SHAPES

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

D6.6 –Pilot Theme 5: Caring for Older Individuals with Neurodegenerative Diseases – Pilot Activities Report

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0.2	12.06.2023	Pedro Rocha (UPORTO)	First draft for SHAPES peer reviewers.
0.3	28.06.2023	Pedro Rocha (UPORTO)	Second draft for SHAPES coordinator.
V1.0	30.06.2023	Pedro Rocha (UPORTO)	Final Version to be submitted.

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Table 2 Deliverable Contributors.

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Table of Acronyms and Abbreviations

Table 3 Acronyms and Abbreviations.

Acronym	Full Term
AAL	Ambient Assisted Living
AI	Artificial Intelligence
App	Mobile Application
AUTH	Aristotle University of Thessaloniki
CE	CE Certification
DPIA	Data Protection Impact Assessment
DS	Digital Solution(s)
ECG	Electrocardiogram
EEG	Electroencephalography
EU	European Union
FDA	Food and Drug Administration
GP	General Practitioner
IAA	Interhemispheric Alpha Asymmetry
IoT	Internet of Things
IT	Information Technology
KPI	Key Performance Indicators
MAST	Model for Assessment of Telemedicine
MCI	Mild Cognitive Impairment
MoCA	Montreal Cognitive Assessment
MVP	Mobile Virtual Patients
NASSS	Non-adoption, abandonment, scale-up, spread, sustainability
NGO	Non-governmental Organization
NHS	National Health System
PSD	Power Spectral Density
PT	Pilot Theme
PwD	People with Dementia
QMCI	Quick Mild Cognitive Impairment
SHAPES	Smart & Healthy Ageing through People Engaging in Supportive Systems
SpO2	Oxygen Saturation
UC	Use Case
UCC	University College Cork
UCLM	Universidad de Castilla - La Mancha
UNRF	University of Nicosia Research Foundation
UPORTO	University of Porto
UX	User Experience
VICOM	VICOMTECH
VPS	Virtual Patient Scenarios
WHO	World Health Organization
WP	Work Package

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Keywords

Healthy Ageing; Dementia; Cognitive Decline; Caregiving (Informal / Formal); iSupport; Training; Assistive Technologies; EEG; Virtual Patients; Pilot Study; SHAPES.

Disclaimer

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Executive Summary

This deliverable contains the work completed by Pilot Theme 5 of the SHAPES Pan-European Pilot Campaign. It details the planning and outcomes of all activities and tasks that have been completed in Phases 1 to 5 of the pilot campaign, for 4 use cases. The work described here is the result of collaboration and dedication of the whole of Pilot Theme 5 including the pilot site leaders and technical partners, and a significant contribution and assistance from other work packages within the SHAPES consortium and local communities. This document reports the pilot activities developed by the participants in each use case, considering the 5 phases of SHAPES methodology; as well as the preliminary outcomes already collected and described. It's organized in 6 sections. The section 1 is dedicated to the Introduction of Pilot Theme 5, addressing their concepts, methodology, and purposes. Sections 2 to 5 are dedicated to the use cases and detail the pilot activities by each phase of deployment. The section 6 develops the conclusions regarding the Pilot Theme 5 and based on the use cases' experiences. There is also a section for references organized by use case and introduction/conclusions.

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1 Introduction

In 2022, there were eight billion people in the Planet (#8BillionStrong)[1], of whom almost 800 million are aged 65 years or over, globally [1-2]. The United Nations (UN) Decade of Healthy Ageing was proclaimed (2021-2030), to get a step into "a world in which all people can live long, healthy lives" through a better "Housing, Health, Long-term Care and Social Protection", combining the social determinants of health (lifestyle, literacy, social participation, public expenditure) and healthcare services for ageing (primary care, long-term care, integrated care) [3]. If this vision is challenging for 'normal' ageing, it could be critical to address the ageing with dementia.

The World Health Organization (WHO) estimates that there were 55 million people with dementia in the world in 2019, and there are 10 million new cases every year. With life expectancy increasing, people with Dementia (PwD) could reach 78 million by 2030 and 139 million by 2050. In 2019, dementia was the seventh leading cause of death (1.6 million deaths and 28.3 million disability-adjusted life-years, in 2019), and it cost US$ 1.3 trillion for medical, social, and informal care. According to this organization, in the next years, dementia will require new health and social services and jobs, but also new skills and training, to prevent, diagnose, treat, and care for people with dementia [4-5].

Dementia is not a single disease, but a range of syndromes caused by brain's diseases or damages (destruction of nerve cells). Dementia is associated with a deterioration in cognitive function (memory, speech, perception, attention), and differs from psychiatric disorders (depression, anxiety, stress), chronic diseases (diabetes, asthma) or those resulting from lifestyle (nutrition, smoking, alcohol). It also differs from age-related cognitive decline which is not classified as a disease but may be a pre-morbid phase, which may progress to dementia [6-10].

Dementia symptoms and signs are associated with progressive changes in mood and behaviours, namely: "forgetting things or recent events; losing or misplacing things; getting lost when walking or driving; being confused, even in familiar places; losing track of time; difficulties solving problems or making decisions; problems following conversations or trouble finding words; difficulties performing familiar tasks; misjudging distances to objects visually; feeling anxious, sad, or angry about memory loss; personality changes; inappropriate behaviour; withdrawal from work or social activities; being less interested in other people's emotions"[2].

Considering these wide range of symptoms and signs, dementia prevention, diagnosis, treatments, and care are a great challenge for healthcare, social care,

[1] To be consulted in: https://www.unfpa.org/8billion (accessed at 08-06-2023).
[2] To be consulted in: https://www.who.int/news-room/fact-sheets/detail/dementia (accessed at 08-06-2023).

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families, and individuals. The *caring of people with neurodegenerative diseases* requires multiple interventions that must integrate individual behaviours or self-care (e.g., healthy and active lifestyle), healthcare services (e.g., medical diagnosis, rehabilitation centres, medication), social care (e.g., homecare, engaging in community), social awareness (e.g., training informal caregivers, awareness-raising campaigns), scientific research and innovation (e.g., digital health, genetics). This complexity is shaped by multiple interventions and studies worldwide [11-15], and global organizations and its work[3].

Digital Health and Care has been understood as a new revolution for health and care, strongly recommended and implemented by governments, companies, entrepreneurs, civil society, and others. This new field evolved from the development in the digital industry (e.g., artificial intelligence, big data analytics, blockchain, advanced computing, robotics, smart wearables, platforms) and its application in health and care sectors, namely: "medical diagnosis, data-based treatment decisions, digital therapeutics, clinical trials, self-management of care and person-centred care" [16]. Although it is new field, there are studies that demonstrate how Digital Health and Care improves the outcomes and the delivery of health and social sectors [17-21], and informal caregiving for older adults with dementia [22-25].

1.1 Rationale and purpose of the deliverable

The SHAPES Pilot Theme 5 "Caring for Older Individuals with Neurodegenerative Diseases" (PT5) is Task 6.6 of the SHAPES Work Package 6, "SHAPES Pan-European Pilot Campaign" (WP6). The PT5 aims to design, build, and validate digital solutions and demonstrate the role played by digital solutions to deliver non-obtrusive and easy-to-use technologies to improve safety and quality of care of older adults with neurodegenerative diseases, especially dementia.

Researchers, IT developers, healthcare providers, and social care organizations address one or more aspects of dementia and its caregiving, (1) to design personalized care models to improve the quality of life and social support of older adults with cognitive decline or dementia, and their formal and informal caregivers, (2) to build methods and digital solutions to care for older adults with neurodegenerative diseases at different stages of the disease, (3) and to demonstrate their efficacy in real-life contexts, by a systematic evaluation of safety, quality, adoption, and governance.

[3] To be consulted in: Dementia Alliance International (https://dementiaallianceinternational.org/); World Dementia Council (https://www.worlddementiacouncil.org/); Alzheimer's Association (https://www.alz.org/); Alzheimer Disease International (https://www.alzint.org/) (accessed at 08-06-2023).

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Framed in the SHAPES Pilot Campaign, PT5 is designing, building, and validating four Use Case or Pilot Studies: UC1. iSupport for Dementia Caregivers; UC2. Assistive Technology for Cognitive Decline in Older Adults living in Community; UC3. The BRAINCODE for a Massive Screening of Cognitive Decline in the Older Population; and UC4. Virtual Patient Scenarios & Mobile Virtual Patients.

Overall, these pilot studies assess solutions related to (1) the caregiving burden, anxiety, and efficacy, (2) the informal caregivers' training, (3) the self-monitoring, self-care, and remote assistance of older adults, (4) the massive and early screening of cognitive decline in older populations provided by local healthcare actors; (5) and the digital scenarios for supporting caregivers (formal and informal).

The Use Cases are developing the SHAPES Methodology, to validate the SHAPES Platform capabilities and benefits to care recipients, caregivers, and care healthcare providers, at the European scale, across different regions, cultures and health and care organizational models. This methodology adopts the user-centred and co-creation to implement in real-life the demonstrations and pilots of the SHAPES Platform, throughout five Phases of implementation [26-27].

- **Phase 1. Plan, Design, and KPIs** This phase is dedicated to the designing and planning of the Use Case, including a realistic persona, story, scenario, requirements, and the methodology to validate it. This phase is the basis for future pilot activities.
- **Phase 2. Mock-up and Prototype Validation** This phase is dedicated to building the digital solution prototype for the Use Case, from the drafts and wireframes to the mock-ups and prototypes. This phase also includes the technical validation to be used autonomously by older adults.
- **Phase 3. Hands-on Experiments** This phase is dedicated to evaluating the digital solutions and to define the critical factors, key performance indicators, and the follow-up/training needs.
- **Phase 4. Deployment in Controlled Environment** This phase is dedicated to implementing the digital solution in real-life, through a small and controlled demonstration. In this phase, the researchers aim to test the methods and solutions for later use in a large-scale demonstration.
- **Phase 5. Deployment in Real-life Use Cases** This phase is dedicated to implementing the digital solution in real-life, through an autonomous demonstration by the end-users. In this phase, the researchers aim to validate the digital solution through a scientific evaluation.

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1.1.1 Deliverable Objectives

The deliverable “D6.6 Caring for Older Individuals with Neurodegenerative Diseases – Pilot Activities Report”, led by UPORTO, describes the activities developed in Pilot Theme 5 of the SHAPES Pan-European Pilot Campaign, and the outcomes achieved and those foreseen yet.

Adopting the SHAPES approaches (co-creation, co-design, co-experimentation, co-deployment, co-execution, and co-evaluation), the report is a result of a collaboration and dedication of all partners, both from SHAPES consortium as outside it, through an intensive communication via online and face-to-face meetings, TEAMS’ chats, email, field work, and continuously reporting. Thereby, this is a narrative report that summarizes those efforts.

Throughout this deliverable, authors (contributors) develop the SHAPES methodology, as explained before, detailing activities undertaken in each phase. This work is materialized in four use cases that include a designing and building a new digital solution, a use case, and a protocol to validate them. Each Use Case lived different challenges and experiences to deploy the methodology in real-life, and those variances are now echoed in different ‘stories’ of the same methodology. This also demonstrates the multiculturality inside Europe and among their scientific and innovation ecosystem.

1.1.2 Key inputs and outputs

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

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

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

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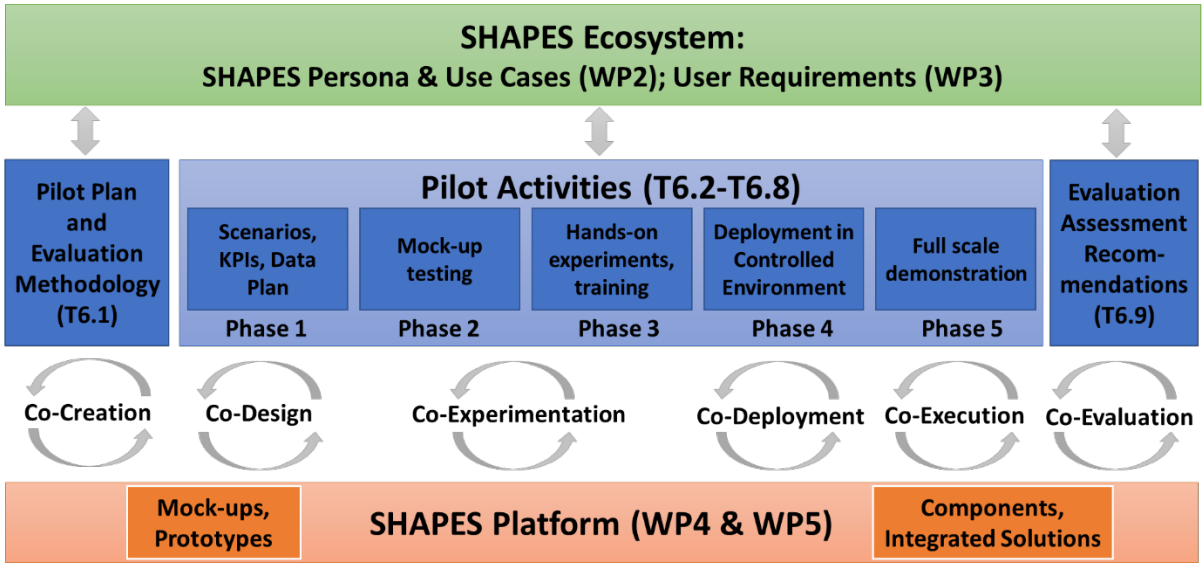

Figure 1: Overview of WP 6.

1.2 Structure of the document

This deliverable is organized in 6 sections.

The section 1 is dedicated to the Introduction of Pilot Theme 5, addressing their concepts, methodology, and purposes.

The sections 2 to 5 are dedicated to the use cases and detail the pilot activities by each phase of deployment.

The section 6 develops the conclusions regarding the Pilot Theme 5 and based on the use cases' experiences.

There is also a section for references organized by use case and introduction/conclusions.

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2 Use case 001

2.1 Introduction

The United Nations Decade of Healthy Ageing was proclaimed (2021-2030), to get a step into “a world in which all people can live long, healthy lives” through a better “Housing, Health, Long-term Care and Social Protection”. The Decade encourages the integrated approaches to provide care to people aged 65 years or over, and a perspective of health ageing that combines the social determinants of health (lifestyle, literacy, social participation, public expenditure) and the healthcare services for ageing (primary care, long-term care, integrated care) [1].

If this vision is challenging for ‘normal’ ageing, it could be critical to address the ageing with chronic diseases. In this context, the World Alzheimer Report 2022 explained that the informal caregiving “is a cornerstone in today’s long-term care for people living with dementia. Indeed, in recent years, healthcare systems have increasingly relied on informal carers, partially because community-based informal care is considered a favourable financial solution compared to professional and especially institutional care, but also because community-based care is preferred over institutional care by the people with dementia (PwD) themselves” [2].

The literature has demonstrated that dementia caregiving causes emotional distress in caregivers. Studies have indicated that caregivers of PwD are exceptionally disposed to depression, anxiety disorders, and burden. The continued cognitive deterioration of the PwD (care recipient) requires a continuous adaptation of their informal caregivers. Changes in family structure, labor market, and the absence of health & care services are reasons to increase the borderline conditions for PwD and their informal caregivers. In this regard, some studies have demonstrated that the caregiving burden is a reason to use the nursing home services [3-11].

In the last years, WHO has recommended tailored services to support the informal caregivers, provide “accessible and evidence-based information, training programmes, respite services and other resources tailored to the needs of carers”, and improve “knowledge and caregiving skills, such as coping with behavior changes related to dementia to enable people living with dementia to live in the community for longer and to prevent stress and health problems for carers” [12].

This use case is addressed to the informal caregivers of people with dementia, i.e., people who provide non-paid care to the people with dementia, and they also have a clinically relevant level of subjective burden, determined by Zarit Burden Interview or depression/anxiety symptoms, determined by the Hospital Anxiety and Depression Scale.

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This target population was selected to correspond to the SHAPES Persona "John and Joan" (Figure 2), as detailed in the "D2.6 – SHAPES Personas and Use V2" (p.11-14, 30):

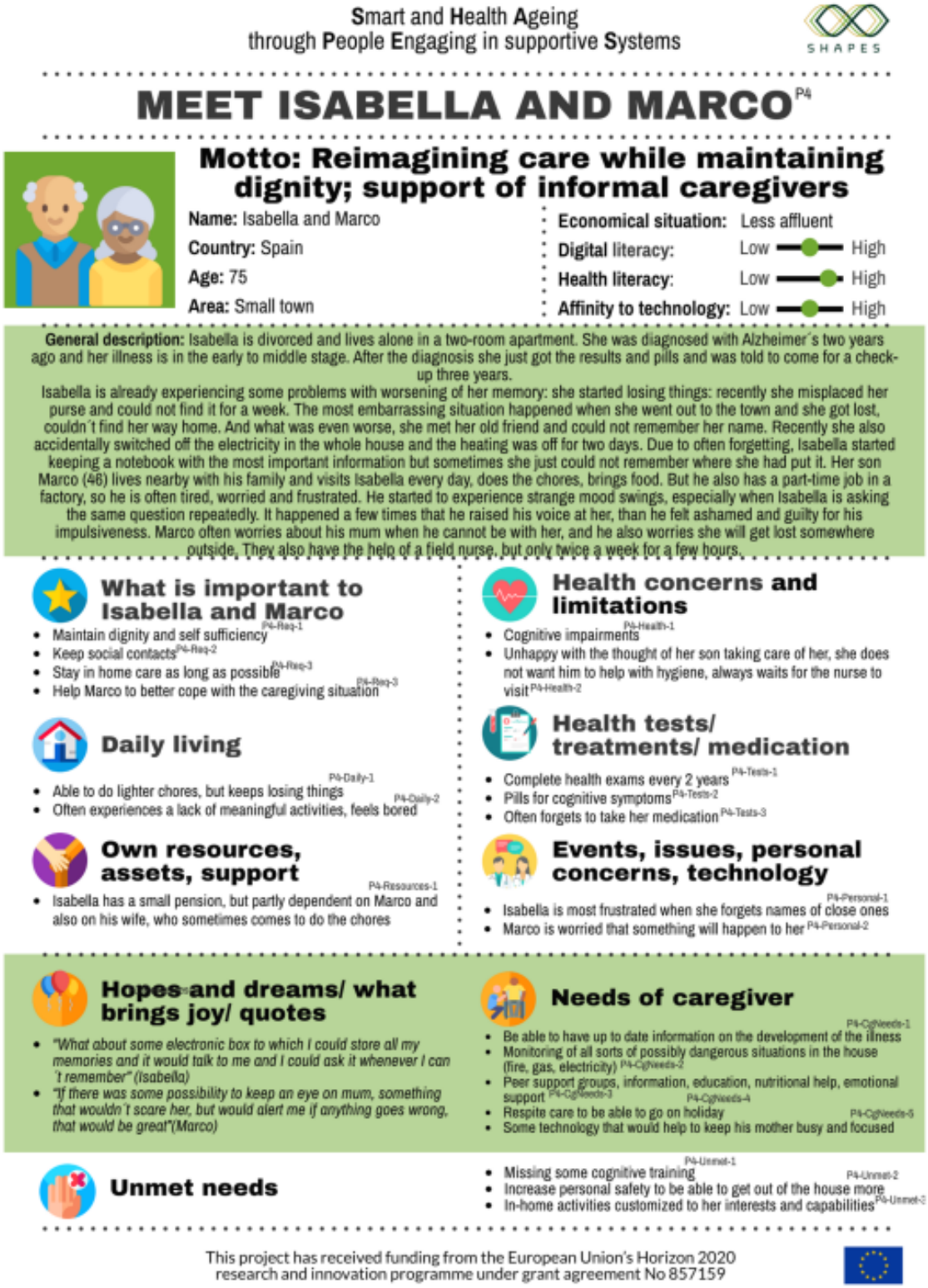

Figure 2: Use Case 1 - SHAPES Persona who represents older adults with neurodegenerative diseases. Source: D2.6 – SHAPES Personas and Use V2" (p.30).

2.2 Description

Code	UC-PT5-001
Title	iSupport - Online Information and Training for Informal Caregivers
Pilot Theme & Task	PT 5 – Caring for Older Individuals with Neurodegenerative Diseases (Task 6.6)
Piloting Sites	UPORTO (Portugal) and UCC (Ireland)
Description	Informal caregivers of people with dementia are at greater risk of developing physical and mental health problems compared both to the general population and to informal caregivers of people with other chronic diseases. Those health problems include depression and anxiety disorders, as well as hypertension, digestive, and breathing problems. Psychoeducational and multicomponent interventions (e.g., skills training, psychoeducation, techniques for self-care, changes in the caregiver's setting) have shown favourable evidence with regards to its effects on subjective well-being, caregiver burden, depression and anxiety symptoms, skills/knowledge, and self-efficacy. However, several reports have stressed the existence of situational barriers impeding informal dementia caregivers of accessing interventions targeting them when delivered in its usual face-to-face format. Barriers may hamper access to these intervention programs (e.g., geographical inequalities, lack of trained workforce, infrastructures to scale up services, and/or funds); or may prevent IC from participating (e.g., social stigma, not managing to make a break from caregiving responsibilities or to arrange transport). Internet-based interventions have been explored for their potential to minimize the negative effects of caring, accounting for their ubiquitous nature, convenient delivery, potential scalability and presumed (cost) effectiveness. Mirroring the encouraging evidence on online interventions, the World Health Organization's (WHO) mental health action plan recommends the development of "comprehensive, integrated and responsive mental health and social care services" and "the promotion of self-care, for instance through the use of electronic and mobile health technologies" [13]. In this sense, a digital tool is needed (1) to provide ubiquitous, accessible and convenient information and training to informal dementia caregivers, (2) and to reach excluded informal dementia caregivers, due to contextual barriers (e.g., inability to arrange

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	transportation or delegate caregiving responsibilities) from usual care practices (i.e., face-to-face interventions).
Digital Solution proposed	iSupport is an internet-based training and support program for informal carers of people with dementia that was originally developed by the World Health Organization. This digital solution is composed by: Modules and lessons: Five modules with 23 lessons cover well-established thematic needs of informal dementia caregivers. It allows the collection of data on the lessons accessed (when and which) and repeated by each user. A sub-component of each lesson is a series of interactive exercises with immediate feedback (e.g., drag and drop, free text, checklist). My plan: functionality allows the definition of a plan of lessons personalized to the convenience and needs of each informal dementia caregiver. Data on lessons added to the personalized plan by all users can be collected. My mood: This module is used for a self-evaluation of the mood status (in a scale on 1 to 10) with the option of adding a description of the mood status. Quantitative and qualitative (text) data can be collected with this module concerning caregivers' mood status. It was a complementary functionality to the program (rather than central to the support and training program). My printouts: module for a personalized printing of lessons that reflect the interaction of users with the system, i.e., each printable document imports interaction elements within the platform such as the answers to all exercises. These printouts reflect the leaning process for each user.
Technical partners	UPORTO, UCC
Components	iSupport is an online educational program accessed by a website through a computer or tablet with internet connection.
Piloting summary	A pilot study developed to assess the scenario proposed in this use case, in terms of acceptance, satisfaction, usability, and efficacy. Adopting the SHAPES methodology, this pilot study had five phases. In Phase 1, academic and technical partners transferred the proposed use case in two scenarios, describing partners, framework, subjects or target groups, activities and roles, interactions, context, environment, functions, technical infrastructures, devices, interfaces, performance indicators, and a

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	timeline. The outcome is the pilot study design and plan, considering the SHAPES methodology and expected impacts, but also the first mock-up of digital solutions, written and summarized. In Phase(s) 2&3, academic and technical partners developed the final prototype to use in the pilot study and test it in the hands-one experience. Additionally, the academic partners provided the social context to deploy a pilot in a real-life environment, namely a community of older people, informal and formal caregivers, and public or private facilities. The outcome is a final prototype not only of digital solutions, but also a real-life scenario that uses technology to integrate pilot' subjects and promote healthy lifestyle in old age. In Phase(s) 4&5, academic partners, supported by technical partners, assessed the pilot study by a scientific protocol. They designed a protocol, submitted it in the ethics committee and data protection office, recruited participants and their signed consent forms, manage logistic and risks, collected and analyse data, and provide regular reports. The outcome is an extensive final report that describe in-depth the five phases and their results (SHAPES D6.6 – Pilot Theme 5: Caring for Older Individuals with Neurodegenerative Diseases). This Use Case was replicated in two pilot sites: UPORTO (Portugal) and UCC (Ireland). Moreover, partners and participants are working to disseminate the experience and results through scientific publications, public events, and social media.
Subject profile (main persona of the piloting)	Beneficiaries: Informal Caregivers of people with dementia. Inclusion Criteria: (1) Adults (≥ 18 years old); (2) Unpaid for care for at least 6 months; (3) Care recipient with formal diagnosis of dementia; (4) Ability to use the internet autonomously; (5) Clinically relevant levels of overload (score ≥ 21 on the Zarit Burden Interview OR of anxious OR depressive symptomatology (score of ≥ 8 on at least one of the subscales of the Hospital Anxiety and Depression Scale). Exclusion Criteria: (1) Not understand written language; (2) No access to a personal device with internet connection at least twice a week; (3) Care Recipient lives in institutional care.

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2.3 Digital solutions used in this use case

The digital solution was tested in this Use Case is the iSupport. This technology is a virtual course for carers of people with dementia that aims to be a "self-help tool". Developed by WHO, the iSupport aims to "provide accessible, evidence-based training and information, tailored to carers' needs. It aims to improve knowledge and caregiving skills, such as carers' ability to cope with dementia symptoms and care for themselves"[4]. The course is organized in five modules, that "were carefully designed to help carers tackle the important challenges that they may face when caring for someone living with dementia"[5] (Figure 3).

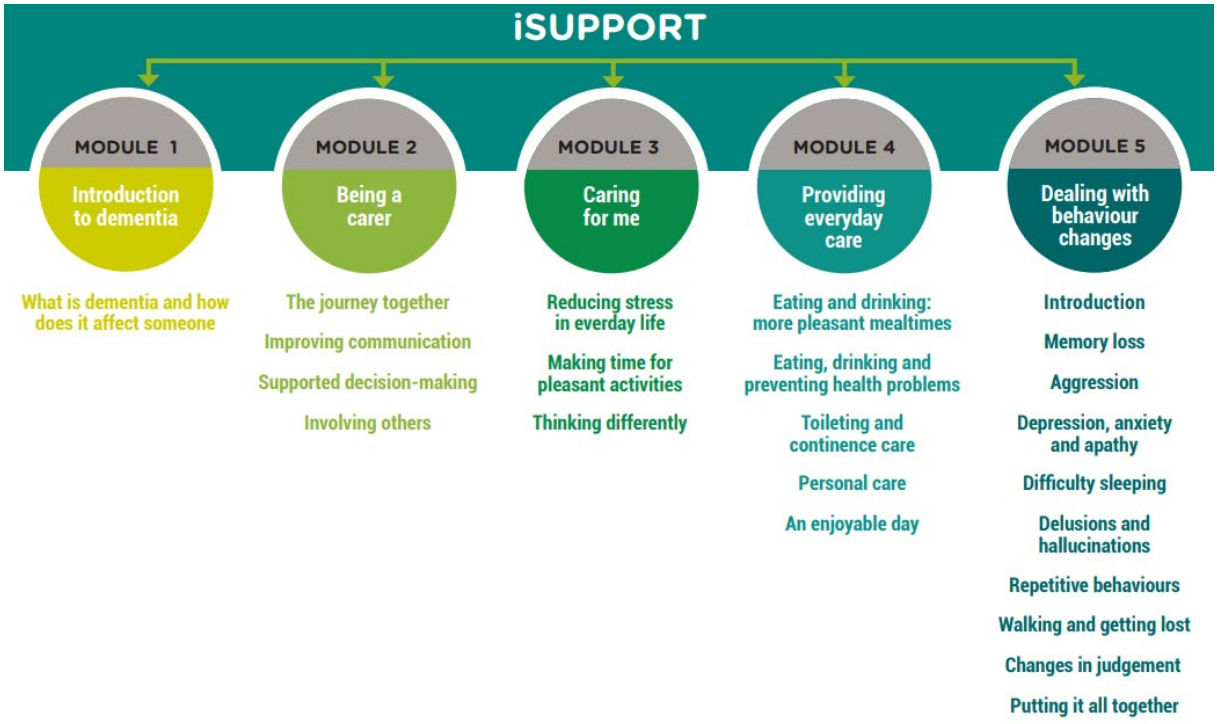

Figure 3: Use Case 1 - List of Modules/Lessons of the iSupport (WHO).

The technology has an online version in four languages[6], but it can be adapted "to national or local contexts and needs. Once adapted, carers can choose to work through all modules and lessons consecutively or select the lessons that are the most relevant to their everyday lives. All lessons have brief readings, descriptive examples, and several exercises. Carers receive feedback as they work through each exercise"[7].

[4] To be consulted in: https://www.who.int/publications/i/item/9789241515863 (accessed on 06-06-2023).
[5] To be consulted in: https://www.who.int/publications/i/item/9789241515863 (accessed on 06-06-2023).
[6] To be consulted in: https://www.campusvirtualsp.org/en/user/login (accessed on 06-06-2023).
[7] To be consulted in: https://accesswho.campusvirtualsp.org/isupport-virtual-course-skills-and-knowledge-training-carers-people-dementia (accessed on 06-06-2023).

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This solution was designed to support informal caregivers, especially familiars, friends, relatives, and others. However, their contents are also useful for other users, namely: "nongovernmental organizations (NGOs) providing skills training, support and/or information to carers of people with dementia; health and social care workers providing care and information to carers of people with dementia; and private sector representatives involved in the development of health technologies for dementia, dementia health care service delivery or health care insurance"[8].

2.3.1 iSupport-Portugal

The Portuguese version of the iSupport was developed with the permission of the WHO by the Department of Behavioral Sciences of the Institute of Biomedical Sciences Abel Salazar of the University of Porto (ICBAS-UP), in partnership with Associação Alzheimer Portugal and Centro de Investigação em Tecnologias e Serviços de Saúde (CINTESIS)[9]. This adaptation is detailed in the articles:

- Teles, S., Napolskij, M. S., Paúl, C., Ferreira, A., Seeher, K. (2020). Training and support for caregivers of people with dementia: The process of culturally adapting the World Health Organization iSupport programme to Portugal. Dementia, 20 (2), 672-697, doi:10.1177/1471301220910333 [14]
- Teles, S., Ferreira, A., Seeher, K., Fréel, S., Paúl, C. (2020). Online training and support program (iSupport) for informal dementia caregivers: protocol for an intervention study in Portugal. BMC Geriatrics 20, 10, doi:10.1186/s12877-019-1364-z [15]

Currently, the iSupport-Portugal is an online platform that users can access by computer, mobile and/or tablet, using the following link: https://isupport.icbas.up.pt/home (Figure 4, Figure 5).

This version is composed by: (1) Modules and Lessons that consists of five modules with 23 lessons about different topics of dementia and caregiving) (Figure 6, Figure 7); (2) My Plan that allows the users decide the personal plan to complete the lessons, adjusted to their needs and interests (Figure 8, Figure 9); (3) My Printouts that allow users print the iSupport contents and the results (Figure 10); (4) and My Mood that allows users self-assess their mood using a scale from 1 to 10 (not implemented yet because technical limitations not solved yet).

[8] To be consulted in: https://www.who.int/publications/i/item/9789241515863 (accessed on 06-06-2023).
[9] To be consulted in: https://isupport.icbas.up.pt/about-us (accessed on 06-06-2023).

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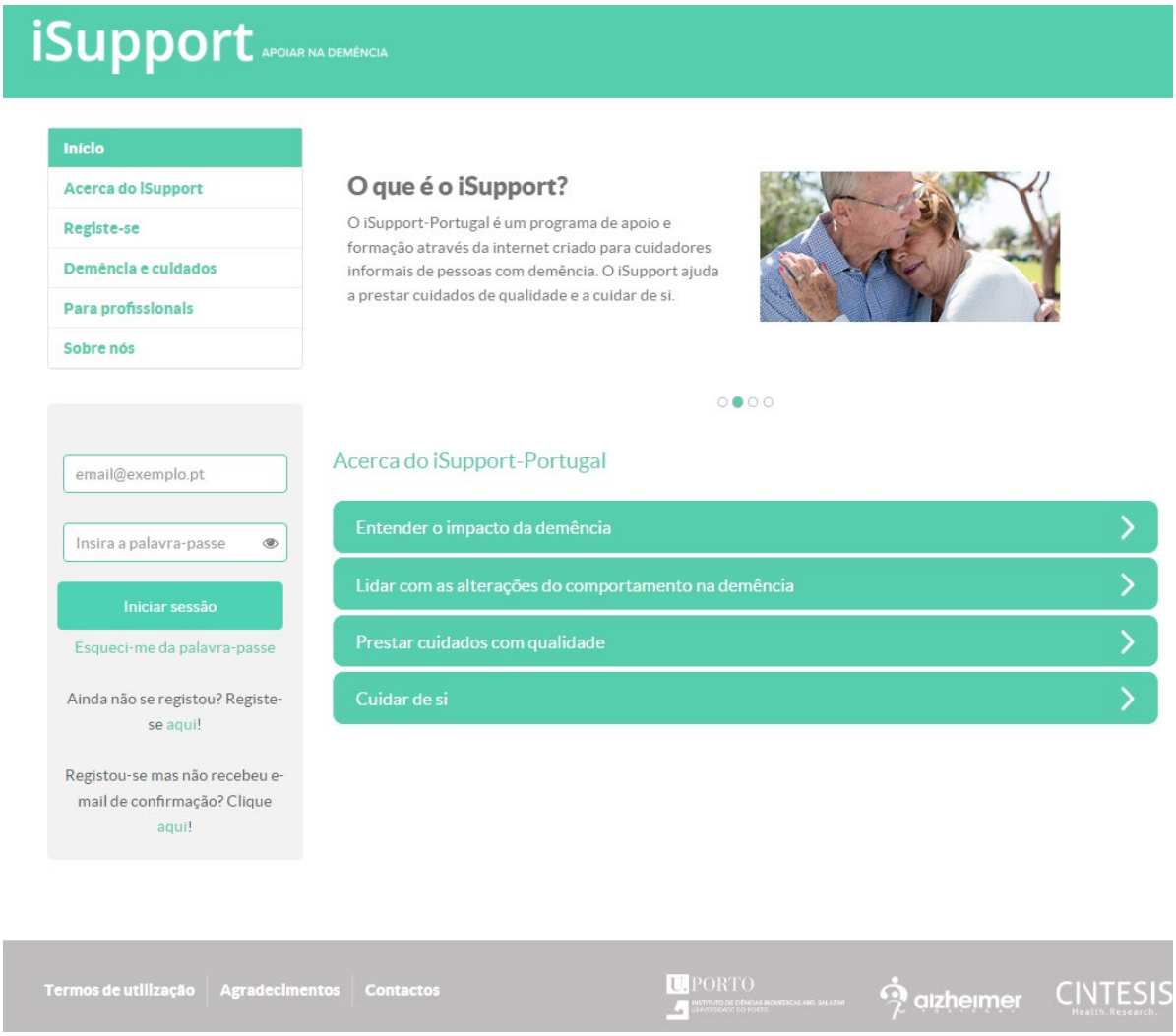

Figure 4: Use Case 1 - Website iSupport-Portugal (Website).

Figure 5: Use Case 1 - iSupport-Portugal Login.

Figure 6: Use Case 1 - iSupport-Portugal Modules/Lessons.

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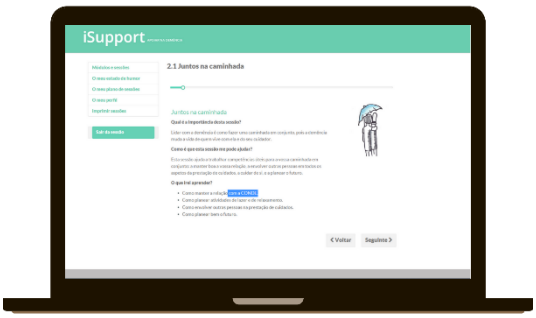

Figure 7: Use Case 1 - iSupport-Portugal lesson.

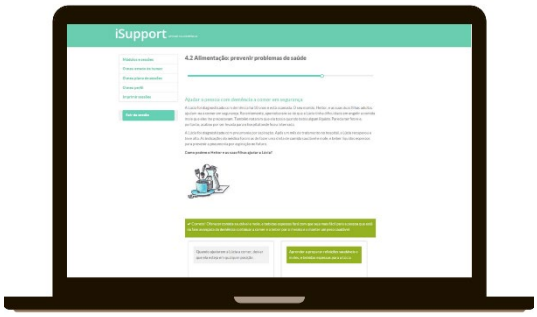

Figure 8: Use Case 1 - iSupport-Portugal Scenarios and Exercises.

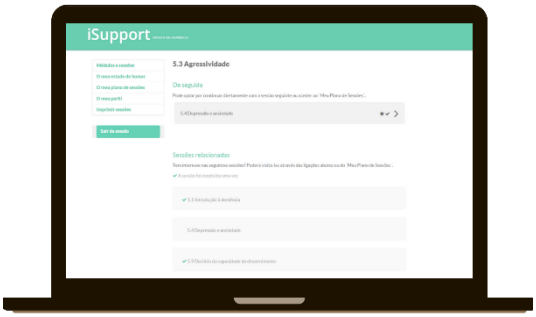

Figure 9: Use Case 1 - iSupport-Portugal Recommendations.

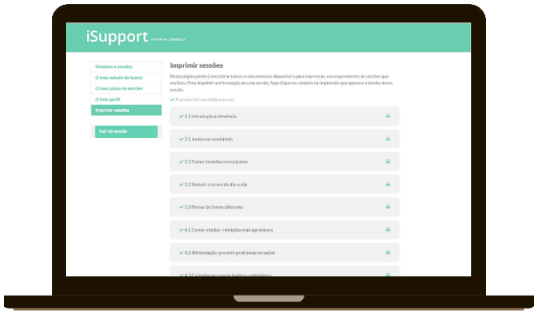

Figure 10: Use Case 1 - iSupport-Portugal Printouts.

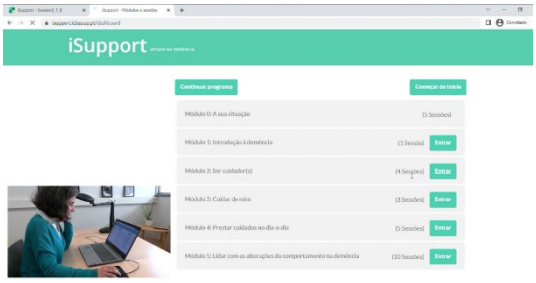

Figure 11: Use Case 1 - iSupport-Portugal used by informal caregiver (simulation).

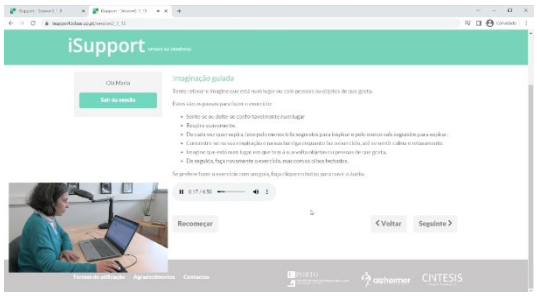

Figure 12: Use Case 1 - iSupport-Portugal used by informal caregiver (simulation).

2.3.2 iSupport-Ireland

The iSupport Irish version reproduces the iSupport for Dementia, Version 1.0, authored by the World Health Organization (WHO), Copyright (2018) (section 2.3 of this deliverable). This version is an online Moodle platform that users can access by computer using the following link: https://isupportfordementia.ie/moodle/isupport/login/index.php (Figure 13, Figure 14). This link opens a webpage and only works if the computer has Internet connection (does not work offline).

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This version was developed as a “demo version”. Like the Portuguese version, this version is composed by: (1) Modules and Lessons that are 5 modules with 23 lessons about different topics of dementia and caregiving) (Figure 16, Figure 17, Figure 18, Figure 19); (2) My Plan that allows the users decide the personal plan to complete the lessons, adjusted to their needs and interests (Figure 22, Figure 15); (3) My Printouts that allow users print the iSupport contents and the results; (4) and My Mood that allows users self-assess their mood using a scale from 1 to 10 (Figure 23).

Once the users sign the ethical consent to participate in the study (section 2.3.4 of this deliverable), they receive the platform link and their personal credentials to access to the platform (username and password). Using these credentials, users have access to a personal account of the iSupport course and functionalities (e.g., mood assessment tool, personal plan, and lessons completed).

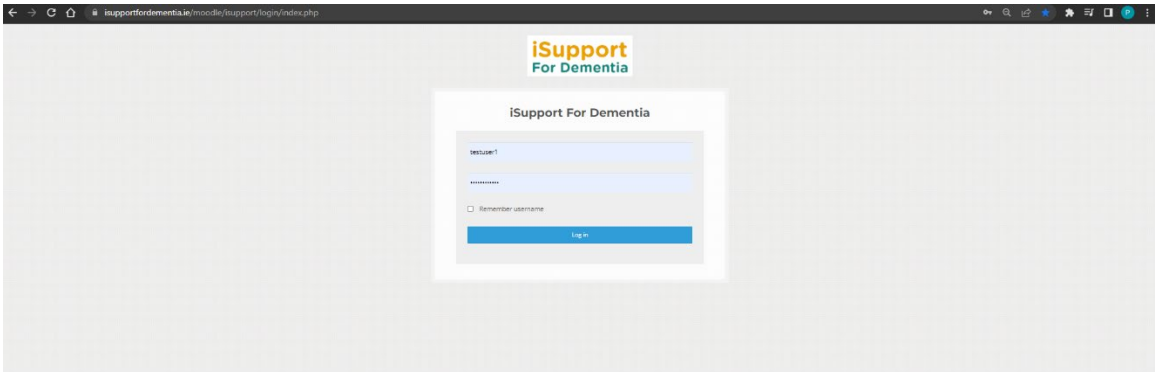

Figure 13: Use Case 1 - Website iSupport-Ireland (Log-in/Log-out).

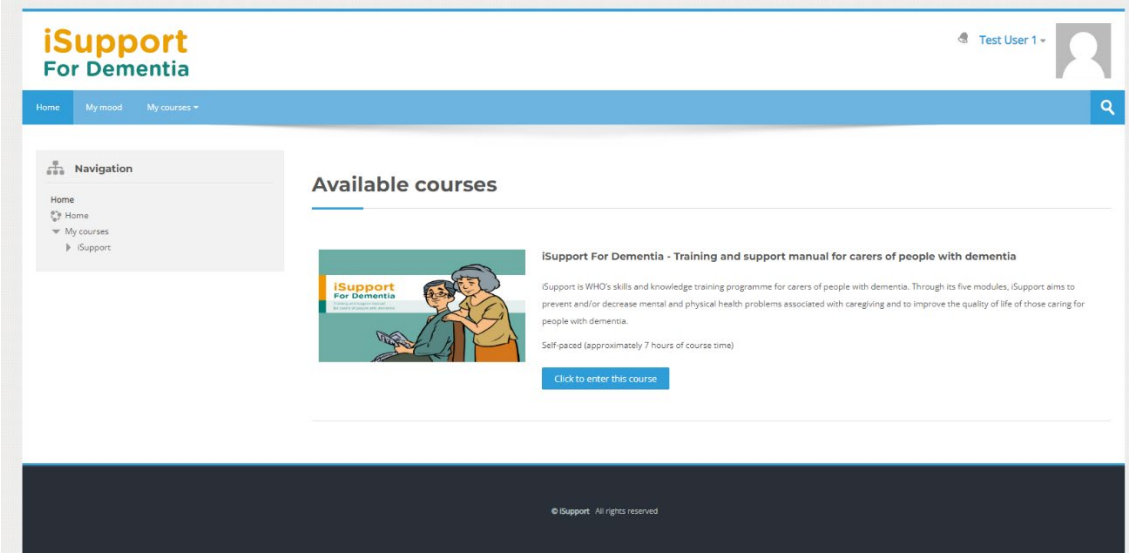

Figure 14: Use Case 1 - iSupport-Ireland Home.

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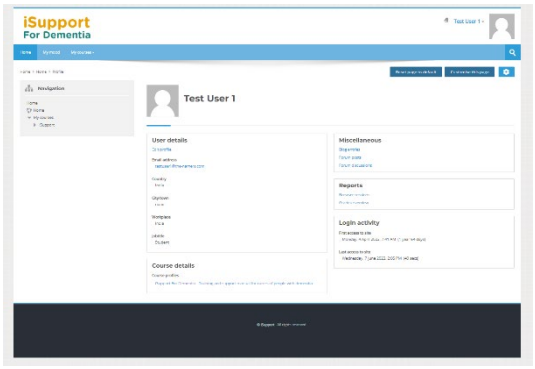

Figure 15: Use Case 1 - iSupport-Ireland Preferences.

Figure 16: Use Case 1 - iSupport-Ireland Modules.

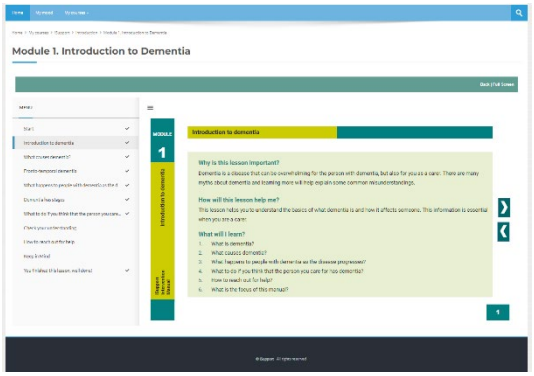

Figure 17: Use Case 1 - iSupport-Ireland Lessons.

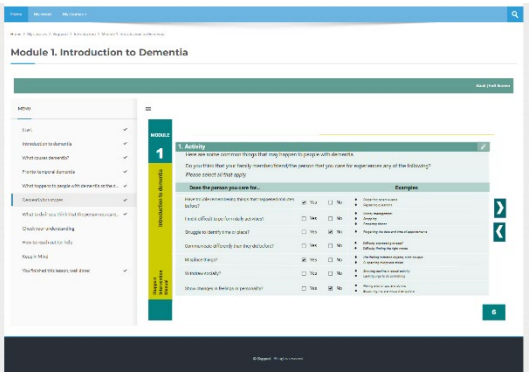

Figure 18: Use Case 1 - iSupport-Ireland Activities.

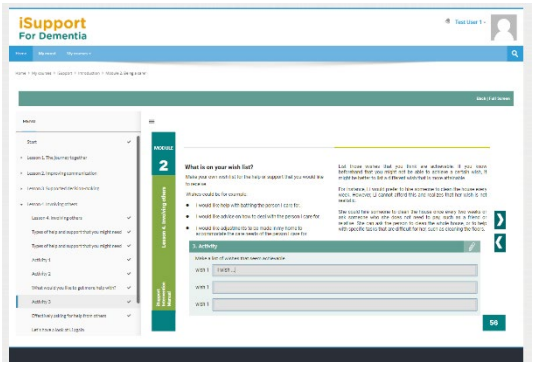

Figure 19: Use Case 1 - iSupport-Ireland Activities.

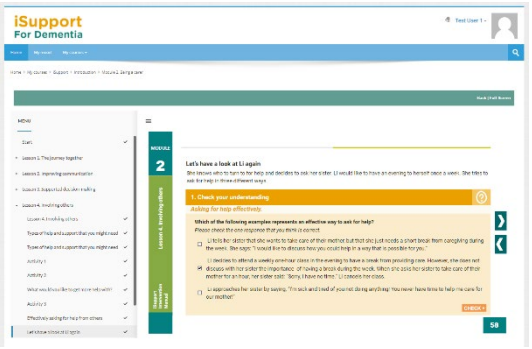

Figure 20: Use Case 1 - iSupport-Ireland Interactions.

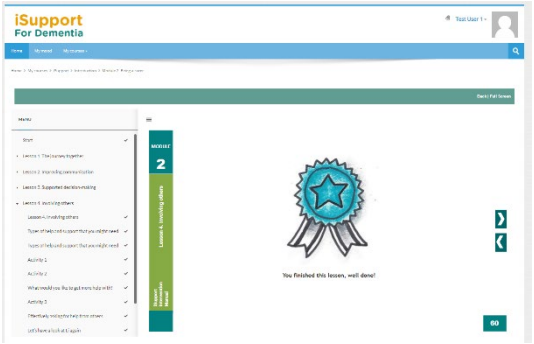

Figure 21: Use Case 1 - iSupport-Ireland Complete.

Present the planning functionality

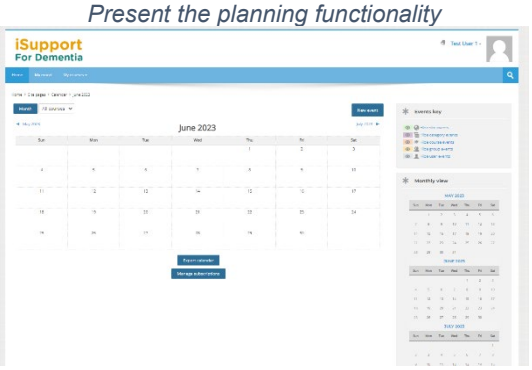

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Figure 22: Use Case 1 - iSupport-Ireland Planning.

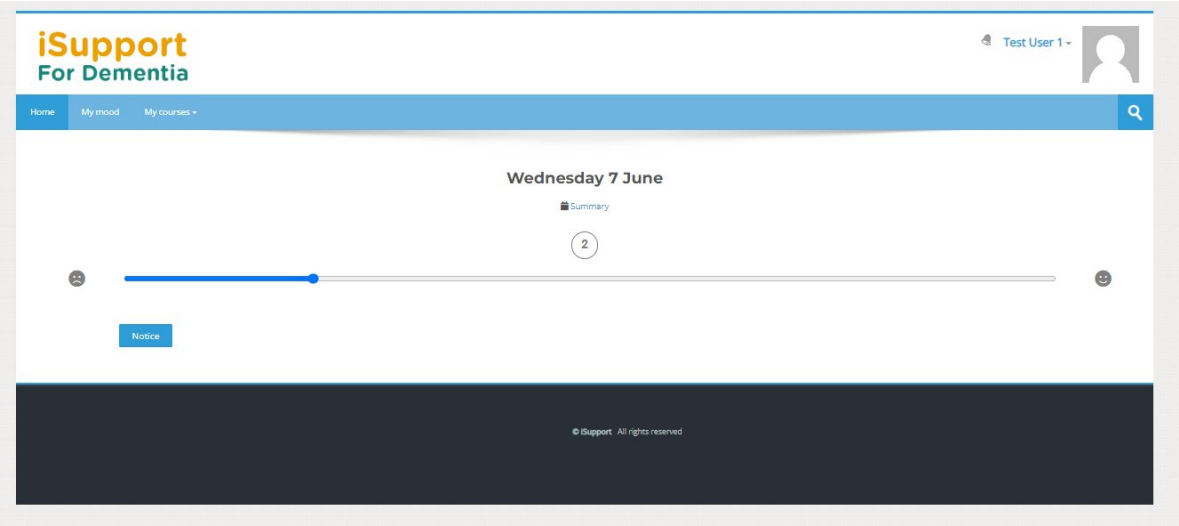

Figure 23: Use Case 1 - iSupport-Ireland Mood Assessment tool.

2.3.3 Digital solutions used for COVID-19 response

Original objective	Opportunities to fight COVID-19	Additional evaluation steps
Self-help online training and support program aimed at providing education, skills training, and support to informal dementia caregivers	Dementia caregivers may experience increased stress due to social isolation and new challenges in care provision. We have identified new realities in care provision. For a profile of younger, offspring, employed and mostly well-educated caregivers: Sons/daughters of community-dwelling individuals with dementia, working full time and caring at the end of the day/weekends have mostly seen the suspension of home help/formal care services. Remote working is frequently combined with supporting children in home-schooling and, for the first time, providing full-time support to a mother/father with dementia. Those caregivers lack practical skills to provide care and have limited time available for the learning process.	No additional steps required for the already existing iSupport version. Evaluation scheme was adjusted in case iSupport in terms of its time frame and outcomes. Evaluation scheme was kept for a possible new module in assessing the overall programme efficacy. New measures of self-reporting might be designed to specifically understand the utility of a new module in

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	For a profile of sons/daughters coordinating the provision of care to a mother/father with a sibling, the decision of one of the siblings assuming entirely the care provision has been common, as a way to minimize social contact. In this situation, there is an increase of the number of hours providing care, a factor that research has shown to be associated with psychological distress (the higher the number of hours providing care, the greater is the likelihood of negative health outcomes). For a profile of caregivers caring full-time before the pandemic situation, attending to medical services and other support services in the community was perceived by those caregivers to get out of the house and have some social time. Routine medical appointments have been postponed or provided by telephone, and community services such as support groups or 'Memory Cafes" have been suspended, increasing the caregivers' sense of isolation and psychological stress. Overall, the breakdown of support services for both dementia patients (e.g., day care centres, home support services) and dementia caregivers (e.g., specialized counselling on dementia, psychological support) increases the chance of undesired upshots for both the caregiver and the care receiver. The *iSupport* programme is fully provided online and is an already well adapted tool to provide remote alternative or adjunct care to informal dementia caregivers in a situation of social isolation and services restrictions. The use of this tool only requires the caregiver to have a device (computer/tablet/smartphone) with internet connection.	addressing COVID-related challenges.

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	However, iSupport is a very comprehensive training tool and even though caregivers may decide to use only some contents, it still requires some available time to dedicate to the learning process. The world health organization is planning iSupport Lite: a complement to the generic version of iSupport providing accessible public health messages aimed at reducing stress and improving mental health of informal dementia caregivers. This consists in an adaptation of iSupport contents to short, practical, support messages of psychological first aid. If necessary, we can negotiate with WHO the integration of iSupport Lite in this pilot. Another option is to negotiate the insertion of new contents in the comprehensive version of iSupport (e.g., a new training module), aimed at discussing and providing training on the new challenges emerging from the pandemic situation (e.g., manage the changes in routines of people with dementia; managing new and additional safety risks on wandering). This might require the conduction of a short needs assessment study to map some of the new pandemic-related challenges.	

2.3.4 Equipment and devices used (from third parties)

The equipment and devices used in this use case were provided by the SHAPES technical partners, namely UPORTO and UCC. Nevertheless, these partners have contracted external services do develop the platform/website to run the iSupport.

