DELIVERABLE

1.4. TRAINING MATERIAL

Editor(s)		Project name	TV-based ASSistive Integrated Service to SupporT European Adults living with Dementia
Author(s)	Fermin Mayoral	Acronym	TV-AssistDem
	Jessica Goodman	Website	www.tvassistdem-aal.eu
		Deliverable	D1.4- Training material
Reviewer(s)	Pilar Bernstein	Nature/type	Plan
	Flavia Boghiu	Dissemination Level	Public
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Deliverable Summary

This task will design specific training sessions aiming at ensuring that each individual clinician fully understands the recruitment protocol and know how many patients they are expected to recruit. The clinicians will also be made aware of reporting lines (both locally and the CL) in case of complications or problems. The pilot SOP developed in T1.2 will form the basis of this training and comprise all the training material required

TV-AssistDem User Testing guidelines: First phase of the feasibility study

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1. Introduction to the installation and training process

The installation and training process will take place at the dyads home: person with mild cognitive impairment or mild dementia (PMCI/MD) and their caregiver. The professional responsible for installation must check the installation set before performing the home visit. The professional who will carry out the assessment must bring the Data Collection Logbook (DCL), writing material, an audio recorder and a chronometer (or a smartphone with these functionalities) to the home visit.

2. Installation process (10 minutes)

Check the installation process ☑ :

Table 1. Installation checklist

Make sure that the set-top-box is plugged in and updated to the latest version.	
Make sure the antenna is connected to the television	
Make sure the webcam is connected to the set-top-box.	
Make sure the WI-FI is connected.	
Make sure you have an audio recorder (if it is a smartphone it must be charged and on flight mode, so as not to receive incoming calls)	
Make sure you have a way to measure time (in seconds) (you can use the stopwatch function of a smartphone)	

Write down any possible installation problems.

3. Introduction to the dyad (10 minutes)

Introduce yourself to the participants and appreciate their time to perform this user test.

Make a brief introduction to the project explaining its main objective. Next, explain what is the aim of this phase of the project: understand how well the platform works for the people to whom it is intended and see what they think about it. Explain the approximate duration of the visit and its different sections:

1. Assessment of tasks: Instructions will be given to explore the different functionalities of the platform and a series of questions will be asked regarding them.

2. Conclusions of the assessment: Analysis of the functionalities and experience during user testing.

3. Delivery of the material: The terms and conditions of use of Tv-AssistDem will be explained. The set-top-box will be left installed at the so that it can be used for several weeks.

Explain that the interview will be recorded in audio for analysis and to support the notes that will be taken during the interview. Clarify that the audio recording will only be heard by the researcher and members of the research team. This recording will be strictly for research, not for public use, advertising, promotion or any other purpose.

Report that the time to perform each task will be timed by the researcher but that it is not determinant nor is it a speed test.

Ask the participants if they have any questions regarding the user test.

- *Do you have any questions?*

4. Assessment of tasks (60 minutes)

(Start audio recording)

a) Introduction to the assessment (5 minutes)

The main purpose of this preliminary interview is to make the PDCL/DL comfortable in this unusual situation. Ask the dyad about their previous experience with similar technologies.

- *Do you have any experience using a SmartTv? If so, how was your experience?*

b) Assessment instructions (5 minutes)

Inform the dyad that they are testing a product, and that the product is not testing them, that there is absolutely nothing they can do wrong. Clarify that, if something seems broken, wrong, strange or especially confusing, it is not their fault. We as researchers and developers want to know about it, in order to create a better platform. Therefore, it is very important to inform when something is not working as expected or desired.

Inform the dyad that what they are testing today is not a finished product, but a product in development, so not all the functionalities that will be in the final platform are available at this moment. This is part of the reason why they're doing the user test early, so the developers can have time to improve the platform before the pilot starts with more participants later this year. In order to make improvements researchers depend on their honest opinions of how the platform works at this time. We want to know features that they like, dislike or that confuse them. Tell them to be as honest as possible, the platform is designed for people like them and we want to know exactly what they think works and does not work for them.

Encourage the PMCI/MD to say their thoughts out loud while using the platform, so that as a researcher you get an idea of what they are thinking when they are doing something. Explain to the dyad that the platform is designed for individual use by the PCDL/DM and for use with their caregiver. For this reason, the PMCI/MD will be given a series of instructions to follow that must be completed as autonomously as possible. When they are not able to complete the task they will have the possibility of requesting help from their caregiver. When the dyad is not able to complete the task, they may ask for the researchers help.

- *Do you have any questions before we start?*

c) First impressions of the platform (5 minutes)

Explain that they will now be asked some questions about their impressions and thoughts about the TV-AssistDem platform. Explain that there are no right or wrong answers to the questions, that we are asking these questions to get their honest impressions and their expectations of the platform.

The questions should be answered firstly by the PMCI/MD and secondly by the caregiver.

