

Sie sollten wissen, dass Ihre Teilnahme an dieser Studie freiwillig ist und dass Sie sich jederzeit gegen eine Teilnahme entscheiden oder Ihre Entscheidung ändern und Ihre Zustimmung zurückziehen können, ohne irgendeine Erklärung abzugeben. Sie können die Löschung der Daten verlangen, sofern diese nicht anonymisiert wurden.

Danksagung

Wie auch immer Ihre Entscheidung ausfällt, sowohl der Projektträger als auch das Forschungsteam möchten Ihnen für Ihre Zeit und Aufmerksamkeit danken. Sie tragen zu einem besseren Verständnis von Zusammenhängen zwischen der Nutzung eines Pflegeroboters, einem potentiellen Einfluss auf die Unterstützung von Bewohnern:innen und die Arbeitsbelastung des Pflegepersonals im Pflegeheim und dem allgemeinen Wohlbefinden

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bei, wovon viele Menschen in Zukunft profitieren können.

Annex 30: Study protocol phase 5 UC-PT2-004b

Smart and Healthy Ageing through People Engaging in Supportive Systems (SHAPES) Night Surveillance Rounds in the Home-Setting. A non-randomized, feasibility study in real world for the evaluation of user engagement and user-perceived usefulness. (UC-PT2-004b-GEWI)



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Summary

The intervention being piloted in this study is a novel system of supporting older individuals (>65 years old) living at home by themselves. This pilot is a feasibility study in order to have a first evaluation of the engagement and user-perceived usefulness of the novel system, which is a robot, in a real-world environment. The project is designed as a non-randomised, single-armed, cross-sectional interventional pilot study with an optional qualitative interview component. This project is undertaken within the European project SHAPES (www.shapes2020.eu), which evaluates several digital solutions addressed to older individuals. Data collected in this project will be anonymised and shared with SHAPES consortium for a pan-European evaluation of digital solutions.

The target group in this study is composed of +65 year old individuals living in their home-setting in the reference site “Oberbergischer Kreis” in Germany. Participants will use the robot in their home environment and interact with it on daily basis. They will receive a presentation and training session on how to use the robot. Participants will be encouraged to start the robot every day/night and use as many functions as possible. The robot will be a big support especially during the night in case of an emergency, like a fall. It will inform a caregiver about the situation by email then. Overall the aim is to improve quality of life and wellbeing by reducing loneliness and boredom, both for older people and the informal caregivers.

6. Introduction

People who are aged 65 years and older account for almost a fifth of the population of the European Union. The number of people in this age group is projected to reach 151 million in 2060¹. Conversely, the proportion of EU citizens who describe themselves as being in ‘good’ or ‘very good’ health is falling and varies considerably between member states (ranges between 43.4% and 83.8%).

As age increases, however, so does the prevalence of people living with long term conditions as well and subsequently more people will be in need of long-term care. The analysis of the “2021 Long-term care report” even estimate a rising number of people potentially in need of long-term care (LTC) from 30.8 million in 2019 to 38.1 million in 2050 (1). Expenditures for LTC in the EU are projected to increase from 1.7% of GDP in 2019 to 2.5% of GDP in 2050 and are thus among the fastest rising social expenditures. Besides that the existing problems in LTC like poor working conditions, stressful working environments and working unlimited hours were just exacerbated by the Covid-19 pandemic (1). In order to face rising care demands and healthcare expenditures, in western countries a lot of the care work is performed by informal caregivers. This and also the fact that the majority of the care receiving older people prefer to stay in their own home and known environment, is reflected in an increased burden of those informal caregivers, which is reflected by worsening of carers’ physical and mental health (1).

One way to react on this could be the use of new technologies, that offer support for both sides: the care receiver and the caregiver. With the right eHealth technology (that are user-friendly and empowering), changes in the caregivers workload and care-receivers quality of living can be potentially maintain on a moderate level early-on. Health literacy and individual involvement will be key elements in the successful introduction of eHealth into the health and social care system. Developments in ICT-based home care, including ways of monitoring wellbeing and providing a secure home environment, and key emerging technologies on robotics and sensors open up the concept of ‘Ambient Intelligence’ and offer the potential for different environments (i.e., at home, in the street, during transportation,) to embed intelligence that helps with everyday life. To date, initiatives to achieve traction in this area have been modest, with experiments involving advanced ICT services supporting health and care through small-scale, localised initiatives.