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2.4 Data plan

2.4.1 Data capture methods to be used

Domain / Variable	Collection		Frequency
	Tool	Method	
Sociodemographic			
Caregiver- related data			
Name or anonymized ID	Questionnaire	Online Self-administration	Baseline
Age	Questionnaire	Online Self-administration	Baseline
Gender	Questionnaire	Online Self-administration	Baseline
Education (years in spent in formal education)	Questionnaire	Online Self-administration	Baseline
Marital status	Questionnaire	Online Self-administration	Baseline
Occupational status	Questionnaire	Online Self-administration	Baseline; T1; T2
Reasons for being unemployment	Questionnaire	Online Self-administration	Baseline
Profession	Questionnaire	Online Self-administration	Baseline; T1; T2
Region of Residence	Questionnaire	Online Self-administration	Baseline
Country of Residence	Questionnaire	Online Self-administration	Baseline
Country of Birth	Questionnaire	Online Self-administration	Baseline
Caregiver (formal / informal)	Questionnaire	Online Self-administration	Baseline
Care Recipient – Related data			

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Age	Questionnaire	Provided by the caregiver	Baseline
Gender	Questionnaire	Provided by the caregiver	Baseline
Current residence (own home; facility)	Questionnaire	Provided by the caregiver	Baseline; T1; T2
Degree of Dependence (subjectively evaluated by the informal caregiver)	Questionnaire	Provided by the caregiver	Baseline; T1; T2
Diagnosed with Dementia	Questionnaire	Provided by the caregiver	Baseline
Duration of Dementia symptoms (as perceived by the by the informal caregivers)	Questionnaire	Provided by the caregiver	Baseline
Type of Dementia	Questionnaire	Provided by the caregiver	Baseline
Caregiving- related data			
Type of care provided (formal/informal)	Questionnaire	Online Self-administration	Baseline; T1; T2
Duration of care provision (months /years)	Questionnaire	Online Self-administration	Baseline; T1; T2
Caring for at least 6 or more months (inclusion criteria)	Questionnaire	Online Self-administration	Baseline
Frequency of care provision	Questionnaire	Online Self-administration	Baseline; T1; T2
Existence of other care providers	Questionnaire	Online Self-administration	Baseline; T1; T2
Relationship with the care recipient	Questionnaire	Online Self-administration	Baseline

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Cohabitation with the care recipient	Questionnaire	Online Self-administration	Baseline; T1; T2
Institutional care (Yes/No; inclusion criteria for caregivers of people NOT in institutional care)	Questionnaire	Online Self-administration	Baseline; T1; T2
Continuation /discontinuation of care (Are you currently still a caregiver?) (Yes/No)	Questionnaire	Online Self-administration	T1; T2
Reasons for stop caring	Questionnaire	Online Self-administration	Baseline; T1; T2
Discontinuation of care (How many weeks ago do you stop caring?)	Questionnaire	Online Self-administration	Baseline; T1; T2
Health / Psychological			
Symptoms of anxiety and depression	Hospital and Anxiety Depression Scale	Online Self-administration	Baseline; T1; T2
Burden in provision of care	ZBI – Zarit Burden Interview	Online Self-administration	Baseline; T1; T2
Health satisfaction	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Physical pain / discomfort prevents	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Body acceptance	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Daily medical treatments	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Cognitive – Concentration	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Sex life satisfaction	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Health services accessibility	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2

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Emotional mood	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Quality of life rate	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Self-satisfaction	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Life enjoying	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Life meaningful	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Safe in daily life	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Healthy physical environment	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Living place satisfaction	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Energy for daily life	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Sense of orientation	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Sleep satisfaction	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Daily activities performance rate	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Personal relationships satisfaction	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Financial resources	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Information availability	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Leisure activities rates	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2
Transports satisfaction	WHOQOL- BREF	Online Self-administration	Baseline; T1; T2

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Positive aspects of caregiving	PAC – Positive aspects of caregiving	Online Self-administration	Baseline; T1; T2
Behavioural			
Efficacy – solve difficult problems	General Self-Efficacy Scale	Online Self-administration	Baseline; T1; T2
Efficacy – unexpected events	General Self-Efficacy Scale	Online Self-administration	Baseline; T1; T2
Efficacy – coping abilities	General Self-Efficacy Scale	Online Self-administration	Baseline; T1; T2
Efficacy – think of a solution	General Self-Efficacy Scale	Online Self-administration	Baseline; T1; T2
Attitudes towards online psychoeducational programmes.	OPI-BAS	Online Self-administration	Baseline; T1; T2
Usability and user Experience			
Task success/failure	iSupport	Online collection	During the pilot
Time on Task	iSupport	Online collection	During the pilot
Number of errors	iSupport	Online collection	During the pilot
Usability	System Usability Scale	Online Self-administration	During the pilot

2.4.2 Planning of evaluation

The planning evaluation of this Use Case was provided by the SHAPES Deliverable "D6.1 - SHAPES Pan-European Pilot Campaign Plan" (pp. 127-183), that suggested the MAST and MAFEIP frameworks to assess the impact of the Use Case. The MAFEIP framework couldn't be adopted due to a small-scale deployment of it.

This Use Case adopted the MAST framework (Model for Assessment of Telemedicine) that assess the Use Case's effectiveness and contribution to quality of care. MAST is a multidisciplinary assessment that focuses in 7 domains: (1) Health problem and characteristics of the application; (2) Safety; (3) Clinical effectiveness; (4) Patient's perspective; (5) Economic aspects; (6) Organizational aspects; (7) and Sociocultural, ethical, and legal aspects [21].

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The researchers did a review of these domains and selected those most relevant to this Use Case, namely: Clinical effectiveness (3); and Patient's perspective (4). The Table 4 describes the data required for the MAST evaluation.

Table 4 Use Case 1 - MAST Framework.

Domain	Topic	Outcome	Data Required	Time Point
Clinical Effectiveness	*Effects on mortality*	*Will not be measured.*		
	Effects on morbidity			
	Physical health	Perception of Physical Wellbeing	WHOQOL-BREF EQ-5D-5L	Phase 5 (Baseline and Post-Intervention)
	Mental health	Perception of Psychological Wellbeing	General Self-Efficacy Scale	
	Effects on health-related quality of life			
	Generic measures of quality of life	Satisfaction with Life	WHOQOL-BREF	Phase 5 (Baseline and Post-Intervention)
		Social Support	OSSS-3	
	Disease specific measures of quality of life	*Will not be measured.*		
	Behavioural outcomes	Active Social Participation	WHOQOL-BREF General Self-Efficacy Scale SHAPES Questionnaires (2 items)	Phase 5 (Baseline and Post-Intervention)
	Utilization of health services	*Will not be measured.*		
Patient perspectives	Satisfaction and acceptance	Motivation to use in the future	SUS	Phase 5 (Post-Intervention)

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	Understanding of information	Successful Recruitment	This information is in section 2.9.1 of this deliverable.	Phase 3 (Hands-on Experiments)
	Confidence (in the treatment)	*Will not be measured.*		
	Ability to use the application	Successful Recruitment	This information is in section 2.9.1 of this deliverable.	Phase 3 (Hands-on Experiments)
	Access	*Will not be measured.*		
	Empowerment, self-efficacy	Motivation to use in the future	Interview	Phase 5 (Post-Intervention)

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

The NASSS and the MOMENTUM frameworks were proposed by SHAPES Project in the public report "D6.1 SHAPES Pan-European Pilot Campaign Plan" (SHAPES-WP6, 2020, pp. 117-118). The NASSS framework (Non-adoption, Abandonment, Scale-up, Spread, and Sustainability) was proposed by Greenhalgh et al. (2017) to assess "challenges to achieving sustained adoption and long-term sustainability", by 19 questions, organized in 7 domains, classified in three levels: simple (straightforward, predictable, few components), complicated (multiple interacting components or issues), or complex (dynamic, unpredictable, not easily disaggregated into constituent components). The MOMENTUM (Advancing Telemedicine Adoption in Europe, 2015) is a "validated and tested method to support the telemedicine implementation process and create enabling environments to accelerate telemedicine". This method helps the stakeholders to identify the telemedicine critical factors on a list composed of a set of guidelines and indicators, the MOMENTUM 18 Critical Success Factors List [19-20].

The iSupport is an online educational tool developed and validated by several WHO's experts, but also adapted and validated for local applications, like the Portuguese version of this technology, iSupport-Portugal. Thereby, regarding the NASSS evaluation, overall, no uncertainties were identified, and therefore, no mitigation measures where needed to be developed to ensure the success of the use case

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(Table 5). Nevertheless, researchers highlighted one uncertain and a respective mitigation measure. The technology is to be used in home, autonomously and when user wish. Thereby, it's no possible to control if the user completes the programme or use it. Considering it, during the intervention time, researchers sent notifications weekly to motivate them to use the technology.

Table 5 Use Case 1 - NASSS Assessment.

Domains	How much you agree with the sentence?		
	Agree	Disagree	Don't Know
A) The Illness or Condition **Think about the illness or other condition that the technology is designed for – and what sort of person has that condition.**			
A1) There are significant uncertainties about the condition e.g., poorly defined, variable manifestations, uncertain course.		X	
A2) Many people with the condition have other co-existing illnesses or impairments that could affect their ability to benefit from this solution.		X	
A3) Many people with the condition have social or cultural factors that could affect their ability to benefit from the technology or service.		X	
A4) The population with the condition, and/or how the condition is treated, is likely to change significantly over the next 3-5 years.		X	
A5) The condition has significant complexity which is likely to affect the project's success.			NO
B) The Technology **Think about the technology (e.g., a tool or piece of software), and how it might affect care.**			
B1) There are significant uncertainties in what the technology is (e.g., it hasn't been fully developed yet).		X	
B2) There are significant uncertainties in where the technology will come from (e.g., supply chain issues, substitutability).		X	
B3) There are significant uncertainties about the technology's performance and dependability (e.g., bugs, crashing, cutting out).		X	

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B4) There are significant uncertainties about the technology's usability and acceptability (e.g., key people don't trust the data it provides).	X	
B5) There are significant technical interdependencies.	X	
B6) The technology is likely to require major changes to organisational tasks and routines.	X	
B7) The technology (and/or the service model it supports) is likely to change significantly within the next 3-5 years.	X	
B8) The technology has significant complexity which is likely to affect the project's success.		NO
C) The Value Proposition **Think about what kind of value the technology might generate for different groups of people. ('Value' can be financial, such as profit, or non-financial, such as control of symptoms)**		
C1) The commercial value of the technology is uncertain.		X
C2) The value to the intended users (e.g., patients, clinicians) is uncertain.		X
C3) The value to the healthcare system (e.g., from efficacy and cost-effectiveness studies) is uncertain.		X
C4) The value to this particular healthcare organisation, given the current situation locally, is uncertain.		X
C5) The technology could generate a negative value (costs are likely to outweigh benefits) for some stakeholders.		X
C6) The value proposition is likely to change significantly over the next 3-5 years.		X
C7) The value proposition has significant complexity which is likely to affect the project's success.		NO
D) The Intended Adopters **Think about who is intended to use the technology and what changes it will bring for them.**		
D1) There is uncertainty about whether and how patients/citizens will adopt the technology (if applicable).	X	
D2) There is uncertainty about whether and how front-line staff will adopt the technology.	X	
D3) There is uncertainty about the implications for people who might be indirectly affected by the technology.	X	

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D4) There will be significant changes to individual users' perceptions of the technology over the next 3-5 years.	X	
D5) There is significant complexity relating to intended adopters which is likely to affect the project's success.		NO
E) Organization readiness **Some organisations are better at taking up innovations than others. What about yours?**		
E1) The organization's capacity to take on technological innovations is limited.	X	
E2) The organization is not ready for this particular innovation.	X	
E3) The organization would find it hard to commission/purchase the innovation.	X	
E4) The work needed to introduce and routinise the innovation has been underestimated and/or inadequately resourced.	X	
E5) The organization(s) involved are likely to have significant restructurings or changes in leadership, mission or strategy over the next 3-5 years.	X	
E6) There is significant complexity relating to one or more participating organizations which is likely to affect the project's success.		NO
F) The External Context **Think about external conditions that could complicate adoption and spread of the innovation.**		
F1) The political and/or policy climate is adverse.	X	
F2) Professional bodies are opposed to the innovation or don't actively support it.	X	
F3) Patient organisations and lobbying groups are opposed to the innovation or don't actively support it.	X	
F4) The regulatory context is adverse.	X	
F5) The commercial context is adverse.	X	
F6) Opportunities for learning from other (similar) organisations are limited.	X	

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F7) Introduction of the technology/innovation could be threatened by external changes that impact on the organisation.	X	
F8) The policy, regulatory and economic context for this innovation is likely to be turbulent over the next 3-5 years.	X	
F9) There is significant complexity relating to the external context which is likely to affect the project's success.		NO

Regarding the MOMENTUM critical success factors (CSFs) [20], this digital solution was ready to provide telemedicine in the healthcare system and in the social care sector. Nevertheless, it was relevant to analyse the use case to consider its scaling up as a telemedicine integrated into healthcare delivery systems.

CSF 1. Cultural readiness for the telemedicine service: Not applicable.

CSF 2. Advantages of telemedicine in meeting compelling need(s): Not applicable.

CSF 3. Ensure leadership through a champion: The technology was developed by an acknowledge organization (WHO), validated, and tested by scientific studies, and recommended by advocacy organization (Alzheimer association).

CSF 4. Involvement of healthcare professionals and decision-makers: iSupport was originally designed to informal caregivers. Professionals can refer iSupport to informal caregivers of people with dementia.

CSF 5. Put the patient at the center of the service: iSupport was originally designed for informal caregivers. This programme helps them provide quality care and self-care, for free, via your computer/mobile/tablet and at a time, place and day that is convenient for the user. Caring for a person with dementia can be rewarding but also difficult, stressful, and tiring. iSupport offers tips, advice and training on how to care, better manage the difficulties associated with caring and promote own wellbeing of informal caregiver.

CSF 6. Ensure that the technology is user-friendly: A mixed-methods study was conducted to evaluate if the technology was user-friendly: a focus group to understand people's beliefs, opinions, and attitudes about it; the usability tests to observe the interactions of users with a system. The study was published in a scientific article [5].

CSF 7. Pull together the resources needed for deployment: The resources required for the deployment of the digital solutions in this UC are provided to SHAPES

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funding and internal resources already allocated. The technical partners of the use case provide all IT competences.

CSF 8. Address the needs of the primary client(s): To be consulted in CSF5.

CSF 9. Prepare and implement a business plan: The solution can't be commercialized.

CSF 10. Prepare and implement a change management plan: It must be evaluated at the end of the project.

CSF 11. Assess the conditions under which the service is legal: The assessment of the conditions under which the service is legal is still to be done. Since this digital solution is not specifically considered a medical device, requirements might not need to be considered. Completion of a Data Protection Impact Assessment (DPIA) to identify and minimize any risks associated with the pilot with input sought from other work packages and the SHAPES Data Protection Officer at AUTH. Data processing agreements to established with relevant partners to permit access to pseudonymized data.

CSF 12. Guarantee that the technology has the potential for scale-up: The Portuguese version is already adopted in a large-scale in Portugal. Results and evidence must be published in scientific reviews as soon as possible. The Irish version is now in the first phase of validation.

CSF 13. Identify and apply relevant legal and security guidelines: GDPR was applied. The system provided implements all security and privacy related regulations.

CSF 14. Involve legal and security experts: This use case was approved by two different national ethical committees: Ethics Committee of the Faculty of Medicine of Porto, 2022 (62/CEFMUP/2022); The Social Research Ethics Committee of University College Cork, 2023. It was assessed by the Data Protection Officer of University of Porto and SHAPES Ethical Advisory Board, detailed in the following documents: Data Plan; Data Mapping; DPIA; and Data Sharing Agreement.

CSF 15. Ensure that telemedicine doers and users are privacy aware: Not applicable.

CSF 16. Ensure that the information technology infrastructure and eHealth infrastructure are available: SHAPES is developing a technology platform for pan-European distribution of telemedicine services. The pilot is being designed to cope with this requirement as well.

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CSF 17. Put in place the technology and processes needed to monitor the service: The IT system should work 24/7. In case of any bugs or issues the development and maintenance team fixed it. UPORTO and UCC are the owners of all the software that is used in the pilot. This means that we don't have any software dependencies with third parties, and that we can fix the source code at any point. The system logs all activities so any incident can be identified and solved quickly.

CSF 18. Establish and maintain good procurement processes: The Portuguese version is already adopted in a large-scale in Portugal. Results and evidence should be published in scientific reviews as soon as possible. The Irish version is now in the first phase of validation.

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2.5 Phase 1

2.5.1 PACT and FICS Scenario

2.5.1.1 PACT

Code	UC-PT5-001
Applicable SHAPES Persona	SHAPES Persona "John and Joan" (P4)
Applicable SHAPES use case	iSupport - Online Information and Training for Informal Caregivers
People Roles and/or actors of typical users involved in delivering and receiving the telemedicine intervention	Beneficiaries: Informal Caregivers of people with dementia. Details: Middle-aged adult (46 years). Well-educated (14 years of formal education; holds a bachelor degree). Employed (full-time job). Middle-income. Offspring caregiver. Digitally literate with high affinity to technology uses of internet daily in his work at the factory using a PC; and uses internet on a daily basis for personal purposes on a tablet or a smartphone. Moderate health literacy. Currently struggling with several stressors regarding care provision including time constraints, lack of time to rest; not able to travel/take holidays; faces financial pressures and needs support. Symptoms of caregiver burden and anxiety: often tired, worried, frustrated, impatient, impulsive, feels guilty and has negative thoughts.
Activities Activities to be performed by the actors in order to provide and receive the telemedicine intervention successfully procedures for the professional and the patient; Parameters that determine the measures used in the intervention	Logs in the iSupport programme webpage, selects lessons according to specific self-perceived needs, self-evaluates his mood status.
Context Social-medical relevance of the telemedicine intervention; privacy issues; risks for the patient; locations	Travel time savings. Increased offer of psychosocial interventions for informal dementia caregivers. 24/7 availability: convenient access. Ubiquitous intervention; can be used anywhere with internet connection.

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	No risks foreseen. Secure platform for data privacy. Customizable to caregivers needs (no need to follow a theme and/or programme).
Technology Type of information/parameter that are relevant in monitoring the health status; type and frequency of accessibility of information; feedback modalities (communication)	iSupport is an internet-based training and support program for informal carers of people with dementia that was originally designed by the World Health Organization. This digital solution contains: Modules and lessons: Five modules with 23 lessons approaching well-established thematic needs of informal dementia caregivers. Allows the collection of data lessons accessed (when and which) and repeated by each user. A sub-component of each lesson is interactive exercises with immediate feedback (e.g., drag and drop, free text, checklist). My plan: functionality allowing the definition of a plan of lessons personalized to the convenience and needs of each informal dementia caregivers. Data on lessons added to the personalized plan by all users can be collected. My mood: module for a self-evaluation of the mood status (in a scale on 1 to 10) with the option of adding a description of the mood status. Quantitative and qualitative (text) data can be collected with this module concerning caregivers' mood status. It was a complementary functionality to the program (rather than central to the support and training program). My printouts: module for a personalized printing of lessons that reflect the interaction of users with the system, i.e., each printable document results in the importation of interaction elements with the platform such as the answers to all exercises. Those printouts should then reflect the leaning process per user.

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2.5.1.2 FICS

Code	UC-PT5-001		
Applicable SHAPES Persona	SHAPES Persona “John and Joan” (P4)		
Applicable SHAPES use case	iSupport - Online Information and Training for Informal Caregivers		
Function and events The functionality of the intended system which is capable of realizing actor’s activities	**Priority level**	**Requirement**	**Justification**
	M	Skills training exercises are available as free text answer, drag & drop or check list.	To accommodate different users’ learning preferences and styles.
	M	The drag & drop and checkbox exercises aimed at training skills and test knowledge present immediate feedback on answers.	To increase users’ engagement with exercises, reduce errors and minimize ‘test anxiety’.
	M	Feedback is provided by using distinctive colours (red- incorrect, green-correct, blue-possible answer) and by offering detailed text-based explanations.	To allow for a quick performance feedback and also for a full and detailed feedback.
	M	The text contents in the programme adapted to users’ information (e.g., name, gender/ name, gender of the person being cared for).	To increase personalization and mimic the targeted approach in face-to-face interventions (where the user is known, treated by his/her name); to increase the user’s sense of engagement.
	M	The intervention plan (lessons to be performed) is chosen by the users according to their own needs and availability.	To increase the sense of personalization and motivation towards the programme; to decrease dropout due to the perception of being trained on unsuitable topics to the user’s particular case.
	M	The intervention plan has by default the suggestion of five core lessons,	To increase the chance of users receiving training on most pressing topics for

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		automatically added to 'my plan'.	dementia caregivers; and to decrease the chance of dropping out before completing 5 core lessons.
	M	The intervention plan set by the user can be modified at any time (lessons can be added or deleted).	To ensure personalization, users can update their training plans to changing needs.
	M	A star icon marks lessons added to my plan and a check icon marks lessons already concluded.	Users must keep track of their training activities in the programme.
	M	Lessons start in the page where the users' left in his/her previous access.	Users must keep track of their training activities; to avoid time spent on locating 'where they were' in the programme.
	M	A mood assessment function is available for self-completion with ratings and free text assessment options. A mood graph/mood history is displayed to represent mood progress over time.	To increase self-awareness of mood status; mood status monitoring is important for burdened, anxious or depressed caregivers.
	S	Mood ratings of 4 or lower should direct the users to relaxation and/or cognitive reframing lessons.	To increase the responsiveness of the programme to the users' mood status.
	M	A printout module is available to print personalized booklets of the sessions mirroring the user learning process.	To cover diverse preferences for reading programme's materials (online vs. paper); to increase engagement by offering personalized booklets of the lessons.
	M	Skills certificates are generated after lesson completion.	To reinforce/motivate the user for the learning process.
	M	Seven different relaxation exercises are available with options based on	Relaxation exercises are important to burdened anxious or depressed persons. To accommodate relaxation preferences

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		muscular relaxation and on imagery-based relaxation.	(mental vs. physical based) and health conditions impeding e.g., muscular relaxation (e.g., paralysis).
	M	Relaxation exercises instructions are available in text and audio.	To accommodate different preferences in learning the instructions of relaxation exercises.
	M	Realistic scenarios are used to train skills.	To increase the degree of users' relatedness with the programme contents; to facilitate skills training through learning by modelling.
	M	Satisfaction ratings (on usefulness and comprehensiveness) are available at the end of each lesson (star ratings).	To increase users' awareness on the usefulness and comprehensiveness of each lesson; to inform in the need to perform a lesson again (if not understood).
	M	Users can add new options to specific answer lists.	To increase accuracy and personalization, option others than listed should be added by the users.
Interactions and usability issues	**Priority level**	**Requirement**	**Justification**
	S	The password registration field must be non-sensitive to spaces entered before and after.	Space sensitive password fields increase the number of failures when looking to login into the programme and increase the number of contacts to the technical support.
	S	The programme logo and the top of the page should have linking options to the landing page of the website.	While using the programme, users sometimes which to come back to the landing page.
	C	More than one mood status could be added per day.	Users may visit the programme more than once a day and experience different mood status in each visit.
	C	The scale for mood assessment should	The scale discriminates only the extremes (1 & 10). The users

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		discriminate the numbers from 1 to 10.	perceive that is easy to classify the mood with all numbers discriminated.
	C	The 'My mood' page should appear automatically at the beginning and end of each lesson.	To prevent underreporting of the users' mood status and to monitor the effects of the lessons on mood status.
	C	The 'next' and the 'previous' buttons in each lesson should be both texts based.	Users tend to use the 'next' button to advance in lessons but use the browser button to visit the previous page.
	C	A button to start the lesson from the beginning could be added.	While the programme memorizes and starts where the users left, off some users would like to start the lesson from the beginning to review the full contents. This is currently only possible by using the back button page by page.
	C	The printing option should be available directly when clicking at each lesson.	In general, the option of printing was overlooked on the menu. The participants suggested that a printing option/icon should be available directly on the lesson list.
	C	Drag and drop exercises should have the feedback displayed in the visible page area.	Feedback on answers given by the users to drag and drop exercises is displayed on the top of the page. When there are several answers options the user may not note that the feedback is being given above.
	C	Information icons in check list exercises should be replaced by automatic display of information when the answer is selected.	Information icons are sometimes overlooked by users and the information is missed.
	C	Professionals should be able to register in the programme in a separate registration page.	While the programme is targeted at caregivers, professionals must be able to visit the programme in order to recommend it. A registration

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			area for professionals would be relevant.
Content and structure Variables of the interaction	**Priority level**	**Requirement**	**Justification**
	M	The home page requires a visual lesson scheme.	While lessons are listed, the users need a visual representation of lessons structure to guide them.
	C	The lesson 'Improve communication' should be added to the 5 core recommended lessons.	Users believe that this is a core lessons that should be included in the recommended list.
	C	Contents on legal aspects, social support mechanisms, disease progression and anticipatory grief should be added to the programme.	Users have reported these needs in terms of training contents.
Style and aesthetics Look and feel of the system	**Priority level**	**Requirement**	**Justification**
	C	Illustrations can be remade.	Some users found the illustrations somehow puerile.
	C	The 'sad' and 'happy' faces in the 'My mood' evaluation should change colours according mood ratings.	A colour scheme reinforces the representation of the mood status.
	C	In drag & drop exercises the answer options should be in a neutral colour rather than in green, while unanswered.	Since correct answers are displayed in green, the fact that unanswered options are also in green is confusing for the users.
	C	Fonts/colour fonts should be different for text containing general information and text for scenarios.	Different fonts/font colours for both types of texts would benefit the readability.
	C	The landing page should have more visual elements (e.g., images, catchy sentences) clarifying who is the platform target group.	Visual elements would benefit the comprehension of the platform's target group immediately after accessing its landing page.

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2.5.2 Key performance indicators

Key Performance Indicators (KPIs) are defined as a set of measures that focus on the factors most critical to a project's success. KPIs are measurable and quantifiable with a target or threshold. They measure performance in critical areas by showing the progress or lack of it towards realizing the objectives of each specific use case. The following KPIs have been chosen to determine whether, or not, the pilot for this use case has been successful. Failure to meet four or more of the KPIs will indicate that repetition or major revisions to the use case and associated digital solutions are needed before entering further development oriented to further validation of technology benefits and commercialization.

The list of KPIs (Table 1) was developed considering the outcomes and lessons learned in the scientific evaluation of the iSupport-Portugal [14-18].

Table 6 Use Case 1 - List of KPIs.

Code	KPIs explained	KPIs	Measurement
KPI_1_OB **Burden**	In a protocol testing pilot carried out with 15 users, caregivers showed an average decrease of one point in burden (ZBI) (11% decrease) three months after registering for the programme. Contrasting the average decrease of burden with the percentage of caregivers showing less burden is relevant to consider those who experienced an increase in burden.	Decreased perceived burden after three months of intervention (10%)	ZBI total average scores (T0-T1).
KPI_2_OA **Anxiety**	In a protocol testing pilot carried out with 15 users, caregivers showed an average decrease of two points in anxiety (HADS) (10% decrease) three months after registering into the programme. Contrasting the overall decrease of anxiety with the percentage of caregivers showing less anxiety is relevant to consider those who seen anxiety increase.	Decreased perceived anxiety after 3 months of intervention (15%)	HADS anxiety subscale total average scores (T0-T1).
KPI_3_OD **Depression**	In a protocol testing pilot with 15 users, caregivers showed an average decrease of only half point in depression (HADS) (2% decrease) three months after registering the	Decreased perceived depression after three months of	HADS depression subscale total

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	programme. Contrasting the overall decrease of depression with the percentage of caregivers showing less depression is relevant to consider those who seen depression increase.	intervention (10%)	average scores (T0-T1).
KPI_4_OPQ **Physical QoL**	In a protocol testing pilot carried with 15 users, caregivers, on average, maintained the scores in WHOQOL-BREF for psychical QoL three months after registering for the programme. Contrasting the overall increase of QoL with the percentage of caregivers showing higher physical QoL is relevant to consider those who seen QoL decreases.	Increase in physical QoL after 3 months of intervention (5%).	WHOQOL-BREF average physical QoL raw scores (T0-T1).
KPI_5_OPSQ **Psychological QoL**	In a protocol testing pilot carried with 15 users, caregivers, on average, maintained the scores in WHOQOL-BREF for psychological QoL three months after registering the programme. Contrasting the overall increase of QoL with the percentage of caregivers showing higher psychological QoL is relevant considering those who seen QoL decrease.	Increase in psychological QoL after three months of intervention (5%)	WHOQOL-BREF average psychological QoL raw scores (T0-T1).
KPI_6_OSQ **Social relationships**	In a protocol testing pilot carried with 15 users, caregivers, on average, maintained the scores in WHOQOL-BREF for social QoL three months after registering into the programme. Contrasting the overall increase of QoL with the percentage of caregivers showing higher social QoL is relevant considering those who seen QoL decrease.	Increase in social QoL after three months of intervention (5%)	WHOQOL-BREF average social QoL raw scores (T0-T1).
KPI_7_OEQ **Environmental QOL**	In a protocol testing pilot carried with 15 users, caregivers, on average, maintained the scores in WHOQOL-BREF for environmental QoL three months after registering into the programme. Contrasting the overall increase of QoL with the percentage	Increase in environmental QoL after three months of intervention (5%)	WHOQOL-BREF average environmental QoL raw scores (T0-T1).

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	of caregivers showing higher environmental QoL is relevant considering those who seen QoL decrease.		
KPI_8_OGS **General Self-efficacy**	In a protocol testing pilot carried with 15 users, caregivers, on average, maintained the scores in GSE scale three months after registering into the programme. Contrasting the overall increase of GSE with the percentage of caregivers showing higher self-efficacy is relevant considering those who seen self-efficacy decrease.	Increase in general self-efficacy after three months of intervention (5%)	GSE average scores (T0-T1).
KPI_9_OPAC **Positive aspects of caring**	In a protocol testing pilot carried with 15 users, caregivers improved one point on average in the PAC scores (9%) three months after registering into the programme. Contrasting the overall increase in PAC with the percentage of caregivers showing higher self-efficacy is relevant considering those who seen PAC decrease.	Increase in positive aspects of caring after three months of intervention (10%)	PAC average scores (T0-T1).

2.5.3 Timeline of pilot activities

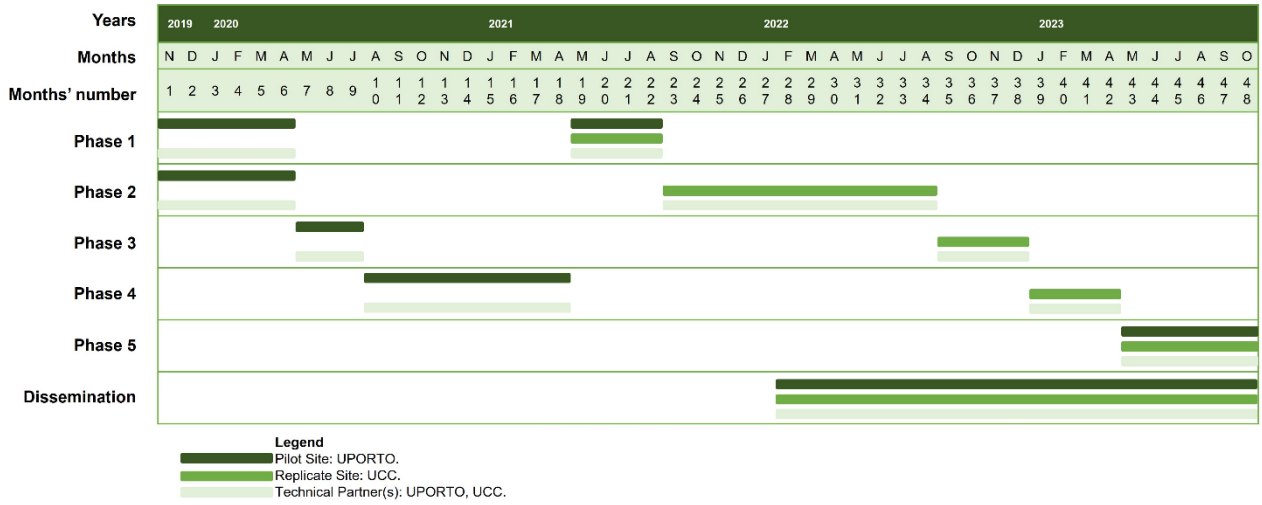

Figure 24: Use Case 1 - Timeline of pilot activities.

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2.6 Phase 2: Testing of mock-ups and prototypes

2.6.1 Methodology of testing

iSupport-Portugal: The technical experiments were developed by the University of Porto IT services, and their outcomes are detailed in a report that identifies the security vulnerabilities. This report is confidential and to request it, please email: incidente.seguranca@uporto.pt.

iSupport-Ireland: The technical experiments were developed by the company Itero Software (Esme Consulting Ltd.), and their outcomes are detailed in a report that identifies the security vulnerabilities. This report is confidential and to request it, please email: richard@itero.ie and prabhin@itero.ie.

2.6.2 Results of testing

The technical tests were developed, and technical experts have ensured that technology was ready to be used with recommendations:

- Cross site scripting: Apply context-dependent encoding and/or validation to user input rendered on a page.
- Vulnerable JavaScript libraries: Upgrade to the latest version.
- Clickjacking (CSP frame-ancestors missing): Configure your web server to include a CSP header with frame-ancestors directive and an X-Frame-Options header. Consult Web references for more information.
- Clickjacking: X-Frame-Options header: Configure your web server to include an X-Frame-Options header and a CSP header with frame-ancestors directive. Consult Web references for more information.
- Cookies with missing, inconsistent or contradictory properties: Ensure that the cookies configuration complies with the applicable standards.
- Cookies without Secure flag set: If possible, you should set the Secure flag for these cookies.
- HTTP Strict Transport Security (HSTS): It's recommended to implement HTTP Strict Transport Security (HSTS) into your web application.
- Content Security Policy (CSP) not implemented: It's recommended to implement Content Security Policy (CSP) into your web application. Configuring Content Security Policy involves adding the Content-Security-Policy HTTP

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header to a web page and giving it values to control resources the user agent is allowed to load for that page.

- Email addresses: Check references for details on how to solve this problem.

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2.7 Phase 3: Hand-on Experiments

2.7.1 Methodology of hands-on experiments

This information is detailed in-depth in the articles:

- Teles, S., Ferreira, A., & Paúl, C. (2022). Feasibility of an online training and support program for dementia carers: results from a mixed-methods pilot randomized controlled trial. BMC Geriatrics, 22, 173, doi.org/10.1186/s12877-022-02831-z

Resume: “A mixed-methods randomized controlled trial with two arms (iSupport-Portugal vs. education-only e-book) was followed. A factual analysis based on qualitative data allows to address the processes of how and why an intervention may work/not work. The study is single blinded as participants are aware of the intervention received. Assessments were taken at baseline (T0), 3months (post-test/T1) and 6months (follow-up/T2) after baseline using self-administered instruments, filled out online, with no interference of researchers. Attrition prevention measures included: 1) sending out analogous weekly email reminders to participants in both arms, to either use iSupport or check the e-book. Reminders were sent from baseline to post-test; 2) contacting, a week after allocation, the participants in iSupport’s arm not yet registered into the program, to check for technical difficulties; and 3) sending out up to two email reminders to fill in post-test and follow-up assessments. (p. 3)” [18]

- Teles, S., Paúl, C., Lima, P., Chilro, R., Ferreira, A. (2021). User feedback and usability testing of an online training and support programme for dementia carers. Internet interventions. 100412, doi.org/10.1016/j.invent.2021.100412

Resume: “A mixed-methods study was conducted. Focus groups discussions and usability test sessions were performed. Focus groups are a useful strategy to understand people's beliefs, opinions and attitudes about a given topic, and especially the development of reasoning in the process of discussing with others (Britten et al., 1995). Usability tests allow observing the interaction of users with a system (International Organization for Standardization, 2010) and may include both qualitative and quantitative data collection techniques. Both carers and professionals participated in focus groups and usability tests: the first as prospective target-users of iSupport, and the second as prospective ‘prescribers’ of the program and knowledgeable persons on the needs of family carers. (p. 3)” [16]

- Teles, S.; Paúl, C.; Ferreira, A. (2021). Acceptability of an online training program for dementia caregivers: Results from a mixed-methods pilot randomized controlled trial (Abstract in journal). Alzheimer's & Dementia (supplement) 17 S11: http://dx.doi.org/10.1002/alz.052309.

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Resume: “A mixed-methods two arm RCT was carried. Participants were recruited through the Alzheimer’s Association. Inclusion criteria are being a non-paid caregiver; for at least six months; experiencing a clinically relevant level of burden (≥ 21 on ZBI) or depression or anxiety symptoms (≥ 8 on HADS). Eligible participants were randomized to either iSupport-Portugal or the control arm (e-book). Repeated measurements were collected at baseline, three (T1) and six months after baseline. Semi-structured interviews were conducted. Usage data until T1 was extracted from iSupport’s platform. A content analysis was performed for interview data. Forty-two participants were allocated to the intervention (n=21) and control (n=21) arms. Caregivers in the intervention arm are mostly female (81%), middle-aged (M 49 years) and highly educated (M 15.8 years of schooling). Most (81%) are children of the person with dementia, provide long-term (Mdn 3 years) and intensive care (Mdn 29 hrs/week). Scores on ZBI (Mdn 38) and HADS-anxiety (Mdn 12) suggest moderate to high levels of burden and anxiety. (Abstract)” [17]

2.7.2 Results of the hands-on experiments

This information is detailed in-depth in the articles:

- Teles, S., Ferreira, A., & Paúl, C. (2022). Feasibility of an online training and support program for dementia carers: results from a mixed-methods pilot randomized controlled trial. BMC Geriatrics, 22, 173, doi.org/10.1186/s12877-022-02831-z

Resume: “Offering accessible, acceptable, and effective interventions for informal dementia carers is a strategic priority in the Global Action Plan on the Public Health Response to Dementia [55]. This study suggests that a European-Portuguese version of the WHO’s iSupport program has good acceptability and promising preliminary results on carers mental health, knowledge, and well-being. However, a full-scale RCT is needed to determine iSupport’s effectiveness and this pilot suggests its feasibility together with measures to optimize the study protocol. Improvements on iSupport’s contents and interface are also suggested. Accounting for the high prevalence of dementia and high rate of informal home care in Portugal, iSupport may be a relevant adjunct support for Portuguese carers. (p. 15)” [18]

- Teles, S., Paúl, C., Lima, P., Chilro, R., Ferreira, A. (2021). User feedback and usability testing of an online training and support programme for dementia carers. Internet interventions. 100412, doi.org/10.1016/j.invent.2021.100412

Resume: “The deployment of accessible, acceptable, and effective training and support interventions for informal dementia carers is a strategic priority on dementia.

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iSupport might be a valuable alternative or adjunct care approach for dementia carers, even more in the current pandemic scenario. In the context of eHealth interventions, a usable interface may reduce barriers to use, enhance user experience and engagement, and minimize dropout. Results from this study were encouraging in suggesting that iSupport is a feasible means of providing accessible information and training for digitally literate informal dementia carers. The fact that several usability issues were uncovered, showed that usability evaluations of eHealth interventions are highly recommended as those support researchers and developers in determining its adequacy and usefulness and may be cost saving. While this study was designed to improve the European-Portuguese version of iSupport, the methods followed to assess usability and gather user requirements can be reproduced as part of a user-centered design in any eHealth intervention. This paper populates the scarce literature on the usability of eHealth interventions, and lessons learnt may offer relevant information to other country specific versions of iSupport under development and to other same-purpose programs. (pp. 10-11)" [16]

- Teles, S.; Paúl, C.; Ferreira, A. (2021). Acceptability of an online training program for dementia caregivers: Results from a mixed-methods pilot randomized controlled trial (Abstract in journal). Alzheimer's & Dementia (supplement) 17 S11: http://dx.doi.org/10.1002/alz.052309.

Resume: "Positive attitudes towards online psychoeducation were revealed (Mdn 24 on OPI-BAS scale). Twelve caregivers were interviewed, including dropouts. At T1, 85.7% of participants have used the program; 38.9% discontinued its use within two weeks, 66.7% within ten. On average, iSupport was accessed 8 times and 12.5 lessons were visited (in 23). One-time-only visitors printed the lessons (n=2); offline use is possible. Lessons on communication and shared decision making were the most visited (>90%). The qualitative data informs on the motivations and deterrents to use iSupport, usage styles, and perceived results. A moderate acceptability of iSupport-Portugal is suggested and might be improved with minor content and interface adjustments. Despite heterogeneous usage patterns, iSupport was mostly used intensively and during a few weeks. Conducting a re-assessment (T1) earlier might be adequate. When nationally releasing iSupport, research on usage data must consider potential biases from unknown offline use. This pilot may inform improvements on iSupport country-specific versions. (Abstract)" [17]

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2.8 Phase 4: Small Scale Live Demonstration

In this use case, the phase 4 corresponded to the evaluation and intervention studies developed in Portugal do build and validate the Portuguese version of iSupport. These studies are documents in detail in the following articles:

- Teles, S., Ferreira, A., Seeher, K., Fréel, S., Paúl, C. (2020). Online training and support program (iSupport) for informal dementia caregivers: protocol for an intervention study in Portugal. BMC Geriatrics 20, 10, doi:10.1186/s12877-019-1364-z
- Teles, S.; Paúl, C.; Ferreira, A. (2021). Acceptability of an online training program for dementia caregivers: Results from a mixed-methods pilot randomized controlled trial (Abstract in journal). Alzheimer's & Dementia (supplement) 17 S11: http://dx.doi.org/10.1002/alz.052309.
- Teles, S., Paúl, C., Lima, P., Chilro, R., Ferreira, A. (2021). User feedback and usability testing of an online training and support programme for dementia carers. Internet interventions. 100412, doi.org/10.1016/j.invent.2021.100412
- Teles, S., Ferreira, A., & Paúl, C. (2022). Feasibility of an online training and support program for dementia carers: results from a mixed-methods pilot randomized controlled trial. BMC Geriatrics, 22, 173, doi.org/10.1186/s12877-022-02831-z

2.8.1 Recruitment of participants

This information is detailed in-depth in the article:

- Teles, S., Ferreira, A., Seeher, K., Fréel, S., Paúl, C. (2020). Online training and support program (iSupport) for informal dementia caregivers: protocol for an intervention study in Portugal. BMC Geriatrics 20, 10, doi:10.1186/s12877-019-1364-z

Resume: “Informal caregivers of people with dementia are screened to assess whether they are (i) Portuguese adults (≥18 years); (ii) giving consent to participate (Electronic Informed Consent); (iii) providing non-paid care for at least 6 months at the time of the recruitment; (iv) caring for a person holding a formal diagnosis of dementia; and (v) be skilled to use the internet. For inclusion, the IC (vi) must also experience either a clinically relevant level of subjective burden, determined by a total score ≥ 21 on the Zarit Burden Interview (ZBI) or depression or anxiety symptoms, determined by a score ≥ 8 in at least one of the subscales of the Hospital Anxiety and Depression

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Scale (HADS). Participants matching the inclusion criteria was excluded if (i) they are unable to comprehend written Portuguese or (ii) do not have access to a device with internet connection at least twice a week. If (iii) the care receiver is in institutional care (e.g., nursing home or continued care unit), the participant is also excluded. How each inclusion and exclusion criteria are ascertained is described below (see 2.2.2. Sampling and recruitment). Both excluded participants and participants assigned to the control group was offered the opportunity to use iSupport after the study closure, in case of manifested interest. A consecutive (nonprobability) sampling strategy is employed, by consecutively selecting subjects who meet the entry criteria. Potential participants are referred by health professionals from national Alzheimer's associations (not for profit organizations offering support in the community to IC of PwD) who are aware of the formal dementia diagnosis of the care receivers. Due to feasibility constraints, an independent diagnosis or second diagnosis of the care receivers wasn't obtained. (p. 3)" [15]

2.8.2 Technical aspects & Logistics

This information is detailed in sections 2.3 and 2.5.1 of this deliverable.

2.8.3 Roles and Responsibilities

This information is detailed in-depth in the article:

- Teles, S., Ferreira, A., Seeher, K., Fréel, S., Paúl, C. (2020). Online training and support program (iSupport) for informal dementia caregivers: protocol for an intervention study in Portugal. BMC Geriatrics 20, 10, doi:10.1186/s12877-019-1364-z

Resume: "iSupport for dementia – European-Portuguese version. The intervention group provided access, for 3 months, to an online self-help training and support program: the iSupport for dementia – European-Portuguese version. The e-program offers information, skills training and support for IC of PwD. It comprises five modules, including twenty-three lessons covering well-established topics on dementia and caregiver support. In line with good practices on digital engagement, the education plan can be personalized by the caregiver. This means that it can be adjusted to the person's availability and lessons can be selected according to particular needs. Each lesson includes interactive exercises with immediate feedback; and positive messages as well as 'skills certificates' are displayed when lessons are completed aiming at increasing adherence. From a methodological perspective, those elements are not

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understood as prompting a differential follow up bias for both arms - the comparison condition does not offer feedback and positive messages - as those are part of the intervention features. Framed as a multi-component intervention, iSupport is grounded in problem-solving and cognitive behavioural therapy techniques including psychoeducation, behavioural activation, cognitive reframing, relaxation and antecedent-behaviour-consequence (ABC) analysis (unpublished observations; Pot, 2018). Together with access to iSupport, the participants allocated to the intervention group received weekly reminders to use the program. (pp.6-7)" [15]

2.8.4 Ethical considerations

This information is detailed in-depth in the article:

- Teles, S., Ferreira, A., Seeher, K., Fréel, S., Paúl, C. (2020). Online training and support program (iSupport) for informal dementia caregivers: protocol for an intervention study in Portugal. BMC Geriatrics 20, 10, doi:10.1186/s12877-019-1364-z

Resume: "This study was approved by the Ethics Committee for Health of the São João University Hospital Center/Faculty of Medicine of the University of Porto (reference 208/18; scientific title "Internet-based support and training for informal caregivers of people living with dementia"; contact: comissao.etica@chsj.min-saude.pt). The Additional file 2 provides the participant information form and the consent form. The trial is set in Portugal and executed by the Institute of Biomedical Sciences Abel Salazar (University of Porto) and Center for Health Technology and Services Research (CINTESIS) with the support of the National Alzheimer's Association (Associação Alzheimer Portugal). Confidentiality was ensured before, during and after the study. Important protocol amendments must be communicated to the Ethics Committee for Health of the São João University Hospital Center/Faculty of Medicine of the University of Porto, to the trial registry (Trials.gov) and to journals publishing trial related information. (p. 11)" [15]

2.8.5 Outcome of the Small-Scale Live Demonstration

This information is detailed in-depth in the article:

- Teles, S., Ferreira, A., Seeher, K., Fréel, S., Paúl, C. (2020). Online training and support program (iSupport) for informal dementia caregivers: protocol for an intervention study in Portugal. BMC Geriatrics 20, 10, doi:10.1186/s12877-019-1364-z

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Resume: “The outcomes of this study have been widely used in intervention studies assessing the effectiveness of internet-based support tools. The primary outcome is caregiver burden measured with the Zarit Burden Interview (ZBI), Portuguese validated version, total score, at t1. The instrument comprises 22 items answered on a 5-point scale, ranging from 0 (never) to 4 (almost always) except for the final question on global burden, rated from 0 (not at all) to 4 (extremely). Total score for the ZBI ranges from 0 to 88 points, with higher scores indicating greater burden. The ZBI has good internal consistency (e.g., α = 0.89), test-retest and interrater reliability as well as construct and concurrent validity, including reports of positive correlation with depression symptoms and time devoted to care provision. Regarding the psychometric properties of ZBI in Portugal, face, content, ecological, discriminant and convergent validity were documented, along with test-retest reliability (ICC = 0.93, CI95% 0.88–0.96, $p < 0.001$) and internal consistency (α = 0.88). The ZBI is one of the most used instruments to measure burden in intervention studies with caregivers. The following variables are included as secondary outcomes: (i) symptoms of depression and anxiety measured through the Portuguese version of the Hospital Anxiety and Depression Scale (HADS), total scores. The instrument comprises two subscales with 7 items each, using a 4-point scale. Total scores for each scale range from 0 to 21, with higher scores indicating more severe anxiety or depression symptoms; (ii) quality of life measured by the Portuguese version of the WHOQOL-BREF physical, psychological, social relationships and environment, total transformed scores. The instrument contains 26 items, for total transformed scores ranging between 0 to 100 points, with higher scores denoting higher quality of life; (iii) positive role appraisals mediating between the stressor and caregiver well-being, measured through the Portuguese version of Positive Aspects of Caregiving (PAC), total score. This instrument comprises 11 items answered in a 5-point scale, for a total score ranging between 11 to 55 points and higher scores representing more positive appraisals; and (iv) general self-efficacy, measured through the total score of the Generalized Self-efficacy Scale. The scale comprises 10 items answered in a 4-point scale for a total score ranging between 10 to 40 points, and higher scores representing a higher general self-efficacy. (pp. 7-8)” [15]

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2.9 Phase 5: Large-scale pilot activity

2.9.1 Recruitment of participants

The participants were informal caregivers of people with dementia, selected by the following eligibility criteria (Table 7).

Table 7 Use Case 1 - Recruitment criteria.

Inclusion Criteria	Exclusion Criteria
• 18 years or older. • Unpaid for care for at least 6 months. • The Care Recipient with a formal diagnosis of dementia. • Ability to use the internet autonomously. • Clinically relevant levels of overload (score ≥ 21 on the Zarit Burden). • OR of anxious OR depressive symptomatology (score of ≥ 8 on at least one of the subscales of the Hospital Anxiety and Depression Scale).	• Not understanding written language. • Not having access to a personal device with internet connection at least twice a week. • The Care Recipient lives in institutional care.

This recruitment process was deployed in 2 pilot sites: (1) Portugal, by UPORTO; (2) and Ireland, by UCC (Cork).

In Portugal, the recruitment was developed essentially in online mode. In an initial phase, it was conducted a survey of the main stakeholders interested in the iSupport program, and a recruitment process through social network promotion was implemented, namely in groups of caregivers where subjects were invited to fill in an expression of interest form.

During this recruitment stage, informal caregivers were invited to register on the platform. Recruitment remained active after this first recruitment phase and there was a reinforcement of dissemination of the opening of the platform through the communication channels of the University of Porto, national newspapers, international congress and with collaboration with Alzheimer Portugal Association. Dissemination was also carried out with Day Care Centres and other similar institutions. Contacts were also made with informal caregiver support groups, known as Memory Cafés and

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health professionals who provide services to people with dementia in the community were invited.

In Ireland, the recruitment was developed in a St. Finbarr' Hospital. A list of potential geriatricians settled on this hospital were invited by email and phone calls (maximum four times per month). There was a meeting with doctors who accepted. In this meeting, the researchers have explained the project, the protocol, and the technology. The participants were recruited by doctors during the regular medical appointment. During the appointment, doctors have explained the study, assessed the recruitment criteria (especially the Zarit Burden Hospital Anxiety and Depression Scales), and invited them to sign the consent form. In the end of this process, caregivers have received the accesses to the iSupport platform and a physical book with the evaluation questionnaires.

2.9.2 Roles and Responsibilities

The phase 5 was developed for 8 months. In Portugal, the phase 5 have replicated the methodology implemented in phase 4 with a different sample of participants only with one group.

In Ireland (UCC / Replicate Site), when participants signed the consent, the researchers did a meeting to explain them how the technology works and to do basic usability tests, i.e., ask to the participant to access the program and use it. During this meeting, participants had a chance to clarify any doubt about the iSupport and the study.

Then, researchers asked to the participants to complete the baseline of the assessment questionnaires and provide them the access key to the iSupport and two paper bags with the post-intervention and follow-up assessment questionnaires. Participants completed the questionnaires at the midway through and at the end of the program. The debriefing consisted of a telephone call whereby the researchers asked to the participant about the progress of the study and clarified doubts.

This research/intervention was organised by University College Cork in collaboration with University of Porto in Portugal, and Professor William Molloy, Consultant Geriatrician and Chair of the Centre for Gerontology and Rehabilitation, led the research. The participation was voluntary, and participants could leave from the study at any time without giving any reason and without there being any negative consequences.

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2.9.3 Ethical Considerations and Risk management

The phase 5 had approval by:

- Ethics Committee of the Faculty of Medicine of Porto, 2022 (62/CEFMUP/2022).
- The Social Research Ethics Committee of University College Cork, 2023.
- This study has a Risk Assess by Data Protection Officer of University of Porto and SHAPES Ethical Advisory Board, detailed in the following documents: Data Plan; Data Mapping; DPIA; Data Processing Agreement; and Data Sharing.
- Additionally, this use case is in compliance with the ethical requirements defined in SHAPES Deliverable "D8.4 - SHAPES Ethical Framework", as it's summarized in the Table 8.

Table 8 Use Case 1 - 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)	To be consulted in sections 2.8.4 and 2.9.3 of this deliverable.
Biomedical Ethics and Ethics of Care (3.2)	To be consulted in sections 2.8.4 and 2.9.3 of this deliverable.
CRPD and supported decision-making (3.3)	To be consulted in sections 2.8.4 and 2.9.3 of this deliverable.
Capabilities approach (3.4)	To be consulted in sections 2.6 and 2.7 of this deliverable.
Sustainable Development and CSR (4.1)	This use case contributes to the SDG 3.
Customer logic approach (4.2)	To be consulted in section 2.3 of this deliverable.
Artificial intelligence (4.3)	Not applicable because this use case didn't use artificial intelligence.
Digital transformation (4.4)	To be consulted in sections 2.8 and 2.9 of this deliverable.
Privacy and data protection (5)	To be consulted in sections 2.8.4 and 2.9.3 of this deliverable.

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Cybersecurity and resilience (6)	To be consulted in sections 2.8.4 and 2.9.3 of this deliverable.
Digital inclusion (7.1)	To be consulted in sections 2.8.4 and 2.9.3 of this deliverable.
The moral division of labour (7.2)	This use case contributes to most fair moral division of labour, especially for non-paid caregivers of people with dementia.
Caregivers and welfare technology (7.3)	To be consulted in sections 2.1, 2.2 and 2.3 of this deliverable.
Movement of caregivers across Europe (7.4)	To be consulted in sections 2.1, 2.2 and 2.3 of this deliverable.

2.9.4 Outcome of large-scale pilot activity

In this phase 5, the researchers aimed to examine the effectiveness of an online self-help program to prevent and/or decrease mental and physical health problems associated with caregiving and to improve the quality of life of those caring for people with dementia. The outcomes selected are detailed in-depth in the article:

- Teles, S., Ferreira, A., Seeher, K., Fréel, S., Paúl, C. (2020). Online training and support program (iSupport) for informal dementia caregivers: protocol for an intervention study in Portugal. BMC Geriatrics 20, 10, doi:10.1186/s12877-019-1364-z

Resume: “The outcomes of this study have been widely used in intervention studies assessing the effectiveness of internet-based support tools. The primary outcome is caregiver burden measured with the Zarit Burden Interview (ZBI), Portuguese validated version, total score, at t1. The instrument comprises 22 items answered on a 5-point scale, ranging from 0 (never) to 4 (almost always) except for the final question on global burden, rated from 0 (not at all) to 4 (extremely). Total score for the ZBI ranges from 0 to 88 points, with higher scores indicating greater burden. The ZBI has good internal consistency (e.g., $\alpha = 0.89$), test-retest and interrater reliability as well as construct and concurrent validity, including reports of positive correlation with depression symptoms and time devoted to care provision. Regarding the psychometric properties of ZBI in Portugal, face, content, ecological, discriminant and convergent validity were documented, along with test-retest reliability (ICC = 0.93, CI95% 0.88–0.96, $p < 0.001$) and internal consistency ($\alpha = 0.88$). The ZBI is one of the most used instruments to measure burden in intervention studies with caregivers. The following variables are included as secondary outcomes: (i) symptoms of

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depression and anxiety measured through the Portuguese version of the Hospital Anxiety and Depression Scale (HADS), total scores. The instrument comprises two subscales with 7 items each, using a 4-point scale. Total scores for each scale range from 0 to 21, with higher scores indicating more severe anxiety or depression symptoms; (ii) quality of life measured by the Portuguese version of the WHOQOL-BREF physical, psychological, social relationships and environment, total transformed scores. The instrument contains 26 items, for total transformed scores ranging between 0 to 100 points, with higher scores denoting higher quality of life; (iii) positive role appraisals mediating between the stressor and caregiver well-being, measured through the Portuguese version of Positive Aspects of Caregiving (PAC), total score. This instrument comprises 11 items answered in a 5-point scale, for a total score ranging between 11 to 55 points and higher scores representing more positive appraisals; and (iv) general self-efficacy, measured through the total score of the Generalized Self-efficacy Scale. The scale comprises 10 items answered in a 4-point scale for a total score ranging between 10 to 40 points, and higher scores representing a higher general self-efficacy. (pp. 7-8)" [15]

2.9.4.1 Preliminary results

The final results of this use case must be presented in detail at the end of the project (October 2023), namely in the SHAPES Deliverables "D6.9 Comprehensive Assessment of the SHAPES Pan-European Pilot Campaign" and "D6.10 Analysis of the User Acceptance, Inclusion and Societal Impact of the SHAPES Platform". At this moment (June 2023), the researchers already have collected the preliminary and descriptive data that are evidenced below.

- **Outcome 1. Recruitment**

  Sociodemographic description: Age; Marital status; Gender; Education; Digital literacy (UPORTO / UCC).

Table 9 Use Case 1 - Preliminary outcomes - sociodemographic variables.

	UPORTO (*N*=40)	UCC (*N*=9)
Age	M= 50.90 ± 11.4	M= 45.89 ± 5.4
Gender	95.0% Females. 5.0% Males.	71.4% Females. 28.6% Males.
Caregiver Type	100% Informal caregivers.	100% Informal caregivers.