- *When you have the main menu of the platform in front of you, what is the first thing your eyes are drawn to?*

- *What is the next thing?*

- *From what you see on the menu, what is this platform about?*

- *Being your first time using the platform, what would you do next? What would you click on? What would you be interested in exploring?*

d) Tasks (45 minutes)

Explain that they will now be given some tasks to perform by using the platform. If they want, they can say out loud what they are thinking while performing the tasks.

The following sections will be assessed in each task:

Task performance. Select the most appropriate response:

0. *Fails to complete the task*
1. *Task completed successfully but very slowly*
2. *Task completed successfully but slowly*
3. *Task completed successfully and fast*

If they fail to perform the task, explain the steps they should have followed to complete it.

Need for help. Select the most appropriate response:

1. *Researcher*
2. *Caregiver*
3. *None*

Write down the time in seconds to perform each task.

After the PMCI/MD performs the task, go through the menus involved in the task and ask the following questions:

- *Do the names of the navigation elements (text/buttons) make sense to you?*

- *Do the elements of the platform work as expected? Is there any element of the platform that does not make sense?*

- *What did you expect to happen when you clicked here? What did you expect to find? Is there something missing that you hope to find? Was it clear what to do here?*

- *What draws your attention from this menu? What are the most important elements in it?*

- *Are there places where you would like additional information?*

CALENDAR AND REMINDERS

Explain that one of the functionalities of the platform is setting up reminders for medication, medical appointments, vital signs measures, physical activities, personal events and surveys. Therefore, the first tasks that they will be asked to do have to do with these reminders. After reading the statement of each task, the researcher will start the chronometer.

1.1. TASK: ADD A PERSONAL EVENT

Add a Personal Event reminder "Start the washing machine in 30 minutes", which would be at __:__ (the researcher must record at what time the reminder is expected to activate). This reminder will activate during the user testing period, check how the PMCI/MD reacts and ask the questions written in the section Reminder Activation.

1.2. TASK: ADD NEW MEDICAL APPOINTMENT

Add a New Medical Appointment reminder "Checkup with Dr. White in the Cardiology Unit in your local hospital", the appointment will be set a month from now, __/__/____. The PMCI/MD must include all the information provided.

1.3. TASK: ADD A NEW MEDICATION SHOT

Add a New Medication Shot reminder "Metformine twice a day (at 9 am and 6 pm)" starting today.

1.4. TASK: ADD A NEW MEASUREMENT CAPTURE

Add a New Blood Pressure Capture reminder in 10 minutes starting now, __:__.

1.5. TASK: EDIT A MEDICAL APPOINTMENT

Edit a Medical Appointment reminder. Postpone one day and one hour.

1.6. TASK: DELETE A MEASUREMENT CAPTURE

Delete the measurement capture added previously.

1.7. TASK: REMINDER ACTIVATION

Record the participants reaction when the reminder activates.

2. VIDEO CONFERENCE

Explain that one of the functionalities of the platform is the Video Conference with the health professional and the family caregiver. Therefore, they will be asked to make and receive calls. After reading the statement of the task, the researcher will start the chronometer.

2.1. TASK: MAKE A CALL TO THE HEALTH PROFESSIONAL

Call the health professional.

2.2. TASK: RECEIVE A CALL FROM THE HEALTH PROFESSIONAL

Receive a call from the health professional.

3. MEASUREMENTS

Explain that one of the functionalities of the platform is the measurement of vital signs: blood pressure, heart rate, glucose and weight. Therefore, they will be asked to record measurements. After reading the statement of the task, the researcher will start the chronometer.

3.1. TASK: ADD A NEW BLOOD PRESSURE MEASUREMENT TAKEN NOW

Add a new Blood Pressure measurement "120/80mmHg" taken now.

3.2. TASK: ADD A NEW WEIGHT MEASUREMENT TAKEN AT A CERTAIN TIME

Add a new Weight measurement "83kg**"** taken at 9am**.**

4. COGNITIVE STIMULATION STIMULUSINTERACTIVE©

Explain that one of the functionalities of the platform is the stimulation of memory through cognitive exercises. Therefore, they will be asked to select an exercise for each cognitive function of StimulusInteractive©, accessing the Free Access Mode. The researcher will start the chronometer when the desired exercise is selected and stop it at the end of the exercise.

4.1. TASK: ACCESS MAIN MENU OF STIMULUSINTERACTIVE©

4.2. TASK: ACCESS FREE ACCESS MODE

4.3. TASK: TEST A MEMORY EXERCISE

4.4. TASK: TEST AN ATTENTION EXERCISE

4.5. TASK: TEST AN EXECUTIVE FUNCTIONS EXERCISE

4.6. TASK: TEST A LANGUAGE EXERCISE

4.7. TASK: TEST A CALCULUS EXERCISE

5. HEALTHCARE EDUCATION

Explain that one of the functionalities of the platform is to offer educational health resources. Therefore, they will be asked to access these resources. After reading the statement of the task, the researcher will start the chronometer.