The Smart & Healthy Ageing through People Engaging in Supportive Systems (SHAPES) Innovation Action (www.shapes2020.eu), a European project in which gewi - Institut für Gesundheitswirtschaft e.V. is a member, intends to build, pilot and deploy a large-scale, EU-standardised open platform. The integration of a broad range of technological, organisational, clinical, educational and societal solutions seeks to facilitate long-term healthy and active ageing and the maintenance of a high-quality standard of life. Mediated by technology, in-home and local community environments interact with health and care networks contributing to the reduction of costs, hospitalisations and institutional care.

SHAPES intends to build an interoperable Platform integrating smart digital solutions to collect and analyse older individuals’ health, environmental and lifestyle information, identify their needs and provide personalised solutions that uphold the individuals’ data protection and trust. Standardisation, interoperability and scalability of the SHAPES Platform aims to increase efficiency gains in health and care delivery across

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Europe, bringing improved quality of life to older individuals, their families, caregivers and care service providers. SHAPES large-scale piloting campaign will engage +2k older individuals in 15 pilot sites in 10 EU Member States, including six European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) Reference Sites, and involve hundreds of key stakeholders. SHAPES multidisciplinary approach to large-scale piloting is reflected across seven themes that, together, provide a clear understanding of the reality of European health and care systems and enable the validation of cost-efficient, interoperable and reliable innovations capable of effectively supporting healthy and independent living of older individuals within and outside the home. These seven themes are as follows:

- Pilot Theme 1: Smart Living Environment for Active Ageing at Home
- Pilot Theme 2: Improving In-Home and Community-based Care Services
- Pilot Theme 3: Medicine Control and Optimisation
- Pilot Theme 4: Psycho-social and Cognitive Stimulation Promoting Wellbeing
- Pilot Theme 5: Caring for Older Individuals with Neurodegenerative Diseases
- Pilot Theme 6: Physical Rehabilitation at Home
- Pilot Theme 7: Cross-border Health Data Exchange Supporting Mobility and Accessibility for Older Individuals

The Oberbergische Kreis in Germany is EIP on AHA (European Innovation Partnership on Active and Healthy Ageing) reference site for this pilot study. The gewi - Institut für Gesundheitswirtschaft e.V. is leading Pilot Theme 2 of the SHAPES pilot: 'Improving In-Home and Community-based Care Services', wherein the SHAPES platform and selected digital solutions will be used to provide an appropriate home setting and an person-aware environment for older individuals, to promote and maintain an individual's autonomy at home and to infer the individual's wellbeing based on relevant activities. Within this pilot theme there are multiple 'use cases' each deploying and evaluating different digital solutions in several European countries according to the type of support required. Four use cases will be used to evaluate this pilot theme. The project in this document describes the piloting of the use case led by gewi - Institut für Gesundheitswirtschaft e.V. and carried out in "Oberbergischer Kreis", Germany.

The use case of this project study focuses on older persons living at home and their informal caregivers. A high quality of life (QOL) of older care receiving person is not only important for themselves but also for their families, providers and policy makers (2). It was shown that social contacts and security and variety of stimuli represent some of the central aspects of subjective quality of life (3). Yet, being home alone and dependent on a caregiver often results in diminishing contacts and a feeling of loneliness (4). Often this cannot be compensated only by the caregivers due to the high workload. In the context of rising numbers of people in need of LTC and the foreseen nursing crisis there is a need for intervention that improve quality of life of residents and the working environment of caregivers simultaneously at best.

Digital solutions belonging to partners of the SHAPES consortium (the robot from Kompai and analytic software from Vicom) can become eHealth tools for supporting different situations in the described situation. In the presented project, the main objective is to evaluate whether users engage with such a system and if it is useful for them (self-perceived usefulness).

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8. Hypothesis and objectives

Hypothesis: This study will test the hypothesis that the SHAPES digital solutions are capable of providing opportunities for supporting older individuals living at home by themselves, especially during the night time.

Objectives

Primary objectives

- To investigate user engagement with the digital solutions (PO1).
- To investigate the user-perceived usefulness of the digital solutions (PO2).

