SHAPES

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

D6.8 – Cross-border Health Data Exchange Supporting Mobility and Accessibility for Older Individuals - Pilot Activities Report

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Revision History

Table A. Revision History

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0.1	28.09.2020	Sonja Grigoleit (FhG)	ToC
0.2	07.06.2023	Fotios Gioulekas (5YPE)	PT7-001, PT7-002, PT7-003 contents, Assessment of Elder people about their digital literacy
0.3	15.06.2023	Fotios Gioulekas, Konstantinos Gounaris (5YPE)	Content Updates PT7-001, PT7-002, PT7-003 and Data Analyses in PT7-002
0.4	19.06.2023	Fotios Gioulekas (5YPE)	Updates on PT7-001, PT7-003
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1.0	28.06.2023	Fotios Gioulekas (5YPE)	Final editing

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Table of Contributors

Table B. Deliverable Contributors

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2. Digital literacy assessment of older adults in the Local Primary Health Care Unit of Ampelokipi	Fotios Gioulekas, Ourania Pinaka, Evangelos Stamatiadis, Athanasios Tzikas, Konstantinos Gounaris, Anna Loukatzikou (5YPE)
3. Use Case PT7-001	Fotios Gioulekas, Ourania Pinaka, Evangelos Stamatiadis, Athanasios Tzikas, Konstantinos Gounaris, Anna Loukatzikou (5YPE), Andreas Andreou (UNRF)
4. Use Case PT7-002	Fotios Gioulekas, Ourania Pinaka, Evangelos Stamatiadis, Athanasios Tzikas, Konstantinos Gounaris, Anna Loukatzikou (5YPE)
5. Use Case PT7-003	Fotios Gioulekas, Ourania Pinaka, Evangelos Stamatiadis, Athanasios Tzikas, Konstantinos Gounaris, Anna Loukatzikou (5YPE)
6. EU's eHealth Digital Service Infrastructure, Standards for Cross-Border Data Exchanged – Assessment of Main Digital Solutions used in PT-7	Fotis Gonidis, Kostas Karkaletsis, Maria Kratouni (GNOMON), Dónal McClean, Matt McCann (ACCESSEARTH), Fotios Gioulekas (5YPE)

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Table of Acronyms and Abbreviations

Table C. Acronyms and Abbreviations

Acronym	Full Term
CSF	Critical success factors
DS	Digital solution
EU	European Union
GP	General Practitioner
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
OSSS-3	Oslo Social Support Scale
PO	Primary objective
PT-7	Pilot theme 7
SD	Standard deviation
SHAPES	Smart and Healthy Ageing through People Engaging in supportive Systems
SO	Secondary objective
SUS	System usability scale
TAM	Technology assessment model
UC	Use Case
UC-PT	Use Case of Pilot Theme
UEQ-S	User Experience Questionnaire -Short
WHO-QOL	World Health Organization Quality of Life

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Keywords

Digital solutions, active and healthy aging, mobility, physical disabilities, independent living, digital literacy and inclusion of older people, cross-border and domestic traveling

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Executive Summary

This deliverable addresses the aspects that encompass Pilot Theme 7 execution of the SHAPES Pan-European Pilot Campaign. It analyses the design, planning and outcomes of all activities and tasks that have been completed in this pilot campaign. Healthy Ageing and Longevity in EU of 21st century also concerns the ensure of digital inclusion for older adults in the era of Artificial Intelligence and Digitisation. The work carried out in Pilot Theme 7 is the result of teamwork and dedication of the pilot site leaders, technical partners and the assistance from other work packages within the SHAPES consortium. Pilot Theme 7 consists of 3 Use cases (studies) exploring digital literacy and inclusion of older people by assessing how the support of digital solutions can improve their quality of life **while they are "on-the-move "or in home**. The details of these studies i.e., eligibility criteria, digital solutions usage, limitations and results analyses are provided along with the conclusion remarks.

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1 Introduction

The Pilot Theme 7 (PT-7) "Cross-border Health Data Exchange Supporting Mobility and Accessibility" focuses on the improvement of individual health status of older persons through the usage of wearables, mobile medical devices and digital platforms or applications. 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 without hindering older individual's need to move. This pilot is a feasibility study towards the evaluation of the engagement and user-perceived usefulness of the novel SHAPES ecosystem in a real-world environment. Additionally, older people can identify travelling destinations and sites that are friendly and accessible to people with disabilities, thus enhancing the individual's confidence to make an informed decision in selecting a tourist destination and/ or activity. Accessing physical spaces is a key requirement for social inclusion and social participation, as well as for instrumental daily activities. Additionally, we investigate how digital solutions can establish a direct contact channel between the patient and the patient's general practitioner (GP) to sustain the bond of mutual trust and safe feeling.

Within this context, 3 Use Cases (studies) have been designed to evaluate this pilot theme. These use cases have been designed as non-randomised, single-armed, cross-sectional interventional studies with qualitative interview component based on the Harmonisation Data Template (Annex 1) as defined by the Project Coordinator (National University of Ireland Maynooth):

- **Study UC-PT7-001** - 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 monitoring older patients with chronic disease when travelling abroad.
- **Study UC-PT7-002** - 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 fostering older people's (with physical disabilities) independent living by identifying accessible locations and routes in other locations (domestic and abroad).
- **Study UC-PT7-003** - 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 establishing direct patient – General Practitioner (GP) communication while on the move.

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Older individuals of more than 60 years old that live in the "Region of Thessaly and Sterea" in Greece and have a chronic disease (e.g., blood pressure, COPD, diabetes, heart diseases) and they are "**on the move**" comprise the target group in Pilot Theme 7 (PT-7). Additionally, within the context of PT7-002, older people with mobility disabilities and visual impairments have been recruited. Therefore, Pilot Theme 7 covers multiple aspects associated with the mobility and accessibility of older individuals - namely the availability of health and care data (exchange) across Europe – including those living with permanent or temporary reduced functions or capabilities, to access health and care services anywhere while traveling. Accessibility of older individuals, and of those experiencing physical disability, visual impairment (blindness) and hearing impairment (hard-of-hearing, deafness, deafblindness), is also addressed from the perspective of the accessibility level of buildings and outdoor environments, which tend to affect the older individuals' mobility and thus their decision-making process with respect to traveling.

1.1 Rationale and purpose of the deliverable

The deliverable D6.8 "Cross-border Health Data Exchange Supporting Mobility and Accessibility for Older Individuals Pilot Activities Report" presents the key findings and results of the SHAPES Pilot Theme 7. It describes the pilot activities and preparatory work undertaken during each phase of the pilot, which closely follows the methodology outlined in Deliverable 6.1.

Pilot Theme 7 is being led by the 5th Regional Health Authority of Thessaly & Sterea (5YPE) in Greece. Study PT7-001 is replicated by the University of Nicosia Research Foundation (UNRF) in Cyprus. The main digital solution to support PT7-001 activities have been recommended by Gnomon The main digital applications incorporated in PT7-002 for evaluating accessibility aspects have been recommended by European Union of The Deaf AISBL (EUD) and the World Federation of The DeafBlind (WFDB). The key digital solution that supports the direct communication between older individuals and General Practitioner (GP) have been recommended by OMNITOR AB (OMN).

1.1.1 Deliverable Objectives

The high-level objectives of this Deliverable are to:

- Introduce the use cases in pilot theme 7 and describe all work completed on the pilot theme to date.
- Describe the methodology, the issues that have been resolved and all the execution process of each one of the 3 use cases.

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- Report on the key findings through the provision of the associated data analysis.

1.1.2 Key inputs and outputs

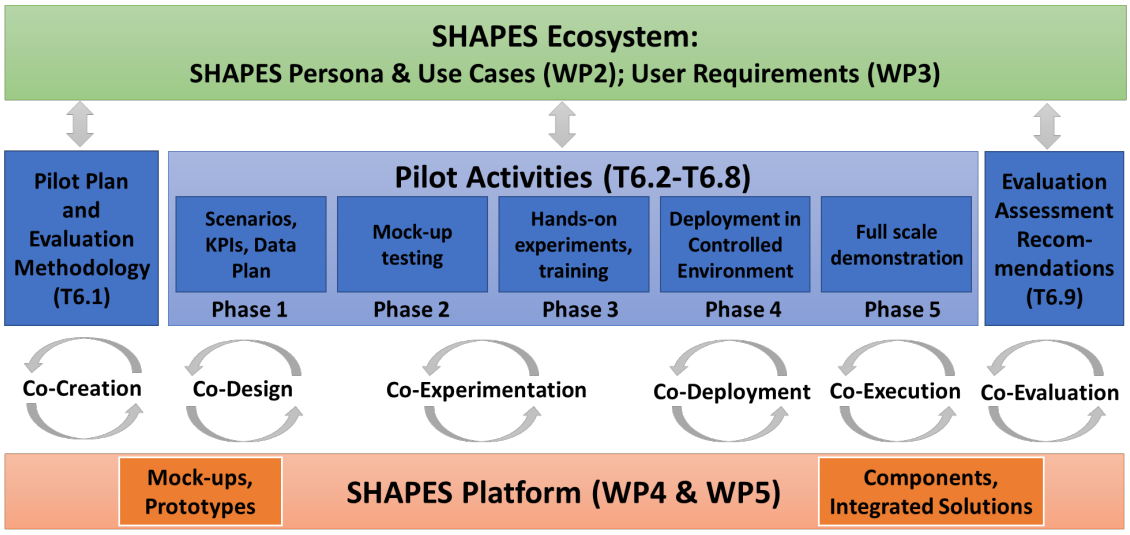

Figure 1: Overview of WP 6.

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 are co-designed, tested and co-executed. The outcome of the co-evaluation process is presented in Task 6.9. Communication and Dissemination

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 Communication and Dissemination

All data being collected in the 3 pilot studies are respectively owned by the organisation conducting the study and the replicators and technical partners (in terms of their technology usage), namely 5YPE and UNRF, GNOMON (GNO), Science for You LTD (SciFy), Access Earth and OMN. The analysis of the results is presented in this Deliverable, as one of the deliverables of the SHAPES Innovation Action. This report will be available via the SHAPES website (www.shapes2020.eu). 5YPE and collaborating partners will also seek to communicate the findings of this study via social media (corporate website, Facebook), and in other, non-peer reviewed, media outlets, conferences of scientific journals or other events related to health care

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technologies in both national and European levels. 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.

1.3 Ethics

Ethical approval has been achieved for the Studies PT7-001, PT7-002 and PT7-003by the Scientific Council for Primary Healthcare (Ethics Committee) of the 5th Regional Health Authority of Thessaly & Sterea in Greece (5YPE) with approval code: 4530/ΕΣ 09, approval Date: 5th of January 2023. Additionally, UNRF has submitted an initial plan for the Use Case Studies PT7-001 activities to the respective National Bioethics Committee of Cyprus and has received a positive response. The principles of maximizing benefit and minimizing harm, social responsibility, dignity of persons, fundamental/human rights and other issues mentioned in the H2020 ethical self-assessment are supported during Pilot Theme 7 execution. 5YPE and UNRF have provided ethical self-assessment together with Data Protection Impact Assessment (DPIA) and delivered to the SHAPES Ethics Management Board and also uploaded to the relevant repository of SHAPES project (i.e., MS TEAMS) along with the Data Lifecycle Management Plan. Furthermore, Information Sheets that have been designed in Greek language to describe the purposes and the process of each one of the use-cases were provided to the participants. Moreover, the contents of the studies were thoroughly explained to the participants while Consent forms were mutually signed between participants and the leaders (GP) of the studies.

1.4 Limitations

Since there are no borders among European Union members and considering COVID-19 restrictions and that there are no extra internet/mobile telephone roaming charges, “on the move” will refer to travelling to another prefecture, a nearby country, a state within a federal state. This was also communicated to the SHAPES consortium and agreed in previous project reviews. This was also since COVID-19 restrictions were taken into account during the definition of the 3 studies to ensure the safety of older people participating in these.

The sample of the participants ranges from 5 to 7 persons per use case and replication sites as restricted by the number of the procured devices and tablets. It should be noted that due to interoperability issues among digital applications and the installation problems faced, as well as the long time spent by National Ethics Committees to approve the studies, we have merged the phases of Pilot Theme 7 to 3 phases, i.e., **initial**, **control** and **execution** phases (instead of having 5 phases) to expedite its

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execution (as described in next sections). The execution phase of the Pilot Theme 7 was shortened to maximum 1 month.

Furthermore, in order 1) not to break the trust bond that has been already developed between the participants and their GP, and 2) avoid the exhaustion of the participants within the period of the execution of the use-cases, some parts of the questionnaires were not assessed. Therefore, we focused more on users' technology acceptance [User Acceptance questionnaire (TAM score)] rather than user experience (UEQ-S score). User experience was collected from the open interview conducted at the end of the studies or during their regular visit to the GP. Within this context, parts of the study that were not well comprehended or were difficult to be followed up (e.g., difficulties to use the applications or to provide feedback about their wellbeing status per day) was not evaluated.

1.5 Structure of the document

This document has been structured to present the activities undertaken and key outcomes of each of the 3 use cases in their entirety. The rest of the deliverable is organised as follows: Section 2 describes our findings regarding the digital literacy of a sample older people to be potential recruited in Pilot Theme 7. Sections 3, 4 and 5 present the design, execution, main outcomes and key recommendations from each of the 3 use cases. Section 6 lists key Open Interoperability Standards and discusses how digital application used in this Pilot Theme can support EU's cross-border data exchange. Finally, Section 7 concludes our work.

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2 Digital literacy assessment of older adults in the Local Primary Health Care Unit of Ampelokipi

The interdisciplinary team of the Local Primary Health Care Unit (LPHCU) in the region of Ampelokipi in Larissa, city of Greece, conducted a survey that concerned the digital literacy of older persons. Eligible were people of age 65 and above who were registered to the LPHCU. UC-PT7-001, UC-PT7-002 and UC-PT7-003 have been executed in this Unit. The survey was conducted between November 2020 and May 2021. The survey was performed by the health professionals of the unit either by making phone calls directly to the registered older participants or during their scheduled visits to the Unit. The survey was based on an anonymous questionnaire with closed questions that was specified by the LPHCU team and is listed in the following table (Table 1).

Table 1: Anonymous questionnaire for elders' assessment on digital literacy

Index	Question	Answers
1	Sex	Male
		Female
2	Age	Open field
3	Do you have an internet connection?	Yes
		No
4	Do you have a personal computer?	Yes
		No
5	Do you use the internet?	Yes
		No
6	Do you pay bills online, use the web-banking?	Yes
		No
7	Do you have a smartphone?	Yes
		No
8	Do you have an email account?	Yes
		No
9	Have you activated the digital prescription in the last 2 years?	Yes
		No
10	Would you be positive to an installation and usage of technological equipment in your home for immediate medical attention?	Yes
		No
11	Have you ever participated in a telemedicine program?	Yes
		No

The analysis of the results survey showed that n=99 registered persons (>65 years old) expressed the willingness to participate in it. Among them, 36 were male (36.4%) and 63 female (63.6%). Their age ranged from 67 to 91 years (Mean=76.56, std=5.54). Figure 2 depicts the evaluation of the received answers.

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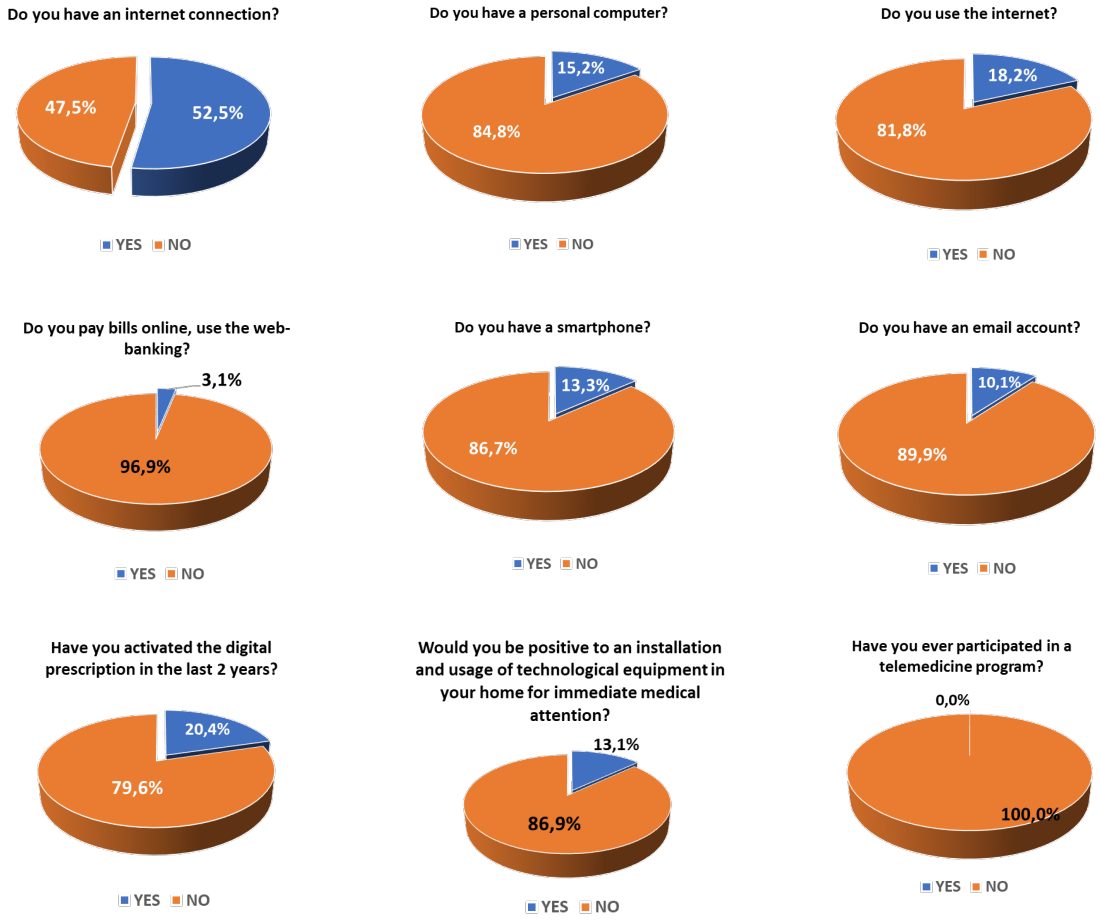

Figure 2: Analysis of the Digital Literacy Responses.

The evaluation of the results has shown that older people, in this specific region of Larissa, are not familiarized with digital technologies. Almost 80% have not activated the national digital prescription service to receive by email or an SMS the medication prescription or the prescribed diagnostics tests (blood analysis, MRI exams, etc.). Instead of this, they prefer printed-out prescriptions because they feel safer and are not able to cope with barcodes or references numbers shown in email messages or SMSs. The finding that almost 85%-90% have not used the internet or gotten an email account, a smart phone or a personal computer justifies their aforementioned preference, although 52.5% had an internet connection to their home. The internet connection was mostly used by their children or grandchildren. On the other hand, they are eager to participate in a digital/remote support system for their health status monitoring although none of them had participated in a telemedicine program. These results delineate that application of SHAPES ecosystem to this specific age of people is really challenging and requires extra effort to both educate elders and make them feel comfortable with the digital technology, and thus enabling solidarity and digital inclusion for older people.

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3 Use case PT7-001

3.1 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 15 (1) 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 growth (2). 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 for 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 reducing risk factors such as unhealthy lifestyles, improving external health determinants and to strengthening accessible healthcare for all (2).

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 age (3). 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 to 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 health (4), 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

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area have been modest, with experiments involving advanced ICT services supporting health and care through small-scale, localised initiatives.

This study is to demonstrate the capability of SHAPES Digital Ecosystem to support availability and access to physiological and medical data, for the patient and for the patient's formal and informal caregivers, when the former travels abroad. Patients and health professionals should be able, through SHAPES Ecosystem, to manage the disease and communicate face to face – as effectively as in a session conducted in the doctor's office or patient's home.

Objectives

Primary objectives

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

Secondary objectives

- To investigate the capability of the novel system to maintain the supervision of the individual health and wellbeing status when leaving home (SO1).
- To investigate the association of home and away from home physical activity classification, sleep quality 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 leaving home (SO3).
- To explore user trust and acceptance of the novel system (SO4).

The use case is based on the needs and life world of the persona "**NIKOLAS**" who is described in more detail in D2.7 and has easy access to the primary Health Care System, TOMY (The Primary Health Care Units, called Topikes Monades Ygias, TOMY in Greek). The health problem he faces is hypertension while he has to check his glucose levels regularly. For his chronic health issues and the prescriptions needed, Nikolas visits the primary health care unit of his region called TOMY1. Ernst persona has also been identified as a potential user from D2.7.

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).

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- O4. Social technological measures: Technology Acceptance Model (TAM) questionnaire (6), 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).
- 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; Glucose and Blood Pressure 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 (SO2).
- O11. Psychosocial measures: WHOQOL-BREF (8), EQ-5D-5L (9), GSES (Self-efficacy) (10) OSSS-3 (social support) and life events (11); 1-item health literacy; SHAPES Participation questionnaire (SO3, TO1, TO2).

In order to relate objectives to socio-demographics of app users:

- O12. 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
- O13. 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)

To enable the login process in the novel system:

- O14. Participants ID (non-identifiable) and password.

To contact participants (data only kept at 5YPE)

- O15. Name, Native Language

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For technical reasons:

- O16. Model, manufacturer and serial number of devices (technical).

It should be noted that data from TREE analytics platform as not analysed due to technical interoperability issues between the different vendors and due to the restricted time of PT7-001 execution. Furthermore, data from the LogMeal application (12) have not been captured due to problems with end user acceptance since it needed input data.

3.2 Description

Older people suffering from chronic diseases (Heart Failure, Type II Diabetes, Chronic Obstructive Pulmonary Disease, etc.) need to be constantly monitored. This need becomes stronger when travelling to another country, adding up to the patients' and their caregiving relatives' anxiety. To empower patients and their relatives to efficiently manage their condition outside their "comfort zone", solutions / tools are required:

- to measure vital signs, track activity levels and evaluate behavioural patterns
- to remind of medication adherence
- to enable patients' caregivers (physicians, nurses) treat them from "back home"

thus, preserving the notion that the patient "never left home". This use case is led by 5YPE replicated by UNRF.

3.3 Digital solutions used

The following SHAPES platform (SHAPES consortium) digital solutions have been utilised:

- eHealthPass (Gnomon) (12): Health and Wellbeing App for the manual entry of fluid intake, Covid-19 symptom checker and provision of personal data (e.g. medical record, social history background) collected during registration process of the participant.
- SHAPES app and web (combination of components from Gnomon and Nutrition App (LogMeal) (13): 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.
- Sleep quality and Physical intensity level (TREE TECHNOLOGY): Analysis of sleep (quality and quantity) and activity measures based on the collected data from the fitness tracker.

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

3.3.1 Digital solutions used for COVID-19 response

In UC-PT7-001, no digital solution for the COVID-19 response was used. However, the COVID-19 had affected the fast feedback and communication between the participants and the General Practitioner. People over 65 years old still take precautions against the COVID-19 that hindered their responses and testing of the equipment.

3.3.2 Equipment and devices used (from third parties)

Public procurement procedures were followed in order to obtain the necessary equipment to capture the vital data according to the study protocol.

- Medisante FORA D40g mg/dL(14), Blood Glucose Plus Blood Pressure Monitoring System (Metrics: glucose and blood pressure measurement), CE Certified with Cloud Connection Support – Medisante M+hub (15). Figures 3 and 4 show the usage of these devices during execution phase.

Figure 3: Glucose measurement using FORA D40g

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Figure 4: Pressure Measurement using FORA D40g

- Withings Wristband: Scanwatch (16) HWA09-model 1-All-Int & HWA09-model 4-All-Int from Withings SAS (Metrics: Heart beat notifications: irregular heart-beat, Heart rate: beats per minute, Breathing disturbances: detection via oxygen saturation, Electrocardiogram: tracing of a 30-seconds ECG recording on a millimetric grid, Clinically validated Oxygen saturation level (SpO2), Walking and running: steps, distance, calories, based on user's profile for high precision, Calories: metabolic calories and total calories expenditure, Running: automatically detected, in-app daily recap of duration and distance, Swimming: automatically detected, in-app recap with duration and calories burned, Sleep: deep and light sleep phases, irregular heartbeat detection, sleep interruptions, Fitness Level: assessment via VO2Max estimation, Elevation: meters and floors climbed), Clinically Validated, CE Certified. Figures 5, 6 and 7 show the usage of these devices during execution phase.
- There were purchased 9 FOR A D40g devices with one used for testing and the other being defective, thus limiting the participant number to 7.