5.1. TASK: ACCESS RESOURCES- INFOGRAPHICS AND VIDEOS

6. MY MEMORIES

Soon available.

7. MY HEALTH

Soon available.

8. GENERAL INFORMATION

Soon available.

5. Conclusions of the assessment (10 minutes)

Ask the participants to turn off the TV and finish with some closing questions

- *How would you describe this platform in a couple of sentences to someone with a level of computer and Internet experience such as yours?*
- *Do you consider it an interesting platform? Is it something you would use?*
- *Is it something you would recommend? Why? Why not?*
- *Can you summarize three good things and three bad things about the platform?*

Tell the participants that the purpose of this last part is that they can ask all the questions they have about the functionalities and use of the platform. Make a list of the questions participants have (and try to answer them as best you can).

- *Do you have any further questions? Comments*

Thank the participants and tell them that they have completed the user testing, and we have one more question about how they have felt during the testing.

- *Do you have any suggestions about how we could run this test better, either in the way it is run or programming terms?*

6. Usability Scale (5 minutes)

The PMCI/MD will complete the System Usability Scale (SUS).

7. Material delivery process (10 minutes)

Check the material delivery process ☑ :

Table 2. Material delivery checklist

Make sure you have explained the terms and conditions of using TV-AssistDem.	
Make sure the participant has signed the "Agreement form to receive the TV-AssistDem set".	
Make sure you have scheduled a preliminary date for the second evaluation of the platform and tell them that you will contact them one week in advance to schedule an exact date and time.	
Make sure you have informed the dyad of your availability to answer any questions that may arise.	
Make sure you have the contact information of the dyad.	

Thank the dyad for their participation and say goodbye.

(End audio recording)

Researcher's

Manual

TV-based Assistive Integrated Service to Support European adults living with Dementia (TV-AssistDem)

Fieldwork

1. Recruitment

Participants will be identified from people with self-perceived cognitive impairment or caregiver perception of cognitive impairment that has been present for more than six months and who meet all the study eligibility criteria. The participants can be under primary care services as well as secondary care services, memory clinics, day hospitals, neurology services etc. Participants will also be identified from patient databases such as those integrated in the network. The clinicians involved in identifying the participants will be physicians (primary care, psychiatry, neurology, and geriatrics), neuropsychologists and nurses or trained researchers.

The identification process by the clinician will consist of screening, using information gathered from medical notes, clinic records and/or clinical consultations, for initial eligibility based on inclusion criteria. A trained clinician must confirm eligibility criteria in all centres during visit 0.

Participants will receive a brief explanation by their clinician. A member of the research team will contact the participant to see if they are willing to participate in the study, and if so, an appointment at their referral centre will be scheduled. Their primary caregiver must attend this visit.

At this visit, the researcher will explain the study in detail and answer any questions the participant or caregiver may have. The participant's eligibility will be confirmed and the Participant Information Sheet will be handed out (Annex 1). An Assessment of Capacity to Consent (Annex 2) will be performed and the participant and caregiver will sign the Consent Form (Annexes 3 and 4). Once signed, the participant will be randomized into the intervention or control group.

Follow-up will begin after the randomization and will be determined by the group allocation. Within one to two weeks after being included in the study, participants allocated in the intervention group will be scheduled a visit for TV-AssistDem installation and training.

1.1. Screening

During this visit, and prior to signing the Consent Form, a screening will be carried out (Annex 5), to check participants eligibility. Confirmation that a participant can enter the study will be done at this visit verifying that all selection criteria are met. For this, the Mini-Mental State Examination (MMSE) will be administered, in which the score to participate will range between 23-27; and the Geriatric Depression Scale (GDS), in which the score must be 10 or less. Both questionnaires are attached in visit 0 (Annex 5). In addition, the other inclusion criteria will be checked.

In order to ensure reporting meets the CONSORT guidelines requirements for clinical trials, the following information will be recorded for any participant who is a potential recruit even if not included in the study (including those who refused to participate despite meeting the eligibility criteria): age, sex, eligibility criteria (including the reason for non-inclusion), and other reasons for dropout/discontinuation with randomization.

1.1.1.Consent Form

An essential requirement when carrying out a research project is that participants have been informed of and understand the purpose of the study, the possible harm which might arise as a result of participation and that appropriate measures have been taken to minimize the likelihood of harm occurring.

Consent must be signed by both the main participant (patient with mild dementia) and the caregiver. Consent will only be considered valid if it has been given by a person with the necessary capacity and provided voluntarily (not obtained under duress), based on the provision of relevant information

To this end, participants will be provided with the information they need to make an informed decision via a Participant Information Sheet. Participants will be given a cooling off period of at least 24 hours between informally agreeing to participate and being invited to formally consent during visit 1.

