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My-AHA

Deliverable 2.19

Ethical Roadmap and End-Users Ethical & Privacy Views – III

(Final update of the Ethical Roadmap and End-Users Ethical & Privacy Views from the Randomized Controlled Trial)

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Abstract

Based on legislation and general ethical principles a version of the project ethical roadmap was previously established in all the my-AHA Clinical Centres. In this updated version, ethical problems related to the Randomized Controlled Study (RCT) and Siegen Living Lab (LL). Adopted solutions to overcome these issues are discussed.

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Executive summary

The ethical road map is a strategic plan containing the basic principles and agreements that all project partners need to comply with during my-AHA project with regard to ethical aspects in research, concerning elderly people.

Based on general ethical principles and legislations of different countries, a version of the project ethical roadmap has been previously established in all the my-AHA Clinical Centres (Deliverable 2.13 - Ethical Roadmap and End-Users Ethical & Privacy Views – I).

The Randomized Controlled Trial (RCT) started in March 2018 with the prescreening and the screening phase in 5 European Research Centres (University of Torino, Italy; IBV/GESMED Valencia, Spain, Johanniter, Austria; Johanniter, Germany; and Johanniter, Belgium) and in two non-European Research Centres (University of Sunshine Coast, Australia; and University of Tohoku, Japan). After a complex screening phase, 246 Pre-Frail subjects, diagnosed according to the Fried Criteria, were enrolled in the study and randomized into the Intervention Group and the Control Group. At present (M39), all subjects completed the first six-month trial period (from T0 to T1).

This deliverable discuss the ethical problems encountered and the solution suggested in the RCT. All the documents regarding the RCT have been submitted to the Ethic Committee of the University of Torino (Italy), the coordinator Centre of the study. All the statements regarding ethical questions have been approved by the “Comitato di Bioetica di Ateneo - CBA” of the University of Torino. Afterwards, all the Clinical Centres involved in the study received the final approval from their own Ethics Committee. Finally, end-users ethical and privacy views will be reported from the Living Lab in Siegen.

In accordance with the General Data Protection Regulation a data management plan and the nomination of data protection officers are necessary to cover legal obligations. This is here presented as example of the Austrian trial site. All partners must have a similar structure of data management plan for their processes available. By consent, the extra EU partners accepted to follow the regulations of data protection of the EU.

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1 Legislation and General Ethical Principles of my-AHA

The members of the Consortium declare that progress in the research project are, at present, in agreement with the current legislation and regulations of the countries in which the research is currently underway.

Most relevant issues have been previously discussed in the Ethical Roadmap and End-Users Ethical and Privacy Views – I (Deliverable D2.13), in the Ethical Roadmap and End-Users Ethical and Privacy Views – II (Deliverable D2.18) and in the Code of Conduct (Deliverable D1.5). Moreover, the research is complying with all relevant EU legislation, especially the:

A. **European Charter of Fundamental Rights**: right to the integrity of the person, respect for private and family life, protection of personal data, and consumer protection

B. **Declaration of Helsinki**: "the well-being of the individual research subject must take precedence over all other interest", "it is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects", "the design and performance of each research study involving human subjects must be clearly described in a research protocol", "the research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins" and "every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity".

C. Convention on Human Rights and Biomedicine of the Council of Europe: "parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental rights with regard to the application of biology and medicine", "the interest and welfare of the human being shall prevail over the sole interest of society or science", "an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it".

D. **Relevant EU Directives and other EU legislation:** Directive 95/46/EC, and Directive 2002/58/EC.

E. New EU regulation on data protection. Directive on 8 April 2016.

Related references 1-4.

Extra-EU partners are undertaking RCT trials in accordance with local ethical regulation, of which the ethical guidelines for each participating extra-EU partner conform to the Declaration of Helskini.

F. **National Health and Medical Research Council of Australia (NHMRC) and Australian Research Council (ARC)** National Statement on Ethical Conduct in Human Research (https://www.nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research)

2 General Ethical Principles in my-AHA Project

As already stated in previous deliverables (D2.13, D2.18, and D1.5), the my-AHA project consortium have agreed to conform to the **RESPECT** Code of Practice, originally developed as a framework for the conduct of ethical socio-economic research in Europe. The RESPECT code of practice is based on three main principles:

1. upholding scientific standards,
2. compliance with the law, and
3. avoidance of social and personal harm.

Based on the above mentioned legislation, My-AHA upholds the following six 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. Any potential risks must be clearly communicated to the elderly person involved.
3. Acknowledge the rights of individuals to privacy, personal data protection and the freedom of movement.
4. Honors the requirement of informed consent and continuous dialogue with the participant.
5. Respect the principle of proportionality: not imposing more than is necessary on the subjects, nor going beyond stated objectives (mission creep).
6. Treat societal concerns seriously – listen to the public/older person and engage with them in a constructive dialogue, transparently, honestly and with integrity.

Related references: 5-7

3 Ethical Roadmap of the Randomized Controlled Trial

3.1 Submission and approval of the request by the Ethic Committee

The purpose of the RCT is to test validity and portability of the platform developed in order to detect as early as possible different frailties and to plan cognitive, physical, psychological and social interventions.

The RCT was planned to be developed in 5 European Clinical Centres of the my-AHA research group:

A. University of Torino, Italy;
B. IBV/Gesmed Valencia, Spain;
C. Johanniter, Austria;
D. Johanniter, Germany;
E. Johanniter, Belgium.

An additional two extra-EU Clinical Centres participated in the RCT:
F. University of the Sunshine Coast, Australia
G. University of Tohoku, Japan

The Torino Centre, being the Coordinator Centre, was the first to contact the local Ethic Committee. Therefore, the ”Comitato di Biotetica dell’Ateneo – CBA” of the University of Torino was selected as the Ethic Committee in charge of providing the authorization for the study.
According to the characteristics of the research protocol, a request for a “Research protocol with human beings” was selected.

All the ethical aspects related to the research are described in details in the Attachment # 1, Attachment # 2, and Attachment # 3 of this deliverable.

The forms of the Comitato di Bioetica dell’Ateneo di Torino have been developed according to guidelines prepared in different European universities, like University of Cambridge (UK) and University of Milano, Bologna and Trento (Italy).

In summary, the main questions to be answered were:

1. Principals investigators: previous experience in conducting clinical trials

2. Collaborators to the research: selection criteria and previous experience

3. Place of the research

4. Characteristics for the enrolment: inclusion and exclusion criteria and protection of at risk subjects

5. Informed consent

6. Management of potential medical risks

7. Collaboration with family physicians

8. Data storage and data protection

9. Confidentiality and anonymization

10. Collaboration with other research centres

All the ethical questions have been described in details and were considered to be in accordance to previously described principles. Therefore, **October 18, 2017** the Comitato di Bioetica di Ateneo –CBA of the University of Torino approved the research project allowing the research to start the enrolment of the subjects (attachment # 4 of this deliverable).

