SHAPES

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

D6.5 – Psycho-social and Cognitive Stimulation Promoting Wellbeing Pilot Activities Report

Project Title	Smart and Healthy Ageing through People Engaging in Supportive Systems
Acronym	SHAPES
Grant Number	857159
Type of instrument	Innovation Action
Topic	DT-TDS-01-2019
Starting date	01/11/2019
Duration	48

Work package	WP6 – SHAPES Pan-European Pilot Campaign
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Version	V1.0
Due date	M43 – 31/05/2023
Submission date	31/05/2023
Dissemination Level	Public

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

Revision History

Table 1 Revision History

Revision #	Date	Editor	Comments
0.1	28.09.2020	Sonja Grigoleit (FhG)	ToC
0.2	15.01.2022	Ana Isabel Martins (UAVR)	Incorporation of all use case information, formatting and final edit of interim deliverable
0.3	01.02.2022	Anabela G. Silva (UAVR)	Revision of interim the deliverable
0.4	19.01.2023	Ana Isabel Martins (UAVR) and Anabela G. Silva (UAVR)	Incorporation of all use case information, formatting and final edit of final deliverable
0.5	10.05.2023	Anabela G. Silva (UAVR)	Revision of the deliverable
1.0	29.05.2023	Anabela G. Silva (UAVR)	Revision of the final deliverable

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Table of Acronyms and Abbreviations

Table 3 Acronyms and Abbreviations

Acronym	Full Term
AEMPS	Spanish Agency of Medicines and Medical Devices
AIAS	Associazione Italiana Asistenza Spastici
AUTH	Aristotle University of Thessaloniki
CE	Conformité Européenne
CH	Clínica Humana
CRF	Case Report Form
CSFs	Critical Success Factors
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
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
SHAPES	Smart and Healthy Ageing Through People Engaging in Supportive Systems
SO	Secondary Objective
SPANE	Scale of Positive and Negative Experience
SUS	System Usability Scale
TAM	Technology assessment model
TO	Tertiary Objective
UAVR	University of Aveiro
UEQ	User Experience Questionnaire
UP	Palacký University Olomouc
WHOQOL-BREF	World Health Organization Quality of Life Instruments – Bref
WP	Work package
SAR	Socially Assistive Robots

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Keywords

Psycho-social, Cognitive Stimulation, Physical activity, Promoting Wellbeing, DanceMove, Digital Solution.

Disclaimer

Table of Contents

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

List of Figures

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

List of Tables

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159

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Executive Summary

This deliverable contains the work completed by Pilot Theme 4 of the SHAPES Pan-European Pilot Campaign. It details the planning, outcomes and results of all activities and tasks completed throughout the five phases of the pilot campaign.

The work described here results from the collaboration and dedication of the whole of Pilot Theme 4, including the pilot site leaders, replicating sites and technical partners and significant contribution and assistance from other work packages (WP) within the SHAPES consortium.

This report contains the following information:

1. An introduction and description of the rationale and purpose of Pilot Theme 4.
2. A detailed description of the work undertaken in each of the five phases of the pilot campaign for use case PT4-001 and its results.
3. A detailed description of the work undertaken in each of the five phases of the pilot campaign for use case PT4-002 and its results.
4. A conclusion of the execution of the pilot and implications of both use cases in SHAPES and society.
5. Control of ethical requirements of Pilot Theme 4.

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1 Introduction

Pilot Theme 4 is dedicated to using and testing technology-mediated interventions in-home environments to promote older adults' physical, social and cognitive well-being. With a holistic token, this pilot theme and its piloting activities benefit from SHAPES psycho-social and cognitive training gaming applications to positively impact older adults' healthy lifestyles and quality of life.

It targets older individuals living in the community who are active and healthy, or who have mild chronic conditions, including chronic musculoskeletal disorders.

Pilot theme 4 is led by the University of Aveiro (UAVR) and encompasses two 'use cases', each deploying and evaluating different digital solutions. These are:

- **PT4-001: Psycho-social and Cognitive Stimulation Promoting Wellbeing.** The technical component consists of a dancing mat and respective software that allows personalizing dance choreographies and music and assesses the user's performance during the choreography. It integrates both a physical and a cognitive component into a ludic and appealing activity (dancing). This use case is led by UAVR and replicated by Aristotle University of Thessaloniki (AUTH) and Palacký University Olomouc (UP).
- **PT4-002: A robot assistant in cognitive activities for older adults**. A social robot is used as an improved channel to present cognitive tasks to older adults in a more personalized and motivating fashion by connecting the robot with a set of cognitive tasks. It is led by Clinica Humana (CH) and replicated by Associazione Italiana Asistenza Spastici (AIAS) and AUTH.

1.1 Rationale and Purpose of the Deliverable

This deliverable describes the work undertaken for Task 6.5 – Pilot Theme 4: Psycho-social and Cognitive Stimulation Promoting Wellbeing. It describes the activities undertaken during each of the five phases of the pilot, which closely follow the methodology outlined in Deliverable 6.1.

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1.1.1 Deliverable Objectives

The high-level objectives of this Deliverable are to:

- Introduce the use cases in pilot theme 4 and describe all work completed in the pilot theme;
- Describe the methodology used to conduct Phases one to five at each pilot site involved in PT4;
- Report on the key findings at each Phase and discuss their implications.

1.1.2 Key Inputs and Outputs

As defined in the SHAPES ecosystem (Figure 1), each use case includes five phases:

- **Phase 1:** The first phase included developing and testing a realistic scenario as a future base for the further planning the pilot activities;
- **Phase 2:** The second phase included the validation of mock-ups and prototypes to integrate this user feedback at an early stage of the technological development process;
- **Phase 3:** In the third phase, the users tested the SHAPES digital solutions of the respective use case to both accustom the user to the technical tool and got further feedback regarding the functional elements of SHAPES;
- **Phase 4:** The fourth phase aimed to test the SHAPES methods and solutions for later use in a large-scale demonstration. This small-scale demonstration was performed with a smaller group of participants to identify factors that could hinder the pilot site from organising and performing a successful large-scale demonstration;
- **Phase 5:** The fifth phase was the large-scale demonstration of the SHAPES digital solutions. In this phase, the SHAPES project's digital solutions, methods and processes were tested under real-life conditions with the targeted users in 15 European reference sites.

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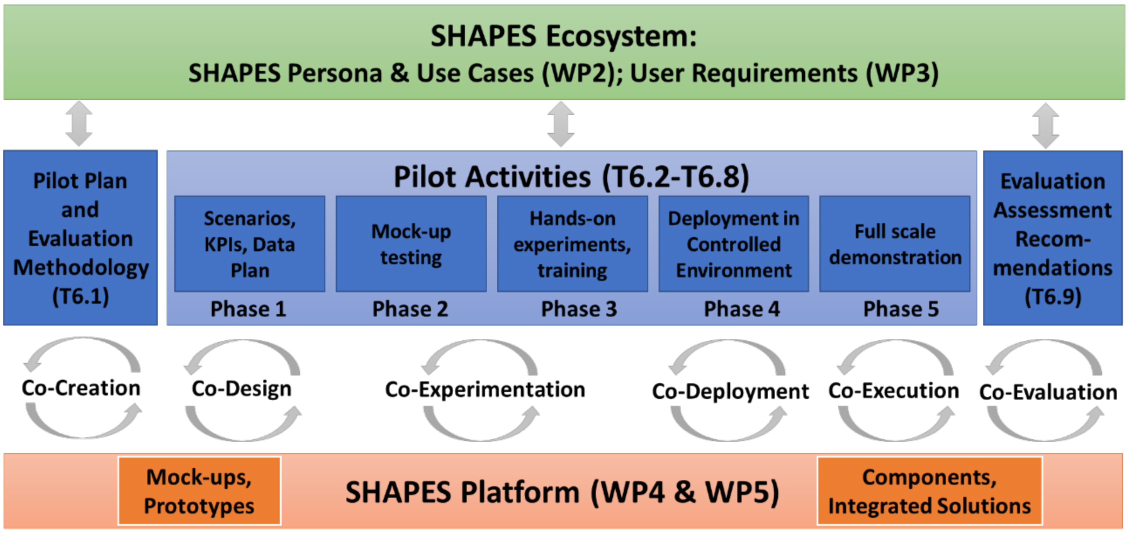

Figure 1. Overview of WP6.

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

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

The design of this pilot further builds on the personas and use cases developed in WP2, as well as on the user requirements presented in D3.7 – D3.9.

1.2 Structure of the Document

This document has been structured to present the activities undertaken and key outcomes of each of the two use cases of Pilot Theme 4.

Besides this introduction, this document presents a detailed description of the work undertaken in each of the five phases of the pilot campaign, including a description of each use case, the digital solutions used, the data plan containing the planning of evaluation using several frameworks to understand the impact of the SHAPES digital

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solutions, and the results of each phase and description of the implications and lessons learned for the following phase (chapter 2 and 3)

Throughout the document, the outcomes evaluated in each phase and the KPIs achieved at the end of the pilot are reported.

Primary outcomes and key recommendations from each use case are then brought together in the Conclusion (chapter 4).

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2 Use case PT4-001

2.1 Introduction

This chapter describes the activities undertaken within Pilot Theme 4: Use Case 1 - Psycho-social and Cognitive Stimulation Promoting Wellbeing.

The pilot's objective was to evaluate the impact of DanceMove on psychosocial, physical and cognitive functioning. The DanceMove includes software and a dance mat that allow the user to perform a dance choreography while listening to a piece of preferred music. Target users of this use case were persons aged 60 and older, living independently in the community (UAVR is the use case leader and AUTH and UP the replicating sites).

The personas for this use case (as defined in D2.7 SHAPES Personas and Use Cases V3) were SHAPES Personas 1 and 2 (Ernst and Roberto) that have the following characteristics:

1. Active, healthy older adults, with satisfactory financial standing and social relationships;
2. Older adults with mild chronic conditions, some reliance on spouses or children;
3. Older adults with chronic musculoskeletal disorders, risk of isolation.

2.2 Description

Combined interventions with a physical and a cognitive component are a means to promote both physical and cognitive functioning and are likely to impact psycho-social functioning. However, the adhesion of older adults to this type of intervention is usually difficult. One way to overcome this limitation is to promote an intervention to which older adults relate and which they find appealing. Dance has the potential to be attractive to older adults and can be adjusted according to individual characteristics (e.g. age, physical limitations, cognitive limitations) and preferences. This pilot theme focused on psycho-social and cognitive stimulation through a technological solution that engages older adults in a ludic activity (dance).

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2.3 Digital Solutions used in this Use Case

This use case employed two digital solutions, DanceMove and eCare that were integrated for SHAPES' purposes.

DanceMove is a digital solution that includes a dancing mat and respective software that allows personalizing dance choreographies and assesses the user's performance during the choreography.

DanceMove allows for the choice of the music and the difficulty level in line with users' preferences and characteristics. The user performs a specific movement in a particular sequence as presented by the software. Therefore, it requires the users' attention and memory, i.e., DanceMove integrates both a physical and a cognitive component into a ludic and appealing activity (dancing). It adapts to the end-users' physical and cognitive functioning, culture, and preferences.

DanceMove is based on the concept of the commercial solution STEPMANIA, a free dance and rhythm game for multiple platforms. Still, it has an adapted interface to meet the expectations and needs of older adults.

To play DanceMove (Figure 2), the user should pay attention to the arrows that scroll upwards on the screen, and when one of them meets a stationary set of target arrows, the player should press the corresponding arrow on the dance mat. The speed of the arrows is defined by the song's beat. The player's performance is scored based on how accurately they can trigger the indicators in time. The software triggers appropriate motivation messages if the player has an excellent or poor performance.

DanceMove communicates with the SHAPES platform via eCare, a bidirectional interface that allows the users to login and the register personal and clinical data. An interchange protocol was developed, allowing DanceMove to store data in the eCare digital solution and eCare to import data on users' performance from the DanceMove database. The communication protocol uses HTTP to exchange messages.

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Participants can view their dance score on the DanceMove at the end of each dance or session. No other data will be displayed or stored in the DanceMove. At the end of each session, data about the dance performance of the users is stored in the database at the UAVR server, protected by a firewall, and then sent to eCare. The users and researchers can access the aggregated user dance performance data on eCare.

Figure 2. DanceMove.

2.3.1 Digital Solutions used for COVID-19 Response

There were no digital solutions used for COVID-19 response in PT4-001.

2.3.2 Equipment and Devices Used (from third parties)

The Stepmania DanceMat, a USB-connected non-slip surface with pressure sensors, is used as an external hardware device in PT4-001. The minimum system requirements to use DanceMove are:

- Windows 7; Linux; Mac OS X 10.6+;
- 2GB MB of RAM;
- 700MHz minimum (Multi-core recommended);

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- Video card that supports 16-bit color, 128MB video RAM and OpenGL 2.1 or higher;
- DirectX 9.0 or later (Windows only);
- Sound card;
- Dance mat;
- Internet connection.

2.4 Data Plan

The data plan for PT4-001 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 provides detailed information about how personal data is collected, processed, and stored.
- DPIA risk assessment that identifies all the risks, its impact and propability and prososes 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 PT4-001.

2.4.1 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

- Scenarios and data plan definition.

Phase 2

- Brainstorming to generate mock-ups;
- A/B tests with domain experts;
- Semi-structured interviews.

Phase 3

- Test with real users in a controlled environment;
- Usability and acceptability questionnaires;
- Physical and cognitive function questionnaires;
- Critical incident registration;
- Logs registration;
- Semi-structured interviews with users.

Phase 4

- Tests of the DanceMove with real users at home for four weeks;
- Usability and acceptability questionnaires;
- Physical and cognitive functioning questionnaires;
- Adverse events;
- Log files registration;
- Semi-structured interviews with users;
- A weekly phone call to collect feedback.

Phase 5

- Tests of the DanceMove with real users at home for eight weeks;
- Usability and acceptability questionnaires;
- Physical and cognitive functioning questionnaires;
- Psychosocial questionnaires;
- Critical incident registration;
- Performance evaluation;

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- Log files registration;
- Adherence rates evaluation;
- Semi-structured interviews with users;
- A weekly phone call to collect feedback.

2.4.2 Planning of Evaluation

As planned in the Deliverable 6.1 – SHAPES Pan-European Pilot Campaign Plan, several frameworks widely used in active and healthy ageing pilot campaigns were used to understand the impact of the SHAPES digital solutions, including the Model for Assessment of Telemedicine Applications (MAST), the Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing (MAFEIP), the MOMENTUM framework and the Non-adoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) framework.

The MAST [1] framework was used to evaluate the effectiveness and contribution of UC-PT4-001 to quality of care. MAST is described as a multidisciplinary process that summarises and evaluates information about the medical, social, economic and ethical issues related to 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 UC-PT4-001. 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-PT4-001.

MAST Domain	Topic	Outcome	Data required	Time point
Clinical Effectiveness	Effects on mortality	Was not measured		
	Effects on morbidity	Was not measured		
	Physical health	Physical functioning	Gait speed test [2]	Phases 3,4 and 5

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		Social support	Oslo Social Support Scale (OSSS-3) (social support) & life events [3]	Phase 5
		Cognitive functioning	Trail Making Test and 6CIT	Phases 3,4 and 5
		Psychosocial and psychological wellbeing - Quality of life	World Health Organization Quality of Life Instruments – Bref (WHOQOL-Bref)[4]	Phase 5
	Effects on health-related quality of life	Health-related quality of life	EQ-5D-5L [5]	Phase 5
	Behavioural outcomes	Dance performance data	Dance score, number of choreographies danced, the ratio of correct steps, time danced, level of difficulty and type of interaction (continuous or erratic)	Phases 3,4 and 5
	Utilization of health services	Was not be measured		
Patient perspectives	Satisfaction and acceptance	Usability	System Usability Scale (SUS) scores [6] [7]	Phases 3,4 and 5
		User Acceptance	Technology assessment model (TAM) score [8]	Phases 3,4 and 5
	Understanding of information	Perception of participants towards the intervention structure and content	Semi-structured interview	Phases 3,4 and 5
	Confidence in the treatment	Adherence	Registrations	Phases 4 and 5

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	Ability to use the application	System Use	Log files	Phases 3,4 and 5
	Access & Accessibility	Was not be measured		
	Empowerment Self-efficacy	User Engagement	Played activities	Phases 4 and 5
			Time length in activities	Phases 4 and 5
			Mode of interaction	Phases 4 and 5
			General Self-Efficacy Scale (GSE) [9]	Phase 5
Economic aspects	Amount and cost of resources used	Was not measured		
	Related changes in use of healthcare resources	Was not measured		

Regarding the MAFEIP, due to the small size of the pilot and the short follow-up, the data needed to be input into this tool are likely to be biased and, therefore, MAFEIP was not used to evaluate UC-PT4-001.

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

MOMENTUM [10] offers critical success factors and performance indicators that help decision makers scale healthcare services from a distance through information technology. It also delivers a self-assessment toolkit that allows an organisation determine whether it is "ready" for telemedicine deployment.

Alternatively, the Non-adoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) framework is based on seven domains: the condition or illness, the technology, the value proposition (the initial assessment of whether the technology is worth developing), the actual or intended adopters (staff, patients, caregivers), the organisation, the broader system (e.g. policy, legal and regulatory context), and the

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process of adaptation over time [11], and is used to detect areas of complexity in the planning of social care projects.

The MOMENTUM blueprint was applied to check if UC-PT4-001 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:

There is a growing tendency for older adults to adhere to physical and cognitive activity programs. Most older adults understand that performing physical activities directly benefits their health and quality of life. Patients usually accept new technologies as far as they have a clear benefit. Users need to know the advantages compared to other devices which may offer similar functionalities.

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

Combined interventions with a physical and a cognitive component are a means to promote both physical and cognitive functioning using a single intervention/activity. The fact that people can play comfortably at home can allow greater motivation to comply with the intervention plan. In-home care, psycho-social and cognitive training gaming applications are envisioned as positively impacting older individuals' healthy lifestyles and quality of life.

CSF 3. Ensure leadership through a champion:

Several professionals who work directly with the older adults and with experience in dance interventions participated in the design of the DanceMove and showed great interest in it and found it relevant for their professional context.

CSF 4. Involvement of healthcare professionals and decision-makers:

The UAVR team has several members who are health professionals (physiotherapy, psychology and gerontology). These professionals were involved in defining the functionalities of the DanceMove and were responsible for conducting tests with end-users. In addition, other health professionals, external to the UAVR team, participated

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in Phase 2 (mock-up), and their feedback was used to inform the development of the DanceMove.

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

Older participants have been involved in the testing of DanceMove in Phases 3, 4 and 5. The tests with users helped the researchers identify and produce information materials and training to support users using DanceMove and getting the best possible results from taking part in the pilot. The tests with users also enabled the researchers to collect information about what to improve in DanceMove. In Phases 4 and 5, users were at the center of the intervention and evaluation, as they used the DanceMove freely for four and eight weeks at home.

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

The DanceMove interface was developed based on the D5.1 – SHAPES User Experience Design and Guidelines and Evaluation that gathers User Interface Design Recommendations to ensure user-friendly interfaces. A user manual was also created to provide the user-friendliness of the DanceMove digital solution. The usability and acceptance of the DanceMove were evaluated during Phases 2 and 3 and adaptations were made to enhance the user experience before the use case was piloted. Usability and acceptance metrics were also collected during Phases 4 and 5 to evaluate the final usability of the system.

CSF 7. Pull together the resources needed for deployment:

The resources required to deploy DanceMove were available thanks to SHAPES funding and internal resources already allocated. Also, the technical partners of the use case, notably EDGE, provided all IT competencies.

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

The adhesion of older adults to interventions for physical and cognitive training is usually complex, and a way to overcome this limitation is to promote an intervention to which older adults relate and which is appealing. Dance has the potential to be attractive to older adults and can be adjusted according to individual characteristics

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(e.g. age, physical limitations, cognitive limitations). Besides that, DanceMove can be used both to prevent aggravation of physical and cognitive conditions as well as to manage existing conditions.

DanceMove's clients can be individuals or public or private social or health institutions that work with older adults.

CSF 9. Prepare and implement a business plan:

A business plan for this digital solution was integrated with the D7.3 SHAPES Business Plan WP7.

CSF 10. Prepare and implement a change management plan:

At the end of the project, the need to prepare and implement a change management plan will be evaluated.

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

Completing a Data Protection Impact Assessment (DPIA) identified and minimized any risks associated with the pilot with input sought from other WP and the SHAPES Data Protection Officer at UAVR and LAUREA. Data processing agreements were established with relevant partners to permit access to pseudonymized data.

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

Although the number of participants in this use case was small, the solution was designed to be scaled to a Pan-European level. The DanceMove has the potential for scale-up as it is a cheap and user-friendly technology that runs on the web and uses a commercial and well-disseminated input device. This dance mat costs around 35 euros, less than other concurrent equipment available on the market. Besides that, DanceMove has a Greek version and a Czech version fully functional, which were tested in Greece and Czech Republic by the replicating sites.

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

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General Data Protection Regulation (GDPR) was applied. The system provided complies with all security and privacy-related regulations.

CSF 14. Involve legal and security experts:

We work with SHAPES partners (for example, with LAUREA, with extensive expertise in this field) mainly because we deal with personal and health data. VICOM was awarded with 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 detailed all the steps that were taken to ensure patients' privacy protection. The project endured a complete ethical evaluation before permission was granted to undertake the study. The informed consent detailed all the aspects of user privacy.

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

The SHAPES technical partner EDGE provided the information technology infrastructure through eCare. Besides the digital solutions, users needed a wireless networking system and a computer with a USB connection.

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

The digital solution works 24/365. In case of any bugs or issues, the development and maintenance team fixed them. UAVR and EDGE own all the software used in the pilot. This means that there were no software dependencies with third parties and could fix the source code at any point. The system logged all activities to identify and solve any incidents quickly. Moreover, it provided an interface to ensure system status monitoring. Participants had direct contact with UAVR.

CSF 18. Establish and maintain good procurement processes

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All technologies in the current version of the digital solution come from SHAPES partners except the dance mat device. Material needed to carry out some activities (paper, pen, printer) was available.

Regarding the NASSS framework [11], it was used to detect areas of complexity in the planning for piloting UC-PT4-001 and, if needed, to make adaptations to the plan. At the time the NASSS framework was applied, of the seven domains, there were three domains ('Technology', 'Intended adopters' and value proposition) in which significant complexities were identified that, if not mitigated or adequately addressed, were likely to affect the project's success at the piloting stage of the use case. Table 5 presents the complexities and mitigation measures in the PT4-001 use case identified using the NASSS framework at early stages of this pilot design.

Table 5 - Complexities and mitigation measures in the PT4-001 use case identified using the NASSS framework.

NASSS complexity domain	Uncertainties detected	Mitigation measures taken
Technology	The communication with e-Care is not fully working yet	Meetings with EDGE were conducted to define the communication protocol
Technology	The exact role and functionality of the platform had not yet been defined/communicated to the use case leaders	Cross-WP alignment meetings were set up between WP leads and pilot leaders to discuss the data flow and functionality of the SHAPES platform
Intended adopters	The acceptability of this kind of technology-mediated dance system is unknown in this population	User testing and prototyping in Phases 2 and 3 aimed to help enhance the user experience before the technology was piloted in Phases 4 and 5.
Intended adopters	Low level of digital literacy of the intended participants. As a minimum requirement service, users must have Wi-Fi installed in their home and have their computer.	User experience evaluation aimed to capture how well the participants accepted the technology.
Value proposition	The value proposition has significant complexity that is likely to affect a future deployment.	The cost-effective barrier needs to be addressed in a full randomized trial with a cost-effectiveness component, which will be informed by the results of Phases 4 and 5.

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2.5 Phase 1

The first phase of the pilot campaign intended the development of a realistic scenario for each use case. These scenarios are based on the People-Activities-Context-Technology (PACT) framework [12] and on the Function and events, Interactions and usability issues, Content and Structure, Style and aesthetics approach (FICS) [12] and are presented in Table 6 and Table 7.

2.5.1 PACT and FICS Scenario

Table 6 – PACT.

Code	UC-PT4-001 | Version 1 | Date 2021/03/16
Applicable SHAPES Persona	Personas 1 to 3
Applicable SHAPES use case	UC-PT4-001 Psycho-social and Cognitive Stimulation Promoting Wellbeing
Point of contact (pilot site)	UAVR
Point of contact (technical provider)	EDGE
People **Roles and/or actors of typical users involved in delivering and receiving the telemedicine intervention**	Older individuals living in the community corresponding to the Personas 1 to 3 (D2.7 SHAPES Personas and Use Cases V3) • Active, healthy older adults, with satisfactory financial standing and social relationships; • Older adults with mild chronic conditions, some reliance on spouses or children; • Older adults with chronic musculoskeletal disorders, risk of isolation; User profiles for DanceMove: • Administrator - profile to access and manage the DanceMove back-office; • Primary User – profile aggregating adults with +65 years living independently in the community; • Researcher – profile to conduct research studies.
Activities **Activities to be performed by the actors in order to provide and receive the telemedicine**	**Older adult** At home, the older adult accesses the DanceMove to carry out the dance activities. **Researcher**

intervention successfully procedures for the professional and the patient; Parameters that determine the measures used in the intervention	• In a face-to-face session, the researcher makes an initial assessment, explains all the DanceMove features and gives security advice on how to use it.
	• Remotely, the researcher can monitor the participant's performance, including:
	  ○ Completed dances;
	  ○ Usage of the DanceMove (i.e., total duration and number of sessions);
	  ○ Performance and scores;
	  ○ The researcher can issue positive reinforcement or alert messages whenever convenient and depending on the user's performance.

Context Social-medical relevance of the telemedicine intervention; privacy issues; risks for the patient; locations	• The DanceMove is meant to be used in older adults' homes; • Maintaining the privacy of data is of the utmost importance. An identification list (including name and age) was held at the local pilot site; • GDPR and ethics in line with WP8; • Data and servers are located within the EU (EDGE and UAVR); • **Location:** Aveiro and Lisbon Portugal; • The risk of falls was mitigated by providing safety instructions on how to avoid falls during the dance sessions. Also, insurance was contracted to protect participants in case of incidents.
Technology Type of information/parameter that are relevant in monitoring the health status; type and frequency of accessibility of information; feedback modalities (communication)	**Older adult** • Age; • Gender (m/f); • Physical functioning; • Cognitive functioning; • Dance performance; • DanceMove use; • Quality of life; • Health-related quality of life; • Social functioning; • Usability and technology acceptance; • Self-efficacy; • Adherence rates; • Adverse events.

Table 7 - FICS (PT4-001).

Category	Details
Function and events	• **DanceMove:** a dancing surface and respective software that allows personalizing dance choreographies and music and assesses the user's performance during the choreography. DanceMove allows for the choice of the music in line with users' preferences. Furthermore, it

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	requires the users' attention and memory to identify the movements and record patterns; • **eCare:** is a bidirectional interface between the DanceMove and the SHAPES platform that allows the registration of users' dance performance and personal and clinical data; • All the profiles have access to the DanceMove/eCare according to the guidelines established for the SHAPES platform. **Dashboard** Each profile has a dashboard with specific functions. The dashboard of the Administrator provides: a) The management of the DanceMove users; b) The management of music/choreography pairs, including the respective metadata (i.e., track title, track number, track artist, album title, music genre, year of the disc, and the characteristics of the associated choreography). In turn, the interface for older adults includes: a) Access to the DanceMove instructions; b) Access to frequently asked questions (FAQs) about the system use; c) Access to the difficulty level selection; d) Access to a pool of diverse music; e) Access to the dance game; f) Access to the performance on DanceMove, namely the last music danced or the session's global score. Moreover, the dashboard of the Researcher allows: a) The dance performance of the participants including: • the completed dances scores; • the total number of sessions and hours of training; • the number of correct/incorrect movements per arrow (left, right, front, back). b) The addition to eCare of new instruments to capture PROMs; c) The management of the study, including: • Study monitoring (e.g., to analyse the completeness of study by determining if the participants in the study have already completed the different data collection instruments); • Completion of participant's PROMs (i.e., acting as a proxy). d) Export the collected data in excel format.
Interactions and usability issues	• To address usability issues, mockup tests were held with users and experts following guidelines identified in D5.1 – SHAPES User Experience Design and Guidelines and Evaluation; • The interface was designed respecting the graphical user interface design guidelines for older adults; • The interface is simple, intuitive and straightforward.

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Content and structure ***Variables of the interaction***	• The front end for the older individuals is a browser-based website (DanceMove). The researcher's front-end is a browser-based website (eCare); • Although DanceMove is the main entry point for the older individuals, they may also connect in eCare (from EDGE) to fill out self-reported questionnaires in this Use case. • The analytics work as back-end services and the results are shown through eCare.
Style and aesthetics ***Look and feel of the system***	• The interface was designed respecting the graphical user interface design guideline for older adults and the guidelines identified in D5.1. – SHAPES User Experience Design and Guidelines and Evaluation; • The interface's colors were based on the colors of the dance mat.

2.5.2 Key Performance Indicators

KPIs are defined as measures that focus on the most critical factors to a project's success. KPIs are measurable and quantifiable with a target or threshold. They measure performance in critical areas by showing the progress or lack of it towards realising the objectives of each specific use case. The following KPIs have been chosen to determine whether or not the pilot for UC-PT1-004 has been successful.

Failure to meet four or more KPIs will indicate that repetition or major revisions to the use case and associated digital solutions are needed before further commercialisation development. In these use case, the following KPIs were defined:

Recruitment and retention: i) At least 80% of the target sample (i.e., 80% of 25 participants for UAVR (lead site), 80% of 6-7 participants for AUTH and 80% of 10 for UP (replicating sites) successfully recruited into the pilot; ii) At least 75% of the recruited participants within the target cohort remained enrolled in the pilot until the end of the study.

User engagement and acceptance: i) At least 60% of participants scored above average (>68) in the SUS [6] [7].

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Collection of data: i) At least 60% of participants completed 75% of the dance sessions during the pilot; ii) At least 60% of the dance sessions happened without critical incidents such as erratic interaction.

Technical performance: i) No failure of any of the technology components for at least 90% of the days; ii) No lost data for participants' dance performance.

Benefits and harms: At least 50% of participants report a change in cognitive, physical and social functioning that corresponds to an actual change in the condition compared with the respective values for minimal detectable change and/or minimal necessary change; ii) No falls or other adverse events.

