



ROBOTS IN ASSISTED LIVING ENVIRONMENTS

UNOBTRUSIVE, EFFICIENT, RELIABLE AND MODULAR SOLUTIONS FOR INDEPENDENT AGEING

Research Innovation Action

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Early Detection methods and relevant system requirements I

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Abstract

This deliverable details the profile and number of participants and how long they will work with the consortium.

History and Contributors

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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 <i>interRAI</i> Home Care Assessment System
interRAI LTCF	The <i>interRAI</i> 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

This deliverable works towards the objective of establishing functional requirements so that the RADIO system is a medically sound alternative to classical care services models based on close supervision and inpatient monitoring.

This deliverable details the profile and number of pilot participants and how long they will work with the consortium, and also presents the relevant informed consent forms.

1.2 Approach

This deliverable is prepared within Task 2.1 *Review of early detection methods and necessary system actuation* and forms the basis for the clinical protocols that will be submitted to the Ethics Committees of the three piloting partners.

1.3 Relation to other Work Packages and Deliverables

This deliverable is a precursor to D2.2 *Early Detection methods and relevant system requirements II* and to D6.1 *Piloting Plan I*. D2.1 was prepared early in order to be used for the clinical protocols of the first trials to be carried out at FSL premises in the context of Task 6.2 *Controlled pilot trials*, project month M4-M6. Further work in Task 2.1 and Task 6.1 *Piloting and Evaluation* will carry out translations where necessary (e.g., the consent form, Appendix I) and refine the clinical protocols for the FHAG and FZ trials due later in the action. As a consequence, this deliverable will be superseded by D2.2 and D6.1 (both due M3).

2 RADIO PROTOCOL

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 patient's 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 uses these observations to establish ADL patterns and identify deviation. Moreover, it will empower new care service provisioning models, which will be based on the remote supervision of the elderly/patients from the medical experts and/or health professionals or care-givers. It will deal 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

2.1 Study Design

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

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 robots 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.

The study will be conducted on 138 user-groups. The user-groups comprise the elderly participants and care-givers.

The number and kind of user groups in each pilot will be distributed as follows:

FSL:

- 66 users
 - 30 during formative phase
 - 36 during intermediate phase

FHAG

- 24 users during the summative phase

FZ

- 24 users during the summative phase
- 24 care-givers

2.2 Formative phase

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.

2.2.1 Outcomes

Usability.

2.2.2 Eligibility criteria

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

2.3 Intermediate phase

This phase is dedicated evaluation of early RADIO components for usability and fitness for purpose. It will last for three months (M16-M18). 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.

2.3.1 Outcomes

Usability and validity of early RADIO prototype.

2.3.2 Eligibility criteria

Inclusion criteria:

- Older than 64 years old.
- Ability to walk without human assistance indoors.
- Need supervision in almost two IADL
- 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.

2.4 Summative phase

This phase is dedicated to validate the prototype of the overall RADIO ecosystem and to provide data for the final, summative user evaluation report and medical evaluation report.

It will last for 12 months (M22-M33). These subjects will be selected from among a population resident at FHAG premises and at the private homes of FZ clients. All subjects will be tested before and after each experimental period through the comprehensive geriatric assessment with interRAI LTCF and HC and on usability through System Usability Scale (SUS), Psychosocial Impact of Assistive Devices Scale (PIADS) and After-Scenario Questionnaire (ASQ).

Data will be collected in two different sets of experiments in each pilot:

- M24-M27, testing the first RADIO prototype
- M30-M33, testing the second RADIO prototype

Each FZ subject will be involved for 4 weeks. Each FHAG subject will be involved for 3 days. During this phase in FZ will be also collect data from 24 caregivers.

2.4.1 Outcomes

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

2.4.2 Eligibility criteria for the elderly users:

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
- Community dwelling participants will have a family member or relative available (not mandatory for nursing home residents)

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
- Deaf
- Blind
- Languages problems
- Participating in another clinical trial.
- 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
- Unable to operate the RADIO system after 2 training sessions

2.4.3 Eligibility criteria for caregivers

- Should be a person related to the participant, who has had a previous known role in the care of him/her
- Enough autonomy to contact with the elder in case of need and contribute to the decision making process in case of emergency
- 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

2.5 Variable and Instruments

This section lists all the variables that had to be measured in order to achieve the objectives of the study and to assess the outcomes. Each variable had to be measured by the means of one or several instruments or indicators, which also are specified below:

- Measure validity of the Radio system
 - Custom-made questionnaire will be created to collect data from caregivers and nurses staff
- Evaluate Functional activities and mood
 - CGA (physical function and mood) using interRAI LTCF (nursing home) or interRAI HC (home care)
 - Physical Function from LTCF (section G, see annex I)
 - MMSE
- Improving Quality of Life
 - InterRAI QoL questionnaire
 - Custom-made questionnaire (care-givers and nurses staff)
- Measure Usability
 - SUS questionnaire
 - ASQ questionnaire
 - PIADS questionnaire

2.6 Statistical analysis

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

2.6.1 Measuring the accuracy of activities of daily life (ADL) recognition.

In order to evaluate RADIO performance we will produce a confusion matrix summarising how many times different activities (ADL / mood) were misclassified by the system compared with ground truth assessment. From this matrix a set of common metrics such precision, recall, accuracy and the F1 score (harmonic mean of precision and recall) will be also calculated for each activity (5).

Precision / Positive Predictive Value: Precision is also known as the Positive Prediction Value (PPV) and measures the likelihood that a detected instance of an activity corresponds to a real occurrence.

Precision is defined as $TP / TP+FP$. Likewise, $(1-precision) = FP / TP+FP$ is the probability of the recognizer incorrectly identifying a detected activity

$$Precision = \frac{TP}{TP+FP}$$

Recall / Sensitivity: Sensitivity, which is also referred to as recall, corresponds to the correct detection rate relative to ground truth. It is the percentage of correctly detected activities out of all true instances of a particular class, averaged overall activities.

Sensitivity is defined as $TP/TP+FN$. Likewise, $(1-sensitivity) = FN / TP+FN$ is the probability of the recognizer failing to detect an instance of an activity.

$$Recall = \frac{TP}{TP+FN}$$

Accuracy: Accuracy measures the percentage of correct identifications after discounting insertion, deletion, and substitution errors. Although accuracy has a maximum value of 100%, for continuous recognition systems, there is no general lower bound due to the penalty for insertion errors. Thus, a poor recognition system with a very low detection threshold could insert more false detections than there are true events, thereby leading to a negative overall accuracy.

$$Accuracy = \frac{TP+TN}{All}$$

F-Measure: The F-Measure combines the precision and recall rates into a single measure of performance. It is defined as the harmonic mean of precision, P, and recall, R.

$$Fmeasure = \frac{(b2+1)PR}{b2P+R}$$

Other performance measures that could be considered for analysis are Receiver Operator characteristics (ROC) and Precision Recall (PR) curves with area under the curve (AUC) and equal error rate (EER) extracted metrics respectively.

2.6.2 Evaluation of functional activities, mood end quality of life

The impact of the system on users' health and functional status will be evaluated with the interRAI – HC and interRAI- LTCF questionnaires. These will be filled before and after system intervention. Different scales for cognition and activities of daily living will be extracted from the interRAI and separately evaluated with longitudinal comparisons with an analysis of variance (ANOVA).

2.6.3 Usability

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.

APPENDIX I

This appendix presents the *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: