# SHAPES

## Smart and Healthy Ageing through People Engaging in supportive Systems

# D6.7 – Physical Rehabilitation at Home

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## Revision History

*Table 1 Revision History*

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| **1** | 20.04.2022 | Maria J. Santofimia (UCLM) | First draft |
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| **3** | 30.05.2023 | Maria J. Santofimia (UCLM) | Use cases detailed |
| **4** | 10/07/2023 | Javier Dorado Chaparro (UCLM) | Data summary and table arrangements |
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## Table of Contributors

*Table 2 Deliverable Contributors*

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| | |

## Table of Acronyms and Abbreviations

*Table 3 Acronyms and Abbreviations*

| Acronym | Full Term |
|---|---|
| **AUTH** | Aristotle University of Thessaloniki |

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| | |
|---|---|
| **CH** | Clínica Humana |
| **DPIA** | Data Protection Impact Assessment |
| **EQ-5D & VAS** | EQ-5D Visual Analog Scale |
| **EU** | European Union |
| **FICS** | Function and events, Interactions and usability issues, Content and structure, Style and aesthetics |
| **GDPR** | General Data Protection Regulation |
| **GSES** | General Self-Efficacy Scale |
| **ICF-US** | Classification of Functioning based Usability Scale |
| **ISO** | International Organization for Standardization |
| **IT** | Information Technology |
| **KOM** | KOMPAI Robotics |
| **KPI** | Key Performance Indicator |
| **MAFEIP** | Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing |
| **MAST** | Model for ASsessment of Telemedicine |
| **NASS** | Non-adoption, Abandonment, Scale-up, Spread, and Sustainability |
| **O** | Outcome |
| **OSSS-3** | Oslo Social Support Scale |
| **PACT** | People-Activities-Context-Technology |
| **PO** | Primary Objective |
| **SAL** | El Salvador Nursing Home |
| **SHAPES** | Smart and Healthy Ageing Through People Engaging in Supportive Systems |
| **SUS** | System Usability Scale |
| **TAM** | Technology Assessment Model |
| **TO** | Tertiary Objective |
| **UCLM** | University of Castilla-La Mancha |
| **VICOM** | Vicomtech |

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| | |
|---|---|
| **WHOQOL-BREF** | World Health Organization Quality of Life Instruments – Bref |
| **WP** | Work package |

## Keywords

Physical activity, wellbeing, rehabilitation, Phyx.io.

## *Disclaimer*



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# Executive Summary

This deliverable, D6.7, presents the outcomes and results of Pilot Theme 6 (PT6) for Physical Rehabilitation at Home within the SHAPES Pan-European Pilot Campaign. The deliverable focuses on four distinct use cases: PT6-UC001: Training Orofacial Musculature, PT6-UC002: Gait Rehabilitation, PT6-UC003: Video-based rehabilitation tool, and PT6-UC004: Wearable Motion Monitoring Device.

The report begins by providing an introduction and rationale for PT6, highlighting the importance of physical rehabilitation at home and the role of technology in enabling effective remote rehabilitation. It establishes the purpose of PT6 in addressing specific use cases and advancing in the field of physical rehabilitation.

For each use case, the deliverable provides a detailed description of the work undertaken in each of the five phases of the pilot campaign. Starting with PT6-UC001 and PT6-UC003, the report outlines the activities, interventions, and assessments carried out to train orofacial musculature and the rest of the body joint range of motion. It presents the results and outcomes achieved, shedding light on the effectiveness of the intervention and its impact on patients' rehabilitation progress.

Moving on to PT6-UC002, the report focuses on evaluating the user engagement and self-perceived usefulness of a digital solution aimed at assisting older adults with their gait. The main objective of this use case is to assess the effectiveness and acceptance of the digital solution in improving gait and mobility among older adults. The report provides insights into the user experiences, feedback, and perceived benefits of the tool. It evaluates the engagement levels and the extent to which the tool is deemed useful by the target users. The findings contribute to understanding the usability and potential impact of the digital solution on older adults' gait and overall mobility.

Next, the deliverable delves into PT6-UC004, which involves the utilization of wearable motion monitoring devices. It discusses the deployment of the devices and their integration into the rehabilitation process. The report presents the data collected through the device and evaluates its effectiveness in monitoring and tracking patients' motion patterns and activity levels, enabling personalized rehabilitation programs.

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# 1 Introduction

Pilot Theme 6: Physical Rehabilitation at Home is led by UCLM and has been mainly piloted in SAL with replicas in CH and AUTH. Different digital solutions, provided by UCLM, VICOM, and KOM, will be evaluated under this Pilot Theme.

The main purpose of this Pilot Theme is to provide a set of digital solutions that support older adults while performing physical rehabilitation routines. These routines might involve physical exercise, physical activity such as walking, or orofacial exercise.

Living a sedentary lifestyle has been identified as a major health hazard, especially as people age. In fact, according to the WHO (WHO, 2016) "*at least 80% of all heart disease, stroke and diabetes and 40% of cancer could be prevented*" by tackling the most common risk factors underlying the most prevalent chronic conditions, such as unhealthy diets, physical inactivity, hypertension or obesity.

Off-the-shelf devices and Apps can be found for physical activity and weight management such as those of Fitbit[1], Apple[2], Google Fit[3] or Xiaomi Mi Band[4]. They all offer a range of functionalities for user engagement, monitoring, reminders for promoting a healthier lifestyle, etc. Most of these commercial solutions offer open APIs, so that third party applications can access the data they collect. Thus, efforts can be focused on what to do with the data rather than how to collect them. However, most studies to date focus on healthy individuals (most of the times, young individuals) rather than on those already suffering from a chronic condition or multi-morbidity, which is the most common case among older adults.

Exercise routines are normally prescribed for older adults to address a specific condition or just to delay the effects of ageing. Ideally, these routines should be supervised by a physical therapist. However, most older adults cannot exercise daily for several reasons such as economic cost, time constraints, or the impossibility to travel to a health centre on a daily basis. In fact, the depopulation effect that rural areas are currently going through is also a major cause for this limited access to professional supervision of exercise routines. There is an important lack of qualified professional in such rural areas.

[1] https://www.fitbit.com [accessed on 12 June 2021]

[2] https://www.apple.com/es/watch/ [accessed on 20 June 2021]

[3] https://www.google.com/fit/ [accessed on 20 June 2021]

[4] https://www.mi.com/es/mi-smart-band-5/ [accessed on 20 June 2021]

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This situation forces older adults to the unsupervised realization of exercise routines. This could be ineffective or, even worse, unsafe (Su, Chiang, & Huang, 2014). Unsupervised activities could lead patients to adopt inappropriate corporal poses that might cause damage. There is, therefore, a trade-off between the need for supervision and the comfort and convenience of exercising at home.

The use of computer-aided systems for physical activity has been extensively explored (Liao, Vakanski, Xian, Paul, & Baker, 2020). Other approaches based on gamification strategies (Xu, y otros, 2020) (Williams, Kennedy-Malone, Thompson, & Monge, 2022) have already being explored and showed positive impact on the adherence levels to exercise programs. Nonetheless, these tools have traditionally been assessed based on the single criteria of accuracy or adherence, among some of the most common ones. These are very important indicators, but little is known about the impact they have on acceptance and its intention to use technology.

The major barriers found by older adults when engaging in exercising are, among the most relevant ones, the lack of time (Ige-Elegbede, Pilkington, Gray, & Powell, 2019), lack of company (Han, y otros, 2016), lack of understanding of the importance of physical activity (Ige-Elegbede, Pilkington, Gray, & Powell, 2019), physical complaints, lack of accessibility, or fear of falling (de Moraes, Furlanetto, Ricci, & Perracini, 2020). Digital solutions that specifically tackle such barriers would have a greater chance of succeeding in engaging older adults in exercising.

Limitations in outdoor mobility is one of the first limitations to occur (Wilkie, Peat, Thomas, & Croft, 2006) as people age. The need to exercise from home has also been evident during the COVID-19 pandemic. Either because of the mobility restrictions or as a preventive measure, many older adults that periodically attended physical exercise classes saw their activity truncated because of the pandemic situation. Despite the efforts of public authorities to promote physical activity during the lockdown, the work in (Chaabene, et al., 2021) have concluded that individuals over 55 years old, reported a reduction in exercise performance (Constandt, et al., 2020). In this sense, not only the pandemic has made evident the need for support systems for at-home physical exercise, but also the need to reach to those older adults that have a very limited mobility outdoor.

The digital solutions evaluated in this Pilot Theme address this challenge by directly tackling the barriers that prevent older adults from engaging in exercise, as previously listed: the lack of time, lack of company, lack of understanding of the importance of physical activity, physical complaints, lack of accessibility, or fear of falling.

This Pilot Theme will mainly revolve around a digital solution named Phyx.io. This is a platform that provides support to both users and health and care providers. Users will find in Phyx.io the list of routines they have been assigned to. During the execution of a certain routine, they will be guided during the execution of each of the exercises comprising the routine and, finally, the data captured during the execution of the

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different exercises will be stored. Phyx.io provides to health and care providers an easy way to manage the rehabilitation process of each of the individuals they supervise. Therapists prepare rehabilitation routines based on a list of predefined exercises or even routine templates. They can manage the progress of the individuals they supervise, as the exercise performance is quantitively tracked along time. These functionalities help addressing the lack of time pointed out by individuals, as it just requires turning on the system (smart mirror, TV, or screen equipped with a camera) and follow the instructions provided by Phyx.io.

Phyx.io addresses the lack of companion by providing a video call service so that trainer and trainee can talk whenever there is a doubt or a need for supervision of the exercise routines. Phyx.io also addresses the lack of understanding of the importance of the physical exercise by providing the user information about the evolution, overtime, in terms of improvements on minutes of activity, joint amplitude range or the number of repetitions achieved. This information is also intended to motivate the user.

Finally, it is also important to address the fear of falling when the individual is exercising alone, at home, as this is a potential risk for older adults. To this end, the same type of sensors that are employed for monitoring the gait analysis are also proposed to perform fall detection in real time. Using the video call functionality provided by Phyx.io a call to a designated contact is launched in case a fall is detected.

These digital solutions are evaluated within a set of use cases, namely:

1. Training of orofacial musculature.
2. Gait rehabilitation.
3. Camera Rehabilitation Tool.
4. Wearable Motion Monitoring Devices.

This Pilot Theme is intended to investigate on the factors that influence user engagement and acceptance in digital solutions that promote physical activity and how these determine the intention to use such technology, among the older adult population. Eventually, this Pilot Theme will also explore the improvement of quality of life as a result of having exercised during the pilot execution.

## *1.1 Rationale and purpose of the deliverable*

This deliverable describes the activities carried out under the Task 6.7: Pilot Theme 6: Physical Rehabilitation at Home. These activities are organized based on the different stages established by the methodology proposed in SHAPES. This methodology establishes five phases for the co-design, co-experimentation, co-deployment, and co-execution.

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This Pilot Theme is organized in four Use Cases that will, in a more detailed manner, address specific challenges and involve different technologies. These use cases will be used to evaluate this pilot theme, and can be summarized as:

UC-PT6-001: Training of orofacial musculature. This use case is led by UCLM and will involve digital solutions provided by VICOM and UCLM. The lead site is SAL with AUTH as a replicating site.

UC-PT6-002: Gait rehabilitation. This use case is led by CH and involves a digital solution provided by KOM. The lead site is CH with replicating sites in SAL and AUTH.

UC-PT6-003: Video-based rehabilitation tool. This use case is led by UCLM and will involve digital solutions provided by UCLM. The lead site is SAL with AUTH as a replicating site.

UC-PT6-004: Wearable motion monitoring devices. This use case is led by UCLM and will involve digital solutions provided by VICOM and UCLM. The lead site is SAL and there are no replication sites.

These use cases will be evaluated following a five-step evaluation methodology proposed in SHAPES. First, the NASSS framework[5] has been applied during Phase 1 to detect whether the activities proposed in the different use cases are too complex, therefore endangering the possibilities of the use case to succeed in achieving the proposed objectives. Also, during Phase 1, MOMENTUM has evaluated a set of critical success factor to determine the degree to which pilot sites are ready for a large-scale deployment of the considered use cases. Still in Phase 1, a set of KPIs have been identified so that the progress of the pilot activities can be monitored and assessed. Then, during Phases 3, 4 and 5, MAST is proposed to assess the effectiveness and contributions of the considered digital solutions for physical rehabilitation at home to quality of care. Finally, if a large-scale deployment is undertaken, the MAFEIP methodology will be also employed to assess the impact of the proposed digital solutions for the person-centred integrated care goal at an EU level.

The use cases proposed under Pilot Theme 6 pursue the goal of investigating which are the most relevant factors that influence user engagement and acceptance in digital solutions that promote physical activity and how these determine the intention to use such technologies, among the older adult population. Eventually, this Pilot Theme will also explore the improvement of quality of life as a result of having exercised during the pilot execution.

[5] Greenhalgh T, Maylor H, Shaw S, Wherton J, Papoutsi C, Betton V, Nelissen N, Gremyr A, Rushforth A, Koshkouei M, Taylor J. The NASSS-CAT Tools for Understanding, Guiding, Monitoring, and Researching Technology Implementation Projects in Health and Social Care: Protocol for an Evaluation Study in Real-World Settings. JMIR Res Protoc. 2020 May 13;9(5):e16861. doi: 10.2196/16861. PMID: 32401224; PMCID: PMC7254278.)

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### 1.1.1 Deliverable Objectives

The overall objective of Pilot Theme 6 is to support the realization of rehabilitation exercises at home, leading to an improvement or maintenance of the physical condition of the individual. To evaluate the level of achievement of this general objective, the following sub-objectives have been identified for the different use cases:

- UC-PT6-001 and UC-PT6-003
  - To provide support for individuals and their health and care providers in the management of the physical rehabilitation interventions.
  - To improve adherence to the prescribed rehabilitation routines.
  - To increase users' awareness about their performance during the rehabilitation intervention.
  - To improve user perception and acceptance about the proposed technologies to have a positive impact on the intention of use.
- UC-PT6-002
  - To explore user trust and acceptance of the novel system.
  - To investigate user engagement with the novel system.
  - To investigate the user-perceived usefulness of the novel system.
  - To investigate the capability of the novel system to optimise the gait rehabilitation process.
  - To investigate the capability of the novel system to improve the management of gait rehabilitation process for health professionals.
  - To investigate the capability of the novel system to improve older individual's quality of life, wellbeing and psychological and psychosocial aspects.
  - To explore the integration of the novel system to align with current care pathways.
  - To improve the facial recognition algorithm.
  - To improve the emotion recognition algorithm.
  - To determine the correlation between the detected emotions and the development of the gait exercises.
  - To study the ability of the new system to quantify the improvement of gait rehabilitation.

- UC-PT6-004
  - To quantitatively evaluate the level of physical activity and to deliver this information to the health and care specialists (GP, therapists, caregivers, etc.).
  - To provide a mechanism to track the evolution of such activity.
  - To provide a mechanism to analyse and characterize the individual's gait and how this evolves in the context of a rehabilitation intervention.
  - To provide feedback to users about their daily activity, therefore contributing to increasing the level of awareness of their own activity.

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- To improve user perception and acceptance about the proposed technology to eventually impact on the intention of use.

### 1.1.2 Key inputs and outputs

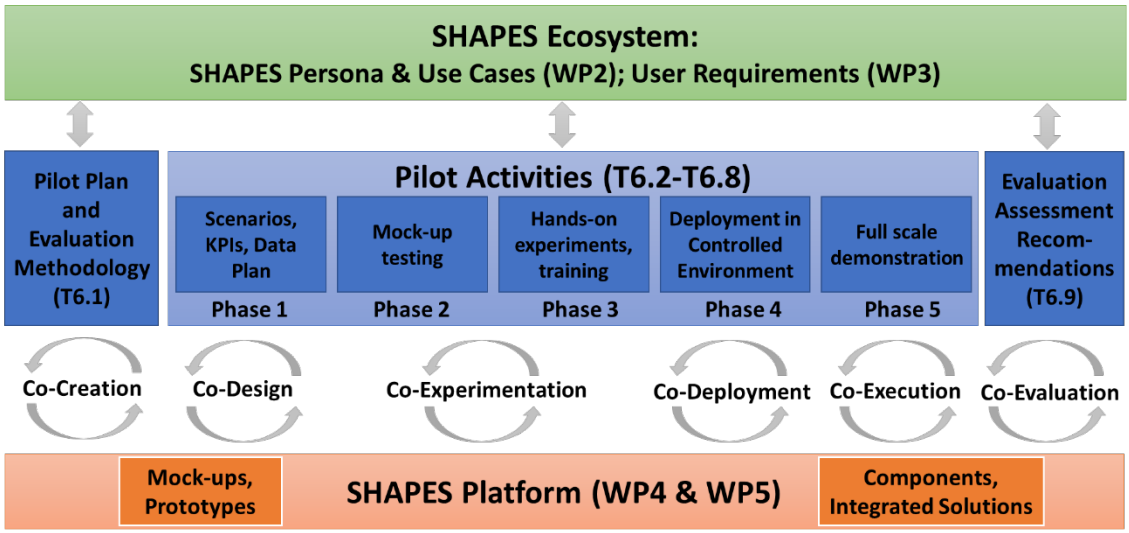


*Figure 1: Overview of WP 6.*

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.

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

## *1.2 Structure of the document*

This document has been structured to present the activities undertaken and the key outcomes of each of the four use cases. Main outcomes and key recommendations from each use case are then brought together in the Conclusions.

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# 2 Use case PT6-UC001: Training orofacial musculature and Use case PT6-UC003: Video-based rehabilitation tool

## *2.1 Introduction*

This section introduces two use cases within Pilot Theme 6 of the SHAPES project, namely PT6-UC001: Training orofacial musculature and PT6-UC003: Video-based rehabilitation tool. These use cases are part of the Phyx.io platform, which aims to provide innovative solutions for physical rehabilitation at home.

PT6-UC001 focuses on the rehabilitation of the orofacial musculature, which plays a crucial role in the swallowing process and speech ability of older adults. The orofacial system can be affected by the natural aging process, as well as conditions like strokes or facial paralysis. To improve or maintain the health of the orofacial system, therapists commonly prescribe a set of exercises that are typically performed in front of a mirror. Figure 2 displays examples of exercises commonly prescribed for orofacial rehabilitation interventions.

PT6-UC003 involves a video-based rehabilitation tool, another component of the Phyx.io platform. This tool caters to older adults who require rehabilitation exercises that target specific muscle groups and joints. The video-based approach provides guided demonstrations and instructions, enhancing the user experience and enabling individuals to perform exercises in an appropriate manner and technique. By utilizing the Phyx.io platform, older adults can access this video-based rehabilitation tool from the comfort of their own homes.

These use cases target older adults who either have existing orofacial musculature conditions or aim to delay the natural deterioration associated with aging. One of the personas in this use case is Jarda, a 68-year-old male who recently suffered a stroke resulting in facial paralysis. Jarda lives alone on the outskirts of a city and is unable to drive, making the Phyx.io platform an ideal choice for his rehabilitation needs.

The primary objective of these use cases is to investigate factors that impact user engagement, acceptance, and the relationship with their intention to use technology. By utilizing the Phyx.io platform and incorporating both the orofacial musculature training and the video-based rehabilitation tool, these use cases seek to enhance user

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experience and promote effective rehabilitation in the comfort of the user's home

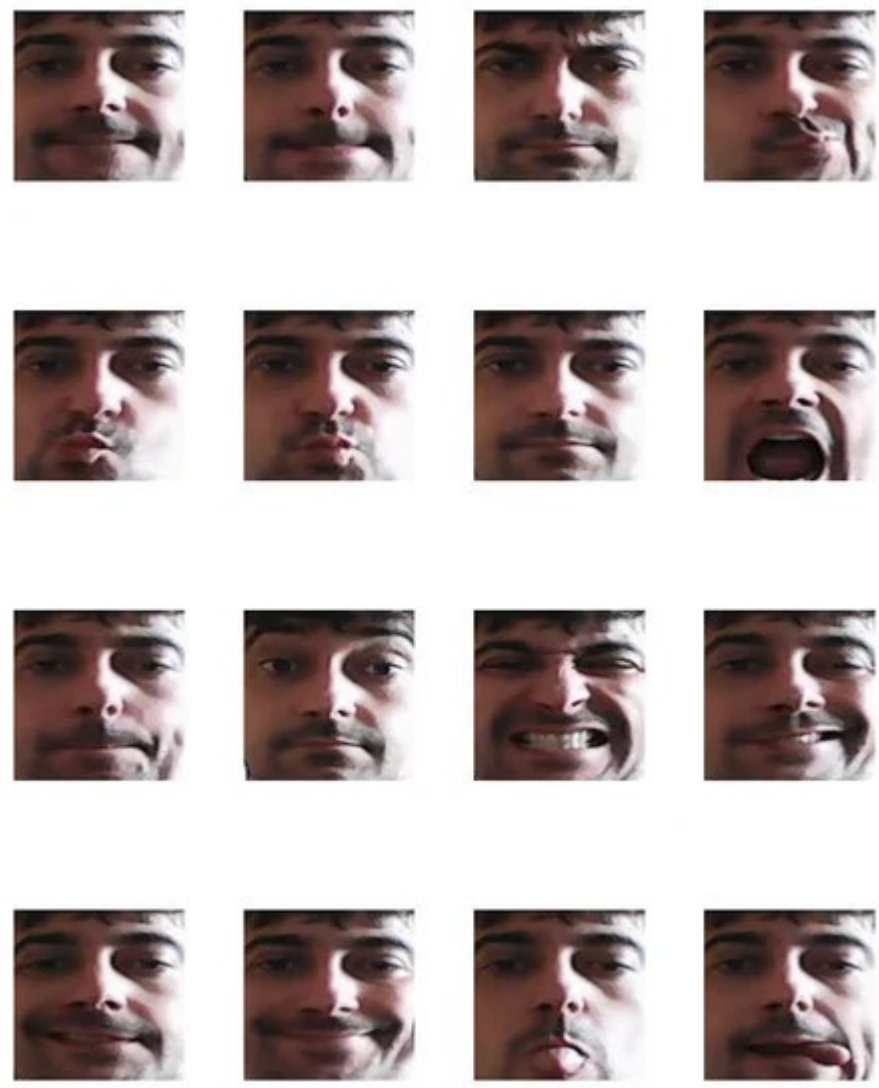

*Figure 2: Examples of orofacial rehabilitation exercises*

## 2.2 Description

The loss of strength of the orofacial and body musculature is a common situation in the aging process. This process may negatively affect several basic activities such as swallowing, talking, and face-to-face communication for orofacial musculature but also, daily live activities. Additionally, it can be increased by several pathologies such as Parkinson, Stroke, and others.

In this context, a set of exercises are normally prescribed by the speech therapists (logopedas) or physiotherapist in order to recover or maintain as long as possible the oral agility, strength, speed and coordination of the orofacial musculature.

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In this sense, a digital tool is needed that guide the user through a set of exercises intended to train these muscles. During the exercise performance, some variables such as time, number of repetitions, or degree of symmetry, are captured to track the evolution as result of the training program.

## 2.3 Digital solutions used in this use case

*Oroface (VICOM)*

This digital solution is intended to guide and supervise the performance of orofacial rehabilitation exercises. It will capture a set of parameters that will determine to which degree the exercises have been performed as expected. This will also evaluate the symmetry degree between the two sides of the face.

*Phyx.io (UCLM)*

This is the platform that will run Oroface, as an exercise module but it will also provide support for physical-rehabilitation exercises. The Phyx.io platform is employed for user management, routine management and access to the recorded data during the execution of the exercise routines.

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

### 2.3.1 Digital solutions used for COVID-19 response

Phyx.io, as an innovative digital platform for physical rehabilitation at home, could have played a pivotal role in leveraging digital solutions to address the challenges posed by the COVID-19 pandemic. This platform offers a range of functionalities that have significant potential to contribute to the pandemic response, ensuring the continuity of physiotherapy services while prioritizing the safety and well-being of patients.

- Telehealth and Remote Consultations: Phyx.io incorporates a video-call functionality that enables patients to have remote consultations with physiotherapists. This telehealth feature has been instrumental in providing uninterrupted care to patients during times of social distancing and lockdowns. Patients can connect with their physiotherapists through secure video calls, discuss their condition, receive guidance on exercises, and seek professional advice without the need for in-person visits. This not only minimizes the risk of exposure to the virus but also ensures that patients receive timely and personalized care from the comfort of their homes.
- Exercise Monitoring and Feedback: Another vital functionality of Phyx.io is its ability to monitor patients' exercise routines and provide valuable feedback. Through the platform, physiotherapists can prescribe personalized exercise

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regimens tailored to each patient's needs. Patients can access these exercise programs through the Phyx.io app, perform the exercises at home, and receive real-time feedback on their form, technique, and progress. This feature enhances patient engagement, motivates adherence to treatment plans, and allows physiotherapists to monitor patients' exercise compliance and make adjustments as needed.

- Secure Data Sharing and Storage: Phyx.io ensures the secure sharing and storage of patient data, maintaining confidentiality and privacy. The platform adheres to strict data protection protocols, complying with relevant healthcare regulations and guidelines. Physiotherapists can securely access and store patient information, including medical history, exercise logs, and progress records. This secure data infrastructure fosters seamless collaboration between physiotherapists and patients, facilitating informed decision-making, personalized treatment plans, and ongoing monitoring of patients' progress.
- Remote Monitoring and Progress Tracking: With Phyx.io, patients can track their progress and share relevant data with their physiotherapists remotely. The platform allows patients to record their exercise sessions, monitor vital signs, and track their daily activity levels. Physiotherapists can access this data, analyse it, and provide evidence-based guidance to optimize treatment plans. This remote monitoring and progress tracking feature not only promotes patient engagement and accountability but also enables physiotherapists to assess the effectiveness of interventions and make data-driven adjustments for better outcomes.
- Enhanced Communication and Support: Phyx.io facilitates enhanced communication and support between physiotherapists and patients. In addition to video consultations, the platform offers secure messaging functionalities that enable patients to communicate with their physiotherapists, ask questions, and seek clarifications. This direct line of communication fosters a collaborative and supportive relationship, empowering patients to actively engage in their rehabilitation process and ensuring that they receive the guidance they need, even when face-to-face interactions are limited.

Phyx.io's functionalities Can potentially address some of challenges experienced during pandemics, offering a comprehensive digital solution that enables remote consultations, exercise monitoring, secure data management, remote monitoring, and enhanced communication. By leveraging technology, Phyx.io has successfully bridged the gap between physiotherapists and patients, ensuring the continuity of care while prioritizing patient safety and convenience.

### 2.3.2 Equipment and devices used (from third parties)

This use case has been designed so that it can run on a general display device like a smart TV or a traditional PC or laptop. Additionally, a smart mirror device has been designed so that it can support the performance of rehabilitation exercises while at the

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same time the user has his/her reflection as though it was exercising in a more traditional environment in which mirrors are typically used.

The following Figure shows the setup that employs a smart TV with a touch screen in a so-called kiosk setup.


*Figure 3: Setup for Phyx.io running oroface with the Kiosk setup.*

The following Figure shows the oroface application running in a standalone mode (outside Phyx.io) in the smart mirror setup.

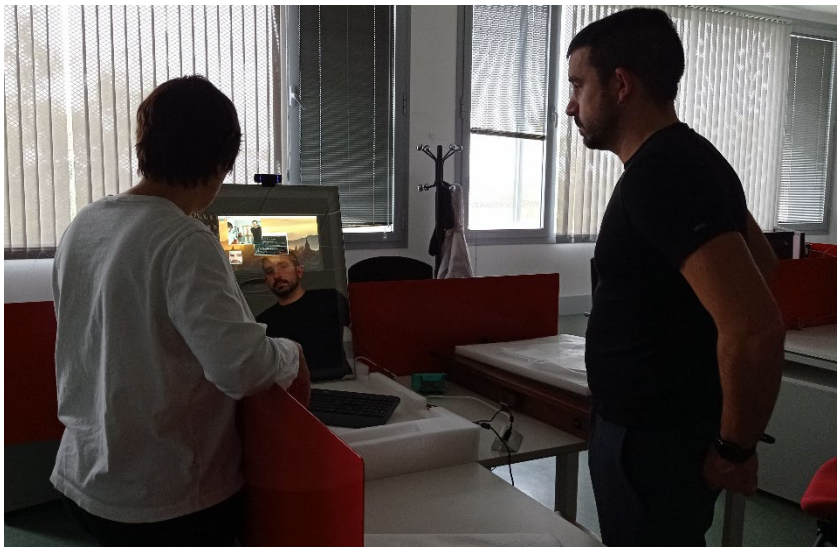

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*Figure 4: Setup for Phyx.io using the Smart Mirror*

## 2.4 Data plan

The data plan for PT6-UC001 and PT6-UC003 includes the:

- Data Protection Impact Assessment (DPIA) document that assesses whether the processing of personal data is on a right level from GDPR point of view and describes the potential corrective actions that has been taken.
- Personal Data Processing Descriptions that provide detailed information about how personal data is collected, processed, and stored.
- DPIA risk assessment that identifies all the risks, its impact and probability and proposes actions for risk mitigation.
- Data Processing agreement that defines the responsibilities and obligations of data controller and a data processor with regard to the processing of personal data.
- Data Sharing Agreement that sets out the purpose, type, and scope of data sharing within PT6-UC001 and PT6-UC003.

### 2.4.1 Data capture methods to be used

A range of different data capture methods will be used during this pilot and are listed below:

Phase 1, 2 and 3:

- Recording of videos from physiotherapist showing the performance of the most commonly used exercises.
- Feedback from experts (therapists mainly) after evaluating the different iterations of the digital solutions.
- User experience questionnaires (e.g.: SUS, TAM)

Phase 4:

- Feedback and error detected from experts and potential users and caregivers when performing a set of tasks.
- User experience questionnaires (e.g.: SUS, TAM)

Phase 5:

- Participant data (see Data Plan)
- Harmonised questionnaires (more details on harmonised data will be provided in Deliverable 6.9)
    - WHOQOL-BREF (Whoqol Group, 1998)

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- EQ-5D-5L (Rabin & de Charro, 2001)
- General Self-Efficacy Scale (Schwarzer & Jerusalem, 1995)
- Oslo Social Support Scale (Kocalevent & et, 2018)
- Single item health literacy scale (Chew, Bradley, & Boyko)
- Participation questions
- System Usability Scale (Martins, Rosa, Queirós, Silva, & Rocha, 2015)
- Technology acceptance questions (Lewis, 2019)

- Questionnaires for the Phyx.io solution regarding the impact in frailty and wellbeing.
  - Sociodemographic Questionnaires
  - Heuristic Evaluation Checklist
  - International Classification of Functioning, Disability and Health - Usability Scale (ICF-US) I and II

### 2.4.2 Planning of evaluation

*MAST*

The MAST framework (Kidholm, et al., 2011) will be used to evaluate the effectiveness and contribution of UC-PT6-001 and UC-PT6-003 to quality of care. MAST is described as a multidisciplinary process that summarises and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine.

A review of the seven dimensions of MAST revealed that three of the seven multidisciplinary dimensions/domains were of specific relevance to the pilot of UC-PT6-001 and UC-PT6-003. These were: Clinical Effectiveness; Patient Perspectives; and Economic Aspects. Table 4 contains the data required for the MAST evaluation.

*Table 4 Data required for MAST evaluation of UC-PT6-001*

| MAST Domain | Topic | Outcome | Data required | Time point |
|---|---|---|---|---|
| **Clinical Effectiveness** | Effects on mortality | Will not be measured | | |
| | Effects on morbidity | Will not be measured | | |
| | Physical health | Will not be measured | | |
| | Mental health | Will not be measured | | |

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|---|---|---|---|---|
| | Effects on health related quality of life | Health related quality of life | EQ-5D-5L and Barthel Index scores | Baseline and end of pilot |
| | Behavioural outcomes | Will not be measured | | |
| | Utilization of health services | Will not be measured. | | |
| **Patient perspectives** | Satisfaction and acceptance | User Experience | TAM | End of pilot |
| | Understanding of information<br><br>Confidence (in the treatment)<br><br>Ability to use the application.<br><br>Access | Usability of application | SUS Scores | End of pilot |
| | Empowerment Self-efficacy | Self-efficacy | General self-efficacy scale | Baseline and end of pilot |
| **Economic aspects** | Amount and cost of resources used. | Cost of devices | Cost as per medical device purchasing invoice | End of pilot |
| | Related changes in use of healthcare resources | Will not be measured. | | |

*MAFEIP*

Due to the evaluation methodology (small-scale deployment, non-case controlled) the MAFEIP tool (Monitoring and Assessment Framework for the European Innovation

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Partnership on Active and Healthy Ageing. [Online] https://www.mafeip.eu/.) will not be used to evaluate these use cases.

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

During the evaluation, a review of the seven dimensions of MAST revealed that three dimensions were particularly relevant to the pilot of UC-PT6-001 and UC-PT6-003. These dimensions are Clinical Effectiveness, Patient Perspectives, and Economic Aspects. Further discussion and analysis on why these domains were considered relevant to the use case, as well as the exclusion of the remaining four dimensions, will be presented in the evaluation report (D6.9).

Table 4 has been prepared to provide the necessary data for the MAST evaluation. The evaluation process using the MAST framework will assess the medical efficacy, social impact, economic implications, and ethical considerations associated with the use of telemedicine in UC-PT6-001 and UC-PT6-003. This comprehensive evaluation will shed light on the effectiveness of the use case and its contributions to improving the quality of care.

By incorporating the MAST framework into our evaluation, alongside the CSFs from MOMENTUM and the NASSS framework, we aim to comprehensively analyse the multifaceted aspects of the use case. This integrated evaluation approach will provide valuable insights into the medical, social, economic, and ethical dimensions of UC-PT6-001 and UC-PT6-003, ultimately guiding decisions and potential improvements for the future implementation and scaling of the use case.

*MOMENTUM*

The MOMENTUM blueprint was applied to check if PT6-UC001 and PT6-UC003 had the critical success factors (CSFs) needed to take it from the pilot phase to large-scale deployment. Details of each CSF are provided below.

**CSF 1. Cultural readiness for the telemedicine service**

The Nursing Home El Salvador have the necessary technological infrastructure to support the use of the Phyx.io platform for telemedicine. This includes reliable internet access, appropriate devices for using the platform, and technical support.

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

Telemedicine services like Phyx.io allow patients with mobility restrictions to participate in rehabilitation exercises from the comfort of their own rooms or homes. This can be a significant advantage for patients who may find it difficult to travel to a physical therapy clinic or who may be at risk of falls or other injuries. Also, telemedicine

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can make it easier for patients to access care, especially in rural or underserved areas where there may be a shortage of healthcare professionals. The use of telemedicine services significantly improve access to care for its residents.

**CSF 3. Ensure leadership through a champion**

The head of the Nursing Home effectively communicated the benefits and importance of the Phyx.io platform to staff, residents, and stakeholders. The leadership at the Nursing Home El Salvador demonstrates a clear commitment to the success of these use cases. This is shown through their active involvement in planning and implementation, their allocation of resources to the project, or their advocacy for the project to other staff, residents, and stakeholders.

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

The healthcare professionals and decision-makers at the Nursing Home El Salvador are involved in the planning and implementation of these use cases. Their expertise and insights have proved to be essential to ensure that the use cases are designed and implemented in a way that meets the needs of the patients and fits within the existing care processes. Furthermore, the healthcare professionals are provided with the necessary training and support to use the Phyx.io platform effectively. This training is provided by the UCLM team.

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

Because residents are well known by the healthcare professionals of the Nursing Home, the patient's preferences, needs and expectations are considered when designing and delivering the rehabilitation platform, Phyx.io.

**CSF 6. Ensure that the technology is user-friendly**

The main digital technology solutions are being delivered through Phyx.io. Phyx.io is easy to use for both the healthcare professionals and the patients at the Nursing Home El Salvador. The platform has a user-friendly interface, clear instructions, and intuitive navigation. Furthermore, adequate training and support are provided to the users of the Phyx.io platform. This ensures they are able to use the platform effectively and confidently.

**CSF 7. Pull together the resources needed for deployment**

The different use cases have been sufficiently funded in terms of financial resources for the deployment of the different technologies. Furthermore, there are enough staff members at the Nursing Home El Salvador who are trained and available to implement and manage these use cases. This includes both the healthcare professionals who will be using the platform with the patients, and any technical staff who will be

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supporting the use of the platform. Finally, sufficient time has been allocated for the deployment of these use cases. This includes time for training the users, implementing the platform, and troubleshooting any issues that arise.

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

This use case, through the Phyx.io platform addresses the patient's need for effective and accessible rehabilitation exercises, the need for personalized care, and the need for support and training. From the perspective of the healthcare professionals, Phyx.io addresses the need for efficient and effective tools for delivering care, and the need for tools that integrate well with their existing workflows. In the overall, these use cases address the need to improve patient outcomes, seek by the Nursing Home, which eventually lead to an increase in efficiency and use of resources.

**CSF 9. Prepare and implement a business plan**

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

**CSF 10. Prepare and implement a change management plan**

After the project, a detailed change management plan will be studied for the implementation of these use cases. A comprehensive change management plan should outline the changes that will be made, the reasons for these changes, the expected benefits of the changes, and the strategies for managing resistance to change.

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

The Phyx.io platform complies with all relevant healthcare regulations in place where the Nursing Home El Salvador is located. This includes regulations related to patient care, privacy, and data protection.

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

The Phyx.io platform is designed in a way that it can handle a larger number of users without a significant decrease in performance or increase in cost. This includes the ability to handle more data, more simultaneous users, and more complex operations as the number of users increases. In terms of infrastructure requirement, as Phyx.io is hosted in a cloud infrastructure, the scale up of the Phyx.io platform does not require significant upgrades to the existing infrastructure. Finally, the cost of scaling up the use of the Phyx.io platform is proportional to the benefits.

**CSF 13. Identify and apply relevant legal and security guidelines**

Guidelines related to data encryption, user authentication, and the secure transmission and storage of patient data has been implemented, as well as data

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protection (GDPR). It's important to state that the platform meets all relevant security standards to protect patient data and privacy.

**CSF 14. Involve legal and security experts**

Through the UCLM team, legal and security experts have been involved in the planning and implementation of these use cases. Their expertise is essential to ensure that the use cases comply with all relevant laws and regulations, and that patient data is protected. The same team conducts regular risk assessments to identify any potential legal or security risks, and to develop strategies to mitigate these risks. Finally, the team is also involved in responding to any legal or security incidents that may occur during the implementation of the use cases.

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

The healthcare professionals and patients at the Nursing Home El Salvador have received training on privacy issues related to the use of the Phyx.io platform. This includes training on data protection laws, the importance of password security, and the risks of sharing sensitive information. Some of these aspects, like the password security, is enforced by the platform itself. The Phyx.io platform includes features to protect user privacy, such as data encryption, user authentication, and secure data transmission. Users are made aware of these features and how to use them.

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

The Nursing Home El Salvador has the necessary IT infrastructure to support the use of the Phyx.io platform. This includes reliable internet access, appropriate hardware (such as kiosks, smart mirrors, or tablets), and the necessary software. There is adequate technical support available to maintain the IT infrastructure and to assist users with any technical issues they may encounter. Finally, there are adequate security measures in place to protect the IT infrastructure from threats such as malware, hacking, and data breaches. This includes firewalls, antivirus software, and regular security audits.

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

The Phyx.io platform includes features for monitoring the use of the service. This includes analytic tools that track usage statistics, performance metrics, and user feedback. Furthermore, there are processes in place to regularly review and analyse the monitoring data. There are clear performance metrics that will be used to evaluate the success of the service.