All other EU study centres, after discussion with local Ethics Committee, adopted the approval of the Comitato di Bioetica di Ateneo of the University of Torino. The University of the Sunshine Coast (AUSTRALIA) and University of Tohoku (JAPAN) undertook submission of full RCT project protocols for approval by local ethical committees independent of approvals granted to EU Clinical Centres.

3.2 Recruitment of the Participants

A complex strategy for subject's recruitment was planned since January 2018. First, a large number of subjects, aged 60 yrs or more, was selected through announcements on newspapers and public conferences. A first group of 4675 subjects (1403 men and 3272 women, mean age 70.5 yrs) was evaluated. Then, according to a standardized protocol, a group of 636 subjects (174 men and 462 women, mean age 70.0 yrs) underwent a complex screening protocol with the evaluation of different frailties.

After this complex procedure, a final group of 246 subjects (60 men and 186 women, mean age 70.8 yrs) was enrolled at baseline (T0) and randomized into the Intervention group (106 subjects) and Control group (130 subjects). All the subjects enrolled into the Intervention group received a smartphone with the My-AHA platform and a wrist band.

All the subjects resulted highly motivated in such experimentation.
Recruited subjects reported no significant ethical problem in collecting personal data and in performing all the tests that have been planned for the RCT (Fried criteria, MMSE, HVTL, ADL, iADL, Corsi, Loneliness Scale, etc.).

In order to adequately protect physiological and clinical data collected during both the screening and the randomization phases of the RCT, in the subjects enrolled in the Intervention group, a complex process of anonymization of personal identity was developed. In details, each subject in the Intervention group received:

A. A clinical ID code, personally delivered by the local Principal Investigator
B. A Google account for the smartphone
C. A Fitbit user account for the registration of the data regarding physical activity and sleep

This process was developed in order to avoid any leakage of the personal data from the middleware network of the My-AHA platform.

3.3 Evaluation of administered tests and devices

The majority of subjects enrolled in the study preferred to use a study-supplied smartphone, specifically devoted for the RCT.

Main explanation for this choice was to avoid inserting new software potentially conflicting with the configuration of their own smartphone.

The embedded programs available for the protocol are Smart Companion and the Dashboard.
The patients regularly used the My-AHA smartphone as detected by the online checking through middleware.

3.4 Potential ethical problems and suggested solutions

At present, no main ethical problem has been encountered during the first six months of the RCT.

Currently, of the 265 participants enrolled in the study a total of 11 participants have withdrawn prior to 12 month assessment. Of the 11, 5 were from the Intervention branch and 6 in the Control branch. The main reasons of study interruption were mainly related to familial problems (need to assist first degree-relatives mainly). No drop-out due to an ethical breach or issue was reported.

Potential problems that may arise during the prosecution of the study are:

- Medical problems. Risk of development during the RCT of cognitive deficit, depression or anxiety. This risk is low, due to the accurate cognitive and psychological screening of the subjects performed at baseline.
- Physical problems. Risk of physical accidents that impair the possibility of the subject to use the smartphone (inability to use the smartphone with his/her own hands due to traumas). In this case, the subjects will be withdrawn from the study. At present (M39) no such event occurred.
- Social isolation. Even in this case, the short period of the study makes unlikely this condition due to the periodic suggestions provided by the researchers in order to maintain an active social life.

4 Data Protection and Privacy Processing of Personal Data

Personal data refer to any information which is relating to an identified or identifiable natural person. My-AHA Consortium, during the RCT, is maintaining privacy of personal data and data collected through neuropsychological tests. All data collected is deidentified at the time of collection through the use of a unique identification code for each participant. Only the Principal Investigator for each Clinical Centre is able to reidentify data for participants at their centre. As such, the Centre PI is responsible for data processing and for ensuring maintenance of protocols to maintain participant privacy.

At the different scheduled times of the RCT (T0, T1, T2, and T3) personal data and neuropsychological test have been and will be collected with a classical "pen and pencil" strategy. All the data, frequently collected by a neuropsychologist, are then supervised by the Centre PI and stored in a room specifically dedicated for the storage of randomized controlled study.

In the meantime, data collected with the paper and pencil method as well as by all the electronic platforms, mainly Smart Companion and Dashboard, are stored in the middleware in a deidentified format. Only the Centre PI has the key that allows to relate personal data with electronic data and only for participants from their centre. Therefore, personal data that may lead to the identification of a participant have been disconnected from the research data.

Personal data gathered for RCT of the my-AHA will only be used for its assigned goals defined in advance, or for objectives that are consistent with these defined goals. At present, the researchers have discussed and adopted all suitable precautionary technical and organisational measures to prevent any loss of data or illegitimate access or processing.

5 Model situation of Austria

5.1 Ethics Committee in Austria

In Austria a small variety of ethic committees exists, but unfortunately no one that is responsible for research in social sciences and humanities. Almost all active ethic committees work in the field of clinical/ medical research and follow partly directives of the European Commission, the declaration of Helsinki and their own guidelines.

Subsequently it isn't surprising that in Austria no national ethics standards for research in social sciences seem to exist too.

This lack is already known by research institutes in Austria and they solve the problem in two ways or almost all with a combination of these two ways:

- No research that is critical and could require an official ethic committee (e.g. involvement of children, mentally ill persons);
- Installation of an own ethics board;

The Johanniter in Austria are forced to take the same path as it seems to be the best solution – for the participants and the researchers: if necessary or critical an ethics board meeting convenes.

5.2 Ethics Board of the Johanniter in Austria

The ethics board of the Johanniter in Austria consists of 5 members:

It is led by o.Univ. Prof. Dr.Dr. Ulrich Körtner, who is director of the Institut für Systematische Theologie und Religionswissenschaft (En.: Institute of Ethics and Rights in Medicine) and also the director of the Institut für Ethik und Recht in der Medizin (En.: Institute for Semantic Theology and Religious Studies) of the medical university of Vienna and the University of Vienna. Further and beside of others, he is a scientific advisory board member of the interdisciplinary centre "Medicine – Ethics – Rights" of the Martin-Luther-Universität Halle-Wittenberg, scientific advisory board member of the Austrian platform for patient safety, scientific advisory board member of the university course "patient safety and quality in health care ". Additional he is award winner of the Viennese award for humanistic age-related research 2015 (De.: Wiener Preis für humanistische Altersforschung 2015) and of the scientist of the year 2001 (Klub der Bildungs- und Wissenschaftsjournalisten; En.: Club of education and science-journalists).