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Level of Education (Years in School)	M= 14.44 ± 3,86	M= 16.63 ± 2,44
Marital Status	35% Married. 15% Cohabiting. 14% Single. 6% Divorced.	66.7% Married. 22.2% Single. 11.1% Divorced.
Occupational Status	65.0% Other (full or part-time). 22.5% Not employed. 10.0 % Retired. 2.5% Full-time.	55.6% Full-time. 22.2% Part-time. 11.1 % Not employed. 11.1% Other.
Caregiving Dedication	67.5% Full-Time 32.5% Part-Time	55.6% Part-time. 44.4% Full-time.
Residence of Care recipient	53.8% Own home 33.3% Caregiver's home 12.8% Other	N/A

- **Outcome 2. MAST Assessment**

  Two dimensions of MAST framework, namely Clinical effectiveness, and Patient perspectives, as detailed in Table 25.

Table 10 Use Case 1 - Preliminary outcomes – psychosocial variables.

	UPORTO (*N*=40)	UCC (*N*=9)
WHOQOL- Bref		
Self-perceived QOL, Health	M= 59.7 ± 20.3	M= 59.9 ± 29.4
Physical	M= 63.1 ± 19.0	M= 67.4 ± 21.9
Psychologic	M= 59.9 ± 16.0	M= 58.8 ± 18.7
Social Relations	M= 54.4 ± 18.3	M= 63.9 ± 19.1

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Environment	M= 62.0 ± 17.1	M= 61.1 ± 15.0
Health related quality of life - EQ - 5D – 5L	N/A	MOBILITY 88,9% I have no problems in walking about. 11.1% I have slight problems in walking about. SELFCARE 100% I have no problems washing or dressing myself. USUAL ACTIVITIES 77.8% I have no problems doing my usual activities. 11.1% I have slight problems doing my usual activities. 11.1% I have moderate problems doing my usual activities. PAIN/DISCOMFORT 55.6% I have slight pain or discomfort. 33.3% I have no pain or discomfort. 11.1% I have moderate pain or discomfort. ANXIETY/DEPRESSION 66.7% I am slightly anxious or depressed. 22.2% I am not anxious or depressed.

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		11.1% I am moderately anxious or depressed.
Health related quality of life (EQ - VAS)	N/A	M=71.1 ± 17.0
General Self-efficacy GSE	M=30.3 ± 4.7	M=31.6 ± 3.1
Social Function OSSS-3	NA	M= 9.8 ± 2.2
1-item Health Literacy	NA	88.9% Extremely Confident. 11.1% Quite a bit.
Did you experience any of these life events [In the last 6 months…]?	NA	55.6% Yes. 44.4% No.
Did you get emotional support from anybody in relation to the event?	NA.	NA (minimal sample).
From whom did you get emotional support?	NA.	NA (minimal sample)
I participate enough in activities that are important to me	NA.	55.6% Agree. 33.3% Strongly Agree. 11.1% Disagree.
Using this technology would make participating in the activities that are important to me		33.3% About the same. 33.3% A little easier 33.3% A lot easier.

2.9.5 Communication and dissemination of pilot activities

This information is provided by SHAPES WP10. Moreover, until the end of the project (October 2023), the final results should be published in scientific reviews and disseminate in the SHAPES Website.

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3 Use case 002

3.1 Introduction

The United Nations Decade of Healthy Ageing was proclaimed (2021-2030), to get a step into “a world in which all people can live long, healthy lives” through a better “Housing, Health, Long-term Care and Social Protection”. The Decade encourages the integrated approaches to provide care to the people aged 65 years or over, and a perspective of health ageing that combines the social determinants of health (lifestyle, literacy, social participation, public expenditure) and the healthcare services for ageing (primary care, long-term care, integrated care) [1].

If this vision is challenging for ‘normal’ ageing, it could be critical to address the ageing with dementia. In the literature, dementia is related to brain changes (memory, speech, perception, attention), and differs from psychiatric disorder (depression, anxiety, stress), chronic disease (diabetes, asthma), lifestyle (nutrition, smoking, alcohol), and cognitive decline, pre-morbid phase which progresses or not to dementia. However, studies also demonstrated that the earlier interventions in cognitive decline (clinic, psychologic, behavioural) change the decline’s progress, with tendency to stabilise in the early stages, like MCI. MCI is being pointed as precursor to dementia, considering events as memory loss, confusion and/or difficulty communicating or finding words [2-12].

Focusing in older population, the assistive technologies or Ambient Assisted Living (AAL) technologies are being developed to provide safe and interconnected environments, combining telemedicine, remote assistance, multimedia services (e.g., amazon, google), capture users’ movements, smart home (IoT sensors, alarms, automation), virtual assistant, health fitness system, voice commands, facial recognition (e.g., depression), individual sensors (e.g., vital signs, falls), detection human intrusion, biometric identification, chat bot, speech recognition, medication sensing platform, call services, assistive robots, behavioural monitoring, virtual coaching, non-pharmacological interventions, and other [13-19].

In this Use Case, older adults (≥ 60 years old) were invited to use daily three digital solutions (Voice Assistant, eHealthPass/CAPTAIN, Smart Mirror). They lived in home, engaged in the community, and they had subjective complains of cognitive decline in minor stage (e.g., lose words, memory issues) and/or a chronic disease (e.g., heart, diabetes). They were assisted by a National Health System (public, private, social) that provided family doctor and nurse in primary care services, emergency services, hospitalizations, and long-term care; and they could invite an informal caregiver.

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This target population was selected to correspond to the SHAPES Persona "John and Joan" (Figure 25), as detailed in the "D2.6 – SHAPES Personas and Use V2" (p.11-14, 30):

Figure 25: Use Case 2 - SHAPES Persona who represents older adults with neurodegenerative diseases. Source: D2.6 – SHAPES Personas and Use V2" (p.30).

3.2 Description

Code	UC-PT5-002
Title	Assistive Technology for Cognitive Decline in Older Adults living in Community
Pilot Theme & Task	PT 5 – Caring for Older Individuals with Neurodegenerative Diseases (Task 6.6)
Piloting Sites	UPORTO (Portugal) and UCC (Ireland)
Description	The WHO acknowledge the healthy lifestyle throughout life increases active and healthy ageing for longer and extends autonomy. Scientific studies have demonstrated that a healthy lifestyle is a social determinant of health, namely of cognitive health. Cognitive ageing or cognitive disease has been pointed out as one of the biggest challenges of the 21st Century, not only for older people with brain disorders (mild/severe), but also for formal/informal caregivers, community, social network, and health and social services. In the context, the Europe's digital decade (Digital Transition) has highlighted the roles of the Assisted Living Technologies (sensors, mobile applications, smart devices, IoT, AI) to promote the healthy lifestyle after 60 years old (e.g., self-care, digital care plan, remote assistance, physical/cognitive exercises, telemedicine). This Use Case intends to build and test these in real-life scenario, to assess the impact of different typologies of Assisted Living Technologies – Personal Assistant (Digital Voice Assistant), Care Assistant (Mobile App, Smart Devices), and Home Assistant (IoT Sensors, AI-based) – to develop a model of integrated care and person-centred care for older people living at home who have subjective complaints of cognitive decline, assisted by technology. The scenario simulates in real-life how digital solutions can integrate older people, informal caregivers, and formal caregivers. The expected evidence supports a list of recommendations about the role of digital health to activate healthy lifestyle of older people living in community.
Digital Solution proposed	Voice Assistant: The prototype is composed by a chatbot commanded by natural voice interactions or digital voice assistant (called NARI) that is interoperable with a four skills/functions digital platform of self-care (called Adilib). Both chatbot and Adilib platform are accessed by individual webpages through internet browsers; while the chatbot webpage must continuously “open” in an internet browser (online), the Adilib webpages are only accessed to program the skills. This prototype “runs” through two technical devices: (1) a tablet with internet browsers (e.g., Google Chrome), internet connection by WIFI, and Bluetooth; (2) and a smart

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	speaker or loudspeaker with Bluetooth. Both devices are connected by Bluetooth. eHealthPass/CAPTAIN: The prototype is composed by the smartwatch Withings (medical device that collect heart rates, ECG, SpO2, sleep patterns, steps and floors) and a mobile application eHealthPass that registers/shows personal healthcare data collected by the smartwatch automatically or by the older people manually (e.g., diets' plan, medicine instructions, medical agenda, health events like hospitalizations or surgeries, health conditions like chronic diseases or medicines); this mobile application is connected with a care platform (with the same name eHealthPass) accessed only by formal caregivers (e.g., GP, nurse, therapist) to monitor and manage the individual care plans (e.g., change items, control parameters) and to communicate with patients (by videocalls, messages, questionnaires, educational tools). Smart Mirror Ecosystem: The prototype is composed by home sensors (movement, temperature, humidity, electric consuming, open/close doors/windows), personal sensors (smart band to collect heart bits, steps, calories, sleep patterns), and a digital platform installed inside a smart mirror (device composed by a touch screen, raspberry, dashboard, internet connection, and Bluetooth); this platform controls the sensors (home and individual), reports the sensors' data, provides a physical and cognitive exercises, show a personal agenda, and support video calls.
Technical partners	VICOM, GNOMON, UCLM, DIGIOTOUCH (Open Call)
Components	Voice Assistant and Adilib Platform eHealthPass and CAPTAIN Smart Mirror Ecosystem
Piloting summary	A pilot study was developed to assess the scenario proposed in this use case, in terms of acceptance, satisfaction, usability, and efficacy. Adopting the SHAPES methodology, this pilot study had 5 Phases. In Phase 1, academic and technical partners transferred the proposed use case in two scenarios, describing partners, framework, subjects or target groups, activities and roles, interactions, context, environment, functions, technical infrastructures, devices, interfaces, performance indicators, and a timeline. The outcome is the pilot study design and plan, considering the SHAPES methodology and expected impacts, but also the first mock-up of digital solutions, written and summarized.

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	In Phase(s) 2&3, academic and technical partners developed the final prototype to use in the pilot study and test it in the hands-one experience. Additionally, the academic partners provided the social context to deploy a pilot in real-life environment, namely a community of older people, informal and formal caregivers, and public or private facilities. The outcome is a final prototype not only of digital solutions, but also a real-life scenario that use technology to integrate pilot' subjects and promote healthy lifestyle in old age. In Phase(s) 4&5, academic partners, supported by technical partners, assessed the pilot study using a scientific protocol. Thereby, they designed a protocol, submitted it to the ethics committee and data protection office, recruited participants, signed consent forms, managed logistics and risks, collected and analyse data, and elaborated regular reports. The outcome is an extensive final report that describes in-depth the 5 phases and their results (SHAPES D6.6 – Pilot Theme 5: Caring for Older Individuals with Neurodegenerative Diseases). This Use Case was replicated in two pilot sites: UPORTO (Portugal) and UCC (Ireland). Moreover, partners and participants worked to disseminate the experience and results of this Use Case through scientific publications, public events, and social media.
Subject profile (main persona of the piloting)	Beneficiaries: Older people (≥ 60 years old) who live at home autonomously with/without chronic diseases, and with complaints about cognitive decline (minor complains). They were the target group of the intervention deployed (beneficiaries) and the principal end-user of the digital solutions tested. Informal Caregivers: Adults (≥ 18 years old) acknowledged (selected) by the "beneficiaries" as the person(s) who provide any type of continuous and daily care because of emotional ties (e.g., familiar, friend, neighbour), availability (e.g., time, distance), or/and informal contract (e.g., payment). Formal Caregivers: Licenced professionals and/or organizations, public or private, who provide healthcare and social support to the "beneficiaries" and/or their "informal caregivers" (gerontologist, nutritionist, nurse, GP, public facilities, pharmacy, primary care centre). Facilities: People and/or organizations, public or private, who ensured the logistics to develop a pilot study in a real-life condition, with dissemination, local guides, healthcare providers, and equipment (e.g., rooms, computer, data show, primary care centres, gerontologic facilities).

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3.3 Digital solutions used in this use case

This use case is composed by three different digital solutions that are under the 'umbrella' of the Assistive Technologies to be adopted in community.

3.3.1 Voice Assistant & Adilib (VICOM)

This digital solution is composed by two interconnected technologies: a voice assistant (NARI) and a care platform (Adilib). Both are provided by the SHAPES partner VICOMTECH (Figure 26).

The voice assistant NARI works through a chatbot that is an interactive solution that comprehends the end-user intention in natural language, plans the next response according to some domain knowledge and give the appropriate response. The care platform Adilib works as a black box which communicates with a chatbot. This platform controls all skills performed in the chatbot (voice assistant). The digital solution works through different web interfaces to control or modify the Adilib Skills, thereby the Chatbot's behaviours (Figure 27, Figure 32). There are the following interfaces:

- WebSocket communication with Adilib: main communication channel to talk with the Chatbots deployed in production.
- Skill User Interface: this web interface allows to modify the behaviour of the skill, adapting and personalizing it to each UC and, if it is necessary, to each user. This interface is intended to be used by the caregivers and non-technical staff.

This prototype provides a simple, transversal, modular and customizable solution to satisfy the demands raised by the SHAPES Pilot Theme 5, namely having a voice assistant with 4 skills:

- Skill 1. Agenda. As programmed (and saved) in Adilib, the voice assistant (NARI) informs users about events like medicine intake, medical appointments, celebrations. This skill is a personal agenda that user asks (Figure 28).
- Skill 2. Notifications. As programmed (and saved) in Adilib, the voice assistant (NARI) automatically notifies users about events. This skill is interoperable with skills 1 and 3, so, items programmed in those skills could be "notified" by this skill (Figure 29).
- Skill 3. Questionnaires. As programmed (and saved) in Adilib, the voice assistant (NARI) sends questionnaires to the users; answers could be free response (users can provide any response); multiple choice (users must choose one option

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among a set of pre-programed values); or numeric scale (users must choose one option among a set of pre-programed values) (Figure 31).

- Skills 4. Tutorials. As programmed (and saved) in Adilib, the voice assistant (NARI) provides a range of “step-by-step” instructions, like a “how-to-use” a TV, a smartphone, a hoover, or a “how-to-do” a meal, a craft (Figure 30).

This prototype works with two different devices/equipment that were tested by the technical partner VICOMTECH: (i) the tablet “Lenovo IdeaPad Duet Chromebook (MediaTek P60T, 4 GB RAM, 128 GB Storage, Chrome OS)”; (ii) and the speaker “Jabra 510 loudspeaker”. These devices are permanent connected by Bluetooth, and the tablet requires a permanent internet connection (minimum 4G) (Figure 26).

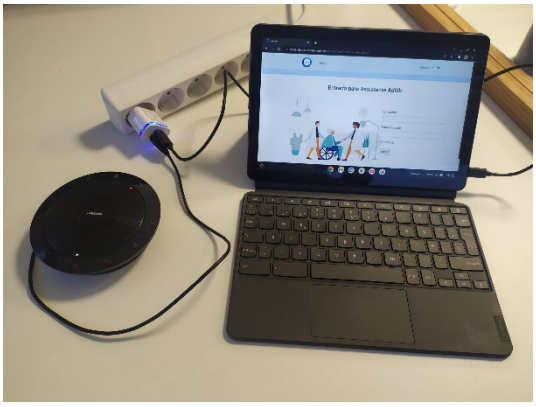

Figure 26: Use Case 2 - Voice Assistant Devices.

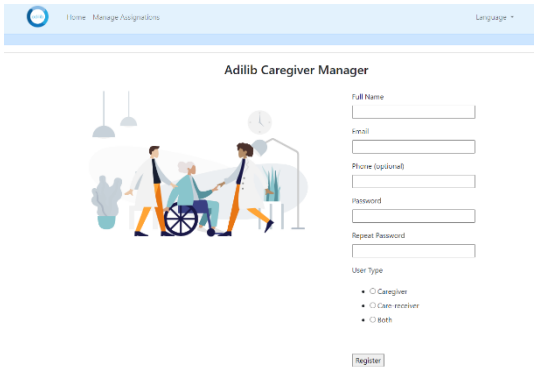

Figure 27: Use Case 2 - Adilib Platform (Caregiver Manager).

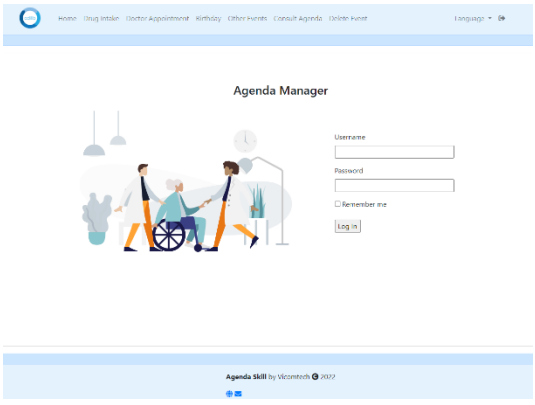

Figure 28: Use Case 2 - Adilib Platform (Agenda Manager).

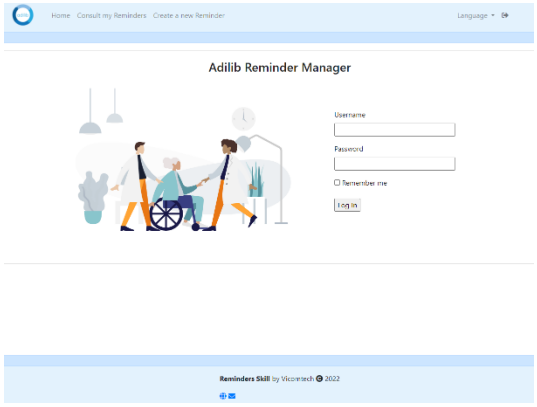

Figure 29: Use Case 2 - Adilib Platform (Reminder Manager).

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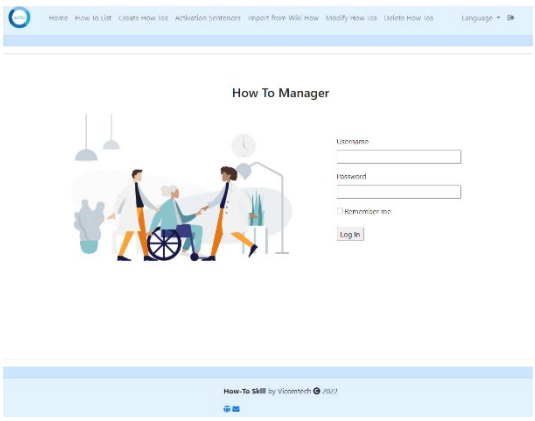

Figure 30: Use Case 2 - Adilib Platform (Tutorials Manager).

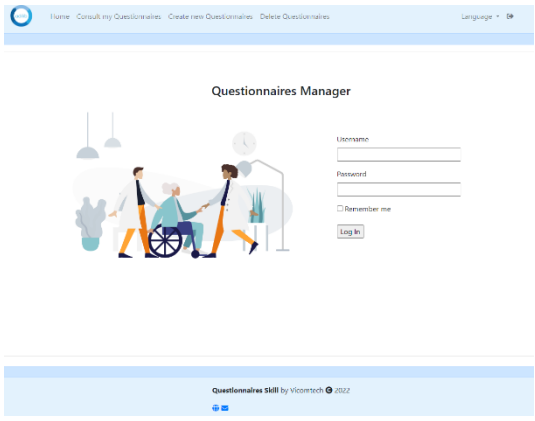

Figure 31: Use Case 2 - Adilib Platform (Questionnaires Manager).

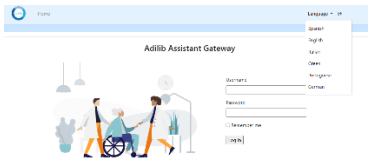

Figure 32: Use Case 2 - Adilib Platform (Chatbot).

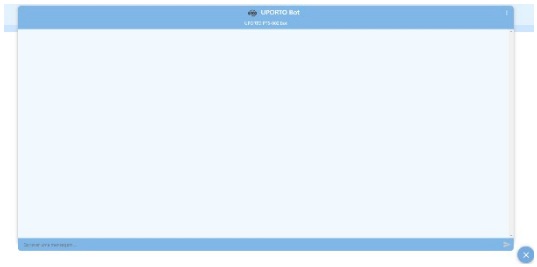

Figure 33: Use Case 2 - Adilib Platform (Chatbot).

3.3.2 eHealthPass & Captain/Smartwatch (GNOMON / DIGIOTOUCH)

This digital solution is composed by two interconnected technologies: a care platform (eHealthPass) and a smartwatch (Withings). While the care platform eHealthPass is provided by the SHAPES partner GNOMON, the smartwatch Withings is provided by a partner selected in the 1st SHAPES Open Call (Digitouch).

The eHealthPass is a care platform that works through a mobile application and a web interface application. This care platform provides to the users an overview of their daily health and care activities, treatment plan, a self-assessment tool with personalised questionnaires (uses a text-based chatbot) and notifications. Within the treatment plan function, users can control the medication, register vital signs monitoring, manage diet and nutrition, and regulate physical activity. Due to the interoperability with their healthcare service provider, the user may also book, manage and cancel medical appointments. The platform also includes educational content (e.g., virtual patients, stories, and practical video tips), a discussion forum, and it can synchronise with other smart devices (e.g., smartwatch) and medical devices (e.g., oximeter).

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In this SHAPES Pilot Theme 5 / Use Case Nr 2, as a prototype, the eHealthPass is connected with the smartwatch Withings using another platform developed by Digitouch, the Captain platform. This platform allows to connect the smartwatch Withings to the eHealthPass platform, sending data collected by the smartwatch to the eHealthPass automatically. This functionality aims to provide to the users an automatic and non-obtrusive monitoring of measurements related with the users' health and wellbeing, including vital signs (heart rate, ECG, SpO2), physical activity (steps, run, swimming), and sleep patterns.

This prototype provides an 'improved healthcare platform' that continuously integrates health and care data from different sources (feed by different sources), namely the smartwatch (automatically), the patient and the healthcare provider (e.g., doctor, nurse, informal caregiver). This 'improved platform' is composed by three devices (hardware/software):

- The web application (eHealthPass provided by GNOMON). This application is to the healthcare providers management: calendar and appointment tool; patient list and patient profile; create questionnaires for the patient; create/Update care plan for patients; monitoring tool for patient's care plan with charts; adherence charts. This application is also accessed by the patients (Figure 39).

- The mobile application (eHealthPass provided by GNOMON). This application is to the patients' management: patient account and social profile; care plan and its agenda; nutritional care plan and its agenda; data base with healthcare events (e.g., medical appointments, hospitalizations) and health conditions (e.g., medicines, allergies, chronical diseases); agenda/notification tool; and a questionnaires tool (Figure 34, Figure 35, Figure 36, Figure 37).

- The smartwatch device and its mobile application (Withings Smartwatch / Health Mate Mobile Application / Captain platform provided by Digitouch). The Withings Smartwatch is to be used by the patients daily. Data collected by the smartwatch is processed by the Health Mate Mobile Application, which is accessed by patients as well the eHealthPass mobile application; the CAPTAIN application is black box that connect Withings Smartwatch / Health Mate Mobile Application with eHealthPass and SHAPES platform (Figure 38).

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Figure 34: Use Case 2 - eHealthPass App (Log-in / Log-out).

Figure 35: Use Case 2 - eHealthPass App (Dashboard Functionalities).

Figure 36: Use Case 2 - eHealthPass App (Device's integration).

Figure 37: Use Case 2 - eHealthPass App (Vital signs and Physical Activity).

Figure 38: Use Case 2 - ScanWatch Withings (connected to eHealthPass).

Figure 39: Use Case 2 - Web application eHealthPass.

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3.3.3 Smart Mirror Ecosystem (UCLM)

This digital solution is an interoperable ecosystem composed by cloud platforms, services, and devices; in this ecosystem, the smart mirror itself works as a computing node for other services and devices (applications and smart wearables), but also as a smart gateway that integrate different hardware and software. This digital solution is provided by the SHAPES partner UCLM. This prototype is an integrated digital ecosystem that works as an assisted home environment (connected with caregivers) and self-care and self-monitoring digital tool, to extend the active, healthy, and independent ageing of older people. This digital solution is composed by a range of equipment (software and hardware) summarized in the Table 11.

Table 11 Use Case 2 - Devices and functions of the Smart Mirror Ecosystem.

Service	Devices	Functionalities
Smart Mirror	Screen. Raspberry Pi 4 8 GiB of RAM memory. Dashboard.	User-friendly dashboard to access functionalities. Easy management of smart mirror services. Grant access to the platform and user profile.
Home Monitoring	Movement Home Sensors. Doors/Windows Sensors. Temperature Sensors. Electricity Consumer Sensor.	To monitor individual movements in home. To control entries & exits from home. To monitor electricity consuming. To monitor household appliances on/off. To detect movements changing patterns.
Physical Activity Monitor	Smart band (Xiomi). Fall Detector (IMU Sensor). Panic Button.	To monitor physical and cognitive changing patterns. To monitor individuals' falls. To notify individuals' falls.

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Call Service	RFID. Microphone. Camera.	Video calls. Easy dial phone numbers. Emergency calls.
Physical and Cognitive Stimulation	Phyx.io (software).	To provide physical activities in home. To provide cognitive activities in home.
Login Service	RFID.	Easy login. User session log.

In this use case, the smart mirror ecosystem is a prototype that aims to create a comfortable and save home environment for older people who already have cognitive decline complains, but also wish to improve the communication with the informal caregiver. Since the prototype is totally installed, the home is equipped with sensors that monitor the people's movements and analyse their patterns and unforeseen events (e.g., leave door/window open, sedentarism in home), but also the electricity consuming (e.g., household appliances consuming); and the older people use smart wearables (smart band, fall sensor, panic button) to monitor heart bits, steps walked, falls and unexpected events (e.g., pain, low blood pressure, dizziness, headache or disorientation, robberies) (Figure 40, Figure 41).

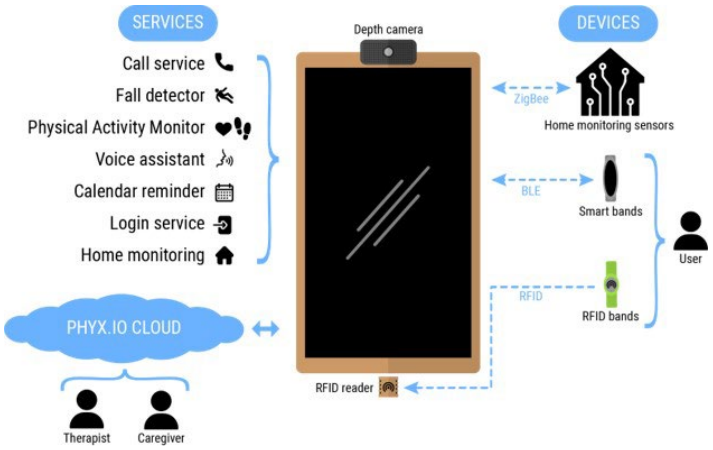

Figure 40: Use Case 2 - Smart Mirror Ecosystem (Architecture).

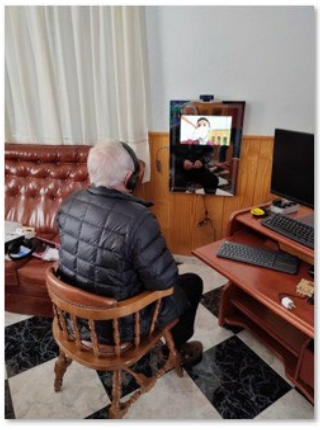

Figure 41: Use Case 2 – Interaction with the Smart Mirror Device.

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3.3.4 Digital solutions used for COVID-19 response

The digital solutions adopted in this Use Case were adapted to respond the COVID-19. This information is detailed in-depth in the public report "D5.4 SHAPES Digital Solutions V3" (pp. 209-238, 282-298, 452-464, 524-544). This use case developed the remote and digital assistance to follow-up older people self-care, and to increase and/or improve the remote communication between care recipients (older people living in home) and caregivers (formal and informal). Researchers have discussed the opportunities to fight COVID-19 provided by this use case.

The COVID-19 has raised new demanding for healthy and active ageing, especially regarding the health and care provision, both formal (hospitals, social support) and informal (families, caregivers), in terms of:

- The offer: the health and care systems may delay and defer provisions already scheduled (medical appointments, treatments, exams, visits, care), which have non expected impacts for the individuals.
- The demand: people with chronic diseases may feel fear, stress and distrust in health and care systems, which may decrease aid requests in crises situations.

Moreover, the Pandemic phenomenon (forced social isolation) decreased the psychological well-being due to increased feelings such as fear, anxiety, frustration, impotence, loss of time. Facing these situations, this use case provided remotely care for older people with dementia or cognitive decline who are living in community. The positive impacts should be:

- Digital Health and Care Solutions: the use case provided digital solutions for monitoring remotely. This improvement was suitable in the situations of social isolation and distance, as well as in the situations of rupture and pressure of health and care systems.
- Digital Literacy: the use case provided educational experiences and materials of digital solutions, both for patients and caregivers (formal and informal), which were useful to expand this new approach for health and care systems.

3.3.5 Equipment and devices used (from third parties)

Overall, the equipment and devices used in this use case were provided by the SHAPES technical partners. Just the voice assistant is composed by a voice layer acquired by a third party, the Google company, to be adapted to the national languages (e.g., Portuguese).

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3.4 Data plan

3.4.1 Data capture methods to be used

Domain	Variable	Tool	Method	Frequency
Sociodemographic	Name	Consent Form	Manually by user	Baseline
	Signature	Consent Form	Manually by user	Baseline
	Age	Questionnaire	Manually by user	Baseline
	Gender	Questionnaire	Manually by user	Baseline
	Education (years in school)	Questionnaire	Manually by user	Baseline
	Marital Status	Questionnaire	Manually by user	Baseline
	Cohabitation (yes / no)	Questionnaire	Manually by user	Baseline
	Care Recipient (yes / no)	Questionnaire	Manually by user	Baseline
	Caregiver (yes / no)	Questionnaire	Manually by user	Baseline
Behavioural	Physical Activity (steps, floors climbed, workout)	Smart Mirror eHealthPass	Automatically by technology	During the intervention
	Nutritional Plan (diets, food, meals, calendar)	Smart Mirror eHealthPass Voice Assistant	Manually by user	During the intervention
	Medication Plan (medicines, doses, calendar)	Smart Mirror eHealthPass Voice Assistant	Manually by user	During the intervention

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	Sport Plan (exercises, places, calendar)	Smart Mirror eHealthPass Voice Assistant	Manually by user	During the intervention
	Social Events Calendar (familiar, friends, cultural)	Smart Mirror eHealthPass Voice Assistant	Manually by user	During the intervention
	WHOQOL-Bref, EQ-5D-5L, GSE, OSSS-3, Life Events Inventory	Questionnaires	Manually by user	Baseline and Post Intervention
Health	Vital signs (heart rate, ECG, SpO2)	Smart Mirror eHealthPass	Automatically by technology	During the intervention
	Calories burned	Smart Mirror eHealthPass	Automatically by technology	During the intervention
	Sleep patterns	Smart Mirror eHealthPass	Automatically by technology	During the intervention
	Body Mass Index (Weight / Height)	Smart Mirror eHealthPass Voice Assistant	Manually by user	During the intervention
Sociotechnical	Accesses (times)	Smart Mirror eHealthPass Voice Assistant	Automatically by technical devices	During the intervention
	Functions used	Smart Mirror eHealthPass Voice Assistant	Automatically by technical devices	During the intervention

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	Time spent per interaction	Smart Mirror eHealthPass Voice Assistant	Automatically by technical devices	During the intervention

3.4.2 Planning of evaluation

The planning evaluation of this Use Case was provided by the SHAPES Deliverable "D6.1 - SHAPES Pan-European Pilot Campaign Plan" (pp. 127-183), that suggested the MAST and MAFEIP frameworks to assess the impact of the Use Case. The MAFEIP framework couldn't be adopted due to a small-scale deployment of it.

This Use Case adopted the MAST framework (Model for Assessment of Telemedicine) that assess the Use Case's effectiveness and contribution to quality of care. MAST is a multidisciplinary assessment that focuses in 7 domains: (1) Health problem and characteristics of the application; (2) Safety; (3) Clinical effectiveness; (4) Patient's perspective; (5) Economic aspects; (6) Organizational aspects; (7) and Sociocultural, ethical, and legal aspects [22].

The researchers did a review of these domains and selected those most relevant to this Use Case, namely: Clinical effectiveness (3); and Patient's perspective (4). The Table 12 describes the data required for the MAST evaluation.

Table 12 Use Case 2 - MAST.

Domain	Topic	Outcome	Data Required	Time Point
Clinical Effectiveness	*Effects on mortality*	*Will not be measured.*		
	Effects on morbidity			
	Physical health	Perception of Physical Wellbeing	WHOQOL-BREF EQ-5D-5L	Phase 5 (Baseline and Post-Intervention)
	Mental health	Perception of Psychological Wellbeing	General Self-Efficacy Scale	
	Effects on health-related quality of life			

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	Generic measures of quality of life	Satisfaction with Life	WHOQOL-BREF	Phase 5 (Baseline and Post-Intervention)
		Social Support	OSSS-3	
	Disease specific measures of quality of life	*Will not be measured.*		
	Behavioural outcomes	Active Social Participation	WHOQOL-BREF General Self-Efficacy Scale SHAPES Questionnaires (2 items)	Phase 5 (Baseline and Post-Intervention)
	Utilization of health services	*Will not be measured.*		
Patient perspectives	Satisfaction and acceptance	Motivation to use in the future	SUS	Phase 5 (Post-Intervention)
	Understanding of information	Successful Recruitment	This information is detailed in section 3.8.1 of this deliverable.	Phase 3 (Hands-on Experiments)
	Confidence (in the treatment)	*Will not be measured.*		
	Ability to use the application	Successful Recruitment	This information is detailed in section 3.8.1 of this deliverable.	Phase 3 (Hands-on Experiments)
	Access	*Will not be measured.*		
	Empowerment, self-efficacy	Motivation to use in the future	Interview	Phase 5 (Post-Intervention)

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

The NASSS and the MOMENTUM frameworks were proposed by SHAPES Project in the public report "D6.1 SHAPES Pan-European Pilot Campaign Plan" (SHAPES-WP6, 2020, pp. 117-118). The NASSS framework (Non-adoption, Abandonment, Scale-up, Spread, and Sustainability) was proposed by Greenhalgh et al. (2017) to assess "challenges to achieving sustained adoption and long-term sustainability", by 19 questions, organized in 7 domains, classified in three levels: simple (straightforward, predictable, few components), complicated (multiple interacting components or issues), or complex (dynamic, unpredictable, not easily disaggregated into constituent components). The MOMENTUM (Advancing Telemedicine Adoption in Europe, 2015) is a "validated and tested method to support the telemedicine implementation process and create enabling environments to accelerate telemedicine". This method helps the stakeholders to identify the telemedicine critical factors on a list composed by a set of guidelines and indicators, the MOMENTUM 18 Critical Success Factors List [20-21].

In this use case, a study was developed by the researchers to assess the use case's critical success factors (MOMENTUM), risks to implement in real-life (NASSS), and to identify a list of potential challenges and a list of Key Performance Indicators (KPI) that researchers must consider during the pilot's deployment.

A sample of potential Assistive Technologies' users and promoters was composed by 11 individuals (n=11) recruited by the Ageing Lab of Municipality of Ílhavo (Portugal): 2 Older adults (≥ 60 years old); 2 Informal Caregivers; 4 professionals of NHS (1 GP; 2 Nurses; 1 Nutritionist); 2 Public Employees (1 Gerontologist; 1 Sociologist); 1 Deputy. The researchers have organized a Focus Group with 4 moments: (1) presentation of the Use Case by a PowerPoint; (2) presentation of the NASSS and MOMENTUM by a PowerPoint; (3) the evaluation by participants using questionnaires; (4) and a Discussion in group. This Focus Group was long 3 hours (1 morning). Researchers have read the questions for the participants and clarified them because questionnaires had general questions designed for different technologies, participants had to evaluated different Use Cases in the same session (Use Case 1 and Use Case 2), and they had different literacies' levels. Then, researchers did a descriptive analysis to find the critical factors and KPIs adjusted to potential users and promoters of this use case.

The **NASSS framework** assessed six dimensions that can determinate the adoption or non-adoption of the technology in real-life, but also its scalability. This evaluation invited the participants to score those dimensions in three levels: simple, complicated or complex to adopt in real-life.

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The participants have assessed the use case as mostly complicate or complex to adopt in real-life context. The domains related to the “Illness or Condition” of the older adult (i.e., cognitive decline and chronic disease), the “Intended Adopter” (i.e., older adults and formal and informal caregivers), the “Organization readiness” (especially the primary care centres from NHS), and the “External Context” (i.e., legal and ethical frameworks) were the domains mostly scored with complicate and complex. In opposition, the “Value Proposition” (i.e., financial, societal) was scored with “simple” and “complicate”, which demonstrated that the participants believed in the use case for the future. It was also relevant that in the domain “Organization Readiness”, there were a division between participants associated with NHS and Public Facilities; the last ones believed that the organization was almost ready to implement the use case. This difference was related with the “External Context”, namely the legal and ethical issues (Figure 42).

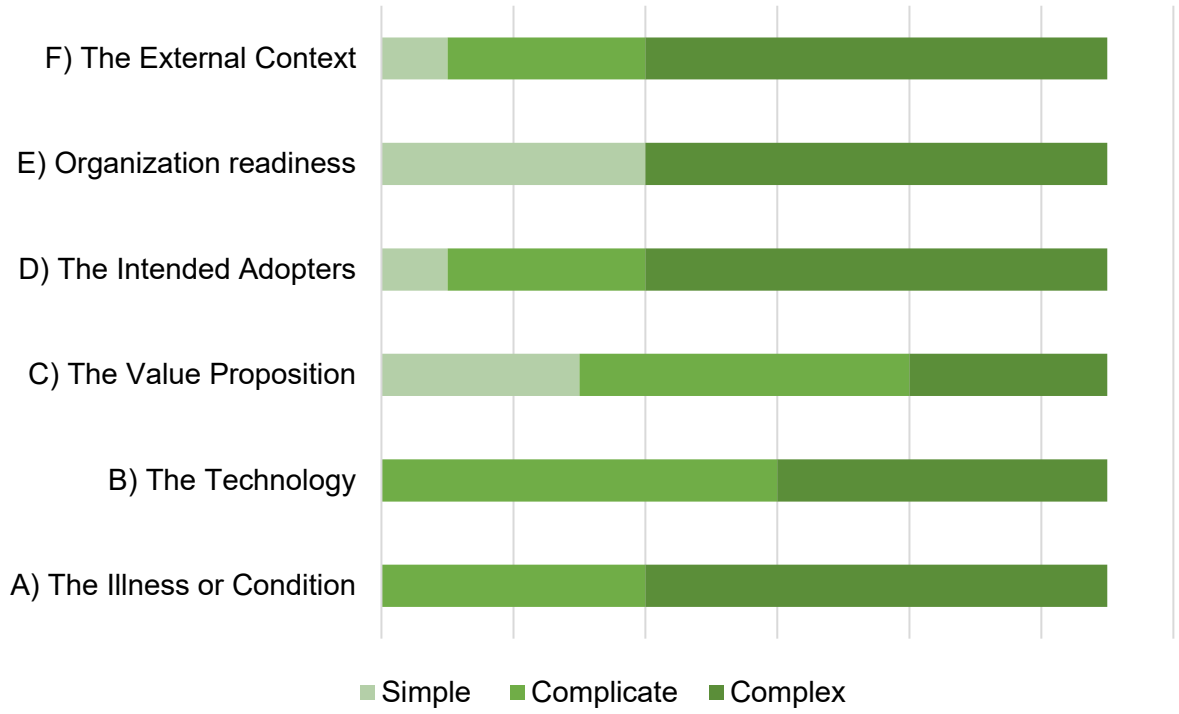

Figure 42: Use Case 2 - NASSS (First Evaluation).

Moreover, the evaluation also invited the participants to score those dimensions by variables in terms of “Agree”, “Disagree”, or “Don’t Know” (Table 13).

The participants’ answers in the domain “Illness and Condition” demonstrated that the health conditions of target population were uncertain due to the ageing process and the high risk of comorbidities without a single and simple solution. Moreover, cultural

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factors as illiteracy and lifestyles (nutrition, alcohol, tabaco, sedentarism) were a barrier for a healthy/active ageing and digital adoption.

In the domain “Technology”, participants understood the technology adoption by the caregivers (formal and informal) was understood with doubts, especially regarding its usability/acceptance, trust and human dependency (lack of human autonomy). Concerns about technical support and suppliers, feasibility and performance, and change on organizations’ workflow were less considered. These perceptions also meant a level of uncertain and complexity for the next years.

In the domain “Value Proposition”, there were different perceptions about it, both for older people and professionals of care, but the tendency was to believe that technology add value to the current healthcare situation (especially economic), with no negative impacts to use it. These perceptions also meant a level of uncertain and complexity for the next years.

In the domain “Intended Adopter”, participants understood that digital solutions required different roles from older adults and professionals of care; by this reason, even if professionals were available to adopt technology, they couldn’t impose it to the older adults, especially because there wasn’t strong evidence about its positive or negative impact for healthcare and quality of life. These perceptions also meant a level of uncertainty and complexity for the next years.

In the domain “Organization Readiness”, the different organizations represented by participants (Primary Care Centre of NHS and Public Facility of the Municipality) were motivated to empower a digital transition and had internal resources to do it, especially human and targets. However, organizations have no technical infrastructures (because it’s a new scope) and they need pilots before a generalized adoption. These perceptions also meant a low level of uncertainty and simplicity for the next years.

In the last domain “External Context”, participants understood the political context was favourable to adopt technology, and there weren’t strong barriers from policy, advocacy or professional associations; even the regulatory context (e.g., GRDP, Bioethics) was prepared to protect users, but the technology wasn’t accessible financially. However, this context was recent and required training for professionals and patients, and the continuity of this option/policy. These perceptions also meant a low level of uncertainty and simplicity for the next years.

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Table 13 Use Case 2 - NASSS Framework (First and Second Evaluation).

Domains	How much you agree with the sentence?			The adoption is:		
	Agree	Disagree	Don't Know	Simple	Complicate	Complex
A) The Illness or Condition				Simple: 0		
A1) There are significant uncertainties about the condition e.g., poorly defined, variable manifestations, uncertain course.	**11**	0	0	Complicate: 4		
A2) Many people with the condition have other co-existing illnesses or impairments that could affect their ability to benefit from this solution.	**11**	0	0	**Complex: 7**		
A3) Many people with the condition have social or cultural factors that could affect their ability to benefit from the technology or service.	**9**	0	3			
A4) The population with the condition, and/or how the condition is treated, is likely to change significantly over the next 3-5 years.	**6**	1	4			
A5) The condition has significant complexity which is likely to affect the project's success.	**11**	0	0			
B) The Technology				Simple: 0		
B1) There are significant uncertainties in what the technology is (e.g., it hasn't been fully developed yet).	**8**	2	1	**Complicate: 6**		
B2) There are significant uncertainties in where the technology will come from (e.g., supply chain issues, substitutability).	0	**11**	0	Complex: 5		
B3) There are significant uncertainties about the technology's performance and dependability (e.g., bugs, crashing, cutting out).	2	0	**9**			
B4) There are significant uncertainties about the technology's usability and acceptability (e.g., key	3	2	**6**			

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people don't trust the data it provides).				
B5) There are significant technical interdependencies.	**9**	0	2	
B6) The technology is likely to require major changes to organisational tasks and routines.	**7**	0	4	
B7) The technology (and/or the service model it supports) is likely to change significantly within the next 3-5 years.	**11**	0	0	
B8) The technology has significant complexity which is likely to affect the project's success.	4	**7**	0	
C) The Value Proposition				Simple: 3 **Complicate: 5** Complex: 3
C1) The commercial value of the technology is uncertain.	3	0	**8**	
C2) The value to the intended users (e.g., patients, clinicians) is uncertain.	2	4	**5**	
C3) The value to the healthcare system (e.g., from efficacy and cost-effectiveness studies) is uncertain.	**7**	0	4	
C4) The value to this particular healthcare organisation, given the current situation locally, is uncertain.	0	0	**11**	
C5) The technology could generate a negative value (costs are likely to outweigh benefits) for some stakeholders.	2	**5**	4	
C6) The value proposition is likely to change significantly over the next 3-5 years.	**11**	0	0	
C7) The value proposition has significant complexity which is likely to affect the project's success.	0	0	**11**	
D) The Intended Adopters				Simple: 1
D1) There is uncertainty about whether and how patients/citizens	**4**	3	**4**	

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will adopt the technology (if applicable).				Complicate: 3 **Complex: 7**
D2) There is uncertainty about whether and how front-line staff will adopt the technology.	0	**11**	0	
D3) There is uncertainty about the implications for people who might be indirectly affected by the technology.	**6**	3	2	
D4) There will be significant changes to individual users' perceptions of the technology over the next 3-5 years.	**10**	0	1	
D5) There is significant complexity relating to intended adopters which is likely to affect the project's success.	**7**	2	2	
E) Organization readiness				**Simple: 4** Complicate: 0 **Complex: 7**
E1) The organization's capacity to take on technological innovations is limited.	0	**7**	4	
E2) The organization is not ready for this particular innovation.	**7**	0	4	
E3) The organization would find it hard to commission/purchase the innovation.	1	0	**10**	
E4) The work needed to introduce and routinise the innovation has been underestimated and/or inadequately resourced.	0	**6**	5	
E5) The organization(s) involved are likely to have significant restructurings or changes in leadership, mission or strategy over the next 3-5 years.	**7**	0	4	
E6) There is significant complexity relating to one or more participating organizations which is likely to affect the project's success.	**7**	0	4	
F) The External Context				Simple: 1

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F1) The political and/or policy climate is adverse.	0	**9**	2	Complicate: 3 **Complex: 7**
F2) Professional bodies are opposed to the innovation or don't actively support it.	0	**7**	4	
F3) Patient organisations and lobbying groups are opposed to the innovation or don't actively support it.	0	**8**	3	
F4) The regulatory context is adverse.	**7**	0	4	
F5) The commercial context is adverse.	1	2	**8**	
F6) Opportunities for learning from other (similar) organisations are limited.	3	**4**	**4**	
F7) Introduction of the technology/innovation could be threatened by external changes that impact on the organisation.	3	**4**	**4**	
F8) The policy, regulatory and economic context for this innovation is likely to be turbulent over the next 3-5 years.	0	**7**	4	
F9) There is significant complexity relating to the external context which is likely to affect the project's success.	**4**	**4**	3	

The **MOMENTUM framework** assessed four dimensions that can determinate the critical success factors of the technology in real-life. This evaluation invited the participants to score those dimensions in three levels: simple, complicated or complex to adopt in real-life.

In this framework, participants have assessed the use case as simple and complicated to adopt. The critical factor "People" was mostly scored as simple, considering the motivation of the professionals and beneficiaries to adopt the technology in real-life. Compared with NASSS that focused on the illness and condition, this framework focused on the user and its relationship with the technology; thereby, participants have scored better on this critical factor, which demonstrated their motivation and readiness

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to adopt it, but also their understanding about the person-centred and universal design adopted in this use case. In opposition, critical factors related to “Run” and “Context” were worst scored by the participants. This evaluation was justified by several answers “Don’t Know”, which could mean uncertainty related with the institutional and organizational implementation of the use case after the pilot study (Figure 43).

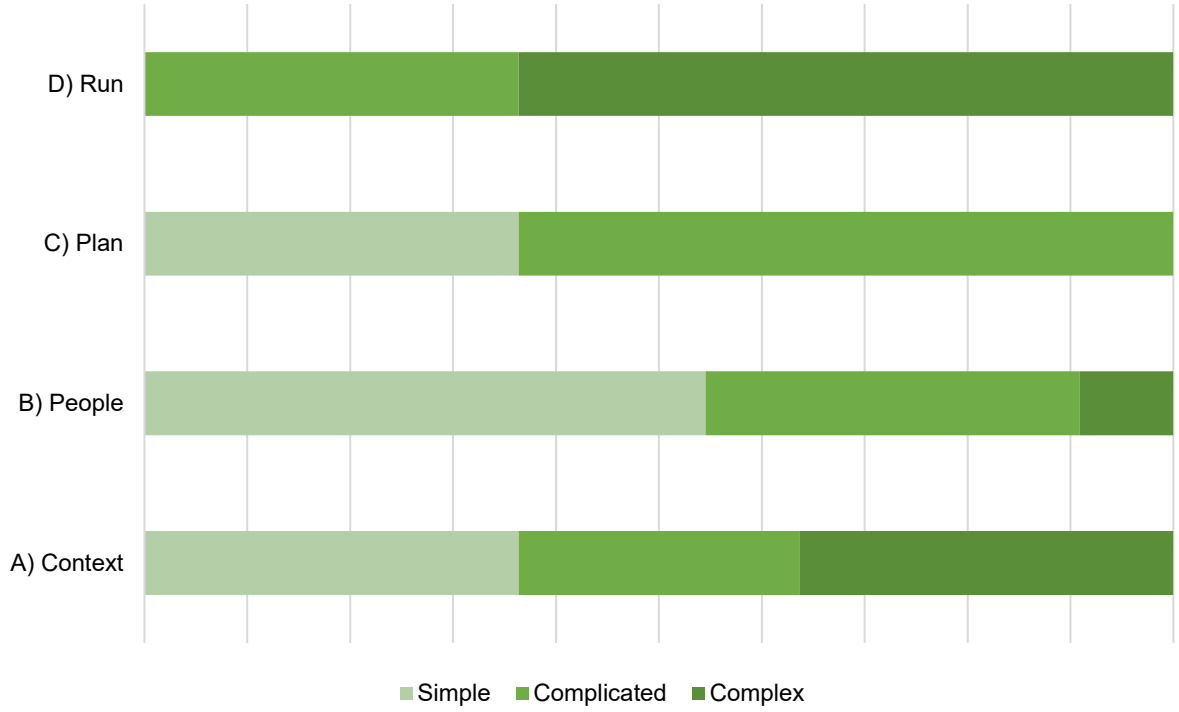

Figure 43: Use Case 2 - MOMENTUM Framework (First Evaluation).

Moreover, the evaluation also invited the participants to score those dimensions by critical success factors in terms of “Agree”, “Disagree”, or “Don’t Know” (Table 14).

In the first set of critical factors (Context), participants assumed that the organizations (NHS and Municipality) weren’t ready (participants didn’t know) to share information about patients through the technology provided, but their professionals were already motivated to transit for a digital society, considering their impacts to improve quality of life and wellbeing of older people who live in community and home. Nevertheless, participants had concerns about financial incentives and resources to develop an integrated care model empowered by technology.

In the second set of critical factors (People), participants have recognized the importance of engaging all stakeholders since the initial phases using a person-centred, universal design and co-creation approaches to adapt the use case and technologies to the users’ interests, motivations, and calendars. This option was a

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relevant requirement both older adults (patients) as professionals, and it should be translated in a suitable and extensive information and training.

In the third set of critical factors (Plan), participants believed that the organizations and their professionals are aware about digital transition is an irreversible pathway and change their professional roles and activities; and they are ready to do it, such as pass by a pilot experience to a large-scale intervention. In this regard, it's a critical requirement to provide detailed information and training, like tutorials, terms and conditions, support, ethical and GRDP regulations, workflow, etc. However, this readiness was limited by the lack of financial resources, digital literacy, and training.

In the last set of critical factors (Run), participants required detailed explanations about legal and ethical frameworks, and security measures, through informative flyers, training sessions, and time to raise issues and concerns. This option was a critical requirement to develop the use case in real-life and to increase the users' awareness and trust to effective adoption. Moreover, participants required an analytic system to monitor if technology is working well, but also a helpdesk support. Participants also understood that, currently, organizations and professionals hadn't enough digital resources and literacy to scale-up the use case, and there wasn't information about contracts and agreements between suppliers and organizations.

Table 14 Use Case 2 - MOMENTUM Framework (First and Second Evaluation).

Domains	**How much you agree with the sentence?**			**The adoption is:**		
	Agree	Disagree	Don't Know	Simple	Complicate	Complex
A) Context				**Simple: 4**		
A1) CSF 1. Ensure that there is cultural readiness for the telemedicine service	3	1	7	Complicate: 3		
A1.1) In my organization/region doctors and other healthcare professionals are ready to share clinical information with each other and with the patient i.e., there is a level of trust among all the stakeholders.	2	2	7	**Complex: 4**		
A1.2) In my organization/region patients and providers (healthcare professionals) are ready to use ICT (e.g., computers, tablets, mobile phones).	0	4	7			

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A1.3) In my organization/region financial and other incentives are aligned with the service to be deployed.	5	3	4	
A1.4) In my organisation/region an underpinning culture embraces technology.	7	0	4	
A1.5) In my organisation/region an underpinning culture welcomes and even promotes change, innovation and shows openness to new ideas.	7	0	4	
A2) CSF 2. Come to a consensus on the advantages of telemedicine in meeting compelling need(s)	3	0	8	
A2.1) In my region/organisation there is general consensus on the current telemedicine solution being the best available solution for meeting a compelling need.	9	0	2	
B) People				**Simple: 6** Complicate: 4 Complex: 1
B1) CSF 4. Involve healthcare professionals and decision-makers	11	0	0	
B1.1) Healthcare professionals have been involved in the development of the content of this project.	11	0	0	
B1.2) Healthcare professionals have been involved in the development of the process and time schedule for this project.	11	0	0	
B1.3) Decision-makers have been involved in the development of the content of this project.	11	0	0	
B1.4) Decision-makers have been involved in the development of the process and time schedule for this project.	11	0	0	
B2) CSF 5. Put the patient at the center of the service	11	0	0	
B2.1) In this project the patients have been sufficiently involved in the	11	0	0	

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development of the telemedicine solution.				
B2.2) In this project telemedicine service is based on the patient´s needs.	11	0	0	
B2.3) In this project enough information and training is provided for the patients in order for them to obtain the best results possible from using the telemedicine solution.	11	0	0	
B3) CSF 6. Ensure that the technology is user-friendly	0	0	11	
B3.1) The telemedicine technology used in our project is user-friendly for patients.	0	1	10	
B3.2) The telemedicine technology used in our project is user-friendly for health professionals.	0	0	11	
B3.3) The telemedicine technology used in our project does not need an extended training process prior to using it.	0	7	4	
C) Plan				Simple: 4 **Complicate: 7** Complex: 0
CSF 7. Pull together the resources needed for deployment	11	0	0	
C1.1) In my region/organization the financial resources needed for deployment of the telemedicine solution are available.	0	7	4	
C1.2) In my region/organization the IT competences needed for deployment of the telemedicine solution are available.	3	4	4	
C1.3) In my region/organization enough time for the training needed in order to implement the telemedicine solution is available.	3	4	4	
C2) CSF 12. Guarantee that the technology has the potential for scale-up	11	0	0	

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C2.1) We are fully aware of what it takes for the technology to be deployed on a large scale.	0	0	11	
C2.2) In our region/organization we are ready for large-scale deployment of the technology.	1	6	4	
C2.3) The project will supply the documentation needed to ensure that there is a basis for large-scale deployment of the project.	11	0	0	
D) Run				Simple: 0 Complicate: 4 **Complex: 7**
CSF 13. Identify and apply relevant legal and security guidelines	4	3	4	
D1.1) The project is carried out in accordance with the relevant guidelines on legal matters.	4	3	4	
D1.2) The project is carried out in accordance with the relevant guidelines on security matters.	4	3	4	
D2) CSF 15. Ensure that telemedicine doers and users are privacy aware	5	4	2	
D2.1) In this project the telemedicine doers are aware of protecting the patients´ privacy in terms of health information and other information collected during the course of the pilot.	7	0	4	
D3) CSF 16. Ensure that the information technology infrastructure and eHealth infrastructure are available	11	0	0	
D3.1) We have ensured that the IT infrastructures needed are in place for deployment and large-scale implementation.	0	7	4	
D3.2) We have ensured that the eHealth infrastructures needed are in place for deployment and large-scale implementation.	0	7	4	

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D4) CSF 17. Put in place the technology and processes needed to monitor the service	5	0	6
D4.1) We have set up a system to monitor our telemedicine service ensure that it is running smoothly at all times.	0	0	11
D4.2) We have set up a system to solve any incident that may occur during the service.	0	0	11
D4.3) We have a system which supports the end-users in resolving any doubts that they might experience with the telemedicine solution.	11	0	0
D5) CSF 18. Establish and maintain good procurement processes	0	3	8
D5.1) We have clear agreements regarding the quality of the deliveries provided by our vendors.	8	3	0
D5.2) We have clear agreements regarding the service level provided by our vendors.	8	3	0

Based on these inquiries (Table 11, Table 12), the researchers identified a list of challenges that could have impact on the implementation in real-life. This list was generated to be a “compass of awareness” to find the mitigation measures while pilot activities were being developed. The list was developed and sent to some participants for validation. The participants were the Public Employees and the Deputy, and they selected by personal contacts with the researchers. The list was organized by 4 categories (People, Technology, Organizations, and Context / Environment) and completed with mitigation measures:

- **People**
  - Challenge 1. Older people have a high risk of develop chronic diseases that can reduce autonomy and independence, namely to the daily self-care.
  - Challenge 2. The health and ageing are complex and multidetermined processes, among other, by social determinants (diet, alcohol, tabaco, sedentarism) that assistive technology can change.