**CSF 18. Establish and maintain good procurement processes**

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There are clear procurement policies in place for the acquisition of the Phyx.io platform and any necessary hardware or services.

*NASSS*

The NASSS (Nonadoption, Abandonment, Scale-up, Spread, and Sustainability) framework is a tool designed to help predict and evaluate the success of a technology-supported health or social care program. The NASSS framework is based on the idea that the success of a technology-supported program is influenced by the complex and interacting factors related to the condition (or conditions) being treated, the technology itself, the value proposition, the adopter system (comprising professional staff, patient, and lay caregivers), the organization(s), the wider (institutional and societal) context, and the interaction and mutual adaptation between all these levels over time.

*Table 5 Complexities and mitigation measures in the PT6-001 and PT6-003 use cases identified using the NASSS framework*

| NASSS complexity domain | Uncertainties detected | Mitigation measures taken |
|---|---|---|
| **The illness or condition** | The condition being treated involves orofacial and joint amplitude range exercises, which may vary in complexity and severity among patients. | The Phyx.io platform allows for remote monitoring and progress tracking, enabling personalized treatment plans. |
| **Technology** | The technology requires a stable network connection, which may not always be the case. | Recommendations have been made to optimize network infrastructure and address potential bottlenecks. |
| **Value Proposition** | The value proposition is dependent on the successful implementation and usage of the technology. | The platform offers remote consultations, exercise monitoring, secure data management, and enhanced communication, providing value to both patients and healthcare providers. |
| **Intended adopters** | Users need to be comfortable with the | Users found Phyx.io to be user-friendly and were able |

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| | | |
|---|---|---|
| | technology and able to use it autonomously. | to navigate the application without much difficulty. |

## 2.5 Phase 1

### 2.5.1 PACT and FICS Scenario

See Annex 1.

### 2.5.2 Key performance indicators

The following potential KPIs were identified to evaluate the success of PT6-001:

- **User Engagement:** Measure the frequency and duration of use of the Phyx.io platforms. At least 80% of the participants will complete the calendar stated at the beginning of the intervention.
- **Exercise Performance**: Track the progress of the exercises performed by the users. Each user will complete, at least, 80% of the list of exercises prescribed for every routine.
- **User Satisfaction**: Conduct surveys or interviews to gauge user satisfaction with the platforms and the exercises. At least 80% of the users will be satisfied with the technology.
- **Technology Acceptance**: Measure the user's intention to continue using the technology. At least 80% of the users will be willing to continue using Phyx.io.

### 2.5.3 Timeline of pilot activities

*Table 6 Timeline of pilot activities*

| | Pilot site | Partici pants | M33 -M34 | | M35 | M36 | M37 | M38 | M39 | M40 | M41 | M42 | M43 | M44 | M45 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **UC1& 3** | SAL | 30 | Phase 4 | | Phase 5 | | | | | | | | | | D6.7 |
| **UC 1& 3** | AUTH | 5 | | | | | | | | | | | | P5 | |
| **UC2** | CH | 10 | | | | | | | | | | | | | |
| **UC2** | SAL | 10 | | | | | | | | | | | P5 | | |
| **UC2** | AUTH | 5 | | | | | | | | | | | | P5 | |
| **UC4** | SAL | 7 | Phase 4 | | Phase 5 | | | | | | | | | | |

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## 2.6 Phase 2: Testing of mock-ups and prototypes

During Phase 2, validation was sought on the design of the user-interface of the digital solution intend<ed for deployment in UC-PT6-001. The Oroface and Phyx.io interface design process was based on an iterative process that included two main phases:

- Brainstorming to generate mock-ups.
- Tests with external domain experts to assess the mock-ups.

### 2.6.1 Methodology of testing

**Brainstorming to Generate Mock-ups**

The first step involved brainstorming sessions to generate mock-ups of the Oroface and Phyx.io platforms. These mock-ups were designed to illustrate the user-interface and functionality of the platforms, with a focus on guiding and supervising the performance of orofacial rehabilitation exercises.

**Tests with External Domain Experts to Assess the Mock-ups**

Once the mock-ups were created, they were tested with external domain experts (physiotherapist from University of Ramon Llull University and University of Aveiro). These experts were asked to assess the mock-ups based on their expertise in orofacial rehabilitation and their understanding of the needs and capabilities of the target user group. The experts provided feedback on the design and functionality of the mock-ups, which was then used to refine the design of the Oroface and Phyx.io platforms.

### 2.6.2 Results of testing

The testing phase for PT6-001 involved the Oroface and Phyx.io platforms. The feedback from the users was collected and analyzed to validate the functionalities and usability of these platforms. The results of the testing phase are as follows:

**User Feedback**

The users provided valuable feedback on the functionalities of the Oroface and Phyx.io platforms. They appreciated the guidance and supervision provided by the Oroface platform for the performance of orofacial rehabilitation exercises. The users also found the user management, routine management, and access to the recorded data during the performance of the exercise routines provided by the Phyx.io platform to be very useful.

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**Usability**

The users found the platforms to be user-friendly and easy to navigate. They were able to perform the prescribed exercises without any difficulties. The users also appreciated the remote monitoring feature of the platforms, which allowed them to perform the exercises at their own convenience without the need for direct contact with a healthcare professional.

**New Functionalities**

Based on the feedback from the users, several new functionalities were identified for potential integration into the Oroface and Phyx.io platforms. These included enhanced feedback mechanisms, more personalized exercise routines, and additional support features.

**Technical Improvements**

The feedback from the users also led to the identification of several areas for technical improvement in the Oroface and Phyx.io platforms. These improvements were aimed at enhancing the performance and reliability of the platforms.

## *2.7 Phase 3: Hand-on Experiments*

### 2.7.1 Methodology of hands-on experiments

The aim of the hands-on experiments is to collect feedback from end-users by giving them the opportunity to try the digital solutions to be deployed in the use case PT6-001 in close-to-final version prototypes.

Participants (older people and therapists or healthcare professionals) were invited to sessions to take part in the hands-on experiments. The Oroface and Phyx.io platforms were presented to the participants in these sessions.

The Oroface and Phyx.io platforms were presented to the participants through a combination of methods. This included demonstration videos showing the use of the platforms, user manuals providing detailed instructions on how to use the platforms, and workshops where participants could try out the platforms under the guidance of the research team. In some cases, an introduction at home was also provided to ensure that the participants were comfortable using the platforms in their own environment.

The feedback was collected from therapists or healthcare professionals (professionals from SAL who participate in the project) who are involved in prescribing or supervising orofacial rehabilitation routines.

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The feedback was collected through a combination of methods including monitoring of the use of the platforms, observation of the participants during the hands-on experiments, questionnaires to gauge user satisfaction and usability, and interviews to collect qualitative feedback.

### 2.7.2 Results of the hands-on experiments

The hands-on experiments for PT6-UC001: Training orofacial musculature were conducted following the methodology outlined in section 2.7.1. The results of these experiments are presented below:

**Outcome of the hands-on experiments**

The hands-on experiments yielded valuable insights into the practical application of the technologies involved in PT6-UC001. Participants were able to interact with the technologies and provide real-time feedback. The specific outcomes of these experiments, in line with chapter 5.1.3 of D6.1, are as follows:

- Participants' feedback: The feedback from the participants was generally positive. They appreciated the interactive nature of the technologies and found them easy to use. However, some participants suggested improvements in the user interface and the responsiveness of the technologies.
- Performance of the technologies: The technologies performed well during the experiments, with minimal technical issues. The real-time monitoring and feedback system was particularly appreciated by the participants.

**Recommendations for technical partner**

Based on the results of the hands-on experiments, the following recommendations are made for the technical partner:

- User Interface Improvements: Some participants suggested that the user interface could be more intuitive. It is recommended that the technical partner reviews these suggestions and considers implementing them in future iterations of the technologies.
- Responsiveness of the technologies: While the technologies were generally responsive, there were instances where they did not respond as expected. It is recommended that the technical partner investigates these issues and takes necessary measures to improve the responsiveness of the technologies.

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## 2.8 Phase 4: Small Scale Live Demonstration

### 2.8.1 Recruitment of participants

The target users for this phase are physiotherapists or healthcare professionals. We recruited 4 participants. These participants were recruited from the SAL partner professionals.

No informed consents were collected at this phase as all participants were researchers participating in the project.

### 2.8.2 Technical aspects & Logistics

**Procurement Procedures**

The procurement procedures for third-party equipment and devices will be carried out in accordance with the guidelines and regulations of the respective organizations. The necessary equipment and devices for the deployment of the Oroface and Phyx.io platforms will be procured in a timely manner to ensure the smooth execution of Phase 4.

**Transport of SHAPES Technologies**

The Oroface and Phyx.io platforms do not require transportation once the kiosk or the smart mirror has been put in place. Oroface and Phyx.io are hosted in the UCLM cloud.

**Local Technical Requirements**

The local technical requirements for the deployment of the Oroface and Phyx.io platforms will be assessed and addressed. This includes ensuring the availability of a stable Wi-Fi connection for the operation of the platforms. The physical space requirements for the deployment of the kiosk or smart mirror will also be taken into consideration. The pilot site will be prepared accordingly to accommodate the platforms and facilitate the hands-on experiments.

### 2.8.3 Roles and Responsibilities

The successful execution of Phase 4 for PT6-001 will involve various stakeholders, each with specific roles and responsibilities. These stakeholders include:

**Responsible Partner in All Pilot Sites**

The responsible partner in the SAL pilot site (UCLM) will oversee the deployment of the Oroface and Phyx.io platforms on the Kiosk or smart mirror platform. They will ensure that the platforms are set up correctly and that all technical requirements are

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met. They will also be responsible for addressing any technical issues that may arise during the deployment.

**Medical Professionals**

Medical professionals will monitor the health and wellbeing of the participants during the deployment. They will also provide feedback on the effectiveness of the Oroface and Phyx.io platforms in supporting orofacial rehabilitation.

### 2.8.4 Ethical considerations

The ethical self-assessment will be conducted to ensure that the deployment of the Oroface and Phyx.io platforms in Phase 4 adheres to all ethical guidelines and regulations. The informed consent procedure will be followed during Phase 5, to ensure that the participants understand the purpose of the study, the procedures involved, and their rights as participants. The necessary approvals are obtained from the relevant authorities before the commencement of Phase 4, although it will not be until Phase 5 when it will be necessary as Phase 4 does only involved researchers.

Data and Privacy Impact Assessment

A data and privacy impact assessment are conducted to ensure that the data collected during Phase 4 is handled in a secure and confidential manner. The Oroface and Phyx.io platforms will be designed to collect only the necessary data and to store and transmit this data in a secure manner. The privacy rights of the participants will be always respected.

Approval from Local Authorities and/or Local Community Health Service

The necessary approvals were obtained from the Ethical Committee (Social Pannel) of the University of Castilla-La Mancha, before the commencement of Phase 4. These approvals will ensure that the deployment of the Oroface and Phyx.io platforms is in compliance with local regulations and guidelines.

In line with chapter 5.2.2.7 of D6.1, all ethical considerations will be taken into account during the planning and execution of Phase 4. This includes ensuring the respect for the person at all stages, considering the users' capabilities when planning the tests, and planning a methodology that respects and protects human rights.

### 2.8.5 Outcome of the Small-Scale Live Demonstration

The small-scale live demonstration of PT6-UC001 and PT6-UC003 gathered a list of outcomes, evaluated as follows:

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**Primary and Secondary Outcomes**

The primary outcome of the small-scale live demonstration will be the usability and feasibility of the Oroface and Phyx.io platforms. This includes the number of accesses, sessions duration, type of features used, and number of errors measured every week.

The secondary outcomes will include the adherence rate, which is the ratio between the number of participants included in the study and the total number of people contacted, and the refusal rate, which is the ratio between the number of subjects who refused to participate in the study and the number of subjects contacted.

**Recommendation for Technical Partners**

Based on the outcomes of the small-scale live demonstration, recommendations will be made for the technical partners. These recommendations will focus on improving the usability and effectiveness of the Oroface and Phyx.io platforms based on the feedback received from the participants.

**Lessons-Learned for Phase 5 of Pilot Campaign**

The outcomes of the small-scale live demonstration will provide valuable lessons for the planning and execution of Phase 5 of the pilot campaign. These lessons will include insights into the recruitment process, the deployment of the Oroface and Phyx.io platforms, and the collection and analysis of data.

## *2.9 Phase 5: Large-scale pilot activity*

The PT6-UC001 is a use case that focuses on the training of orofacial musculature using the Phyx.io and Oroface digital solutions. This use case is part of the SHAPES Pan-European Pilot Campaign, which aims to improve the quality of life and independence of older adults through the use of digital solutions.

The purpose of PT6-UC001 is to provide older adults with a means to train their orofacial musculature at home, using digital solutions that are easy to use and effective. This use case is particularly relevant for older adults who may have difficulty accessing traditional face-to-face therapy services, whether due to mobility issues, geographical location, or the ongoing COVID-19 pandemic.

In this section, we will provide a detailed description of the phase 5 of the PT6-UC001 use case, including the digital solutions used, the data plan, and the results from the various phases of the pilot activities. We will also discuss the challenges encountered during the implementation of this use case and the solutions that were developed to address these challenges.

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### 2.9.1 Recruitment

#### *2.9.1.1 Inclusion and Exclusion Criteria*

The inclusion criteria for the recruitment process will be as follows:

- Participants must be aged 65 or older.
- Participants must be able to provide informed consent.
- Participants must be able to perform basic daily activities independently.
- Participants must be able to communicate effectively in the language of the study.

The exclusion criteria will be as follows:

- Participants with severe cognitive impairment.
- Participants with severe visual or hearing impairment.
- Participants with severe mobility issues that would prevent them from participating in the study activities.

#### *2.9.1.2 Sample size*

To conduct this study, we have a sample of participants who live or carry out daily activities at the "El Salvador" Nursing Home. For the usability and acceptability phase, which will be developed in the baseline of the pilot, we have a sample of 30 people (19 women and 11 men) with an average age of 82.87 years and a standard deviation of 6.64 years.

On the other hand, from the same sample, 15 people will participate in the study in the usability and feasibility phase, which takes place at the baseline, 4 weeks, and 8 weeks, respectively, after starting the intervention with Phyx.io. This sample of 15 volunteers (in the "Usability and feasibility" column of the following table are marked with a "Yes" value) consists of 9 women and 6 men, with an average age of 82.13 years and a standard deviation of 7.59 years.

*Table 7 Sample description for PT6-UC001 and PT6-UC003*

| | **Usability group (baseline)** | **Intervention group (baseline)** |
|---|---|---|
| | **SAL (*N*=30)** | **SAL (*N*=15)** |
| **Age (years) mean(sd)** | 82.75 (±6.64) | 82.13 (±7.59) |
| **Gender**<br><br>**(female)** | 19 | 9 |

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| | | |
|---|---|---|
| **Education (Years)** | 5.43 (±4.27) | 5.47 (±4.08) |
| **Health Literacy (How confident are you filling out medical forms by yourself?)** | Extremely – 10% (n=3)<br>Quite a bit 10% (n=3)<br>Somewhat 30% (n=9) A little bit 26.7% (n=8) Not at all 23.3% (n=7) | Extremely – 6.67% (n=1)<br>Quite a bit 13.3% (n=2)<br>Somewhat 33.3% (n=5) A little bit 33.3% (n=5) Not at all 13.3% (n=2) |

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*Sample size:* The target sample size for phase 5 included five (5) participants and two (2) healthcare professionals.

*Duration of the pilot: 1 month*

*Table 8 Timeline of pilot activities*

| **Demographics** | | |
|---|---|---|
| | **AUTH (*N*=5)** | |
| **Age** (years) mean(sd) | 63.40 (±10.21) | |
| **Gender** | 60% Male<br>40% Female | |
| **Level of education** | 60% Upper secondary school certificate<br>20% Vocational training Institute Certificate<br>20% Primary school certificate or Lower secondary school certificate | |
| **Marital status** | 40% Married<br>20% Single<br>20% Widows<br>20% Divorced | |
| **Level of Digital Literacy** | 60% Intermediate Users<br>40% Basic Users | |
| **Country of residence** | 100% Greece | |
| **Occupational status** | 60% Employed<br>40% Retired | |
| | **Pre** | **Post** |

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| | | |
|---|---|---|
| **Health Literacy (How confident are you filling out medical forms by yourself?)** | Extremely – 60% (n=3)<br>Quite a bit 20% (n=1)<br>A little bit 20% (n=1) | Extremely – 60% (n=3)<br>Quite a bit 20% (n=1)<br>A little bit 20% (n=1) |

**Methods**

Large-scale pilot activities were conducted in the Thessaloniki Action for HeAlth & Wellbeing Living Lab – Thess-AHALL Living Lab that operates since 2014 under the auspices of the Lab of Medical Physics and Digital Innovation, School of Medicine of Aristotle University of Thessaloniki. The lab fosters initiatives encouraging regional development and healthcare systems sustainability by the provision of novel technologies and innovation being a core member of the European Network of Living Labs (ENoLL), and the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) where Thess-AHALL is a three-star awarded reference site. Thess-AHALL was selected as AUTH pilot site as it is actively engaged with older people, vulnerable populations and other relevant community stakeholders, actively pursuing co-creation and co-design of technological solutions to improve health and social conditions and facilitate independent living. Staffed by an interdisciplinary team and researchers (psychologists, technologists, physicians etc.) the Thess-AHALL envisages to facilitate the ultimate aim of speeding up innovation, collaboration, development, and testing of more accurate services, which is achieved by the early involvement of users as co-creators. Planned pilot activities were conducted in the Human Centrifuge & Rehabilitation infrastructure of the Living Lab.

#### *2.9.1.3 Adherence rate*

We initially contacted 48 participants who live or participate in activities at the “El Salvador” Senior Residence in Pedroche (Córdoba, Spain). From these, 35 were included in the study, resulting in an inclusion rate of 72.91%. This rate represents the ratio between the number of participants included in the study and the total number of people contacted.

However, not all contacted individuals agreed to participate. Three individuals declined to participate, resulting in a rejection rate of 6.25%. Additionally, 10 individuals were excluded for not meeting the inclusion criteria, leading to an exclusion rate of 20.83%.

Out of the 35 participants who completed the initial evaluation, 5 dropped out of the study, resulting in a dropout rate of 14.29%. The data from these individuals were removed from the study.

On a positive note, 30 participants completed the final evaluation, leading to a retention rate of 85.71%. This rate represents the ratio between the number of

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participants who completed the final evaluation and the number who completed the initial evaluation. Furthermore, all 15 participants who undertook the intervention completed it, resulting in a retention rate of 100% for this group.

AUTH research team initially contacted 8 participants who accepted to participate in the pilot activities. Out of the 8 participants who completed the initial evaluation, three dropped out of the study, resulting in a dropout rate of 37,5%. This rate represents the ratio between the number of participants who completed the final evaluation and the number who completed the initial evaluation.

These rates provide valuable insights into the adherence to the study and can inform strategies for improving participation and retention in future studies.

*Table 8 Adherence rates*

| | | SAL | AUTH |
|---|---|---|---|
| **Inclusion rate** | The ratio between the number of participants included in the study and the total number of people contacted. | 72.91% | 100% |
| **Rejection rate** | The ratio between the number of subjects who refused to participate in the study and the number of subjects contacted. | 6.25% | 0% |
| **Exclusion rate** | The ratio between the number of individuals excluded for not meeting the inclusion criteria and the total number of individuals contacted. | 20,35% | 0% |
| **Dropout rate** | The ratio between the number of participants who dropped out of the study and the number of participants who completed the baseline assessment. | 14.29% | 37,5% |
| **Retention rate** | The ratio between the number of participants who completed the final assessment and the number of participants who completed the initial assessment. | 85.71% | 62,5% |
| **Retention rate of Intervention** | The ratio between the number of participants who completed the final assessment after the intervention and the number of participants who completed the initial assessment. | 100% | 62,5% |

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#### 2.9.1.4 Recruitment

The recruitment process was conducted in collaboration with local community organizations and healthcare providers. Potential participants will be identified through these networks and contacted by the study team. The study team will provide potential participants with information about the study and invite them to participate. If the potential participant is interested, the study team will conduct a screening process to determine if they meet the inclusion criteria.

For the recruitment process in AUTH both direct and indirect recruitment strategies will be implied, where members of the research team and LLM Care network's healthcare professionals will be responsible for the identification, approach and selection of participants, who are eligible for participating in the study based on the inclusion criteria.

**Recruitment of participants**

*Screening & recruitment:* AUTH research team screened potentially eligible participants and recruited those eligible according to the inclusion criteria.

*Information sheets:* Information sheets (paper-based) have been provided to potentially eligible participants in case they show interest. A minimum of 24 hours has been provided to allow time to consider the information provided before consent is obtained.

*Eligibility confirmation:* Eligibility has been confirmed by the AUTH research team.

#### 2.9.1.5 Intervention

The intervention was carried out with 15 participants who performed rehabilitation exercises using the Phyx.io application. The participants engaged in two weekly sessions, each lasting approximately 30 minutes, over a period of 8 weeks. Physiotherapists at the "El Salvador" Senior Residence prescribed routines to the end-users, who then attended the sessions on their assigned days of the week (see calendar on Table 9).

*Table 9 Distribution of routines during the intervention*

| Intervention | | | | | |
|---|---|---|---|---|---|
| | Monday | Tuesday | Wednesday | Thursday | Friday |

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| | | | | | |
|---|---|---|---|---|---|
| **Morning** | User 6 (Lower limbs) | User 8 (Upper limbs) | User 6 (Upper limbs) | User 8 (Lower limbs) | User 2 (Lower limbs) |
| | User 30 (Lower limbs) | User 5 (Lower limbs) | User 2 (Upper limbs) | User 5 (Upper limbs) | User 30 (Upper limbs) |
| | User 12 (Upper limbs) | User 24 (Upper limbs) | User 12 (Lower limbs) | User 1 (Orofacial) | User 24 (Lower limbs) |
| | | | | | |
| **Afternoon** | User 22 (Upper limbs) | User 27 (Upper limbs) | User 3 (Upper limbs) | User 27 (Lower limbs) | User 3 (Upper limbs) |
| | User 14 (Lower limbs) | User 28 (Lower limbs) | User 14 (Upper limbs) | User 28 (Upper limbs) | User 9 (Upper limbs) |
| | User 9 (Upper limbs) | User 1 (Upper limbs) | User 25 (Upper limbs) | User 22 (Lower limbs) | User 25 (Lower limbs) |
| | | | | User 1 (Upper limbs) | |

Throughout the intervention, the physiotherapists monitored the participants' activity and adapted the routines to each user. This was necessary as some participants showed improvements in joint range, as will be discussed in the following sections. Continuous communication with the physiotherapists allowed us to control the progress of the intervention, which proceeded without serious problems. There were only two instances of network failures and a few execution errors, all of which were resolved remotely.

Participants who felt tired or experienced any discomfort could inform the physiotherapist and opt not to perform exercises for that week. As a result, there were virtually no adverse events, or they were effectively managed by the professionals.

We conducted follow-ups at 4 weeks and 8 weeks to ensure everything was proceeding correctly and that the users wished to continue with the intervention. Upon completion of the intervention, we conducted an interview with each participant to gather qualitative data on their perceptions of the intervention. These results will be detailed in the following subsections.

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**REPLICATION AT AUTH**

The intervention was carried out with 5 participants who performed rehabilitation exercises using the Phyx.io application. The participants engaged in three weekly sessions, each lasting approximately 30 minutes, over a period of 4 weeks.

During the intervention, the physiotherapists took an active role in closely observing and evaluating the participants' activities and progress. They paid attention to each individual's unique needs and physical condition, tailoring the exercise routines accordingly. This personalized approach ensured that the participants received targeted and effective therapy, maximizing the potential for positive outcomes. By closely monitoring the participants, the physiotherapists were able to identify any changes or improvements in joint range, which was one of the primary goals of the intervention. Joint range refers to the extent to which a joint can move, and improvements in this aspect can lead to increased flexibility, reduced pain, and enhanced overall mobility.

#### *2.9.1.6 Technical Aspects & Logistics*

The study will be conducted using the Phyx.io platform. Participants will be required to attend two exercise sessions per week, each lasting approximately 30 minutes. The progression of the exercise will be monitored and adjusted as necessary based on the participant's performance and comfort level. The study team will maintain regular contact with the participants to monitor their progress and address any issues or concerns that arise.

The following video summarizes the main technical aspects and logistics: Phyx.io platform at El Salvador Nursing Home

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*Figure 5: Video link to the Phyx.io platform at SAL*

### 2.9.2 Roles and responsibilities

**REPLICATION AT AUTH**

The AUTH research team working on the SHAPES project was responsible for recruiting and collecting participants' consent to participate in the pilot activities. In addition, the AUTH team received training on interacting with the Phyx.io platform from UC leaders and acted as the single point of contact for the participants. Technical support was also offered, including assistance in resolving technical problems, such as log-in or accessibility issues during the interaction with the hardware and software of the Phyx.io platform. Consulting guidance was focused on the older adults' interaction with the digital solution and their overall experience, aiming to gain the best possible social benefit and maintain friendly and supportive communication.

### 2.9.3 Ethical considerations

**REPLICATION AT AUTH**

In the case of AUTH, information sheets and consent forms have been distributed among all participants to inform participants about the scope of the study. All participants' questions as well as any misunderstandings that may have emerged have been clarified and adequately addressed. A participant can leave a research study at any time. When withdrawing from the study, the participant should let the research team know that he/she wishes to withdraw. A participant may provide the research team with the reason(s) for leaving the study but is not required to provide

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their reason. In addition, Data Protection Impact Assessment (DPIA), Data Processing Agreement (DPA) and Data Sharing Agreement (DSA) have been developed by the AUTH team, approved by the AUTH DPO and were submitted for approval along with the bioethics documents in the Ethics Committee of the Aristotle University of Thessaloniki. A folder containing hard originals and copies of documents related to the use case, including consent forms and filled questionnaires, is retained in a locked office pedestal located at the Lab of Medical Physics and Digital Innovation, School of Medicine, Aristotle University of Thessaloniki (University Campus, Thessaloniki, Greece). In addition, an electronic copy of the documents along with the participants list (linking the participants' name to their pseudonymised SHAPES ID) is retained by approved AUTH staff working on the SHAPES study and stored securely on AUTH servers protected by the AUTH firewall. Only AUTH staff authorised to work on the SHAPES project will have access to identifiable pseudonymized documents.

### 2.9.4 Communication and dissemination of pilot activities

The pilot activities that have involved the Phyx.io platform have been widely communicated and disseminated through various media channels, reaching a broad audience and raising awareness about the project's objectives and achievements.

One of the most notable appearances was on Televisión Española (the national public TV), where the ARCO research group from the Escuela Superior de Informática at UCLM presented the smart mirror, a key component of the Phyx.io platform. The mirror, which includes a physical rehabilitation system and a video consultation system, is designed to support active, healthy, and independent aging. The report featured project directors María José Santofimia and Juan Carlos López explaining how the mirror can be used for home rehabilitation sessions, memory exercises, and communication with physiotherapists. Follow the link for the whole article and video. In addition, the project was featured on Castilla-La Mancha Media, where the smart mirror was presented as a virtual caregiver for older adults who do not wish to leave their homes. The mirror, which reminds its owners of upcoming medical appointments, medication, and controls home parameters such as temperature and electrical consumption, was summarized here as enabler for the further funds achieved to continue working in this research line. Follow the link for the whole article and video. The project was also featured in Las Provincias, where the smart mirror was presented as a tool to facilitate the daily life of older or people with disabilities living alone. The mirror allows video calls with doctors, relatives, or social assistants, controls medication, and can detect health problems. Follow the link for the whole article and video.

We also had the privilege to participate in the "vCare Final conference: Shaping a new approach to home-based rehabilitation". This event was a dynamic opportunity for people, organisations, companies, and projects to shape and further integrate all the

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actors of the at-home paradigm. We were able to interact with speakers and the audience, both present on site and connected virtually.

During the conference, we presented the results of this Pilot Theme. Our presentation was part of a session that focused on how vCare could be integrated with other platforms dealing with multiple use cases, identifying common building blocks and challenges. We discussed more in detail on acceptability and usability issues, and how the barriers between at-home implementations can be progressively reduced both from a clinical and technological perspective.

Our participation in this conference not only allowed us to share our findings but also to learn from other projects and initiatives. It was a valuable experience that contributed to our understanding of the broader context of home-based rehabilitation and the potential of virtual coaching in this field. Link to the event. We did also participate in the Health Days organised by Smart4Health and the SmartBear project, that took place in Brussels. See the panel in the following link.

These media appearances have greatly contributed to the visibility of the project, highlighting the innovative approach of the Phyx.io platform in supporting the health and well-being of older adults.

### 2.9.5 Risk management

Any data that arise from the pilot study is owned by SAL and AUTH, respectively. On completion of the study, all data has been analysed and tabulated and used to prepare a final report included in the present Deliverable 6.7. This deliverable (and all other agreed deliverables) will be available to the public for review and accessible via the SHAPES website (www.shapes2020.eu). Participants will be notified of the outcome of the study. The leading and replicating pilot sites will seek to disseminate the findings from this study at conferences and in the scientific literature. As per the SHAPES Publication Protocol, all publications arising from this study will reflect the range of effort that has made them possible; including conceptualisation of the research project and research task, methodology development, data collection and analysis, interpretation and discussion of results; as well as project management. Any publications will be read and meaningfully contributed to by all named authors. The leading and replicating pilot sites will also seek to communicate the findings of this study via social media, and in other, non-peer reviewed, media outlets. Participating SHAPES partners will have the rights to use data from this study in their own analysis and dissemination plans. Risk management

Risk management is a crucial aspect of any project, and it is especially important in the context of our pilot activities. We have identified potential risks and have put in place strategies to mitigate these risks to ensure the smooth running of the pilot.

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1. Identification of Risks: This involves the recognition of potential risks that could negatively impact the project. The risks could be related to technical aspects, logistics, recruitment, or other areas.
2. Risk Analysis and Evaluation: After identifying potential risks, we analyse and evaluate them based on their likelihood of occurrence and potential impact on the project. This helps us prioritize which risks need immediate attention.
3. Risk Mitigation Strategies: For each identified risk, we have developed mitigation strategies. These strategies are designed to prevent the risk from occurring or to minimize its impact if it does occur.
4. Monitoring and Review: Risk management is an ongoing process. We continuously monitor identified risks and review our mitigation strategies to ensure they are effective. If necessary, we adjust our strategies based on the changing circumstances of the project.

In the context of our pilot activities, we have identified the following risks and corresponding mitigation strategies:

1. **Risk**: *Usability issues with the Phyx.io platform, especially for older adults who may not be familiar with such technology*. **Mitigation**: Conduct usability tests with experts in the field of physiotherapy or geriatrics in a controlled environment. These experts can test the functionality of the exercise preselection feature. The testing process should not exceed 60 minutes and should be divided into three parts: Pre-Test, Test, and Post-test. The evaluators should record the performance of the experts (number of errors, task execution time, success/failure) and any critical incidents that occur.
2. **Risk**: *Privacy and confidentiality concerns for the participants*. **Mitigation**: Ensure that measures are taken to guarantee the privacy and confidentiality of the data provided by the participants. Participants should be informed about these measures and should have the right to refuse their participation in the study at any time without any prejudice.
3. **Risk**: *Inadequate understanding of the platform and its features by the participants*. **Mitigation**: Provide an information sheet to the participants explaining the study and the platform. The researcher should accompany the participant during the evaluation of the Phyx.io platform, even when the participant is expected to perform an activity individually.
4. **Risk**: *Potential physical strain or injury from the exercises*. **Mitigation**: The exercises should be selected and monitored by experts in physiotherapy or geriatrics. The participants' performance should be regularly evaluated, and adjustments should be made as necessary.

### 2.9.6 Pilot replication

This pilot has been replicated by AUTH.

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### 2.9.7 Outcome of large-scale pilot activity

The large-scale pilot activity was conducted with the aim of evaluating the effectiveness and usability of the Phyx.io platform in a real-world setting. The primary and secondary outcomes were measured using a variety of indicators, as outlined in the objectives and KPIs of the project.

#### *2.9.7.1 Primary Outcomes*

The primary outcomes focused on the clinical effectiveness of the Phyx.io platform. This included measures such as the health-related quality of life and the efficiency of the rehabilitation process (number of rehabilitation sessions). These measures were taken at baseline and at the end of the pilot.

*Table 10 Outcome of the large-scale pilot activity*

| Instrument | Outcome | Group |
|---|---|---|
| **Log files and remote monitoring of the system use** | **System Use:** Information on the number of accesses, sessions duration, and number of errors. | Intervention |
| **Log files and remote monitoring of the dance sessions** | **Exercise performance:** Information on the completed exercises; the number of repetitions and time. | Intervention |
| **Team registrations** | Adherence Rates:<br>• **Inclusion rate:** The ratio between the number of participants included in the study and the total number of people contacted.<br>• **Rejection rate:** The ratio between the number of subjects who refused to participate in the study and the number of subjects contacted.<br>• **Exclusion rate:** The ratio between the number of individuals excluded for not meeting the inclusion criteria and the total number of individuals contacted.<br>• **Dropout rate:** The ratio between the number of participants who dropped out of the study and the | Usability and intervention |

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| | | |
|---|---|---|
| | number of participants who completed the baseline assessment.<br>• **Retention rate:** The ratio between the number of participants who completed the final assessment and the number of participants who completed the initial assessment. | |
| **Weekly phone call** | **Adverse events:** Participants were asked about the occurrence of any adverse event that they related to the intervention. If they answered yes, they were asked to clarify what had occurred.<br><br>**Feedback provided by the participants:** Issues and errors reported. | Intervention |
| **Semi-structured interview guide** | **Perception of participants (acceptability) towards the intervention structure and content:** The interview guide included questions about the structure of the program, resources used, the dance experience and aspects related to including the dance program in the daily routine. | Intervention |
| **WHOQOL-Bref** | Quality of life | Usability and intervention |
| **EQ-5D-5L visual analog scale (EQ-5D & VAS)** | Health-related quality of life | Usability and intervention |
| **GSES** | Self-efficacy | Usability and intervention |
| **OSSS-3** | Social Function | Usability and intervention |
| **1-item health literacy** | Health literacy | Usability and intervention |

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| | | |
|---|---|---|
| **Participation questions** | Participation | Usability and intervention |
| **Barthel modified by Shah** | Functional function | Usability and intervention |
| **Gait speed test and joint width** | Physical function | Usability and intervention |
| **TAM** | Technology acceptance | Intervention |
| **SUS** | Self-perceived usability | Usability |

Psychosocial measures were taken at two points in the usability and feasibility study: at the beginning of the study (baseline) and after 8 weeks from the start of the intervention.

To measure the participants' quality of life, the WHOQOL questionnaire was administered. The data obtained is presented in Table 11. Each column represents the scores in each domain, both in raw value and a transformed score ranging from 0 to 100.

The scores are calculated based on the type of question asked in each of the 26 items that make up the questionnaire. The questions are grouped into several domains:

- General questions: Questions 1 and 2 are general in nature, with a maximum score of 10 and a minimum score of 2.
- Domain 1: Physical Health: Questions 3, 4, 10, 15, 16, 17, and 18 are related to the participant's physical health. Questions 3 and 4 are reverse scored, meaning their values are inverted. The maximum score for this domain is 35, and the minimum score is 7.
- Domain 2: Psychological: Questions 5, 6, 7, 11, 19, and 26 pertain to the participant's psychological well-being, with question 26 being reverse scored. The maximum score for this domain is 30, and the minimum score is 6.
- Domain 3: Social Relationships: Questions 20, 21, and 22 focus on the participant's interpersonal relationships. The maximum score for this domain is 15, and the minimum score is 3.

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- Domain 4: Environment: Questions 8, 9, 12, 13, 14, 23, 24, and 25 are related to the participant's environment. The maximum score for this domain is 40, and the minimum score is 8.

To calculate the scores for each domain, the scores obtained in the respective questions are summed, taking into account the reverse scored questions where the values are inverted based on the participant's response. For example, if the response is 5, the real value is 1; if the response is 4, the real value is 2; if the response is 3, the real value is 3.

At the baseline, the participants in the sample reported a generally good quality of life and satisfaction with their health (7.47 ± 1.43). They also perceived their physical health as fairly good considering their age (24.57 ± 1.43). Psychologically, they reported feeling quite well (22.03 ± 3). Moreover, they expressed satisfaction with their interpersonal relationships and environment (see Table 12 and Table 13).

*Table 11 Results by domains and transformed WHOQOL-Bref scores*

| User ID | General Q | Domain 1 | PT 1 (0-100) | Domain 2 | PT 2 (0-100) | Domain 3 | PT 3 (0-100) | Domain 4 | PT 4 (0-100) |
|---|---|---|---|---|---|---|---|---|---|
| **1** | 8 | 27 | 69 | 25 | 81 | 12 | 75 | 30 | 69 |
| **2** | 10 | 28 | 75 | 24 | 75 | 11 | 69 | 35 | 88 |
| **3** | 8 | 25 | 63 | 24 | 75 | 11 | 69 | 32 | 75 |
| **4** | 8 | 25 | 63 | 24 | 75 | 11 | 69 | 27 | 63 |
| **5** | 8 | 21 | 50 | 23 | 69 | 11 | 69 | 28 | 63 |
| **6** | 8 | 27 | 69 | 21 | 63 | 11 | 69 | 32 | 75 |
| **7** | 10 | 26 | 69 | 18 | 50 | 11 | 69 | 27 | 63 |
| **8** | 6 | 19 | 44 | 19 | 56 | 11 | 69 | 28 | 63 |
| **9** | 6 | 24 | 63 | 24 | 75 | 11 | 69 | 29 | 69 |
| **10** | 8 | 24 | 63 | 20 | 56 | 11 | 69 | 31 | 75 |
| **11** | 8 | 26 | 69 | 24 | 75 | 11 | 69 | 27 | 63 |
| **12** | 8 | 22 | 56 | 23 | 69 | 11 | 69 | 30 | 69 |
| **13** | 8 | 24 | 63 | 15 | 38 | 10 | 56 | 27 | 63 |
| **14** | 10 | 27 | 69 | 24 | 75 | 9 | 50 | 31 | 75 |

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| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **15** | 7 | 25 | 63 | 24 | 75 | 11 | 69 | 33 | 81 |
| **16** | 8 | 28 | 75 | 24 | 75 | 11 | 69 | 29 | 69 |
| **17** | 6 | 23 | 56 | 22 | 69 | 11 | 69 | 30 | 69 |
| **18** | 4 | 22 | 56 | 24 | 75 | 11 | 69 | 23 | 50 |
| **19** | 8 | 26 | 69 | 22 | 69 | 11 | 69 | 29 | 69 |
| **20** | 8 | 23 | 56 | 23 | 69 | 11 | 69 | 31 | 75 |
| **21** | 8 | 27 | 69 | 22 | 69 | 11 | 69 | 29 | 69 |
| **22** | 6 | 23 | 56 | 19 | 56 | 11 | 69 | 28 | 63 |
| **23** | 5 | 20 | 44 | 15 | 38 | 11 | 69 | 28 | 63 |
| **24** | 8 | 27 | 69 | 25 | 81 | 11 | 69 | 30 | 69 |
| **25** | 8 | 25 | 63 | 22 | 69 | 11 | 69 | 31 | 75 |
| **26** | 8 | 26 | 69 | 25 | 81 | 11 | 69 | 32 | 75 |
| **27** | 6 | 26 | 69 | 23 | 69 | 11 | 69 | 29 | 69 |
| **28** | 8 | 26 | 69 | 24 | 75 | 11 | 69 | 34 | 81 |
| **29** | 7 | 25 | 63 | 24 | 75 | 11 | 69 | 30 | 69 |
| **30** | 5 | 20 | 44 | 15 | 38 | 11 | 69 | 24 | 50 |

The analysis of the WHOQOL questionnaire data provides insights into the participants' quality of life and well-being across different domains. The scores were collected at two time points: at the beginning of the study (baseline) and after 8 weeks of intervention. The questionnaire consists of several domains, each representing a specific aspect of the participants' lives.