Secondary objectives

- To investigate the capability of the digital solutions to support older individuals:
 - Night surveillance and walking assistance (SO1).
- To investigate the capability of the digital solutions to support older individuals:
 - Entertainment (games, reminders) (SO2).
- To investigate the capability of the novel system to improve older individual's quality of life, wellbeing and psychological and psychosocial aspects (SO3).
- To explore user trust and acceptance of the novel system (SO4).

Tertiary objectives

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

- To validate the capability of the SHAPES Digital Solutions to support and extend healthy and independent living for older individuals (TO1).
- To validate the capability of the SHAPES Digital Solutions to improve the older individuals' health and wellbeing outcomes and quality of life (TO2).
- To validate the capability of the SHAPES Digital Solutions to gain the older individuals' trust and acceptance (TO3).
- To validate the capability of the SHAPES Digital Solutions to contribute for the reduction of the workload of the informal care givers (TO4).

Outcomes

In relation to at least one primary objective (related objectives in brackets):

- O1. Timestamps of login into the novel system (PO1).
- O2. Technology Acceptance Model (TAM) questionnaire (PO2, SO4, TO3)(5)
- O3. Short version of User Experience Questionnaire (UEQ-S) (PO2, SO4, TO3)(6).
- O4. Notes taken at an unstructured interview at the end of the use of the novel system (PO1, PO2, S1, SO2, TO4).

In relation to the secondary and tertiary objectives (related objectives in brackets):

- O5. The following questionnaires: WHOQOL-BREF (7), EQ-5D-5L(8), GSES(9), OSSS-3(10), SHAPES participation questions (SO3, TO1, TO2).
- O6. System Usability Scale (SUS) (SO4, TO3)(11).

In order to relate objectives to socio-demographics of app users:

- O7. Number of years of formal education; date of birth; 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.
- O8. SHAPES health literature measure.
In order to contact participants (data only kept at gewi Institut)
- O9. Name, telephone number, address

Table 1: Outcomes collected in the study. Novel system user is any participant who uses any component of the technology at any time. 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.

Outcome code	Outcome	Addressed to	Conducted by	Time of collection	Objective
O1	Use of features in novel systems	Novel system users	Automatic	I	PO1
O2	TAM	Novel system users	Self-complete	E	PO2, SO4, TO3
O3	UEQ – S	Novel system users	Self-complete	E	PO2, SO4, TO3
O4	Unstructured interview	Novel system users	Researcher	E	PO1, PO2, SO1, SO2, TO4
O5	WHOQOL-BREF, EQ-5D-5L, GSES, OSSS-3, SHAPES Participation Questionnaire	Older person	Self-complete	B, E, F	SO3, TO1, TO2
O6	SUS	Novel system users	Self-complete	E	SO4, TO3
O7	Socio-demographic data: Number of years of formal education; date of birth; gender; marital status; country.	Older person	Researcher	B	Socio-demographic analysis
O7, O8	Socio-demographic data: marital status; occupational status; caregiver status; help from family; professional help, neighbourhood environment; residence type; co-living with someone Literature measure	Older person	Researcher	B, E, F	Socio-demographic analysis
O9	Contact details	Novel system user	Researcher	R	Contact

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Outcomes which are not referenced have been designed in the project definition of the use case.

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9. Methodology: Materials and methods

Study design: non-randomised, single-armed, cross-sectional interventional pilot study with an optional qualitative interview component. Period of intervention: 1 months.

Participants - Target users: people older than 65 years living at home by themselves. *Eligibility:* 1) person aged 65 years old or older at the time of recruitment; 2) living in the OBK; 3) self-reported capacity to consent

Sample size: 1 participant. These sample size was selected pragmatically to be as representative as possible within the scope of resources available.

Materials

CE-marked devices: Kompai robot.

Other software: Excel, Libreoffice; Questionnaires: Those listed in outcomes.

Methods: Recruitment of older persons and caregivers

Recruitment activities: Several actions will be displayed to draw attention to the project. These entail displaying articles in regional newspapers, using mailing lists and contacting relevant gatekeeper from the network by applying face to face recruitment.

Screening: Interested participants can make contact via mail, letter or phone. A first screening of the responses will be performed for potentially eligible participants. As interested participants actively contact the research team, no consent of contact will be provided.

Invitation: First communication about the pilot will be conducted via phone from the research team to present all relevant information and answer questions from the potential participants.

Information sheets: Information sheets and consent forms will be sent out to eligible participants in case they still show interest.