2.5.3 Timeline of pilot activities

As per the original timeline of pilot activities, Phase 1 occured between May and July 2021, Phase 2 between August and October 2021, and Phase 3 between November 2021 and January 2022. Phase 4 occurred between February 2022 and June 2022, and Phase 5 between July 2022 and May 2023. The due date for the deliverable was extended from M37 to M40, and therefore Phase 5 was extended till May 2023. The replication took place for all replicating sites during Phase 5.

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 DanceMove for deployment in UC-PT4-001. The DanceMove interface design process was based on an iterative process that included two main phases:

- Internal (research team) brainstorming to generate mock-ups;
- Tests with external domain experts to assess the mock-ups.

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2.6.1 Methodology of Testing

2.6.1.1 Internal brainstorming to generate mock-ups

The brainstorming to generate mock-ups took place across several research team meetings. Seven experts participated in the brainstorming, including one physiotherapist, one gerontologist, two engineers, one social scientist, one designer and one person from the communication sciences.

The discussion focused on the functionalities to be included in each part of the DanceMove and, after each meeting, the designer produced a non-functional mock-up, used in the next brainstorming meeting. After generating these non-functional mock-ups, the pros and cons of each mock-up were discussed concerning the aim of the digital solution and the target population.

Two non-functional mock-ups were concluded and transformed into functional mock-ups for further assessment by domain experts external to the research team.

2.6.1.2 Tests with domain experts to assess the mock-ups

To choose between the two interface possibilities that arose from the brainstorming sessions conducted by the team, A/B tests with five external experts on physiotherapy, gerontology and psychology were conducted. The primary objective of this study was to assess which of the two interfaces was likely to better fulfil the aim of performing physical and cognitive training for older adults. Figure 3 and Figure 4 show the test setup and a participant during the test.

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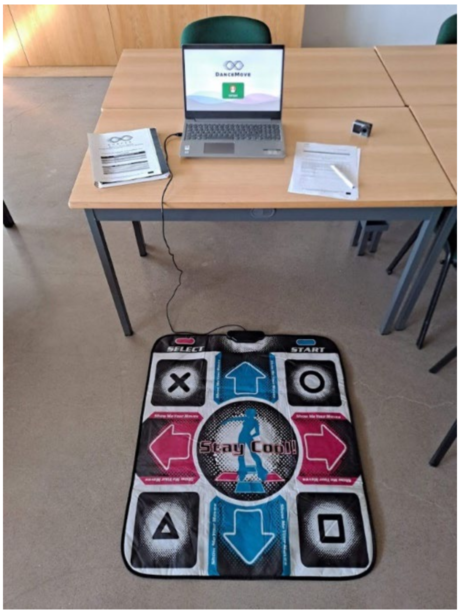

Figure 3. DanceMove test set up.

Figure 4. DanceMove test.

The test procedures were:

1. **Pre-test:** the researcher explained the study objectives, clarified any doubts the participant had and requested the informed consent signature and the filling of the sociodemographic questionnaire.
2. **Test:** throughout the test, the evaluator encouraged the verbalization of the participant's thoughts reinforcing the idea that there were no right or wrong answers.
   a) **Intuitiveness:** The evaluator explained the objectives of the DanceMove, presented interface number one and asked the participant to interact freely with it (without detailing how the interaction with the mat was made to evaluate the intuitiveness). Then, the evaluator presented interface number 2 and asked the participant to repeat the procedure and interact freely with it. The evaluator recorded aspects related to the participant's ease or difficulty interacting with the interfaces and the time each participant took to understand the interaction mechanism. The order of testing the interfaces was alternated, i.e., participant one started with interface number one, participant two started with interface number two, participant three started with interface number one, and so on.

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b) **Mock-up selection:** The evaluator asked each participant to decide which interface was most appropriate and why, considering the objectives and target audience of the system. The participant continued to interact freely with the chosen interface.

3. **Post-test:** The evaluator interviewed the participant following the script:

a) This system is intended to be a cognitive and physical training tool. Given these goals, which interface would you choose and why?

b) Considering the objective and target audience, what changes do you suggest to improve the system?

c) Other questions:

- What is the maximum number of arrows on the screen acceptable for the older adults?
- What do you think about the size of the icons?
- Do you think this technology is suitable for the older adults? What difficulties do you foresee in using DanceMove?
- Do you think this technology could be used in your workplace?

2.6.2 Results of Testing

2.6.1.3 Brainstorming to generate mock-ups

The history of mock-ups and improvement rationale resulting from the brainstorming sessions is described below.

1. **Explanation screens**

The explanation screens evolved to facilitate the understanding of the buttons. The image of the mat was replicated on the screen for the user to recognize the image of the buttons and their location on the mat (Figure 5).

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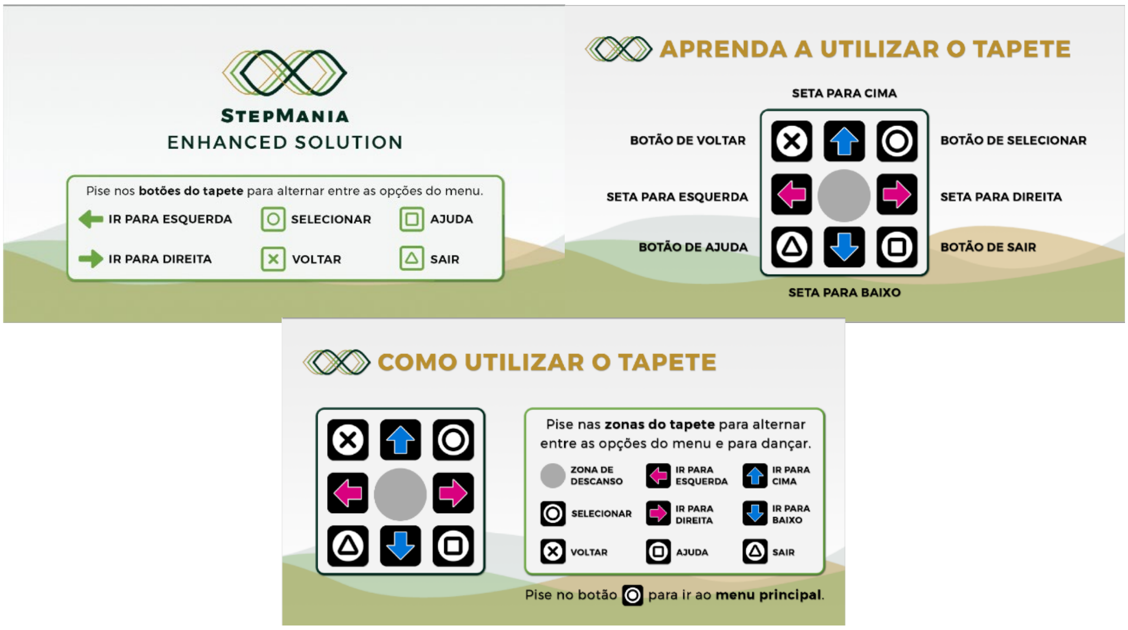

Figure 5. Explanation screens.

2. Music selection

Initially, the DanceMove had three levels of difficulty for each song (easy, medium and difficult), however, based on the mock-up test results, each song was then categorized only in one of the levels (Figure 6).

Figure 6. Music selection.

3. Game

Regarding the game screens (Figure 7), these have no background, and a canvas was placed on the playing field so that the user could focus his attention only on the arrows. Similarly, the total score was placed only at the end of the game. The format of the timer was designed to convey the idea of the game's progression. Intending to make it easier for the user, a dashed line was used to indicate the "path" of the arrows, but field tests proved that this was a confusing feature and for that reason, it was abandoned.

In the first version of the interface, instead of the arrows coming from below and overlapping the arrows on the screen, a neutral symbol (without direction) was used (a circle). The goal was to reduce confusion by the number of arrows that were on the screen at the same time. However, field tests showed that using arrows made it easier for the user to know the direction of the arrow they would have to trigger.

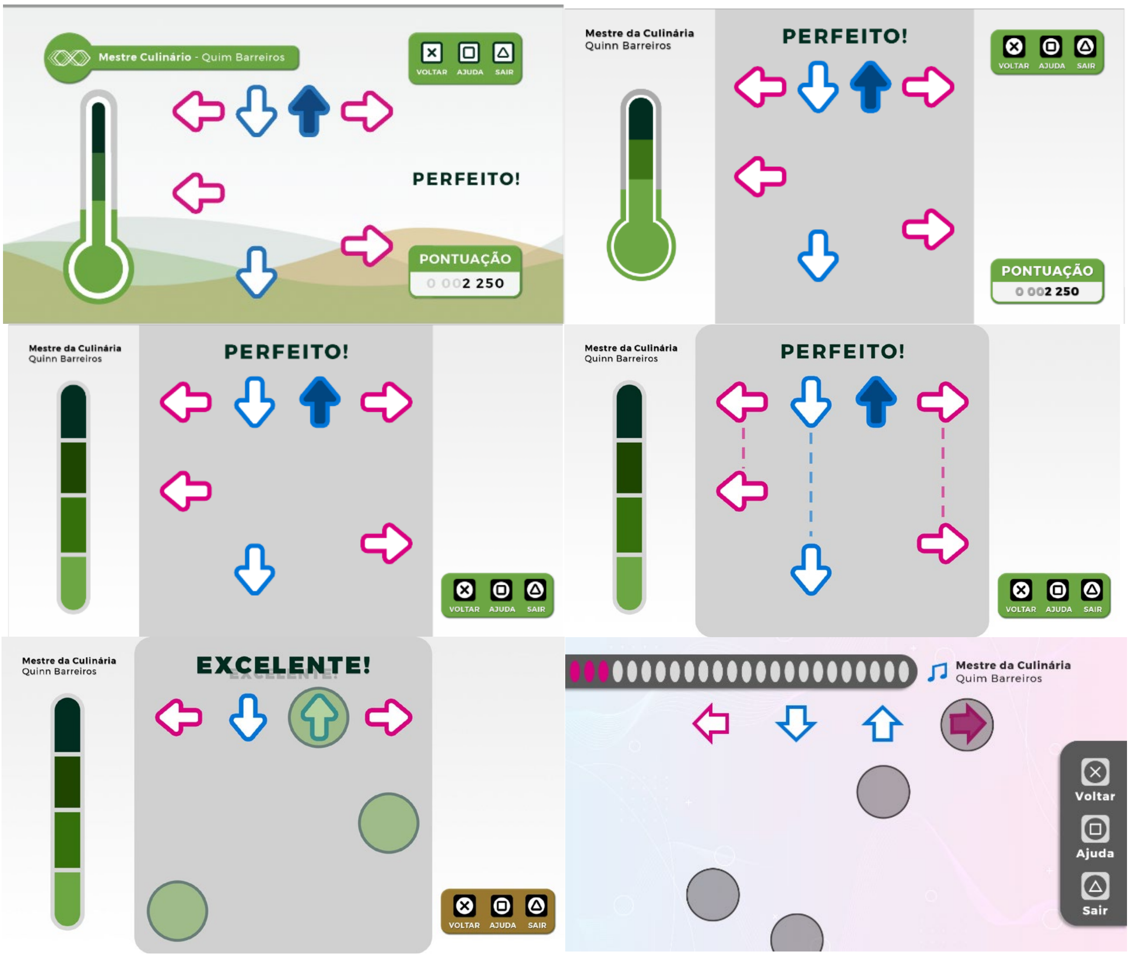

Figure 7. Game.

4. Performance and scoring

The performance was initially scored as a total score and, posteriorly, changed to a percentage of correct steps. In addition to the dance score, an option to consult the session score was also included (mean average from the scores of all dances performed during a session).

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Motivational messages were added to the interface according to the score obtained. For example:

- **Less than 50% correct steps:** Keep dancing.
- **Between 50% and 70% correct steps:** Good dance moves.
- **More than 70% correct steps:** Congratulations! Excellent dance moves.

Figure 8 presents the performance and scoring screens.

Figure 8. Performance and scoring.

The final visual design of the DanceMove interface was inspired by the colours of the dance mat and followed the good practices for user interface design within SHAPES digital solutions as stated in D5.1 – SHAPES User Experience Design and Guidelines and Evaluation. Prints of the final graphical user interface are presented in Figure 9.

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Figure 9. Final visual design of the DanceMove interfaces.

The brainstorming sessions resulted in four different mocks, from which two were chosen for further testing and transposed into functional mock-ups:

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Figure 11. Mock up 1.

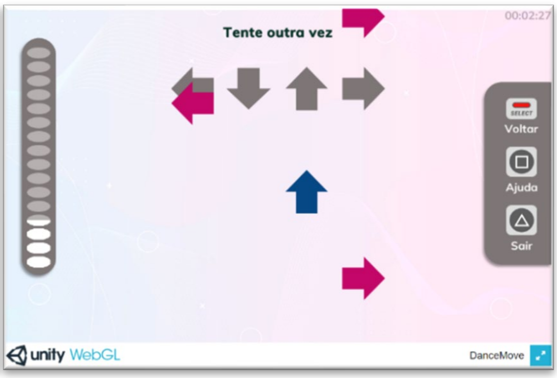

Figure 10. Mock up 2.

2.6.1.4 Tests with domain experts

The results showed that the interface from Mock-up 2 (Figure 11) was the best fit for performing physical and cognitive training for older adults. Participants considered that this mock-up 2 is more challenging from a cognitive point of view and allows for a higher dancing speed. Mock-up 1 (Figure 10) was excluded because it limited the maximum speed of the game and, therefore, the choreography, and also there were too many elements on the screen (too much visual noise).

During A/B tests, experts made recommendations related to the interface and related to the intervention with DanceMove:

1. Interface:
   a) The size of the screen should be large.
2. Intervention:
   a) Minimize the risk of falls associated. For example, place a non-slip net under the rug. It can be a danger on slippery ground;
   b) It would be good to have bars, a chair with a good support base or to do the exercises against a wall where the person can support if needed. Perhaps the caregiver can be on the other side to provide support also;
   c) The first few times, users must have supervision.

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2.7 Phase 3: Hand-on Experiments

2.7.1 Methodology of Hands-on Experiments

Hands-on experiments were performed in Phase 3 of the SHAPES Pilot Campaign to collect end-users feedback and evaluate the performance of DanceMove. Hands-on experiments were conducted with a functional prototype that was prepared based on the results of previous phases. The study protocol for the hands-on experiment study with users was approved by the ethics commission and DPO of the UAVR (Process number 27-CED/2021).

Study Objectives

To collect feedback about the usability and acceptability of the DanceMove from end-users by allowing them to try it in a close-to-final version prototype.

Inclusion Criteria

For this study, participants with the following characteristics were selected:

- People living independently in the community;
- Being 60 years old or older;
- With mild to no cognitive impairment;
- With independent gait and without the use of walking aids.

Exclusion Criteria

Potential participants were excluded if:

- History of cardiovascular pathology;
- Taking drugs that could impair cognition in the past 3 months;
- Taking alcohol or having a history of substance abuse in the previous 2 years;
- Reporting recent dizziness or feelings of unbalance.

Recruitment

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Participants were recruited from the gerontological activity group of the Municipality of Albergaria in Aveiro, Portugal.

Ethics

Information Sheet and Informed Consent

All subjects who wanted to participate were given an information sheet containing all the information about the study objective and procedures. Also, the researcher provided verbal information on the study objectives and data collection aspects, the duration of the study and all the phases involved. The participants had the opportunity to ask for further clarifications on the study and were informed about the possibility of withdrawing their participation at any time without any personal damage or the need to further justify their decision.

Following the information on the study, each person interested in participating was asked to sign an Informed Consent, in accordance with the Declaration of Helsinki.

Confidentiality of data was guaranteed, and no personal data was shared with third parties.

Data collection and confidentiality

Due to the nature and objectives of the service, participants were required to provide information that may be considered personal (clinical information, identification and contact). All clinical data was provided voluntarily and preceded by the user's informed consent.

The data collected was intended only for DanceMove system operation, user characterization, quality control and anonymous statistical analysis.

Research Design

The data collected included parameters of the user interface, system performance, bugs and errors, user acceptance, usability, cognitive and physical functioning evaluation.

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The usability assessment was conducted using a multi-method approach that encompassed:

a) User self-perceived usability and acceptability were assessed using System Usability Scale (SUS) [6][7] and Technology assessment model (TAM) [8];
b) Usability evaluation based on the perspective of the usability evaluator, was assessed using the International Classification of Functioning Usability Scale (ICF-US) [13];
c) Performance evaluation, recorded in log files and critical incident registration.

Individual Usability test session

A set-up was explicitly assembled for the usability tests in the physical activity hall of the Municipality of Albergaria in Aveiro.

Since participants at this stage had no knowledge or experience with the DanceMove, they followed a script to walk through the system's main features and give feedback about them.

The evaluation session had the following moments:

1. **Pre-test:** The evaluator applied the sociodemographic questionnaire, trail making test and gait speed test [2];
2. **Test:** The evaluator delivered the session script to the user, explaining orally all the information contained therein. Users performed the tasks described in the script. At the same time, the observer recorded the occurrence of unforeseen events in the critical incident log sheet. Log files were also recorded during the session;
3. **Post-test:** The participant filled in the SUS [6][7] and TAM [8], and the evaluator filled in the ICF-US [13].

Instruments Used

The gait speed test requires participants to walk 4 meters in a straight line at their normal pace. Participants were positioned immediately before the mark signalling the test path and the timer started when the participants began walking. The time taken to

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perform the test is measured in seconds and the outcome measure is converted to meters per second (m/s). This test is valid and reliable (ICC values generally above 0.90 for both intra and inter-rater reliability) [2]

The Trail Making Test (TMT) has two parts (part A and part B), both consisting of 25 circles that the person has to connect as quickly as possible without lifting the pen from the sheet of paper. In Part A, the circles are numbered 1 – 25, and the person was asked to draw lines to connect the numbers in ascending order. In Part B, the circles include both numbers (1 – 13) and letters (A – L) and the person was asked to draw lines to connect alternate numbers and letters (e.g., 1-A-2-B-3-C). Both the number of errors committed, and the time taken to complete the test were measured. If after five minutes the patient has not completed both parts of the test, it stops [14].

SUS [6][7] is a 10-item scale to evaluate self-reported usability and is considered a gold standard in usability evaluation. Each item is scored on a 5-point Likert scale and the final score ranges from 0 to 100, and higher values indicate better usability. According to Brooke (1996), usability above 68 is considered acceptable and any value below 68 has the potential for improvement.

The TAM [8] is a 3 questions instrument to evaluate the technology acceptance based on the Technology Acceptance Model. The three questions based on the TAM [8] are: i) The technology is easy to use?; ii) Is this technology useful to me?; iii). If this technology was available to me in the future, I would use it?, were scored on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree). The total score ranges from 3 to 21.

The ICF-US [13] is a usability assessment scale based on the opinion of the usability assessment moderator. This tool is in line with the International Classification of Functioning Disability and Health conceptual model and consists of two subscales (ICF-US I and the ICF-US II) and allows for a comprehensive usability assessment.

Table 8 lists the Instruments used for sample characterization and usability evaluation.

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Table 8 - Instruments used for sample characterization and usability evaluation for each moment of phase 3.

Instruments	Pre-test	Test	Post-test
Sociodemographic Questionnaire	X		
Trail Making Test	X		
Gait speed Test [2]	X		
Session Script		X	
Log files		X	
Critical incident log sheet		X	
SUS[6][7]			X
TAM [8]			X
ICF-US [[13]			X
Overall Satisfaction Rating Question			X

SUS – System Usability Scale | TAM – Technology acceptance questions | ICF-US - International Classification of Functioning based Usability Scale

2.7.2 Results of the Hands-on Experiments

The hands-on experiments were conducted in October 2021. Fourteen older adults (11 females), with a mean (± standard deviation – sd) age of 72±7 years old and a mean (±sd) of 11 (±5) years of formal education entered this study (Figure 12). The participants took a mean (±sd) of 37.1 ±18.2 seconds to fill the TMT A and three participants made at least one mistake. On the TMT B, the mean time was 143.8 ±86.3 seconds and seven participants made at least one mistake. Regarding the gait speed test the mean was 0.8±0.1 m/s.

Figure 12. Photos of users testing the DanceMove.

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The mean±sd sample score for the first dance was 53.0±19.6 out of a maximum of 100, and 68.0±16.5 for the second and 72.0±20.1 for the third. These results suggest a learning curve when beginning to use the DanceMove. In the first dance, it takes a few moments for the user to understand the game's logic and start stepping on the arrows at the right time.

Despite high levels of formal education, seven participants had low levels of digital literacy and did not know how to use a computer (they only used a smartphone or tablet). For this reason, it was not possible to test all tasks that were part of the session script with all participants, such as the tasks: open the browser or enter the password.

SUS values indicate an acceptable level of usability for user self-reported usability (78.3±18.7) as usability score above 68 is considered acceptable. The mean±sd for the TAM questions was 16.0±5.2 out of a maximum of 21 and in terms of user satisfaction. Regarding the usability reported by the evaluator, DanceMove was considered a small facilitator (9.8±12.4 out of 30).

Two participants struggled to use the DanceMove because of balance loss.

Although the interaction with the DanceMove can be done using the dance mat, and its utilization was encouraged, the participants simply got off the mat, approached the computer, picked up the mouse and performed the tasks using it (or pressed the screen despite not being a touch screen), i.e., participants did not use the dance mat for anything other than dancing.

Lessons learned from Phase 3 that inform Phase 4

The tests in Phase 3 made it possible to identify a series of problems, whose solutions can be from a technological point of view or they can be from the point of view of the intervention framework (teaching strategies, the information provided to the participant…), namely:

- Emphasize training issues;
- Consider taking breaks in the first dance, interspersing with explanations; about the game, scoring and safety;
- Adjust expectations and explain very well what usability tests consist of;

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- Consider interviewing at the end to collect qualitative feedback;
- Consider and define strategies to maximise security when using DanceMove.

The results showed that DanceMove presents a good level of usability and acceptability, however, the interface can be improved. The following recommendations (Table 9) arose from the usability tests:

Table 9 - Recommendations for technical partners (problem identified and technical solution)

Problem identified	Technical Solution
Opening the browser and writing the DanceMove link was a problem for most participants due to issues related to low digital literacy.	Create a desktop shortcut for direct access to DanceMove.
Some participants stepped outside the game area and pressed the help or exit menu, interrupting the game.	The mat buttons (square, triangle, circle and cross) must be disabled during the game.
Often participants did not use the buttons on the mat but instead got off the mat to click using the mouse (and it did not work).	All interface buttons must be clickable.
Participants have difficulty deleting the "insert text" on the username field to write their username.	Delete the "insert text“ on the username field.
Some participants used the tab key to advance from the username field to the password field, which was not working.	Enable the possibility to use the tab key to change fields.
The interaction is not well classified as erratic or continuous. All tests were recorded as erratic interaction, even in tests where participants had high scores.	Clarify the rationale for classifying the interaction and correct it on the system.

2.8 Phase 4: Small Scale Live Demonstration

A small-scale live demonstration of the SHAPES Platform and digital solutions being deployed in Pilot theme 4 (UC-PT4-001) was conducted during Phase four of the SHAPES Pan-European pilot campaign at the UAVR. The demonstration tested the methods and procedures later applied in the pilot at a larger scale. The DanceMove was tested in a real-world environment for four weeks, and the data collected included those related to the usability and feasibility of a physical and cognitive intervention mediated by the DanceMove. It provided information to apply amendments to the processes, logistics or documentation used in the large-scale pilot. It assessed the

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feasibility of using DanceMove and the dance mat, the resources needed, and how the participants reacted. Information collected during this phase informed the study protocol of Phase 5.

Phase 4 was also used to test the strategy for recruiting participants for the pilot in Phase 5. This was useful to assess the ability of the research team to identify the appropriate cohort of participants and informed them on the need to adjust the eligibility criteria.

Study Objectives

To determine the feasibility of using DanceMove to promote physical and cognitive functioning for at least four weeks at participants' homes.

2.8.1 Recruitment of Participants

Inclusion Criteria

For Phase 4 small-scale live demonstrations, participants with the following characteristics were selected:

- Living independently in the community;
- Being 60 years old or older;
- Presenting mild to no cognitive impairment;
- Having independent gait and no use of walking aids;
- Having access to a personal computer and internet;
- For older adults unable to use a computer, a proxy or carer with digital literacy needs to be identified for the older adult to enter the study.

Exclusion Criteria

Potential participants were excluded if they reported:

- History of cardiovascular pathology;
- Taking drugs that could impair cognition in the past 3 months;

- A history of substance abuse in the previous 2 years;
- Reporting recent dizziness or feelings of unbalance.

Sample Size

DanceMove was tested with five subjects living in the community.

Recruitment

Participants were recruited from the gerontological activity group of a Municipality in Aveiro, Portugal.

Technical Aspects & Logistics

The integration of DanceMove with e-Care was used and tested during Phase 4, namely the transfer of data and the synchronization of the DanceMove database.

In terms of logistics, the following conditions had to be fulfilled for the conduction of Phase 4:

- The aspects related to the participant house and equipment (access to a personal computer and internet access; house with an available area, with non-slippery floor, to place the dance mat);
- Availability of the dance mats to deliver to the participants.

Each participant received a dance mat to use at home and instructions on how to open the DanceMove and use the mat correctly and safely, and user manuals were also provided. Each participant was asked to, ideally, use the system for at least 30 minutes, three times a week for four weeks, i.e., the intervention consisted of using the DanceMove and the mat to dance for 30 minutes three times a week. In each session, participants could choose the music from the music pool presented in DanceMove. The participant chose from a set of songs of different genres.

Every week, the researcher made a phone call to each participant to motivate them for the intervention and investigate the occurrence of possible adverse events or difficulties in use.

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A log of all requests for support was kept and analysed after the demonstration. This process informed about the type of technical support required for the large scale pilot and allowed the research team to make the necessary arrangements.

Participants' data were gathered in a browser-based researcher dashboard in eCare. Researchers were able to view each participant's dance performance data.

A user log was kept during the four weeks of using DanceMove. During this time, the dance score, number of choreographies danced, ratio of correct steps (left, right, up, down), time danced, difficulty level and type of interaction (continuous or erratic) were collected. Errors were also recorded including system crashes, error messages, dead links, or unsaved data.

The logs were reviewed by the pilot site researchers and the technical partners to determine the cause of the error and how to rectify or prevent it.

Participants were also asked to suggest any amendments or additions they felt were needed in the user manual for DanceMove.

2.8.2 Roles and Responsibilities

The SHAPES pilot site researchers at UAVR were responsible for recruiting and collecting participants consent to participate in the live demonstration. In addition, UAVR provided training and was the single point of contact for the participants. Finally, the technical partner EDGE provided technical support (via UAVR) to participants if needed.

UAVR researchers collected data and supported questionnaire filling and were the contact point of participants for any doubts or technical issues. All technical issues were communicated to the technical team, led by EDGE, who acted accordingly. Researchers from UAVR did the face-to-face visits necessary to solve technical issues.

During this phase, the replicating sites prepared the replication of the PT4-001. In addition, AUTH and UP researchers translated the DanceMove interfaces and

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materials (such as the user manual) and prepared the study documentation, namely the protocol, to submit to the ethics commission. All this documentation (e.g., consent form, study protocol, user manual) was provided by UAVR to each replicating sites in English.

2.8.3 Ethical Considerations

The study protocol for the PT4-001 Phase 4 was approved by DPO and the Ethics Committee of the University of Aveiro (Process number 27-CED/2021). An information sheet was provided to each participant specifying the nature of the research, including the processing of personal data. Written consent was obtained from each participant before entering this study phase.

The data collected with DanceMove only concerns system usage data (how many times each participant danced and for how long and dance score) and not personal data or sensitive data. These data were stored on a server at the UAVR, and there was no data transfer to other locations. The server complies with current regulations, and regular backups were made.

The data collected by the researchers through questionnaires and other instruments (personal and health data) was physically stored at the UAVR in a place with restricted access and was subject to a pseudo-anonymization process. Also, informed consents were kept separately from the remaining data in the office of the researcher Ana Isabel Martins. The code that allowed identifying the participants and the personal data was destroyed approximately nine weeks after starting the study (i.e. when they were no longer needed).

2.8.4 Outcome of the Small-Scale Live Demonstration

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2.8.5 Results of the Small Scale Live Demonstration

The Small Scale Live Demonstration data collection was conducted during February and March 2022 in Albergaria, Aveiro. Five older adults (all female), with a mean (±sd) age of 71.2±6.0 years old and a mean (±sd) of 13.0±6.0 years of formal education entered this study. None of the participants had cognitive impairment measured with the 6-CIT (mean±sd = 0.2±0.5). Participants took (mean±sd) 38.7 ±11.3 seconds to fill the TMT A and made 0.6±0.5 errors. On the TMT B, the time taken to complete it was 99.1±46.3 seconds and participants made a mean of 0.6±1.3 errors. The gait speed test results were 0.9±0.0 m/s.

Regarding usability, the mean±sd for the TAM questions was 17.8±1.3 out of a maximum of 21 and 88.0±8.2 for SUS out of a maximum of 100, indicating high level of acceptance and self-reported usability, respectively. Table 10 presents a summary of the participants characteristics and usability results.

Table 10 - Characteristics of participants in Phase 4.

	Physical function	Cognitive function				Usability	
Participant	Gait speed (m/s)	TMT-A Time (s)	TMT-A Errors (n)	TMT-B Time (s)	TMT-B Errors (n)	SUS (0-100)	TAM (3-21)
PT1	0.8	26.6	1	87.3	0	97,5	17
PT2	0.8	29.9	1	72.3	0	75	18
PT3	0.9	48.7	0	67.3	0	90	19
PT4	0.9	52.0	0	180.4	3	87.5	16
PT5	0.9	36.0	1	88.0	0	90	19
Mean (SD)	0.9 (0.0)	38.7 (11.3)	0.6 (0.5)	99.1 (46.3)	0.6 (1.3)	88.0 (8.2)	17.8 (1.3)

During the four-week study, three participants, performed between eight and 17 sessions and two participants performed only one session due to health problems. The dance sessions duration varied between 6.2 and 15.1 minutes. The participants preferred easy or moderately difficult choreographies, and the mean session score varied between 60 and 81.4 (out of 100). Backwards stepping showed a tendency for the lowest scores. Table 11 presents the performance data from DanceMove usage in Phase 4.

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Table 11 - DanceMove performance data.