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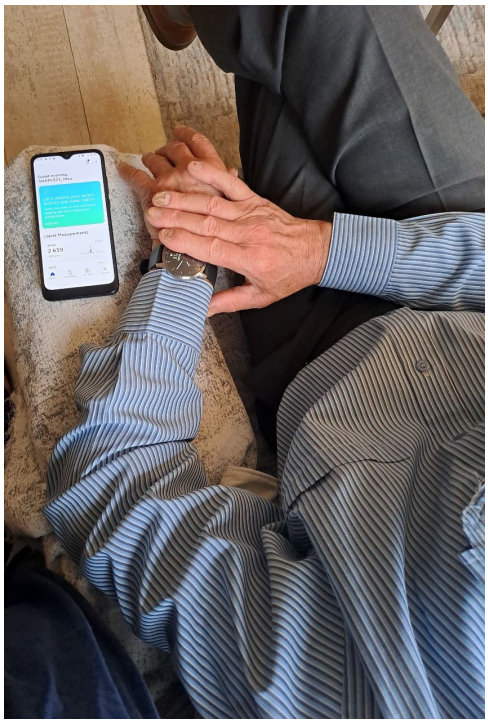

Figure 5: BPM measurement using Scanwatch

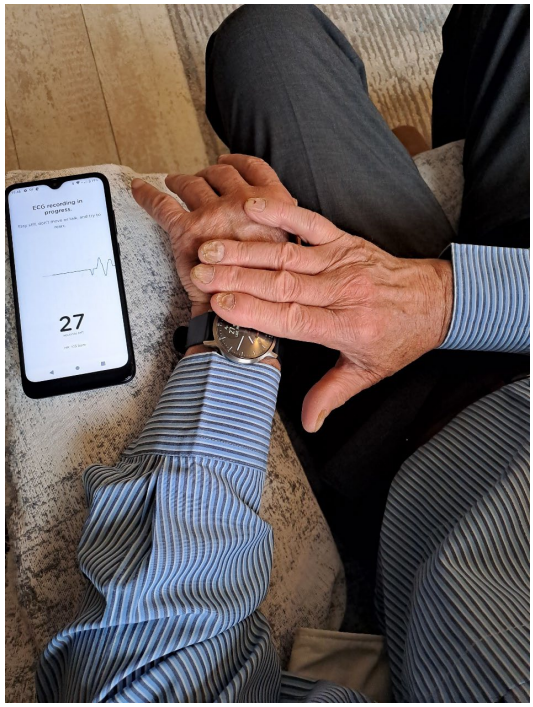

Figure 6: ECG Measurement using Scanwatch

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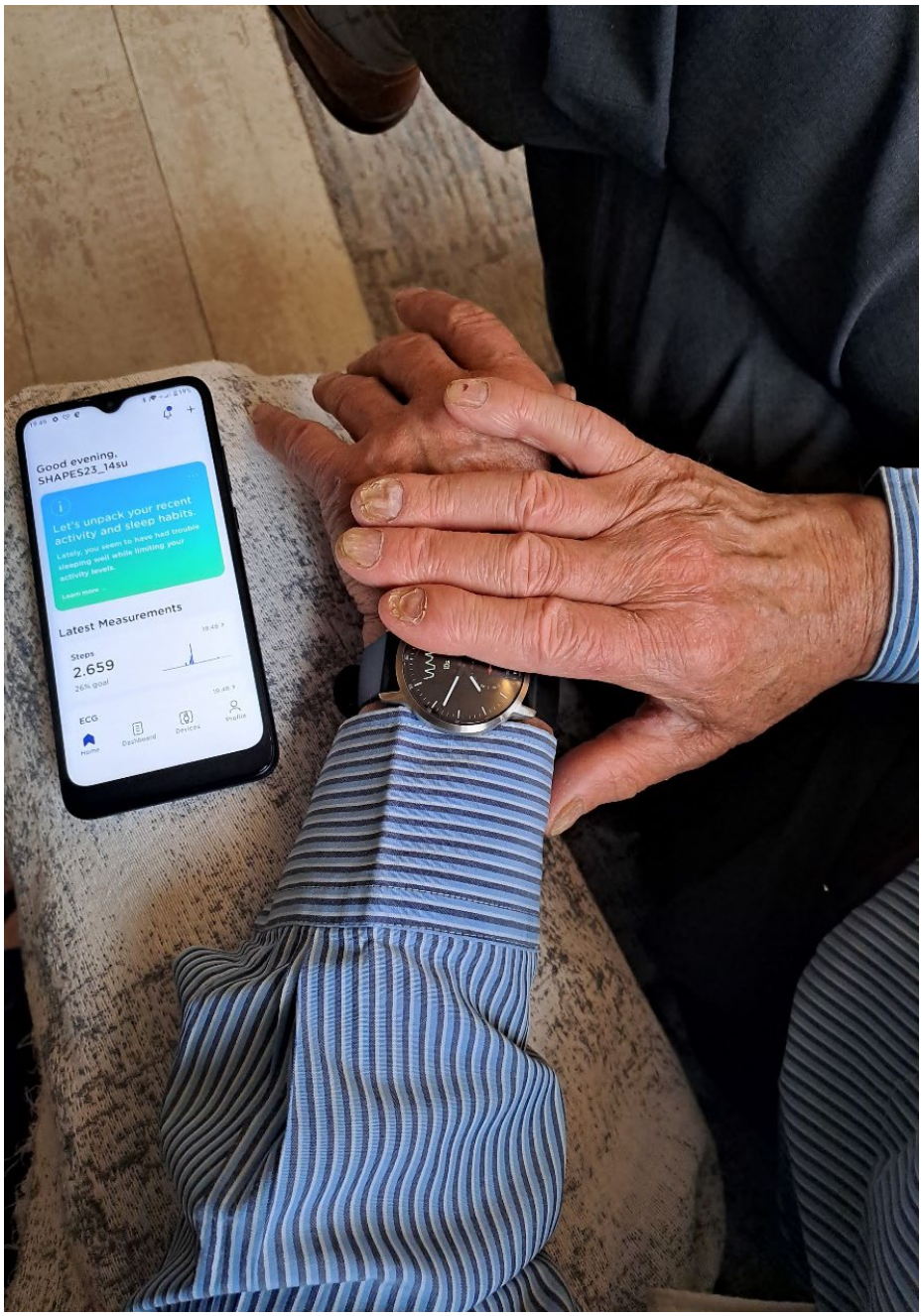

Figure 7: SpO2 Measurement using Scanwatch

- Smartphone: An Alcatel Android OS Smartphone was utilized to receive the data through Bluetooth and transmit them either via 5G or WIFI to the SHAPES platform.

The measurements from the devices were transferred to the SHAPES platform and more specifically to the eHealthPass Application. Data Interoperability issues were experienced between the Withings and Medisante Cloud Functionalities and SHAPES TREE Analytics. Figures 8, 9, 10 and 11 show the eHealthPass digital dashboard on the GP's side.

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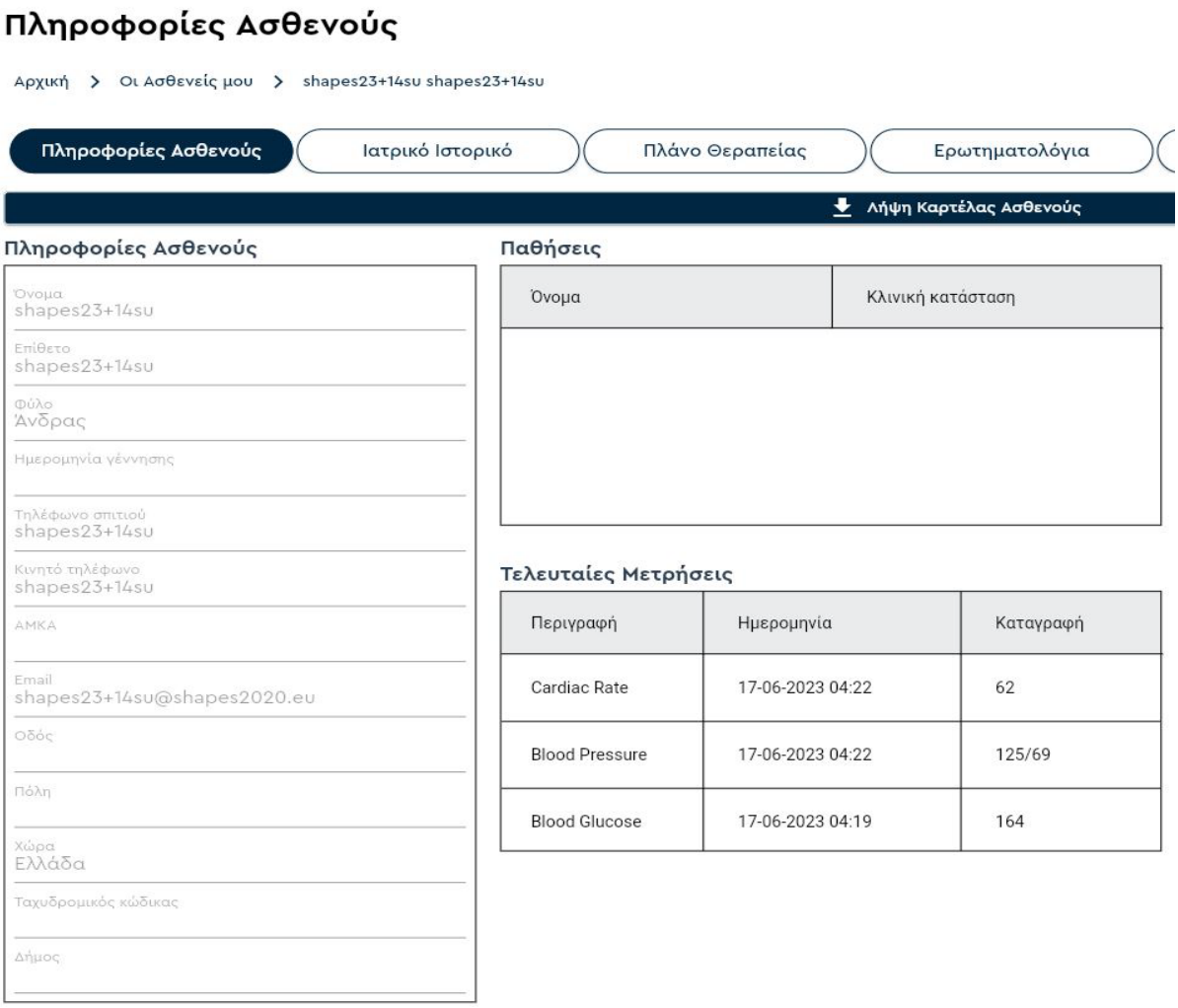

Figure 8: eHealthPass Patient's Info

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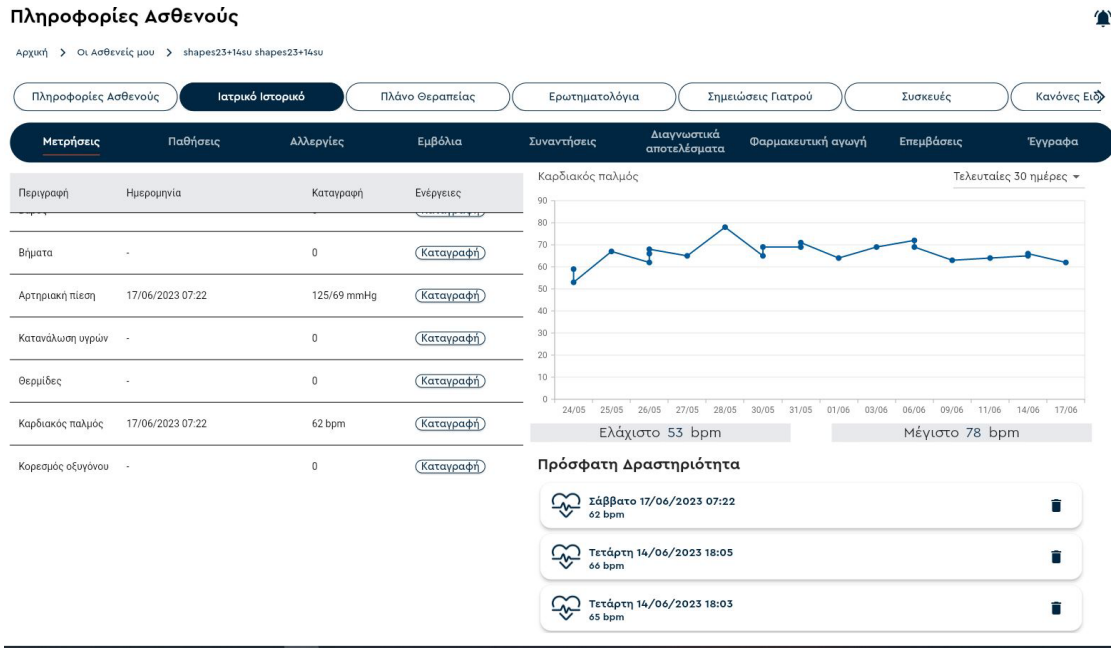

Figure 9: eHealthPass Patient's Cardiac Pulse Activity

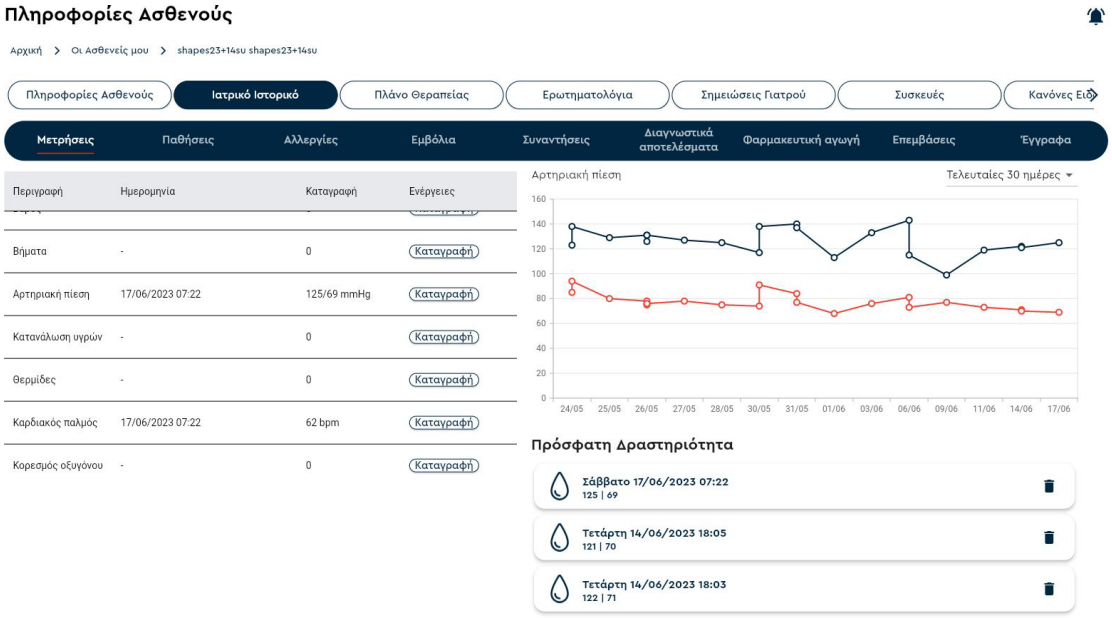

Figure 10: eHealthPass Patient's Blood Pressure Activity

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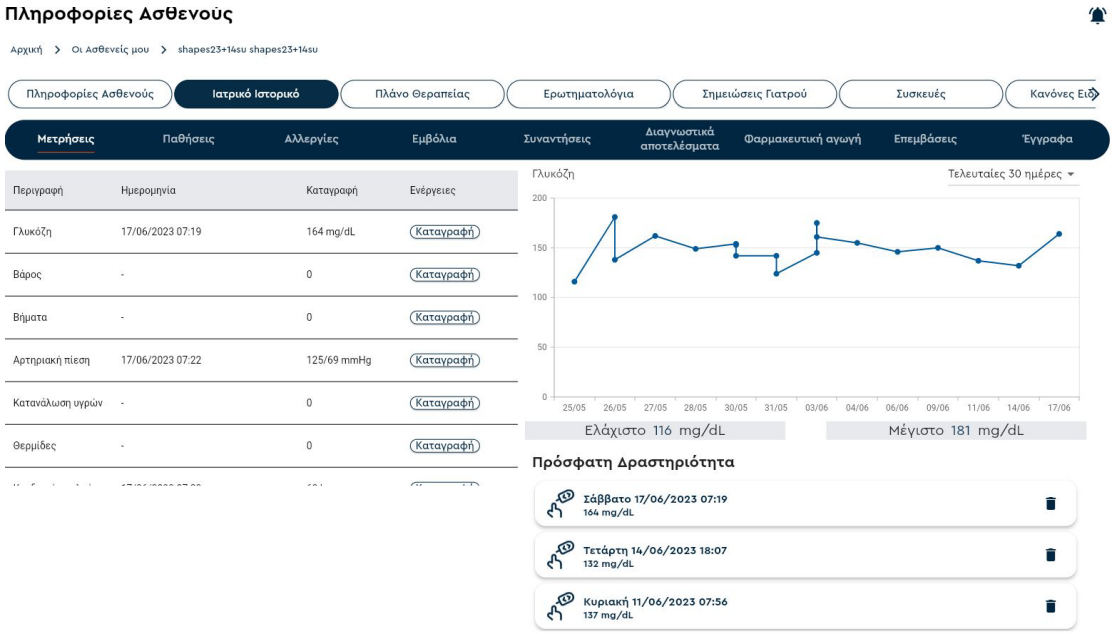

Figure 11: eHealthPass Glucoze Activity

The SHAPES applications that utilised by UNRF replicator site were the following:

- eHealthPass by GNOMON. Health and Wellbeing App for the manual entry of fluid intake, Covid-19 symptom checker and provision of personal data (e.g. medical record, social history background) collected during registration process of the participant.
- eCare by EDGE. Remote monitoring platform which displays heart frequency, steps, physical activity, sleep quality, wellbeing status and survey data gathered manually or automatically (using connected devices like the fitness tracker and the tablet) in home environment.

The devices used to undergo the study by UNRF are presented in the following list:

- Blood pressure monitor: OMRON M7 Intelli IT.
- LIBERTY smartbands by VIDAVO.
- Tablet device: LENOVO TABLET TAB M10 TB-X306F HD 2ND GEN (for the participants that do not own a tablet or smartphone).
- Wireless Wi-Fi plug sockets (for the participants that do not have access to Wi-Fi).

3.4 Data plan

Patients and health professionals should be able, through SHAPES Ecosystem, to manage the disease and communicate face to face – as effectively as in a session conducted in the doctor's office or patient's home. The daily usage of wearables,

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sensors and other devices can enable individuals to remain independent for longer through the provision of specific tips, recommendations, and consulting.

The key health parameters considered in this use case are wellbeing, steps, sleep, activity, heart rate, blood pressure, blood glucose and nutrition. A smartphone, a wearable fitness tracker and an IoT device for blood pressure / glucose measurement will be provided to the participant during the deployment of the use case. Figure 12 depicts the SHAPES ecosystem along with the devices used within the activities of PT7-001.

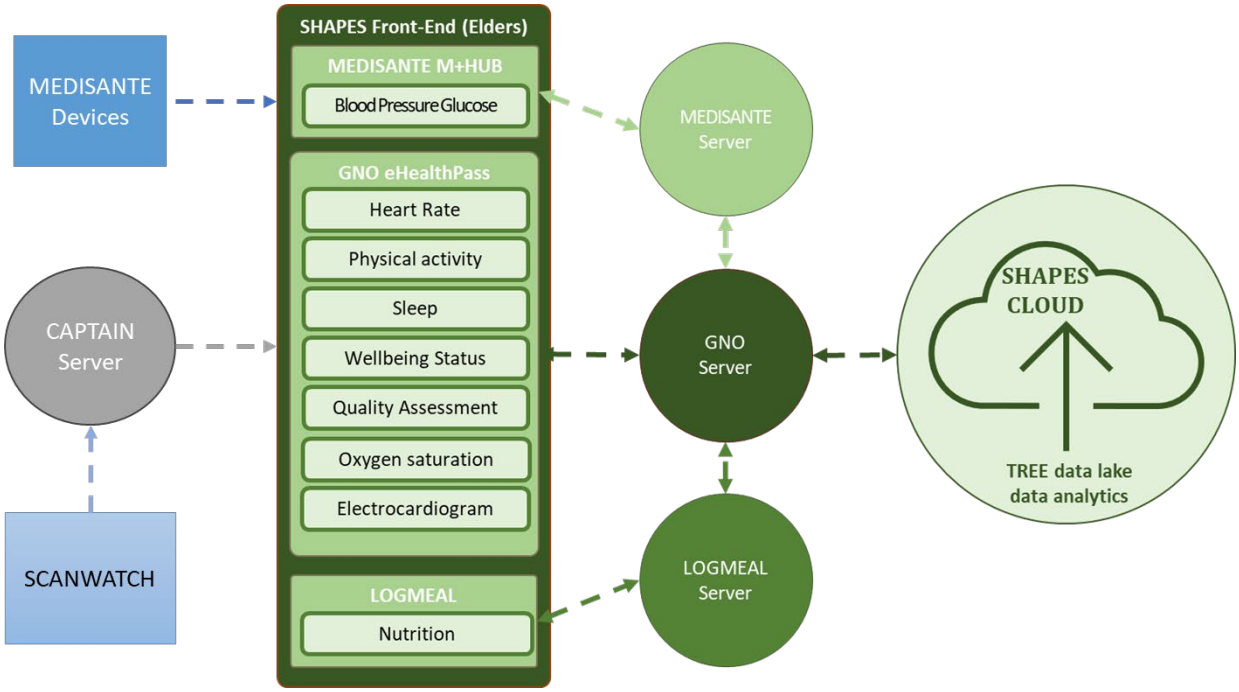

Figure 12: Architecture of SHAPES digital ecosystem used by the PT7-001

Once a participant is consented to participate in the pilot, identifiable information (including participant name, address, phone number, date of birth and alternative contact person name and phone number) are handwritten in the 5YPE's clinical study documents and are held by the GP's office. In the replication site this data is stored in UNRF servers behind a firewall. The above information is identified in the UC-PT7-001 data plan as being stored 5YPE-ID or UNRF-ID. This identifiable information will be kept confidential and only accessed by approved members of the 5YPE and UNRF research teams who may need to contact the participant during the pilot. All other information not stored 5YPE-ID or UNRF-ID will be pseudonymised. A participant list linking the pseudonymisation ID, participant name and date of birth will be stored on UNRF servers behind a firewall and only accessed by approved members of the UNRF research team. Only pseudonymised data will be shared, with consent, to SHAPES

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partners involved in the pilot and analyses. On 5YPE's site the aforementioned link is handwritten and kept in a hard-copy folder and stored in a secure location.

Data is provided through the medical devices (blood pressure monitor, blood glucometer and smart wrist bands) via Bluetooth to the SHAPES application on the participant's android smartphone or tablet device. Participants will be able to view their own clinical parameters and their answers to questions through the SHAPES app. Pseudonymised data on the SHAPES app is then uploaded via Wi-Fi to the associated digital solution and stored in EDGE (only for the replication site) or Gnomon's servers (GNO server). This data is then transferred from the digital solutions via Wi-Fi to the SHAPES big data platform where our analytics partners may access these data to perform analyses on it. The transformed data is then presented back to the EDGE and GNO servers and displayed via browser-based dashboard to enable researchers to track adherence to the pilot. Researchers may also add data e.g., baseline demographic information and questionnaire answers directly to the researcher dashboard which will be transferred to the SHAPES big data platform via EDGE (only for the replication site) or GNO servers. CAPTAIN Cloud (digital solution obtained from Open Calls) and MEDISTANTE Hubs are located in the EU and protected by GDPR rules. They are used by 5YPE to transmit data from Scanwatches or FOR A D40g devices to GNO servers.

Separate files containing data investigating how users interact with the SHAPES front-end app, including time, date and frequency of logins will be collected from user event logs. GNO or EDGE will securely transfer these files to 5YPE or UNRF, respectively, for further analysis.