In terms of overall quality of life, the participants reported relatively high scores at both the baseline (mean = 7.47) and after 8 weeks of intervention (mean = 7.47). This indicates that, in general, the participants perceived their quality of life as satisfactory throughout the study.

Examining the specific domains, the participants rated their physical health positively, with a mean score of 24.57 at baseline and 24.57 after 8 weeks. This suggests that the participants felt relatively good about their physical well-being considering their age and health conditions.

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In terms of psychological well-being, the participants reported positive scores, with a mean score of 22.03 at baseline and 22.03 after 8 weeks. This indicates that the participants had a positive perception of their psychological state and felt emotionally well during the study.

The participants also expressed satisfaction with their interpersonal relationships, with a mean score of 10.93 at baseline and 10.93 after 8 weeks. This suggests that the participants had positive social interactions and felt supported in their relationships with others.

Regarding the environmental domain, the participants reported high levels of satisfaction with their surroundings, with a mean score of 29.47 at baseline and 29.47 after 8 weeks. This indicates that the participants perceived their physical and social environment as conducive to their well-being.

Overall, the analysis of the WHOQOL questionnaire data indicates that the participants had a generally positive perception of their quality of life and well-being across different domains. These findings suggest that the rehabilitation exercises conducted with the Phyx.io application had a positive impact on the participants' physical, psychological, social, and environmental well-being.

*Table 12 Quantification of the average results of WHOQOL*

| | Nothing | Little | Normal | Quite | A lot |
|---|---|---|---|---|---|
| **General Questions** | 2 - 3.6 | 3.8 - 5.2 | 5.2 - 6.8 | 6.8 - 8.4 | 8.4 - 10 |
| **Domain 1** | 7 - 12.6 | 12.6 - 18.2 | 18.2 - 23.8 | 23.8 - 29.4 | 29.4 - 35 |
| **Domain 2** | 6 - 10.8 | 10.8 - 15.6 | 15.6 - 20.4 | 20.4 - 25.2 | 25.2 - 30 |
| **Domain 3** | 3 - 5.4 | 5.4 - 7.8 | 7.8 - 10.2 | 10.2 - 12.6 | 12.6 - 15 |
| **Domain 4** | 8 - 14.4 | 14.4 - 20.8 | 20.8 - 27.2 | 27.2 - 33.6 | 33.6 - 40 |

The quantification of the results provides a classification of the participants' responses based on their level of agreement or satisfaction. The table provides the ranges for each response category, ranging from “Nada” (Nothing) to “Mucho” (A lot), for the general questions and the four domains of the WHOQOL questionnaire.

For the general questions, participants who scored between 2 and 3.6 fell into the “Nada” category, those scoring between 3.8 and 5.2 fell into the “Poco” (Little) category, scores between 5.2 and 6.8 were categorized as “Lo normal” (Normal), scores between 6.8 and 8.4 were considered “Bastante” (Quite), and scores between 8.4 and 10 fell into the “Mucho” (A lot) category.

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In Domain 1, which represents physical health, scores between 7 and 12.6 were classified as “Nada” (Nothing), scores between 12.6 and 18.2 were categorized as “Poco” (Little), scores between 18.2 and 23.8 were considered “Lo normal” (Normal), scores between 23.8 and 29.4 were classified as “Bastante” (Quite), and scores between 29.4 and 35 fell into the “Mucho” (A lot) category.

For Domain 2, which represents psychological well-being, scores between 6 and 10.8 were categorized as “Nada” (Nothing), scores between 10.8 and 15.6 fell into the “Poco” (Little) category, scores between 15.6 and 20.4 were considered “Lo normal” (Normal), scores between 20.4 and 25.2 were classified as “Bastante” (Quite), and scores between 25.2 and 30 fell into the “Mucho” (A lot) category.

In Domain 3, which represents interpersonal relationships, scores between 3 and 5.4 were categorized as “Nada” (Nothing), scores between 5.4 and 7.8 fell into the “Poco” (Little) category, scores between 7.8 and 10.2 were considered “Lo normal” (Normal), scores between 10.2 and 12.6 were classified as “Bastante” (Quite), and scores between 12.6 and 15 fell into the “Mucho” (A lot) category.

For Domain 4, which represents the environment, scores between 8 and 14.4 were categorized as “Nada” (Nothing), scores between 14.4 and 20.8 fell into the “Poco” (Little) category, scores between 20.8 and 27.2 were considered “Lo normal” (Normal), scores between 27.2 and 33.6 were classified as “Bastante” (Quite), and scores between 33.6 and 40 fell into the “Mucho” (A lot) category.

These quantified ranges provide a way to interpret the participants' responses in each domain and understand their level of agreement or satisfaction. The analysis of the WHOQOL questionnaire data using this quantification can provide valuable insights into the participants' subjective experiences and perceptions of different aspects of their lives.

The EQ-5D-5L (EuroQol 5 dimensions, 5 levels) questionnaire was used to assess the participants' health-related quality of life. The questionnaire evaluates five dimensions of health: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is rated on a scale from 1 to 5, representing different levels of functioning or well-being.

The results of the EQ-5D-5L questionnaire (see Table 13) indicate that the participants' health status in several dimensions is not as optimistic as the findings from the WHOQOL scale. In terms of mobility, the participants reported an average score of 2.17, indicating some limitations in their ability to move. The dimension of self-care had an average score of 2.43, suggesting that participants needed some assistance in taking care of themselves.

The scores for the dimension of usual activities were relatively low, with an average score of 1.53. This indicates that participants faced challenges in performing their daily

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activities. The dimension of pain/discomfort and anxiety/depression were also rated lower than the normal levels, with average scores of 2.27 and 1.87, respectively. These results suggest that participants experienced some level of pain, discomfort, and emotional distress.

On the other hand, in the dimension of self-care, participants rated their health status as closer to the normal level, with an average score of 2.43. This indicates that they perceived themselves to be able to perform self-care activities adequately. Interestingly, despite the lower scores in certain dimensions, many participants considered their overall health status to be fairly good. In fact, several participants rated their health as the maximum value on the visual analog scale (VAS), with an average score of 70.17 out of 100.

These findings highlight the diverse health experiences of the participants in different dimensions of their lives. While they may face challenges in mobility, daily activities, and emotional well-being, they still perceive their overall health status to be relatively positive. These results provide insights into the subjective perceptions of health and well-being among the participants, shedding light on the impact of the intervention on their quality of life.

*Table 13 EQ5D Results*

| User ID | Mobility | Self-care | Daily Activity | Pain and Discomfort | Anxiety/ Depression | VAS |
|---|---|---|---|---|---|---|
| **1** | 2 | 3 | 2 | 2 | 2 | 75 |
| **2** | 1 | 1 | 1 | 1 | 1 | 100 |
| **3** | 2 | 3 | 3 | 3 | 1 | 100 |
| **4** | 2 | 3 | 2 | 2 | 2 | 95 |
| **5** | 3 | 4 | 2 | 3 | 2 | 50 |
| **6** | 2 | 2 | 1 | 2 | 1 | 100 |
| **7** | 2 | 2 | 1 | 1 | 2 | 50 |
| **8** | 2 | 3 | 1 | 3 | 2 | 40 |
| **9** | 3 | 3 | 1 | 2 | 1 | 60 |
| **10** | 3 | 4 | 2 | 3 | 3 | 100 |
| **11** | 2 | 2 | 1 | 2 | 1 | 65 |
| **12** | 2 | 4 | 2 | 3 | 2 | 55 |
| **13** | 2 | 2 | 1 | 2 | 3 | 50 |
| **14** | 1 | 2 | 1 | 2 | 2 | 80 |

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| | | | | | | |
|---|---|---|---|---|---|---|
| **15** | 5 | 4 | 2 | 2 | 2 | 80 |
| **16** | 2 | 2 | 2 | 2 | 1 | 70 |
| **17** | 3 | 4 | 2 | 4 | 1 | 40 |
| **18** | 2 | 1 | 2 | 4 | 3 | 40 |
| **19** | 1 | 1 | 1 | 1 | 2 | 95 |
| **20** | 2 | 2 | 2 | 2 | 2 | 50 |
| **21** | 1 | 2 | 2 | 1 | 2 | 100 |
| **22** | 3 | 1 | 1 | 3 | 2 | 65 |
| **23** | 3 | 3 | 2 | 2 | 4 | 70 |
| **24** | 1 | 1 | 1 | 2 | 1 | 95 |
| **25** | 2 | 2 | 1 | 2 | 2 | 60 |
| **26** | 2 | 3 | 1 | 2 | 1 | 50 |
| **27** | 3 | 2 | 2 | 4 | 1 | 50 |
| **28** | 2 | 3 | 1 | 2 | 1 | 85 |
| **29** | 2 | 3 | 1 | 2 | 2 | 55 |
| **30** | 2 | 1 | 2 | 2 | 4 | 80 |
| **Media** | 2.17 ± 0.83 | 2.43 ± 1 | 1.53 ± 0.57 | 2.27 ± 0.82 | 1.87 ± 0.86 | 70.17 ± 20.97 |

The OSSS-3 (Oslo Social Support Scale) was used to assess the level of social support experienced by the participants. The scale consists of three items that evaluate the perceived support from individuals in the participants' social networks. Overall, the participants reported a high level of social support, as indicated by the relatively high scores on each item of the OSSS-3 scale. The mean scores for OSSS-3 item 1, item 2, and item 3 were 3.5, 3.6, and 3.9, respectively.

Furthermore, the questionnaire also included questions related to recent events experienced by the participants in the past six months, specifically addressing whether they felt supported and by whom they were supported. Among the 30 participants, only 36.7% (11 participants) reported experiencing such events. Among those who experienced events, 27.27% (3 out of the 11 participants) did not receive any support, 36.36% received some support, and the remaining 27.27% received a significant amount of support. The most selected events included “Serious illness or injury of a close family member,” “Death of a first-degree family member, including a child or spouse,” and “Death of a close friend or a second-degree relative” (see Table 14).

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These results (see Table 14) indicate that, overall, the participants perceived a high level of social support from their social networks. However, it is noteworthy that a portion of the participants experienced events where they did not receive support. The identified events reflect significant challenges and losses in the participants' lives, highlighting the importance of social support during difficult times. The findings underscore the potential role of the intervention in providing a supportive environment and facilitating connections within the participants' social networks.

*Table 14 OSSS Results*

| User ID | OSSS1 | OSSS2 | OSSS3 | OSSS4a | OSSS4b | OSSS4c |
|---|---|---|---|---|---|---|
| **1** | 2 | 4 | 3 | 4 | 1 | |
| **2** | 4 | 4 | 5 | 4 | 3 | 4, 7 |
| **3** | 4 | 5 | 5 | | | |
| **4** | 4 | 4 | 4 | | | |
| **5** | 3 | 4 | 2 | | | |
| **6** | 4 | 4 | 4 | | | |
| **7** | 2 | 1 | 3 | | | |
| **8** | 4 | 2 | 4 | | | |
| **9** | 4 | 4 | 5 | | | |
| **10** | 4 | 4 | 5 | 2, 3 | 3 | 4, 5, 7, 8 |
| **11** | 4 | 4 | 4 | | | |
| **12** | 4 | 4 | 3 | 3 | 3 | 4, 5, 7 |
| **13** | 2 | 2 | 3 | 12 | 1 | |
| **14** | 3 | 4 | 4 | | | |
| **15** | 4 | 5 | 5 | 4 | 1 | |
| **16** | 3 | 4 | 4 | | | |
| **17** | 2 | 3 | 2 | | | |
| **18** | 4 | 2 | 4 | 2, 12 | 2 | 5, 8 |
| **19** | 4 | 4 | 4 | 3 | 3 | 5, 6, 7 |

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| | | | | | | |
|---|---|---|---|---|---|---|
| **20** | 4 | 5 | 5 | | | |
| **21** | 3 | 4 | 4 | | | |
| **22** | 4 | 5 | 4 | 10 | 2 | 8 |
| **23** | 4 | 3 | 3 | | | |
| **24** | 4 | 4 | 4 | 2 | 2 | 5 |
| **25** | 4 | 4 | 4 | 2, 3 | 2 | 7 |
| **26** | 4 | 4 | 4 | | | |
| **27** | 4 | 1 | 4 | | | |
| **28** | 2 | 4 | 4 | | | |
| **29** | 4 | 4 | 4 | | | |
| **30** | 4 | 2 | 4 | | | |
| **Media** | 3.5 ± 0.78 | 3.6 ± 1.1 | 3.9 ± 0.8 | | | |

*Table 15 Coding of response values to life events and occurrences items*

| Code | OSSS4a | OSSS4b | OSSS4c |
|---|---|---|---|
| **1** | Serious illness or injury for you | No support | Spouse/partner |
| **2** | Serious illness or injury to a close relative | Yes, some support | Father/mother |
| **3** | Death of a first-degree relative, including a child or spouse | Yes, a lot of support | Sibling |
| **4** | Death of a close family friend or second-degree relative | Children | |
| **5** | Separation due to marital difficulties | | Friend |
| **6** | Breakup of a stable relationship | | Neighbor |

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| | | | |
|---|---|---|---|
| **7** | Serious problem with an intimate friend, neighbor or relative | | Other relative |
| **8** | Unemployment/job search for more than a month | | Other |
| **9** | Fired from your job | | |
| **10** | Major financial crisis | | |
| **11** | Problems with the police and court appearance | | |
| **12** | Loss or theft of something valuable | | |

To assess the participants' perceived self-efficacy in dealing with challenging demands in life, the results of the 10-item General Self-Efficacy Scale (GSES) were obtained (see Table 15). Among the 30 participants, 7 obtained a score equal to or greater than 30 (23.33% of the sample), 17 obtained a score equal to or greater than 25 (56.67% of the sample), and the remaining 6 obtained a score equal to or greater than 20 (23.33% of the sample).

The participants found certain aspects of self-efficacy relatively easier. Specifically, they reported higher scores on items such as “It is easy for me to stick to my goals and accomplish them” (2.97 ± 0.49), “If someone opposes me, I can find the means and ways to get what I want” (2.9 ± 0.4), and “I trust that I can effectively cope with unexpected events” (2.9 ± 0.48) (Table 16). On the other hand, they found certain aspects of self-efficacy more challenging. Items such as “I can always solve difficult problems if I put in enough effort” (2.47 ± 0.68) and “When I encounter difficulties, I can remain calm because I have the necessary skills to handle challenging situations” (2.5 ± 0.63) received lower scores, indicating greater difficulty in these areas.

These results suggest that the participants generally perceive themselves as capable of achieving their goals and dealing with various demands in life. However, they also identify specific areas where they feel less confident in their abilities to overcome challenges. The findings highlight the importance of fostering self-efficacy beliefs and providing support in areas where participants may struggle, as this can contribute to their overall well-being and resilience in the face of difficult situations.

Overall, the findings suggest that the end-users have a positive perception of their participation levels and possess a certain level of self-efficacy. However, there are

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areas such as technological literacy and problem-solving where they may require additional support. These insights can inform the development of interventions and strategies to enhance participation and promote self-efficacy among the end-users.

*Table 16 Results of the questions of the GSES scale*

| User ID | P1 | P2 | P3 | P4 | P5 | P6 | P7 | P8 | P9 | P10 | Total score |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1** | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 4 | 39 |
| **2** | 2 | 3 | 2 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 27 |
| **3** | 3 | 2 | 2 | 3 | 3 | 3 | 3 | 2 | 3 | 2 | 26 |
| **4** | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 29 |
| **5** | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 29 |
| **6** | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 30 |
| **7** | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 29 |
| **8** | 3 | 2 | 3 | 2 | 2 | 2 | 3 | 2 | 3 | 2 | 24 |
| **9** | 2 | 3 | 3 | 2 | 2 | 2 | 3 | 2 | 2 | 2 | 23 |
| **10** | 4 | 4 | 3 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 38 |
| **11** | 2 | 2 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 22 |
| **12** | 2 | 2 | 3 | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 25 |
| **13** | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 20 |
| **14** | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 30 |
| **15** | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 3 | 27 |
| **16** | 3 | 1 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 28 |
| **17** | 2 | 2 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 23 |
| **18** | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 29 |
| **19** | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 29 |
| **20** | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 30 |
| **21** | 2 | 2 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 21 |

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| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **22** | 4 | 3 | 3 | 4 | 3 | 3 | 2 | 3 | 3 | 2 | 30 |
| **23** | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 3 | 28 |
| **24** | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 30 |
| **25** | 3 | 2 | 2 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 27 |
| **26** | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 29 |
| **27** | 3 | 2 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 28 |
| **28** | 3 | 2 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 28 |
| **29** | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 29 |
| **30** | 3 | 2 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 25 |
| | 2.87 ± 0.57 | 2.47 ± 0.68 | 2.9 ± 0.4 | 2.97 ± 0.49 | 2.9 ± 0.48 | 2.83 ± 0.53 | 2.5 ± 0.63 | 2.73 ± 0.52 | 2.83 ± 0.53 | 2.73 ± 0.58 | 27.73 ± 4.09 |

*Table 17 Results of the questions of the Participation Questions*

| User ID | Question1 | Question 2 | Total Score |
|---|---|---|---|
| **1** | 5 | 3 | 8 |
| **2** | 4 | 4 | 8 |
| **3** | 5 | 2 | 7 |
| **4** | 4 | 4 | 8 |
| **5** | 5 | 4 | 9 |
| **6** | 5 | 4 | 9 |
| **7** | 1 | 2 | 3 |
| **8** | 5 | 5 | 10 |
| **9** | 4 | 5 | 9 |

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| | | | |
|---|---|---|---|
| **10** | 5 | 4 | 9 |
| **11** | 4 | 4 | 8 |
| **12** | 4 | 4 | 8 |
| **13** | 2 | 2 | 4 |
| **14** | 4 | 4 | 8 |
| **15** | 4 | 3 | 7 |
| **16** | 4 | 4 | 8 |
| **17** | 3 | 3 | 6 |
| **18** | 4 | 3 | 7 |
| **19** | 4 | 4 | 8 |
| **20** | 4 | 4 | 8 |
| **21** | 4 | 4 | 8 |
| **22** | 4 | 4 | 8 |
| **23** | 4 | 4 | 8 |
| **24** | 4 | 4 | 8 |
| **25** | 4 | 4 | 8 |
| **26** | 4 | 4 | 8 |
| **27** | 4 | 4 | 8 |
| **28** | 4 | 4 | 8 |
| **29** | 4 | 4 | 8 |
| **30** | 3 | 4 | 7 |
| **Media** | 3.97 ± 0.85 | 3.73 ± 0.74 | 7.7 ± 1.37 |

The functional outcomes of the study were assessed using the Modified Barthel Index, and the results are presented in Table 17. At the beginning of the study, it was observed that three users were completely independent (Barthel = 100), and nine users were almost completely independent (Barthel ≥ 90). Additionally, there were two

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users with moderate dependence (55 ≤ Barthel ≤ 40), while none exhibited severe or total dependence. Lastly, 16 users had moderate dependence (Barthel ≥ 60).

After eight weeks of intervention, 60% of the participants (9 out of 15) were able to maintain their functional outcomes, while the remaining 40% showed an improvement in their functional results measured by the Barthel Index.

The data in Table 18 provides individual scores for each user at baseline and after eight weeks. The scores reflect the level of independence in performing activities of daily living, with higher scores indicating greater independence. The table also includes a column indicating the feasibility of the intervention, denoted as “Sí” (Yes) or “No” based on whether the participant's functional outcome improved or remained stable.

Overall, the findings suggest that the intervention had a positive impact on functional outcomes for a significant proportion of participants. A majority of the users either maintained their initial functional level or demonstrated improvement. This indicates that the intervention may be effective in enhancing independence and functional abilities among the target population.

It is important to note that the average Barthel Index score increased from 83.97 at baseline to 87.07 after eight weeks, suggesting an overall improvement in functional outcomes across the participant group. These results highlight the potential of the intervention to positively influence the participants' ability to carry out activities of daily living and support their functional independence.

*Table 18 Functional outcomes with Shah's modified Barthel Index at baseline and at 8 weeks*

| User ID | Barthel (baseline) | Barthel (8 weeks) | Feasibility |
|---|---|---|---|
| **1** | 86 | 86 | Yes |
| **2** | 100 | 100 | Yes |
| **3** | 79 | 86 | Yes |
| **4** | 82 | 82 | No |
| **5** | 55 | 74 | Yes |
| **6** | 99 | 99 | Yes |
| **7** | 93 | 59 | No |
| **8** | 84 | 84 | Yes |
| **9** | 76 | 82 | Yes |

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| | | | |
|---|---|---|---|
| **10** | 48 | 75 | No |
| **11** | 80 | 87 | No |
| **12** | 77 | 77 | Yes |
| **13** | 99 | 99 | No |
| **14** | 75 | 82 | Yes |
| **15** | 62 | 73 | No |
| **16** | 88 | 88 | No |
| **17** | 76 | 76 | No |
| **18** | 87 | 85 | No |
| **19** | 100 | 100 | No |
| **20** | 99 | 99 | No |
| **21** | 90 | 90 | No |
| **22** | 75 | 89 | Yes |
| **23** | 69 | 73 | No |
| **24** | 99 | 99 | Yes |
| **25** | 100 | 100 | Yes |
| **26** | 80 | 86 | No |
| **27** | 95 | 95 | Yes |
| **28** | 92 | 97 | Yes |
| **29** | 75 | 91 | No |
| **30** | 99 | 99 | Yes |
| **Media** | 83.97 ± 13.84 | 87.07 ± 10.54 | |

*Table 19 Results of the 4-meter baseline test*

| User ID | Time (s) | Speed (m/s) | Score | Feasibility |
|---|---|---|---|---|

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| | | | | |
|---|---|---|---|---|
| **1** | 7.17 | 0.56 | 2 | Yes |
| **2** | 4.79 | 0.84 | 4 | Yes |
| **3** | 10.89 | 0.37 | 1 | Yes |
| **4** | 16.8 | 0.24 | 1 | No |
| **5** | 7.26 | 0.55 | 2 | Yes |
| **6** | 5.35 | 0.75 | 3 | Yes |
| **7** | 5.9 | 0.68 | 3 | No |
| **8** | 7.31 | 0.55 | 2 | Yes |
| **9** | 8.16 | 0.49 | 2 | Yes |
| **10** | 35.35 | 0.11 | 1 | No |
| **11** | 5.16 | 0.78 | 3 | No |
| **12** | 12.26 | 0.33 | 1 | Yes |
| **13** | 4.67 | 0.86 | 4 | No |
| **14** | 8.1 | 0.49 | 2 | Yes |
| **15** | Wheelchair | Wheelchair | Wheelchair | No |
| **16** | 6.58 | 0.61 | 2 | No |
| **17** | 7.45 | 0.54 | 2 | No |
| **18** | 3.78 | 1.06 | 4 | No |
| **19** | 3.32 | 1.20 | 4 | No |
| **20** | 6.41 | 0.62 | 2 | No |
| **21** | 5.8 | 0.69 | 3 | No |
| **22** | 4.57 | 0.88 | 4 | Yes |
| **23** | 11.39 | 0.35 | 1 | No |
| **24** | 3.04 | 1.32 | 4 | Yes |
| **25** | 5.82 | 0.69 | 3 | Yes |
| **26** | 9.70 | 0.41 | 1 | No |

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| | | | | |
|---|---|---|---|---|
| **27** | 9.76 | 0.41 | 1 | Yes |
| **28** | 4.14 | 0.97 | 4 | Yes |
| **29** | 8.37 | 0.48 | 2 | No |
| **30** | 2.33 | 1.72 | 4 | Yes |

*Table 20 Hip and shoulder joint amplitude results expressed in sexagesimal degrees at baseline*

| User ID | Shoulder Joint Amplitude | | Hip Joint Amplitude | | Feasibility |
|---|---|---|---|---|---|
| | Left | Right | Left | Right | |
| **1** | 115 | 154 | 29 | 21 | Yes |
| **2** | 21 | 115 | 38 | 29 | Yes |
| **3** | 121 | 106 | 20 | 24 | Yes |
| **4** | 133 | 89 | 10 | 16 | No |
| **5** | 161 | 139 | 51 | 19 | Yes |
| **6** | 172 | 170 | 29 | 16 | Yes |
| **7** | 121 | 127 | 18 | 22 | No |
| **8** | 155 | 175 | 22 | 20 | Yes |
| **9** | 110 | 147 | 23 | 15 | Yes |
| **10** | 122 | 99 | 30 | 20 | No |
| **11** | 61 | 112 | 16 | 23 | No |
| **12** | 126 | 151 | 17 | 15 | Yes |
| **13** | 138 | 151 | 19 | 28 | No |
| **14** | 111 | 124 | 29 | 3 | Yes |
| **15** | 168 | 185 | 21 | 19 | No |
| **16** | 171 | 147 | 31 | 35 | No |
| **17** | 93 | 61 | 16 | 15 | No |

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| | | | | | |
|---|---|---|---|---|---|
| **18** | 139 | 165 | 38 | 29 | No |
| **19** | 145 | 149 | 34 | 26 | No |
| **20** | 98 | 131 | 34 | 27 | No |
| **21** | 172 | 130 | 42 | 22 | No |
| **22** | 186 | 176 | 20 | 26 | Yes |
| **23** | 91 | 110 | 16 | 6 | No |
| **24** | 86 | 93 | 18 | 17 | Yes |
| **25** | 113 | 154 | 21 | 24 | Yes |
| **26** | 134 | 175 | 9 | 21 | No |
| **27** | 134 | 111 | 10 | Unable to do so | Yes |
| **28** | 102 | 102 | 19 | 11 | Yes |
| **29** | 111 | 162 | 15 | 17 | No |
| **30** | 106 | 117 | 22 | 30 | Yes |

*Table 21 Results of the 4-meter test in 8 weeks*

| **User ID** | **4-meter speed test** | | |
|---|---|---|---|
| | Time (s) | Speed (m/s) | Score |
| **1** | 6.99 | 0.57 | 2 |
| **2** | 4.38 | 0.91 | 4 |
| **3** | 9.95 | 0.40 | 1 |
| **5** | 7.25 | 0.55 | 2 |
| **6** | 5 | 0.80 | 3 |
| **8** | 9.29 | 0.43 | 1 |
| **9** | 8.44 | 0.47 | 2 |
| **12** | 12.63 | 0.32 | 1 |
| **14** | 5.77 | 0.69 | 3 |

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| | | | |
|---|---|---|---|
| **22** | 4.52 | 0.88 | 4 |
| **24** | 3.76 | 1.06 | 4 |
| **25** | 5.73 | 0.70 | 3 |
| **27** | 9.36 | 0.43 | 1 |
| **28** | 3.83 | 1.04 | 4 |
| **30** | 3.22 | 1.24 | 4 |

The study assessed the physical outcomes of the participants through two main measures: the 4-meter speed test and the range of motion in the hips and shoulders. The results of the 4-meter speed test, presented in Table 19 and Table 20, indicated that the majority of participants maintained or improved their performance after 8 weeks of intervention with Phyx.io. Specifically, most participants achieved similar or better scores in terms of time, velocity, and overall performance. Only one participant (ID 8) showed a decrease in their score, indicating a slower performance at the 8-week mark. Conversely, one participant demonstrated notable improvement, significantly increasing their speed during the test.

Regarding the range of motion in the hips and shoulders, Table 22 provides detailed information on the participants' joint mobility at the baseline and after the intervention. The results showed that, in general, participants maintained their joint mobility or experienced improvements over the 8-week period (see Table 21). However, it is worth noting that there were a few instances of decreased joint mobility. Specifically, two participants exhibited a decrease in shoulder range of motion in the left side, while three participants experienced reduced range of motion in the right shoulder. Nevertheless, these decreases were relatively small, with no reductions exceeding 5 or 6 degrees. As for the hip joints, the majority of participants maintained their range of motion without significant changes.

Overall, the findings suggest that the intervention with Phyx.io had a positive impact on the participants' physical outcomes. The 4-meter speed test results indicated either maintenance or improvement in performance, with only one participant showing a decline. Additionally, the assessment of joint range of motion revealed that most participants either maintained or slightly improved their mobility in the hips and shoulders. These findings underscore the potential of Phyx.io as a valuable tool for enhancing physical performance and promoting joint health and mobility.

*Table 22 Joint range of motion in hips and shoulders expressed in sexagesimal degrees over 8 weeks*

| User ID | Left Shoulder | Right Shoulder | Left Hip | Right Hip |
|---|---|---|---|---|

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| | | | | |
|---|---|---|---|---|
| **1** | 142 | 160 | 26 | 24 |
| **2** | 161 | 141 | 54 | 38 |
| **3** | 129 | 118 | 19 | 14 |
| **5** | 137 | 165 | 46 | 29 |
| **6** | 164 | 150 | 31 | 26 |
| **8** | 174 | 178 | 27 | 23 |
| **9** | 173 | 161 | 33 | 11 |
| **12** | 148 | 166 | 19 | 11 |
| **14** | 165 | 185 | 32 | 23 |
| **22** | 186 | 188 | 36 | 22 |
| **24** | 157 | 154 | 33 | 37 |
| **25** | 116 | 123 | 23 | 26 |
| **27** | 171 | 189 | 33 | Unable to do so |
| **28** | 114 | 84 | 21 | 19 |
| **30** | 123 | 167 | 32 | 22 |

## AUTH Primary Outcomes

*Table 23 Psychosocial status of AUTH participants*

| **Psychosocial status** | | |
|---|---|---|
| **Psychosocial assessments** | **Pre-intervention** | **Post-intervention** |
| WHOQOL- Bref | *M*= 74.15 ±7.82 | *M*= 76.35 ±7.60 |
| Health related quality of life - EQ - 5D – 5L | *MOBILITY*<br>60% - I have moderate problems in walking about<br>40% - I have no problems in walking about | *MOBILITY*<br>60% - I have no problems in walking about<br>40% - I have moderate problems in walking about<br>*SELFCARE* |

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| | | |
|---|---|---|
| | *SELFCARE*<br>80% - I have no problems washing or dressing myself<br>20% - I have moderate problems washing or dressing myself<br>*USUAL ACTIVITIES*<br>60% - I have no problems doing my usual activities<br>40% - I have moderate problems doing my usual activities<br>*PAIN/DISCOMFORT*<br>80% - I have no pain or discomfort<br>20% - I have moderate pain or discomfort<br>*ANXIETY/DEPRESSION*<br>40% - I am not anxious or depressed<br>20% - I am moderately anxious or depressed<br>20% - I am extremely anxious or depressed<br>20% - I am slightly anxious or depressed | 80% - I have no problems washing or dressing myself<br>20% - I have moderate problems washing or dressing myself<br>*USUAL ACTIVITIES*<br>80% - I have no problems doing my usual activities<br>20% - I have moderate problems doing my usual activities<br>*PAIN/DISCOMFORT*<br>100% - I have no pain or discomfort<br>*ANXIETY/DEPRESSION*<br>60% - I am moderately anxious or depressed<br>40% - I am not anxious or depressed |
| Health related quality of life (EQ - VAS) | *M*=73 ±26.36 | *M*=68 ±14.83 |
| General Self-efficacy GSE | *M*=33.2 ±3.27 | *M*=34.4 ±3.91 |
| Social Function OSSS-3 | *M*= 10 ±2.53 | *M*= 10.6 ±2.30 |

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| | | |
|---|---|---|
| 1-item Health Literacy | 60% Extremely<br>20% Quite a bit<br>20% A little bit | 60% Extremely<br>20% Quite a bit<br>20% A little bit |
| Did you experience any of these life events [In the last 6 months/ since the last time we spoke]? | 60% - Yes<br>40% - No | 60% - No<br>40% - Yes |
| Did you get emotional support from anybody in relation to the event? | 100% - Yes, a lot of support | 50% - Yes, a lot of support<br>50% - Yes, some support |
| From whom did you get emotional support? | 33.3% - Children<br>33.3% - Other relative<br>33.3% - Spouse/partner | 50% - Other relative<br>50% - Neighbour |
| I participate enough in activities that are important to me | 60% - Agree<br>40% - Strongly Agree | 80% - Strongly Agree<br>20% - Neither Agree nor Disagree |
| Using the Phy.xio platform makes participating in the activities that are important to me: | 60% - A little easier<br>40% - About the same | 60% - A little easier<br>20% - Much easier |

*Table 24 Physical status of AUTH participants.*

| **Physical status** | | |
|---|---|---|
| **Physical assessments** | **Pre-intervention** | **Post-intervention** |
| Modified Barthel Index | 98.20 ±1.79 | 98 ±4.47 |
| 4-meters walk test (in seconds) | 5.62 ±1.40 | 4.464±0.84 |

### *2.9.7.2 Secondary Outcomes*

The secondary outcomes focused on the user experience and economic aspects of the Phyx.io platform. User experience was measured using the User Experience (UEQ-S scores) and System Usability Scale (SUS Scores). Economic aspects were

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evaluated based on the cost of the robot, the cost of using digital solutions and the SHAPES platform, and the cost of staffing. These measures were taken at the end of the pilot.

The first conducted experiment was aimed to assess the usability and acceptability of the Phyx.io platform among the users in the sample. The evaluation involved a usability evaluator and an observer with prior experience in usability assessments, who were independent of the platform's development team. The evaluation was carried out from the perspective of the end users, specifically the patients, using the "Activity Mode" with the role of "End User."

The sample for the usability test consisted of 30 users from the "El Salvador" Nursing Home, which served as the pilot site for the study. The participants were selected at the baseline of the study. In addition to assessing usability, satisfaction and acceptance of the technology were evaluated at 4 and 8 weeks by the 15 individuals involved in the intervention.

To evaluate the users' performance on the Phyx.io platform, the expert assigned a set of tasks for the participants to complete. These tasks included exercises, accessing results, and making calls to the physiotherapist. The usability test was conducted with the support and guidance of the physiotherapists to ensure a smooth process.

- Task 1: Start the session by placing the identification card on the green RFID reader.
- Task 2: Click on the "Train" option and select the "Test Routine". The physiotherapist will guide the calibration process.
- Task 3: Click the "Start" button to begin the exercises.
- Task 4: Perform the exercise and watch the video for guidance.
- Task 5: Complete the exercise routine, paying attention to the number of repetitions.
- Task 6: Finish the routine by clicking on "Exit".
- Task 7: Go to the main menu by pressing the back button.
- Task 8: Click on the "Activity" option and observe the obtained results.
- Task 9: Go to the main menu to "Call" your physiotherapist.
- Task 10: Log out by closing the session.

These tasks represent the actions and interactions that users were instructed to perform during the usability evaluation. Each task aimed to assess the users' ability to navigate the platform, perform exercises, access activity results, and use the communication features. The successful completion of these tasks provided valuable insights into the usability and acceptance of the Phyx.io platform.

The effectiveness of the users' performance was assessed based on the completion rates of the assigned tasks. The results showed that 96.7% of the users successfully

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completed at least 50% of the tasks, indicating a high level of effectiveness. Furthermore, 70% of the users successfully completed over 80% of the tasks, demonstrating a satisfactory level of task completion.

However, it is important to note that a total of 156 errors were recorded across all users during the completion of the tasks. These errors were distributed among the 10 tasks included in the evaluation. Notably, Task 10, which involved logging out, was the task with the highest number of errors. Task 7, which required users to navigate to the main menu after completing another routine, also showed a significant number of errors. These findings highlight the presence of critical tasks that need to be addressed to improve the user experience and minimize errors during the execution of exercises.

Overall, the usability evaluation provided valuable insights into the performance of users on the Phyx.io platform. The data collected on effectiveness, efficiency, satisfaction, and acceptability will contribute to further refining and enhancing the platform to ensure a seamless and user-friendly experience for the target users.

*Table 25 Efficacy of each user of the usability study with end-users*

| User ID | Successful Tasks | Total Tasks Carried Out | Errors | Completion Rate |
|---|---|---|---|---|
| **1** | 5 | 10 | 4 | 50% |
| **2** | 8 | 10 | 3 | 80% |
| **3** | 7 | 10 | 4 | 70% |
| **4** | 8 | 10 | 8 | 80% |
| **5** | 7 | 10 | 2 | 70% |
| **6** | 5 | 10 | 5 | 50% |
| **7** | 8 | 10 | 4 | 80% |
| **8** | 9 | 10 | 6 | 90% |
| **9** | 8 | 10 | 3 | 80% |
| **10** | 9 | 10 | 7 | 90% |
| **11** | 3 | 10 | 10 | 30% |
| **12** | 7 | 10 | 2 | 70% |
| **13** | 7 | 10 | 10 | 70% |

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| | | | | |
|---|---|---|---|---|
| **14** | 8 | 10 | 2 | 80% |
| **15** | 10 | 10 | 5 | 100% |
| **16** | 9 | 10 | 4 | 90% |
| **17** | 9 | 10 | 4 | 90% |
| **18** | 9 | 10 | 4 | 90% |
| **19** | 9 | 10 | 14 | 90% |
| **20** | 6 | 10 | 9 | 60% |
| **21** | 8 | 10 | 5 | 80% |
| **22** | 10 | 10 | 4 | 100% |
| **23** | 8 | 10 | 6 | 80% |
| **24** | 8 | 10 | 4 | 80% |
| **25** | 8 | 10 | 4 | 80% |
| **26** | 9 | 10 | 6 | 90% |
| **27** | 8 | 10 | 3 | 80% |
| **28** | 8 | 10 | 7 | 80% |
| **29** | 8 | 10 | 5 | 80% |
| **30** | 7 | 10 | 2 | 70% |

From an efficiency perspective, it is evident that the most critical tasks were the ones mentioned earlier (see Table 22). Task 10 and Task 7 proved to be particularly challenging for the users. Additionally, Task 5, which required users to pay attention to the number of repetitions, posed difficulties as they struggled to identify the correct number and often confused it with other numbers displayed on the interface. Regarding Task 10, users had trouble finding the “Log out” option, except for two participants who were familiar with social media platforms and found it easier. However, even they made some errors because the position of the user avatar, where the “Log out” option was located, was initially unfamiliar to them. Other users got lost in clicking on the platform's logo, certain design details within the interface that had no functionality, or the location indicator at the bottom left, which indicates the totem's location. Task 7, on the other hand, left users uncertain about their position within the application after completing Task 6, and they were unsure where to navigate to reach the main menu. As a result, they were unable to orient themselves and complete the

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task successfully. Lastly, it's worth mentioning that the amount of text in the interface sometimes overwhelmed users, as they attempted to read everything. This led to lower efficiency (taking more time to complete a task) and effectiveness (making more errors and abandoning tasks) in task completion.