	Number of sessions (n)	Duration of sessions (minutes; Mean±SD)	Songs per session (n)	Songs level of difficulty (%)	Total score (Mean±SD)
P1	1	6.2	2	Easy -100%	60.0
P2	1	10.1	3	Easy -67 Moderate – 33	62.7±29.5
P3	8	10.5±2.2	3	Easy – 16 Moderate – 72 Difficult - 12	81.4±14.6
P4	9	15.1±14.1	1 to 11	Easy – 53 Moderate – 29 Difficult - 18	81.4±23.2
P5	17	7.0±1.2	2	Easy - 47 Moderate – 53	71.9±23.4

The feedback at the end of the four weeks, resulting from the final interviews, is presented in Table 12. The interviews were conducted with the three participants that performed more than one dance session.

Table 12 - Results from the final interviews with Phase 4 participants.

Participant	Quotations
PT3	I enjoyed using DanceMove, I danced with pleasure. I started on the easy level but found it too stagnant, so I switched to medium and still went to the hardest level a few times. Overall, I think it went very well. My routine changed, in the sense that I took time away from other things to be on the computer, dancing. Dancing with the mat made me lift my feet more, which is great. I feel that I trained movements, attention, and concentration, and I think that is very important. I felt it was a little monotonous because it was always the same songs. The rhythm of the songs was not always right with the moment that we had to press the arrows, which sometimes made me lose.
PT4	Every time I wanted to dance, I had to move a table in the room. It wasn't much work, but it's always a foreign body you have in the middle of the room. I only used it in my spare time, when I had nothing else to do, I don't think it implied changes in my habits. In my case, it was interesting, but it was not totally useful because I had to stop, due to back pain and when I could dance again, I only danced the easier songs.

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	I would have liked to have had this system in the winter because at this time of summer I am always outside in the garden and doing other types of activities. This would be great for rainy days and bad weather when you spend more time at home and do less physical activity. The system is very good because it makes you move. At first, I did it very slowly, but after I "get the hang of it" it became much easier. There should have been more modern songs and not so traditional songs.
PT5	It forces you to move and at the same time be paying attention to the arrows. I enjoyed participating in the study; for me, it was even a game, in the evening I would set aside 10 minutes and tell my husband "now I'm going to go to the mat for a while". I did it practically every day and I got fatigued. The difficult level is really hard, I found it a mess. I was already used to exercising at home, I have a treadmill and a shaking machine; the mat was one more to diversify.

2.9 Phase 5: Large-Scale Pilot Activity

A large-scale live demonstration of the SHAPES was deployed in the UC-PT4-001 during Phase 5 of the SHAPES Pan-European pilot campaign.

Implementing the SHAPES large-scale Pan-European pilot campaign aimed to validate the SHAPES capabilities and benefits to care recipients, caregivers and care service providers across different regions, cultures and health and care organizational models. It also aimed to assess the impact of the SHAPES in supporting healthy ageing and independent living and the definition of improved integrated care policies and measures.

A randomized and controlled study was conducted with the DanceMove in Phase five.

Phase 5 aimed to pilot test the effectiveness of using the DanceMove to promote physical and cognitive functioning by monitoring participants over eight weeks using the DanceMove freely at their homes.

The experimental group was requested to use the DanceMove and the mat to dance ideally up to three times a week, for up to 30 minutes, while the control group did their usual activities.

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Participants were assessed at baseline, at the end of the eight weeks and at three months follow-up.

2.9.1 Recruitment of Participants

2.6.1.5 Eligibility criteria

Inclusion Criteria

Participants in both groups were included if:

- Living independently in the community;
- Being 60 years old or older;
- Presenting mild to no cognitive impairment;
- Having independent gait and no use of walking aids;
- Having access to a personal computer and Internet;
- For older adults unable to use a computer, a proxy or carer with digital literacy needs to be identified for the older adult to enter the study.

Exclusion Criteria

Potential participants were excluded if they reported:

- History of cardiovascular pathology;
- Taking drugs that could impair cognition in the past 3 months;
- Taking alcohol or having a history of substance abuse in the previous 2 years;
- Recent dizziness or feelings of unbalance.

Sample Size

DanceMove was tested with 30 older adults living in the community with mild to no cognitive impairment, who were randomized into an experimental or a control group. The replicating sites recruited 5 older adults at the AUTH and 11 at the UP using similar inclusion criteria.

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Recruitment

At UAVR, participants were recruited from several social and health institutions dispersed across Portugal and that worked directly with older adults in the regions of Aveiro, São João da Madeira, Ovar and Lourinhã, including senior groups, Senior Universities, City Councils and informal community networks. The replicating sites followed a similar strategy in their own countries.

At UP, participants were recruited through the Olomouc University Social Health Institute (OUSHI) social networks. The older adults were dispersed across different regions of the Czech Republic.

At AUTH, participants' recruitment has been actualized within the network of the Living Lab Thess-AHALL ecosystem: municipalities and public entities, hospitals, rehabilitation centres and nursing homes as well as a significant number of individuals/beneficiaries. Both direct and indirect recruitment strategies have been implied, where members of the AUTH research team were responsible for the identification, approach and selection of participants, who are eligible for participating in the study based on the inclusion criteria. The AUTH research team screened potentially eligible participants and recruited those eligible according to the inclusion criteria. Information sheets and consent forms have been distributed among all participants, to inform them about the scope of the study. All participants' questions as well as any misunderstandings that may arise have been clarified and adequately addressed. Participants have been informed that they could withdraw from the pilot activity at any time.

Logistic and practical constraints made it challenging to include a control group in this piloting activity. This was due to difficulties in recruiting and retaining participants as well as time constraints. It is important to note that the AUTH team understands that the absence of the control group could limit the ability to establish causality or make definitive conclusions about the effectiveness of the DanceMove digital solution. To this end, the AUTH team chose to allocate resources towards other aspects of the piloting activity including enhancing data collection methods and conducting additional analyses.

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Technical Aspects & Logistics

The technical and logistical aspects are similar to those already mentioned for phase 4, namely:

- Each participant received a dance mat to use at home and instructions on how to use the DanceMove and connect the mat correctly and safely, and user manuals with information both on the system and how to use and on personal safety measures were provided. Each participant was asked to, ideally, use the system up to three times a week for up to 30 minutes. In each session, participants chose from a pool of music presented in DanceMove.
- Every week, the researcher made a phone call to each participant to motivate him/her for the intervention and to enquire on the occurrence of possible adverse events or difficulties of using DanceMove.
- A log of all requests for support was kept and analysed after the pilot.
- Participants' data were gathered in a browser-based researcher dashboard in eCare. Researchers were able to view each participant's dance performance data.
- A user log was kept during the intervention of using the DanceMove.

An aspect that was different in this phase compared to the previous one was the fact that the intervention lasted for 8 weeks instead of 4.

2.9.2 Roles and Responsibilities

The SHAPES pilot site researchers at UAVR were responsible for designing the study protocol, preparing and requesting all the necessary authorizations to implement the study, liaising with EDGE as the technical partner and implementing the pilot in Portugal. Also, UAVR provided all the study related documentation to the replicating sites as well as training. The technological partner EDGE, was responsible for providing technical support (via UAVR) to participants, when needed.

UAVR researchers, recruited participants, collected data and supported questionnaire filling and were the contact point of participants for any doubts or technical issues. All technical problems were communicated to an internal member of the UAVR team that either solved or requested help from EDGE. The face-to-face visits necessary to solve technical issues were done by personnel of UAVR.

The replicating sites were responsible for recruiting, collecting data and supporting questionnaire filling and were the contact point of participants for any doubts or technical issues in Greece and Czech Republic. All technical issues were communicated to UAVR team that took action, together with EDGE to solve it.

2.9.3 Ethical Considerations

The study protocol for the PT4-001 Phase 5 was approved by the University of Aveiro Ethics Committee (Process number 17-CED/2022). In addition, an ethical self-assessment for Phases 1–5 of this use case was completed.

For Phase 5, an information sheet was provided specifying the procedures and nature of the research, including the processing of personal data as part of the research and on the SHAPES platform. In addition, written consent from each participant was obtained before entering the study.

The data collected with DanceMove only concerns system usage data (how many times each participant danced, for how long and the respective dance score) and not personal data or sensitive data. These data were stored on a server at the UAVR, and there was no data transfer to other locations. The server complies with current regulations, and regular backups were made.

The data collected by the researchers through questionnaires and other instruments (personal and health data) was physically stored at the UAVR in a place with restricted access and was subject to a pseudo-anonymization process. Also, informed consents were kept separately in the office of the researcher Ana Isabel Martins. The code that allowed identifying the participants and the personal data was destroyed approximately five months after starting the study (i.e. when they were no longer needed).

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Data Processing Agreements were finished before the start of the recruitment of participants. UAVR was the data controller and had access to the entire dataset. Data Processing Agreements to facilitate sharing pseudonymised data with specific SHAPES partners for particular purposes were also established.

2.9.4 Preparation of the Pilot Replication

Table 13 presents the procedures conducted to prepare the replication and respective dates, within PT4-001 Pilot.

Table 13 - List of actions conducted to prepare for the replication of UC-PT4-001.

Actions	Dates
Meeting with AUTH to present the replication plan.	21/09/2021
UAVR sent an excel with the DanceMove content in English for translation.	10/01/2022
AUTH translated the DanceMove content into Greek.	14/01/2022
Meeting with AUTH and UP to prepare the replication, present the replication plan and discuss next steps.	15/02/2022
UP translated the DanceMove content into Czech.	15/02/2022
UAVR sent test credentials for the replication sites to test the DanceMove (in Portuguese) and requested Greek and Czech songs for each difficulty level. For each song, the following information was requested (music file in WAV, an image of the singer or album cover, name of the music and name of the artist).	16/02/2022
AUTH sent the pool of Greek music.	22/03/2022
UP sent the pool of Czech music.	11/04/2022
UAVR sent the SHAPES Data Processing Agreement and the SHAPES Data Sharing Agreements for review.	01/5/2022
UAVR sent the study protocol for PT4-001 in English to be translated and adapted to the replicating sites.	11/07/2022
AUTH signed the SHAPES Data Processing Agreement and the SHAPES Data Sharing Agreements.	26/09/2022
PT4-001 meeting in Thessaloniki during the SHAPES plenary meeting for procedures and doubts clarification.	14/09/2022
UAVR sent the login credentials for the participants of the replicating sites.	18/10/2022
UP signed the SHAPES Data Processing Agreement and the SHAPES Data Sharing Agreements.	27/10/2022

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2.9.5 Outcome of the large-scale pilot activity

Several instruments were used at this phase, including SUS [6][7], TAM [8], ICF-US [13], gait speed test [2] and TMT [14] previously described in Phase 3. Additional instruments were the Oslo Social Support Scale (OSSS-3) [3], the WHOQOL-BREF) [4][15], the Single-item Health Literacy Measure [16], the Functional Reach Test (FRT)[17], the EQ-5D-5L [5], the General Self-Efficacy (GSE) [9], the participation questions and the UCLA-6 [18].

The OSSS-3 [3] is a 3-item self-reported measure of the level of social support. It consists of three items that ask for the number of close confidants, the sense of concern from other people, and the relationship with neighbours, focussing on the accessibility of practical help. The final score ranges from 3 to 14, with high values representing stronger social support and lower values representing poorer social support. The OSSS-3 sum score can be operationalized into three broad categories of social support: a) 3–8 poor social support, b) 9–11 moderate social support, c) 12–14 strong social support [3].

The WHOQOL-BREF measures the quality of life of individuals and populations and is a shorter version of the WHOQOL-100 developed by the World Health Organization. It is a self-administered questionnaire that comprises 26 questions on the individual's perceptions of their health and well-being over the previous two weeks. Responses to questions are on a 5-Point Likert scale where 1 represents "disagree" or "not at all" and 5 represents "completely agree" or "extremely". The WHOQOL-BREF covers four domains each with specific facets, including physical health, psychology, social relationships and environment and the score varies between 0 to 100 [4][15].

The Health Literacy Measure consists of a single question: “How confident are you filling out medical forms by yourself?”, answered using a 5-Point Likert scale that varies from not at all, to extremely confident [16].

The FRT is a measure of dynamic balance in a simple task. It consists of measuring the maximum distance that can be reached beyond the length of the arm, maintaining a fixed base of support in the standing position. It was developed to predict falls in

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older adults people; being unable to reach more than 15 centimetres represents a high risk of falling and frailty[17].

The EQ-5D-5L is a standardised measure of health-related quality of life that consists of two parts: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has five levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The patient is asked to indicate their health state by ticking the box next to the most appropriate statement in each of the five dimensions. This decision results in a 1-digit number that expresses the level selected for that dimension. The digits for the five dimensions can be combined into a 5-digit number that describes the patient's health state. The EQ VAS records the patient's self-rated health on a vertical visual analogue scale, where the endpoints are labelled 'The best health you can imagine' and 'The worst health you can imagine'. The VAS can be used as a quantitative measure of health outcome that reflect the patient's judgement [5].

The GSE is a ten-item scale that assesses the strength of an individual's belief in his/her ability to respond to novel or difficult situations and to deal with any associated obstacle or setbacks. It uses a Likert scale with a 4-Point scale ranging from 1 (not at all true) to 4 (exactly true). A total score, on a scale of 10 to 40, or a mean scale score, on a scale of 1 to 4, can be calculated. Higher scores indicate higher perceived general self-efficacy and lower scores indicate lower perceived general self-efficacy [9].

The UCLA-6 [18]. measures subjective feelings of loneliness and social isolation and consists of 6 items, each with 4 possible answers, related to the frequency with which the respondent feels/experiences a certain situation (never, rarely, sometimes, often). The quotation of each answer is determined between 1 and 4 values, with 1 value for each answer "never", 2 values for "rarely", 3 values for "sometimes" and 4 values for "often". However, in the question "I feel that I am part of a group of friends", the quotation applied will be inverted (1 value for "often", 2 values for "sometimes", 3 values for "rarely" and 4 values for "never"). The higher the score obtained, the greater the degree of loneliness. That is, lower scores indicate social satisfaction and absence of loneliness [18].

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In addition, several adherence rates (inclusion rate, refusal rate, exclusion rate, dropout rate and retention rate) were also calculated. Table 14 presents the instruments used and respective outcome per group (control or experimental).

Table 14 - 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.	Experimental
Log files and remote monitoring of the dance sessions	**Dance performance:** Information on the completed dances scores; the number of correct/incorrect movements per arrow (left, right, front, back).	Experimental
Team registrations	Adherence Rates: • **Inclusion rate:** The ratio between the number of participants included in the study and the total number of people contacted; • **Refusal rate:** The ratio between the number of subjects who refused to participate in the study and the number of subjects contacted; • **Exclusion rate:** The ratio between the number of individuals excluded for not meeting the inclusion criteria and the total number of individuals contacted; • **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; • **Retention rate:** The ratio between the number of participants who completed the final assessment and the number of participants who completed the initial assessment.	Experimental and control
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; **Feedback provided by the participants:** Issues and errors reported.	Experimental
Semi-structured interview guide	**Perception of participants (acceptability) towards the intervention structure and content:** The interview guide included	Experimental

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	questions about the structure of the program, resources used, the dance experience and aspects related to including the dance program in the daily routine.	
WHOQOL-Bref	Quality of life	Experimental and control
EQ-5D-5L visual analog scale (EQ-5D & VAS)	Health-related quality of life	Experimental and control
GSES	Self-efficacy	Experimental and control
OSSS-3	Social Function	Experimental and control
1-item health literacy	Health literacy	Experimental and control
Participation questions	Participation	Experimental and control
Trail Making Test and 6CIT	Cognitive function	Experimental and control
Gait speed test and FRT	Physical function	Experimental and control
TAM	Technology acceptance	Experimental
SUS	Self-perceived usability	Experimental

To assess the effectiveness of the DanceMove in cognitive, physical and social functioning the values of the baseline, post intervention and follow up were compared with the respective values for minimal detectable change.

For the gait speed test the minimal detectable change was 0.17 seconds for institutionalized ambulatory older adults (mean age=82.32 ± 8.12) [19].

For the FRT, the minimal detectable change was 8.28 centimeters for healthy adults (mean age= 40.58 ± 10.40) [17] as no data was found for older adults.

For TMT A, the minimal detectable change was 5.16 seconds and 12.7 for TMT-B for healthy older adults (mean age = 72.2±4.6) [20].

No data were found for the minimal detectable change for the remaining scales used in the pilot.

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2.9.6 Results of the Large-Scale Pilot Activity

The large-scale pilot was conducted in the period between July 2022 and April 2023.

Adherence Rates

Adherence rates reveal the recruitment difficulties experienced during the conduction of the study and are presented in Table 15.

Table 15 - Adherence rates for phase 5.

		UAVR	UP	AUTH
Inclusion rate	The ratio between the number of participants included in the study and the total number of people contacted.	25%	55%	50%
Refusal rate	The ratio between the number of subjects who refused to participate in the study and the number of subjects contacted.	79.2%	45%	50%
Exclusion rate	The ratio between the number of individuals excluded for not meeting the inclusion criteria and the total number of individuals contacted.	28.3%	5%	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.	13%	0%	0%
Retention rate	The ratio between the number of participants who completed the final assessment and the number of participants who completed the initial assessment.	80%	100%	100%

Demographics of participants entering the pilot

Thirty older adults entered the study at UAVR, with a mean (±sd) age of 69.0 ±4.1 years old, of whom 77% were females.

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In UP 11 older adults participated in the study, with a mean (±sd) age of 73.2 ±8.9 years old, of whom all of them were females. Together they were average of 15.7 ±4.1 years educated.

In AUTH 5 older adults participated in Phase 5 of the pilot study. Specifically, their mean age was 72.8±1.9. Table 16 presents the demographics data for the participants in both the experimental (participants that used the DanceMove) and control groups.

Table 16 - Demographics data for the participants in the experimental and control group (Phase 5).

	Experimental group (baseline)			Control group (baseline)		
	UAVR (*N*=17)	UP (n=6)	AUTH (*N*=5)	UAVR (*N*=13)	UP (n=5)	AUTH
Demographics						
Age (years) mean(sd)	67.9 (3.4)	75.7 (11.2)	72.8 (±1.9)	70.3 (4.4)	70.2 (4.3)	NA
Gender (female)	15	6	4	9	5	NA
Education (Years)	12.9 (4.8)	15.5 (2.7)	8.4 (±3.3)	7.1 (4.8)	16.0 (2.7)	NA
Health Literacy (How confident are you filling out medical forms by yourself?)	Extremely – 18% (n=3) Quite a bit 35% (n=6) Somewhat 24% (n=4) A little bit 24% (*n*=24)	Extremely – 16.6% (n=1) Quite a bit 16.6% (n=1) Somewhat 50% (n=3) A little bit 16.6% (n=1)	Quite a bit 40% (n=2) Somewhat 40% (n=2) Not at all 20% (n=1)	Quite a bit 8% (n=1) Somewhat 28% (n=5) A little bit 54% (n=7)	Quite a bit 100% (n=5)	NA

DanceMove Usage

UAVR

Of the 17 participants in the experimental group in UAVR, four were unable to use the DanceMove at all, two due to health problems and two due to technical problems (the participant's personal computers were outdated and DanceMove did not work properly). Two other participants had to stop using DanceMove after four and seven

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sessions due to health problems. The other 11 participants used the DanceMove during the eight weeks as planned.

Regarding the DanceMove use, the participants in the experimental group danced a total of 1382 songs in a total of 246 valid sessions. The medium level of difficulty was the most played with 51.8% of the dances, followed by the difficult level with 31.5% of the dances and finally the easy level with 16.7% (Table 17).

On average, each one of the 11 participants danced 125.0±75.6 choreographies and a minimum of 15 and a maximum of 295. The number of dance sessions performed by each participant varied between 7 and 44 over the eight weeks, on average, each participant performed 22.4±9.5 sessions over the eight weeks.

Table 17 - DanceMove usage data for the 11 participants in the intervention group at UAVR.

Valid sessions (continuous interaction)* (n)	Invalid sessions (erratic interaction)* (n)	Songs danced (n)	Songs' level of difficulty (n, %)		
			Easy	Medium	Difficult
246	12	1382	231 (16.7%)	716 (51.8%)	435 (31.5%)

*Continuous interaction happens when the DanceMove collects more than 10% of the dance steps while Erratic interaction happens when less than 10% of the dance steps are considered correct.

Regarding the dance performance, at UAVR the mean dance score was 91.4±0.1 out of 100 and the scores were generally high across all difficulty levels. This is likely due to the fact that difficulty level was chosen by each participant according to their preferences. Backward stepping showed a tendency for the lowest scores in all difficulty levels. Table 18 and Table 19 present a summary of the dance performance of the participants according to the difficulty levels (total and per direction of the stepping).

Table 18 – UAVR DanceMove performance data.

	Number of sessions (n)	Time Danced (minutes)	Total songs danced (n)	Songs per session (n)	Songs level of difficulty (%)	Total score (Mean±SD)
P1	14	311	86	6	Easy – 2 Moderate – 97	95.6±7.6

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					Difficult - 1	
P2	26	528	159	6	Easy – 18 Moderate – 28 Difficult - 55	84.5±11.7
P3	32	991	295	9	Easy – 15 Moderate – 51 Difficult - 34	95.9±6.9
P4	22	583	163	7	Easy – 53 Moderate – 29 Difficult - 18	96.1±4.1
P5	23	518	150	7	Easy – 31 Moderate – 56 Difficult - 13	89.8±11.2
P6	44	510	146	3	Easy – 6 Moderate – 14 Difficult - 80	91.0±23.7
P7	9	94	15	2	Moderate – 87 Difficult - 13	97.9±1.9
P8	24	512	156	7	Moderate – 87 Difficult - 13	96.1±3.3
P9	18	168	44	2	Easy – 93 Moderate – 5 Difficult - 2	61.7±25.0
P10	16	271	76	5	Easy – 93 Moderate – 5 Difficult - 2	80.5±14.0
P11	18	362	92	5	Easy – 46 Moderate – 50 Difficult - 4	94.7±14.2

Table 19 - UAVR Dance Performance according to the level of difficulty in phase 5 (maximum score is 100).

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Dance level of difficulty	Total score Mean (SD)	Left total score Mean (SD)	Right total score Mean (SD)	Forward total score Mean (SD)	Backward total score Mean (SD)
All	91.4 ±12.2	93.3 ±14.1	92.0 ±14.7	91.2 ±14.7	89.3 ±16.1
Easy	87.2 ±18.3	89.9 ±17.9	87.8 ±19.6	88.3 ±18.6	82.9 ±22.2
Medium	94.1 ±10.7	95.9 ±10.2	94.7 ±10.6	93.4 ±11.9	92.2 ±12.7
Difficult	89.4 ±15.7	90.9 ±16.2	89.5 ±16.6	89.2 ±16.1	87.7 ±15.9

In terms of usability, the TAM questions yielded an average score of 19.1±2.1 out of a maximum of 21, while the SUS had a score of 91.5±3.9 out of a maximum of 100. These results indicate a remarkably high level of acceptance and self-reported usability.

UP

Regarding DanceMove use at UP, the participants in the experimental group danced 1458 songs in a total of 171 valid sessions. The easy level of difficulty was the most played with 67.1% of the dances, followed by the medium level with 18.7% of the dances and finally the difficult level with 14.2% of the dances (Table 20).

On average, each of the 6 participants danced 243.0±100.2 choreographies, a minimum of 76 songs, and a maximum of 348 songs. Regarding the number of dance sessions performed by each one, it varied between 6 and 52 over the eight weeks and, on average, each participant performed 11.9±9.6 sessions over the eight weeks.

Table 20 - UP DanceMove usage data for the 6 participants in the intervention group.

Valid sessions (continuous interaction)* (n)	Invalid sessions (erratic interaction)* (n)	Songs danced (n)	Songs' level of difficulty (n, %)		
			Easy	Medium	Difficult
171	0	1458	979 (67.1%)	273 (18.7%)	206 (14.2%)

*Continuous interaction happens when more than 10% of the dance steps are collected by the DanceMove while Erratic interaction happens when less than 10% of the dance steps are considered correct.

Regarding the dance performance, the mean dance score was 87.6±17.3 out of 100 and the scores were generally high across all difficulty levels. Backward stepping showed a tendency for the lowest scores in all difficulty levels. Table 21 and Table 22

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present a summary of the dance performance of the participants according to the difficulty levels (total and per direction of the stepping).

Table 21 - UP DanceMove performance data.

	Number of sessions (n)	Time Danced (minutes)	Total songs danced (n)	Songs per session (n)	Songs level of difficulty (%)	Total score (Mean±SD)
P1	52	824	277	5	Easy – 31 Moderate – 36 Difficult - 33	96.2±5.6
P2	9	222	76	8	Easy – 99 Moderate – 1	38.9±11.4
P3	32	772	242	7.5	Easy – 10 Moderate – 46 Difficult - 44	95.4±4.5
P4	6	569	188	31	Easy – 83 Moderate – 15 Difficult - 2	74.3±21.8
P5	29	534	348	12	Easy – 90 Moderate – 9 Difficult - 1	79.5±9.2
P6	43	467	327	8	Easy – 100	86.1±11.4

Table 22 - UP Dance Performance according to the level of difficulty in phase 5 (maximum score is 100).

Dance level of difficulty	Total score Mean ± SD	Left total score Mean±SD	Right total score Mean±SD	Forward total score Mean±SD	Backward total score Mean±SD
All	87.6 ±17.3	88.9 ±19.3	88.1 ±19.6	88.1 ±18.5	85.5 ±18.1
Easy	85.7 ±17.0	87.0 ±20.0	86.6 ±20.7	86.3 ±18.1	83.6 ±17.7
Medium	90.0 ±20.8	91.5 ±21.0	90.3 ±19.9	90.3 ±22.4	87.9 ±21.5
Difficult	93.3 ±10.5	94.9 ±9.8	92.5 ±10.7	94.3 ±11.6	91.5 ±12.2

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Regarding usability, the mean(±sd) for the TAM questions was 14.5±3.51 out of a maximum of 21 and 73.3±10.1 for SUS out of a maximum of 100, indicating a very high level of acceptance and self-reported usability.

AUTH

The experimental group in AUTH (n=5) danced 711 songs over 115 valid sessions within an eight weeks period performed at different levels of difficulty (Table 23).

On average, each one of the five participants danced 142.0 ±26.3 choreographies and a minimum of 97 songs and a maximum of 163 songs. Regarding the number of dance sessions performed by each one, it varied between 17 and 25 over the eight weeks and, on average, each participant performed 23.0 ±3.4 sessions over the eight weeks.

Table 23 – AUTH DanceMove usage data for the 5 participants in the intervention group.

Valid sessions (continuous interaction)* (n)	Invalid sessions (erratic interaction)* (n)	Songs danced (n)	Songs' level of difficulty (n, %)
			Easy
115	0	711	711 (100%)

*Continuous interaction happens when the DanceMove collects more than 10% of the dance steps while Erratic interaction happens when less than 10% of the dance steps are considered correct.

Regarding dance performance, the mean dance score was 92.8 ±10.2 out of 100. Table 24 and Table 25 summarise the dance performance of the participants in AUTH (total and per direction of the stepping).

Table 24 – AUTH DanceMove performance data.

	Number of sessions (n)	Time Danced (minutes)	Total songs danced (n)	Songs per session (n)	Songs level of difficulty (%)	Total score (Mean±SD)
P1	24	192	158	6.5	Easy – 100	96.2±4.9
P2	25	197	163	6.5	Easy – 100	96.7±3.3
P3	25	191	147	6	Easy – 100	87.8±13.2
P4	17	188	97	6	Easy – 100	94.7±8.9

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P5	24	200	146	6	Easy – 100	88.8±12.9

Table 25 – AUTH Dance Performance according to the level of difficulty in phase 5 (maximum score is 100).

Dance level of difficulty	Total score Mean±SD	Left total score Mean±SD	Right total score Mean±SD	Forward total score Mean±SD	Backward total score Mean±SD
All (Easy)	92.8 ±10.2	95.3 ±10.8	92.9 ±11.4	93.2±11.2	89.9 ±13.5

Regarding usability, SUS outcomes with a mean of 82.5±15.8 and TAM scores with a mean of 13.8±2.68, indicated a very high level of technology acceptance and self-reported system usability.

Quality of Life, Social Support, Cognitive and Physical Function

UAVR

Detailed data on the quality of life, social support, cognitive and physical functioning at baseline, eight weeks and three months follow up are presented in Table 26.

Table 26 - Characteristics of the participants that completed phase 5 at UAVR (results presented as mean±sd).

	Experimental group (n=17)			Control group (n=13)		
	Baseline	**8 weeks**	**3 month**	**Baseline**	**8 weeks**	**3 month**
Quality of life and social support						
WHOQOL -Bref (0-100)	96.5±9.7	98.1±9.8	97.6±10.7	93.4±11.1	96.6±11.9	99.9±7.8
Health related quality of life - EQ - 5D – 5L (5-25)	6.00±1.1	6.5±1.5	7.1±1.8	7.1±2.7	7.3±3.6	5.4±0.8
Health related quality of life (EQ - VAS) (0-100)	78.5±14.1	83.1±9.5	76.2±15.3	76.2±16.0	76.1±22.5	89.3±9.8
Self-efficacy	31.5 ±4.0	31.9±3.4	32.5±3.7	30.6±4.0	30.8±3.8	32.1±2.4

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GSE (10-40)						
Social Function OSSS-3 (3-14)	7.0±1.4	7.6 ±1.4	6.9±1.2	7.2±1.4	7.2±1.2	7.4±1.4
Loneliness (UCLA-6) (6-24)	9.9±3.8	9.9±3.3	10.5±4.2	10.6±2.7	11.2±3.6	7.6±3.6
Cognitive function						
TMT-A Time	31.3±14.1	29.6±9.7	29.0±13.0	54.0±31.0	50.4±25.1	33.1±9.0
TMT-A Errors	0.4 ±1.1	0.2±0.4	0.2±0.4	0.6±1.0	0.6±1.1	0.1±0.4
TMT-B Time	97.6±71.7	87.4±62.3	74.3±40.2	154.7±90.9	138.1±70.4	112.2 ±55.6
TMT-B Errors	1.6±3.7	1.1±1.6	1.0±1.2	2.3±3.1	1.3±1.4	1.1±1.9
Physical function						
Gait speed test	1.3±0.2	1.3±0.2	1.2±0.2	1.4±0.2	1.3±0.3	1.5±0.2
Functional Reach test	29.2±7.9	32.1±4.8	29.2±6.7	32.9±4.8	33.2±5.2	32.7±5.1

Considering that four participants could not use DanceMove at all and two did have to interrupt its use earlier than the eight weeks, the individual data for the 11 participants that used the DanceMove are presented in Table 27 and Table 28.