3.4.1 Data capture methods to be used

Data capture methods used during this pilot are listed below:

- Semi-structured interview
- Key performance indicators
- User execution questionnaire-short version (UEQ-S)
- Participant error reporting log (to follow in final deliverable)

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
    - EQ-5D-5L

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- General Self-Efficacy Scale
- Oslo Social Support Scale
- Single item health literacy scale
- Participation questions
- System Usability Scale
- Technology acceptance questions
- UEQ-S

The SHAPES app eHealthpass to capture the following data that were generated by the eCare, Withings, LogMeal, Medisante applications:

- Health parameters:
  - heart rate
  - step count
  - fluid intake
  - nutrition intake
  - sleep parameters
  - glucose
  - SpO2
  - ECG
  - wellbeing
- Tracking data (e.g., user logs)
- Service user and healthcare professional interviews (schedule to follow in final deliverable)

3.4.2 Planning of evaluation

The MAST framework (model for assessment of telemedicine) (17) will be applied as it provides a structured approach for assessing the effectiveness and contribution of UC-PT7-001 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-PT7-001, three of the seven dimensions of MAST were identified/found to be of importance to consider. These were: Clinical effectiveness, Patient perspectives and Economic aspects. A further exploration and description of the reasons for selection/inclusion will be provided in the evaluation report (D6.9). Table 2 shows a summary of the MAST evaluation data.

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Table 2: Data required for MAST evaluation of UC-PT7-001

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 Confidence (in the treatment) Ability to use the application Access & Accessibility	Usability of application	SUS Scores 1-item health literacy	End of pilot
	Empowerment Self-efficacy	User engagement	Number of logins	During pilot
		Self-efficacy	SHAPES Participation questionnaire	During pilot
			GSES (Self-efficacy)	During pilot

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The MAFEIP tool (18) will not be applied to evaluate PT7-001 due to a small-scale deployment and a non-case-controlled study design of this particular use case. MOMENTUM and NASS were not used because it would be overwhelming for the participants, and we tried to mitigate possible dropouts from the trial.

3.5 Initial Phase

3.5.1 PACT and FICS Scenarios

For the execution of the PACT Scenario, the Ernst along with Nikolas personas have been used (Table 3).

Table 3: PACT (UC-PT7-001)

Code	UC-PT7-001	**Version**	0.2	**Date**	2023/06/21
Applicable SHAPES Persona	ERNST				
Applicable SHAPES use case	UC-PT7_001 Monitor older patient with chronic disease when travelling abroad				
People Roles and/or actors of typical users involved in delivering and receiving the telemedicine intervention	• Patient- 75+. Ernst, together with his wife, lives in their own home. He exercises daily and he is in good health with minor knee and back aches. His wife Alberta is recovering from head stroke, and she has to follow cognitive training exercises, medical check-ups every 6 months and is always worried about the results. However, they like travelling abroad every with ERNST always looking after his wife. He uses a smartwatch to monitor his heart rate, pressure and steps taken daily. Ernst has an average level of computer literacy and good knowledge of smart watches. • Patient- 75+. His wife Alberta is recovering from head stroke, and she has to follow cognitive training exercises, medical check-ups every 6 months and is always worried about the results. She has low knowledge of computer literacy. • Personal Healthcare professional (HCP) reviews clinical data regularly and reminds the patient of the upcoming regular checks especially in the case of long vacation in a foreign country. HCPs will have an average level of computer literacy and access to a laptop/PC. • Foreign HCP: In the case of the medical test being performed in the foreign country, the foreign doctor must contact the Personal HCT and then send the tests to the personal Doctor for further review and record. HCPs will have an average level of computer literacy and access to a laptop/PC.				
Activities Activities to be performed by the actors in order to successfully provide and receive the	**Patient1 Ernst** • Measure blood pressure daily using smartwatch. • Measure weight/body composition twice daily • Measure heart rate once daily using smartwatch. • Measure oxygen saturation once daily using smartwatch. • Complete daily/weekly/monthly/one-off questionnaires				

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telemedicine intervention *procedures for the professional and the patient; Parameters that determine the measures used in the intervention*	• Send the data from these measurements to the cloud/platform. • Access medical status information and alerts for his wife while he is abroad. **Patient2 Ernst's wife** • Measure blood pressure once in the foreign country • Measure blood glucose once in the foreign country • Measure weight/body composition once in the foreign country • Measure heart rate once in the foreign country • Measure oxygen saturation once in the foreign country • Complete daily/weekly/monthly/one-off questionnaires • Send the data from these measurements to the cloud/platform. • Follow cognitive training exercises daily. **Personal Healthcare professional** • Personal Healthcare professional reviews clinical data on a regular basis and make changes to patient care as required. The HCP uses video calls to check whether the cognitive training exercises are followed. The HCP reminds of the medical checkups, the medication, a phone call to review/make changes to medication, schedule a clinic appointment, prescribe further medication and test to be performed to the foreign country. • Use predictive model to identify if patient's health condition is deteriorating and interventions taken to avoid this e.g., decompensations in heart failure, high blood pressure. **Foreign Healthcare professional** • The foreign HCP must be able to access the patient's health record and communicate with the personal HCP of the patient. • In the case of a medical checkup in a foreign country, the results must be transmitted easily to the personal HCP for review and recording
Context *Social-medical relevance of the telemedicine intervention; privacy issues; risks for the patient; locations*	• Smart clinical devices to be used in patient's foreign travel location. They will monitor patients with multiple health conditions (head strokes and body pains). The daily data recorded by patients are transmitted and reviewed by the personal healthcare professionals who can then adjust treatment plans as indicated. The foreign HCPs must communicate with the personal HCTs. One of the key goals is the adherence to treatment to improve patient outcomes and reduce unplanned urgent care episodes e.g., hospital admissions. • Maintaining privacy of data is of the utmost importance and would normally be upheld by allocating each participant a unique study number. An identification list (including name and date of birth) would be held at the local pilot site. The remote HCP must be able to access the local medical records. • GDPR and ethics in line with WP8 • Data and servers must be located within the EU. • Language translation techniques • Home country: Germany; Foreign country: Greece
Technology *Type of information/parameter that are relevant in*	• Baseline demographic information- Age (year not DOB) Sex (M/F) Smoking history (Never smoked/used to smoke/current smoker) Height (cm)

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monitoring the health status; type and frequency of accessibility of information; feedback modalities (communication)	Education Alcohol use Baseline social and medical living status Marital status Family composition Housing conditions Medical Financial Aid Medical Status • Baseline medical history- Medicine (number of medicines/chronic or as required/name/ strength/ frequency/ date) Diagnoses (medical condition and date of diagnoses) Supplemental oxygen (yes/no) Implanted cardiac device (pacemaker/ implanted cardioverter defibrillator/ cardiac resynchronization therapy) Left ventricular ejection fraction (%) Rhythm (atrial fibrillation/ sinus rhythm/ atrial flutter) Pacemaker present (yes/no) • Changes to medication as the pilot progresses (stop/start/change strength/change frequency) • Heart rate (beats per minute) once daily • Oxygen saturation (%) once daily • Blood pressure diastolic and systolic (mmHg) twice daily • Blood glucose twice daily (mmol/L) • Weight (kg) twice daily • Body composition: body fat (%), body water (%), body muscle (%) • Questionnaires • Reminder/alert to complete questionnaires and use clinical devices. • Feedback to participants that their clinical parameters are within or the normal range. • Feedback via app to participant on whether all tasks have been completed. • Feedback via browser to HCP to highlight clinical parameters outside the normal range. • Contact details of the personal HCP • Location tracking • Remote Access to the medical records • Electronic transfer of the results

Although Table 3 contains many parameters as mentioned in section 1, we consider participants on the move instead of cross-border travels while the Greek GP monitors them. The opening of new primary health care units in December 2017 was an effort towards establishing modern, people-centred primary health care services in Greece. The Primary Health Care Units, called Topikes Monades Ygias (TOMY) in Greek, are key elements of the newly designed primary health care system and serve as the first point of contact and the main coordinator of care for people in the area. Multidisciplinary teams (general practitioners/family doctors, paediatricians, nurses,

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health visitors and social workers) provide health care for people in a continuous manner, looking at disease prevention, health promotion, diagnosis, treatment, monitoring and care.

Scenarios

Ernst or Nicolas dream of traveling all over the world. Unfortunately, her health condition discourages her from selecting the recreational experience of travelling to other locations (abroad or domestic). Both the need for medical assistance (especially with her chronic diseases) and the little-to-no knowledge of the destinations' accessibility and safety conditions, act as a turn-off for any decision-making process for traveling and tourism activities. Assessing and identifying the safety/accessibility levels of potential destinations, as well as being able to navigate her way when she visits those destinations, can enhance her travelling decision-making capability and overall contribute to her active and independent living.

Ernst's wife, as well as Nikolas and his wife, need to have their health condition constantly monitored. This need becomes stronger when travelling to another country, adding up to theirs and their caregivers' anxiety. Therefore, they must be empowered to efficiently manage their condition outside their "comfort zone". Additionally, certain conditions carry the risk of resulting in critical events (e.g., heart failure), often with life-threatening implications. Monitoring and analysing their health and lifestyle data can act as predictors of such events, thus triggering specific precaution measures to avoid those events from happening (or to give them enough time to reach an emergency room).

In case of an emergency situation, it is of critical significance that access to their medical data (medication and patient summary) is available, as well as communication between them, their physician (back home) and the emergency physician (visiting destination), to perform the best-informed medical practice.

Ensuring the above will increase the participants feeling of safety, preserving the feeling that they "never left home".

Table 4: 5YPE's personas requirements (FICS)

User requirements for above mentioned personas	
An eHealth call centre to support platform user needs to be available 24/7 for all users.	FR-HS-1
The platform should include tutorials and help cards regarding its use and the use of the devices connected to it. Also, a glossary of terms should be available.	FR-HS-2

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Health data collection and management (and sharing) of health parameters	FR-HS-3
Processing of health data: risk assessments, action plans	FR-HS-4
Recording the perceived state of well-being / self-assessment tool	FR-HS-5
Help for dealing with legal issues (e.g., advanced care plans; end-of-life care)	FR-HS-6
Medication reminder / support Reminder for clinical readings/appointments	FR-HS-7
Pain management system	FR-HS-8
Medical emergency alert system	FR-HS-9
Track and record clinical device characteristics regarding maintenance/calibration, make, model number	FR-HS-10
SHAPES platform should be explicit about the benefits of its use (prompts, feedbacks, rewarding messages, etc.)	FR-HS-11

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-PT7-001.

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, except for the activity wristband, for at least 90% of the days.

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User Engagement and Acceptance

4. At least 60% of participants continued to login to use the app daily after two weeks of the pilot.
5. At least 60% of participants scored an above average rating (>68) in the 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

3.5.3 Timeline of pilot activities

The timeline was needed to be adapted, due to several factors. First, the procurement of the tablets was delayed due to bureaucratic reasons. Then, the study was finally approved by the ethics committee in early January 2023 due to time-consuming procedures needed for clinical studies and trials. Afterwards, the applications were installed but were not fully operational in android tablets (some of the features where not functioning correctly) and needed to be troubleshooted and upgraded by the technical partners. Moreover, some of the participants were infected by COVID-19 and it was very difficult to contact them during that period (one of them needed approximately 3 weeks to recover). The adapted timeline is shown in Table 5.

Table 5: Adapted timeline for UC-PT7-001 execution

	Mar 2023	Apr 2023	May 2023	June 2023	July 2023	Aug 2023	Sep 2023	Oct 2023
Initial Phase (Recruitment)								
Control Phase (Applications Setup)			1-2 older person participants					

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Execution Phase (Study)			Baseline → Intervention (2 month) → 3-month follow-up				
Execution Phase (Data Analysis)					De-identified data transferred to SHAPES platform		

3.6 Control Phase: Configuration of Digital Solutions and Testing

3.6.1 Methodology of testing

- In previous phase initial ideas of the technology of UC-PT7-001 were demonstrated in person. The functionality was presented and primarily used to evaluate design and potential functions by developers and participants. The technology comprised the SHAPES front-end eCARE app (EDGE) at UNRF and the eHealthpass app (GNOMON) at 5YPE along with the Withings and Medisante Applications
- The demonstrations were conducted by the General practitioners in person at the Health Units. The participants were informed about the background of the SHAPES project and the use case.
- *Participants*
- Phase 2 was conducted with seven 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 (see Annex) 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.

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3.7 Execution Phase: Hand-on Experiments and Data Analysis

3.7.1 Methodology of hands-on experiments

- In the pilot activity for data acquisition from older adults, effective communication among all participants was crucial for the success of the project.
- In the pilot activity, communication between all participants for data acquisition from older adults was conducted through a clear, open, positive, and focused approach. The key stakeholders involved in the communication process include relatives, researchers from UNRF and the 5YPE staff, and the participants themselves. Here's how each aspect of communication was addressed:
- Clear and concise communication was emphasized throughout the pilot. The objectives, requirements, and expectations of the data acquisition process were communicated to all participants in a transparent manner. This ensured that everyone involved had a shared understanding of the project's goals and their respective roles.
- An open communication environment was fostered, encouraging participants to express their thoughts, concerns, and suggestions freely. Regular meetings, such as kick-off meetings, progress updates, and feedback sessions, were held to aid in case technological difficulties occurred. Participants were encouraged to ask questions, provide input, and share their experiences and expertise related to data acquisition from smartbands and blood/glucose pressure.
- A positive communication atmosphere was maintained throughout the pilot. The technical partners emphasized the importance of maintaining a supportive and collaborative environment. This included recognizing and appreciating the efforts and contributions of all participants, providing constructive feedback, and celebrating achievements and milestones. Positive reinforcement helped motivate participants and create a sense of shared purpose.
- Communication was focused on the specific goals and requirements of data acquisition from older adults. The discussions and interactions were centered around topics such as data collection methodologies, privacy and security concerns, patient consent processes, data quality assurance, and any potential challenges or barriers that emerged. The communication efforts were directed towards ensuring efficient and effective data acquisition while maintaining patient privacy and compliance with relevant regulations.
- To facilitate communication, various communication channels may have been used, such as in-person meetings, video calls, or instant messaging platforms. The choice of communication channels would depend on the preferences and needs of the participants.

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3.7.2 Results of the hands-on experiments

3.7.2.1 5YPE main site

The participants responded to the questionnaires in a positive way towards the SHAPES platform. The ease of use of the devices was a critical factor. Their positive feedback focused on the basic operations of simply keeping the devices charged and taking the measurements. The participant could easily transfer the devices upon travelling and operate them even if there was no internet connection because the data were cached on the memory of the devices and then sent to SHAPES cloud.

Their negative feedback focused on when there was a need to interact and input data on the devices especially on the smartphone which was on the one hand ideal for traveling since all the devices could be carried within one small bag, but on the other hand too small for them. Furthermore, the credential exchange between the applications of the different vendors resulted in a continuous technical support in order to be depicted on the SHAPES patient monitoring environment of the doctor.

3.7.2.2 UNRF replication site

Older adults' feedback regarding their experience with SHAPES platform:

Many older adults appreciate the convenience of remote monitoring, as it allows them to receive healthcare services from the comfort of their own homes.

Remote monitoring provides a sense of security for older adults, knowing that their physiological signs are being monitored regularly, and any abnormalities can be detected early.

Some older adults find that remote monitoring empowers them to take an active role in managing their health and well-being.

The ability to monitor physiological signs remotely can minimize the need for frequent hospital visits, which is often a relief for older adults.

3.7.2.3 Challenges and Requests obtained from both sites

Challenges:

Older adults faced difficulties in using the technology associated with remote monitoring platforms. Issues like setting up devices, connecting to the internet, or navigating the platform's interface were a barrier.

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Some older adults struggle with the newness of the technology or feel overwhelmed by the learning curve associated with remote monitoring platforms.

Inadequate technical support or insufficient guidance in using the platform could lead to frustration and a lack of confidence among older adults.

Older adults expressed concerns about the privacy and security of their personal health data transmitted through remote monitoring systems.

Requests:

Older adults would appreciate intuitive and user-friendly platforms that are easy to navigate, with clear instructions and larger font sizes for readability.

Providing simplified setup processes for devices and step-by-step instructions can make it easier for older adults to get started with remote monitoring.

Offering comprehensive training, both in-person and through accessible resources, would help older adults feel more confident and comfortable in using the platform.

Implementing robust privacy and security measures, such as encryption of data and transparent data handling policies, can address the concerns of older adults and foster trust in the platform.

3.7.3 Recruitment of participants in Greece (5th YPE) and Ethical Considerations

Recruitment

The full testing period lasted 2 weeks in the pilot site. The participants involved were people older than 65 years old with chronic disease living in the reference site of Thessaly & Sterea. The sample size were 7 target users that were properly identified and selected by the General Practitioner working in TOMY 1, at Larissa City, in Greece. The participant's eligibility was the following:

1) person aged 65 years old or older at the time of recruitment

2) living in the area of Thessaly & Sterea

3) self-reported capacity to wear the activity wristband, operate the glucose/pressure meter and use the apps installed on the smartphone/tablet

4) self-reported capacity to consent

5) has daily access to internet

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6) suffering from chronic disease;

7) Capability of traveling

Ethical Considerations

Research ethics approval

Approval to conduct the pilot was sought from a Research Ethics Committee of 5YPE (Scientific Committee) before the start of the recruitment process. This protocol and all other relevant documents have been submitted. Prior to submission to the REC, this protocol has been reviewed and approved for submission by colleagues within the SHAPES consortium.

Protocol amendments

There were not any substantial amendments that required review by Research Ethics Committee (REC) of 5YPE. Therefore, nothing was implemented without the approval of the REC of 5YPE.

Informed Consent Procedure

All participants were asked to provide voluntary, informed consent for their participation in the pilot. The consent form included the following explicit consents: All participants till reaching objectives: participation in the tests under controlled environment.

Declaration of interests

Research collaborators are employees of GNOMON, LogMeal and TREE TECHNOLOGY, proprietaries of eHealthPass, Logmeal4SHAPES, Datalake & Data-analytics, respectively.

Access to data

5YPE is 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

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At the end of the pilot the devices provided to participants will be removed and access to the SHAPES app will be stopped.

3.7.4 Recruitment of participants in Cyprus (UNRF) and Ethical Considerations

Potential participants who stay in Strovolos day centre were invited to participate in the pilot in Cyprus. On this note and because the numbers are small, participants were selected on the basis of convenient and random sampling. Sampling was convenient because participants would be available at the day centre. Five (5) participants were selected to participate in the pilot acceptability study in Cyprus.

The inclusion criteria

The following inclusion criteria that were applied to both acceptability and validation studies and both study and control groups:

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

Prior to study initialization, all seniors would sign the Informed Consent form. Individuals who did not sign the Informed Consent were excluded.

Exclusion Criteria

The following exclusion criteria were applied to both acceptability and validation studies and both study and control groups:

- subjects not living in the catchment area (Nicosia)
- any acute medical condition,
- any surgery in the last 3 months
- major neurocognitive disorder
- moderate and severe depression
- existing disability (needs human help in one or more basic activities of daily living)
- heart failure functional class
- angina pectoris
- uncontrolled high blood pressure (>160 mmHg systolic)
- heart arrhythmias that could interfere with functionality
- peripheral arterial disease

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- any terminal illness
- frailty syndrome
- risk of falls
- any condition that might limit mobility (e.g., Parkinson's disease, severe arthritis, stroke sequela)
- visual impairment (best corrected visual acuity of worse than either 20/40 or 20/60)

Exclusion criteria were documented by medical history.

If the person gives informed consent, then is included in the study and continues with Compliance Form.

If the person does not fully complete baseline questionnaires, then is excluded from the study.

If person does not fully comply with SHAPES instructions or does not appropriately use SHAPES items, person is excluded from study.

The eligible participants were service users of Strovolos Day Centre in Cyprus or in the community and include people with diabetes, over 65 years with access to android smartphone or tablet and stable Wi-Fi. This cohort is a vulnerable group due to possible multi-morbidity.

Ethical considerations

UNRF commit to uphold ethical research standards, including the European Code of Conduct for research integrity. The principles of maximizing benefit and minimizing harm, social responsibility, dignity of persons, fundamental/human rights and other issues mentioned in the H2020 ethical self-assessment are supported during pilot 7 by taking into use ethical self-assessment procedure before the implementation. UNRF has provided ethical self-assessment with attached documents and delivers it to EM and uploads to WP8 Microsoft TEAMS. UNRF also follows local guidelines and regulations regarding piloting 3 activities with the citizens, including also practices with incidental. In case problems occur, they are to be discussed with EM and in the EAB. EM will record the activities in the ethics paper trail and finally report it as part of the ethical progress report.

The validation/verification/assessment of ethical features of SHAPES

The ethical requirements related to SHAPES technology and the use of it will be validated as part of the general SHAPES validation approach during the pilots. This includes not only ethical features of the various digital services and data analytics, but also e.g., validation of consent to be collected on the SHAPES platform. The ethical

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requirements relating to privacy and data protection will be assessed as part of the SHAPES privacy and data protection impact assessment (DPIA) process (D8.10 and D8.11).

UNRF as a replicating site follows the Data Lifecycle Management Plan from the leading site NUIM that describes how the data will be used in the pilot and how the general data management principles have been taken into account. DLMPs were stored in pilot's 7 own Microsoft Teams folder.

UNRF has submitted an initial plan for the pilot activities to the respective National Bioethics Committee of Cyprus and have received a positive response.

Table 6: Guidelines

Functional limitation	**Guidelines for tutors of SHAPES app**
Decline in hearing	• Get the listener's attention before you speak • Look at the listener as you speak • Speak naturally • Use simple words and sentence structure • Avoid ambient noise • Use visual signs and gestures
Cognitive impairment	• Provide slow and clean lines of communication • Use a calm and focused communication • Be aware the listener may lack confidence • Evaluate whether the listener understands • Find another way to express the information if the listener does not seem to understand
Mobility limitations	• Take a seat at the same level and apply eye contact with the listener/speaker • Treat the potential wheelchair as part of the listener's/speaker's personal space • Use natural lip movements, voice tone, and volume

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	• Use condescending language • Use non-patronizing language and actions
Visual function impairments	• Consult with the person as to the type of communication needed (e.g., large font, disk, Braille, text-to-speech) • Use natural volume and tone • Ask for feedback to evaluate if the listener understands • Check related software and hardware for visually impaired people

3.7.5 Results Analysis

The Socio-demographics of the participants of 5YPE's and UNRF's use cases are shown in Tables 7 and 8, respectively.

Table 7: Analysis of the socio-demographics of the 5YPE's participants in UC-PT7-001

Variables	Number of participants	Value
Age (years)	7	M = 72,29 SD = 4,64
Male	7	Number = 2 (28,57%)
Country: Greece	7	Number = 7 (100%)
Marital status	7	Married: 3 (42,86%) Widowed: 4 (57,14%)
Occupational status: retired	7	Number = 6 (85,71%)
Occupational status: other	7	Number = 1 (14,29%)
Residence: own home	7	Number = 7 (100%)

Table 8: Analysis of the socio-demographics of the UNRF's participants in UC-PT7-001

Variables	Number of participants	Value
Age (years)	5	M = 71,8 SD = 5,21

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Male	5	Number = 2 (40%)
Country: Cyprus	5	Number = 5 (100%)
Marital status	5	Married: 4 (80%) Widowed: 1 (20%)
Occupational status: retired	5	Number = 4 (80%)
Occupational status: employed full time	5	Number = 1 (20%)
Residence: own home	5	Number = 5 (100%)

3.7.5.1 Measurements of KPIs at 5YPE's UC-PT7-001

Recruitment and retention

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

Table 9: Recruitment Status in 5YPE for UC-PT7-001

Parameter	DYPE5
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 10: 5YPE's Participants' adherence in UC-PT7-001

Parameter	DYPE5
Number of participants at baseline	7
Number of withdrawals	0
Number of participants at end of study	7
Percentage retained	100%

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KPI 3 At least 60% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Table 11: SUS in 5YPE for UC-PT7-001

Parameter	Value
Number of participants at end of pilot	7
Number of participants scoring >68 in SUS	0 M = 53,21 SD = 4,01 Med = 52,5 Min = 47,5 Max = 60
Percentage of participants scoring > 68 in SUS	0%

Overview of KPI achievement

Table 12: KPIs achievements in 5YPE for UC-PT7-001

Key performance indicator	*Achieved during pilot activity (yes/no)*	*Comments*
KPI 1	*yes*	
KPI 2	*yes*	
KPI 3	*no*	It is difficult for the participants to enter the codes frequently so that they can use the applications on the mobile devices.

Evaluation of MAST

The MAST framework was used to evaluate the effectiveness and contribution of UC-PT7-001 to foster older people's (with physical disabilities) independent living by identifying accessible locations and routes in other locations. The evaluated data/outcome are presented in Table 13.