Methods: Informed consent (all types of participants): Informed consent (duplicate) will be obtained in-person or remotely with the following format of signatures collected where appropriate: handwritten; typewritten; scanned; an electronic representation of a handwritten signature. The principal investigator of this study will countersigned both documents and one will be delivered to the participants as acknowledgment of reception.

Methods: Test in a controlled environment: Pre-study testing will take place in the premises of the gewi institute. This testing phase will last until the start of the pilot and is considered out of pragmatical reasons. Transportation of the robot and potential damage to the material will be avoided this way.

Methods: Baseline procedures: Within one week before start of the pilot the pre-deployment procedure will start in the participants home. This procedure includes a power point presentation of the robot and its functionalities, a Q&A, a workshop with the robot and the deployment with training session.

Methods: Intervention procedures

All participants: On the first day, the robot will be set up in the target environment. A researcher will be present for the day to provide further training sessions. The participant will be encouraged to contact the researcher for any technical issue or doubt about the use of the novel system during the entire period of the pilot. If needed, additional training sessions will be provided by the researcher.

Methods: End of intervention (Within 14 days after the end of the intervention; For collected data, see Table 1): These data will be collected in face-to-face, one-to-one interviews or through forms to fill individually with the presence of a researcher for resolving doubts.

Methods: Follow-up study procedures (3-month follow-up, +/- 7days; For collected data, see Table 1): These data will be collected in face-to-face, one-to-one interviews or through forms to fill individually with the presence of a researcher for resolving doubts.

Protocol deviations: This pilot is examining the real-world use of the SHAPES app and associated devices. Therefore, if participants do not use the solution as requested, this will not be documented as a protocol deviation, rather this will give insight into the usability of the solution. An interview (O4) will be done to find out reasons for the lack of engagement. They will not be penalised and will be analysed in terms of integration of the novel system into the current care pathway. If replacement is not possible, the study will only include analysis on older person/caregiver self-management.

Data management: Data processed in this pilot will be subject to the General Data Protection Regulation (GDPR) (679/2016) about personal data protection and warranties on digital rights, in agreement with the GDPR. gewi - Institut für Gesundheitswirtschaft e.V. will be the data controller for all data collected during this pilot. Data Processing Agreements will be put in place between gewi and each SHAPES partner who processes data (VICOMTECH, TREE TECHNOLOGY, National University of Ireland Maynooth). During data collection and intervention, data processing will be pseudonymised. In analysis period, data processed by partners will be de-identified.

The data collected for this study will be stored securely, and kept contemporaneous and accurate. If a participant withdraws from the study, clarification sought as to what data may need to be erased. This data will be identified and erased without delay. Personal data will be kept in a form that permits identification until October 2023. Personal data will be de-identified at the end of the SHAPES Innovation Action (Oct 2023), kept this way for five years and then aggregated (anonymisation). Anonymised aggregated data will be offered to the scientific community through the SHAPES consortium.

Personal data processing is described in the following project documents: Data Protection Impact Assessment, the Personal Data Processing Descriptions and the Risk Assessment.

Data analysis: Demographic characteristics will be summarised and reported to describe the sample population.

Quantitative and qualitative data analysis methods will be employed and findings reported. De-identified data pertaining to the tertiary outcomes that align with other pilots in the SHAPES pan-European piloting campaign (harmonised O5, O7 and O8 questionnaires and socio-demographic data) will be analysed by the SHAPES coordinators at National University Ireland Maynooth.

Statistical methods: Where appropriate, descriptive statistics will be reported for all quantitative data, the mean and standard deviation (SD) will be reported where data are approximately normally distributed, and the median and interquartile range (IQR) reported where data are non-normally distributed. Differences in outcomes measured at baseline and at the end-of-pilot will be compared using paired t-test or Wilcoxon Signed Rank test (or appropriate alternative), depending on the distribution of the data. Confidence intervals and effect size will be calculated and reported to provide an estimation of the size and direction of intervention effect.

Missing data: Every effort will be made to reduce the potential for missing data, however, if missing data occurs it will be coded as 999 (participant declined to answer), 998 (administration error or failure), 997 (equipment error or failure), 996 (unknown after human check), 995 (other reason) or empty *NULL* (unknown, automatic).

