engAGE

Managing cognitivE decliNe througH theatre therapy, Artificial intelligence and social robots drivEn interventions

D3.1 Code of conduct, recruitment of end-users and test protocol

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Contents

List of acronyms

Acronym	Description
AAL	Ambient Assisted Living
MCI	Mild Cognitive Impairment
SMCI	Senior with Mild Cognitive Impairment
IC	Informal Caregiver
FC	Formal Caregiver

Executive summary

To generate a qualitative product for the market, international projects such as engAGE require extensive and accurate evaluations on the use and usability of the platform, composed of four main parts: a social robot, a tablet application, an activity tracker, and a machine learning algorithm that analyses data coming from the first three components. In the first instance, a lab test will then be conducted to improve all related interfaces by ensuring that the features and the design globally match the end users' needs. The aim of those assessments is to reduce risks and to maximize the system's benefits and market fit, as an improving tool regarding the cognitive decline of older people with mild cognitive impairment and a viable solution regarding carer's workload and treatment pressure.

To appraise the strength of adhesion, but also to rank the system's strengths and weaknesses, a field trial will be set up in order to introduce and install engAGE platform in the natural environment of older people with mild cognitive impairment that need assistance and physical and cognitive stimulation. The field trial will then take place at both the healthcare organization and older people's home and will allow us to check back if the ideas, concepts, clickable mock-ups and prototype are satisfactorily designed and if there are still elements left to be improved to satisfy the client's needs.

Evaluations' outcomes will conduct, step by step, to the final product development, taking also risks, and significant social or ethical issues into account. All evaluations are therefore endowed with ethical values and principles that are indispensable for the smooth running of the project.

1 Introduction

The engAGE platform co-design has been based on the requirements identified in the previous set of interviews with end users: older people with mild cognitive impairment (MCI) and (in)formal caregivers (IC and FC).

A whole set of different evaluations have then been considered, to progressively check if the produced elements of engAGE meet the global expectations and needs of the end users. Assessments' iterations on the prototypes created are then necessary to know whether the improvements gradually made are indeed responding to the needs and requirements identified earlier. On this purpose, two tests will be run: the **engAGE 1st integrated prototype** will be evaluated in the lab testing, whereas the **2nd engAGE integrated prototype** will be evaluated in the field trial.

The focus of this deliverable is to explain in broad terms all the required evaluations during the **lab test** and the **field trial**, and to provide information about participants' recruitment, methodology and measurements.

1.1 Objectives

The objectives of the engAGE project are to counteract and slow down cognitive decline progression, to enhance the intrinsic capacity of the users, and to support the wellbeing of older persons with mild cognitive impairment (MCI) by providing an ecosystem of services based on an innovative system that integrates social robots, IoT-based monitoring, and machine learning techniques.

engAGE targets the following challenges and needs for the main end-user groups: older people with MCI, informal caregivers (family caregivers), and formal caregivers (healthcare professionals).

The project is primarily focused on **older people with MCI**, aiming to improve their quality of life and well-being, allowing them to preserve their identity, to reduce stress, memory loss, or communication challenges. The social robot can be a great tool in engaging older adults in this kind of activities. It is always available and able to provide verbal clues or suggestions according to older adult's wishes, needs and memories. Moreover, the social robots may coach the older adults to perform daily activities with greater independence (i.e. coaching stepwise prompting to complete activities in-home) and support to caregivers as well.

Since caring for people with MCI puts a significant burden on **informal caregivers**, having the support of a technological platform can reduce anxiety, worries, and stress. The caregivers can personalize the content of interventions to the wishes and preferences of the older adults. Together with the older adults, they can be involved with the robot in joyful and fun activities like drama playing, storytelling, etc.

The **formal caregivers** who need to keep track of older adult progress which is a difficult and time-consuming process due to the lack of objective monitoring of cognitive decline and wellbeing may get valuable support from the cognitive assessment procedure implemented by the ML algorithm. Also, the social robot and tablet may facilitate the follow-up of older adults through reminders and cognitive interventions.

For the purpose of engAGE, the following end-users will be involved in two rounds of experimentation (a lab test and a field trial), as follows:

Table 1. Participants for lab test

Older adults			Secondary end users (informal caregivers)			Secondary (centres)		
Italy	Switzerland	Norway	Italy	Switzerland	Norway	Italy	Switzerland	Norway
5	5	5	5	5	5	1	1	1

Table 2. Participants for field trials

Primary end users (SMCI)			Secondary end users (informal caregivers)			Secondary (centres)	Control group
Italy	Switzerland	Norway	Italy	Switzerland	Norway	All pilot sites	
20-22	20-23	8-10	20-22	20-23	8-10	≥2	≥30 (≥10 per each pilot site)

1.2 Overview of the platform

In this section, an overlook of the platform is presented to the reader. The engAGE system will offer four main services built around a social robot for self-managing and sustaining the cognitive function of older adults with MCI: (i) holistic monitoring of daily life activities and perceived health state and wellbeing (Monitoring, Self-Reporting and Big Data Processing Service - MSRBD), (ii) assessment of cognitive state and potential decline by leveraging on machine learning (ML) algorithms (ML-based Cognitive Decline Assessment Service - MLCDA),(iii) personalized cognitive function support and coaching using drama or storytelling and social robots as main tools (Social Robot Coaching and Cognitive Stimulation - SRCCS) and support, communication and personalization for end-users (Communication Platform and Intelligent Personalization - CPIP). The following figure (Fig. 1) schematizes the engAGE platform that integrates social robots, IoT-based monitoring, and machine learning techniques.

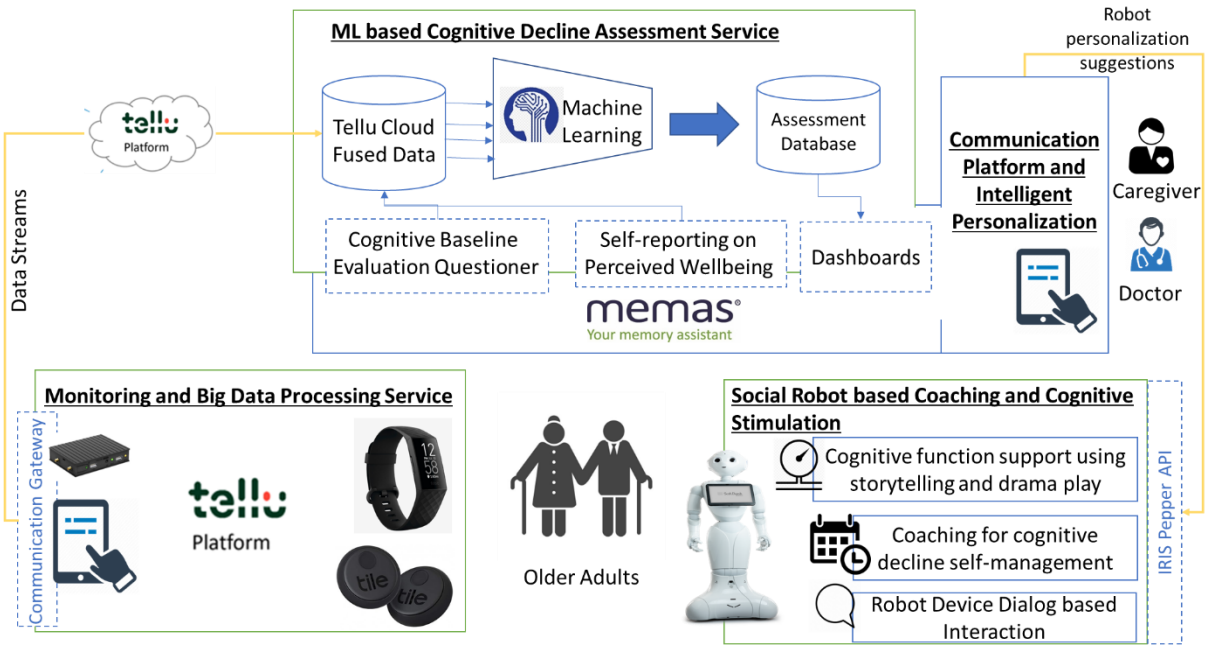

Figure 1. Engage platform architecture

The primary end users will interact with 3 devices: the Pepper robot, a tablet, and an activity tracker through three services dashboards:

- MSRBD service: the Tellu platform allows the collection of data from sensor device through a mobile app that pushes the data to MLCDA. It will feature an Android app to be used by the end-users as gateway of data collection process. Parameters such as heart rate, sleep status, activities, etc. are monitored and will be further used by the MLCDA service as input for ML algorithms.
- CPIP service - MEMAS application can be considered as the hub of the whole system for providing the dashboards for end-user interactions. It will be a web application with several dashboards in which all the end user categories can communicate through MEMAS which shows the results of the ML analysis, and allows the personalization of the services. Also, CPIP will help collecting self-assessment data through questionnaires and make this data available to MLCDA service that will fuse it with the rest of the monitored data and use it as input for ML algorithms.
- SRCCS service: The Android version of Pepper's tablet offers personalized games and activities to the user through an easy-to-use interface. The games will be also integrated into MEMAS to allow the user to play at home. The games results will be made available to MLCDA service to be further processed and fused into the ML process.

The informal caregivers can set reminders and, more in general, an agenda for the cared senior through the MEMAS application. Thus, the senior can use the tablet to fulfil other activities such as listening to the music, watching photos, and so on.

The formal caregivers supervise the execution of activities by the SMCI and help them when needed.

1.3 Dashboards

In this section, the single dashboards that compose the platform are described in detail.

1.3.1 MEMAS

The MEMAS system is a Life Mastering Assistant or a cognitive aid that is suitable for people with MCI.

The MEMAS system contains functionality which will help people e.g., with MCI:

- Calendar with reminders
- Step by step instructions for daily activities in form of series of images with spoken comments or videos
- Entertainment functions
- Photos with spoken comments and videos
- Music
- Easy access to radio channels
- Easy access to network newspapers
- Cognitive games
- Training exercises
- Weather forecasts
- Self-reporting questioners
- Very simple to operate video communication system
- Display the results from the ML algorithms for the secondary end-users

The MEMAS system is usable by both primary and secondary users. The primary user is the person with MCI who physically owns a device with a MEMAS client, and who uses MEMAS as an aid to organize their everyday life. Secondary users are relatives and others in the support system around the primary user, who assist with this in various ways. A primary user can be connected to several secondary users. A secondary user can assist several primary users. In the administration module (a website page), the secondary user can manage an activity calendar, build albums with photos and videos, configure access to favourite radio channels and newspapers etc. As the cognitive state of the person with MCI deteriorates, the secondary user may remove some of the MEMAS functionality from the primary user's device. In general, the secondary user can edit the primary user's interface in order to make the use of MEMAS as simpler as possible, and tailored to the primary user's needs.

1.3.2 Pepper

Pepper is a humanoid social robot able to dialogue with the user by speaking, moving, and expressing emotions. Pepper is also equipped with an Android tablet placed at its chest. The user logs through the tablet at every session, then it interacts with the robot and play the planned activities (drama play, cognitive games, physical games). In order to track the user's progress, each performance is recorded and scores are sent to the cloud along with the user ID.

Once the type of game is selected, the SMCI will be redirected to a new screen in which all the games corresponding to the type selected will be displayed. As a result of the co-creation phase and requirements specification (D2.1 and D2.2) we have identified different categories of cognitive games that can be implemented for older adults with MCI:

- “Familiar games” (5 different games): crossword, karaoke, memory card, sudoku, and find 7 differences game.
- “Quizzes” (3 different games): a picture quiz, a musical quiz or a cultural quiz.
- “Physical games” (3 different games): miming, dancing and yoga.
- “Story/play telling” (2 different games): story listening or plays/poems reciting.

The games will be iteratively developed and included in the platform in the different versions of the prototype while considering end-users' feedback.

When the SMCI is playing and succeeding a task, the robot will congratulate with him/her. To be sure that the SMCI will understand what the robot says, the words are displayed on the screen like subtitles. Alternatively, the robot makes a sound or vibrates when the SMCI put wrong answers to signal SMCI that the system is involved in the game they are playing. However, SMCI can also choose to have a robot which won’t react to false answers, as some will maybe find it childish or demotivating.

1.3.3 Mobile application gateway

The Monitoring, Self-Reporting and Big Data Processing service has little user interaction outside of the use of sensor devices. This service features a mobile application gateway which transfers data from sensor devices and into the cloud (see D2.2 Section 4.1.1). In the first iteration, it will transfer Fitbit data from the Fitbit service. It does so automatically while running in the background on the mobile device (Android tablet) of the primary user. There will be a one-time initiation where the user needs to authenticate with both TelluCare and the Fitbit service. Thereafter the user does not normally need to interact with the app, but it needs a user interface to show status and allow turning data transfer off and/or logging out of accounts.

The app and its usage are described in D1.1, section 5.1.4. Once the login and Fitbit authentication has been established, the app will run in the background, regularly polling data from the Fitbit service. The user will be notified with an Android notification if there is an error with the data transfer. The app user interface has a status field to indicate the current status. This is colour-coded green/yellow/red, but any issue/error is also communicated with text.

2 Lab Test

2.1 Procedure

engAGE 1st integrated prototype will be tested and evaluated in a lab setting. The aim of the test is to assess the usability of the prototype, the user experience, the perceived usefulness, and integration of everyday activities. To this purpose, 30 end users (15 older users and 15 FC/IC) will be recruited over the 3 test sites. Before arrival, all participants will receive information about the engAGE project and they will be asked to complete a brief questionnaire providing demographic, health and wellbeing state, and technology-related data. Moreover, participants will be informed on the collection, storage, and privacy management of their data (the participants will sign an informed consent). In a controlled setting, all volunteers will be trained so that they will be aware of how to use the engAGE ICT solutions and how to interact with the social robot. The following methods are going to be applied: (i) mock-ups will deliver fast feedback about main navigation and rough design of the services interfaces, (ii) the solutions will be used in controlled environments to test the re-used solution effectiveness for the defined main use cases to determine improvements and adaptation if needed and (iii) initial prototypes will be tested with usability methods, combining questionnaires, thinking aloud and observations. The end-user partners will set up focus group sessions to define/refine the scenarios and personas. The focus groups will receive a short training, with explicitly designed material (flyers, training videos, devices, etc.), giving a complete overview of the aims of the study and its tasks.

- **Recruitment phase (R)**: the recruitment protocol will include demographic information on the subjects, as well as information about their health status and cognitive condition. The information will be collected with the help of the caregiver/family member if needed.
- **Baseline evaluation (T0)**: it will consist of collecting information about wellbeing state and technology-related data, in order to understand the needs and the technological literacy of the end users.
- **Feedback (T1)**: at the end of the test the end users will answer structured questionnaires on usability and provide general impressions on the prototype. Moreover, problems occurred during the testing and experienced difficulties will be reported.

2.2 Inclusion and exclusion criteria

In this section, the inclusion and exclusion criteria for involving end users in engAGE lab test are described.

2.2.1 Inclusion criteria

- PRIMARY END USERS:
  - over 65 years old;
  - self-reported initial memory loss.
- SECONDARY END USERS (**INFORMAL CAREGIVERS**):
  - Over 18 years old;
  - Primary informal caregiver of people with memory loss.
- TERTIARY END USERS (**FORMAL CAREGIVERS**):
  - Over 1 year experience;
  - Psychologist, neurologist, occupational therapist, nurses from health care facilities or paid by the participants.

