ROBOTS IN ASSISTED
LIVING ENVIRONMENTS

UNOBTRUSIVE, EFFICIENT, RELIABLE AND MODULAR
SOLUTIONS FOR INDEPENDENT AGEING

Research Innovation Action

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DELIVERABLE 6.1

Piloting Plan I

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Abstract

This report documents the criteria to be used for subject selection and the procedures followed for deploying the RADIO system and executing the pilot. It also describes the data that will be collected and the policies for data retention and analysis. This report also includes the original text of the consent forms signed by the subjects and their English language translations. Moreover, it includes the approval of the Ethical committee.

History and Contributors

Ver	Date	Description	Contributors
01	2 June 2015	First draft, working on document structure and incorporating the information regarding the study participants.	NCSR-D, FZ, FSL, FHAG
02	10 July	Formative Phase piloting plan (Section 2 and appendices)	FSL
03	12 July	Additions and comments regarding the Smart Home platform that will be used in the pilot	S&C
04	13 July 2015	Internal review	NCSR-D
Fin	15 July 2015	Final document preparation and submission	NCSR-D

Abbreviations and Acronyms

ADL	Activities of Daily Living
ASQ	After-Scenario Questionnaire
IADL	Instrumental Activities of Daily Living
interRAI	International collaborative to improve the quality of life of vulnerable persons through a seamless comprehensive assessment system. Cf. http://www.interrai.org
interRAI HC	The *interRAI* Home Care Assessment System
interRAI LTCF	The *interRAI* Long-Term Care Facilities Assessment System
MMSE	Mini Mental State Examination
PIADS	Psychosocial Impact of Assistive Devices Scale
SUS	System Usability Scale

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1 INTRODUCTION

1.1 Purpose and Scope

RADIO presents a domestic assistant and home automation profile to the end-user, which most importantly acts as an unobtrusive health monitoring system.

RADIO's main objective is an unobtrusive monitoring system whose equipment is an obvious and accepted part of the user's daily life, by adopting a smart home/assistant robot approach, where the sensing equipment actively strives to be obvious and closely located to the user; that is, we propose that robot companions and assistants are used to collect the data needed for medical monitoring.

RADIO system will provide a pool of ICT based in-home services that will be offered to elderly users that live at home to improve time to be spent autonomously at home. Although the RADIO system is primarily presenting a domestic assistant and home automation profile, it is also acting as an unobtrusive health monitoring system and as an instrument for medical evaluation. It will ensure the timely availability of the patients' clinical and behavioral data to allow timely prognosis and clinical actions. Through its direct involvement in end-users daily activities, RADIO observes *activities of daily life* and *mood*. These observations are used to establish patterns and identify deviation. Moreover, RADIO empowers new care service provisioning models based on the remote supervision of the elderly/patients from the medical experts and/or health professionals or care-givers. It deals with the extraction/derivation of reinforced medical knowledge associated with symptoms, good practices, treatments and personalized patterns of treatment for elderly users.

Objectives of the study:

- Measure validity of the Radio system
- Evaluate functional activities and mood
- Improving Quality of Life
- Measure Usability

The work reported in this deliverable plans the usability tests of the user interfaces of existing systems (home automation and robotic platform) in order to inform the development of user interfaces within the project. More specifically, this report details the profile and number of pilot participants and how long they will work with the consortium and the criteria to be used for subject selection. It then describes the usability testing methodology that will be applied, the data that this methodology requires to be collected, and the procedures and policies regarding data collection, analysis, and retention. This report also records the consent forms for the study subjects and the safety certification of the used hardware (Appendices).

1.2 Approach

This is a multicentre and multinational non-experimental clinical study. The target population is elderly people who need assistance in order to maintain their independence and quality of life.

The study will be distributed in three phases:

1. Formative phase; first pilot at FSL
1. Intermediate phase; second pilot of RADIO components at FSL
2. Summative phase; final RADIO pilots