Two members of the board, Dr. jus. Heinrich Weninger and Dr. jus. Robert Brandstetter, are legal experts. Dr. Weninger is moreover member of the executive board of the Johanniter in Austria and still active as voluntary emergency paramedic. Dr. Brandstetter is the CEO of the Johanniter. Prim. Dr.med. Christian Emich is chief physician in the Evangelischen Krankenhaus (En.: evangelical hospital) in Vienna, leads a doctor's office and is in his private time also active for the Johanniter; as physician he is in regular contact with patients, their family members and informal carers and therefore confronted with ethical issues in his everyday working life. The member DI Johannes Bucher is the president of the Johanniter in Austria and therefore strong advocate of Christian values – like the other ethics board members too.

5.3 Data Protection Authority and Registration Requirements

The Austrian Data Protection Authority is named Österreichische Datenschutzbehörde (DSB; www.dsb.gv.at) that has the tasks – beside of others - to manage the data processing register, decision making of submitted complaints and the control in the case of reasonable suspicion.

In the data processing register data controllers and their data applications are listed.

"Data controller" shall mean a natural or legal person (...) that determined the purposes and means of the processing of **personal data** ... the controller or the specific criteria for his nomination may be designed by national or community law [EU Data Protection Directive 95/46/E, Article 2 (d)].

Before commencing a data application, a notification must be filed by the data controller. Therefor the DSB provides a list of notification requirements that include, for example [see "Handbuch zur DVR-Meldung" (En.: Manual for Registration of Data Application) http://www.dsb.gv.at/DocView.axd?CobId=59352] :

- the name and address of the controller and, where applicable, of her representative
- the purpose of the data application and the legal basis for the same
- categories of data subjects and of personal data processed
- categories affected by the transfer of data and categories of recipients, including possible recipient states abroad
- file of the permit number to the extent one is required by the DSB
- a description of security measures.

5.4 Personal and Sensitive Personal Data

The DSG describes personal data as information about an identified or identifiable person. "Persons" include natural persons and legal entities. Personal data can be parted into two categories:

- *Direct data* is personal data for which the identity of the subject can be found through legal means.
- *Indirect data* is personal data for which the identity of the subject can be found only through illegal means.

Further, *sensitive personal data* is defined as information about a natural person's racial or ethnic origin, political opinions, trade union membership, religious or philosophical beliefs, health or sex life.

5.5 Data Collection and Processing

In a first step the data controller must generally inform the data subject of the purpose of the processing and the name and address of the controller. Further, the data subject must be informed of other information if good faith dictates it, such as whether the subject has the right to object to the processing or transmission of data.

The *data subject* is every natural or legal person whose data are used.
Personal data may be processed if, for example:

- an explicit authorization or obligation to use the data exists
- the data subject has given his revocable consent
- the vital interest of the data subject requires the use
- overriding legitimate interests pursued by the controller or by a third party require the use of the data. In particular, this occurs if the use of the data is required to protect the vital interests of a third party
- it is necessary for the fulfilment of a contract between the controller and data subject or concerns the exercise of a public office by the data subject
- Sensitive data may only be processed, in the absence of unambiguous revocable consent from the data subject, if:
- the data subject has obviously made the data public himself
- the data are used only in indirectly personal form

- the obligation or authorization to use the data is stipulated by laws, insofar as these serve an important public interest
- the use is made by a controller of the public sector in fulfilment of his obligation to give inter-authority assistance
- the data solely concerns the exercise of a public office by the data subject
- the data subject has unambiguously given his consent, which can be revoked at any time
- the processing or transmission is in the vital interest of a third party or of the data subject and the data subject's timely consent cannot be obtained
- the use is necessary for establishment, exercise or defence of legal claims of the controller before a public authority and the data has been legitimately collected
- the data are used for private purposes or purposes relating to certain scientific, statistical, and public purposes, or for interviewing, or in the case of a catastrophe in accordance with the other provisions of the DSG
- the use is required according to the rights and duties of the controller in the field of employment law and civil service regulations and, is legitimate according to specific legal provisions
- the data are required for the purposes of preventative medicine, medical diagnosis, the provision of health care or treatment or the management of 14 health-care services, and the use of the data is performed by medical personnel or other person's subject to an equivalent duty of secrecy
- A political, philosophical, religious or trade union non-profit organization processes the data in the course of their legitimate activities, in a manner that reveals the data of members who display an interest in the aim of the organization on a regular basis.

5.6 Data Transfer

Data transfer within Austria, including when the controller allows a different party to process the data, is only allowed if the recipient can show that it can ensure legal and secure processing.

Data subjects do not need to be informed of the transfer where the processing is required by law, the subject cannot be reached, or the infringement on the subject's rights is very unlikely, and the costs of informing all data subjects are excessively high. Further, the controller has no duty to inform the data subject if the controller would not be required to notify the DSB of the transfer.

International Data Transfer of data requires prior authorization from the DSB, unless:

- the data subject has given unambiguous consent
- the transmission is to a recipient within a signatory state of the European Economic Area
- the transmission is to a country that has been declared in an Austrian ordinance to have an adequate level of protection
- the data has been legitimately published in Austria
- the data are only indirectly personal to the recipient
- the transmission is authorized by regulations that are equivalent to Austrian statutes
- the data is for private or journalistic purposes
- a contract between the controller and the data subject or a third party that has been concluded clearly in the interest of the data subject cannot be fulfilled except by the international transmission of data
- the transmission is necessary for the establishment, exercise or defence of legal claims before a foreign authority and the data were collected legitimately
- the transmission is expressly named in a standard or model ordinance
- the data is being exchanged with Austrian governmental missions and offices in foreign countries
- The transmissions are made from a data application that is exempted from notification under the statute. There is another exception, where the transmission is necessary to safeguard an important public interest or the vital interest of a person and timely authorization cannot be obtained. However, in that case the DSB must be notified immediately.
- The data are transferred to countries with an adequate level of protection and include those that have been recognized by the European Commission in accordance with the European Data Protection Directive 95/46/EC.

5.7 Data Security

Although the type and extent of security measures varies with the type of data processed and other factors, all security measures must ensure:

- protection against accidental or illegal destruction of data,
- proper processing and
- the data is only accessible to authorized persons.

These include a number of measures, for example, regulation of access to the premises, instruction to every operative regarding his or her duties and maintenance of logs with information on processing.