Consent process for people with mild cognitive impairment or mild dementia

Due to the special condition of the study subjects, consent is understood in this context as a "process" instead of an "event", and therefore the researchers will actively seek the consent of the participants in all visits. Researchers will use a two-stage test to assess the subject's capacity to consent (Annex 2). In addition, when giving their initial consent (Annex 3), all participants with dementia will be asked to assign a person to act as a consultant.

The consultant (which is usually the caregiver) is a person designated to give their consent on behalf of the person with dementia in case of losing the capacity to do so on their own. If the consultant does not take responsibility of the participant's consent process, it will be registered in the study database

Consent process for informal caregivers

Researchers must gain consent from informal caregivers at the start of the trial using the Consent Form (Annex 4) process but do not need to regain consent on each occasion of the trial procedure. However,

if a new individual becomes the informal caregiver during the trial period, consent must be obtained from that person before they can become involved in the trial.

2. Follow-up

Participants will be assessed for 18 months. After the baseline visit or visit 1 in which all the variables of the study will be collected, follow-up visits will be carried out every six months in both the control group and the intervention group.

In these follow-up visits, researchers will assess the quality of life, adherence to prescribed medication, functional status, medical visits attendance and hospital admissions. Researchers will also evaluate the caregivers burden. In addition, in the intervention group, the usage data of the TV-AssitDem platform will be collected.

2.1. Patient Visiting Process

2.1.1. VISIT 0 (Screening)

Once the patients have been recruited, a telephone call will be made by the research team to explain the study and invite them to participate in it formally. An appointment will be made in which the patient and the caregiver will receive oral and written information about the project (Annex 1), the patient´s capacity to consent will be assessed and they will give informed consent (Annexes 2-4).

In this visit the following sections will be completed (Annex 5):

1.- Centre and researcher: where the patient has been recruited: Primary care Centre, Neurology Service or Social association that participate as recruiting centres and the member of the research team that carries out the visit.

2.- Date of birth: dd/mm/yy and (age).

3.- Sex: male or female.

4.- Medical Record Number: the identification number in the public health system.

5.- Date: of the visit, dd/mm/yyyy.

6.- Telephone: to facilitate the communication between the participant and the researcher team.

INCLUSION CRITERIA

To be included in the study, all sections must be answered with a YES.

2.- ≥60 years: check what applies YES/NO.

7.- Self-perceived cognitive impairment or caregiver´s perception of cognitive impairment that has been present for more than six months: check what applies YES/NO.

8.- Mini-Mental State Examination score 23-27: check what applies YES/NO.

9.- Lives independently: check what applies YES/NO.

10.- Pharmacological treatment for chronic conditions and in charge of own medication: check what applies YES/NO.

11.- Informal caregiver: check what applies YES/NO. Defined as the person who is unwaged for this role and who spends the most time with the participant and whom the participant declares his/her informal caregiver, for care or support of care, and who does not take part in a formal network of organized care.

12.- Consent Form: check what applies YES/NO.

EXCLUSION CRITERIA

To be included in the study, all sections must be answered with a NO.

13.-Severe Depression (GDS) score >11: check what applies YES/NO.

14.-Terminal disease: check what applies YES/NO. Less than three years of life expectancy.

15.- Conditions that make impossible the use of the platform: check what applies YES/NO. And specify which.

Fill in the following questionnaires:

8.- Mini-Mental State Examination (annex 5)

13.- Geriatric Depression Scale- Yesavage test (GDS) (annex 5)

2.1.2. VISIT 1 (Inclusion)

Once the patients have been selected, the following sections will be completed during this visit (Annex 6):

16.- ID: of the patient, a code that will identify the patient during the study. Patients will be given consecutively ID numbers ranging from 1-150.

1 = SPAIN

2 = ROMANIA

17.- Date: (see 5).

18.- Telephone: (see 6)

19.- Centre: (see 1)

20.- Researcher: (see 7).

ANTHROPOMETRIC AND SOCIODEMOGRAPHIC DATA

21.- Date of birth: dd/mm/yy and (age).

22.- Sex: male or female.

23.- Weigh: the participant will be measured without shoes or coat and the weight will be recorded in kilograms (Kg).

24.- Height: the participant will be measured without shoes and the height will be recorded in metres (m).

25.- BMI: is defined as the body mass (kilograms) divided by the square of the body height (metres).

26.- Marital status: check what applies between the options (single, married, divorced, widowed, couple).

27.- Level of education: check what applies between the options (illiterate, less than elementary, elementary school, secondary school, higher education, other).

28.- Living arrangements: who the patient lives with. Check what applies between the options (alone, with a partner, with children, other).

29.- Hobbies: specify.

30.- Do you have any disabilities: check what applies (Yes/No). Specify.

31.- Do you have internet at home: check what applies (Yes/No).

32.- Are you a smoker or have you been a smoker? check what applies between the options (Has never smoked/Currently Smokes/Former smoker)

If the participant currently smokes or has been a smoker, complete the following:

- Nº of years smoking: Duration of consumption
- Nº of cigars a day: Amount of consumption.