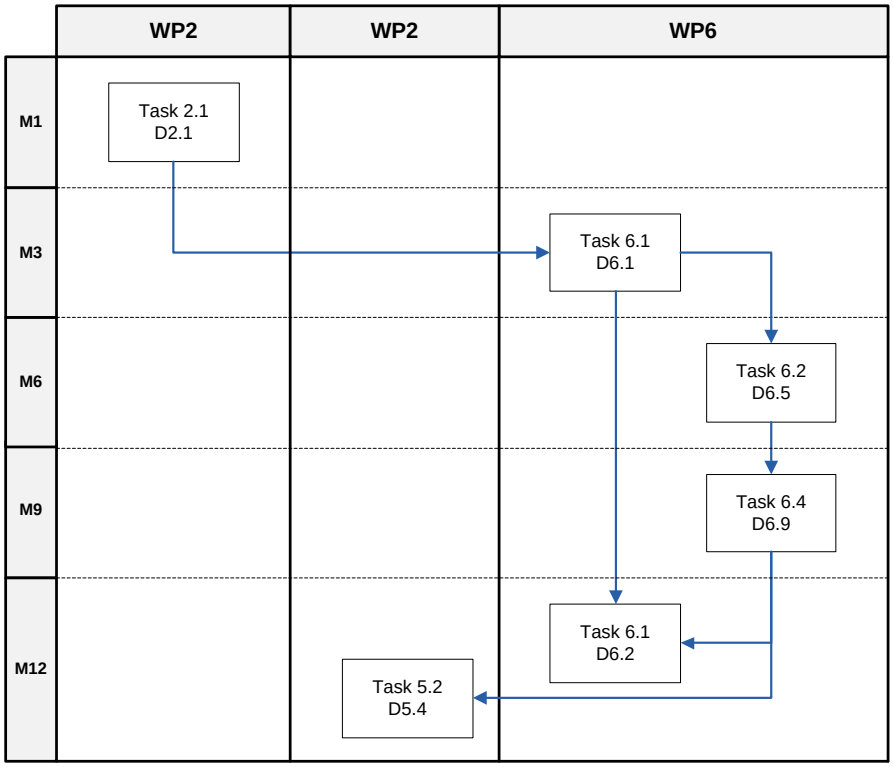

Figure 1: Dependencies between this deliverable and other deliverables.

Formative phase: The first pilot will be carried out at FSL premises with elderly end-users. The objectives of this pilot are (a) to provide data for a purely formative evaluation of the usability of existing user interfaces for controlling home automation and (b) to refine the piloting plan itself into its second version.
Intermediate phase: The second round of pilot, also at FSL premises, will be realized with the first versions of user interfaces, devices, and the robotic platform delivered on M12 and M15. The objectives of this pilot are (a) to provide data for the formative evaluation of early RADIO components for usability and fitness for purpose; and (b) to refine the piloting plan itself into its third version.

Summative phase: This final phase includes two sets of pilots, one at FHAG premises and one at the private homes of FZ clients who have volunteered to participate, implementing the third version of the piloting plan. The objectives of these pilots are (a) to validate the prototype of the overall RADIO ecosystem; and (b) to provide data for the final, summative user evaluation report and medical evaluation report.

This deliverable plans the formative piloting phase.

1.3 Relation to other Work Packages and Deliverables

This deliverable is prepared within Task 6.1 *Piloting plan development* and forms the basis for the clinical protocol that will be submitted to the FSL Ethics Committee.

This deliverable extends the clinical protocols included in D2.1 *Early Detection methods and relevant system requirements I*. D2.1 is superseded by D2.2 *Early Detection methods and relevant system requirements II* and this deliverable.

In particular, this deliverable also:

- Uses the outcomes of the architectural discussion carried out during the Kick-Off Meeting in order to include a list of the hardware that will be used in the tests and the relevant safety certifications.
- Provides the Italian language translation of the consent form prepared in the context of D2.1.

This report plans the trials that will be carried out at FSL premises in the context of Task 6.2 *Controlled pilot trials* (M4-M6) to produce D6.5 *Controlled pilot trials report I*.

In its turn, work in Task 6.2 will refine the piloting plan. Specifically, the main purpose of D6.9 *User evaluation report I* is to report findings that are useful for designing the RADIO user interfaces (D5.4), but it might also include additional requirements for the second piloting plan (D6.2) in order to address usability aspects that could not be evaluated by the outcomes of D6.5.

These dependencies and interactions are also graphically depicted in Figure 1.

2 FORMATIVE PHASE: MATERIALS AND METHODS

This phase is dedicated to evaluation of the usability of user interfaces. It will last for three months (M3-M6). These subjects will be selected from among a population resident at FSL. All subjects will be tested on ADL, IADL, mood-behaviour and cognitive aspects through interRAI LTCF specific sections and on usability through System Usability Scale (SUS), Psychosocial Impact of Assistive Devices Scale (PIADS) and After-Scenario Questionnaire (ASQ). Data will be collected for each subject for 1 week.

2.1 Participants

The user-groups comprise 30 elderly participants.

Inclusion criteria

- Older than 64 years old
- Ability to walk without human assistance indoors
- Need supervision in almost two IADLs
- Willing to participate in the study and wanting to co-operate in all its parts, accepting the performance regulations and procedures provided by the researchers

Exclusion criteria

- Moderate/severe mental disease, such as dementia, according to clinical criteria -DSM-IV-TR and MMSE score ≤18 or neuropsychiatric disorders.
- Moderate/Severe disability ADL< 4
- Acute medical conditions
- Unable to fully understand the potential risks and benefits of the study and give informed consent. Subjects who are unable or unwilling to cooperate with study procedures.
- Blind
- Deaf
- Languages problems

2.2 Study Design

Description of Smart Home environment

The test will take place inside the Assistive Technology Laboratory in the IRCCS – Fondazione S. Lucia premises. The scenario will be tested with volunteer subjects.