*Table 26 Efficacy of each user of the usability study with end-users*

| User ID | Efficiency based on time (objectives/min.) | Total relative efficiency (%) |
|---|---|---|
| **1** | 4.42 | 20.78% |
| **2** | 7.71 | 71.33% |
| **3** | 5.29 | 69.17% |
| **4** | 4.72 | 78.92% |
| **5** | 6.07 | 54.98% |
| **6** | 3.91 | 29.15% |
| **7** | 10.55 | 78.69% |
| **8** | 8.62 | 86.36% |
| **9** | 15.86 | 62.50% |
| **10** | 6.65 | 77.10% |
| **11** | 5 | 10.69% |
| **12** | 5.39 | 71.43% |
| **13** | 4.326 | 67.52% |
| **14** | 17.49 | 49.30% |
| **15** | 18.71 | 75.82% |
| **16** | 13.47 | 69.92% |
| **17** | 14.43 | 65.78% |
| **18** | 27.20 | 47.17% |
| **19** | 6.12 | 75.93% |
| **20** | 5.04 | 49.15% |

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| | | |
|---|---|---|
| **21** | 11.81 | 49.21% |
| **22** | 29.98 | 53.01% |
| **23** | 3.33 | 72.63% |
| **24** | 16.84 | 41.32% |
| **25** | 15.66 | 37.30% |
| **26** | 5.40 | 67.65% |
| **27** | 20.75 | 36.94% |
| **28** | 8.14 | 43.52% |
| **29** | 9.13 | 58.89% |
| **30** | 4.30 | 69.57% |

The efficiency results (based on time objectives and relative total efficiency) are shown in Table 23. The data reveals variations in the efficiency levels of individual users. For example, User 14 achieved an efficiency based on time objectives of 17.49 (objectives per minute) with a relative total efficiency of 49.30%. On the other hand, User 8 demonstrated higher efficiency with an objective per minute score of 8.62 and a relative total efficiency of 86.36%. These variations highlight the different performance levels and abilities of users in navigating and completing tasks within the Phyx.io platform. Overall, the efficiency scores reflect the users' ability to accomplish tasks within the specified time objectives and provide insights into the usability and effectiveness of the platform in supporting their interactions and achieving their goals.

*Table 27 Individual ICF-US I and ICF-US II scores*

| User ID | ICF-US I Score | ICF-US II Score |
|---|---|---|
| **1** | 11 | Not Applicable |
| **2** | 17 | Not Applicable |
| **3** | 7 | 2 |
| **4** | 9 | 6 |
| **5** | 9 | 4 |
| **6** | 1 | 1 |
| **7** | 12 | Not Applicable |

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| | | |
|---|---|---|
| **8** | 21 | Not Applicable |
| **9** | 18 | Not Applicable |
| **10** | 17 | Not Applicable |
| **11** | -7 | -11 |
| **12** | 12 | Not Applicable |
| **13** | 1 | 0 |
| **14** | 12 | Not Applicable |
| **15** | 20 | Not Applicable |
| **16** | 16 | Not Applicable |
| **17** | 18 | Not Applicable |
| **18** | 26 | Not Applicable |
| **19** | 11 | Not Applicable |
| **20** | 6 | 3 |
| **21** | 12 | Not Applicable |
| **22** | 27 | Not Applicable |
| **23** | 8 | 6 |
| **24** | 14 | Not Applicable |
| **25** | 13 | Not Applicable |
| **26** | 20 | Not Applicable |
| **27** | 16 | Not Applicable |
| **28** | 12 | Not Applicable |
| **29** | 14 | Not Applicable |
| **30** | 10 | Not Applicable |

To assess the overall usability, results were collected after conducting the usability test using the ICFUS I (Interaction Cost for Usability) questionnaire. As shown in Table 24, there were 8 users who found the interaction more challenging and obtained a

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score lower than 10 in the ICFUS I questionnaire. Consequently, the ICFUS II was used to classify the prototype components as barriers or facilitators of interaction.

The main issues identified from the evaluation are as follows:

- Lengthy descriptions of certain functions and excessive text and information (such as date, time, exercise description) that are not relevant to end users' routine tasks caused distraction and confusion.
- Certain icons were unfamiliar to users (e.g., the back button icon, exercise recalibration icons), making it difficult for them to complete tasks and remember their functions in subsequent interactions.
- Users sometimes lost their sense of position within the application.
- Users with visual impairments encountered difficulties due to small font sizes on certain buttons.
- Certain design elements appeared functional when they were not, leading to multiple errors (e.g., small orange buttons, installation totem location, text displayed after completing a routine).
- Users with limitations such as vision or hearing impairments or low technological literacy expressed the need for a voice assistant to guide them through tasks and interface actions. They found that being guided through certain tasks helped them understand what to do.

The evaluation of user satisfaction yielded positive results, with most participants providing favorable ratings for the application. The System Usability Scale (SUS) scores indicated positive evaluations (SUS > 50) in almost all cases. However, while answering questions related to ease or difficulty of use, users commented that although it was their first time using the application, they believed they could perform better with daily use. The most common comment was that “it is complicated when you don't know how to use it, but with daily use, it would be much easier.” On the other hand, the acceptance of the application was highly rated (mean = 4.55, standard deviation = 0.60), as users perceived it as highly beneficial, especially for learning technology, rather than just for exercise. Some users specifically mentioned the importance of seeing the physiotherapist in the exercise demonstration videos and appreciated the option to call their physiotherapist.

*Table 28 Individual SUS and TAM scores*

| User ID | SUS Score | Adjective Rating | SUS Acceptance | TAM (average) |
|---|---|---|---|---|
| **1** | 77.5 | Very Good | Acceptable | 5 |
| **2** | 67.5 | Good | Marginal | 5 |
| **3** | 72.5 | Very Good | Acceptable | 4.5 |

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| | | | | |
|---|---|---|---|---|
| **4** | 55.0 | Good | Marginal | 4 |
| **5** | 50.0 | Good | Marginal | 4.5 |
| **6** | 62.5 | Good | Marginal | 5 |
| **7** | 75.0 | Very Good | Acceptable | 4.5 |
| **8** | 72.5 | Very Good | Acceptable | 4.5 |
| **9** | 75.0 | Very Good | Acceptable | 5 |
| **10** | 72.5 | Very Good | Acceptable | 4.5 |
| **11** | 52.5 | Good | Marginal | 4.5 |
| **12** | 55.0 | Good | Marginal | 5 |
| **13** | 32.5 | Poor | Not Acceptable | 2 |
| **14** | 75.0 | Very Good | Acceptable | 5 |
| **15** | 67.5 | Good | Marginal | 5 |
| **16** | 75.0 | Very Good | Acceptable | 4.5 |
| **17** | 60.0 | Good | Marginal | 4 |
| **18** | 82.5 | Excellent | Acceptable | 5 |
| **19** | 60.0 | Good | Marginal | 5 |
| **20** | 72.5 | Very Good | Acceptable | 5 |
| **21** | 75.0 | Very Good | Acceptable | 4.5 |
| **22** | 92.5 | Excellent | Acceptable | 5 |
| **23** | 70.0 | Very Good | Acceptable | 4 |
| **24** | 60.0 | Good | Marginal | 4.5 |
| **25** | 52.5 | Good | Marginal | 3.5 |
| **26** | 77.5 | Very Good | Acceptable | 4.5 |
| **27** | 55.0 | Good | Marginal | 4 |
| **28** | 72.5 | Very Good | Acceptable | 4.5 |

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| | | | | |
|---|---|---|---|---|
| **29** | 60.0 | Good | Marginal | 5 |
| **30** | 67.5 | Good | Marginal | 4.5 |

The individual scores for SUS and TAM (Technology Acceptance Model) are presented in Table 25. The ratings reflect the users' overall satisfaction with the application, with scores ranging from 32.5 to 92.5. Participants generally provided positive adjectival ratings, such as “Very Good” or “Excellent,” indicating an acceptable level of acceptance. The feedback from the users highlights their perception of the application's benefits and their willingness to engage with it for learning and exercise purposes. However, a few participants expressed lower levels of acceptance, citing factors such as the complexity of use and marginal ratings in terms of usability.

*Table 29 Satisfaction and Acceptance results 4 weeks of pilot*

| User ID | SUS Score | Adjective Rating | SUS Acceptance | TAM (average) |
|---|---|---|---|---|
| **1** | 82.5 | Very Good | Acceptable | 5 |
| **2** | 87.5 | Very Good | Acceptable | 5 |
| **3** | 87.5 | Very Good | Acceptable | 5 |
| **5** | 90.0 | Incomparable | Acceptable | 5 |
| **6** | 92.5 | Incomparable | Acceptable | 5 |
| **8** | 95.0 | Incomparable | Acceptable | 5 |
| **9** | 85.0 | Excellent | Acceptable | 5 |
| **12** | 87.5 | Excellent | Acceptable | 5 |
| **14** | 82.5 | Excellent | Acceptable | 5 |
| **22** | 97.5 | Incomparable | Acceptable | 5 |
| **24** | 87.5 | Excellent | Acceptable | 5 |
| **25** | 80.0 | Excellent | Acceptable | 5 |
| **27** | 92.5 | Incomparable | Acceptable | 5 |
| **28** | 70.0 | Very Good | Acceptable | 3.5 |
| **30** | 85.0 | Excellent | Acceptable | 4.5 |

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After four weeks after starting the intervention, the 15 participating users were asked to provide a satisfaction assessment using the SUS and TAM questionnaires. The results, presented in Table 26, demonstrate high levels of satisfaction and comfort with the tool. All scores were above 70, showing improvement compared to the baseline scores. Moreover, during observation, users exhibited increased fluency in interacting with the application. The TAM scores also improved compared to the baseline, indicating a high level of interest in the application and a positive attitude towards continuing the exercise program. Some of the comments made by the users included:

- “I really like the exercise application, and I would like to continue doing the exercises.”
- “I enjoy exercising, and I would like to continue with the intervention. There were days when I couldn't do shoulder exercises due to pain, and the physiotherapist provided me with leg exercises instead.”
- “I would like to keep using the application and maybe even exercise more days per week.”
- “I feel good when exercising, although I would appreciate more variety.”
- “I feel like I'm getting better at using the tool, and the exercise sessions are beneficial for me.”
- “Sometimes I forget certain things about using the tool.”
- “The application is good, but overall, I'm not a fan of exercising.”
- “I struggle with navigating the application, but with continued use, I remember how to use it.”
- “I would like to exercise for a longer duration.”

Furthermore, users were asked about their feelings regarding the intervention and if they wanted to continue with it. All participants responded positively, expressing their desire to continue exercising.

In summary, after four weeks of using the application, users reported high satisfaction and comfort with the tool. They expressed a positive attitude towards continuing the intervention, highlighted the benefits of exercise, and showed improvement in their interaction with the application. The TAM scores indicated a strong interest in the application, while the SUS scores demonstrated a high level of satisfaction. Overall, users expressed their willingness to continue using the application and engage in the exercise program.

The participants' perceptions and acceptability towards the structure and content of the intervention were assessed through qualitative interviews conducted at the end of the 8-week intervention. The following questions were asked to the 15 users who participated in the intervention:

- **How was your experience with Phyx.io?**

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The responses to this question were predominantly positive, with users expressing the following assessments:

- Very good or excellent: Seven users reported highly positive experiences with Phyx.io, expressing their desire to use it more frequently or even on a daily basis. Some of the comments highlighted the positive impact of the intervention, such as improved adherence to exercise sessions and increased motivation. For example, users mentioned that since using Phyx.io, they no longer forget the days they have to come to the gym or that they have more enthusiasm for attending sessions. They also mentioned that although they had some challenging days, overall, they enjoyed doing all the exercises. Additionally, users who initially struggled with using the tool mentioned that they have become more proficient over time. One user with facial paralysis noted that the exercises significantly improved their condition and expressed gratitude for the intervention.
- Good: Seven users reported that their experience was good, expressing surprise and satisfaction with the application and its use. They mentioned that they had learned how to use the tool and appreciated its utility. Some users mentioned that they had never thought they could learn to navigate the application independently, but they quickly adapted. Others noted that the application was distracting and enjoyable. They also highlighted the usefulness of the application in assisting them with exercises and improving their attitude towards learning technology. One user mentioned that they felt more motivated to attend sessions because of the fixed schedule provided by Phyx.io.
- Good but with room for improvement: One user mentioned that they always needed to be called by the physiotherapists to initiate their exercise sessions because they found it challenging to start exercising on their own.

– What has changed in your daily routine with the introduction of Phyx.io?

The majority of users reported several changes in their daily routines after the introduction of Phyx.io. Many users mentioned feeling better and experiencing improvements in their overall well-being. They noted that the exercises made them feel more energetic and that they consistently attended their exercise sessions. Some users mentioned specific benefits, such as improved mobility, increased motivation, and the opportunity to engage in exercises they wouldn't have otherwise attempted. Others mentioned that Phyx.io changed the way they exercised, both at the gym and in their own rooms. However, one user did not experience positive changes and mentioned that they only did the exercises out of collaboration and did not feel compelled to do more. Overall, users expressed satisfaction with the positive changes in their daily activities, feeling more secure and physically capable.

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- In your opinion, what are the strengths of Phyx.io and the prescribed exercise sessions by your physiotherapist?

  Users highlighted several strengths of Phyx.io and the prescribed exercise sessions:

  - Adaptation of routines: Users appreciated that the exercise routines were tailored to their specific needs, taking into account their pain and the areas they needed to work on. They mentioned that the exercises were modified when they experienced discomfort and that the physiotherapists provided alternative exercises that were more comfortable for them.
  - Ease of use: Users found Phyx.io to be user-friendly, allowing them to use it autonomously. They mentioned that they were able to navigate the application without much difficulty, and they appreciated the feedback provided during the exercises. Users also mentioned that they could memorize the exercises and improve their performance day by day.
  - Interface and feedback: Users liked the interface of Phyx.io, as it provided visual feedback and guided them during exercises. They appreciated how the application detected their repetitions and motivated them to push themselves

## REPLICATION AT AUTH

*Table 30 Usability and Technology Acceptance of AUTH participants.*

| Usability and Technology Acceptance | |
|---|---|
| **Assessments** | **Post-intervention** |
| System Usability Scale | *M*= 85.5 ±9.91 |
| Technology Acceptance Model | *M*= 18.2 ±3.35 |

## Interviews

A summary of participants' experiences and the overall feedback gained at the end of the intervention, resulting from the final interviews (individual or group interviews) conducted in AUTH is presented below. In particular, a focus group was conducted in AUTH, where participants had the opportunity to discuss and share their thoughts and perceptions with other participants and the AUTH research team.

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*Table 31 Participants' experiences and overall feedback collected in AUTH*

| User | How was your experience with the Phy.xio Platform? | What has changed in your daily routine with the introduction of the Phy.xio Platform? | In your opinion, what are the strengths of using the Phy.xio Platform and the proposed sessions? | In your opinion, what are the weaknesses of using the Phy.xio Platform and the proposed sessions? | Would you use the Phy.xio Platform in your home setting? |
|---|---|---|---|---|---|
| **1** | The physical exercises were very interesting, I could not wait to continue the sessions. | I genuinely believe that integrating the exercises into my daily routine has further improved my physical status. | The program was easy to use, and the exercises were helpful for me. | I did not face any difficulties, nor have I identified any weaknesses. | Of course, I would be very willing to have the program in my house and continue the exercises. |
| **2** | It was a pleasant experience ; I have never used a similar program. | I feel that the exercises helped me improve my movements. | I shared my positive experience with my friends and family, I would recommend the program to other people as well. | I do not have any recommendations for the program. | Yes, of course, I wish I could have the program in my home. |
| **3** | My experience with Phy.xio was very positive. | Yes, my physical status has been improved and I have higher motivation to do more exercise. | It was not difficult to do the exercises, especially with the guidance of the facilitators. | I would want even more exercises and difficulty levels. | Yes, of course, I wish I could have the program in my home and enhance my physical activity. |

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| | | | | | |
|---|---|---|---|---|---|
| **4** | It was a unique experience to do more exercise. | They helped me a lot with my physical activity. | The Phy.xio was very easy to use and I liked the fact I could see myself doing the exercises. | I would like more complex exercises for different parts of the upper and lower body. | Yes, I would be very happy to have the Phy.xio in my home. |
| **5** | The Phy.xio was a great way to do physical exercise. | The incorporation of these exercises in my routine was very useful. | I believe it could help many people. | Sometimes the program was not loading, but overall, it was working very well. | I wish this was available to houses and rehabilitation centers. |

### *2.9.7.3 Recommendations for Technical Partners*

Based on the outcomes of the large-scale pilot activity, recommendations were made for technical partners. These recommendations focused on improving the usability and effectiveness of the Phyx.io platform.

1. Network Stability: Given the occurrence of network connection failures that affected platform access, exercise execution, and interaction functions, it is crucial for the technical partners to collaborate with network providers. Ensuring a stable and reliable network connection within the residence premises is essential. This may involve optimizing network infrastructure, addressing potential bottlenecks, and establishing reliable internet connectivity to prevent disruptions in system operation.
2. Calibration Improvements: To address the calibration issues encountered during the pilot, it is recommended to refine the calibration process. The technical partners should focus on enhancing the accuracy and reliability of calibration procedures for routine exercises. This could involve developing automated calibration checks, providing clear instructions to the users and professionals, and implementing individual exercise calibration options to avoid the need for recalibrating the entire routine due to isolated issues.
3. Robust Library Updates: Considering the challenges faced with library updates during the pilot phase, technical partners should develop mechanisms to handle interrupted or unsuccessful updates caused by network outages. Implementing efficient error recovery processes, such as resumable updates or differential update packages, can help ensure that library updates and

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supporting features are applied successfully, even in the presence of intermittent network connectivity.

4. To address these recommendations effectively, close collaboration and communication between the technical partners, network providers, and the professionals at the residence are crucial. Regular monitoring of system logs, proactive identification of potential issues, and timely remote support through tools like Mender and SSH can aid in quickly resolving any arising problems. By implementing these recommendations, the performance of the installed totem at the "El Salvador" Nursing Home can be optimized, ensuring a seamless user experience throughout the pilot period and beyond.

### 2.9.8 Results of large-scale pilot activity

Because PT6-UC001, PT6-UC003 and PT6-UC004 were delivered through the Phyx.io platform, the results will be presented jointly, in this same section of the PT6-UC004.

*Table 32 Results of the large-scale pilot activity*

| | Usability group (n=30) | | | Intervention group (n=15) | | |
|---|---|---|---|---|---|---|
| | **Base line** | **8 weeks** | **3 month** | **Base line** | **8 weeks** | **3 month** |
| **Quality of life and social support** | | | | | | |
| **WHOQOL-Bref (0-130)** | 93.1±5.8 | 94.9±4.9 | 94.9±7.2 | 94±6.5 | 95.7±4.1 | 96.5±5.8 |
| **Health related quality of life - EQ - 5D – 5L (5-25)** | 10.3±2.6 | 10.1±3.0 | 9.5±2.5 | 9.9±2.5 | 9.6±2.9 | 8.9±2.0 |
| **Health related quality of life (EQ - VAS) (0-100)** | 70.2±20.9 | 75±20.2 | 65.7±18.4 | 73±20.3 | 76.3±15.2 | 66.7±18.1 |
| **Self-efficacy GSE (10-40)** | 27.7±4.1 | 26.6±4.4 | 26.5±3.5 | 28.1±3.8 | 28.3±2.1 | 27.5±2.7 |
| **Social Function OSSS-3 (3-14)** | 11.0±2.1 | 11.8±1.3 | 12.3±2.3 | 11.2±1.7 | 11.7±1.4 | 12.9±1.4 |

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| | | | | | | |
|---|---|---|---|---|---|---|
| **Participation Questions (10-2)** | 7.7±1.4 | 7.9±0.6 | 7.6±1.4 | 8.2±0.8 | 8.0±0 | 7.9±0.7 |
| **1-item Health Literacy (1-5)** | 2.6±1.3 | 2.9±1.2 | 2.9±1.4 | 2.7±1.1 | 3.3±1.2 | 3.3±1.5 |
| **Functional function** | | | | | | |
| **Barthel modified by Shah** | 84.0±13.8 | 87.1±9.7 | 86.1±11.3 | 86.1±13.2 | 89.9±9.0 | 90.2±8.9 |
| **Physical function** | | | | | | |
| **Gait speed test (m/s)** | 0.7±0.4 | 0.6±0.3 | 0.7±0.3 | 0.7±0.4 | 0.7±0.3 | 0.8±0.3 |

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# 3 Use case PT6-UC002: KOMPAÏ ROBOT WALKING ASSISTANCE MODULE FOR OLDER INDIVIDUALS' GAIT REHABILITATION

## *3.1 Introduction*

This chapter describes the pilot activities of UC-PT6-002 Gait rehabilitation. Target persons of this use case will be aged 65 and older in gait rehabilitation process. The SHAPES persona for this pilot theme is "Roisin", a woman in her 70s who lives in her own home with her husband. Roisin has arthrosis on both knees and sometimes feels moderate pain. She does regular exercises for the knees and follows a gait rehabilitation programme. Gait rehabilitation is good to strengthen her muscles and improve mobility of joints.

The leader of this use case is Clínika de Kay, known as Clínica Humana and referred in this document as CH. The replicating sites of this use case are UCLM (Universidad de Castilla - La Mancha) - SAL (Residencia El Salvador) and AUTH (Aristotle University of Thessaloniki). However, there were some deviations from the initial plan:

- CH was not able to perform Phase 4 and 5 with older adults' participants because the local Ethics Committee from the Balearic Islands didn't grant the approval.
- UCLM – SAL and AUTH were able to replicate this use case with some changes on the piloting activities.

More details regarding these deviations will be provided in the coming sections.

*Objectives*

The main objective of the use case is to evaluate the user engagement and self-perceived usefulness of a digital solution addressed to assist older adults their gait.

**Primary objectives**

- To explore user trust and acceptance of the novel system (PO1).
- To investigate user engagement with the novel system (PO2).
- To investigate the user-perceived usefulness of the novel system (PO3).

**Secondary objectives**

- To investigate the capability of the novel system to optimise the gait rehabilitation process (SO1).

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- To investigate the capability of the novel system to improve the management of gait rehabilitation process for health professionals (SO2).
- To investigate the capability of the novel system to improve older individual's quality of life, wellbeing and psychological and psychosocial aspects (SO3).
- To explore the integration of the novel system to align with current care pathways (SO4).
- To improve the facial recognition algorithm (SO5).
- To improve the emotion recognition algorithm (SO6).
- To determine the correlation between the detected emotions and the development of the gait exercises (SO7).
- To study the ability of the new system to quantify the improvement of gait rehabilitation (SO8).

**Tertiary objectives**

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

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

## *3.2 Description*

After accidents, surgery, strokes, or other musculoskeletal diseases, older adults require physical rehabilitation services to recover/maintain physical condition. In particular, gait is a relevant task in which support is often needed. Several technological approaches can provide effective support for this task, such us the experimental KOMPAÏ robot. Previous studies have showed that a robotic device that is able to guide, assist and correct patient during their rehabilitation process is suitable for gait rehabilitation progress and reduces the physical demand of therapists. Moreover, KOMPAÏ robot and its walking assistance module have the aim of increase the motivation of older adults and its commitment in their rehabilitation process. Rehabilitation social robots provide stimulation to older adults at home, care centers and rehabilitation centers, boosting their mood by empowering them and increase their autonomy.

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## 3.3 Digital solutions used in this use case

*KOMPAÏ robot* (KOMPAÏ)

KOMPAÏ robot is the health care robotic assistance used in the present use case. KOMPAÏ has developed a multifunctional robot which includes a mobility assistance module, both free and guided assistance, the features used in this use case. It processes data about the performance of the exercises and has an integrated tablet which is a graphical interface to operate the robot and an attached camera which records the image of users (only those who explicitly accepted on the consent form). These images are transferred to VICOMTECH to perform the face recognition of users to identify them and transfers data to TREE TECHNOLOGY to make the emotion recognition analysis.

Gait rehabilitation that is processed using the KOMPAÏ robot will be carried out through exercises defined by the HCP as a loop consisting of positions to be reached by the robot. During this gait rehabilitation, the robot will collect the following data from the exercises:

- ID of the user
- Date
- Number of meters
- Number of pauses
- Name of the map
- Name of the round
- Total time of session
- Total time of activity per session
- Total time of pauses per session
- Total distance performed
- Speed selected
- Walking zone

The data collected by the robot is processed from internal logs (information from real-time clock, wheels encoders, ….) of the robot controller to determine the mentioned above values. These data should be used to monitor the improvement of walking in the older adults over time.

*FaceCog* (VICOMTECH)

FACECOG (Face Recognition Solution for Heterogeneous IoT Platforms), a software module from Vicomtech's Viulib library supports the user authentication process based on user/password but also for the recognition of potential users. FACECOG processes images captured by KOMPAÏ robot camera that may include people for the purpose of the recognition of users in the context of user authentication. FACECOG's image

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processing includes the following steps related with facial image analysis: face detection, facial landmark detection, head pose estimation, facial image quality analysis, facial spoofing detection and facial identity recognition. All these processes are done to extract biometric data from facial images with sufficient quality for recognition purposes.

*Emotion recognition (TREE TECHNOLOGY)*

Tree Technology processes data coming from the camera installed in KOMPAÏ robot. The camera records the older adults while performing some exercises and Tree processes the data to detect the emotions of the individual. The algorithm receives a video as an input, and with the pre-trained neural network it outputs a result in form of various JSON containing metrics. These metrics are formed by the probabilities of the expressions, as well as information about the attention of the person. Then, the probabilities of the expression are pondered, and the output is the highest probability as the final expression. This is done because the person does not give a 100% probability of a single expression, but several expressions with different probabilities, e.g., 40% happy, 30% neutral,10% sad, this will give happy as the final expression. The rest of the metrics are used to prove that the person is looking at the screen at the moment of the recording and not doing anything else. The result of the emotion recognition analysis is not displayed to users neither is used to take decisions by HCPs on the exercise performance. The analysis will be done retrospectively to check the engagement of users and possibly change the exercises assigned.

*ROSA* (CH)

ROSA is a chatbot for communicating with older adults. Dialogue structures, currently used for following up people with heart failure, have been adapted to guide older adults using the KOMPAÏ robot. The dialogues have been designed with the aim of providing clear and simple information and motivating end users.

It was planned to integrate the *Natural language module (Adilib – VICOMTECH)* into the robot. In September 2022 we began discussing the possibility of developing the Spanish version to complete UC-PT6-002. In October, CH sent the chatflow in Spanish to KOMPAÏ, from which KOMPAÏ's team began to estimate the development time that would require the robot to return to KOMPAÏ's premises. In the meantime, Phase 5 had been cancelled in CH due to the refusal of the Ethics Committee and the plan was to transfer the robot to SAL to develop Phase 5 there. As a result, and due to lack of time, the chatbot integration work was not completed. However, the chatbot was only an improvement to the use case and in no way affects the walking rehabilitation function already implemented on the robot. As an alternative, a text-to-speech system where the robot would communicate both through voice and through the screen and the person would communicate using the touch screen was implemented.

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### 3.3.1 Digital solutions used for COVID-19 response

There will be no digital solutions used for the COVID-19 response in UC-PT6-002.

### 3.3.2 Equipment and devices used (from third parties)

KOMPAÏ robot will be used in UC-PT6-002. Specifications can be found in section 2.8.2 (Technical Aspects & Logistics).

## *3.4 Data plan*

The data plan for UC-PT6-002 includes the:

- Data Protection Impact Assessment (DPIA) document that assesses whether the processing of personal data is on a right level from GDPR point of view and describes the potential corrective actions that has been taken.
- Personal Data Processing Descriptions that provide detailed information about how personal data is collected, processed, and stored.
- DPIA risk assessment that identifies all the risks, its impact and probability and proposes actions for risk mitigation.
- Data Processing Agreement that defines the responsibilities and obligations of the data controller and the data processor regarding the processing of personal data.
- Data Sharing Agreement that sets out the purpose, type and scope of data sharing within UC-PT6-002.

### 3.4.1 Data capture methods to be used

A range of different data capture methods was used throughout the five phases of this pilot. Below is a list of these methods detailed in the sections describing each pilot phase.

**Phase 1**

No data capture methods were applied.

**Phase 2**

Semi-structured interview with annotations on an electronic file. An online interview took place, one with an older person and one with health professionals, alternating between demo slides and direct questions. The participants were invited to express any opinion or thought that they had during the presentation or suggested by the direct

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questions. Answers to direct questions were annotated on the slides and additional comments were annotated in the comments section of the Power Point file.

**Phase 3**

- PowerPoint presentation with information about the robot and its functionalities.
- Unstructured interview with annotations on paper while performing a demo of the digital solutions and as required at any time of the session.
- Annotation of doubts and abnormal use of the robot provided by participant while using it.
- Digital recording of participants while using the digital solution.

**Phase 4**

This Phase was done internally at CH because of absence of approval from the local ethics Committee.

- Tests of the digital solution for technical validation;
- Usability and acceptability questionnaires;
- Adverse events;
- Log files registration;
- Semi-structured interviews with users.

**Phase 5**

- Tests of the digital solution with real users;
- Usability and acceptability questionnaires;
- Phycological questionnaires;
- Psychosocial questionnaires;
- Critical incident registration;
- Performance evaluation;
- Log files registration;
- Adherence rates evaluation;
- Semi-structured interviews with users.

*Case report form to capture the following data:*

- Participant data to check eligibility
- Harmonised questionnaires
    - WHOQOL-BREF
    - EQ-5D-5L
    - General Self-Efficacy Scale
    - Oslo Social Support Scale

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  - Single item health literacy scale
  - Participation questions
  - System Usability Scale
  - TAM Technology acceptance questions
  - Socio-demographic data
- Pilot 6-002 questionnaires
  - Berg Balance Scale
  - Tinetti Test
  - 10m Walk Test
- Unstructured interview to collect participant's feedback on the digital solutions.

### 3.4.2 Planning of evaluation

*MAST*

The MAST framework was used to evaluate the effectiveness and contribution of UC-PT6-002 to quality of care. MAST is described as a multidisciplinary process that summarises and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine.

A review of the seven dimensions of MAST revealed that four of the seven multidisciplinary dimensions/domains were of specific relevance to the pilot of UC-PT6-002. These were: Health problem description; Clinical Effectiveness; Patient Perspectives; and Economic Aspects. Table 29 contains the data required for the MAST evaluation.

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

*Table 33 Data required for MAST evaluation of UC-PT6-002*

| MAST Domain | Topic | Outcome | Data required | Time point |
|---|---|---|---|---|
| **Health problem and characteristics of the application** | Clinical/health issues | Inclusion / Exclusion criteria | Medical information about patients | Recruitment |
| | Description of the application | Maturity of the application | Analysis of results | At the end of the pilot |

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| | | | | |
|---|---|---|---|---|
| **Clinical Effectiveness** | Effects on health-related quality of life | Health related quality of life | EQ-5D-5L scores | Baseline and end of pilot |
| | Utilization of health services | Rehabilitation process length and efficiency | Number of rehabilitation sessions | Baseline (past 3 months) and at end of pilot |
| **Patient perspectives** | Satisfaction and acceptance | User Experience | UEQ-S scores | End of pilot |
| | Understanding of information | Usability of application | SUS Scores | End of pilot |
| | Empowerment<br><br>Self-efficacy | Self-efficacy | General self-efficacy scale | Baseline and end of pilot |
| **Economic aspects** | Amount and cost of resources used | Cost of robot | Cost as per robot purchasing invoice | End of pilot |
| | | Cost of using digital solutions and SHAPES platform | Costs to be provided by SHAPES | End of pilot |
| | | Cost of staffing | Timesheets and costing data | End of pilot |
| | Related changes in use of healthcare resources | Cost of rehabilitation | Cost of length of rehabilitation process | End of pilot |



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Due to the evaluation methodology (small-scale deployment, non-case controlled) the MAFEIP tool has not been used to evaluate UC-PT6-002.

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

*MOMENTUM*

The MOMENTUM blueprint was applied to check if UC-PT6-002 had the critical success factors (CSFs) needed to take it from the pilot phase to large-scale deployment. Details of each CSF are provided below.

**CSF 1. Cultural readiness for the telemedicine service**

The leader of the use case, CH, has been working with telemedicine solutions for +7 years on a daily basis. In addition, data sharing and collaborative work is part of the methodology. Deployment of PT6-002 solution in other sites may involve a slower process.

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

Remote monitoring is a clear opportunity for a tighter follow-up of older adults with mobility restrictions while addressing the shortage of skilled HCP and keeping reasonable costs.

**CSF 3. Ensure leadership through a champion.**

The CEO of CH is directly involved in the definition and deployment of the use case. CH is committed to promote the incorporation and use of the digital solution.

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

HCP and decision-makers from CH have been involved in the definition and development of the content of the project. In addition, HCP were participants of Phase 2 (mock-up presentations), Phase 3 (hand-on experiments) and Phase 4 (technical validation) and their feedback was collected and implemented in the co-design process.

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

Patients have been involved with the development of the DS through the planned activities for Phase 2 and 3 of the pilots — mock-ups and hands-on — at CH. Such activities have also helped the investigators identify and produce information materials and training to support patients to use the robot and get the best possible results from

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taking part in the pilot. All pilot sites agree that the service is based on the patient's needs.

**CSF 6. Ensure that the technology is user-friendly**

Older adults and HCP have been specifically asked about user friendliness of the digital solutions during Phase 2 and 3 of the pilot and adaptations have been made to enhance the user experience before the use case is piloted. User-friendliness has been tackled for all technologies addressed to the older adults. Regarding professionals, digital solutions have been developed for the sake of completion of monitoring and assessment of patients' performance within the robot; the design has followed usefulness guidelines, but friendliness has not been achieved as much as desired. Usability and acceptance metrics can be used here to evaluate the final usability of the system. In this sense we propose to use the SUS score.

**CSF 7. Pull together the resources needed for deployment**

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

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

Evaluations have identified insurances and rehabilitation centres are primary clients. They are very much in need of reduction of health costs of their users with mobility restrictions, based on direct experience at CH. Cost of service could be a barrier, mainly due to the cost of the robot itself. The solution addresses the needs for efficiency improvement and improvement of quality in the health sector.

**CSF 9. Prepare and implement a business plan**

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

**CSF 10. Prepare and implement a change management plan**

It will be evaluated after the end of the project.

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

The robot is not classified a medical device, as it is under development. The most critical factor is the physical use of the robot by end users, they have to touch it while walking. For the present study is up to each local Ethics Committee to determine whether the development of the piloting activities is permitted.

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

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Although the participants in the pilot are limited, the solution is being designed with the intention to scale it to a pan-European level. The use of human resources has been evaluated during the pilot, with a proper analysis of resources needed in relationship with the supervision of the rehabilitation sessions.

**CSF 13. Identify and apply relevant legal and security guidelines**

GDPR has been applied. The system provided implements all security and privacy related regulations.

**CSF 14. Involve legal and security experts**

CH has been working with other SHAPES partners (for example with LAUREA, with extensive expertise in this field), particularly because we have been dealing with health data. VICOM was awarded the ISO 27001 certification for information security management. HMU and VICOM have extensive expertise in IT infrastructure security.

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

The protocol for the pilot details all the steps that have been taken to ensure patients' privacy is protected. The project underwent a full ethical evaluation by each local Ethics Committee.

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

SHAPES is developing a technology platform for pan-European distribution of telemedicine services. The pilot is being designed to cope with this requirement as well.

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

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

**CSF 18. Establish and maintain good procurement processes**

The SHAPES project provides the servers that are needed to run the solution. Those servers meet the service level needed to run the pilot successfully.

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*NASSS*

The NASSS framework was used to detect areas of complexity in the project plan for piloting UC-PT6-002 and, if needed, to make adaptations to the plan. The short version of the NASSS-CAT questionnaire was considered and completed by the pilot team. Of the six domains, there were four domains in which significant complexities were identified that, if not mitigated or addressed, were likely to affect the project's success at the piloting stage of the use case. Their description, along with the mitigation action that have been or are being undertaken are listed in Table 30.

