Acronym:	Active@Home
Name:	Social Exergaming, Dancing and Tai Chi for wellbeing and fall prevention
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D2.1 Ethical Roadmap

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Partners involved (leader in bold): **ETHZ**, UNIKBO, CKEEPERS
Authors: ETHZ, UNIKBO, CKEEPERS

[1] L = Legal agreement, O = Other, P = Plan, PR = Prototype, R = Report, U = User scenario
[2] PU = Public, PP = Restricted to other programme participants (including the Commission Services), RE = Restricted to a group specified by the consortium (including the Commission Services), CO = Confidential, only for members of the consortium (including the Commission Services)

Partner list

Nr.	Partner name	Short name	Org. type	Country
1	Dividat GmbH *(coordinator)*	DIVIDAT	SME	Switzerland
2	Fraunhofer AICOS	AICOS	R&D	Portugal
3	MIRALab SARL	MIRALAB	SME	Switzerland
4	ETH Zurich	ETHZ	R&D	Switzerland
5	Unie KBO	UNIEKBO	End-U	The Netherlands
6	Conforto em Casa, Lda.	CKEEPERS	SME	Portugal

Revision history

Rev.	Date	Partner	Description	Name
1	15.06.2016	ETHZ	Created the first version	Manuela Omlin
2	22.06.2016	UNIEKBO	Comments and additions	Ciska van Harten
3	24.06.2016	AICOS	Comments and additions	Vania Guimaraes
4	24.06.2016	ETHZ	Integration of comments and further revision	Manuela Omlin
5	30.06.2016	ETHZ	Final revision	Manuela Omlin

6	30.06.2016	**Approved by ETHZ**

Disclaimer

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1. Introduction

This document is part of *Task 2.1: Ethical roadmap* within *Work package 2: User Requirements and Specifications*. The lead partner of this work package and task is ETH Zurich (ETHZ). The document describes an ethical roadmap which is a strategic plan containing the basic ethical principles and agreements that all project partners need to comply with during the Active@Home project.

During the project, this ethical roadmap needs to be the foundation on which many other documents are based. These could be for example questionnaires, leaflets, informed consent, study protocols etc.

When necessary in the course of the project, the document will be updated.

This document is subdivided into eleven sections, containing a short description of the project, current legislation on international and national level, internal ethical review board, Active@Home's general ethical principles and their practical application, inclusion and exclusion criteria, recruitment of participants, informed consent, privacy and data protection, risks and safety, reporting and publishing and benefits for society and individual participants.

2. Overview

The Active@Home project's main goal is to develop a technology-based training game (so called exergame) containing physical exercise with Tai Chi and dance elements to improve strength, balance, coordination and general physical functioning. The home-based solution should not only focus on physical but also on cognitive and social aspects and aims to foster fall prevention and general wellbeing. This video game intends to be challenging, motivating and captivating. The main focus of this holistic approach is on increasing the physical activity and functioning of elderly people.

The user interaction and investigation within the Active@Home project will be carried out in three phases:

1) *Understanding and conceptualizing phase (Investigation phase):* In the first phase, senior citizens will play an active role to get a clearer picture of users' needs, attitudes and expectations towards technology and thus the specification of the systems and the design of the Active@Home training program. The method used will be a survey/questionnaire with at least 50 elderly people participating in every involved country (Switzerland, the Netherlands, and Portugal). In parallel to the survey a focus group with stakeholders will be conducted in every country, in order to gain useful knowledge for the promotion of the system and its future exploitation. The main goal of this first phase is to get profiles of archetypical end-users and stakeholders which provide a solid basis for the development phase.

2) *Developing phase (Development phase):* In the second phase, small groups of users will be involved during the system development stage to help creating a working prototype. User-centred design techniques will be applied to define and validate the game user interface and to guarantee that all aspects can be easily understood by the target group. End-users might also have an active participation in the construction of a dataset of movements which will then be used to develop algorithms for signal processing so that movement evaluation techniques can be created on top. The main goal of this phase is a user-centred system and design development.