In the area to be used as “home environment”, participants will use a home automation system to manage their daily home activities and increase their comfort level. The S&C Smart Home system makes it possible to control the environment in a way suited to various occasions. The system is able to memorize a certain combination of commands or configurations and repeat them with a scenario command for the ambience chosen for that occasion.

The equipment available at FSL during the Formative phase include the following products:

- 1 Gateway for communication
- 1 Door/Window sensor
- 1 Multi-sensor 4X1 (Motion, Temperature, Humidity and luminosity)
- 2 Smart Energy Plug (Electricity measuring and on/off)

These products will be used to realize these services:

- Security
  - Detection if door/window is open or close
  - Movement detection
  - Arm/Disarm (intrusion detection)
- Control
  - To turn on/off equipment
  - Scheduling
- Consumption
  - Information on electricity consumption
- Scheduling
- Comfort
  - Knowledge about comfort values at home (temp and humidity)

Scenarios in Smart Home

Participants will be recruited among those relate to Day Hospital. For the pilot study all subjects will give written informed consent for participation in the study. In this phase we will enroll patients that satisfy inclusion/exclusion criteria as defined in the D2.1 and agree to participate in the study.

Before starting any experimental test each user will be assessed trough multidimensional evaluation by InterRAI (see D2.1). After the baseline assessment the scheduled program will consist of 2 sessions per week for each participant lasting an average of 1 hour.

We plan to evaluate 30 subjects from July 13th until September 25th with the following scheduling:

- July: 12 patients
- August: 6 patients (considering vacation experiment will be not carried out from August 10th to 22th)
- September: 12 patients

Training Description

During the day before the experimental session, when patient will arrive to the Laboratory dedicate to the experiment, he will be encouraged to familiarize himself with the test interface and go through this interface at least 3 times.

Scenario Description

Mario Rossi is a 70 year old patient affected by a Parkinson disease for 5 years. He was admitted to perform a rehabilitative training.

When the patient arrives to the dedicate laboratory, FSL team will ask to perform some actions in order to access home automation functionality trough a tablet.

At the beginning researchers will show to the patient the smart home environment and tablet with S&C service. Later FSL team will ask to the patient to perform an appropriate scenario for usability testing in order to ensure that it will be 1) realistic and typical for how people actually use the system, when they are on their own time, doing their own activities; 2) encourages users to interact with the interface.

Below the selected scenario:

"You are planning to move away from your home for 2 days. Always when you leave you get stressed regarding security of your home, so you would like to check from afar if everything is ok. Moreover, you would like to have the light and heater switched on before coming back home in order to find it more confortable."

Please try to make the following activities

1. *Arm the system (intrusion detection)*
2. *Switch on a lamp*
3. *Switch off a heater*
4. *Verify if a possible burglar moving in home*
5. *Schedule the lighting of the lamp and heater and locking at a predefined time*
6. *Verify the amount of on electricity consumption*
7. *Verify alarm message*

During the scenario, observers will watch carefully and take notes how users interact with the website to see if the interface is inhibiting users from accomplishing their desired goals.

Patient will come back after two days. During this phase researchers will ask to him to try again the scenario proposed in the previous meeting.

Objectives

1. To test usability of the interface

2. To measure how much time and how many steps are required for the user to complete basic tasks; how many mistakes users make when trying to perform these tasks and how fatal are the mistakes

3. To record how the user feels about the tasks he had to complete. If the person was stressed or confident

4. After a period of non-use, evaluate how much a person remembers about the interface and the browsing process

2.3 Variable and Instruments

This section lists the instruments and procedures that will be used to measure the usability variables that are the focus of this study.

2.3.1 Procedures

Right after that patient finished his scenario each user will be evaluated with usability questionnaires:

- System Usability Scale (SUS)
- Psychological Impact of Assistive Device Scale (PIADS)
- After Scenario Questionnaire

2.3.2 Questionnaires

The **System Usability Scale (SUS)** is a simple, ten-item scale giving a global view of subjective assessments of usability. It consists of a 10 item questionnaire with five response options for respondents: from Strongly agree to Strongly disagree. Originally created by John Brooke in 1986 [1], it allows to evaluate a wide variety of products and services, including hardware, software, mobile devices, websites and applications.

The System Usability Scale actually cover a variety of aspects of system usability, such as the need for support, training, and complexity, and thus have a high level of face validity for measuring usability of a system. SUS scores have a range of 0 to 100.