10. Workplan

Research team:

- ..., head of gewi - Institut für Gesundheitswirtschaft e.V.
- ..., scientific researcher at gewi - Institut für Gesundheitswirtschaft e.V.
- ..., project manager at gewi - Institut für Gesundheitswirtschaft e.V.

- National University Ireland Maynooth: Coordinator SHAPES project (Coord-SHAPES)

Technical team: for technical incidences, technical departments at Kompai, VICOMTECH and TREE TECHNOLOGY

Sponsor: gewi - Institut für Gesundheitswirtschaft e.V.

Stages and tasks

1. Recruitment & collection of informed consent

Scheduled period: February-April 2022

Team members and tasks: Researcher at gewi - Institut für Gesundheitswirtschaft e.V. will be in charge of the recruitment process. They will confirm eligibility, will countersigned consent and deliver 1 consent form to participants.

2. Test in a controlled environment

Scheduled period: May 2022

Intervention time length: 1 month

Team members and tasks: Researcher will perform all testing activities. They will collect incidences, if any, and will communicate them to the technical team if necessary.

3. Pilot study

Scheduled period: September 2022

Intervention time length: 1 months

Baseline:

Team members and tasks: Researcher will carry out pre-deployment procedure in the participants home.

Intervention period:

Team members and tasks: On the first day, the robot will be set up in the target environment. A researcher will be present for the day to provide further training sessions and will be the reference contact point of participants for any technical issue or doubt and will contact the Technical Team if necessary.

End of intervention interview:

Team members and tasks: Researcher will carry out face-to-face, one-to-one interviews and collection of data in excel file.

Follow-up, 3 months after end of intervention (+/- 7days):

Team members and tasks: Researcher will carry out face-to-face, one-to-one interviews and collection of data in the excel file.

5. Data analysis

Scheduled period: November-December 2022

Team members and tasks: Researcher will perform statistical analysis. Data will be kept pseudonymised at gewi until October 2023. After this year, gewi will de-identify data and will be kept in this form for 5 years more, when individual data will be deleted and an anonymous, aggregated dataset will be stored indefinitely.

	Feb 2022	Mar 2022	Apr 2022	May 2022	Jun 2022	Jul 2022	Aug 2022	Sep 2022	Oct 2022	Nov 2022	Dec 2022	• • •	Oct 2023
Recruitment													
Test controlled environment				Conducted by researcher									
Study								Baseline → Intervention (1 months) → 3-month follow-up					
Data analysis										UC-PT2-004b			
SHAPES data analysis											De-identified data transferred to SHAPES platform		

11. Ethical considerations

Research ethics approval

Approval to conduct the pilot will be sought from a Research Ethics Committee (Ethik Kommission der Ärztekammer Nordrhein) before the start of the recruitment process. This protocol and all other relevant documents will be submitted. Prior to submission to the REC, this protocol will be reviewed and approved for submission by colleagues within the SHAPES consortium.

Protocol amendments

Any substantial amendments that require review by Ethik Kommission der Ärztekammer Nordrhein will not be implemented until the Ethik Kommission der Ärztekammer Nordrhein grants a favourable opinion for the trial, and all correspondence with the Ethik Kommission der Ärztekammer Nordrhein will be retained in the Trial Master File

Consent

All participants will be asked to provide voluntary, informed consent for their participation in the pilot.

Access to data

gewi - Institut für Gesundheitswirtschaft e.V. will be the data controllers and as such will have access to the full dataset. Data Processing Agreements will be in place to facilitate the sharing of pseudonymised data with specific SHAPES partners for specific purposes during the undertaking of the pilot. For process of data regarding analysis Data Processing Agreements will be in place to facilitate the sharing of de-identified data. De-identified data will be offered to the scientific community through the SHAPES platform.

Ancillary and post-trial care

At the end of the pilot the robot provided to participants will be removed.

Dissemination policy

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159



Any data that arise from the pilot study will be owned by the sponsor gewi - Institut für Gesundheitswirtschaft e.V. On completion of the study, all data will be analysed and tabulated and used to prepare a final report, available as one of the agreed deliverables of the SHAPES Innovation Action — Deliverable D6.3. 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 outcome of the study. gewi - Institut 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. gewi - Institut 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 will be in place to facilitate the sharing of pseudonymised or de-identified data with specific SHAPES partners for specific purposes. De-identified data will also be shared with the scientific community through the SHAPES platform.