5.8 Breach Notification

If the data controller becomes aware of breach because data has been systematically and seriously misused and the data subjects may suffer damages, the controller must immediately notify the subjects in an appropriate manner.
However, if notification would require disproportional effort and cost compared to what would likely be minor damage to the data subjects, there is no notification obligation.

5.9 Enforcement & Penalties

In the case of infringement of the DSG a data subject may file a complaint with the DSB.
The wilful infringement of data protection with the intention of unjustified enrichment or to harm another person carries a criminal sanction of up to one year in prison. Other more minor violations of the DSG can result in administrative penalties of up to €25,000.

5.10 Informed Consent

The informed consent for my-AHA was reported in D7.4 Consensus document for participation. This document was also translated to German by JOAFG and has to be translated to the other language (Italian, Spanish) by the partners.

5.11 Update after GDPR enforcement

Since the enforcement of the GDPR in all EU countries, further developments on data management were undertaken by the consortium to be in line with the requirements of the GDPR.

Following the entry into force of the European Legislation on GDPR, the Rector of the University of Torino has nominated data protection manager for UNITO Prof. Sergio Foà, the Rector delegate for legislative questions. In this frame, prof. Foà will be asked any question regarding data protection emerging in My-AHA.

The processes of data flows have been evaluated and are available as flow chart for the project. As example for the Austrian trial site, the process core data is executed as follows in the flow charts below.

According to the needs of the GDPR, data protection officers (DPO) have been announced for the project itself and by each partner as well. For Austria, Dr. Leopold Weninger was announced as DPO for Johanniter and Georg Aumayr as responsible person for the my-AHA project in Austria.

Pls. refer to annex regarding related processes.

6 End-User Perspective on Ethics and Privacy

Beside the RCT, there are also insights in this topic from the Siegen Living Lab (LL). We conducted several workshops focusing on these aspects. Several themes with respect to this emerged during workshops and interviews: the context of data privacy and sharing, legal aspects and regulations, collaboration and social activities; individual and social motivation; and negative experiences and frustration. In the following, these themes will be used to structure the topic and illustrating how the different components of the My-AHA system were perceived by end users (seniors).

6.1 Data Sharing and Privacy

In a workshop about "Data Sharing, Privacy and Security", we invited several seniors from the living lab as well as stakeholders from the field who are related to this topic. The topics of the agenda were divided into different categories, covering aspects like reliability, trust in technologies, willingness to share data, accessibility, transferability, abusive use of data gathered. After an introduction round and small working groups, the diverse topics and their underlying discussion were presented by the groups. In what follows we give an overview about the perspectives and statements of the stakeholder involved:

With regard to the **reliability of the components** involved in the study, a female senior citizen asked "*how **reliable** the measurement devices are. Isn't it posing some difficulties for doctors, since they rely on insecure and inaccurate measurements?*". Regarding the contacts, there need to be specifications, which show what **sort of contact** is meant (doctors/nurses etc.), since many contacts gather after some time and it is possible to lose the overview even though the people are known to you. Another point mentioned by the workshop participants was that data must be accessible for the senior citizens as an **history** (course of activities). This needs to be allowed to share in case of change of doctor for instance, so that he can access the individual history. A participant described this situation in a question. "*When I change my [general practitioner] and take it away from the former, I have to be able to transfer it to the next*" (Senior from LL). Since not all Applications are tested, certified or hand out certifications senior citizen are insecure about how their date is used and analyzed. Workshop participants are questioning this and describing their concerns by asking, "i*s my data safe? – the question cannot be answered. They are not safe – this is for sure*" (LL USER 3).

In terms of inaccurate measurements or malfunctions and subsequent deviations of health data, the procedure not wanted by the potential patient and responsible doctor, if e.g. small anomalies occur in the blood pressure data (**self-monitoring)** is that one can decide what action to take and that the doctor does not summon you: "*the doctor could summon me for whatever reason, just because I got agitated and my blood pressure rose. I'd like to control that myself* (LL USER 3)." *I'd like to decide for myself*" (LL USER 3). Another female senior citizen replied to that, "*I don't think that this is that relevant. A doctor has so much experience, seeing that the pressure is built high just once. It isn't about that. It's about observing how the blood pressure behaves on a regular basis* (LL USER 1)."

The male senior citizens are facing the problem that the doctor could being **flooded** with information and that therefore the doctor would be **overloaded** with information that all have to be analyzed. The female senior citizen comments in this regard: "*Things should be only shown if they reach a **critical level** and display a risk factor. The device must be able to do that. That a person is only checked, if something moves out of the norm*" (LL USER 2).

In general, female participants are perceiving the My-AHA system and its potential for the future as a **possible relief for health care structures**. Such a futuristic platform has accentuated in a positive light, since it can avoid that doctors **drive long distances** just to measure the blood pressure for instance, since there are only few doctors especially in rural areas: In line with this a participant stated that, *"…a system that we do not have now, but will have at some point when there are fewer physicians in rural areas. Then it will be **very helpful**, since he can't simply drive 20 km to measure blood pressure. One can see by means of these charts what is necessary*" (LL USER 2). The benefit and value of sharing anonymized data is connected with skeptical aspects. A participant said, that "*I would say no anyway. […] that's nobody's business, why should I make the information available*?!" (LL USER 4).

Regarding **data transition**, various stakeholders reported that background for the data sharing must be accessible to the person, as well as what the **benefits** from sharing it are: "*I need to see the purpose as something useful […] whether I have urinary incontinence, or I am depressed, I would not want to share this. If I see an important and interesting connection, or if it's really relevant, then I would share the information*" (LL USER 2). One participant would like to determine who receives the data (personalized) and demands total control of the data. "*I'd still like to decide who I tell what, who is allowed to know what about me. I want to maintain my sovereignty over that* (LL USER 3)." This is further extending by another participant who wants to see her personal data and sees it as obligatory before sharing any of it: "*I first have to see what [data] there is and what I would share. I most certainly will not push any button and then release all data and I don't know which it was. I have to definitely see them*."

In order to agree to the anonymized data sharing, **background information** are needed to build trust: "*there is more background information needed, before answering something like that. Even if it is anonymized*" (LL USER 1). Another participant added to this "*what do they do with it*?" (LL USER 2), and explained further, *"I'd need to know, that there is an important project […] why do they want to know this*" (LL USER 2). These arguments are further complemented by another participant who said that "*I need a plausible explanation*" (LL USER 4). "Anonymized data" and it´s concept is viewed very critically; a female workshop participant described that she does not really "*believe that anonymity in the digital world exists*". She explained that, "*I'd have great difficulties with this. Because I only give my personal data to people who must promise security due to their work's ethics, e.g. doctors, psychiatrists. […] That some association, where changing people have access to my information, people that I don't know, I would refuse vehemently, even with (the risk of) high blood pressure and hair loss*" (LL USER 4).