In case of smoking cessation, specify number of years since the cessation.:

- Nº of years since the cessation
- Nº of years smoking before cessation
- Nº cigars per day before cessation

COGNITIVE IMPAIRMENT DATA

These data should be collected preferably from the patient's medical history, if it is not possible they can be collected from the patient/caregiver.

33.- Diagnosis: Have you been diagnosed with dementia or mild cognitive impairment or dementia? check what applies (Yes/No). If yes, Dementia/Cognitive impairment.

34.- Type: check what applies between the options (Alzheimer, vascular dementia, Lewy body dementia, frontotemporal dementia, other, does not know/answer).

35.- Time of diagnosis: the time elapsed since the diagnosis, for this the date that appears in the patient's medical record will be noted. If this is not registered, the date will be taken from the information the patient provides.

36.- Family history of dementia: check what applies Yes/No, and type (Alzheimer, Parkinson, Vascular, Other)

37.- Medication for dementia: check what applies (Yes/No). Type (Acetylcholinesterase inhibitor, Memantine, Antipsychotics, Antidepressants, Other). If other, specify which.

38.- Neuroimaging test: check what applies (Yes/No). Date of neuroimaging test, type (nuclear magnetic resonance, CT scan) and result.

OTHER MEDICAL CONDITIONS

These data should be collected preferably from the patient's medical history, if not, they can be collected from the patient/caregiver

39.- Comorbidities: Check all the medical conditions that the patient has. Those medical conditions that are not explicitly specified in the list included in visit 1, will be noted as "other" and will be specify.

40.- Do you need vital sign tracking: check what applies (Yes/No). Specify.

USE OF RESOURCES

41.- CSRI: These data should be collected preferably from the patient's medical record, if not, they can be collected from the patient/caregiver.

Admissions in the last year:

- Nº of admissions: number of times the patient was admitted in hospital.
- Nº of consultations in emergency a primary care centre: number of times the patient consulted for an emergency in a primary care centre.
- Nº of consultations in emergency a public hospital: number of times the patient consulted for an emergency in a public hospital.
- Nº of consultations in emergency a private hospital: number of times the patient consulted for an emergency in a private hospital.
- Nº of admissions in a public hospital: number of times the patient was admitted in a public hospital.
- Nº of admissions in a private hospital: number of times the patient was admitted in a private hospital.
- Nº of inpatients days in hospital: number of days as an inpatient.
- Nº of admissions in Intensive Care Unit: number of times admitted in an Intensive Care Unit.
- Nº of inpatient days in an Intensive Care Unit: number of days as an inpatient in an Inpatient Care Unit.

Nº of visits to the Specialist Doctor in the last year:

- Nº of total visits: number of times the patient visited the Specialist Doctor.
- Nª of visits due to dementia: number of times the patient visited the Specialist Doctor due to dementia. Do not consider the which were exclusively for medication prescription.

Nº of visits to Primary Care in the last year:

- Nº of total visits: number of times the patient visited Primary Care.
- Nª of visits due to dementia: number of times the patient visited Primary Care due to dementia. Do not consider the which were exclusively for medication prescription.

Nº of home visits in the last year:

- Nº of medical visits: number of times the patient was visited by a doctor.

- Nª of nurse visits: number of times the patient was visited by a nurse.

Treatment related to hospital admissions or illness exacerbation: Product name, active substance and dosage, nº of prescribed and nº of administered dose/day.

TREATMENT

42.- Treatment: Register the treatment the patient is currently taking and specify. Only include long-term drugs (6 month or more):

- Product name.

- Active substance.

- ATC code: The Anatomical Therapeutic Chemical (ATC) Classification System is used for classifying active ingredients of drugs according to the organ or system on which they act and their therapeutic pharmacological and chemical properties. It is controlled by the World Health Organization Collaborating Centre for Drug Statistics Methodology (WHOCC).

  For locate the ATC code: https://www.whocc.no/atc_ddd_index/

- Dose (strength): dose of prescribed medication (e.g. 500 mg).

- Administration form: presentation of the medication (e.g. Capsules, tablets).

- Route of administration: (e.g. Oral, topical, inhaled…).

- Frequency of prescription: amount of the medication a day prescribed by clinician (e.g. 1 per day). This information will be found in the medical record.

- Frequency of administration: amount of medication

- Units per package.

- Time of the day: the patient will be asked what time of the day the medication is taken (before, during or after breakfast; before, during or after lunch; before, during or after dinner) or the time frame, if done regularly.

ASSESSMENT OF TREATMENT ADHERENCE

43.- Dose count**:** two of the prescribed medications will be chosen, if possible those for dementia, if not, those prescribed for a chronic disease (diabetes, hypertension, hypercholesterolemia etc.) The patient will be asked to provide the medication he/she is taking (boxes) in the first visit to make the first count of the two chosen medications. He will be informed that a phone call will be made once a month to redo the count of the two chosen medications (the patient will be asked to choose medication which is exclusively used by the patient to facilitate the task).