Comparing mean individual differences against the minimal detectable difference for gait speed three participants increased their mean gait speed by at least this amount from baseline to eight weeks. Interestingly, the gains return to baseline values at three months follow-up. Considering the Functional and Reach Test, only one participant changed from baseline to the eight weeks after using the DanceMove above the minimal detectable difference. Nevertheless, three other participants improved their scores between 3,5 and 5,5 cm. Similarly, to gait speed, values tended to return to baseline values at three months follow-up.

Considering the TMT- A, only one participant changed from baseline to the eight weeks after using the DanceMove above the minimal detectable difference. Yet, another participant improved the time by four seconds. In the TMT- B, two participants

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changed from baseline to the eight weeks after using the DanceMove above the minimal detectable difference. Four other participants decreased the time by at least four seconds.

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Table 27 - Quality of life and social data for the 11 participants that used the DanceMove at UAVR.

Participants that used the DanceMove – Quality of live and social evaluation (n=11)																		
	WHOQOL-Bref (0-100)			EQ - 5D - 5L (5-25)			EQ – VAS (0-100)			Self-efficacy GSE (10-40)			Social Function OSSS-3 (3-14)			Loneliness (UCLA-6) (6-24)		
	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU
P1	95	87	98	5	7	7	70	90	80	29	27	25	7	8	8	9	7	9
P2	90	93	95	8	6	9	50	80	85	31	33	30	6	9	7	16	15	13
P3	105	101	102	5	7	8	95	90	70	35	37	37	8	6	5	7	8	9
P4	94	106	99	6	6	6	75	90	90	30	29	33	6	6	8	8	8	7
P5	84	95	76	5	5	6	75	70	50	35	34	33	9	10	8	12	12	11
P6	96	109	-	6	6	-	80	90	-	32	35	-	6	6	-	11	9	-
P7	85	85		8	9		55	60		36	32		7	8		16	15	
P8	111	116		5	7		80	80		33	37		7	8		13	8	
P9	90	90		7	10		50	75		21	27		6	6		9	9	
P10	106	100		6	6		90	95		35	36		8	10		16	12	
P11	87	88		6	5		75	75		29	29		7	7		9	11	
Mean±sd	94.8 ±9.0	98.5 ±8.3	94 ±10.4	6.1 ±1.1	6.2 ±0.8	7.2 ±1.3	72.3 ±15.1	85 ±8.4	75 ±15.8	31.5 ±4.3	32.4 ±3.8	31.6 ±4.4	7 ±1.0	7.5 ±1.8	7.2 ±1.3	11.2 ±3.6	9.8 ±3.1	9.8 ±2.3

*Baseline - BL | Eight-week evaluation (post intervention) - 8W | Follow-up - FU

Table 28 - Physical and cognitive data for the 11 participants that used the DanceMove at UAVR.

Participants that used the DanceMove – Physical and cognitive evaluation (n=11)																		
	TMT-A Time (s)			TMT-A Errors (n)			TMT-B Time (s)			TMT-B Errors (n)			Gait Speed Test (m/s)			Functional Reach test (cm)		
	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU
P1	30.0	26.8	26.2	0	1	0	48.0	44.6	45.6	0	0	1	1.2	1.6	1.5	31,7	37.2	27.9
P2	71.0	48.4	58.2	0	1	1	202.0	173.8	168	3	3	3	1.2	1.7	1.0	22,0	30.4	18.7

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P3	20.4	26.1	16.7	0	1	0	55.0	48.5	41.5	1	0	0	1.1	1.3	1.1	24.3	27.8	25
P4	24.4	24.6	27.4	0	0	1	38.3	42	41.6	0	0	0	1.3	1.4	1.4	21.7	25.5	21.5
P5	42.9	-	-	0	-	-	209.0	-	-	5	-	-	1.4	-	-	33.6	-	-
P6	14.7	15	-	0	0	-	59.1	40	-	0	0	-	1.7	1.6	-	32,3	26	-
P7	30.0	39.0		0	0		69.3	102.0		0	1		1.0	1.0		32.3	30.3	
P8	20.2	28.6		1	0		62.6	53.93		0	0		1.3	1.2		27.7	29.3	
P9	90.65	-		4	-		293	-		15	-		0.8	-		12.7	-	
P10	27.9	25.9		0	0		43.9	34.7		0	0		1.4	1.1		38.5	40.0	
P11	19	33.9		0	0		53	82.6		0	1		1.2	1.1		37.7	33.0	
Mean± sd	30.1 ±16.4	29.8 ±9.6	32.1 ±18.1	0.5 ±1.2	1.1 ±2.5	0.5± 0.6	102.9 ±87.8	69.0 ±45.1	74.2 ±62.6	2.2 ±4.6	0.6 ±1.0	1 ±1.4	1.3 ±0.2	1.3 ±0.2	1.3 ±0.2	28.6 ±7.8	31.1 ±4.9	22.8 ±3.9

*Baseline - BL | Eight-week evaluation (post intervention) - 8W | Follow-up - FU

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UP

Detailed data on the quality of life, social support, cognitive and physical functioning at baseline, eight weeks and three months follow-up of UP participants are presented in Table 29, Table 30 and Table 31.

Table 29 - Characteristics of the participants that completed phase 5 at UP (results presented as mean±sd).

	Experimental group (n=12)			Control group (n=13)		
	Baseline	**8 weeks**	**3 month**	**Baseline**	**8 weeks**	**3 month***
Quality of life and social support						
WHOQOL-Bref (0-100)	91.7 ±13.1	91.7 ±11.4	-	99.6 ±9.9	92.2±15.1	-
Health related quality of life - EQ - 5D – 5L (5-25)	9.2 ±2.6	9 ±2.2	-	6.8 ±1.48	8.8 ±3.0	-
Health related quality of life (EQ - VAS) (0-100)	74.2 ±14.3	81.7±10.3	-	78 ±16.8	79.6 ±2.9	-
Self-efficacy GSE (10-40)	29.8 ±6.49	32 ±8.17	-	29.4 ±4.7	27.2 ±5.81	-
Social Function OSSS-3 (3-14)	15.3 ±5.5	10.0 ±2.0	-	17.6 ±3.7	11.4 ±3.1	-
Loneliness (UCLA-6) (6-24)	12.5 ±3.0	12.7 ±2.07	-	9.8±1.3	8.6±5.6	-
Cognitive functionn						
TMT-A Time	37.5 ± 14.8	36.1 ± 19.3	-	34.2±22.4	25.6±11.8	
TMT-A Errors	0±0	0.17 ± 0.41	-	0.2±0.45	0 ± 0	
TMT-B Time	107 ±62.1	100 ± 77.3	-	53.8±17.4	57.2±16.3	
TMT-B Errors	2±4.43	0.67± 0.82	-	0.8±1.79	1±1.73	
Physical function						
Gait speed test	0.90±0.32	0.842 ± 0.3	-	1 ± 0.21	0.94±0.19	
Functional Reach test	39.7±21	42.3 ± 19	-	42.3 ± 19.4	41.6±20.7	

* The 3 month follow up was not conducted yet

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Table 30 - Quality of live and social data for the 6 participants that used the DanceMove at UP

Participants that completed the intervention – Quality of live and social evaluation (n=11)																		
	WHOQOL-Bref (0-100)			EQ - 5D - 5L (5-25)			EQ – VAS (0-100)			Self-efficacy GSE (10-40)			Social Function OSSS-3 (3-14)			Loneliness (UCLA-6) (6-24)		
	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU
P1	91	88		7	8		90	90		22	22		9	6		14	12	
P2	95	96		12	12		70	65		22	21		14	9		12	10	
P3	106	106		6	6		85	90		35	36		12	7		9	13	
P4	78	83		8	8		50	90		30	38		11	7		16	15	
P5	75	76		12	9		80	80		33	37		9	7		15	15	
P6	105	101		10	11		70	75		37	38		9	7		9	11	
Mean ±sd	91.7 ±13.1	91.7 ±11.4		9.17 ±2.56	9 ±2.19		74.2 ±14.3	81.7 ±10.3		29.8 ±6.5	32 ±8.17		10.7 ±2.07	7.17 ±0.98		12.5 ±3.0	12.7 ±2.1	

*Baseline - BL | Eight week evaluation (post intervention) - 8W | Follow-up - FU

Table 31 - Physical and cognitive data for the 6 participants that used the DanceMove at UP

Participants that completed the intervention – Physical and cognitive evaluation (n=6)																		
	TMT-A Time			TMT-A Errors			TMT-B Time			TMT-B Errors			Gait Speed Test			Functional Reach test		
	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU
P1	22	22		0	0		52	37		0	2	1	0.87	0.75	1.5	37.7	37.2	27.9
P2	63.7	73.54		0	0		172.72	228.06		11	1	3	0.52	0.45	1.0	81.7	30.4	18.7
P3	26	24		0	-		41	38		0	-	0	-	-	1.1		27.8	25
P4	42	36		0	1		143.22	152.17		1	1	0	1.87	1.04	1.4	25	25.5	21.5
P5	33.8	25.16	-	0	0	-	62.35	45.8	-	0	0	-	0.82	0.85	-	31	-	-
P6	37,5	36.14	-	0	0		94,26	100,21	-	0	0	-	0.60	0.65	-	29.3	26	-

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Mean ±sd	37.5 ± 14.8	36.1 ± 19.3		0 ±0			107 ±62.1	100 ± 77.3		2 ±4.43	0.67± 0.82		0.90±0.32	0.842 ± 0.3		39.7±21	42.3 ± 19	

*Baseline - BL | Eight week evaluation (post intervention) - 8W | Follow-up - FU

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Comparing mean individual differences against the minimal detectable difference for gait speed only one participant increased the mean gait speed by at least this amount from baseline to eight weeks. Nevertheless, two other participants improved the gait speed between 0.07 and 0.12 seconds. Considering the Functional and Reach Test, only one participant changed from baseline to the eight weeks after using the DanceMove above the minimal detectable difference.

Considering the TMT- A, only one participant changed from baseline to the eight weeks after using the DanceMove above the minimal detectable difference. Yet, another two participants improved the time by two to six seconds. In the TMT- B, two participants changed from baseline to the eight weeks after using the DanceMove above the minimal detectable difference.

AUTH

Detailed data on the quality of life, social support, cognitive and physical functioning at baseline, eight weeks and three months follow up of the AUTH participants are presented in Table 32, Table 33 and Table 34.

Table 32 - Characteristics of the participants that completed Phase-5 at AUTH (results presented as mean±sd).

	Experimental group (N=5)			Control group (N=0)		
	Baseline	8 weeks	3 month	Baseline	8 weeks	3 month*
Quality of life and social support						
WHOQOL- Bref (0-100)	58.2 ±11.14	63.75 ±10.0	-	-	-	-
Health related quality of life - EQ - 5D – 5L (5-25)			-	-	-	-
Health related quality of life (EQ - VAS) (0-100)	70 ±18.7	79 ±21	-	-	-	-
Self-efficacy GSE (10-40)	27.4 ±8.5	30.6 ±10	-	-	-	-
Social Function OSSS-3 (3 -14)	8.4 ±1.8	9 (3.31		-	-	-

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Loneliness (UCLA-6) (6-24)	13.4 ±2.8	18.6 ±7.95	-	-	-	-
Cognitive function						
TMT- A Time	89.4 ±45	76.8 ±40	-	-	-	-
TMT- A Errors	-	-	-	-	-	-
TMT- B Time	232.4 ±100	189.2 ±69.53	-	-	-	-
TMT- B Errors	-	-	-	-	-	-
Physical function						
Gait speed test	1.2 ±0.3	1.3 ±0.3	-	-	-	
Functional Reach test	15.2 ±1.59	18.3 ±4	-	-	-	-

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Table 33 - Quality of life and social data for the 5 participants that used the DanceMove at AUTH.

Participants that completed the intervention – Quality of live and social evaluation (N=5)																		
	WHOQOL-Bref (0-100)			EQ - 5D - 5L			EQ – VAS (0-100)			Self-efficacy GSE (10-40)			Social Function OSSS-3 (3-14)			Loneliness (UCLA-6) (6-24)		
	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU
P1	68,75	72	-			-	95	85	-	29	35	-	8	9	-	10	9	-
P2	42,25	61	-			-	90	100	-	14	13	-	6	6	-	12	24	-
P3	54,75	54,75	-			-	55	45	-	37	38	-	9	10	-	19	26	-
P4	56,25	54,5	-			-	60	75	-	26	32	-	8	6	-	21	23	-
P5	69	76,5	-			-	50	90	-	31	35	-	11	14	-	12	11	-

*Baseline - BL | Eight-week evaluation (post intervention) - 8W | Follow-up - FU

Table 34 - Physical and cognitive data for the 5 participants that used the DanceMove at AUTH.

Participants that completed the intervention – Physical and cognitive evaluation (N=5)																		
	TMT-A Time			TMT-A Errors			TMT-B Time			TMT-B Errors			Gait Speed Test			Functional Reach test		
	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU	BL	8W	FU
P1	156	143	-	-	-	-	341	215	-	-	-	-	1.6	1.6	-	15	15.6	-
P2	116	85	-	-	-	-	311	218	-	-	-	-	1.2	1.2	-	14,3	14.3	-
P3	55	53	-	-	-	-	252	276	-	-	-	-	1.0	1.0	-	15	22.3	-
P4	65	44	-	-	-	-	141	106	-	-	-	-	0.9	1.0	-	18	23	-
P5	55	59			-	-	117	131	-	-	-	-	1.3	1.4	-	14	16.3	-

*Baseline - BL | Eight-week evaluation (post intervention) - 8W | Follow-up - FU

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Comparing mean individual differences against the minimal detectable difference for gait speed none of the participants increased their mean gait speed by at least this amount from baseline to eight weeks. Furthermore, considering the Functional and Reach Test, none of the participants changed from baseline to the eight weeks after using the DanceMove above the minimal detectable difference. Nevertheless, two participants improved their scores between 5 and 7.3 cm.

Considering the TMT- A, three participants changed from baseline to the eight weeks after using the DanceMove above the minimal detectable difference. In the TMT- B, three participants changed from baseline to the eight weeks after using the DanceMove above the minimal detectable difference.

Interviews results

A summary of older adults' experiences and the overall feedback gained at the end of the eight weeks, resulting from the final interviews (individual or group interviews) conducted in UAVR, AUTH and UP is presented in Table 35. In particular, a focus group was conducted in AUTH which participants had the opportunity to discuss and share their thoughts and perceptions with other participants and the AUTH research team. Experiences and information discussed among participants are categorized in seven discrete categories: i) technology adoption and barriers, ii) user experience and ease of use, iii) communication and social connections, iv) health and well-being, v) willingness to pay the DS and vi) DanceMove provision and vii) recommendations for improvement.

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Table 35 - Results from the final interviews with Phase-5 participants.

Thematic	Quotations
Technology Adoption and Barriers • Some older adults seemed to have a lack of familiarity with or understanding of new technologies; • Some of them (especially visual impaired) commented on the difficulties they encountered due to inaccessible design and small text sizes; • Participants expressed motivation and interest in interacting with the DanceMove.	"I was initially hesitant to embrace technology, but members of the AUTH team motivated me to give it a try." (AUTH) "I think that without the help of the caregivers it would be difficult for me to read and navigate fully autonomously through the interface" (AUTH) "I was amazed by how DanceMove enabled me to dance and exercise at the same time! " (AUTH) "I have never had any problem with the washer and the program controls. I started dancing at the easiest level and to avoid getting bored, I soon moved to the hardest level. Unfortunately, even that got boring after a while. It was the same thing over and over again (songs and moves) and my thoughts went elsewhere. It was too monotonous and not enough movement for me. I completed the task just to fulfill what I had promised. If I hadn't promised, I would have quit soon and gone for a walk instead." (UP P3) "At my age, my daughter has to stand by my side to support me - I was afraid I would lose my balance. I enjoyed the exercise, but I also enjoyed the fact that I was done" (UP -PT6). At the beginning, every day I would do 10 to 12 minutes, but then I started enjoying it and doing more, around 30 minutes. I started with the easy level and then moved on to the medium level. I tried a few times on the hard level, but I would lose my balance a lot, so I started getting frustrated with it. I couldn't do it, so I switched back to the medium level (UAVR). I had difficulties at the beginning getting into the program (UAVR). I found it funny, I found it to be an innovative experience. At first, I had a slightly negative impact because I thought I wouldn't be able to do it, but with consistency, I started finding it super easy and exciting (UAVR).
User Experience and Ease of Use • Overall, participants found DanceMove easy and fun to use.	"DanceMove made it so easy for me to follow along with the dance and exercise routines. The instructions were clear, and the visuals helped me understand the movements better." (AUTH). "I was initially worried that I wouldn't be able to keep up with the DanceMove, but the interface was intuitive and user-friendly. It allowed me to adjust the pace and difficulty level to match my abilities." (AUTH).

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	"The technology incorporated music and visuals that made the workout more engaging and enjoyable. It felt like I was dancing to my favorite tunes while getting a good workout "(AUTH). "I really liked the dance mat. But when I was losing a lot of points, it demotivated me. Like I'm not up to it anymore. And then I didn't enjoy it because I made more mistakes" (UP-PT2) "I had to concentrate on the darts, which was quite challenging. The faster tracks were a problem for me. I made it a part of my daily routine to dance either in the morning or in the evening when my husband was watching the news. Songs that were from my youth and also competition for points". (UP-PT4) "At first, I didn't understand anything, fortunately my daughter explained everything and installed it. At first, I did poorly, but then I improved rapidly. At first, I only lasted one or two dances, now I can dance for half an hour just fine." (UP-PT6). For me the music was unimportant because I don't hear much - I mainly watched the darts. When I pay attention, I'm 100%. If I don't, by the time I catch myself in the right exercise, I have a lot of wrong attempts. After a while, maybe I'll continue on my own. I've gotten a little bit of momentum going. The fact that it was a research obligation bothered me" (UP-PT6). I absolutely loved using the mat. I used it every day, and when I traveled and was away from it, I missed it. I was supposed to bring the mat with me, but it didn't work out, and I missed it so much (UAVR)
Communication and Social Connections • DanceMove seemed to facilitate connections with a broader community of other older people joining the pilot activities, encourage interactions and provide opportunities for collaboration and sharing experiences.	"DanceMove allowed me to connect with others who share my love for dancing and exercise." (AUTH) "By using DanceMove, I was able to join dance sessions specifically designed for the pace of people of my age. During the sessions I met a lot of people also joining the program. It was a fantastic opportunity to connect with like-minded people and celebrate our shared passion." (AUTH). I loved using the dance mat; I'm sorry to have to return it. I wished my son could see me dancing with the mat, but he didn't happen to come here (UAVR).
Health and Well-being • Participants have highlighted improvements in physical fitness,	"Using DanceMove for dancing and exercise has greatly improved my well-being. I feel more energetic, and my stamina has increased" (AUTH) "The combination of dancing and exercise through DanceMove has helped me maintain a good shape. It's like having a fun workout routine"(AUTH)

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enjoyment and motivation.	"Using DanceMove for dancing and exercise has become a part of my daily routine. It's something I look forward to each day, and it has become an essential component of maintaining my overall well-being''(AUTH) I didn't feel pain when I exercised, I was just tired (UP PT6) One thing I felt is that I am a very scattered person, but I started paying more attention; there, you have to be focused, your attention has to be there, and I felt that (UAVR). It's a challenge for one's concentration, as you have to be focused on where you place your feet and on the arrows. You really have to be highly concentrated; otherwise, the arrows will pass, and you won't do anything. It demands concentration, which is good (UAVR)
Willingness to pay the DS • Overall, participants declared that they would prefer to access DanceMove for free.	''I would prefer it to be free, but if I had to I would pay 5-10 euros per month'' (AUTH) ''I would rather not pay for the DanceMove'' (AUTH) ''If I had to pay, I would say 21-50 euros per month'' (AUTH) I want you to put it on the market so that I can buy one for myself, God willing (UAVR).
DanceMove provision • Participants mainly highlighted that DanceMove it should be funded by state care services.	''The state should undertake all the costs and provide it cost-free to people'' (AUTH) ''People in our age should have the opportunity to access it in some regional or local care service'' (AUTH)
Recommendations for Improvement • Participants' Recommendations and suggestions were focused on customization options, inclusivity, progress tracking, social features, accessibility and warm-up/cool-down exercises.	"It would be helpful if the DanceMove provided additional guidance and modifications for people with specific physical limitations or mobility issues. Including seated variations or exercises for different fitness levels would make it more inclusive." (AUTH) "Having a built-in progress tracker that shows a visual representation of my improvement over time would be motivating. It could be a great way to see how I've progressed and set new goals for myself "(AUTH) ''Add other kind of music, like traditional for example'' "Adding a social feature that allows users to connect and share their progress, challenges, and success stories would create a stronger sense of community. It would be great to have a platform to support and cheer each other on." (AUTH) "Improving accessibility features, such as voice-guided instructions or closed captions, would benefit users with hearing impairments or those who prefer audio cues over visual prompts." (AUTH)

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	"Including warm-up and cool-down exercises as part of the session would be essentially beneficial. It's important for people our age to properly prepare our body before physical activity."(AUTH) “The songs were nice, but you couldn't dance to the rhythm - the arrows pointed differently than the rhythm. Then it was harder - to hit. And I couldn't step backwards either. I always stepped a little bit wrong, and the program counted the mistakes. But otherwise, it was very interesting. I hope to dance again sometime”. (UP-PT2) “Some songs at a faster pace I was not able to complete I made more mistakes”. (UP – PT4) “If it had been without music, it would have been absolutely the best. But then I probably wouldn't call the mat "dancing" (UP-PT6). “At first, I was looking forward to the "dances". I took it as fun and a little bit as a task I had to fulfill, that I had a "duty". I was also motivated by the rewards of research. That I was doing it for myself, for my health - that motivated me in the beginning, but what disgusted me the most was that I couldn't watch a movie while I was doing it. Here are the things that bothered me and disgusted me: - Heavily installed music that couldn't be turned down. When I watched the movie while practicing (which was often), you couldn't hear the actors over the music. - The music couldn't be adjusted (for example, for 10 minutes) and I kept having to start a new song from the beginning - which was tedious and annoying. - I was able to understand and install the program myself but with my mother (93 years old) it was not so. I had to install it for her myself. - The song selection was impossible, I didn't like them. I couldn't watch the series at the same time. - Listening to those songs annoyed me. Next to the movie I would practice, perfectly fine" and with pleasure.” (UP PT6) - I would like it if there were different movements so that it wouldn't always be the same foot movements (UAVR).

Adverse events

No adverse events were reported.

KPIs compliance

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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 36 lists the KPIs planned and critically analyses its fulfilment.

In this pilot, six KPIs were achieved while two were not. These relate to the number of participants completing at least 75% of the sessions and the number of participants achieving minimal detectable differences. For the first, the main reason was outside the control of UAVR as the main reason for dropouts was related to health issues of the participants unrelated to the study. For the second, potential reasons might be related to the intensity of use of the DanceMove (e.g., a period longer than eight weeks or longer sessions might be needed) for the DanceMove to impact the studied variables.

Table 36 - KPIs planned vs. achieved.

	Planned	Achieved /Not achieved
Recruitment and retention	At least 80% of the target sample (i.e., 80% of 25 participants for UAVR (lead site), 80% of 6-7 participants for AUTH and 80% of 11 for UP (replicating sites) successfully recruited into the pilot.	☑ In UAVR, AUTH and UP at least 80% of the target sample was achieved.
	At least 75% of the recruited participants within the target cohort remained enrolled in the pilot until the end of the study.	☑ In UAVR, AUTH and UP, 80% of the recruited participants within the target cohort remained enrolled in the pilot until the end of the study.
User engagement and acceptance	At least 60% of participants scored above average (>68) in the SUS.	☑ In UAVR, 100% of participants scored above average (>68) in the SUS. In AUTH 80% of participants scored above average (>68) in the SUS. In UP 83% of participants scored above average (>68) in the SUS.
Collection of data	At least 60% of participants completed 75% of the dance sessions during the pilot.	☒ In UAVR, 50% of the participants completed 75% of the planned dance sessions during the pilot.

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		☑ In AUTH, 80% of the participants completed 75% of the planned dance sessions during the pilot and in UP 66% of the participants completed 75% of the planned dance sessions during the pilot.
	At least 60% of the dance sessions happen without critical incidents such as erratic interaction.	☑ In UAVR, 94% of the dance sessions happened without critical incidents such as erratic interaction. In AUTH and UP 100% of the dance sessions happened without critical incidents such as erratic interaction.
Technical performance:	i) No failure of any of the technology components for at least 90% of the days.	☑ In UAVR, no failure of the technology components for 97% of the days. In AUTH and UP no failure of the technology components was identified.
	ii) No lost data for participants' dance performances.	☑ In UAVR, AUTH and UP, no data was lost for participants' dance performance.
Benefits and harms:	At least 50% of participants report a change in cognitive, physical and social functioning that corresponds to an actual change in the condition compared with the respective values for minimal detectable change.	☒ In UAVR, AUTH and UP, less than 50% of participants report a change in cognitive, physical and social functioning that corresponds to an actual change in the condition compared with the respective values for minimal detectable change.
	No falls or other adverse events.	☑ In UAVR, AUTH and UP no falls or other major adverse events occurred.

2.9.7 Communication and Dissemination of Pilot Activities

The UAVR owns all the data collected during the pilot. Once the study was completed, all data were analysed, tabulated and used to prepare this final report, available as one of the agreed deliverables of the SHAPES Innovation Action — Deliverable D6.5. This deliverable (and all other agreed deliverables) will be available to the public for review

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and accessible via the SHAPES website (www.shapes2020.eu). In addition, UAVR, AUTH and UP will seek to disseminate the findings from this study at conferences and in the scientific literature. UAVR will also seek to communicate the findings of this study via social media and in other non-peer-reviewed media channels. Participating SHAPES partners will have the right to use this study anonymised data in their analysis and dissemination plans. As detailed under 'Access to Data', Data Processing Agreements are in place to facilitate sharing pseudonymised data with specific SHAPES partners for particular purposes.

2.9.8 Risk Management

All foreseeable data-related risks have been compiled into detailed risk assessment documents, which form part of the DPIA for Phase 5 PT4-001 conducted in UAVR. A risk classification, root cause, name, and consequences were assigned for each risk identified. Once identified, each risk was analyzed and attributed a score from 1 (unlikely/minor) to 4 (almost certain/critical) for probability and impact. Subsequently, appropriate mitigation actions were assigned, and an appropriate person responsible was identified. These risks were reviewed periodically, and proper mitigation strategies were implemented. Table 37 presents the risks identified and the strategies used to mitigate them. All risks were avoided.

Table 37 - Risks identified during the pilot and mitigation strategies implemented to address the risks.

Risk	Mitigation strategy
Recruit of participants: Since participants in this pilot theme had to be active and live in the community, it can be challenging to reach these people as the partner institutions in the health and social area deal mainly with older adults with some degree of disability which is not what we are looking for in this study.	To mitigate the risk of recruitment difficulties, we increased the base of institutions contacted to present the project. Institutions that typically deal with active older adults were included, namely senior universities, seniors' groups and city councils.
Adherence to the intervention: due to digital literacy issues, demotivation, difficulties in physical coordination, cognitive difficulties, or lack of interest.	To increase the chances of adherence to the intervention, a series of options were taken during the development of DanceMove. We opted for the developing an attractive and fun interface, associated with a fun dance task. In addition, very close monitoring was carried out with the participants, including phone calls for motivation.

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Risks associated with technology functioning at participants' homes: such as device malfunction, difficulties assembling the equipment, or the set-up for a dance session.	To minimize the risks associated with technology in the participants' homes, a step-by-step user manual was created with all the information needed to assemble the equipment and set-up for a dance session. In addition, the participants had a helpline they called in case of doubts. Finaly, in cases of problems that neither the participant nor the caregiver could solve, the researcher went to the participant's home.
Risks related to health and wellbeing of participants: such as risk of fall and injuries as a consequence of dancing.	To minimize the risks associated with falls or injuries because of dancing, a series of safety procedures were defined that were taught and well emphasized during the participant's inclusion in the study. In addition, personal insurance was taken out for the participants to ensure their treatment in the unfortunate event of a fall.
Risks related to the pandemic situation: the increase in the number of cases of people infected with Covid-19 may imply delays in data collection.	Hygiene and safety measures were implemented to minimize the risks arising from the Covid-19 pandemic. In addition, because it was completely impossible to carry out tests with the older adults for some time, as soon as it was possible to resume work, we expanded the recruitment base to recruit the same number of participants in less time.

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3 Use case PT4-002

3.1 Introduction

This chapter describes the pilot activities of UC-PT4-002 social robot to engage older adults in cognitive activities. Target persons of this use case are 60 and older, living independently at home or in residential care homes. The SHAPES persona for this pilot theme is 'Isabella':

- Mild cognitive impairment;
- She refuses some help from her son;
- Essential to keep dignity and self-sufficiency.

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 people in cognitive activities. The digital solution will be SciFy's DiAnoia and Memor-i games integrated with PAL's humanoid social robot ARI.

CH is the use case leader and AIAS and AUTH replicate the use case.

3.2 Description

Many older adults with early-stage dementia can live independently. Studies have shown that cognitive training can have positive effects [21]. However, this type of intervention is sometimes not given, or, in case they are, the procedure could be further improved to reach an optimal outcome. Some of the reasons that prevent an optimal implementation of cognitive training are:

- People need to go to the facilities where the training is given. This is an important issue for people with reduced mobility, low motivation or far from training centres;
- Caregivers (or care partners) who can help assist during the cognitive tasks may not know how to follow directions or provide guidance properly;

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- People participating in group activities may need a more personalized intervention to adjust difficulty level and have greater motivation in the activity.

A social robot (such as ARI, from PAL ROBOTICS) can be an improved channel to give cognitive tasks in a more personalized and motivating fashion by connecting ARI (Figure 13) with:

- A set of cognitive tasks (cognitive exercises and paper activities offered by Dianoia, memory games offered by Memor-i) developed by SciFY. There is the possibility of creating extra material for these apps through the crowdsourcing platforms "Dianoia Marketplace" and "Memor-i Studio", respectively;
- A chatbot technology to guide how to perform cognitive tasks (Adilib chatbot engine from VICOMETECH and ROSA dialogue flows from CH);
- Technologies which enable smooth interaction with humans (visual and speech recognition, VICOMTECH, PAL);
- Emotion detection while doing the exercises (TREE TECHNOLOGY). This data will only be collected for analysis.