Using software on a smartphone or tablet requires not only **trust** in the company who developed it, but also in the **distribution channels.** Several stakeholders were aware and skeptical about the appropriate use of the in-app data created, especially towards health care applications with personal data. A participant said that "*just using an app and trying it out – I'd really get stomach aches from that. If I know what is behind that and where it originates from – well, that changes the situation*" (LL USER 1). Building up on this, another participant reported that "*there is a different medium than the mobile phone needed*" (LL USER 2).

Another important topic arose in the discussion that described the factor **trust.** The topic Trust is a very sensitive and personal issue of senior citizens, that has, based on the statements, been "abused**"** often and should be treated with care. Different stakeholder explained that, "we all became suspicious. Especially because so much is done to elderly people. We might not be an authentic example. When you are in an association, you might have a different critical view towards particular topics. […] Also because of the education, work and life experience" (LL USER 2). Another participant stated that, "*the fear to be deceived has become really great*" (LL USER 2). In terms of recommendations and what aspects would help to build trust to the Application: "*Well, through the newspaper for instance […] when someone is responsible for it and explains it*" (LL USER 2) or via **radio, newspaper, Tv** "*Than I would have a leap of faith*" (LL USER 2) or via doctors, communities "the community would be ideal" (LL USER 1). One participant explained that she does not want the app to transmit the saved the data (which she shared) in real-time. She wants to control each data transaction: "I *would rather decide that myself. If I use such an app, I can see what is happening and then I'll see 'hey, there is something not right or not normal', then I can transmit the data… I think that I'd rather to that myself. I might forget it at some point, and it wouldn't be current data, I know. I don't like the automatization*". (LL USER 1)

6.2 Data Privacy and Security (GDPR)

With the launch of the GDPR (General Data Protection Regulation) a few of our participants from Siegen became insecure and asked us many questions when they received several emails about it. Even with those emails the participants did not understand what the GDPR really is about. The news did not report about it until a few days before launch, so it was difficult to prepare for it especially for one of our participants that still owns a company. Therefore, we organized a workshop to discuss this topic with regard to ICT-based health innovations and consider this feedback for further recommendations.

We invited experts on this field to a workshop together with five of our participants and ourselves. The workshop was also perfect to discuss what could be considered secure, trustworthy and how a platform for

medical data should be designed if they want to share data with their doctors. During the workshop, we found out that the participants would like to have the option to flexibly give the rights to analyze their medical data to doctors or persons but to also have the options to revoke them whenever they want to. This however could lead to problems as the doctors need to be fully informed how long they are allowed to use the data. Another problem would be that this might cause the user interface to become more complex. That is why another proposal was made to give the rights for a certain amount of time and to just click a button after that period to renew or revoke the rights. In general, they would like to have the entire process more transparent as to what kind of data the company needs and what they want to do with it. They also would like to have an overview of all the data that has been gathered about them so far. With regard to trust in smartphone/tablet-based applications, the opinions were rather diverse. While some of our participants were rather cautious about the new technologies' others admired the new options, they had because of it. One of the participant distrusts online banking as it confuses her, and she would have "*the feeling of being watched while doing it*" (LL USER 3) while another participant loved online banking as she "*didn't have to walk to the bank anymore" (*LL USER 1). As long as the perceived use was high enough the participants were willing to make compromises.

Regarding social media most participants were skeptical about posting private data such as photos or stories. However, one participant was interested in watching the content of others. The participants mentioned that they would "*rather trust something that is written in an analogue newspaper than on the internet*" (LL USER 2) as it feels more real. We found that it was difficult for our participants to trust someone on the internet as someone could easily fake their identity, though we also have to judge persons in real life based on factors like the outlook whether someone might be reliable. As a solution the participants proposed some kind of certificate based on the GDPR in order to have a better basis on trust. In order to achieve this, however, it would be necessary to have a better clarification about digital media awareness. The GDPR was an important step into the right direction as it gives us a tool in order to find out what data is gathered about us. Before everyone had this right too but it was not widely known and often companies refused to comply with a request to get the data without legal basis. Afterwards we conducted interviews with two of our participants subsequent to the workshop at hand. The two had different backgrounds in knowledge about the GDPR and its changes. One of them had touching points with it due to having his own foundation while the other did not have to deal with it before the GDPR came into full effect. The former company owner explained: "*every change was so extensive of every institution that you cannot grasp it in detail. I tend to just tick the check box because it is too much trouble for me to read four pages of fine print*." (LL USER 3) The topics and contents of the discussion were perceived as very interesting by all participants. Though it was mentioned that sometimes the discussion strayed away from deeper insights into the specific topics, which they recognized to be due to the depth, lack of time and natural flow of conversation.

The participants explained that, with regard to the initial mind-set they had before going into this discussion, the new regulations - GDPR – are promising and might be useful in different contexts. On the other side, some of the workshop participants admitted that it was hard to learn much about it and that they did not know where to get relevant information. All information and multiple suggestions only came up shortly before the law became legal and at that point, the participants difficult to get a good overview of their possibilities. A participant explained that, "*what annoyed me was the lack of information about the new regulation itself. It had been established for two years and yet you could barely get any appropriate information about it. "* (LL USER 1)

It turned out in the workshop that especially the topics **data sharing** and **data security** were often perceived as troublesome that in would be necessary that a user must agree to what the service demands of a user's information without being aware who will end up getting the data. A participant mentioned that she was pleased with the possibility to be able to investigate that specific information and ask the service provider to give full information on this regard. While some people are better protected and do not share photos or messages with information about their locations, she herself did not mind doing such things even if there was a small chance of the information being abused. The participants also stated that their opinion and mind-set towards the GDPR changed in a way that made them realize they had to be mindful and pay more attention about the rights that applications might have without carefully reading the terms of service.

6.3 Regular Workshops

In our regular monthly workshops, together with the independently living older adults in Siegen, we invited them to discuss on their regular use of the my-AHA Applications provided by the University. In a focus group setting with four of our seniors, we guided the conversation with a few questions and collected their feedback to find out what areas made usage unappealing or what kind of factors played into it that they had not mentioned in their interviews. The following categories and passages are summarizing the core topics that have been discussed since the regular workshops have been invented:

General insecurities

Part of the reason why the participants stated they did not use the applications from the overall my-AHA system so much was because; they were influenced by their general insecurities in using technology. Primarily the smartphone itself was a big factor due to its complexity and the array of different notifications as well as the number of apps in general. A fear of not being able to revert one's actions was stated by several of the participants. But not only this slowed them down or prevented them from using apps. Sometimes the language barrier interfered with the usage of devices like Beddit to track their sleep behavior. With the lack of understanding of the language, they remain unsure about what to do when something unpredicted happens.