44-. Morisky-Green Test: the patient will be asked different questions and the answers will be recorded. The patient is considered compliant if the 4 questions are answered correctly, that is, No / Yes / No / No.

45.- Batalla Test: the questions of the test will be referred to a chronic disease for which the patient has treatment (diabetes, hypertension etc.). If the patient has several diseases, choose one of them.

QUALITY OF LIFE

46.- QoL-AD Scale (Quality of Life-Alzheimer's Disease Scale): The scale consists of 13 items or issues related to the patient's well-being. The scoring range goes from Poor, Fair, good to excellent. It refers to their quality of life at the present time.

47.- EuroQol-5D-5L: this scale refers to the patient´s state of health today and has two parts: a first part, in which questions are asked and the patient must indicate the answer that best suits their situation, and a second part in which they must indicate their current state of health in a visual analogue scale, that goes from 0 to 100, being the worst state of health imaginable, and the 100 the best state of health imaginable.

FUNCTIONAL ASSESSMENT

48.- LAWTON – BRODY Instrumental Activities Of Daily Living Scale (IADL): this scale assesses the ability of the person to carry out the necessary instrumental activities to live independently in the community (using the telephone, making purchases, preparing food, handling money taking medication, etc.). It assesses instrumental activities, which are therefore, lost before the basic activities of daily living. It must be clinician-administered asking the patient or his/her caregiver.

COGNITIVE EVALUATION

In addition to the Mini-mental, the cognitive evaluation is complemented with other exams:

49.- Photo Test: the instructions to complete the test are included in the CRF. The image sheet that is required is attached as an annex.

50.- The Clock Drawing Test: give a blank sheet of paper, a pencil, an eraser, and the instructions: "Draw the face of a clock, a large round circle, fill in the circle with the numbers of each hour and set the time to eleven past ten. If you make a mistake, here is an eraser so you can correct it. This test does not have a time limit, so we ask you to take your time, paying all the attention you can."

The instructions are repeated as many times as needed. If patients forget a number after drawing the clock, they are asked if there are any missing numbers, allowing them to correct the drawing if they become aware of the mistake.

If, on the other hand, they do not realize the mistake, either because there is an extra or missing number, they are reminded of the time setting instruction. Once the numbers are drawn, they are reminded to place the hands at eleven past ten.

If after some time, they have not drawn the hands or are missing one of them, they will be asked if they have finished. If affirmative, the task is completed.

2.1.3. VISIT 2 AND 3 (6 and 12 months after inclusion).

The following sections will be completed:

16.- ID: (see 16).

17.- Date: (see 5).

18.- Telephone: (see 6).

19.- Centre: (see 1).

20.- Researcher: (see 7).

SOCIODEMOGRAPHIC CHANGES

51.- Change of caregiver: Yes/No.

52.- Change of marital status: Yes/No. If affirmative, specify current one.

53.- Change of living arrangements: Yes/No. If affirmative, specify current one.

COGNITIVE IMPAIRMENT DATA

Fill in if there have been any changes since the last visit. This information will be found in the patient's medical record, otherwise, the patient/caregiver will be asked to provide this information.

33.- Diagnosis: (see visit 1).

34.- Type: (see visit 1).

35.- Time of diagnosis: (see visit 1).

37.- Medication for dementia: (see visit 1).

38.- Neuroimaging test: (see visit 1).

OTHER MEDICAL CONDITIONS

39.- Comorbidities: (see visit 1).

TREATMENT

42.- Treatment: Register the treatment the patient is currently taking and specify. (see visit 1).

54.- Has your treatment changed since the last visit?: The patient will be asked about treatment changes. The medical record will be consulted too if there are any doubts. Select the appropriate answer YES / NO. If affirmative fill in the chart:

- Previous treatment
- New treatment
- Reasons for change

ASSESSMENT OF TREATMENT ADHERENCE

43. Dose count: (see visit 1).

44.- Morisky-Green Test: (see visit 1).

45.- Batalla Test: (see visit 1).

QUALITY OF LIFE

46.- QoL-AD Scale (Quality of Life-Alzheimer's Disease Scale): (see visit 1).

47.- EuroQol-5D-5L: (see visit 1).

FUNCTIONAL ASSESSMENT

48.- LAWTON – BRODY Instrumental Activities Of Daily Living Scale (IADL): (see visit 1).

COGNITIVE EVALUATION

8.- Mini-Mental State Examination: (see visit 0).

49.- Photo Test: (see visit 1).

50.- The Clock Drawing Test: (see visit 1).

DEPRESSION

13.- Geriatric Depression Scale (GDS): (see visit 0).

USABILITY

55.- System Usability Scale: For participants on the intervention group.

2.1.4. VISIT 4 (18 months after inclusion)

The following sections will be completed:

16.- ID: (see 16).