The **Psychological Impact of Assistive Device Scale (PIADS)** [2] is a scale designed to measure the impact of assistive product of the quality of the subject's life. This questionnaire is composed by self-administered 26-item and it investigate three psycho-social aspects:

- Competence: Measures feelings of competence and usefulness.
- Adaptability: Signifies a willingness to try new things.
- Self-esteem: Indicates feelings of emotional wellbeing and happiness

The competence subscale is composed of 12 items related to perceived functional capability, independence, and performance (examples: adequacy, efficiency, and skillfulness). The adaptability subscale is composed of 6 items that reflect inclination or motivation to participate socially and take risks (examples: ability to participate, willingness to take chances, and ability to take advantage of opportunities). The self-esteem subscale is composed of 8 items reflecting self-confidence, self-esteem, and emotional wellbeing (examples: sense of control, happiness, and self-confidence).

PIADS can be used to assess the impact of any assistive device (AD), prosthesis or medical procedure, and can be used with people of all ages and abilities. The test is self-administered in pencil-and-paper form. Each item in scored through a 7-points scale. Scores can range from –3 (max. negative impact) to +3 (max. positive impact).

The **After Scenario Questionnaire** [3] is to be given to a study subject after he/she has completed a normal condition scenario. The user is to circle their answers using the provided 7 point scale (the lower the selected score, the higher the subject's usability satisfaction with their system). After the user has completed the ASQ, the ASQ score can be calculated by taking the average (arithmetic mean) of the 3 questions:

- Overall, I am satisfied with the ease of completing this task.
- Overall, I am satisfied with the amount of time it took to complete this task.
- Overall, I am satisfied with the support information (on-line help, messages, documentation) when completing this task

2.3.3 Statistical analysis

Below we provide an introduction of the statistical methodology to evaluate RADIO objectives.

As already introduced in D2.1 usability analysis will be performed by a descriptive study of the results of the various questionnaires used for this purpose. Where appropriate, the results will be compared with previously established limits in the operating instructions of these questionnaires.

About PIADS, positive scores above the midpoint (0) will be considered as a perceived positive change in competence, adaptability and self-esteem as a result of using the device.

About SUS a score above 68 (the average score among 500 studies[1]) will be considered as a general positive perceived usability of the tool. Moreover, a specific evaluation of each scenario will be obtained with the ASQ questionnaire and scores of this scale will be correlated with the general score obtained at SUS.

2.4 Data Retention

All reports and communications relating to study subjects will identify the subject only by his/her initials and case number. The investigator will complete subject identification on a confidential site log, which will be used for the purposes of traceability and follow-up. This will be treated with strict adherence to professional standards of confidentiality, and will be filed under adequate security and restricted accessibility.

The Principal Investigator, or his designee, in accordance with institutional policy, will obtain an Informed Consent that is reviewed and accepted by the Ethics Committee. A written consent form bearing the full name, date and signature of the patient and the local investigator will be obtained from each patient. The signed Informed Consent constitutes a confidential document and therefore should be archived in the study binder. A copy of the consent should be given to the patient.

[1] Please cf. http://www.measuringu.com/sus.php

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2. Jutai J, Day H. Psychosocial Impact of Assistive Devices Scale (PIADS). *Technology and Disability* 2004; 14:107-111
3. Lewis JR. An after-scenario questionnaire for usability studies: Psychometric Evaluation over three trials. SIGCHI Bull., Vol. 23, No. 4. (1991)

APPENDIX I

This appendix presents the English-language *Participant Information and Consent Form* that informs participants about the project and explains the tests and treatments involved.

Participant Information and Consent Form (PICF)

Project: Robots in assisted living environments:

Unobtrusive, efficient, reliable and modular solutions for independent ageing (RADIO)

H2020-PHC-2014-single-stage 643892

Headed with Institution's name or on Institution's Letterhead

Participant Information and Consent Form

[Insert Institution's name]

Full Project Title: Robots in assisted living environments: Unobtrusive, efficient, reliable and modular solutions for independent ageing (RADIO)

Principal Researcher: ***[Insert researcher name]***

1. Introduction

You are invited to take part in the RADIO project. This innovation project will develop and evaluate a platform, which enables to improve time to be spent autonomously at home by users. It will ensure the timely availability of the user's clinical and behavioural data to allow timely prognosis and clinical actions from the medical expert and/or health professional or care-givers.

This Participant Information and Consent Form informs you about the project. It explains the tests and treatments involved. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

Participation in this project is **voluntary**. If you don't wish to take part, you don't have to. **You will receive the best possible care whether you take part or not**.

If you decide you want to take part in the project, you will be asked to sign the consent section. By signing it you are telling us that you:

- ☐ understand what you have read;
- ☐ consent to take part in the project;
- ☐ consent to have the tests and treatments that are described;
- ☐ consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2. What is the purpose of this research?

The project will develop and evaluate a platform, which enables to improve time to be spent autonomously at home by users. Technological partners will provide their innovative solutions to be integrated in the new platform and evaluated by several healthcare organizations across Europe.

The goal of RADIO is to develop methods for detecting the activities of daily life (ADL) and mood conditions that are pertinent for detecting early symptoms of cognitive impairment; frailty, and social exclusion, and to compare them against what can be achieved by more obtrusive setups (that affect quality of life of primary end users) or by placing the burden of constant monitoring on their care givers.