Other factors included a lack of perceived safety when interacting with unfamiliar applications and their lack of recognizable brand names that they were used to from devices before their current ones. Like the branding of older generations of cellphones, they expected legitimate applications to feature big names like "*Telekom*" and other widely known companies to feel a sense of **security**. Fear of having **data stolen** by interacting with any sort of illegitimate app held them back from exploring their smartphone's functionalities. The main conclusion all participants drew from their discussions was their lack of experience with devices of a certain complexity or general IT and the wish to learn more about it to calm the unease.

7 Conclusions

In conclusion, we can say that inside a RCT ethical issues including data safety and privacy are well controlled and therefore represent a minor issue for the end users because of the ethical committees and guidance by the study investigators. Member state related issues and cultural differences can be taken into account and adjusted, even with study groups outside the EU (Australia and Japan).

On the other hand, as could be shown in a less controlled use situation like the living labs, privacy issues and data safety are very important for older adult users of ICT-based platforms like My-AHA. Seniors, and especially the community-dwelling older adults who are not that familiar with the use of ICT, feel very insecure with regards to this, even in the light of the new GDPR which allows for more options but also needs to be explained in more detail to the older adults.

Usually there are new mechanisms for data control by means of the new GDPR, but the average senior does not fully understand all of these options, and thus the "privacy by design" directive needs to be followed carefully together with practice-based participatory design approaches in order to implement an ICT-based system for older adults like My-AHA, that provides good usability and is able to establish maximum trust by an appropriate design and educative actions.

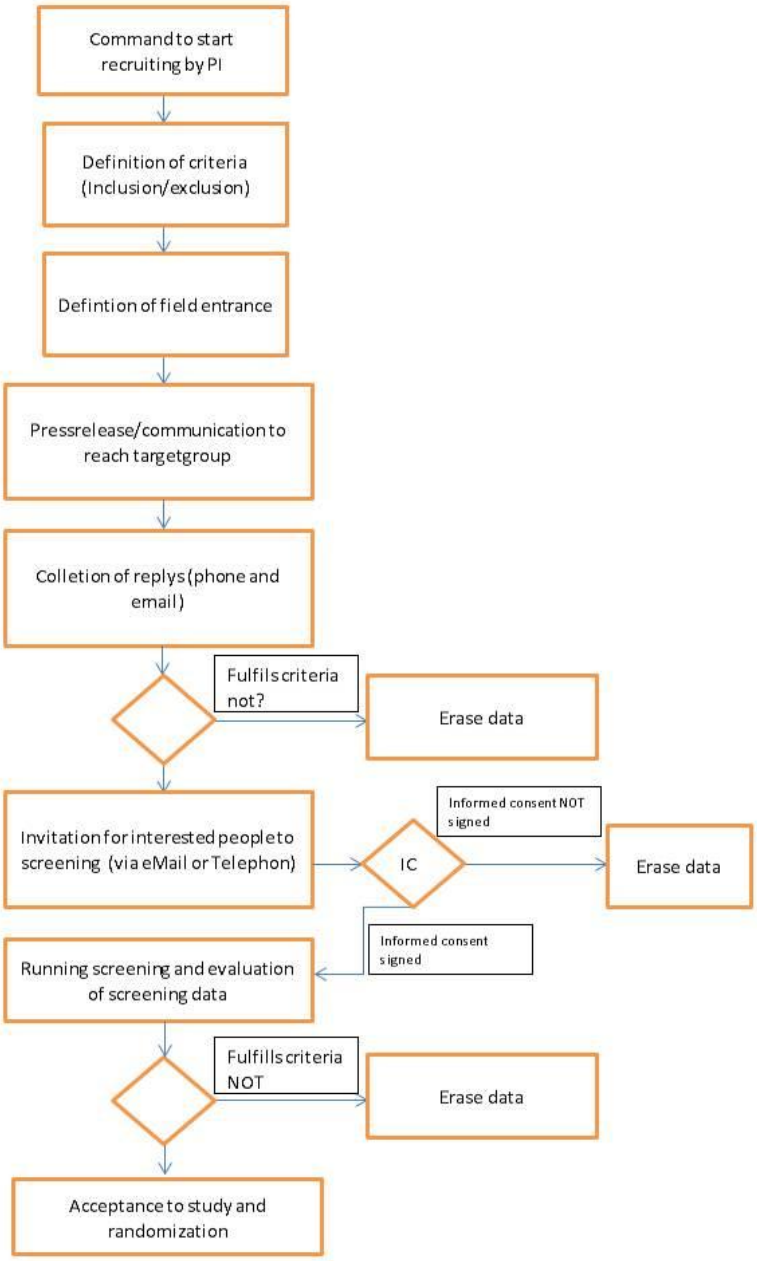
8 Annex

8.1 Process core data

Table 1 Recruiting

Head database of process	
Name of process	Recruiting
Aim of process	Recruiting participants for trial
Importance of process	High
Relation to other processes?	Yes, related to processes: Project management, staff planning, controlling
Description of process	Collection of data (personal data and general data) about potential participants
Associated people and support	
Responsible person for process	PI, coPI
Participating at the process	Own staff: Researcher
	External staff: Freelance
Other support or equipment needed to run the process	Hand dynamometer, scale, tape, laptop, blood pressuremeter, pulse oxymeter
Start of process	
How is process initiated	Fixed time: no
	Fixed action: Project start
	Sonstiges:
Information needed to start the process	YES: Process diagram for screening, evidence of all questionnaires and all forms in local language, evaluation matrix, data collector form
Other process in advance of this	yes, process: Development of research design and protocol
End of process	
Termination of process?	Fixed date:
	Fixed action: Command of project.
	Sonstiges:
Expected results?	Predefined number of participants for the study
Is there a follow up process?	Yes, process: Evaluation of data

Figure 1 Recruitment



8.2 Data collection

Table 2 Data collection

Head database of process	
Name of process	Data collection
Aim of process	Data collection to answer research questions
Importance of process	High
Relation to other processes?	Yes, related to processes: Project management, recruiting
Description of process	Collection of standardized data for an evaluation ready data sample
Associated people and support	
Responsible person for process	coPI, Researcher
Participating at the process	Own staff: Researcher
	External staff: Freelance
Other support or equipment needed to run the process	Excel, SPSS, MAWQDA, Word, memo-device, video camera
Start of process	
How is process initiated	Fixed time: following project plan
	Fixed action: following recruitment
	Sonstiges:
Information needed to start the process	YES: Process diagram for evaluation, evidence and filling of all questionnaires and all forms in local language, evaluation matrix, data collector form, informed consent of participant
Other process in advance of this	yes, process: recruitment
End of process	
Termination of process?	Fixed date: following project plan
	Fixed action: end of trial
	Sonstiges:
Expected results?	Standardized questionnaires are available in protocol conform way
Is there a follow up process?	Yes: data analysis