17.- Date: (see 5).

18.- Telephone: (see 6).

19.- Centre: (see 1).

20.- Researcher: (see 7).

SOCIODEMOGRAPHIC CHANGES:

51.- Change of caregiver: (see visit 2).

52.- Change of marital status: (see visit 2).

53.- Change of living arrangements: (see visit 2).

COGNITIVE IMPAIRMENT DATA

Fill in if there has been any change since the last visit. This information will be found in the patient's medical record or provided by the patient/caregiver.

33.- Diagnosis: (see visit 1).

34.- Type: (see visit 1).

35.- Time of diagnosis: (see visit 1).

37.- Medication for dementia: (see visit 1).

38.- Neuroimaging test: (see visit 1).

OTHER MEDICAL CONDITIONS

39.- Comorbidities: (see visit 1).

USE OF RESOURCES

41.- CSRI: (see visit 1)

TREATMENT

42.- Treatment: Register the treatment the patient is currently taking and specify. (see visit 1).

54.- Has your treatment changed since the last visit?: (see visit 2).

ASSESSMENT OF TREATMENT ADHERENCE

43. Dose count: (see visit 1).

44.- Morisky-Green Test: (see visit 1).

45.- Batalla Test: (see visit 1).

QUALITY OF LIFE

46.- QoL-AD Scale (Quality of Life-Alzheimer's Disease Scale): (see visit 1).

47.- EuroQol-5D-5L: (see visit 1).

FUNCTIONAL ASSESSMENT

48.- LAWTON – BRODY Instrumental Activities Of Daily Living Scale (IADL): (see visit 1).

COGNITIVE EVALUATION

8.- Mini-Mental State Examination: (see visit 0).

49.- Photo Test: (see visit 1).

50.- The Clock Drawing Test: (see visit 1).

DEPRESSION

13.- Geriatric Depression Scale (GDS): (see visit 0).

USABILITY

55.- System Usability Scale: For participants on the intervention group.

2.2. Caregiver Visiting Process:

16.- ID:.

17.- Date: (see 5).

18.- Telephone: (see 6)

19.- Centre: (see 1)

20.- Researcher: (see 7).

SOCIODEMOGRAPHIC DATA

56.- Caregiver´s date of birth: dd/mm/yy and (age).

57.- Caregiver´s sex: male or female.

58.- Caregiver´s Marital status: check what applies between the options.

59.- Caregiver´s Level of education: check what applies between the options.

60.- Caregiver´s Living arrangements: who the caregiver lives with. Check what applies between the options.

61.- Caregiver currently working: check what applies YES/NO.

62.- Sick leave because of caregiver-role?: check what applies YES/NO.

63.- Caregiver´s relationship with the patient: Specify.

64.- Patient/caregiver cohabitation: check what applies between the options.

65.- Time together: If "Not living together" was the answer selected for question 64, specify how much time the caregiver spends with the patient.

66.- Technological device: check what applies YES/NO.

QUALITY OF LIFE

67. QoL-AD Scale (Quality of Life-Alzheimer's Disease Scale): The caregiver must complete the questionnaire according to their perspective of their family members quality of life

68.- EuroQol-5D-5L Questionnaire: The caregiver´s health today.

CAREGIVER BURDEN

69.- Zarit Burden Interview. Caregivers must answer selecting the option that best describes how they feel about having to take care of another person. They should be reminded that there are no right or wrong answers, that it is about their experience.

FUNCTIONAL ASSESSMENT

70.- LAWTON – BRODY Instrumental Activities Of Daily Living Scale (IADL): Caregivers must select the option that best represents the patient's current capabilities according to the their own point of view.

3. Recruitment, visiting and recapturing processes

The mechanisms of recruitment and visiting process have been described earlier in this manual, in the recruitment section.

3.1. Recapturing process

Up to three phone calls will be made to retrieve lost patients which do not attend the annual review. If the measurement of the response variable is not achieved, as much information as possible will be collected, to compare at the end of the study the characteristics of the lost subjects with those who complete the study.

3.2. Loss minimization mechanisms

The following mechanisms are intended to minimize loss of follow-up of the population under study:

- Accurate information and motivation of the participants included in the study:
    - Information Sheet provided during recruitment, before obtaining informed consent.
    - Trained researcher.
    - Accessibility to the research team: it is important that participants know the names of the members of the research team of their centre and how to access them (the team´s contact information will be provided in the information sheet).
- Inclusion in the study according to the selection criteria.
- Telephone reminder the week before the scheduled visit.

3.3. Data Collection:

The Case Report Form (CRF) will be used to collect data following these rules:

- Write clearly.
- Check that all relevant questions are answered and that empty sections are not left.
- The corrections of the data will be made by drawing a straight line on the incorrect data and writing the correct information next to the data that has been crossed out and including a signature and date on the side.