*Table 34 Complexities and mitigation measures in the PT6-002 use case identified using the NASSS framework*

| NASSS complexity domain | Uncertainties detected | Mitigation measures taken |
|---|---|---|
| **The illness or condition** | The conditions of eligible people for the study are too wide and not very specific. Gait restrictions can be caused by multiple factors which can be a limitation for the benefit of the solution. | Inclusion and exclusion criteria should be more specific in order to identify a more proper target group. Moreover, we need to make the technology accessible to people with different conditions and situations. |
| **Technology** | The robot has been already used and even commercialised for other uses in the health field but it is the first time that this technology is adapted to assist in the rehabilitation process. Given the early stage of development there are many uncertainties about the benefits of the technology achieving the final goal. | During this project, the technology and its benefits for stakeholders (patients, HCP and health institutions) will be analysed. |
| **Value Proposition** | The robot hasn't been used for rehabilitation purposes so the value of the robot as it is now being uncertain.<br><br>We don't know if this particular organization will be able to absorb the benefits of the product. We understand that the work | This study will help to collect feedback from HCP and patients in order to optimise the product and its efficiency.<br><br>During and after the pilot a plan to adapt the technology to the reality of the daily work processes will have to be |

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| | processes will have to change in case of incorporation of the product. | developed and implemented. |
| **Intended adopters** | The front-line staff is from Clínica Juaneda Salvà, an independent clinic which has a rehabilitation service. During the pilot, CH staff will have minimum control over the performance of the HCP conducting the pilot so it is difficult to ensure they engagement and commitment. | Changing/adapting the rehabilitation sessions by introducing the robot is a concern that has to be discussed deeply in the design of the pilot. Moreover, the commitment of the staff responsible to conduct the pilot has to be ensured. |

## *3.5 Phase 1*

### 3.5.1 PACT and FICS Scenario

*Table 35 PACS (PT6-UC002)*

| **Code** | UC-PT6-002 | **Version** | 0.1 | **Date** | 2020/09/11 |
|---|---|---|---|---|---|
| **Applicable SHAPES Persona** | Roisin | | | | |
| **Applicable SHAPES use case** | UC12 Motor exercising with robot. | | | | |
| **People**<br><br>**Roles and/or actors of typical users involved in delivering and receiving the robot-assisted gait rehabilitation** | • Older adults, 65+ years, care recipient, who have suffered an accident, a stroke, has gone into surgery or have a musculoskeletal disease and, because of that, they require physical rehabilitation services to recover/maintain physical condition. In particular, they require gait rehabilitation, a relevant task in which support is often needed. Older adults in this situation go to a rehabilitation center where a health professional guides the rehabilitation session. E-literacy is diverse, usually from medium (for example, they use smartphones and WhatsApp) to none.<br>• HCP:<br>○ Physiotherapist with high digital literacy or<br>○ A formal caregiver, potentially with specialty focused knowledge and skills such as nurses, | | | | |

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| | |
|---|---|
| | physiotherapists, experienced in providing care in frail older people and capable of providing effective, high quality, integrated care for older adults with complex health care needs. Additionally, digital literacy and affinity to technology are considered essential. |
| **Activities**<br><br>**Activities to be performed by the actors in order to successfully provide and receive the robot-assisted gait rehabilitation**<br><br>**procedures for the professional and the patient; Parameters that determine the measures used in the intervention** | **Older adults / care receiver**<br><br>• Have never had interaction with robots.<br>• To receive gait rehabilitation session with robot according to guidelines given by the health professional.<br><br>**HCP**<br><br>• To schedule exercises, their difficulty and session time for every older adult.<br>• To review clinical data regularly and update scheduling sessions if necessary.<br>• To readjust session exercises at the start of every session if necessary.<br>• To supervise all aspects, including security measures, while executing the gait rehabilitation session.<br>• To efficiently manage a potential accident (an older adult's fall, injury etc.) during the session. |
| **Context**<br><br>**Social-medical relevance of the robot-assisted gait rehabilitation intervention; privacy issues; risks for the patient; locations** | • Pilot participants are provided with the robot and the necessary space for the rehabilitation session.<br>• The use case comprises two objectives to achieve for the older adults:<br>  ○ To feel motivated for the whole session.<br>  ○ To gain self-confidence in gait.<br>• Maintaining privacy of data is of the utmost importance. An identification list (including name and date of birth) will be held at the local pilot site.<br>• GDPR and ethics are in line with WP8.<br>• Data and servers must be located within the EU.<br>• Spanish language (leader: CH and replicating site: SAL); Greek (replicating site: AUTH).<br>• Location: Mallorca, Spain (leader: CH); Córdoba, Spain (replicating site: SAL); Thessaloniki, Greece (replicating site: AUTH). |
| **Technology**<br><br>**Type of information / parameter that are relevant in monitoring the health status; type and** | **Older adult / care receiver**<br><br>• Full name<br>• Telephone number<br>• Address of residence<br>• Email |

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| | |
|---|---|
| **frequency of accessibility of information; feedback modalities (communication)** | • Age<br>• Gender<br>• Years of formal education<br>• Biometric data: Emotion recognition, face recognition<br>• Data collected through robot (internal logs)<br>• Data to complete questionnaires (harmonised and no-harmonised) |
| **Scenario** | **Older adult**<br><br>Roisin is a woman in her 70s who lives in her own home with her husband. Roisin has arthrosis on both knees and sometimes feels moderate pain. She does regular exercises for the knees and follows a gait rehabilitation programme. Gait rehabilitation is good to strengthen her muscles and improve mobility of joints. Roisin goes to gait rehabilitation in Clínica Juaneda Salvà twice a week with a physiotherapist and sometimes contacts the doctor at CH in case of acute pain.<br><br>Roisin wakes up at 8.00. A care giver comes at 8.30 to assist her and her husband with the morning routine. Roisin needs some supervision regarding mobility, specially to mitigate the risk of falling. She performs the self-care activities in a semi-autonomous way:<br><br>- Bathing<br>- Dressing<br>- Breakfast<br>- Medication intake<br><br>Every Tuesday and Thursday at 10.00h the care giver takes Roisin to Clínica Juaneda Salvà by car to start her gait rehabilitation session at 10.30, which lasts until 11.30. During this hour Roisin performs some mobility exercises with the support of KOMPAÏ robot. Those exercises have been pre-determined by the physiotherapist based on the autonomy of Roisin, her walking style, her confidence with mobility and her progress throughout the previous sessions.<br><br>The interaction starts with the face recognition of Roisin. The robot identifies her and the physiotherapist selects the exercise using the graphical interphase (integrated tablet). The exercise starts and Roisin interacts with the robot by voice and/or through the tablet, where the robot gives the instructions to Roisin on how to perform the exercise plus motivation messages during the activity. |

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|---|---|
| | After the session, Roisin and her care giver run some errands and after they go home and have lunch. In the evening, Roisin perform some exercises stated by the physiotherapist in order to keep active between sessions. Some days, Roisin, her husband and their children and grandchildren go for a walk, get an ice cream or a coffee or go to the cinema. Roisin always walks with a walker and with supervision.<br><br>**HCP**<br><br>Physiotherapists have access to the robot and to performance data from patients.<br><br>• User ID<br>• Date and time of session<br>• Walking distance<br>• Pauses<br>• Speed<br>• Map<br>• Route<br>• Time to perform the exercise<br><br>The physiotherapist will evaluate the performance of Roisin and will develop personalised exercises with KOMPAÏ robot accordingly to ensure the progression of Roisin in her gait rehabilitation. |

*Table 36 FICS (PT6-UC002)*

| | |
|---|---|
| **Function and events**<br><br>*Functionality of the intended system which is capable to realize actor's activities* | In this pilot there are two main actors: 1) Roisin, the target old person and 2) the physiotherapist or caregiver. The system provides different functionalities for these two main actors.<br><br>For Roisin:<br><br>1) Roisin uses the KOMPAÏ robot during her gait rehabilitation sessions.<br>2) The KOMPAï robot authenticates the user.<br>3) The system offers mobility assistance:<br>a. Free walking mode<br>b. Guided walking mode<br>c. Face recognition<br>d. Emotion recognition |

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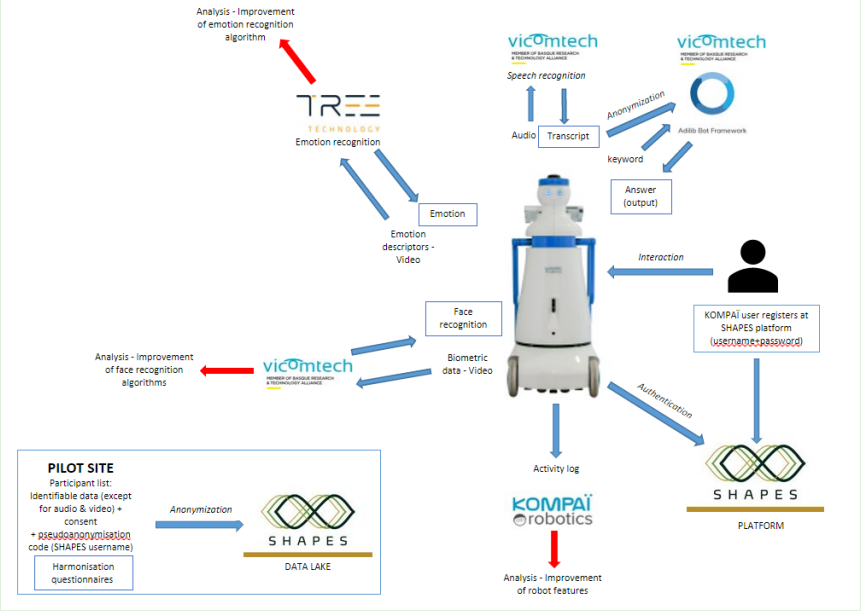
| | |
|---|---|
| | e. Text-to-speech interaction (ROSA dialogues)<br><br>For the physiotherapist or caregiver:<br><br>1) The robot provides a control panel through the graphical interphase (tablet) where the professional is able to track the performance of older adults.<br>2) The option to design new exercises and circuits.<br>3) The option to play music during the session.<br><br>The system stores all data related to the use case and allows its exploitation in the future. |
| **Interactions and usability issues**<br><br>*User-system or system-component interactions meditating actor's activities; Types of the interactions, e.g. unidirectional data streaming service or reliable messaging service* | In order to facilitate the interaction to the maximum, a text-to-speech mechanism has been integrated into the KOMPAÏ robot and it is used as the main interaction method with the system, combined with the touch screen system.<br><br>The voice communication is unidirectional where the robot communicates with the user by giving voice and text messages at the same time. Through the graphical interphase, the robot gives instructions to the user as well, ensuring clarity and simplicity. Then, the user chooses the desired option through the touch screen. |
| **Content and structure**<br><br>*Variables of the interaction* |  <br><br>*Figure 6. System-component interactions* |

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**Style and aesthetics**

*Look and feel of the system*

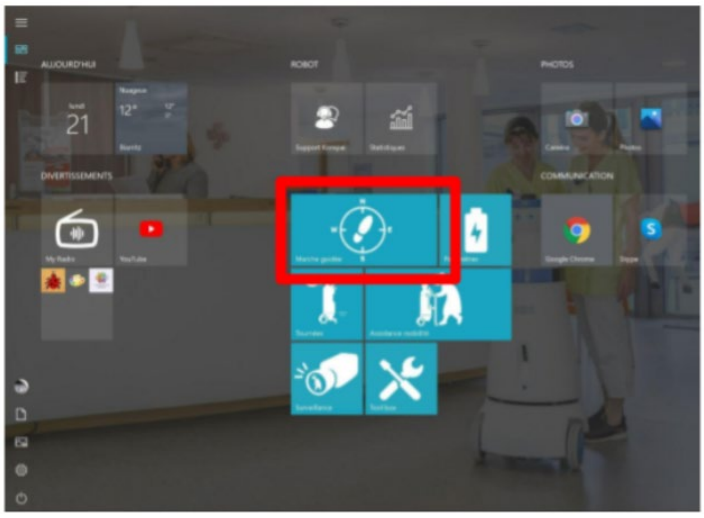

*Figure 7 KOMPAÏ robot's main interface*

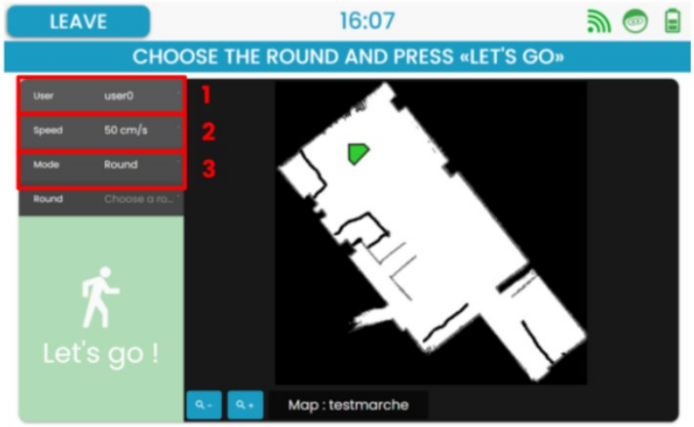


*Figure 8 Guided walk application*


*Figure 9 Map on the application to follow the route*

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*Figure 10 Visual instructions on KOMPAÏ robot' screen*

### 3.5.2 Key performance indicators

KPIs are defined as a set of measures that focus on the factors most critical to a project's success. KPIs are measurable and quantifiable with a target or threshold. They measure a performance in critical areas by showing the progress or lack of it towards realising the objectives of each specific use case. The following KPIs have been chosen to determine whether, or not, the pilot for UC-PT6-002 has been successful.

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

Recruitment and retention

- At least 80% of the target cohort (older adults) were successfully recruited into the pilot during the recruitment period (i.e., 8 participants were recruited in CH; 8 participants were recruited in SAL; 2 participants were recruited in AUTH).
- At least 80% of recruited participants within the target cohort remained enrolled in the pilot until the end of the study.

Technical performance

- There is no re-start of any of the components of the technology for at least 90% of the days.
- Less than 2 technical incidents reported per week.

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User engagement and acceptance

- Most older adults agree or strongly agree that the technology is useful to them and that they would use it in the future in the Technology Acceptance Model (TAM).
- At least one HCP/caregiver scored one of the following functionalities above average rating (>68) in the System Usability Scale (SUS):
    - Free mode
    - Assisted mode

### 3.5.3 Timeline of pilot activities

The original timeline is shown in Figure 11, which has been followed with some changes. Phase 1 was conducted as planned and Phase 2 was conducted the following month, earlier than planned. Phase 3 was planned to be developed by CH between January and February 2022 but once the robot arrived at CH some technical issues raised, and the technical team needed some time to tackle them. This fact created a delay on the development of Phase 3, which was held in April 2022, and therefore on the Interim Deliverable, which was finalised in May 2022, with two months delay. Phase 4 was planned to be developed by CH in May 2022 and Phase 5 in June 2022. However, Phases 4 and 5 were not conducted as planned due to Ethical limitations. The Ethics Protocol was presented to the Balearic Ethics Committee, but approval was not granted, this is why Phase 4 was performed internally at CH without involving older adults. Then, all feedback from Phase 4 was incorporated and the robot was transported to SAL (Spain) and AUTH (Greece) to perform Phase 5. SAL performed Phase 5 in May 2023, then the robot was transported to AUTH in June 2023 and the replication is planned to be performed in July 2023, after the submission of this Deliverable. The results from AUTH replication will be included in Deliverable 6.9.

| Pilot Site | Number of participants | Set up | Duration of Phase 4 | Duration of Phase 5 | Duration of intervention | jul-21 | ago-21 | sep-21 | oct-21 | nov-21 | dic-21 | ene-22 | feb-22 | mar-22 | abr-22 | may-22 | jun-22 | jul-22 | ago-22 | sep-22 | oct-22 | nov-22 | dic-22 | ene-23 | feb-23 | mar-23 | abr-23 | may-23 | jun-23 | jul-23 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | M21 | M22 | M23 | M24 | M25 | M26 | M27 | M28 | M29 | M30 | M31 | M32 | M33 | M34 | M35 | M36 | M37 | M38 | M39 | M40 | M41 | M42 | M43 | M44 | M45 |
| ORIGINAL TIMELINE | | | | | | Phase 1 | | | Phase 2 | | | Phase 3 | | D | Phase 4 | | | | | Phase 5 | | | | | | | | | | D |
| CH - leader | 10 | 1 month | 1 week | 1 month | 2,5 months | 1 | 2 | | | | | | | | 3 | | | | | | | 4 | 4 | 4 | | | | | | |
| SAL - rep | 10 | 2 month | NA | 1 month | 2 months | | | | | | | | | | | | | | | | | | | | Transport | Pilot site preparation | | 5 | | |
| AUTH - rep | 3 | 3 month | NA | 1 month | 2 months | | | | | | | | | | | | | | | | | | | | | | | | Transport | 5 |

*Figure 11: Timeline of activities for PT6-UC002*

## 3.6 Phase 2: Testing of mock-ups and prototypes

### 3.6.1 Methodology of testing

**Introduction**

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Mock-ups were performed in Phase 2 of the SHAPES Pilot Campaign where a simplified representation of the actual design of a digital solution was presented through pictures and text descriptions. Early user engagement activities wherein mock-ups were shown to users and their feedback was collected to inform developers on how the practicability and usability of their designs can be assessed and improved in the target user group, as well as identify and rectify potential problems at an early stage.

**Aim**

To validate the functionalities of technologies in UC-PT6-002 and the way they are planned to be implemented, including the interaction with the users, based on the feedback provided. In addition, this research study also aimed at collecting new functionalities. The outcome of this research study has provided technical partners the opportunity to integrate user feedback at an early stage of the technological development process.

**Overview**

The solution for UC-PT6-002 underwent a co-design and user-testing process to validate the functionalities offered to the users and their usability. Mock-ups of the solution, its behaviour and the way users interact with interfaces were shown to the respective users:

- KOMPAÏ robot and its functionalities: older adults and HCPs / caregivers

Feedback on how the current functionalities solve their needs, usability comments and ideas for new functionalities were collected. All study activities were conducted presentially in the format of slide presentation and semi-structured interviews.

**Recruitment**

Participants

1. Oder adults: 1) ≥ 65 years old; 2) they participate in rehabilitation sessions in Clínica Juaneda Salvà. At least 2 people were expected to be recruited.
2. HCPs: physiotherapists working at the rehabilitation service in Clínica Juaneda Salvà. At least 1 person was expected to be recruited.

Identification of participants

*Older adults*

Eligible participants were identified within patients from Clínica Juaneda Salvà rehabilitation service.

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*HCPs*

Eligible participants were identified from personnel at Clínica Juaneda Salvà rehabilitation service.

Informed consent procedure

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

- Older adults: participant information sheet for older adults.
- HCPs: participant information sheet for health professionals.

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

- Older adults consent form.
- HCPs consent form.

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

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

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

**Method**

Presentation of mock-ups

The SHAPES project manager at CH visited the rehabilitation service at Clínica Juaneda Salvà to hold a PowerPoint presentation including pictures of the KOMPAÏ robot and explanation of its functionalities. The presentation allowed users to propose ideas for new functionalities.

After each functionality, the SHAPES project manager at CH asked questions about the utility of the functionalities according to participant's needs in several scenarios. These questions were a combination of open and closed questions designed to obtain both general and specific feedback about the functionalities.

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

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

Data collection and analysis

Notes were taken during the interview by personnel of CH. A report was elaborated including a table listing all questions and filled with participant's answers. Similar questions throughout the different types of users were grouped together. Other comments and opinions collected at the interviews were posted after the table or within a particular cell if the information is related to the question. Completed reports and collated findings, including any recommendations, were presented to technical partners.

### 3.6.2 Results of testing

**Execution**

A group session was held with the participation of an older adult currently under gait rehabilitation and 3 HCPs (a physiotherapist, the manager and a medical doctor). The SHAPES project manager at CH delivered a PowerPoint presentation followed by open questions. After the presentation, participants expressed their opinions about the different functionalities.

**Outcome of the feedback**

*Older adults*

- He liked the idea of an automated walker, as he was already using a conventional walker and thought it could be useful.
- He preferred signs on the screen to voice instructions.
- He didn't like to receive commands; they should be perceived as suggestions.
- The solution was valued positively.

*HCPs*

- They liked the assisted mode as this is an option they don't have.
- They were unsure about voice interaction in a room with background noise.
- They were worried about the potential presence of cables in the room.
- They were concerned about the weight and the stability of the robot and the material of the handles, which should be anti-slip.
- WIFI stability should be considered.
- They valued positively and liked the type of exercises, duration and sequence.

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**Recommendations for technical partners**

- Visualization by professionals of number of steps, time walking, walked distance. It was agreed with the KOMPAï technical team that an interface for professionals would be developed for them to be able to see the history of participants and then design more appropriate exercises.
- Definition of the end of the exercise; the robot to return to home base and transmit a signal of “end of session”. This was discussed and implemented.
- Ensure the stability and adequate materials of the robot.
- Ensure WIFI stability or include a sim card to avoid connection dependencies.

Some other recommendations were formulated, however, after discussion with technical partners it was decided that they were impossible to be achieved in this pilot:

- Option for the older adults to sit down.
- To detect older adult’s movement while following a video and give corrections.

## *3.7 Phase 3: Hand-on Experiments*

After the implementation of some of the recommendations collected during the mock-up testing, the ones feasible within the pilot limitations, hands-on experiments were performed in Phase 3 of the SHAPES Pilot Campaign. The objective was to collect feedback from end-users and evaluate the performance of the digital solution in the actual pilot setting. The end-users were confronted with prototypes of the tools developed and improved during Phases 1 and 2.

### 3.7.1 Methodology of hands-on experiments

The aim of the Hands-on experiments was to collect feedback (user experience) from end-users by giving them the option to try the DS to be deployed in the use case PT6-002 in a close-to-final version prototype. To train HCPs in the DS they will be using in the use case. To collect feedback about the stability of the DS and their connections.

The solution for UC-PT6-002 underwent a user-testing process to validate the functionalities offered to the users and their usability. Hands-on training of the solution, its behaviour and the way users interact with it were shown practically to older adults and HCPs.

The participants tried the robot and gave feedback on how the current functionalities solve their needs, usability comments and ideas for new functionalities. All study activities were conducted presentially in the format of slide presentation, physical demonstration, physical testing and semi-structured interviews.

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**Recruitment**

Participants

1. Oder adults: 1) ≥ 65-year-old; 2) they participate in rehabilitation sessions in Clínica Juaneda Salvà. At least 2 people were expected to be recruited.
2. HCPs: physiotherapists working at the rehabilitation service in Clínica Juaneda Salvà. At least 1 person was expected to be recruited.

Identification of participants

*Older adults*

Eligible participants were identified within patients from Clínica Juaneda Salvà rehabilitation service.

*HCPs*

Eligible participants were identified from personnel at Clínica Juaneda Salvà rehabilitation service.

Informed consent procedure

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

- Older adults: participant information sheet for older adults.
- HCPs: participant information sheet for health professionals.

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

- Older adult consent form.
- HCP consent form.

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

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

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

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**Method**

Hands-on training

The SHAPES project manager at CH visited the rehabilitation service at Clínica Juaneda Salvà to hold a PowerPoint presentation including pictures of the KOMPAÏ robot and explanation of its functionalities. Afterwards, the project manager did a physical demonstration of the mentioned functionalities, followed by the intervention of end-users, who interacted with the KOMPAÏ robot. The session allowed users to propose ideas for new functionalities and provide feedback on the current ones.

After each functionality, the SHAPES project manager at CH asked the participants questions about the utility of the functionalities according to their needs in several scenarios. These questions were a combination of open and closed questions designed to obtain both general and specific feedback about the functionalities.

There was a unique PowerPoint presentation for older adults and HCPs.

The following number of sessions, and time length, were expected:

- Older adults: 1 session, 1h.
- HCPs: 1 session, 1h.

Data collection and analysis

Notes were taken during the interview by personnel of CH. A report was elaborated to include a table listing all questions and filled with participant's answers. Similar questions throughout the different types of users were grouped together. Completed reports and collated findings, including any recommendations, were presented to technical partners for its discussion and implementation.

### 3.7.2 Results of the hands-on experiments

**Execution**

The previous day to the Hands-on training the SHAPES project manager at CH went to Clínica Juaneda Salvà to do the space installation: Mapping, POI, routes, QR installation and localization of the robot. The day of the Hands-on training, a Power Point presentation explaining the features and functions of the robot was delivered. Then, she did a demonstration of the features (Free and Guided mobility, Rounds, Charging and Localization method). Finally, a practical session with physiotherapists and another with one older adult was held, followed by a collection of suggestions and opinions.

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4 physiotherapists participated in the practical sessions. All of them tried both the Free and Guided Mobility Assistance, asked questions and made suggestions. They had recruited some older adults to participate in the Hands-on training but after testing the KOMPAÏ robot they decided some of the potential participants were no eligible (not enough stability, risk of falling, Parkinson…) and therefore just one older adult participated in the practical sessions. He tried both the Free and Guided Mobility Assistance, asked questions and made suggestions.

Questions asked to all participants after the session:

- Do you like the aesthetics of the robot?
- Do you think the robot is useful to be used during the gait rehabilitation sessions?
- What parts or features of the robot would you change?
- Opinions and suggestions

**Outcome of the feedback**

*Older adult*

The older adult was quite autonomous, with a little unsteady and broken gait. He walked without walking aids and was quite tall and overweight.

- Even if I explained how to use the robot, he claimed that he walked better without it.
- He proposed to make the walking zone wider and solve the issue of the breaks, as they were quite rough.
- Also, he couldn't understand the features on the screen, he said they were not very user friendly.
- Opinion: "This is for people with less mobility than me and with a specific type of walking: small steps."

*HCPs*

- They thought that the walker was too standarised and quite small. Not everyone has the same walking style and the robot must be able to adapt.
- Oral and visual instructions were not always right wrong and were not provided with enough anticipation. Thay thought that was not easy to understand what the robot asked you to do (how to position, where to go, etc).
- Not adapted to all physical profiles and walking styles. For most of the participants the "walking zone" was too small.
- They found the breaks and the turns to be too rough and therefore there was a risk of falling.

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- In the turns, for instance, to the left, the left handlebar kicked the abdomen of the user (more when the person is overweight). Moreover, if you want to avoid this, you had to leave the walking zone and the robot would stop.
- Sometimes, when the robot stopped because the person was outside the walking zone, to start again they had to press “Go”, it would restart automatically.
- If there was an obstacle on the floor, quite short, it wouldn’t detect it.
- Professionals could not track the user sessions (the HCPs interface was still under development).

In general, participants liked very much the aesthetics of the robot. They thought an improved version of the current technology could be beneficial but the actual state is not very useful. In their opinion, if the issues of stability, breaks and turns are not solved there is falling risk. They saw it as a motivation tool for people to move but not a rehabilitation tool (in the current state).

**Recommendations for technical partners**

- Recommended to make it adjustable to the hinge.
- Correct the oral and visual instructions (arrows) and anticipate the moves (map on the screen).
- Make it adjustable depending on the height and walking style of the person.
- Progressive breaks. Meaning that the speed slows progressively until the robot stops.
- Less rough turns.
- Inform about the lower obstacles including a lower camera.
- Apply weight sensors on the handlebars (HR and fall risk).
- Interface for professionals to see the progress.

Feedback and recommendations were discussed with technical partners and a full action plan was developed by KOMPAÏ to tackle those feasible recommendations.

## *3.8 Phase 4: Small Scale Live Demonstration*

Phase 4 Small Scale Live Demonstration aimed at validating the technological aspects of the KOMPAÏ robot and the digital solutions integrated into it to be able to proceed to Phase 5. This phase was performed internally at CH because to perform Phase 4 with older adults it was necessary to have the Ethics Protocol approved by the Balearic Islands Ethics Committee. At that time, the Ethics Committee had requested amendments on the protocol and some clarifications. It was decided to proceed performing Phase 4 internally at CH to avoid more delays in the pilot, as at the end Phase 4 aims to check all technical aspects before proceeding with the large-scale pilot activities where participants use the solutions in a real-life environment and data is collected.

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A small-scale live demonstration of the SHAPES Platform and digital solutions being deployed in UC-PT6-002 was undertaken during Phase 4 of the SHAPES pan-European pilot campaign at CH. The demonstration tested the methods and procedures that were to be used when the pilot is conducted at a larger scale in the target population. The aim was to identify any issues with technical performance, connectivity and transfer of data. It also considered if amendments needed to be made to the processes, logistics or documentation to be implemented in Phase 5.

### 3.8.1 Recruitment of participants

Regarding participants in Phase 4, 2 workers from CH performed the technical tests reproducing a real-life situation. A set of tests and a specific methodology to detect and address potential errors were developed. Then, the errors / improvements / suggestions were compiled in a report and discussed with technical partners.

**Inclusion criteria**

- Workers from CH;
- Having consent capacity;
- Being of legal age.

**Exclusion criteria**

- Being involved in the SHAPES project or having previous detailed knowledge about the use cases;
- Not having consent capacity;
- Not being of legal age.

**Sample size**

Two participants were recruited to perform Phase 4.

**Duration**

Two sessions with each participant, a total of four sessions on two different days within one week.

**Method**

No financial incentives were provided for participating in Phase 4.

SHAPES Project Manager at CH screened potential eligible participants within CH workforce. The first communication about the pilot was directed from the project manager to the potential participants. Information sheets (paper-based) were provided to potentially eligible participants that showed interest. Potential participants were

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contacted after 24 hours to allow time to consider the information provided. Eligibility was confirmed by the principal investigator at pilot site and the project manager countersigned the informed consent, obtained in a handwritten format, and delivered a copy to participants as an acknowledgment of reception.

Informed consent procedure

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

Those who agreed to take part were given a consent form by personnel of CH. Signed consent forms and contact details were then handed over to CH personnel to proceed with the study activities.

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

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

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

This includes acceptance of the following:

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

### 3.8.2 Technical aspects & Logistics

**Validations**

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

- Create a map of the space where the robot would operate.
- Create different points of interest (POI).
- Create a route combining the POIs.
- Create a QR to localise the robot at any moment; test the process of localising.

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- Install the charging station and charge the robot.
- Use the guided walking mode following the route created.
- Use the free walking mode.
- Use the face recognition.
- Identification of participants through ASAPA.
- Check the emotion recognition (outputs not displayed but stored).
- Transfer of data between different digital solutions and to the Data Lake.
- Proper visualisation of patient's data in the HCP dashboard.

**Hardware**

The physical shape of the KOMPAï robot used in UC-PT6-002 and its components are showed in the Figure 12.

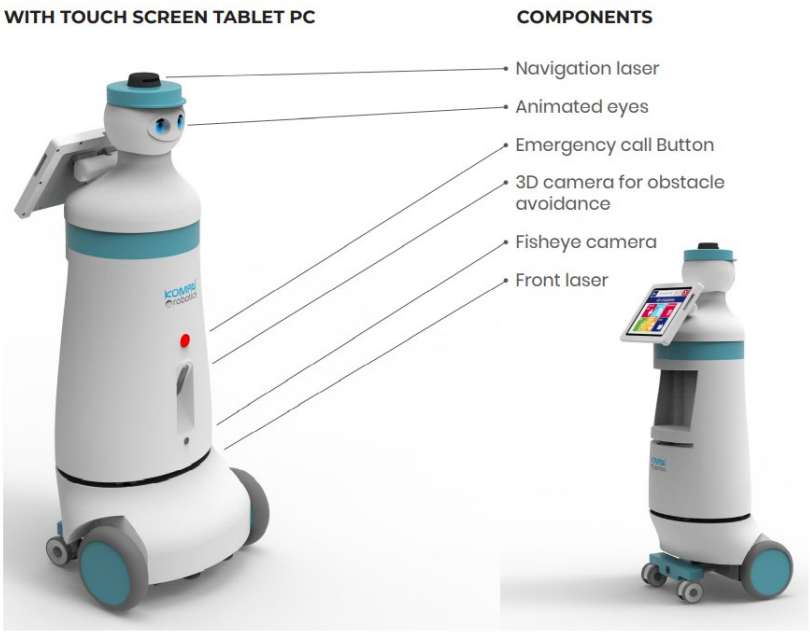


*Figure 12: KOMPAÏ robot's features*

For this study, the robot was equipped with two sided handgrips as showed in the Figure 13 so users could follow the mobility assistance mode.

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*Figure 13: KOMPAÏ robot with handgrips*

Moreover, technical specifications of the KOMPAÏ robot are showed in the Figure 14.

**TECHNICAL SPECIFICATIONS**

| | |
|---|---|
| MOTORS | 2 X 80W BRUSHLESS MOTORS |
| PROPULSION | STEERING BY DIFFERENTIAL DRIVE |
| DIMENSIONS HEIGHT X WIDTH X LENGTH | 1186 X 495 X 420 mm |
| OBSTACLE CLEARANCE (VERTICAL STEP) | ~2 cm |
| MAXIMUM SLOPE | 10% |
| AUTONOMY | ABOUT 6 H (DEPENDS OF USAGE SCENARIO) |
| SENSORS | |
| NAVIGATION SENSOR | 360° 2D LIDAR ON TOP OF THE HEAD, INCLUDING MAPPING AND PATH PLANNER |
| OBSTACLES DETECTION | 2 LASER, 3D CAM AND INFRARED |
| ONBOARD COMPUTING & FUNCTIONS | |
| MAIN CONTROLLER | NVIDIA JETSON TX2 BOARD RUNNING LINUX, PURE LOW LEVEL CONTROLLER AND NAVIGATION SOFTWARE |
| APP & HMI | TOUCH SCREEN TABLET PC (MICROSOFT SURFACE), CAN BE REPLACED BY ANDROID |
| OTHERS | |
| CERTIFICATION | CE, MACHINE DIRECTIVE 2006/42/CE AND ISO 13482 |

*Figure 14: Technical specifications of KOMPAÏ robot*

The robot presents some limitations regarding the physical space where it is operated:

- If the robot is called to pass through doors, the width of the door must be at least 830 mm
- Have corridors at least 1m wide for better circulation of the robot
- Do not have a clearance (door bottom for example) greater than 1.5 cm on the ground

Moreover, the robot needs 4G/5G and/or Wi-Fi connectivity to operate and can be accessed remotely if needed for technical support.

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**Software**

To fully support the older adults in gait rehabilitation, the following software were integrated into the KOMPAÏ robot (see Table 33).

*Table 37 Software integrated into the robot*

| Software's name | Owner (Company) | Description |
|---|---|---|
| FaceCog | VICOMTECH (SHAPES project collaborator) | Image processing algorithm for facial recognition to identify persons. |
| Emotion recognition | TREE Technologies (SHAPES project collaborator) | Image processing algorithm for emotion recognition to identify user engagement. |

### 3.8.3 Roles and Responsibilities

**CH managing personnel CH**

- Overview of the UC-PT6-002: monthly meetings, coordination among different stakeholders.
- Set up of the robot: Installation and adaptation to CH.
- Ethical considerations: Development of all ethics documentation, including the Ethics Protocol to be approved by the Balearic Islands Ethics Committee.
- Translations to English to allow replicating sites the translation to the local language.
- Recruitment of participants.
- Training process.
- Development of dialogues (in Spanish) to be implemented into the robot.

**CH technical team**

- Technical tests to check both hardware and software performance.
- Creation of SHAPES accounts.
- Coordination with KOMPAÏ, VICOM and TREE technical team to solve technical issues.

**KOMPAÏ, VICOM and TREE technical team**

- Address technical issues.
- Check correct data flow.

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- Implement feedback and suggestions from participants.

**UCLM / SAL team (replicating site)**

- Coordination with the leading site to implement the piloting activities.
- Creation of SHAPES accounts.
- Ethical considerations (Ethics Protocol).

**AUTH team (replicating site)**

- Coordination with the leading site to implement the piloting activities.
- Creation of SHAPES accounts.
- Ethical considerations (Ethics Protocol).
- Translation of dialogues from English to the local language (Greek).

### 3.8.4 Outcome of the Small-Scale Live Demonstration

The small-scale live demonstration was performed in November. The technical tests lasted two weeks and after that, the research team at CH compiled all the findings, recommendations and feedback from participants to share it and discuss it with technical partners.

Table 34 shows the outcomes for Phase 4.

- Each participant used the robot and its functionalities.
- The data flow among different digital solutions was checked.
- The errors reported by participants were noted.
- Feedback was collected from participants.
- Completion of Pilot Site Checklist (documentation and questionnaires were properly filled in).

*Table 38 Outcomes of Phase 4*

| Outcome | Measurement | Instrument |
|---|---|---|
| **KOMPAÏ robot performance** | Technical information about the KOMPAÏ robot performance during sessions. | Log files |
| **Technical aspects** | Analysis of the different functionalities of the robot. | 10-Point Likert Scale |

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| | | |
|---|---|---|
| **Adverse events** | Participants were asked about the occurrence of any adverse event or system errors. | Question at the end |
| **Trust and technology acceptance** | Scale Score | TAM |
| **Self-perceived usability** | Scale Score | SUS, UEQ-S |
| **Participants' perception** | KOMPAÏ robot walking assistance module for older individuals' gait rehabilitation in the framework of SHAPES project (Smart and Healthy Ageing through People Engaging in Supportive Systems). A non-randomized, feasibility study in a real-world environment for the evaluation of user engagement and user-perceived usefulness. | Open interview |

The Project Manager at CH presented the KOMPAÏ robot and all its functionalities to Phase 4 participants. After a group introduction, she scheduled the four sessions within two weeks, two sessions per participant. Participants were asked to test the following functionalities to provide feedback, paying particular attention to the technical performance of the digital solution; free walking mode, guided walking mode, face recognition. They were also asked about the dialogues, responsiveness and speed of the robot and the screen structure.

### 3.8.5 Results of the Small-Scale Live Demonstration

After the total four sessions, individual face-to-face interviews were conducted to collect feedback from participants. The results are shown in Table 35 and Table 36.

*Table 39 10-Point Likert Scale to collect feedback about technical aspects*

| Participant | Responsiveness | Speed | Dialogues | Screen structure | Overall satisfaction | TOTAL |
|---|---|---|---|---|---|---|
| **P1** | 7 | 7 | 8 | 8 | 8 | 7.6 |
| **P2** | 7 | 7 | 9 | 7 | 7 | 7.4 |

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| | | | | | | |
|---|---|---|---|---|---|---|
| **TOTAL** | 7 | 7 | 8.5 | 7.5 | 7.5 | **7.5** |

*Table 40 10-Point Likert Scale to collect feedback about functionalities*

| Participant | Free walking mode | Guided walking mode | Face recognition | TOTAL |
|---|---|---|---|---|
| **P1** | 7 | 8 | 8 | 7.66 |
| **P2** | 7 | 7 | 8 | 7.5 |
| **TOTAL** | 7 | 7.5 | 8 | **7.58** |

From the two previous tables it's possible to see that the overall satisfaction with the technology and the performance of the different functionalities are quite positive, being 7.5 out of 10.

Table 37 shows the results of TAM and SUS questionnaires.

*Table 41 Trust, acceptance and self-perceived usability of Phase 4 participants*

| Participant | TAM (21) | SUS (100) |
|---|---|---|
| **Participant 1** | 16 | 70 |
| **Participant 2** | 13 | 67.5 |
| **TOTAL (mean/sd)** | 14.5 (2.12) | 68.75 (1.77) |

Table 38 shows the results of UEQ-S questionnaire.

*Table 42 UEQ-S for Phase 4 participants in relation to existing values from a benchmark data set*

| Scale | Mean | Comparison to benchmark | Interpretation |
|---|---|---|---|
| **Pragmatic Quality** | 1,00 | Below average | 50% of results better, 25% of results worse |

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| | | | |
|---|---|---|---|
| **Hedonic Quality** | 1.63 | Excellent | In the range of the 10% best results |
| **Overall** | 1.31 | Good | 10% of results better, 75% of results worse |

Table 39 gathers some quotations from Phase 4 participants.

*Table 43 Feedback from Phase 4 participants in an open interview*

| Participant | Quotation |
|---|---|
| **Participant 1** | I like the idea of a robot that supports older adults with walking. Most of all, I think it is a powerful motivation tool. However, the functioning of the robot should be more adapted to people in a rehabilitation process. For instance, they should have the option to sit down and the stop button should be closer to the person as they are not agile with movements." |
| **Participant 2** | "I love the aesthetics of the robot and I find it interesting but the robot has a lot of space limitations and in not too big spaces the turns become quite difficult. This should be improved because some people may live in small apartments." |

After Phase 4, CH research team analysed the data collected from participants and developed a technical report, which was sent to KOMPAÏ, VICOM and TREE technical teams. Moreover, a technical meeting was held to discuss the results of Phase 4 and take the proper action before Phase 5. Nevertheless, some of the suggestions proposed by participants had already been discussed in earlier phases but most suggestions entailed changes that were not feasible within the project framework.

## 3.9 Phase 5: Large-scale pilot activity

In Phase 5, a non-randomised, single-armed, cross-sectional interventional pilot study with an optional qualitative interview component was conducted. The pilot was planned to be leaded by CH and replicated by SAL and AUTH. As explained, CH was not able to perform Phase 5 but it continued leading the use case.

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**Hypothesis:** This study will test the hypothesis that the KOMPAÏ robot is capable of providing opportunities for supporting the gait rehabilitation process of older patients and is accepted and perceived as useful for patients and health professionals.

**Objectives**

*Primary objectives*

- To explore user trust and acceptance of the novel system (PO1).
- To investigate user engagement with the novel system (PO2).
- To investigate the user-perceived usability of the novel system (PO3)

*Secondary objectives*

- To investigate the capability of the novel system to optimise the gait rehabilitation process (SO1).
- To investigate the capability of the novel system to improve the management of gait rehabilitation process for health professionals (SO2).
- To investigate the capability of the novel system to improve older individual's quality of life, wellbeing and psychological and psychosocial aspects (SO3).
- To explore the integration of the novel system to align with current care pathways (SO4).
- To improve the facial recognition algorithm (SO5).
- To improve the emotion recognition algorithm (SO6).
- To determine the correlation between the detected emotions and the development of the gait exercises (SO7).
- To study the ability of the new system to quantify the improvement of gait rehabilitation (SO8).

*Tertiary objectives*

- The following objectives align with the general purposes of the SHAPES large-scale piloting campaign:
- To validate the capability of the SHAPES Platform and Digital Solutions to support and extend healthy and independent living for older individuals who are facing permanently or temporarily reduced functionality and capabilities (TO1).
- To validate the capability of the SHAPES Platform and Digital Solutions to improve the older individuals' health outcomes and quality of life (TO2).
- To validate the capability of the SHAPES Platform and Digital Solutions to gain the older individuals' trust and acceptance (TO3).
- To validate the capability of the SHAPES Platform and Digital Solutions to gain the care professionals' trust and acceptance (TO4).
- To validate the capability of the SHAPES Platform and Digital Solutions to contribute for the reduction of the workload of medical professionals (TO5).

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- To validate the capability of the SHAPES Platform and Digital Solutions to deliver efficiency gains in health and care delivery across Europe (TO6).

### 3.9.1 Recruitment

#### *3.9.1.1 Inclusion and Exclusion criteria*

The inclusion and exclusion criteria were the same for the leading and replicating sites.

The inclusion criteria:

- Participants aged 65 or older.
- Participants able to provide informed consent.
- Participants able to perform basic daily activities independently.
- Participants able to communicate effectively in the language of the study.

The exclusion criteria:

- Participants with severe cognitive impairment.
- Participants with severe visual or hearing impairment.
- Participants with severe mobility issues that would prevent them from participating in the study activities.

#### *3.9.1.2 Sample size*

The target sample size for Phase 5 was 10 older adults and 1 or 2 professionals at CH and SAL. As explained, the pilot activities could not be carried out at CH but "El Salvador" Nursing Home (SAL) did replicate the use case with the participation of 10 older adults so from now on, we are going to focus on the replication by SAL.

Five (5) participants and four (4) healthcare professionals supporting the session were recruited in AUTH to participate in the pilot activities.

Table 41 gathers sociodemographic data of UC-PT6-002 participants at SAL.