3) *Testing phase (Trial phase):* In the third phase, the developed prototype will be tested and evaluated in the field. Before any field trial, the subjects will be trained on how to use the system. Subjects will be able to use the system during an extended period of time in real life conditions to ensure realistic environments (at home). The technology will be tested by 20 independently living older adults per study site (Switzerland, the Netherlands, Portugal) recruited from the community. Another 20 older adults per involved country will be recruited as control group. Trials will be organized into two consecutive stages. On the first (shorter) stage, users will validate the system from a technical point of view. On the second (longer) stage, the main goal is evaluating the training program by measuring key performance indicators.

3. Legislation and general ethical principles

The members of the Consortium declare that the Active@Home project will comply with the current legislation and regulations of the countries in which the research is to be carried out. Moreover, the project will comply with all relevant European Union (EU) legislation, especially the legislation below:

3.1 The European Charter of Fundamental Rights

The EU is founded on a common ground of shared values laid out in the European Charter of Fundamental Rights. The Charter acknowledges a range of personal, civil, political, economic and social rights. The Cologne European Council of June 1999 entrusted the task of drafting a charter to a convention. The Lisbon Treaty incorporates the Charter into the Treaty on the European Union, giving the charter an equal legal effect, and states that all European legislation needs to conform to the principles of the Charter. Consequently, this also applies to the European research policy.

The European Charter of Fundamental Rights contains several principles which can be relevant in the context of research. These principles form the basis of important ethics guidelines but also support the conduct of research. The most important articles are mentioned here (shortened to the relevant parts):

Article 3 – Right to the integrity of the person

Everyone has the right to respect for his or her physical and mental integrity.

In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law.

Article 7 – Respect for private and family life

Everyone has the right to respect for his or her private and family life, home and communications.

Article 8 – Protection of Personal Data

Everyone has the right to the protection of personal data concerning him or her.

Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.

Compliance with these rules shall be subject to control by an independent authority.

3.2 New EU regulation on data protection

According to the European Charter of Fundamental Rights, natural persons have the fundamental right to the protection of personal data concerning him or her.

The European Commission adopted new legislation on this subject. Currently the old legislation still applies. But within the project we will adhere to the new legislation already.

The Council adopted the Regulation and the Directive on 8 April 2016. The Regulation and the Directive were adopted by the European Parliament on 14 April 2016. **The Regulation (EU) 2016/679 (General Data Protection Regulation)**, repealing Directive 95/46/EC, will enter into force on 24 May 2016 and shall apply from 25 May 2018. **The Directive (EU) 2016/680 (Data Protection Directive)** will enter into force on 5 May 2016 and shall apply from 6 May 2018.

The Eurobarometer survey on protection and personal data, conducted among 28'000 EU citizens in March 2015 reveals concern among EU citizens. For example, a majority agrees that "providing personal information is an increasing part of modern life" (71%), "that their explicit approval should be required in all cases before their data is collected and processed" (69%), or "that they would want to be informed should their data ever be lost or stolen".

Further, eight out of ten EU citizens feel that they do not have complete control of their personal data. However, General Data Protection Regulation applies adapted regulations, which build and maintain trust. The overall change concerns the same data protection rights across EU. This means for businesses that the single, pan-European law for data protection build consistency between 28 countries. Moreover, one-stop shop involves one single supervisory authority (Data Protection Authority, DPA), which will promote clarity and make it cheaper for companies to do business in the EU. Same rules apply when goods and services are offered on

the EU market. By means of a risk-based approach, rules will be tailored to risks and therefore avoid one-size-fits-all obligation. Rules incentivize businesses to innovate, by means of data protection by design, meaning to build data protection safeguards into products and services from the earliest stage of development. Techniques as 'anonymization', 'pseudonymization' and 'encryption' are promoted to protect personal data (important in terms of big data) and thereby enable big data innovation. Transparency is core to the adapted version on data protection, stating that organization should publish transparent and easily accessible data protection policies. Simple icons on a website could explain how, by whom and under whose responsibility personal data will be processed.