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- Challenge 3. Stakeholders (Older people, Formal/Informal Caregivers, Facilities, Decision-makers) need continuous education and training to design, plan, adopt and assess digital health solutions in real-life contexts of use.

  Mitigation Measure(s): For the pilot study, researchers should recruit older adults with minor and subjective complains related to cognitive decline; moreover, researchers should provide continue assistance to the participants during the pilot study.

- **Technology**
  - Challenge 4. Assistive Technology demand a high level of human-machine interactions, and values like trust, satisfaction, efficacy, skills, and readiness.
  - Challenge 5. The use case is successful if technology link self-care (older people) and preventive care (caregivers).
  - Challenge 6. Digital Transition must engage all stakeholders since the designing phase to ensure that technology respect the human agency.

    Mitigation Measure(s): During the pilot study (Phases 4 and 5), the technical functionalities available should be progressive, i.e., from the basic to the complex, and this progress should be according to the participants' request.

- **Organizations**
  - Challenge 7. Digital health solutions are changing the roles, tasks, tools, conditions of all professionals in healthcare and social care sectors.
  - Challenge 8. Organizations and employees demand resources, equipment, training, strategic plans, to successful adopt digital health.
  - Challenge 9. Organizations and employees require new legal and ethical frameworks to use technology with security, literacy, rightness, and fairness.

    Mitigation Measure(s): For the pilot study, formal/informal caregivers (i.e., care team) were not required, and they were replaced by an active and healthy ageing manual provided to the participants (i.e., older adults).

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- **Context / Environment**
  - Challenge 10. The macrosocial and microsocial contexts are favourable (Novelty Effect) to adopt assistive technology by older people and their networks.
  - Challenge 11. The technological infrastructures (software and hardware) demand high changes in life-environments (e.g., home, public spaces).
  - Challenge 12. Authorities must provide new legal and ethical frameworks to use technology with security, literacy, rightness, and fairness.

    Mitigation Measure(s): The pilot study must have the approval from national ethical committees (Portugal and Ireland) and, at least, an assessment risk from a legal DPO (provided by the Use Case Leader).

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3.5 Phase 1

3.5.1 PACT and FICS Scenario

3.5.1.1 PACT

Code	UC-PT5-002
Applicable SHAPES Persona	SHAPES Persona "John and Joan" (P4)
Applicable SHAPES use case	Assistive Technology for Cognitive Decline in Older Adults living in Community
People Roles and/or actors of typical users involved in delivering and receiving the telemedicine intervention	Beneficiaries: Older people (≥ 60 years old) who live at home autonomously with/without chronic diseases and complains of cognitive decline. They were the target group of the intervention deployed (beneficiaries) and the principal end-user of the digital solution tested. Informal Caregivers: Adults (≥ 18 years old) acknowledged (selected) by the "beneficiaries" as the person(s) who provide any type of continuous and daily care because emotional ties (e.g., familiar, friend, neighbour), availability (e.g., time, distance), or/and informal contract (e.g., payment). Formal Caregivers: Licenced professionals and/or organizations, public or private, who provide healthcare and social support to the "beneficiaries" and/or their "informal caregivers" (gerontologist, nutritionist, nurse, GP, public facilities, pharmacy, primary care centre). Facilities: People and/or organizations, public or private, who ensure the logistics to develop a pilot study in a real-life condition, namely dissemination, local guides, healthcare providers, and equipment (e.g., rooms, computer, data show, primary care centres, gerontologic facilities). Researchers: People and/or organizations, public or private, who design and implement the pilot study, namely IT developers or technical partners and pilot sites or academic partners.
Activities Activities to be performed by the actors in order to provide and receive the telemedicine intervention successfully procedures for the professional and the patient; Parameters	Voice Assistant: Older people interact with the technology individually to command a digital voice assistant that is an interactive personal agenda, an automatic events' notification and confirmation system, an infinite list of step-by-step tutorials acceded digitally, an automatic self-assessment tool by question-answer, and an automatic caregivers' alert system. Users personalize the digital functionalities by completing online forms through an internet webpage. Then, they command these

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that determine the measures used in the intervention	functionalities using voice interaction with a smart speaker (e.g., column, smartphone). Formal/informal caregivers are only required to program the skills and receiving/consulting reports and alerts. eHealthPass/CAPTAIN: Older adults (and informal caregiver) interact with technology individually to improve their own self-care management and behaviours, but also to have a higher communication with a healthcare provider (or other formal caregivers). They use a smartwatch and a related mobile application to control health and behavioural parameters (e.g., heart bit, steps, sleep, nutrition plan, medical appointments, medicines indications). The smartwatch collects automatically health and behavioural data and sends this data to the mobile application. The mobile application centralizes data collected by the smartwatch (heart bits, steps, ECG, SpO2) and manually by the older adults (e.g., self-assessment, health events, diet plan) or healthcare provider (e.g., consultation, medicines instructions). Each older adult can be connected with many healthcare providers; each healthcare provider can be connected with many older people. Smart Mirror Ecosystem: Older people's homes are equipped (improved) with IoT sensors (movement, temperature, humidity, electric consumption, panic button, human falls) centralized in a digital and technical platform (smart mirror) that provides an age-friendly dashboard (touched screen) to control the sensors and access to their regular reports; the reporting tool also includes data provided by smart wearables (e.g., smart band). This platform also integrates a software with several physical and cognitive exercises (stimulation) for older people including a digital evaluation tool to assess performance.
Context Social-medical relevance of the telemedicine intervention; privacy issues; risks for the patient; locations	These digital solutions are installed in the users' homes and used by users daily in the community, both in Portugal and Ireland. Each user has a SHAPES ID (SU1, SU2, …) and SHAPES email to create a personal profile for the digital solution. The GDPR and ethics in line with SHAPES WP8, and national DPO and Ethical Committees.
Technology Type of information/parameter that are relevant in monitoring the health status; type and	Voice Assistant: The prototype is composed by a chatbot commanded by natural voice interactions or digital voice assistant (called NARI) that is interoperable with a four skills/functions digital platform of self-care (called Adilib). Both chatbot and Adilib platform are accessed by individual webpages through internet browsers; while the chatbot webpage must continuously "open" in

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frequency of accessibility of information; feedback modalities (communication)	an internet browser (online), the Adilib webpages are only accessed to program the skills. This prototype "runs" through two technical devices: (i) a tablet with internet browsers (e.g., Google Chrome), internet connection by WIFI, and Bluetooth; (ii) and a smart speaker or loudspeaker with Bluetooth. Both devices are connected by Bluetooth. Components: (1) Lenovo IdeaPad Duet Chromebook; (2) Jabra 510 loudspeaker; (3) Charger; (4) Computer or tablet with internet browsers; (5) Webpage links. eHealthPass/CAPTAIN: The prototype is composed by the smartwatch Withings (medical device that collect heart rates, ECG, SpO2, sleep patterns, steps and floors, blood pression) and a mobile application eHealthPass that registers/shows personal healthcare data collected by the smartwatch automatically or by the older people manually (e.g., diets' plan, medicine instructions, medical agenda, health events like hospitalizations or surgeries, health conditions like chronic diseases or medicines); this mobile application is connected with a care platform (with the same name eHealthPass) accessed only by formal caregivers (e.g., GP, nurse, therapist) to monitor and manage the individual care plans (e.g., change items, control parameters) and to communicate with patients (by videocalls, messages, questionnaires, educational tools). Components: (1) Smartphone or Tablet with Bluetooth and Internet connection 4G; (2) Mobile application Health Mate (Withings); (3) Mobile application SHAPES-eHealthPass; (4) Computer or tablet with internet browsers; (5) Webpage links. Smart Mirror Ecosystem: The prototype is composed by home sensors (movement, temperature, humidity, electric consuming, open/close doors/windows), personal sensors (smart band to collect heart bits, steps, calories, sleep patterns), and a digital platform installed inside a smart mirror (device composed by a touch screen, raspberry, dashboard, internet connection, and Bluetooth); this platform controls the sensors (home and individual), reports the sensors' data, provides a physical and cognitive exercises, show a personal agenda, and support video calls. Components: (1) Smart Mirror; (2) Smart Band; (3) Panic Button; (4) Home Sensors; (5) RIFD Cards.

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3.5.1.2 FICS

Code	UC-PT5-002
Applicable SHAPES Persona	SHAPES Persona "John and Joan" (P4)
Applicable SHAPES use case	Assistive Technology for Cognitive Decline in Older Adults living in Community
Function and events The functionality of the intended system which is capable of realizing actor's activities	Voice Assistant: (1) a digital agenda with an automatic notification system, (2) a digital handbook with many and different tutorials (step-by-step guidelines), (3) a digital screen tool to register and assess personal indicators (e.g., mood, heath parameters), (4) and a digital alert system to communicate with a third party automatically. eHealthPass/CAPTAIN: (1) a digital system to automatically collect health and behavioural indicators and send them to a platform accessed by the data subjects (older people) and their formal and/or informal caregivers; (2) a mobile application to self-management an individual care plan and monitor health and behavioural indicators; (3) a digital platform for formal/informal caregivers monitor and manage remotely an individual care plan. Smart Mirror Ecosystem: (1) a digital system to monitor events inside home and differentiate normal vs accidental events (e.g., movements, falls, doors/windows open/close, theft, electricity consuming, temperature), but also individual events (e.g., heart bits, calories, sleep patterns); (2) a digital system to report the older people and informal caregivers (e.g., weekly reports), but also to notify automatically informal caregivers (e.g., phone call and message); (3) a digital stimulation system to provide physical and cognitive activities to do in home; (4) and a digital agenda with automatic notifications (e.g., medical appointments, social events, calendar).
Interactions and usability issues	Voice Assistant: Older people and/or their informal caregivers access the Adilib platform to configure the four skills commanded by NARI voice assistant (chatbot). The Adilib is accessed by an internet browser (e.g., Google, Mozilla), using different webpages, a webpage per skill. There are four webpages for four skills, and one webpage for the registration: https://adilib.shapes.vicomcloud.net/skills/signup/ Agenda: https://adilib.shapes.vicomcloud.net/agenda/login/?next=%2Fagenda%2F

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	Notifications: https://adilib.shapes.vicomcloud.net/reminders/login/?next=%2Freminders%2Fhome%2F Tutorial: https://adilib.shapes.vicomcloud.net/how_tos/login/?next=%2Fhow_tos%2Fhome%2F Questionnaires: https://adilib.shapes.vicomcloud.net/questionnaires/login/?next=%2Fquestionnaires%2Fhome%2F When users access to the Adilib platform using the skills' webpages, they find a digital form to complete with missed information that "feed" or "teach" the chatbot/voice assistant. Each skills' webpage asks specific information that should be provided by open or multi-optional answers. Also, the chatbot with the voice assistant works through a webpage accessed by an internet browser. This webpage must be "opened" continuously to the voice assistant works: Chatbot / Voice: https://adilib.shapes.vicomcloud.net/deploy/login/?next=%2Fdeploy%2F The (programmed) skills are commanded through voice interactions between older people and a "Personal Assistant". Older people ask to the "Personal Assistant" for agenda, notifications, tutorials, and questionnaires; and the "Personal Assistant" answer them (e.g., "Older people: Hey! What is my agenda for today?", "Voice: You are free today"); the "Personal Assistant" also send automatic messages for informal caregivers if any (predefined in Adilib) accidental event happens (e.g., send an email to a relative if the older individual doesn't answer a questionnaire or a notification). eHealthPass/CAPTAIN: Older people install a mobile application in their own smartphones or tablets and wear a smartwatch daily. Data collected by the smartwatch is accessible in the mobile application and can be transferred by email in PDF format (e.g., heart bits, blood pressions, ECG, SpO2, sleep patterns, steps walked). The mobile application is integrated with a formal/informal caregiver through a care platform accessible by an internet browser (webpage). In this platform, formal caregiver (as GP, nurse) can define an individual care plan and manage it remotely (consult vital signs, change instructions, update medication, schedule events, assess perceptions); they also can

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	use videocalls with older people and send them educational materials. Smart Mirror Ecosystem: The older people's home is equipped with home sensors; older people are provided with smart wearables/sensors (smart band, falls' sensor, and panic button); both home sensors and individual smart wearables send data to a digital platform (Smart Mirror). The digital platform analyses data received to define "normal" and "unnormal" daily events according to predefined scenarios. All events are registered and reported weekly; reports are downloaded from the platform manually by older people and/or informal caregivers (if they have permission). Additionally, the digital platform can send alerts to the older people (first) and informal caregivers (second) if some unnormal events happen (e.g., falls, low heart bit). The digital platform also provides physical/cognitive exercises to do in home (video demonstrations; written instructions; quiz), personal agenda with automatic notifications, and a videocall functionality. The platform functions (reporting, automatic notifications system, physical/cognitive exercises, agenda, videocall) are accessed and commanded by the older people (and/or informal caregivers) through a dashboard age-friendly in the Smart Mirror. The dashboard only uses icons to touch and multi-optional answers (without written slots).
Content and structure Variables of the interaction	This information is detailed in-depth in section 3.3 of this deliverable.
Style and aesthetics Look and feel of the system	This information is detailed in-depth in section 3.3 of this deliverable.

3.5.2 Key performance indicators

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

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repetition or major revisions to the use case and associated digital solutions are needed before entering further development oriented to further validation of technology benefits and commercialization.

The KPIs are detailed in the Table below (Table 8), and they are related with the outcomes detailed in section 3.8.5 of this deliverable.

- **KPI 1. To recruit older adults in the community**

  Outcome 1: The researchers planned different events to disseminate and recruit older adults considering the recruitment criteria and process.

  - Outcome 1.1. From a list of 70 public events (workshops) and private events (home visits), researchers would like to develop at least 50% (35 events).
  - Outcome 1.1. From a list of 100 potential older adults to participant in the public and private events, both in Portugal and Ireland, researchers would like to receive a manifestation of interest at least by ¼ (25 older adults).

- **KPI 2. To pilot Assistive Technology in real-life**

  Outcome 1. The researchers planned to develop the pilot in the real-life, with older adults who live in home and in the community.

  - Outcome 1.2. From a list of planned 40 older adults to participate in pilot study, researchers would like to successfully recruit 50% (20 participants).
  - Outcome 1.2. From a protocol with 3 moments of evaluation (T1, T2, T3), researchers would like to collect questionnaires from all participants (100%) at least in the Time 1 and from half of the participants (50%) in T1 and T2.
  - Outcome 1.3. From an expected daily use of the digital solutions, researchers would like the participants use them once time a week (measured by a number of accesses to the technology).

- **KPI 3. To improve the psychosocial variables of the pilot's participants**

  Outcome 2: The researchers believe that the daily using of digital solutions tested improves the participants' psychosocial variables.

  - Outcome 2.1. Using the digital solutions daily keeps stable the quality of life of the participants, assessing with WHOQOL-Bref (Same score between T1 and T3).

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- Outcome 2.2. Using the digital solutions daily keeps stable the capacity to self-care of the participants, assessing with EQ-5D-5L and GSE scales (Same score between T1 and T3).
- Outcome 2.4. Using the digital solutions daily keeps stable the social support of the participants, assessing with OSSS-3 scale (Same score between T1 and T3).

- **KPI 4. To increase digital usability and literacy**

  Outcome 2: The researchers believe that the daily using of digital solutions tested improves the participants' digital usability and literacy.

  - Outcome 2.3. Using the digital solutions daily keeps stable the digital usability and literacy of the participants, assessing with SUS scale (Same score between T1 and T3).

3.5.3 Timeline of pilot activities

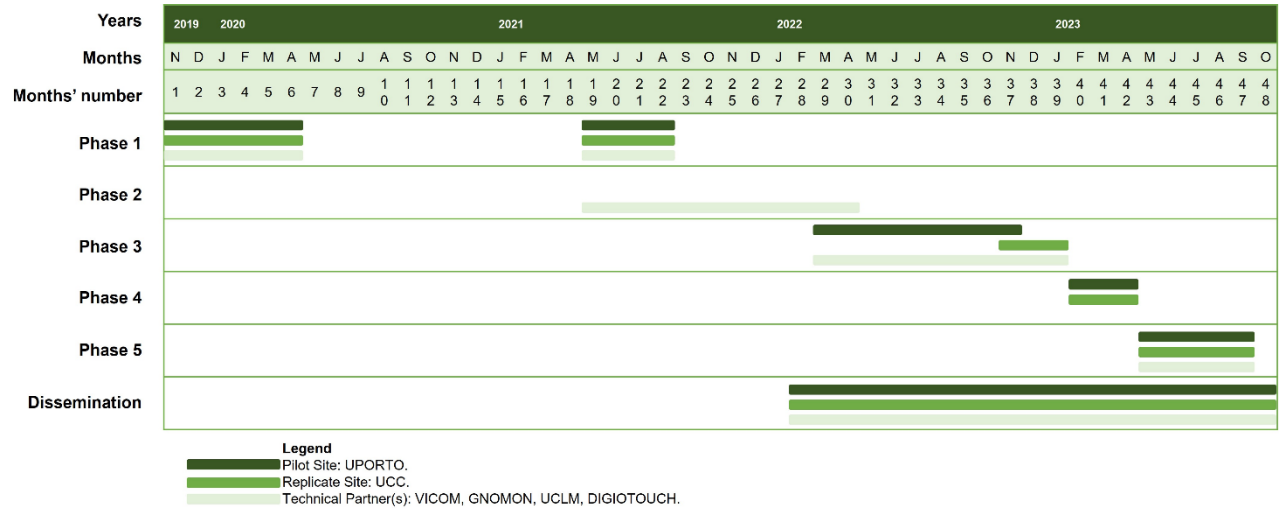

Figure 44: Use Case 2 - Timeline of pilot activities.

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3.6 Phase 2: Testing of mock-ups and prototypes

3.6.1 Methodology of testing

This information is detailed in-depth in the SHAPES Deliverable "D5.4 SHAPES Digital Solutions V3" (SHAPES-WP5, 2022, pp. 209-238, 282-298, 452-464, 524-544).

3.6.2 Results of testing

This information is detailed in-depth in the SHAPES Deliverable "D5.4 SHAPES Digital Solutions V3" (SHAPES-WP5, 2022, pp. 209-238, 282-298, 452-464, 524-544). Furthermore, this phase was concluded when all prototypes were ready to use in real-life as detailed in section 3.3 of this deliverable.

3.7 Phase 3: Hand-on Experiments

3.7.1 Methodology of hands-on experiments

The user experiments were developed to trainee / familiarize participants to use technologies autonomously. This phase was a 'selection process' that finished with the final sample of participants. There were two types of activities:

- Public workshops addressed to the older population. These events aim present the study and show the technologies to the audience; the audience can use the technologies as an experiment. These events were developed only in Portugal (pilot site) in collaboration with a centre of gerontology. There were 3 public workshops, one per technology, and participants were recruited in these events.
- Home visits addressed to a selected population. These events aimed to create the conditions to use technology autonomously in home, such as practical lessons, demonstrations, experimental use (without support), and written guidelines adapted to each participant. In Ireland, there were only home visits because the researchers already had a pre-selected sample.

During the home visits, researchers have assessed the participants' acceptance, satisfaction, and autonomy/readiness. The evaluation adopted a qualitative approach based on direct observations and interventions (trainee, lessons, demonstrations). The observations were evaluated by the researchers using an Observation Grid that included the System Usability Scale and the Think Aloud Protocol. During the event/session, researchers should complete one grid per visit to register the participants' progress, but especially the participant's feedback and comments

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(section 3.7.2 of this deliverable). The Figure 45 demonstrates an example of the observation grids adopted and already completed by the researchers.

Observation Grid to evaluate participants during the hands-on experiments

Based on System Usability Scale and Think Aloud Protocol

Participant (CODE)	SU 5
Date	17 - 03 - 2023
Place	Ireland - [illegible] (the + [illegible])

eHealth Pass/Captain

To be completed by the researcher.

Topic	SUS					Think Aloud Protocol
	1	2	3	4	5	
I think that I would like to use this system frequently.					X	
I found the system unnecessarily complex.		X				
I thought the system was easy to use.				X		Just the watch / APP is differ[illegible]
I think that I would need the support of a technical person to be able to use this system.						
I found the various functions in this system were well integrated.				X		why there are 2 Apps?
I thought there was too much inconsistency in this system.						Don't know / Don't understand
I would imagine that most people would learn to use this system very quickly.					X	Already has a Smartwatch
I found the system very cumbersome to use.						
I felt very confident using the system.					X	
I needed to learn a lot of things before I could get going with this system.		X				

Acceptance Do / did you know this technology(ies)? What do you think about it? Do you wish use it? Is it challenging? Are you able to use it? How I can help you (training? more experiments? time? change the structure?) What can you already do? How did you learn? Do you have issues? Did you understand the risks of use? Do you wish to participate?	there are no connection between APPs. Don't want APP. Just watch
Satisfaction Do you like the technology? Is difficult/easy to use it? Is the technology useful for you and your life? Can you describe me what you feel and think when you are using it? Trust? Fear? Anxious? Curiosity? Are you motivated to use it? What functions are more used by participants? Pros and cons?	✓
Autonomy/Readiness Are you ready to use the technology autonomously? What are the functionalities you have more or less issues and challenges? Do you know call to the helpdesk? What will be your needs to use it autonomously (training, follow-up, visits, meetings, use few functions)?	✓
Other observations	

Figure 45: Use Case 2 - Observation Grid used.

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3.7.2 Results of the hands-on experiments

Hands-on experiments	Conclusions
Acceptance	
Leader: UPORTO (Portugal) • Pilot Site: Ageing Lab of Ílhavo Municipality. • SHAPES Partners: VICOM, UCLM, GNOMON. • Digital Solutions: VA; HW; SM. • Participants: 35 participants self-registered. • Especial participants: 1 deputy from Ílhavo Municipality and 4 professionals from Ageing Lab of Ílhavo Municipality. • **3 Public workshops** to explain the use case and pilot, demonstrate technologies (mock-ups; wireframes; demos), and collect consents (verbally). The first workshop was attended by 25 participants, 19 participants in the second, and the final sample in the third (11 participants). **Leader: UCC (Ireland)** • Pilot Site: Community (Rural Area). • SHAPES Partners: GNOMON. • Digital Solutions: HW. • Participants: 10 older people pre-selected by the geriatrician based on phone call between patient and doctor. • **20 Home visits** to explain the use case and pilot (activities), demonstrate technologies (mock-ups; wireframes; demos), and collect consent forms (verbally). There were 2 visits per participant, temporally distanced 15 days. During this period, participants should use the technology to self-evaluate their motivation.	**Accept** • Novelty Effect: Participants love new IT gadgets and life challenges. • Contagion Effect: Participants are motivated and invited by friends who participate. • Vision of Future: Participants, namely the Decision-makers as a City Hall / Municipality, believe in digital transition. **Don't Accept** • Deniers: "I don't know", "I have no time", "I don't believe". • Not interested: "I don't need", "This is not useful", "Not now". • Internet: Participants have no internet connection at home. **Limits to Accept** • Legal and Ethics: Participants from NHS (formal caregivers) need approval from Regional Administration that was not achieve yet (May 2023). • Part-time: Participants use to be informal caregiver in part time and aren't fully engaged.

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- **Materials**: 7 Observation Grids.

Satisfaction

UPORTO (Portugal)

- Pilot Site: Community (Urban Area).
- SHAPES Partners: VICOM, UCLM, GNOMON.
- Digital Solutions: VA; HW; SM.
- Participants: 11 older people (final sample).
- **22 Home visits** to demonstrate in real-life technology (demo prototype) to participants individually and observe their interactions with technology, inquiry their motivations to use it, and their availability and feelings regarding the technology and pilot study. There were 2 visits per participant, temporally distanced 15 days. During this period, participants should use the technology to self-evaluate their motivation.
- **Materials**: 11 Observation Grids.

UCC (Ireland)

- Pilot Site: Community (Rural Area).
- SHAPES Partners: UCC, GNOMON.
- Digital Solutions: HW.
- Participants: 7 older people (final sample).
- **14 Home visits** to demonstrate in real-life technology (demo prototype) to participants individually and observe their interactions with technology, inquiry their motivations to use it, and their availability and feelings regarding the technology and pilot study.
- **Materials**: 7 Observation Grids.

Daily Use

- Basic: Participants use technologies daily because it's easy and non-obtrusive (smartwatch, home sensors).
- Premium: Participants use technology because it's a challenging task.
- Non-digital natives: Overall participants are non-digital natives and need practice to use technology autonomously.
- Helpdesk: Participants use the helpdesk service provided by researchers by phone.

Suggestions

- Follow-up: Participants ask / demands a continuous follow-up presential (home visits) and remotely (phone), until be totally autonomous.
- Intuitive: Participants suggest interfaces and commands easier to understand and use.
- Readiness: Participants feel frustration and no-interest because technology is not ready in the first interaction.
- Training: Participants required a training because they are non-digital natives and technologies are complex.

Autonomy

Leader: UPORTO (Portugal)

Case Studies

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- Pilot Site: Community (Urban Area).
- SHAPES Partners: VICOM, UCLM, GNOMON.
- Digital Solutions: VA; HW; SM.
- Participants: 11 older people (final sample).
- **33 Home visits (1 visit per month / 3 months)** to train the participants to use technology autonomously, and to assess the participants' autonomy to use technology and to contact helpdesk.
- **Materials**: 22 Observation Grids.

Leader: UCC (Ireland)

- Pilot Site: Community (Rural Area).
- SHAPES Partners: UCC, GNOMON.
- Digital Solutions: HW.
- Participants: 7 older people (final sample).
- **21 Home visits (1 visit per month / 3 months)** to train the participants to use technology autonomously, and to assess the participants' autonomy to use technology and to contact helpdesk.
- **Materials**: 14 Observation Grids.

- 22 Older People: The number of participants (≥ 60 years old) who are using technologies in real-life (Phases 4 and 5).
- 18 Researchers: The number of researchers, IT developers, gerontologists, and other employees engaged.
- 7 Partners: The number of stakeholders engaged from university, researcher centre, start-up, public facilities, and political authorities
- 5 Countries: The number of European countries engaged in a European Pilot Campaign (Portugal, Ireland, Spain, Greece, and Estonia).
- 3 Assistive Technologies: The number of digital solutions tested under the same model (integrated and person-centred care).

Risks

- Dropouts: Participants leave for any reason.
- Delays: The full-planned intervention requires more time to develop in real-life.
- Prototyping: Technical and digital redesign and updates are complex and expensive.
- Obsoleting: Technologies and use case must be continuous adapted to the participants' leanings/skills.

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3.8 Phase 4: Small Scale Live Demonstration

3.8.1 Recruitment of participants

The participants are older people – and, if it's possible, their direct caregivers – who live in the community, selected by the following criteria (Table 15):

Table 15 Use Case 2 - Recruitment Criteria.

Inclusion Criteria	Exclusion Criteria
Older People	
• People aged 60 years or over. • Living in home, autonomously and can decide. • Subjective complains of cognitive decline, in the last 6 months. • Chronic diseases controlled by GP or nurse in healthcare system. • Having internet connection (WIFI, 4G). • Having a consent form.	• Having a severe medical condition or event, in the last 6 months. • Interrupts the participation in the study.
Caregivers	
• People aged 18 years or over. • Having the permission by older adults. • Being healthcare provider (GP or nurse) OR informal caregivers, in the last 6 months. • Having internet connection (WIFI, 4G). • Having a consent form.	• Having a severe medical condition or event, in the last 6 months. • Interrupts the participation in the study.

The recruitment process has developed in the community, by the SHAPES consortium and the community. Researchers have contacted these stakeholders to develop an awareness campaign addressed to the older people, composed by public events (e.g., workshops, seminars) and home visits (Figure 46).

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These events correspond to the hands-on phase and aim recruit older people in the criteria: the older person who lives in home, autonomously, and he/she has minor subjective complains of cognitive decline; he/she has participated in the hands-on tests and is able to use the digital solution autonomously in home/community and assess it fairly. Only the older people selected by the hangs-on experiences participate in the intervention, including the caregivers. The final participants and the researchers have a meeting to collect the consent forms, establish the calendar for the follow-up meetings, and finally technology settings (hardware / software).

This recruitment process was deployed in 2 pilot sites: (1) Portugal, by UPORTO and Ageing Lab of Municipality of Ílhavo; (2) and Ireland, by UCC and St. Finbarr' Hospital (Cork). The recruitment process differed according to the pilot sites: while in Portugal, participants rate was decreasing during the recruitment (from hangs-on to intervention) and there are no caregivers recruited; in Ireland, participants are constant and there is one caregiver (a geriatrician volunteer in Ireland).

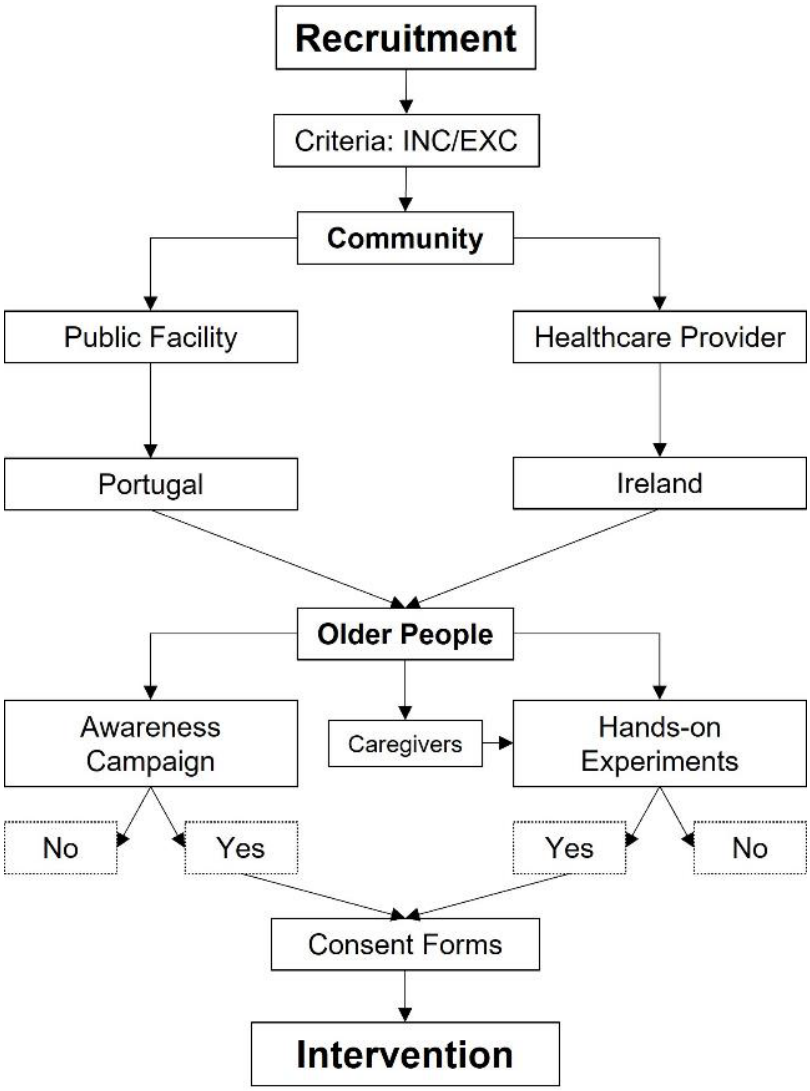

Figure 46: Use Case 2 - Recruitment Scheme.

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This use case was developed with a sample composed by 22 older adults, 15 from Portugal (UPORTO pilot site) and 7 from Ireland (UCC pilot site). The Table 16 resumes the sociodemographic data of this sample and the digital solution adopted by participants.

Table 16 Use Case 2 - Overview of the Sample.

Digital Solution	Portugal	Ireland (UCC)
Voice Assistant	4 Older Adults 4 Women	Not recruited
eHealthPass/CAPTAIN	7 Older Adults 4 Men | 3 Women	7 Older Adults 5 Men | 2 Women
Smart Mirror Ecosystem	4 Older Adults 3 Women | 1 Man	Not recruited
Total	**15 Older Adults** 10 Women | 5 Men	**7 Older Adults** 5 Men | 2 Women

3.8.2 Technical aspects & Logistics

This use case has piloted three different technologies. Overall, these technologies were installed and provided in the participants' homes (Smart Mirror, Voice Assistant, eHealthPass/CAPTAIN in Ireland and Portugal) and/or in the community, namely in a public facility (eHealthPass/CAPTAIN in Portugal). The Table 17 summarizes the logistic for each technology int both pilot sites.

Table 17 Use Case 2 - Description of the Technical Aspects & Logistics.

Digital Solution	Portugal	Ireland (UCC)
Voice Assistant	• Technical partner (VICOM) has provided all the devices, manuals, and workshops (online) to the researchers who must install the voice	• Technical partner has provided all the devices, manuals, and workshops (online) to the researchers who must install the digital

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	assistant in the participants' homes. • The researchers have tested the technology and elaborated a report with minor errors or "demo errors" (e.g., translations, velocity of answers, difficulty in voice interaction). • Despite those minor errors, researchers decided to install in the participants' homes, considering the technology was using software to improve (e.g., voice recognition is a machine learning software). • Researchers have installed the voice assistant in the participants' homes, considering the suitable place in home (e.g., kitchen, living room, bedroom) to use the technology regularly. • The installation was connecting the Table to the homes' WIFI; the loudspeaker to the Tablet by Bluetooth; and to plug in both devices to electricity. • As a hands-on experiments, researchers provided workshops in the participants' homes to support them to use the technology. Then, researchers provided a phone number to the participants and a schedule	solution in the participants' homes. • The researchers have tested the technology and elaborated a report with minor errors or "demo errors" (e.g., translations, velocity of answers, difficulty in voice interaction). • The final decision was don't pilot this technology until the errors are not solved considering an ethical committee recommendation.

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	to call if any challenge happens. • Technologies were installed successfully, and participants had used them autonomously. • The "demo errors" have continued and the participants have some difficulty to setting the skills. • Researchers decided to extend the phases 4 and 5 until the end of the project.	
eHealthPass **CAPTAIN**	• First technical partner (GNOMON) has provided the eHealthPass Mobile APP, manuals, and workshops (online) to the researchers install the digital solution in the participants' smartphones. • The researchers have tested the Mobile APP and there weren't technical errors. The tests were done in the researchers' smartphones. • Researchers have installed and tested the eHealthPass APP in the participants' smartphones. This activity was developed in the participants' homes to evaluate the WIFI connection or the mobile internet. • Second technical partner (DIGIOTOUCH) has provided the smartwatches and the respective mobile	• UCC has bought the devices required, namely the smartwatches and the Tablets. This option was forced because participants didn't have suitable smartphones to run the eHealthPass APP. • First Technical partner (GNOMON) has provided the eHealthPass Mobile APP, manuals, and workshops (online) to the researchers install the digital solution in the Tablets. • Second technical partner (DIGIOTOUCH) has provided the smartwatches and the respective mobile APP (Health Mate / Withings) to the researchers; and a CAPTAIN software to connect the smartwatches to the eHealthPass.

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	APP (Health Mate / Withings) to the researchers; and a CAPTAIN software to connect the smartwatches to the eHealthPass. • The researchers have installed the second APP in the participants smartphones and connected them with the smartwatches using the Bluetooth. These activities were developed in the participants' homes. • When the two APPs were installed in the smartphones and connected to the smartwatches, researchers have trained the participants to use them autonomously.	• Researchers have installed the Mobile APPs in the Tablets and connected them to the smartwatches. • Researchers have tested each Tablet (two APPs) and Smartwatches. • Researchers were visited the participants in their own homes to supply them with the devices and connected them to homes' WIFI.
Smart Mirror Ecosystem	• Technical partner (UCLM) has installed the Smart Mirror in the participants' homes and provide them with all devices required (e.g., smart band, panic button); a UCLM team (Spain) came to Portugal for a month. • Technical partner has installed the smart mirror in the participants' homes, considering the suitable place in home (e.g., kitchen, living room, bedroom) to use the technology regularly. • The installation included per participants' home: to put home sensors by the house, to connect cables to the mirror, to connect and	Not applicable because this digital solution wasn't tested by UCC.

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	program the IoT devices to the Smart Mirror, to program the functionalities (e.g., monitoring, panic button, video call). • In this phase, the digital solution worked with few functionalities (e.g., home monitoring, smart band, panic button, video call). This is occurring because a technical problem related to technical remote control, not solved yet; the solution requires a re-installing the smart mirror. Researchers and technical partner are organizing the new visit to the participants' homes (i.e., a Spanish team came to Portugal for a month again).	
SHAPES accounts	Personal accounts were generated using the SHAPES emails to provide the participants with a pseudonymized SHAPES account in the SHAPES Platform.	

3.8.3 Roles and Responsibilities

Older adults (≥ 60 years old) were invited to use daily three digital solutions for eight months. They lived in home, engaged in the community, and they had subjective complains of cognitive decline in minor stage (e.g., lose words, memory issues) and/or a chronic disease (e.g., heart, diabetes). They were assisted by a National Health System (public, private, social) that provided family doctor and nurse in primary care services, emergency services, hospitalizations, and long-term care; and they could invite an informal caregiver.

For this time, older adults (≥ 60 years old) used the digital solutions daily, helped by a list of instructions developed during the hands-on experiences (e.g., workshops, home visits, training, interviews), and a helpdesk team worked continually (e.g., phone calls, videocalls, messages). The activities and interactions with the digital solutions helped

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older people to self-monitor health and activity indicators (Heart Rate, ECG, calories, steps, sleep patterns) and to self-care (reminders, medicines intake, medical appointments, nutrition, physical and cognitive stimulation); and a communication system to connect older people and their formal/informal caregivers (e.g., chatbot, videocall, alerts).

This intervention was deployed in 4 phases: (1) Recruitment: Researchers invited the older adults (≥ 60 years old) in the community, through a public facility (Portugal) and a healthcare provider (Ireland); (2) Hands-on: Participants (older people, public facility, and healthcare provider) were trained to use digital solutions in real-life, and researchers installed/provided them to the participants; (3) Demonstration: Participants used the digital solutions in real-life (home, community) with the researchers' supervision; (4) Evaluation: Participants evaluated if digital solutions had impacts in self-monitor, self-care and in the communication with caregivers (Figure 47).

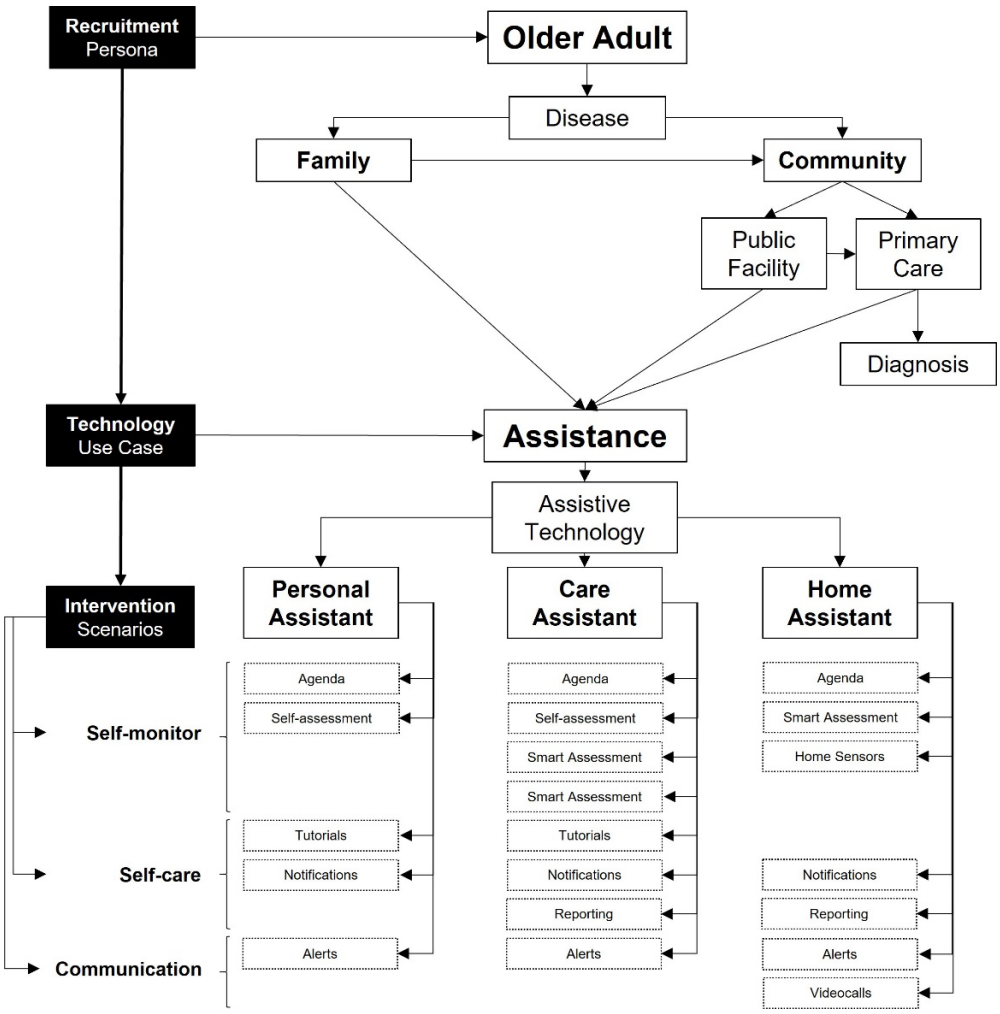

Figure 47: Use Case 2 - Intervention Scheme.

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3.8.4 Ethical considerations

This pilot study has the approval by:

- The Ethical Committee of School of Medicine and Biomedical Sciences and Central Hospital of Santo António. Approval Code: GS/HCC/123-2022/CE/P20(P398/CETI/ICBAS).
- The Social Research Ethics Committee of University College Cork, 2023.

This study has a Risk Assess by Data Protection Officer of University of Porto and SHAPES Ethical Advisory Board, detailed in the following documents: Data Plan; Data Mapping; DPIA; Data Processing Agreement; and Data Sharing. Additionally, this use case follows the ethical requirements defined in SHAPES Deliverable "D8.4 - SHAPES Ethical Framework", as it's summarized in the Table 18.

Table 18 Use Case 2 - 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)	To be consulted in section 3.8.4 of this deliverable.
Biomedical Ethics and Ethics of Care (3.2)	To be consulted in section 3.8.4 of this deliverable.
CRPD and supported decision-making (3.3)	To be consulted in section 3.8.4 of this deliverable.
Capabilities approach (3.4)	To be consulted in sections 3.6 and 3.7 of this deliverable.
Sustainable Development and CSR (4.1)	This use case contributes to the SDG 3.
Customer logic approach (4.2)	To be consulted in section 3.3 of this deliverable.
Artificial intelligence (4.3)	To be consulted in sections 3.3 and 3.6 of this deliverable.
Digital transformation (4.4)	To be consulted in sections 3.3 and 3.6 of this deliverable.
Privacy and data protection (5)	To be consulted in section 3.8.4 of this deliverable.

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Cybersecurity and resilience (6)	To be consulted in section 3.8.4 of this deliverable.
Digital inclusion (7.1)	To be consulted in section 3.8.4 of this deliverable.
The moral division of labor (7.2)	This use case contributes to most fair moral division of labour, especially for non-paid caregivers of people with dementia.
Caregivers and welfare technology (7.3)	Not applicable because this use case is not developed with caregivers (formal and informal). Nevertheless, the use case intents to be adopted to increase the communication between older adults and their formal and informal caregivers (To be consulted in sections 3.2 and 3.5 of this deliverable).
Movement of caregivers across Europe (7.4)	Not applicable because this use case is not developed with caregivers (formal and informal). Nevertheless, the use case intents to be adopted to increase the communication between older adults and their formal and informal caregivers (To be consulted in sections 3.1 and 3.2 of this deliverable).

3.8.5 Outcome of the Small-Scale Live Demonstration

This pilot study adopted a multiple case study methodology with a mixed methods of collection and analysis data. As pilot study, the methodology was addressed to a small group of participants and aimed (1) to validate if the intervention changes the outcomes, (2) to evaluate the users' performance in real-life with digital health solutions, (3) and to analyse the users' feedback and suggestions (Figure 48).

The study used an experimental method to evaluate and validate. Participants assessed the intervention three times: before the intervention starts (Baseline); 2 Months late (Time 2); and 5 Months late (Time 3). The evaluated was implemented using the WHO Quality of Life Bref, the EQ-5D-5L, the General Self-Efficacy Scale, the Oslo Social Support Scale, and the Life Events Inventory, the SUS scale, and questions about participation, technology acceptance, and literacy. The questionnaires were completed in a paper version during the researchers' home visits. The answers were analysed by a statistical method (SPSS), to find and measure the intervention's effects in the outcomes and validate if they (outcomes) are better (have a positive change), worst (have a negative change), or equal (have no change).

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Additionally, the study used a narrative method supported by semi-structured interviews, direct observation with written notes, and brief questionnaires. Since Hands-on phase (section 3.7 of this deliverable), the researchers collected qualitative data, in the workshops and home visits (Follow-up / Helpdesk / Phone calls). These data were analysed with a content analysis method to describe/systemize the process done by the participants to use digital solutions daily and successfully; but also, to list their feedback, testimonies, and recommendations.

Finally, the study included a secondary data collection method related to the digital data processed by the digital solutions. During the intervention, technology was continually and automatically tracking users' vital signs, health indicators (e.g., ECG, SpO2), physical activity (e.g., steeps, miles), and sleep patterns. Moreover, participants were invited to use the technologies to manually share data about clinical story, medicine intake, health events, nutrition, and social events. These digital data could be 'translated' into reports using the Data Analysis software provides by SHAPES platform. Data collected by the technologies could be triangulated with data provided by the other methods to validate the intervention (the secondary outcomes) and evaluate the users' performance.

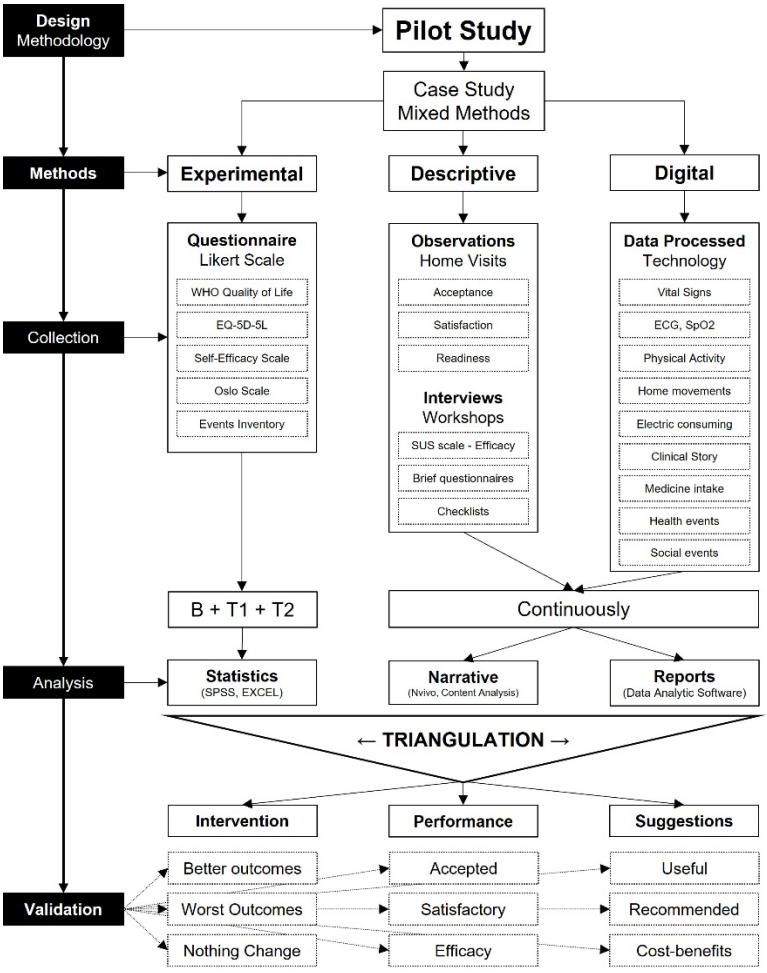

Figure 48: Use Case 2 - Methodology Scheme.

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Using this methodology, the researchers assessed if the intervention has / hasn't impact in 7 outcomes (Table 19) related to (1) acceptance, satisfaction, and usability of older adults to use daily Assistive Technologies for self-monitoring, self-caring, and communication, (2) and efficacy of these digital solutions to improve the quality of life, the efficacy for daily activities, the health perception, and the care networking,

Table 19 Use Case 2 - Outcomes.

Category	Variable	Tool	Measure	Outcome	
				Planned	Min.
Principal Outcomes					
OC 1 **Acceptance, Satisfaction, Usability**	**OC 1.1** Dissemination attendance	List of Events	Nr. of Events concluded	70	35
		Participants' attendance	Nr. of the Participants	100	25
	OC 1.2 Successful recruitment	Signed Consents	Nr. of Consent forms	40	15
		Participation	Nr. of Questionnaires	T1+T2+T3 from all participants	T1 from all participants T1+T2 from 50% of participants
	OC 1.3 Effective and continued use	Dropouts	Nr. of Questionnaires	T1+T2+T3	T1+T2
		Technology	Nr. of Accesses	Daily	Once a Week
Secondary Outcomes					
OC 2 **Digital Efficacy**	**OC 2.1** Quality of Life	WHOQOL-Bref	Statistic	Better score between T1 and T3	Same score between T1 and T3
	OC 2.2 Self-care	EQ-5D-5L	Statistic		
		GSE scale	Statistic		
	OC 2.3 Usability	SUS scale	Statistic		
	OC 2.4 Social Support	OSSS-3 scale	Statistic	Better score between T1 and T3	Same score between T1 and T3

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3.9 Phase 5: Large-scale pilot activity

3.9.1 Outcome of large-scale pilot activity

In this use case, researchers decided to merge the phases 4 and 5. There were two main reasons to explain this option.

First, due to the COVID-19 restrictions, it wasn't possible to recruit older people in the community, even to develop the phase 3. During the Pandemic context (almost 2,5 years, from March 2020 to December 2022), the researchers couldn't install and training the older adults to use the technology. Despite it, they have deployed remote meetings by phone calls and online meetings (i.e., using ZOOM) to recruit older adults and/or organizations (e.g., Day-care Centres). These "encounters" were relevant to develop the technology itself (section 3.7 of this deliverable) and to define the requirements to use it. However, the phase 3 only initiated in March 2022.

Second, the pilot activities, especially the recruitment and the intervention, was developed in the community (in the participants' homes and daily life). The research team (technical partners) must install a technical infrastructure in the participants' homes. This infrastructure was difficult to remove and install in another place. Moreover, the intervention required trained participants to use the technology correctly. During the phase 4, the researchers understood that the participants needed more time and training than planned to use the technology correctly. Once installed the technology in the participants' homes (and trained them) to develop the phase 4, it wasn't recommended and feasible to remove it in 1 or 2 months. Facing this evidence (situation), they decided to use the same participants and protocol in phases 4 and 5.

Facing these two situations, the researchers have decided to develop one protocol in both phases (e.g., recruitment, roles and responsibilities, outcomes, ethical considerations), and to recruit one single sample of participants who must use the technology for a long period of time (at least, 8 months). Currently (June 2023), the participants have initiated the phase 5 because they are using the technology autonomously as part of their daily life. This phase finish in September 2023 when researchers must assess the use case the second time. Additionally, in both pilot sites, there is a commitment to continue the pilot activities after the project between the researchers and the participants (both older adults and organizations recruited).

3.9.1.1 Preliminary results

The final results of this use case must be presented in detail at the end of the project (October 2023), namely in the SHAPES Deliverables "D6.9 Comprehensive Assessment of the SHAPES Pan-European Pilot Campaign" and "D6.10 Analysis of

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the User Acceptance, Inclusion and Societal Impact of the SHAPES Platform". At this moment (June 2023), the researchers already have collected the preliminary and descriptive data that are evidenced below.

- **Outcome 1. Recruitment**

  Sociodemographic description: Age; Marital status; Gender; Education; Digital literacy (UPORTO / UCC).

Table 20 Use Case 2 - Preliminary outcomes - sociodemographic variables.

	UPORTO (*N*=15)	UCC (*N*=7)
Age	M= 70.2 ± 7.3	M= 65.57 ± 4.5
Gender	73.3% Females. 26.7% Males.	71.4% Males. 28.6% Females.
Level of Education (Years in School)	M= 7.2 ± 4.5	M= 18.14 ± 4.1
Marital Status	41.7% Married. 16.7% Cohabiting. 16.7% Separated. 16.7% Widowed. 8.3% Divorced.	71.4% Married. 28.6% Cohabiting.
Occupational Status	83.3% Retired 16.7% Employed Full-time.	71.4% Employed Full-time. 14.3% Employed Part-time. 14.3 % Retired
Is a caregiver	83.3% No 16.7% Yes Part-time	100% No.
Do you receive help from a family member or friends	83.3% Never. 16.7% Rarely	100% Never.
Do you receive help from a caregiver,	83.3% Sometimes. 8.3% Rarely	85.7% Rarely. 14.3% Sometimes

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health professional or support service…	8.3% Often.	
Residence	83.3% Own home. 16.7% Other.	100% Own home.
Is your neighbourhood	58.3% Suburban. 33.3% Urban. 8.3% Rural.	57.1% Rural. 42.9% Suburban.
Is your household able to makes ends meet	41.7% Fairly easy. 33.3% With some difficulty 16.7% With difficulty 8.3% Easily	100% Fairly easy.

- **Outcome 2. MAST Assessment**

  Two dimensions of MAST framework, namely Clinical effectiveness, and Patient perspectives, as detailed in Table 25.

Table 21 Use Case 2 - Preliminary outcomes – psychosocial variables.

	UPORTO (*N*=40)	UCC (*N*=9)
WHOQOL- Bref		
Self-perceived QOL, Health	M= 70.5. ± 22.6	M= 78.5 ± 9.4
Physical	M= 63.3 ± 20.1	M= 80.0 ± 9.0
Psychologic	M= 68.2 ± 19.7	M= 68.8 ± 8.6
Social Relations	M= 71.9 ± 14.0	M= 79.8 ± 9.4
Environment	M= 57.5 ± 16.9	M= 67.5 ± 5.8
Health related quality of life - EQ - 5D – 5L	MOBILITY 41.7% I have no problems in walking about.	MOBILITY 71,4% I have no problems in walking about.

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33.3% I have slight problems in walking about.

16.7% I have moderate problems in walking about.

8.3% I have severe problems in walking about.

SELFCARE

81.8% I have no problems washing or dressing myself.

9.1% I have slight problems washing or dressing myself.

9.1% I have severe problems washing or dressing myself.

USUAL ACTIVITIES

75.0% I have no problems doing my usual activities.

16.7% I have slight problems doing my usual activities.

8.3% I have moderate problems doing my usual activities.

PAIN/DISCOMFORT

41.7% I have slight pain or discomfort.

25.0% I have no pain or discomfort.

16.7% I have moderate pain or discomfort.

14.3% I have slight problems in walking about.

14.3% I have moderate problems in walking about.

SELFCARE

100% I have no problems washing or dressing myself.

USUAL ACTIVITIES

85.7% I have no problems doing my usual activities.

14.3% I have slight problems doing my usual activities.

PAIN/DISCOMFORT

71.4% I have slight pain or discomfort.

14.3% I have no pain or discomfort.

14.3% I have moderate pain or discomfort.

ANXIETY/DEPRESSION

50.0% I am not anxious or depressed.

50.0% I am slightly anxious or depressed.