There will be two data generating modules:

1. Data of the outcome measures and complementary measures.

2. Data of the TV-AssistDem platform- usage behavior data.

The data of the outcome measures and complementary measures will be collected in an electronic Case Report Form (eCRF). The usage behavior data of the TV-AssistDem platform will be integrated into another database. The integration and analysis of data sets from the two databases will be activated through the ID numbers.

The data of the participants will be anonymized in the two databases. All participants will be assigned an ID number. The members of the research team of each participating centre will have restricted access to all the documentation that links the names of the subjects with dementia and the caregivers, with the identification numbers.

At the end of the study, the researcher will receive all the data of the participants of the centre in a legible format so that it can be filed in the study records. These data as well as the correction document will be maintained in the system for future data audits.

3.4. Data of the outcome measures and complementary measures

The eCRF will be completed by the research members (previously trained). The eCRF will be reviewed, signed and electronically dated by the researcher or designee.

All scales, tests and questionnaires within the outcome measures and complementary data will be accessible in the shared database. The interviews will be completed on paper, and the researcher will scan the answer sheet and then transcribe the responses to the eCRF.

The data of the participants and caregivers will not be stored in the devices of the health professionals, but will be sent to the database as soon as the administration is completed.

Once the data have been sent to the server there will be no possible modification. In the event that the researcher cannot access the database during the evaluation (due to a loss of connection, for example), the scales will be completed on paper and then entered by the researcher into the system when the connection is restored.

Valid and accurate data collection will be evaluated through verification and cross-check of the eCRF researcher's records (verification of the source document). The verification of the source document will be carried out in 5% of the participants.

A verification and integral validation of data program will be used to verify the data of the eCRF. Discrepancies and queries according to the eCRF will be resolved online by the researcher. In addition, the eCRF will review the data based on medical and scientific plausibility.

4. Incidents

An incident is any anomaly or variation of the protocol related to:

- Visiting process: because it is a follow-up study consisting of several visits, the failure to attend one of them does not imply the exclusion from the study, but rather it would be an incident in which the reason for non-attendance would be recorded.
- Methodology conducting the visit:
    - Measurement procedure: due to technical problems (e.g. measurement made by untrained personnel, uncalibrated measuring device, etc.), or related to the participant (e.g. presence of acute pathology that may alter the measurement, concomitant treatment that may alter the measurement, etc.)
    - Completion of questionnaires (e.g. if the researcher forgets to complete or write down any section from the forms, illegible handwriting etc.).
- Premature discontinuation of clinical trial: The participants included in the study may leave at any time without having an impact on their usual health monitoring. In this case, the incident will be noted and the reasons for study abandonment will be indicated.

ANNEX 1. Participant Information Sheet.

The information sheet will be provided to all participants since it includes the study explanation and contact information in case the participant needs to cancel appointments or ask any questions. This sheet will be common for the patient and caregiver since both will participate in the study.

ANNEX 2. Assessment of Capacity to Consent.

The researcher must complete the participant´s name, date and time of assessment, as well as his/her name and signature. All sections of the form must be completed.

ANNEX 3. Patient Consent Form.

The consent form will be filled out by the researcher including his/her own data, the patient´s care centre data and the patient´s and witness´s data. Finally, it will be signed by the patient, researcher and a witness.

ANNEX 4. Caregiver Consent Form.

The consent form will be filled out by the researcher including his/her own data, the caregivers care centre data and the caregiver´s and witness´s data. Finally, it will be signed by the caregiver, researcher and a witness.

ANNEX 5. Patient CRF. Visit 0.

ANNEX 6. Patient CRF. Visit 1. Visits 2 and 3. Visit 4.

All visits may be found in the same annex.

ANNEX 7. Caregiver CRF. Visits 1,2,3 and 4.

ANNEX 8. Photo Test Sheet.

TELEPHONE CALL PROTOCOL

Good morning Mr/Mrs …….. My name is …….. and I´m calling in behalf of INGRIJIRI LA DOMICILIU. Your doctor has thought you may benefit from participating in a European study which is going to be carried out in Romania about quality of life in people with cognitive problems and their caregivers. You will be interviewed every six months during a year and a half about your quality of life: health and wellbeing, daily activities, memory, mood, caregiver support, etc. There are two possible groups you may be randomized to: one of them will receive a TV-based assistive service with different functionalities such as medication reminders and cognitive exercises, while the other group will not receive this service.

Confidentiality and protection of personal data comply with the provisions of the Romanian legislation. Before scheduling an interview to provide you with further information, we would like to confirm the following data.

	YES	NO
2. >60 years		
9. Lives independently		
10. In charge of own medication		
11. Informal caregiver (explain what this means)		
15. Conditions that make impossible the use of the platform		

Do you consent to a first interview?

YES = Schedule an interview.

NO = “Thank you very much for your time and sorry for any inconvenience”.

In case of doubt = “We encourage you to participate, we believe that it can be positive for you and would not be too time consuming for you”.