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Table 13: MAST evaluation results of UC-PT7-001 in 5YPE

MAST Domain	Topic	Outcome	Timepoint: Start of pilot (mean/SD)	Timepoint: End of pilot (mean/SD)
Clinical Effectiveness	Mental health	OSSS-3 (social support) and life events	M = 12 SD = 0,78 Med = 12 Min = 11 Max = 13 **"strong social support"**	M = 12,14 SD = 1,07 Med = 12 Min = 11 Max = 14 **"strong social support"**
	Effects on health-related quality of life	EQ-5D-5L VAS scores	**Health Status** M = 90 SD = 0 Med = 90 Min = 90 Max = 90	**Health Status** M = 89,29 SD = 1,89 Med = 90 Min = 85 Max = 90
		WHOQOL-BREF scores	**Domain 1:** M = 86,71 SD = 7,78 Med = 88 Min = 75 Max = 94	**Domain 1:** M = 88,71 SD =4,42 Med = 88 Min = 81 Max = 94
			Domain 2: M = 83 SD = 6,14 Med = 81 Min = 75 Max = 94	**Domain 2:** M = 85,86 SD = 5,01 Med = 88 Min = 81 Max = 94
			Domain 3: M = 76,71 SD = 4,54 Med = 75 Min = 69 Max = 81	**Domain 3:** M = 79,29 SD = 4,54 Med = 81 Min = 69

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				Max = 81
			Domain 4: M = 86,86 SD = 4,56 Med = 88 Min = 81 Max = 94	**Domain 4:** M = 91,14 SD = 8,05 Med = 94 Min = 81 Max = 100
Patient perspectives	Satisfaction and acceptance	User Experience (UEQ-S scores)	M = NA SD = NA	M = NA SD = NA
		User acceptance (TAM score)	**Usefulness:** M = 3,57 SD = 0,53 Med = 4 Min = 3 Max = 4	**Usefulness:** M = 4 SD = 0 Med = 4 Min = 4 Max = 4
			Future use: M = 3,71 SD = 0,49 Med = 4 Min = 3 Max = 4	**Future use:** M = 4 SD = 0 Med = 4 Min = 4 Max = 4
	Understanding of information Confidence (in the treatment) Ability to use the application Access & Accessibility	Usability of application (SUS Scores)	M = 62,5 SD = 4,08 Med = 62,5 Min = 55 Max = 67,5	M = 53,21 SD = 4,01 Med = 52,5 Min = 47,5 Max = 60
		Usability of application (1-item health literacy)	M = 5 SD = 0 Med = 5 Min = 5 Max = 5	M = 5 SD = 0 Med = 5 Min = 5 Max = 5

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	Empowerment Self-efficacy	Self-efficacy (SHAPES Participation questionnaire)	Participation in activities: M = 5 SD = 0 Med = 5 Min = 5 Max = 5	Participation in activities: M = 4,5 SD = 0,55 Med = 4,5 Min = 4 Max = 5
			Effect of using DS on participation in activities: M = 4,43 SD = 0,53 Med = 4 Min = 4 Max = 5	Effect of using DS on participation in activities: M = 3,67 SD = 0,52 Med = 4 Min = 3 Max = 4
		Self-efficacy (GSES)	M = 39,57 SD = 0,79 Med = 40 Min = 38 Max = 40	M = 38,14 SD = 2,48 Med = 40 Min = 34 Max = 40

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, the number of notifications and access to data history. All the participants were accustomed to using smartphone/tablet technologies. Regarding the interaction the participants mentioned to provide motivational recommendations, the possibility of selecting one owns 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. Furthermore, it was proposed to have the possibility to test the devices which was already planned for the next phase.

The participants were able to interact with the app, test its different functionalities and use all three components of the app (SHAPES frontend and eHealthpass), which were interlinked and presented to users as ‘one’ app for the first time. This way, potential navigation issues or inconsistencies were 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

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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. This phase will provide the opportunity to test the functionality of the app in a real-world environment. The testing participants found very difficult the interaction will all the applications at the same time. Their age is an obstacle to continuously filling in data in a smartphone application on a regular basis, thus the LogMeal application was not tested. Although it successfully recognized single fruits, the process of recognizing complex food asking for continuous input of its calories/kilograms was prohibitive.

Withings Scanwatch Medical Device: what did the participants say?

- Very important for the participants to be able to count their steps on a daily basis so that they can reach the goal set by their doctor in order to be able to regulate their weight better.
- The possibility of an electrocardiogram which is recorded on the mobile phone is extremely useful. In fact, at the end of the cardiogram, the result is written, i.e., whether it is normal or not. Also, there is the possibility to send the electrocardiogram to the doctor by text or email, which makes the patient feel very safe about his health. The application is particularly useful for patients with a history of atrial fibrillation.
- Particularly useful is the ability for participants to be able to measure spO2. This feature can be particularly useful in patients with chronic respiratory problems such as chronic obstructive pulmonary disease and asthma. In fact, it could be useful during the covid-19 period for both doctors and patients.
- Some of the participants mentioned that they were not used to the daily use of the watch and for this reason they might forget to wear it. Also, some others reported that it bothered them to wear it during the night. On the positive side of the watch is its long battery life, so that it does not need to be charged often.

FORA D40 gr Medical Device: what did the participants say?

- Easy-to-use dual device for both blood pressure and blood sugar measurement ensures participants the possibility of greater self-care and self-management of their health.

The ability to record the results of the patients on the platform ensures better monitoring both by them and by the doctor who can control them remotely.

Recommendation for technical partners

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Several meetings were 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. These referred to the navigation through the app, fixing bugs as well as changes in wording or design. Several technical issues were raised on the interoperability of the applications and the transfer of the user credentials between the different vendors.

3.7.5.2 Measurement of KPIs at UNRF's UC-PT7-001

Recruitment and retention

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

Table 14: Recruitment Status in UNRF for UC-PT7-001

Parameter	DYPE5
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 15: UNRF's Participants' adherence in UC-PT7-001

Parameter	DYPE5
Number of participants at baseline	5
Number of withdrawals	0
Number of participants at end of study	7
Percentage retained	100%

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KPI 3 At least 60% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Table 16: SUS in UNRF for UC-PT7-001

Parameter	Value
Number of participants at end of pilot	5
Number of participants scoring >68 in SUS	0 M = 53,5 SD = 3,79 Med = 52,5 Min = 50 Max = 57,5
Percentage of participants scoring > 68 in SUS	0%

Overview of KPI achievement

Table 17: KPIs achievements in UNRF for UC-PT7-001

Key performance indicator	*Achieved during pilot activity (yes/no)*	*Comments*
KPI 1	*yes*	
KPI 2	*yes*	
KPI 3	*no*	It is difficult for the participants to enter the codes frequently to use the applications on the tablet.

Evaluation of MAST

The MAST framework was used to evaluate the effectiveness and contribution of UC-PT7-001 to foster older people's (with physical disabilities) independent living by identifying accessible locations and routes in other locations. The evaluated data/outcome are presented in Table 18.

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Table 18: MAST evaluation results of UC-PT7-001 in UNRF

MAST Domain	Topic	Outcome	Timepoint: Start of pilot (mean/SD)	Timepoint: End of pilot (mean/SD)
Clinical Effectiveness	Mental health	OSSS-3 (social support) and life events	M = 7 SD = 2,35 Med = 6 Min = 5 Max = 10 **"poor social support"**	M = 6,4 SD = 0,89 Med = 7 Min = 5 Max = 7 **" poor social support"**
	Effects on health-related quality of life	EQ-5D-5L VAS scores	**Health Status** M = 60 SD = 10 Med = 60 Min = 50 Max = 70	**Health Status** M = 55 SD = 11,18 Med = 50 Min = 50 Max = 75
		WHOQOL-BREF scores	**Domain 1:** M = 53,8 SD = 5,76 Med = 50 Min = 50 Max = 63	**Domain 1:** M = 52,8 SD = 10,52 Med = 50 Min = 38 Max = 63
			Domain 2: M = 53,6 SD = 5,37 Med = 56 Min = 44 Max = 56	**Domain 2:** M = 67,4 SD = 12,74 Med = 63 Min = 56 Max = 81
			Domain 3: M = 61,2 SD = 10,38 Med = 56 Min = 50 Max = 75	**Domain 3:** M = 42,4 SD = 19,07 Med = 31 Min = 25 Max = 69
			Domain 4:	**Domain 4:**

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			M = 63,8 SD = 11,21 Med = 63 Min = 50 Max = 75	M = 54 SD = 24,72 Med = 63 Min = 13 Max = 75
Patient perspectives	Satisfaction and acceptance	User Experience (UEQ-S scores)	M = NA SD = NA	M = NA SD = NA
		User acceptance (TAM score)	**Usefulness:** M = NA SD = NA	**Usefulness:** M = 4,6 SD = 0,55 Med = 5 Min = 4 Max = 5
			Future use: M = NA SD = NA	**Future use:** M = 4,4 SD = 0,55 Med = 4 Min = 4 Max = 5
	Understanding of information Confidence (in the treatment) Ability to use the application Access & Accessibility	Usability of application (SUS Scores)	M = NA SD = NA	M = 53,5 SD = 3,79 Med = 52,5 Min = 50 Max = 57,5
		Usability of application (1-item health literacy)	M = 3,4 SD = 1,82 Med = 4 Min = 1 Max = 5	M = 2,8 SD = 0,84 Med = 3 Min = 2 Max = 4
	Empowerment Self-efficacy	Self-efficacy (SHAPES Participation questionnaire)	Participation in activities: M = 4 SD = 0 Med = 4 Min = 4	Participation in activities: M = 2,6 SD = 0,89 Med = 2 Min = 2

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			Max = 4	Max = 4
			Effect of using DS on participation in activities: M = 2,6 SD = 1,14 Med = 3 Min = 1 Max = 4	Effect of using DS on participation in activities: M = 1,4 SD = 0,55 Med = 1 Min = 1 Max = 2
		Self-efficacy (GSES)	M = 31,8 SD = 3,9 Med = 32 Min = 28 Max = 38	M = 27,4 SD = 2,61 Med = 27 Min = 24 Max = 30

The pilot has demonstrated positive impacts on the health outcomes of multimorbid older people. It facilitated better management of their multiple chronic conditions, resulting in enhanced quality of life and reduced healthcare utilization.

The pilot implemented personalized interventions based on individual patient needs, considering their specific multimorbid conditions. This approach could have led to more targeted and effective care strategies.

The pilot might have resulted in higher levels of patient satisfaction due to the improved coordination, personalized care, and better health outcomes they experienced.

Challenges:

One of the challenges in supporting multimorbid older people is integrating and consolidating data from various healthcare systems and providers. The pilot has faced obstacles in accessing and aggregating data, hindering comprehensive patient assessment and care coordination.

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Encouraging multimorbid older people to adhere with technology was challenging. The pilot has faced difficulties in ensuring patient compliance and engagement with the recommended procedures to sign in by entering their credentials each time.

The team worked with a standby person using shifts to allow continues monitoring and remind the patients to acquire their data. Reminders done by phone calls or face to face assistance in case the technology couldn't accomplish the data acquisition.

Areas for improvement:

Addressing data integration challenges by implementing robust interoperability solutions and standards to enable seamless exchange and aggregation of patient data from various sources.

Implementing strategies to educate and empower multimorbid older patients about their conditions, technology plans, and self-management techniques. This can enhance patient adherence and engagement.

Designing the pilot with long-term evaluation metrics to assess its sustained impact on patient outcomes, cost-effectiveness, and scalability. This can provide valuable insights for future interventions.

Conducting a thorough assessment and analysis tailored to the specific use case is crucial for meaningful insights and successful implementation.

Contact:

In the pilot activity for data acquisition from older adults, effective communication among all participants was crucial for the success of the project.

In the pilot activity, communication between all participants for data acquisition from older adults was conducted through a clear, open, positive, and focused approach. The key stakeholders involved in the communication process include relatives, researchers from UNRF, and the participants themselves. Here's how each aspect of communication was addressed:

Clear and concise communication was emphasized throughout the pilot. The objectives, requirements, and expectations of the data acquisition process were communicated to all participants in a transparent manner. This ensured that everyone involved had a shared understanding of the project's goals and their respective roles.

An open communication environment was fostered, encouraging participants to express their thoughts, concerns, and suggestions freely. Regular meetings, such as kick-off meetings, progress updates, and feedback sessions, were held to aid in case

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technological difficulties occurred. Participants were encouraged to ask questions, provide input, and share their experiences and expertise related to data acquisition from smartbands and blood pressure.

A positive communication atmosphere was maintained throughout the pilot. The technical partners emphasized the importance of maintaining a supportive and collaborative environment. This included recognizing and appreciating the efforts and contributions of all participants, providing constructive feedback, and celebrating achievements and milestones. Positive reinforcement helped motivate participants and create a sense of shared purpose.

Communication was focused on the specific goals and requirements of data acquisition from older adults. The discussions and interactions were centered around topics such as data collection methodologies, privacy and security concerns, patient consent processes, data quality assurance, and any potential challenges or barriers that emerged. The communication efforts were directed towards ensuring efficient and effective data acquisition while maintaining patient privacy and compliance with relevant regulations.

To facilitate communication, various communication channels may have been used, such as in-person meetings, video calls, or instant messaging platforms. The choice of communication channels would depend on the preferences and needs of the participants.

Goals:

It was essential for the objectives of the use case to be clearly communicated to all participating partners and the UNRF team. This includes defining the overall goals of the project, such as improving healthcare management, enhancing patient outcomes, or optimizing care coordination. The objectives were specific, measurable, achievable, relevant, and time-bound to ensure a shared understanding among all stakeholders.

As aforementioned effective communication channels were established to convey the objectives to the participating partners and the UNRF team.

The expectations of the use case for older adults were clearly communicated and understood by both the technical partner and the UNRF team. This includes outlining the specific roles and responsibilities of each party, as well as the expected outcomes and deliverable. Clear expectations help set the right direction and ensure alignment between the technical partner's capabilities and the needs.

Throughout the project, regular feedback loops were established to address any misunderstandings or gaps in understanding. Thus, we created an open and

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supportive environment where participants can freely ask questions, seek clarifications, and provide input. Regular check-ins and progress updates help monitor whether the objectives and expectations were being met and make necessary adjustments if needed.

Ultimately, the clarity of objectives and expectations in the use case depended on effective communication, active engagement, and continuous dialogue among all involved parties. It was important to establish a collaborative atmosphere where concerns and questions could be addressed, ensuring a shared understanding and alignment of goals.

Older adults' feedback regarding their experience with SHAPES platform:

Many older adults appreciate the convenience of remote monitoring, as it allows them to receive healthcare services from the comfort of their own homes.

Remote monitoring provides a sense of security for older adults, knowing that their physiological signs are being monitored regularly, and any abnormalities can be detected early.

Some older adults find that remote monitoring empowers them to take an active role in managing their health and well-being.

The ability to monitor physiological signs remotely can minimize the need for frequent hospital visits, which is often a relief for older adults.

Challenges:

Older adults faced difficulties in using the technology associated with remote monitoring platforms. Issues like setting up devices, connecting to the internet, or navigating the platform's interface were a barrier.

Some older adults struggle with the newness of the technology or feel overwhelmed by the learning curve associated with remote monitoring platforms.

Inadequate technical support or insufficient guidance in using the platform could lead to frustration and a lack of confidence among older adults.

Older adults expressed concerns about the privacy and security of their personal health data transmitted through remote monitoring systems.

Requests:

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Older adults would appreciate intuitive and user-friendly platforms that are easy to navigate, with clear instructions and larger font sizes for readability.

Providing simplified setup processes for devices and step-by-step instructions can make it easier for older adults to get started with remote monitoring.

Offering comprehensive training, both in-person and through accessible resources, would help older adults feel more confident and comfortable in using the platform.

Implementing robust privacy and security measures, such as encryption of data and transparent data handling policies, can address the concerns of older adults and foster trust in the platform. Figures 14 and 15 illustrate the digital solution functionalities while on operation.

Devices:

1. Blood pressure monitor: OMRON M7 Intelli IT.
2. LIBERTY smartbands by VIDAVO.
3. Tablet device: LENOVO TABLET TAB M10 TB-X306F HD 2ND GEN (for the participants that do not own a tablet or smartphone).
4. Wireless Wi-Fi plug sockets (for the participants that do not have access to Wi-Fi).

Applications:

1. eHealthPass by GNOMON.
2. eCare by EDGE.

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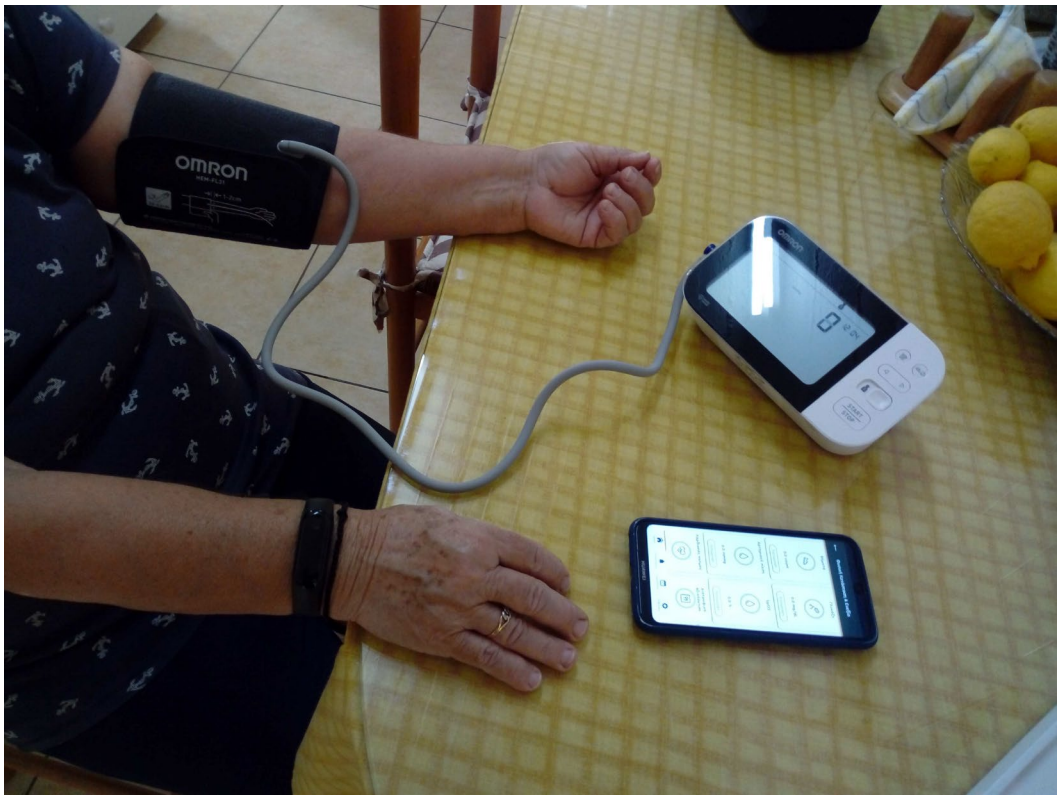

Figure 13: On field usage of Omron and Liberty devices in UNRF's replication

Figure 14: Dashboard of the eCare android app in the participant's table from the UNRF replication, where measurements from the devices are depicted

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3.7.5.3 Overall analysis of the objective goals of the UC-PT7-001

Table 15 summarises the feedback we received during the execution of UC-PT7-001 in both main and replication sites, with respect to the defined objectives of the study.

Table 19: Objectives Analysis in 5YPE (UC-PT7-001)

PO1
To investigate user engagement with the novel system (PO1)
The participants did not face any problems using the applications and devices. In fact, most reported that although they themselves were not familiar with the technology, the devices were quite easy to use The study ended with all participants using the applications in a daily basis.
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 them with the sense of being more independent despite their health problems. Their opinions are reflected in their feedback.
SO1
To investigate the capability of the novel system to maintain the supervision of the individual health and wellbeing status while on the move
The use of the smart watches with the ability to record the step count as well as the spO2 and heart rate as well as the ability of eHealthPass & eCare application to directly provide data from the participants to GP has created a feeling of security and confidence in patients regarding their health
SO2
To investigate the association of home and away from home physical activity classification, sleep quality analysis, fluid intake and nutrition analysis with the individual perceived wellbeing

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This was not measured since it was difficult for the participants to cope with the relevant apps.
SO3
To investigate the capability of the novel system to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects while on the move (SO3)
Measuring the steps, kilometres walked by the patient helps to assess the health status of the patient. The ability to communicate not only by phone but also by camera enables the doctor to assess the patient's psychological state and to be able to empower him when needed
SO4
To explore user trust and acceptance of the novel system
All participants showed great interest in using apps and devices and considered them important in maintaining a good quality of health and life
SO5
To investigate the capability of the novel system to establish direct communication between the patient and his/her personal physician, thus making older individuals feel safer while on the move
Being able to communicate and see the doctor wherever you are offers great security to people of more than 65 years old.
SO6
To investigate the capability of the novel system to be used for scheduled regular videoconference sessions between the patient and his/her personal physician without the patient visiting the physician's office (SO6)
Checking blood pressure and blood glucose readings without having to contact the doctor themselves helps to reduce travel and waiting times at doctor's offices**.**
SO7

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To investigate the capability of the novel system to bring the patient closer to his/her personal physician, thus increasing the sense of attention that older individuals feel (SO7).
Communication through the application is no less than face-to-face communication. The patient can express his health concerns to his doctor and the doctor through the monitoring of the applications has a complete picture about his patient's health

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4 Use case PT7-002

4.1 Introduction

According to data from World Population Prospects: the 2015 Revision (United Nations, 2015), the number of older persons has increased substantially in recent years in most countries and regions, and that growth is projected to accelerate in the coming decades. Between 2015 and 2030, the number of people in the world aged 60 years or over is projected to grow by 56 per cent, from 901 million to 1.4 billion, and by 2050, the global population of older persons is projected to reach nearly 2.1 billion. Furthermore, the higher disability rates among older persons, as a result of an accumulation of health risks across a lifespan of disease, injury, and chronic illness contributes to the higher disability rates among older people, urges countries to review and further explore the complementarities between the discourses on ageing and on disability[1]. Around the world, persons with disabilities face a number of obstacles including attitudinal, environmental and institutional barriers preventing their full and equal participation in all aspects of life such as travelling, participating in activities and others. Often older persons with disabilities are among the most adversely affected, facing further age barriers in society.

Health literacy and individual involvement will be key elements in the successful introduction of eHealth into the health and social care system, thus emerging technologies need to be user-friendly and empowering. Innovative systems such as information and communication technologies Access Earth (AELTD)[2], ICSee (SciFy)[3] offer great opportunities to support and enhance independence for older adults and may be related to independence maintenance, and social inclusion in advanced age. With the support of technology like the mentioned above, older people with disabilities can achieve a more accessible, safe and inclusive life.

The use case PT7-002 *Foster older people's (with physical disabilities) independent living by identifying accessible locations and routes in other locations (domestic and abroad)* of this project study focuses on fostering older people with physical disabilities, independent leaving by identifying accessible locations and routes in other locations (domestic and/or abroad). This use case shall be used to demonstrate that SHAPES Digital Ecosystem can identify travelling destinations and sites that are friendly and accessible to people with disabilities. SHAPES will access the safety and accessibility level of potential destinations, suggest routes and sites, provide

[1] United Nations. Department of Economic and Social Affairs Disability. https://www.un.org/development/desa/disabilities/disability-and-ageing.html
[2] https://www.accessearth.com/
[3] https://www.scify.gr/site/en/impact-areas-en/assistive-technologies/icsee

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navigation and assistance, thus enhancing the individual's confidence to make an informed decision in selecting a tourist destination and/or activity.

The use of platforms and other devices can empower these individuals to improve access in hotels, restaurants, cafes and public assembling buildings (museums, theatres), reflect on their own health and wellbeing status and adapt new lifestyles that reduce loneliness and isolation and aim to embody older people in the community. 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.

People older than 60 years old living at home in the reference site region of Thessaly and Sterea, Greece participated in the study. They were all persons aged 60 years old or older at the time of recruitment with self-reported capacity to use the apps installed on the tablet and with daily access to internet. A total of 5 people with disabilities, 2 people with vision problems and 3 people with mobility problems participated.

Participants were asked to use the SHAPES app on the tablet provided by the 5th Regional Health Authority of Thessaly & Sterea (henceforth 5thYPE). Additionally, participants received Android Tablets with the applications of ACCESS EARTH (from AELTD) and ICSee (from SciFy) being installed. Participants were encouraged to identify travel destinations and activities apart from the anxiety of accessibility and security.