2.3 Channels of recruitment

To ensure that the right participants are included in the evaluations, each partner must have its own recruitment technique, and ensure that the inclusion criteria mentioned above are met. Several channels are available for this purpose and everyone is free to proceed in the easiest perceived way.

2.3.1 Italy (INRCA)

Regarding the recruitment channel, Italian partners will use the contact list of their neurology unit and Alzheimer day-care centre to communicate with potential participants of previous projects and initiatives, as well as with other people who might be interested in contributing to the project evaluations. This method makes possible to be in contact with clients met before and with whom a relationship of trust has been already established.

2.3.2 Switzerland (HUG)

Swiss partners will contact the different units of the HUG in neurology, the memory center and the day care center in Geneva. They will be contacted to know if they are interested to participate in the development of the project by introducing us to potential participants to evaluate the project.

2.3.3 Norway (KARDE)

Norwegian partners will recruit participants through day care centres in Arendal municipality as well as other people who might be interested in contributing to the project evaluations, and who are known to Karde from previous AAL-projects. Some recruitment may also be conducted through Karde's social media accounts and by announcements on the project's web page on karde.no.

2.4 Scales and tools

Table 3. Protocol of questionnaires on Lab test for older people with MCI

PROTOCOL of QUESTIONNAIRES for OLDER USER	**R**	**T0**	**T1**
Socio-demographics checklist	X		
Technology literacy		X	
System Usability Scale (SUS)			X
Semi-structured questionnaire on usability, acceptance, willingness to pay			X

Table 4. Protocol of questionnaires on Lab test for informal and formal caregivers

PROTOCOL of QUESTIONNAIRES for IC/FC	**R**	**T0**	**T1**
Socio-demographics checklist	X		
Technology literacy		X	

System Usability Scale (SUS)			X
Semi-structured interview on acceptance, usability, willingness to pay, quality of work			X

The quantitative tools are all standardized, and they are:

The **System Usability Scale (SUS)** [9] is a reliable tool for measuring usability. It consists of a 10-item questionnaire with five response options for respondents, from 'Strongly agree' to 'Strongly disagree'. It allows for evaluation of a wide variety of products and services, including hardware, software, mobile devices, websites and applications. It is easy to administer to participants and can be used on small sample sizes with reliable results and can effectively differentiate between usable and unusable systems.

Finally, a **semi-structured Interview** to evaluate the formal/informal caregivers' perspective on acceptability, usability and demand & cost information is built ad hoc, as the interview for the SMCI on willingness to pay and problems and/or suggestions about the prototype functionalities (see Annex).

2.5 Description of the testing

In this section, the testing is descripted in detail.

The tests will take place in a controlled environment in each pilot site:

- Italy (INRCA): Youse Lab (Laboratory of technology usability) inside INRCA hospital;
- Switzerland (HUG): EvaLab (Laboratory of technology usability) inside HUG hospital;
- Norway (KARDE): Partly in Karde's premises and partly at day care centres in Arendal.

At the controlled environment, the older user interacts with the social robot and the tablet and is supervised by the relative informal caregiver, by one researcher (at least) and one technical assistant.

The interaction will consist in practicing the following activities in this order:

- Introduction to the project and explanation (by researcher)
- wearing activity tracker and use the dialogue app (log in and sharing data);
- free dialogue with the robot;
- cognitive game with the robot - Crossword;
- physical game with the robot – Miming game;
- do one task on MEMAS (search for photo, creating account).

This interaction is planned to last about 1 hour. Before the interaction the end user (and his/her informal caregiver) will answer the questionnaires (T0). During the interaction every problem occurred or any suggestion provide by end users will be annotated and reported in the final report along with questionnaires asked after the test (T1).

3 Field trial

3.1 Study design

The field trial will be conducted as a controlled longitudinal study, with a before and after design where the observations are made on a series of enrolled individuals, receiving the intervention described below with control group, with data collected before and after the installation and use of the technical solution. The goal of trial evaluation is to assess the engAGE technology integration into everyday life, effectiveness on mitigating the cognitive decline, acceptance over six months, security and reliability of proposed solutions as well as the business perspective reflecting the market demand (including the willingness to pay) for the developed services. The field trial procedure will be divided into two different phases, after the recruitment of the participants: Baseline evaluation (T0, M1) and Final evaluation (T1, M6), with the aim of collecting data as follows:

- **Recruitment phase** (R): the recruitment protocol will include general information on the subjects, in particular, health status and cognitive condition. The information will be collected with the help of the caregiver/family member if needed.
- **Baseline evaluation** (T0, M1): that will consist of the first real contact with the users and their families, before the start of the field trial.
- **Mid-term evaluation** (T1, M3): the aim of mid-term evaluation is to collect useful information on the use of the engAGE platform after a short period of use for detecting and analysing the technology acceptance and usability issues.
- **Final evaluation** (T2, after six months of use, M6): the aim of this phase is to collect useful information on the whole benefits perceived by the users after a meaningful period of use of the system. The final evaluation will be conducted after the system de-installation, to detect and analyse the impact of the system in the daily life of the older people and their family. Moreover, the final evaluation aims to gain knowledge on elderly technology acceptance and usability issues to be compared with mid-term results (T1), in order to assess the longterm acceptance and provide methodological approach for further studies in the field.

The field trial is a pilot study, that is, a small-scale study, conducted mainly to control whether and how the developed services are perceived useful and usable. The defined qualitative and quantitative key performance indicators (KPI) will be evaluated and used to assess the degree to which engAGE meets the elders' needs, wishes and priorities in all trial sites (i.e. achieving better engagement, better social interaction, and accurate measurement of cognitive decline based on machine learning techniques). The measurements collected from the real-life trials will be elaborated and evaluated, to assess the ecosystem performance and validate the success of the project-developed technologies. The field trial will conduct only a partial evaluation of the effectiveness of services in relation to some dimensions of cognitive status of older people with MCI.

In the following scheme (Fig. 2) the study design is summarized. A certain number of people are recruited for the study, then those who do not meet the criteria or decline the participation are excluded. The remaining participant are randomly assigned to the experimentation group or to the control group. In randomization technique based on a single sequence of random assignments is used. A list of random numbers generated by the computer is used and subject is assigned a number based on their order of inclusion in the study. According to this technique, the 80 subjects are randomly assigned to one of the 2 study groups. The remaining participant are randomly assigned to the

experimentation group or to the control group. Then, for both the groups it has to be taken note of who loose follow up, discontinued intervention, and/or are excluded from analysis.

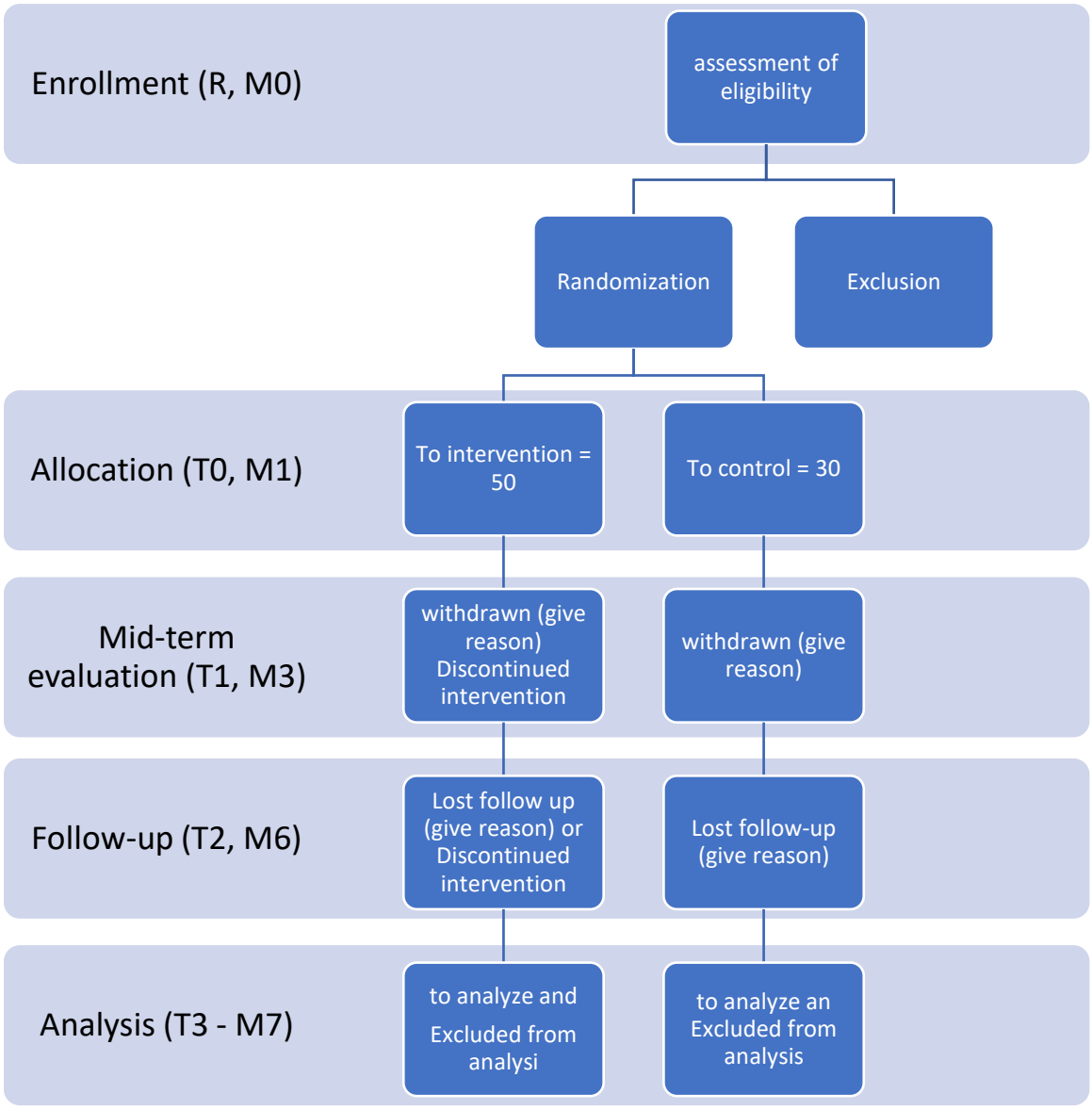

Figure 2. Field trial - study design

3.2 Informed consent and ethical approval

Each pilot site must obtain ethical approval before testing the engAGE platform and services. Moreover, according to the Declaration of Helsinki, any participant must provide his/her consent to the study. For this reason, a general consent form is created and shared with all partners to allow each of them to update and translate it, in any case of need (Annex 1). The consent form contains general information about the project, the stage in which end-users' participant will be requested, with a quick description of the tasks to be completed. At the end of the document, the rights of the participants as well as the criteria for participation are specified. By dating and signing the document's last page participants give their consent to take part into the evaluation process.

How any pilot site deals with informed consent, final compensation, and ethical approval is described in the sections below.

3.2.1 Italy (INRCA)

INRCA will submit the study protocol to its own Ethical Committee, in order to receive review and finally get the ethical approval.

The consent form will be delivered to the end user at recruitment stage, before asking any personal data and questionnaire. Before the planned evaluation, the consent form should be signed and returned to the researcher, if him/her want to be involved in the study process.

Due to Italian legislation, the participants will not receive money as a financial compensation for their contribution on the research activity, but laboratory exams and training on everyday technologies will be offered as compensation mean for the participation.

3.2.2 Switzerland (HUG)

HUG will submit the study protocol to the Swiss Ethical Committee to get the ethical approval.

The consent form will be delivered to the end user at the recruitment stage, before asking any personal data and questionnaire. The consent should be signed and returned to the researcher before asking personal data and questionnaire. Participants will be informed that their data will be anonymous, that they are free not to answer all the questions, that they can withdraw at any time from the study without justification and that if they agree their data can be used for scientific publications.

Participants will receive money as financial compensation for their contribution on the research activity.

3.2.3 Norway (KARDE)

In Norway, this project sorts under the NENT The Norwegian National Committee for Research Ethics in Science and Technology. For the purposes of the engAGE project (development of technology), we do not have to apply for an ethical approval. Consequently, Karde will not collect any personal medical information from the participants. Karde's WP4 leader, Dr. Hellman has by The Norwegian Data Protection Authority been registered to be Karde's privacy ombud. She has the competency and capacity to monitor and supervise all ethical aspects connected to the engAGE project's Norwegian part. Inclusion and exclusion criteria

In this section, the inclusion and exclusion criteria for involving end users in engAGE lab test and field trials are described.

3.2.4 Inclusion criteria

- PRIMARY END USERS (**SMCI**):
    - over 65 years old;
    - MoCA score 21 – 25;
    - MAC-Q ≥ 25;
    - Reisberg scale 2 – 4;
    - Clinical Frailty Scale score 1 – 3;
    - 4-items GDS score ≤ 1.
- SECONDARY END USERS (**INFORMAL CAREGIVERS**):
    - Over 18 years old;
    - Primary informal caregiver of the user (see the user at least 2 times per week);

- TERTIARY END USERS (**FORMAL CAREGIVERS**):
    - Over 1 year experience;
    - Psychologist, neurologist, occupational therapist, nurses from health care facilities or paid by the participants.

3.2.5 Exclusion criteria

The exclusion criteria consist of

- Concomitant participation in other studies;
- Lack of written informed consent;
- Not meeting the inclusion criteria
- Previous diagnosis of dementia or other neurodegenerative diseases;
- Psychiatric illnesses that could affect cognitive functioning;
- Chronic neurological or systemic disorders not compensated pharmacologically that could affect cognitive functioning;

3.3 Channels of recruitment

To ensure that the right participants are included in the evaluations, each partner must have its own recruitment technique, and ensure that the inclusion criteria mentioned above are met. Several channels are available for this purpose, and everyone is free to proceed in the easiest perceived way. Each pilot site should give priority to those who participated in the laboratory tests

3.3.1 Italy (INRCA)

Regarding the recruitment channel, Italian partners will use the contact list of their neurology unit and Alzheimer day-care centre to communicate with potential participants of previous projects and initiatives, as well as with other people who might be interested in contributing to the project evaluations. This method makes possible to be in contact with clients met before and with whom a relationship of trust has been already established.

3.3.2 Switzerland (HUG)

Swiss partners will contact the different units of the HUG in neurology, the memory center and the day care center in Geneva. They will be contacted to know if they are interested to participate in the development of the project by introducing us to potential participants to evaluate the project.

3.3.3 Norway (KARDE)

Karde is in contact with Arendal municipality and test users will mainly be recruited from two day-centres in Arendal. Information meetings will be conducted in collaboration with Arendal

3.4 Outcomes

In this section the outcomes measured throughout the field trials are reported. The main focus of the engAGE project, and so of the field trial, is the perceived stability of cognitive capabilities of people with MCI. In second place, the acceptance and the usability of the platform, as well as the caregivers' benefits have to be assessed. Thus, the outcomes are the following:

- PRIMARY END USERS (**SMCI**):
    - Primary outcome: perceived stability of cognitive status (MAC-Q)

- Secondary outcomes: Adherence to intervention, wellbeing, quality of life, acceptance and usability, cost-benefit analysis

- SECONDARY END USERS (**INFORMAL CAREGIVERS**):
  - Reduction/stability of informal caregiver's burden
  - Improvement of well-being, psychological status
  - Acceptability, usability and affordability of the solution
- TERTIARY END USERS (**FORMAL CAREGIVERS**):
  - Improving quality of work.