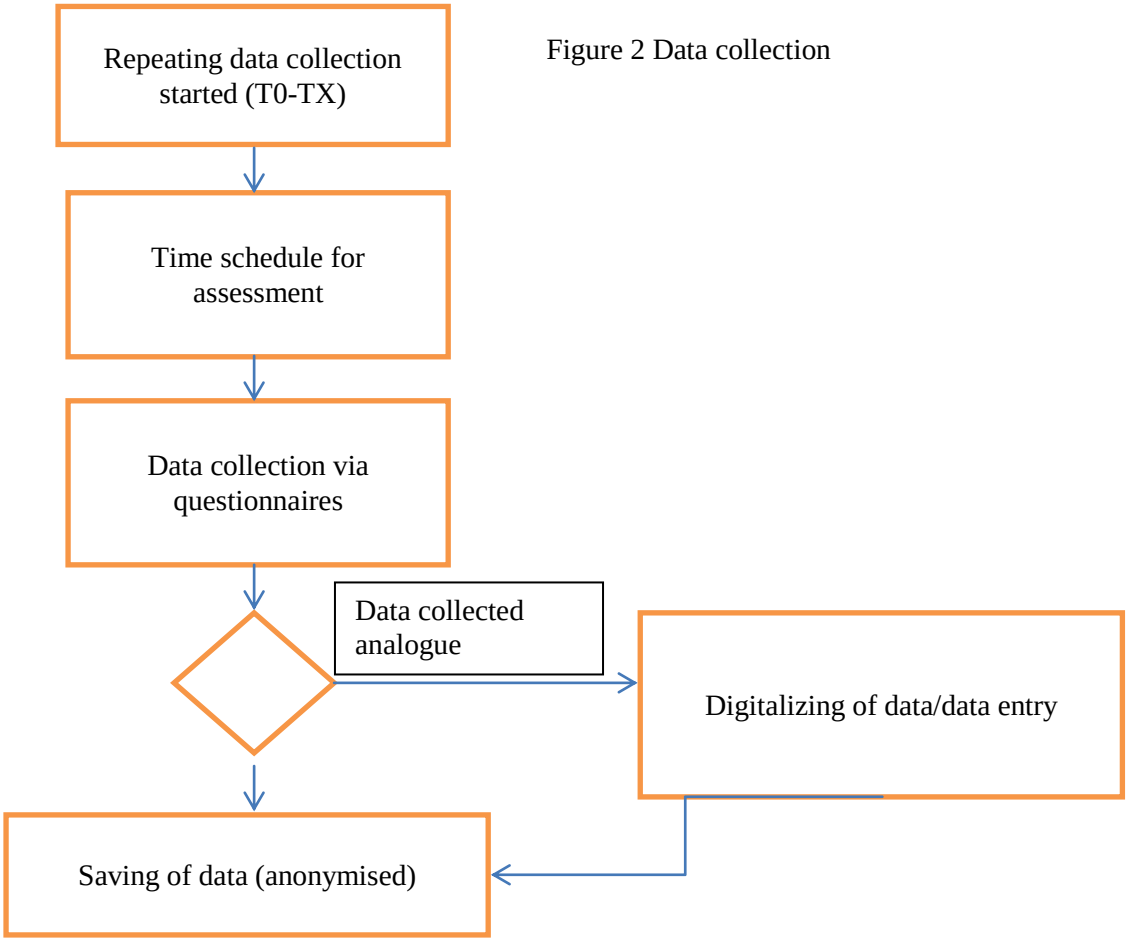


Figure 2 Data collection

8.3 Data analysis

Table 3 Data analysis

Head database of process	
Name of process	Data analysis
Aim of process	Analyzing data following the research protocol
Importance of process	High
Relation to other processes?	Yes, related to processes: Project management, recruiting, data collection
Description of process	Evaluation of data sample following the data collection process.
Associated people and support	
Responsible person for process	PI
Participating at the process	Own staff: Researcher
	External staff: UNITO
Other support or equipment needed to run the process	Excel, SPSS, MAWQDA, Word, memo-device, video player
Start of process	
How is process initiated	Fixed time: no
	Fixed action: following data collection
	Sonstiges:
Information needed to start the process	YES: Process diagram for analysis, evidence and filling of all questionnaires and all forms in local language, evaluation matrix, data collector form, informed consent of participant
Other process in advance of this	yes, process: data collection
End of process	
Termination of process?	Fixed date: following project plan
	Fixed action: end of trial
	Sonstiges:
Expected results?	Standardized evaluation protocol and syntax are available in protocol conform way
Is there a follow up process?	NO