*Table 44 Sociodemographic data of UC-PT6-002 participants at SAL*

| Variable | USER ID | | | | | | | | | | Mean (SD) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |
| Age | 89 | 82 | 79 | 85 | 86 | 86 | 59 | 72 | 85 | 84 | 80.7 (8.97) |
| Gender | F | M | F | M | F | F | F | M | F | M | 60% F |

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| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | 40% M |
| Level of studies (years) | 7 | 7 | 1 | 6 | 5 | 2 | 11 | 1 | 12 | 3 | 5.5 (3.89) |

## REPLICATION AT AUTH

*Sample size:* The target sample size for phase 5 included five (5) participants and four (4) healthcare professionals. Table 42 gathers sociodemographic data of UC-PT6-002 participants at AUTH.

*Duration of the pilot: 1 month*

*Table 45 Sociodemographic data of UC-PT6-002 participants at AUTH*

| **Demographics** | | |
|---|---|---|
| | **AUTH (*N*=5)** | |
| **Age** (years) mean(sd) | 63.40 (±10.21) | |
| **Gender** | 60% Male<br>40% Female | |
| **Level of education** | 60% Upper secondary school certificate<br>20% Vocational training Institute Certificate<br>20% Primary school certificate or Lower secondary school certificate | |
| **Marital status** | 40% Married<br>20% Single<br>20% Widows<br>20% Divorced | |
| **Level of Digital Literacy** | 60% Intermediate Users<br>40% Basic Users | |
| **Country of residence** | 100% Greece | |
| **Occupational status** | 60% Employed<br>40% Retired | |
| | **Pre** | **Post** |
| **Health Literacy (How confident are you filling out medical forms by yourself?)** | Extremely – 60% (n=3)<br>Quite a bit 20% (n=1)<br>A little bit 20% (n=1) | Extremely – 60% (n=3)<br>Quite a bit 20% (n=1)<br>A little bit 20% (n=1) |

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| | |
|---|---|
| **Are you a caregiver?** | 80% No<br>20% Yes - full time |
| **Do you receive help from a family member or friend for daily activities?** | 80% Never<br>20% Often |
| **Do you receive help from a caregiver, health professional, or support service for daily activities?** | 80% Never<br>20% Often |
| **Residence (Where do you live currently?)** | 100% Own home |
| **Do you live alone?** | 100% No |
| **Is your neighbourhood...?** | 40% Rural<br>40% Urban<br>20% Suburban |

#### *3.9.1.3 Duration of the pilot*

Phase 5 at SAL had a duration of 2 weeks (15/05/2023 to 28/05/2023).

The large-scale pilot activities in AUTH had a duration of 4 weeks and were conducted during June hand July 2023.

#### *3.9.1.4 Methods*

The recruitment process was conducted in collaboration with local community organizations and healthcare providers. Potential participants were identified through these networks and contacted by the study team. The study team provided potential participants with information about the study and invite them to participate through informed consent. If the potential participant was interested, the study team conducted a screening process to determine if they met the inclusion criteria.

AUTH participants' recruitment has been actualized within the network of the Thessaloniki Action for HeAlth & Wellbeing Living Lab – Thess-AHALL Living Lab Living Lab: including municipalities and public entities, hospitals, rehabilitation centres and nursing homes as well as a great number of individuals/beneficiaries. Both direct and indirect recruitment strategies have been implied, where members of the AUTH research team were responsible for the identification, approach and selection of participants, who are eligible for participating in the study based on the inclusion criteria. The AUTH research team screened potentially eligible participants and

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recruited those eligible according to the inclusion criteria. Information sheets and consent forms have been distributed among all participants, in order to inform them about the scope of the study. All participants' questions as well as any misunderstandings that may arise have been clarified and adequately addressed. Participants have been informed that they could withdraw from the pilot activity at any time.

#### *3.9.1.5 Adherence rate*

The research team initially contacted 15 participants who live or participate in activities at the "El Salvador" Senior Residence in Pedroche (Córdoba, Spain). From these, 10 were included in the study, resulting in an inclusion rate of 66.67% (see Table 43). This rate represents the ratio between the number of participants included in the study and the total number of people contacted.

However, not all contacted individuals agreed to participate. 1 individual declined to participate, resulting in a rejection rate of 6.67%. Additionally, 4 individuals were excluded for not meeting the inclusion criteria, leading to an exclusion rate of 26.67%.

Out of the 10 participants who completed the initial evaluation, no one dropped out of the study, resulting in a dropout rate of 0%. 10 participants completed the final evaluation, leading to a retention rate of 100%. This rate represents the ratio between the number of participants who completed the final evaluation and the number who completed the initial evaluation.

These rates provide valuable insights into the adherence to the study and can inform strategies for improving participation and retention in future studies.

AUTH research team initially contacted 8 participants who accepted to participate in the pilot activities. Out of the 8 participants who completed the initial evaluation, three dropped out of the study, resulting in a dropout rate of 37,5%. This rate represents the ratio between the number of participants who completed the final evaluation and the number who completed the initial evaluation.

These rates provide valuable insights into the adherence to the study and can inform strategies for improving participation and retention in future studies.

*Table 46 Adherence rates of UC-PT6-002*

| | | AUTH |
|---|---|---|
| **Inclusion rate** | The ratio between the number of participants included in the study and the total number of people contacted. | 100% |

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| | | |
|---|---|---|
| **Rejection rate** | The ratio between the number of subjects who refused to participate in the study and the number of subjects contacted. | 0% |
| **Exclusion rate** | The ratio between the number of individuals excluded for not meeting the inclusion criteria and the total number of individuals contacted. | 0% |
| **Dropout rate** | The ratio between the number of participants who dropped out of the study and the number of participants who completed the baseline assessment. | 37,5% |
| **Retention rate** | The ratio between the number of participants who completed the final assessment and the number of participants who completed the initial assessment. | 62,5% |
| **Retention rate of Intervention** | The ratio between the number of participants who completed the final assessment after the intervention and the number of participants who completed the initial assessment. | 62,5% |

#### *3.9.1.6 Intervention*

Walking rehabilitation sessions with the KOMPAÏ robot were performed 2 or 3 times per week. Each session consisted of a forward journey of 44 meters and a return journey of 44 meters. The following number of sessions were conducted per participant:

- User 1: 6 sessions
- User 2: 5 sessions
- User 3: 5 sessions

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- User 4: 5 sessions
- User 5: 5 sessions
- User 6: 5 sessions
- User 7: 5 sessions
- User 8: 5 sessions
- User 9: 4 sessions
- User 10: 5 sessions

Regarding the training of participants, a preliminary test session was conducted with each user to perform facial recognition for login and to conduct a walking session.

Then, the following activities were performed:

- Baseline:
  - Harmonised questionnaires
  - Berg
  - 10 meters test
- End of pilot:
  - Harmonised questionnaires
  - Berg
  - 10 meters test
  - Final interview

Two professionals were involved: a physiotherapist with a bachelor's degree in physiotherapy and 7 and a half years of experience, and a physiotherapist with a diploma in physiotherapy and 19 years of experience.

**REPLICATION IN AUTH**

During Phase 5 at AUTH participants underwent 10 sessions, 3 times per week including walking rehabilitation sessions with the KOMPAÏ robot during a 1-month period. To ensure the participants received comprehensive support and guidance during their interactions with the robot, four (4) healthcare professionals actively participated in the training sessions.

To provide a progressive and challenging experience, technical partners developed four different walking routes with the KOMPAÏ robot. Each route was designed with increasing levels of difficulty, serving as milestones for the participants' rehabilitation journey. The walking routes included options for 1 round, 3 rounds, 6 rounds, and 10 rounds, allowing participants to gradually advance and improve their walking abilities. Throughout the intervention, the participants had the opportunity to engage with each of the four walking routes progressively. This approach allowed them to build upon their achievements and gradually adapt to more demanding challenges, ultimately fostering better rehabilitation outcomes.

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### 3.9.2 Roles and responsibilities

The CH research team was responsible for the coordination of the piloting activities at the replication sites. CH hosted periodic meetings with all stakeholders to ensure the proper implementation of Phase 5, following the study protocol and use case guidelines.

The AUTH research team working on the SHAPES project was responsible for recruiting and collecting participants' consent to participate in the pilot activities. In addition, the AUTH team received training on interacting with the KOMPAI robot from technical leaders and acted as the single point of contact for the participants. Technical support was also offered, including assistance in resolving technical problems, such as log-in or accessibility issues during the interaction with the hardware and software of the Phyx.io platform. Consulting guidance was focused on the older adults' interaction with the digital solution and their overall experience, aiming to gain the best possible social benefit and maintain friendly and supportive communication.

### 3.9.3 Ethical considerations

Approval from local Ethics Committee (Comitè d'Ètica de la Investigació de les Illes Balears, CE-IB) was not granted since this institution requested the KOMPAÏ's robot to be certified as a medical product to allow the implementation of the piloting activities. The list of actions taken are listed hereafter:

- April 2022: The Ethics Protocol for UC-PT6-002 was submitted to the Balearic Islands Ethics Committee, along with all the documentation requested.
- July 2022: A formal request for amendments was received where the Ethics Committee stated the following: *"After consulting the AEMPS (Spanish Agency of Medicines and Medical Products), it is necessary to consider conducting a study with a medical device, and therefore, it should be submitted as such, with the relevant documentation."*
- July 2022: CH research team made an inquiry to the Spanish Agency of Medicines and Medical Products (AEMPS) regarding whether UC-PT6-002 should be considered a study involving a medical product, providing the detailed study protocol to the AEMPS.
- July 2022: The AEMPS provided the following response the CH inquiry:

*Medical products have been regulated since May 26, 2021, by Regulation 2017/745 on medical products. In this regulation, they are defined as:*

*"Medical product": any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used,*

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*alone or in combination, for human beings, for one or more of the following specific medical purposes:*

- *diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation, or compensation for an injury or disability,*
- *investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state,*
- *obtaining information by examining samples derived from the human body, including organs, blood, and tissues, in vitro, and which does not achieve its principal intended action on or in the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.*

*The following products shall also be deemed to be medical devices:*

- *products for the control or support of conception,*
- *products specifically intended for cleaning, disinfection, or sterilization of the products covered by Article 1(4) and the first paragraph of this point.*

- August 2022: Reply to the Balearic Islands Ethics Committee:

*Based on the response from the AEMPS, specifically the quote "instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used [...] for one or more of the following specific medical purposes," the KOMPAÏ robot used in this study is not a medical product as it does not have a medical purpose in this UC-PT6-002. The purpose of this study, as emphasized in the project title itself, is the evaluation of user participation and perceived usefulness. The aim is to determine whether this product is perceived positively by both older adults and professionals.*

*The opinions and recommendations of participants after using this product in the current study will enable the future development of a solution better suited to the needs and preferences of the target population.*

*After analyzing the results of the research study, consideration will be given to further developing this product in the future and validating a higher Technology Readiness Level (TRL) where the efficiency of the technology itself will be studied.*

*Based on the above, we kindly request this Committee to consider the present study under the category of "Research Project" instead of "Clinical research with medical products".*

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- November 2022: Another formal request for amendments was received where the Ethics Committee stated the following:

  *This Committee agrees to request the sponsor to provide the following clarifications:*

  - *It is a study where "participants' opinions and recommendations after using this product" are evaluated, considered a medical product.*
  - *The study's title refers to "its application as a mobility support for rehabilitation," implying that the use of the robot, considered a medical product, serves a medical purpose in accordance with the AEMPS.*
  - *It should be assessed as a medical product; therefore, the submission should include the CE marking and notification to the AEMPS.*

Despite the extended explanation provided by CH arguing that the main purpose of the robot was to evaluate the level of acceptance of the technology by older adults' participants, instead of evaluating its clinical effectiveness, it was not possible to get the ethics approval and therefore, CH was not allowed to perform Phase 5 as planned.

A plan was discussed with the WP6 coordinator, the use case coordinator, the technical partners and the replicating sites. It was agreed that CH would continue leading the piloting activities even if Phase 5 was not possible at CH and the replicating sites would proceed to Phase 5 as planned.

By the time, all the ethical documentation was developed and complete, including the study protocol, information sheets, consent forms, the Data Protection Impact Assessment (including the data risk assessment) and the Data Processing Agreements. This documentation was shared with the replication sites to facilitate the implementation of the piloting activities.

In case of CH, a folder containing hard originals and copies of documents related to the use case, including consent forms and filled questionnaires, will be retained in a locked office pedestal located CH (Palma de Mallorca, Balearic Islands). In addition, an electronic copy of the documents and the participants list (linking the participants' names to their pseudonymised SHAPES ID) will be retained by approved CH staff working on the SHAPES study and stored securely on CH servers protected by the CH firewall. Only CH staff authorised to work on the SHAPES project will have access to identifiable pseudonymized documents.

In the case of UCLM/SAL, the informed consent procedure was followed during Phase 5, to ensure that the participants understood the purpose of the study, the procedures involved, and their rights as participants. The necessary approvals were obtained from the Ethical Committee (Social Pannel) of the University of Castilla-La Mancha as well as the Data and Privacy Impact Assessment to ensure that the data collected was

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handled in a secure and confidential manner. The Oroface and Phyx.io platforms will be designed to collect only the necessary data and to store and transmit this data in a secure manner. The privacy rights of the participants will be always respected.

In the case of AUTH, information sheets and consent forms have been distributed among all participants to inform participants about the scope of the study. All participants' questions as well as any misunderstandings that may have emerged have been clarified and adequately addressed. A participant can leave a research study at any time. When withdrawing from the study, the participant should let the research team know that he/she wishes to withdraw. A participant may provide the research team with the reason(s) for leaving the study but is not required to provide their reason. In addition, Data Protection Impact Assessment (DPIA), Data Processing Agreement (DPA) and Data Sharing Agreement (DSA) have been developed by the AUTH team, approved by the AUTH DPO and were submitted for approval along with the bioethics documents in the Ethics Committee of the Aristotle University of Thessaloniki. A folder containing hard originals and copies of documents related to the use case, including consent forms and filled questionnaires, is retained in a locked office pedestal located at the Lab of Medical Physics and Digital Innovation, School of Medicine, Aristotle University of Thessaloniki (University Campus, Thessaloniki, Greece). In addition, an electronic copy of the documents along with the participants list (linking the participants' name to their pseudonymised SHAPES ID) is retained by approved AUTH staff working on the SHAPES study and stored securely on AUTH servers protected by the AUTH firewall. Only AUTH staff authorised to work on the SHAPES project will have access to identifiable pseudonymized documents.

### 3.9.4 Communication and dissemination of pilot activities

Any data that arise from the pilot study is owned by the CH, SAL and AUTH, respectively. On completion of the study, all data has been analysed and tabulated and used to prepare a final report included in the present Deliverable 6.7. This deliverable (and all other agreed deliverables) will be available to the public for review and accessible via the SHAPES website (www.shapes2020.eu). Participants will be notified of the outcome of the study. The leading and replicating pilot sites will seek to disseminate the findings from this study at conferences and in the scientific literature. As per the SHAPES Publication Protocol, all publications arising from this study will reflect the range of effort that has made them possible; including conceptualisation of the research project and research task, methodology development, data collection and analysis, interpretation and discussion of results; as well as project management. Any publications will be read and meaningfully contributed to by all named authors. The leading and replicating pilot sites will also seek to communicate the findings of this study via social media, and in other, non-peer reviewed, media outlets. Participating SHAPES partners will have the rights to use data from this study in their own analysis and dissemination plans.

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### 3.9.5 Risk management

All foreseeable data-related risks have been compiled into detailed risk assessment documents, part of the Data Protection Impact Assessments for Phase 5 PT6-002. First, a risk classification, root cause, name, and consequences were assigned for each risk identified. Once identified, each risk was then analysed and attributed a score from 1 (unlikely/minor) to 4 (almost specific/critical) for probability and impact. Subsequently, appropriate mitigation actions were assigned and a reasonable person responsible was identified. These risks were reviewed periodically, and these documents have been updated along all the study's phases to include all new identified risks.

In addition to data risks, a potential threat to participants due to the unlikely occurrence of a device malfunction was also identified and mitigation actions were put in place. However, there has been no need to implement those actions as no undesirable events compromising participants' integrity have occurred during the piloting activities.

### 3.9.6 Outcome of large-scale pilot activity

In relation to at least one primary objective (related objectives in brackets):

- O1. Notes taken at an interview with older adults at the end of the use of the novel system (PO1, PO2, PO3).
- O2. Technology Acceptance Model (TAM) questionnaire (PO2, TO3, TO4).
- O3. System Usability Scale (SUS) (PO3, TO5, TO6).

In relation to the secondary and tertiary objectives (related objectives in brackets):

- O4. The following questionnaires: Berg Balance Scale, Tinetti Test,10m Walk Test, Open interview with older person (SO1, SO2, SO3, SO4, SO8).
- O5. Facial recognition outcomes (SO5).
- O6. Emotion recognition outcomes (SO6, SO7).
- O7. The following questionnaires: WHOQOL-BREF, EQ-5D-5L, GSES, OSSS-3, SHAPES participation questions (TO1, TO2).

In order to relate objectives to socio-demographics of users (older persons):

- O8. 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

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(urban/rural); residence type (own home/caregiver's home/long-term care facility/other); co-living with someone (yes/no); country.

- O9. SHAPES health literature measure

In order enable login process in the novel system:

- O10. User (non-identifiable) and password.
- O11. Name, telephone number, email

### 3.9.7 Results of large-scale pilot activity

Primary outcomes focused on the user engagement, acceptability and user-perceived usability of the KOMPAÏ's robot. Table 44 gathers older adults' answers to the end of pilot interview.

*Table 47 Interview to Phase 5 participants from SAL*

| User | How was your experience with the gait rehabilitation robot? | What has changed in your daily routine with the introduction of the gait rehabilitation robot? | In your opinion, what are the strengths of using the gait rehabilitation robot and the proposed walking sessions? | In your opinion, what are the weaknesses of using the gait rehabilitation robot and the proposed walking sessions? | Did you notice any impact from the intervention with the robot? If so, what impact did it have? |
|---|---|---|---|---|---|
| **1** | The first time was complicated and then, with the support of a professional, I was able to do better. | I was feeling more confident when walking because the robot guided me. | I like the fact that the user can choose the speed of the robot. | Sometimes the robot would get too close to walls or doors and was difficult to operate. | Yes, more self-confident while walking because the robot provided gait support. |
| **2** | The experience was good. | Nothing changed. | It helps people that have difficulties walking. | The robot sometimes stopped for no reason or it turned earlier | No impact. |

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| | | | | | |
|---|---|---|---|---|---|
| | | | | than it supposed. | |
| **3** | The experience was good. | Nothing changed. | I like the option to adjust the speed. | The indications were not always clear and someone have to be near the robot because it gets close to walls. | It did have no impact. |
| **4** | It was all right. | Nothing changed. | I think the robot might be a good motivation to walk for some people. | Sometimes I didn't understand what I had to do. | I didn't notice any impact. |
| **5** | My experience was good and without complications. | Nothing changed. | I don't know. | I don't think it is well adapted to older adults. | It did have no impact. |
| **6** | My experience was not good. | Nothing changed. | I don't know. | I didn't understand what I had to do. | I don't recall any impact. |
| **7** | My experience was good. | Nothing really changed but I like the purpose of the robot of | I like that the user can choose the speed. Moreover, when the robot | It gets too close to walls and doors. | No impact in my case. |

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| | | | | | |
|---|---|---|---|---|---|
| | | supporting gait. | detects someone or you are not in the right position, it informs you. | | |
| **8** | My experience was good. | Nothing changed. | I like the fact that the robot provides instructions and directions. | I don't recall any weaknesses. | It didn't have any impact. |
| **9** | It was a good experience. | Nothing changed in my routine. | It helps me distract myself and it's enjoyable. | It gets very close to walls. | No impact. |
| **10** | The experience using the robot was good. | Nothing changed but I like the robot. | I think the aid with walking is very useful. | I didn't notice any weakness. | I didn't notice any impact in my case. |

Table 45 gathers the results of the TAM questionnaire from older adults.

*Table 48 TAM results*

| TAM | USER ID | | | | | | | | | | Mean (SD) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |
| This technology is useful to me | 4 | 4 | 4 | 3 | 3 | 1 | 5 | 4 | 3 | 4 | **3.5 (1.02)** |
| If this technology was available to me in future, I would use it | 4 | 4 | 4 | 2 | 4 | 1 | 5 | 4 | 4 | 4 | **3.6 (1.11)** |

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| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **RESULT** | **8** | **8** | **8** | **5** | **7** | **2** | **10** | **8** | **7** | **8** | **7.1 (2.07)** |

***Strongly disagree=1,*** *Disagree=2,* ***Neither disagree nor agree=3,*** *Agree=4,* ***Strongly agree=5***

**Comments from users in relation to the TAM questions:**

- **User 1:** I use it but I always need company. I couldn't hear what the robot said so I relied on the arrows on the screen.
- **User 2:** The robot helps me walking and I adapt myself well to the walking speed.
- **User 3:** I need support from someone to use the robot.
- **User 4:** The robot is easy to operate but its utility depends on the mentality of the person.
- **User 5:** I am not sure whether this tool will be able to help or not people in the future. To set the robot is necessary to have someone that knows how to do it.
- **User 6:** I had difficulties to follow the speed and adapt my gait. I don't think the robot is useful.
- **User 7:** The robot gets very close to doors and walls. It was necessary to set the speed and choose the route before doing the exercise.
- **User 8:** I like it and it is easy to use. It is important to control your feet to perform the exercises properly.
- **User 9:** It gets very close to walls and doors. I like to use it but I don't find it an essential tool.
- **User 10:** The robot is all right but the support of someone is required to use it.

Table 46 and Table 47 gather the results of the usability scale from both older adults' participants and HCPs.

*Table 49 SUS results (older adults)*

| SUS | USER ID | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** |
| SUS1: I think that I would like to use this technology frequently | 5 | 5 | 5 | 5 | 4 | 1 | 5 | 5 | 4 | 4 |
| SUS2: I found this technology unnecessarily complex | 2 | 1 | 1 | 2 | 2 | 5 | 1 | 1 | 2 | 1 |

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| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| SUS3: I thought this technology was easy to use | 5 | 5 | 5 | 4 | 5 | 1 | 5 | 5 | 5 | 5 |
| SUS4: I think that I would need the support of a technical person to be able to use this technology | 5 | 4 | 5 | 4 | 2 | 5 | 3 | 5 | 5 | 5 |
| SUS5: I found the various functions in this technology were well integrated | 4 | 5 | 5 | 3 | 4 | 1 | 5 | 5 | 4 | 4 |
| SUS6: I thought there was too much inconsistency in this technology | 2 | 2 | 1 | 2 | 1 | 5 | 4 | 2 | 4 | 2 |
| SUS7: I would imagine that most people would learn to use this technology very quickly | 3 | 3 | 3 | 3 | 1 | 3 | 4 | 2 | 3 | 3 |
| SUS8: I found this technology very cumbersome (awkward) to use | 4 | 1 | 2 | 2 | 2 | 4 | 1 | 2 | 2 | 3 |
| SUS9: I felt very confident using this technology | 5 | 5 | 5 | 4 | 5 | 2 | 5 | 5 | 5 | 4 |
| SUS10: I needed to learn a lot of things before I could get going with this technology | 4 | 1 | 5 | 3 | 1 | 4 | 1 | 1 | 1 | 2 |
| **Result** | **62.5** | **85** | **72.5** | **65** | **77.5** | **12.5** | **85** | **77.5** | **67.5** | **67.5** |
| **Mean (SD)** | **67.25 (20.8)** | | | | | | | | | |

***Strongly disagree=1,*** *Disagree=2,* ***Neither agree nor disagree=3,*** *Agree=4,* ***Strongly agree=5***

*Table 50 SUS results (HCPs)*

| SUS | USER ID | |
|---|---|---|
| | 1 | 2 |

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| | | |
|---|---|---|
| SUS1: I think that I would like to use this technology frequently | 4 | 4 |
| SUS2: I found this technology unnecessarily complex | 2 | 3 |
| SUS3: I thought this technology was easy to use | 3 | 3 |
| SUS4: I think that I would need the support of a technical person to be able to use this technology | 3 | 3 |
| SUS5: I found the various functions in this technology were well integrated | 4 | 4 |
| SUS6: I thought there was too much inconsistency in this technology | 1 | 2 |
| SUS7: I would imagine that most people would learn to use this technology very quickly | 3 | 3 |
| SUS8: I found this technology very cumbersome (awkward) to use | 2 | 3 |
| SUS9: I felt very confident using this technology | 4 | 3 |
| SUS10: I needed to learn a lot of things before I could get going with this technology | 2 | 3 |
| **Result** | **70** | **57.5** |
| **Mean (SD)** | **63.75 (8.84)** | |

Secondary and tertiary outcomes focused on the effectiveness of the novel system to assist older adults in the gait rehabilitation process. The following measures were taken at baseline and at the end of the pilot.

- **Berg Balance Scale:** is used to objectively determine a patient's ability (or inability) to safely balance during a series of predetermined tasks The test consists of 14 predetermined tasks, each of which are scored on a scale from 0 to 4. The higher the score, the better your balance. The punctuation ranges from 0 to 56. Results are shown in Table 48.

*Table 51 Berg Balance Scale Results*

| | **Berg Balance Scale Results** |
|---|---|

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| User | Baseline | End of pilot | Difference (%) |
|---|---|---|---|
| **1** | 33 | 39 | +18.18% |
| **2** | 55 | 55 | 0% |
| **3** | 31 | 30 | -3.23% |
| **4** | 48 | 53 | +10.42 |
| **5** | 44 | 40 | -9.09% |
| **6** | 45 | 48 | +6.67% |
| **7** | 55 | 56 | +1.82% |
| **8** | 51 | 53 | +3.92% |
| **9** | 46 | 53 | +15.22% |
| **10** | 56 | 56 | 0% |
| **Mean (SD)** | **46.4 (8.75)** | **48.3 (8.94)** | **+4.39% (0.08)** |

Comparing the Berg Balance Scale results at baseline and at the end of the pilot, we can conclude that the overall balance of older adults increased 4.39% on average during the intervention.

- **Tinetti Test:** assesses a person's perception of balance and stability during activities of daily living and their fear of falling. It is a very good indicator of the fall risk of an individual. The Tinetti test has a gait score and a balance score. It uses a 3-point ordinal scale of 0, 1 and 2. Gait is scored over 12 and balance is scored over 16 totalling 28. The lower the score on the Tinetti test, the higher the risk of falling. A score of 18 or lower indicates a high risk of falling, a score between 19 and 23 indicates a moderate risk and a score of 24 or higher indicates a low risk. The results are shown in Table 49.

*Table 52 Tineti Test Results*

| User | Tineti Test Results | | | | | | |
|---|---|---|---|---|---|---|---|
| | Baseline | | | End of pilot | | | Total difference (%) |
| | Gait | Balance | Total | Gait | Balance | Total | |
| **1** | 8 | 15 | 23 | 8 | 15 | 23 | 0% |

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| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **2** | 12 | 16 | 28 | 12 | 16 | 28 | 0% |
| **3** | 9 | 13 | 22 | 9 | 13 | 22 | 0% |
| **4** | 12 | 16 | 28 | 12 | 16 | 28 | 0% |
| **5** | 8 | 16 | 24 | 8 | 16 | 24 | 0% |
| **6** | 12 | 13 | 25 | 12 | 13 | 25 | 0% |
| **7** | 9 | 14 | 23 | 9 | 14 | 23 | 0% |
| **8** | 12 | 16 | 28 | 12 | 16 | 28 | 0% |
| **9** | 12 | 16 | 28 | 12 | 16 | 28 | 0% |
| **10** | 12 | 16 | 28 | 12 | 16 | 28 | 0% |
| **Mean (SD)** | **10.6 (1.84)** | **15.1 (1.29)** | **25.7 (2.54)** | **10.6 (1.84)** | **15.1 (1.29)** | **25.7 (2.54)** | **0%** |

The results of the Tinetti Test at baseline and at the end of the pilot are the same for every older adult which means that the risk of falling (measured with the present tool) didn't change during the intervention.

- **10m Walk Test:** is a performance measure used to assess walking speed in meters per second over a short distance. It can be employed to determine functional mobility, gait, and vestibular function. The results are shown in Table 50.

*Table 53 10 meters Walk Test Results*

| **User** | **10m Walk Test Results** | | | | | |
|---|---|---|---|---|---|---|
| | **Baseline** | | **End of pilot** | | | |
| | **Time to walk 10 meters** | **Speed (m/s)** | **Time to walk 10 meters** | **Speed (m/s)** | **Difference time (%)** | **Difference speed (%)** |
| **1** | 15,85 | 0,63 | 14,02 | 0,71 | -11,55% | 13,05% |
| **2** | 6,8 | 1,47 | 5,9 | 1,69 | -13,24% | 15,25% |
| **3** | 12,99 | 0,77 | 13,5 | 0,74 | 3,93% | -3,78% |
| **4** | 10,68 | 0,94 | 9,42 | 1,06 | -11,80% | 13,38% |

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| | | | | | | |
|---|---|---|---|---|---|---|
| **5** | 12,42 | 0,80 | 12,14 | 0,80 | -2,25% | 0,00% |
| **6** | 9,22 | 1,08 | 9,3 | 1,08 | 0,87% | -0,86% |
| **7** | 8,66 | 1,15 | 8,26 | 1,21 | -4,62% | 4,84% |
| **8** | 8,08 | 1,24 | 7,32 | 1,37 | -9,41% | 10,38% |
| **9** | 11,28 | 0,89 | 9,51 | 1,05 | -15,69% | 18,61% |
| **10** | 7,57 | 1,32 | 6,00 | 1,67 | -20,74% | 26,17% |
| **Mean (SD)** | **10.36 (2.83)** | **1.03 (0.27)** | **9.54 (2.89)** | **1.14 (0.35)** | **-8.45% (7.75)** | **9.70% (9.53)** |

Comparing the 10 meters Walk Test results at baseline and at the end of the pilot, we can conclude that older adults decreased the time to walk 10 meters in 8.45% and increased the speed in 9.70%, on average during the intervention.

In order to validate the capability of the SHAPES Platform and Digital Solutions to support and extend healthy and independent living for older individuals who are facing permanently or temporarily reduced functionality and capabilities the capability to improve the older individuals' health outcomes and quality of life, the following questionnaires were used: WHOQOL-BREF, EQ-5D-5L, GSES, OSSS-3, SHAPES participation questions.

Table 51 shows the aggregated results of WHOQOL-BREF, EQ-5D-5L, GSES and OSSS-3.

*Table 54 Quality of life and social aggregated data for participants (older adults) in Phase 5*

| **Quality of life and social support questionnaires (*N*=10)** | | |
|---|---|---|
| | **Baseline Mean (SD)** | **End of pilot Mean (SD)** |
| **Quality of life and social support** | | |
| WHOQOL-Bref (0-100) | 73.29 (4.64) | 73.92 (8.05) |
| Health related quality of life - EQ-5D-5L (5-25) | 8.20 (1.99) | 9.10 (2.64) |
| Self-efficacy GSE (10-40) | 27.50 (3.21) | 30.30 (2.75) |

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| | | |
|---|---|---|
| Social Function OSSS-3 (3-14) | 12.90 (1.60) | 12.2 (1.32) |

Table 52 shows the individual results of WHOQOL-BREF, EQ-5D-5L, GSES and OSSS-3.

*Table 55 Quality of life and social individual data for participants (older adults) in Phase 5*

| | WHOQOL-Bref (0-100) | | EQ - 5D - 5L (5-25) | | Self-efficacy GSE (10-40) | | Social Function OSSS-3 (3-14) | |
|---|---|---|---|---|---|---|---|---|
| | BL | EP | BL | EP | BL | EP | BL | EP |
| **P1** | 74.52 | 84.05 | 8 | 9 | 30 | 33 | 14 | 14 |
| **P2** | 72.32 | 73.90 | 6 | 5 | 23 | 30 | 12 | 12 |
| **P3** | 79.17 | 73.51 | 10 | 12 | 29 | 31 | 9 | 14 |
| **P4** | 75.95 | 68.51 | 7 | 10 | 30 | 30 | 14 | 12 |
| **P5** | 74.40 | 61.28 | 12 | 14 | 26 | 29 | 13 | 11 |
| **P6** | 70.12 | 87.08 | 9 | 10 | 28 | 31 | 13 | 11 |
| **P7** | 75.00 | 71.22 | 10 | 9 | 30 | 34 | 14 | 14 |
| **P8** | 75.83 | 74.64 | 6 | 6 | 30 | 32 | 14 | 12 |
| **P9** | 73.69 | 65.24 | 7 | 8 | 28 | 29 | 14 | 11 |
| **P10** | 61.93 | 79.79 | 7 | 8 | 21 | 24 | 12 | 11 |
| **RESULT** | **73.29 (4.64)** | **73.92 (8.05)** | **8.20 (1.99)** | **9.10 (2.64)** | **27.50 (3.21)** | **30.30 (2.75)** | **12.90 (1.60)** | **12.20 (1.32)** |

*Baseline - BL | End of pilot evaluation (post intervention) - EP

Table 53 shows the answers to the SHAPES Participation questions at the end of the pilot.

Based on the results of the WHOQOL-Bref, older adults reported a slightly better quality of life at the end of the pilot (73.92) compared to baseline (73.29). However, based on the EQ - 5D – 5L, they reported a slightly worse quality of life at the end of the pilot (9.10) compared to baseline (8.20), as for the EQ - 5D – 5L, higher scores mean worse quality of life.

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Based on the GSE, older adults reported higher perceived general self-efficacy at the end of the pilot (30.30) compared to baseline (27.50). Finally, older adults reported a slightly worse social function at the end of the pilot (12.20) compared to baseline (12.90).

Given the short intervention time and that results from baseline to end of the pilot are quite similar, we cannot extract significant conclusions from the previous questionnaires.

*Table 56 SHAPES Participation questions' results of participants (older adults) in Phase 5*

| Participants | I participate enough in activities that are important to me | Using the KOMPAÏ robot makes participating in the activities that are important to me |
|---|---|---|
| **P1** | Agree | A little easier |
| **P2** | Agree | A little easier |
| **P3** | Strongly agree | A little easier |
| **P4** | Agree | A little easier |
| **P5** | Agree | A little easier |
| **P6** | Agree | A little easier |
| **P7** | Agree | A little easier |
| **P8** | Neither agree nor disagree | A little easier |
| **P9** | Agree | A little easier |
| **P10** | Disagree | A little easier |
| **RESULTS** | **10% Neither agree nor disagree<br>70% Agree<br>10% Strongly agree** | **100% A little easier** |

The participation questions' results are quite promising, as 100% of participants think that using the KOMPAÏ robot makes a little easier participating in activities that are important to them.

**Face recognition**

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Once users registered in the system (with the permission of the ASAPA server), it worked quite well and it only failed occasionally. The physiotherapists highly appreciated not having to manually enter the usernames and passwords for each user. Therefore, we can say that face recognition-based login worked quite well and greatly facilitated user access during each intervention.

**Emotion recognition**

During walking sessions with the KOMPAÏ robot, emotion scans were taken every 20 seconds and a % for each emotion was provided (neutral, sad, happy, anger, surprise). The data analysis reveals that the most detected emotion was “happy” (31,56% on average), followed by “surprise” (24,36% on average) and “neutral emotion” (21,31% on average). “Sad” and “anger” were detected in a quite low percentage, 13,83% and 8,93% on average, respectively. These results denote a quite good level of acceptability by end-users. Also, we can see that the KOMPAÏ robot generates a feeling of surprise in users, which was expected since most participants had not interacted with robots like the KOMPAÏ before the SHAPES project.

**KPIs compliance**

The KPIs determined for this use case intend to measure performance in critical areas towards realising its objectives that were established during the planning of the Pilot in Phase 1. Table 54 lists the KPIs planned and critically analyses its fulfilment.

In this pilot, five out of six KPIs were achieved.

*Table 57 KPIs planned vs. achieved in PT6-002*

| | Planned | Achieved /Not achieved |
|---|---|---|
| **Recruitment and retention** | At least 80% of the target cohort were successfully recruited into the pilot during the recruitment period. (i.e., 8 participants were recruited in CH; 8 participants were recruited in SAL; 2 participants were recruited in AUTH). | ☑ Achieved: 15 participants were recruited (83%) Phase 5 was performed at SAL with 10 participants and at AUTH with 5 participants. |
| | At least 80% of recruited participants within the target cohort remained enrolled in the pilot until the end of the study. | ☑ Achieved: 100% of recruited participants (10 in total) remained enrolled in |

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| | | |
|---|---|---|
| | | the pilot until the end of the study. |
| **Technical performance** | There is no re-start of any of the technology components for at least 90% of the days. | ☑ Achieved: No re-start was required during the two-weeks intervention period at SAL. |
| | Less than 2 technical incidents reported per week. | ☑ Achieved: No technical incidents were reported during the two-weeks intervention period at SAL. |
| **User engagement and acceptance** | Most older adults agree or strongly agree in the Technology Acceptance Model (TAM) that the technology is useful to them and that they would use it in the future. | ☑ Achieved: 60% of older adults agree or strongly agree that the technology is useful to them and 80% agree or strongly agree that they would use it in the future. |
| | At least one HCP/caregiver scored the technology above average rating (>68) in the System Usability Scale (SUS). | ☑ Achieved: one HCP scored the technology above average (70) in the SUS. The other HCP scored 57.5, getting a total SUS score of 63.75. |

## REPLICATION AT AUTH

AUTH Primary Outcomes

*Table 58 Psychosocial status of AUTH participants*

| Psychosocial status |
|---|

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| Psychosocial assessments | Pre-intervention | Post-intervention |
|---|---|---|
| WHOQOL- Bref | *M*= 74.15 ±7.82 | *M*= 76.35 ±7.60 |
| Health related quality of life - EQ - 5D – 5L | *MOBILITY*<br>60% - I have moderate problems in walking about<br>40% - I have no problems in walking about<br>*SELFCARE*<br>80% - I have no problems washing or dressing myself<br>20% - I have moderate problems washing or dressing myself<br>*USUAL ACTIVITIES*<br>60% - I have no problems doing my usual activities<br>40% - I have moderate problems doing my usual activities<br>*PAIN/DISCOMFORT*<br>80% - I have no pain or discomfort<br>20% - I have moderate pain or discomfort<br>*ANXIETY/DEPRESSION*<br>40% - I am not anxious or depressed<br>20% - I am moderately anxious or depressed | *MOBILITY*<br>60% - I have no problems in walking about<br>40% - I have moderate problems in walking about<br>*SELFCARE*<br>80% - I have no problems washing or dressing myself<br>20% - I have moderate problems washing or dressing myself<br>*USUAL ACTIVITIES*<br>80% - I have no problems doing my usual activities<br>20% - I have moderate problems doing my usual activities<br>*PAIN/DISCOMFORT*<br>100% - I have no pain or discomfort<br>*ANXIETY/DEPRESSION*<br>60% - I am moderately anxious or depressed<br>40% - I am not anxious or depressed |

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| | | |
|---|---|---|
| | 20% - I am extremely anxious or depressed<br>20% - I am slightly anxious or depressed | |
| Health related quality of life (EQ - VAS) | *M*=73 ±26.36 | *M*=68 ±14.83 |
| General Self-efficacy GSE | *M*=33.2 ±3.27 | *M*=34.4 ±3.91 |
| Social Function OSSS-3 | *M*= 10 ±2.53 | *M*= 10.6 ±2.30 |
| Geriatric Depression Scale | *M*= 2.4 ±1.34 | *M*= 0.8 ±0.84 |
| 1-item Health Literacy | 60% Extremely<br>20% Quite a bit<br>20% A little bit | 60% Extremely<br>20% Quite a bit<br>20% A little bit |
| Did you experience any of these life events [In the last 6 months/ since the last time we spoke]? | 60% - Yes<br>40% - No | 60% - No<br>40% - Yes |
| Did you get emotional support from anybody in relation to the event? | 100% - Yes, a lot of support | 50% - Yes, a lot of support<br>50% - Yes, some support |
| From whom did you get emotional support? | 33.3% - Children<br>33.3% - Other relative<br>33.3% - Spouse/partner | 50% - Other relative<br>50% - Neighbour |
| I participate enough in activities that are important to me | 60% - Agree<br>40% - Strongly Agree | 80% - Strongly Agree<br>20% - Neither Agree nor Disagree |
| Using the KOMPAI platform makes participating in the activities that are important to me: | 60% - A little easier<br>40% - About the same | 60% - A little easier<br>20% - Much easier |

*Table 59 Physical status of AUTH participants*

| **Physical function** | | |
|---|---|---|
| **Physical assessments** | **Pre-intervention** | **Post-intervention** |
| **Modified Barthel Index** | 98.20 ±1.79 | 98 ±4.47 |
| **4-meters walk test (in seconds)** | 5.62 ±1.40 | 4.464±0.84 |
| **Personal Risk Factors** | M= 1.6 ±1.52 | M= 1.8 ±1.10 |
| **Chair Stand test in 30 sec.** | M=9.2 ±3.77 | M=10.6 ±2.88 |
| **Arm Curl Test in 30 sec.** | M=21.8 ±9.78 | M=20.2 ±5.67 |

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| | | |
|---|---|---|
| **2-minute Step tests (number of steps)** | M= 44 ±11.73 | M= 53.6±26.58 |
| **Chair Sit and Reach Test (in cm)** | M= 4.5 ±6.36 | M= -8 ±11.20 |
| **Back Scratch Test (in cm)** | M=-49±26.87 | M=-35.6±28.30 |
| **8- Foot Up-and-Go Test (in sec)** | M= 12.18 ±4.59 | M= 9.692 ±4.13 |
| **Berg Balance Scale** | M= 47.6 ±7.89 | M= 49 ±5.24 |
| **Tinetti Test** | M= 21.5 ±3.87 | M= 26.8 ±1.10 |
| **Stork Balance Stand test** | M= 12.38 ±16.46 | M=15.69 ±21.83 |
| **Body Mass Index** | M=30.1±3.36 | M= 29.74 ±2.85 |
| **Self-selected Velocity average time (in sec)** | M= 7.48 ±3.33 | M= 7.884 ±1.46 |
| **Fast Velocity average time (in sec)** | M= 6.098± 2.50 | M= 6.25±0.98 |
| **Actual Velocity - average Self-Selected Velocity (in m/s)** | M= 0.942±0.47 | M= 0.788±0.17 |
| **Actual Velocity - average Fast Velocity (in m/s)** | M= 1.174±0.64 | M= 0.978 ± 0.16 |

*Table 60 Usability and Technology Acceptance of AUTH participants*

| **Usability and Technology Acceptance** | |
|---|---|
| **Assessments** | **Post-intervention** |
| System Usability Scale | *M= 80.8 ±8.84* |
| Technology Acceptance Model | *M*= 13.8 ±3.35 |

## Interviews

A summary of participants' experiences and the overall feedback gained at the end of the intervention, resulting from the final interviews (individual or group interviews) conducted in AUTH is presented below. In particular, a focus group was conducted in AUTH, where participants had the opportunity to discuss and share their thoughts and perceptions with other participants and the AUTH research team.