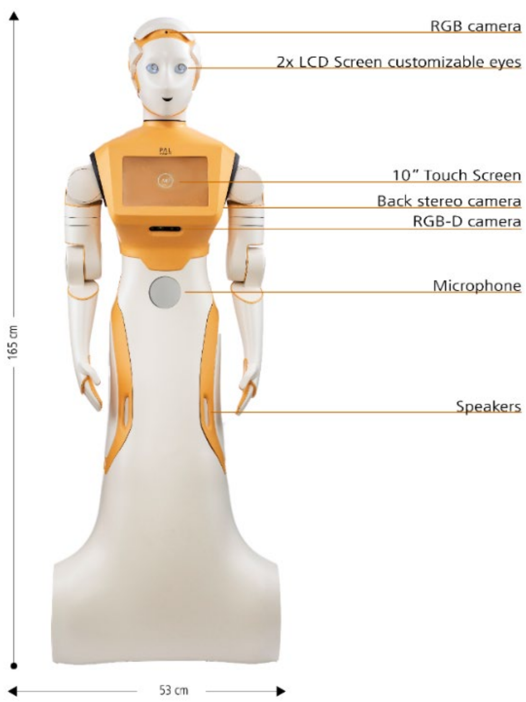

Figure 13. ARI.

The use case can be implemented in 2 scenarios (which define the two title options):

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- **Scenario 1:** The users will give cognitive tasks in their own homes. If users live at different locations, the robot will stay with them 24/7. Alternatively, CH treats patients in residential care homes and it may be feasible that several users can share one robot at the same place.
- **Scenario 2:** People living in private apartments can access common areas in the building where a professional trainer gives group activities. Some of these activities include cognitive tasks. In this second scenario, the robot could provide training while the others do group-guided cognitive activities.

In order to equip ARI with the necessary features, the following developments were carried out:

- User identification via facial recognition and credentials. The robot authenticates the user so that the session is delivered to the right person (identification of the user in the activity group or within the family members or potential visitors in their own home);
- Speech Natural Language Processing enables natural, accessible communication through voice in the user's language;
- Integration of DiAnoia/Memor-i with the chatbot;
- Touch-screen front-end to select and display different game options;
- Integration of a back Android tablet to show some games;
- Integration and connectivity of the different technologies, including connectivity with ARI input/output devices: microphone, speakers and camera;
- Identifying the emotions by facial recognition to have a non-intrusive monitoring of motivation. This data will only be collected for analysis;
- Translation of diAnoia and Memor-i (currently in Greek only) into the users' language. Technical translation supervised by a health professional.

3.3 Digital Solutions used in this use case

ARI (PAL)

Digital solution interacting with target users. ARI is a social humanoid robot with the possibility of autonomous navigation, the capability of moving arms and head and is provided with speakers, a microphone, a front screen and an attached tablet for user

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interaction. ARI will be adapted to provide the functionalities presented in the description section and integrate additional SHAPES Digital Solutions pointed out in this section.

DiAnoia & DiAnoia Marketplace (SciFY)

A smartphone app & marketplace (diAnoia & diAnoia marketplace, Figure 14 and Figure 15) provides a collection of non-pharmaceutical interventions and activities. The application is available for Android and iOS smartphones/tablets. It allows formal caregivers and health professionals to learn simple techniques of non-pharmaceutical interventions and use them to help older people (at home or non-specialized structures, such as public structures for older adults) when they cannot attend a Day Center for various reasons. In addition, the marketplace app (web application) will serve as a way for users to upload and create their own cognitive exercises, which will then be available through the diAnoia smartphone app.

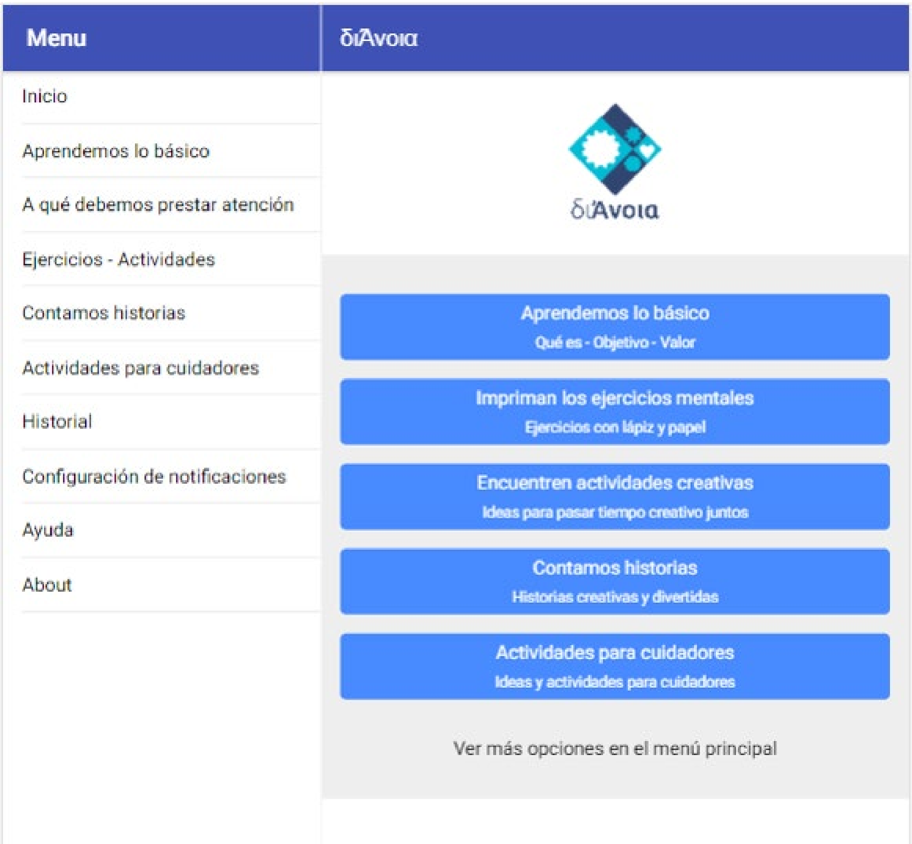

Figure 14. DiAnoia's main menu.

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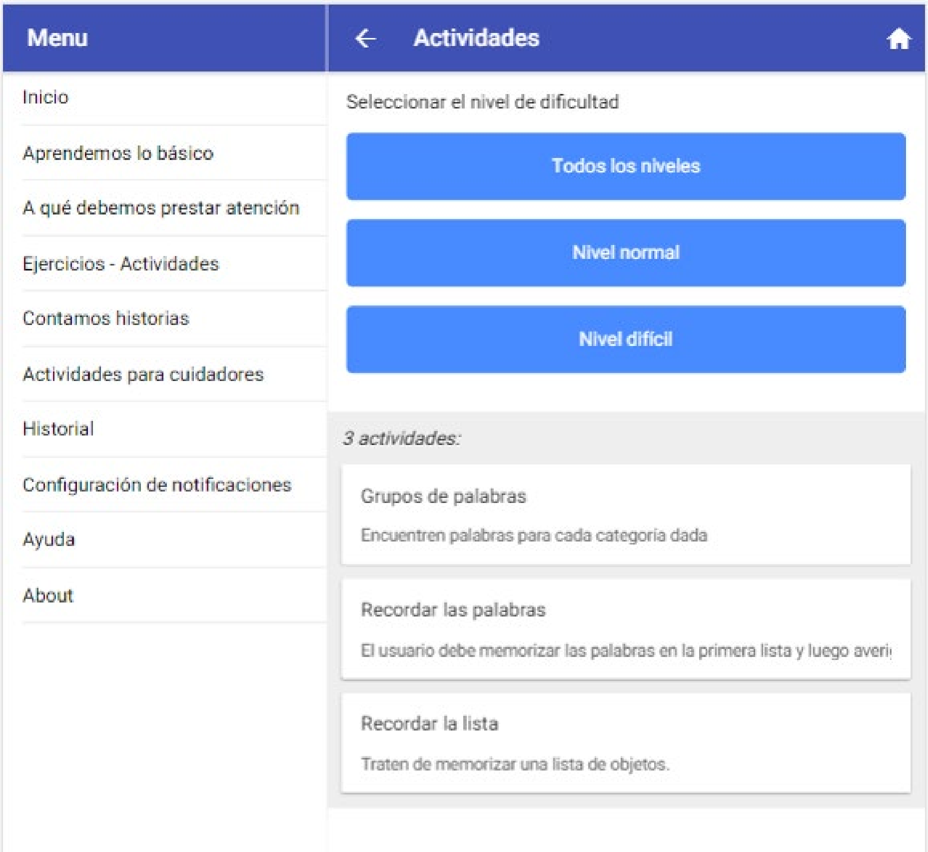

Figure 15. Activity and difficulty level selection in DiAnoia.

Memor-i & Memor-I Studio (SciFY)

This game emulates the classic, old memory game with cards and is an excellent resource for practicing memory skills while playing. This game is offered as a desktop application for Windows and Linux platforms and does not require an Internet connection in order to be used. Additionally, SciFY incorporated new languages into the game.

Memor-i Studio (Figure 16 and Figure 17) is a web application that serves as a crowdsourcing portal for people to create new variations for the Memor-i game. First, users upload sets of images and sound files to create new versions for Memor-i. Then, the games produced are submitted for approval by an admin, and the approved ones are available through the Memor-i desktop application.

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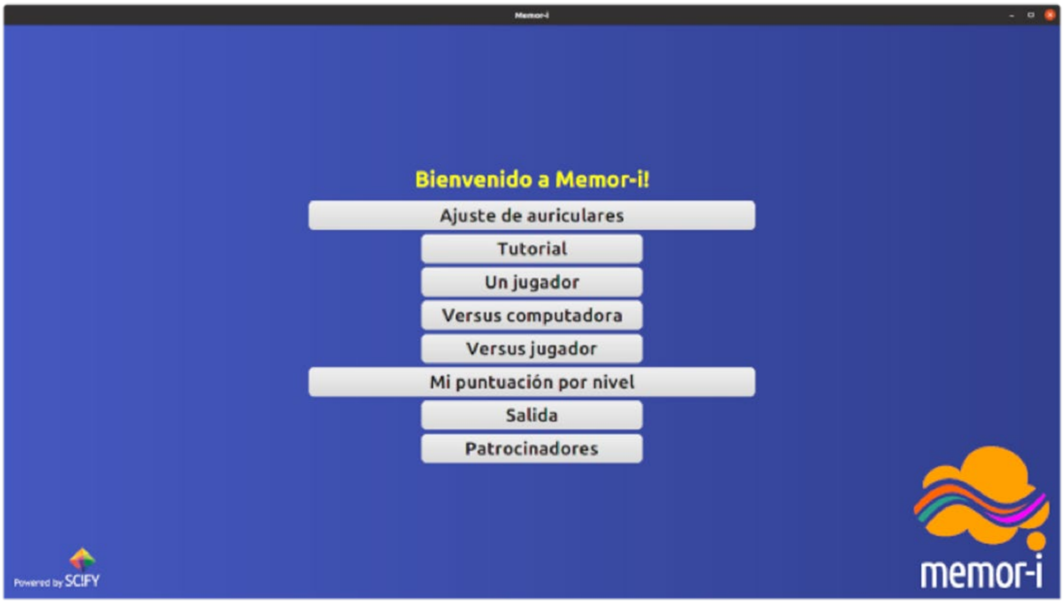

Figure 16. Memor-i's main menu.

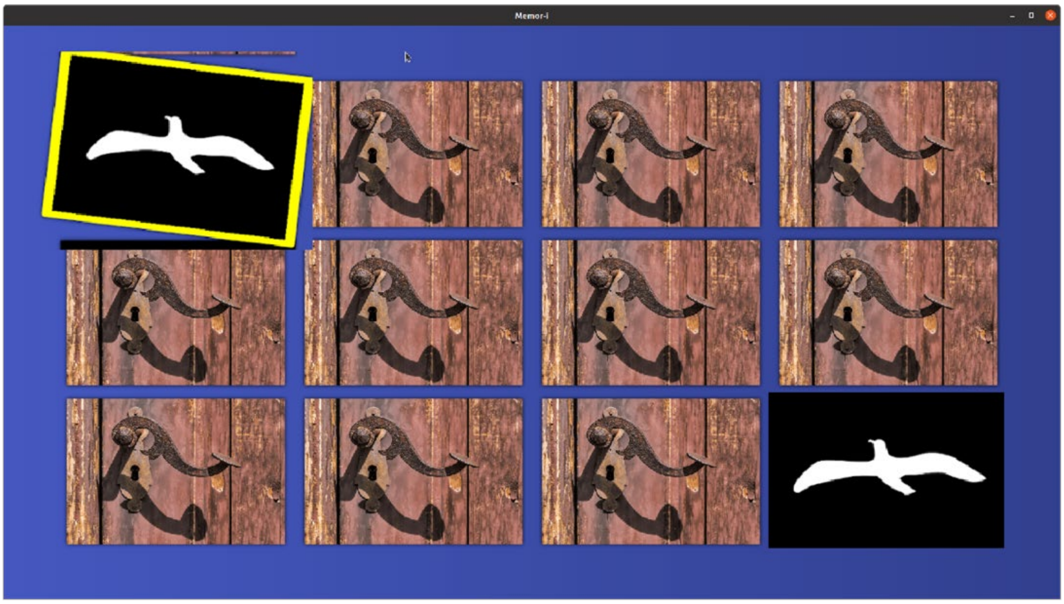

Figure 17. Memor-i game example.

Face recognition (VICOM)

An algorithm integrated into ARI to support the user authentication process. Face recognition verifies whether the person in front of ARI's frontal head camera is the expected user. The expected user is that of the token provided by ASAPA for a limited time in the initial authentication. This way, the interaction during the subsequent authentications is improved, as the number of times the user should write the username and password is reduced (ideally, only the first time).

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Adilib chatbot engine (VICOM)

The chatbot technology enables natural language interaction with robot users. Coupled with the speech recognition module, the chatbot will interpret what the user says to provide navigation through ARI's menu and have trivial conversations through voice. Opposite to simple speech recognition (the user has to say the desired option strictly, strict words to be recognised), a chatbot offers natural language communication. New conversations are designed and adjusted based on user needs and provided in the end-user's language.

ROSA dialogue flow (CH)

ROSA is a dialogue flow system for communicating with older adults. Dialogue structures, currently used for following up with people with heart failure, will be adapted to instruct cognitive activities.

Wake-up word and speech recognition (VICOM)

Speech recognition enables the transcription of user voice messages to text. Speech recognition will be installed in the SHAPES platform and will communicate with ARI online. Speech recognition is necessary to enable user voice interaction with the Adilib chatbot, for this use case, in Spanish, Greek or Italian language. The wake-up module can identify a specific word sound to activate listening for speech recognition. A constant readiness must listen to the user without high-power consumption and maintain user privacy. Thanks to this, users can choose when to start the conversation, e.g. "Hello ARI, I want to play a game".

Emotion detection (TREE)

An algorithm that analyses face biometrics to detect emotions within a category set, while the user interacts with the robot (performing a specific activity, like a memory game). It will be activated only if the user gives consent. Emotion recognition will analyse engagement during different interactions, but this information will not be displayed to users, nor will it intervene on the user-robot interaction. Instead, this solution will evaluate the user-robot interaction based on the emotions detected. This digital solution will also support the selection of activities for the users.

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3.3.1 Digital solutions used for COVID-19 response

Temperature monitoring is incorporated into the robot (Figure 18) where the robot captures user temperature through its thermal camera, and if the temperature is too high, it offers the option to send an email to the user's caregiver. In any case, the temperature monitoring method of the robot is not a validated medical method and this is communicated to users when the application is open.

Figure 18. Temperature detection integrated into robot ARI.

3.3.2 Equipment and devices used (from third parties)

An Android tablet will be the additional hardware external device for UC-PT4-002.

3.4 Data plan

The data plan for PT4-001 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.

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- Personal Data Processing Descriptions that provides 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 PT4-002.

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

- Scenarios and data plan definition.

Phase 2

- Brainstorming to generate mock-ups;
- A/B tests with domain experts;
- Semi-structured interviews.

Phase 3

- Test with real users in a controlled environment;
- Usability and acceptability questionnaires;
- Phycological questionnaires;
- Critical incident registration;
- Logs registration;
- Semi-structured interviews with users.

Phase 4

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

Phase 5

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

3.4.2 Planning of evaluation

MAST

The MAST framework was used to evaluate the effectiveness and contribution of UC-PT4-002 to the quality of care. MAST is described as a multidisciplinary process that summarises and assesses information about the medical, social, economic and ethical issues related to telemedicine [1] .

A review of the seven dimensions of MAST revealed that two of the seven multidisciplinary dimensions/domains were relevant to the pilot of UC-PT4-002. These were Clinical Effectiveness and Patient Perspectives. Table 38 contains the data required for the MAST evaluation.

Table 38 - Data required for MAST evaluation of UC-PT4-002.

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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	Psychosocial and psychological wellbeing	WHOQOL-BREF [9], [15]	Baseline, end of pilot, 3-month follow up
			GSES [9]	Baseline, end of pilot, 3-month follow up
			OSSS-3 [9]	Baseline, end of pilot, 3-month follow up
			SPANE [22]	Baseline, end of pilot, 3-month follow up
	Effects on health-related quality of life	Health related quality of life	EQ-5D-5L [5]	Baseline, end of pilot, 3-month follow up
	Behavioural outcomes	Will not be measured		
	Utilization of health services	Will not be measured		
Patient perspectives	Satisfaction and acceptance	User Experience	UEQ-S [23]	End of pilot
		User acceptance	TAM [8]	End of pilot
	Understanding of information	Usability of application	SUS [6]	End of pilot
	Confidence in the treatment			
	Ability to use the application			
	Access & Accessibility			
	Empowerment Self-efficacy	User engagement	Played activities	During pilot
			Time length in activities	During pilot
			Mode of interaction	During pilot

MAFEIP

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Due to the evaluation methodology (small-scale deployment, non-case controlled) the MAFEIP tool will not be used to evaluate UC-PT4-002.

2.6.1.6 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-PT4-002 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 [10].

CSF 1. Cultural readiness for the telemedicine service:

In CH, all healthcare professionals share information through EHR, also used to communicate/transfer tasks among professionals. CH is starting to provide e-tools to patients to share clinical data and promote health education. Patients usually accept new technologies as far as they have a clear benefit. Older adults' acceptance of a robot is uncertain, as many are still adapting to smaller devices such as cell phones and tablets. Users need to know the advantages compared to other devices which may offer similar functionalities.

A financial strategy must be developed. Cost-benefit needs to be analyzed for each organisation.

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

In-home care, robots are envisioned as having high potential to offering in-home diverse support, such as cognitive activities. Although the cost and final design of the robot is still under discussion, social robots with functionalities offering cognitive activities are a need. In addition, improvements in higher interaction skills and adaptation to different users and scenarios could speed up acceptance and incorporation into real-life scenarios.

CSF 3. Ensure leadership through a champion:

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The CEO of CH has already promoted the internal deployment of ICT solutions. Notably, she believes in the benefits that the robot can offer in places where it can be shared among many older adults, such as residential care homes and private apartments.

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

The CEO and doctors of CH have been involved in defining the functionalities of digital solution to adapt them to older adults' needs. In addition, interviews in Phase 2 were carried out with healthcare staff at private apartments Ca'n Granada.

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

Older adults' representatives of final users have been involved in mock-up presentations in Phase 2 and hands-on training in Phase 3.

Many older adults are recommended to follow cognitive activities. They need to receive stimulation and adapt to their needs. Affinities and frustration tolerance as cognitive decline increases with age, such as attention, memory, and executive functions, compromise daily activities. Cognitive training and rehabilitation are effective countermeasures to reduce adverse effects.

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

Significant effort is made within the SHAPES consortium to define requirements to present the robot as user-friendly as possible to older adults. Half-day training is expected to be sufficient. A follow-up of older adults to check their adaptation may be required for 2-3 weeks. In addition, many resources are invested in integrating different interacting modes so every user can adopt the one that best suits them.

CSF 7. Pull together the resources needed for deployment:

The resources required to deploy 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 competencies.

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

SciFY has designed most games in collaboration with health professionals. The robot will provide different ways of interaction (tablet, front screen, voice interaction, printing-out) to adapt to different types of users. Further feedback will be collected through interviews to refine the modes of interaction and determine the more appealing activities. Regarding care professionals, although for some types of activities only, the robot includes some functionalities, such as creating new activities, modifying activities to adapt to older adults' affinities, and relaxing activities.

CSF 9. Prepare and implement a business plan:

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

CSF 10. Prepare and implement a change management plan:

At the end of the project the need to prepare and implement a change management plan will be evaluated.

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

The service is permitted under the required CE and AEMPS certifications. Permissions for the pilot are being evaluated, but no further certification is expected for the pilot. They will be evaluated after the pilot.

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

To be done after the pilot. Scaling up robot manufacturing is a complex process and needs to be evaluated along with the cost-efficiency analysis. For this use case, the price of the robot is especially critical as it is pretty high. It is essential to do a cost-efficient analysis to identify the benefits of having a social robot supporting cognitive activities in a nursing home. In this regard, some arguments are the staff shortage foreseen in health care, the ability of social robots to communicate in many different languages and the fact that, even if nowadays the prices of robots are still quite high, prices are expected to decline as more technological development is done in this field.

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

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GDPR will be applied. The system provided complies with all security and privacy-related regulations.

CSF 14. Involve legal and security experts:

CH is working with SHAPES partners (e.g., with LAUREA, with extensive expertise in this field) mainly because they will be 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:

Healthcare workers at CH already work with data protection protocols. They will also be instructed to apply for data protection within the new technologies introduced in the pilot. Older adults and informal caregivers will be informed about data collection and procedures, and consents will be collected.

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

SHAPES partners provide all parts of the infrastructure; the only requirement to use the provided solution is a wireless networking system that the device can connect to. Large-scale implementation will be evaluated after the pilot. The main bottleneck is manufacturing the robot and shipping it from one site to another, but the assistant IT infrastructure is straightforward.

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

The system will work from 9.00-19.00 approximately, to be adjusted by each site. In case of any bugs or issues, the development and maintenance team will fix it. The team will be composed of technicians at CH, SciFY and PAL. CH, PAL, VICOM, SciFY and TREE are the owners of all the software used in the pilot. This means that there are no software dependencies with third parties and that the source code can be quickly fixed at any point if it is needed.

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The system logs all activities to identify and solve any incident. Moreover, it provides a set of web interfaces to ensure system status monitoring.

Apart from the user manual, CH has access to the software developers of the system, so in case of doubts or questions, they can answer them directly. Furthermore, participants will have direct contact with CH. Every participant in the pilot has a current relationship with CH as patients, assuring smooth communication.

CSF 18. Establish and maintain good procurement processes:

All digital solutions in the current version of the technology come from SHAPES partners. Material which may be helpful to carry out some activities (paper, pen, printer) will be available.

NASSS

The NASSS framework was used to detect areas of complexity in the project plan for piloting UC-PT4-002 and, if needed, to make adaptations to the plan. The pilot team considered and completed the short version of the NASSS-CAT. When the NASSS framework was applied, significant uncertainties were identified in the technology domain. These were:

- **The technology:** the list of activities to be implement hasn't yet been defined. There are many uncertainties about their adaptation in the robot. However, several alternatives have been identified – selecting the most adaptable activities, printing out and displaying simple images;
- **The value proposition:** the value proposition has significant complexity that will likely affect a future deployment. The cost-effective barrier needs to be addressed in future steps;
- **The organisation:** a significant initial investment is expected in a commercial deployment. It does not impede the undertaking of the pilot, as it will be used to properly analysis of cost-effectiveness, needed to elaborate the business model;
- **The external context:** regulatory context needs further evaluation for future commercial development.

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3.5 Phase 1

3.5.1 PACT and FICS Scenario

Table 39 - PACT Scenario.

Applicable SHAPES Persona	**Isabella**
Applicable SHAPES use case	UC4: In-home cognitive training
Point of contact (pilot site)	CH
Point of contact (technical provider)	PAL Robotics

People
Roles and/or actors of typical users involved in delivering and receiving the telemedicine intervention
	• Older adults, 60+ years old, living independently in their homes or residential care homes. They will have none to minor literacy level;
	• Assistant: the person who may accompany the older adults while doing the activities. They will be supervising the activities are done typically. They may not be required when the older adult has enough confidence to interact with the robot. Different types of people can represent the assistant:
	    ○ Health professional;
	    ○ Caregiver (formal or informal);
	    ○ Family member;
	    ○ Staff at the care provider.
	• The assistant may schedule or define a set of activities for each older adult.

Activities
Activities to be performed by the actors in order to successfully provide and receive the telemedicine intervention procedures for the professional and the patient; Parameters that determine the measures used in the intervention
	Older adult/care receiver
	• Before starting (several scenarios) individual activities, the caregiver may define actions for users or groups of users;
	• Recognition: The older person has to be in front of the robot to be recognised and select an activity. Alternatively, ARI opens the SHAPES login page on the front-screen/back tablet;
	• Selection of activities:
	    ○ Some older adults may select the action on their own;
	    ○ Some older adults may suggest activities, selected by caregivers;
	    ○ The older adult selects the activity on the screen/tablet dashboard/printing-out, by voice or tapping. In the case of voice, they

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	will be instructed on how they can request for each game.
	• Depending on the method of development selected to perform the chosen game (Memor-I or diAnoia), the robot will either instruct the user to pick up the tablet from its back, continue with the front touchscreen or instruct on how to print the game;
	• The older adult will listen to the directions of the activity with some visual support if necessary;
	• Activities. The older adult will perform de following actions within the context of the activities as answers to the activity's questions, depending on the type of game (Memor-I, diAnoia, adapted):
	  ○ Adapted DiAnoia: Mentioning words or short sentences out loud or typing them on the front screen. What the user says does not need to be registered;
	  ○ Adapted Memor-I: Selection of items (words, pictures, boxes, parts of the screen) differently (circling, underlying, touching).
	• As the activities are carried out, this information should be stored for later revision for button clicks or written text. In the case of adapted games, also no need to capture audio but only text. Before starting the proper activity, the older adult will have the chance to test the activity with a guided example, in the case of adapted games;
	• The older adult will have the option to quit by pressing a button on the touchscreen or by voice (stop request, such as "Hey ARI, stop the game"). In addition, the older adult will have the option to change the activity at any time;
	• Temperature monitoring will be constantly available through the dashboard.
	Assistant
	• Will intervene if the interaction between the older adult and the robot is unsuccessful;
	• Will assist the older adult with the activity if necessary;
	• Will be able to take over the robot at any time;
	• Will be able to select specific activities for the older adult at any time of the session.

Context Social-medical relevance of the telemedicine intervention; privacy issues; risks for the patient; locations	Many older adults with early-stage dementia can live independently. Studies have shown that cognitive training can have positive effects. However: • If an older adult has joined a group cognitive activity, they don't attend regularly and miss many days; • Older adults need to go to the facilities where the training is given. This is an important issue for

	people with reduced mobility, low motivation or far from activity centres; • The offer of cognitive activities in nearby centres is low (a few times a week); • Older adults and their caregivers (or care partners) do not have the knowledge to provide cognitive activities on their own; • Some older adults may prefer individual activities instead of group activities; • Some older adults may need a more personalised intervention to adjust the difficulty level, preference of activities, change of activity in case of frustration or boredom, etc. The older adults will be provided or given access to the following devices/software and respective connectivity with the SHAPES platform: • Social robot ARI; • Printer + Paper + Pencil; • DiAnoia activities; • Memor-i activity. The main objective is that older adults spend more time doing cognitive activities (within recommended ranges): • Being more regular doing their sessions; • Having the motivation to do cognitive activities on their own; • Caregivers have the tools to provide cognitive activities to older adults. Other context points: • Maintaining the privacy of data is of the utmost importance. Therefore, any identifiable data will be held at the local pilot site; • GDPR and ethics in line with WP8; • Data and servers must be located within the EU; • Spanish, Italian, Greek and English languages.
Scenario **<u>The older adult, interaction</u>** Option 1: Older adult approaches ARI and activates the option "Play now"., the interaction starts. Option 2: ARI navigates looking for a specific older adult to offer a pre-determined game by the assistant. ARI finds the person through face scanning and interaction starts. **<u>Older adult, activity</u>** Older adult has a set of cognitive activities to do. After selecting one activity, ARI gives the option to do it through the front screen, back-tablet or printing. In case of back-tablet, ARI explains how to get the tablet to the older adult. The activity starts with a brief explanation and example case, which the user can skip if familiar with the activity. Then the older person plays as usual, being able to interact by tapping on the screen or by voice. Older adults can quit an activity or the whole session at any time.	

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After quitting, ARI returns to the docking station, if it is not already there. **Assistant** Assistants may adapt activities for older adults, personalised for each individual or group of people.	
Technology **Type of information/parameters that are relevant in monitoring the health status; type and frequency of accessibility of information; feedback modalities (communication)**	**Older adults** • Age; • Gender (m/f); • Cognitive functioning; • Robot interaction; • Activity performance; • Quality of life; • Health-related quality of life; • Social functioning; • Usability and technology acceptance; • Self-efficacy; • Adherence rates; • Adverse events.

Table 40 – FICS scenario.