All in all, red tape will be reduced, meaning that no more notifications (fees for processing data) need to be provided to supervisory authorities. Small- and medium-sized businesses are for example also able to charge a fee for providing access to data (every penny counts). Data protection officers do not need to be appointed by the large majority of small- and medium-sized businesses. However, when the core activities involve "regular and systematic monitoring of data subjects on a large scale" a data protection officer need to be appointed. Only very risky data processing activities will need to carry out data protection impact assessments. Thereby, a privacy-friendly environment will be created.

In terms of controlling personal data and in order to build and maintain trust in online environment, the adopted Regulation states that easier access to personal data is ensured. Also, EU citizens have the right to data portability, which means that data can be transferred between services by the user. Thereby, trust is strengthened and fair competition created: especially small- and medium-sized businesses can compete giants within the single market. The right to be forgotten means that if requested, data must be deleted. Moreover, users have the right to know when data has been hacked. Thus, by means of clear affirmative actions, meaning that users give their consent for processing personal data. In case of data breaches, the data protection authority of each Member State as well as the user need to be informed as soon as possible – where feasible within 72 hours.

All in all, the adapted Regulation ensures:

- Enhancing transparency
- Fostering consumers' trust
- Boosting competition through new right of data portability
- Creation of a level playing field for all companies active in the single market

3.3 Other relevant laws and regulations

- Declaration of Helsinki of the World Medical Association (WMA) adopted by the 18th WMA General Assembly in June 1964 (latest version October 2013)
- EU-ICH-Guideline for Good Clinical Practice E6(R1) of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use of 10 June 1996

- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
- International Ethical Guidelines for Biomedical Research Involving Human Subjects by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the Word Health Organization (WHO) signed in Geneva in 2002
- Convention of the Council of Europe on Human Rights and Biomedicine signed in Oviedo on 4 April 1997
- Additional Protocol to the Convention of the Council of Europe on Human Rights and Biomedicine concerning Prohibition of Cloning Human Beings signed of 12 January 1998
- Additional Protocol to the Convention of the Council of Europe on Human Rights and Biomedicine concerning Biomedical Research of 25 January 2005
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (there will be a new Directive apply from 25 May 2018, see above)
- Code of Conduct on privacy for mobile health apps - The Code of Conduct on privacy for mobile health apps has now been formally submitted for comments to the Art 29 Data Protection Working Party

Nothing in the Active@Home project may conflict the opinions of the European Group of Advisors on the Ethical Implications of Biotechnology (1991-1997) and the opinions of the European Group on Ethics in Science and New technologies (as from 1998).

Within the Active@Home project, the research using participating elderly people is mainly conducted in Switzerland, the Netherlands and Portugal. Therefore the prevailing regulations will apply to these countries. Furthermore and very importantly all project activities need to be approved by the respective Ministry of Health/the respective ethics authority. These authorities and the organization, procedure and time course/deadlines may vary in the different countries involved. Below the national specifications are described. The information sent to the respective ethical committee include objectives of the research project, methodology of the study, description of intervention and their potential benefits and risks and informed consent template.

Switzerland:

In Switzerland there is the local ETHZ's ethical committee where submissions (study protocols) can be sent. Answers from this committee can normally be expected in 2 months following submission. There is also a cantonal ethical committee (Kantonale Ethikkommission Zürich). Answers from this ethical committee can normally be expected in 6 month after submission.

Beyond the international EU regulations mentioned above there are some Swiss regulations and guidelines:

- Federal Act on Research involving Human beings, Human research act (HRA) of 30 September 2011 (status as of 1 January 2014)
- Ordinance on Clinical Trials in Human Research (ClinO) of 20 September 2013 (status as of 1 January 2014)
- Ordinance on Human Research with the Exception of Clinical Trials (HRO) of 20 September 2013 (status as of 1 January 2014)
- Federal Act on Data Protection (FADP) of 19 June 1992 (status as of 1 January 2014)

The Netherlands:

- Wet Bescherming Persoonsgegevens (WBP) / Personal Data Protection Act (6 July, 2000)
  With regard to this law it's important the gathered information in the project can not be easily used to identify a person. In addition the emphasis is on the voluntary consent based on complete information about data collection and storage.
- Wet medisch-wetenschappelijk onderzoek met mensen (WMO) / Law on medical research with human subjects (26 February, 1998)
  If a study falls under the scope of the Medical Research Involving Human Subjects Act (WMO) then it must undergo a prior review by an accredited Medical Ethical Reviewing Committee (MREC) or the Central Committee on Research Involving Human Subjects (CCMO).
  Research falls under the WMO if the following criteria are met:
  1. It concerns medical/scientific research and
  2. Participants are subject to procedures or are required to follow rules of behaviour.

Portugal:

In Portugal there are national authorities that need to be contacted if a new system (software and exercise protocol used) is to be considered a clinical trial: a) The Portuguese Authority for ethical purpose is CEIC (National Ethics Committee for Clinical Research) ; b) Infarmed (National Authority of Medicines and Health Products) and c) CNPD (Portuguese Data Protection Authority). There are also local ethical committees where submissions can be sent (e.g. at Universities).

In the case of Active@Home, the purpose is to develop a training software, not a clinical trial, so the new system must be compliant with Portuguese Data Protection Requirements published by CNPD and according Portuguese Law 67/98 (Data Personal Protection Law). However, AICOS has already an authorization for data collection and treatment. It is then necessary to list all data that will be collected in the scope of this project and then check if all items are considered in this authorization. If not, the project needs to obtain an authorization from CNPD to capture, process, store and present or disseminate personal information from users. The Portuguese Law 67/98 is consistent with Directive 5/46/CE issued by European Parliament in October 25th, 1995.

Also, there may be a need to get approval from an ethical committee before proceeding with the field trials. Again, considering that these are not clinical trials, there's no need to go for highest courts (for instance, Administração Regional de Saúde), which usually take longer to answer. For this project, the first option will go to CEUP (Comissão de Ética da Universidade do Porto). In case of a positive answer, the submission process must be prepared and includes the following documents:

- Submission form (CEUP template);
- Letter directed to the President of CEUP asking for approval;
- Description of the project, including the partners;
- Informed Consent;
- Identification of the researchers and their Curriculum vitae.

In case it is not possible, the best alternative will be to use other ethical committee from another university.

3.3 General ethical principles of Active@Home

Based on the above mentioned legislation, the Active@Home project will uphold the following five general ethical principles:

1. Respect for the integrity and dignity of persons: protecting them from being used for any other purpose than stipulated.

2. Follow the "do no harm" principle: clearly communicating any potential risks to the elderly person involved.

3. Acknowledge the rights of individuals to privacy, personal data protection and the freedom of movement.

4. Honour the requirement of informed consent and continuous dialog with elderly constructively and transparently.

5. Respect the principle of proportionality: not imposing more than is necessary on the subjects, nor going beyond stated objectives (mission creep).

4. Internal ethical review board

All the ethical issues should be supervised by an internal ethical review board. The supervision by an internal ethics committee should help to ensure the project's full adherence to the important ethical aspects. The internal ethical board has the following members:

- Eling De Bruin (ETHZ)
- Ciska Van Harten (UNIEKBO)
- Jorge Monteiro (CKEEPERS)
- Bujar Badalli (DIVIDAT)

All issues with an ethical content should receive first the approval of the ethical review board of Active@Home. The internal ethics committee is especially responsible for:

- Evaluation and approval of inclusion and exclusion criteria
- Supervision of the recruitment process of participants
- Support of developing the informed consent document
- Evaluation and approval of rules for privacy and data protection
- Evaluation of potential risks and analysis of safety issues
- Approval of all documents containing ethical issues (especially reports)
- Supervision and support of the approval by the national ethical committees especially defining the timeframe for writing and submitting to the relevant authorities at the national level

5. Target group and inclusion/exclusion criteria

The main target group of this project is represented by elderly people aged 65 years and older without severe illness/disability that live independently.