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	8.3.% I have severe pain or discomfort. 8.3% I have extreme pain or discomfort. <u>ANXIETY/DEPRESSION</u> 45.5% I am not anxious or depressed. 27.3% I am severely anxious or depressed. 18.2% I am moderately anxious or depressed. 9.1% I am slightly anxious or depressed.	
Health related quality of life (EQ - VAS)	M=69.2 ± 15.6	M=73.6 ± 8.5
General Self-efficacy GSE	M=34.0 ± 4.9	M=31.0 ± 3.2
Social Function OSSS-3	M = 10.2 ± 2.2	M= 11.0 ± 0.8
1-item Health Literacy	100% Extremely confident.	N/A
I participate enough in activities that are important to me	58.3% Agree. 33.3% Strongly agree. 8.3% Neither agree/disagree	85.7% Agree. 14.3% Neither agree/disagree.

- **Outcome 3. Usability (visual evidence)**

  Visual portfolio composed by 28 photos related to the phases 3 and 4/5, especially the hands-on experiments and baseline of the phases 4/5, both in UPORTO and UCC.

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Figure 49: Use Case 2 - Setting Activities (Voice Assistant).

Figure 50: Use Case 2 - Training Session (Voice Assistant).

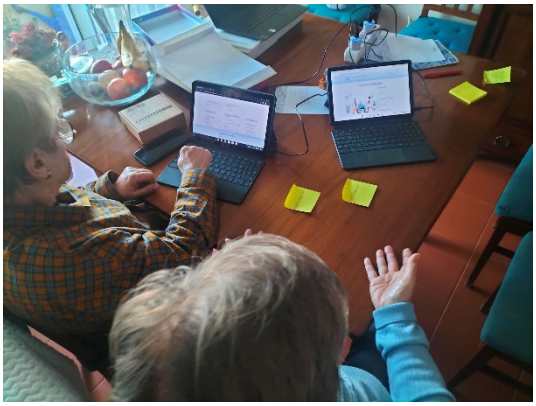

Figure 51: Use Case 2 - Training Session (Voice Assistant).

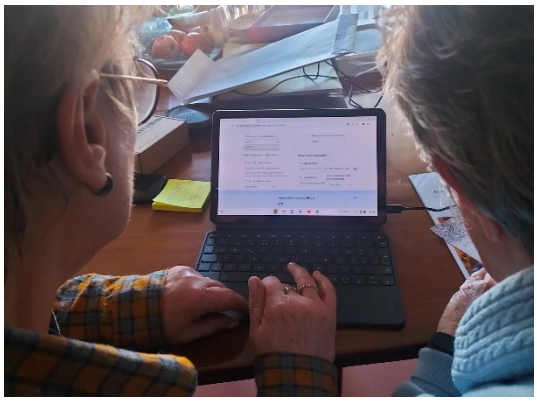

Figure 52: Use Case 2 - Training Session (Voice Assistant).

Figure 53: Use Case 2 - Recruitment and Baseline (eHealthPass/Withings - UPORTO).

Figure 54: Use Case 2 - Recruitment and Baseline (eHealthPass/Withings - UPORTO).

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Figure 55: Use Case 2 – Training Session (eHealthPass/Withings - UPORTO).

Figure 56: Use Case 2 – Training Session (eHealthPass/Withings - UPORTO).

Figure 57: Use Case 2 - Recruitment and Baseline (eHealthPass/Withings - UCC).

Figure 58: Use Case 2 - Recruitment and Baseline (eHealthPass/Withings - UCC).

Figure 59: Use Case 2 - Recruitment and Baseline (eHealthPass/Withings - UCC).

Figure 60: Use Case 2 - Training Session (eHealthPass/Withings - UCC).

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Figure 61: Use Case 2 - Testing in real-life (Smart Mirror - UPORTO).

Figure 62: Use Case 2 - Testing in real-life (Smart Mirror - UPORTO).

Figure 63: Use Case 2 - Implementation in community (Smart Mirror - UPORTO).

Figure 64: Use Case 2 - Implementation in community (Smart Mirror - UPORTO).

Figure 65: Use Case 2 - Implementation in community (Smart Mirror - UPORTO).

Figure 66: Use Case 2 - Implementation in community (Smart Mirror - UPORTO).

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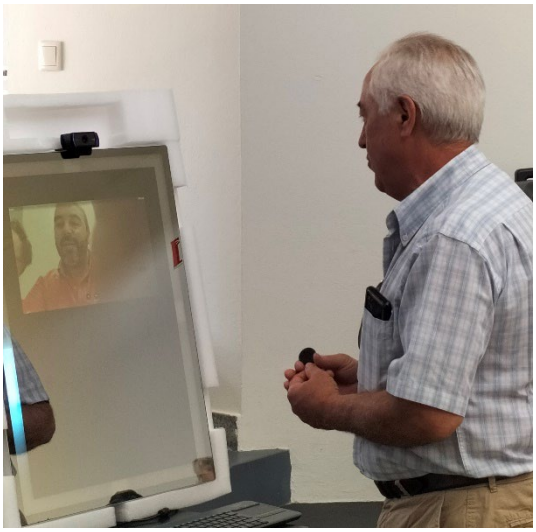

Figure 67: Use Case 2 – Hands-on experiments in community (Smart Mirror - UPORTO).

Figure 68: Use Case 2 – Hands-on experiments in community (Smart Mirror - UPORTO).

Figure 69: Use Case 2 – Hands-on experiments in community (Smart Mirror - UPORTO).

Figure 70: Use Case 2 – Hands-on experiments in community (Smart Mirror - UPORTO).

Figure 71: Use Case 2 - Recruitment in community (Smart Mirror - UPORTO).

Figure 72: Use Case 2 - Recruitment in community (Smart Mirror - UPORTO).

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3.9.2 Communication and dissemination of pilot activities

This information is provided by SHAPES WP10. Moreover, until the end of the project (October 2023), the final results should be published in scientific reviews and disseminate in the SHAPES Website.

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4 Use case 003

4.1 Introduction

The World Alzheimer Report 2021 estimated that 75% of people with dementia have not been correctly diagnosed, amongst other reasons, because of lack of resources, beliefs, and popularization of digital self-assessment tools. In USA, the primary care doctors argued other barriers: medical diagnosis not being essential; lack of clarity regarding what to do with a dementia diagnosis; limited time; undervaluing of the importance of assessment and diagnosis; other patients' problems taking precedence over cognitive problems; a lack of concrete guidelines or cut-off for screening dementia [1-2].

For these and other reasons, in the older population, the cognitive impairment can be confused with normal ageing and/or ignored because of ageism. This challenge is worst if the people are less educated, belong to lower social conditions or to non-normative groups (e.g., gender, ethnicity, location, class, income, education, social participation, religion, nutrition), or there are ethical and legal issues related [3-4].

The electroencephalography (EEG) is widely recommended by clinicians because the human brain is compound of billions of interconnected neurons that communicate as electrical activity to keep cognitive processes; the voltage fluctuations can be measured by electrodes over the surface of the scalp. The brain's activity is screened to provide a differential diagnosis and biomarkers to distinguish different neurocognitive disorders or other diseases, to define brain's markers for a specific neurocognitive disorder or another brain's activity, for instance, pain, or because it's an easy, fast, cheap and non-invasive [5-12].

The traditional Electroencephalogram system focuses on the measurement of frequency and amplitude EEG signals. But there are challenges regarding EEG: the waveforms are affected by external factors like age, consciousness, activity (physical / mental), biological and environmental stimuli, and medicines; special equipment is necessary to collect and store data about the brain's frequency that allow distinguish a pathological brain activity [5-12]. The correct interpretation of the frequency activity is necessary for a correct diagnosis "an interprofessional team approach, including physicians, nurses, and mid-level providers, correctly trained in the discipline of EEG interpretation and subsequent treatment" [13].

Currently, new digital EEG medical devices are being built to improve dementia diagnosis, to provide the early, massive, correct, differential, and cost-effective clinical diagnosis of neurocognitive disorders. In an aged society as Europe, the earlier diagnosis and stages (e.g., MCI) are relevant to the disease's progress and its care-management because the healthcare institutions (e.g., primary care, nursing homes)

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can provide timely and correctly treatments and neuroprotective interventions that could avoid or slow down the severe symptoms. This target population was selected to correspond to the SHAPES Persona "John and Joan" (Figure 73) and "Roisin" (Figure 74), as detailed in the "D2.6 – SHAPES Personas and Use V2" (p.11-17, 30-31):

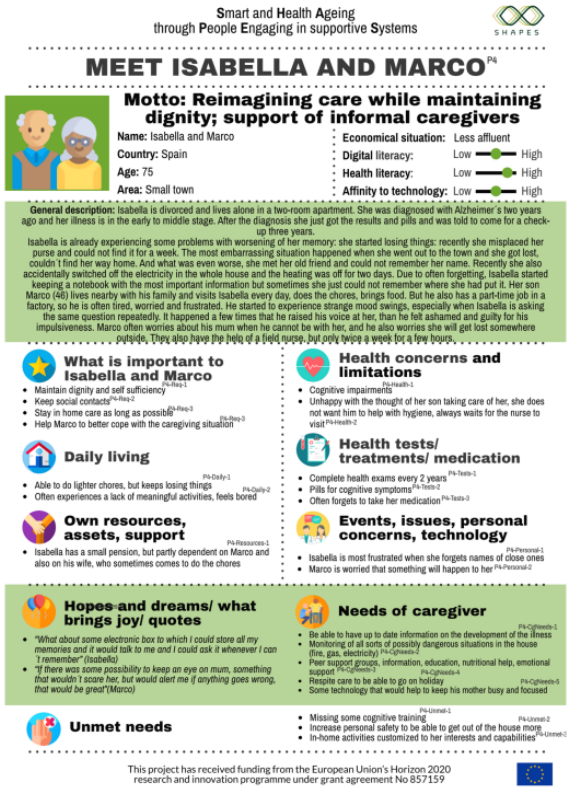

Figure 73: Use Case 3 - SHAPES Persona who represents older adults with neurodegenerative diseases. Source: D2.6 – SHAPES Personas and Use V2" (p.30).

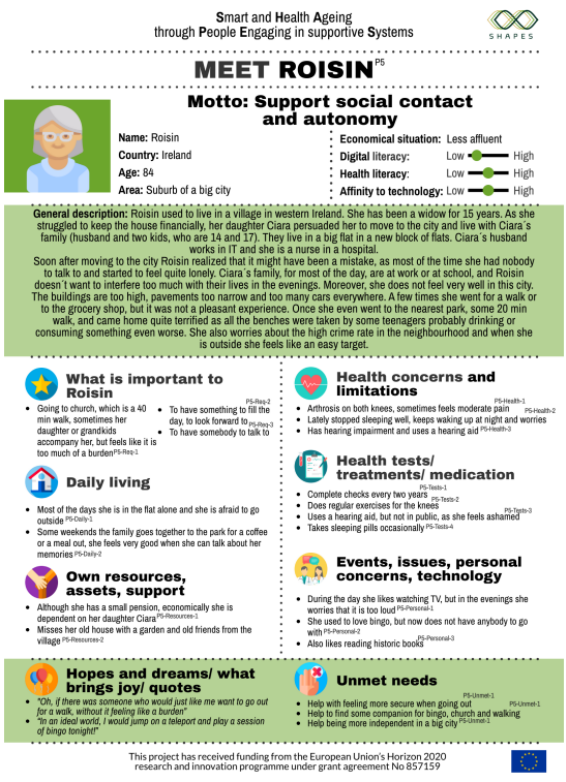

Figure 74: Use Case 3 - SHAPES Persona who represents older adults lonely and/or socially isolated older adults. D2.6 – SHAPES Personas and Use V2" (p.31).

4.2 Description

Code	UC-PT5-003
Title	BRAINCODE for a Massive Screening of the Cognitive Decline in Older Adults
Pilot Theme & Task	PT 5 – Caring for Older Individuals with Neurodegenerative Diseases (Task 6.6)
Piloting Sites	UPORTO (Portugal) and UCC (Ireland)
Description	STARLAB wishes to scale its previous work on neurodegenerative diseases to build a new technology for providing a massive screening of cognitive decline in older adults: the BRAINCODE. This technology can detect a normal or abnormal brain condition through an EEG biomarkers evaluation, and 'translate' it in an assessment report of cognitive decline in 24 hours. Additionally, the technology is portable and easy-to-use, and can be sent to the local healthcare providers, like primary care, nursing homes, centres of treatments, and pharmacies. For the SHAPES researchers, this technology could support individuals and families to have an earlier and accessible screening to the cognitive decline and neuroprotective interventions to prolong healthy brain lifetime. It represents a disruptive opportunity to supply the communities with a digital medical device that reduce worst impacts of cognitive impairment on older population, by an early diagnosis, treatments, and clinical decisions. Funded by the SHAPES Open Topic ST7, this Use Case intents to build the end point application to install in the SHAPES Platform, test the data processing pipelines with predictive capabilities. Integrated in SHAPES Pilot Campaign, it also aims to evaluate the BRAINCODE's efficacy in terms of correct differentiation of 'Normal' ageing, mild cognitive impairment, and dementia. Currently, the BRAINCODE works comparing the individual EEG results with normative values calculated by scores from an older population (normal/pathological) available on scientific literature or data bases. This evaluation is critical to validate if the BRAINCODE's results corresponds to other diagnosis, and to increase the users' trust.
Digital Solution proposed	The BRAINCODE is a portable, easy-to-use, and non-invasive Electroencephalography technology (EEG), composed by a hardware (ENOBIO) and a software (NIC Desktop Software Platform). The ENOBIO is a certified EEG medical device (CE, FDA) that works with the NIC to provide a wireless, easy-to-use, and cost-effective brain activity measuring system. This medical device consists in a heads-calp (wearable) with electrodes in standard channel locations along, to measure the voltage between each location and a reference.

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	These technologies have made possible that BRAINCODE, an analysis engine that extracts a report to assess cognitive decline. Based on the EEG band power ratios, this technology requires large and validated datasets and standardized protocols (montages, analysis techniques). The BRAINCODE compares the EEG results with the reference population and the normative values of cognitive impairment. The final digital solution includes medical hardware and software (ENOBIO/NIC), and a protocol: (1) the ENOBIO acquisition; (2) the NIC analysis; (3) and the BRAINCODE Report. The individual Report is generated and sent by an email or print to the patients; its design follows user experience design instructions to select colour, typography, scale, size, terminology, graphics, simple and direct sentences, and legible typography to the users in terms of font size, type, and contrast. The report includes a typical power spectrum analysis, in which quality analysis such as time signal plots and percentage of artefactual signal is also shown; artifacts correspond to segments of recording which contain signals not generated by the brain, such as noise from movement, cardiac activity, ocular effects.
Technical partners	STARLABS (1st SHAPES Open Topic ST7)
Components	ENOBIO: Electroencephalography technology (EEG). NIC Desktop Software Platform.
Piloting summary	A pilot study was developed to assess the scenario proposed in this use case, in terms of acceptance, satisfaction, usability, and efficacy. Adopting the SHAPES methodology, this pilot study had 5 Phases. In Phase 1, academic and technical partners transferred the proposed use case in two scenarios, describing partners, framework, subjects or target groups, activities and roles, interactions, context, environment, functions, technical infrastructures, devices, interfaces, performance indicators, and a timeline. The outcome is the pilot study design and plan, considering the SHAPES methodology and expected impacts, but also the first mock-up of digital solutions, written and summarized. In Phases 2&3, academic and technical partners developed the final prototype to use in the pilot study and test it in the hands-one experiments. Additionally, the academic partners provided the social context to deploy a pilot in real-life environment, namely a community of older people, informal and formal caregivers, and

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	public or private facilities. The outcome is a final prototype not only of digital solutions, but also a real-life scenario that use technology to integrate pilot' subjects and promote healthy lifestyle in old age. In Phases 4&5, academic partners, supported by technical partners, assessed the pilot study by a scientific protocol. Thereby, they designed a protocol, submitted it in the ethics committee and data protection office, recruited participants, signed consent forms, managed logistic and risks, collected and analyse data, and elaborated regular reports. The outcome is an extensive final report that describe in-depth the 5 phases and their results (SHAPES D6.6 – Pilot Theme 5: Caring for Older Individuals with Neurodegenerative Diseases). This Use Case was replicated in two pilot sites: UPORTO (Portugal) and UCC (Ireland). Moreover, partners worked to disseminate the experience and results of this Use Case through scientific publications, public events, and social media.
Subject profile (main persona of the piloting)	Healthcare Providers with no expertise in neurology and EEG: primary care, nursing homes, centres of treatments, pharmacies. They use the BRAINCODE to support their decisions. Older adults who have subjective complains of cognitive decline and demand a rapid and low-cost cognitive exam in a place where there aren't experts. They were screened by the BRAINCODE, for instance in the pharmacy or nursing home. Decision-makers who can decide the adoption / non adoption of BRAINCODE in healthcare system to increase the number of people diagnosed with dementia or MCI. They provided the regulation and conditions to allow the massive use of the technology.

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4.3 Digital solutions used in this use case

This digital solution was not provided by a SHAPES partner, but a by a partner who was part of the consortium by a SHAPES Open Call. Thereby, the information used in this chapter is from the private report "D1.1 – BRAINCODE Design and Integration in SHAPES Platform" (SHAPES-WP9, 2022).

4.3.1 BRAINCODE Platform

Based on previous work on dementia and cognitive decline, Starlab proposed a new technology to support key groups such as clinicians and researchers for the screening of cognitive impairment in the older population.

BRAINCODE is an easy-to-use and non-invasive brain monitoring technology of Electroencephalography (EEG) providing means to make data-driven informed clinical decisions. The current prototype developed by STARLAB considered the guidelines in recommended in the SHAPES D5.1 User Experience and Guidelines Deliverable to design the BRAINCODE solution such as:

- Usefulness: utility to the end users.
- Usability: effectiveness, efficiency, satisfaction by user's perspective.
- Accessibility: how much access is (e.g., user, knowledge, territory, price, easy-to-use).
- Findability: how easy information can be accessed/founded by users.
- Credibility: how much users trust on information (reducing second opinions/diagnosis).
- Desirability: emotional impact and recommend (aesthetics, pleasure, fun).

The functionality of the SHAPES platform was based on a series of the interaction of the clinician with a series of elements to be run in a sequential order to work. The following diagram (Figure 75) shows the sequence of events required to run BRAINCODE. Each of these steps are described in more detail in the next sections.

1) In the first stage, clinician records the EEG signal of the patient and uploads the signal onto the assigned synchronized folder.

2) After this, clinician logins (or register first if they are a first-time user) to SHAPES platform in order to complete the patient metadata.

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3) In the last step, clinician uses the BRAINCODE GUI to upload the patient metadata after which the report is automatically generated and saved in the synchronized folder.

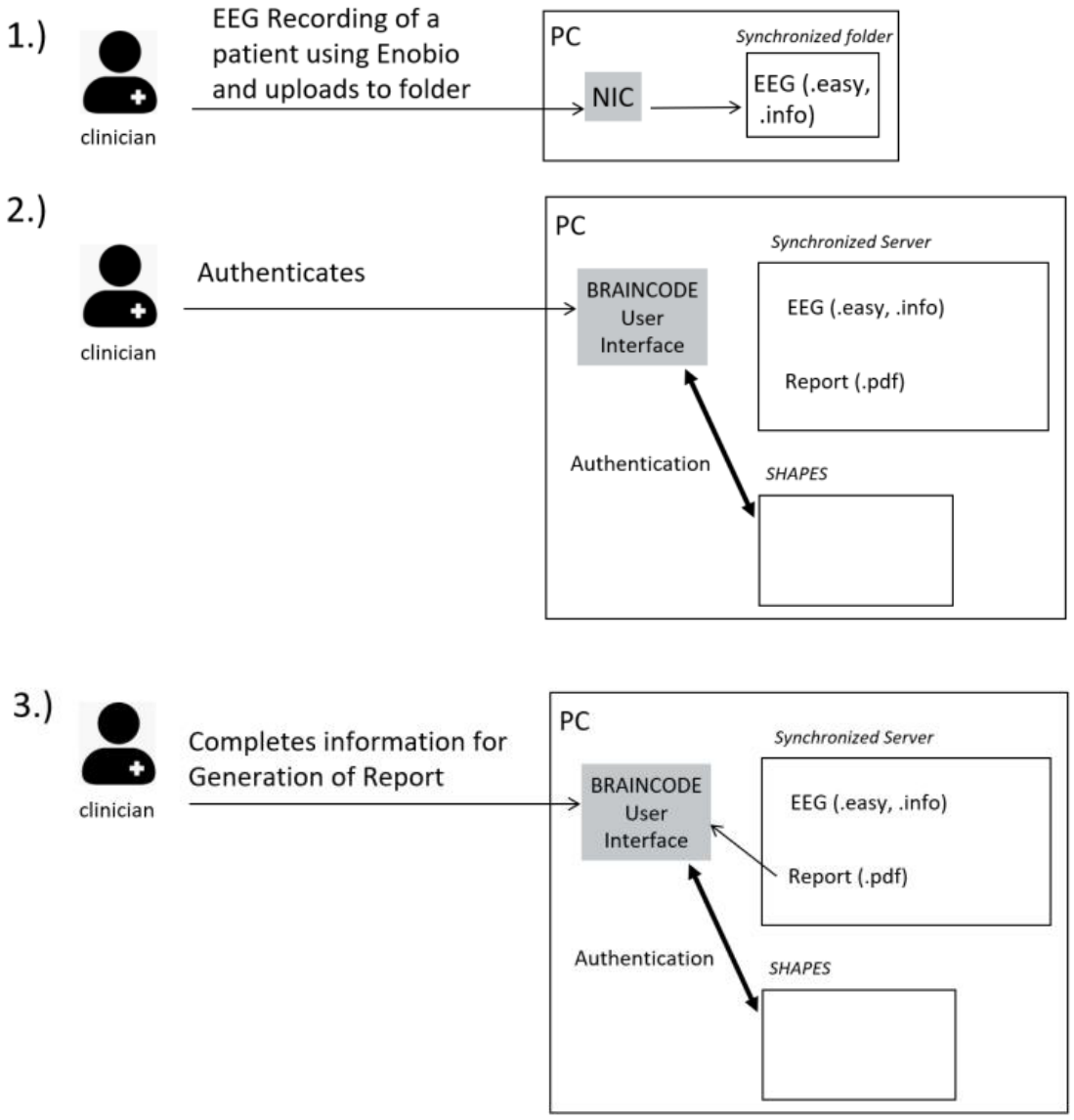

Figure 75: Use Case 3 - General use of BRAINCODE diagram. Source: Starlab.

4.3.1.1 Recording of EEG data

The first step in the use of BRAINCODE is the recording of Electroencephalogram (EEG) signals from the patients. EEG is a non-invasive procedure which has the objective of measuring electrical activity in the brain using electrodes which are in contact with the scalp. EEG is thus able to read the voltage fluctuations which

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originates from the electrical activity simultaneously generated by brain neurons travelling along the brain to keep cognitive processes.

Neuroelectrics is a Starlab's spin-off that develops and commercializes digital technologies for monitoring brain activity. ENOBIO is a medical certified (CE, FDA) EEG device (hardware), that provides wireless, easy-to-use, and cost-effective electrophysiological recording capabilities. Besides being used to record brain activity it can be used to acquire heart and muscle activity as well. This device operation consists of placing electrodes in standard channel locations along the heads-scalp and measuring the voltage between each location and a reference. An image of the ENOBIO device can be seen in Figure 76.

Figure 76: Use Case 3 - ENOBIO Device Core (Left) and Helmet (Right) Source: Starlab.

The Neuroelectrics Instrument Controller (NIC2) is an integrated environment for end-to-end management of ENOBIO devices from a computer. This platform offers basic and advanced modes to design and monitor any experiment involving electroencephalography (EEG). The clinician interacts with NIC2 in the following way:

1) Once ENOBIO has been mounted on the patient and switched on, NIC2 is used to connect the device to the computer (Figure 77).

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2) After a successful connection, the clinician selects the protocol necessary to record data for the evaluation of cognitive decline. The necessary protocol was pre-loaded in NIC2 beforehand (Figure 78).

3) The EEG interface screen appears and shows the EEG signals in real time (Figure 79).

4) If the clinicians decide the signal is of sufficient quality (they are trained beforehand to evaluate this), they should press the start button for the protocol to begin.

5) When the protocol has finished the files was saved locally on the computer and the clinician should transfer them to the synchronized folder.

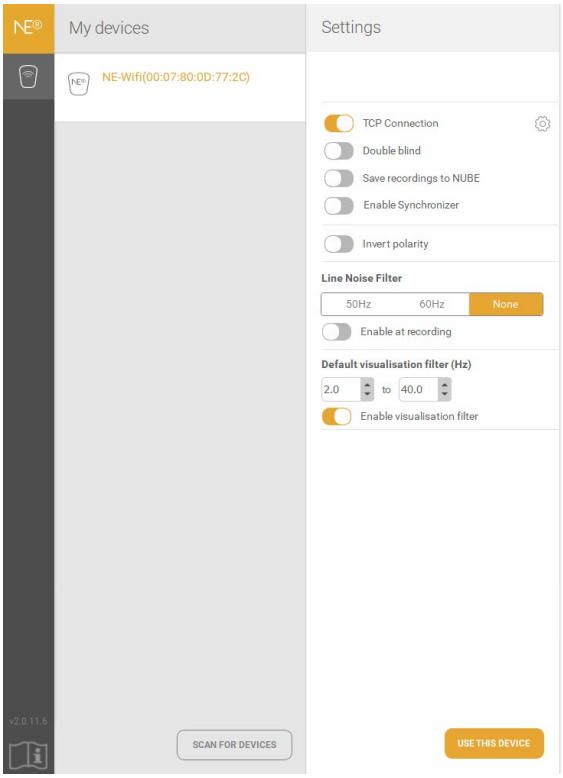

Figure 77: Use Case 3 - NIC Device Connection Screen. Source: Starlab.

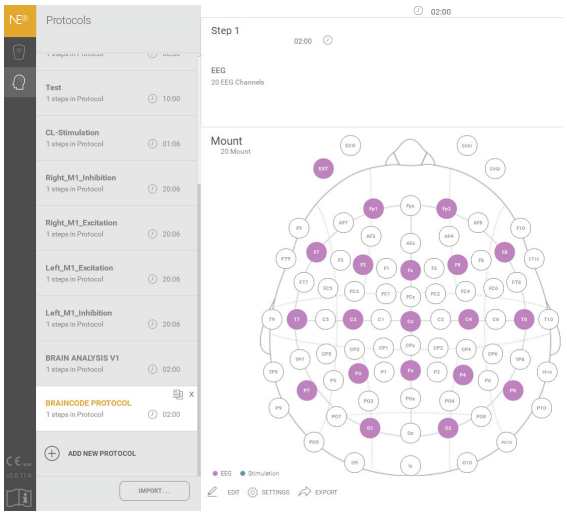

Figure 78: Use Case 3 - Montage Selection Screen NIC. Source: Starlab.

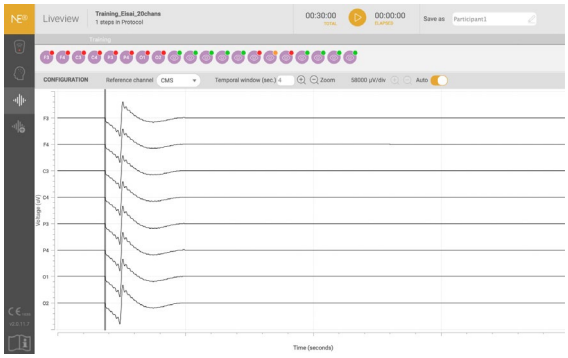

Figure 79: Use Case 3 - Protocol Manager Screen NIC. Source: Starlab.

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4.3.1.2 Authentication with SHAPES platform

The next step to generate the report is the authentication to the SHAPES platform, which shall be mandatory to be able to use BRAINCODE. Only subject's logged to SHAPES platform have permission to use BRAINCODE. It is after this first step that the GUI can be used. First, the clinician opens the BRAINCODE software in their PC and the GUI opens, showing the welcome screen, as seen in Figure 80.

The user is to press the “Connect to SHAPES Platform” after which they presented with the authentication with ASAPA screen. Users uses their user email and password to "Login”. If users are new, they must create their account and press the “First Time Registration” button. After their account has been created, they must use the credentials they used to register. If the credentials are incorrect, a notification banner notifies the user. The Figure 81 shows an image of the ASAPA login screen in the GUI.

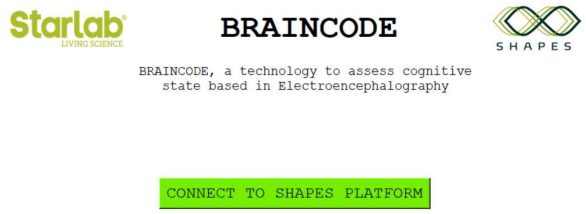

Figure 80: Use Case 3 - GUI Basic design. First banner with the option for Authentication and to Generate Report. Source: Starlab.

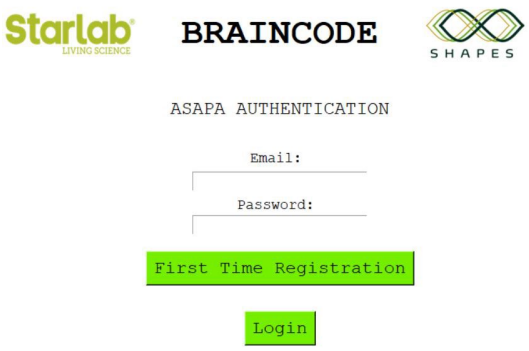

Figure 81: Use Case 3 - GUI Basic design. Third Banner once ASAPA authentication is Ok. Options to insert metadata information and recording information. Source: Starlab.

After successfully login with the ASAPA platform, the final step of the process is to add the relevant metadata of the subject to start the generation of the report, which is saved in an Excel file in the synchronized project folder. Once all the metadata has been correctly introduced in the generate report button is to be pressed. If any field is left empty, a warning message appears in the GUI. The Figure 82 shows the design for the GUI for the introduction of the metadata for the report generation.

If all steps are followed correctly, the user should receive a notification stating that the report is being generated. After the report has been generated another notification in the GUI indicates that the report is ready in the synchronized folder.

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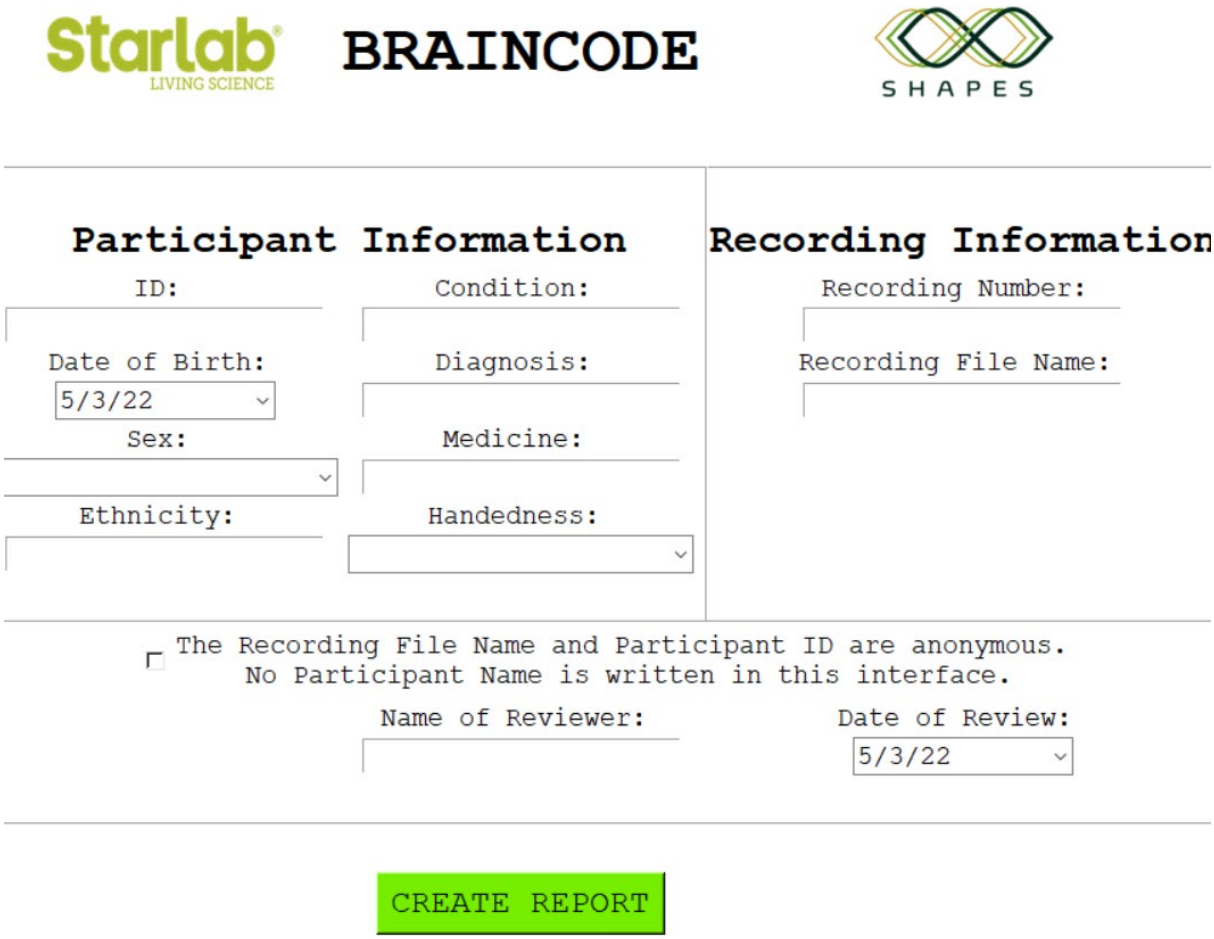

Figure 82: Use Case 3 - GUI Basic design. Third Banner once ASAPA authentication is Ok. Options to insert metadata information and recording information. Source: Starlab.

4.3.1.3 Automated Report Generation

After successfully login with the ASAPA platform, the clinician can use the GUI to input the relevant metadata into the system and initiate the report generation. The metadata is shared in a .csv file in the synchronized folder, which serves as a record of all the subjects that have been recorded in the clinical site.

BRAINCODE is designed to automatically generate the cognitive status report for all subjects that have the necessary EEG data and metadata uploaded in the synchronized folder. The automation is achieved using a virtual machine located in the Starlab facilities, which is constantly running and looking for files that can be used to generate a report. The following Sequence Diagram (Figure 83) schematize the chronology of events for the automated report generation.

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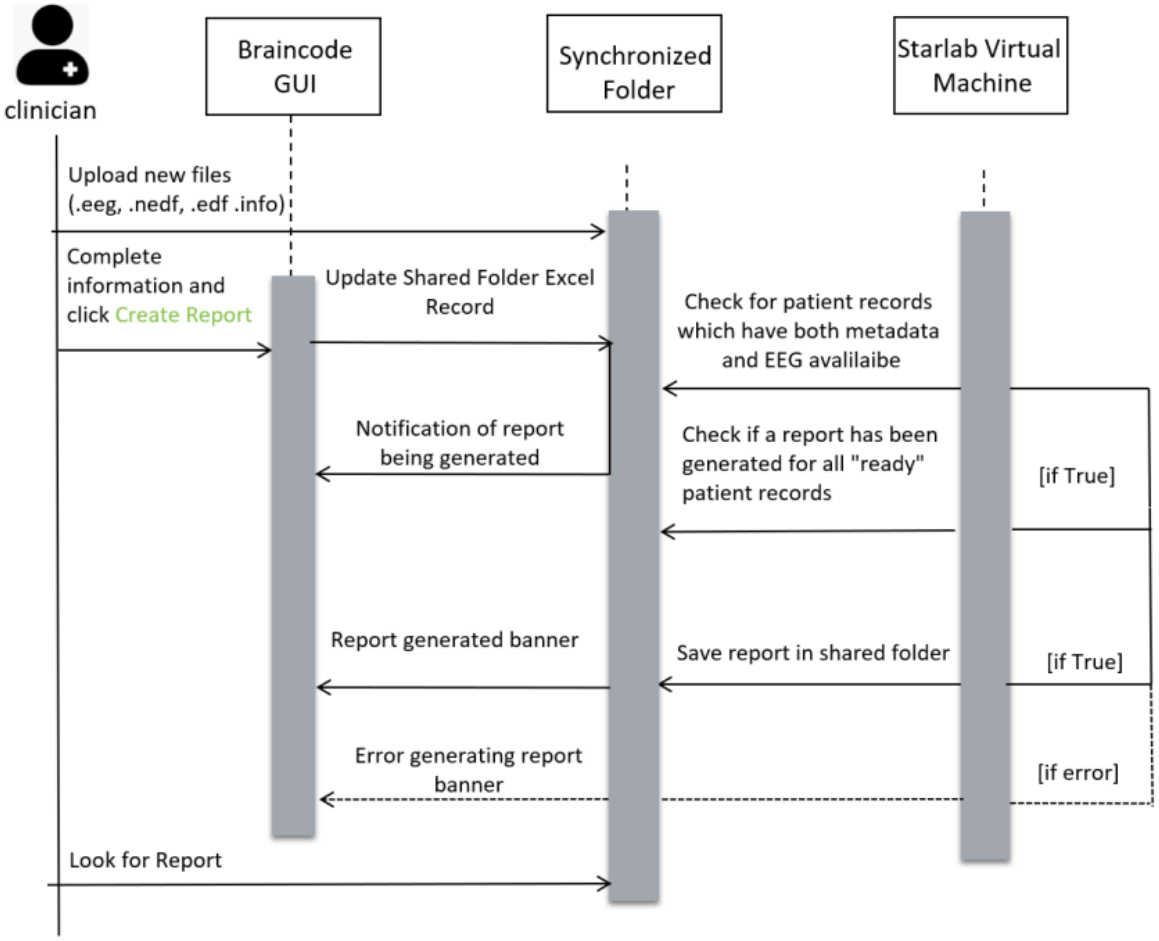

Figure 83: Use Case 3 - Sequence Diagram for Generating Report. Source: Starlab.

The Starlab virtual machine is constantly checking the synchronized folder: (1) the .csv patient record; (2) the uploaded EEG files; (3) and the generated patient reports.

Any upload by the clinician of metadata or EEG data is detected by the virtual machine: (1) the Virtual Machine reads all of the patient records in the excel and checks if they have the required EEG files to generate a report (.eeg, .edf, .easy, .info). If they do, the patient record is flagged as “Data available”; (2) the Virtual Machine checks all the “ready to generate report” entries that have not had a report generated and flags them “Ready to generate report”; (3) the Virtual Machine generates reports for all patients flagged as “ready to generate report” and uploads them onto the synchronized folder.

The GUI also notifies the clinician of the different steps of the procedure: (1) notifies that the system trying to generate a report; (2) if there is an error of any kind, it is shown in the GUI; (3) and when the report is complete a banner is shown to notify this.

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Using the metadata and the EEG data uploaded by the clinician, the data driven report is generated based on resting state EEG features, generally used as markers of age and cognitive decline. This report is used for cognitive screening, by presenting EEG features of a participant, and normative values calculated in a population to be used as reference, when applicable.

The final report contains features such as slow-to-fast ratio and interhemispheric alpha asymmetry (IAA) as well as classical Power Spectral Density (PSD). Quality analysis such as time signal plots and percentage of artifacts per channel is also included, as well characteristics of the participant (e.g., age) and recording information (e.g., date). The Figure 84 shows the chronology of events to generate a cognitive status report.

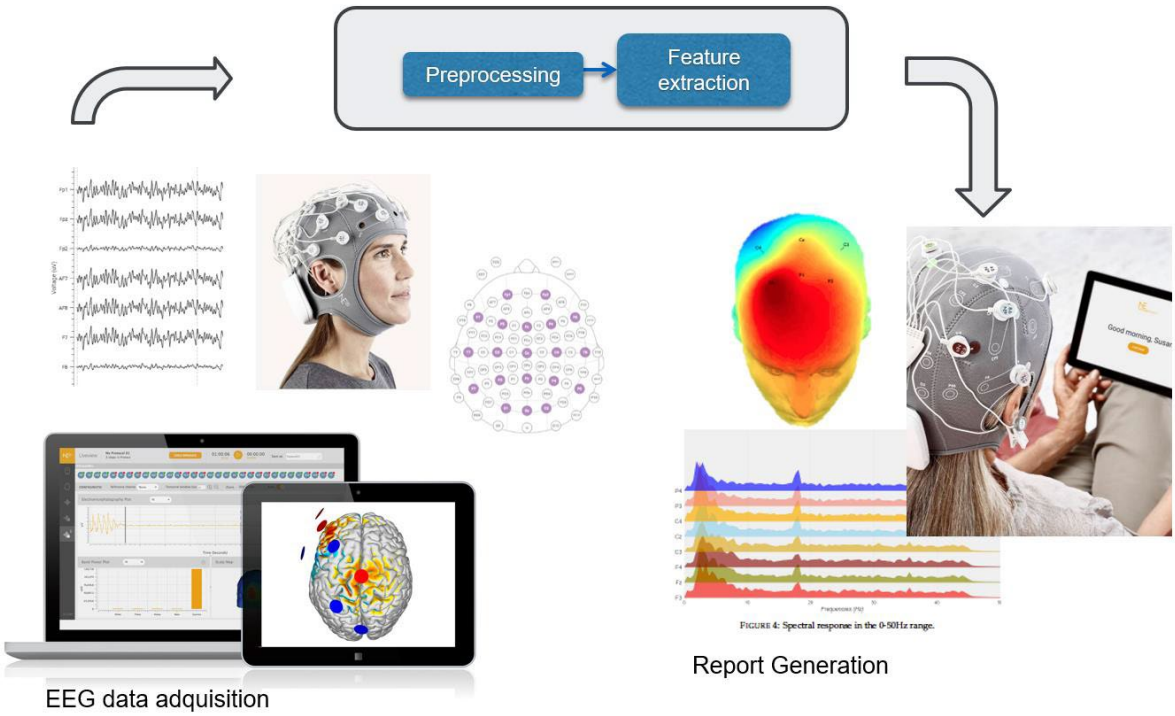

Figure 84: Use Case 3 - BRAINCODE EEG Data Driven Report methodology. Source: Starlab.

This chronology is organized in 4 steps:

- (1) EEG Data Acquisition is performed using the ENOBIO device, the EEG and the NIC software is used to control the device. NIC can launch custom EEG protocols that read and record EEG brain activity and save them on file. The files generated are fed to the algorithm to generate the report.
- (2) Pre-processing: EEG signals are prone to have noise and artifacts hence it is necessary to clean these signals before performing any further analysis or extracting biomarkers. This includes steps such as filtering the signal, re-

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referencing the signal and the detection and removal of segments of the signal that are contaminated by noise, such as movement, cardiac activity or ocular effects.

- (3) Feature Extraction: Once the signals have been pre-processed different biomarkers that can help in evaluating the cognitive state of the patient can be extracted.
- (4) Report Generation: Plots are generated using the features that have been calculated and compared with benchmark population when applicable and an analysis of the signal quality. A final report (in pdf format) which displays all the relevant information is automatically generated for the clinician to evaluate.

4.3.1.4 Integration in SHAPES Platform

This chapter describes the integration of the BRAINCODE system in the SHAPES platform. The following elements are necessary to run the BRAINCODE system:

BRAINCODE GUI: The GUI, installed in the clinician´s computer, allows them to authenticate with ASAPA, upload metadata the synchronized folder and receive notifications on the status of the report generation. The Figure 85 shows a UML diagram with the relationships and functions of the GUI.

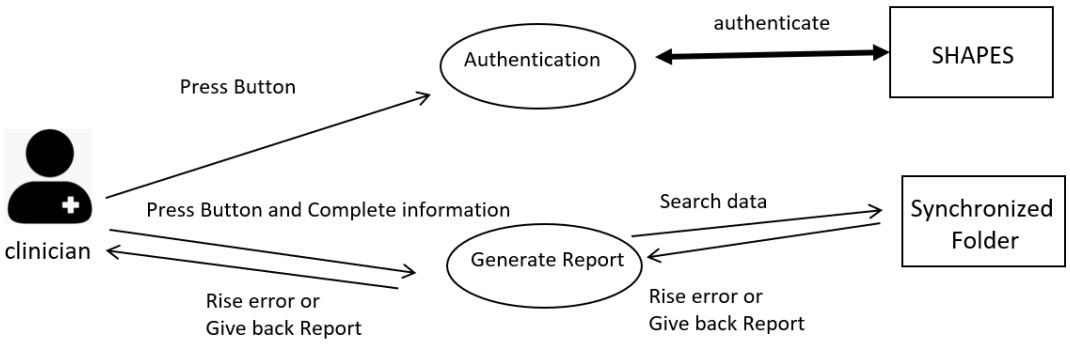

Figure 85: Use Case 3 - BRAINCODE UML Diagram. Source: Starlab.

SYNCHRONIZED FOLDER: The synchronized folder stores all the material necessary to generate and display the report. The sub-components are listed below:

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- EEG folder: This folder is required for clinician to upload the EEG data.
- Tracking file: File used to track all participants in a clinical site saved in .csv format. Contains a record of all subjects with all the relevant clinical metadata.
- The subject identity is pseudonymized to comply with the Fundamental Rights of the EU CFR.
- Report Folder: Contains all the cognitive status reports generated by BRAINCODE, saved in .pdf format.

STARLAB VIRTUAL MACHINE: Virtual machine located in the Starlab facilities, which is constantly running and looking for subject entries which have both EEG and metadata to run the report generation algorithm.

ASAPA: Module used to authenticate with the SHAPES, which is required to be able to use BRAINCODE.

Authentication via ASAPA to the SHAPES platform, is required to be able to use BRAINCODE. Only users logged to SHAPES platform have permission to use BRAINCODE. After authentication with ASAPA has been completed, the reports can be generated. The following Sequence Diagram (Figure 86) shows the chronology of events followed by the user in the GUI for authentication with ASAPA.

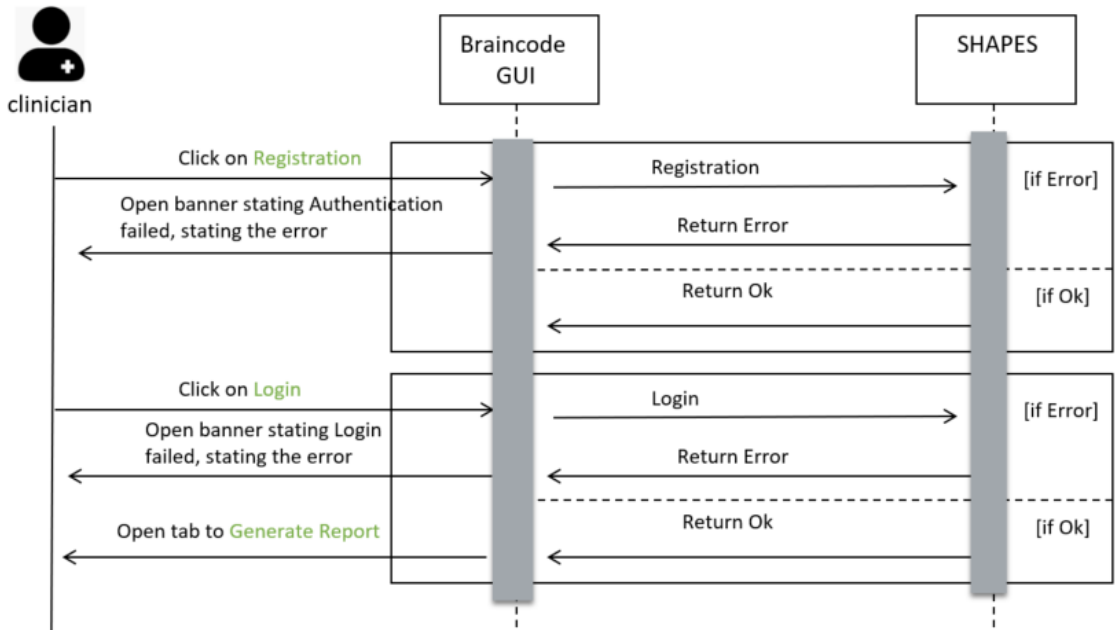

Figure 86: Use Case 3 - Sequence Diagram for Authentication with ASAPA. Source: Starlab.

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First time users are to register in the platform before they can login. This is done by setting an email and a password and pressing the “First Time Registration” button in the GUI. After this, users are to reintroduce the details in the corresponding text boxes and press the “Login” button.

The interaction of BRAINCODE with ASAPA is described here: ASAPA registration: The registration of a new user is carried out sending a post message to the API end point of ASAPA passing the email of the user and the password. For the communication we use the Shapes provided key that is passed in the header of the call to the API.

API registration end point: https://kubernetes.pasiphae.eu//shapes/asapa/auth/register.

ASAPA login: The login of a new user is carried out sending a post message to the API end point passing the data of the email and the password. When the data is correct the user them successfully authenticate through ASAPA.

API registration end point: https://kubernetes.pasiphae.eu//shapes/asapa/auth/login.

4.3.2 Digital solutions used for COVID-19 response

This digital solution was not originally designed to respond the COVID-19.

4.3.3 Equipment and devices used (from third parties)

Overall, the equipment and devices used in this use case were provided by the SHAPES technical partners, through the 1st SHAPES Open Call.

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4.4 Data plan

4.4.1 Data capture methods to be used

Domain	Variable	Tool	Method	Frequency
Sociodemographic	Name	Consent Form	Manually by user	Baseline
	Signature	Consent Form	Manually by user	Baseline
	Age	Questionnaire	Manually by user	Baseline
	Gender	Questionnaire	Manually by user	Baseline
	Education (years in school)	Questionnaire	Manually by user	Baseline
	Marital Status	Questionnaire	Manually by user	Baseline
	Cohabitation (yes / no)	Questionnaire	Manually by user	Baseline
	Care Recipient (yes / no)	Questionnaire	Manually by user	Baseline
	Caregiver (yes / no)	Questionnaire	Manually by user	Baseline
Behavioural	Laterality (hands)	Self-report	Manually by doctor	Baseline
	Usability Assessment	SUS Scale	Manually by psychologist	Baseline
Health	Medical report (predefined template: have / no have cognitive impairment; have mild cognitive impairment / have dementia; type of dementia)	Medical Report	Manually by doctor	Baseline

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	Electrophysiological signal (easy/nedf/edf & info files)	Enobio/Nic	Automatically by a medical device	Baseline
	BRAINCODE Report	BRAINCODE report system	Automatically by a BRAINCOCE	Baseline
Sociotechnical	Accesses (times)	SHAPES Platform	Automatically by technical devices	During the intervention
	Reports Generated	BRAINCODE report system	Automatically by a BRAINCOCE	Baseline
	Time spent per interaction	BRAINCODE report system	Automatically by technical devices	During the intervention

4.4.2 Planning of evaluation

The planning evaluation of this Use Case was provided by the SHAPES Deliverable "D6.1 - SHAPES Pan-European Pilot Campaign Plan" (pp. 127-183), that suggested the MAST and MAFEIP frameworks to assess the impact of the Use Case. The MAFEIP framework couldn't be adopted due to a small-scale deployment of it.

This Use Case adopted the MAST framework (Model for Assessment of Telemedicine) that assess the Use Case's effectiveness and contribution to quality of care. MAST is a multidisciplinary assessment that focuses in 7 domains: (1) Health problem and characteristics of the application; (2) Safety; (3) Clinical effectiveness; (4) Patient's perspective; (5) Economic aspects; (6) Organizational aspects; (7) and Sociocultural, ethical, and legal aspects [28].

The researchers did a review of these domains and selected those most relevant to this Use Case, namely: Clinical effectiveness (3); and Patient's perspective (4). The Table 22 describes the data required for the MAST evaluation.

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Table 22 Use Case 3 - MAST.

Domain	Topic	Outcome	Data Required	Time Point
Clinical Effectiveness	*Effects on mortality*	*Will not be measured.*		
	Effects on morbidity (Physical health / Mental health)	*Will not be measured.*		
	Effects on health-related quality of life			
	Generic measures of quality of life	Satisfaction with Life	WHOQOL-BREF	Phase 5 (Post-Intervention)
	Disease specific measures of quality of life	Cognitive Decline	QMCI and MoCA	
	Behavioural outcomes	Active Social Participation	General Self-Efficacy Scale SHAPES Questionnaires (2 items)	Phase 5 (Post-Intervention)
	Utilization of health services	*Will not be measured.*		
Patient perspectives	Satisfaction and acceptance	Motivation to use in the future	SUS	Phase 5 (Post-Intervention)
	Understanding of information	Clinicians understand the BRAINCODE Report easily.	Interview	Phase 5 (Post-Intervention)
	Confidence (in the treatment)	BRAINCODE results corresponds to medical diagnosis	Comparative Analysis	Phase 5 (Post-Intervention)
	Ability to use the application	Clinicians use the BRAINCODE autonomously	SUS	Phase 3 (Hands-on Experiments)

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	Access	*Will not be measured.*		
	Empowerment, self-efficacy	Motivation to use in the future	Interview	Phase 5 (Post-Intervention)

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

The NASSS and the MOMENTUM frameworks were proposed by SHAPES Project in the public report "D6.1 SHAPES Pan-European Pilot Campaign Plan" (SHAPES-WP6, 2020, pp. 117-118). The NASSS framework (Non-adoption, Abandonment, Scale-up, Spread, and Sustainability) was proposed by Greenhalgh et al. (2017) to assess "challenges to achieving sustained adoption and long-term sustainability", by 19 questions, organized in 7 domains, classified in three levels: simple (straightforward, predictable, few components), complicated (multiple interacting components or issues), or complex (dynamic, unpredictable, not easily disaggregated into constituent components). The MOMENTUM (Advancing Telemedicine Adoption in Europe, 2015) is a "validated and tested method to support the telemedicine implementation process and create enabling environments to accelerate telemedicine". This method helped the stakeholders to identify critical factors to adopt telemedicine in real-life [14-15].

In this use case, a study was developed by the researchers to assess the use case's critical success factors (MOMENTUM), risks to implement in real-life (NASSS), and to identify a list of potential challenges and a list of Key Performance Indicators (KPI) that researchers must consider during the pilot's deployment.

A sample of potential BRAINOCDE's users and promoters was composed by 8 individuals (N=8) recruited in Open Training Course in Digital Health deployed in UPORTO: 3 pharmacists, 1 Doctor (GP in Primary Care), 2 IT developers, and 2 social workers. The researchers have organized a Lesson with 4 moments: (1) presentation of the Use Case by a PowerPoint; (2) presentation of the NASSS and MOMENTUM by a PowerPoint; (3) the evaluation by participants using questionnaires; (4) and a Discussion in group. This Lesson was long 2 hours. The questionnaires were read by the researchers during the participants' answering because the questions required to be adapted to this Use Case, and the participants had different literacies regarding health and digital health. Then, researchers did a descriptive analysis to understand what potential users and promoters understood about the conditions (uncertain vs certain) to implement this use case in real-life.

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In this use case, the researchers didn't use the MOMENTUM questionnaire because they hadn't time to do it. Instead, during the discussion in group about the results from the NASSS questionnaire, participants have compared them with the MOMENTUM critical factors.

The NASSS framework assessed six dimensions that can determinate the adoption or non-adoption of the technology in real-life, but also its scalability. This evaluation invited the participants to score those dimensions in three levels: simple, complicated or complex to adopt in real-life. Confronted with this Use Case, the participants have assessed the Use Case mostly as complicate or simple to adopt in real-life context. The domains related with "Technology" and "Value Proposition" were better scored; in opposition, the domains related with "Illness or Condition", "Organization readiness" and "External Context" were worst scored. The domain "Intended Adopter" was mostly scored as complicate (Figure 87).