*Table 61 Participants' experiences and overall feedback collected in AUTH*

| **User** | How was your experience with the gait rehabilitation robot? | What has changed in your daily routine with the introduction of the gait rehabilitation robot? | In your opinion, what are the strengths of using the gait rehabilitation robot and the | In your opinion, what are the weaknesses of using the gait rehabilitation robot and the |
|---|---|---|---|---|

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| | | | | |
|---|---|---|---|---|
| | | | proposed walking sessions? | proposed walking sessions? |
| **1** | I really enjoyed the robot; it was very different from any other rehabilitation processes I have ever experienced. | I have a similar walking aid in my house, which allows me to walk with ease. In the past, I was reluctant to use it, but now, after experiencing robot-assisted rehabilitation, it has motivated me even more to utilize the walking aid. | I liked the appearance of the robot and its ease of use. | I did not find any particular weaknesses; it was very interesting for me. |
| **2** | I must say it was an incredibly unique and enjoyable experience. I would also suggest it to other people. | I shared this experience of mine with my family and friends, they were very excited for me. | It was very easy to use it and it was functioning properly throughout the sessions. | I cannot think of any drawbacks of using the robot, it was a very pleasant experience and other people should be aware of its benefits. |
| **3** | For me, I felt that the robot did not provide the assistance I had hoped for during the rehabilitation process. | It allowed me to walk more and enhanced my rehabilitation process. | It has many potentials, believe incorporating more complex functionalities could enhance its effectiveness and make the experience more engaging. | I experience difficulties in my upper extremity, so it was not very easy for me to grab the robots' handgrips. However, healthcare professionals could help me in this matter. |

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|---|---|---|---|---|
| **4** | The robot-assisted rehabilitation process brought me happiness, although there were moments when I wanted to do more exercises. | It was a new addition to my daily routine, but it didn't create a significant change in my everyday activities. | It was working very well and was not bugging at all; I would want it to talk more and have more exercises. | I would want more difficulty levels and additional exercises. |
| **5** | I had a very positive experience with the robot. | The addition of the robot enhanced my gait rehabilitation. | It was very easy to use it, it could recognize me and personalize the walking routes according to my needs. | Nothing in particular. |

**Final recommendations for tech-partners during and after the pilot**

Hereafter we list general recommendations for technical partners to be considered after the SHAPES Project.

1. Adapt solutions to end user's needs. Many participants have complained about the robot claiming that it was not well adapted to older adults with walking limitations. In this Use Case the main goal was to test the acceptability of the technology but for the future technical developments, end user needs must be carefully considered.
2. Include end users in the design process. This could be a solution to the previous point. In SHAPES, end users have been included in the design process from Phase 1 but they were not able to test the actual product until Phase 3, as in previous phases the robot was still under development. This have caused that useful feedback from older adults and HCPs was collected too late in the process of development.
3. Improve the performance of the robot in terms of turns, stops and route, as many older adults emphasised that the robot gets too close to walls and doors.
4. Develop clear and understandable user manuals aiming a smooth adaptation of end user to the technological development. This way older adults will be able to operate the robot without significant support.

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# 4 Use case PT6-UC004: Wearable motion monitoring device

## *4.1 Introduction*

The increasing age of the global population has led to a surge in the need for effective and efficient care for older adults. This demographic shift, coupled with the rapid advancement of technology, has opened up new avenues for the use of wearable devices in monitoring and improving the health and well-being of this population. This use case focus on the use of the Xiaomi Mi Band 4 and the MetaMotion R devices to address the needs of older adults.

The Xiaomi Mi Band 4, a popular fitness tracker, offers functionalities such as step counting, heart rate monitoring, sleep quality analysis, and activity recognition and tracking. Its long battery life and connectivity features make it a suitable device for continuous monitoring of physical activities. On the other hand, the MetaMotion R device, equipped with a 9-axis IMU and environmental sensors, provides detailed data on movement and environmental conditions. Its rechargeable battery and various connectivity options make it a versatile tool for data collection.

The target group for this study comprises older adults residing in a nursing home in Pedroche, Spain. The study aims to address the needs of these individuals by monitoring their physical activities, heart rate, and environmental conditions. The data collected from these devices will be used to assess the physical condition of the participants and track their progress over time.

The study setting is a nursing home environment, where participants may require walking assistance. Therefore, the devices' data will also be used to monitor the use of walking aids and detect falls, providing valuable insights into the mobility of the participants.

The local environment, characterized by its rural setting, presents unique challenges and opportunities. The use of wearable devices in such a setting can provide valuable insights into the lifestyle and physical activity patterns of older adults in rural areas.

The information provided by the wearable devices, Xiaomi Mi Band 4 and the MetaMotion R, is integrated into a health dashboard provided by phyx.io. This dashboard serves as a comprehensive platform for monitoring various health metrics and activities. The Xiaomi Mi Band 4, for instance, offers functionalities such as step counting, heart frequency monitoring, sleep quality analysis, and activity recognition and tracking (running, treadmill, walking, cycling, swimming). On the other hand, the MetaMotion R device is equipped with a 9-axis IMU (Bosch BMI160 6-axis Accelerometer + Gyroscope, BMM150 3-axis Magnetometer) with an environmental

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sensor (BMP280 Temperature, BMP280 Barometer/Pressure/Altimeter, LTR-329ALS Luminosity/Ambient Light).

The data collected by these devices is processed and presented on the phyx.io dashboard, providing a holistic view of the user's health status. This allows for a more personalized and effective care for older adults, enabling healthcare providers to monitor their health and well-being in real-time and make informed decisions based on the data. The use of such technology not only enhances the quality of care but also empowers older adults to take control of their health, promoting independence and improving their overall quality of life.

The following video summarizes the main aspects of this use case and its integration into Phyx.io: Physical activity monitoring with commercial smart bands

*Figure 15: Video presenting the use of smartbands at SAL*

The main objectives and ideas of this use case revolve around the use of wearable devices, specifically the Xiaomi Mi Band 4 and the MetaMotion R, to aid in the rehabilitation and monitoring of older adults. The primary focus is on the evaluation of gait quality and the tracking of physical activity levels, which are crucial aspects of health and well-being in this demographic.

One of the key objectives is the development of a gait analysis algorithm that works upon the data collected by the MetaMotion R. This algorithm aims to provide a detailed analysis of the user's gait, which can be a significant indicator of health issues such as mobility impairment, risk of falls, and overall physical fitness. The data collected by

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the MetaMotion R, which includes a 9-axis IMU and environmental sensors, provides a comprehensive set of information that can be used to evaluate gait quality.

The Xiaomi Mi Band 4, on the other hand, is intended to provide feedback about the activity level of the user. It offers functionalities such as step counting, heart frequency monitoring, sleep quality analysis, and activity recognition and tracking. This information can be employed by physiotherapists to track the evolution of a user under a rehabilitation routine, providing valuable insights into the user's progress and helping to tailor the rehabilitation program to the user's specific needs.

The information collected by these devices is integrated into a health dashboard provided by phyx.io. This dashboard serves as a comprehensive platform for monitoring various health metrics and activities, providing a holistic view of the user's health status. This allows for a more personalized and effective care for older adults, enabling healthcare providers to monitor their health and well-being in real-time and make informed decisions based on the data.

UCLM is leading this use case and it is responsible for overseeing the implementation and execution of the use case, ensuring that the objectives are met and that the technology is effectively utilized to improve the health and well-being of older adults. The piloting activities for this use case will be hosted by SAL and they will be responsible for the practical application of the technology in a real-world setting, providing valuable insights and feedback that will help refine the use case and maximize its impact. On the other hand, VICOM will be in charge of the development of the gait analysis algorithm. Their expertise in algorithm development and data analysis is instrumental in the success of this project. The algorithm they develop will work on the data collected by the MetaMotion R device, providing a detailed analysis of the user's gait. This information is crucial for evaluating the user's physical condition and progress, and for tailoring the rehabilitation program to the user's specific needs. This information will be integrated into Phyx.io.

Jarda is a user persona who is highly relevant to this use case. He is a 68-year-old man living in the South of Spain. Jarda is well-educated, middle-income, and uses technology and the internet daily for various activities such as catching up with news, social media, managing his bank account, and shopping online. He is comfortable with technology and enjoys using mildly sophisticated devices like smartwatches.

Four months ago, Jarda suffered a stroke, resulting in partial paralysis on his left side. His doctor recommended a set of exercises that could potentially help with the paralysis. Living alone and unable to drive, Jarda decided to use the Phyx.io platform for his rehabilitation.

The Phyx.io platform, along with the Xiaomi Mi Band 4 and the MetaMotion R devices, provides a comprehensive solution for Jarda's rehabilitation. The platform guides Jarda through his exercise routines, monitors his performance, and provides

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feedback. The MetaMotion R device, with its gait analysis algorithm, helps evaluate Jarda's physical condition and progress. The Mi Band 4 tracks Jarda's activity level, providing valuable data that can be used to adjust his rehabilitation routine.

Moreover, the platform's fall detection feature ensures Jarda's safety during his exercises. The platform also allows for video conferences with Jarda's therapists, who can monitor his progress and adjust his rehabilitation program as needed.

In summary, Jarda's situation represents a key demographic that this use case aims to address - older adults living alone who need assistance with physical rehabilitation. The use of wearable devices and a comprehensive health dashboard allows for personalized, effective, and safe rehabilitation in the comfort of one's home.

## 4.2 Description

The use case titled "Wearable Motion Monitoring Devices" (UC-PT6-004) focuses on the use of wearable motion monitoring devices attached to the user's shoes and a wristband to track the evolution of rehabilitation processes and the condition of the user. This use case is part of the Physical Rehabilitation at Home (T6.7) pilot theme and is being piloted at the Residencia de Mayores el Salvador (SAL).

The use case is applicable in two scenarios: at-home and nursing-home. The roles involved include the user, who is the patient undergoing the rehabilitation process, the therapeutic who gets periodic reports from the wearables, the psychologist who receives overall physical KPIs, and the technical staff.

The user interaction with the system involves wearing the device all day. This smart band sends data periodically during the charging process. The wearables are also used during specific supervised rehabilitation routines.

The digital solution proposed involves an ankle attached Motion Monitoring Device based on IMU technologies and a wristband. The wearables include a microcontroller-based wearable with a battery, sensors (IMU), and BLE connectivity. They connect through a Bluetooth/Wi-Fi gateway. The system also includes a mounting band and body adjustment system for the ankle and smart band.

The technical partners involved in this use case are UCLM, who are responsible for device development and integration with the SHAPES platform, and Vicom, who handle data analytics.

The pilot will involve two groups proposed by SAL, each ranging from 4 to 20 people. Group 1 will consist of people carrying out physical rehabilitation, and Group 2 will consist of people not carrying out physical rehabilitation. The main goal of this use case is to keep track and assess the evolution of ambulation capabilities of users during rehabilitation.

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## 4.3 Digital solutions used in this use case

The digital solution employed in this Use Case is a comprehensive health monitoring system designed to improve the care and rehabilitation of older adults. The system leverages the capabilities of two wearable devices, the Xiaomi Mi Band 4 and the MetaMotion R, to collect a wide range of health and activity data.

The Xiaomi Mi Band 4 is used to monitor the activity level of the users, providing valuable feedback about their daily routines. This information is particularly useful for physiotherapists, who can use it to track the progress of a user under a rehabilitation routine. The data collected by the Mi Band 4 is also integrated into the health dashboard provided by phyx.io, offering a holistic view of the user's health status.

The Mi Band 4 smart band records these health parameters and stores them internally. This information is not sent to the Xiaomi cloud as privacy and data protection are major concerns of the smart mirror platform. The information is instead retrieved through a Bluetooth connection between the Mi Band 4 and the smart mirror, as depicted in Figure 11.


*Figure 16: Description of the process of data download from the smart bands*

A service has been developed to establish a point-to-point connection between the Mi Band 4 smart band and the smart mirror. This service has been built on the Python library Pygatlib (https://github.com/oscaracena/pygattlib). A full recipe description is also available in https://arcogroup.bitbucket.io/shapes/integrating_miband_with_smart_mirror/

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The MetaMotion R, on the other hand, is used to evaluate the gait quality of the users. It collects raw data from various sensors, which is then processed by a gait analysis algorithm developed by VICOM. This algorithm extracts meaningful features from the data and provides a comprehensive report on the user's gait, including details like gait spatio-temporal parameters, symmetry and repeatability.

Once the information is retrieved from the smart band, it does not necessarily mean that this has to remain locally in the smart mirror. It can be sent to a private cloud, from where the Phyx.io system can access it for displaying purposes. Phyx.io has a built-in dashboard, in which such health parameters can be explored, as shown in Figure 12.


*Figure 17: Dashboard of the physical activity monitor*

Phyx.io does not only monitor physical activity parameters, but it also intervenes by making recommendations and by supervising the performance of physical-exercise routines intended to recover or maintain the physical condition. The description of the Phyx.io is not reproduced here as it has already been described for PT6-UC001 and PT6-UC003.

Recommendations are made through the Mi Band 4 smart band. These can be intended to promote physical activity, either by encouraging to walk and achieve a step goal or by means of remainders of a scheduled physical exercise routine. Recommendations can also be addressed to ensure the general wellbeing, such as to drink water recommendations on hot days or general remainders. These recommendations are configured by the caregiver or the therapist.

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The gait analysis algorithm developed by VICOM relies on the biomechanical modelling of the gait and signal analysis techniques that allow to analyse and assess the gait of the subject with a very simple and inexpensive setup.

### 4.3.1 Digital solutions used for COVID-19 response

Please, refer to the content of section 2.3.1.

### 4.3.2 Equipment and devices used (from third parties)

The MetaMotion R is a versatile and compact sensor device that is capable of capturing high-resolution, 3D motion data. It is equipped with an array of sensors, including an accelerometer, gyroscope, and magnetometer, which together enable it to track and record a wide range of movements. The device is small and lightweight, making it easy to wear or attach to different parts of the body. This makes it particularly suitable for gait analysis, as it can be used to capture detailed data on the movements of the feet and legs.

*Figure 18: User wearing the IMU sensor*

The Xiaomi Mi Band 4 is a popular wearable device that offers a range of features designed to support health and fitness. It includes a heart rate monitor, sleep tracker, and activity monitor, among other features. The device is also capable of tracking steps and distance travelled, making it a useful tool for monitoring physical activity levels. The data collected by the Mi Band 4 can be used to provide feedback to users and healthcare professionals, helping to inform decisions about exercise and

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rehabilitation routines. In the following video further details are provided: Phix.io: A comprehensive system for rehabilitation and physical activity

*Figure 19: Video describing Phyx.io*

The Smart Mirror is a unique device that serves as a central hub for collecting and displaying data from the MetaMotion R and Mi Band 4. The Smart Mirror is equipped with a set of digital solutions designed to support older adults' use of technology at home and wearable devices on the move. The mirror can display information from the "health dashboard" provided by phyx.io, giving users easy access to data from their wearable devices. This includes information on their activity levels, heart rate, sleep patterns, and more. The Smart Mirror also supports video conferencing, providing a means for users to communicate with healthcare professionals and receive feedback on their progress.

## 4.4 Data plan

The following data have been considered:

**MetaMotion R:**

1. Acceleration: The device's accelerometer can measure acceleration forces in three dimensions (x, y, and z). This can be used to detect movements and changes in orientation.
2. Angular Velocity: The gyroscope can measure the rate of rotation around the device's three axes. This can be used to track changes in orientation and detect rotational movements.

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3. Magnetic Field: The magnetometer can measure the strength and direction of the magnetic field around the device. This can be used to determine the device's orientation relative to the Earth's magnetic field.
4. Temperature: The device can measure the ambient temperature.
5. Pressure: The device can measure atmospheric pressure, which can be used to calculate altitude.

**Xiaomi Mi Band 4:**

1. Heart Rate: The device can measure the user's heart rate in beats per minute.
2. Sleep Tracking: The device can monitor the user's sleep patterns, including the duration and quality of sleep.
3. Steps: The device can count the number of steps the user takes.
4. Distance: The device can estimate the distance the user has travelled based on the number of steps taken.
5. Calories: The device can estimate the number of calories the user has burned based on their activity level.
6. Activity Type: The device can detect different types of physical activity, such as walking, running, and swimming.

### 4.4.1 Data capture methods to be used

The Phyx.io platform is evaluated according to the information provided for PT6-UC001 and PT6-UC003. So, for the sake of conciseness, this will not be described here.

The data collection process for the Xiaomi Mi Band 4 and the MetaMotion R is designed to be as seamless and user-friendly as possible.

For the Xiaomi Mi Band 4, data collection is automated thanks to a service developed specifically for this purpose, as described in the guide. This service, known as miband-dc, runs continuously on the Smart Mirror device. When the Mi Band 4 is within the range of the Smart Mirror, the service automatically collects data from the wearable device using Bluetooth Low Energy (BLE) technology. The data is then stored in a PostgreSQL database for further analysis and visualization. This process does not require any manual intervention from the user, making it highly convenient and efficient. For further details please refer to https://arcogroup.bitbucket.io/shapes/integrating_miband_with_smart_mirror/

The MetaMotion R, on the other hand, requires a manual data download process. This is because the device collects high-resolution, 3D motion data, which can be quite large in size. To download the data, the sensor needs to be connected to a PC via a Bluetooth connection. Once connected, the data can be downloaded and stored for further analysis.

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In both cases, the data collected from the wearable devices is securely stored and managed, ensuring the privacy and confidentiality of the user's information. The data can then be used to provide valuable insights into the user's health and well-being, informing decisions about care and rehabilitation.

### 4.4.2 Planning of evaluation

Because this use case is similar to PT6-UC001 and PT6UC003 please refer to Planning of evaluation (Section 2.4.2) for further details about the planning of evaluation.

## *4.5 Phase 1*

### 4.5.1 PACT and FICS Scenario

The scenario is the same as for the PT6-UC001 and PT6-UC003 so please refer to Section 2.5.1 for further details.

### 4.5.2 Key performance indicators

The following KPIs have been considered for this use case:

- Quality of Gait: Using the gait analysis algorithm, changes in the quality of gait could be tracked over time. Improvements would indicate progress in the rehabilitation process.
- User Satisfaction: Surveys or interviews could be used to assess how satisfied users are with the wearable devices and the overall rehabilitation program.
- Adherence to Rehabilitation Routine: The degree to which users follow their prescribed rehabilitation routine. This could be tracked through the data collected by the wearable devices.

User satisfaction and adherence to rehabilitation routines will be evaluated through the evaluation of the Phyx.io platform (PT6-UC001 and PT6-UC003). In this use case, only the quality of gait will be evaluated.

### 4.5.3 Timeline of pilot activities

See Table 6 for the timeline of pilot activities.

## *4.6 Phase 2: Testing of mock-ups and prototypes*

In the second phase of our use case PT6-UC004, our primary objective was to delve into the current advancements and practices in the field of gait analysis. We aimed to understand the most commonly used parameters for characterizing gait quality, which is a crucial aspect of rehabilitation for older adults. This exploration was not limited to

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theoretical understanding but extended to practical testing of mock-ups and prototypes. The insights gained from this phase were instrumental in shaping our approach to developing a solution that is both technologically advanced and tailored to the needs of our target group. This phase served as a bridge between the initial planning and the subsequent implementation, ensuring that our solution is grounded in the latest research and best practices in the field of gait analysis.

### 4.6.1 Methodology of testing

The methodology of testing for Phase 2 of the PT6-UC004 use case was designed to ensure a comprehensive evaluation of the gait analysis algorithms, with a particular focus on the data they generate and how this data could be used to calculate the parameters that characterize the quality of gait.

**Digital Solutions Tested**

At this stage of the use case, our primary focus was on the gait analysis algorithms. We aimed to understand the potential of these algorithms in terms of the data they generate and how this data could be utilized to calculate the parameters that are commonly used to characterize the quality of gait. It's important to note that the testing at this stage was not about the performance of the algorithms themselves, but rather about the potential use of the data they produce.

Also, during this stage, the smart bands were being evaluated in terms of the information provided and gathered in the database (no visualisation was available at this stage, so mock-ups were employed).

**Presentation of Technologies**

The results obtained from the state-of-the-art review were presented using PowerPoint presentations. These presentations provided a detailed overview of the current advancements in gait analysis and the parameters commonly used to characterize gait quality. In addition to the presentations, workshops were conducted to facilitate in-depth discussions about the data. These workshops provided an interactive platform for the participants to engage with the data and share their insights and perspectives.

**Feedback Providers**

The feedback on the presentations and workshops was provided by the physiotherapist professionals at the SAL nursing home. These professionals, with their expertise and experience in rehabilitation and gait analysis, were ideally positioned to provide valuable insights into the potential use of the data generated by the gait analysis algorithms.

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**Feedback Collection**

The feedback from the physiotherapist professionals was collected through a combination of different spreadsheets and informal interviews. The spreadsheets allowed for structured and quantifiable feedback, while the informal interviews provided an opportunity for the professionals to share their thoughts and insights in a more open-ended and qualitative manner. This combination of methods ensured a comprehensive collection of feedback, capturing both the quantitative and qualitative aspects of the professionals' perspectives.

This methodology of testing ensured a thorough evaluation of the potential use of the data generated by the gait analysis algorithms, providing valuable insights that informed the subsequent stages of the use case.

### 4.6.2 Results of testing

The testing phase for PT6-UC004 was primarily focused on the evaluation of gait analysis algorithms, specifically in terms of the data they generate and how this data could be used to calculate parameters that characterize the quality of gait. The results of this testing phase were insightful and provided valuable direction for the subsequent stages of the use case.

The state-of-the-art review presented in PowerPoint presentations and discussed in workshops revealed a range of parameters that are commonly used in the field to characterize gait quality. These parameters, derived from the data generated by the gait analysis algorithms, provided a comprehensive understanding of the potential of these algorithms in the context of our use case.

The feedback from the physiotherapist professionals at the SAL nursing home was instrumental in shaping our understanding of the practical application of these parameters. The professionals, with their expertise and experience, provided valuable insights into how these parameters could be used in real-world scenarios to inform decisions about care and rehabilitation.

The feedback was collected through spreadsheets and informal interviews, providing a mix of quantitative and qualitative data. The spreadsheets allowed for structured feedback on specific aspects of the data and its potential use, while the informal interviews provided a platform for the professionals to share their broader thoughts and insights.

The results of the testing phase confirmed the potential of the gait analysis algorithms in providing valuable data for characterizing gait quality. The feedback from the professionals highlighted the practical applicability of these parameters in the context of rehabilitation for older adults. These results have provided a strong foundation for

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the subsequent stages of the use case, informing the development of a solution that is both technologically advanced and tailored to the needs of our target group.

Based on the results of the testing phase and the feedback received, we have identified a few areas where improvements could be made to enhance the usability and effectiveness of the gait analysis algorithms and the associated devices. Here are our recommendations for our technical partners:

1. **Improve Bluetooth Connectivity**: During the testing phase, we encountered some issues with the Bluetooth connectivity of the MetaMotion R sensor. The connection was found to be unstable at times, which could potentially impact the reliability of the data collected. We recommend exploring ways to enhance the stability of the Bluetooth connection to ensure consistent and reliable data collection.
2. **Enhance Data Downloading Application**: The application provided with the MetaMotion R sensor for downloading the data was found to be somewhat difficult to use. The user interface could be made more intuitive, and the process of downloading the data could be simplified. Improving the usability of this application would make it easier for the physiotherapist professionals and other users to download and access the data.
3. **Provide Comprehensive Training**: Given the technical nature of the gait analysis algorithms and the devices used, it would be beneficial to provide comprehensive training to the users. This training could cover the operation of the devices, the use of the data downloading application, and the interpretation of the data generated by the algorithms. Providing this training would ensure that the users are well-equipped to use these technologies effectively.

These recommendations aim to address the challenges encountered during the testing phase and enhance the overall usability and effectiveness of the gait analysis algorithms and the associated devices. Implementing these recommendations would contribute to the successful implementation and outcomes of the use case.

## *4.7 Phase 3: Hand-on Experiments*

### 4.7.1 Methodology of hands-on experiments

The methodology for the hands-on experiments in Phase 3 of the PT6-UC004 use case was designed to ensure a comprehensive evaluation of the digital solutions in a practical setting. This phase involved the collection and analysis of data from both the MetaMotion R sensor and the Xiaomi Mi Band 4, the presentation of the developed application, and the collection of feedback from physiotherapist professionals.

**Digital Solutions Tested**

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In this phase, we collected data using the MetaMotion R sensor and the Xiaomi Mi Band 4. The data from the MetaMotion R sensor was passed in the form of CSV files to our technical partners at VICOM for post-processing and analysis. The results of this analysis were then discussed with the physiotherapist professionals at the SAL nursing home to assess their coherence with the professionals' evaluations.

Simultaneously, the data collected from the Xiaomi Mi Band 4 was displayed on a dashboard created using Grafana. This visual representation of the data allowed for an intuitive evaluation of the information collected by the smart band.

**Presentation of Technologies**

In response to the feedback received in Phase 2, we developed an Android application to gather the data, overcoming the limitations of the previously used applications. This application was presented to the physiotherapist professionals at the SAL nursing home. The application was designed to be user-friendly and intuitive, making it easy for the professionals to collect and access the data. Additionally, the Grafana dashboard was presented as a tool for visualizing and interpreting the data collected from the Xiaomi Mi Band 4.

**Feedback Providers**

The feedback on the hands-on experiments was provided by the physiotherapist professionals at the SAL nursing home. Their expertise and experience in rehabilitation and gait analysis made them ideally positioned to provide valuable insights into the practical application of the digital solutions.

**Feedback Collection**

The feedback from the physiotherapist professionals was collected through a combination of different spreadsheets and informal interviews. The spreadsheets allowed for structured and quantifiable feedback on specific aspects of the digital solutions, while the informal interviews provided a platform for the professionals to share their broader thoughts and insights.

This methodology of hands-on experiments ensured a thorough evaluation of the digital solutions in a practical setting, providing valuable insights that informed the subsequent stages of the use case.

### 4.7.2 Results of the hands-on experiments

The hands-on experiments conducted in Phase 3 of the PT6-UC004 use case yielded insightful results, providing valuable feedback on the practical application of the digital solutions.

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The data collected from the MetaMotion R sensor was post-processed and analyzed by our technical partners at VICOM. The results of this analysis, which focused on the quality of gait, were discussed with the physiotherapist professionals at the SAL nursing home. The professionals found the results to be coherent with their own evaluations, validating the effectiveness of the gait analysis algorithms. The data provided by the MetaMotion R sensor was found to be valuable in characterizing the quality of gait and informing decisions about care and rehabilitation.

Simultaneously, the data collected from the Xiaomi Mi Band 4 was displayed on a Grafana dashboard. This visual representation of the data allowed the professionals to easily interpret the information collected by the smartband. The Xiaomi Mi Band 4 was found to be effective in tracking the activity levels of the individuals, providing a clear picture of their physical activity patterns. This information was found to be useful in monitoring the progress of the individuals and adjusting their rehabilitation programs as needed.

The feedback collected from the physiotherapist professionals through spreadsheets and informal interviews was largely positive. The professionals appreciated the user-friendly design of the Android application and the intuitive layout of the Grafana dashboard. They also found the data collected by the MetaMotion R sensor and the Xiaomi Mi Band 4 to be valuable in their work.

Based on the feedback received from the hands-on experiments in Phase 3, we have identified a few areas where improvements could be made to further enhance the usability and effectiveness of the digital solutions. Here are our recommendations for our technical partners:

1. **Simplify Data Gathering Process**: Despite the improvements made since Phase 2, the physiotherapist professionals at the SAL nursing home still find the data gathering process to be somewhat challenging. We recommend further simplifying this process, perhaps by automating certain steps or by redesigning the user interface of the application to make it more intuitive.
2. **Improve Error Reporting**: The current error reporting system could be improved to provide more meaningful and actionable information. When a connection error or other issue occurs, the system should provide a clear explanation of what went wrong and suggest potential solutions. This would help the professionals to troubleshoot issues more effectively and reduce the need for external technical support.
3. **Provide Comprehensive Training**: Given the technical nature of the data gathering process, it would be beneficial to provide more comprehensive training to the users. This training could cover the operation of the devices, the use of the data gathering application, and the troubleshooting of common issues. Providing this training would ensure that the users are well-equipped to use these technologies effectively.

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These recommendations aim to address the challenges encountered during the hands-on experiments and enhance the overall usability and effectiveness of the digital solutions. Implementing these recommendations would contribute to the successful implementation and outcomes of the use case.

## *4.8 Phase 4: Small Scale Live Demonstration*

### 4.8.1 Recruitment of participants

The target users for this phase are physiotherapists or healthcare professionals. We recruited 4 participants. These participants were recruited from the SAL partner professionals.

No informed consents were collected at this phase as all participants were researchers participating in the project.

### 4.8.2 Technical aspects & Logistics

The procurement procedures for third-party equipment and devices will be carried out in accordance with the guidelines and regulations of the respective organizations. The necessary equipment and devices for the deployment of the technologies involved in PT6-UC004 will be procured in a timely manner to ensure the smooth execution of Phase 4.

Regarding the local technical requirements for the deployment of the digital solutions this only includes ensuring the availability of a stable Wi-Fi connection for the operation of the platforms. The physical space requirements for the deployment of the kiosk or smart mirror will also be taken into consideration. The pilot site will be prepared accordingly to accommodate the platforms and facilitate the hands-on experiments.

### **4.8.3** Roles and Responsibilities

The successful execution of Phase 4 for PT6-004 will involve various stakeholders, each with specific roles and responsibilities. These stakeholders include:

**Responsible Partner in All Pilot Sites**

The responsible partner in the SAL pilot site (UCLM) will oversee the deployment of the MetaMotion R sensor and the Mi Band 4. They will ensure that the devices are set up correctly and that all technical requirements are met. They will also be responsible for addressing any technical issues that may arise during the deployment.

**Medical Professionals**

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Medical professionals will monitor the health and wellbeing of the participants during the deployment. They will also provide feedback on the effectiveness of the analysis and data visualization tools.

### 4.8.4 Ethical considerations

The ethical self-assessment will be conducted to ensure that the deployment of the MetaMotion R and the Xiaomi Mi Band 4 devices in Phase 4 adheres to all ethical guidelines and regulations. The informed consent procedure will be followed during Phase 5, to ensure that the participants understand the purpose of the study, the procedures involved, and their rights as participants. The necessary approvals are obtained from the relevant authorities before the commencement of Phase 4, although it will not be until Phase 5 when it will be necessary as Phase 4 does only involved researchers.

**Data and Privacy Impact Assessment**

A data and privacy impact assessment are conducted to ensure that the data collected during Phase 4 is handled in a secure and confidential manner. The MetaMotion R and the Xiaomi Mi Band 4 rely on applications that have been designed fit-for-purpose to collect the data without involving the manufacturer cloud. Furthermore, only the necessary data and to store and transmit this data in a secure manner. The privacy rights of the participants will be always respected.

Approval from Local Authorities and/or Local Community Health Service

The necessary approvals were obtained from the Ethical Committee (Social Pannel) of the University of Castilla-La Mancha, before the commencement of Phase 4. These approvals will ensure that the deployment of the technologies involved in PT6-UC004 is in compliance with local regulations and guidelines.

In line with chapter 5.2.2.7 of D6.1, all ethical considerations will be taken into account during the planning and execution of Phase 4. This includes ensuring the respect for the person at all stages, considering the users' capabilities when planning the tests, and planning a methodology that respects and protects human rights.

### 4.8.5 Outcome of the Small-Scale Live Demonstration

The small-scale live demonstration of Phase 4 of the PT6-UC004 use case yielded significant outcomes, providing valuable insights into the effectiveness of the digital solutions and informing the direction for the subsequent phase of the pilot campaign.

**Primary and Secondary Outcomes**

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The primary outcome of the live demonstration was the validation of the effectiveness of the MetaMotion R sensor and the Xiaomi Mi Band 4 in achieving the objectives set out at the beginning of this use case. The MetaMotion R sensor was found to be effective in evaluating the quality of gait, providing valuable data that could inform decisions about care and rehabilitation. Similarly, the Xiaomi Mi Band 4 was successful in tracking the level of physical activity of the individuals, providing a clear picture of their physical activity patterns.

The secondary outcome was the identification of areas for improvement in the digital solutions. Despite the overall success of the live demonstration, there were aspects of the digital solutions that could be improved to enhance their usability and effectiveness.

**Recommendations for Technical Partners**

Based on the outcomes of the live demonstration, we recommend that our technical partners integrate the data visualization into the Phyx.io platform. This would allow for a more streamlined and intuitive presentation of the data collected by the MetaMotion R sensor and the Xiaomi Mi Band 4. A new tab could be created on the Phyx.io platform to visualize both the activity data and the results of the gait quality evaluation.

**Lessons-Learned for Phase 5 of Pilot Campaign**

One of the key lessons learned from the live demonstration was the need for flexibility in the evaluation schedule. Initially, we had envisioned that the evaluation would be performed periodically. However, based on the feedback received and our experience during the live demonstration, we realized that this approach may not be the most effective. Instead, we decided that the evaluation should be performed once per year or in response to a significant event, such as a fall. This approach would ensure that the evaluations are meaningful and relevant, contributing to the overall effectiveness of the use case.

These outcomes, recommendations, and lessons learned from the small-scale live demonstration have provided a strong foundation for the subsequent stages of the use case, informing the development of a solution that is both technologically advanced and tailored to the needs of our target group.

## *4.9 Phase 5: Large-scale pilot activity*

The large-scale pilot activity in Phase 5 of the PT6-UC004 use case is designed to test and validate the digital solutions in a real-world setting. This phase involves the implementation of a comprehensive methodology that ensures the effective collection and analysis of data, the presentation of the digital solutions, and the collection of feedback from physiotherapist professionals.

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### 4.9.1 Recruitment

For the sake of conciseness, as the PT6-UC004 was conducted simultaneously with PT6-UC001 and PT6-UC003, the reader is referred to section 2.9.1 of this document for the details of this section. The only difference is the intervention that it is described underneath.

#### *4.9.1.1 Intervention*

The intervention in Phase 5 of the PT6-UC004 use case was designed to evaluate the impact of physical activity on gait quality, using the MetaMotion R sensor and the Xiaomi Mi Band 4 as the primary tools for data collection. This intervention was conducted with the same participants who were involved in PT6-UC001 and PT6-UC003, providing a consistent user base for the evaluation.

The intervention involved two measurement periods: one before the start of the pilot (November 2022) and another at month M4 (March 2023). During these periods, the participants were instructed to walk a distance of 20 meters in a straight line, using any walking aid they normally use. The MetaMotion R sensor, placed on the right ankle of the participant, and the Xiaomi Mi Band 4, worn on the wrist, collected data before, during, and after this walk. The participants were also instructed to remain completely at rest for 5 seconds before and after the walk.

The data collected during these measurement periods was then analyzed to evaluate the quality of gait and the level of physical activity of the participants. The aim was to explore the potential impact of physical activity on gait quality. Although the length of the pilot was not sufficient to obtain results that could be extrapolated to a larger population, the findings provided interesting insights into the relationship between physical activity and gait quality.

The intervention was conducted using a custom software developed by UCLM using the API of the sensors. This software facilitated the collection of data in a consistent and reliable manner, ensuring the accuracy and validity of the results.

This intervention provided valuable insights into the potential of the involved digital solutions in a real-world setting, demonstrating their effectiveness in evaluating gait quality and physical activity levels. These insights will inform the subsequent stages of the use case, contributing to the development of a solution that is both technologically advanced and tailored to the needs of the target group.

### 4.9.2 Communication and dissemination of pilot activities

Similarly, the results of this pilot activities were communicated and disseminated alongside the results of PT6-UC001 and PT6-UC003.

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### 4.9.3 Outcome of large-scale pilot activity

The large-scale pilot activity in Phase 5 of the PT6-UC004 use case provided valuable insights into the effectiveness of the Xiaomi Mi Band 4 and the MetaMotion R in a real-world setting. Take into account that those aspects related to Phyx.io (dashboard) have already been evaluated during PT6-UC001 and PT6-UC003 and for the sake of conciseness, results are not listed again here. Please, refer to Outcome of large-scale pilot activity (Section 2.9.3) for further details.

The primary and secondary outcomes of this activity are discussed below.

**Primary Outcomes**

The following tables will present the results obtained from the 4-meter walk test and the Barthel Index assessments conducted at the baseline and after 8 weeks of intervention. These results provide valuable insights into the impact of the intervention on the participants' gait quality and their ability to perform activities of daily living.