3.5 Scales and tools

In this section the questionnaires/scales asked to the end users are presented in the following tables, by indicating also at which time of the intervention a questionnaire/scale is asked.

Table 5. Questionnaires and scales asked to the senior with MCI during the field trial

PROTOCOL of QUESTIONNAIRES for SMCI	**R**	**T0**	**T1**	**T2**
Socio-demographics checklist*		X		
Montreal Cognitive Assessment (MoCA) [IT - SW]	X			X
Reisberg Scale	X			
4-items Geriatric Depression Scale (GDS)	X			
Clinical Frailty Scale	X			
Memory Assessment Clinics – Questionnaire (MAC-Q)	X			X
Adherence to the system use (to be collected technically)			X	X
UCLA loneliness scale (social connectedness)		X		X
Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)		X		X
EQ-5D-5L (VAS)		X		X
Unified theory of acceptance and use of technology (UTAUT)			X	X
Quality of Life–Alzheimer's Disease (QoL-AD)		X		X
System Usability Scale (SUS)			X	X

Semi-structured interview on acceptance, usability, willingness to pay			X	X

Table 6. Questionnaires and scales for formal and informal caregivers

PROTOCOL of QUESTIONNAIRES for IC/FC	R	T0	T2
Socio-demographics checklist	X		
Zarit Burden Interview		X	X
Adherence to the system use (to be collected technically)			X
UCLA loneliness scale (social connectedness)		X	X
Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)		X	X
EQ-5D-5L		X	X
System Usability Scale (SUS)			X
Semi-structured interview on acceptance, usability, willingness to pay, quality of work			X

The quantitative tools are all standardized, and they are:

The **Montreal Cognitive Assessment (MoCA)** [1] is a widely used screening assessment for detecting cognitive impairment. The MoCA is a one-page 30-point test administered in approximately 10 minutes. The test and administration instructions are available for clinicians online. The test is available in 46 languages. The MoCA assesses several cognitive domains: the short-term memory recall task (5 points), visuospatial abilities (4 points), alternation task (1 point), verbal abstraction task (1 point), attention, concentration, and working memory (6 points), language (6 points), abstract reasoning (2 points), and orientation to time and place (6 points).

The **Reisberg Scale** [2] consists of 7 major clinical stages. It is used by clinicians and in care settings, but may be especially helpful for caregivers, as it is noticeably detailed regarding the general abilities of an individual at each stage and provides information about what to expect at different stages. The scores go from no cognitive decline (1) to very severe cognitive decline (7), through stages 2, 3, and 4 that are respectively: Very mild cognitive decline (age-associated memory impairment), mild cognitive impairment, and moderate cognitive decline.

The **4-items Geriatric Depression Scale (GDS)** [3] is a 4-items scale whose answers are yes or no. If all the items are answered negatively then the depression is excluded; if only one item is answered positively then the situation is uncertain; if at least 2 items are answered positively, the patient is depressed. Thus, this scale is easy and quick, and very useful in excluding depression.

The **Memory Assessment Clinics – Questionnaire (MAC-Q)** [4] is a 6-item scale that uses a 5-item Likert scale from "much better now"=1 to "much worse now"=5, and the last question scores double. The questionnaire asks the person to compare his or her memory with a previous period to measure age-related memory decline. Five items address specific situations frequently reported as problematic by those who experience memory loss with age. One item is a global item assessing general memory decline. A cutoff of 25 points or more indicates that the individual has a memory disorder.

Clinical Frailty Scale (CFS). [5] This descriptive scale divides the older participants into 9 classes based on the information provided by them and their relatives: between 1 and 3 the patient is non-frail, pre-frail if 4, he is frail from 5 to 9.
The **UCLA scale** [10] is a 20-item scale designed to measure one's subjective feelings of loneliness as well as feelings of social isolation. Participants rate each item as either O ("I often feel this way"), S ("I sometimes feel this way"), R ("I rarely feel this way"), N ("I never feel this way").

EQ Visual Analogue Scale (EQ VAS) [11] records the respondent's self-rated health on a 20 cm vertical, visual analogue scale with end-points labelled 'the best health you can imagine' and 'the worst health you can imagine'. This information can be used as a quantitative measure of health as judged by the individual respondents.

The **Warwick-Edinburgh Mental Wellbeing Scales (WEMBS)** [12] is used to enable the measuring of mental wellbeing in the general population. The 14-item scale WEMWBS has 5 response categories, summed to provide a single score. The items are all worded positively and cover both feeling and functioning aspects of mental wellbeing, thereby making the concept more accessible. The scale has been widely used nationally and internationally for monitoring, evaluating projects and programmes and investigating the determinants of mental wellbeing.

The **Unified Theory of Acceptance and Use of Technology (UTAUT)** [7] is a 20-item questionnaire that examines the acceptance of technology, determined by the effects of performance expectancy, effort expectancy, social influence and facilitating conditions.

The **Quality of Life – Alzheimer's Disease (QoL-AD)** [13] uses a scale of 1–4 (poor, fair, good, or excellent) to rate a variety of life domains, including the patient's physical health, mood, relationships, activities, and ability to complete tasks.

The **Zarit Burden Interview (ZBI)** is a caregiver self-report measure [9], containing 22 items. Each item on the interview is a statement which the caregiver is asked to endorse using a 5-point scale. Response options range from 0 (Never) to 4 (Nearly Always).

The **System Usability Scale (SUS)** [8] is a reliable tool for measuring usability. It consists of a 10-item questionnaire with five response options for respondents, from 'Strongly agree' to 'Strongly disagree'. It allows for evaluation of a wide variety of products and services, including hardware, software, mobile devices, websites and applications. It is easy to administer to participants and can be used on small sample sizes with reliable results and can effectively differentiate between usable and unusable systems.

Finally, a **semi-structured Interview** to evaluate the formal/informal caregivers' perspective on acceptability, usability and demand & cost information is built ad hoc, as the interview for the SMCI on usability and acceptability.

3.6 Description of the intervention

In this section, the intervention is descripted in details.

The experimental group (EG) use the engAGE system in two different settings: at healthcare organization and at home. At the healthcare organization, the primary end user (SMCI) interacts with Pepper. The interaction **at healthcare organization** is supervised by tertiary end users (formal caregivers, i.e., occupational therapist, psychologist, nurse, etc…) and includes the following activities: dialoguing with the robot, storytelling, drama play, cognitive and physical games. This interaction is planned to last about **1 hour and to be scheduled twice a week for 6 months**. **At his/her home**, the older user interacts with the tablet and is supervised by the relative informal caregiver. Also in this case, the user plays cognitive and physical games installed on MEMAS app. Even this activity is **performed for 0,5 hour, every day for 6 months**. Throughout the whole period of experimentation (unless (s)he decides otherwise), the older user wears the smartwatch that measures his/her physiological parameters and the steps. Any activity performed by the seniors is assigned by formal caregiver and can be personalized taking into account the user's abilities (difficulty levels of the games), lifestyle (reminding and monitoring services), and social interactions.

The activities performed by the user through the engAGE system are schematized in the figure below:

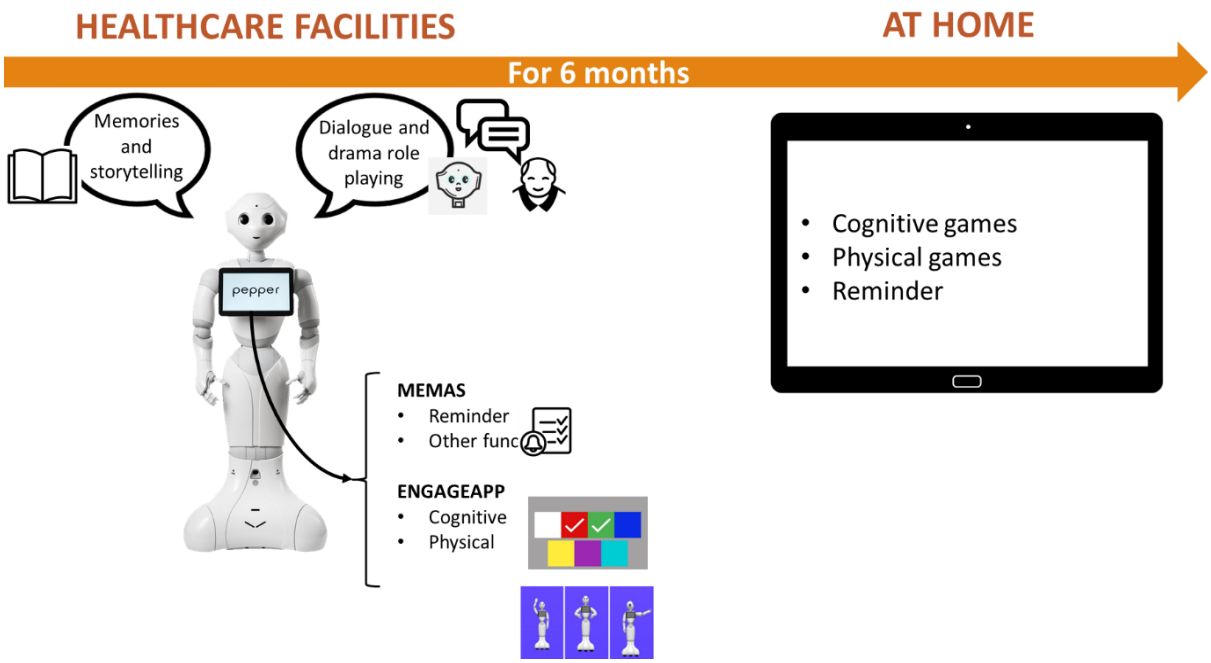

Figure 3. Summary of engAGE activities

Table 7. Games of the Engage platform

Name of games	Description
Familiar games	

Crossword	Helps with long term memory, having to find common words based on their definition or pictures.	★: easy level (infinite tips) ★★: medium level (limited tips) ★★★: hard level (no tips)
Karaoke	Helps SMCI to have fun while singing songs they already know (train memory without noticing).	
Memory card	Helps with spatial memory, which can help SMCI to find lost objects in the future.	
Sudoku	Helps with visual memory, using numbers instead of letters can be easier and more enjoyable. It's an appreciated game for SMCI.	
2 differences game	Helps to stay focus, observe, retain the information to seek.	
Quizzes		
Picture quiz	Find the celebrities/animals behind.	
	★: picture★ ★: pixelated photo ★ ★ ★: silhouette	
Musical quiz	Seniors interviewed share a common passion for music. Musical games and quizzes should be implemented. SMCI will have to complete lyrics of famous songs, recognize singers or the name of the songs and determine some noises.	
	★: remember the singer ★ ★: remember the song's name ★ ★ ★: remember both	
Cultural quiz	Questions regarding arts & literature, entertainment, geography, history, science & nature, and sports & leisure. SMCI will have to answer in different manners.	
	★: two options ★ ★: four options ★ ★ ★: free answer	
Physical games		
Miming	The robot being able to move, it can show SMCI some moves to train their physical condition. The robot can show some videos to the senior that he/she will copy. It can also show a picture that the senior has to interpret.	
	★: reproduce robot actions ★ ★: copy actions on video ★ ★ ★: interpret, mimics an image	
Dancing	Dancing on songs they know and like, with simple dance steps.	

	★: reproduce robot steps ★ ★: learn new steps in video★ ★ ★: learn new choreography	
Doing yoga	Few SMCI have balance problem which can be helped by doing some simple exercises yoga.	
	★: breath exercises ★★: some relaxing exercises (meditation) ★★★: balance exercises	
Story / plays telling		
Story listening	SMCI have to listen to the story told by the robot and answer questions that appear during the story telling.	No difficulties levels will be set up, but scores will show the performance of the SMCIs.
Plays/poems reciting	SMCI have to listen to theatre plays or songs and learn them with the robot (only short and well-known parts) "Be or not to be".	

3.6.1 The control group

The control group (CG) will be given a booklet containing some suggested activities to do at home.

They will be evaluated at T0 and at T6 like the EG.

A first and a final meeting will take place in order to introduce and explain the project to the volunteers, and to show the results collected during the experimentation.

3.7 Work hypothesis

Work hypothesis

In this section, the hypothesis is presented along with solutions to measure the impact on those aspects.

1. Is there any improvement in the cognitive status?
    - Comparison of MAC-Q (before and after)
        - between groups (EG Vs CG)
        - intra-group (EG)
2. Is the system usable for people with MCI?
    - Analysis of SUS in the EG
    - Analysis of UTAUT in the EG
    - stratifying for MCI
3. Is it the system effective in supporting lifestyle of people with MCI and their carers?
    - Adherence to the system to be assessed technically:
        - Nr. of interactions
        - Nr. planned activities respected
4. And the quality of life of the participants?

- Comparison of QoL and WEMBS (before and after)
    - between groups (EG Vs CG)
    - intra-group (EG)
- For Carers: Comparison of QoL and ZARIT (before and after)
    - between groups (EG Vs CG)
    - intra-group (EG)
    - improvement of quality of work for Formal carers (from semi structured interview)

5. From semi-structured interview:

- analysis of single modules' effectiveness/perception;
- cost-benefit analysis;
- willingness to pay.

4 Data Management

4.1 Statistical Analysis

The first step of the data analysis will deal with the description of the sample. Continuous variables will be reported as either mean and standard deviation or median and interquartile range on the basis of their distribution (assessed using Kolmogorov-Smirnov test). Categorical variables will be expressed as an absolute number and percentage. Mann-Whitney U tests (for non-normal distribution), or Chi-Square tests (normal or non-normal) will be used to compare the independent and dependent variables between the pre- and post- conditions, in addition to simple descriptive statistics (means, medians and SDs as appropriate).

In order to verify the achievement of the primary endpoint (i.e., MAC-Q), subscales of the questionnaire will be calculated. Means and standard deviation or medians and iqr of the scores will be reported according to their distribution. Correlation coefficients (Pearson for normally distributed variables, Spearman for non-normally distributed variables) of the sub-scales with the other rating scales at each stage of the study and with the main characteristics of the subjects will be calculated to check for potential determinants of higher acceptability.

4.2 Risk management and mitigation

No negative effects are expected on the health of users related use of the technology platform. The hardware devices used are commercial devices and CE certified and/or safety certification, the applications for older people and caregivers will be loaded on the hardware held by the users.

Technological dependence, especially on AI devices, represents a major ethical dilemma in today's society and scientific community. In order to limit the risk, the European Commission's international programmes have introduced guidelines for conducting studies that require the introduction of a new technology, called Responsible Innovation. The core principles of Responsible Innovation are also applied within the engAGE project. In particular, a strategy underlying the prevention of technological dependence is the inclusion of different actors around the older people, in the process of acquiring skills and daily use of technology. In this way, technological solutions such as those proposed by engAGE, respond to the definition of socio-technological system rather than technological, since they are placed in a care context that does not involve the replacement of the caregiver but stimulates the user to play a leading role in the management of their health.

The services proposed are intended to support the maintenance or improvement of cognitive abilities through specific activities and do not replace (in whole or in part) the support from professional services.

During the installation of the technology, moreover, information will be provided to the caregiver about the limits of the technology, which can in no way replace the role of the familiar and formal assistant, but only assist in some activities.