This study tests the hypothesis that the SHAPES platform and Digital Solutions (novel system) can foster older people's - with physical disabilities - independent living, by identifying accessible locations and routes in other locations (domestic and abroad).

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 identify travelling destinations and sites that are friendly and accessible to people with disabilities (SO1).
- To investigate the capability of the novel system to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects when travelling (domestic and abroad) (SO2).
- To explore user trust and acceptance of the novel system (SO3).
- To understand the broader and different context of the lives of older individuals (SO4).

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- To create more accessible public physical pathways in our social spaces (SO5).

This use case is led by 5YPE.

The use case is based on the needs and life world of the persona "**Fredrik**" (8) who is described in more detail in SHAPES's D2.5. He is 75 years old and he has hearing and vision impairments since birth. He started facing deafblindness in the 1980s, so he needs to have access to guide-interpreter services, to remain living independently at his own house as long as possible and to communicate with friends and family.

4.2 Description

Older people with physical disabilities (including deafness and blindness) are usually discouraged from choosing the recreational experience of travelling to other locations (abroad and domestic). Both they require for medical assistance (especially when a chronic disease is also involved) and especially the little-to-no knowledge of the destinations accessibility and safety conditions act as a turn-off for any decision-making process for traveling and tourism activities. To support this process and the activities that follow it, solutions / tools are required:

- to assess and identify the accessibility / safety levels of potential destinations
- to enable them to make their way once they have visited their selected destination

thus, contributing to their active and independent living in an assertive way.

4.3 Digital solutions used in this use case

4.3.1 ACCESS EARTH Digital Solution

Access Earth is a global platform that uses smart AI and crowd sourced data gathering methods to provide the world with details on the accessibility assets within local bars, restaurants, shops, and other businesses venues.

Its mission is to provide tools and resources (including application for android smartphones/tablets) to measure, improve, and celebrate accessibility in communities and businesses everywhere.

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Figure 15: Access Earth application

4.3.2 ICSee Digital Solution

ICSee is an innovative application which runs on small mobile devices (android smartphone/tablets) and facilitates reading texts and recognizing details in objects in a simple way, convenient and always available. More specifically, ICSee processes the image/video of the device's camera in real-time, applies a series of filters and shows on screen a result easier to be read or recognized.

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Figure 16: ICSee application

4.3.3 Digital solutions used for COVID-19 response

In UC-PT7-002, no digital solution for the COVID-19 response was used.

4.3.4 Equipment and devices used (from third parties)

The following external devices have been used in UC-PT7-002: **Android tablet: Lenovo Tab M10 (3rd Gen) model TB328XU.**

4.4 Data plan

The data plan for execution phase is summarized in the following table:

Table 20: Data plan for UC-PT7-002

Variable	Format	When	Variable Levels
Age	Continuous	Baseline (T0)	
Gender	Nominal	Baseline (T0)	
Education (years spent in formal education)	Continuous	Baseline (T0)	
Marital status	Nominal	Baseline (T0)	1=Married, 2=cohabiting, 3=single (never married), 4=separated, 5=divorced, 6=widowed

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Occupational status ("Do you work for payment/money?")*	Nominal	Baseline (T0)	1=Employed full-time, 2=employed part-time, 3=not employed, 4=retired, 5=other
Are you a caregiver? [informal]	Ordinal	Baseline (T0)	1=No, 2=Yes (part-time), 3=Yes (full-time)
Do you receive help from a family member or friend for daily activities?	Nominal	Baseline (T0)	1=Never, 2=Rarely, 3=Sometimes, 4= Often
Do you receive help from a caregiver, health professional, or support service for daily activities?	Nominal	Baseline (T0)	1=Never, 2=Rarely, 3=Sometimes, 4=Often
Residence (Where do you live currently?)	Nominal	Baseline (T0)	1=Own home, 2=caregiver's home, 3=long-term care facility (nursing home), 4=other
Do you live alone?	Dichotomous	Baseline (T0)	1=Yes, 2=No
Is your neighborhood…	Nominal	Baseline (T0)	1=Urban, 2=Suburban, 3=Rural
Country of residence	Nominal	Baseline (T0)	
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….?	Ordinal	Baseline (T0)	Very easily=1, Easily=2, Fairly easily=3, With some difficulty=4, With difficulty=5, With great difficulty=6

4.4.1 Data capture methods to be used

Data capture methods used during this pilot are listed below:

Initial phase (Recruitment)

- Semi-structured interviews

Control phase (Applications Setup)

- Data from initial phase was used

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Execution phase (Study and Data Analysis)

Excel file to capture the following data:

- Participant data
- Harmonised questionnaires (more details on harmonised data will be provided in Deliverable 6.9)
    - WHOQOL-BREF
    - EQ-5D-5L
    - General Self-Efficacy Scale
    - Oslo Social Support Scale
    - Single item health literacy scale
    - Participation questions
    - System Usability Scale
    - Technology acceptance questions

An assessment of digital solutions also took place through open (non-structured) interviews

4.4.2 Planning of evaluation

The MAST framework (model for assessment of telemedicine) (9) will be applied as it provides a structured approach for assessing the effectiveness and contribution of UC-PT7-002 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-PT7-002, two of the seven dimensions of MAST were identified/found to be of importance to consider:

- Clinical effectiveness
- Patient perspectives

A further exploration and description of the reasons for selection/inclusion will be provided in the evaluation report (D6.9). Table 21 shows a summary of the data required for MAST evaluation.

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Table 21: Data required for MAST evaluation of UC-PT7-002

MAST Domain	Topic	Outcome	Data required	Time point
Clinical Effectiveness	Mental health	OSSS-3 (social support) and life events		End of pilot
	Effects on health-related quality of life	Health related quality of life and wellbeing	EQ-5D-5L scores; WHOQOL-BREF scores	End of pilot
Patient perspectives	Satisfaction and acceptance	User Experience	UEQ-S scores	End of pilot
		User acceptance	TAM score	End of pilot
	Understanding of information Confidence (in the treatment) Ability to use the application Access & Accessibility	Usability of application	SUS Scores 1-item health literacy	End of pilot
	Empowerment Self-efficacy	Self-efficacy	SHAPES Participation questionnaire	End of pilot
			GSES (Self-efficacy)	End of pilot

The MAFEIP tool (10) will not be applied to evaluate UC-PT7-002 due to a small-scale deployment and a non-case controlled study design of the UC.

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

MOMENTUM (19) blueprints about telemedicine/telehealth, so it was not used in this use case. NASSS (20) framework (Nonadoption, Abandonment, Scale-up, Spread and Sustainability) was not used neither the short version of NASSS questionnaire because it was overwhelming to the participants with disabilities.

4.5 Initial Phase

4.5.1 PACT and FICS Scenario

For the execution of the PACT and FICS Scenario, the Fredrik persona has been used (Tables 22 & 23).

Table 22: PACT (UC-PT7-002)

Code	UC-PT7-002	**Version**	0.5	**Date**	2023/06/21
Applicable SHAPES Persona	Fredrik (P8), 75 years old, is a person with deafblindness since 1980s and lives alone since his divorce in 1980.				
Applicable SHAPES use case	UC-PT7_002 Foster older people's (with physical disabilities) independent living by identifying accessible locations and routes in other locations (domestic and abroad)				

People
 	
Roles and/or actors of typical users involved in delivering and receiving the telemedicine intervention
	• Older people aged 60+ with disabilities (moving, vision & hearing impairments)
	  • These individuals want to live independent by identifying accessible locations and routes in other places (domestic and/or abroad.
	  • They want to maintain close relationships with family and friends.
	  • They want to be active members of their community and participate in social activities.
	  • In order to do so, they need tools and applications to enhance their confidence in selecting a destination suitable for them.
	  • Loneliness and isolation feelings are reduced, and the health outcomes & the quality of life can be maintained or possibly even improved, enabling them to remain independent for longer.				

Activities Activities to be performed by the actors in order to successfully provide and receive the telemedicine intervention	**Patient** • Location tracking • Route planning • Selecting a recreational destination and/or activity (hotels, restaurants, cafes and public assembling buildings e.g., museums, theatres) • Being able to read newspapers, leaflets, signs, restaurant menus, bills, doorbells etc.				

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procedures for the professional and the patient; Parameters that determine the measures used in the intervention	
Context *Social-medical relevance of the telemedicine intervention; privacy issues; risks for the patient; locations*	• There are participants with different impairments (moving, vision and hearing) so it is important to focus on how easy is for them to use the device and the applications independently on a daily basis. Depending on their disabilities, some of them might need support from the researchers during pilot execution. • 24/7 availability of the applications: convenient access • GDPR and ethics in line with WP8 • Data and servers must be located within the EU. • Language: Greek • Home country: Greece • Location: city of Larissa, Thessaly
Scenario	• Fredrik wants to make a surprise to his daughter and take her to a restaurant to celebrate his birthday (Access Earth can be used for choosing the safest route to an accessible restaurant and ICSee can be used for reading the restaurant menu, paying the bill etc.)
Technology *Type of information/parameter that are relevant in monitoring the health status; type and frequency of accessibility of information; feedback modalities (communication)*	**Baseline demographics** • Age • Gender • Education • Marital status • Occupational status • Caregiver status • Help received from family/friends for daily activities. • Help received from caregiver/health professional/support service for daily activities. • Current residence • Living alone • Urban/suburban/rural neighborhood • Country of residence • Economic status and meeting daily needs. **Psychosocial assessment (post-intervention)** • OSSS-3 (social support) and life events • EQ-5D-5L • WHOQOL-BREF • 1-item health literacy • SHAPES Participation questionnaire

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	• Self-efficacy (GSES) **Technology interaction (post-intervention)** Usability • System Usability Scale (SUS) Technology Acceptance • Technology acceptance model (TAM) • UEQ-S

Table 23: FICS (UC-PT7-002)

Category	Detail
Function and events *Functionality of the intended system which is capable to realize actor's activities*	This use case presents one actor, Fredrik. He will use an android tablet to launch the provided applications (Access Earth and ICSee). The functionalities accessible to the actor are: • Authentication of the actor, provided by the SHAPES Platform, via the SHAPES Front-end App. • View detailed info about assessable destinations to people with moving impairments • Select desired destination and receive detailed route to it • Enhance quality of reading small texts (like the bill or a restaurant menu, the taximeter fare, a name on a bell)
Interactions and usability issues *User-system or system-component interactions meditating actor's activities; Types of the interactions, e.g., unidirectional data streaming service or reliable messaging service*	In this use case, we expect to have 1 user: • Fredrik There will be only one user interface for Fredrik. The applications have 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.
Content and structure	The interface of Fredrik will be the android tablet and Fredrik will have access to the installed applications (Access Earth and

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Variables of the interaction	ICSee). The interaction will use the touch screen interface of the tablet.
Style and aesthetics *Look and feel of the system*	We need some screenshots from the tablets (SHAPES application login screen, Access Earth and ICSee screenshots) Access Earth live demo 

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	ICSee live demo 

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-PT7-002.

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Recruitment and retention

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

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

User engagement and acceptance

KPI 3: At least 60% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

4.5.3 Timeline of pilot activities

The timeline needed to be adapted, due to several factors. First, the procurement of the tablets was delayed due to bureaucratic reasons. Then, the study was finally approved by the ethics committee in early January 2023 due to time-consuming procedures needed for clinical studies and trials. Afterwards, the applications were installed but were not fully operational in android tablets (some of the features were not functioning correctly) and needed to be troubleshooted and upgraded by the technical partners. Moreover, some of the participants were infected by COVID-19 and it was very difficult to contact them during that period (one of them needed approximately 3 weeks to recover).

The adapted timeline can be found in the following table (Table 24).

Table 24: Adapted timeline of activities for UC-PT7-002)

	Feb 2023	Mar 2023	Apr 2023	May 2023	…	Oct 2023
Initial Phase						
Control Phase (Applications Setup)		1 older person participant				
Execution Phase (Study)			Baseline → Intervention (3 weeks)			
Execution Phase (Data Analysis)				Based on harmonised		

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				data from UC-PT7-002	

Due to the above-mentioned delays, the final number of phases was 3 (Initial Phase, Control phase, Execution phase) and the pilot was executed only for 3 weeks.

The pilot of the SHAPES UC-PT7-002 was conducted between start date 20-3-2023 and end date of 15-04-2023 with 5 participants and 1 GP.

In initial phase, basic ideas of the technology of UC-PT7-002 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.

During this phase, a comprehensive market search for suitable android tablets took place. The clinical study was finalised in this phase and DPIA assessment was also made. The digital solution providers (AELTD, SCIFY) were contacted in order to get familiarized with the functionality of the applications. The execution of the pilot study was designed in initial phase.

Recruitment of the Participants

The initial phase was conducted with five people fulfilling the age criteria to be 60 years and older and having disabilities.

People older than 60 years old living at home in the reference site region of Thessaly and Sterea, Greece participated in the study, with self-reported capacity to use the applications installed on the tablet and with daily access to internet. A total of 5 people with disabilities, 2 people with vision problems and 3 people with mobility problems participated.

Initially, a visit was made by the researchers to the offices of the Disabled Association in the city of Larissa. At this first meeting, which was attended by about 10 people with disabilities, the SHAPES program was presented and informational material about the program was shared. Five of the members of the Disabled Association agreed to participate voluntarily in the study.

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

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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
- Handwritten signature

Data collection

Socio-demographics data was collected using a questionnaire (see Annex) comprising of closed questions. The Socio-demographics of the participants are shown in Table 25.

Table 25: Socio-Demographic characteristics (UC-PT7-002)

Variables	Number of participants	Value
Age (years)	5	M = 63,2 SD = 3,11
Male	5	number = 3 (60%)
Country: Greece	5	100%
Marital status	5	Married: 2 (40%) Cohabiting: 1 (20%) Separated: 1 (20%) Divorced: 1 (20%)
Occupational status: retired	5	Number = 3 (60%)
Occupational status: not employed	5	Number = 1 (20%)
Occupational status: employed full-time	5	Number = 1 (20%)
Residence: own home	5	100%

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4.6 Control Phase: Configuration of Digital Solutions and Testing

4.6.1 Methodology of testing

During Control phase, one of the five participants was chosen, and the applications and digital solutions were demonstrated to him. Afterwards, the applications were installed but at first place, they were not fully operational in android tablets (some of the features where not functioning correctly) and needed to be troubleshooted and upgraded by the technical partners.

4.6.2 Results of testing

In summary, the overall perception of the use case was high, and the participant did understand the context. In terms of IT-behaviour, the design of the mock-up was clear.

4.7 Execution Phase: Hand-on Experiments and Data Analysis

4.7.1 PT7-002 Execution and results analysis

Participants

During Execution phase, a second visit was made by the researchers to the offices of the Disabled Association in the city of Larissa, and the tablets were delivered to the five participants.

Method

A detailed presentation of the applications of ACCESS EARTH (AELTD), ICSee (SciFy) was made to the participants, and they were asked to make use of the applications during their daily activities or when moving outside home. After the end of the first week, participants were contacted via telephone to resolve doubts and concerns about the use of the novel system during the entire period of the pilot.

Collection of feedback

After the end of the intervention, data were collected in face-to-face interviews with the presence of the researcher for resolving doubts (due to the characteristics of the participants, questionnaires were used only at the end of the pilot).

A concurrent ‘think out loud’ approach was applied to collect reactions to the applications and identify any areas that will require particular attention. The participants were encouraged to verbalise their reactions, thoughts, feelings, and opinions about the use of the applications throughout their engagement with the researcher. Notes were taken by the researcher throughout the session.

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Participants feedback about the use of digital tools

Access Earth: what did the participants say?

- Useful and helpful app. It is also very important that it provides information concerning not only people with mobility disabilities but also people with sensory disabilities (blindness)
- The information about the use of protective measures related to covid-19 was particularly useful.
- Not keeping the details (sometimes) that were passed by the participants for a specific location.
- The need to frequently use the codes to start the application made it difficult for the participants.

ICSee: what did the participants say?

- The opportunity to select a filter is important (the participant with macular degeneration preferred the filter with a white background and black letters while the participant with benign intracranial hypertension preferred the filter with a black background and white letters)
- The voice instructions were helpful, but sometimes they "stuck" the operation of the application
- Difficulty using the application outdoors because they had to hold the smartphone or tablet where the application is past while holding the walking stick or doing any other activity (at this point the participants mentioned another application they use called "Be my eyes" with which, through a live video call, volunteers provide visual assistance to visually impaired people such as preparing food, matching clothes, etc.)
- A weakness of the application was that the participants had to enter the codes at regular intervals to start, which made it very difficult for them.

The KPIs performance is shown in the following tables.

Recruitment and retention

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

Table 26: Recruitment Status in UC-PT7-002

Parameter	5YPE
Target number of participants	5

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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 27: Participants' adherence in UC-PT7-002

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

User engagement

KPI 3 At least 60% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Table 28: SUS in UC-PT7-002

Parameter	Value
Number of participants at end of pilot	5
Number of participants scoring >68 in SUS	0 M = 48,5 SD = 18,08 Med = 55 Min = 22,5 Max = 65
Percentage of participants scoring > 68 in SUS	0%

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Overview of KPI achievement

Table 29: KPIs achievements in UC-PT7-002

Key performance indicator	*Achieved during pilot activity (yes/no)*	*Comments*
KPI 1	*yes*	
KPI 2	*yes*	
KPI 3	*no*	It is difficult for the participants to enter the codes frequently so that the applications can start. Especially for blind people, it is very difficult to login to the applications. All users where finally logged in with the help of the researchers and never logged out again during the pilot execution.

Evaluation of MAST

The MAST framework was used to evaluate the effectiveness and contribution of UC-PT7-002 to fostering older people's (with physical disabilities) independent living by identifying accessible locations and routes in other locations. The evaluated data/outcome are presented in Table 30.

Table 30: MAST evaluation results of UC-PT7-002

MAST Domain	Topic	Outcome	Timepoint: End of pilot (mean/SD)
Clinical Effectiveness	Mental health	OSSS-3 (social support) and life events	M = 12,75 SD = 0,96 Med = 12,5 Min = 12 Max = 14 **"strong social support"**
		EQ-5D-5L VAS scores	**Health Status** M = 75 SD = 12,25

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	Effects on health-related quality of life		Med = 80 Min = 60 Max = 90
		WHOQOL-BREF scores	**Domain 1:** M = 73,8 SD = 7,82 Med = 75 Min = 63 Max = 81
			Domain 2: M = 72,6 SD = 5,37 Med = 69 Min = 69 Max = 81
			Domain 3: M = 81,4 SD = 12,5 Med = 81 Min = 69 Max = 94
			Domain 4: M = 65,2 SD = 10,4 Med = 63 Min = 50 Max = 75
Patient perspectives	Satisfaction and acceptance	User Experience (UEQ-S scores)	M = NA SD = NA
		User acceptance (TAM score)	**Usefulness:** M = 4 SD = 0,71 Med = 4 Min = 3 Max = 5

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			Future use: M = 4,6 SD = 0,55 Med = 5 Min = 4 Max = 5
	Understanding of information Confidence (in the treatment) Ability to use the application Access & Accessibility	Usability of application (SUS Scores)	M = 48,5 SD = 18,08 Med = 55 Min = 22,5 Max = 65
		Usability of application (1-item health literacy)	M = 4,8 SD = 0,45 Med = 5 Min = 4 Max = 5
	Empowerment Self-efficacy	Self-efficacy (SHAPES Participation questionnaire)	Participation in activities: M = 5 SD = 0 Med = 5 Min = 5 Max = 5
			Effect of using DS on participation in activities: M = 4,2 SD = 1,3 Med = 5 Min = 2 Max = 5
		Self-efficacy (GSES)	M = 37,8 SD = 2,59 Med = 39 Min = 35 Max = 40

Secondary outcomes

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Besides, the pilot aimed at testing the capability of SHAPES platform and Digital Solutions to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects when travelling (domestic and abroad). Participants will be encouraged to identify travel destinations and activities apart from the anxiety of accessibility and security. Table 31 analyses the achievement of the objectives' goals in UC-PT7-002.

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 identify travelling destinations and sites that are friendly and accessible to people with disabilities (SO1).
- To investigate the capability of the novel system to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects when travelling (domestic and abroad) (SO2).
- To explore user trust and acceptance of the novel system (SO3).
- To understand the broader and different context of the lives of older individuals (SO4).
- To create more accessible public physical pathways in our social spaces (SO5).

Table 31: Objectives Analysis in UC-PT7-002

PO1
To investigate user engagement with the novel system (PO1)
The participants faced problems because login procedure was needed frequently so that the applications could start. Especially for blind people, it is very difficult to login to the applications. All users were finally logged in with the help of the researchers and never logged out again during the pilot execution. The study ended with all participants using the applications in a daily basis.
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 being more independent despite their disabilities.

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Their opinions are reflected in their feedback.
SO1
To investigate the capability of the novel system to identify travelling destinations and sites that are friendly and accessible to people with disabilities (SO1)
The use of platforms and other devices can empower people of more than 65 years old with disabilities to improve access in hotels, restaurants, cafes and public assembling buildings (museums, theatres) reflect on their own health and wellbeing status and adapt new lifestyles that reduce loneliness and isolation and aim to include older people in the community.
SO2
To investigate the capability of the novel system to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects when travelling (domestic and abroad) (SO2)
Technological tools (apps and devices) can be very useful and helpful to improve older people's quality of life. These tools provide information concerning not only people with mobility disabilities but also people with sensory disabilities (blindness).
SO3
To explore user trust and acceptance of the novel system (SO3)
The participants' interviews showed that both digital solutions have a great potential, but they need to be improved in some aspect related to accessibility and usability.
SO4
To understand the broader and different context of the lives of older individuals (SO4)
The higher disability rates among older persons, as a result of an accumulation of health risks across a lifespan of disease, injury, and chronic illness contributes to the higher disability rates among older people. Health problems often increase and can even lead to disability such as vision loss, hearing loss. For this reason, it is important to develop applications that will recognize the needs of the individuals of more than 65 years old and improve their quality of life.
SO5

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To create more accessible public physical pathways in our social spaces (SO5)
Applications that inform about the accessibility of various places such as theatres, museums, cinemas make it easier for people with disabilities because they can know in advance to choose the appropriate one.

Recommendations for technical partners

One of the participants said that he put the application on his mobile phone and hung it around his neck to make it easier for him to do outside chores, since that way he would have his hands free, but still he had some difficulties. So, what he proposed was to integrate the app into eyeglasses with interchangeable filters.

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5 Use case PT7-003

5.1 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 2060. 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 growth. 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 all.

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 age [3]. 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 to actions can be taken - resulting in better and longer health, independence and quality of life.

Citizens, including older individuals, must be seen as custodians of their own health, 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 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 use case PT7-003 *Smart and Healthy Ageing through People Engaging in Supportive Systems (SHAPES) digital app and platform for remote monitoring of key*

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health parameters of older individuals. A non-randomized, feasibility study in real world for establishing direct patient - GP communication while on the move of this project study focuses on old people suffering from chronic diseases (like Blood Pressure, Type II Diabetes, Chronic Obstructive Pulmonary Disease etc.) and more specifically, how to establish a direct communication channel between them and their personal physician while on the move.

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. This part of the study is also covered by UC-PT7-001-5thYPE study (Monitor older patient with chronic disease when travelling abroad). The current study extends the goal of UC-PT7-001-5thYPE study by focusing mainly on establishing a direct communication channel between the patient and his/her personal physician while on the move.

The SHAPES Ecosystem shall provide an easy and direct way for both the patient and his/her personal physician back home to communicate with each other. There are many cases where this kind of communication is necessary. For example, when the patient is on the move and he/she cannot find his/her medicine at the local pharmacies, then he/she shall communicate with his/her personal physician in order to take advice for an alternative drug. Sometimes, the patient needs to take an over-the-counter drug in addition to his/her regular medication and he/she wants to know if there is any possible interaction. Once again, he/she shall communicate with his/her personal GP using the SHAPES Ecosystem.

There are also some circumstances where the communication needs to be initiated not by the patient but by his/her personal physician. When the physician detects some irregular vital signals, he/she shall contact the patient using the SHAPES ecosystem and start a remote videoconference with him/her for consultation and guidance. Moreover, if the patient doesn't show up in the physician's office for a scheduled appointment (either for examination or prescription) then the physician shall once again communicate with the patient using the SHAPES ecosystem, in order e.g., to re-arrange the appointment and to evaluate the patient's condition if necessary. Finally, the physician shall use the SHAPES ecosystems for scheduled videoconference sessions on a regular basis, resulting in more frequent touch with the patient.