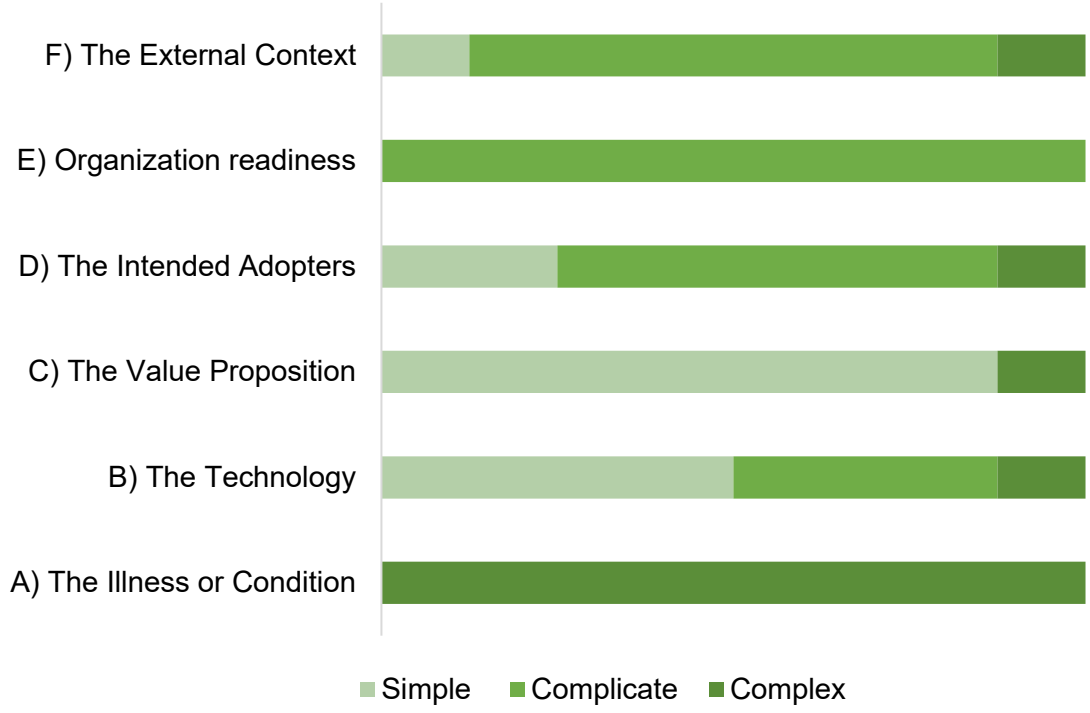

Figure 87: Use Case 3 - NASSS (First Evaluation).

Moreover, the evaluation also invited the participants to score those dimensions by variables in terms of "Agree", "Disagree", or "Don't Know" (Table 23).

This evaluation demonstrated that participants understand the illness and condition of the target population complex and with no chance to change in the next hears. During the group discussion, participants were aware about dementia and chronic diseases

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and how much these conditions affect the older population. Participants understood ageing as a complex process, and for this reason, they assessed this domain as complex. They assumed that each older adults could have different behaviours and subjective approaches in face the same illness and condition.

Regarding the second and third domains, “Technology” and its “Value Proposition”, there were many participants who haven’t enough knowledge and especially know-how to assess the Use Case. However, there were two trends in que questionnaire and discussion. First, participants from NHS were more conservative regarding the adoption in real-life. Second, participants from pharmacy and social work (i.e., nursing homes) found an optimal chance to increase the business model of those organizations, providing new services to the community. Moreover, overall, participants have understood the Use Case, especially the technology, as an important device to increase the impact of the healthcare and social care focused on people with or without dementia.

In this regard, participants were unanimous regarding the advantages of this Use Case to the “Intended Adopter”, despite they couldn’t detail the reasons. They just believed that an early and massive screen of cognitive decline could help the NHS and people to have a better preventive care and an earlier diagnosis. Moreover, participants agreed that the Use Case didn’t have any difficulty for the target population, namely older adults.

In opposition, participants had some concerns regarding the domains “Organization Readiness” and “External Context”. Despite the technology didn’t require changes in the infrastructures and organizational system, participants had pointed out the necessity of a pathway for a massive screen of the cognitive decline, and a confirmation system. In this regard, participants looked to the NHS with limitations to massively receive patients requested a better diagnosis of dementia. Additionally, currently, there are already diagnosis methods more accurate and accessible, like genetic exams.

Focusing in the “External Context”, especially the participants from pharmacy and nursing homes had doubts regarding the legal and ethical framework to adopt this Use Case in real-life, but also the lobby from other professionals, like neurologists, radiologists, geneticists.

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Table 23 Use Case 3 - NASSS Framework (First and Second Evaluation).

Domains	How much you agree with the sentence?			The adoption is:		
	Agree	Disagree	Don't Know	Simple	Complicate	Complex
A) The Illness or Condition				Simple: 0		
A1) There are significant uncertainties about the condition e.g., poorly defined, variable manifestations, uncertain course.	**6**	0	2	Complicate: 0		
A2) Many people with the condition have other co-existing illnesses or impairments that could affect their ability to benefit from this solution.	**6**	0	2	**Complex: 8**		
A3) Many people with the condition have social or cultural factors that could affect their ability to benefit from the technology or service.	**6**	0	2			
A4) The population with the condition, and/or how the condition is treated, is likely to change significantly over the next 3-5 years.	**6**	0	2			
A5) The condition has significant complexity which is likely to affect the project's success.	**6**	0	2			
B) The Technology				**Simple: 4**		
B1) There are significant uncertainties in what the technology is (e.g., it hasn't been fully developed yet).	**5**	2	1	Complicate: 3		
B2) There are significant uncertainties in where the technology will come from (e.g., supply chain issues, substitutability).	0	**8**	0	Complex: 1		
B3) There are significant uncertainties about the technology's performance and dependability (e.g., bugs, crashing, cutting out).	0	0	**8**			
B4) There are significant uncertainties about the technology's usability and acceptability (e.g., key	0	0	**8**			

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people don't trust the data it provides).				
B5) There are significant technical interdependencies.	0	2	**6**	
B6) The technology is likely to require major changes to organisational tasks and routines.	1	**5**	2	
B7) The technology (and/or the service model it supports) is likely to change significantly within the next 3-5 years.	2	0	**6**	
B8) The technology has significant complexity which is likely to affect the project's success.	1	**5**	2	
C) The Value Proposition				**Simple: 7** Complicate: 0 Complex: 1
C1) The commercial value of the technology is uncertain.	0	**6**	2	
C2) The value to the intended users (e.g., patients, clinicians) is uncertain.	0	**6**	2	
C3) The value to the healthcare system (e.g., from efficacy and cost-effectiveness studies) is uncertain.	1	**5**	2	
C4) The value to this particular healthcare organisation, given the current situation locally, is uncertain.	0	**5**	3	
C5) The technology could generate a negative value (costs are likely to outweigh benefits) for some stakeholders.	0	0	**8**	
C6) The value proposition is likely to change significantly over the next 3-5 years.	2	0	**6**	
C7) The value proposition has significant complexity which is likely to affect the project's success.	0	0	**8**	
D) The Intended Adopters				Simple: 2
D1) There is uncertainty about whether and how patients/citizens	0	**8**	0	

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will adopt the technology (if applicable).				**Complicate: 5** Complex: 1
D2) There is uncertainty about whether and how front-line staff will adopt the technology.	1	3	**4**	
D3) There is uncertainty about the implications for people who might be indirectly affected by the technology.	0	0	**8**	
D4) There will be significant changes to individual users' perceptions of the technology over the next 3-5 years.	**6**	0	2	
D5) There is significant complexity relating to intended adopters which is likely to affect the project's success.	1	**5**	2	
E) Organization readiness				Simple: 0 **Complicate: 8** Complex: 0
E1) The organization's capacity to take on technological innovations is limited.	**3**	**3**	2	
E2) The organization is not ready for this particular innovation.	**3**	**3**	2	
E3) The organization would find it hard to commission/purchase the innovation.	0	0	**8**	
E4) The work needed to introduce and routinise the innovation has been underestimated and/or inadequately resourced.	0	2	**6**	
E5) The organization(s) involved are likely to have significant restructurings or changes in leadership, mission or strategy over the next 3-5 years.	0	0	**8**	
E6) There is significant complexity relating to one or more participating organizations which is likely to affect the project's success.	0	0	**8**	
F) The External Context				Simple: 1

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F1) The political and/or policy climate is adverse.	1	**7**	0	**Complicate: 6** Complex: 1
F2) Professional bodies are opposed to the innovation or don't actively support it.	**5**	3	0	
F3) Patient organisations and lobbying groups are opposed to the innovation or don't actively support it.	3	0	**5**	
F4) The regulatory context is adverse.	**8**	0	0	
F5) The commercial context is adverse.	0	2	**6**	
F6) Opportunities for learning from other (similar) organisations are limited.	0	2	**6**	
F7) Introduction of the technology/innovation could be threatened by external changes that impact on the organisation.	**8**	0	0	
F8) The policy, regulatory and economic context for this innovation is likely to be turbulent over the next 3-5 years.	**6**	0	2	
F9) There is significant complexity relating to the external context which is likely to affect the project's success.	**8**	0	0	

Regarding the critical success factors (CSFs), this digital solution was ready to provide telemedicine in the healthcare system and in the social care sector. Nevertheless, it was relevant to analyse the use case to consider its scaling up as a telemedicine integrated into healthcare delivery systems.

CSF 1. Cultural readiness for the telemedicine service: There are challenges, ethical and legal, to implement this device in the NHS or in the social care sector.

CSF 2. Advantages of telemedicine in meeting compelling need(s): Older adults haven't a high accessibility to a medical device for screening the cognitive decline; this

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device could be a solution for a massive screening, deployed even for non-experts with a remote support from experts.

CSF 3. Ensure leadership through a champion: Despite the technology adopted (hardware) is medical certified, the BRAINCODE, as a program that works based on algorithms, requires more tests in real-life and comparing with a medical diagnosis.

CSF 4. Involvement of healthcare professionals and decision-makers: The potential users and promoters require continuous education and training to design, plan, adopt and assess this digital solution in real life, especially if they decided to implement it in territories with no high health access or expertise.

CSF 5. Put the patient at the center of the service: The BRAINCODE is easy-to-use and has results immediately about two levels of cognitive decline (Have or Don't have; MCI or Dementia), but also it is portability and usability can increase the classes of healthcare providers available to screen the cognitive decline.

CSF 6. Ensure that the technology is user-friendly: To be consulted in CSF5.

CSF 7. Pull together the resources needed for deployment: The resources required for the deployment of the digital solutions in this UC are provided to SHAPES funding and internal resources already allocated. The technical partners of the use case provide all IT competences.

CSF 8. Address the needs of the primary client(s): To be consulted in CSF5.

CSF 9. Prepare and implement a business plan: The solution is already commercialized by its owner. However, it is recommended more studies to increase the trust in the solution and its massive commercialized.

CSF 10. Prepare and implement a change management plan: It should be evaluated at the end of the project.

CSF 11. Assess the conditions under which the service is legal: The organizations and employees require new legal and ethical frameworks to use technology with security, literacy, rightness, and fairness; and authorities must provide those new legal and ethical frameworks.

CSF 12. Guarantee that the technology has the potential for scale-up: To be consulted in CSF9.

CSF 13. Identify and apply relevant legal and security guidelines: GDPR should be applied. The system provided implements all security and privacy related regulations.

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CSF 14. Involve legal and security experts: This technology and its use case was assessed positively by the Data Protection Officer of University of Porto and SHAPES Ethical Advisory Board, detailed in the following documents: Data Plan; Data Mapping; DPIA; and Data Sharing Agreement.

CSF 15. Ensure that telemedicine doers and users are privacy aware: To be consulted in CSF14.

CSF 16. Ensure that the information technology infrastructure and eHealth infrastructure are available: SHAPES is developing a technology platform for pan-European distribution of telemedicine services. The pilot is being designed to cope with this requirement as well.

CSF 17. Put in place the technology and processes needed to monitor the service: The technology's owner has a permanent helpdesk to support 24/7 the users.

CSF 18. Establish and maintain good procurement processes: To be consulted in CSF5.

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4.5 Phase 1

4.5.1 PACT and FICS Scenario

4.5.1.1 PACT

Code	UC-PT5-003
Applicable SHAPES Persona	SHAPES Persona “John and Joan” (P4) and “Roisin” (P5)
Applicable SHAPES use case	BRAINCODE for a Massive Screening of the Cognitive Decline in Older Adults
People Roles and/or actors of typical users involved in delivering and receiving the telemedicine intervention	Healthcare Providers with no expertise in neurology and EEG: primary care, nursing homes, centres of treatments, pharmacies. They use the BRAINCODE to support their decisions. Older adults who have subjective complains of cognitive decline and demand a rapid and low-cost cognitive exam in a place where there aren’t experts. They were screened by the BRAINCODE, for instance in the pharmacy or nursing home.
Activities Activities to be performed by the actors in order to provide and receive the telemedicine intervention successfully procedures for the professional and the patient; Parameters that determine the measures used in the intervention	The first step of the BRAINCODE is the patients’ recording of Electroencephalogram (EEG) signals, using a non-invasive EEG device, the ENOBIO, that scans the electrical activity in the brain using electrodes which are in contact with the scalp. The Neuroelectrics Instrument Controller (NIC2) is an integrated environment for end-to-end management of ENOBIO devices from a computer. This platform offers basic and advanced modes to design and monitor any experiment involving the EEG. The clinician interacts with NIC2 in the following way: (1) Once ENOBIO is mounted on the patient and switched on, NIC2 is used to connect the device to the computer. (2) After a successful connection, the clinician selects the protocol necessary to record data for the evaluation of cognitive decline. The necessary protocol is pre-loaded in NIC2 beforehand. (3) The EEG interface screen appears and shows the EEG signals in real time. (4) If the clinician decides the signal is good (they were trained before-hand to evaluate it), they should start the protocol. (5) When the protocol is finished, the files are saved. The next step is to generate the BRAINCODE Report by the authentication to SHAPES platform. Only subject's logged to SHAPES platform have permission to access the reports. The clinician opens the BRAINCODE application, showing the welcome screen. The clinician presses the “Connect to SHAPES Platform” and logins using the email and the password. If the

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	clinician is new to BRAINCODE, he/she must create an account in “First Time Registration”.
Context Social-medical relevance of the telemedicine intervention; privacy issues; risks for the patient; locations	The local healthcare providers are the key-context to use the BRAINCODE because its portability and non-expert usability. After a training process, doctors or nurses who are non-EEG experts, can use the BRAINCODE during a health consultation, namely with the GP, the family nurse, the pharmacist, or the therapist.
Technology Type of information/parameter that are relevant in monitoring the health status; type and frequency of accessibility of information; feedback modalities (communication)	The BRAINCODE is portable, easy-to-use, and non-invasive Electroencephalography technology (EEG), composed by a hardware (ENOBIO) and a software (NIC Desktop Software Platform). The ENOBIO is a certified EEG medical device (CE, FDA) that works with the NIC to provide a wireless, easy-to-use, and cost-effective brain activity measuring system. This medical device consists in a headcap (wearable) with electrodes in standard channel locations along, to measure the voltage between each location and a reference. These technologies have made possible the BRAINCODE, an analysis engine that extracts a report to assess cognitive decline. Based on the EEG band power ratios, this technology requires large and validated datasets and standardized protocols (montages, analysis techniques). The BRAINCODE compares the EEG results with the reference population and the normative values of cognitive impairment. The final digital solution includes medical hardware and software (ENOBIO/NIC), and a protocol: (1) the ENOBIO acquisition; (2) the NIC analysis; (3) and the BRAINCODE Report.

4.5.1.2 FICS

Code	**UC-PT5-003**
Applicable SHAPES Persona	SHAPES Persona “John and Joan” (P4) and “Roisin” (P5)
Applicable SHAPES use case	BRAINCODE for a Massive Screening of the Cognitive Decline in Older Adults
Function and events The functionality of the intended system which is capable of realizing actor’s activities	Using the metadata and the EEG data provided by the clinicians using ENOBIO and NIC, the data driven report is generated based on resting state EEG features, generally used as markers of age and cognitive decline. This report supports the cognitive assessment, by presenting EEG features of a participant, and normative values calculated in

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	a population to be used as reference, when applicable. It contains features such as slow-to-fast ratio and interhemispheric alpha asymmetry (IAA) as well as classical Power Spectral Density (PSD). Quality analysis such as time signal plots and percentage of artifacts per channel are also included, and the characteristics of the patients (e.g., age, sex, education). These events are chronologically generated by four functions: • EEG Data Acquisition: it's performed by the ENOBIO device, controlled by NIC software. NIC reads and records EEG brain activity and save them on file. The files generated are fed to the algorithm to generate the report. • Pre-processing: EEG signals are prone to have noise and artifacts hence it is necessary to clean these signals before performing any further analysis or extracting biomarkers. This includes steps such as filtering the signal, re-referencing the signal and the detection and removal of segments of the signal that are contaminated by noise, such as movement, cardiac activity, or ocular effects. • Feature Extraction: Once the signals have been pre-processed, the biomarkers are extracted to assess the patients' cognitive state. • Report Generation: A final report (in pdf format) is automatically generated and sent to the clinician.
Interactions and usability issues	The first step of the BRAINCODE is the patients' recording of Electroencephalogram (EEG) signals, using a non-invasive EEG device, the ENOBIO, that scans the electrical activity in the brain using electrodes which are in contact with the scalp. The Neuroelectrics Instrument Controller (NIC2) is an integrated environment for end-to-end management of ENOBIO devices from a computer. This platform offers basic and advanced modes to design and monitor any experiment involving the EEG. The clinician interacts with NIC2 in the following way: (1) Once ENOBIO is mounted on the patient and switched on, NIC2 is used to connect the device to the computer. (2) After a successful connection, the clinician selects the protocol necessary to record data for the evaluation of cognitive decline. The necessary protocol is pre-loaded in NIC2 beforehand. (3) The EEG interface screen appears and show the EEG signals in real time. (4) If the clinician decides the signal is good (they were trained before-hand

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	to evaluate it), they should start the protocol. (5) When the protocol is finished, the files are saved. The next step is to generate the BRAINCODE Report by the authentication to SHAPES platform. Only subject's logged to SHAPES platform have permission to access the reports. The clinician opens the BRAINCODE application, showing the welcome screen. The clinician presses the "Connect to SHAPES Platform" and logins using the email and the password. If the clinician is new to BRAINCODE, he/she must create an account in "First Time Registration". After successfully login, if the EEG data was correctly processed by the technology, the clinician receives a notification stating that the report is being generated. After the report has been generated another notification indicates that the report is ready in the synchronized folder.
Content and structure Variables of the interaction	This information is detailed in-depth in section 4.3 of this deliverable.
Style and aesthetics Look and feel of the system	This information is detailed in-depth in section 4.3 of this deliverable.

4.5.2 Key performance indicators

Key Performance Indicators (KPIs) are defined as a set of measures that focus on the factors most critical to a project's success. KPIs are measurable and quantifiable with a target or threshold. They measure performance in critical areas by showing the progress or lack of it towards realizing the objectives of each specific use case. The following KPIs have been chosen to determine whether, or not, the pilot for this use case has been successful. Failure to meet four or more of the KPIs will indicate that repetition or major revisions to the use case and associated digital solutions are needed before entering further development oriented to further validation of technology benefits and commercialization.

The KPIs are detailed in the Table below (Table 24) and they are related with the outcomes detailed in section 4.8.4 of this deliverable.

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Table 24 Use Case 3 - List of KPIs.

Outcomes	KPI	Measurement
Outcome 1. To integrate the BRAINCODE in the SHAPES Platform: 1.1. To develop an application to connect technologies. 1.2. To develop a BRAINCODE dashboard to use by SHAPES Platform. 1.3. To update the BRAINCODE sensitivity based on the results.		
	KPI 1 Improved BRAINCODE's prototype Improved BRAINCODE's prototype integrated on SHAPES Technical Platform successfully	User Interface integrated in SHAPES
	KPI 2 Digital Healthcare Organization Decision makers' average for a usability/satisfaction evaluation (answers with a positive scores)	Minimum: 60% Maximum: 90%
Outcome 2. To evaluate the BRAINCODE's usability and satisfaction: 2.1. To assess participants with a SUS and satisfaction questionnaire. 2.2. To assess experts with NASSS and MOMENTUM frameworks.		
	KPI 3 Clinicians Recruitment Number of recruited clinicians with ethical approvement from their healthcare organization	Minimum: 1 Maximum: 3
	KPI 4 Patients Recruitment Number of recruited patients who sign ethical consent and participate in all pilot activities	Minimum: 7 Maximum: 12
OC3. To validate the BRAINCODE's efficacy: 3.1. To distinguish cognitive impairment / 'normal' cognitive decline. 3.2. To distinguish MCI / Dementia. 3.3. To be adopted by non-expert healthcare providers.		
	KPI 5 Innovative Medical Device	Minimum: 60% Maximum: 90%

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Clinicians' average for a usability/satisfaction evaluation (answers with a positive scores)	
KPI 5 Comfortable Medical Exam Patients' average for a usability/satisfaction evaluation (answers with a positive scores)	Minimum: 60% Maximum: 90%
KPI 3 Data Quality Number of patients with equivalent scores in BRAINCODE, QMCI, and medical diagnosis	Minimum: 7 Maximum: 12

4.5.3 Timeline of pilot activities

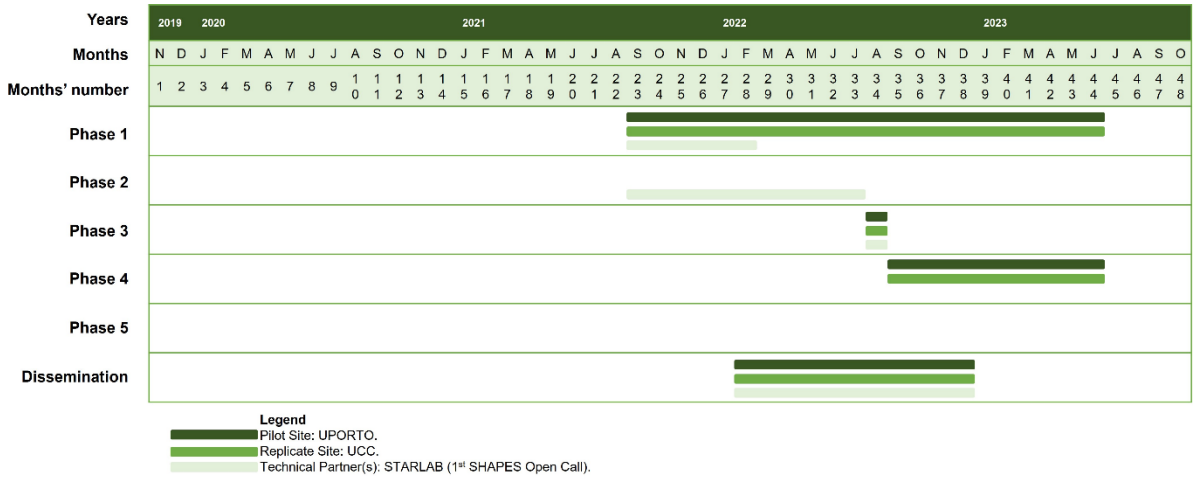

Figure 88: Use Case 3 - Timeline of pilot activities.

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4.6 Phase 2: Testing of mock-ups and prototypes

4.6.1 Methodology of testing

The BRAINCODE digital technology was designed under Doorley et al. (2018) and Koominos et al. (2020) five stages methodology and transparency: (i) Empathize with the user; (ii) Define a problem; (iii) Ideate; (iv) Prototype; (v) and Test [16-17]. The first three steps are necessary to understand, explore and address user requirements lead to the ideation of BRAINCODE's solution. During these steps, BRAINCODE's users and applications in real contexts (ideate and benefits) were defined. The last steps are necessary to build and test prototypes and collected feedbacks. At this moment, Starlab already built a first prototype of BRAINCODE, as it was described above. Manuals and Videos for the EEG recording and acquisition using ENOBIO can be downloaded on Neuroelectrics Webpage[10].

4.6.2 Results of testing

The digital solution (BRAINCODE) is composed by technical devices (ENOBIO / NIC) that already were medical devices certified by the (1) CE Marking certification, (2) and the U.S. Food & Drug Administration (FDA).

4.7 Phase 3: Hand-on Experiments

4.7.1 Methodology of hands-on experiments

The researchers developed a satisfaction/acceptance study with a sample of potential users and promoters, composed by 8 individuals (N=8) recruited in Open Training Course in Digital Health deployed in UPORTO: 3 pharmacists, 1 Doctor (GP in Primary Care), 2 IT developers, and 2 social workers. During that lesson, the researchers have presented the Use Case and invited the participants to assess it using a questionnaire with 9 questions. Then, they did a descriptive analysis to understand the main preferences of potential users of the BRAINCODE. The questionnaire and analysis are detailed in the Table 25.

Additionally, the Empathy Mapping study was developed by the BRAINCODE's owners. This method is a design thinking method do evaluate the user experience by "a collaborative visualization" that allows to integrate what developers want to know (questions) and what are end-users' perspectives (answers). The Empathy Mapp

[10] To be consulted in: https://www.neuroelectrics.com/resources/manuals and https://www.neuroelectrics.com/resources/videos (accessed at 08-06-2023).

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assesses four categories: (1) “Says” that include what is verbally expressed by the users about the device and its experience (e.g., I cannot press a BRANCODE buttons); (2) “Thinks” that includes thoughts and ideas that users don’t verbalize if they are not pushed to do it (e.g., I think BRAINCODE is useful on primary care); (3) “Does” includes user’s concrete interactions with devices (e.g., Users should be relaxed to use BRAINCODE; (4) “Feels” includes users’ emotional classification, often expressed by adjectives, sentiments, and comments (e.g., I like the BRAINCODE colours and design).

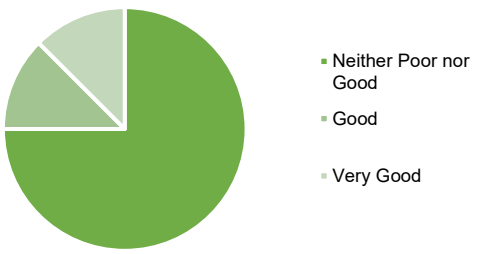
4.7.2 Results of the hands-on experiments

Based on the results from the satisfaction/acceptance study, the researchers understood that this Use Case has laid a foundation for further exploration and development of the novel EEG tool. Future efforts should address the ethical considerations, seek appropriate approvals, and continue the recruitment of doctors to conduct comprehensive evaluations and generate meaningful results. The potential benefits of integrating BRAINCODE into the SHAPES Platform are evident, and the technology holds promise for advancing neurocognitive disorder diagnosis and improving patient care in clinical settings.

Table 25 Use Case 3 - Questionnaire for assessing satisfaction/acceptance.

Questionnaire / Answers	Description
Age	
Occupation	
How would you rate your understanding of BRAINCODE?	

Very Poor	Poor	Neither Poor nor Good	Good	Very Good
0	0	6	1	1



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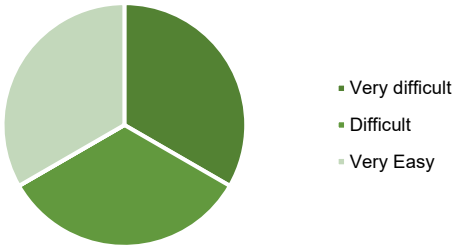
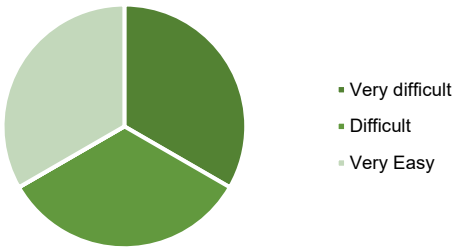
How would you perceive using BRAINCODE in your current work?

Very difficult	Difficult	Neither Difficult nor Easy	Easy	Very Easy
3	3	0	0	3



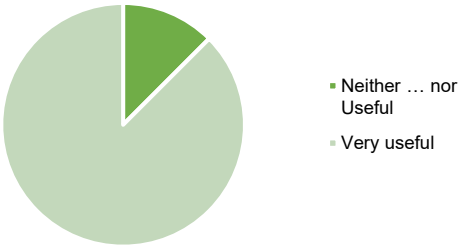
How you perceive the integration BRAINCODE in healthcare system?

Very difficult	Difficult	Neither Difficult nor Easy	Easy	Very Easy
3	2	0	0	3



How useful is BRAINCODE for the healthcare system?

Nothing useful	Somehow useful	Neither nor Useful	Useful	Very useful
0	0	1	0	7



How will the BRAINCODE impact the healthcare system?

1 To reduce sub-diagnosis and/or later diagnosis.

2 To reduce the negative impacts of neurocognitive disorders.

3 To deliver an early, extensive, cost-effective diagnosis.

4 To complement conventional diagnosis methods.

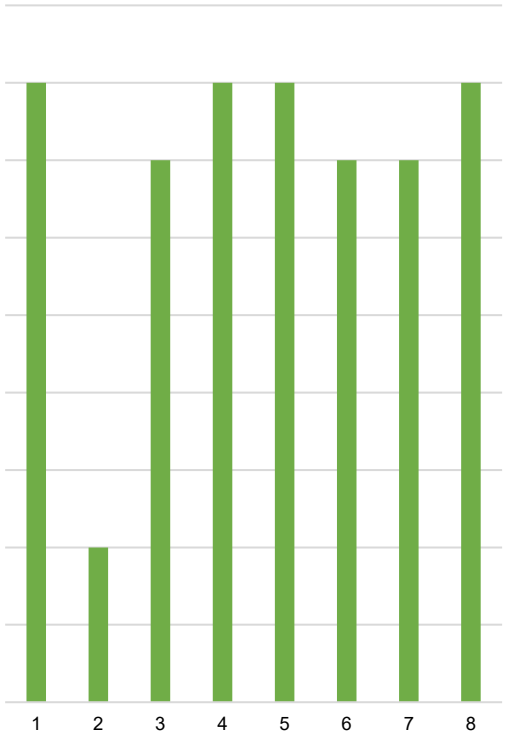
5 To surpass limitations of classical exams (i.e., psychologic).

6 To increase neuroprotective interventions.

7 To prolong healthy brain lifetime.

8 To extend brain diagnosis in isolated territories.

9 Other



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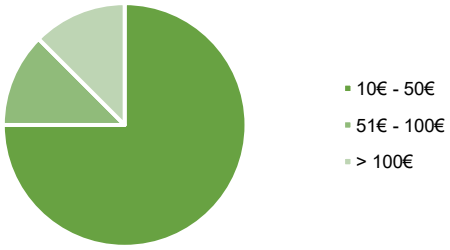
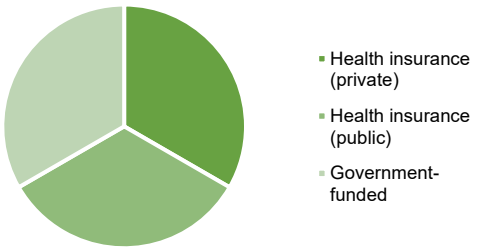
How much would you pay per BRAINCODE?

0€	< 10€	10€ - 50€	51€ -100€	> 100€
0	0	6	1	1



Who should pay for it?

Individual end-user	Health insurance (private)	Health insurance (public)	Government-funded	Other
0	8	8	8	0



The Empathy Mapping requires a qualitative methodology to collect data. In this use case, the researchers did a focus group with one representative of potential user and promoters, namely: a healthy older adult, a clinician, and a decision-maker from the NHS. The data collected was resumed in sticky notes that are positioned on the empathy map categories during by a researcher and users or user (Figure 89). Based in this method, the researcher concluded:

- The “Patients” understood thar BRAINCODE beneficiates patients who need an accessible EEG (Pains) if this technology is easy-to-do, non-evasive, cheap, and nearby (Gains). The patients’ demands are justified by the symptoms of cognitive decline felt by the generally of older adults (Feel), but also by the importance of the screening to take a health decision (Think) and go to the better chance inside the NHS (Do) with a screening information (Say).

- The “Healthcare Professionals” understood that BRAINCODE as a new chance to do, easily and cheap, an EEG exam (Do) for older adults with a subjective complains of cognitive decline (Thinks / Feels), especially if they haven’t a nearby access to classic EEG equipment (Pains), to take better and early decisions (Gains) regarding patients complains (Say).

- The “Decision Makers” understood the BRAINCODE as favourable to implement a more accessible and sustainable NHS (Do) if the technology efficacy and efficiency was validated by scientific studies (e.g., clinical trials) (Think / Feel), and the ‘promises’ of easy-to-do, non-evasive, cheap, and nearby (Gains) are feasible in territories with no health access (Say / Pains).

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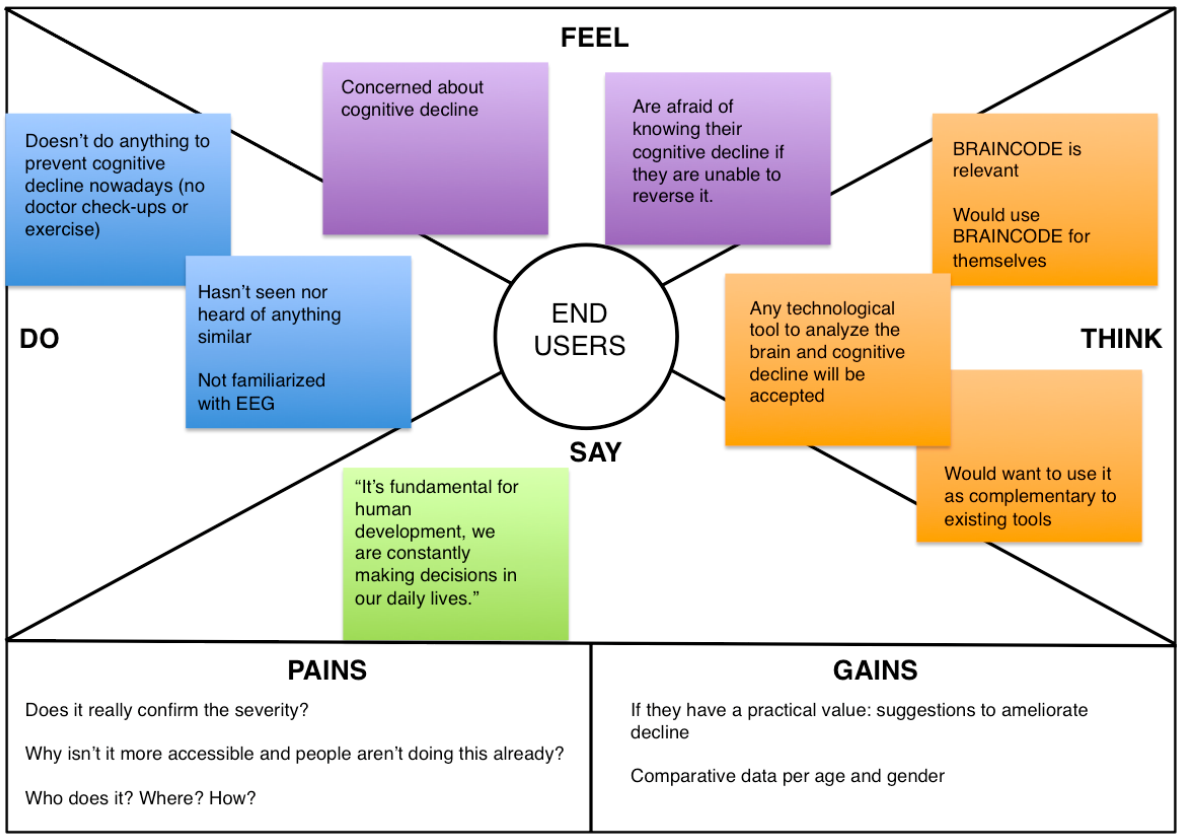

Figure 89: Use Case 3 - Empathy Mapping to evaluate users. Source: Starlab.

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4.8 Phase 4: Small Scale Live Demonstration

4.8.1 Recruitment of participants

The participants are doctors (e.g., neurologists, geriatricians) and their patients with caregivers. The group of patients is the experimental group; the group of caregivers is the control group. A list of potential doctors from neurology, psychiatric or geriatric services, settled on healthcare organizations with an ethical committee, are invited by email and phone calls (maximum four times per month). The patients and caregivers are selected by the doctors in the regular medical appointments (Figure 90).

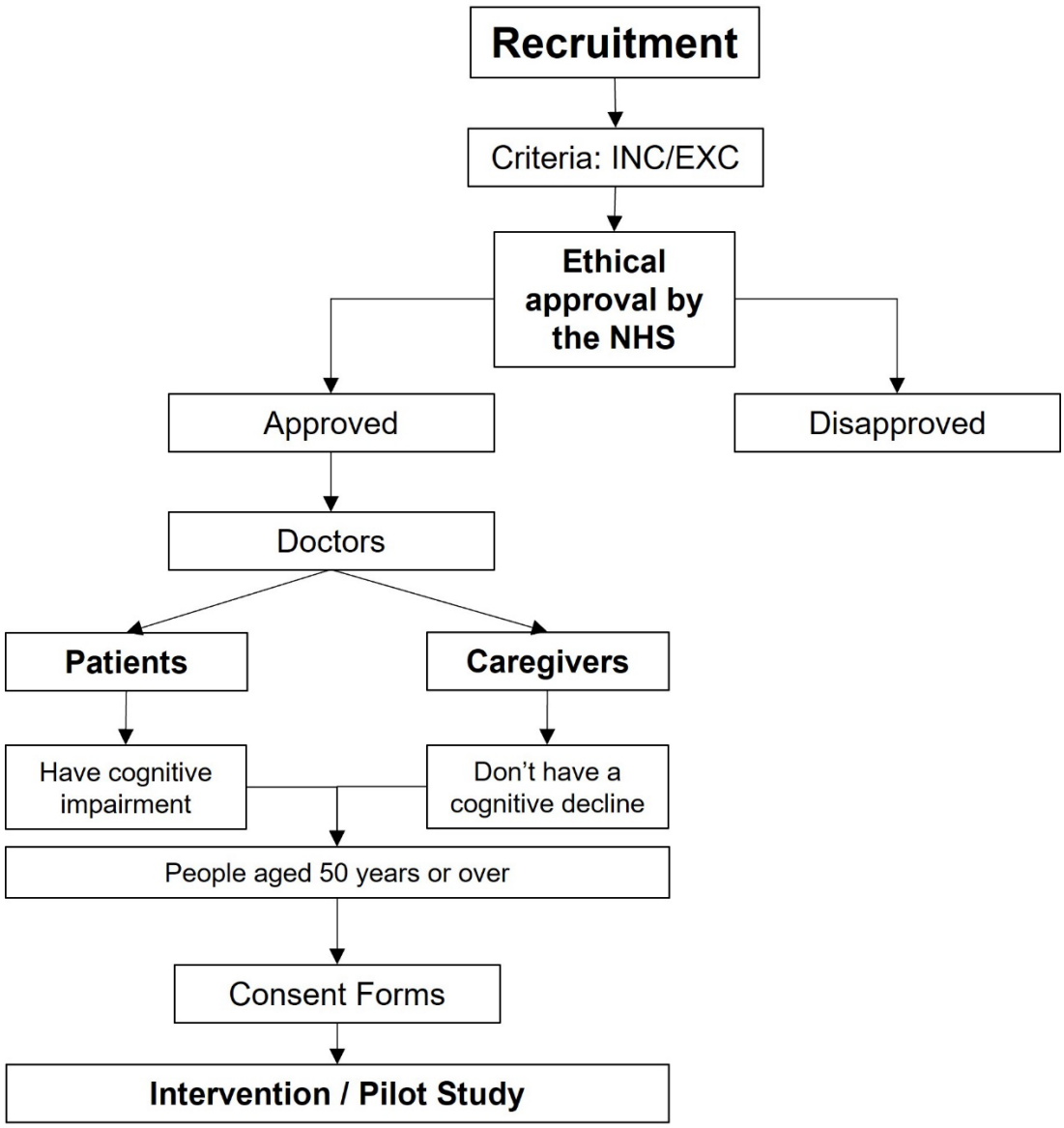

Figure 90: Use Case 3 - Recruitment Scheme.

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The inclusion and exclusion criteria are detailed in the Table 26.

Table 26. Use Case 3 - Recruitment Criteria.

Participants	Criteria	
	Inclusion	**Exclusion**
Doctors	• Being a medical doctor (e.g., neurologist, psychiatric, geriatric). • Working in a healthcare organization with ethics committee. • Obtain ethical approvements from their own healthcare organization. • Use to work with neurodegenerative disease. • Have regular practice with patients who are >= 50 years old.	• Don't sign data protection agreements. • Null experience with EEG analysis and/or recording.
Patients Control Group	• Older Adults (≥ 50 years old). • Having a diagnosis of minor or major neurodegenerative impairment (MCI or Dementia). • Subjective complaint of memory loss by the patient or the family during the last 6 months. • Being able to attend a medical appointment. • Provide an ethical consent form, and data protection consent form.	• Having other severe medical conditions (e.g., stroke, epilepsy, meningoencephalitis, brain tumour, severe concussion, multiple sclerosis). • Having history of previous psychiatric disease within the last 10 years (bipolar disorder, posttraumatic stress disorder, severe depression, psychosis, attempted suicide). • Being drug addict (e.g., alcohol, MDMA, amphetamines, cocaine, opiates, benzodiazepine, cannabis) • Interrupts the research participation process.
Caregivers	• Older Adults (≥ 50 years old).	• Having severe medical and or psychiatric conditions (e.g.,

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Experimental Group	• Without neurodegenerative disease diagnosed. • Having no subjective memory complains. • Provide an ethical consent form, and data protection consent form.	stroke, epilepsy, meningoencephalitis, brain tumour, severe concussion, multiple sclerosis). • Subjective complaint of memory loss during the last 6 months.

These criteria must ensure that the doctors have and select patients who have a medical diagnosis of cognitive impairment that identifies the bias from neurobiological markers, psychiatric disorders, pathogenetic epigenetic factors, and chronic diseases. The idea to recruit participants older than 50 years and not only older ones aims to address on one hand the rise in younger people with dementia, and on the other to allow the future use of BRAINCODE as a prevention tool to deploy early customized intervention for MCI. For the caregivers, the criteria must only ensure that have a similar age and education and deny subjective complains of memory or psychiatric disorders, in the last 6 months.

The pilot study is developed in two SHAPES Pilot Sites. In Portugal, the UPORTO should invite the doctors who work as researchers and clinicians in the National Health System. In Ireland, UCC must replicate the process. The doctors are responsible for proving the Ethical approval from the healthcare system, and the researchers from the academic Committee. The number of the study's participants is highly dependent on the number of patients and caregivers recruited by the doctors. The minimum number expected is 6 to 10 participants per pilot site, as it established for the first phase of a clinical trial [18].

4.8.2 Technical aspects & Logistics

This information is detailed in section 4.3 of this deliverable.

4.8.3 Roles and Responsibilities

STARLAB is a spin-off company that aims to translate science into technology that can have a positive impact on society. It delivers disruptive solutions based on scientific research and sound engineering, for Space and Neuroscience sectors. The

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Neuroscience Research department develops solutions related to the biomarkers, the brain stimulation, the advanced data analysis, and the brain physiology. In last years, STARLAB has been developing a digital technology for improving diagnosis of brain activity based on the EEG device called ENOBIO, which is currently commercialized by its linked company Neuroelectrics®.

ENOBIO is a certified EEG medical device (CE, FDA) that works with the NIC Desktop Software Platform to provide a wireless, easy-to-use, and cost-effective brain activity measuring system. This medical device consists in a heads-calp (wearable) with electrodes in standard channel locations along, to measure the voltage between each location and a reference. With the NIC Desktop Platform, the analysis engine extracts the reports and images. These technologies have made it possible to develop a digital solution to assess cognitive impairment in older people, the BRAINCODE.

The BRAINCODE is mainly oriented to collect biomarkers of cognitive impairment and support the neurophysiological analysis. This technology aims to differentiate the normal from the pathologic brain condition, based in an EEG biomarkers evaluation at subject individual level. Based on the EEG band power ratios, this technology requires large and validated datasets and standardized protocols (montages, analysis techniques). The BRAINCODE compares the EEG results with the reference population and the normative values of cognitive impairment. The final digital solution includes medical hardware and software (ENOBIO/NIC), and a protocol: (1) the ENOBIO acquisition; (2) the NIC analysis; (3) and the BRAINCODE Report.

Funded by the SHAPES Open Topic ST7, the BRAINCODE's intervention aimed to build the end point application to install in the SHAPES Platform, test data processing pipelines with predictive capabilities. Integrated in the SHAPES Pilot Campaign, it also aimed to evaluate the BRAINCODE's efficacy in terms of correct differentiation of 'Normal' ageing, mild cognitive impairment, and dementia (Figure 64). Currently, the BRAINCODE works comparing the individual EEG results with normative values calculated by scores from an older population (normal/pathological) available on scientific literature or data bases.

4.8.4 Outcome of the Small-Scale Live Demonstration

The BRAINCODE's pilot study intended to validate the technology's efficacy, to confirm a regular medical diagnosis and neuropsychologic tests to discriminate 'normal' from pathologic cognitive decline and differentiates mild cognitive impairment from dementia in older adults with/without subjective cognitive complains (Figure 91).

The study adopted a case-control methodology to compare the BRAINCODE's performance with medical diagnosis and neuropsychologic test(s) (e.g., MoCA, QMCI)

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(40-48). The evaluation protocol divided the participants in two groups (control and experimental), and each group was assessed with 3 diagnoses for cognitive decline: the medical diagnosis; the BRAINCODE exam; and the neuropsychologic tests.

First, during the medical appointment, doctors (e.g., neurologists, geriatricians) invited the 'patients' (experimental group) and the 'caregivers' (control group) to participate in the study. While the 'caregivers' were selected by denying subjective cognitive complains, 'patients' were selected because they had a medical diagnosis of cognitive decline (have / don't have cognitive impairment; if have, MCI or Dementia).

This diagnosis corresponded to all the usual procedures that doctors use to deliver a medical diagnosis of neurocognitive disorder or mild cognitive impairment. The list of exams depended on each situation but often includes clinical history, laboratorial exams, psychiatric and neuropsychological examinations. Finally, doctors sent a report to researchers with the participants' diagnosis: control / experimental group; have / don't have cognitive decline; is MCI or Dementia.

Second, the participants were assessed by the BRAINCODE technology. This diagnosis consisted of EEG recording for 15 minutes exam of interleaved eyes open and closed in resting state using an ENOBIO and NIC devices. The montage consisted of 32 electrodes filled with gel[11]. The signals collected by ENOBIO and NIC were analysed by the BRAINCODE to generate an individual Report and sent it to the researchers' email.

Third, immediately after the BRAINCODE exam, the participants were evaluated by two neuropsychologic tests to differentiate normal from pathological cognitive decline. The MoCA test is used worldwide by healthcare professionals because its sensitivity. The maximum score is 30 points; the authors suggested a cut off score of 26. This test assesses memory, attention, language, abstraction, and orientation; the test is adapted to 12 years of formal education. The administration takes 10 min by a professional. The QMCI test is used as a complement to clinical examinations and evaluates orientation, words, drawing, delays recall, verbal category fluency and logical memory. It's a quick neuropsychological test (3-5 min) implemented by a professional, and the total score is 100 points with an optimal established cut-off of 62 after correction of education and culture [19-26]. The tests' results were sent to the researchers by email.

[11] Note: It was important to note that dry electrodes could also be used in the future (e.g., for EEG home applications), which reduce montage time and participant's ease-to-use (since the hair is not wet). This pilot always used gel to obtain signals with the standard usage to get a reference evaluation and validation.

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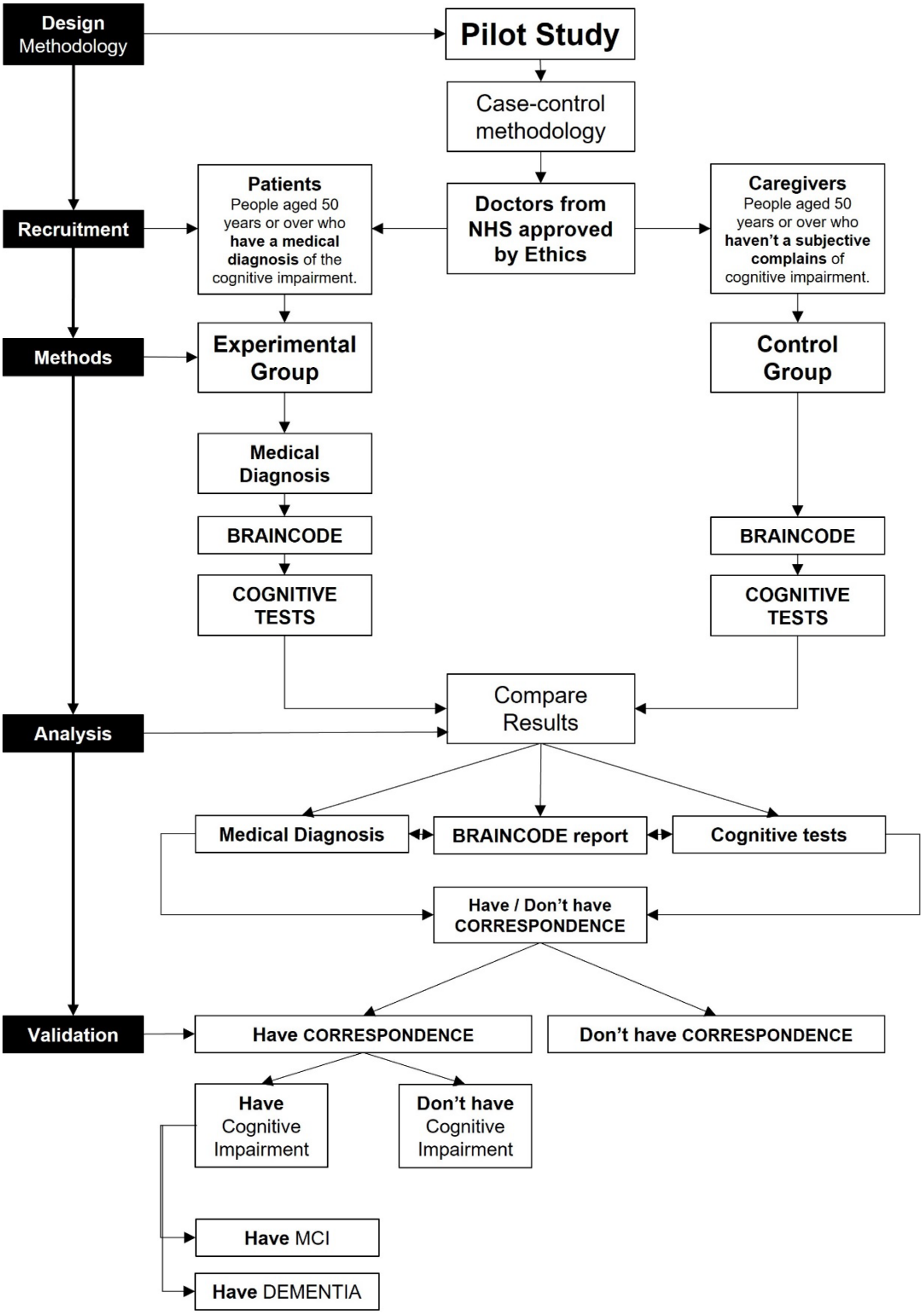

Figure 91: Use Case 3 - Intervention and Methodology Scheme.

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These procedures and their results were blinded to all the evaluators and the participants (e.g., doctors, BRAINCODE owners, and psychologists). Only the researchers knew the results provided by the three diagnoses. Finally, results provided information about the design and the methodology, namely if it's feasible and reliable to validate the BRAINCODE results. First, this is a pilot study with a small number of participants that cannot control many variables associated with cognitive impairment (e.g., social, genetic, hereditary). Second, the control group or 'caregivers' is only controlled/selected by a subjective method (e.g., questions about having or not subjective memory complains). And third, participants can be from different countries which may introduce additional cultural variance.

The intervention intends the following outcomes:

- Outcome 1. To integrate the BRAINCODE in the SHAPES Platform:
    - 1.1. To develop an application to connect technologies.
    - 1.2. To develop a BRAINCODE dashboard to use by SHAPES Platform.
    - 1.3. To update the BRAINCODE sensitivity based on the results.
- Outcome 2. To evaluate the BRAINCODE's usability and satisfaction:
    - 2.1. To assess participants with a SUS and satisfaction questionnaire.
    - 2.2. To assess experts with NASSS and MOMENTUM frameworks.
- OC3. To validate the BRAINCODE's efficacy:
    - 3.1. To distinguish cognitive impairment / 'normal' cognitive decline.
    - 3.2. To distinguish MCI / Dementia.
    - 3.3. To be adopted by non-expert healthcare providers.

4.8.5 Ethical Considerations

This pilot study hasn't received the approval by the Ethical Committees, both Portugal and Ireland, because it wasn't possible to recruit doctors available to test the technology in the NHS. The main reasons addressed by the doctors invited were: (1) lack of time and human resources; (2) participation in other clinical trials; (3) financial issues (e.g., expenses required by the healthcare system); (4) legal regulation to use technology in National Healthcare System; (5) and conflict of interests.

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Nevertheless, this study has a Risk Assess by Data Protection Officer of University of Porto and SHAPES Ethical Advisory Board, detailed in the following documents: Data Plan; Data Mapping; DPIA; Data Processing Agreement; and Data Sharing. Additionally, this use case follows the ethical requirements defined in SHAPES Deliverable "D8.4 - SHAPES Ethical Framework", as it's summarized in the Table 27.

Table 27 Use Case 3 - 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)	BRAINCODE's technology is centred in the user and the person being assessed, it takes into consideration people's Fundamental Rights at all stages
Biomedical Ethics and Ethics of Care (3.2)	All involved during the evaluation and improvement of BRAINCODE's technology in terms of design and usability respected avoiding hurt or discomfort.
CRPD and supported decision-making (3.3)	Preferences of older people were respected assuring and guaranteeing the anonymity and confidentially of data at all stages.
Capabilities approach (3.4)	The interface design and usability respected the user's capabilities and needs.
Sustainable Development and CSR (4.1)	This use case contributes to the SDG 3.
Customer logic approach (4.2)	Technology design and usability involved the user during all stages.
Artificial intelligence (4.3)	Not applicable.
Digital transformation (4.4)	The quality, usability, and efficacy of BRAINCODE were evaluated and improved, when applicable, during all stages of the pilot tests.
Privacy and data protection (5)	Anonymity and confidentiality of data done at all stages.
Cybersecurity and resilience (6)	Privacy and security were guaranteed in the technology's interface design.
Digital inclusion (7.1)	The user was contemplated during all developmental steps thus ensuring adequate usability.

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The moral division of labor (7.2)	The user was contemplated during all developmental steps thus ensuring adequate usability.
Caregivers and welfare technology (7.3)	The user was contemplated during all developmental steps thus ensuring adequate usability.
Movement of caregivers across Europe (7.4)	The portability of the technology enables it to be used in different locations.

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4.9 Phase 5: Large-scale pilot activity

This use case provided a complete protocol to validate successfully the BRAINCODE in a real medical context, an acceptance study with potential users and promotors, and a DPO Risk Assessment report.

Despite preliminary and descriptive, these results demonstrated that the users and promoters have more confidence in the technology if it's validated by clinical and scientific work. The participants' perspectives highlighted the BRAINCODE-SHAPES as a new early screening option for patients with additional cognitive profiling but at a price point and ease of use that allows wider adoption than comparable neuroimaging modalities; and a solution to change the health&care sectors, including new products and services that can: (1) improve the life of people who are prompt to suffer cognitive impairment leading to different types of dementias; (2) reduce the expenses of public health systems by delaying the onset of the gravest stages of mental diseases; (3) and extend number of years that a person stays active and productive in society.

A scientific article about this use case comments: "a disruptive opportunity to reduce sub and/or late diagnosis, and negative impacts of neurocognitive disorders on older population. Since it represents an opportunity to deliverable an early, extensive, accurate, and cost-effective clinical diagnosis of neurocognitive disorders, this technology could increase neuroprotective interventions to prolong healthy brain lifetime; its portability and easiness to use also represents an opportunity for isolated territories and primary care services, without easy and direct access to medical experts and EEG equipment" [27].

Additionally, the technical partners worked to integrate the BRAINCODE into the SHAPES platform, specifically for user authentication purposes. This technical integration is totally documented in section 4.6 of this deliverable, that describes the compatibility and adaptability within a larger framework designed for healthcare applications, successful user authentication of any healthcare platform, secure access and protect sensitive patient information.

This use case didn't find the conditions to develop the phases 4 and 5, namely the demonstration in real-life (small and large). There were especial and critical conditions that justify and explain this situation.