Users who take part in the study will not incur any direct or indirect costs related to the use of the technology platform. The platform will be provided to the subjects by the Experimental sites and must be returned to the research team at the end of the trial.

4.3 Data Management

In the case of the engAGE project, a critical area of security is the servers (cloud or on-premises) where the solutions will be deployed, or on which data will be stored. These need to be provided with physical and logical protection. Also, the communication network architecture should consider implementing mechanisms of comprehensive network protection against intrusion such as IPS (Intrusion Prevention System), firewall and network antivirus filter. The core system should be placed in a secure area (Secured Zone) excluding the necessary communication modules located in the DMZ (demilitarized zone), enabling data exchange with engAGE services, devices, and components. In the case of communication via an external network, strong mechanisms are required to guarantee the protection of transmitted data, their integrity, confidentiality and non-repudiation (e.g., TLS – Transport Layer Security). Authorization procedures should be implemented specifying who is authorized to access the network and network services - access to services should be possible only for authorized users/devices by providing authentication and authorization mechanisms. Access to individual applications must require a user ID and authentication (password, authentication certificate). The application functionality available to individual users should be limited by the user's rights. The system architecture should include solutions that eliminate or significantly reduce the system's vulnerability to attacks as recommended in the Open Web Application Security Project (OWASP).

Different types of data will be collected in the engAGE project:

- Credentials - usernames, passwords, email addresses and similar security information used for authentication and account access in different services of the platform (i.e., Tellu web and Dialog app, Fitbit application, Memas, Pepper tablet, etc.);
- personal data such as first name, last name, gender, age, weight, height, email address, contact address, phone number, etc. of older adults' end-users in different services of the platform;
- answer to specific questions in self-assessment questioners (Memas);
- games scores from the Pepper applications;
- measurements and monitored parameters such as weight, heart rate, blood pressure, physical activities of older adults' end-users gathered through the monitoring infrastructure in the Tellu platform storage;
- historical data about the above measurements and monitored parameters for training and using ML algorithms for each older adult in the ML service.

In the engAGE testing and evaluation phase, the following data will be processed:

- information and results from questionnaires;
- cognitive games scores
- historical data for each end-user collected measurements;
- any information the end-users decide to share through discussions / interviews as well as data providing feedback from trials.

In the designed solution, data will be transferred using REST APIs. To secure data transmission, it is recommended to use the HTTPS protocol using the TLS protocol to encrypt data especially for web applications. This approach gives the opportunity to use three levels of data access security. Security of an access to health data can be also achieved based on the use of a firewall with appropriate security rules. In engAGE different types of databases are used for storing data. These database

servers give the option of encryption at several levels, and provide flexibility in protecting data from disclosure such as:

- password storage encryption - database user passwords are stored as MD5 hashes;
- encryption for Specific Columns - allows certain fields to be stored encrypted; this is useful if only some of the data is sensitive;
- data partition encryption - an entire file system partition can be encrypted on disk, and decrypted by the operating system;
- encrypting data across a network - SSL connections can encrypt all data sent across the network: the password, the queries, and the data returned.

engAGE consortium will store and keep data for as long as necessary to fulfil the project purposes unless otherwise required by law and the contract for the project. During the research and development phases of the project's lifetime phases each **technical partner** will provide its own infrastructure for hosting the developed services and storing the associated data.

4.3.1 Storage in Tellu premisses

Data stored in Tellu's TelluCare cloud platform is kept to the minimum required to use a mobile app connected to this platform. Firstly, TelluCare includes an authentication broker, where user names and passwords are stored in an encrypted database. The authentication broker is an instance of Keycloak, an Open-Source state-of-the-art Identity and Access Management application following the latest industry standards in security. No other service has access to this information, as all authentication must be done through the web interface or API of the broker, and it will only give out time-restricted tokens which can be used to access Tellu APIs. Secondly, a Dialogg user associated to an ID in the authentication broker must be registered to use the mobile app. A name and email address can be registered here, but these need not be real. An audit log is kept, to show when a user has access data in TelluCare. No other information will be stored in TelluCare – specifically, no sensor measurements, such as from Fitbit, will be stored here.
Tellu will use their production cloud deployment in engAGE. This is hosted in Microsoft's Azure cloud platform, with a data centre located in Norway. This is the same cloud deployment which is used for real patient data, following the high security requirements of ISO 27001, but with a separate network domain set up for engAGE. Tellu is ISO 27001 certified, and all data storage in engAGE is handled according to this standard. Access to Tellu's Azure nodes is through VPN and only available to key Tellu personnel. As all data is encrypted, access to the databases running in Azure does not give access to the data itself.
No data is stored in the mobile gateway app, except for the time-limited refresh tokens used to access TelluCloud and Fitbit services, and these are stored encrypted (so that the user does not need to log in each time). The app does not have access to user credentials for these services, as authentication is done by the user in the secure web interfaces of the respective service, which is not inside or accessible to the app. The app only gets the tokens issued by the authentication services. For Fitbit, this token is used to get access to collected data from the Fitbit API. This data is transmitted to the engAGE MLCDA service for processing and storage.

4.3.2 Storage in INRCA premisses

INRCA will keep all written test recordings (filled in moderator's guide, informed consent, demographic & and all survey results) in electronic format (audio recordings an word/excel files) in a secured repository. All the physical data (papers of questionnaires, interviews, demographics) will be kept on a locked drawer.

All data acquired through third part systems, such as Fitbit (see below) are subject to the policies of the third part, which have been clarified to all participants.

4.3.3 Storage in Karde premisses

In the engAGE project, we will collect anonymous end-user data which will be delivered to the data handling partners ('behandlingsansvarlig') partners technical University of Cluj-Napoca (coordinator, Romania) and INRCA (responsible for end user studies, Italy) for overall aggregated analyses and conclusions for improvement of the technology, seen from the end user perspective.

These data will concern only the end user experience that report the engAGE prototype's usability and accessibility in different stages of maturity of the engAGE software/hardware. No information of diagnoses or medication concerning MCI or dementia will be asked for or stored.

The end user participants will therefore be shielded from any intrusive or unnecessary questions as far as the project's (one and only) technology goal is concerned.

The Norwegian research will only concern levels of everyday function and IADL (i.e., practical level of performance ability concerning activities of daily living and self-sufficiency), connected to the technology of the engAGE project. Data not directly connected to the improvement of the engAGE technology, will not be posed.

Karde AS will be the responsible partner for collecting and creating the aggregated Norwegian data for the consortium. Following aspects cover our data management approach:

- All individual data sheets of the end-user participating in the tests and trials, will be coded and not include any information that allows to identify the individual participant.
- Karde AS or Tellu AS do not keep these data over time neither electronic nor on paper.
- Karde's or Tellu's data sheets with interview data will be destroyed at the end of the project.

Our understanding is that the project coordinator and other project participants will follow all necessary rules and guidelines for data management concerning the project's data.

Contact person for data management in Karde AS is Dr. Riitta Hellman ('personvernombud', appointed for Karde AS by the Norwegian Data Protection Authority). She will act as the contact person for data management for both Norwegian project partners.

4.3.4 Storage in TUC premisses

TUC stores historical data for the ML service in its premises in Cluj-Napoca, Romania. TUC has allocated a specific state of the art server for storing engAGE data. This server is isolated from other research and development activities done in other projects implemented by TUC, it is dedicated to engAGE. Physical security measures for protecting the data stored on the server:

- the server is in a secured area with fire protection, proper ventilation and cooling;
- only authorized personnel have access to the server room (TUC team researchers);
- access in the server room is done based on secure key cards, which are kept in a locked office when not used;
- the server room has an allocated alarm system which is permanently activated when authorized personnel are not in the room. Passwords for alarm system are known only by engAGE TUC personnel;
- the server has backup batteries for power outage.

Logical security measures for data protection on TUC server:

- The server HDDs use RAID techniques for backing up data in case of one HDD failure;
- the operating system (OS) is a Linux kernel is protected through authentication and authorization. Only engAGE TUC personnel has the credentials for accessing the OS level services;
- the communication network uses mechanisms of comprehensive network protection against intrusion such as: IPS (Intrusion Prevention System), firewall and network antivirus filter;
- remote access to the server is possible only through secured VPN connections and only TUC personnel from the project have credentials and details how to access it;
- the MLCDA service is isolated at the OS level using Docker containers; the DB servers deployed on the physical server are protected against intrusions using password authentication. DB passwords are known only by TUC engAGE personnel.

The personal data collected by each of the end-user organizations (HUG, INRCA, KARDE) in trials must be securely stored on local hard drives as password protected files under specific authorization measures; the physical forms should be kept in locked, fireproof drawers. Data will be pseudonymized – Identity of data subjects will be concealed by replacing their names with codes; access to pseudonymized data will be given only to authorised researchers at the pilot sites; all data that is included in internal reports, tables, internal communications, public deliverables will be anonymized and will not contain identifiable details; any questionnaires or input acquired from voluntary participants in the scope of the engAGE project will be handled in the strictest confidence;

4.3.5 Storage at HUG

HUG will keep all written test recordings (filled in moderator's guide, informed consent, demographic and all survey results), scanned when required, in a protected institutional area with institutional access policies restricted to the lab involved in the project. All the electronic data (audio/video recordings, filled excel spreadsheet) will be kept on a secured repository.

All data acquired through third part systems, such as Fitbit (see below) are subject to the policies of the third part, which have been clarified to all participants.

All collected data will be destroyed 5 years after the end of the project and will be used only in the scope of the project to evaluate the system for scientific purpose.

4.4 Ethics

The principles of the Declaration of Helsinki and Good Clinical Practice guidelines will be adhered to. Participants in this study provide written informed consent.

Personal data collected during the trial will be handled and stored in accordance with the General Data Protection Regulation (GDPR) 2018. Use of the study data will be controlled by the principal investigator. All data and documentation related to the trial will be stored in accordance with applicable regulatory requirements and access to data will be restricted to authorized trial personnel.

The acquisition of informed consent from people with cognitive impairment is a long-debated issue.

Although degenerative neurological syndromes over time lead to a progressive decline in cognitive functions and with them the ability to express valid consent, the diagnosis of Alzheimer's disease or dementia does not in itself lead to the loss of this ability. The legal capacity and the capacity to act remain, unless proven otherwise, from the age of majority until the death of the person. Only a judicial

measure can protect the person with dementia who is unable to provide informed consent by appointing a legal representative.

The person with dementia can maintain decision-making skills about some or many aspects of their life and health for a long time.

From a neuropsychological point of view, the impairment of executive functions (abstraction ability, problem solving, judgment and criticism, planning, farsightedness, 'decision making' ...) is directly proportional to the decrease in capacity both in a general sense that in the various fields: health and economic decisions, driving skills, etc. However, these cognitive functions can be spared in the early stages of the disorder (MMSE> 19), unlike others that are affected early, such as memory and orientation.

It is also common clinical experience that, even if unable to understand the contents of a standard "informed consent" form (which must certainly be simplified), the person with dementia is often able to express his/her choices in line with his lifestyle, preferences and values. This underlines the importance of preserving the possibility for potential participants to use their skills to share possible choices.

Informed consent is a legal condition in which a person accepts an action that is proposed to him/her (in our case, active participation in the feasibility study). To be "informed", consent must be based on a full understanding of the action itself and the implications it can bring. This implies that:

every effort must be made to guarantee and respect any residual capacity for autonomous decision, considering consent as an instrument through which the subject realizes his autonomy.

The autonomy of the subject requires that all information be understood the person's consent presupposes his/her ability to choose freely on the basis of his preferences, moral values, life stages and circumstances.

It is therefore necessary first of all to inform the person with dementia, adapting the information to the cognitive abilities of the same, making every effort so that the patient can directly or indirectly communicate his preferences. With this in mind, the opinion of family members, for example, may be requested, but considered secondary to that of the patient.

The person with dementia who gave his/her informed consent to participate and is not comfortable during the sessions may at any time withdraw from the trial without any consequences.

In the specific case of our study, neither serious harmful effects on the person with dementia are foreseeable nor is there bad faith in our treatment proposal. On the contrary, literature studies demonstrate the potential benefits of the proposed intervention.

With this in mind, we proceed to ask the person with dementia to provide their informed consent to participate and we strive to:

- ensure that he/she clearly understands the content of the information sheet and the consequences of his/her participation;
- create the best conditions in which he/her can ask questions and express his/her will;
- monitor throughout the course of the trial the persistence of his/her willingness to participate.

During the clinical interview, the contextual assessment of the ability to express an autonomous choice will be carried out, assessing the presence of:

- Ability to express a choice;
- Ability to understand information relating to consent;
- Ability to give due weight to the situation and its possible consequences;
- Ability to use information rationally.

In the event that this evaluation gives a positive result, informed consent will be acquired from the person him/herself. Time and effort will be devoted to providing correct and full information, the information sheets and the consent form will be read together with the person with dementia and their caregiver, the opportunity to ask questions will be given and the best conditions will be created to make a decision. An additional opinion will be requested from the main and reference caregiver on whether or not the person with dementia should participate in the project, what his/her wishes and feelings about participation may not have been expressed. If the subject then shows signs of dissent before and during each training session or shows behaviours that suggest that he/she is no longer willing to participate, the sessions will be terminated and the consent will be automatically withdrawn.

For people unable to express valid consent, on the other hand, European Regulation 536/2014 identify in the figure of the legally designated representative (support administrator) the person who must be involved in the information process and from whom informed consent must be obtained. Even in this case, however, the will of the person directly concerned to participate in the "double consent" mode will be tested.

The equipment needs electric power. However, the tablet and the mobile router are rechargeable and low power consumption. The user will be informed on how much electric power is supposed to be consumed and how much it will cost to him/her. No refund to the end user is planned.

5 Management activities & Code of conduct

5.1 Contact with end users along the experimentation

In order to create a safe and inclusive environment for all end users (including control group), they will be allowed to contact the researcher in any moment for asking information and/or assistance. They will be treated fairly, fully informed about the reasons why questionnaires are asked and the purpose of the research, and updated about the ongoing of the project.

At this purpose, the researcher will be in contact daily with the participants. Even if this risk of technology dependency is present, however, technology has not yet achieved the level of sophistication required for natural human-robot interaction. At the moment, in fact, there is limited progress in the development of social robots capable of minimal and limited social interaction involving emotional, and psychological engagement with users under controlled conditions. Nevertheless, adjustments required to use safely social robots in emotional, social and psychological terms avoiding future addition towards them should be applied, as the provision of adequate training and daily support/monitoring of the researcher.

Finally, if after the experimentation, the participants would ask for a longer use of the system, they will be asked to be involved in similar studies to assure the continuity of use of the technology. Moreover, after the end of the study, the opportunity of receiving a personalized support on everyday technology will be offered to the participants, about eHealth literacy and similar solutions for health.

5.2 Technical support and assistance

Each pilot site will guarantee the technical support on site. The technical support can be delivered in the following ways, depending on the nature of the issue:

- Remote support (phone calls, video-calls);
- On-site support when remote support is not successful.

In case end user partners cannot solve the issue, they can ask technical partners for support. On this purpose, a WhatsApp group with both end user and technical partner members will be created to quickly tackle the problem, as well as increasing knowledge on risks, issues, and solutions among all the partners.

Any participant will receive a handbook with instructions on how to use the system and to tackle recurring issues.