Function and events *The functionality of the intended system which is capable of realizing the actor's activities*	The system will offer to older adults the robotic device and the functionality to: • Play cognitive games using the front-touch screen of the robot, the back Android tablet or printed; • Autonomously navigate the room to specific rooms to carry out tailored cognitive games with the user; • Provide feedback using the robot's multi-modal interaction capabilities – e.g., speech, touch-screen displays and LEDs, in the language of the pilot site; • Measure and monitor temperature (COVID-19 solution) and send alerts through email if needed; • Store user engagement for each type of game for future analysis; • Specify games to play (by the assistant) using the robot's interface for each specific user.
Interactions and usability issues *User-system or system-component interactions meditating actor's activities; Types of the interactions, e.g. unidirectional data streaming service or reliable messaging service*	In this use case, we expect to have two users: • Older adult; • Assistant. There will be three front ends in total: the front-touch screen of the robot, the back Android tablet, a web-based interface to introduce user information and a list of games to carry out. The front end also includes robot behaviour such as LEDs, gestures, and speech for the first two. The older adult will have access to the following data through the robot's dashboard: • Possible actions they can do with the robot: measure temperature, play games using the front touchscreen

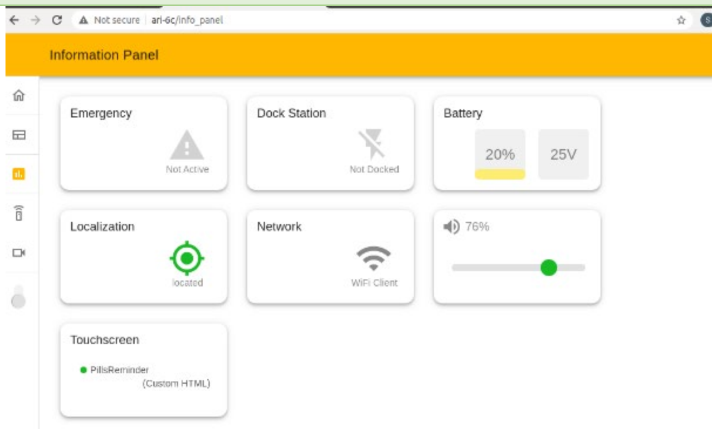
<table>
<tr><td></td><td>(Memor-I games or tailored DiAnoia games) or play games using the back Android tablet (diAnoia games, diAnoia Marketplace);
• Make the robot navigate to specific rooms to initiate cognitive training sessions (option on front screen or through icon in user’s cell phone);
• Interact with each respective game using button clicks of the touchscreen/tablet and speech interaction;
• Temperature measurements through speech and touchscreen.
The assistant will be able to add new games, specify what games to be made available and select specific games using the robot. They will also be able to receive notifications and metrics from the robot (too high a temperature, little interaction). They will also be able to visualize and monitor the status of the robot (battery level, camera output, etc).</td></tr>
<tr><td>Content and structure
Variables of the interaction</td><td>The older adult's front-end will be the ARI robot and its integrated front touchscreen (Ubuntu) and back Android tablet, which can be retrieved from the robot’s support. The interaction will use speech, gestures as well as the touch-screen interface.
The assistant will interface through the SHAPES Android app and the robot’s Web GUI interface, where they will be able also to add new touch-screen content for the robot.</td></tr>
<tr><td>Style and aesthetics
Look and feel of the system</td><td>

Figure 19. ARI dashboard for remote control.
The robot offers multimodal behaviour by enabling interaction with the tablet and combining it with speech interaction, change of LED effects, expressive gestures with the arms and head, and animated eyes.</td></tr>
</table>

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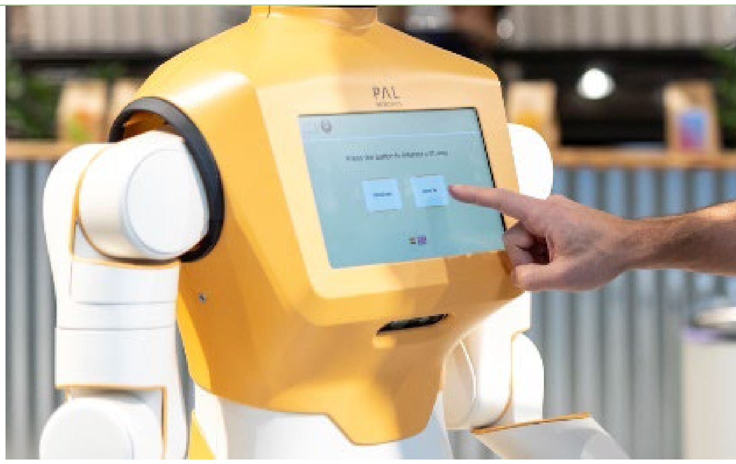

Figure 20. Touch screen interaction.

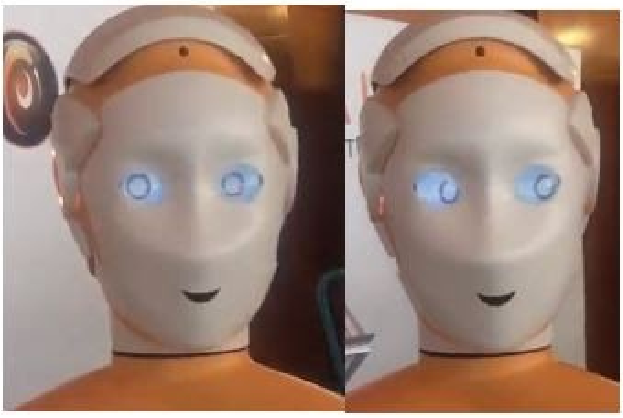

Figure 21. Eye movement as a way of increase user engagement during interaction.

3.5.2 Key performance indicators

KPIs are defined as measures that focus on the most critical factors to a project's success. KPIs are measurable and quantifiable with a target or threshold. They measure performance in critical areas by showing the progress or lack of it towards realising the objectives of each specific use case. The following KPIs have been chosen to determine whether the pilot for UC-PT4-002 has been successful.

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

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Recruitment and retention

- At least 80% of the target cohort (older adults) were successfully recruited into the pilot during the recruitment period;
- 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 technology components for at least 90% of the days;
- Less than 2 incidents were reported per week;
- The user successfully recognized 80% of the interactions.

User engagement and acceptance

- The overall user experience quality of the robot as measured using the short version of the User Experience Questionnaire (UEQ-S) was classified as 'Excellent', 'Good' or 'Above average' based on published benchmark data;
- At least 50% of the older people play twice a week;
- At least one care provider/caregiver scored one of the following functionalities above-average rating (>68) in the SUS (suggestion, game selection, game feedback).

3.5.3 Timeline of pilot activities

According to the description of work, the original timeline of pilot activities was to conduct Phases 1, 2 and 3 between May 2021 and January 2022, then Phase 4 (deployment in a controlled environment) in February 2022-June 2022 and Phase 5 between July 2022 and November 2022. However, due to the logistics of the robot, Covid-19 situation and development issues, Phase 4 and 5 were conducted later than planned. Phase 4 was conducted in March 2023 and Phase 5 in May 2023. This was possible thanks to an extension of the deliverable submission from M37 to M40.

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3.6 Phase 2: Testing of mock-ups and prototypes

3.6.1 Methodology of testing

Aim

To validate the functionalities of technologies in UC-PT4-002 and the way they are planned to be implemented, including the interaction with the users, based on the feedback provided by users. In addition, this research study also aims at collecting new functionalities. This research study will allow technical partners to integrate user feedback of the technological development process.

Overview

The robot and related assisting technologies for UC-PT4-002 undergo a co-design and user-testing process to validate the functionalities offered to the users and their usability. Mock-ups of the robot on a PowerPoint slide format and its behaviour were shown to the respective users.

Feedback on how the current functionalities address their needs, usability comments and ideas for new functionalities were sought.

Recruitment

Participants

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

1. Oder adults: ≥ 60 years old residents at Ca'n Granada. At least two people were expected to be recruited;
2. Assistant, worker of Ca'n Granada.

Informed consent procedure

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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 agreed to participate.

- **Older adults:** participant information sheet for older adults;
- **Assistant:** participant information sheet for care professionals.

CH personnel gave those who agreed to take part a consent form. Signed consent forms and contact details were then provided to CH to proceed with the study activities.

- **Older adults:** consent form for older adults;
- **Assistant:** consent form for care professionals.

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

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

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

The following data was collected:

- **Name:** in the consent form, for identification of the accepted consent.

Method

Presentation of mock-ups

Validation was sought on the utility and usability of:

- Interacting modes with the robot;
- Type of activities.

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

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A presential group session was conducted with participants. Mock-ups (images, text descriptions inserted in the presentations, and paper mock-ups of some of the screens) of activities and modes of interactions were presented to participants.

After each type of activity and mode of interaction, the presenter asked questions to participants 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 general and specific feedback about the functionalities. Some questions required an evaluation from 1 to 5, and others needed to rank several options.

Participants were given a copy of the slides with the notes taken by the presenter. They were told to review the notes and send more feedback, corrections or clarification if they had time, with the support of personnel from Ca’n Granada. We recommended that they send back further comments within 15 days. The copy was electronic and was sent to the supervisor for its distribution.

The following number of sessions, and time lengths, were carried out:

- **Older adults:** 1 session of 1 hour duration;
- **Assistant (supervisor of cognitive sessions at Ca’n Granada):** 1 session of 1 hour duration.

Data collection and analysis

Notes were taken during the interview by the presenter. A report was drawn up to include a table listing all questions and filled with participants' answers. Similar questions throughout the different types of users were grouped in a table. Other comments and opinions collected at the interviews were posted after the table or within a particular cell if the information was related to the question. Completed reports and collated findings, including recommendations, were presented to technical partners.

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3.6.2 Results of testing

Phase 2 sessions with recruited participants (three older adults and one assistant) were conducted on the 2nd of July and 13th of July 2021, respectively. Presentations were conducted face-to-face with older adults and remotely with the cognitive session supervisor via Google Meet video conferencing platform. Notes were taken during the session and shared with partners after removing personal data. Key points of the results are:

- Older adults:
  - Diverse e-literacy. One had a tablet; the other did not. The person without a tablet showed a more reluctant attitude towards using the robot;
  - They thought robot ARI was big, and eye movement was perceived as disturbing;
  - They would prefer to do all interaction by voice;
  - They would prefer to do DiAnoia activities on paper;
  - While interacting with the front screen, users would prefer to sit but the robot ARI is quite tall. They need a tablet pencil to reach comfortably;
  - They were familiar with the types of activity DiAnoia and DiAnoia adapted to the front screen. They know the activity Memor-i (without sounds) but not from their cognitive sessions. They like this activity;
  - They understood the example activities on their own. They could see the text and read it (none had serious hard-of-seeing);
  - They would not like to have the free choice to do any cognitive activity with ARI. They would like to be instructed;
- Assistant (Cognitive session supervisor):
  - She sees ARI as helpful in two ways: 1) suggesting activities to her users in their free time; 2) helping her do the activities during the sessions. In the sessions, she prefers doing group activities;
  - The DiAnoia (back tablet), is better for printting the games out;
  - Currently, all users have a similar level of cognitive skills. She would suggest the same activities to everyone;

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- She would like to register activities for every user and the resolution pathway (this will help her adjust the group activities);
- She would like to report any metric related to frustration;
- She would like to use ARI in group activities in the following way:
  - Activities could be projected to TV in the session room (new feature). She would like to launch their Power Point presentations she already uses. CH could help in adapting some of them to the front screen;
  - The activity will be done in a group, and the psychologist will tap the consensus result on the front screen;
- DiAnoia MarketPlace: no, she is more interested in group activities;
- Memor-i MarketPlace: yes, she would like to upload her creations. No problem in sharing them with other professionals;
- She would have 1h a week for creating and uploading exercises;
- Temperature measurement is now centralized at the front desk. She will not make use of it;
- Relaxing exercises:
  - She sometimes does mindfulness and relaxing activities;
  - She would prefer to read the texts instead of ARI;
  - Sometimes, she reads relaxing texts to older adults, but in other settings;
  - However, the setting where this use case may be carried out is not stressful (independent people, good relationship among users). She would not do relaxing/mindfulness activities in the currently planned use case setting.

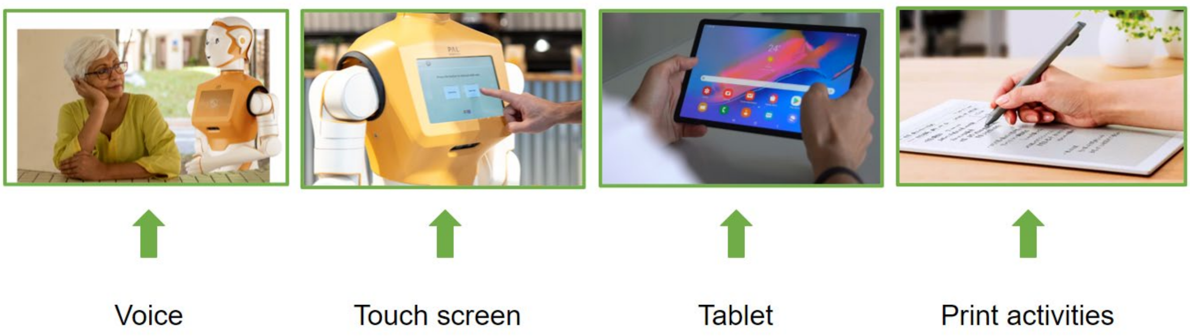

Figure 22. Mock-up presentation: Interaction mode.

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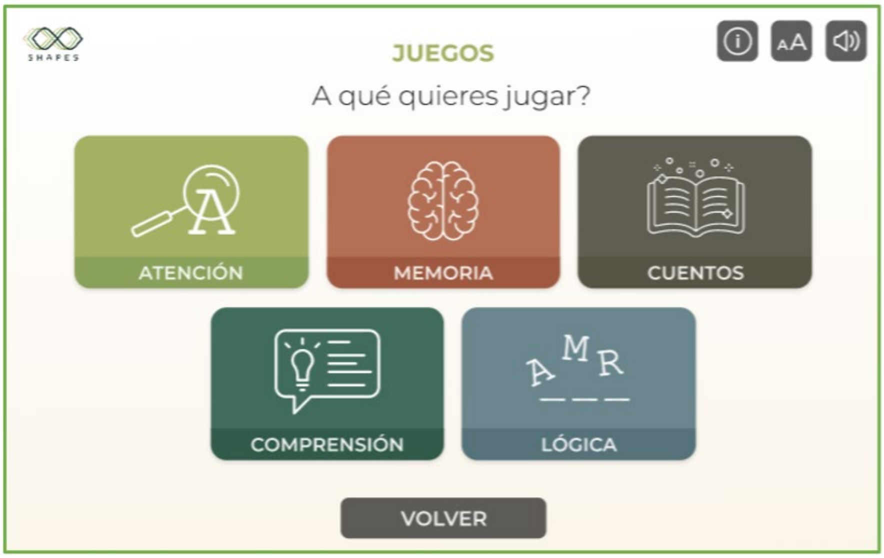

Figure 23. Mock-up presentation: Game selection.

Table 41 below summarizes the interviewer's answers during the presentation along with comments.

Table 41 - Feedback from older adults/assistant in mock-up presentations.

Questions to older adult	older adult 1	older adult 2	older adult 3	Professional	*Questions to professional*
Context of interviewees					
Age	86	83	81		
Do you currently attend cognitive sessions?	yes	yes	yes	Psychologists in cognitive activity sessions	What relation do you have with people you know who may be interested in using ARI?
Are cognitive activity sessions given by a professional?	yes	yes	yes	-	-
Do you like the way your cognitive activity sessions are given?	yes	yes	yes	-	-
Do you like the activities	yes	yes	yes	-	-

Questions to older adult	**older adult 1**	**older adult 2**	**older adult 3**	**Professional**	***Questions to professional***
in your cognitive activity sessions?					
How long do the sessions last?	1 h/week	1 h/week	1 h/week	1 h/week	How long do the sessions last? (At the centre of potential users of ARI)
	-	-	-	2 h/week	How much time do you take to prepare your cognitive activity sessions?
What are the formats in which the activities are given?	group sessions / voice interaction	group sessions / voice interaction	group sessions / voice interaction	group sessions / power point presentation / voice interaction	
	-	-	-	Psychologist	What is your professional background?
				no	Is your activity a medical treatment?
Location of ARI					
Would you have problems going to the standard room where ARI would be placed eventually?	no	no	no	-	-
Would you like ARI to wander around the premises, familiar places?	no	no	no	-	-

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Questions to older adult	older adult 1	older adult 2	older adult 3	Professional	*Questions to professional*
Would you like ARI to approach you to suggest cognitive activities?	no	no	no	The older adult goes to the room where ARI is located	Would you prefer ARI approaching the older adult (active suggestion) or the other way round?
Use of ARI					
Would you like to have the freedom to choose the activities in ARI?	no	no	no	-	-
Would you like ARI to tell you what activities to do? (they are defined by a professional)	yes	yes	yes	yes	Would you like to program what activities ARI will suggest to users?
	-	-	-	no	Would you like to personalize activities? (at the center of potential users of ARI)
	-	-	-	other times	Would you prefer using ARI in your sessions or that older adults use it individually at other times?
	-	-	-	optional	If you prefer to suggest using of ARI outside cognitive sessions, would the exercises be mandatory or optional?
Would you like to	no	yes	yes	-	-

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Questions to older adult	older adult 1	older adult 2	older adult 3	Professional	*Questions to professional*
interact with ARI by voice?					
Did you understand what ARI said?	yes	yes	yes	-	-
1-5 scale (1- not at all; 5- very much): Did you like how ARI told story?	2	3	4	-	-
Would you like ARI to take your temperature?	yes	yes	yes	no	Do you need ARI to take the temperature?
Would you like ARI message someone trusted if your temperature is high?	no	no	no	no	Would you like to receive a notification if the temperature is high?
Cognitive activities					
DiAnoia backtablet					
Did you like the activities?	yes	yes	yes	-	-
Did you feel comfortable?	yes	yes	yes	-	-
Are they similar to the ones you currently do?	yes	yes	yes	-	-
DiAnoia paper					
Did you like the activities?	yes	yes	yes	-	-
Did you feel comfortable?	yes	yes	yes	-	-
Are they similar to the ones you currently do?	yes	yes	yes	-	-
Do you prefer a DiAnoia tablet or DiAnoia paper?	paper	paper	paper	paper	Do you think older adults would prefer the DiAnoia

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Questions to older adult	**older adult 1**	**older adult 2**	**older adult 3**	**Professional**	***Questions to professional***
					tablet or Dianoia paper?
	-	-	-	no	Would you print out DiAnoia activities for your sessions?
DiAnoia front screen					
Did you like the activities?	yes	yes	yes	-	-
Did you feel comfortable?	no	yes	uncertain	-	-
Are they similar to the ones you currently do?	yes	yes	yes	-	-
Do you prefer DiAnoia front screen, DiAnoia tablet or DiAnoia paper?	paper	paper	paper	paper	Do you think older adults prefer DiAnoia front screen, DiAnoia tablet or Dianoia paper?
Memor-i (front screen)					
Did you like the activities?	yes	yes	yes	-	-
Did you feel comfortable?	no	yes	uncertain	-	-
Are they similar to the ones you currently do?	no	no	no	-	-
General					
	--	-	-	Other times	Would you prefer using ARI in your sessions or that older adults use it individually at other times?
External devices					
Where do you have an	Front desk	Front desk / At home	Front desk	Front desk	Where do you have an

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Questions to older adult	older adult 1	older adult 2	older adult 3	Professional	*Questions to professional*
accessible printer?					accessible printer?
Data collection					
Would you mind if we collected data regarding your activities to research how to improve ARI?	no	no	no	-	-
Would you mind if we collect data regarding the time you spend in each activity with ARI to research how to improve ARI?	no	no	no	-	-
Would you mind if ARI analyses your emotions (face analysis) to research into what activities you like most?	yes	yes	yes	-	-

3.7 Phase 3: Hand-on Experiments

3.7.1 Methodology of hands-on experiments

Aim

To collect feedback (user experience) from end-users by allowing them to try the digital solutions to be deployed in the use case PT4-002 in close-to-final version prototypes.

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Overview

Participants (older adults and assistant, being the cognitive activity supervisor) were invited to sessions with CH personnel to take part in the hands-on experiments:

- **Older adults:** face-to-face group session with all participants in Ca'n Granada (retirement home, Mallorca Spain);
- **Cognitive activity supervisor:** one or two individual face-to-face/online sessions.

Participants

Phase 3 hands-on experiments were expected to be conducted with at least three target users of ARI (i.e., ≥ 60 years old; ability to consent). Gender equality was sought in the group of older adults participants.

Phase 3 hands-on experiments were expected to be conducted with one cognitive activity supervisor. The cognitive activity supervisor was personnel of CH. The mental activity supervisor identified eligible target users among the residents of Ca'n Granada.

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

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

Method

ARI was expected to be presented as a prototype for older adults. The SHAPES project manager at CH was expected to guide the participant through a series of steps and tasks to demonstrate the different functionalities of the robot.

The steps and tasks were designed to include the following:

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Demonstration to older adults

1. Log-in process;
2. Doing an activity with DiAnoia back tablet, touchscreen mode;
3. Doing an activity with Memor-i front screen, touchscreen mode;
4. Doing an activity with DiAnoia adapted activities on front screen, touchscreen mode;
5. Processes 1-3 with voice interaction;
6. Calling ARI to come;
7. Printing out activities.

The pace of the session was expected to be determined by the participant. After each demonstration point, the participant was encouraged to use ARI following the same process, with the presenter still present and available to be asked questions and troubleshoot any issues.

Demonstration to the cognitive activity supervisor

1. Moving ARI from the main floor to the cognitive activity room (face-to-face session);
2. Process of projecting a cognitive activity group session presentation (face-to-face session);
3. How to assign activities to older adults (face-to-face or online session);
4. Process of uploading an activity in the DiAnoia marketplace (face-to-face or online session);
5. Process of uploading an activity in Memor-i marketplace (face-to-face or online session);

After each demonstration point, the participant was encouraged to practice, with the presenter still present and available to be asked questions and troubleshoot any issues.

Feedback at any session was collected as detailed below.

Collection of feedback

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In the sessions, feedback was expected to be collected at a different time points using several other methods.

A concurrent 'think out loud' approach was expected to collect reactions to ARI or marketplaces and identify any areas requiring particular attention during the demonstration of the app and hands-on user experience. The participants were encouraged to verbalise their reactions, thoughts, feelings, and opinions about the prototype throughout their engagement with the presenter and the presenter took notes. When the user interacted with ARI, video recordings were taken only if the participant explicitly accepted this in the consent form. Accepting or rejecting being recorded was not a variable of the eligibility criteria.

After the hands-on experience, participants were asked to complete the User Experience Questionnaire (UEQ) to collect quantitative data about the impression of the participants about user experience. The UEQ assesses six aspects of user experience (attractiveness, perspicuity, efficiency, dependability, stimulation and novelty). There are 26 items and respondents mark on a seven-stage scale between two terms in each item (e.g., attractive ○ ○ ○ ○ ○ ○ ○ unattractive).

At the end of the session, participants were interviewed by the presenter to collect the participant's experience using ARI. An interview schedule/topic guide was followed during the interview, but the presenter also refered to conversations and topics raised during the sessions. In addition, semi-structured questions explored users' general feedback about the app, including:

a) Ease of use;
b) Design;
c) Utility;
d) Gender equality;
e) Quality of hands-on experience;
f) Overall satisfaction.

Data analysis

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Results of the UEQ were expected to be compared against published benchmark data and findings reported alongside interview data in a feedback report. However, no identifiable information was recorded on the feedback reports.

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

3.7.2 Results of the hands-on experiments

Hands-on training with older adults, attempt at Ca'n Granada

Context

- older adults who usually attend cognitive sessions at Ca'n Granada;
- 1 supervisor of the cognitive sessions;
- 1 presenter from CH.

The supervisor informed older adults in previous cognitive sessions that on the 10th of December, there would be hands-on training with a robot that assists in cognitive activities. After the hands-on training attempt, the supervisor told the presenter that some of them said that they did not like robots. Still, she made clear that the session was a demo to collect feedback and that did not imply participating in any later pilot.

The presenter arrived at the room, and older adults were already there (there was a room change at the last minute). The presenter entered the room with ARI, and after a short, trivial, hello conversation, one of the older adults started a discussion about the recent introduction of robots in some areas and they commented that they did not like the idea. Two other older adults in the room joined the conversation. The first person led that. The other two remained quiet. The statements they said were:

- I don't like talking to robots;
- I want to come to the supervisor's sessions, not do them with a robot;
- Robots don't have feelings;
- Robots are replacing people's jobs;
- I don't like using new technologies;
- I like talking to people not machines;

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- I already know the robot.

The presenter didn't interrupt the conversation because he considered their conversation feedback. He only mentioned that a robot is a tool, as PowerPoint is in their current sessions, and CH wants to know whether it can be helpful. Also, the presenter showed different functionalities than the last time he came (referring to PT1-004 hands-on training, which was also performed at Ca'n Granada).

The supervisor entered the room, and after a brief, trivial chat, she introduced the presenter from CH. He started distributing the consent form, and the previous conversation started over again. The supervisor said that it was only a demo and everyone could say whether they liked it or not. However, the conversation went on around the same points.

The presenter asked older adults who wanted to do the session because it was not mandatory (Figure 24). Three attendants answered that they would prefer to do the usual cognitive session. The other two were asked again directly and nodded. They agreed with their mates.

Figure 24. First attempt of Hands-on training at Ca'n Granada.

Potential factors that could have led to the rejection of the session

- The hands-on training was replacing their usual cognitive session;

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- Some (two or three) were already in the PT1-004 hands-on training sessions;
- They were a group of people not used to trying new technologies;
- They were a group of people who did not like changes;
- They felt the robot was competing with the supervisor;
- They were not interested in the cognitive benefits that much but instead in attending a group session;
- External factors (news on robots, high unemployment, covid-19 social crisis, ...).

Re-formulation of Phase 3 Hands-on training

After the first attempt of the Hands-on training, it was decided to change the approach of the pilot. First, the role of the cognitive session's supervisor was no longer possible because after the reaction of participants in the session, she was afraid of losing some of the participants if she tried to introduce ARI within the regular cognitive sessions. Then, the role of the assistant was left as "optional" and the use case was re-designed.

Context (theoretical session)

- older adults living in Ca'n Granada who have shown some interest for new technologies;
- 1 presenter from CH;
- 1 caregiver from Ca'n Granada (this person would mediate between older adults and the presenter, but would not actively intervene in the session).

With the support of the management team at Ca'n Granada, CH personnel organized a theoretical session on the 13th of May 2022 simulating a Mock-up session with the participation of four older adults.

Method (theoretical session)

To introduce the robot ARI in a softer way to minimize adverse reaction among participants, a short visual survey was presented to older adults to understand their general impressions on robots. A general question was asked "Are you afraid of robots?" and they had to answer through a 5-Point Likert scale as shown in Figure 25.

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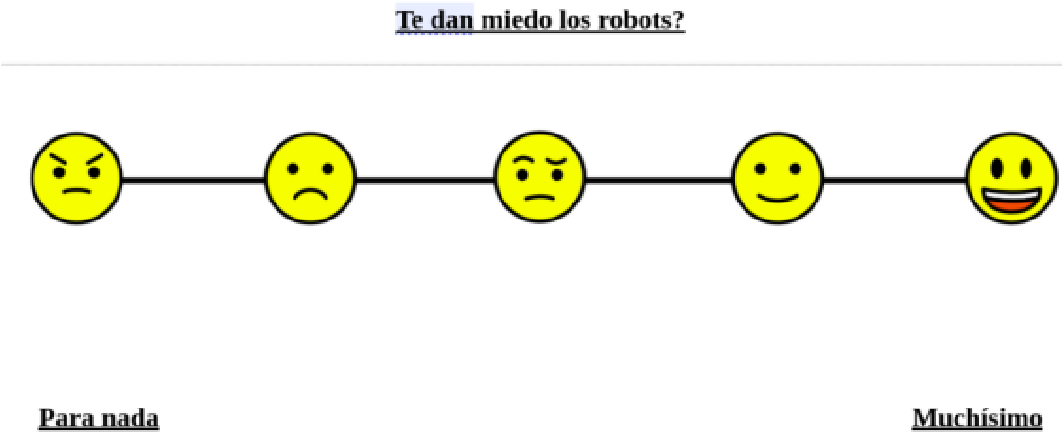

Figure 25. 5-Point Likert scale displayed on the survey previous at the Hands-on-training.

To help participants answer the question, examples of common devices and robots were displayed, such as those in Figure 26.

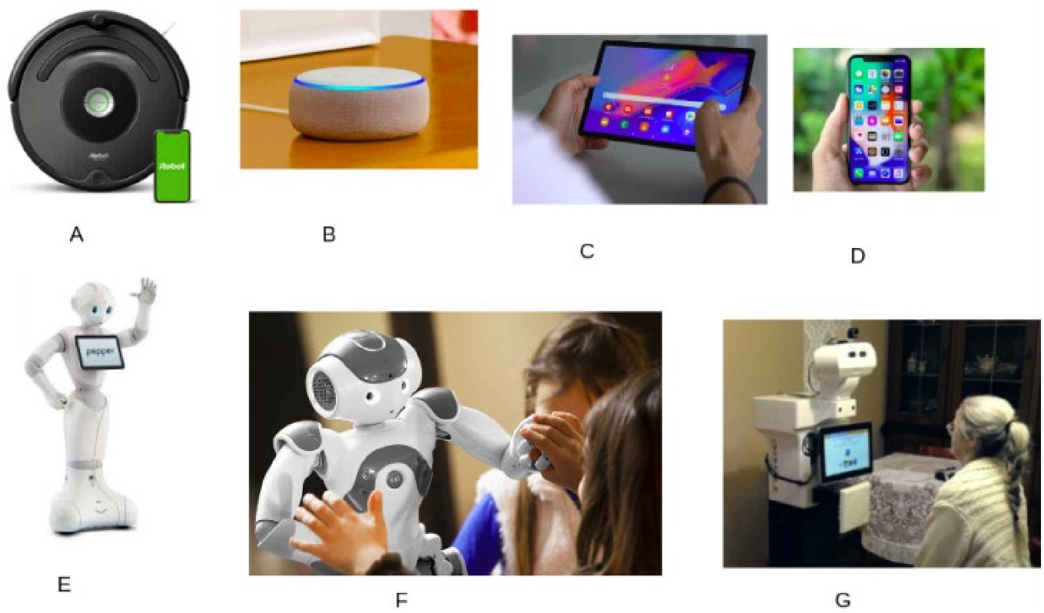

Figure 26. Examples of robots displayed on the survey previous at the Hands-on-training.

Feedback was collected from participants, which is shown in Table 42.

Table 42. Feedback from the survey previous at the Hands-on training.

Participant	Are you afraid of robots?				
	Not at all (1)	Not much (2)	Neutral (3)	A little bit (4)	A lot (5)
P1		X			
P2	X				
P3			X		
P4		X			

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From the feedback we can see that after being shown pictures of common robots, older adults declared they were not afraid of robots.

After that, a PowerPoint presentation was displayed to participants, showing pictures of ARI. In this session it was highlighted that the robot is not a tool aiming to substitute the cognitive session with the psychologist; the project aims to collect suggestions and opinions about the solution. Then, the presenter asked the participants who would be keen to attend a practical session (the Hands-on training) and most participants seemed eager to do so.

Context (practical session)

- older adults living in Ca'n Granada, ideally those attending the previous theoretical session;
- 1 presenter from CH;
- 1 caregiver from Ca'n Granada (this person would mediate between older adults and the presenter, but would not actively intervene in the session).