Elderly with mild mobility impairments and mild cognitive impairments will not be excluded. But it's necessary that participants are able to stand and move without any aid. Concerning the cognitive state people with severe cognitive impairment (dementia) have to be.

The elderly involved in the different project phases will be more precisely described in the methodology definitions (e.g. which procedures are used to secure the determined criteria). In following work packages the target groups will be more precisely formulated resulting in different scenarios/use cases which will define the elderly involved and the trial-environment in the three different countries.

6. Recruitment of participants

User groups will be selected and recruited in Switzerland, Portugal and the Netherlands.

Potential participants can be addressed in many different ways (face-to-face, advertising, publicity, homepage etc.). They have to be informed about research goals and methods/procedures. This information will be handed out in writing (e.g. information letter, leaflet) and orally. Potential participants will be notified in their own language and in a comprehensible way.

The researchers will make future participants aware that their participation is completely voluntary, that they have the right to refuse to participate and that if they agree to participate they can still terminate their participation at any time and without any given reason for their decision. The researchers will inform participants on a number of important factors which could influence their decision to participate (like risks/benefits, potential inconveniences or adverse consequences, restrictions to confidentiality etc.). Participants should get ample opportunity to read through the information, to ask the researcher any question and to consider their potential participation.

The Active@Home project will not approach people who are unable to give their informed consent (see chapter 7). In case such a situation would accidentally occur, the approach will be terminated immediately.

In order to recruit participants, no suitable high financial compensations or any other rewards may be used. It is nonetheless allowed to give participants a small and suitable present (costs have to be paid by the organization conducting the research).

7. Informed consent

Declared one of the most important principles in research ethics in many international conventions and guidelines, informed consent is meant to guarantee the voluntary participation in research and is probably the most important procedure regarding integrity and privacy issues.

Informed consent consists of three important components: adequate information, voluntariness and competence. This implies that, prior to consenting the participation, participants should be clearly informed about research goals and procedures, potential risks and the possibility to refuse participation or withdraw from research at any time and without consequences. It's important that participants are competent to understand the information and should be fully aware of the consequences of their consent. Therefore people incapable of making their own choices will not be approached for the Active@Home project.

Participants will be asked for their informed consent by signing the informed consent document on the basis of the provided information. Numerous anthropological studies have pointed out that participants rarely recall what they agreed to when just signing an informed consent form. That's why a more interactive approach would be desirable and could address this issue (e.g. elaborating the written information and the informed consent document verbally).

In each phase of the Achtive@Home project the respective information and informed consent needs to be adapted to the research goal.

To summarize, the informed consent document covers:

- Goals of the project and research
- Research methods and procedures
- Potential risks and discomfort
- Anticipated benefits to participants and society
- Gratuity for participation
- Data protection, privacy and confidentiality
- Use and publication of data
- Withdrawal of participation
- Emergency care, compensation for injury or damage
- Identification of investigators (e.g. for further questions/information)
- Rights and duties of research subjects

The informed consent has to be prepared in advance, as it needs the approval from the Ethics Committee.

8. Privacy and data protection

Privacy is a fundamental right which needs to be protected at all time. Privacy can mean many different things in different contexts. Not all people have the same notion of the right of privacy, but most people want to maintain control over personal information and communication. If personal information is disclosed, we expect this information to be treated confidentially. Data protection is meant to guarantee our right to privacy. It includes both measures with regard to access to data and the conservation of data. Data protection refers to the technical framework and security procedures designed to guarantee that all personal data are safe from unforeseen and unintended use.

Within the Active@Home project with three study sites it is unavoidable that data will travel across borders inside the EU. As a result, data concerning the citizens of one member state are sometimes processed in another member state of the EU. Therefore regulations on data transfer become necessary and are implemented and observed in the Active@Home project.

The directive to follow during the project until Mai 2018 is the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. All personal health data will be treated as 'sensitive personal data'. As a result, the personal data of all citizens will have equivalent protection across the EU. The member states of the EU are required to bring their national legislation in line with the provisions of this directive.