- **Conditions related to the open call**

  The digital solution tested in this use case (BRAINCODE) derived from the 1st SHAPES Open Call. The pilot activities initiated later (comparing with the other use cases) and must be completed in 16 months because the legal agreements with the technical partner. In this timeline, researchers and technical partners

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must integrate the BRAINCODE in SHAPES platform (concluded in July 2022) and design and implement a use case (pilot activities). Since the phase 1, there were challenges to implement the use case, namely (1) there still were COVID-19 restrictions to access the NHS facilities, (2) and the pilot study must be approved by NHS ethical committees and administrations.

- **Conditions related to the pilot theme / use case**

  This use case was framed in pilot theme 5 that aimed to design and implement activities to assess digital solutions for caring older adults with dementia and subjective complains of cognitive decline. This inclusion was justified by the main functionality of the BRAINCODE, i.e., an EEG technology that can provide an early, massive, accurate, and cost-effective screening of cognitive decline of older adults. Initially, this technology had been tested only in lab context with a few participants, and SHAPES researchers aimed to test it in real-life with the largest number of participants. This option required a hospital or other healthcare organization to participate in the pilot, but the pilot theme hadn't partners with this criterion. As academic partners, researchers (UPORTO and UCC) should invite partners from outside the SHAPES consortium, which was unfortunately denied because (1) human resources (e.g., administrative, assistances), participants (e.g., doctors, patients, caregivers), (2) ethics (e.g., approval from health ethical committee) and (3) administrative expenses (e.g., fees, taxes).

- **Conditions related to the subjects profile**

  This use case demanded participants with especial and critical requirements to participate. Group 1. Doctors: The digital solution should be adopted by professionals with experience in EEG exams and a list of suitable patients and caregivers to participate in the study. The healthcare professionals contacted by the researchers weren't available to participate in the study because (1) lack of time and human resources; (2) participation in other studies; (3) financial issues (e.g., expenses required by the healthcare system); (4) legal regulation to use technology in National Healthcare System; (5) and conflict of interests. Group 2. Older adults: The older adults were patients diagnosed with dementia (medical diagnosis) and their caregivers with no symptoms of dementia or mild cognitive impairment. This group of participants, especially the caregivers, needed a new administrative clinical profile (provided by doctors) in healthcare organizations, which is used only during the study. This legal proceeding has a financial expense didn't support by the partners (e.g., fees, taxes, daily allowance, insurance).

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- **Ethical limitations**

  This use case developed pilot activities that required an approval from ethical committees in human health and clinic sciences. As academic partners, the use case leaders haven't clinical conditions to develop the pilot activities; in a time, they couldn't recruit healthcare professionals and organizations to complete the totally criteria and requirements of the ethical committees. Additionally, the technology tested (ENOBIO and NIC) should be connected to the NHS's internet network which required the approval from the ethical committee of the NHS.

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5 Use case 004

5.1 Introduction

Contemporary medical education has been increasingly advancing, incorporating a wide variety of learning resources and domain-specific educational activities that have become more and more digitized. The rapid development of new reliable information technologies enabled the creation of contemporary learning activities that could not be previously achieved. Much of this potential of information and communication technology (ICT) in medical education is due to the advancement of Web technology and the development of interactive learning environments with immediate, content-related feedback [1-3].

In this context, Virtual Patient Scenarios (VPS) and Mobile Virtual Patients (MVP) have been increasingly used as educational resources in many medical educational institutions. More specifically, they are defined as specific types of computer-based programs that simulate real-life scenarios where learners emulate the roles of health care providers. They can be deployed as problem-based learning activities and are considered an innovative approach which may lead to effective outcomes in education [4-7].

They are widely used across various academic institutions because they consist of an open-source toolset that allows the creation and delivery of a wide range of pathway-based educational activities with an easy-to-use, code-free interface [8-9]. Therefore, these effective learning tools facilitate the transfer of real-life challenges in engaging scenarios which mimic the tensions, distractions and uneven issues that make real-life decisions more difficult. In particular, the methodology followed is to provoke the learner to think through a few solutions or options to move forward in the scenario.

In this vein, caregivers can interact with diverse virtual cases through scenarios and therefore familiarize themselves with a range of neurodegenerative diseases (including Alzheimer's, Parkinson's, dementia, stroke) and other chronic diseases (diabetes, heart disease, etc.), aiming at enhancing their learning skills about symptoms, diagnosis and treatment. Thus, they are considered as being valuable for caregivers in encouraging decision making, reasoning skills, as well as self-assessment.

This Use Case aims to explore whether the Virtual Patients and Mobile Virtual Patients help formal caregivers and medical students develop decision making, reasoning, and training skills to care older adults with Dementia and Mild Cognitive Impairment (MCI) in the workplace. This target population was selected to correspond to the SHAPES Persona "Daphe" (Figure 92), as detailed in the "D2.6 – SHAPES Personas and Use V2":

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Figure 92: Use Case 4 – SHAPES Persona who represents formal caregivers. Source: D2.6 – SHAPES Personas and Use V2".

5.2 Description

Code	UC-PT5-004
Title	Virtual Patient Scenarios (VPS) - Mobile Virtual Patients (MVP)
Pilot Theme & Task	PT 5 – Caring for Older Individuals with Neurodegenerative Diseases (Task 6.6)
Piloting Sites	AUTH (Greece), UNRF (Cyprus)
Description	Contemporary medical education has been increasingly advancing, incorporating a wide variety of learning resources and domain-specific educational activities that have become more and more digitized [1]. The rapid development of new reliable information technologies enabled the creation of contemporary learning activities that could not be previously achieved [2]. Much of this potential of information and communication technology (ICT) in medical education is due to the advancement of Web technology and the development of interactive learning environments with immediate, content-related feedback [3].
Digital Solution proposed	Virtual Patient Scenarios (VPS) and Mobile Virtual Patients (MVP) have been increasingly used as educational resources in many medical educational institutions. More specifically, they are defined as specific types of computer-based programs that simulate real-life scenarios where learners emulate the roles of health care providers [4]. They can be deployed as problem-based learning activities [5] and are considered an innovative approach which may lead to effective outcomes in education [4,6,7]. VPS are developed using the OpenLabyrinth (http://vp.med.auth.gr), an open-source platform for creating and playing virtual patients, while MVP using the Open-Source Framework Drupal. They are widely used across various academic institutions because they consist of an open-source toolset that allows the creation and delivery of a wide range of pathway-based educational activities [8] with an easy-to-use, code-free interface [9]. Therefore, these effective learning tools facilitate the transfer of real-life challenges in engaging scenarios which mimic the tensions, distractions and uneven issues that make real-life decisions more difficult. In particular, the methodology followed is to provoke the learner to think through a few solutions or options to move forward in the scenario. In this vein, caregivers can interact with diverse virtual cases through scenarios and therefore familiarize themselves with a range of neurodegenerative diseases (including Alzheimer's, Parkinson's, dementia, stroke) and other chronic diseases

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	(diabetes, heart disease, etc.), aiming at enhancing their learning skills with regard to symptoms, diagnosis and treatment. Thus, they are considered as being valuable for caregivers in encouraging decision making, reasoning skills, as well as self-assessment.
Technical partners	AUTH (Greece)
Components	Mobile Applications
Piloting summary	A pilot study was developed to assess the scenario proposed in this use case, in terms of acceptance, satisfaction, usability, and efficacy. Adopting the SHAPES methodology, this pilot study had 5 Phases. In Phase 1, academic and technical partners transferred the proposed use case in two scenarios, describing partners, framework, subjects or target groups, activities and roles, interactions, context, environment, functions, technical infrastructures, devices, interfaces, performance indicators, and a timeline. The outcome is the pilot study design and plan, considering the SHAPES methodology and expected impacts, but also the first mock-up of digital solutions, written and summarized. In Phases 2&3, academic and technical partners developed the final prototype to use in the pilot study and test it in the hands-one experiments. Additionally, the academic partners provided the social context to deploy a pilot in real-life environment, namely a community of older people, informal and formal caregivers, and public or private facilities. The outcome is a final prototype not only of digital solutions, but also a real-life scenario that use technology to integrate pilot' subjects and promote healthy lifestyle in old age. In Phases 4&5, academic partners, supported by technical partners, assessed the pilot study by a scientific protocol. Thereby, they designed a protocol, submitted it in the ethics committee and data protection office, recruited participants, signed consent forms, managed logistic and risks, collected and analysed data, and elaborated regular reports. The outcome is an extensive final report that describe in-depth the 5 phases and their results (SHAPES D6.6 – Pilot Theme 5: Caring for Older Individuals with Neurodegenerative Diseases). This Use Case was replicated in two pilot sites: AUTH (Greece) and UNRF (Cyprus). Moreover, partners worked to disseminate the experience and results of this Use Case through scientific publications, public events, and social media.

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Subject profile (main persona of the piloting)	Healthcare professionals & Medical students.

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5.3 Digital solutions used in this use case

Virtual Patient Scenarios and Mobile Virtual Patients are developed using the OpenLabyrinth (http://vp.med.auth.gr), an open-source platform for creating and playing virtual patients, while MVP using the Open-Source Framework Drupal. They can be used in different learning activities and contain a wide range of features that make them fit for individual purposes.

- Provision of different learning settings and activities: (a) Large Group Teaching, (b) Small Group Teaching, (c) Self-Directed.
- Structure of Scenario: Virtual Scenarios can differ in their structure. The three main structures are linear, semi-linear and branched.
- Enrich with media: extensive media enhancement, or just be simple text.
- Assessment steps or questions: free text, multiple choice, list-based questions and others.
- Interactive Scenarios: VPS can include many different types of interactivities.
- Disciplines: VPS can be used in a range of different disciplines and there have been very popular within the medical and healthcare settings.
- Languages: VPS can be developed in many languages.

In the Table 28, it's listed the actions which should be performed by both digital solutions: Virtual Patient Scenarios and Mobile Virtual Patients.

Table 28 Use Case 4 - Detailed descriptions (texts and images) of the VPS and MVP.

Virtual Patient Scenarios	Mobile Virtual Patients
• User logs in to the OpenLabyrinth platform (http://vp.med.auth.gr) where a list of healthcare-related use case scenarios is available. • User selects to perform a VPS. • User performs the VPS. In particular, he/she is confronted with interactive computer simulations of real-life scenarios for the purpose of health care and medical training, education or assessment. Users have the opportunity to interact with diverse virtual cases through scenarios therefore familiarize	• User accesses the SHAPES Mobile Virtual Patients App (https://shapes-26bd2.web.app/) where a list of healthcare-related use case scenarios is available. • User selects to perform an MVP. • User performs the MVP. In particular, he/she is confronted with interactive computer simulations of real-life scenarios for the purpose of health care and medical training, education or assessment. Users have the opportunity to interact with diverse virtual cases

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themselves with a range of neurodegenerative diseases (including Alzheimer's, Parkinson's, dementia, stroke) and other chronic diseases (diabetes, heart disease, etc.). • User is engaged in an enquiry-based approach to learning and thus, a variety of features are available to them, including, multiple nodes and links, media files, info buttons, counters and skins, all these provided through a user-friendly interface and a visual editor. • User is required to make essential in relation to the use case scenario aiming to follow the right ''pathway'' and proceed in proper healthcare-related practices	through scenarios therefore familiarize themselves with a range of neurodegenerative diseases (including Alzheimer's, Parkinson's, dementia, stroke) and other chronic diseases (diabetes, heart disease, etc.). • User is engaged in an enquiry-based approach to learning and thus, a variety of features are available to them, including, multiple nodes and links, media files, info buttons, counters and skins, all these provided through a user-friendly interface and a visual editor. • User is required to make essential in relation to the use case scenario aiming to follow the right ''pathway'' and proceed in proper healthcare-related practices

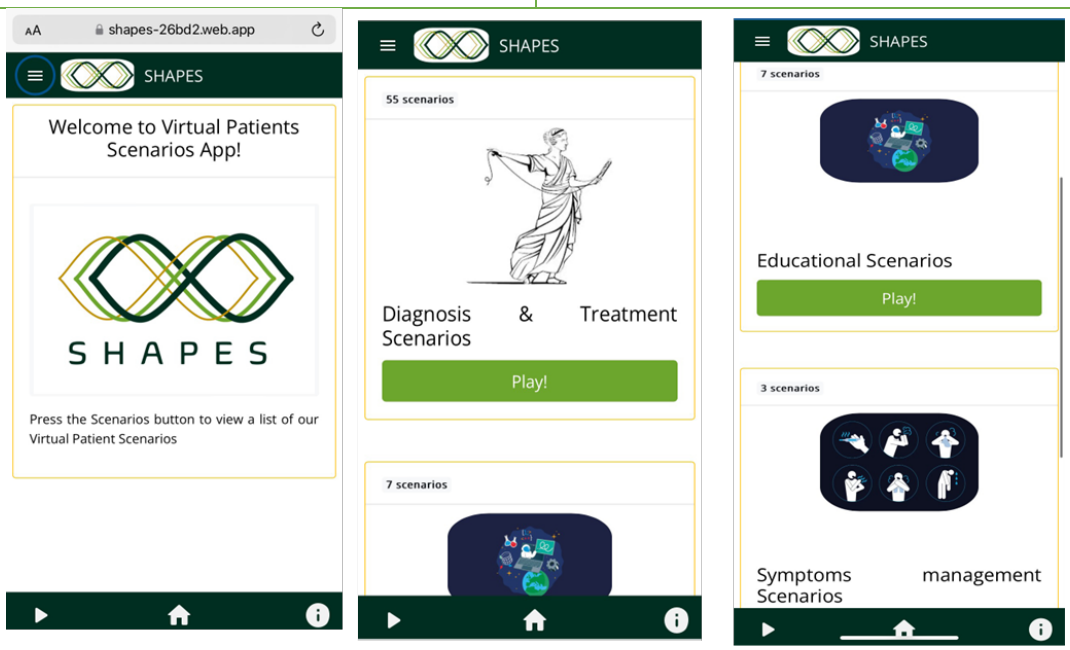

Figure 93: Use Case 4 - Mobile Interfaces (VPS / MVP).

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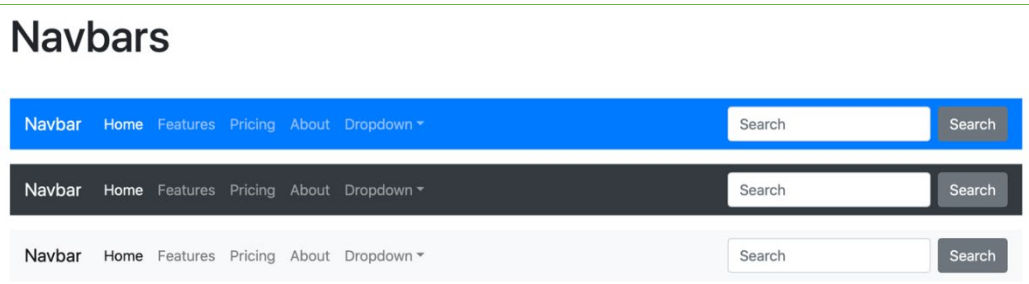

Figure 94: Use Case 4 - Application Navbars.

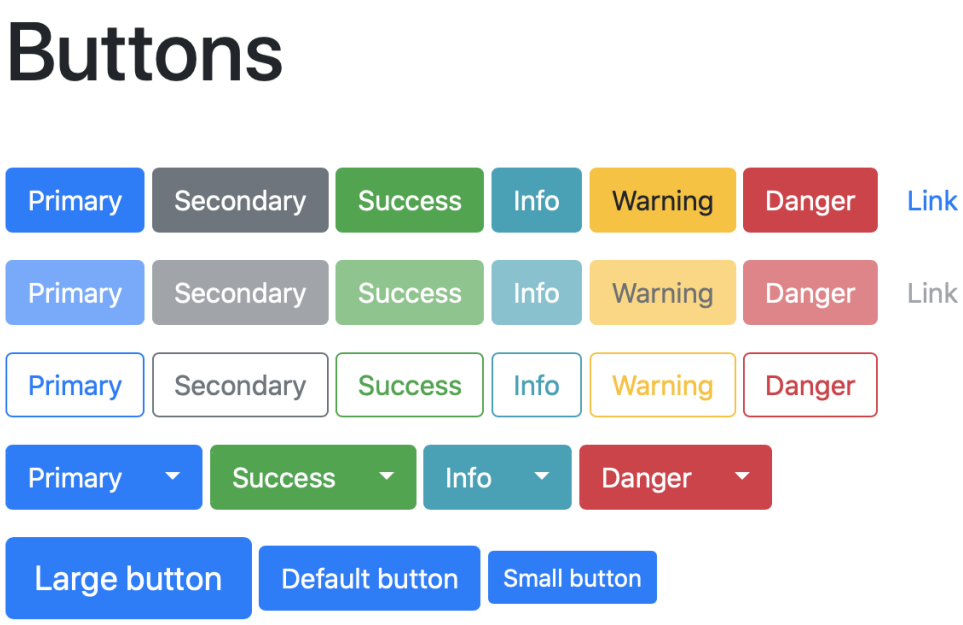

Figure 95: Use Case 4 - Application Buttons.

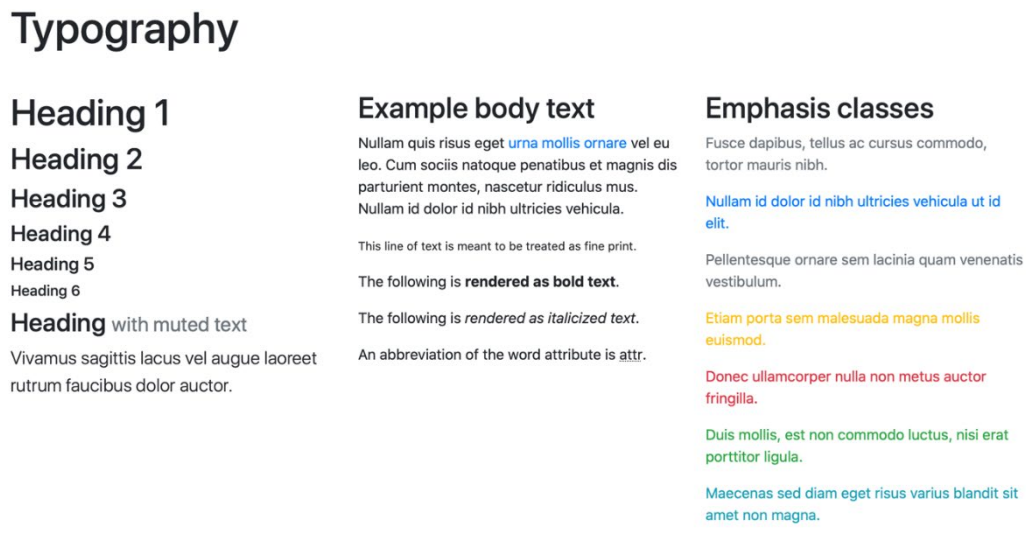

Figure 96: Use Case 4 - Application Typography.

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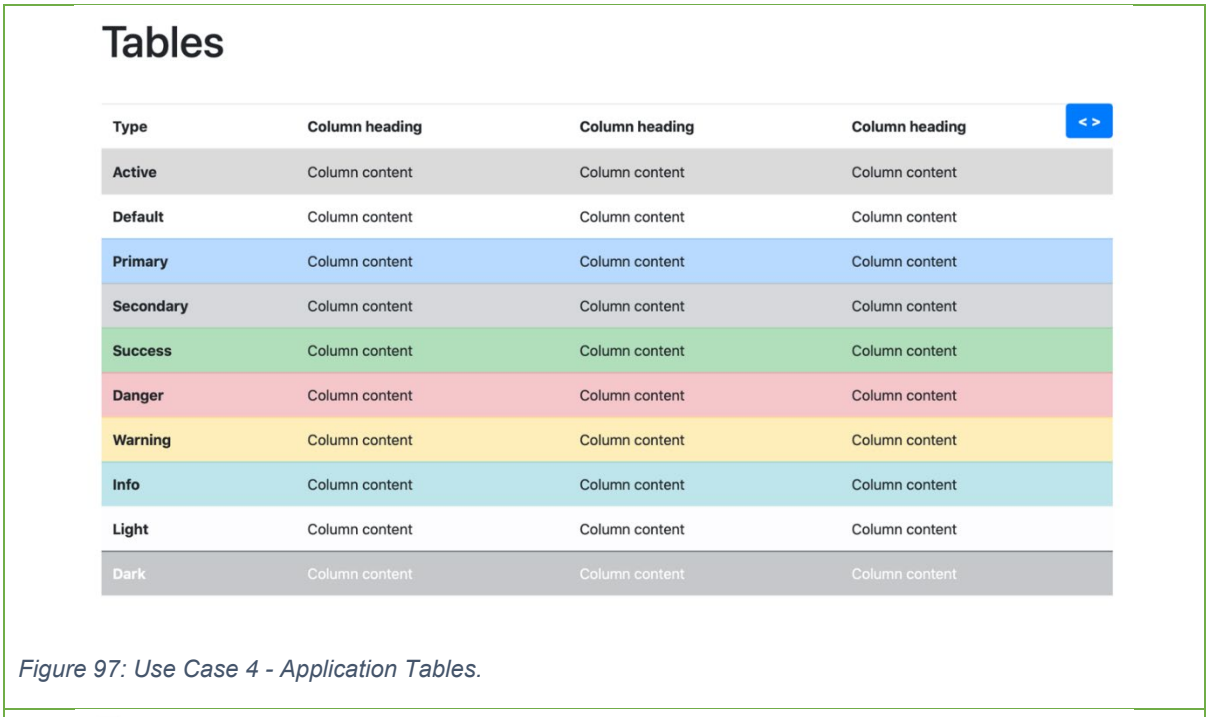

Figure 97: Use Case 4 - Application Tables.

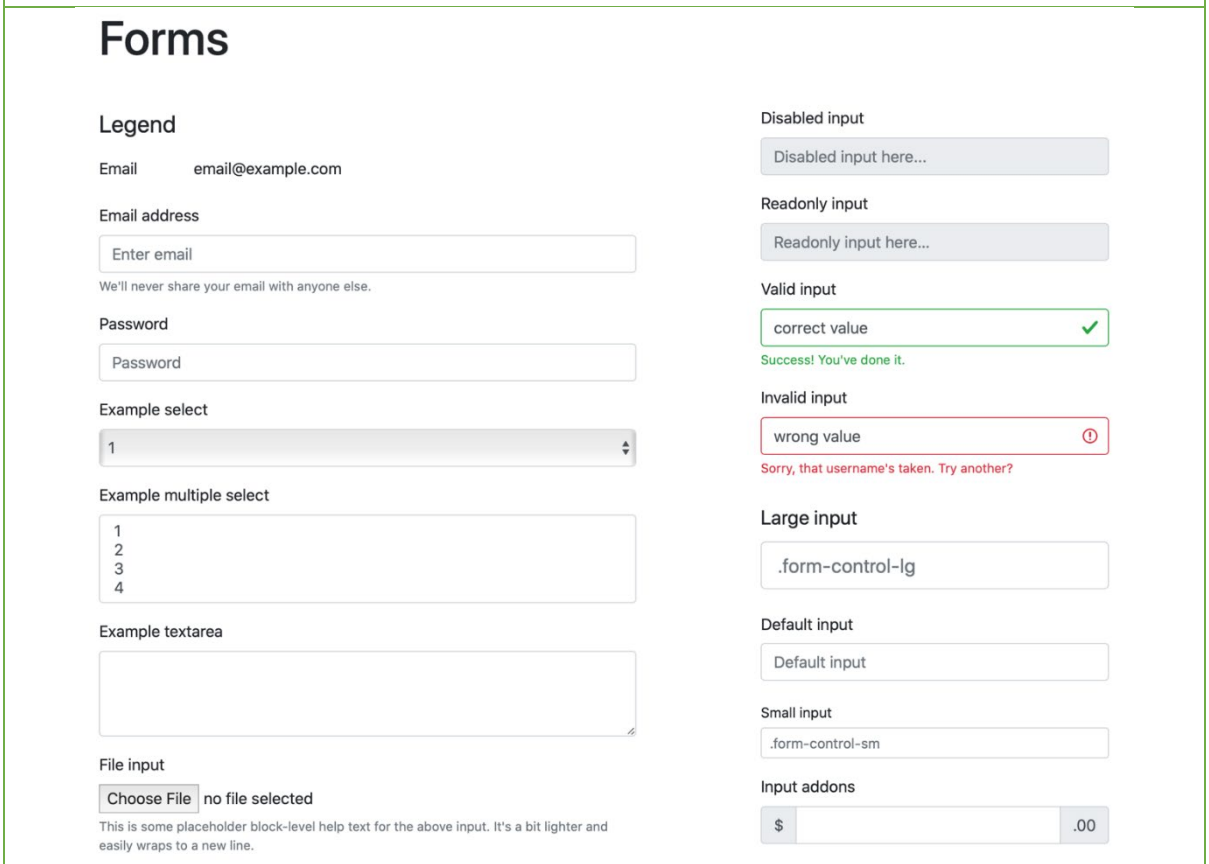

Figure 98: Use Case 4 - Application Forms.

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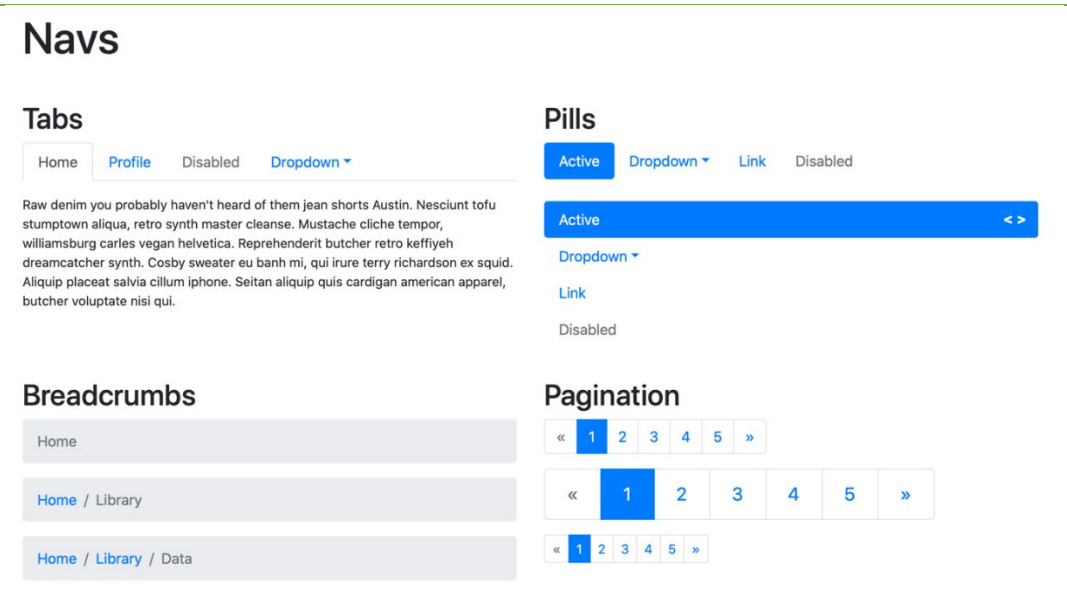

Figure 99: Use Case 4 - Application Navs.

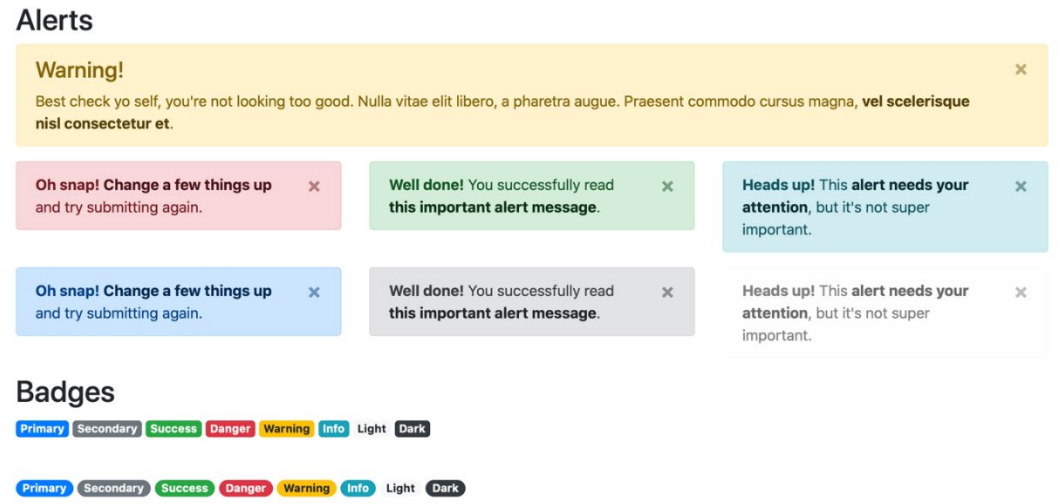

Figure 100: Use Case 4 - Application Alerts.

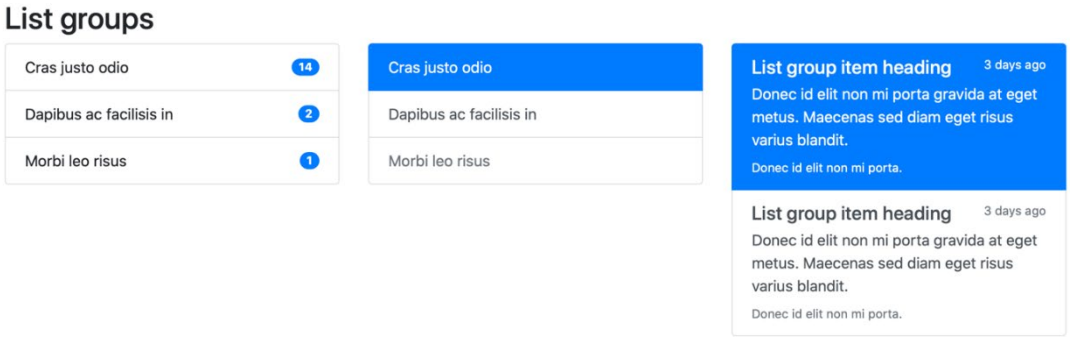

Figure 101: Use Case 4 - Application Groups.

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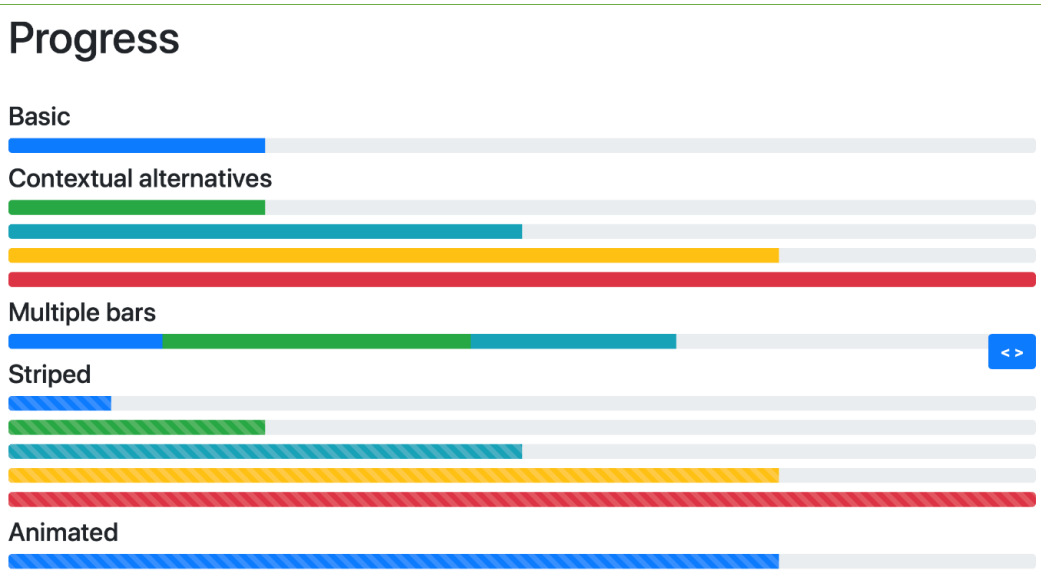

Figure 102: Use Case 4 - Application Progress.

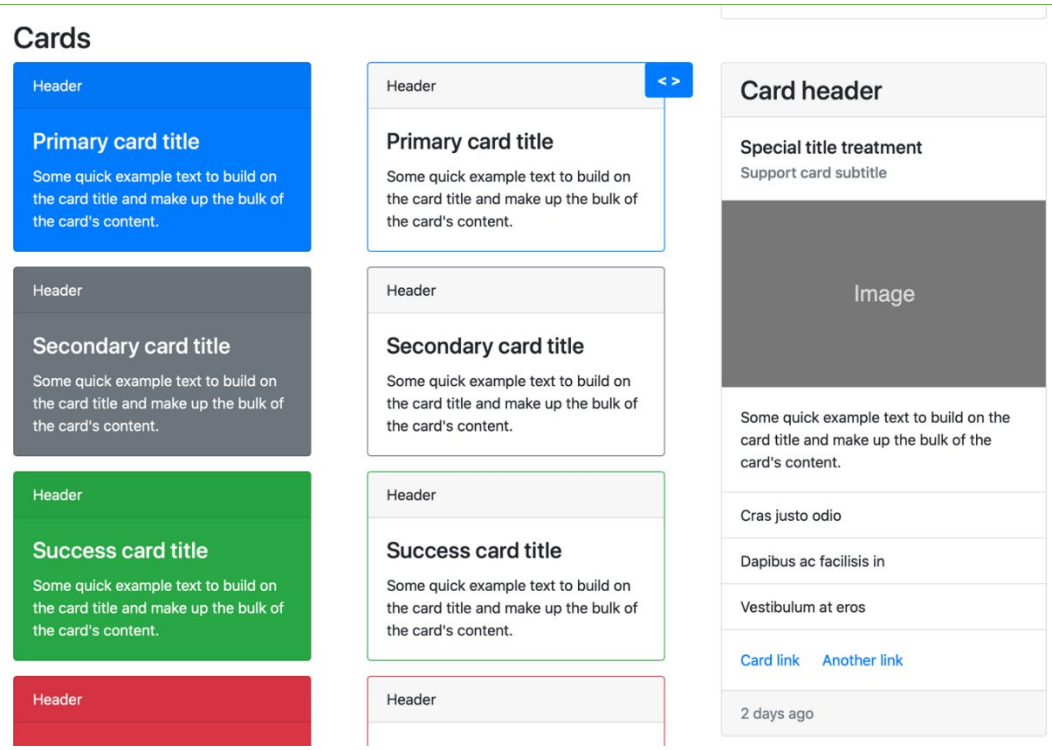

Figure 103: Use Case 4 - Application Cards.

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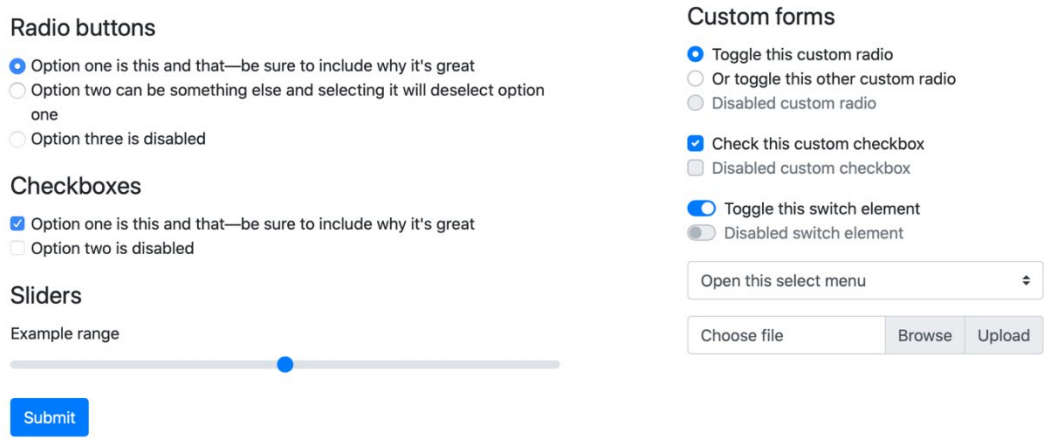

Figure 104: Use Case 4 - Application Customizations.

5.3.1 Digital solutions used for COVID-19 response

This digital solution was not originally designed to respond the COVID-19.

5.3.2 Equipment and devices used (from third parties)

Overall, the equipment and devices used in this use case were provided by the SHAPES partners AUTH and UNRF

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5.4 Data plan

5.4.1 Data capture methods to be used

Outcomes of VPS & MVP	Domain	Type of variable	Frequency of assessment
Demographics			
Participant's ID	Socio-demographic	nominal	Baseline
Age	Socio-demographic	continuous	Baseline
Gender (m/f)	Socio-demographic	nominal	Baseline
Native language	Socio-demographic	nominal	Baseline
Medical speciality	Socio-demographic	nominal	Baseline
Education	Socio-demographic	nominal	Baseline
Psychosocial measures			
WHOQOL-Bref	Quality of life	ordinal	Baseline/Post-intervention
1-item health literacy	Health literacy	ordinal	Baseline/Post-intervention
General Self-efficacy (GSES)	Perceived self-efficacy	ordinal	Baseline/Post-intervention
EQ-5D & VAS	Subjective perception of health status	ordinal	Baseline/Post-intervention
Oslo Social Support Scale (OSSS-3) with Life Events Scale	Social support	ordinal	Baseline/Post-intervention
Perceived Stress Scale (PSS)	Perceived stress	ordinal	Baseline/Post-intervention
Participation questions (x2)	Ultimate outcome	ordinal	Baseline/Post-intervention
Data stored in VPS/MVP regarding formal caregiver			
Detailed log of detection and tracking of user's pathway	Tracking of progress	discrete	During intervention

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Time spent in each node of the VPS/MVP	Tracking of progress	continuous	During intervention
Milestone tracking	Tracking of progress	discrete	During intervention
Rate of successful completion of VPS/MVP	Tracking of progress	discrete	During intervention
Connection with learning outcomes	Tracking of progress	discrete	During intervention
Usability & Technology Acceptance measures			
System Usability Scale (SUS)	Usability	ordinal	Post - intervention
Technology Acceptance Model (TAM)	Acceptance	ordinal	Baseline/Post-intervention
eHEALS: The eHealth Literacy Scale	Digital literacy	ordinal	Baseline/Post-intervention
Scenario-based learning (SBL) experience assessment			
eViP evaluation tool - clinical reasoning	Learning and clinical reasoning experiences with VPs	ordinal	Post- intervention
eViP evaluation tool - reviewer checklist	Clinical reasoning skills development	ordinal	Post- intervention
User SBL Experience Survey	User satisfaction	ordinal	Post- intervention
SBL Case Quality Assessment Tool	Quality of SBL cases	ordinal	Post- intervention

5.4.2 Planning of evaluation

The planning evaluation of this Use Case was provided by the SHAPES Deliverable “D6.1 - SHAPES Pan-European Pilot Campaign Plan” (pp. 127-183), that suggested the MAST and MAFEIP frameworks to assess the impact of the Use Case. The MAFEIP framework couldn’t be adopted due to a small-scale deployment of it.

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This Use Case adopted the MAST framework (Model for Assessment of Telemedicine) that assess the Use Case's effectiveness and contribution to quality of care. MAST is a multidisciplinary assessment that focuses in 7 domains: (1) Health problem and characteristics of the application; (2) Safety; (3) Clinical effectiveness; (4) Patient's perspective; (5) Economic aspects; (6) Organizational aspects; (7) and Sociocultural, ethical, and legal aspects [13].

The researchers did a review of these domains and selected those most relevant to this Use Case, namely: Clinical effectiveness (3); and Patient's perspective (4). The Table 29 describes the data required for the MAST evaluation.

Table 29. Use Case 4 - MAST.

Domain	Topic	Outcome	Method	Time
Clinical Effectiveness	Quality of life	Health related quality of life and wellbeing	• Beck Anxiety Inventory (BAI) • Geriatric Depression Scale-15 (GDS-15) • Friendship Scale Assessment • WHOQOL-BREF • 1-item health literacyEQ-5D-VAS • Oslo Social Support Scale (OSSS-3) with Life Events Scale • Self-efficacy (GSES) • UCLA-6 Loneliness Scale • Participation questions (x2)	Baseline Post-intervention
Patient perspectives	Satisfaction and acceptance	User Experience	System Usability Scale (SUS)	Post-intervention
		User acceptance	Technology Acceptance Model (TAM)	Post-intervention

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	• Understanding of information • Confidence in the treatment • Ability to use the application • Access & Accessibility	Usability of application	System Usability Scale (SUS) 1-item health literacy	Post-intervention
	Perceived impact	User engagement	Interview	Post-intervention

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

The NASSS and the MOMENTUM frameworks were proposed by SHAPES Project in the public report "D6.1 SHAPES Pan-European Pilot Campaign Plan" (SHAPES-WP6, 2020, pp. 117-118). The NASSS framework (Non-adoption, Abandonment, Scale-up, Spread, and Sustainability) was proposed by Greenhalgh et al. (2017) to assess "challenges to achieving sustained adoption and long-term sustainability", by 19 questions, organized in 7 domains, classified in three levels: simple (straightforward, predictable, few components), complicated (multiple interacting components or issues), or complex (dynamic, unpredictable, not easily disaggregated into constituent components). The MOMENTUM (Advancing Telemedicine Adoption in Europe, 2015) is a "validated and tested method to support the telemedicine implementation process and create enabling environments to accelerate telemedicine". This method helps the stakeholders to identify the telemedicine critical factors on a list composed of a set of guidelines and indicators, the MOMENTUM 18 Critical Success Factors List [10-11].

Regarding the NASSS evaluation, no uncertainties were identified, and therefore, no mitigation measures where needed to be developed to ensure the success of the use case. The causes leading to loneliness can be very different and they change with age. Unfortunately, however, all people who suffer from loneliness for longer periods of time have one thing in common: their health, both physical and mental, suffers.

This use case aimed therefore to support the interaction of the older individual with the community. If older individuals are already somewhat distanced from their community and they don't take part in day-to-day activities within the community, they also don't necessarily hear about new developments or opportunities for engagement, sports, educational or cultural events. It needs to be ensured that they have easy

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access to suitable opportunities and developments in the community, such as specialized transport services, and are actively informed about e.g., weather conditions that allow for exercise outdoors but also activities such as readings, bingo, exhibitions, and other opportunities to engage in activities taking place in local communities (Table 30).

Table 30 Use Case 4 - NASSS Assessment.

Domains	How much you agree with the sentence?		
	Agree	Disagree	Don't Know
A) The Illness or Condition **Think about the illness or other condition that the technology is designed for – and what sort of person has that condition.**			
A1) There are significant uncertainties about the condition e.g., poorly defined, variable manifestations, uncertain course.		X	
A2) Many people with the condition have other co-existing illnesses or impairments that could affect their ability to benefit from this solution.		X	
A3) Many people with the condition have social or cultural factors that could affect their ability to benefit from the technology or service.		X	
A4) The population with the condition, and/or how the condition is treated, is likely to change significantly over the next 3-5 years.		X	
A5) The condition has significant complexity which is likely to affect the project's success.			NO
B) The Technology **Think about the technology (e.g., a tool or piece of software), and how it might affect care.**			
B1) There are significant uncertainties in what the technology is (e.g., it hasn't been fully developed yet).		X	
B2) There are significant uncertainties in where the technology will come from (e.g., supply chain issues, substitutability).		X	
B3) There are significant uncertainties about the technology's performance and dependability (e.g., bugs, crashing, cutting out).		X	

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B4) There are significant uncertainties about the technology's usability and acceptability (e.g., key people don't trust the data it provides).	X	
B5) There are significant technical interdependencies.	X	
B6) The technology is likely to require major changes to organisational tasks and routines.	X	
B7) The technology (and/or the service model it supports) is likely to change significantly within the next 3-5 years.	X	
B8) The technology has significant complexity which is likely to affect the project's success.		NO
C) The Value Proposition **Think about what kind of value the technology might generate for different groups of people. ('Value' can be financial, such as profit, or non-financial, such as control of symptoms)**		
C1) The commercial value of the technology is uncertain.	X	
C2) The value to the intended users (e.g., patients, clinicians) is uncertain.	X	
C3) The value to the healthcare system (e.g., from efficacy and cost-effectiveness studies) is uncertain.		X
C4) The value to this particular healthcare organisation, given the current situation locally, is uncertain.		X
C5) The technology could generate a negative value (costs are likely to outweigh benefits) for some stakeholders.	X	
C6) The value proposition is likely to change significantly over the next 3-5 years.	X	
C7) The value proposition has significant complexity which is likely to affect the project's success.		NO
D) The Intended Adopters **Think about who is intended to use the technology and what changes it will bring for them.**		
D1) There is uncertainty about whether and how patients/citizens will adopt the technology (if applicable).	X	
D2) There is uncertainty about whether and how front-line staff will adopt the technology.	X	
D3) There is uncertainty about the implications for people who might be indirectly affected by the technology.	X	

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D4) There will be significant changes to individual users' perceptions of the technology over the next 3-5 years.		X
D5) There is significant complexity relating to intended adopters which is likely to affect the project's success.		NO
E) Organization readiness **Some organisations are better at taking up innovations than others. What about yours?**		
E1) The organization's capacity to take on technological innovations is limited.	X	
E2) The organization is not ready for this particular innovation.	X	
E3) The organization would find it hard to commission/purchase the innovation.	X	
E4) The work needed to introduce and routinise the innovation has been underestimated and/or inadequately resourced.	X	
E5) The organization(s) involved are likely to have significant restructurings or changes in leadership, mission or strategy over the next 3-5 years.	X	
E6) There is significant complexity relating to one or more participating organizations which is likely to affect the project's success.		NO
F) The External Context **Think about external conditions that could complicate adoption and spread of the innovation.**		
F1) The political and/or policy climate is adverse.	X	
F2) Professional bodies are opposed to the innovation or don't actively support it.	X	
F3) Patient organisations and lobbying groups are opposed to the innovation or don't actively support it.	X	
F4) The regulatory context is adverse.	X	
F5) The commercial context is adverse.	X	
F6) Opportunities for learning from other (similar) organisations are limited.	X	

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F7) Introduction of the technology/innovation could be threatened by external changes that impact on the organisation.	X	
F8) The policy, regulatory and economic context for this innovation is likely to be turbulent over the next 3-5 years.		X
F9) There is significant complexity relating to the external context which is likely to affect the project's success.		NO

Regarding the critical success factors (CSFs), this digital solution was ready to provide telemedicine in the healthcare system and in the social care sector. Nevertheless, it was relevant to analyse the use case to consider its scaling up as a telemedicine integrated into healthcare delivery systems.

CSF 1. Cultural readiness for the telemedicine service: The digital solutions being replicated in this UC are not considered telemedicine neither medical device. To this end, no clinical data and information are to be exchanged between different health care providers.

CSF 2. Advantages of telemedicine in meeting compelling need(s): The digital solutions being replicated in this UC are not considered telemedicine neither medical device. Therefore, the advantages of telemedicine are not directly explored.

CSF 3. Ensure leadership through a champion: Engaging key stakeholders, including healthcare providers, researchers, project managers, IT personnel, and older people, is essential for successful telemedicine implementation. Facilitators should promote open communication, solicit feedback, and address concerns to ensure a collaborative approach.

CSF 4. Involvement of healthcare professionals and decision-makers: The involvement of healthcare professionals and decision-makers in telemedicine is vital to ensure clinical expertise, patient safety, continuity of care, and quality assurance. In this UC both healthcare professionals and medical students are directly involved in all the design phases.

CSF 5. Put the patient at the center of the service: Healthcare professionals and medical students were involved in the development of this digital solution through upcoming activities of the next phases. The development was based on their needs and appropriate training for using the digital solutions is planned.

CSF 6. Ensure that the technology is user-friendly: The next phases of the project aim to consider especially the user-friendliness and trustworthiness of the digital

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solutions. Potential participants should be asked about their opinion and experience with the solution, and all feedback should be included in the final development. This evaluation included metrics like the System Usability Scale (SUS).

CSF 7. Pull together the resources needed for deployment: The resources required for the deployment of the digital solutions in this UC are provided to SHAPES funding and internal resources already allocated. The technical partners of the use case provide all IT competences.

CSF 8. Address the needs of the primary client(s): Healthcare professionals and medical students in this UC are considered primary clients. Their personalized needs and requirements were explored through the next phases (Mock-up, Hands-on training, Small-scale pilot). Based on the results and feedback collected, the UC leader and technical partners should proceed in essential improvements considering the older adults' needs and preferences and ensure smooth pilot activities.

CSF 9. Prepare and implement a business plan: A business plan for the solution is developed in D7.3 SHAPES Business Plan WP7.

CSF 10. Prepare and implement a change management plan: It is evaluated at the end of the project.

CSF 11. Assess the conditions under which the service is legal: The assessment of the conditions under which the service is legal is still to be done. Since this digital solution is not specifically considered a medical device, requirements might not need. Completion of a Data Protection Impact Assessment (DPIA) to identify and minimize any risks associated with the pilot with input sought from other work packages and the SHAPES Data Protection Officer at AUTH. Data processing agreements is established with relevant partners to permit access to pseudonymized data.

CSF 12. Guarantee that the technology has the potential for scale-up: Although the participants in the pilot are limited, the solution is being designed with the intention to scale it to a pan-European level. The use of human resources is evaluated during the pilot, with a proper analysis of resources needed in relationship with the monitoring protocol.

CSF 13. Identify and apply relevant legal and security guidelines: GDPR was applied. The system provided implements all security and privacy related regulations.

CSF 14. Involve legal and security experts: Advice from legal experts and experts on data security matters is received from project partners (for example LAUREA, that has extensive expertise in this field). AUTH acting both as technical partner was awarded the ISO 9001 certification for Software Design, Development and Production. Design & Implementation of Education/Training programs.

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CSF 15. Ensure that telemedicine doers and users are privacy aware: The protocol for the pilot details all the steps that have been taken to ensure older adults' privacy is protected. The project undergoes a full ethical evaluation before permission is granted to undertake the study.

CSF 16. Ensure that the information technology infrastructure and eHealth infrastructure are available: SHAPES is developing a technology platform for pan-European distribution of telemedicine services. The pilot is being designed to cope with this requirement as well.

CSF 17. Put in place the technology and processes needed to monitor the service: The IT system works 24/7. In case of any bugs or issues the development and maintenance team fixes it. AUTH is the owner of all the software that is used in the pilot. This means that we don't have any software dependencies with third parties, and that we can fix the source code at any point. The system logs all activities so any incident can be identified and solved quickly.

CSF 18. Establish and maintain good procurement processes: The devices' requirements are already defined and vendors. The SHAPES project provides the servers that are needed to run the solution. Those servers meet the service level needed to run the pilot successfully.

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5.5 Phase 1

5.5.1 PACT and FICS Scenario

5.5.1.1 PACT

Code	UC-PT5-004
Applicable SHAPES Persona	SHAPES Persona "Daphne"
Applicable SHAPES use case	Virtual Patient Scenarios (VPS) - Mobile Virtual Patients (MVP)
People Roles and/or actors of typical users involved in delivering and receiving the telemedicine intervention	Healthcare professionals & Medical students
Activities Activities to be performed by the actors in order to provide and receive the telemedicine intervention successfully procedures for the professional and the patient; Parameters that determine the measures used in the intervention	Users access the Virtual Patient App (https://shapes-26bd2.web.app/) where a list of healthcare-related virtual patient scenarios is available. Users select to interact with different scenarios. The scenarios are divided into four (4) categories: 1) Diagnosis and Treatment Scenarios, 2) Symptom Management Scenarios, 3) Educational Scenarios, and 4) Empowerment Scenarios. During interaction with the scenarios: In particular, users are confronted with interactive computer simulations of real-life scenarios for the purpose of health care and medical training, education or assessment. They have the opportunity to interact with diverse virtual cases through scenarios therefore familiarize themselves with a range of neurodegenerative diseases (including Alzheimer's, Parkinson's, dementia, stroke) and other chronic diseases (diabetes, heart disease, etc.). They are engaged in an enquiry-based approach to learning and thus, a variety of features are available to them, including, multiple nodes and links, media files, info buttons, counters and skins, all these provided through a user-friendly interface and a visual editor.
Context Social-medical relevance of the telemedicine intervention; privacy	The use of Virtual Patients is increasing in healthcare, partly in response to increasing demands on health care professionals and education of students but also because they allow opportunity for students to practice in a safe environment [1].

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issues; risks for the patient; locations	Need for safer and more effective means of supporting the development of clinical reasoning skills required in medical education. Practice in a safe and no patient risk environment that can be repeatedly used by any caregiver without regard to time and place. Implementation of interactive educational activities. User-centred training aiming at giving more emphasis to active learning and clinical skills reasoning. 24/7 availability: convenient access. Ubiquitous intervention; can be used anywhere with internet connection. No risks foreseen. Secure platform for data privacy. Customizable to caregivers needs (no need to follow a theme and/or program strict structure).
Technology Type of information/parameter that are relevant in monitoring the health status; type and frequency of accessibility of information; feedback modalities (communication)	The mobile VP app is delivered as PWA app. A progressive web application (PWA) is a type of application software delivered through the web, built using common web technologies including HTML, CSS and JavaScript. It is intended to work on any platform that uses a standards-compliant browser. Functionality includes working offline, push notifications, and device hardware access, enabling creating user experiences similar to native applications on desktop and mobile devices. Since a progressive web app is a type of webpage or website known as a web application, there is no requirement for developers or users to install web apps via digital distribution systems like Apple App Store or Google Play. The system supports two-way interaction: User activities and tracking are sent to the main database. After some process using machine learning algorithms and statistics, the user get feedback regarding its process, learning outcomes and more. The interface is expected to be as natural as possible and gesture and/or touch screens should support this interaction.

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	The mobile VP app is able to track the following user data: (1) Detailed log of detection and tracking of pathway; (2) Time spent in each node of the VPS/MVP; (3) Milestone tracking; (4) Rate of successful completion of VPS/MVP; (5) and Connection with learning outcomes.

5.5.1.2 FICS

Code	UC-PT5-004
Applicable SHAPES Persona	SHAPES Persona “Daphne”
Applicable SHAPES use case	Virtual Patient Scenarios (VPS) - Mobile Virtual Patients (MVP)
Function and events The functionality of the intended system which is capable of realizing actor’s activities	The mobile VP app is able to track the following user data: (1) Detailed log of detection and tracking of pathway. (2) Time spent in each node of the VPS/MVP. (3) Milestone tracking. (4) Rate of successful completion of VPS/MVP. (5) and Connection with learning outcomes.
Interactions and usability issues	Users access the Virtual Patient App (https://shapes-26bd2.web.app/) where a list of healthcare-related virtual patient scenarios is available. Users select to interact with different scenarios. The scenarios are divided into four (4) categories: 1) Diagnosis and Treatment Scenarios, 2) Symptom Management Scenarios, 3) Educational Scenarios, and 4) Empowerment Scenarios. During interaction with the scenarios: In particular, users are confronted with interactive computer simulations of real-life scenarios for the purpose of health care and medical training, education or assessment. They have the opportunity to interact with diverse virtual cases through scenarios therefore familiarize themselves with a range of neurodegenerative diseases (including Alzheimer’s, Parkinson’s, dementia, stroke) and other chronic diseases (diabetes, heart disease, etc.).

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	They are engaged in an enquiry-based approach to learning and thus, a variety of features are available to them, including, multiple nodes and links, media files, info buttons, counters and skins, all these provided through a user-friendly interface and a visual editor.
Content and structure Variables of the interaction	This information is detailed in-depth in section 5.3 of this deliverable.
Style and aesthetics Look and feel of the system	This information is detailed in-depth in section 5.3 of this deliverable.

5.5.2 Key performance indicators

Key Performance Indicators (KPIs) are defined as a set of measures that focus on the factors most critical to a project's success. KPIs are measurable and quantifiable with a target or threshold. They measure performance in critical areas by showing the progress or lack of it towards realizing the objectives of each specific use case. The following KPIs have been chosen to determine whether, or not, the pilot for this use case has been successful. Failure to meet four or more of the KPIs will indicate that repetition or major revisions to the use case and associated digital solutions are needed before entering further development oriented to further validation of technology benefits and commercialization.