Therefore, older individuals will feel safer and thus more confident while on the move and they will continue to engage with family members and friends living away. 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.

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Objectives

Primary objectives

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

Secondary objectives

- To investigate the capability of the novel system to maintain the supervision of the individual health and wellbeing status while on the move (SO1).
- To investigate the association of home and away from home 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 while on the move (SO3).
- To explore user trust and acceptance of the novel system (SO4).
- To investigate the capability of the novel system to establish direct communication between the patient and his/her personal physician, thus making older individuals feel safer while on the move (SO5).
- To investigate the capability of the novel system to be used for scheduled regular videoconference sessions between the patient and his/her personal physician without the patient visiting the physician's office (SO6).
- To investigate the capability of the novel system to bring the patient closer to his/her personal physician, thus increasing the sense of attention that older individuals feel (SO7).

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 safe and independent traveling 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).

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This study is to demonstrate the capability of SHAPES Digital Ecosystem to establish a direct communication channel between the patient and his/her personal physician while on the move. Patients and physicians should be able, through SHAPES Ecosystem, to communicate face to face – as effectively as in a session conducted in the physician's office or patient's home. The use case is based on the needs and life world of the persona **"Ernst"** who is described in more detail in SHAPES's D2.5. He is 75 years old and in good health, he suffers from minor knee and back aches. He uses a smartwatch to monitor his heart rate and steps taken daily. His wife is recovering from a stroke. Ernst needs to have access to guide-interpreter services, to remain in good health himself and to keep in a good health his wife.

5.2 Description

It is not unusual for people of more than 65 years old to enjoy life by visiting various places, domestic or abroad. That kind of travel is usually for leisure or for visiting close relatives and friends. When on the move, patients and their caregiving relatives would like to have an easy way of communicating with their personal physician back home. So, for older individual to feel comfort and capable of visiting their children and grandchildren and preserving the notion that the patient "never left home", solutions and tools are required:

- to measure vital signs, track activity levels and evaluate behavioural patterns
- to remind of medication adherence
- to enable patients' caregivers (physicians, nurses) treat them from back home
- to communicate with their personal physician back home

5.3 Digital solutions used in this use case

Omnitor eCtouch

eCtouch[4] is an app designed to make it possible for people with disabilities to communicate remotely without any obstacles. With eCtouch, you communicate smoothly with your friends, family, authorities, colleagues and customers both at work and home. eCtouch is adapted for assistive technologies such as screen readers, screen magnifiers and braille display. eCtouch also works with different types of relay services (remote interpreter services).

[4] https://omnitor.com/en/products

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Figure 17: eCtouch application

Additionally, we also used the apps that were used in PT7-001. Specifically, software from SHAPES partners: SHAPES platform (SHAPES consortium); eHealthPass (Gnomon); eCtouch (Omnitor); Datalake (TREE TECHNOLOGY); SHAPES app and web (combination of components from Gnomon and Nutrition App (LogMeal); Sleep quality and Physical intensity level (TREE TECHNOLOGY).

5.3.1 Digital solutions used for COVID-19 response

In UC-PT7-003, no digital solution for the COVID-19 response was used.

5.3.2 Equipment and devices used (from third parties)

The following external devices have been used in UC-PT7-003:

CE-marked devices:

- Wristband: Scanwatch HWA09-model 1-All-Int & HWA09-model 4-All-Int from Withings SAS (Metrics: Heart beat notifications: irregular heart-beat, Heart rate: beats per minute, Breathing disturbances: detection via oxygen saturation,

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Electrocardiogram: tracing of a 30-seconds ECG recording on a millimetric grid, Clinically validated Oxygen saturation level (SpO2), Walking and running: steps, distance, calories, based on user's profile for high precision, Calories: metabolic calories and total calories expenditure, Running: automatically detected, in-app daily recap of duration and distance, Swimming: automatically detected, in-app recap with duration and calories burned, Sleep: deep and light sleep phases, irregular heartbeat detection, sleep interruptions, Fitness Level: assessment via VO2Max estimation, Elevation: meters and floors climbed), Clinically Validated, CE Certified.

- Medisante FORA D40g mg/dL, Blood Glucose Plus Blood Pressure Monitoring System (Metrics: glucose and blood pressure measurement), CE Certified.

5.4 Data plan

The data plan for execution phase is summarized in the following table (Table 32).

Table 32: Data plan for UC-PT7-003

Variable	Format	When	Variable Levels
Age	Continuous	Baseline (T0)	
Gender	Nominal	Baseline (T0)	
Education (years spent in formal education)	Continuous	Baseline (T0)	
Marital status	Nominal	Baseline (T0)	1=Married, 2=cohabiting, 3=single (never married), 4=separated, 5=divorced, 6=widowed
Occupational status ("Do you work for payment/money?")*	Nominal	Baseline (T0)	1=Employed full-time, 2=employed part-time, 3=not employed, 4=retired, 5=other
Are you a caregiver? [informal]	Ordinal	Baseline (T0)	1=No, 2=Yes (part-time), 3=Yes (full-time)
Do you receive help from a family member or friend for daily activities?	Nominal	Baseline (T0)	1=Never, 2=Rarely, 3=Sometimes, 4= Often
Do you receive help from a caregiver, health professional, or support service for daily activities?	Nominal	Baseline (T0)	1=Never, 2=Rarely, 3=Sometimes, 4=Often
Residence (Where do you live currently?)	Nominal	Baseline (T0)	1=Own home, 2=caregiver's home, 3=long-term care

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			facility (nursing home), 4=other
Do you live alone?	Dichotomous	Baseline (T0)	1=Yes, 2=No
Is your neighborhood…	Nominal	Baseline (T0)	1=Urban, 2=Suburban, 3=Rural
Country of residence	Nominal	Baseline (T0)	
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….?	Ordinal	Baseline (T0)	Very easily=1, Easily=2, Fairly easily=3, With some difficulty=4, With difficulty=5, With great difficulty=6

5.4.1 Data capture methods to be used

Data capture methods used during this pilot are listed below:

Initial phase (Recruitment)

- Semi-structured interviews

Control phase (Applications Setup)

- Data from initial phase was used

Execution phase (Study and Data Analysis)

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
  - EQ-5D-5L
  - General Self-Efficacy Scale
  - Oslo Social Support Scale
  - Single item health literacy scale
  - Participation questions
  - System Usability Scale
  - Technology acceptance questions

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An assessment of digital solutions also took place through open (non-structured) interviews.

5.4.2 Planning of evaluation

The MAST framework (model for assessment of telemedicine) (9) will be applied as it provides a structured approach for assessing the effectiveness and contribution of UC-PT7-003 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-PT7-003, two of the seven dimensions of MAST were identified/found to be of importance to consider:

- Clinical effectiveness
- Patient perspectives

A further exploration and description of the reasons for selection/inclusion will be provided in the evaluation report (D6.9). Table 33 shows a summary of the data required for MAST evaluation.

Table 33: Data required for MAST evaluation of UC-PT7-003

MAST Domain	Topic	Outcome	Data required	Time point
Clinical Effectiveness	Mental health	OSSS-3 (social support) and life events		End of pilot
	Effects on health-related quality of life	Health related quality of life and wellbeing	EQ-5D-5L scores; WHOQOL-BREF scores	End of pilot
Patient perspectives	Satisfaction and acceptance	User Experience	UEQ-S scores	End of pilot
		User acceptance	TAM score	End of pilot

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	Understanding of information Confidence (in the treatment) Ability to use the application Access & Accessibility	Usability of application	SUS Scores 1-item health literacy	End of pilot
	Empowerment Self-efficacy	Self-efficacy	SHAPES Participation questionnaire	End of pilot
			GSES (Self-efficacy)	End of pilot

The MAFEIP tool will not be applied to evaluate UC-PT7-003 due to a small-scale deployment and a non-case-controlled study design of the UC. MOMENTUM and NASS were not used because it would be overwhelming for the participants, and we tried to mitigate possible dropouts from the trial.

5.5 Initial Phase

5.5.1 PACT Scenario

PACT is shown in the following table.

Table 34: PACT UC-PT7-003

Code	*UC_PT7*	***Version***	*0.2*	***Date***	*2020/09/10*
Applicable SHAPES Persona	*ERNST*				
Applicable SHAPES use case	*UC-PT7_003* ***Preventing and/or handling a medical emergency while visiting another country***				
People *Roles and/or actors of typical users involved in delivering and receiving*	• *Patient- 75+. Ernst, together with his wife, lives in their own home. He exercises daily and he is in good health with minor knee and back aches. His wife Alberta is recovering from head stroke, and she has to follow cognitive training exercises, medical check-ups every 6 months and is always worried about the results. However they like travelling abroad every with ERNST always looking after his wife. He uses a smartwatch to monitor his heart rate, pressure and steps taken*				

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the telemedicine intervention	*daily. Ernst has an average level of computer literacy and good knowledge of smart watches.* • *Patient- 75+. His wife Alberta is recovering from head stroke, and she has to follow cognitive training exercises, medical check-ups every 6 months and is always worried about the results. She has low knowledge of computer literacy.* • *Personal Healthcare professional (HCP reviews clinical data regularly and reminds the patient of the upcoming regular checks especially in the case of long vacation in a foreign country. HCPs will have an average level of computer literacy and access to a laptop/PC.* • *Foreign HCP: In the case of the medical test being performed in a foreign country, the foreign doctor must contact the Personal HCT and then send the tests to the personal Doctor for further review and record. HCPs will have an average level of computer literacy and access to a laptop/PC.*
Activities *Activities to be performed by the actors in order to successfully provide and receive the telemedicine intervention procedures for the professional and the patient; Parameters that determine the measures used in the intervention*	***Patient1 Ernst*** • *Measure blood pressure daily using smartwatch.* • *Measure weight/body composition twice daily* • *Measure heart rate once daily using smartwatch.* • *Measure oxygen saturation once daily using smartwatch.* • *Complete daily/weekly/monthly/one-off questionnaires* • *Send the data from these measurements to the cloud/platform.* • *Access medical status information and alerts for his wife while he is abroad.* ***Patient2 Ernst's wife*** • *Measure blood pressure once in the foreign country* • *Measure blood glucose once in the foreign country* • *Measure weight/body composition once in the foreign country* • *Measure heart rate once in the foreign country* • *Measure oxygen saturation once in the foreign country* • *Complete daily/weekly/monthly/one-off questionnaires* • *Send the data from these measurements to the cloud/platform.* • *Follow cognitive training exercises daily.* ***Personal Healthcare professional*** • *Personal Healthcare professional reviews clinical data on a regular basis and make changes to patient care as required. The HCP uses video calls to check whether the cognitive training exercises are followed. The HCP reminds of the medical checkups, the medication, a phone call to review/make changes to medication, schedule a clinic appointment, prescribe further medication and test to be performed to the foreign country.*

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	• *Use predictive model to identify if patient's health condition is deteriorating and interventions taken to avoid this e.g. decompensations in heart failure, high blood pressure.* ***Foreign Healthcare professional*** • *The foreign HCP must be able to access the patient's health record and communicate with the personal HCP of the patient.* • *In the case of a medical checkup in a foreign country, the results must be transmitted easily to the personal HCP for review and recording*
Context *Social-medical relevance of the telemedicine intervention; privacy issues; risks for the patient; locations*	• *Smart clinical devices to be used in patient's foreign travel location. They will monitor patients with multiple health conditions (head strokes and body pains). The daily data recorded by patients are transmitted and reviewed by the personal healthcare professionals who can then adjust treatment plans as indicated. In the case of an emergency the foreign HCPs must communicate with the personal HCTs. One of the key goals is the adherence to treatment to improve patient outcomes and reduce unplanned urgent care episodes e.g. hospital admissions. In the case of medical emergency, e.g. hospital admissions, the foreign hospital must access the patient's data and should there be any more complex tests, their results must be transmitted to the personal HCT.* • *Maintaining privacy of data is of the utmost importance and would normally be upheld by allocating each participant a unique study number. An identification list (including name and date of birth) would be held at the local pilot site. The remote HCP must be able to access the local medical records.* • *GDPR and ethics in line with WP8* • *Data and servers must be located within the EU.* • *Language translation techniques* • *Home country: Germany; Foreign country: Greece*

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-PT7-002.

Recruitment and retention

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

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

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User engagement and acceptance

KPI 3: At least 60% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

5.5.3 Timeline of pilot activities

The timeline was needed to be adapted, due to several factors. First, the procurement of the tablets was delayed due to bureaucratic reasons. Then, the study was finally approved by the ethics committee in early January 2023 due to time-consuming procedures needed for clinical studies and trials. Afterwards, the applications were installed but were not fully operational in android tablets (some of the features where not functioning correctly) and needed to be troubleshooted and upgraded by the technical partners. Moreover, some of the participants were infected by COVID-19 and it was very difficult to contact them during that period (one of them needed approximately 3 weeks to recover). The adapted timeline is shown in Table 35.

Table 35: Adapted Timeline for the UC-PT7-003 execution

	Mar 2023	Apr 2023	May 2023	June 2023	July 2023	Aug 2023	Sep 2023	Oct 2023
Initial Phase (Recruitment)								
Control Phase (Applications Setup)			1-2 older person participants					
Execution Phase (Study)			Baseline → Intervention (2 month) → 3-month follow-up					
Execution Phase (Data Analysis)					De-identified data transferred to SHAPES platform			

Due to the above-mentioned delays, the final number of phases was 3 (Initial Phase, Control phase, Execution phase) and the pilot was executed only for 3 weeks.

The pilot of the SHAPES UC-PT7-003 was conducted between start date 24-05-2023 and end date of 15-06-2023 with 7 participants and 1 GP.

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In initial phase, basic ideas of the technology of UC-PT7-003 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.

During this phase, a comprehensive market search for suitable android mobiles took place. The clinical study was finalised in this phase and DPIA assessment was also made. The digital solution providers were contacted in order to get familiarized with the functionality of the applications. The execution of the pilot study was designed in initial phase.

Recruitment of the Participants

Initial phase was conducted with seven people fulfilling the age criteria to be 65 years old or older at the time of recruitment, living in the region of Thessaly & Sterea with self-reported capacity to wear the activity wristband and use the apps installed on the mobile and with daily access to internet. The participants were suffering from at least one chronic condition and were capable of traveling.

A total of 7 people with chronic diseases participated in the research. All participants were receiving medication for health reasons. The majority of participants were taking more than one medication in their daily life. The most common diseases suffered by the patient-participants were high blood pressure, diabetes mellitus and hyperlipidaemia.

Initially, a presentation was held to 15 randomly selected patients aged over 65 years who are served by the local primary healthcare unit where the general practitioner works. At the meeting, the SHAPES project was presented by the doctor, while at the same time informative material related to the program was distributed. About 15 people were present at the meeting, of these 10 showed interest and finally 7 accepted to participate. A week later the doctor proceeded to meetings, which were held in the clinic face-to-face with the participants in order to inform them about the devices and applications. One of the participants lives permanently in a village and for this reason the doctor visited her at her home after a scheduled appointment. 3 people out of 7 still needed an additional visit to address some difficulties they were having with the technology tools.

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

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consent for all participants was taken with the following format of signatures collected where appropriate:

- Typewritten
- Handwritten signature

Data collection

Socio-demographics data was collected using a questionnaire (see Annex) comprising of closed questions. The Socio-demographics of the participants are shown in Table 36.

Table 36: Socio-demographics characteristics (UC-PT7-003)

Variables	Number of participants	Value
Age (years)	7	M = 72,29 SD = 4,64
Male	7	Number = 2 (28,57%)
Country: Greece	7	Number = 7 (100%)
Marital status	7	Married: 3 (42,86%) Widowed: 4 (57,14%)
Occupational status: retired	7	Number = 6 (85,71%)
Occupational status: other	7	Number = 1 (14,29%)
Residence: own home	7	Number = 7 (100%)

5.6 Control Phase: Configuration of Digital Solutions and Testing

5.6.1 Methodology of testing

During Control phase, one of the seven participants was chosen, and the applications and digital solutions were demonstrated to him. Afterwards, the applications were installed but at first place, they were not fully operational in android tablets (some of the features where not functioning correctly) and needed to be troubleshooted and upgraded by the technical partners.

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5.6.2 Results of testing

In summary, the overall perception of the use case was high, and the participant did understand the context. In terms of IT-behaviour, the design of the mock-up was clear. The digital solution of eCtouch was easy to be installed in the devices and configured to enable the participants to use it without further testing or training during the execution phase.

5.7 Execution Phase: Hand-on Experiments and Data Analysis

5.7.1 Ethical considerations

Approval to conduct the pilot was sought from a Research Ethics Committee of 5thYPE (Scientific Committee) before the start of the recruitment process. Prior to submission to the REC, the protocol was reviewed and approved for submission by colleagues within the SHAPES consortium. All participants were asked to provide voluntary, informed consent for their participation in the pilot. The consent form included the following explicit consents: All participants till reaching objectives participated in the tests under controlled environment.

5.7.2 Risk management

The study was conducted in the period May - June 2023, during which the covid -19 pandemic appears to be in remission. Nevertheless, the meetings of the participants with the doctor and the other researchers took place maintaining all hygienic protocols.

5.7.3 PT7-002 Execution and results analysis

Participants

During Execution phase, a second visit was made by the researchers to the offices of the Disabled Association in the city of Larissa, and the tablets were delivered to the five participants.

Methods

A detailed presentation of the applications of eCtouch, Withings Scan watch, FORA D40gr was made to the participants, and they were asked to make use of the applications and devices during their daily activities or when moving outside home. After the end of the first week, participants were contacted via telephone to resolve doubts and concerns about the use of the novel system during the entire period of the pilot.

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Collection of feedback

After the end of the intervention, data were collected in face-to-face interviews with the presence of the researcher for resolving doubts.

A concurrent 'think out loud' approach was applied to collect reactions to the applications and identify any areas that will require particular attention. The participants were encouraged to verbalise their reactions, thoughts, feelings, and opinions about the use of the applications throughout their engagement with the researcher. Notes were taken by the researcher throughout the session.

Participants feedback about the use of digital tools

eCtouch: what did the participants say?

- Useful and helpful app. You can contact your doctor without having to search the contact list, just by pressing a button.
- The application ensures immediacy in communication since you can not only talk to your doctor but also see him.
- Through this application, participants report that they can feel safe and secure even if they are far from their place of residence.
- This application can be particularly useful for patients who live in remote areas (mountainous villages, islands) but also significantly helpful for patients who are sick with infectious diseases such as covid-19 and were not allowed to have direct contact with their doctor.

In fact, in two of the participants' cases, the general practitioner noticed elevated morning sugars (in non-diabetic patients) and contacted them in order to give them instructions.

Figure 19 depicts the on-field operation of the eCtouch digital solution when a participant did initiate a video call to seek for assistance by the associated GP.

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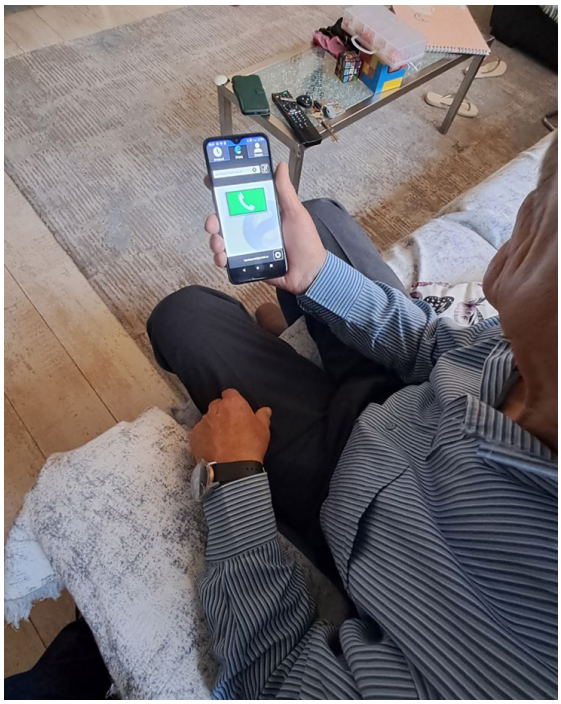

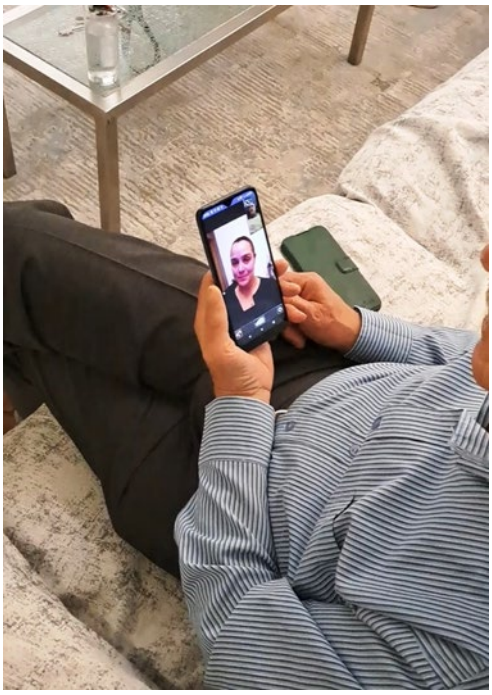

Figure 18: Operation of eCtouch application during the execution of UC-PT7-003

5.7.3.1 Measurements of KPIs - UC-PT7-001

Recruitment and retention

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

Table 37: Recruitment Status for UC-PT7-003

Parameter	DYPE5
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 38: Participants' adherence in UC-PT7-003

Parameter	DYPE5

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Number of participants at baseline	7
Number of withdrawals	0
Number of participants at end of study	7
Percentage retained	100%

KPI 3 At least 60% of participants scored an above average rating (>68) in the System Usability Scale (SUS).

Table 39: SUS in 5YPE for UC-PT7-003

Parameter	Value
Number of participants at end of pilot	7
Number of participants scoring >68 in SUS	0 M = 60 SD = 5,59 Med = 60 Min = 50 Max = 65
Percentage of participants scoring > 68 in SUS	0%

Overview of KPI achievement

Table 40: KPIs achievements for UC-PT7-003

Key performance indicator	*Achieved during pilot activity (yes/no)*	*Comments*
KPI 1	*yes*	
KPI 2	*yes*	
KPI 3	*no*	It is difficult for the participants to enter the codes frequently in order to use the app installed in smart phones quite frequently.

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Evaluation of MAST

The MAST framework was used to evaluate the effectiveness and contribution of UC-PT7-003 to foster older people's (with physical disabilities) independent living by identifying accessible locations and routes in other locations. The evaluated data/outcome are presented in Table 41.