This project will enable to evaluate how well the RADIO-provided information can serve the purpose of detecting early symptoms of cognitive impairment, so that admissions and days spent in care institutions for precautionary reasons can be drastically reduced.

The effectiveness of the solutions will be evaluated by over 100 elderly users/patients across different countries, cultures, age groups and risk factors.

The RADIO system will consist in a domestic assistant robot that robot exhibits a behaviour akin to that of a pet.

This research is being conducted by the RADIO Consortium and sponsored by the European Commission under the H2020 program - H2020-PHC-2014-single-stage 643892.

3. What does participation in this research involve?

An experimental multicentre and multinational clinical trial will be performed. The study will be conducted on 164 elderly participants living at home or in residential care. The participants will be located in 3 pilot sites.

To be included in the trial each user must meet a set of conditions called, inclusion criteria. Participants who satisfy inclusion criteria will be assigned to one of the following groups:

1. 30 participants will be enrolled in the Formative phase group; the pilot at Fondazione Santa Lucia – FSL (Italy)

2. 36 participants will be enrolled in the Intermediate phase group; the pilot of RADIO components at FSL: 36 users

3. 82 participants will be enrolled in the Summative phase group; 24 users at Granoillers- FHAG (Spain), 24 users and 24 caregivers at Frontida - FZ (Grece)

1. Formative phase. The first pilot will be carried out at FSL premises. This phase will be used to collect data useful for the following phase. Each patient will be required to attend one session. Each session will be 30 minutes duration.

2. Intermediate phase. The second round of pilot, also at FSL premises, will be realized with the first versions of user interfaces, devices, and the robotic platform. Each patient will be required to attend two sessions. Each session will be 1-hour duration

3. Summative phase. This final phase includes two sets of experiments, one at FHAG premises and one at the FZ. The objectives of these pilots are to validate the RADIO system and to provide results to support their validity.

[INSERT PARTICIPATION PROTOCOL HERE]

[START SAMPLE PARTICIPATION PROTOCOL]

Each training process will be executed in 2 sessions per week for 12 weeks (24 sessions). Duration of each session: 1 hour.

All the participants in the study will be followed during 9 months.

[END SAMPLE PARTICIPATION PROTOCOL]

You will not be paid for your participation in this research.

4. What are the possible benefits?

We cannot guarantee or promise that you will receive any benefits from this research, however, possible benefits may include:

- prolonging the time that elderly people can live independently at home by providing ICT service;
- delivering evidence of improvements in the quality of life of older people and their families;
- facilitating wide take-up of ICT based independent living related solutions across Europe.

5. What are the possible risks?

No side effects are expected for this experimentation based on using at home a robot which collect data about daily activities and mood and has been developed to help user during emergency situation trough an alert send to care-giver/doctors and helps users in remind some activities as take a medications.

6. What if new information arises during this project?

During the project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information and your doctor will discuss whether this new information affects you.

7. Can I have other treatments during this project?

It is important to tell your doctor and the research staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your doctor about any changes to these during your participation in the research.

8. Are there alternatives to participation?

Participation in this trial is not your only option. Your other options may include the standard care. Discuss these options with your doctor before deciding whether or not to take part in this research project.

9. Do I have to take part in this project?

Participation in any research project is voluntary. If you do not wish to take part you don't have to. If you decide to take part and later change your mind, you are **free to withdraw** from the project at any time.

Your decision whether to take part or to not take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with [your Institution's name].

10. What if I withdraw from this project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to inform you if there are any health risks or special requirements linked to withdrawing.

If you decide to leave the project, the researchers would like to keep the personal and health information about you that have been collected. This is to help them make sure that the results of the research can be measured properly. If you do not want them to do this, you must tell them before you join the research project.

11. Could this research project be stopped unexpectedly?

This research project may be stopped for a variety of reasons before completion. These may include reasons such as:

- Unacceptable side effects;
- The intervention being shown not to be effective;
- The intervention being shown to work and not need further testing;

12. What else do I need to know?

What will happen to the information about me?

Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of this research project. It will only be disclosed with your permission, except as required by law. All personal and medical information will be treated securely and in accordance with privacy rules and with EU Data Protection and confidentiality laws.

Your health records and any information obtained during the study are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, the European Commission, [INSERT ORGANIZATION NAME] or as required by law. By signing the consent section, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

What happens if I am injured as a result of participating in this research project?

The Hospitals and/or Care Centers involved in these trials unilaterally accept full and formal duty of care for patients involved in the study. For this reason, if you suffer an injury as a result of participating in this research project, hospital care and treatment will be provided by the public health service at no extra cost to you if you elect to be treated as a public patient.

If, for any reason you cannot benefit of public health service, hospital care and treatment will be directly provided by the hospitals and care center leading the trials.

13. Consent

I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to [name of Institution] concerning my disease and treatment that is needed for this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described.