5.3 Risk-benefit analysis and exit strategy

This study poses little risk to participants however, there are some risks. There is a risk that the elderly person may wish to stop interacting with the technological devices (for example because they do not like the robot). In this case the experiment will be immediately stopped and terminated.

To protect the safety of participants:

- Participants will be informed about the appropriate use of the devices (especially the social robot);
- The researcher will train the participant in the use of the devices and be available in case of problems;

- The technological devices (tablet and mobile connection) will be placed in the participant's home in a configuration that allows them to be used safely.

In the event of adverse events occurring despite the precautions described above (section 5.2):

- Participants will be instructed to press the "off" button on the device or to disconnect it according to the instructions in the user manual;
- Participants will call the researcher, who will assist the participant in case of problems.
- Participants will be able to call the researcher, who will come and ensure that no damage has been caused to the participants or to any other person.

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Annex 1 – Informed consent

Information form for participants

Dear Sir/Madam,

This document gives you information about the study "Field trial of engAGE platform", which is part of a European research project. Before the study begins, it is important that you learn about the procedure followed in this study and that you give your informed consent for voluntary participation. Please read this document carefully.

About this study

engAGE is a 30-month long Active and Assisted Living (AAL) research project that aims to design, develop and evaluate a platform to support/intended to support seniors diagnosed with Mild Cognitive Impairment, in order to counteract their cognitive decline. The platform is composed of three main devices: the social robot Pepper, the tablet, and the activity tracker. You will use the Pepper at homecare organization, supported by professionals, whereas the tablet is intended to be used at your own home. Both the social robot and the applications on the tablet can provide support to the traditional care through cognitive and physical games, drama play (only the robot), as well as reminding daily activities. Furthermore, the platform can offer monitoring health and well-being and aspects of their daily lives. The informal caregiver can set up the engAGE app settings in order to customize it according the senior's needs and preferences.

Several European partners are involved in this project: Technological University of Cluj-Napoca (Romania), Iris robotics (Romania), INRCA (Italy), Tellu (Norway), Karde (Norway), and the Department of Medical Information Sciences of the University Hospitals of Geneva (Switzerland).

Aim and benefit of the study

The aim of this study is to evaluate the functioning of the engAGE platform, consisting of a social robot, a mobile application, and an activity tracker in a real-life setting, including homecare organization and senior's home. This information is used to further develop the engAGE platform and to find out what the impact of such a system might be on older people with mild cognitive impairment. This study is performed by [end user partner name]. [NAME RESEARCHER], a [JOB TITLE, OR: student under the supervision of NAME SUPERVISOR] of the [unit name].

Participants

In order to evaluate the current prototype of engAGE, we are looking for seniors who are diagnosed with mild cognitive impairment, would be willing to use the engAGE platform in a healthcare organization and in their homes together with their (in)formal carer. The aim is to use the platform in a triad (senior, informal carer, formal carer).

Procedure

If you are willing to participate in this study you are able to test the engAGE platform for six months. This means we will ask the senior to use the robot twice a week at healthcare organization and the tablet application twice a week at home. In the meanwhile, the senior should be always the activity

tracker. For this time period, a formal caregiver will lead the intervention at the healthcare organization, whereas an informal caregiver will be asked to follow and support the use of the platform at home. Additionally, the research will consist of the following sessions:

1. Training & Equipment session at senior's home (2 hours)

We will install the engAGE app, the activity tracker, and a mobile connection. Together we will set up the system and will show you how to use the system.

2. Weekly follow-up call (about 15 min)

We will contact each participant weekly for a short interview. This call will give you the opportunity to share any problems you encountered.

3. Mid-term evaluation (about 1 hour)

We will contact you after three months of use to ask several questions and questionnaires about the use of the platform.

4. Debriefing session at senior's home (2 hours)

Once the testing period is over, the senior, formal and informal carer are invited for a general assessment of their user experience. During this session we will uninstall the engAGE platform and ask you to answer several questions and questionnaires.

During the interviews audio recordings are made that could identify you. They will not be distributed and will not be played back in the presence of persons other than the researchers. The material will be used only for scientific analysis, and deleted after transcribing the data

Risks

The study does not involve any risks, detrimental side effects, or cause discomfort. It will mainly take up some of your time, because it is necessary to answer several questions and questionnaires. The instructions, measurements and debriefing will take approximately 5-6 hours.

Voluntary

Your participation is completely voluntary. You can refuse to participate without giving any reasons and you can stop your participation at any time during the study. You can also withdraw your permission to use your data up to 24 hours after they were recorded [OR WHEN NO PERSONAL INFORMATION IS STORED AND YOU CAN ONLY IDENTIFY A PARTICIPANT BASED ON THE ENTRY IN A DATAFILE: You can also withdraw your permission to use your data immediately after completing the study]. None of this will have any negative consequences for you whatsoever.

Confidentiality and use, storage, and sharing of data

All research conducted at the [research team/pilot site] adheres to the [ethics law], and this study has been approved by the [ethical committee].

In this study personal data such as your age, gender, educational level, living situation ([FOR EXAMPLE YOUR AGE, GENDER, AND PARTICIPANT DATABASE ID - ADD VARIABLES AS APPLICABLE]) and experimental data ([FOR EXAMPLE YOUR RESPONSES TO QUESTIONNAIRES, AND RESPONSE TIMES - ADD VARIABLES AS APPLICABLE]) will be recorded, analyzed, and stored. The goal of collecting, analyzing, and storing this data is to answer the research question and publish the results in the

scientific literature. To protect your privacy, all data that can be used to personally identify you will be stored on an encrypted server of the [research team/institute] for at least 10 years that is only accessible by selected staff members. No information that can be used to personally identify you will be shared with others.

The data collected in this study might also be of relevance for future research projects within the [institute or research team OR FOR OPEN ACCESS: as well as for other researchers]. The aim of those studies might be unrelated to the goals of this study.

The collected data will therefore also be made available to the general public.] [OR: authorized researchers from other institutions, but not the general public OR OTHER IF APPLICABLE] in an online data repository [OR: in an online data repository with restricted access OR OTHER IF APPLICABLE]. The coded data collected in this study and that will be released to the public will (to the best of our knowledge and ability) not contain information that can identify you. It will include all answers you provide during the study, including demographic variables (e.g., age and gender) if you choose to provide these during the study. [OR: The data shared online will not contain demographic variables, and we will also remove all open text questions OR OTHER IF APPLICABLE].

At the bottom of this consent form, you can indicate whether or not you agree with the use of your data for future research within the [research institute] [FOR OPEN ACCESS: and the distribution of your data by means of a secured online data repository with open access for the general public. You are not obliged to letting us use and share your data. However, you must give your consent to share your data in this way in order to participate in this study. If you do not give your consent, you cannot participate in this study.] [OR: If you are not willing to share your data in this way, you can still participate in this study. Your data will be used in the scientific article but not shared with other researchers.]

[OR: We will not share personal information about you or your responses in this study with anyone outside of the research team. Only the researchers will know your identity and responses and we will store that information in an encrypted and password protected database.]

Further information

If you want more information about this study, the study design, or the results, you can contact

RESEARCHER NAME (contact email: XXXXXXX@XXX.XX) (mobile/phone: XXXXXXXXXXX)

If you have any complaints about this study, please contact the supervisor, [NAME SUPERVISOR] ([EMAIL ADDRESS SUPERVISOR]). You can report irregularities related to XXXXXXX.

Informed consent form

Evaluation of the engAGE platform

I have read and understood the information of the corresponding information form for participants.

I have been given the opportunity to ask questions. My questions are sufficiently answered, and I had sufficient time to decide whether I participate.

I know that my participation is completely voluntary. I know that I can refuse to participate and that I can stop my participation at any time during the study, without giving any reasons. I know that I can withdraw permission to use my data up to 24 hours after the data have been recorded.

I agree to voluntarily participate in this study carried out by [name of the institute].

I know that no information that can be used to personally identify me or my responses in this study will be shared with anyone outside of the research team.

I □ do □ do not

give permission to make my anonymized recorded data available to others in a public online data repository, and allow others to use this data for future research projects unrelated to this study.

Certificate of consent

I, _____ born on ____/___/_____ in _____ and living in _____ address _____ want and provide consent to participate in this study.

Date: ___/____/_____

Participant's Signature:

_____

Annex 2 – Lab testing protocols

SENIOR

RECRUITMENT PROTOCOL

Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

SOCIO-DEMOGRAPHIC QUESTIONNAIRE

Date of birth (dd /mm /yyyy) _____/_____/_____

1. **Gender:** □ male □ female □ diverse

2. **Residence:** □ City □ Suburban □ Rural community

3. **Housing situation:** □ Alone □ Shared apartment

   □ With (marriage) partner □ Family □ Other: _____

4. **Marital status:** □ Single □ widowed

   □ married / registered civil partnership □ divorced □ solid partnership

5. **Do you have children?** □ no □ yes → *if yes, how much:* _____

6. **Do you have grandchildren?** □ no □ yes → *if yes, how much:* _____

7. **Highest level of education:** □ No school degree □ High school

□ Secondary school □ Specialized baccalaureate □ Junior high school

□ University degree □ Other: _____

8. **Are you currently employed?** □ no □ yes → *if yes, please mark where applicable:* □ Full-Time □ Part-Time □ Minijob
9. **Are you currently retired?** □ no □ yes → *if yes, since when:*_____ (Year)
10. **Which of the following devices do you use frequently** (more than once a week)? (multiple answers possible) ☐ Computer ☐ Tablet ☐ Smartphone ☐ None
11. **How would you rate your experience using these devices** (e.g., video calling, emailing, WhatsApp) **on a scale of 1 (no experience) to 5 (a lot of experience)?** ☐ Very little experience ☐ Little experience ☐ Not a little/not a lot ☐ Somewhat ☐ Very much

SYSTEM USABILITY SCALE (SUS)

	Strongly disagree → Strongly agree				
1. I think that I would like to use this system frequently	☐	☐	☐	☐	☐
2. I found the system to be simple	☐	☐	☐	☐	☐
3. I thought the system was easy to use	☐	☐	☐	☐	☐
4. I think that I could use the system without the support of a technical person	☐	☐	☐	☐	☐
5. I found the various functions in the system were well integrated	☐	☐	☐	☐	☐
6. I thought there was a lot of consistency in the system	☐	☐	☐	☐	☐
7. I would imagine that most people would learn to use the system very quickly	☐	☐	☐	☐	☐
8. I found the system very intuitive	☐	☐	☐	☐	☐
9. I felt very confident using the system	☐	☐	☐	☐	☐
10. I could use the system without having to learn anything new	☐	☐	☐	☐	☐

SEMI-STRUCTURED QUESTIONNAIRE

USABILITY	

Did you find the system easy to use? If not, what could make it easier?	
How long did it take you to be able to use the system independently?	
Do you think it is necessary to have technological skills to be able to use the system to its fullest?	
Was it easy to perform the proposed exercises and activities?	
Was the information and commands needed to perform the activities easy to understand?	
Did you encounter problems while using it? What did you do? If the same problem recurred, would you be able to solve it on your own?	
What were the activities/features that you preferred? And those that you did not like?	
Could the system be improved? In what ways?	

ACCEPTANCE	
Did you enjoy using the system or did you perceive it as an obligation?	
Did you feel safe using the system?	
Does the product exactly match your needs? If not, what would you like to see added?	
Do you have concerns about privacy and the use of your data and personal information?	
What were the activities/features that you preferred? And those that you did not like?	

Do you think that continued use over time will benefit you in any way?	
Do you think there are any risks or negative effects of using the system that we have not discussed?	

WILLINGNESS TO PAY	
If the system will be launched, how should it be financed?	
How much would you pay the engAGE service per month?	
Do you think that such kind of service should be provided/payed by healthcare insurance or national healthcare system?	

Annex 3 – Field trial protocols

SENIOR WITH MILD COGNITIVE IMPAIRMENT

RECRUITMENT PROTOCOL

Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

SOCIO-DEMOGRAPHIC QUESTIONNAIRE

Date of birth (dd /mm /yyyy) _____/_____/_____

12. **Gender:** □ male □ female □ diverse

13. **Residence:** □ City □ Suburban □ Rural community

14. **Housing situation:** □ Alone □ Shared apartment

□ With (marriage) partner □ Family □ Other: _____

15. **Marital status:** □ Single □ widowed

□ married / registered civil partnership □ divorced □ solid partnership

16. **Do you have children?** □ no □ yes → *if yes, how much:* _____

17. **Do you have grandchildren?** □ no □ yes → *if yes, how much:* _____

18. **Highest level of education:** □ No school degree □ High school

□ Secondary school □ Specialized baccalaureate □ Junior high school

□ University degree □ Other: _____

19. **Are you currently employed?** □ no □ yes → *if yes, please mark where applicable:* □ Full-Time □ Part-Time □ Minijob
20. **Are you currently retired?** □ no □ yes → *if yes, since when:*_____ (Year)
21. **Which of the following devices do you use frequently** (more than once a week)? (multiple answers possible) ☐ Computer ☐ Tablet ☐ Smartphone ☐ None
22. **How would you rate your experience using these devices** (e.g., video calling, emailing, WhatsApp) **on a scale of 1 (no experience) to 5 (a lot of experience)?** ☐ Very little experience ☐ Little experience ☐ Not a little/not a lot ☐ Somewhat ☐ Very much
23. **No acute or untreated medical problems; severe autonomic system dysfunction; severe behavioral syndromes not compensated by medication; concomitant neurological diseases; severe systemic diseases with life expectancy < 1 year; diagnosed dementia or other neurodegenerative diseases; diagnosed psychiatric diseases** □ no □ yes

Clinical Frailty Scale score: ___

MOCA score: ___

GDS score: ___

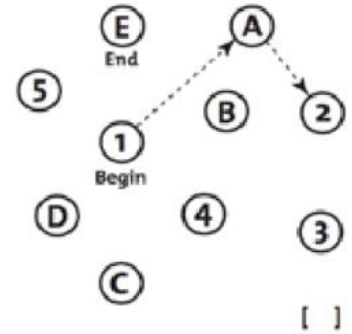
MAC-Q score : _____

MONTREAL COGNITIVE ASSESSMENT (MOCA)

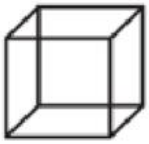
MONTREAL COGNITIVE ASSESSMENT (MOCA)

NAME :
Education : Date of birth :
Sex : DATE :

VISUOSPATIAL / EXECUTIVE — POINTS



Copy cube



[ ] [ ]

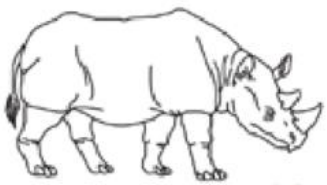
Draw CLOCK (Ten past eleven) (3 points)

[ ] Contour [ ] Numbers [ ] Hands

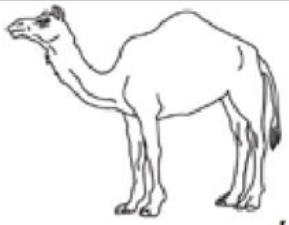
__/5

NAMING

[ ]



[ ]



[ ]

__/3

MEMORY — Read list of words, subject must repeat them. Do 2 trials. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

ATTENTION — Read list of digits (1 digit/ sec.).