Table 41: MAST evaluation results of UC-PT7-003

MAST Domain	Topic	Outcome	Timepoint: Start of pilot (mean/SD)	Timepoint: End of pilot (mean/SD)
Clinical Effectiveness	Mental health	OSSS-3 (social support) and life events	M = 12,29 SD = 1,25 Med = 13 Min = 11 Max = 14 **"strong social support"**	M = 13,14 SD = 0,38 Med = 13 Min = 13 Max = 14 **"strong social support"**
	Effects on health-related quality of life	EQ-5D-5L VAS scores	**Health Status** M = 90,83 SD = 2,04 Med = 90 Min = 90 Max = 95	**Health Status** M = 90 SD = 0 Med = 90 Min = 90 Max = 90
		WHOQOL-BREF scores	**Domain 1:** M = 82,43 SD = 11,15 Med = 88 Min = 69 Max = 94	**Domain 1:** M = 84,14 SD = 7,29 Med = 88 Min = 75 Max = 94
			Domain 2: M = 82,43 SD = 9,91 Med = 88 Min = 69 Max = 94	**Domain 2:** M = 84 SD = 6,32 Med = 81 Min = 75 Max = 94
			Domain 3:	**Domain 3:**

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			M = 81,29 SD = 11,93 Med = 81 Min = 69 Max = 100	M = 75 SD = 4,9 Med = 75 Min = 69 Max = 81
			Domain 4: M = 79,57 SD = 8,72 Med = 75 Min = 69 Max = 94	**Domain 4:** M = 85,71 SD = 10,13 Med = 81 Min = 75 Max = 100
Patient perspectives	Satisfaction and acceptance	User Experience (UEQ-S scores)	M = NA SD = NA	M = NA SD = NA
		User acceptance (TAM score)	**Usefulness:** M = 3,71 SD = 0,49 Med = 4 Min = 3 Max = 4	**Usefulness:** M = 4 SD = 0 Med = 4 Min = 4 Max = 4
			Future use: M = 3,71 SD = 0,49 Med = 4 Min = 3 Max = 4	**Future use:** M = 4 SD = 0 Med = 4 Min = 4 Max = 4
	Understanding of information Confidence (in the treatment) Ability to use the application Access & Accessibility	Usability of application (SUS Scores)	M = 61,07 SD = 8,02 Med = 57,5 Min = 55 Max = 72,5	M = 60 SD = 5,59 Med = 60 Min = 50 Max = 65
		Usability of application (1-item health literacy)	M = 4,67 SD = 0,52 Med = 5 Min = 4 Max = 5	M = 4,29 SD = 0,49 Med = 4 Min = 4 Max = 5

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	Empowerment Self-efficacy	Self-efficacy (SHAPES Participation questionnaire)	Participation in activities: M = 4,86 SD = 0,38 Med = 5 Min = 4 Max = 5	Participation in activities: M = 5 SD = 0 Med = 5 Min = 5 Max = 5
			Effect of using DS on participation in activities: M = 4,33 SD = 0,52 Med = 4 Min = 4 Max = 5	Effect of using DS on participation in activities: M = 3,71 SD = 0,49 Med = 4 Min = 3 Max = 4
		Self-efficacy (GSES)	M = 37,86 SD = 2,34 Med = 38 Min = 33 Max = 40	M = 37,14 SD = 2,79 Med = 36 Min = 34 Max = 40

Table 42: Objectives Analysis in UC-PT7-003

PO1
To investigate user engagement with the novel system (PO1)
The participants did not face any problems using the applications and devices. In fact, most reported that although they themselves were not familiar with the technology, the devices were quite easy to use The study ended with all participants using the applications in a daily basis.
PO2
To investigate the user-perceived usefulness of the novel system (PO2)

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The execution of the study was very well accepted by the participants because it provided them with the sense of being more independent despite their health problems. Their opinions are reflected in their feedback.
SO1
To investigate the capability of the novel system to maintain the supervision of the individual health and wellbeing status while on the move
The use of the scan watch with the ability to record the electrocardiogram as well as the spO2, the eCtouch application with the ability to communicate directly with the doctor as well as the recording of blood pressure and sugar measurements create a feeling of security and confidence in patients regarding their health
SO2
To investigate the association of home and away from home physical activity classification, sleep quality analysis, fluid intake and nutrition analysis with the individual perceived wellbeing
This was not measured since it was difficult for the participants to cope with the relevant apps.
SO3
To investigate the capability of the novel system to improve and maintain older individual's quality of life, wellbeing, psychological and psychosocial aspects while on the move (SO3)
Measuring the steps, kilometres walked by the patient helps to assess the health status of the patient. The ability to communicate not only by phone but also by camera enables the doctor to assess the patient's psychological state and to be able to empower him when needed.
SO4
To explore user trust and acceptance of the novel system
All participants showed great interest in using apps and devices and considered them important in maintaining a good quality of health and life
SO5

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To investigate the capability of the novel system to establish direct communication between the patient and his/her personal physician, thus making older individuals feel safer while on the move
Being able to communicate and see the doctor wherever you are offers great security to the people of 65+ years old.
SO6
To investigate the capability of the novel system to be used for scheduled regular videoconference sessions between the patient and his/her personal physician without the patient visiting the physician's office (SO6)
Checking blood pressure and blood glucose readings without having to contact the doctor themselves helps to reduce travel and waiting times at doctor's offices**.**
SO7
To investigate the capability of the novel system to bring the patient closer to his/her personal physician, thus increasing the sense of attention that older individuals feel (SO7).
Communication through the application is no less than face-to-face communication. The patient can express his health concerns to his doctor and the doctor through the monitoring of the applications has a complete picture about his patient's health

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6 EU's eHealth Digital Service Infrastructure, Standards for Cross-Border Data Exchanged – Assessment of Main Digital Solutions used in PT-7

The eHealth Digital Service Infrastructure (eHDSI) is a pan-european digital infrastructure that enables the cross-border exchange of healthcare documents, namely the Patient Summary, e-Prescriptions and Original Clinical Documents. Each Member State participating in the eHDSI implements the open National Contact Point (NCP) nodesvia which they exchange healthcare document with other Member States NCP nodes requesting it.

As shown in the Figure 20 below, the eHDSI implements the following two scenarios:

1. A doctor that treats a European citizen can request the patient summary of the citizen from the country of their origin.
2. A European citizen that goes to another Member State can get their medications from a pharmacy using the e-prescriptions documents.

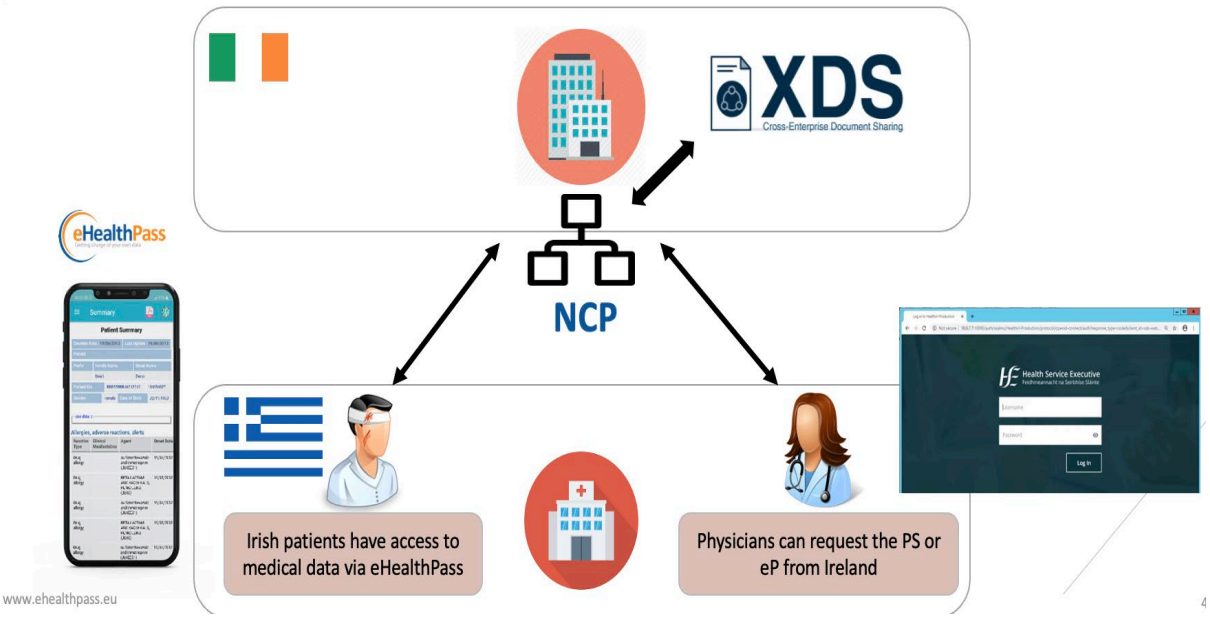

Figure 19: Incorporation of eHealthPass digital solution into the eHDSI scenarios

eHealthPass solution, that was evaluated in evaluated in UC-PT7-001 & UC-PT7-003, is compliant with the standards used in the eHDSI and can facilitate the access of the patient to the healthcare documents. The interactions within the eHDSI utilise the profiles proposed by the Integrated Healthcare Enterprise (IHE):

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- XCPD: For patient discovery.
- XCA: For document querying and retrieval.
- XDS: For searching patient information across multiple repositories and registries.

Those IHE profiles are based on the proper orchestration of international standards such as HL7 version 2.5 or newer, HL7 CDA, HL7 FHIR, DICOM, DICOM Web, eBXML, OASIS SAML 2.0, OASIS XACML, OAuth and many more.

The use of IHE profiles to set up an interoperability framework and architecture has been recommended by the EU commission with its Commission Decision (EU) 2015/1302 of 28 July 2015 on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement (Text with EEA relevance). eHealthPass uses a set of Open Standards for handling both the content of the information and the description of the services that exchanges it. A small description of the selected standards and profiles are listed in Table 48.

Table 43: Open Interoperability Standards

IHE ATNA	IHE XDS	IHE BPPC	IHE XDM
Audit Trail and Node Authentication: offers basic security through (a) functional access controls, (b) defined security audit logging and (c) secure network communications.	**Cross Enterprise Document Sharing:** shares and discovers EHR documents between healthcare enterprises, physician offices, clinics, acute care in-patient facilities and PHRs.	**Basic Patient Privacy Consents:** provides a mechanism to record the Patient privacy consent(s) and a method for Content Consumers to use to enforce the privacy consent appropriate to the use.	**Cross-Enterprise Document Media Interchange:** provides document interchange using a common file and directory structure over several standard media. This permits the Patient to use physical media to carry medical documents
IHE XCA	**IHE DCP**	**IHE PDQm**	**IHE XCPD**
Cross-Community Access: offers the means to query and retrieve Patient relevant medical data held by other communities. A community can contain EHRs, PHRs and other	**Dynamic Care Planning** The Dynamic Care Planning (DCP) Profile provides the structures and transactions for care planning, creating, updating and sharing Care Plans that meet the needs of many, such as	**Patient Demographics Query for Mobile:** defines a lightweight RESTful interface to a Patient demographics supplier (identical to IHE PDQ profile) leveraging technologies readily available to mobile applications and	**Cross-Community Patient Discovery:** offers the means to locate communities which hold Patient relevant health data and the translation of Patient identifiers across communities holding the same Patient's data. A

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systems and healthcare applications.	providers, patients and payers.	lightweight browser-based applications.	community can contain EHRs, PHRs and other systems.
IHE XUA	**IHE IUA**	**IHE MHDS**	**IHE IPS**
Cross-Enterprise User Assertion: provides a means to communicate claims about the identity of an authenticated principal (user, application, system, etc.) in transactions that cross enterprise boundaries. The XUA Profile supports enterprises with different authentication mechanisms.	**Internet User Authorization** The actors in the profile manage the tokens used for authorization of access to HTTP RESTful services. The Authorization Client actor provides the authorization token that is incorporated into HTTP RESTful transactions to indicate that is authorized. The Resource Server actor provides the server-side interaction to verify that the HTTP RESTful request is authorized. It blocks unauthorized uses.	**Mobile Health Document Sharing** This profile shows how to build a Document Sharing Exchange using IHE profiled FHIR standard, rather than the legacy IHE profiles that is dominated by XDS & HL7® v2. This profile assembles profiles and define a Document Registry. These IHE profiles include support for patient identification, health document location & retrieval, provider directories, & the protection of privacy & security.	**International Patient Summary** This IPS profile uses the HL7's IPS Implementation Guides that realize the CEN EN 17269 IPS dataset. This IPS Profile directly follows a joint project between CEN TC/251 and HL7 that has produced a content specification (CEN), with a global perspective, and two Implementation Guides for CDA and FHIR, which conform to the CEN IPS dataset and business rules
IHE MHD	**PCHA**	**HL7 CDA**	**HL7 FHIR**
Mobile access to Health Documents: defines a simple HTTP interface to an XDS like environment for mobile devices. It defines transactions to: (a) Submit a new document and metadata from the mobile device to a document receiver; (b) Get the metadata for	**Personal Connected Health Alliance** Formerly known as Continua Health Alliance, PCHAlliance is an international not-for-profit industry organization enabling end-to-end, plug-and-play connectivity of devices and services for personal health management and healthcare delivery.	**HL7 Clinical Document Architecture v3 R2** The following set of suggested CDA document structures are based into the following group of guidelines and constraints: **CDA** General Architecture; Continuity of Care Document (**CCD**) constraints;	**FHIR® – Fast Health Interoperable Resources** (hl7.org/fhir) – is a next generation standards framework created by HL7. FHIR combines the best features of HL7's Version 2, Version 3 and CDA® product lines while leveraging the latest web standards and applying a tight focus on implementability.

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an identified document; (c) Find document entries containing metadata based on query parameters; (d) Retrieve a copy	PCHAlliance is working toward establishing systems of interoperable tele-health devices and services in three major categories: chronic disease management, aging independently, and health and physical fitness.	IHE Patient Care Coordination (**IHE PCC**) constraints; At a first level, the compatibility with General CDA and Continuity of Care Document will always be assured.

Furthermore, the Access Earth's digital solution empowers older people by providing them with the tools and information they need to plan their travels within the EU confidently. It promotes independence, inclusion, and a more accessible travel experience for older adults, enhancing their overall well-being and enjoyment while exploring different countries. It supports the following features which have been evaluated in UC-PT7-002.

- **Accessible Venue Information:** The app provides detailed accessibility information about various venues across different countries within the EU. This includes hotels, restaurants, transportation hubs, tourist attractions, and more. Older people can use the app to search for and find venues that meet their specific accessibility needs, ensuring a more comfortable and hassle-free travel experience.
- **User Reviews and Ratings:** Access Earth allows users to share their experiences and rate venues based on their accessibility features. Older people can benefit from reading these reviews to get insights into the accessibility of different places before visiting. This helps them make informed decisions about which venues to choose, ensuring they are well-prepared and can enjoy their travels to the fullest.
- **Filter and Search Options:** The app offers filtering and search functionalities, enabling older people to refine their venue search based on specific accessibility criteria. They can filter venues by features such as wheelchair accessibility, the presence of ramps, elevators, accessible parking, accessible restrooms, and more. This helps them find venues that cater to their specific needs, ensuring a smoother travel experience.
- **Community and User Contributions:** Access Earth fosters a community of users who actively contribute to the app's accessibility information. Older people can benefit from the collective knowledge and experiences shared by others in the community. They can also contribute their own reviews and

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ratings, thereby helping fellow travellers and contributing to the improvement of accessibility information for future users.

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7 Conclusion

This deliverable described in detail the activities performed in the 3 studies of Pilot Theme 3 (i.e., UC-PT7-001, UC-PT7-002, UC-PT7-003). Apart from the evaluation of the digital solutions special attention was given to the engagement of the older people towards the comprehension of how technology can help them to improve their daily activities. We would like to indicate here that the close relatives of the recruited participants and families were the cornerstone in this effort. As mentioned in the previous sections, the vast majority elder people in Greece and in Cyprus are digitally illiterate. COVID-19 crisis has affected the PT-7 execution and the time schedule was modified in order to sufficiently manage to execute the scenarios in the various use-cases.

Interoperability issues among the digital solutions and the frequent time out of the login period challenged the execution of the pilot. We tried to not stress the participants by enforcing them to utilise all the available features or features that were difficult to comprehend so as to avoid possible drop-out from the studies. In the nutshell, the participation of the elder people in this Pilot Theme has strengthen the feeling of safety according to the comments received during the interviews. Overall, older individuals articulated their interest to the technological devices and to the SHAPES ecosystem, since of them were either capable or eager to learn to handle the solutions and in many cases, they requested to extend the period of the usage of devices. We showed our appreciation to them by letting them to use the solutions after the completion of studies.

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Ethical requirements check

Table 44: 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)	5YPE and UNRF as replicator have applied non-discriminatory selection criteria as well as language. 5YPE 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 the recruitment phase. Feedback from participating individuals was included in this deliverable.
Convention on the Rights of Persons with Disabilities and supported decision-making (3.3)	The will and preferences of older people and persons with disabilities were respected and prioritised at all stages. They were involved in the different phases of the 3 studies and especially for UC-PT7-002. Their feedback was taken into account. Anonymity and confidentiality of data has been guaranteed at all stages. Ethical self-assessments were conducted to discover and minimize potential risks by developing according to mitigation actions.
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)	PT-7 aims to contribute to the digital inclusion of elder people as well as the mobility support of people with disabilities and vision problems. - SDG1 End poverty: PT-7 contributes to promoting access to innovative health and care services without out-of-pocket payments - SGD3 Good Health and Wellbeing: PT-7, 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.

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	- SDG4 Good Education: PT-7 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 and improve digital literacy - SDG5 Gender Equality: PT-7 enforced gender equality in the design of its use cases, including all genders. - SDG9 Industry, Innovation and Infrastructure: PT-7 incorporated innovative solutions provided by open call partners, hence stimulated innovation, promoted data analytics as well as CE medical devices; SHAPES partners involved in PT-7 further developed IT infrastructure capabilities for integrated health and care solutions - SDG10 Reduced Inequalities: PT-7 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: PT-7 was set in the region of Larissa City (Greece) and in Strovolos (Cyprus) and their immediate surroundings. The rural setting of PT-7 is particularly welcoming to solutions reducing CO2 emissions (less individual car drives). With their focus on health promotion, the 3 use cases intended, among other, to avoid the development of chronic diseases (e.g., 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 Digital Solutions.
Artificial intelligence (4.3)	ALTAI tool (Assessment List for Trustworthy Artificial Intelligence) has been conducted in cooperation with the technical partner (Laurea) to address potential risks that might occur by the use of Artificial Intelligence. ALTAI results have been also published in MDPI Healthcare Journal: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10217990/

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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 one of the 3 use cases. Ethical approval was received for the 3 use cases.
Cyber security and resilience (6)	The database is stored safely on a firewall protected server in and in safety locations for keeping the hard-copy data of the 3 studies and signed consents of the participants.
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)	Formal caregivers have not been considered in the 3 use cases. However, the assistance of participant close persons was involved toward the 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 1

1) Sociodemographics

Variable Code	Variable	Variable Type	Possible Responses	Administer at T0
HSD01	Age	Continuous		Yes
HSD02	Gender	Nominal		Yes
HSD03	Education (years spent in formal education)	Continuous		Yes
HSD04	Marital status	Nominal	**1=Married,** 2=cohabiting, **3=single (never married),** 4=separated, **5=divorced,** 6=widowed	Yes
HSD04_T1	*Marital status*	*Nominal*	***1=Married,*** *2=cohabiting,* ***3=single (never married),*** *4=separated,* ***5=divorced,*** *6=widowed*	
HSD04_T2	*Marital status*	*Nominal*	***1=Married,*** *2=cohabiting,* ***3=single (never married),*** *4=separated,* ***5=divorced,*** *6=widowed*	
HSD05	Occupational status ("Do you work for payment/money?")*	Nominal	**1=Employed full-time,** 2=employed part-time, **3=not employed,** 4=retired, **5=other**	Yes
HSD05_T1	*Occupational status ("Do you work for payment/money?")**	*Nominal*	***1=Employed full-time,*** *2=employed part-time,* ***3=not employed,*** *4=retired,* ***5=other***	

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HSD05_T2	*Occupational status ("Do you work for payment/money?")**	*Nominal*	***1=Employed full-time,** 2=employed part-time, **3=not employed,** 4=retired, **5=other***	
HSD06	Are you a caregiver? [informal]	Ordinal	**1=No,** 2=Yes (part-time), **3=Yes (full-time)**	Yes
HSD06_T1	*Are you a caregiver? [informal]*	*Ordinal*	***1=No,** 2=Yes (part-time), **3=Yes (full-time)***	
HSD08_T2	*Are you a caregiver? [informal]*	*Ordinal*	***1=No,** 2=Yes (part-time), **3=Yes (full-time)***	
HSD07	Do you receive help from a family member or friend for daily activities?	Nominal	**1=Never,** 2=Rarely, **3=Sometimes,** 4= Often	Yes
HSD07_T1	*Do you receive help from a family member or friend for daily activities?*	*Nominal*	***1=Never,** 2=Rarely, **3=Sometimes,** 4= Often*	
HSD07_T2	*Do you receive help from a family member or friend for daily activities?*	*Nominal*	***1=Never,** 2=Rarely, **3=Sometimes,** 4= Often*	
HSD08	Do you receive help from a caregiver, health professional, or support service for daily activities?	Nominal	**1=Never,** 2=Rarely, **3=Sometimes,** 4=Often	Yes
	Do you receive help from a caregiver, health professional, or support service for daily activities?	*Nominal*	***1=Never,** 2=Rarely, **3=Sometimes,** 4=Often*	
	Do you receive help from a caregiver, health professional, or support service for daily activities?	*Nominal*	***1=Never,** 2=Rarely, **3=Sometimes,** 4=Often*	

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HSD09	Residence (Where do you live currently?)	Nominal	**1=Own home,** 2=caregiver's home, **3=long-term care facility (nursing home)**, 4=other	Yes
	Residence (Where do you live currently?)	*Nominal*	***1=Own home,*** *2=caregiver's home,* ***3=long-term care facility (nursing home)****, 4=other*	
	Residence (Where do you live currently?)	*Nominal*	***1=Own home,*** *2=caregiver's home,* ***3=long-term care facility (nursing home)****, 4=other*	
HSD10	Do you live alone?	Dichotomous	1=Yes, 2=No	Yes
	Do you live alone?	*Dichotomous*	*1=Yes, 2=No*	
	Do you live alone?	*Dichotomous*	*1=Yes, 2=No*	
HSD11	Is your neighbourhood…	Nominal	**1=Urban**, 2=Suburban, **3=Rural**	Yes
	Is your neighbourhood…	*Nominal*	***1=Urban****, 2=Suburban,* ***3=Rural***	
	Is your neighbourhood…	*Nominal*	***1=Urban****, 2=Suburban,* ***3=Rural***	
HSD12	Country of residence	Nominal		Yes
HSD13	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….?	Ordinal	**Very easily=1**, Easily=2, **Fairly easily=3,** With some difficulty=4, **With difficulty=5,** With great difficulty=6	Optional

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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….?	*Ordinal*	***Very easily=1**, Easily=2, **Fairly easily=3,** With some difficulty=4, **With difficulty=5,** With great difficulty=7*	Optional
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….?	*Ordinal*	***Very easily=1**, Easily=2, **Fairly easily=3,** With some difficulty=4, **With difficulty=5,** With great difficulty=8*	Optional

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2) T0 Baseline

Variable Code	Variable	Variable Type	Possible Responses	Administer at T0
HB001_T1	Participated at T0	Nominal	Yes/No	Yes
Variable Code	**WHOQOL-Bref**	**Variable Type**	**Possible Responses**	**Administer at T0**
HE101_T0	WHOQOL BREF 1: How would you rate your quality of life?	Ordinal	Very poor=1, Poor=2, Neither poor nor good=3, Good=4, Very good=5	Yes
HE102_T0	WHOQOL BREF 2: How satisfied are you with your health?	Ordinal	Very dissatisfied=1 Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE103_T0	WHOQOL BREF 3: To what extent do you feel that physical pain prevents you from doing what you need to do?	Ordinal	Not at all=1, A little=2, A moderate amount=3, Very much=4, An extreme amount=5	Yes
HE104_T0	WHOQOL BREF 4: How much do you need any medical treatment to function in your daily life?	Ordinal	Not at all=1, A little=2, A moderate amount=3, Very much=4, An extreme amount=5	Yes
HE105_T0	WHOQOL BREF 5: How much do you enjoy life?	Ordinal	Not at all=1, A little=2, A moderate amount=3, Very much=4, An extreme amount=5	Yes
HE106_T0	WHOQOL BREF 6: To what extent do you feel your life to be meaningful?	Ordinal	Not at all=1, A little=2, A moderate amount=3, Very much=4, An extreme amount=5	Yes
HE107_T0	WHOQOL BREF 7: How well are you	Ordinal	Not at all=1, A little=2, A moderate amount=3, Very	Yes

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	able to concentrate?		much=4, An extreme amount=5	
HE108_T0	WHOQOL BREF 8: How safe do you feel in your daily life?	Ordinal	Not at all=1, A little=2, A moderate amount=3, Very much=4, An extreme amount=5	Yes
HE109_T0	WHOQOL BREF 9: How healthy is your physical environment?	Ordinal	Not at all=1, A little=2, A moderate amount=3, Very much=4, An extreme amount=5	Yes
HE110_T0	WHOQOL BREF 10: Do you have enough energy for everyday life?	Ordinal	Not at all=1, A little=2, Moderately=3, Mostly=4, Completely=5	Yes
HE111_T0	WHOQOL BREF 11: Are you able to accept your body appearance?	Ordinal	Not at all=1, A little=2, Moderately=3, Mostly=4, Completely=5	Yes
HE112_T0	WHOQOL BREF 12: Have you enough money to meet your needs?	Ordinal	Not at all=1, A little=2, Moderately=3, Mostly=4, Completely=5	Yes
HE113_T0	WHOQOL BREF 13: How available to you is the information that you need in your day-to-day life?	Ordinal	Not at all=1, A little=2, Moderately=3, Mostly=4, Completely=5	Yes
HE114_T0	WHOQOL BREF 14: To what extent do you have the opportunity for leisure activities?	Ordinal	Not at all=1, A little=2, Moderately=3, Mostly=4, Completely=5	Yes
HE115_T0	WHOQOL BREF 15: How well are you able to get around?	Ordinal	Very poor=1, Poor=2, Neither poor nor good=3, Good=4, Very good=5	Yes
HE116_T0	WHOQOL BREF 16: How satisfied are you with your sleep?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes

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HE117_T0	WHOQOL BREF 17: How satisfied are you with your ability to perform your daily living activities?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE118_T0	WHOQOL BREF 18: How satisfied are you with your capacity for work?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE119_T0	WHOQOL BREF 19: How satisfied are you with yourself?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE120_T0	WHOQOL BREF 20: How satisfied are you with your personal relationships?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE121_T0	WHOQOL BREF 21: How satisfied are you with your sex life?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE122_T0	WHOQOL BREF 22: How satisfied are you with the support you get from your friends?	Ordinal	Very dissatisfied | Dissatisfied | Neither satisfied nor dissatisfied | Satisfied | Very satisfied	Yes
HE123_T0	WHOQOL BREF 23: How satisfied are you with the conditions of your living place?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE124_T0	WHOQOL BREF 24: How satisfied are you with your access to health services?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE125_T0	WHOQOL BREF 25: How satisfied are you with your transport?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes

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HE126_T0	WHOQOL BREF 26: How often do you have negative feelings such as blue mood, despair, anxiety, depression?	Ordinal	Never=1, Seldom=2, Quite often=3, Very often=4, Always=5	Yes
HE127_T0	Comments in relation to the WHOQOL-Bref	Qualitative	Optional, free text comments that reflect either comments from the participants, or comments of the researcher, etc.	Optional
	EQ-5D-5L	**Variable Type**	**Possible Responses**	**Administer at T0**
HE201_T0	**EuroQol EQ-5D-5L**	**Nominal**	**Summary index score**	Yes
HE202_T0	EQ-5D-5L: Mobility	Ordinal	**1=I have no problems in walking about,** 2=I have slight problems in walking about, **3=I have moderate problems in walking about,** 4=I have severe problems in walking about, **5= I am unable to walk about**	Yes
HE203_T0	EQ-5D-5L: Self-care	Ordinal	**1=I have no problems washing or dressing myself,** 2=I have slight problems washing or dressing myself, **3= I have moderate problems washing or dressing myself**, 4= I have severe problems washing or dressing myself, **5=I am unable to wash or dress myself**	Yes
HE204_T0	EQ-5D-5L: Usual activities (e.g. work, study, housework, family or leisure activities)	Ordinal	**1=I have no problems doing my usual activities,** 2=I have slight problems doing my usual activities, **3= I have moderate problems doing my usual activities,** 4= I have severe problems doing my usual activities, **5= I am unable to do my usual activities**	Yes

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HE205_T0	EQ-5D-5L Pain/Discomfort	Ordinal	**1= I have no pain or discomfort,** 2= I have slight pain or discomfort, **3= I have moderate pain or discomfort,** 4= I have severe pain or discomfort, **5= I have extreme pain or discomfort**	Yes
HE206_T0	EQ-5D-5L Anxiety/Depression	Ordinal	**1=I am not anxious or depressed**, 2=I am slightly anxious or depressed, **3= I am moderately anxious or depressed,** 4= I am severely anxious or depressed, **5= I am extremely anxious or depressed**	Yes
HE207_T0	EQ-5D VAS. We would like to know how good or how bad your health is TODAY. This scale is numbered from 0-100. 100 means the best health you can imagine. 0 means the worst health you can imagine	Continuous	0-100	Yes
HE208_T0	Comments in relation to the EQ-5D-5L	Qualitative	Optional, free text comments that reflect either comments from the participants, or comments of the researcher, etc.	Optional
	General self-efficacy scale			
HE301_T0	GSES1: I can always manage to solve difficult problems if I try hard enough	Ordinal	**Not at all true=1,** Hardly true=2, **Moderately true=3,** Exactly true=4	Yes
HE302_T0	GSES2: If someone opposes me, I can find the means and ways to get what I want	Ordinal	**Not at all true=1,** Hardly true=2, **Moderately true=3,** Exactly true=4	Yes

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HE303_T0	GSES3: It is easy for me to stick to my aims and accomplish my goals.	Ordinal	**Not at all true=1,** Hardly true=2, **Moderately true=3,** Exactly true=4	Yes
HE304_T0	GSES4: I am confident that I could deal efficiently with unexpected events.	Ordinal	**Not at all true=1,** Hardly true=2, **Moderately true=3,** Exactly true=4	Yes
HE305_T0	GSES5: Thanks to my resourcefulness, I know how to handle unforeseen situations.	Ordinal	**Not at all true=1,** Hardly true=2, **Moderately true=3,** Exactly true=4	Yes
HE306_T0	GSES6: I can solve most problems if I invest the necessary effort.	Ordinal	**Not at all true=1,** Hardly true=2, **Moderately true=3,** Exactly true=4	Yes
HE307_T0	GSES7: I can remain calm when facing difficulties because I can rely on my coping abilities.	Ordinal	**Not at all true=1,** Hardly true=2, **Moderately true=3,** Exactly true=4	Yes
HE308_T0	GSES8: When I am confronted with a problem, I can usually find several solutions.	Ordinal	**Not at all true=1,** Hardly true=2, **Moderately true=3,** Exactly true=4	Yes
HE309_T0	GSES9: If I am in trouble, I can usually think of a solution	Ordinal	**Not at all true=1,** Hardly true=2, **Moderately true=3,** Exactly true=4	Yes
HE310_T0	GSES10: I can usually handle whatever comes my way.	Ordinal	**Not at all true=1,** Hardly true=2, **Moderately true=3,** Exactly true=4	Yes
HE311_T0	GSES Total Score	Continuous	SUM all scores {HE301_T0, … HE310_T0}	Optional

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HE312_T0	Comments in relation to the GSES	Qualitative	Optional, free text comments that reflect either comments from the participants, or comments of the researcher, etc.	Optional
	OSSS-3	**Variable Type**	**Possible Responses**	**Administer at T0**
HE401_T0	OSSS1: How many people are so close to you that you can count on them if you have serious problems	Ordinal	**none'=1, '**1 or 2' = 2, '**3 to 5' = 3, '**6+' = 4	Yes
HE402_T0	OSSS2: How much concern do people show in what you are doing?	Ordinal	**A lot of concern and interest=5,** Some concern and interest=4, **Uncertain=3**, Little concern and interest=2, **No concern and interest=1**	Yes
HE403_T0	OSSS3: How easy can you get practical help from neighbours if you should need it?	Ordinal	**Very easy=5,** Easy=4, **Possible=3**, Difficult=2, **Very difficult=1**	Yes
HE404_T0	OSSS4a: Did you experience any of these life events ***[in the last 6 months / since the last time we spoke]***?	Nominal	**1=Serious illness or injury to you,** 2=Serious illness or injury to a close relative, **3=Death of first-degree relative, including a child or spouse,** 4=Death of close family friend or second-degree relative, **5= Separation due to marital difficulties,** 6=Broke off a steady relationship, **7=Serious problem with a close friend, neighbour or relative,** 8=Unemployed/seeking work for more than one month, **9=Sacked from job,** 10=Major financial crisis, **11=Problems with police and court appearance,** 12=Something valuable lost or stolen	Yes

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HE405_T0	OSSS4b: Did you get emotional support from anybody in relation to the event? If you had more than one event, please think of the most serious one	Ordinal	**Yes, a lot=3,** Yes, some=2, **No support=1**	Yes
HE406_T0	OSSS4c: From whom did you get emotional support?	Nominal	**For multiple values, please input each value separated by a comma. For 'other', if the participant elaborates(not required!), feel free to add that to the comment column.** 1=Spouse/Partner, **2=Parent,** 3=Brother/sister, **4=Children,** 5=Friend, **6=Neighbour**, 7=Other relative, **8=Other.**	Yes
HE407_T0	Comments in relation to the OSSS	Qualitative	Optional, free text comments that reflect either comments from the participants, or comments of the researcher, etc.	Optional
	Participation Questionnaire	**Variable Type**	**Possible Responses**	**Administer at T0**
HE501_T0	**Participation 1: I participate enough in activities that are important to me**	**Ordinal**	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Yes
HE502_T0	More detail	Qualitative	Add free text	Yes
HE503_T0	**Participation 2: Using this technology would make participating in the activities that are important to me**	**Ordinal**	**Much more difficult=1,** A little more difficult=2, **About the same=3,** A little easier=4, **A lot easier=5**	Optional
HE504_T0	More detail	Qualitative	Add free text	Optional

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HE505_T0	Comments in relation to the participation questions	Qualitative	Optional, free text comments that reflect either comments from the participants, or comments of the researcher, etc.	Optional
	Health Literacy Measure	**Variable Type**	**Possible Responses**	**Administer at T0**
HE601_T0	**HLM1: How confident are you filling out medical forms by yourself?**	**Ordinal**	**Not at all=1,** A little bit=2, **Somewhat=3,** Quite a bit=4, **Extremely=5**	Yes
HE602_T0	Comments in relation to the health literacy question	Qualitative	Optional, free text comments that reflect either comments from the participants, or comments of the researcher, etc.	Optional
	System Usability Scale (SUS)	**Variable Type**	**Possible Responses**	**Administer at T0**
HE702_T0	SUS1: I think that I would like to use this technology frequently	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Optional
HE703_T0	SUS2: I found this technology unnecessarily complex	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Optional
HE704_T0	SUS3: I thought this technology was easy to use	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Optional
HE705_T0	SUS4: I think that I would need the support of a technical person to be able to use this technology	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Optional
HE706_T0	SUS5: I found the various functions in this technology were well integrated	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Optional

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HE707_T0	SUS6: I thought there was too much inconsistency in this technology	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Optional
HE708_T0	SUS7: I would imagine that most people would learn to use this technology very quickly	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Optional
HE709_T0	SUS8: I found this technology very cumbersome (awkward) to use	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Optional
HE710_T0	SUS9: I felt very confident using this technology	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Optional
HE711_T0	SUS10: I needed to learn a lot of things before I could get going with this technology	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Optional
HE712_T0	Comments in relation to the SUS	Qualitative	Optional, free text comments that reflect either comments from the participants, or comments of the researcher, etc.	Optional
	Technology Acceptance Model	**Variable Type**	**Possible Responses**	**Administer at T0**
HE801_T0	This technology is useful to me	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither disagree nor agree=3,** Agree=4, **Strongly agree=5**	Optional
HE802_T0	If this technology was available to me in future, I would use it	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither disagree nor agree=3,** Agree=4,**Strongly agree=5**	**Optional. Administering this item at T0 would be particularly useful from a research standpoint but remains optional.**

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HE803_T0	Comments in relation to the TAM questions	Qualitative	Optional, free text comments that reflect either comments from the participants, or comments of the researcher, etc.	Optional

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3) T1 end of pilot

Variable Code	Variable	Variable Type	Possible Responses	Administer at T1
HB001_T1	Participated at T1?	Nominal	Yes/No	Yes
HB002_T1	Participant alive at T1?	Nominal	Yes/No	Yes
	WHOQOL-Bref			**Administer at T0**
HE101_T1	WHOQOL BREF 1: How would you rate your quality of life?	Ordinal	Very poor=1, Poor=2, Neither poor nor good=3, Good=4, Very good=5	Yes
HE102_T1	WHOQOL BREF 2: How satisfied are you with your health?	Ordinal	Very dissatisfied=1 Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE103_T1	WHOQOL BREF 3: To what extent do you feel that physical pain prevents you from doing what you need to do?	Ordinal	Not at all=1, A little=2, A moderate amount=3, Very much=4, An extreme amount=5	Yes
HE104_T1	WHOQOL BREF 4: How much do you need any medical treatment to function in your daily life?	Ordinal	Not at all=1, A little=2, A moderate amount=3, Very much=4, An extreme amount=5	Yes
HE105_T1	WHOQOL BREF 5: How much do you enjoy life?	Ordinal	Not at all=1, A little=2, A moderate amount=3, Very much=4, An extreme amount=5	Yes
HE106_T1	WHOQOL BREF 6: To what extent do you feel your life to be meaningful?	Ordinal	Not at all=1, A little=2, A moderate amount=3, Very much=4, An extreme amount=5	Yes
HE107_T1	WHOQOL BREF 7: How well are you able to concentrate?	Ordinal	Not at all=1, A little=2, A moderate amount=3, Very much=4, An extreme amount=5	Yes
HE108_T1	WHOQOL BREF 8: How safe do you feel in your daily life?	Ordinal	Not at all=1, A little=2, A moderate amount=3, Very	Yes

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			much=4, An extreme amount=5	
HE109_T1	WHOQOL BREF 9: How healthy is your physical environment?	Ordinal	Not at all=1, A little=2, A moderate amount=3, Very much=4, An extreme amount=5	Yes
HE110_T1	WHOQOL BREF 10: Do you have enough energy for everyday life?	Ordinal	Not at all=1, A little=2, Moderately=3, Mostly=4, Completely=5	Yes
HE111_T1	WHOQOL BREF 11: Are you able to accept your body appearance?	Ordinal	Not at all=1, A little=2, Moderately=3, Mostly=4, Completely=5	Yes
HE112_T1	WHOQOL BREF 12: Have you enough money to meet your needs?	Ordinal	Not at all=1, A little=2, Moderately=3, Mostly=4, Completely=5	Yes
HE113_T1	WHOQOL BREF 13: How available to you is the information that you need in your day-to-day life?	Ordinal	Not at all=1, A little=2, Moderately=3, Mostly=4, Completely=5	Yes
HE114_T1	WHOQOL BREF 14: To what extent do you have the opportunity for leisure activities?	Ordinal	Not at all=1, A little=2, Moderately=3, Mostly=4, Completely=5	Yes
HE115_T1	WHOQOL BREF 15: How well are you able to get around?	Ordinal	Very poor=1, Poor=2, Neither poor nor good=3, Good=4, Very good=5	Yes
HE116_T1	WHOQOL BREF 16: How satisfied are you with your sleep?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE117_T1	WHOQOL BREF 17: How satisfied are you with your ability to perform your daily living activities?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE118_T1	WHOQOL BREF 18: How satisfied are you with your capacity for work?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE119_T1	WHOQOL BREF 19: How satisfied are you with yourself?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither	Yes

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			satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	
HE120_T1	WHOQOL BREF 20: How satisfied are you with your personal relationships?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE121_T1	WHOQOL BREF 21: How satisfied are you with your sex life?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE122_T1	WHOQOL BREF 22: How satisfied are you with the support you get from your friends?	Ordinal	Very dissatisfied | Dissatisfied | Neither satisfied nor dissatisfied | Satisfied | Very satisfied	Yes
HE123_T1	WHOQOL BREF 23: How satisfied are you with the conditions of your living place?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE124_T1	WHOQOL BREF 24: How satisfied are you with your access to health services?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE125_T1	WHOQOL BREF 25: How satisfied are you with your transport?	Ordinal	Very dissatisfied=1, Dissatisfied=2, Neither satisfied nor dissatisfied=3, Satisfied=4, Very satisfied=5	Yes
HE126_T1	WHOQOL BREF 26: How often do you have negative feelings such as blue mood, despair, anxiety, depression?	Ordinal	Never=1, Seldom=2, Quite often=3, Very often=4, Always=5	Yes
HE127_T1	Comments in relation to the WHOQOL-Bref	Qualitative	Optional, free text comments that reflect either comments from the participants, or comments of the researcher, etc.	Optional
	EQ-5D-5L			**Administer at T0**
HE201_T1	**EuroQol EQ-5D-5L**	**Nominal**	**Summary index score**	Yes

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HE202_T1	EQ-5D-5L: Mobility	Ordinal	**1=I have no problems in walking about,** 2=I have slight problems in walking about, **3=I have moderate problems in walking about,** 4=I have severe problems in walking about, **5= I am unable to walk about**	Yes
HE203_T1	EQ-5D-5L: Self-care	Ordinal	**1=I have no problems washing or dressing myself,** 2=I have slight problems washing or dressing myself, **3= I have moderate problems washing or dressing myself**, 4= I have severe problems washing or dressing myself, **5=I am unable to wash or dress myself**	Yes
HE204_T1	EQ-5D-5L: Usual activities (e.g. work, study, housework, family or leisure activities)	Ordinal	**1=I have no problems doing my usual activities,** 2=I have slight problems doing my usual activities, **3= I have moderate problems doing my usual activities,** 4= I have severe problems doing my usual activities, **5= I am unable to do my usual activities**	Yes
HE205_T1	EQ-5D-5L Pain/Discomfort	Ordinal	**1= I have no pain or discomfort,** 2= I have slight pain or discomfort, **3= I have moderate pain or discomfort,** 4= I have severe pain or discomfort, **5= I have extreme pain or discomfort**	Yes
HE206_T1	EQ-5D-5L Anxiety/Depression	Ordinal	**1=I am not anxious or depressed**, 2=I am slightly anxious or depressed, **3= I am moderately anxious or depressed,** 4= I am severely anxious or depressed, **5= I am extremely anxious or depressed**	Yes

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HE207_T1	EQ-5D VAS. We would like to know how good or how bad your health is TODAY. This scale is numbered from 0-100. 100 means the best health you can imagine. 0 means the worst health you can imagine	Continuous	0-100	Yes
HE208_T1	Comments in relation to the WHOQOL-Bref	Qualitative	Optional, free text comments that reflect either comments from the participants, or comments of the researcher, etc.	Optional
	General self-efficacy scale			**Administer at T0**
HE301_T1	GSES1: I can always manage to solve difficult problems if I try hard enough	Ordinal	**1=Not at all true,** 2= Hardly true, **3= Moderately true,** 4= Exactly true	Yes
HE302_T1	GSES2: If someone opposes me, I can find the means and ways to get what I want	Ordinal	**1=Not at all true,** 2= Hardly true, **3= Moderately true,** 4= Exactly true	Yes
HE303_T1	GSES3: It is easy for me to stick to my aims and accomplish my goals.	Ordinal	**1=Not at all true,** 2= Hardly true, **3= Moderately true,** 4= Exactly true	Yes
HE304_T1	GSES4: I am confident that I could deal efficiently with unexpected events.	Ordinal	**1=Not at all true,** 2= Hardly true, **3= Moderately true,** 4= Exactly true	Yes
HE305_T1	GSES5: Thanks to my resourcefulness, I know how to handle unforeseen situations.	Ordinal	**1=Not at all true,** 2= Hardly true, **3= Moderately true,** 4= Exactly true	Yes
HE306_T1	GSES6: I can solve most problems if I invest the necessary effort.	Ordinal	**1=Not at all true,** 2= Hardly true, **3= Moderately true,** 4= Exactly true	Yes
HE307_T1	GSES7: I can remain calm when facing difficulties because I can rely on my coping abilities.	Ordinal	**1=Not at all true,** 2= Hardly true, **3= Moderately true,** 4= Exactly true	Yes

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HE308_T1	GSES8: When I am confronted with a problem, I can usually find several solutions.	Ordinal	**1=Not at all true,** 2= Hardly true, **3= Moderately true,** 4= Exactly true	Yes
HE309_T1	GSES9: If I am in trouble, I can usually think of a solution	Ordinal	**1=Not at all true,** 2= Hardly true, **3= Moderately true,** 4= Exactly true	Yes
HE310_T1	GSES10: I can usually handle whatever comes my way.	Ordinal	**1=Not at all true,** 2= Hardly true, **3= Moderately true,** 4= Exactly true	Yes
HE311_T1	GSES Total Score	Continuous	SUM all scores {HE301_T0, … HE310_T0}	Optional
HE312_T1	Comments in relation to the WHOQOL-Bref	Qualitative	Optional, free text comments that reflect either comments from the participants, or comments of the researcher, etc.	Optional
	OSSS-3			**Administer at T0**
HE401_T1	OSSS1: How many people are so close to you that you can count on them if you have serious problems	Ordinal	**none'=1, '**1 or 2' = 2, **'3 to 5' = 3, '**6+' = 4	Yes
HE402_T1	OSSS2: How much concern do people show in what you are doing?	Ordinal	**A lot of concern and interest=5,** Some concern and interest=4, **Uncertain=3**, Little concern and interest=2, **No concern and interest=1**	Yes
HE403_T1	OSSS3: How easy can you get practical help from neighbours if you should need it?	Ordinal	**Very easy=5,** Easy=4, **Possible=3**, Difficult=2, **Very difficult=1**	Yes

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HE404_T1	OSSS4a: Did you experience any of these life events ***[in the last 6 months / since the last time we spoke]***?	Nominal	**1=Serious illness or injury to you,** 2=Serious illness or injury to a close relative, **3=Death of first-degree relative, including a child or spouse,** 4=Death of close family friend or second-degree relative, **5= Separation due to marital difficulties,** 6=Broke off a steady relationship, **7=Serious problem with a close friend, neighbour or relative,** 8=Unemployed/seeking work for more than one month, **9=Sacked from job,** 10=Major financial crisis, **11=Problems with police and court appearance,** 12=Something valuable lost or stolen	Yes
HE405_T1	OSSS4b: Did you get emotional support from anybody in relation to the event? If you had more than one event, please think of the most serious one	Ordinal	**Yes, a lot=3,** Yes, some=2, **No support=1**	Yes
HE406_T1	OSSS4c: From whom did you get emotional support?	Nominal	**For multiple values, please input each value separated by a comma. For 'other', if the participant elaborates(not required!), feel free to add that to the comment column.** 1=Spouse/Partner, **2=Parent,** 3=Brother/sister, **4=Children,** 5=Friend, **6=Neighbour**, 7=Other relative, **8=Other.**	Yes
HE407_T1	Comments in relation to the OSSS	Qualitative	Optional, free text comments that reflect either comments from the participants, or comments of the researcher, etc.	Optional

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	Participation Questionnaire			**Administer at T0**
HE501_T1	**Participation 1: I participate enough in activities that are important to me**	**Ordinal**	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Yes
HE502_T1	More detail	Qualitative	Add free text	Yes
HE503_T1	**Participation 2: Using this technology makes participating in the activities that are important to me**	**Ordinal**	**Much more difficult=1,** A little more difficult=2, **About the same=3,** A little easier=4, **A lot easier=5**	Yes
HE504_T1	More detail	Qualitative	Add free text	Yes
HE505_T1	Comments in relation to the participation questions	Qualitative	Optional, free text comments that reflect either comments from the participants, or comments of the researcher, etc.	Optional
	Health Literacy Measure			**Administer at T0**
HE601_T1	**HLM1: How confident are you filling out medical forms by yourself?**	**Ordinal**	**Not at all=1,** A little bit=2, **Somewhat=3,** Quite a bit=4, **Extremely=5**	Yes
HE602_T1	Comments in relation to the health literacy question	Qualitative	Optional, free text comments that reflect either comments from the participants, or comments of the researcher, etc.	Optional
	System Usability Scale (SUS)			**Administer at T0**
HE701_T1	**System Usability Scale (SUS)**	**Continuous**	**0-100**	
HE702_T1	SUS1: I think that I would like to use this technology frequently	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Yes
HE703_T1	SUS2: I found this technology unnecessarily complex	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Yes

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HE704_T1	SUS3: I thought this technology was easy to use	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Yes
HE705_T1	SUS4: I think that I would need the support of a technical person to be able to use this technology	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Yes
HE706_T1	SUS5: I found the various functions in this technology were well integrated	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Yes
HE707_T1	SUS6: I thought there was too much inconsistency in this technology	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Yes
HE708_T1	SUS7: I would imagine that most people would learn to use this technology very quickly	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Yes
HE709_T1	SUS8: I found this technology very cumbersome (awkward) to use	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Yes
HE710_T1	SUS9: I felt very confident using this technology	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Yes
HE711_T1	SUS10: I needed to learn a lot of things before I could get going with this technology	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither agree nor disagree=3,** Agree=4, **Strongly agree=5**	Yes
HE712_T1	Comments in relation to the SUS	Qualitative	Optional, free text comments that reflect either comments from the participants, or comments of the researcher, etc.	Optional
	Technology Acceptance Model			**Administer at T0**
HE801_T1	This technology is useful to me	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither**	Yes

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			disagree nor agree=3, Agree=4, **Strongly agree=5**	
HE802_T1	If this technology was available to me in future, I would use it	Ordinal	**Strongly disagree=1,** Disagree=2, **Neither disagree nor agree=3,** Agree=4,**Strongly agree=5**	Yes
HE803_T1	Comments in relation to the TAM questions	Qualitative	Optional, free text comments that reflect either comments from the participants, or comments of the researcher, etc.	Optional

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