I understand that I will be given a signed copy of this document to keep.

Participant's name (printed) ……

Signature Date

Name of witness to participant's signature (printed) ……

Signature Date

Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's name (printed) ……

Signature Date

* A senior member of the research team must provide the explanation and provision of information concerning the research project.

Note: All parties signing the consent section must date their own signature.

14. Who can I contact?

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

For further information or appointments:

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal researcher or any of the following people:

Name:

Role: principal investigator (and 24-hour medical contact)

Telephone:

Name:

Role:

Telephone:

For complaints:

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Name:

Position:

Telephone*:*

APPENDIX II

This appendix presents the Italian-language *Participant Information and Consent Form* that informs participants of the FSL trials about the project and explains the tests and treatments involved. This form is based on the English-language form in Appendix I.

FOGLIO INFORMATIVO PER LA RICHIESTA DI CONSENSO INFORMATO ALLA PARTECIPAZIONE AD ATTIVITA' DI RICERCA SCIENTIFICA ED AL CONSEGUENTE TRATTAMENTO DEI DATI PERSONALI

Gentile Signore/a ……..

la Fondazione Santa Lucia è un Istituto di Ricovero e Cura riconosciuto a Carattere Scientifico, che svolge, insieme all'attività di assistenza, quella di ricerca sanitaria e di formazione nel settore della riabilitazione neuromotoria e delle neuroscienze.

Nell'ambito di tale esercizio, è in corso una ricerca dal titolo "RADIO - Robots in assisted living environments: Unobtrusive, efficient, reliable and modular solutions for independent ageing".

Questo progetto di ricerca propone un sistema integrato per il monitoraggio e l'assistenza dell'anziano a domicilio. L'obiettivo principale è di fornire un sistema di monitoraggio non intrusivo all'interno dell'abitazione, la cui struttura lo renda parte integrante della vita quotidiana degli utenti; a tal fine RADIO utilizzerà un approccio caratterizzato da un assistente robot integrato con una casa domotica che da un punto di vista della relazione con la persona anziana possa essere assimilato a un animale domestico.

Il sistema RADIO nel suo insieme è composto da un robot mobile costituito da sensori in grado di rilevare movimento dell'utente, registrazioni audio, riconoscimento delle espressioni facciali e una interfaccia touch screen e/o vocale per il controllo del robot e della casa domotica.

In particolare le ADL monitorate dal sistema saranno: bagno, igiene personale, vestirsi (parte superiore e parte inferiore), deambulazione, trasferimenti, uso del bagno, mobilità a letto, mangiare.

Il riconoscimento delle emozioni sarà ottenuto attraverso l'analisi della raccolta di informazioni audio-visive basate (ad es. tonalità della voce, espressioni facciali,ecc).

I benefici previsti sono soprattutto legati alla possibilità di:

sviluppare un metodo per rilevare le attività della vita quotidiana e i disturbi del tono dell'umore

sviluppare un'interfaccia per l'utente anziano con i massimi requisiti di usabilità e facilità di fruizione;

sviluppare un assistente domestico per le attività di routine (portare oggetti, ricordare le medicine, portare da bere etc) all'interno di una casa domotica

I candidati che rispettano i criteri di inclusione saranno reclutati tra i pazienti ricoverati presso l'Unità Operatica C della Fondazione Santa Lucia. Lo studio sarà diviso in 2 fasi: una prima fase dedicata alla valutazione dell'interfaccia (tablet/smartphone) e una seconda fase dedicata alla valutazione dell'usabilità del prototipo (robot).

A ciascun partecipante della prima fase, dopo un periodo di training, sarà chiesto di provare un tablet e uno smartphone per la gestione di semplici attività domotiche quali accendere e spegnere una luce, bloccare e sbloccare una porta, controllare e regolare la temperatura ambientale, controllare il consumo energetico.

Inoltre, per i partecipanti anche alla seconda fase dello studio, sarà chiesto di essere affiancati dal sistema RADIO che dovrà monitorare le sue attività diarie. I risultati ottenuti dal sistema RADIO saranno confrontati con la registrazione effettuata dal care-giver attraverso un diario.

Ciascun soggetto potrà scegliere a una o entrambe le fasi.

La sua partecipazione è prevista della durata di circa 1 ora al giorno per un periodo complessivo di 1 settimana per ciascuna fase.

Non è previsto nessun effetto collaterale derivante dall'utilizzo del sistema.

Con il presente modulo Le viene proposto di prendere parte al programma di studio, il cui responsabile scientifico è la Dott.ssa Roberta Annicchiarico.

Se Lei deciderà di partecipare allo studio, sarà inserito, dopo la raccolta dei suoi dati da parte del personale addetto, nel gruppo di studio.

Durante lo studio verrà effettuata una valutazione multidimensionale consistente nella somministrazione di alcuni questionari e di scale di valutazione. La valutazione complessiva richiederà circa 1 ora e verrà effettuata all'inizio e alla fine dello studio.