Subject has to repeat them in the forward order [ ] 2 1 8 5 4

Subject has to repeat them in the backward order [ ] 7 4 2

__/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

__/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65

4 or 5 correct subtractions: 3 pts, 2 or 3 correct: 2 pts, 1 correct: 1 pt, 0 correct: 0 pt

__/3

LANGUAGE — Repeat : I only know that John is the one to help today. [ ]

The cat always hid under the couch when dogs were in the room. [ ]

__/2

Fluency / Name maximum number of words in one minute that begin with the letter F [ ] ____ (N ≥ 11 words)

__/1

ABSTRACTION — Similarity between e.g. banana - orange = fruit [ ] train – bicycle [ ] watch - ruler

__/2

DELAYED RECALL

	Has to recall words WITH NO CUE	FACE	VELVET	CHURCH	DAISY	RED	Points for UNCUED recall only
		[ ]	[ ]	[ ]	[ ]	[ ]	
Optional	Category cue						
	Multiple choice cue						

__/5

ORIENTATION [ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

__/6

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www.mocatest.org

Normal ≥ 26 / 30

TOTAL __/30

Add 1 point if ≤ 12 yr edu

REISEBERG SCALE

Level	Clinical characteristics
1 No cognitive decline	No subjective complaints of memory deficit. No memory deficit evident on clinical interview.
2 Very mild cognitive decline (Age Associated Memory Impairment)	Subjective complaints of memory deficit, most frequently in following areas: (a) forgetting where one has placed familiar objects; (b) forgetting names one formerly knew well. No objective evidence of memory deficit on clinical interview. No objective deficits in employment or social situations. Appropriate concern with respect to symptomatology.
3 Mild cognitive decline (Mild Cognitive Impairment)	Earliest clear-cut deficits. Manifestations in more than one of the following areas: (a) patient may have gotten lost when traveling to an unfamiliar location; (b) coworkers become aware of patient's relatively poor performance; (c) word and name finding deficit becomes evident to intimates; (d) patient may read a passage or a book and retain relatively little material; (e) patient may demonstrate decreased facility in remembering names upon introduction to new people; (f) patient may have lost or misplaced an object of value; (g) concentration deficit may be evident on clinical testing. Objective evidence of memory deficit obtained only with an intensive interview. Decreased performance in demanding employment and social settings. Denial begins to become manifest in patient. Mild to moderate anxiety accompanies symptoms.
4 Moderate cognitive decline (Mild Dementia)	Clear-cut deficit on careful clinical interview. Deficit manifest in following areas: (a) decreased knowledge of current and recent events; (b) may exhibit some deficit in memory of ones personal history; (c) concentration deficit elicited on serial subtractions; (d) decreased ability to travel, handle finances, etc. Frequently no deficit in following areas: (a) orientation to time and place; (b) recognition of familiar persons and faces; (c) ability to travel to familiar locations. Inability to perform complex tasks. Denial is dominant defense mechanism. Flattening of affect and withdrawal from challenging situations frequently occur.
5 Moderately severe cognitive decline (Moderate Dementia)	Patient can no longer survive without some assistance. Patient is unable during interview to recall a major relevant aspect of their current lives, e.g., an address or telephone number of many years, the names of close family members (such as grandchildren), the name of the high school or college from which they graduated. Frequently some disorientation to time (date, day of week, season, etc.) or to place. An educated person may have difficulty counting back from 40 by 4s or from 20 by 2s. Persons at this stage retain knowledge of many major facts regarding themselves and others. They invariably know their own names and generally know their spouses' and children's names. They require no assistance with toileting and eating, but may have some difficulty choosing the proper clothing to wear.

6 Severe cognitive decline (Moderately Severe Dementia)	May occasionally forget the name of the spouse upon whom they are entirely dependent for survival. Will be largely unaware of all recent events and experiences in their lives. Retain some knowledge of their past lives but this is very sketchy. Generally unaware of their surroundings, the year, the season, etc. May have difficulty counting from 10, both backward and, sometimes, forward. Will require some assistance with activities of daily living, e.g., may become incontinent, will require travel assistance but occasionally will be able to travel to familiar locations. Diurnal rhythm frequently disturbed. Almost always recall their own name. Frequently continue to be able to distinguish familiar from unfamiliar persons in their environment. Personality and emotional changes occur. These are quite variable and include: (a) delusional behavior, e.g., patients may accuse their spouse of being an impostor, may talk to imaginary figures in the environment, or to their own reflection in the mirror; (b) obsessive symptoms, e.g., person may continually repeat simple cleaning activities; (c) anxiety symptoms, agitation, and even previously nonexistent violent behavior may occur; (d) cognitive abulla, i.e., loss of willpower because an individual cannot carry a thought long enough to determine a purposeful course of action.
7 Very severe cognitive decline (Severe Dementia)	All verbal abilities are lost over the course of this stage. Frequently there is no speech at all -only unintelligible utterances and rare emergence of seemingly forgotten words and phrases. Incontinent of urine, requires assistance toileting and feeding. Basic psychomotor skills, e.g., ability to walk, are lost with the progression of this stage. The brain appears to no longer be able to tell the body what to do. Generalized rigidity and developmental neurologic reflexes are frequently present.

4-ITEMS GERIATRIC DEPRESSION SCALE (GDS)

Geriatric Depression Scale (GDS-4)

Questions	Circle One answer		Score
Are you basically satisfied with your life?	**yes**	**NO**	
Do you feel that your life is empty?	**YES**	**no**	
Are you afraid that something bad is going to happen to you?	**YES**	**no**	
Do you feel happy most of the time?	**yes**	**NO**	
Total			

Geriatric Depression Scale (GDS-4)

The 4 item Geriatric Depression Scale is easy and quick to perform with a high sensitivity and specificity.

GDS-4 is of limited clinical value in monitoring the severity of the depressive episode but more useful in excluding depression.
If depression is indicated then use the GDS-15 scale.

Care must be taken as dementia and depression often co-exist.

To Score: If answer chosen is in CAPITALS then give 1 mark otherwise 0

Results:
0 = Not Depressed
1 = Uncertain
2 to 4 = Depressed

MEMORY ASSESSMENT CLINICS-QUESTIONNAIRE (MAC-Q)

As compared to when you were in high school or college, how would you describe your ability to perform the following tasks involving your memory?

Activities	Much better now	Somewhat better now	About the same	Somewhat poorer now	Much poorer now
Remembering the name of a person just introduced to you	1	2	3	4	5
Recalling telephone numbers or zip codes that you use on a daily or weekly basis	1	2	3	4	5
Recalling where you put objects (such as keys) in your home or office	1	2	3	4	5
Remembering specific facts from a newspaper or magazine article you have just finished reading	1	2	3	4	5
Remembering the item(s) you intend to buy when you arrive at the grocery store or pharmacy	1	2	3	4	5
In general, how would you describe your memory compared to the past?	2	4	6	8	10
Total score					

CLINICAL FRAILTY TEST

1		**Very Fit** - People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.
2		**Well** - People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally.
3		**Managing Well** - People whose medical problems are well controlled, but are not regularly active beyond routine walking.
4		**Vulnerable** - While not dependent on others for daily help, often symptoms limit activities. A common complaint is being "slowed up", and/or being tired during the day.
5		**Mildly Frail** - These people often have more evident slowing, and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and house work.
6		**Moderately Frail** - People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.
7		**Severely Frail** - Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).
8		**Very Severely Frail** - Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.
9		**Terminally Ill** - Approaching the end of life. This category applies to people with a life expectancy < 6 months, who are not otherwise evidently frail.

Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

UCLA SCALE

Statement	Never	Rarely	Sometimes	Often
I feel in tune with the people around me[a]	1	2	3	4
I lack companionship	1	2	3	4
There is no one I can turn to	1	2	3	4
I do not feel alone[a]	1	2	3	4
I feel part of a group of friends[a]	1	2	3	4
I have a lot in common with the people around me[a]	1	2	3	4
I am no longer close to anyone	1	2	3	4
My interests and ideas are not shared by those around me	1	2	3	4
I am an outgoing person[a]	1	2	3	4
There are people I feel close to[a]	1	2	3	4
I feel left out	1	2	3	4
My social relationships are superficial	1	2	3	4
No one really knows me well	1	2	3	4
I feel isolated from others	1	2	3	4
I can find companionship when I want it[a]	1	2	3	4
There are people who really understand me[a]	1	2	3	4
I am unhappy being so withdrawn	1	2	3	4
People are around me but not with me	1	2	3	4
There are people I can talk to[a]	1	2	3	4
There are people I can turn to[a]	1	2	3	4

. The total score is the sum of all 20 items.
m should be reversed (i.e., 1 = 4, 2 = 3, 3 = 2, 4 = 1) before scoring

WARWICK-EDINBURH MENTAL WELLBEING SCALE (WEMWBS)

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
1. I've been feeling optimistic about the future	1	2	3	4	5
2. I've been feeling useful	1	2	3	4	5
3. I've been feeling relaxed	1	2	3	4	5
4. I've been feeling interested in other people	1	2	3	4	5
5. I've had energy to spare	1	2	3	4	5
6. I've been dealing with problems well	1	2	3	4	5
7. I've been thinking clearly	1	2	3	4	5
8. I've been feeling good about myself	1	2	3	4	5
9. I've been feeling close to other people	1	2	3	4	5
10. I've been feeling confident	1	2	3	4	5
11. I've been able to make up my own mind about things	1	2	3	4	5
12. I've been feeling loved	1	2	3	4	5
13. I've been interested in new things	1	2	3	4	5
14. I've been feeling cheerful	1	2	3	4	5

Below are some statements about feelings and thoughts. Please tick the box that best describes your experience of each over the last 2 weeks.

EQ-5D-5L

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

- I have no problems in walking about ❑
- I have slight problems in walking about ❑
- I have moderate problems in walking about ❑
- I have severe problems in walking about ❑
- I am unable to walk about ❑

SELF-CARE

- I have no problems washing or dressing myself ❑
- I have slight problems washing or dressing myself ❑
- I have moderate problems washing or dressing myself ❑
- I have severe problems washing or dressing myself ❑
- I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

- I have no problems doing my usual activities ❑
- I have slight problems doing my usual activities ❑
- I have moderate problems doing my usual activities ❑
- I have severe problems doing my usual activities ❑
- I am unable to do my usual activities ❑

PAIN / DISCOMFORT

- I have no pain or discomfort ❑
- I have slight pain or discomfort ❑
- I have moderate pain or discomfort ❑
- I have severe pain or discomfort ❑
- I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

- I am not anxious or depressed ❑
- I am slightly anxious or depressed ❑
- I am moderately anxious or depressed ❑
- I am severely anxious or depressed ❑
- I am extremely anxious or depressed ❑

QUALITY OF LIFE – ALZHEIMER'S DISEASE (QOL-AD)

T2 – AFTER SIX MONTHS

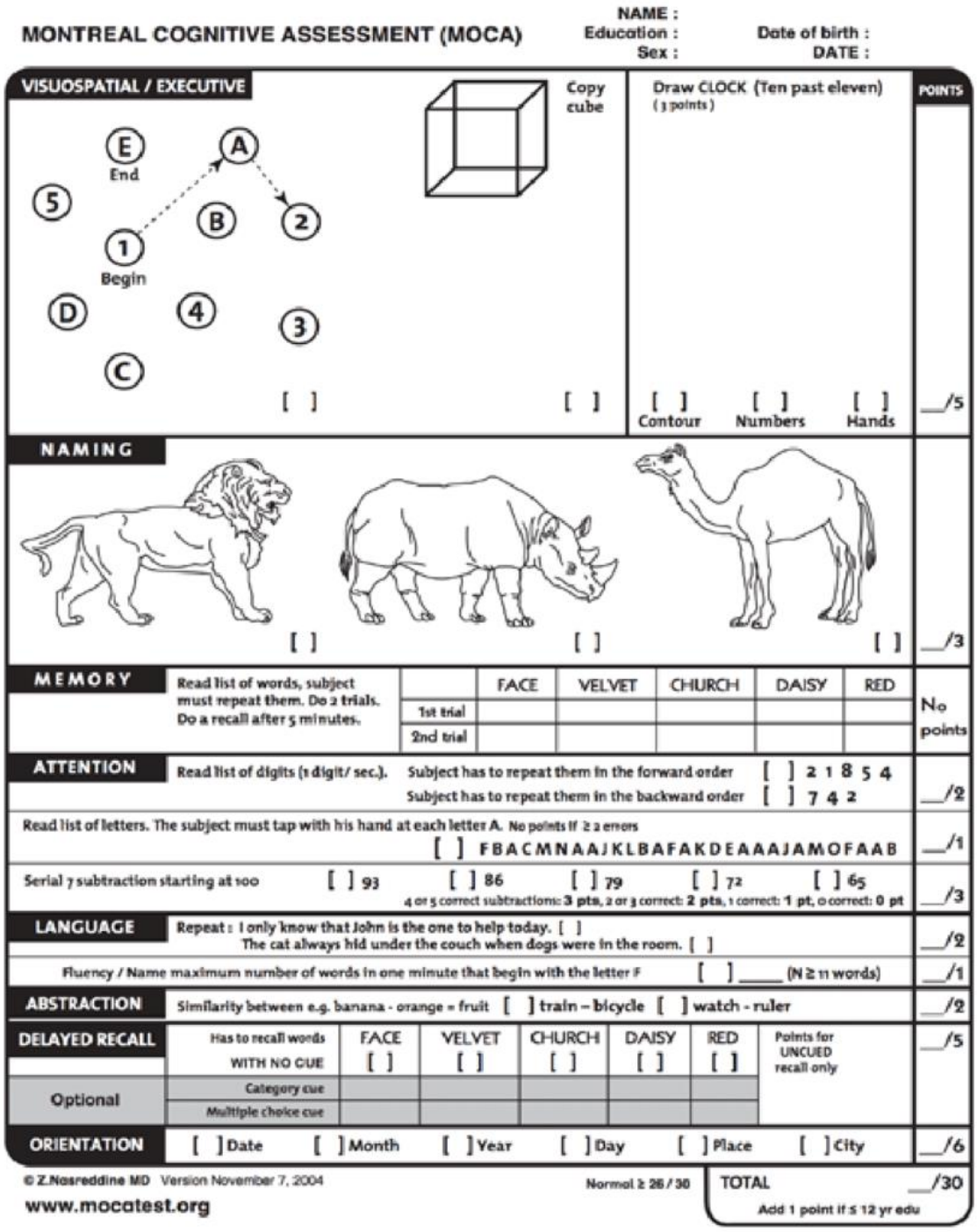
Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

MONTREAL COGNITIVE ASSESSMENT (MOCA)



MONTREAL COGNITIVE ASSESSMENT (MOCA)

NAME :
Education :
Sex :
Date of birth :
DATE :

VISUOSPATIAL / EXECUTIVE

Copy cube

Draw CLOCK (Ten past eleven) (3 points)

POINTS

E End, A, 5, B, 2, 1 Begin, D, 4, 3, C

[ ] [ ]

[ ] Contour [ ] Numbers [ ] Hands

__/5

NAMING

[ ] [ ] [ ]

__/3

MEMORY

Read list of words, subject must repeat them. Do 2 trials. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

ATTENTION

Read list of digits (1 digit/ sec.). Subject has to repeat them in the forward order [ ] 2 1 8 5 4

Subject has to repeat them in the backward order [ ] 7 4 2

__/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

__/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65

4 or 5 correct subtractions: 3 pts, 2 or 3 correct: 2 pts, 1 correct: 1 pt, 0 correct: 0 pt

__/3

LANGUAGE

Repeat : I only know that John is the one to help today. [ ]

The cat always hid under the couch when dogs were in the room. [ ]

__/2

Fluency / Name maximum number of words in one minute that begin with the letter F [ ] ____ (N ≥ 11 words)

__/1

ABSTRACTION

Similarity between e.g. banana - orange = fruit [ ] train – bicycle [ ] watch - ruler

__/2

DELAYED RECALL

	Has to recall words WITH NO CUE	FACE	VELVET	CHURCH	DAISY	RED	Points for UNCUED recall only
		[ ]	[ ]	[ ]	[ ]	[ ]	
Optional	Category cue						
	Multiple choice cue						

__/5

ORIENTATION

[ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

__/6

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www.mocatest.org

Normal ≥ 26 / 30

TOTAL __/30

Add 1 point if ≤ 12 yr edu

MEMORY ASSESSMENT CLINICS-QUESTIONNAIRE (MAC-Q)

As compared to when you were in high school or college, how would you describe your ability to perform the following tasks involving your memory?