With the support of the management team at Ca'n Granada, CH personnel organized a practical session on the 20th of May 2022 simulating a Hand-on training with the participation of four older adults, two of whom attended the theoretical session on the previous week.

Method (practical session)

The presenter from CH arrived at the room and set up the robot ARI before the beginning of the session. Once all participants arrived, the presenter introduced ARI, showed the functionalities, and then encouraged older adults to use the robot and ask questions. The methodology applied was the one described in the previous section.

Results

At the end of the session, participants were interviewed by the presenter to gather their experiences using ARI regarding six different aspects (Figure 27). The questions and answers are presented in Table 43.

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Figure 27. Successful Hands-on training at Ca'n Granada.

Table 43. Answers to the interview from Hands-on training participants.

Topic/Theme	Interview question and answer
Ease of use	• Were you able to easily use ARI/Marketplaces? **Everyone: Yes, it is easy.** • Tell me about any concerns you had while using ARI/Marketplaces? **Some participants: I have difficulties to see appropriately. Some participants: I have difficulties to hear properly. Some participants: I have problems standing for a long time and ARI is too tall.** • What do you think might prevent you from using ARI/Marketplaces? **Some participants: Nothing, I like it. Some participants: I don't think I would like to use it because I can already play games in other ways. Some participants: I cannot stand for a long time to play the games, but I could use it the tablet.**
Design	• Do you think ARI/Marketplaces are nice to look at? **Most participants: Yes, I like it, it is beautiful. One participant: I don't like the eyes. It is ugly.** • Are the colours used in ARI/Marketplaces appealing? **Everyone: Yes, I like the colours.** • Were there any sections of ARI/Marketplaces that you could not read/see clearly? **Some participants: Yes, it is difficult for me to read.**
Utility	• Do you think ARI/Marketplaces are suitable for your needs? **Some participants: Yes. Some participants: No, it should give the option to sit down.** • Which features in ARI/Marketplaces do you think are most relevant to you? **Everyone: The games**

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	• What other features would be useful for you? **Everyone: I would like to play music and do karaoke. Sometimes I get tired of playing games.**
Gender neutrality	• Do you think ARI/Marketplaces are in any way too masculine or feminine? **Some participants: I don't know. One participant: Masculine.** • Do you think ARI/Marketplaces would appeal more to men or women, or to both about the same? **Everyone: To both.**
Quality of training	• Was there any information missing in the demonstration that would have been useful to know when you used the ARI/Marketplaces? **Everyone: No, the training was ok.** • Would you need any further support to use ARI/Marketplaces? **Everyone: I don't know, maybe in the future.**
Overall satisfaction	• What is your overall impression of the app/dashboards? **Some participants: It is nice, but I am unsure if I would like to use it, I don't like new technologies much. Some participants: I would like to use it.** • How would people in your age group respond to being asked to use ARI/Marketplaces? **Most participants: They won't use it much.** • How often would you use ARI/Marketplaces? **Some participants: I don't know, maybe a few times per week to try and I will keep using it if I like it.** • Did it meet your expectations? **Some participants: It is nice but not very useful to me. Some participants: Yes, I like it.** • Is there anything you would improve? **Some participants: Option to sit, introduce music and karaoke and dance.**

Moreover, all older adults answered the User Experience Questionnaire (UEQ) individually and the results were compared against published benchmark data. This analysis is shown in Table 44.

Table 44. Results of UEQ compared against published benchmark data.

Scale	Mean	Comparisson to benchmark	Interpretation
Pragmatic Quality	0,938	Below average	50% of results better, 25% of results worse
Hedonic Quality	1,500	Good	10% of results better, 75% of results worse
Overall	1,22	Above Average	25% of results better, 50% of results worse

From the User Experience Questionnaire analysis, CH can conclude that the overall participants' impressions of the robot ARI were above average, being better rated the hedonic quality than the pragmatic quality.

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The Hands-on training with the cognitive session supervisor as assistant in the use case was conducted via the Google Meet video conferencing platform and could not be performed until the 17th of October 2022, as she was on maternity leave. The methodology applied was the one described in the previous section. After the session, she answered the SUS with a total score of 82.5 and an unstructured interview. The feedback collected at the interview in quotation form is detailed hereafter:

- "I like the idea of introducing robots in the cognitive sessions";
- "I think ARI could be useful for cognitive stimulation, but I am not sure whether older adults at Ca'n Granada will engage with it";
- "Ca'n Granada is a complex of private apartments and residents are very independent, which sometimes makes it difficult to ensure attendance to organized activities;
- "I like ARI but I will only use it if residents are willing to because I don't want to compromise my cognitive sessions";
- "I really like the games and the option to create new ones and get ideas from other professionals";
- "I think ARI should remain in one place due to security and logistics";
- "Most older adults cannot stand for long periods and ARI is quite tall".

3.8 Phase 4: Small Scale Live Demonstration

Following experience in phase 3, Phases 4 and 5 were redesigned to provide users a more gradual introduction of ARI. In addition, another residential care home was proposed as, even if the second attempt of the Hand-on training was successful, most of the residents that had participated in the session didn't live at Ca'n Granada anymore at the time of Phases 4 and 5. There were not enough residents willing to participate in the study and commit to use ARI.

The residential care home chosen was La Porcíncula, also located in Palma de Mallorca. However, since amendments on the already approved Ethics Protocol were required due to the location change, there was no time to conduct Phase 4 at La Porcíncula with older adults. Instead, it was decided to conduct Phase 4 internally, as

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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. Therefore, Phase 4 was performed with workers from CH not previously involved in the SHAPES project.

However, before performing the official testing, CH project manager performed a technical test that lasted a few weeks to identify technical issues that would compromise the good course of the study. As a result, the following issues were detected and communicated to PAL:

- **Hardware issues:** sometimes ARI doesn't move the head correctly. Functionality needed to, for instance, look at the user to check the temperature, as the thermal camera on the front of the head;
- **Voice layer:** This functionality not always work; it seems ARI sometimes is not "listening";
- **Games:** One adapted dynamic tale, "Porud of grandchildren" has a screen that doesn't work in ARI;
- **Other adjustments:**
    - On one screen, the "exit" button is missing;
    - One game appears just half-screen;
    - Correction of grammar errors.

All the errors internally detected were addressed and fixed and the proposed improvements were implemented before the recruitment of participants to develop the official Phase 4 of the use case.

3.8.1 Recruitment of participants

Inclusion criteria

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

Exclusion criteria

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- 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.

Recruitment

No financial incentives were provided for participating in Phase 4.

SHAPES project manager 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 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.

Technical Aspects & Logistics

When developing Phase 4 the robot was placed in a quiet room at CH. The robot was set up and introduced to participants by the SHAPES project manager. ARI stayed at this location for the whole length of Phase 4. The project manager monitored and responded to any doubt or technical issue that participants had, with the support of SHAPES technical partners.

At this time, SHAPES ID's were created for this use case. CH research team did the necessary tests to check that the data flow was correct and adjusted to the data plan,

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including the integration with ASAPA for user identification and data transfer to the Data Lake.

3.8.2 Roles and Responsibilities

SHAPES project manager at CH oversaw the setup of the robot and the training process. She carried on all tasks related to the ethic requirements. The technical team at CH developed the chatbot in Spanish using the Adilib platform. This process that started early on and finished just before Phase 4 and was responsible for adjusting the screen structure based on feedback collected during previous phases, together with PAL technical team. Once participants started testing the digital solution within Phase 4, the project manager was their contact person for any technical issues, which were communicated to the technical team led by PAL, and they were responsible for taking the proper actions by accessing remotely to the robot when needed and solving doubts.

During this phase, AIAS and AUTH prepared to replicate the use case PT4-002. They received one robot ARI each on its premises and proceeded with all the necessary technical arrangements and settings. Technical teams at AIAS and AUTH were responsible for translating all the dialogues to build the chatbot in the local language and managing all the essential hardware and software pending arrangements under the guidance of the use case leader and technical team from CH and PAL. Moreover, they prepared the research protocol and Data Protection Impact Assessment (DPIA), Data Processing Agreement (DPA) and Data Sharing Agreement (DSA) under the guidance of the UCs leader to be checked by their DPO and then to be submitted for approval along with the bioethics documents in the corresponding Ethics Committee.

3.8.3 Ethical considerations

Approval from the local Ethics Committee was obtained before starting the recruitment process of participants. This includes acceptance of the following:

- Information sheet for participants;

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- Consent form;
- Study protocol.

Data Protection Impact Assessment was finished before the start of the recruitment of participants (including data risk assessment).

Data Processing Agreements were finished before the start of the recruitment of participants. The pilot site, in this case CH, is the data controller and has access to the entire dataset. In addition, data Processing Agreements were implemented to facilitate sharing pseudonymised data with specific SHAPES partners for particular purposes.

Ethical self-assessment was rechecked before sending the protocol to the local Ethics Committee.

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

3.8.4 Outcome of the Small-Scale Live Demonstration

The small-scale live demonstration took place in January 2023. The evaluation of the outcomes is presented in Table 45.

Table 45 – Outcomes of Phase 4.

Outcome	Measurement	Instrument
ARI performance	Technical information about ARI performance during sessions.	Log files and remote monitoring of ARI sessions.
Technical aspects	Analysis of the different functionalities of ARI.	Semi-structured interview guide.
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	The perception of the digital solution and its purpose of cognitive stimulation through	Open interview.

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	cognitive activities. Analysis of games offered and their integration into ARI.	

The project manager at CH presented ARI and all its functionalities to Phase 4 participants. After a group introduction, she scheduled the four sessions within one week, 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.

Due to integration difficulties, face recognition was not used in this use case. At the end of Phase 4 this functionality stopped working in the robot ARI located at CH due to a bug. The configuration process was really time consuming, and it was decided to leave this functionality out and focus on improving the performance of the functionalities that specifically target cognitive stimulation. Moreover, at earlier stages of the use case, the possibility of using ARI in group sessions was contemplated; in this scenario it was very convenient to reorganise participants through face recognition. However, the robot ARI and the integrated games were piloted at La Porcíncula in individual sessions, so the benefit of face recognition wasn't that high anymore. Even though this functionality would have added value for participants, after a cost-benefit analysis we decided to carry on without it.

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 the Table 46 and Table 47.

Table 46. 10-Point Likert Scale to collect feedback about technical aspects.

Participant	Responsiveness	Speed	Chatbot performance	Screen structure	Overall satisfaction	TOTAL
P1	6	5	7	10	8	7.2
P2	7	6	5	9	7	6.8
TOTAL	6.5	5.5	6	9.5	7.5	

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Table 47. 10-Point Likert Scale to collect feedback about functionalities.

Participant	Temperature	Memor-i	Dynamic tales	DiAnoia (ARI)	DiAnoia (tablet)	TOTAL
P1	8	10	9	9	9	9
P2	7	9	9	8	8	8.2
TOTAL	7.5	9.5	9	8	8.5	

From the two previous tables it's possible to see that the overall satisfaction with the technology is quite positive, but functionalities are better rated than technical performance, this shows that proper integration of the different digital solutions is key for a good user experience.

Among the four sessions, the following errors were reported, being a total of four. The results are shown in the Table 48.

Table 48. Errors reported by Phase 4 participants.

Error	Type of error	Times reported (n)	Mitigation action & result
Error 1	The robot doesn't "listen" enough time after asking a question to the user, so voice interaction is impossible.	3	The PAL technical team fixed a more extended listening period, giving the user more time to respond.
Error 2	During the interaction, at a certain point ARI stopped responding neither through voice nor through the touch screen. As a result, the screen froze and interaction was not possible.	1	System restarted, after that the robot ran properly again. This was considered an isolated event.

Table 49 shows the results of TAM and SUS questionnaires.

Table 49. Trust, acceptance and self-perceived usability of Phase 4 participants.

Participant	TAM (21)	SUS (100)
Participant 1	18	77.5
Participant 2	15	72.5
TOTAL (mean/sd)	16.5 (2.12)	75 (3.54)

Table 50 shows the results of UEQ-S questionnaire.

Table 50. UEQ-S for Phase 4 participants in relation to existing values from a benchmark data set.

Scale	Mean	Comparison to benchmark	Interpretation

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Pragmatic Quality	1,125	Below average	50% of results better, 25% of results worse
Hedonic Quality	2,250	Excellent	In the range of the 10% best results
Overall	1,69	Excellent	In the range of the 10% best results

Table 51 gathers some quotations from Phase 4 participants about the DS.

Table 51. Feedback from Phase 4 participants in an open interview.

Participant	Quotation
Participant 1	"I like the robot and I think it is a good motivation for older adults to keep active playing games differently, however, the robot is a little slow and for the voice interaction to work, users must talk in an obvious way, which makes it difficult".
Participant 2	"The robot looks good, but the overall performance could be better to avoid frustration, especially the chatbot, which does not always work properly".

After Phase 4, CH research team analysed the data collected from participants and developed a technical report, which was sent to PAL technical team. Moreover, a technical meeting was held between CH and PAL to discuss the results of Phase 4 and take the proper action before Phase 5.

During Phase 4 CH could check that most of the technical issues internally detected had been fixed and just some problems with the chatbot persisted, which were addressed. Regarding the overall performance of ARI in terms of speed and responsiveness, these issues are probably due to the number of integrations within the system. They are difficult to be improved within the scope of this research project. However, this aspect should be considered in the future to enhance user experience.

3.9 Phase 5: Large-scale pilot activity

CH considered many retirement homes in Mallorca to develop Phase 5, but not all of them had the resources to take ARI and perform the piloting activities. Therefore, Phase 5 was performed at La Porcíncula, a retirement home only for Franciscan Fairs so all residents are men, being 18 residents in total. The retirement home counts with nursing service, and residents follow a semi-structured daily routine based on exercises, meal service, group activities, etc. La Porcíncula was a suitable place to perform the large-scale pilot activities, because there are two health workers per shift,

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which allow them to spend time on alternative activities outside the daily routine. Moreover, there are shared spaces to place ARI, which was a limitation for other retirement homes that were also considered for this study.

Hypothesis: Social robot ARI and the integrated functionalities can promote cognitive activities in older adults.

Primary objectives

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

Secondary objectives

- To explore user trust and acceptance of the novel system (SO1);
- To investigate the correlation between emotion recognition and user engagement (SO2);
- To analyse the novel system's capability to improve older individuals' quality of life, well-being, and psychological and psychosocial aspects (SO3);
- To improve the face recognition algorithm (SO4);
- To improve the emotion recognition algorithm (SO5);
- To improve human-robot interaction (SO6).

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 adults who are facing permanently or temporarily reduced functionality and capabilities (TO1);
- To validate the capability of the SHAPES Platform and Digital Solutions to improve older adults' health outcomes and quality of life (TO2);
- To validate the capability of the SHAPES Platform and Digital Solutions to gain the older adults' trust and acceptance (TO3);

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- To validate the capability of the SHAPES Platform and Digital Solutions to gain the care professionals' trust and acceptance (TO4).

Methodology

Methods: Recruitment of older adults and caregivers

Older adults screening procedure:

- **Screening:** the care team of La Porcíncula screened their user list for potentially eligible participants;
- **Invitation:** the first communication about the pilot was directly from the care team of La Porcíncula to the potential participants;
- **Information sheets:** information sheets (paper-based) were provided to potentially eligible participants that showed interest. 24 hours were provided to allow time to consider the information before consent was obtained;
- **Eligibility confirmation:** eligibility was confirmed by the principal investigator at CH.

Methods: Informed consent (all types of participants)

The SHAPES project manager obtained informed consent in a handwritten format.

In addition to full name, explicit and optional acceptance of being recorded (video) and getting emotions analysed were collected in consent.

The SHAPES project manager at the pilot site countersigned the informed consent, and a copy was delivered to participants as an acknowledgment of reception.

Methods: procedures and data collection

Before baseline procedures (all types of participants):

With the procedure described in the 'Recruitment sections' above, full name and eligibility criteria checks were collected for eligibility confirmation and informed consent.

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Baseline procedures:

- **Older adults:** some data were collected in face-to-face, one-to-one interviews and other through forms to fill individually in the presence of a researcher to resolve doubts;
- **Questionnaires:** WHOQOL-BREF[15], EQ-5D-5L [5], GSES [9], OSSS-3 [3], SHAPES participation questions; Scale of Positive and Negative Experience (SPANE) [22]. (SO3, TO1, TO2);
- **Demographic data:** 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 family (never/rarely/sometimes/often); professional help (never/rarely/sometimes/often), neighborhood environment (urban/rural); residence type (own home/caregiver's home/long-term care facility/other); co living with someone (yes/no); country. SHAPES health literature measure.

At the baseline interview, a training session took place to use the robot. In addition, manuals and supporting material in paper format were provided to participants.

- **Health professionals:** training session at baseline for the use of the dashboards. No data has been collected. However, manuals and supporting material in paper format were provided.

Study procedures

- **Older adults:** will use the robot as they wish. The robot will collect data regarding used functionalities and modes if interaction, along with timestamps and length of each interaction;
- **Formal caregivers:** will define at any time for assigned older adults: 1) type of activities;
- **All participants:** the first week of the pilot will be considered a run-in period. Participants will be contacted after the run-in period to resolve doubts and concerns. Participants will be encouraged to contact the project management

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team for any technical issues or doubts about using the novel system. In addition, participants will be contacted monthly to resolve technical doubts and concerns.

End of pilot interview:

This data was collected within the 14 days after the end of the pilot in face-to-face, one-to-one interviews and through forms to fill individually with the presence of a researcher for resolving doubts.

- **Questionnaires:** Technology Acceptance Model (TAM) [8]; Short version of User Experience Questionnaire (UEQ-S) [23]; System Usability Scale (SUS) [6] [7]; SHAPES participation questions and those carried out at baseline. In addition, there will be a non-structured interview;
- **Medical and non-medical cost data:** questions to perform a cost-benefit analysis.

Follow-up study visits and procedures:

These data will be collected at a three months follow-up (+/- seven days) in face-to-face, one-to-one interviews and through forms to fill individually with the presence of a researcher for resolving doubts.

- **Questionnaires:** These carried out at baseline.

Data collection tools

Automatic data collected by the robot is stored in an internal hard disk in as rosbag data (http://wiki.ros.org/rosbag), a file format in ROS (Robotics Operating System) for storing ROS message data such as camera streams and robot logs.

Data for authentication has been stored in the SHAPES platform (ASAPA).

Data collection for the interview participants and filling forms were documented on a case report form (CRF). In addition, paper questionnaires form part of the CRF, and the CRF was the source for questionnaires.

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All data has been transcribed onto an electronic database using Excel or LibreOffice Calc and analysed using Excel or LibreOffice Calc.

3.9.1 Recruitment

CH

The recruitment process started by contacting the care team at the retirement home La Porcíncula. CH research team communicated the eligibility criteria and went over the resident's profile to select potential participants. Then, potential participants were approached and those eligible based on the inclusion criteria and willing to participate were recruited. As a result, four older adults were recruited among a pool of 11 participants, of whom seven didn't feel like interacting with ARI robot. Moreover, one formal caregiver was also recruited, comprising five participants.

AIAS

The study involved a convenience sample of 11 older adults living in a residential facility in Bologna. The participants were selected among a pool of 17 participants, of whom six did not want to participate because they did not want to interact with the robot (n = 5) or considered the cognitive training unuseful (n = 1). To be included in the study, participants had to (a) live in the residential facility; (b) be able to understand and sign the consent form by themself; and (c) have never had used/interacted with a SAR before.

AUTH

Participants' recruitment has been actualized within the network of the Living Lab Thess-AHALL ecosystem: 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 identifying, approaching and selecting participants who are eligible for the study based on the inclusion criteria. The AUTH research team screened potentially eligible participants and recruited those eligible

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

3.9.2 Eligibility criteria

Inclusion criteria:

- Older adults 60+ with or without neurodegenerative diseases, mild cognitive impairment and mild dementia, chronic and mental disorders;
- The time commitment to the training protocol;
- Good hearing and sight;
- No signs of any significant mobility difficulties;
- Self-reported consent capacity.

Exclusion criteria

- Diagnosis of severe neurological or psychiatric disorders;
- Drug abuse;
- Concurrent participation in another study.

3.9.3 Roles and responsibilities

CH

The CH research team is responsible for recruiting, including collecting consent from participants. Moreover, it is responsible for collecting questionnaires from participants at baseline and at the end of the phase to analyse the result of the piloting activities and train participants on how to use the robot ARI. The SHAPES project manager is responsible for setting up the robot at La Porcíncula (transportation, WiFi network connection, etc.) and is the contact person of the pilot site to communicate any issues or to solve questions. PAL technical team is responsible for addressing major technical

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issues that difficult the completion of the piloting activities. Finally, CH research team is responsible for analysing the data, getting conclusions and writing up the study results.

AIAS

The AIAS research team is responsible for recruiting participants, including collecting of consent and questionnaires. Moreover, it is responsible for the training of participants and supporting and controlling the robot ARI during the session, as AIAS conducted Phase 5 in a more controlled environment with the presence of the researcher at all times. Finally, after piloting activities, the research team is responsible for analysing and reporting results.

AUTH

The AUTH research team working on the SHAPES project is responsible for recruiting and collecting participants' consent to participate in the pilot activities. In addition, the AUTH team provides training on interacting with the ARI robot and is the single point of contact for the participants. Technical support is 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 ARI robot. Consulting guidance is focused on the older adults' interaction with digital solutions and their overall experience, aiming to gain the best possible social benefit and maintain friendly and supportive communication.

3.9.4 Ethical considerations

The study protocol for the PT4-002 Phase 5 was approved by the Ethics Committee of the Balearic Islands (Process number IB4885/22 PI). In addition, an ethical self-assessment for Phases 1–5 of this use case was completed, including a Data Protection Impact Assessment (DPIA). This document forms the assessment of whether the processing of personal data is on the right level from a GDPR point of view, and it also describes the potential corrective actions to be taken if needed. By this DPIA the pilots could also assess that they implemented all ethical privacy and

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data protection requirements set in SHAPES D8.4. Moreover, individual Data Processing Agreements were signed with each of the technical partners before the start of the recruitment of participants.

Regarding the data procession inside the robot ARI, the main purpose is to know how often the robot is used anonymously, to make sure it is working properly and evaluate its general usage but will not be linked to the user in question. The complete anonymized dataset which will be analyzed later is sent to the Data Lake. For Phase 5, participants were provided an information sheet specifying the procedures involved and the nature of the research, including the processing of personal data as part of the research and on the SHAPES platform. Written consent from each participant was obtained before phase 5.

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.

Under the guidance of CH, as the Use Case leader, AIAS and AUTH proceed with the required ethical considerations. They reviewed and contributed to developing the Data Protection Impact Assessment (DPIA), Data Processing Agreement (DPA) and Data Sharing Agreement (DSA) and adapted the Ethics Protocol to be approved by their local Ethics Committee.

In the case of AUTH, 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 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) will be retained by approved AUTH staff working on the SHAPES study and stored

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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.

In the case of AIAS, 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 at the AIAS Bologna onlus - WeCareMore Research and Innovation Center (Bologna, Italy). In addition, an electronic copy of the documents along with the participants list (linking the participants' names to their pseudonymised SHAPES ID) will be retained by approved AIAS staff working on the SHAPES study and stored securely on AIAS servers protected by the AIAS firewall. Only AIAS staff authorised to work on the SHAPES project will have access to identifiable pseudonymized documents.

Appropriate agreements will be in place to facilitate the processing of pseudonymised data by other SHAPES partners explicitly described in DPA and DSA documents.

3.9.5 Preparation of pilot replication

Table 52 details the procedures conducted to prepare the replication and respective dates, within the PT4-002 use case.

Table 52. List of actions conducted to prepare for the replication of UC-PT4-002.

Actions	Dates
First PT4-002 meeting to present the Use Case and the replication plan.	23/04/2020
Monthly meetings to discuss the progress of the Use Case and its replication by AUTH and AIAS.	From September 2020
CH shared Data Plan, Data Flow, Risk Assessment, Personal Data Processing, DPIA, SHAPES Data Processing Agreement, SHAPES Data Sharing Agreement with replicating sites for its review and contributions.	03/03/2022
ARI arrives at AUTH and AIAS premises, respectively.	13/05/2022
Specific meeting with replicating sites "SHAPES PT4-002 Adaptation Replicating sites - Chatbot & General questions".	01/06/2022
Translation of story tales into Greek and Italian and adaptation.	02/06/2022
KPI's review between the pilot leader and replicating sites.	08/06/2022
Technical meeting with replicating sites and technical leader to solve technical issues.	14/07/2022

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CH sent a document with the dialogue flow and screen structure in English for translation into Greek and Italian and chatbot development instructions.	01/09/2022
PT4-002 meeting in Thessaloniki during the SHAPES plenary meeting for procedures and doubts clarification.	14/09/2022
AIAS starts Phase 5 piloting activities.	25/11/2022
ARI Technical review meeting between PAL, AUTH and CH to discuss technical issues.	08/02/2023
The technical meeting between PAL and AUTH technical team to address technical issues.	10/02/2023
Final meeting to discuss the submission of Deliverable 6.5.	04/05/2023

3.9.6 Outcome of large-scale pilot activity

Several instruments were used at this phase. At the Baseline the instruments used were the World Health Organization Quality of Life – BREF (WHOQOL-BREF) [15], the EuroQol 5 Dimensions 5 Levels (EQ-5D-5L) [5], the General Self-Efficacy (GSE) [9], the Oslo Social Support Scale (OSSS-3) [3], the Single-item Health Literacy Measure [16], Sociodemographic questions, the Loneliness Scale (UCLA) [18] and the Scale of Positive and Negative Experience (SPANE)[22]. At the end of the pilot all these questionnaires were repeated to evaluate the impact created by using the technology. Moreover, some other instruments were used to evaluate the overall experience of users; the System Usability Scale (SUS) [6], the Technology Acceptance Model (TAM) [8], the User Experience Questionnaire – Short Version (UEQ-S) [23], the SHAPES participation questions and some general questions on the perceived impact.

Concerning the primary objectives:

- **O1. Older adult:** Start/end timestamp of interaction (session), including end of robot's action if it is automatic (user abandons interaction). *Health professional*: timestamp of logins to marketplace (PO1);
- **O2. Older adult:** Selected activities in a session. *Health professional*: number of uploads per logged session (PO1);
- **O3.** Duration of each activity (PO1);
- **O4.** The final status of activity (finished, quitted, abandoned) (PO1);

- **O5.** The mode of interaction in activity is the device (front screen, tablet, printing) (PO1);
- **O6.** Mode of interaction inactivity, means and number of actions of each (touch, voice, both) (PO1);
- **O7.** Mode of execution inactivity (robot, paper-printed out) (PO1);
- **O8.** Technology Acceptance Model (TAM) questionnaire [8] (PO2, SO1, TO3, TO4);
- **O9.** The short version of User Experience Questionnaire (UEQ-S)[23] (PO2, SO1, TO3, TO4);
- **O10.** Notes were taken at an unstructured interview at the end of the period of use of the novel system (PO1, PO2).

Concerning the secondary and tertiary objectives:

- **O11.** SUS [6] (SO1, TO3, TO4);
- **O12.** Emotions are recognised inactivity (SO2, if explicitly accepted by older person participant);
- **O13.** The following questionnaires: WHOQOL-BREF[15], EQ-5D-5L [5], GSES [9], OSSS-3 [3], SHAPES participation questions; SPANE [22] (SO3, TO1, TO2);
- **O14.** General Attitudes Towards Robots Scale (GAToRS) [24] - only used by AIAS;
- **O15.** Video at emotion recognition (SO5, optional, if explicitly accepted by the participant);
- **O16.** Videos of human-robot interaction (SO6, optional, if explicitly accepted by the participant).

For technical reasons:

- **O17.** Id of the session;
- **O18.** Acceptance of being analysed by emotion recognition (older person) and being recorded in the video to improve algorithms;
- **O19.** Descriptors for emotion recognition;
- **O20.** Log in.

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

- **O20.** 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 family (never/rarely/sometimes/often); professional help (never/rarely/sometimes/often), neighborhood environment (urban/rural); residence type (own home/caregiver's home/long-term care facility/other); co-living with someone (yes/no); country;
- **O21.** SHAPES Health Literature Measure.

3.9.7 Results of the Large-Scale Pilot Activity

The large-scale pilot in CH lasted two weeks and was conducted between the 21st of April 2023 and the 5th of May 2023 with a total of five participants.

The large-scale pilot in AIAS lasted four weeks and was conducted between the 25th of November 2022 and the 23rd of December 2022 with a total of 11 participants.

AUTH didn't perform the large-scale pilot. The reasons are explained hereafter.

Adherence Rates

Adherence rates reveal the recruitment difficulties experienced during the conduction of the study and are presented in Table 53 and Table 54.

Table 53. CH Adherence rates for phase 5.

Adherence rate	Calculation method	CH
Inclusion rate	The ratio between the number of participants included in the study (5) and the total number of people contacted (13).	38.46%
Refusal rate	The ratio between the number of subjects who refused to participate in the study (6) and the number of subjects contacted (11).	54.54%

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Exclusion rate	The ratio between the number of individuals excluded for not meeting the inclusion criteria (2) and the total number of individuals contacted (13).	15.38%
Dropout rate	The ratio between the number of participants who dropped out of the study (0) and the number of participants who completed the baseline assessment (5).	0%
Retention rate	The ratio between the number of participants who completed the final assessment (5) and the number of participants who completed the initial assessment (5).	100%

Table 54. AIAS Adherence rates for phase 5.

Adherence rate	Calculation method	AIAS
Inclusion rate	The ratio between the number of participants included in the study (11) and the total number of people contacted (17).	64.7%
Refusal rate	The ratio between the number of subjects who refused to participate in the study (6) and the number of subjects contacted (17).	35.3%
Exclusion rate	The ratio between the number of individuals excluded for not meeting the inclusion criteria (0) and the total number of individuals contacted (17).	0%
Dropout rate	The ratio between the number of participants who dropped out of the study (0) and the number of participants who completed the baseline assessment (11).	0%
Retention rate	The ratio between the number of participants who completed the final assessment (11) and the number of participants who completed the initial evaluation (11).	100%

Demographics of participants entering the pilot

In CH, four older adults participated the study, with a mean (±sd) age of 84.5 ±5.8 years old, of whom 100% were males and 0% were females. In this case, we could not comply with gender equality in the CH study because the chosen retirement home is only for men.