From Mai 2018, the project will comply with Regulation (EU) 2016/679 (General Data Protection Regulation), updated in 27 April 2016 and applying in May 25, 2018. According to Regulation (EU) 2016/679, the same data protection rights across the European Union apply in the European-wide project Active@Home.

Data protection and privacy are fundamental rights, which need to be respected. Privacy covers the right to manage one's personal information, while being free from secret surveillance. Data protection entails the integrity and control of one’s data with regard to the purposes of data processing. It has to be stated explicitly that data will be transferred from one partner to another within the EU only after it was made anonymous. The international laws include the obligation to process data always fairly and in a secure manner and use it only for explicit and legitimate purpose. National laws also guarantee a series of rights for individuals, such as the right to be informed when personal data has been processed and the reason for this processing, the right to access the data and if necessary the right to have the data amended or deleted.

The project will work as much as possible according to the principle of ‘Design by default’: The design of the system will automatically apply privacy settings. In other words, no manual change to the privacy settings should be required on the part of the user.

Some principles of privacy and data protection in Active@Home: How to handle personal data

Personal data is understood as any piece of data regarding an identified or identifiable natural person.

- Active@Home consortium will handle personal data in an appropriate way and is bound to the applying rules and regulations.
- The privacy of all of the participants is respected: personal data is treated as confidential sensitive data. Personal data that may lead to the identification of a participant will be disconnected from the research data.
- Within the Active@Home research, personal data will be used for its assigned goals, as determined beforehand, or for targets that are consistent with the goals mentioned.
- Members of the Active@Home consortium will not hand over any personal data to any third party without the participant's prior consent. Passing personal data to any third party is only allowed if this would serve scientific research.
- If a systematic database, with directly identifiable personal data, would eventually be constructed within the project, the researchers must provide its registration according to national rules.
- The researchers will take all suitable precautionary technical and organizational measures to prevent any loss of data or illegitimate access or processing.

9. Risks and safety

If there would be any risks for elderly people participating in the Active@Home project these would be encountered most likely in the testing phase or in the developing phase.

As the project wants to develop and test a video game containing physical exercise, the highest risks seem to be included in the movements because there is always a risk of injury as in any other daily life movement and especially sport games and sports in general. It has to be stated that the physical exercise tasks are not very complicated and will be designed specifically for elderly people, taking into account the specificities of this target group. Participants will be well introduced, instructed and supervised by the researchers.

The potential risks will be well clarified to the participants during the recruitment process and they will be specified in the informed consent.

A plan should be designed (including insurance cover) for emergency situations that might occur during the testing.

10. Reports and data publication

The dissemination and publication of the results obtained are an important goal of the scientific research. Publishing research results also involves a conflict between the privacy interests of individual participants and the need for free exchange between scientific experts. There are a number of good practice codes and regulations that guide researchers in handling this conflict. The Helsinki Declaration in its latest version states the following:

"Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication."

All partners in the Active@Home project will adhere to the Declaration of Helsinki. For statistical analysis only data that is anonymized is used and results will only be published as summary statistics in order to prevent re-identification of individual participants.

11. Applying the ethical principles to the Active@Home project in the different phases

In this chapter practical applications for the ethical principles in the different research phases are described.

11.1 Investigation phase

Goal: It is essential that elderly people participate in this phase in order to get insights in the end-users' needs, attitudes and expectations. The goal is to fulfil their needs in the best possible way while developing the Active@Home system. Another goal is to describe the archetypical stakeholders.

Ethical principle	**Specification**
Inclusion/exclusion criteria	Healthy independently living elderly people aged 65 years and older (no severe cognitive impairment)
Recruitment of participants	Questionnaire (end users): 50 per involved country Focus group (stakeholders): one per involved country
Informed consent	Questionnaire: necessary information will be on the questionnaire, optionally more verbal information (phone number of researcher) Focus group: written informed consent (adjusted for this subsection)
Privacy and data	Taking part in the questionnaire will be anonymous. The participants will be asked whether they'd like to participate in the following research. In

protection	case participants want to, then the personal data which is minimally required for this will have to be registered like name and email address. Research publication will always be anonymized. Any data transfer between the participating countries will take place without personal data. The filled out questionnaires within the Active@Home project will be destroyed six months after the project has ended. Destruction will be carried out by the project coordinators in the respective countries.
Risks and safety	There are no risks for the participants at all in this phase.
Reports and data publication	Reports will be situated within the project.