Activities	Much better now	Somewhat better now	About the same	Somewhat poorer now	Much poorer now
Remembering the name of a person just introduced to you	1	2	3	4	5
Recalling telephone numbers or zip codes that you use on a daily or weekly basis	1	2	3	4	5
Recalling where you put objects (such as keys) in your home or office	1	2	3	4	5
Remembering specific facts from a newspaper or magazine article you have just finished reading	1	2	3	4	5
Remembering the item(s) you intend to buy when you arrive at the grocery store or pharmacy	1	2	3	4	5
In general, how would you describe your memory compared to the past?	2	4	6	8	10
Total score					

UCLA SCALE

Statement	Never	Rarely	Sometimes	Often
I feel in tune with the people around me[a]	1	2	3	4
I lack companionship	1	2	3	4
There is no one I can turn to	1	2	3	4
I do not feel alone[a]	1	2	3	4
I feel part of a group of friends[a]	1	2	3	4
I have a lot in common with the people around me[a]	1	2	3	4
I am no longer close to anyone	1	2	3	4
My interests and ideas are not shared by those around me	1	2	3	4
I am an outgoing person[a]	1	2	3	4
There are people I feel close to[a]	1	2	3	4
I feel left out	1	2	3	4
My social relationships are superficial	1	2	3	4
No one really knows me well	1	2	3	4
I feel isolated from others	1	2	3	4
I can find companionship when I want it[a]	1	2	3	4
There are people who really understand me[a]	1	2	3	4
I am unhappy being so withdrawn	1	2	3	4
People are around me but not with me	1	2	3	4
There are people I can talk to[a]	1	2	3	4
There are people I can turn to[a]	1	2	3	4

. The total score is the sum of all 20 items.
m should be reversed (i.e., 1 = 4, 2 = 3, 3 = 2, 4 = 1) before scoring.

WARWICK-EDINBURH MENTAL WELLBEING SCALE (WEMWBS)

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
1. I've been feeling optimistic about the future	1	2	3	4	5
2. I've been feeling useful	1	2	3	4	5
3. I've been feeling relaxed	1	2	3	4	5
4. I've been feeling interested in other people	1	2	3	4	5
5. I've had energy to spare	1	2	3	4	5
6. I've been dealing with problems well	1	2	3	4	5
7. I've been thinking clearly	1	2	3	4	5
8. I've been feeling good about myself	1	2	3	4	5
9. I've been feeling close to other people	1	2	3	4	5
10. I've been feeling confident	1	2	3	4	5
11. I've been able to make up my own mind about things	1	2	3	4	5
12. I've been feeling loved	1	2	3	4	5
13. I've been interested in new things	1	2	3	4	5
14. I've been feeling cheerful	1	2	3	4	5

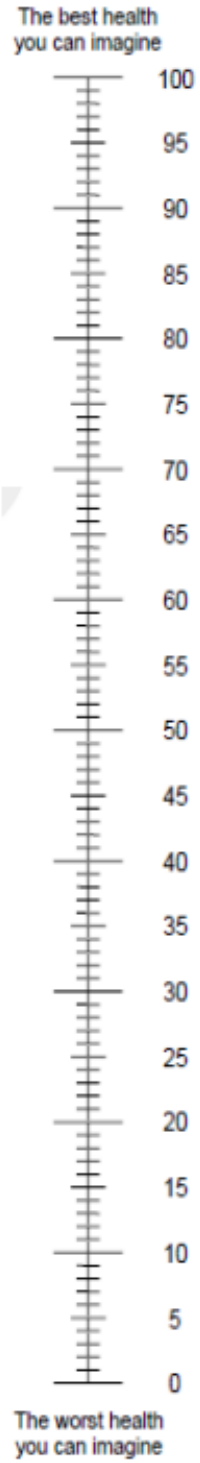
Below are some statements about feelings and thoughts. Please tick the box that best describes your experience of each over the last 2 weeks.
"Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS). ©NHS Health Scotland, University of Warwick and University of Edinburgh, 2006, all rights reserved."

EQ-5D-5L

Health Questionnaire (EQ-5D-5L)

- We would like to know how good or bad your health is **TODAY**.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is **TODAY**
- Now, please write the number you marked on the scale in the below.

YOUR HEALTH TODAY = ☐



SYSTEM USABILITY SCALE (SUS)

	Strongly disagree → Strongly agree				
1. I think that I would like to use this system frequently	☐	☐	☐	☐	☐
2. I found the system to be simple	☐	☐	☐	☐	☐
3. I thought the system was easy to use	☐	☐	☐	☐	☐
4. I think that I could use the system without the support of a technical person	☐	☐	☐	☐	☐
5. I found the various functions in the system were well integrated	☐	☐	☐	☐	☐
6. I thought there was a lot of consistency in the system	☐	☐	☐	☐	☐
7. I would imagine that most people would learn to use the system very quickly	☐	☐	☐	☐	☐
8. I found the system very intuitive	☐	☐	☐	☐	☐
9. I felt very confident using the system	☐	☐	☐	☐	☐
10. I could use the system without having to learn anything new	☐	☐	☐	☐	☐

UNIFIED THEORY ON ACCEPTANCE AND USABILITY OF TECHNOLOGY (UTAUT)

1. If I were to use the system, I would be afraid of making mistakes.
2. If I were to use the system, I would be afraid of breaking something.
3. The system scares me
4. The system frightens me
5. I think it is a good idea to use the system
6. Using the system would make my life more interesting.
7. It is good to use the system
8. I have everything I need to use the system correctly
9. I know enough about the system to be able to use it correctly
10. I think I will use the system in the next few days
11. I am certain that I will use the system in the next few days.
12. I am planning to use the system in the next few days.
13. I believe the system can accommodate my needs.
14. I believe the system will only do what I need it to do at the moment.
15. I believe the system will help me when I feel it is necessary.
16. I enjoy that the system communicates with me.
17. I enjoy performing operations with the system.

18. I think the system is fun.
19. I think the system is interesting.
20. I think the system is boring
21. I think I will learn to use the system quickly.
22. I think the system is easy to use.
23. I believe that I can use the system without help.
24. I think I could use the system with someone beside me.
25. I think I could use the system with a manual
26. I think the system is useful for me
27. It would be convenient for me to have the system
28. I believe the system can help me in many activities.
29. I think the staff would be happy if I use the system.
30. I think I would make a good impression if I were to use the system.
31. I think I would believe the system if it gave me a warning
32. I would follow the warnings the system would give me

SEMI-STRUCTURED QUESTIONNAIRE

USABILITY	
Did you find the system easy to use? If not, what could make it easier?	
How long did it take you to be able to use the system independently?	
Do you think it is necessary to have technological skills to be able to use the system to its fullest?	
Was it easy to perform the proposed exercises and activities?	
Was the information and commands needed to perform the activities easy to understand?	

Did you encounter problems while using it? What did you do? If the same problem recurred, would you be able to solve it on your own?	
What were the activities/features that you preferred? And those that you did not like?	
Could the system be improved? In what ways?	

ACCEPTANCE	
Did you enjoy using the system or did you perceive it as an obligation?	
Did you feel safe using the system?	
Does the product exactly match your needs? If not, what would you like to see added?	
Do you have concerns about privacy and the use of your data and personal information?	
What were the activities/features that you preferred? And those that you did not like?	
Do you think that continued use over time will benefit you in any way?	
Do you think there are any risks or negative effects of using the system that we have not discussed?	

WILLINGNESS TO PAY	

If the system will be launched, how should it be financed?	
How much would you pay the engAGE service per month?	
Do you think that such kind of service should be provided/payed by healthcare insurance or national healthcare system?	

FORMAL CAREGIVER

RECRUITMENT PROTOCOL

Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

SOCIO-DEMOGRAPHIC QUESTIONNAIRE

1. Date of birth _____/_____/_____
2. Sex M F
3. Please specify what is your marital status at present:

Married (living with the spouse/wife)
Full time relationship
Separated (married, but living separately)
Divorced
Single
Widowed
Don’t know
Refused

4. Can you indicate which of the following education level have you reached?

No education
Primary education
Secondary education
Tertiary education (university or further education level)
Don’t know
Refused

5. Total years of education _____
6. Please indicate your present working situation (multiple answers possible):

6.1 Retired	
6.2 Still working full time	
6.3 Still working part time	
6.4 Unemployed	
6.5 Work inside the home	
6.6 Don’t know	
6.7 Refused	

7. What are your personal income sources? (multiple answers possible)

7.1 Work	
7.2 Pension	
7.3 Unearned income	
7.4 Help from relatives	

7.5 Welfare state provision	
7.6 Other	
7.7 Don't know	
7.8 Refused	

8. If "other", please specify _____
9. Who lives in your home with you? (multiple answers possible)

Category	**Code**	**Number of…**
1. No one		N.A.
2. Spouse/partner		N.A.
3. Sons and daughters		
4. Grandchildren		
5. Children's spouses		
6. Brothers/Sisters		
7. Mother/Father		
8. Paid caregiver (not relative)		
9. Others		
10. Refused		N.A.

(Note for the interviewer: Sign the exact number of people that live with the elder _____)

If "other", please specify _____

10. Do you have more than 4 years of experience in assisting persons with dementia?

Please, specify how many years of experience you have? ___

Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

ZARIT BURDEN INTERVIEW

0: NEVER
1: RARELY
2: SOMETIMES
3: QUITE FREQUENTLY
4: NEARLY ALWAYS

Please circle the response the best describes how you feel.

Question	Score
1 Do you feel that your relative asks for more help than he/she needs?	0 1 2 3 4
2 Do you feel that because of the time you spend with your relative that you don't have enough time for yourself?	0 1 2 3 4
3 Do you feel stressed between caring for your relative and trying to meet other responsibilities for your family or work?	0 1 2 3 4
4 Do you feel embarrassed over your relative's behaviour?	0 1 2 3 4
5 Do you feel angry when you are around your relative?	0 1 2 3 4
6 Do you feel that your relative currently affects our relationships with other family members or friends in a negative way?	0 1 2 3 4
7 Are you afraid what the future holds for your relative?	0 1 2 3 4
8 Do you feel your relative is dependent on you?	0 1 2 3 4
9 Do you feel strained when you are around your relative?	0 1 2 3 4
10 Do you feel your health has suffered because of your involvement with your relative?	0 1 2 3 4
11 Do you feel that you don't have as much privacy as you would like because of your relative?	0 1 2 3 4
12 Do you feel that your social life has suffered because you are caring for your relative?	0 1 2 3 4

UCLA SCALE

Statement	Never	Rarely	Sometimes	Often
I feel in tune with the people around me[a]	1	2	3	4
I lack companionship	1	2	3	4
There is no one I can turn to	1	2	3	4
I do not feel alone[a]	1	2	3	4
I feel part of a group of friends[a]	1	2	3	4
I have a lot in common with the people around me[a]	1	2	3	4
I am no longer close to anyone	1	2	3	4
My interests and ideas are not shared by those around me	1	2	3	4
I am an outgoing person[a]	1	2	3	4
There are people I feel close to[a]	1	2	3	4
I feel left out	1	2	3	4
My social relationships are superficial	1	2	3	4
No one really knows me well	1	2	3	4
I feel isolated from others	1	2	3	4
I can find companionship when I want it[a]	1	2	3	4
There are people who really understand me[a]	1	2	3	4
I am unhappy being so withdrawn	1	2	3	4
People are around me but not with me	1	2	3	4
There are people I can talk to[a]	1	2	3	4
There are people I can turn to[a]	1	2	3	4

. The total score is the sum of all 20 items.
[illegible] should be reversed (i.e., 1 = 4, 2 = 3, 3 = 2, 4 = 1) before scoring.

WARWICK-EDINBURH MENTAL WELLBEING SCALE (WEMWBS)

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
1. I've been feeling optimistic about the future	1	2	3	4	5
2. I've been feeling useful	1	2	3	4	5
3. I've been feeling relaxed	1	2	3	4	5
4. I've been feeling interested in other people	1	2	3	4	5
5. I've had energy to spare	1	2	3	4	5
6. I've been dealing with problems well	1	2	3	4	5
7. I've been thinking clearly	1	2	3	4	5
8. I've been feeling good about myself	1	2	3	4	5
9. I've been feeling close to other people	1	2	3	4	5
10. I've been feeling confident	1	2	3	4	5
11. I've been able to make up my own mind about things	1	2	3	4	5
12. I've been feeling loved	1	2	3	4	5
13. I've been interested in new things	1	2	3	4	5
14. I've been feeling cheerful	1	2	3	4	5

Below are some statements about feelings and thoughts. Please tick the box that best describes your experience of each over the last 2 weeks.
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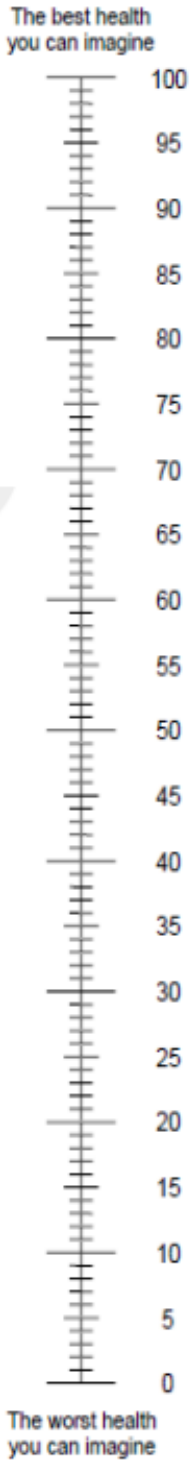
EQ-5D-5L - VAS

Health Questionnaire (EQ-5D-5L)

- We would like to know how good or bad your health is **TODAY**.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is **TODAY**
- Now, please write the number you marked on the scale in the below.