In AIAS, 11 older adults participated in the study, with mean age of 75 years old, of whom four were males and seven females.

Table 55 presents the demographics data for the PT4-002 participants in CH and AIAS.

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Table 55. Demographics data for the participants (older adults) in phase 5.

Demographics	CH (*N*=4)	AIAS (*N*=11)
Age (years) mean(sd)	84.5 (±5.8)	75
Gender (female)	0	7
Health Literacy (How confident are you in filling out medical forms yourself?)	Extremely 25% (*N*=1) Quite a bit 25% (*N*=1) Somewhat 25% (*N*=0) A little bit 25% (*N*=1) Not confident 25% (N=1)	-

Clínica Humana results (Use Case leader)

The piloting activities were developed in a real-world environment. ARI was placed in a common room at La Porcíncula retirement home and participants could use ARI freely. The health professional would encourage participants to use ARI but, in the end, they would decide to use or not use the digital solution.

The intervention included the following cognitive activities (a) memory ("memorize the words" and "find pairs"), (b) dynamic tales ("the surprise party" and "proud of grandchildren"), (c) language ("synonyms and anonyms" and "possible reasons"), (d) logic ("find the words" and "complete the sentences") and (e) attention ("copy correctly" and "fix the errors"). Moreover, participants could also check their temperature thanks to an integrated thermal camera.

The robot was left at the retirement home over a period of two weeks and participants were asked to interact with the robot freely with the guidance of the formal caregiver participating in the study. At the end of the pilot, participants reported their levels of enjoyment of the activities using a 0-10-Point Likert scale (higher scores imply higher enjoyment). Moreover, one-to-one interviews with participants were conducted at the end of Phase 5 to explore their overall experiences and collect feedback.

Table 56 shows the overall use of the Digital Solution per participant (older adults). It details the number of days each participant used the robot ARI, the tablet and printed any of the activities and the number of sessions with ARI, with the tablet and printed activities. In the last columns, total days and total sessions are specified and a general comment from each participant.

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Table 56. Overall use of the DS and type of interaction

Participant	days (n) ARI	sessions (n) ARI	days (n) tablet	sessions (n) tablet	days (n) print	sessions (n) print	TOTAL DAYS	TOTAL SESSIONS	Comment
P1	4	5	2	2	0	0	6	7	I like the robot but it is uncomfortable to play in a stand-up position. I have also used the tablet and I have played games through my computer.
P2	2	3	2	3	0	0	4	6	I like the robot ARI because I think it is a good entertainment for me. I really like the story tales.
P3	1	1	2	2	1	1	3	4	I found it difficult to play through the robot because it is hard for me to stand for long periods. I really like the story tales. I have used the tablet and printed games.
P4	1	1	0	0	1	1	1	2	I like the robot but I didn't have much time to interact. I would probably use it in the future if it would be available. I like it because it helped me to acquire knowledge about new technologies.
TOTAL	**8**	**10**	**6**	**7**	**2**	**2**	**14**	**19**	

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Table 57 shows the type of activities performed by participants.

Table 57. Data about type of activities performed.

Sessions (n)	Type of activity					
	Temperature checking	Cognitive exercises = 26				
		Memory	Tales	Language	Logic	Attention
19	11	5 (19.2%)	9 (34.6%)	5 (19.2%)	5 (19.2%)	2 (7.7%)

After the piloting activities, participants reported enjoyment with an average of 7.25 (out of 10) (*SD* = 0.96) representing a positive interest for the robot ARI and the actions performed.

Regarding usability, the TAM questions yielded an average score of 13.25 ±2.06 out of a maximum of 21, while the SUS had a score of 55 ±9.13 out of a maximum of 100. These results indicate a good level of acceptance but a low self-reported usability if we compare it with benchmark results. Analysing the results of the SUS we see that 3 out of 4 participants thought that the DS, the robot ARI was "cumbersome (awkward) to use". This might be due to the low level of familiarisation of participants with humanoid robots, as for all of them it was the first time to interact with this kind of technology. The results are shown in Table 58 and Table 59.

Table 58. Trust, acceptance and self-perceived usability of Phase 5 participants (older adults).

Participant	TAM (21)	SUS (100)
P1	11	50
P2	13	60
P3	16	65
P4	13	45
TOTAL (mean / sd)	13.25 (2.06)	55 (9.13)

Table 59. UEQ-S for Phase 5 participants (older adults) in relation to existing values from a benchmark data set.

Scale	Mean	Comparisson to benchmark	Interpretation
Pragmatic Quality	1,19	Above average	25% of results better, 50% of results worse
Hedonic Quality	2,13	Excellent	In the range of the 10% best results
Overall	1,66	Excellent	In the range of the 10% best results

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As shown in Figure 28, the participants' experience interacting with the robot ARI has been "Excellent" compared to the existing values from benchmark data, which means that the results are in the range of the 10% best results. Therefore, even if participants rate the DS below average in terms of usability (SUS), the user experience is rated as excellent (UEQ-S).

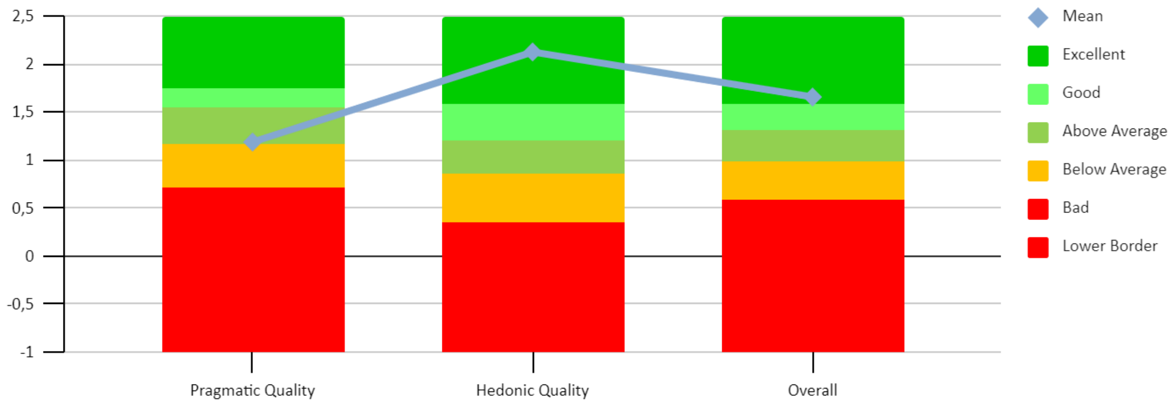

Figure 28. SUS results for Phase 5.

Positive and Negative Experience (SPANE)

Every participant (older adult) answered The Scale of Positive and Negative Experience (SPANE) at the baseline and at the end of the pilot. SPANE is a brief 12-item scale asking respondents to rate how often they experience various states. The scale can serve as useful feedback for clients who undergo an intervention to increase their positive feelings. The results are shown in Table 60.

Table 60. SPANE results for the participants. Comparison between baseline (BL) and end of pilot (EP).

SPANE (1 to 5)	P1		P2		P3		P4		TOTAL		Difference
	BL	EP	BL	EP	BL	EP	BL	EP	BL mean(sd)	EP mean(sd)	
Positive	4	5	4	4	5	5	4	4	4.25 (0.5)	4.5 (0.6)	**5.6%**
Negative	1	1	2	2	1	1	3	3	1.75 (1)	1.75 (1)	0%

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Good	4	4	5	5	4	4	4	4	4.25 (0.5)	4.25 (0.5)	0%
Bad	1	1	1	1	1	1	1	1	1 (0)	1 (0)	0%
Pleasant	4	4	5	5	5	5	4	4	4.5 (0.6)	4.5 (0.6)	0%
Unpleasant	1	1	1	1	1	1	1	1	1 (0)	1 (0)	0%
Happy	4	4	3	4	5	5	5	5	4.25 (1)	4.5 (0.6)	**5.6%**
Sad	1	1	1	1	1	1	1	1	1 (0)	1 (0)	0%
Afraid	1	1	1	1	2	2	4	4	2 (1.4)	2 (1.4)	0%
Joyful	4	5	3	4	5	5	5	5	4.25 (1)	4.75 (0.5)	**10.5%**
Angry	1	1	1	1	2	1	1	1	1.25 (0.5)	1 (0)	**-25%**
Content	5	5	4	4	5	5	4	4	4.5 (0.6)	4.5 (0.6)	0%

Comparing the results of the SPANE at the baseline and at the end of the pilot we appreciate a slight increase of the following feelings: "positive", happy" and "joyful". Moreover, we results reflect a decrease of the feeling "angry". Even if the differences are not very significant, it seems that the use of ARI improves some of the positive feelings and decreases some of the negative feelings.

Quality of Life, Social Support, Cognitive and Physical Function

Detailed data on the quality of life, social support and cognitive at baseline and end of pilot is presented in Table 61. Three months follow up data has not been collected yet and will be presented in the coming deliverables.

Table 61. Characteristics of the older adults' participants that completed phase 5 at CH (results presented as mean (sd)).

Quality of life and social support questionnaires (*N*=4)			
	Baseline	**End of pilot**	**3 months**
Quality of life and social support			
WHOQOL-Bref (0-100) [4]	72.1 (9.63)	73.44 (9.64)	NA
Health related quality of life - EQ-5D-5L (5-25) [5]	7.75 (2.22)	7.75 (2.22)	NA
Self-efficacy GSE [9](10-40)	26.75 (8.34)	27.25 (8.26)	NA
Social Function OSSS-3 [3](3-14)	13 (0)	13 (0)	NA
Gijón's social-familial scale[25] (5-25)	14 (2.45)	14 (2.45)	NA
Loneliness (UCLA-6) [18](6-24)	9.75 (1.26)	9.25 (0.96)	NA

The individual data for the older adults that used the robot ARI are presented in Table 62. Considering the UCLA-6 [18] test, the total score slightly decreased from the baseline to the end of the pilot. This means that the overall sense of loneliness decreased after the use of the robot ARI.

Table 62. Quality of live and social data for participants (older adults) in phase 5 at CH.

	WHOQOL-Bref (0-100)		EQ - 5D – 5L (5-25)		Self-efficacy GSE (10-40)		Social Function OSSS-3 (3-14)		Gijón's social-familial scale (5-25)		Loneliness (UCLA-6) (6-24)	
	BL	EP	BL	EP	BL	EP	BL	EP	BL	EP	BL	EP
P1	72.02	72.74	7	7	37	37	13	13	17	17	10	10
P2	63.84	65.39	9	9	19	19	13	13	14	14	11	10
P3	66.9	68.45	10	10	21	22	13	13	14	14	10	9
P4	85.63	87.17	5	5	30	31	13	13	11	11	8	8
TOTAL	**72.1**	**73.44**	**7.75**	**7.75**	**26.75**	**27.25**	**13**	**13**	**14**	**14**	**9.75**	**9.25**

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

SHAPES Participation Questions

Table 63 shows the answers to the SHAPES Participation questions.

Table 63. SHAPES Participation questions' results of participants (older adults) in phase 5 at CH.

Participants	I participate enough in activities that are important to me	Using the robot ARI makes participating in the activities that are important to me
P1	Strongly Agree	A little easier
P2	Agree	A little easier
P3	Strongly Agree	A little easier
P4	Neither Agree nor Disagree	About the same
RESULTS	**50% Strongly Agree 25% Agree 25% Neither Agree nor Disagree**	**75% A little easier 25% About the same**

75% of participants think that using the robot ARI makes a little easier participating in activities that are important to them.

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Questions on the perceived impact

Table 64 shows the perceived impact of participants using the DS.

Table 64. Overall perceived impact of participants (older adults) in phase 5 at CH.

How has the use of the DS impacted your everyday life?							
	Health-literacy	Self-management of health condition	Support for active and healthy ageing	Improving quality of life	Supporting extended living at home	No impact	Other
P1			x				
P2			x				
P3			x				
P4			x				x Entertainment
TOTAL	0%	0%	100%	0%	0%	0%	25%

Even if the results of the SUS were lower than benchmark results, we can see that all participants reported a perceived impact of the DS as a support for an active and healthy aging.

Table 65 and Table 66 show the willingness to pay of participants to use the DS and their opinions about who should pay for it.

Table 65. Willingness to pay of participants (older adults) in phase 5 at CH.

Health cost data If this innovation was available to use in the future, how much would you be willing to pay for it per month?							
	< 5€	5-10€	11-20€	21-50€	51-100€	> 100€	I would not be willing to pay for it
P1							x
P2							x
P3							x
P4	x						
TOTAL	25%	0%	0%	0%	0%	0%	75%

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Table 66. Financing of the DS.

Who should pay for the DS?					
	Individual end-user	Health insurance (private)	Health insurance (public)	Government-funded	Other:
P1				x	
P2				x	
P3				x	
P4				x	
TOTAL	0%	0%	0%	100%	0%

Just one of the participants would be willing to pay for the DS. This might be since the totality of participants believe that this technology should be funded by the government.

Interviews results

A summary of participants' experiences and the overall feedback gained at the end of Phase 5, resulting from the final interviews is presented in Table 67 (older adults) and Table 68 (formal caregivers). Experiences and information discussed among participants are categorized in five discrete axes: (i) Technology adoption and barriers, (ii) User experience and ease of use, (iii) Communication and social connections, (iv) Health and well-being and (v) Recommendations for improvement.

Table 67. Results from final interviews to phase 5 participants (older adults) at CH.

Thematic	Quotations
Technology Adoption and Barriers	P1: "I like it but it is something very innovative and I would need more time to adapt myself." P2: "Interacting with ARI has been challenging due to my difficulty standing up for long periods." P3: "ARI doesn't bend and it doesn't have an option for users to sit down." P4: "I would need more time to adapt to this technology".
User Experience and Ease of Use	P1: "My experience using the technology has been positive." P2: "My experience and the experience from my carers has been good." P3: "I really like the shape and general aesthetics of ARI and the applications." P4: "I am very curious and amazed about this technology but I think I am not prepared for it; it is too innovative".

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Communication and Social Connections	P1/P3: "I like the idea that these kinds of technologies can help us to be more connected to our relatives and friends."
Health and Well-being	P1: "I think that the long-term use of the robot ARI could be a huge support for entertainment activities." P2: "The use of the robot ARI had a positive impact in my behavior towards health." P3: "I perceive this technology as a support for entertainment." P4: "I think this technology provides support to acquire knowledge about new technologies and robotics, however, I didn't perceive a specific impact for me.
Recommendations for Improvement	P1/P4: "I would need time to adapt to the use of this technology." P2/P3: "I would recommend to have the option of sitting while interacting with ARI, as some people have mobility problems like myself."

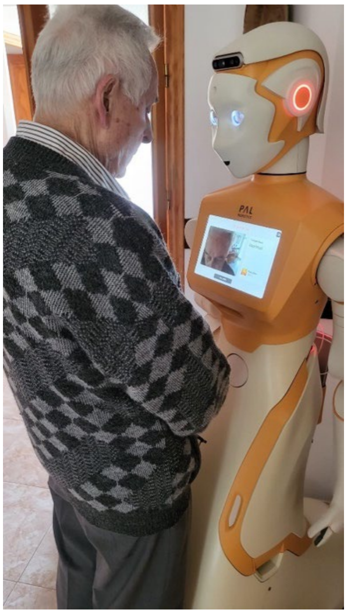

Figure 29. Older adult playing a DiAnoia game with ARI's tablet during phase 5 at CH.

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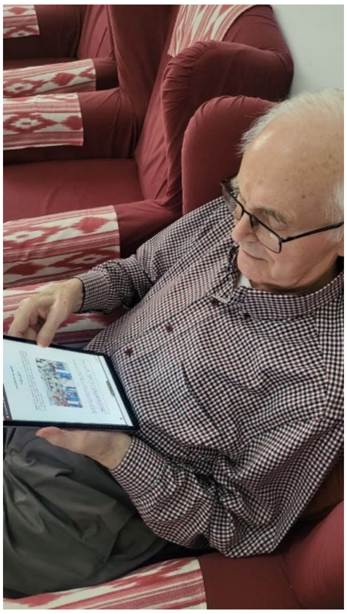

Figure 30. Older adult playing a DiAnoia game with ARI's tablet during phase 5 at CH.

Table 68. Results from final interviews to phase 5 participant (formal caregiver) at CH.

Thematic	Quotations
Technology Adoption and Barriers	"I have noticed a certain curiosity on some older adults to know what it was, and what it did. However, there was also a lack of interest in some of them, understanding its functionality as something impossible for them, "too much technology". Those that I have managed to attract to it (ARI) have understood that it does not have any complexity in its operation." "As a comment, I have noticed, that he generated distrust and little security to handle it alone (robot), for fear of not knowing what to do, or of damaging it, for which reason they only dared to touch it when I was present. If I left for 1 minute, they already lost the thread of the activity and many left. I imagine that as time goes by, and seeing it more as a tool, this will pass, and they will be encouraged to be alone in front of it."
User Experience and Ease of Use	"As for its use, if I have found difficulties, for example, standing up to use it." "Regarding the applications used, we have played memor-i, trying to remember where each image was, and some tales. Not much, because of what I was telling you about staying upright." "We have looked at the temperature, they found it curious to see themselves on the screen, although they did want to

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	know the exact result and not just “normal” or “high” temperature.” “We've used the function “alerts” and we have sent out some, so older adults know that this tool is available to them. However, this functionality is not really usefull for us, as there is always a caregiver with them.” “We have used the tablet to read stories and investigate the activities.”
Communication and Social Connections	“The development of ARI will achieve the inclusion of older adults and improve their quality of life.”
Health and Well-being	“I think it is a very important and necessary project to bring technology to older adults, and above all, provide them with care support in their daily activities.”
Recommendations for Improvement	“Perhaps if the same thing was on the tablet, or if it could be used sitting down, the experience would have improved.”
Overall satisfaction	“Personally it has been very entertaining, having this tool for the day to day of the users.”

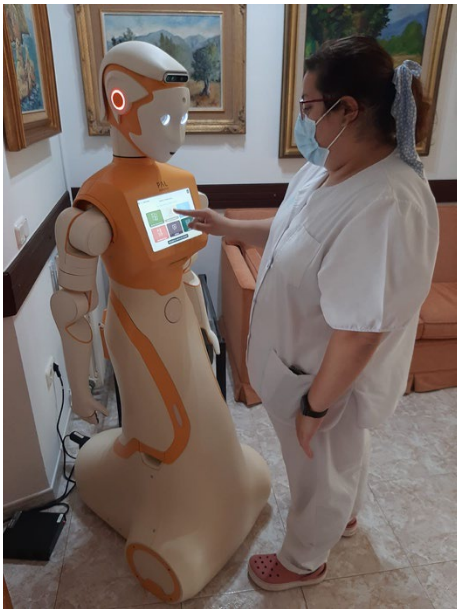

Figure 31. Formal caregiver interacting with ARI robot during phase 5 at CH.

The formal caregiver participating in the piloting activities rated the DS with a SUS score of 85, which shows a high perceived usability.

AIAS results (Replicating Site)

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A deviation from the agreed SHAPES protocol was considered necessary to document the results of the present replicating pilot. Specifically, the measurements used to document the effects of AIAS's replicating pilot differed from those proposed by SHAPES (i.e., WHOQOL [15], EQ5D5L [5], GSE [9], OSSS3 [3], UCLA 6 [18]., and SPANE[22]) based on the following considerations:

- Due to early-stage cognitive impairments combined with other disabilities, the involved participants presented with an average level of limitations and restrictions in activities and participation as assessed by the WHODAS II (scoring: 0% = no limitations; 100% = severe limitations) of 46,2% (range: 31,25%-58,33). Such limitations would have made it difficult for the respondents to provide reliable answers to the proposed SHAPES measurements;
- Also, according to formal caregivers, the measurements proposed would have been (i) poorly understandable and (ii) too long and burdensome for the participants, with the consequence of increasing the risk of their immediate drop-out from the pilot.

In light of such considerations, AIAS proposed an alternative measurements protocol that could be both cognitively accessible for end users and easy to implement.

The piloting activities were developed in a semi-controlled environment (Figure 31). All the activities were delivered with the support of a researcher through the robot ARI, which a human operator controlled during the training sessions developed at WeCareMore Research and Innovation Center premises.

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Figure 32. Phase 5 piloting activities at AIAS.

AIAS pilot included three main phases. A baseline phase during which participants could meet ARI and interact with it. At the end of this introductory meeting, participants were requested to sign the informed consent in case they agreed to participate in the intervention. In this first phase, those who signed the informed consent questionnaire were administered to collect socio-demographic information. The second phase included the cognitive rehabilitation intervention which included the following cognitive activities (a) memory, (b) dynamic tales, (c) language, (d) logic and (e) attention (Table 69). Moreover, other additional activities were offered such as riddles or the possibility to ask the robot some curiosity about itself.

In total, 22 activities were performed within four cognitive training sessions over a period of four weeks. Each session lasted about 45 minutes.

Table 69. Robot ARI usage data for phase 5 participants at AIAS.

Activities (n)	Type of activity				
	Cognitive exercises				
	Memory	Tales	Language	Logic	Attention
Not completed	2	0	1	2	4
Completed	1	2	6	3	1
% of completion	33%	100%	86%	60%	20%
22	**3**	**2**	**7**	**5**	**5**

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At the end of each session, participants self-reported their enjoyment of the activities using a 0-10-Point Likert scale (higher scores imply higher enjoyment). Then, two follow-up focus groups with the participants in the cognitive training activities (n = 6) and their formal caregivers (n= 4) were conducted to explore their overall experiences and collect feedback.

Two questionnaires were further administered: The General Attitudes Towards Robots Scale (GAToRS)[24] and the TAM questionnaire [8].

The General Attitudes Towards Robots Scale (GAToRS) was used to assess the overall attitudes of older adults towards robots. The GAToRS includes 20 items and assesses four distinct factors (i.e., subscales): a) comfort and enjoyment around robots, b) unease and anxiety around robots, c) reasonable hopes about robots in general and d) reasonable worries about robots in general. All items were presented as statements and participants were asked to answer based on how much they agreed with each statement. All items were anchored from 1 (“completely disagree”) to 7 (“completely agree”). The subscale scores were calculated by averaging the scores of the items in the subscale. In addition, the Technology Acceptance Model (TAM) questionnaire (Perceived Usefulness subscale) was used to quantify the informal caregivers’ perceived usefulness of the interventions. It included 5 items (i.e., statements). Scores ranged from 1 (“strongly disagree”) to 5 (“strongly agree”), with higher scores indicating higher perceived usefulness.

Across the sessions, participants' self-reported enjoyment ranged from an average of 6 (SD = 3,7) of the first session to 10 (SD = 0) in the last session, documenting a stable increase in the interest in participating in SAR-based activities. The GAToRS showed an overall participants’ positive attitude towards the robots, with high scores in the “comfort and enjoyment around the robots” subscale (M = 5,05), and “reasonable hopes about robots in general” subscale (M = 5,2). The GAToRS also highlighted very low scores in the “unease and anxiety around robots” subscale (M = 1,6). Still, they showed somewhat high scores in the “reasonable worries about robots in general” subscale (M = 4,5). Overall, the results from the post-intervention questionnaire suggest an overall positive users experience with the SAR-based cognitive training activities, which is also reflected in a positive attitude towards the use of SAR in general. Participants, however, reported some worries which were further explored in

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more detail in the focus group. While formal caregivers were all positive towards the impact of SAR on the proposed training activities, half of the older adults were more sceptical. In detail, while the older adults seemed to have enjoyed the activities, they complained about the lack of intelligence (i.e., autonomy) of the robot as well as its limited behavioral repertoire. Nevertheless, both formal caregivers and older adults enjoyed the activity "create a story with the robot" which should be considered for a possible refinement of the proposed intervention.

As a general conclusion for the piloting activities developed by AIAS in a semi-controlled environment, we could say that the SAR-based cognitive training intervention conducted was accepted by all stakeholders. Data on the enjoyment of participants suggest that they did not experience a "novelty effect" of the proposed innovation, but longer sessions are needed to confirm this result. The request to have a more "intelligent" and flexible robot, in our opinion, should be considered a positive result, in that it may imply the willingness of participants to keep interacting with an artificial agent over more extended periods of time.

AUTH results

Large-scale pilot activities were planned to be conducted in the Thessaloniki Action for HeAlth & Wellbeing Living Lab – Thess-AHALL Living Lab that operated 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 the co-creation and co-design of technological solutions to improve health and social conditions and facilitate independent living. Staffed by an interdisciplinary team and reseacrhers (psychologists, technologists, physicians etc.) the Thess-AHALL envisages facilitating 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.

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Planned pilot activities were to be conducted in the e-home infrastructure that consists of a room that resembles an actual house kitchen and living room. The room is equipped with home appliances and furniture so as to better reach an older adult's home. Monitoring devices are also installed (e.g., 3D depth sensor camera, fisheye camera). The ARI robot was delivered by technical partners and set by the AUTH team for Phase 5.

Four older adults were recruited to participate in Phase 5. However, due to unforeseen technical issues and logistical challenges, AUTH could not carry out the pilots in the planned time framework. In particular, during the final testing of the robot AUTH was confronted with performance issues and hardware failure with the voice interaction and chatbot operation of the ARI robot. Therefore, despite the continuous collaboration with technical partners and the essential guidance received from the Use Case leader necessary amendments and further testing both with the hardware and software of the ARI robot needed to be performed and made it impossible to carry out the planned activities within this pilot timeframe. However, AUTH still plans to replicate this use care and will report the results on the Annex of D6.9.

The AUTH team aims to identify and address any potential technical issues before carrying out the pilot activities and have contingency plans in place in case other unexpected problems arise during the pilots. This will help to minimize any other adverse delays and ensure the pilot activities will be carried out successfully.

Adverse events

No adverse events were reported.

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 70 lists the KPIs planned and critically analyses its fulfilment.

In this pilot, seven out of eight KPIs were achieved. CH did not achieve recruitment target and the use case could not be replicated in time by AUTH as planned, so recruitment KPI was not achieved by CH and AUTH, but it was achieved by AIAS, the other replicating site.

The reason why CH did not recruit the target sample is because there were a small number of total residents at the pilot site (La Porcíncula), some of the residents didn't comply with the eligibility criteria and others were not willing to participate due to lack of interest in new technologies and robotics.

Table 70. KPIs planned vs. achieved in PT4-002.

	Planned	Achieved /Not achieved
Recruitment and retention	At least 80% of the target sample (i.e., 80% of 10 participants for CH (lead site), 80% of 5 participants for AIAS and 80% of 5 for AUTH (replicating sites) successfully recruited into the pilot.	☒ In CH the target sample was not achieved. ☑ In AIAS the target sample was achieved.
	At least 80% of the recruited participants within the target cohort remained enrolled in the pilot until the end of the study.	☑ In CH the retention rate was 100%. ☑ In AIAS the retention rate was 100%.
Technical performance	There is no re-start of any of the technology components for at least 90% of the days.	☑ In CH just one re-start of the robot was needed within the 15 days pilot period, so there was no re-start for 93% of the days. ☑ In AIAS no re-start was needed.
	Less than 2 technical incidents reported per week.	☑ In CH there was just one incident reported within the whole piloting period. ☑ In AIAS there was no incident reported.
	The user successfully recognized 80% of the interactions.	Face recognition was not used at the end, users would be identified through their SHAPES username and password. ☑ In CH users were successfully recognized 100% of the time.

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		☑ In AIAS users were successfully recognized 100% of the time.
User engagement and acceptance	The overall user experience quality of the robot as measured using (UEQ-S) was classified as 'Excellent', 'Good' or 'Above average' based on published benchmark data.	☑ In CH, the overall experience was classified as 'Excellent'. In AIAS this questionnaire was not administrated.
Collection of data	At least 50% of participants played twice per week.	☑ In CH, this KPI was achieved. In AIAS, participants' sessions were once a week, so this KPI hasn't been considered.
	At least one care provider/caregiver scored one of the following functionalities above-average rating (>68) in the SUS (suggestion, game selection, game feedback).	☑ In CH, 100% of caregivers (one caregiver involved) provided an overall SUS score of 85. In AIAS, there was no caregiver role, so this KPI hasn't been considered.

Deviations from the initial plan

- The face recognition software by VICOMTECH hasn't been used in Phase 5 for users' identification. This functionality was tested during Phase 3 and 4 and the performance was pretty good. However, just before Phase 5 and due to a bug, the software stopped working on the robot. Due to the time constraint and since face recognition was not considered key to the project success, it was decided to proceed without this functionality.
- The Wake Up word functionality hasn't been used neither because it required the WebSocket to be open for it to work. In other words, it was a requirement that the user was already logged in his/her session for the Wake Up word to work. This didn't make much sense since the purpose of the Wake Up word in this use case was to allow users to start the interaction through this functionality.
- Emotion recognition data will be analysed in coming deliverables due to difficulties on interpreting the data set as it was stored. Technical partners are currently modeling the dataset to obtain meaningful results.

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- AUTH didn't replicate the use case PT4-002 due to the already mentioned reasons.

3.9.8 Communication and dissemination of pilot activities

Dissemination policy

The sponsor will own any data that arise from the pilot study. On completion of the study, all data has been analysed, tabulated and used to prepare a final report, available as one of the agreed deliverables of the SHAPES Innovation Action — Deliverable D6.5. 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. In addition, the sponsor will seek to disseminate the findings from this study at conferences and in the scientific literature. As per the SHAPES Publication Protocol, all publications 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, and project management. Any publications will be read and meaningfully contributed to by all named authors. The sponsor 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 right to use this study data in their analysis and dissemination plans. As detailed under 'Access to Data', Data Sharing Agreements are in place to facilitate sharing pseudonymised data with specific SHAPES partners for particular purposes.

3.9.9 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 PT4-002. 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.

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4 Conclusion

In summary, both Pilot Theme 4 use-cases have successfully completed Phases 1–5. Necessary preparatory work conducted in Phase 1 has contributed to the effective planning and implementation of the pilots. Many of the hurdles encountered early on in the pilot campaign have been resolved and not impacted upon revised timescales. Engagement with users, carers, and health professionals in Phases 2 and 3 has resulted in adaptations to the user-facing components of the digital solutions deployed during the last phase. Phase 5 has been developed by both use case leaders showing positive results and interesting insights. User feedback and acceptance has been generally very positive. Regarding the replication of the use cases, only one replicant was not able to replicate one of the use cases within this pilot timeframe and for reasons already mentioned. However, this replication will take place in the near future and results reported on the annex of D6.9.

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5 Ethical requirements check

Table 71 - 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 centred, 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 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 that 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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