11.2 Development phase

Goal: It is necessary to have elderly people participating in this phase in order to get sufficient feedback especially on the user interaction with the Active@Home system so that adjustments to the final system can be made.

Ethical principle	**Specification**
Inclusion/exclusion criteria	Healthy independently living elderly people aged 65 years and older (no severe mobility or cognitive impairment)
Recruitment of participants	A small number in the main country of development procedure (Portugal)
Informed consent	Written informed consent (adjusted for this subsection) that needs to be signed by the participants
Privacy and data protection	All data will be anonymized.
Risks and safety	Risks because of physical exercising but it will be in a controlled environment and there is always at least one project member for support
Reports and data publication	Reports will be situated within the project.

11.3 Trial phase

Goal: Having elderly people involved in this phase is very important in order to get some final feedback on technical aspects of the system and also to evaluate the promising effect of the new developed program through the measurement of key performance indicators.

Ethical principle	**Specification**
Inclusion/exclusion criteria	Healthy independently living elderly people aged 65 years and older (no severe mobility or cognitive impairment – there will be guidelines in the methodology definition in order to determine whether these people are physically and cognitively fit enough to participate in the field trials)
Recruitment of	Intervention group: 20 per involved country

participants	Control group: 20 per involved country
Informed consent	Written informed consent form with all the detailed information that needs to be signed by the participants, information will also be given orally and any questions will be answered, participants should get enough time to make their decision.
Privacy and data protection	In the methodology definition the access and storage respectively safety of the data will be discussed.
Risks and safety	Risks because of physical exercising but tasks will be designed specifically for elderly people, taking into account the specificities of this target group.
Reports and data publication	Reports will be situated within the project and results may be published in respectively research journals and thereby be open to the public.

12. Benefits of the project

Active@Home is a solution for increasing physical activity and promoting fall prevention of European older healthy adults. It is well-known that falling constitutes a huge problem to our society with serious consequences not only to the health care system but mainly to the seniors and their families who suffer more closely from the consequences. The Active@Home project is aimed to have benefits not only on the individual level but also for the society.

12.1 Benefits for the individuals

Falling can lead to injuries, restrictions of movement, loss of independence, social isolation, depression and a general decrease in well-being and quality of life of the affected senior. Furthermore there could be the restricting anxiety of falling again. As a consequence of a fall, the older adults become often dependent on their family members and caregivers who become highly involved and frequently suffer themselves from a reduced quality of life. The proposed solution will increase end-users' physical activity, strength, balance, coordination and also motor-cognitive-interplay and thereby reduce the risk of falling and improve independence, well-being and the quality of life. Indirectly, there will also be an improvement in life quality of family members and caregivers. Therefore, the approach of the proposed solution is based mostly on the prevention of adverse falls and their consequences but also on supporting and motivating elderly towards healthier and more active lifestyles which will allow them to fully experience their advanced ageing and retirement years, maintaining their independence and full control of their lives. And moreover, Active@Home is not only physical exercise but provides also a lot of entertainment and fun.

12.2 Benefits for the society

Current numbers demonstrate that one out of three people aged 65 and older fall annually and 20-30% of falls result in injury and hospitalization. Any intervention aiming to prevent the occurrence of these events may also result in a reduction of the direct costs related to the medical services and also the indirect costs related to other health and care pathways (due to the lack of independence, social isolation, depression among others). Considering that there is also an evaluation phase included in the project, impactful results together with analysis of the costs associated to the installation requirements and equipment may be sufficient to influence health care funders, community organizations and even public policies toward more appropriate management of falls in the older age. The evaluation will be conducted in different European countries, taking into account the differing social and organizational needs across Europe. The Active@Home project can result in a positive influence on current strategies for falls management in Europe.