Non è previsto nessun pagamento per la partecipazione a questa sperimentazione.

Il medico referente, nella persona della Dott.ssa Roberta Annicchiarico, sarà sempre a Sua disposizione per qualsiasi chiarimento, La informerà prontamente di qualunque notizia si renda disponibile durante lo studio e provvederà a sospendere la Sua partecipazione allo studio qualora ciò risulti nel suo interesse, comunicandoLe i motivi di tale sospensione.

Nel corso dello studio al quale prenderà parte, Lei sarà assicurato a copertura di eventuali danni da esso derivante.

La partecipazione allo studio non comporta per Lei alcun aggravio di spesa.

Lo studio è stato approvato dal Comitato Etico Indipendente della Fondazione Santa Lucia ed il suo svolgimento ed i suoi risultati sono monitorati dallo stesso Comitato.

Lei ha il diritto di non partecipare allo studio che Le viene proposto. Questo non comporterà assolutamente una minore assistenza nei Suoi confronti e Lei sarà in ogni caso sottoposto al miglior trattamento possibile per il suo stato di malattia.

Anche nel caso di accettazione a partecipare allo studio, Lei ha il diritto di ritirarsi dallo stesso in qualsiasi momento, senza essere obbligato a fornire alcuna giustificazione.

Si precisa che i risultati dello studio verranno portati a conoscenza della comunità scientifica ed i dati raccolti durante la sperimentazione non potranno rimanere di proprietà di singoli o gruppi che li possano utilizzare secondo il loro esclusivo interesse.

La procedura dello studio garantisce, peraltro, la riservatezza dei Suoi dati personali con riferimento al relativo Codice (D.lgs. del 30 giugno 2003, n. 196), ai sensi del cui art. 13 si sottopone la seguente informativa.

in conformità alle disposizioni del Codice in materia di protezione dei dati personali (di seguito "Codice"), la Fondazione Santa Lucia La informa che intende svolgere attività di trattamento di dati personali (di seguito "Dati"), anche sensibili , che La riguardano.

FINALITA' E MODALITA' DEL TRATTAMENTO DEI DATI

I Dati forniti vengono acquisiti e trattati nel rispetto della normativa sopra richiamata, con il supporto di mezzi cartacei, informatici o telematici atti a memorizzare, gestire e trasmettere i dati stessi e comunque mediante strumenti idonei a garantire la loro sicurezza e riservatezza, nel rispetto delle regole fissate dal Codice, per le finalità della ricerca in precedenza descritta riguardo agli obiettivi, alle procedure, ai benefici ed rischi della partecipazione, all'impegno operativo e temporale richiesto

NATURA DEL CONFERIMENTO E CONSEGUENZE DI UN EVENTUALE RIFIUTO

L'eventuale rifiuto di fornire i Dati funzionali all'esecuzione della ricerca su menzionata, non comporta alcuna conseguenza relativamente ad eventuali trattamenti terapeutici in corso, salva l'eventuale impossibilità di dare seguito alle operazioni connesse alla ricerca.

Lei è libero/a di non partecipare alla ricerca o di ritirarsi dallo stessa anche senza preavviso o motivazione. Qualora, durante la ricerca, divengano disponibili dati che possano influenzare la Sua volontà di continuare Lei sarà tempestivamente ed opportunamente informato e, se necessario, Le sarà richiesto nuovamente il Consenso Informato a proseguire il trattamento in corso

COMUNICAZIONE DEI DATI

I Dati potranno inoltre venire a conoscenza dei responsabili della cui opera la Fondazione Santa Lucia si avvale nell'ambito di rapporti di esternalizzazione per la fornitura di servizi, nonché dei responsabili e degli incaricati del trattamento dei dati per le finalità di cui alla presente informativa, l'elenco aggiornato dei quali è a disposizione presso la sede della Fondazione Santa Lucia.

I Dati relativi ai risultati della ricerca sono strettamente confidenziali e soggetti ad anonimato. I risultati potranno essere portati a conoscenza di terzi o pubblicati, ma escludendo ogni possibile riferimento personale al paziente

DURATA DEL TRATTAMENTO

I Dati verranno trattati dalla Fondazione Santa Lucia solamente per la durata della ricerca prevista in 3 anni.