- **Recruitment and retention**
  - At least 80% of recruited participants remains enrolled in the pilot until the end of the study.
  - At least 2 pilot sites from SHAPES consortium remain enrolled in the pilot until the end of the study.
- **User usability and acceptance**
  - At least 75% of recruited participants scores above average rating (>68) in the System Usability Scale (SUS).
  - At least 75% of recruited participants answers "Agree" or "Strongly Agree" in the question "Does the technology improve the quality of your practice?"

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- **Technical performance**
  - There is no re-start of any of the technology for at least 90% of the time spent.
  - The technology is fully integrated on the SHAPES platform and marketplace, and accessible for users.
- **Benefits for users**
  - At least 50% of recruited participants has a better score in the harmonization questionnaires (WHOQOL-Bref, EQ-5D-5L, GSE, OSSS-3) after intervention.
  - At least 75% of recruited participants has reported a mean score of greater than 4 in the eVIP Evaluation Tool.

5.5.3 Timeline of pilot activities

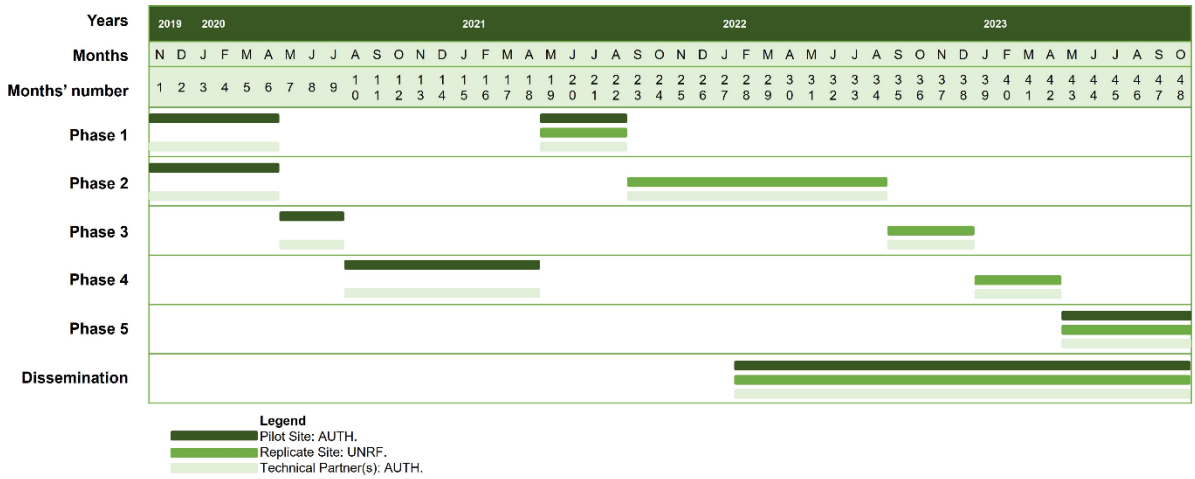

Figure 105: Use Case 4 - Timeline of pilot activities.

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5.6 Phase 2: Testing of mock-ups and prototypes

5.6.1 Methodology of testing

The aim of the mock-ups was to validate the digital solutions deployed in this Use Case and provide technical partners the opportunity to integrate user feedback at an early stage of the technological development process. In particular, the digital solutions for this use case underwent a co-design and user-testing process to optimise their usability and acceptability amongst end-users and receive feedback on the design and functionality of the digital solutions respectively.

The mock-ups were conducted virtually using the Zoom platform. Participants included two formal caregivers and two medical students, three moderators and two technical partners. Eligible individuals were provided with a consent form and a brief information section, where the background and purpose of the study were further explained along with what participants could expect to happen in case they agree to participate in the session.

A PowerPoint presentation was shown to participants, where they were introduced with brief background information about the SHAPES project and its scope along with an overview of the purpose of this use case. Mock-ups of the digital solution, in particular visual images of all the types of screens participants are likely to encounter when using the app, were then presented to them.

Technical partners were asking questions on the design and layout of the mock-ups during participants' interaction with the mock-up of the VPs and MVP. These questions were predefined and comprised a combination of open and closed questions designed to obtain both general and specific feedback about the mock ups.

5.6.2 Results of testing

The mock-ups session was held virtually and recorded, capturing participants' audio responses. After the conduction of the session participants were given an online form, where quantitative standardized measurements regarding technology usability and acceptance along with open-ended questions focusing on the digital solution functionalities, were included. Findings and related feedback, including any recommendations by participants, were presented, and sent out to technical partners, to proceed with further amendments of the digital solution.

Existing VP systems, such as Open Labyrinth are web-based and, thus, can be run using a mobile browser. But as these applications are not optimized for mobile viewing, the user experience (UX) suffers in small screens. Hidden areas of the screen are

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clearly spotted, inconsistent buttons sizes etc. Considering that nowadays more than 50% of the users, navigate the web through a mobile device, one of the main actions was to develop a standalone mobile player for accessing VP content, to enhance the usability and the user experience.

More information is detailed in-depth in the public report “D5.4 SHAPES Digital Solutions V3” (SHAPES-WP5, 2022, pp. 545-554), and in section 5.3 of this deliverable.

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5.7 Phase 3: Hand-on Experiments

5.7.1 Methodology of hands-on experiments

The hands-on experiments of the Use Case ‘‘Virtual Patient Scenarios (VPS) and Mobile Virtual Patients (MVP)’’ has been successfully conducted under the collaboration of the Aristotle University of Thessaloniki (AUTH) research team and partners from the University of Nicosia Research Foundation (UNRF). In this phase, these experiments aimed to engage healthcare professionals in the actual process of developing virtual patient scenarios.

The participants were two medical students, two SHAPES project partners from the UNRF, three healthcare professionals working in the "Archangelos Michael" Nursing Home (AMEN) and three facilitators from the AUTH team. The informed consent was obtained from all participants.

During an online session, the participants were initially introduced to the SHAPES project aim and objectives, followed by a comprehensive presentation of the Virtual Patients Scenarios’ & Mobile Virtual Patients’ platforms. Then, AUTH research team presented a short demo-scenario to help participants become familiar with the application. The demo consisted of basic instructions on how to navigate through the application’s environment and how to choose the preferred option from the available ones, to progress the scenario.

Finally, the participants completed questionnaires addressing the beneficial effects of VPs on future self-management activities to evaluate the application and both scenarios. Participants also was the chance to provide personal comments to improve the implementation of the application based on their own needs and preferences. A usability evaluation was also developed through the System Usability Scale (SUS) with open-ended questions (likes/dislikes about the app and recommended changes), and a 5-point Likert scale as follows: 1 = Completely disagree to 5 = Completely agree.

5.7.2 Results of the hands-on experiments

The hands-on experiments were performed to collect the participants feedback about the functionalities and usability of the digital solution. The participants had the chance to provide feedback and amendments that improve the digital solution. Adopting the participatory design and the concurrent ‘think out loud’ approach, the researchers encouraged the participants to verbalise reactions, thoughts, feelings, and opinions about the prototype.

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Additionally, the participants had the opportunity to navigate through the two different platforms and interact with available virtual patient scenarios. Afterwards, the main topics for the development of scenarios were highlighted by participants through an interactive poll. Participants were then allocated in break-out rooms, to engage in a brainstorming session. During this session, participants were divided into two groups and proceeded with the preparation and development of two scenarios' scripts through fruitful discussions and active brainstorming.

This experiment was relevant to the participants interact with virtual scenarios in real life, develop their own with essential content, and provide inputs to the demo version of the prototype. Through sequential steps, participants (healthcare professionals and medical students) have experimented the technology to recreate the real scenarios of caring older adults with neurodegenerative diseases. The researchers aimed to collect useful data to develop a final prototype that reflect the real-life contexts.

Overall, participants have improved the ability to develop skills of self-management, but they also reported problems regarding the implementation in their care practice and addressed questions about the properly navigation throughout the technology environment. They also have listed the beneficial effects of VPs on future self-management activities, and personal comments to improve the implementation of the application based on their own experiments.

Other results can be consulted in section 5.9.4 of this deliverable.

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5.8 Phase 4: Small Scale Live Demonstration

5.8.1 Recruitment of participants

The recruitment process was developed by the partner leader AUTH, supported by a network composed by the Thessaloniki Active and Healthy Ageing Living Lab (Thess-AHALL), the Lab of Medical Physics and Digital Innovation of Aristotle University of Thessaloniki (AUTH), and the Integrated Health and Social Care System Long Lasting Memories Care (LLM Care) ecosystem: municipalities and public entities, hospitals, rehabilitation centres, and nursing homes.

The AUTH adopted recruitment strategies to identify and select the participants considering the eligible criteria predefined (Table 31). In phase 4, the AUTH research team approached a group of eligible participants to explain the study, the recruitment criteria, and to collect the consent form. This period was relevant to answer the participants' misunderstandings. In this phase, there were three participants.

Table 31. Use Case 4 - Recruitment Criteria.

Participants	Criteria	
	Inclusion	Exclusion
Professionals	• Healthcare professionals. • Formal caregivers. • Working in hospitals, day-care centres, nursing homes. • Professional experience with older population (65 years or over). • Time commitment to the training protocol. • Good hearing and sight. • Sign the consent form.	• Diagnosis of severe neurological or psychiatric disorders. • Drug abuse. • Concurrent participation in another study.
Students	• Undergraduate medical students (>4th year). • Time commitment to the training protocol. • Good hearing and sight. • Sign the consent form.	

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5.8.2 Technical aspects & Logistics

During this phase, the partners AUTH and UNRF worked to implement the digital solution in real-life in both pilot sites. Thereby, AUTH was the main partner to the technical issues, who provided technical and educational support to UNRF, monitored, and answered the participants' demands, and developed and decided about the technical equipment or installation. Moreover, AUTH team prepared the study documentation, namely the research protocol and training manuals to be shared with the replicating site.

5.8.3 Roles and Responsibilities

During this phase, AUTH, as pilot leader and technical partner, helped UNRF partners to familiarize and test the SHAPES Mobile Virtual Patients App, and clarified doubts and technical issues. In this phase, there weren't specific technical arrangements and special hardware equipment, or software installation was essential to set and run the pilot activities.

This phase took place during February and March 2023 only in AUTH, in which all digital solutions were demonstrated and tested by healthcare professionals and medical students. These participants attended at two different sessions to interact with the digital solutions. The participants interacted autonomously with virtual scenarios divided in four categories:

- Diagnosis & Treatment Scenarios, which consisted of 55 scenarios. These scenarios aimed to simulate various medical conditions and their corresponding treatment plans. The healthcare professionals could interact with these scenarios to gain insights into the app's diagnostic capabilities and treatment recommendations.
- Educational Scenarios, comprising seven scenarios. These scenarios focused on providing educational content to healthcare professionals. They could explore these scenarios to learn about new medical techniques, procedures, or guidelines.
- Symptoms Management, which included three scenarios. These scenarios were designed to simulate patients' symptoms and enable the healthcare professionals to practice managing and treating them effectively.
- Empowerment category consisted of four scenarios. These scenarios aimed to empower patients and enhance their self-management skills. The healthcare professionals could engage with these scenarios to explore features and tools

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within the app that encourage patient empowerment and active participation in their healthcare.

This intervention aimed to aimed evaluate the implementation of the SHAPES Mobile Patients App (Virtual Patients and Mobile Virtual Patients) in real-life to support formal caregivers and medical students to develop skills in their workplace (related to caring of older people with neurodegenerative diseases like Alzheimer, Parkinson, and Mild Cognitive Impairment). The Table 32 details the objectives defined by the researchers for this phase (small demonstration).

Table 32. Use Case 4 - Objectives of the Intervention.

Primary objectives	Secondary objectives	Tertiary objectives
• To assess potential improvement in formal caregivers' and medical students' skills related to older adults' symptoms, diagnosis, and treatment as well as in decision making, reasoning and self-assessment skills (PO1). • To validate the capability of the proposed Digital Solutions to improve formal caregivers' and medical students' quality of life (PO2). • To measure Scenario-based learning (SBL) experience among formal caregivers and medical students (PO3).	• To explore usability and technology acceptance of the proposed Digital Solutions (SO1). • To collect demographics data from participants (SO2).	• To validate the capability of the SHAPES Platform and Digital Solutions to support and extend healthy and independent living for older individuals who are facing permanently or temporarily reduced functionality and capabilities (TO1). • To validate the capability of the SHAPES Platform and Digital Solutions to improve the older individuals' health outcomes and quality of life (TO2). • To validate the capability of the SHAPES Platform and Digital Solutions to gain the older individuals' trust and acceptance (TO3). • To validate the capability of the SHAPES Platform and Digital Solutions to gain the care professionals' trust and acceptance (TO4).

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5.8.4 Ethical considerations

Data Protection Impact Assessment (DPIA), Data Processing Agreement (DPA) and Data Sharing Agreement (DSA) have been developed by the AUTH team, approved by the AUTH DPO, and were submitted for approval along with the bioethics documents in the Ethics Committee of the Aristotle University of Thessaloniki.

A folder containing hard originals and copies of documents related to the use case, including consent forms and filled questionnaires, has been retained in a locked office pedestal located at the Lab of Medical Physics and Digital Innovation, School of Medicine, Aristotle University of Thessaloniki (University Campus, Thessaloniki, Greece). An electronic copy of the documents along with the participants list (linking the participants' name to their pseudonymized SHAPES ID) has been retained by approved AUTH staff working on the SHAPES study and stored securely on AUTH servers protected by the AUTH firewall. Only AUTH staff who are approved to work on the SHAPES project had access to identifiable pseudonymized documents. Appropriate agreements have been put in place to facilitate the processing of pseudonymized data by other SHAPES partners which are explicitly described in DPA and DSA documents.

Additionally, this use case follows the ethical requirements defined in SHAPES Deliverable "D8.4 - SHAPES Ethical Framework", as it's summarized in the Table 33.

Table 33 Use Case 4 - 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)	To be consulted in section 5.8.4 of this deliverable.
Biomedical Ethics and Ethics of Care (3.2)	To be consulted in section 5.8.4 of this deliverable.
CRPD and supported decision-making (3.3)	To be consulted in section 5.8.4 of this deliverable.
Capabilities approach (3.4)	To be consulted in sections 5.6 and 5.7 of this deliverable.
Sustainable Development and CSR (4.1)	This use case contributes to the SDG 3.
Customer logic approach (4.2)	To be consulted in section 5.3 of this deliverable.
Artificial intelligence (4.3)	To be consulted in sections 5.3 and 5.6 of this deliverable.

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Digital transformation (4.4)	To be consulted in sections 5.3 and 5.6 of this deliverable.
Privacy and data protection (5)	To be consulted in section 5.8.4 of this deliverable.
Cybersecurity and resilience (6)	To be consulted in section 5.8.4 of this deliverable.
Digital inclusion (7.1)	To be consulted in section 5.8.4 of this deliverable.
The moral division of labor (7.2)	This use case contributes to improve the skills of healthcare professionals and students, especially regarding dementia.
Caregivers and welfare technology (7.3)	This use case contributes to improve the skills of healthcare professionals and students, especially regarding dementia.
Movement of caregivers across Europe (7.4)	This use case contributes to improve the skills of healthcare professionals and students, especially regarding dementia.

5.8.5 Outcome of the Small-Scale Live Demonstration

The small-scale demonstration was conducted only at AUTH. This phase aimed to test the methods and digital solution, which were to be tested in the following large-scale pilot activities, as well as identify potential challenges and issues. During this phase, AUTH, as pilot leader and technical partner, helped UNRF partners to familiarize and test the SHAPES Mobile Virtual Patients App, and clarified doubts and technical issues. In this phase, there weren't specific technical arrangements and special hardware equipment, or software installation was essential to set and run the pilot activities.

This phase took place during February and March 2023 only in AUTH, in which all digital solutions were demonstrated and tested by healthcare professionals and medical students. These participants attended at two different sessions to interact with the digital solutions, namely, to autonomously navigate in the app and select to interact with scenarios. Then, the participants have assessed their experience using several measures and instruments, as listed in the Table 34.

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Table 34. Use Case 4 - Small demonstration evaluation details.

Outcome	Measurement	Instrument
Performance	Technical information about SHAPES Mobile Virtual Patients app performance during sessions.	Log files and remote monitoring of digital solution
Technical aspects	Analysis of the different functionalities of digital solution.	Focus group
Adverse events	Participants were asked about the occurrence of any adverse event or system errors.	Focus group
Acceptance	Scale Score.	Technology acceptance questions
Usability	Scale Score.	SUS
Affinity	Participants were asked about their affinity and use of technology.	Focus group
Perception	Participants' perceptions regarding the acceptability and adequacy of the intervention program, structure of the training program, resources used, experience on the digital solution used and aspects related to UC were discussed in the focus group.	Focus group

The small demonstration was developed in AUTH by four participants: two healthcare professionals and two medical students.

Overall, the participants' experience was highly positive. They expressed genuine enthusiasm and satisfaction with the scenarios they interacted with expressing that they appreciated the opportunity to explore and engage with novel digital solutions, which allowed them to enhance their decision making, reasoning and training skills in their workplace competency and provide sufficient day care and support to older people.

Participants also had the ability to provide personal comments to improve the implementation of the application based on their own needs and preferences. They found the SHAPES Mobile Virtual Patients App intuitive and user-friendly, enabling them to quickly grasp the functionalities and navigate through different features. They particularly enjoyed the interactive interfaces, which made the experience more engaging and enjoyable.

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Based on their feedback and observations, AUTH team identified some potential recommendations to further improve the user experience for healthcare professionals and medical students.

Basically, participants commented on integrate multimedia content: include relevant multimedia content such as videos, images, or audio clips to enhance the learning experience and incorporate interactive assessments: integrate interactive quizzes, assessments, or decision-making exercises within the application. This allows users to actively engage with virtual patients and test their knowledge and skills.

The AUTH team shared these recommendations with technical partners and discussed proceeding with minor adaptations that could be adopted to respond to participants' feedback.

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5.9 Phase 5: Large-scale pilot activity

5.9.1 Recruitment of participants

The recruitment process was developed by the partner leader AUTH, supported by a network composed by the Thessaloniki Active and Healthy Ageing Living Lab (Thess-AHALL), the Lab of Medical Physics and Digital Innovation of Aristotle University of Thessaloniki (AUTH), and the Integrated Health and Social Care System Long Lasting Memories Care (LLM Care) ecosystem: municipalities and public entities, hospitals, rehabilitation centres, and nursing homes.

As the phase 4, the AUTH adopted recruitment strategies to identify and select the participants considering the eligible criteria (Table 31). Two groups of participants were recruited: the healthcare professionals or/and formal caregivers; and the medical students. The researchers provided information sheets participants, and organized meetings to clarify all participants' questions and misunderstandings. In the Table 35, there is a resume about participants in the phase 5, including the sample size, by pilot site (SUTH / UNRF).

Table 35. Use Case 4 - Sociodemographic description of the participants.

	AUTH (*N*=7)	UNRF(*N*=9)
Age	*M*= 29.9 ±10.9	*M*= 22.1 ± 2.4
Gender	85.7% Females. 14.3% Males.	66.7% Females. 33.3% Males.
Profession	100% Formal caregivers.	100% Medical students.
Level of education	42.9% Bachelor's degree. 28.6% Master's degree. 14.2% Ph.D. or higher. 14.2% Other – Psychology student.	66.7% Lower secondary school certificate. 33.3% Bachelor's degree.
Level of Digital Literacy	42.8% Basic Users. 14.3% Intermediate Users. 42.8% Advanced user.	22.% Basic Users. 33.3% Intermediate Users. 44.5% Advanced user.

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5.9.2 Roles and Responsibilities

In this phase, UNRF replicated the pilot activities implemented by main pilot site, AUTH, in phase 4. Also, during this phase, AUTH provided technical and educational support to UNRF, monitored, and answered the participants' demands, and developed and decided about the technical equipment or installation.

5.9.3 Ethical Considerations and Risk management

In this phase, UNRF replicated the ethical activities implemented by main pilot site, AUTH, in phase 4.

5.9.4 Outcome of large-scale pilot activity

The large-scale demonstration was implemented by AUTH and UNRF, replicating the phase 4. In this phase, the pilot sites implemented another assessment protocol. Thereby, they met several times to discuss protocol and recruitment, and the risks and mitigation measures.

5.9.4.1 Preliminary results

The final results of this use case must be presented in detail at the end of the project (October 2023), namely in the SHAPES Deliverables "D6.9 Comprehensive Assessment of the SHAPES Pan-European Pilot Campaign" and "D6.10 Analysis of the User Acceptance, Inclusion and Societal Impact of the SHAPES Platform". At this moment (June 2023), the researchers already have collected the preliminary and descriptive data that are evidenced below.

- **Outcome 1. Recruitment**

  Sociodemographic questionnaire: Age; Marital status; Gender; Education; Digital literacy. The results are detailed in section 5.9.1 of this deliverable.

- **Outcome 2. MAST Assessment**

  Two dimensions of MAST framework, namely Clinical effectiveness, and Patient perspectives, as detailed in Table 35.

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Table 36 Use Case 4 - Preliminary outcomes – psychosocial variables.

AUTH		
Psychosocial assessments	**Pre-intervention** (N=7)	**Post-intervention** (N=7)
WHOQOL- Bref	M= 77.5 ±7.8	M= 70.7 ±11.7
Health related quality of life - EQ - 5D – 5L	MOBILITY 100% - I have no problems in walking about. SELFCARE 100% I have no problems washing or dressing myself. USUAL ACTIVITIES 85.7% I have no problems doing my usual activities. 14.3% I have moderate problems doing my usual activities. PAIN/DISCOMFORT 71.4% I have no pain or discomfort. 28.6% I have moderate pain or discomfort. ANXIETY/DEPRESSION 42.8% I am not anxious or depressed. 28.6% I am slightly anxious or depressed. 28.6% I am moderately anxious or depressed.	MOBILITY 100% I have no problems in walking about. SELFCARE 100% I have no problems washing or dressing myself. USUAL ACTIVITIES 71.4% I have no problems doing my usual activities. 28.6% I have slight problems doing my usual activities. PAIN/DISCOMFORT 85.7% I have no pain or discomfort. 14.3% I have moderate pain or discomfort. ANXIETY/DEPRESSION 28.6% I am not anxious or depressed. 28.8% I am slightly anxious or depressed. 42.6% I am moderately anxious or depressed.

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Health related quality of life (EQ - VAS)	M=87.6 ±8.6	M=90 ±7.3
General Self-efficacy GSE	M=25 ±9.9	M=31.6 ±4
Social Function OSSS-3	M= 9.6 ±0.9	M= 9.3 ±1.4
UCLA-6 Loneliness Scale	M= 12.6 ±3.9	M= 12.7 ±4.1
1-item Health Literacy	57.2% Extremely Confident. 42.8% Quite a bit.	42.6% Extremely Confident. 28.6% Quite a bit. 28.8% Somewhat.
Did you experience any of these life events [In the last 6 months/ since the last time we spoke]?	57.1% Yes. 42.9% No.	57.1% Yes. 42.9% No.
Did you get emotional support from anybody in relation to the event?	50% Yes, a lot of support. 50% Yes, some support.	25% Yes, a lot of support. 75% Yes, some support.
From whom did you get emotional support?	50% Brother/sister. 50% Parents.	50% Brother/sister. 50% Parents.
I participate enough in activities that are important to me	42.8% Strongly Agree. 28.6% Agree. 28.6% Disagree.	42.8% Strongly Agree. 28.6% Agree. 28.6% Disagree.
Using Virtual Patients makes participating in the activities that are important to me:	28.6% Much easier. 57.1% A little easier. 14.2% About the same.	42.6% Much easier. 42.6% A little easier. 14.8% About the same.
UNRF		
Psychosocial assessments	**Pre-intervention** (N=9)	**Post-intervention** (N=7)
WHOQOL- Bref	M= 75.7 ±6.3	M= 83.7 ±9.4
Health related quality of life - EQ - 5D – 5L	MOBILITY	MOBILITY

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	100% I have no problems in walking about. SELFCARE 100% - I have no problems washing or dressing myself. USUAL ACTIVITIES 100% - I have no problems doing my usual activities. PAIN/DISCOMFORT 88.9% I have no pain or discomfort. 11.1% I have slight pain or discomfort. ANXIETY/DEPRESSION 33.3% I am not anxious or depressed. 22.2% I am slightly anxious or depressed. 44.5% I am moderately anxious or depressed.	100% I have no problems in walking about. SELFCARE 100% I have no problems washing or dressing myself. USUAL ACTIVITIES 100% I have no problems doing my usual activities. PAIN/DISCOMFORT 71.4% I have no pain or discomfort. 28.6% I have slight pain or discomfort. ANXIETY/DEPRESSION 28.6% I am not anxious or depressed. 14.2% I am slightly anxious or depressed. 28.6% I am moderately anxious or depressed. 28.6% I am extremely anxious or depressed.
Health related quality of life (EQ - VAS)	M=92.5 ±4.7	M=88.6±7.5
General Self-efficacy GSE	M=32.5 ±3.6	M=33.6 ±4.6
Social Function OSSS-3	M= 9.5 ±2	M= 9.3 ±2.6
UCLA-6 Loneliness Scale	M= 12.1 ±3.3	M= 11.6 ±4.8
1-item Health Literacy	33.3% Extremely Confident.	57.1% Extremely Confident.

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	55.5% Quite a bit. 11.2% A little bit.	42.9% Quite a bit.
Did you experience any of these life events [In the last 6 months/ since the last time we spoke]?	66.7% Yes. 33.3% No.	71.4% Yes. 28.6% No.
Did you get emotional support from anybody in relation to the event?	83.3% Yes, a lot of support. 16.7% Yes, some support.	80% Yes, a lot of support. 20% Yes, some support.
From whom did you get emotional support?	50% Friends. 33.3% Brother/sister. 16.6% Parents.	60% Friends. 20% Brother/sister. 20% Parents.
I participate enough in activities that are important to me	66.6% Strongly Agree 33.4% Agree	57.1% Strongly Agree 42.9% Agree
Using Virtual Patients makes participating in the activities that are important to me:	44.4% Much easier. 33.3% A little easier. 22.2% About the same.	57.1% Much easier. 28.6% A little easier. 14.3% About the same.

Table 37 Use Case 4 - Preliminary outcomes – learning and clinical reasoning experiences with virtual patients.

AUTH	
Axis of learning and clinical reasoning experiences	**Post-intervention** (N=7)
Authenticity of patient encounter and the consultation	
While working on this case, I felt I had to make the same decisions a doctor would make in real life	M= 3.86±0.90
While working on this case, I felt I were the doctor caring for this patient	M= 4.14±0.69
Professional approach in the consultation	

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While working through this case, I was actively engaged in gathering the information (e.g., history questions, physical exams, lab tests) I needed, to characterize the patient's problem	M= 4.29±0.76
While working through this case, I was actively engaged in creating a short summary of the patient's problem using medical terms.	M= 4±0.58
While working through this case, I was actively engaged in thinking about which findings supported or refuted each diagnosis in my differential diagnosis.	M= 4±0.58
Coaching during consultation	
I felt that the case was at the appropriate level of difficulty for my level of training.	M= 2.86±0.9
The questions I was asked while working through this case were helpful in enhancing my diagnostic reasoning in this case	M= 3.57±0.79
Learning effect of consultation	
After completing this case, I feel better prepared to confirm a diagnosis and exclude differential diagnoses in a real life patient with this complaint.	M= 3.71±0.95
After completing this case I feel better prepared to care for a real life patient with this complaint.	M= 3.86±0.9
Overall judgment of case workup	
Overall, working through this case was a worthwhile learning experience	M= 4.14±0.69
UNRF	
Axis of learning and clinical reasoning experiences	**Post-intervention** (N=7)
Authenticity of patient encounter and the consultation	
While working on this case, I felt I had to make the same decisions a doctor would make in real life	M= 4.29±0.49
While working on this case, I felt I were the doctor caring for this patient	M= 4.14±0.69

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Professional approach in the consultation	
While working through this case, I was actively engaged in gathering the information (e.g., history questions, physical exams, lab tests) I needed, to characterize the patient's problem	M= 4.57±0.53
While working through this case, I was actively engaged in creating a short summary of the patient's problem using medical terms.	M= 4.14±0.69
While working through this case, I was actively engaged in thinking about which findings supported or refuted each diagnosis in my differential diagnosis.	M= 4.57±0.53
Coaching during consultation	
I felt that the case was at the appropriate level of difficulty for my level of training.	M= 4±0.82
The questions I was asked while working through this case were helpful in enhancing my diagnostic reasoning in this case	M= 4.57±0.53
Learning effect of consultation	
After completing this case, I feel better prepared to confirm a diagnosis and exclude differential diagnoses in a real-life patient with this complaint.	M= 4.14±0.69
After completing this case I feel better prepared to care for a real-life patient with this complaint.	M= 4.29±0.76
Overall judgment of case workup	
Overall, working through this case was a worthwhile learning experience	M= 4.29±1.11

- **Outcome 3. Participants' perspectives**

  A summary of healthcare professionals' experiences and the overall feedback gained at the end of the pilot activities, resulting from the final interviews (group interviews) conducted in AUTH is presented. A focus group was conducted in AUTH, where participants had the opportunity to discuss and share their thoughts and perceptions with other participants and the AUTH research team.

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Experiences and information discussed among participants are categorized in seven discrete categories: (1) technology adoption and barriers, (2) user experience and ease of use, (3) communication and social connections, (4) health and well-being, (5) willingness to pay the DS, (6) Digital solution provision, (7) and recommendations for improvement.

Table 38 Use Case 4 - Preliminary outcomes – participants' perspectives.

AUTH
Technology Adoption and Barriers Participants commented that the VPs can offer a safe environment to practice and develop clinical skills, leading to improved competence and confidence. Through interaction with the VPs healthcare professionals felt that they could learn to identify and differentiate various conditions, leading to more accurate diagnoses in real patient encounters. Plenty of details were given about each incident and emphasis was given on the part of differential diagnosis, enhancing their level of preparedness regarding the future treatment of similar incidents. With regard to barriers, one participant commented that introducing virtual patients as a new technology may encounter initial resistance from some healthcare professionals who are accustomed to traditional learning and patient interaction methods. Overcoming this barrier requires effective change management strategies, education, and clear communication about the benefits of virtual patients.
User Experience and Ease of Use Participants considered VPs an immersive experience that can enhance their learning and enable them to develop critical clinical skills. VPs can offer a wide range of scenarios, covering different medical conditions and situations. Especially, the immediate feedback to healthcare professionals based on their interactions and decisions was ranked highly. They also felt that they could move between different scenarios or sections effortlessly. In general, positive aspects of user experience and ease of use of VPs were stated.
Communication and Social Connections Interacting with virtual patients can provide healthcare professionals with opportunities to practice and improve their communication skills as well as offer a safe environment for healthcare professionals to practice and develop skills in delivering difficult news, discussing sensitive topics, or managing challenging patient interactions.
Health and Well-being VPs interactions provide healthcare professionals with an opportunity to make mistakes, learn from them, and refine their approach without any potential harm to real patients. This can contribute to better quality of care and minimize risks associated with learning on actual patients. In addition, regular engagement with virtual patients can boost healthcare

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professionals' confidence and competence in managing various medical conditions and scenarios. This increased proficiency can positively impact their overall well-being, job satisfaction, and ultimately improve patient care outcomes.

Willingness to pay the DS

Participants consistently expressed their Willingness with the program's affordability, citing no challenges or concerns related to payment. In fact, they advocated for entities and organizations' funding to ensure widespread accessibility to all healthcare professionals who possess an interest in the program, thereby safeguarding its long-term sustainability.

Recommendations for Improvement

The team involved in the program received high praise from participants. Participants' feedback consistently emphasized the importance of developing and including a variety in non-pathological scenarios as well. In addition, they commented that terminologies used, may not be widely understood. Finally, one participant stated that during interaction with the scenarios they had the option to seek information and help to answer correctly.

UNRF

Technology Adoption and Barriers

VPs offer an immersive and interactive learning environment where medical students can apply their knowledge in simulated clinical situations. This hands-on experience can enhance their clinical reasoning skills, decision-making abilities, and overall understanding of patient care. These applications can be accessed anytime and anywhere, allowing medical students to learn at their own pace. They can practice and review scenarios repeatedly, reinforcing their understanding and improving their skills. The flexibility and accessibility of VPs make them convenient for students with different learning styles and schedules. VPs can be designed to be engaging and interactive, capturing the attention and interest of medical students. The gamified elements, such as rewards, progress tracking, and competition, can motivate students to actively.

Regarding the barriers adequate technological infrastructure, such as reliable internet access and compatible devices, is essential for utilizing VPs effectively. Medical educators need to be trained in using VPs and incorporating them into the curriculum effectively. Lack of training and support for faculty can be a barrier to adoption as they may struggle to integrate the technology into their teaching methods. Incorporating VPs into the existing medical curriculum requires careful planning and coordination. Integration challenges may arise if there is resistance from faculty or a lack of alignment with existing learning objectives and assessment methods. Some students and faculty may have reservations about the effectiveness of virtual patient scenarios compared to traditional methods. Resistance to change or scepticism about the technology's ability to replicate real patient encounters can impede adoption. VPs may require financial investment in terms of software licenses, hardware, and ongoing maintenance. Limited financial resources can be a barrier, especially for institutions with tight budgets. Privacy and confidentiality of patient information must be upheld when using VPs.

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User Experience and Ease of Use

VPs should have a user-friendly interface that is intuitive and easy to navigate. Clear instructions, well-organized menus, and logical workflows contribute to a positive user experience. The app should provide realistic patient scenarios that accurately reflect clinical situations. High-quality graphics, multimedia elements, and interactive features can enhance the immersion and engagement of medical students, making the experience more authentic and effective. This includes features like realistic dialogue, the ability to ask questions, perform physical examinations, order tests, and make treatment decisions. Responsive and natural interactions contribute to a more immersive and engaging experience. The app should provide timely and constructive feedback to students based on their actions and decisions during the virtual patient encounter. This feedback helps students understand their strengths and areas for improvement, facilitating their learning process. Many medical students rely on mobile devices for learning. Ensuring that the VPs are compatible with various mobile platforms (iOS, Android) and screen sizes can enhance accessibility and ease of use. The app should be stable, fast, and responsive. Long loading times, glitches, or crashes can frustrate users and hinder their learning experience. Regular updates and bug fixes contribute to a smoother user experience. Offering customization options within the app can allow students to tailor their learning experience to their individual needs. The ability to adjust difficulty levels, select specific cases, or revisit previous encounters can enhance the app's usability. Integrating the VPs with existing learning management systems used in medical schools can streamline access for students and facilitate the integration of virtual patient encounters into the curriculum. Access to technical support and responsive customer service is essential to address any issues or difficulties that students may encounter while using the app. Prompt assistance contributes to a smoother user experience and helps students stay engaged. Collecting user feedback and regularly updating the app based on user suggestions and needs can enhance the overall user experience. Engaging students in the development process and incorporating their input fosters a sense of ownership and ensures the app meets their requirements.

Communication and Social Connections

VPs can facilitate interprofessional collaboration by enabling students from different healthcare disciplines to work together in simulated clinical encounters. This promotes teamwork, communication, and a better understanding of each other's roles and perspectives. These apps can facilitate communication and collaboration among medical students who may be geographically dispersed. Students can engage in virtual patient cases together, discuss diagnostic and treatment strategies, and learn from each other's experiences, regardless of their physical location. VPs can foster peer-to-peer learning and support. Students can engage in discussions, share insights, and provide feedback to their peers based on their virtual patient encounters. This promotes a collaborative and supportive learning environment. In addition to peer feedback, VPs can enable faculty or mentors to provide feedback and guidance to students. Through the app, mentors can review students' interactions with virtual patients, offer personalized feedback, and provide mentoring remotely. VPs can help medical students develop and refine their communication skills. Students can practice taking patient histories, conducting interviews, and delivering explanations or treatment plans. They can receive feedback on their communication techniques, such as active listening, empathy, and

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clarity of information. VPs can encourage reflective practice among medical students. After each virtual patient encounter, students can review their performance, identify areas for improvement, and engage in self-reflection. This self-assessment and reflection can enhance their learning and professional development. VPs can provide platforms for students to connect with a broader community of learners. Online forums or communities associated with the app can facilitate discussions, knowledge sharing, and support among medical students interested in virtual patient scenarios. Through VPs, medical students can connect with healthcare professionals, researchers, and experts who may be involved in the development or use of the app. This can create networking opportunities, opening doors to potential collaborations or mentorship. These apps can emphasize patient-centered communication skills by focusing on aspects such as empathy, cultural competence, and shared decision-making. Students can learn to navigate challenging conversations and develop skills to effectively communicate with patients from diverse backgrounds. VPs that span across multiple years of medical education can enable students to build longitudinal connections. They can revisit cases, track progress, and witness the development of their clinical skills over time. This continuity can enhance the sense of community and social connections within the app.

Health and Well-being

VPs can facilitate interprofessional collaboration by enabling students from different healthcare disciplines to work together in simulated clinical encounters. This promotes teamwork, communication, and a better understanding of each other's roles and perspectives. These apps can facilitate communication and collaboration among medical students who may be geographically dispersed. Students can engage in virtual patient cases together, discuss diagnostic and treatment strategies, and learn from each other's experiences, regardless of their physical location. VPs can foster peer-to-peer learning and support. Students can engage in discussions, share insights, and provide feedback to their peers based on their virtual patient encounters. This promotes a collaborative and supportive learning environment. In addition to peer feedback, VPs can enable faculty or mentors to provide feedback and guidance to students. Through the app, mentors can review students' interactions with virtual patients, offer personalized feedback, and provide mentoring remotely. These apps can help medical students develop and refine their communication skills. Students can practice taking patient histories, conducting interviews, and delivering explanations or treatment plans. They can receive feedback on their communication techniques, such as active listening, empathy, and clarity of information. VPs can encourage reflective practice among medical students. After each virtual patient encounter, students can review their performance, identify areas for improvement, and engage in self-reflection. This self-assessment and reflection can enhance their learning and professional development. VPs can provide platforms for students to connect with a broader community of learners. Online forums or communities associated with the app can facilitate discussions, knowledge sharing, and support among medical students interested in virtual patient scenarios. Through VPs, medical students can connect with healthcare professionals, researchers, and experts who may be involved in the development or use of the app. This can create networking opportunities, opening doors to potential collaborations or mentorship. These apps can emphasize patient-centered communication skills by focusing on aspects such as empathy, cultural competence, and shared decision-making. Students can learn to navigate challenging conversations and develop skills to

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effectively communicate with patients from diverse backgrounds. VPs that span across multiple years of medical education can enable students to build longitudinal connections. They can revisit cases, track progress, and witness the development of their clinical skills over time. This continuity can enhance the sense of community and social connections within the app.

Willingness to pay the digital solution

It's important to note that while VPs can offer opportunities for communication and social connections, they should not replace real patient interactions and face-to-face communication experiences during clinical rotations and practical experiences. These apps should be seen as complementary tools to augment medical education and promote skills development in a simulated environment.

Recommendations for Improvement

Enhance the realism of virtual patient scenarios by incorporating diverse and realistic cases that cover a wide range of medical conditions and patient demographics. Provide customization options within the app to allow students to adjust the difficulty level or specific aspects of the scenarios to align with their learning needs and progress. This flexibility can accommodate students at different stages of their medical education. Develop sophisticated feedback mechanisms within the app that provide detailed and constructive feedback to students based on their performance. Feedback should focus on clinical decision-making, communication skills, and areas for improvement, enabling students to reflect on their actions and enhance their learning. Integrate AI technologies into the app to simulate more dynamic and responsive patient interactions. AI can enhance the realism of virtual patients' responses, adapt scenarios based on student actions, and provide personalized feedback tailored to individual student needs. Foster collaboration and social interaction among students by incorporating features such as discussion forums, chat functionalities, or virtual team-based activities within the app. This encourages peer-to-peer learning, knowledge sharing, and teamwork. Seamlessly integrate the VPs with existing learning management systems used by medical schools. This integration simplifies access for students, enables tracking of progress and performance, and facilitates integration into the broader curriculum. Integrate real-time communication tools (e.g., video conferencing or instant messaging) into the app to allow students to communicate with peers, mentors, or faculty members during virtual patient encounters. Incorporate gamification elements and interactive features into the app to increase engagement and motivation. Elements such as rewards, challenges, simulations, and interactive decision-making can make the learning experience more enjoyable and immersive. Regularly update the app with new cases, features, and improvements based on user feedback and evolving medical knowledge. Engage with medical students and faculty to gather input on their needs and preferences, ensuring the app remains relevant and effective. Incorporate assessment tools within the app to allow for formative and summative evaluation of students' performance. Integration with existing assessment methods or the ability to generate performance reports can facilitate evaluation and tracking of student progress.

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- **Outcome 4. Usability**

  System Usability Assessment, Technology Acceptance Model and Learning Experience (AUTH / UNRF)

Table 39 Use Case 4 - Preliminary outcomes – usability and acceptance.

AUTH	
Data collected in AUTH regarding usability indicate that SUS was M=86.2 ±11.1 and TAM scores M=13.9 ±1.6, highlighting a very high level of technology acceptance and self-reported system usability. Lastly, the results from the eViP evaluation tool kit for use with VPs. In all 14 questions the majority of healthcare professionals agreed that the VPs improved their learning experiences focusing on the development of their clinical reasoning skills.	
Assessments	**Post-intervention**
System Usability Scale (SUS)	*M*= 86.2 ±11.1
Technology Acceptance Model (TAM)	*M*= 13.9 ±1.6
eViP evaluation tool - clinical reasoning	*M*= 38.4 ±6.7
UNRF	
Data collected in UNRF regarding usability indicate that SUS was M= 77.5 ±6.6 and TAM scores M=13 ±2, highlighting a very high level of technology acceptance and self-reported system usability. Lastly, the results from the eViP evaluation tool kit for use with VPs. In all 14 questions the majority of medical students agreed that the VPs improved their learning experiences focusing on the development of their clinical reasoning skills.	
Assessments	**Post-intervention**
System Usability Scale (SUS)	*M= 77.5 ±6.6*
Technology Acceptance Model (TAM)	*M= 13 ±2*
eViP evaluation tool - clinical reasoning	*M= 43 ±5.2*

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- **Outcome 5. Cost-benefit**

  Interview to assess the cost-benefit integrated in SHAPES Task 7.2. (UNRF)

Table 40 Use Case 4 - Preliminary outcomes – cost-benefit assessment.

UNRF	
Questions	**Answers**
Perceived usefulness *How have you perceived the usefulness of the digital solutions?*	This was similar to the projects we had for our course. It was engaging and caused you to think. It was interesting and useful. In some scenarios, we did not have all the information to answer. It was useful. It was good that when I made mistakes it took me back. If I chose the wrong answer, it took me back.
How did it support you? What did it support you with? How did it help enhance your knowledge?	It depended on the scenarios. For the scenarios we had information, yes, our knowledge was enhanced. Some scenarios were more useful than others. It was very good revision material. It supported my learning. Based on my existing knowledge, I learned more from a clinical perspective. The fact that it was in Greek was a limitation because we are familiar with the terminology in English. Because of the Greek, we had to translate.
Strength and weaknesses *What did you like about the SHAPES digital solutions?*	Picked up something I did not know. It gets you to think clinically.

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	If wrong, it takes you back. Gave new information. I got more on the topics I knew already about. It makes you think like a clinician. It enhances knowledge.
What did you like least about the SHAPES digital solutions?	Some scenarios would not open up. For example, some pictures and links could not open. Some scenarios had only two options, so there was not much thinking. In some scenarios, the wrong answer was explained. In others, it just took you back without explanation. Pictures would be useful. Some pictures were missing or could not open. It did not have any serious issues. Sometimes, more information was needed.
Willingness of use of SHAPES *Under what conditions would you be willing to continue using the digital solutions beyond the end of this pilot?*	If I wanted to learn new things, new scenarios, new conditions, I would use it. If learning in small groups. For revision. After finishing my studies, I would use it for revision, understanding and clinical reasoning. In later years, I would use it for revision. Useful for revision.
Would you be willing to use it as clinicians?	In its current state, it would not be that useful for clinicians because the scenarios test basic knowledge. It is good for students, however.

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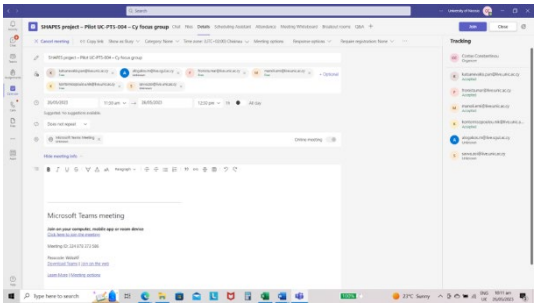
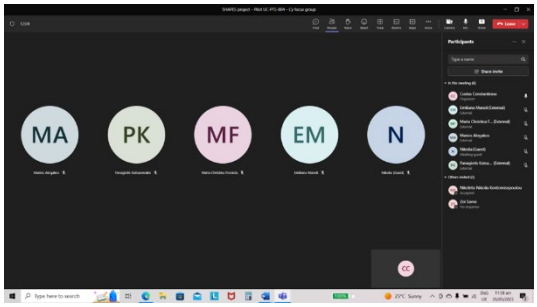
Health cost data *If this innovation was available to use in the future, how much would you be willing to pay for it per month?* < 5€ / 5-10€ / 11-20€ / 21-50€ / 51-100€ / > 100€ / I would not be willing to pay for it	5-10 11-20 if improvement made especially regarding the use of pictures
Who should pay for the DS? Individual end-user / Health insurance (private) / Health insurance (public) / Government-funded / Other	Institutions, Universities. Institutions because the scenarios are necessary for learning. Nice if institutions paid, but each individual could also pay.
Additional feedback *Do you have any further thoughts/experience/impressions you would like to share with us?*	Good experience overall. Useful resource for students, but not for clinicians especially senior one. Could be used to assess new information. Would make good resource for the exam. Screenshots of the focus groups Before starting the discussion, participants gave their consent to take screenshots of the group in Microsoft teams.
 	

Figure 106: Use Case 4 - Screenshots of the Focus Group.

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5.9.5 Communication and dissemination of pilot activities

This information is provided by SHAPES WP10. Moreover, until the end of the project (October 2023), the final results will be published in scientific reviews and disseminate in the SHAPES Website.

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6 Conclusion

The pilot theme 5 was framed in the SHAPES Pan-European Pilot Campaign to develop several activities to validate the SHAPES platform, namely small- and large-scale pilots and demonstrations at the European scale (regions, cultures and health and care organisational models) to assess the impact of SHAPES in supporting healthy ageing and independent living and improved integrated care models. Through the pilots and demonstrations, researchers and technical partners (SHAPES partners) should assess the impact of the platform in three levels: societal, economic, and scientific and technological.

- In the societal level, the use cases developed personas and scenarios to improve the quality of life and health status of older adults with dementia and/or cognitive decline, as well as their formal and informal caregivers. The digital solutions tested were relevant to improve the physical, cognitive and social wellbeing of the participants, but also to increase the digital literacy, acceptance, and usability (UC1, UC2, UC3, UC4).

- In the economic level, the use cases collected the users' perspectives about the cost-benefits for users, and the personal and organizational conditions to adopt digital health solutions in real-life. Adopting the NASSS and MOMENTUM frameworks, the researchers understood that some digital solutions (UC1, UC4) were easiest to implement in real-life than others (UC2, UC4), with a faster economic return.

- In the scientific and technological level, the use cases designed and tested different digital solutions for caring older adults with dementia or cognitive decline, but also provide educational materials and experiences that increase the participants' digital literacy and skills. Additionally, these digital solutions were integrated in the SHAPES platform (UC2, UC3, UC4) and/or its marketplace (UC1, UC2, UC3, UC4).

Following the SHAPES recommendations, the use cases monitored and evaluated these impacts using three Evaluation Frameworks widely adopted on active and healthy ageing pilot campaigns: the MAST, the NASSS, and the MOMENTUM.

- Overall, the use cases adopted the MAST as a multidisciplinary assessment focus on societal and scientific/technological levels. This framework was relevant to establish the domains, measures, and outcomes. Among different domains, the researchers used MAST to assess the use case impact in clinical effectiveness and patient perspectives. The preliminary results highlighted the importance of the technology to improve the access to / quality of the healthcare systems (UC3, UC4), the self-monitoring the physical/mental health indicators

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(UC2, UC3), and the self-caring (UC1, UC2). Furthermore, the use cases had impact in the users' perspectives especially about the technology. As older adults (UC2) or informal/formal caregivers (UC1, UC3, UC4), the users increased their own digital literacy and skills. Nevertheless, the researchers couldn't evaluate if these improvements are transferable for other digital solutions.

- The NASSS was adopted by the use cases to assess the human factors and socio-organisational processes of the digital solution, i.e., the socially meaningful use case that combines people, tools, and rules, and accommodates the users' diversity. After this evaluation, the researchers acknowledged that all use cases involved different users' profiles, and the technologies were able to help the cross-over of individual, community and clinical aspects of health and care. While some use cases were focused the interactions between complex systems like NHS and patients (UC3) or NHS and professionals/students (UC4), others were focused on the users' dynamic network like older adults with dementia / cognitive decline and their informal caregivers (UC1, UC2). Overall, the use cases provided information and evidence about how much the technology-supported change needed a multitude of interactions between users and researchers/technical partners (especially the UC2).

- The MOMENTUM framework was implemented to identify the critical success factors that determined the successfully transfer from a design phase to a demonstration phase of the use cases. Based on the relevant performance indicators, researchers identified the positive or negative aspects that could help or damage the pilot in real-life, thereby, the real-life implementation of the new digital health solution. Despite the framework is focused on telemedicine, the use cases developed technology that could support telemedicine solutions, namely educational solutions (UC1, UC4), communicational systems (UC2, UC3), assistive technology (UC2), and medical devices (UC3). The use cases found relevant opportunities to scale-up the digital solutions in the health and care ecosystem in Europe, namely new services to trainee the informal and formal caregivers of people with dementia (UC1, UC4), to assist older adults with cognitive decline in-home (UC2), and to complement the brain diagnosis (UC3).

The SHAPES pilot campaign was divided in 5 Phases of Implementation that aimed, among others, to engage the use case users in the pilot activities since the planning stage, to build prototypes of digital health solutions and test them in real-life scenarios of use, and to elaborate a range of documentation to support the use cases' scalability.

- The phase 1 dedicated to the use case designing and planning was concluded by all use cases. The results achieved can be used to develop new use cases for different types of caring older adults with cognitive diseases. The documentation elaborated by the researchers (e.g., personas, use case, scenarios, evaluation methodologies) contains a useful and feasible collection of

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concepts and tutorials/instructions for other European and large-scale pilots. Moreover, this work provided a rich contribution to develop the legal and ethical frameworks, the user requirements for technology, and the data protection risk assessment, based on scientific and technical information.

- The phases 2 and 3 were dedicated to build and test a prototype of a digital solution for caring older adults with cognitive problems. Also, these phases were concluded by all use cases. However, they achieved different stages of readiness to implement the use case in real-life with feasibility: while some use cases tested final digital solutions already in the market and community (UC1, UC3), others were tested prototypes (UC2, UC4). These phases were critical limited by the COVID-19 restrictions because it wasn't possible recruit people and organizations to test technical prototypes; the Pandemic addressed new challenges, and the researchers and technical partners decided update the initial plans and prototypes, namely: to develop an online and technical tool to recruit informal caregivers (UC1) and to train formal caregivers (UC4); and to design a use case with one care model for different assistive technologies (UC2). During these phases, the researchers and technical partners built and tested four SHAPES digital solutions, and elaborated tutorials and requirements for the users. The users' comments were mainly addressed to the usability and literacy (UC1, UC2, UC4); in the UC3, researchers didn't achieve all requirements to deploy real-life activities; facing it, they realized a study with key-stakeholders which suggested a non-hospital context to pilot the technology in real-life, namely the pharmacies and private organizations.

- The phases 4 and 5 were dedicated to the real-life demonstrations. These phases are being deployed now, and each use case is in a different level. All use cases designed and prepared the final protocols, assessment methods and materials, and legal and ethical approvals. Only the UC3 didn't conclude the recruitment and the ethical approval processes, thereby the phase 4. The UC4 concluded the phase 5, and the researchers are now analysing the results. The UC1 and UC2 are now running the phase 5. Despite these considerations, the pilot theme 5 are testing three use cases / digital solutions in phase 5, in three European countries (Portugal, Ireland, Greece), with a sample composed by 22 older adults, 49 informal caregivers, and 16 formal caregivers. These participants are, now, using the technology autonomously in daily life, both in home or community as in working place, and the researchers only do a technical support when demanded by users. The researchers must collect the results during until September 2023, to include in the SHAPES deliverables 6.9 and 6.10.

The experience and the lessons learned in the pilot theme 5 were relevant to define the next steps until the end of the project and afterwards. The UC1 and UC2 are committed to collect all data required to complete phase 5, and provide them to other SHAPES WP (WP3, WP7, WP10). The UC4 already concluded the phase 5, and the

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researchers are now providing data to the other SHAPES WP (WP3, WP7, WP10). These activities require three months of efforts until collect and analyse all data, and the results will be included in other SHAPES deliverables. The UC3 hasn't now a technical partner because the agreement with SHAPES was concluded, and researchers stopped the study; but the researchers are elaborating a new proposal to deploy this use case in real-life.

In conclusion, the deliverable demonstrates that pilot activities and partners engaged in the pilot theme 5 were successful implemented (not concluded) to cover the delivery of care to older adults living in community with dementia or cognitive decline, from the care recipients' and the caregivers' perspectives. The use cases developed educational tools, assistive technology, digital cognitive screening, virtual scenarios of patients and treatments, which can improve the wellbeing and quality of life of older adults living in community and support their informal and formal caregivers. Finally, the use cases were able to develop multi-component human-machine interventions focused on caring of older adults in home environments, which were framed by the European and national legislation and ethical requirements, namely GRDP and ethical committees.

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7 Ethical Requirements Checklist

Additionally, this pilot theme is in compliance with the ethical requirements defined in SHAPES Deliverable "D8.4 - SHAPES Ethical Framework", as it's summarized in the Table 8.

Table 41 Ethical Requirements Checklist for pilot theme 5.

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)	To be consulted in sections 2.8.4, 2.9.3, 3.8.4, 4.8.5, and 5.8.4 of this deliverable.
Biomedical Ethics and Ethics of Care (3.2)	To be consulted in sections 2.8.4, 2.9.3, 3.8.4, 4.8.5, and 5.8.4 of this deliverable.
CRPD and supported decision-making (3.3)	To be consulted in sections 2.8.4, 2.9.3, 3.8.4, 4.8.5, and 5.8.4 of this deliverable.
Capabilities approach (3.4)	To be consulted in sections 2.6, 2.7, 3.6, 3.7, 4.6, 4.7, 5.6 and 5.7 of this deliverable.
Sustainable Development and CSR (4.1)	This pilot theme contributes to the SDG 3.
Customer logic approach (4.2)	To be consulted in section 2.3, 3.3, 4.3 and 5.3 of this deliverable.
Artificial intelligence (4.3)	To be consulted in sections 2.8.4, 2.9.3, 3.8.4, 4.8.5, and 5.8.4 of this deliverable.
Digital transformation (4.4)	To be consulted in sections 2.8, 2.9, 38, 39, 4.8, 4.9, 5.8 and 5.9 of this deliverable.
Privacy and data protection (5)	To be consulted in sections 2.8.4, 2.9.3, 3.8.4, 4.8.5, and 5.8.4 of this deliverable.
Cybersecurity and resilience (6)	To be consulted in sections 2.8.4, 2.9.3, 3.8.4, 4.8.5, and 5.8.4 of this deliverable.
Digital inclusion (7.1)	To be consulted in sections 2.8.4, 2.9.3, 3.8.4, 4.8.5, and 5.8.4 of this deliverable.
The moral division of labour (7.2)	This pilot theme 5 tested digital solutions that contributes to a fair moral division of labour between non paid and paid caregivers, to improve the technical skills for professional of care and healthcare, to reduce burden of

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	the informal caregivers, and to develop new services and products for older adults.
Caregivers and welfare technology (7.3)	The pilot theme 5 designed, built and tested digital solutions for healthcare and social care, especially to connect older adults and their formal and informal caregivers.
Movement of caregivers across Europe (7.4)	The pilot theme 5 tested technologies with 49 informal caregivers, and 16 formal caregivers.

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