YOUR HEALTH TODAY = ☐



Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

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4 Do you feel embarrassed over your relative's behaviour?	0 1 2 3 4
5 Do you feel angry when you are around your relative?	0 1 2 3 4
6 Do you feel that your relative currently affects our relationships with other family members or friends in a negative way?	0 1 2 3 4
7 Are you afraid what the future holds for your relative?	0 1 2 3 4
8 Do you feel your relative is dependent on you?	0 1 2 3 4
9 Do you feel strained when you are around your relative?	0 1 2 3 4
10 Do you feel your health has suffered because of your involvement with your relative?	0 1 2 3 4
11 Do you feel that you don't have as much privacy as you would like because of your relative?	0 1 2 3 4
12 Do you feel that your social life has suffered because you are caring for your relative?	0 1 2 3 4

UCLA SCALE

Statement	Never	Rarely	Sometimes	Often
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I lack companionship	1	2	3	4
There is no one I can turn to	1	2	3	4
I do not feel alone[a]	1	2	3	4
I feel part of a group of friends[a]	1	2	3	4
I have a lot in common with the people around me[a]	1	2	3	4
I am no longer close to anyone	1	2	3	4
My interests and ideas are not shared by those around me	1	2	3	4
I am an outgoing person[a]	1	2	3	4
There are people I feel close to[a]	1	2	3	4
I feel left out	1	2	3	4
My social relationships are superficial	1	2	3	4
No one really knows me well	1	2	3	4
I feel isolated from others	1	2	3	4
I can find companionship when I want it[a]	1	2	3	4
There are people who really understand me[a]	1	2	3	4
I am unhappy being so withdrawn	1	2	3	4
People are around me but not with me	1	2	3	4
There are people I can talk to[a]	1	2	3	4
There are people I can turn to[a]	1	2	3	4

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[a] should be reversed (i.e., 1 = 4, 2 = 3, 3 = 2, 4 = 1) before scoring.

WARWICK-EDINBURH MENTAL WELLBEING SCALE (WEMWBS)

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
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3. I've been feeling relaxed	1	2	3	4	5
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5. I've had energy to spare	1	2	3	4	5
6. I've been dealing with problems well	1	2	3	4	5
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8. I've been feeling good about myself	1	2	3	4	5
9. I've been feeling close to other people	1	2	3	4	5
10. I've been feeling confident	1	2	3	4	5
11. I've been able to make up my own mind about things	1	2	3	4	5
12. I've been feeling loved	1	2	3	4	5
13. I've been interested in new things	1	2	3	4	5
14. I've been feeling cheerful	1	2	3	4	5

Below are some statements about feelings and thoughts. Please tick the box that best describes your experience of each over the last 2 weeks.
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SYSTEM USABILITY SCALE (SUS)

	Strongly disagree → Strongly agree				
1. I think that I would like to use this system frequently	☐	☐	☐	☐	☐
2. I found the system to be simple	☐	☐	☐	☐	☐
3. I thought the system was easy to use	☐	☐	☐	☐	☐
4. I think that I could use the system without the support of a technical person	☐	☐	☐	☐	☐
5. I found the various functions in the system were well integrated	☐	☐	☐	☐	☐
6. I thought there was a lot of consistency in the system	☐	☐	☐	☐	☐
7. I would imagine that most people would learn to use the system very quickly	☐	☐	☐	☐	☐
8. I found the system very intuitive	☐	☐	☐	☐	☐
9. I felt very confident using the system	☐	☐	☐	☐	☐
10. I could use the system without having to learn anything new	☐	☐	☐	☐	☐

SEMI-STRUCTURED QUESTIONNAIRE

ACCEPTANCE	
Did you feel safe using the system?	
Do you have any concerns about the senior's privacy?	
What activities/features did you find most useful? And those that you did not like? Do you miss anything?	
Do you think that constant and continued use will benefit your loved one/patient?	
Do you think there are any risks or negative effects of using the system that we have not discussed?	
Was it constraining to have to set up the activities for your loved one/patient?	

Do you think you can adapt the system well enough to fit the personal situation (wishes and needs) of the senior?	
USABILITY	
What is your impression of the system after using it for this period?	
Did you find the system easy to use? If not, what could make it easier?	
Describe your experience introducing the system to the senior: Did the senior had a lot of questions for you? What did you do to help?	
Was it easy to learn how to use the System?	
How long did it take you to fully understand the system?	
What actions did you have difficulty with? What took a lot of time to do?	
Was there a time when you got stuck in using it? Bugs in the system?	
How often did you check the dashboard? What did you look at? Was the information clear?	
Do you feel confident while using the system?	
Could the system be improved? In what ways?	

QUALITY OF WORK						
Read the following statements and ask participants to what extent they agree with them	1. Strongly disagree	2. Disagre	3. Neutral	3. Neutral	5. Strongly agree	Na
Using the system helps me keep track of my patient's cognitive health status	☐	☐	☐	☐	☐	☐
The system helps me to be more involved in my patient's care	☐	☐	☐	☐	☐	☐

The system can help me provide better care for my patient	☐	☐	☐	☐	☐	☐
Thanks to the system, I can reduce my workload while keeping quality intact	☐	☐	☐	☐	☐	☐

INFORMAL CAREGIVER

RECRUITMENT PROTOCOL

Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

SOCIO-DEMOGRAPHIC QUESTIONNAIRE

11. Date of birth _____/_____/_____
12. Sex M F
13. Please specify what is your marital status at present:

Married (living with the spouse/wife) Full time relationship

Separated (married, but living separately)
Divorced
Single
Widowed
Don’t know
Refused

14. Can you indicate which of the following education level have you reached?

No education
Primary education
Secondary education
Tertiary education (university or further education level)
Don’t know
Refused

15. Total years of education _____

16. Please indicate your present working situation (multiple answers possible):

6.1 Retired	
6.2 Still working full time	
6.3 Still working part time	
6.4 Unemployed	
6.5 Work inside the home	
6.6 Don’t know	
6.7 Refused	

17. What are your personal income sources? (multiple answers possible)

7.1 Work	
7.2 Pension	
7.3 Unearned income	
7.4 Help from relatives	
7.5 Welfare state provision	
7.6 Other	

7.7 Don't know	
7.8 Refused	

18. If "other", please specify _____

19. Who lives in your home with you? (multiple answers possible)

Category	**Code**	**Number of…**
1. No one		N.A.
2. Spouse/partner		N.A.
3. Sons and daughters		
4. Grandchildren		
5. Children's spouses		
6. Brothers/Sisters		
7. Mother/Father		
8. Paid caregiver (not relative)		
9. Others		
10. Refused		N.A.

(Note for the interviewer: Sign the exact number of people that live with the elder _____)

If "other", please specify _____

20. Do you have more than 4 years of experience in assisting persons with dementia?

Please, specify how many years of experience you have? ___

Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

ZARIT BURDEN INTERVIEW

0: NEVER
1: RARELY
2: SOMETIMES
3: QUITE FREQUENTLY
4: NEARLY ALWAYS

Please circle the response the best describes how you feel.

Question	Score
1 Do you feel that your relative asks for more help than he/she needs?	0 1 2 3 4
2 Do you feel that because of the time you spend with your relative that you don't have enough time for yourself?	0 1 2 3 4
3 Do you feel stressed between caring for your relative and trying to meet other responsibilities for your family or work?	0 1 2 3 4
4 Do you feel embarrassed over your relative's behaviour?	0 1 2 3 4
5 Do you feel angry when you are around your relative?	0 1 2 3 4
6 Do you feel that your relative currently affects our relationships with other family members or friends in a negative way?	0 1 2 3 4
7 Are you afraid what the future holds for your relative?	0 1 2 3 4
8 Do you feel your relative is dependent on you?	0 1 2 3 4
9 Do you feel strained when you are around your relative?	0 1 2 3 4
10 Do you feel your health has suffered because of your involvement with your relative?	0 1 2 3 4
11 Do you feel that you don't have as much privacy as you would like because of your relative?	0 1 2 3 4
12 Do you feel that your social life has suffered because you are caring for your relative?	0 1 2 3 4

UCLA SCALE

Statement	Never	Rarely	Sometimes	Often
I feel in tune with the people around me[a]	1	2	3	4
I lack companionship	1	2	3	4
There is no one I can turn to	1	2	3	4
I do not feel alone[a]	1	2	3	4
I feel part of a group of friends[a]	1	2	3	4
I have a lot in common with the people around me[a]	1	2	3	4
I am no longer close to anyone	1	2	3	4
My interests and ideas are not shared by those around me	1	2	3	4
I am an outgoing person[a]	1	2	3	4
There are people I feel close to[a]	1	2	3	4
I feel left out	1	2	3	4
My social relationships are superficial	1	2	3	4
No one really knows me well	1	2	3	4
I feel isolated from others	1	2	3	4
I can find companionship when I want it[a]	1	2	3	4
There are people who really understand me[a]	1	2	3	4
I am unhappy being so withdrawn	1	2	3	4
People are around me but not with me	1	2	3	4
There are people I can talk to[a]	1	2	3	4
There are people I can turn to[a]	1	2	3	4

. The total score is the sum of all 20 items.
n should be reversed (i.e., 1 = 4, 2 = 3, 3 = 2, 4 = 1) before scoring.

Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
1. I've been feeling optimistic about the future	1	2	3	4	5
2. I've been feeling useful	1	2	3	4	5
3. I've been feeling relaxed	1	2	3	4	5
4. I've been feeling interested in other people	1	2	3	4	5
5. I've had energy to spare	1	2	3	4	5
6. I've been dealing with problems well	1	2	3	4	5
7. I've been thinking clearly	1	2	3	4	5
8. I've been feeling good about myself	1	2	3	4	5
9. I've been feeling close to other people	1	2	3	4	5
10. I've been feeling confident	1	2	3	4	5
11. I've been able to make up my own mind about things	1	2	3	4	5
12. I've been feeling loved	1	2	3	4	5
13. I've been interested in new things	1	2	3	4	5
14. I've been feeling cheerful	1	2	3	4	5

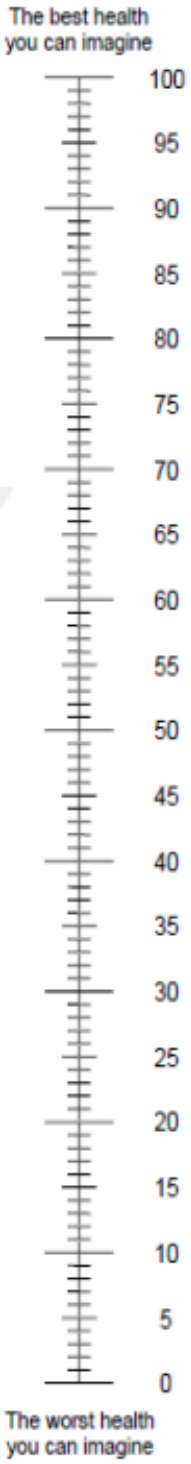
Below are some statements about feelings and thoughts. Please tick the box that best describes your experience of each over the last 2 weeks.
"Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS). ©NHS Health Scotland, University of Warwick and University of Edinburgh, 2006, all rights reserved."

EQ-5D-5L

Health Questionnaire (EQ-5D-5L)

- We would like to know how good or bad your health is **TODAY**.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is **TODAY**
- Now, please write the number you marked on the scale in the below.

YOUR HEALTH TODAY = ☐



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4 Do you feel embarrassed over your relative's behaviour?	0 1 2 3 4
5 Do you feel angry when you are around your relative?	0 1 2 3 4
6 Do you feel that your relative currently affects our relationships with other family members or friends in a negative way?	0 1 2 3 4
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8 Do you feel your relative is dependent on you?	0 1 2 3 4
9 Do you feel strained when you are around your relative?	0 1 2 3 4
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There are people I can talk to[a]	1	2	3	4
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. The total score is the sum of all 20 items.
[a] should be reversed (i.e., 1 = 4, 2 = 3, 3 = 2, 4 = 1) before scoring.

WARWICK-EDINBURGH MENTAL WELLBEING SCALE (WEMWBS)

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
1. I've been feeling optimistic about the future	1	2	3	4	5
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3. I've been feeling relaxed	1	2	3	4	5
4. I've been feeling interested in other people	1	2	3	4	5
5. I've had energy to spare	1	2	3	4	5
6. I've been dealing with problems well	1	2	3	4	5
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10. I've been feeling confident	1	2	3	4	5
11. I've been able to make up my own mind about things	1	2	3	4	5
12. I've been feeling loved	1	2	3	4	5
13. I've been interested in new things	1	2	3	4	5
14. I've been feeling cheerful	1	2	3	4	5

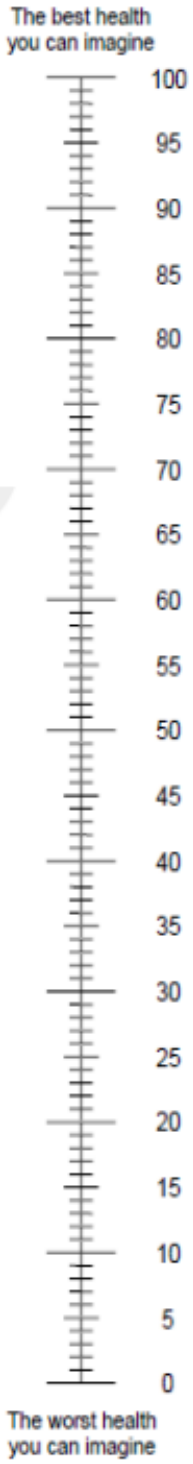
Below are some statements about feelings and thoughts. Please tick the box that best describes your experience of each over the last 2 weeks.
"Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS).

EQ-5D-5L

Health Questionnaire (EQ-5D-5L)

- We would like to know how good or bad your health is **TODAY**.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is **TODAY**
- Now, please write the number you marked on the scale in the below.

YOUR HEALTH TODAY = ☐



SYSTEM USABILITY SCALE (SUS)

	Strongly disagree → Strongly agree				
1. I think that I would like to use this system frequently	☐	☐	☐	☐	☐
2. I found the system to be simple	☐	☐	☐	☐	☐
3. I thought the system was easy to use	☐	☐	☐	☐	☐
4. I think that I could use the system without the support of a technical person	☐	☐	☐	☐	☐
5. I found the various functions in the system were well integrated	☐	☐	☐	☐	☐
6. I thought there was a lot of consistency in the system	☐	☐	☐	☐	☐
7. I would imagine that most people would learn to use the system very quickly	☐	☐	☐	☐	☐
8. I found the system very intuitive	☐	☐	☐	☐	☐
9. I felt very confident using the system	☐	☐	☐	☐	☐
10. I could use the system without having to learn anything new	☐	☐	☐	☐	☐

SEMI-STRUCTURED QUESTIONNAIRE

ACCEPTANCE	
Did you feel safe using the system?	
Do you have any concerns about the senior's privacy?	
What activities/features did you find most useful? And those that you did not like? Do you miss anything?	
Do you think that constant and continued use will benefit your loved one/patient?	
Do you think there are any risks or negative effects of using the system that we have not discussed?	
Was it constraining to have to set up the activities for your loved one/patient?	

Do you think you can adapt the system well enough to fit the personal situation (wishes and needs) of the senior?	
USABILITY	
What is your impression of the system after using it for this period?	
Did you find the system easy to use? If not, what could make it easier?	
Describe your experience introducing the system to the senior: Did the senior had a lot of questions for you? What did you do to help?	
Was it easy to learn how to use the System?	
How long did it take you to fully understand the system?	
What actions did you have difficulty with? What took a lot of time to do?	
Was there a time when you got stuck in using it? Bugs in the system?	
How often did you check the dashboard? What did you look at? Was the information clear?	
Do you feel confident while using the system?	
Could the system be improved? In what ways?	