DIRITTI DELL'INTERESSATO

L’art. 7 del Codice riconosce all’interessato numerosi diritti che La invitiamo a considerare attentamente. Tra questi, Le ricordiamo sinteticamente i diritti di:

- ottenere la conferma dell’esistenza o meno dei Dati che lo riguardano, anche se non ancora registrati, e la loro comunicazione in forma intelligibile;
- ottenere l’indicazione dell’origine dei Dati, delle finalità e modalità del trattamento, degli estremi identificativi del titolare, dei responsabili, dei soggetti o delle categorie di soggetti ai quali i Dati possono essere comunicati o che possono venirne a conoscenza in qualità di responsabili o incaricati;
- ottenere l’aggiornamento, la rettificazione o l’integrazione dei Dati (qualora vi sia un interesse in tal senso) ovvero la cancellazione, la trasformazione in forma anonima o il blocco dei dati trattati in violazione di legge, nonché l’attestazione che tali operazioni sono state portate a conoscenza di coloro ai quali i Dati sono stati comunicati o diffusi;
- opporsi, in tutto o in parte, al trattamento dei Dati che lo riguardano per motivi legittimi ovvero per fini di invio di materiale pubblicitario o di vendita diretta o per il compimento di ricerche di mercato o di comunicazione commerciale.

Lei, per l'intera durata del trattamento, potrà chiedere informazioni o porre domande al medico circa i dati acquisiti nel corso della sperimentazione e circa l'andamento della stessa relativamente al suo caso; allo stesso modo, al termine della ricerca, se richiesto, i risultati che La riguardano saranno comunicati a Lei ed al suo medico di base.

TITOLARE DEL TRATTAMENTO

Titolare del trattamento è la Fondazione Santa Lucia, Via Ardeatina, n. 306 , Roma.

Per qualsiasi ulteriore informazione, chiarimento e comunicazioni è a disposizione il responsabile dei dati nella persona del responsabile della sperimentazione dott.ssa Roberta Annicchiarico".

Dott. Responsabile della sperimentazione: Dott.ssa Roberta Annicchiarico

Reparto: UOC

Roma, lì 08 giugno 2015.

MODULO CONSENSO INFORMATO

Io sottoscritto ……..……., familiare del paziente…… dichiaro di aver preso visione del protocollo concernente lo studio “FATE: Rilevatore di cadute per anziani” che si svolgerà presso la Fondazione Santa Lucia.

In particolare dichiaro

- di aver ricevuto, all'interno di tale foglio illustrativo, l'informativa prevista dall'articolo 13 del D.lgs. 196/2003 riguardo al trattamento dei dati personali.
- di avere avuto a disposizione tempo sufficiente per poter leggere attentamente e comprendere quanto contenuto nel suddetto foglio illustrativo.
- di aver ricevuto dalla Dott.ssa Roberta Annicchiarico che opera presso la UOC esaurienti spiegazioni in merito alla richiesta di partecipazione allo studio.
- di essere stato informato del diritto di ritirarmi dalla ricerca in qualsiasi momento, senza dover dare spiegazioni e senza compromettere l'assistenza medica futura.
- Di aver ricevuto il nominativo del Dott.ssa Roberta Annicchiarico come medico referente per qualsiasi ulteriore chiarimento o informazione relativa alla sperimentazione
- Di aver avuto modo di esporre le mie considerazioni e di domandare ulteriori precisazioni, nonché di avere avuto il tempo necessario per prendere una decisione ponderata e non sollecitata.

Pertanto, sono consapevole delle attività previste e delle modalità di una mia adesione.

Ciò premesso dichiaro

di acconsentire ☐

di non acconsentire ☐

a partecipare allo studio ed al conseguente trattamento dei miei dati personali sensibili.

cognome e nome della persona	firma della persona
_____	_____

oppure

cognome e nome del rappresentante legalmente valido	firma del rappresentante legalmente valido
_____	_____
cognome e nome del medico che raccoglie il consenso	firma del medico che raccoglie il consenso
_____	_____

NB: il presente modulo è valido solo se accompagnato dal corrispondente foglio illustrativo

APPENDIX III

Ethical Committee approval.

FONDAZIONE SANTA LUCIA

ISTITUTO DI RICOVERO E CURA A CARATTERE SCIENTIFICO
Ospedale di rilievo nazionale e di alta specializzazione per la riabilitazione neuromotoria
00179 Roma -Via Ardeatina, 306 - Tel +39 06515011 - Fax +39 065032097 - www.hsantalucia.it
COMITATO ETICO

Ufficio di Segreteria
Resp. : Dr. Stefano Paolucci
Segreteria: Sig.ra Elisa Battisti
- tel. 0651501491
- fax 0651501453
e-mail comitatoetico@hsantalucia.it

Dr.ssa Roberta Annicchiarico
Fondazione Santa Lucia
Sede

Prot. CE/PROG.511 26-06-15

Visti gli atti propri del Comitato Etico operante presso la Fondazione Santa Lucia di Roma, con sede in Via Ardeatina 306, 00179 Roma

Si comunica

in data 22 Giugno 2015 si è svolta la riunione del Comitato Etico, durante la quale é stata esaminata tra l'altro, la proposta di studio da Lei avanzata dal titolo **"Robots in assisted living environments: Unobtrusive, efficient, reliable and modular solutions for independent ageing".**

Dopo la discussione il Comitato decide di approvare lo studio all'unanimità.

Distinti Saluti.

Per la Segreteria
Elisa Battisti