The 4-meter walk test, a commonly used measure of gait speed in older adults, was conducted to evaluate the participants' mobility and balance. This test is a reliable and valid tool for assessing physical performance and predicting future health outcomes in older adults. The results of this test, conducted at the baseline and after 8 weeks, will provide insights into the changes in the participants' gait speed and mobility over the course of the intervention.

The Barthel Index, a widely used measure of functional independence in activities of daily living, was also employed. This tool assesses the individual's ability to perform ten basic activities, providing a quantitative estimate of the individual's level of independence. The results of the Barthel Index assessments, conducted at the baseline and after 8 weeks, will provide insights into the impact of the intervention on the participants' functional independence.

By comparing the results obtained at the baseline and after 8 weeks, we aim to evaluate the effectiveness of the intervention in improving gait quality and functional independence. These results will provide valuable insights into the potential benefits of the intervention, informing future strategies for promoting physical activity and improving gait quality in older adults.

*Table 62 Functional outcomes with Shah's modified Barthel Index at baseline and at 8 weeks*

| User ID | Barthel (base line) | Barthel (8 weeks) | Viabilitu |
|---|---|---|---|

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| | | | |
|---|---|---|---|
| 1 | 86 | 86 | Yes |
| 2 | 100 | 100 | Yes |
| 3 | 79 | 86 | Yes |
| 4 | 82 | 82 | No |
| 5 | 55 | 74 | Yes |
| 6 | 99 | 99 | Yes |
| 7 | 93 | 59 | No |
| 8 | 84 | 84 | Yes |
| 9 | 76 | 82 | Yes |
| 10 | 48 | 75 | No |
| 11 | 80 | 87 | No |
| 12 | 77 | 77 | Yes |
| 13 | 99 | 99 | No |
| 14 | 75 | 82 | Yes |
| 15 | 62 | 73 | No |
| 16 | 88 | 88 | No |
| 17 | 76 | 76 | No |
| 18 | 87 | 85 | No |
| 19 | 100 | 100 | No |
| 20 | 99 | 99 | No |
| 21 | 90 | 90 | No |
| 22 | 75 | 89 | Yes |
| 23 | 69 | 73 | No |
| 24 | 99 | 99 | Yes |
| 25 | 100 | 100 | Yes |
| 26 | 80 | 86 | No |

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| | | | |
|---|---|---|---|
| 27 | 95 | 95 | Yes |
| 28 | 92 | 97 | Yes |
| 29 | 75 | 91 | No |
| 30 | 99 | 99 | Yes |
| Media | 83.97 | 87.07 | |

*Table 63 Results of the 4-meter baseline test*

| User ID | Time (s) | Speed (m/s) | Score | Viability |
|---|---|---|---|---|
| 1 | 7.17 | 0.56 | 2 | Yes |
| 2 | 4.79 | 0.84 | 4 | Yes |
| 3 | 10.89 | 0.37 | 1 | Yes |
| 4 | 16.8 | 0.24 | 1 | No |
| 5 | 7.26 | 0.55 | 2 | Yes |
| 6 | 5.35 | 0.75 | 3 | Yes |
| 7 | 5.9 | 0.68 | 3 | No |
| 8 | 7.31 | 0.55 | 2 | Yes |
| 9 | 8.16 | 0.49 | 2 | Yes |
| 10 | 35.35 | 0.11 | 1 | No |
| 11 | 5.16 | 0.78 | 3 | No |
| 12 | 12.26 | 0.33 | 1 | Yes |
| 13 | 4.67 | 0.86 | 4 | No |
| 14 | 8.1 | 0.49 | 2 | Yes |
| 15 | Weel chair | Weel chair | Weel chair | No |
| 16 | 6.58 | 0.61 | 2 | No |
| 17 | 7.45 | 0.54 | 2 | No |
| 18 | 3.78 | 1.06 | 4 | No |

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| | | | | |
|---|---|---|---|---|
| 19 | 3.32 | 1.20 | 4 | No |
| 20 | 6.41 | 0.62 | 2 | No |
| 21 | 5.8 | 0.69 | 3 | No |
| 22 | 4.57 | 0.88 | 4 | Yes |
| 23 | 11.39 | 0.35 | 1 | No |
| 24 | 3.04 | 1.32 | 4 | Yes |
| 25 | 5.82 | 0.69 | 3 | Yes |
| 26 | 9.70 | 0.41 | 1 | No |
| 27 | 9.76 | 0.41 | 1 | Yes |
| 28 | 4.14 | 0.97 | 4 | Yes |
| 29 | 8.37 | 0.48 | 2 | No |
| 30 | 2.33 | 1.72 | 4 | Yes |

*Table 64 Results of the 4-meter test in 8 weeks*

| User ID | 4-meter speed test | | |
|---|---|---|---|
| | Time (s) | Speed (m/s) | Score |
| 1 | 6.99 | 0.57 | 2 |
| 2 | 4.38 | 0.91 | 4 |
| 3 | 9.95 | 0.40 | 1 |
| 5 | 7.25 | 0.55 | 2 |
| 6 | 5 | 0.80 | 3 |
| 8 | 9.29 | 0.43 | 1 |
| 9 | 8.44 | 0.47 | 2 |
| 12 | 12.63 | 0.32 | 1 |
| 14 | 5.77 | 0.69 | 3 |
| 22 | 4.52 | 0.88 | 4 |

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| | | | |
|---|---|---|---|
| 24 | 3.76 | 1.06 | 4 |
| 25 | 5.73 | 0.70 | 3 |
| 27 | 9.36 | 0.43 | 1 |
| 28 | 3.83 | 1.04 | 4 |
| 30 | 3.22 | 1.24 | 4 |

For the physical activity tracking, the primary outcome of the large-scale pilot activity was the successful collection and display of data from the Xiaomi Mi Band 4. The participants wore the band as part of their daily routine, and the data collected provided a clear picture of their physical activity levels. This data was displayed on the Phyx.io platform, providing an intuitive and accessible way for the physiotherapist professionals at the SAL nursing home to monitor the participants' activity levels.

The data collected from the Xiaomi Mi Band 4 was found to be valuable in tracking the activity levels of the participants. This information could be used to inform decisions about care and rehabilitation, providing a practical tool for the professionals to monitor the progress of the participants and adjust their rehabilitation programs as needed.

**Secondary Outcomes**

Regarding the gait analysis, Figure 20 and Figure 21 show a box plot of the spatial and temporal metrics, respectively, obtained at month 1 and month 4 of the pilot by using the Gait Analysis DS. Each box plot presents the result of the participants grouped by the walking aid used by them (walker, own means, cane, crutch). The spatial metrics (Figure 20), namely, stride length and stride velocity (for both higher is better), show an improvement in all the groups of participants, except for the crutch one, which remained almost the same.

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## Pilot M1 vs. M4 – spatial metrics

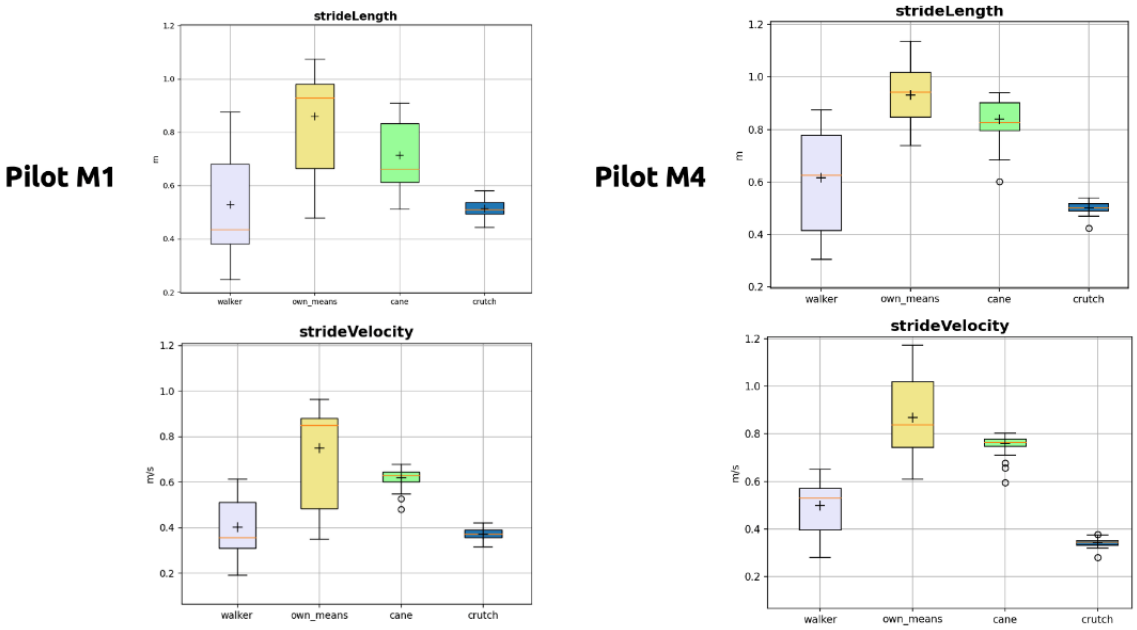


*Figure 20. Comparison of the output spatial metrics produced by the Gait Analysis DS between the gait captures obtained at month 1 of the pilot (M1) and month 4 (M4).*

In the case of the temporal metrics (Figure 21), i.e., stride time (lower is better) and swing ratio (it should be between 40 and 50%), we observe a similar behaviour of the groups to what we obtained for the spatial metrics. This is, all groups show improvement in the gait performance, except for the crutch one.

Comparing this result with what is reported in the primary outcomes, with see a positive correlation with the general improvement in the Barthel scores, which includes, related physical activities, like mobility on level surfaces and stairs. Regarding the correlation with the 4-meter test, the situation is unclear due to missing data at the follow-up (8 weeks) of almost half of the subjects.

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## Pilot M1 vs. M4 – temporal metrics

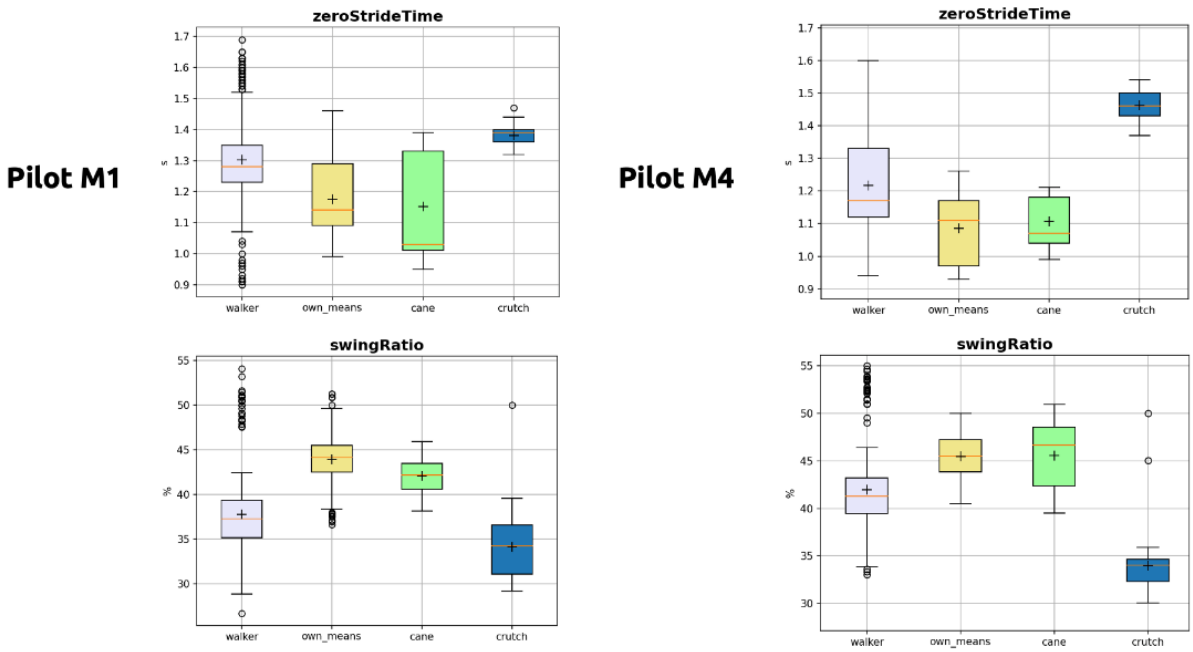


*Figure 21. Comparison of the output temporal metrics produced by the Gait Analysis DS between the gait captures obtained at month 1 of the pilot (M1) and month 4 (M4)*

Finally, Figure 22 shows an example of the evolution of a subject at 3 dates. The first one (in blue) is before starting the pilot (no rehabilitation), the second one (in red) at month M1 of the pilot and at M4 of the pilot. In this case, the stride length and stride velocity show a significant increment over the time. On the other hand, the stride time show a major reduction, while the swing-stance ration remained stable for the left leg and improved for the right leg. All these results depict a favourable recuperation of the gait function and is in good agreement with the reported Barthel score and the 4-meter walk test results.

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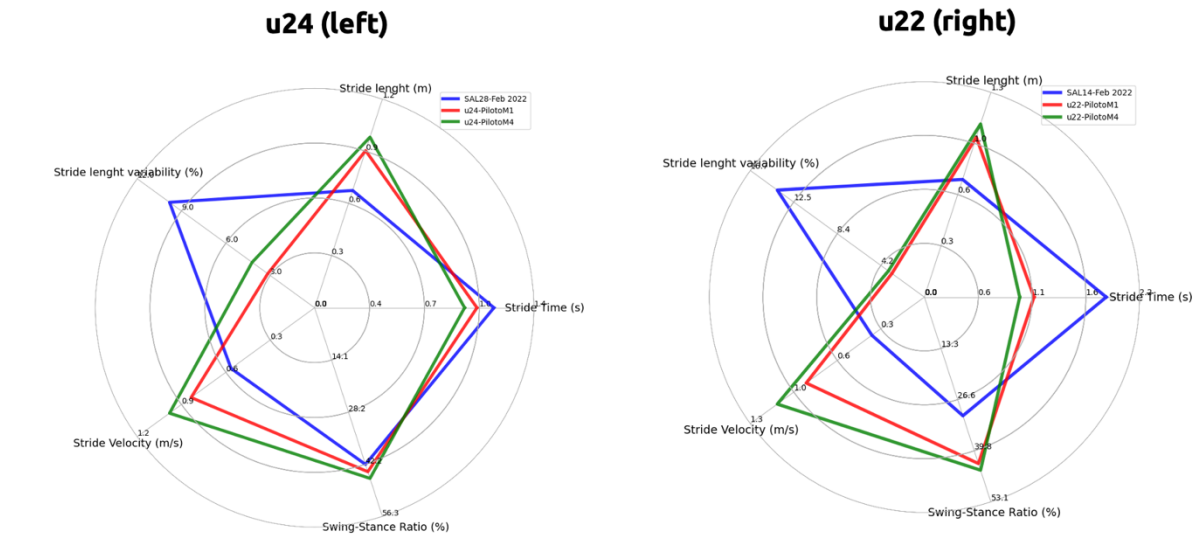


*Figure 22. Comparison of the output spatio-temporal metrics produced by the Gait Analysis DS between the gait captures obtained from a specific subject at three different dates*

For the physical activity tracking, the secondary outcome of the large-scale pilot activity was the identification of areas for improvement in the data collection and display process. While the Xiaomi Mi Band 4 was effective in collecting data, there were aspects of the data display on the Phyx.io platform that could be improved. For instance, the platform could be enhanced to provide more detailed visualizations of the data, making it easier for the professionals to interpret the information.

Furthermore, the large-scale pilot activity highlighted the potential of the Xiaomi Mi Band 4 as a tool for long-term monitoring of physical activity levels. The ease of use of the band and the valuable data it provides suggest that it could be effectively used in a long-term care setting, providing ongoing insights into the physical activity levels of the participants.

In addition to physical activity tracking, the large-scale pilot activity also aimed to assess gait quality using wearable motion monitoring devices. The analysis of gait parameters provided valuable insights into the mobility and functional capabilities of the participants. By capturing data such as step counts, stride length, and gait speed, the wearable motion monitoring devices offered objective measurements of gait quality.

The analysis revealed promising results in terms of the impact of the digital solution on gait quality. Participants showed improvements in various gait parameters over the course of the pilot activity. Increased step counts, longer stride lengths, and improved gait speed were observed, indicating enhanced mobility and functional performance.

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These findings highlight the potential of the digital solution in facilitating gait improvements among older adults. The objective measurements provided by the wearable motion monitoring devices offer a reliable and quantitative assessment of gait quality, enabling healthcare professionals to monitor progress and tailor interventions accordingly.

These outcomes of the large-scale pilot activity provide a strong foundation for the subsequent stages of the use case, informing the development of a solution that is both technologically advanced and tailored to the needs of the target group.

### 4.9.4 Results of large-scale pilot activity

Because PT6-UC001, PT6-UC003 and PT6-UC004 were delivered through the Phyx.io platform, this section presents the results of the large-scale pilot activity for these three use cases.

Based on the conducted questionnaires, the following findings can be drawn:

- WHOQOL-Bref Scores: The average score at baseline was 73.29 (SD=4.64), and after the intervention, it increased to 73.92 (SD=8.05). This indicates an improvement in the participants' quality of life.
- EQ5D Results: The average score at baseline was 8.20 (SD=1.99), and after the intervention, it increased to 9.10 (SD=2.64). This suggests an improvement in health-related quality of life.
- OSSS Results: The average score at baseline was 12.90 (SD=1.60), and after the intervention, it decreased slightly to 12.20 (SD=1.32). The Oslo Social Support Scale (OSSS) measures the social support an individual receives, and the slight decrease suggests a minor change in perceived social support.
- GSES Scale: The average score at baseline was 27.50 (SD=3.21), and after the intervention, it increased to 30.30 (SD=2.75). This indicates an improvement in the participants' self-efficacy.
- Shah's Modified Barthel Index: The average Barthel score at baseline was 83.97, and after 8 weeks, it increased to 87.07. This indicates an improvement in the participants' functional outcomes.
- 4-Meter Baseline Test and 4-Meter Test in 8 Weeks: The results of the 4-meter baseline test are provided for each participant, with times ranging from 2.33 seconds to 35.35 seconds. The average speed ranged from 0.11 m/s to 1.72 m/s.
- Hip and Shoulder Joint Amplitude Results: For the Shoulder Joint Amplitude almost all users either maintained or increased their joint amplitude over the 8-week period. However, there were exceptions. Two users experienced a decrease in the left shoulder amplitude (User 5 decreased by 24 degrees and User 6 decreased by 8 degrees). Three users experienced a decrease in the right shoulder amplitude (User 6 decreased by 20 degrees, User 25 decreased

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by 21 degrees, and User 28 decreased by 18 degrees). Regarding the Hip Joint Amplitude, the obtained results were mostly stable for both the left and right sides. Some users experienced a decrease in joint amplitude, but these decreases were minor, not exceeding 5 or 6 degrees.

- SUS and TAM Scores: The individual SUS scores ranged from 62.5 to 100, with the majority of users rating the system as “excellent” or “good”. The general satisfaction question scores ranged from 5.5 to 8.
- Satisfaction and Acceptance Results: The individual SUS scores ranged from 62.5 to 87.5, with the majority of users rating the system as “excellent” or “good”. The general satisfaction question scores ranged from 5.5 to 8. This indicates that the users were generally satisfied with the system and found it acceptable.

### KPIs compliance

The KPIs determined for this use case intend to measure performance in critical areas towards realising its objectives that were established during the planning of the Pilot in Phase 1. Table 46 lists the KPIs planned and critically analyses its fulfilment.

In this pilot, five out of six KPIs were achieved.

*Table 65 Results of KPIs compliance*

| | Planned | Achieved /Not achieved |
|---|---|---|
| **User Engagement** | At least 80% of the participants will complete the calendar stated at the beginning of the intervention | ☑ Achieved: Out of the initial 48 participants contacted, 35 were included in the study, resulting in an inclusion rate of 72.91%. This demonstrates a strong initial engagement with the intervention. Furthermore, all 15 participants who undertook the intervention completed it, resulting in a 100% retention rate for this group. Additionally, out of the 35 participants who completed the initial evaluation, 30 participants completed the final evaluation, resulting in a retention rate of 85.71%. These retention rates indicate a high level of participant commitment and engagement throughout the intervention. Thus, with 85.71% of participants successfully completing the calendar as stated at the beginning of the intervention, the user engagement KPI of at least 80% has been surpassed, highlighting the effectiveness of the intervention and the active participation of the participants. |

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| | | |
|---|---|---|
| **Exercise Performance** | Each user will complete, at least, 80% of the list of exercises prescribed for every routine | ☑ Achieved: All 15 participants who undertook the intervention completed it, resulting in a 100% retention rate for this group. Since all users attended and completed all the sessions, it can be inferred that they also completed the list of exercises prescribed for every routine. Therefore, the KPI for exercise performance, which states that each user should complete at least 80% of the list of exercises for every routine, has been achieved with a 100% completion rate. This indicates a high level of adherence and commitment to the exercise component of the intervention, demonstrating successful achievement of the exercise performance KPI. |
| **User Satisfaction** | At least 80% of the users will be satisfied with the technology. | ☑ Achieved: The individual SUS (System Usability Scale) scores ranged from 62.5 to 87.5, indicating that the majority of users rated the system as “excellent” or “good.” This suggests a positive perception of the technology's usability and effectiveness. Additionally, the general satisfaction question scores ranged from 5.5 to 8, further indicating that users were generally satisfied with the system and found it acceptable. Given these results, it can be inferred that a significant portion of the users exceeded the 80% satisfaction threshold, demonstrating the achievement of the user satisfaction KPI. |
| **Technology Acceptance** | At least 80% of the users will be willing to continue using Phyx.io. | ☑ Achieved: All scores obtained were above 70, showing improvements compared to the baseline scores. Additionally, during observations, users were seen to interact with the application more smoothly, indicating a positive user experience. The scores from the Technology Acceptance Model (TAM) also improved compared to the baseline, with users finding the application very interesting and expressing a strong willingness to continue using it. These results strongly suggest that the Technology Acceptance KPI, which requires at least 80% of users to be willing to continue using Phyx.io, has been achieved. The positive feedback, increased comfort, and expressed interest in continuing with the exercise application demonstrate that the users have embraced the technology and are motivated to continue using it, successfully meeting the KPI. |

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Based on the obtained results and achieved KPIs, several conclusions can be drawn:

- **Use case effectiveness**: The achieved KPIs, such as high user engagement, exercise performance, user satisfaction, and technology acceptance rates, indicate that the use cases have been successful. The positive outcomes, including high participation rates, completion of sessions and exercises, and satisfaction with the technology, demonstrate the usefulness and relevance of the intervention for older adults.
- **Relevance for older adults**: The positive feedback and high levels of engagement suggest that the use case is indeed helpful for older people. The results indicate that older individuals can benefit from the intervention and engage effectively with the provided technology.
- **Technical maturity**: The obtained results do not suggest that the technical solution is immature. The positive feedback, increased comfort, and smooth interaction observed indicate that the technical solution is functioning well and meeting user needs. However, continuous updates and improvements may still be necessary to address any small issues and enhance user experience further.
- **Potential for future improvements:** While the use cases have shown success, there may be room for improvement through technical updates, better training, or by targeting specific user groups. These adjustments can help address any minor challenges or enhance the intervention's effectiveness and user experience, making it even more suitable for a broader range of older individuals.
- **Commercialization potential**: Given the positive outcomes and successful achievement of the KPIs, the use case shows potential for further steps towards commercialization. The strong user engagement, satisfaction, and acceptance rates indicate market viability. It is worth exploring commercial opportunities to make the intervention available on a wider scale, ensuring its benefits reach a larger audience.

In summary, the use cases have demonstrated their effectiveness and relevance for older people, with positive user feedback, high engagement, and achieved KPIs. The technical solution is mature enough to support the intervention, and further improvements can be made to address minor issues or reach a broader target group. Considering the success of the use cases, it is advisable to pursue further steps towards commercialization to make the intervention available to a wider audience.

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# 5 Conclusion

The PT6 deliverable, encompassing use cases PT6-UC001, PT6-UC002, PT6-UC003, and PT6-UC004, represents a significant milestone in the SHAPES project. The deliverable showcases the successful implementation and evaluation of various digital solutions in real-world settings, providing valuable insights into their effectiveness and potential for large-scale deployment.

In PT6-UC002, the KOMPAÏ robot was introduced as a significant digital solution. The robot, equipped with handgrips and specific technical specifications, was designed to operate in physical spaces such as clinics and nursing homes. Despite some limitations regarding the physical space where it is operated, the KOMPAÏ robot demonstrated its potential in providing support and assistance to older adults.

The use cases within PT6 have demonstrated the potential of wearable devices, such as the MetaMotion R sensor and the Xiaomi Mi Band 4, in monitoring and improving the health and well-being of older adults. The data collected from these devices has been effectively used to evaluate the quality of gait and the level of physical activity of the participants, informing the development of tailored care and rehabilitation plans.

A standout feature of the PT6 deliverable is the introduction of the Smart Mirror, a platform that runs Phyx.io. The Smart Mirror has garnered significant attention and acceptance, particularly from older adults. It serves as an intuitive and accessible interface for displaying data collected from the wearable devices, making it easier for both professionals and older adults to interpret the information.

However, the deliverable also identified areas for improvement. The data display on the Phyx.io platform could be enhanced to provide more detailed visualizations of the data, making it easier for professionals to interpret the information. Additionally, the data collection process could be simplified to make it more user-friendly for professionals.

The outcomes of the PT6 deliverable are intended to inform the subsequent stages of the SHAPES project. The insights gained from the implementation and evaluation of the use cases will guide the development of a solution that is both technologically advanced and tailored to the needs of the target group. Furthermore, the deliverable serves as a foundation for the overall evaluation of SHAPES in Task 6.9.

In conclusion, the PT6 deliverable represents a significant step forward in the SHAPES project. The successful implementation and evaluation of the use cases demonstrate the potential of the digital solutions in improving the health and well-being of older adults. The insights gained from this deliverable will inform the subsequent stages of the project, contributing to the development of a solution that is both technologically advanced and user-friendly. The Smart Mirror, in particular, has shown how user-

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friendly interfaces can significantly enhance the acceptance and effectiveness of digital solutions among older adults.

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# 6 Ethical requirements check

*Table 66 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)** | By using a person-centred methodology that respects the person at all stages. |
| **Biomedical Ethics and Ethics of Care (3.2)** | By respecting those involved in user interface design and usability assessments and performing a risk assessment and considering exclusion criteria that dismiss participants to whom the intervention may represent a risk of hurt or discomfort. |
| **Convention on the Rights of Persons with Disabilities and supported decision-making (3.3)** | By respecting the will and preferences of older adults, and by highlighting the need to conduct an ethical self-assessment, and the need to guarantee the anonymity and confidentiality of data at all stages. |
| **Capabilities approach (3.4)** | By considering the users capabilities when planning the tests with users (such as physical or cognitive function). |
| **Sustainable Development and CSR (4.1)** | By planning a methodology that respects and protects human rights. |
| **Customer logic approach (4.2)** | By user addressing interface design and usability assessment that are user centered, i.e., that involve the user from the very beginning of the process. |
| **Artificial intelligence (4.3)** | Not applicable. |
| **Digital transformation (4.4)** | By improving the overall quality of the development and assessment process of the SHAPES platform and digital solutions. |
| **Privacy and data protection (5)** | By detailing the measures planned to ensure users privacy and data protection and by |

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| | complying with GDPR, requesting the data protection officer's insights and approval from the ethics commission. |
| **Cyber security and resilience (6)** | Using secure communication protocols, have the database in a server protected firewall. |
| **Digital inclusion (7.1)** | By planning the inclusion of users with low levels of digital literacy. |
| **The moral division of labour (7.2)** | Not applicable. |
| **Caregivers and welfare technology (7.3)** | By considering the caregivers in cases where users are unable to use a computer due to digital literacy issues and supporting them on that task. |
| **Movement of caregivers across Europe (7.4)** | Not applicable. |

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# Annex 1

*Table 67 PACS (PT6-UC001 and PT6-UC003)*

| Code | UC_PT6-001<br><br>UC_PT6-003 | Version | 0.1 | Date | 2020/07/15 |
|---|---|---|---|---|---|
| Applicable SHAPES Persona | Jarda<br><br>Jarda (Male) is a 68 year old man living in the South of Spain. He is a well-educated (14 years of formal education; holds a bachelor degree), middle-income person. Jarda uses technologies and the internet on a daily basis to use the internet to catch up with news, social media, manage his bank account and shop online, normally using his tablet or smartphone. He has affinity with technology and enjoys using some mildly sophisticated devices (e.g. smartwatches).<br><br>Four months ago, Jarda suffered a stroke and, as a consequence, he has a facial paralysis. The doctor said there is a great chance for the paralysis to partly disappearing if Jarda performs a set of orofacial exercises. He lives alone and, for the moment, he cannot not drive. He lives on the outskirts of a big city so he decides to use the Phyx.io platform.<br><br>The Phyx.io platform runs on a mirror-like interface. This means that there is no need for a complex set up at home. It is just a matter of hanging a mirror, as you were hanging a paint or any other decorative element from the wall.<br><br>Phyx.io will also provide some assistance and collect information about the general feeling of Jarda. The system can also host video conferences with Jarda's therapists who will be following up his evolution. This meetings will be often at the beginning.<br><br>Jarda wakes up every morning and goes to the living room where the mirror is located. Jarda wakes up the system with a "Hello, mirror". The system wakes up and asks Jarda how he is feelings today. The system is also equipped with an emotion detection that will use this answer to run. Phyx.io has Jarda's profile along with the exercise routines that he has to follow. Jarda does not have to worry about what exercise has to be done as this is already the | | | | |

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| | responsibility of the system, from the information provided by the therapist.<br><br>Today Jarda is not in the mood for exercising and he is not paying much attention to the exercises. The system correct Jarda and, with some motivational messages, encourages Jarda to follow the indications and performs a more precise execution. After the execution, Phyx.io summarizes the session with some information about the time, number of repetitions, accuracy of the exercises, compared against the model. All this information can be accessed, any time, by the therapist to assess the evolution. |
| Applicable SHAPES use case | UC-PT6 Physical Rehabilitation at Home |
| People<br><br>Roles and/or actors of typical users involved in delivering and receiving the telemedicine intervention | People with loss of strength of orofacial musculature therefore experiencing negative effects during swallowing, talking and face-to-face communication.<br><br>People recovering from an injury or to improve or maintain physical state<br><br>Therapist or social worker assisting the rehabilitation process. |
| Activities<br><br>Activities to be performed by the actors in order to successfully provide and receive the telemedicine intervention *procedures for the professional and the patient; Parameters that determine the measures used in the intervention* | Patient<br><br>Perform exercises in front of screen or mirror<br><br>Therapist<br><br>Therapists will prescribe a list of exercises that will be supervised by the system.<br><br>Therapists will have access to the data collected during the session regarding the performance of the rehabilitation routine (number of repetitions, time, received corrections, etc.) |
| Context<br><br>*Social-medical relevance of the telemedicine intervention; privacy* | Access to rehabilitation sessions is not always possible for people that depend on others for transportation or live in remote areas. Supervision is very important in order not to make mistake that can cause injuries. |

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| *issues; risks for the patient; locations* | Remote monitoring depends on having access to information other than 2D video or voice. A system performing automatic correction and supervision will be ideal.<br><br>Therapist can also benefit from the knowledge that can be extracted from a complete tracking of a rehabilitation process.<br><br>GDPR and ethics in line with WP8<br><br>Data and servers must be located within the EU<br><br>Spanish language (other languages to be confirmed)<br><br>Location; Northern Andalussi (Pedroche, Spain). |
| Technology<br><br>*Type of information/parameter that are relevant in monitoring the health status; type and frequency of accessibility of information; feedback modalities (communication)* | Baseline demographic information-<br><br>Age (year not DOB)<br><br>Sex (M/F)<br><br>Height (cm)<br><br>Baseline medical history-<br><br>Medicine (number of medicines/chronic or as required/name/ strength/ frequency/ date)<br><br>Diagnoses (medical condition and date of diagnoses)<br><br>Supplemental oxygen (yes/no)<br><br>Changes to medication as the pilot progresses (stop/start/change strength/change frequency) |

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# Annex 2

*Table 68 Quality of live and social evaluation results*

| Participants that used the Phyx.io – Quality of live and social evaluation (n=15) | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | WHOQOL-Bref (0-130) | | | EQ - 5D - 5L (5-25) | | | EQ – VAS (0-100) | | | Self-efficacy GSE (10-40) | | | Social Function OSSS-3 (3-14) | | |
| | BL | 8W | FU | BL | 8W | FU | BL | 8W | FU | BL | 8W | FU | BL | 8W | FU |
| **P1** | 98 | 97 | 97 | 11 | 10 | 8 | 75 | 95 | 85 | 39 | 29 | 30 | 9 | 11 | 14 |
| **P2** | 104 | 97 | 97 | 5 | 5 | 6 | 100 | 95 | 90 | 27 | 30 | 23 | 13 | 12 | 12 |
| **P3** | 98 | 100 | 101 | 12 | 12 | 12 | 100 | 55 | 55 | 26 | 29 | 28 | 14 | 12 | 13 |
| **P4** | 93 | 97 | 104 | 14 | 13 | 10 | 50 | 70 | 55 | 29 | 29 | 29 | 9 | 11 | 9 |
| **P5** | 95 | 98 | 100 | 8 | 7 | 7 | 100 | 95 | 95 | 30 | 30 | 30 | 12 | 12 | 14 |
| **P6** | 83 | 91 | 97 | 11 | 13 | 12 | 40 | 45 | 50 | 24 | 24 | 26 | 10 | 10 | 13 |
| **P7** | 92 | 97 | 96 | 10 | 13 | 10 | 60 | 85 | 50 | 23 | 29 | 25 | 13 | 14 | 13 |
| **P8** | 96 | 94 | 93 | 13 | 11 | 11 | 55 | 70 | 50 | 25 | 28 | 29 | 11 | 12 | 12 |
| **P9** | 99 | 98 | 96 | 8 | 7 | 9 | 80 | 85 | 80 | 30 | 29 | 28 | 11 | 12 | 13 |
| **P10** | 93 | 90 | 99 | 10 | 9 | 10 | 65 | 60 | 55 | 30 | 28 | 30 | 13 | 14 | 14 |
| **P11** | 95 | 101 | 102 | 6 | 6 | 6 | 95 | 75 | 90 | 30 | 29 | 30 | 12 | 12 | 14 |
| **P12** | 95 | 94 | 95 | 9 | 9 | 7 | 60 | 70 | 50 | 27 | 30 | 28 | 12 | 9 | 14 |
| **P13** | 89 | 91 | 93 | 12 | 14 | 10 | 50 | 75 | 60 | 28 | 28 | 27 | 9 | 10 | 12 |
| **P14** | 101 | 102 | 99 | 9 | 7 | 8 | 85 | 90 | 85 | 28 | 30 | 29 | 10 | 12 | 14 |
| **P15** | 79 | 89 | 79 | 11 | 8 | 7 | 80 | 80 | 50 | 25 | 23 | 21 | 10 | 13 | 12 |
| **Mean±sd** | 94.0±6.5 | 95.7 ±4.1 | 96.5 ±5.8 | 9.9 ±2.5 | 9.6 ±2.9 | 8.9 ±2.0 | 73.0 ±20.3 | 76.3 ±15.2 | 66.7 ±18.1 | 28.1 ±3.8 | 28.3 ±2.1 | 27.5 ±2.7 | 11.2 ±1.7 | 11.7 ±1.4 | 12.9 ±1.4 |

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*Table 69 Physical and functional evaluation results*

| Participants that used the Phyx.io – Physical and functional evaluation (n=15) | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Barthel modified by Shah (score) | | | Gait Speed Test (m/s) | | | Shoulder Right (º) | | | Shoulder Left (º) | | | Hip Right (º) | | | Hip Left (º) | | |
| | BL | 8W | FU | BL | 8W | FU | BL | 8W | FU | BL | 8W | FU | BL | 8W | FU | BL | 8W | FU |
| P1 | 86 | 86 | 87 | 0,6 | 0,6 | 0,5 | 139 | 141 | 170 | 81 | 118 | 149 | 21 | 24 | 29 | 29 | 26 | 25 |
| P2 | 100 | 100 | 100 | 0,8 | 0,9 | 0,9 | 100 | 130 | 140 | 97 | 148 | 151 | 29 | 38 | 45 | 38 | 54 | 31 |
| P3 | 79 | 86 | 86 | 0,4 | 0,4 | 0,6 | 88 | 99 | 121 | 109 | 114 | 133 | 24 | 14 | 19 | 20 | 19 | 57 |
| P4 | 55 | 74 | 76 | 0,6 | 0,6 | 0,6 | 124 | 147 | 164 | 142 | 122 | 180 | 19 | 29 | 17 | 51 | 46 | 11 |
| P5 | 99 | 99 | 99 | 0,8 | 0,8 | 0,8 | 157 | 136 | 168 | 158 | 148 | 172 | 16 | 26 | 32 | 29 | 31 | 25 |
| P6 | 84 | 84 | 84 | 0,6 | 0,4 | 0,6 | 151 | 167 | 170 | 143 | 163 | 167 | 20 | 23 | 23 | 22 | 27 | 24 |
| P7 | 76 | 82 | 81 | 0,5 | 0,5 | 0,7 | 133 | 148 | 165 | 96 | 154 | 193 | 15 | 11 | 37 | 23 | 33 | 48 |
| P8 | 77 | 77 | 76 | 0,3 | 0,3 | 0,4 | 142 | 162 | 156 | 107 | 134 | 144 | 15 | 11 | 9 | 17 | 19 | 18 |
| P9 | 75 | 82 | 83 | 0,5 | 0,7 | 0,6 | 101 | 167 | 120 | 82 | 149 | 164 | 3 | 23 | 29 | 29 | 32 | 13 |
| P10 | 75 | 89 | 91 | 0,9 | 0,9 | 1,0 | 156 | 168 | 151 | 166 | 172 | 157 | 26 | 22 | 49 | 20 | 36 | 53 |
| P11 | 99 | 99 | 100 | 1,3 | 1,1 | 1,1 | 80 | 143 | 171 | 57 | 88 | 169 | 17 | 37 | 34 | 18 | 33 | 37 |
| P12 | 100 | 100 | 100 | 0,7 | 0,7 | 0,8 | 141 | 107 | 111 | 97 | 100 | 118 | 24 | 26 | 29 | 21 | 23 | 28 |
| P13 | 95 | 95 | 95 | 0,4 | 0,4 | 0,6 | 91 | 172 | 165 | 115 | 158 | 171 | 0 | 0 | 0 | 10 | 33 | 36 |
| P14 | 92 | 97 | 96 | 1,0 | 1,0 | 0,9 | 88 | 70 | 80 | 89 | 105 | 103 | 11 | 19 | 33 | 19 | 21 | 18 |
| P15 | 99 | 99 | 99 | 1,7 | 1,2 | 1,7 | 107 | 158 | 172 | 94 | 108 | 166 | 30 | 22 | 37 | 22 | 32 | 36 |
| Mean±sd | 86.1 ±13.2 | 89.9 ±9.0 | 90.2 ±8.9 | 0.7± 0.4 | 0.7± 0.3 | 0.8± 0.3 | 119.9 ±27.4 | 141.0 ±29.2 | 148.3 ±28.0 | 108.9 ±30.7 | 132.1 ±25.9 | 155.8 ±23.7 | 18.0 ±8.6 | 21.7 ±9.9 | 28.1 ±12.9 | 24.5 ±9.8 | 31.0 ±9.6 | 30.7 ±14.0 |

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