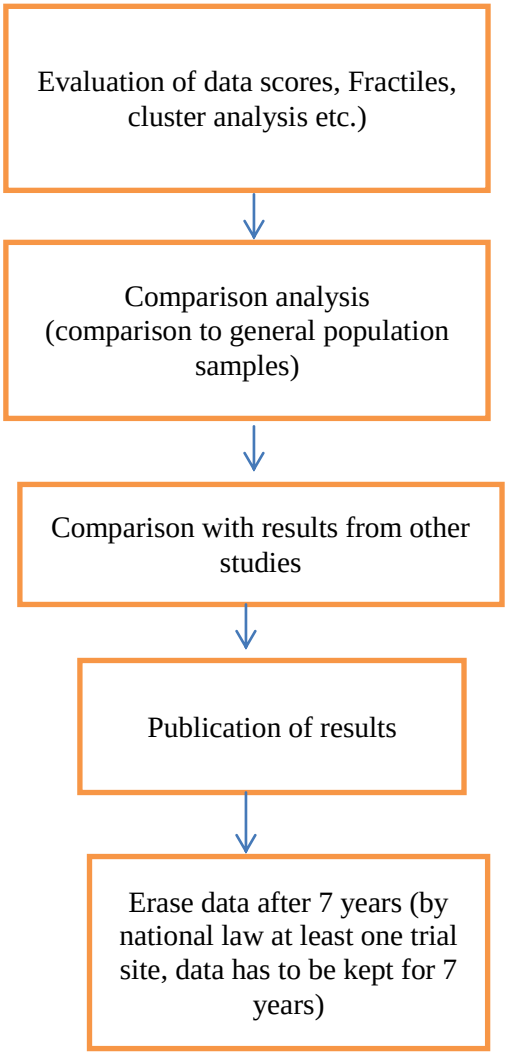


Figure 3 Data analysis

References

[1] Veerus P, Lexchin J, Hemminki E. Legislative regulation and ethical governance of medical research in different European Union countries. J Med Ethics. 2014, 40:409-413.
[2] Hernandez R, Cooney M, Dualé C, et al. Harmonisation of ethics committees' practice in 10 European countries. J Med Ethics. 2009;35:696-700.
[3] Druml C, Wolzt M, Pleiner J, Singer EA. Research ethics committees in Europe: trials and tribulations. Intensive Care Med 2009;35:1636-1640.
[4] Salvi M. Conflict of interest in biomedical research: a view from Europe. Sci Eng Ethics. 2003;9:101-108.
[5] Zilgalvis P. The Council of Europe's instruments on biomedical research: how is conflict of interest addressed? Sci Eng Ethics 2002;8:277-81.
[6] Bilbault P, Belorgey C, Zannad F, et al. Clinical Trials Legislation - preparing for the revision of the European Directive Scheduled for 2011. Therapie 2010 Jul-Aug; 65:301-308.
[7] http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10 001597.

Annex A

UNIVERSITÀ DEGLI STUDI DI TORINO
COMITATO DI BIOETICA DELL'ATENEO (CBA)

PROTOCOLLO DI PRESENTAZIONE DEL PROGETTO DI RICERCA CON PARTECIPANTI UMANI

SEZIONE A: CARATTERISTICHE GENERALI DEL PROGETTO DI RICERCA
PRESENTAZIONE DEL PROGETTO

A.1 **Titolo del progetto di ricerca**

My Active and Healthy Aging (my-AHA)
Alpha wave

A.2 **Responsabili del progetto di ricerca (Allegati 1 e 2)**

Prof. Alessandro VERCELLI	Ordinario di Anatomia	Coordinatore
Prof. Innocenzo RAINERO	Associato di Neurologia	Responsabile WP7

A.3 **Altri ricercatori coinvolti, qualifica, enti di appartenenza, attività svolta (Allegare i curricula sintetici e mirati)**

Il documento è ispirato a quelli in uso presso altri Comitati Etici nazionale e internazionali per la ricerca che vede coinvolti partecipanti umani: *University of Cambridge* – UK; Università degli Studi di Milano Bicocca; Università degli Studi di Bologna; Università degli Studi di Milano Statale Università degli Studi di Trento.

Ricercatori coinvolti attivamente nella ricerca e sperimentazione (allegati 3 – 7)

1.Dr.ssa Marcella CAGLIO	Assegnista di Ricerca	Neuropsicologa
2. Dr.ssa Elisa RUBINO	Assegnista di Ricerca	Tester
3. Dr.ssa Flora GOVONE	Specializzanda	Tester
4. Dr. Alessandro VACCA	Specializzando	Tester
5. Dr .ssa Annalisa GAI	Specializzando	Tester

A.4 **Sede/i della ricerca**

Dipartimento di Neuroscienze dell'Università di Torino,
via Cherasco 15, 10126 - TORINO

A.5 **È necessaria l'autorizzazione di altri Enti (ad es., ospedali, scuole, carceri) per l'accesso ai dati o il coinvolgimento di partecipanti? Se sì, allegare copia della lettera di autorizzazione**

NO

A.6 **È necessario il consenso di un rappresentante legale (genitore, tutore, titolare della potestà)? Se sì, allegare copia della lettera di consenso**

NO

A.7 **Durata prevista della ricerca (in mesi)**

Dieci mesi

A.8 **Data prevista di inizio della ricerca (GG.MM.AAAA)**

01.02.2017

A.9 **Il progetto di ricerca è sostenuto da uno sponsor?**

❑ NO

A.10 **Descrivere sinteticamente la tipologia e i termini del sostegno da parte dello sponsor**

Non pertinente

A.11 **In caso di risposta affermativa al punto A.10, indicare se, e secondo quali criteri e modalità, lo sponsor avrà accesso ai dati che riguardano i partecipanti coinvolti nella ricerca (o anche solo a parte di essi).**

Non pertinente

A.12 **Quali accorgimenti sono previsti per garantire da parte dello sponsor la confidenzialità e/o l'anonimato dei dati raccolti?**

Non pertinente

SEZIONE B: DATI SULLA RICERCA

B.1 **Abstract del progetto di ricerca** . Il progetto my-AHA ha come obiettivo un rilevamento precoce delle condizioni di fragilità (frailty) del soggetto anziano tramite una piattaforma Information and Communication Technology (ICT) based, affinché un intervento precoce e personalizzato possa rallentare la conversione in una demenza conclamata. La condizione di frailty verrà interpretata con un approccio multidimensionale in cui la fragilità fisica, la fragilità cognitiva, la fragilità psicologica e la fragilità sociale concorrono in modo congiunto a rendere il soggetto più vulnerabile alle patologie età-correlate. Il progetto è articolato su due fasi. Nella prima fase (**alpha wave – oggetto specifico della richiesta**) verranno testati, in un numero limitato di soggetti, diversi devices per valutarne la portabilità, la sensibilità e la specificità. In aggiunta, verrà valutata la possibilità di effettuare una training cognitivo e fisico nel soggetto a rischio. Nella seconda fase, secondo una strategia tipo randomized controlled study (**RCT – verrà nuova autorizzazione**), verrà valutata l'efficacia della piattaforma nel diagnosticare precocemente le condizioni di frailty e nel monitorizzare le strategie di intervento cognitivo e fisico. L'alpha wave si svolgerà in 4 siti (Torino, Vienna, Siegen, Valencia), con il reclutamento di 5 soggetti per sito. Ai soggetti reclutati verrà data la possibilità di testare, per un limitato periodo di tempo (3 mesi), diversi devices che monitoreranno l'attività fisica, l'attività cognitiva, le condizioni emotive e l'attività sociale del soggetto. I soggetti verranno controllati ogni mese e, in caso di ridotta attività cognitiva o fisica verranno somministrati, tramite smartphone, esercizi di stimolazione cognitiva (exergames) o suggerimenti per attività fisica specifica costantemente monitorizzata.

B.2 **Parole chiavi (almeno 3) identificative della ricerca**

Fragilità	Stimolazione cognitiva
Fragilità cognitiva	Prevenzione del rischio
Fragilità fisica	Device

B.4 **Base di partenza e giustificazione teorica della ricerca**

Il progressivo invecchiamento della popolazione generale ha portato le patologie legate all'aging al primo posto tra le problematiche sanitarie nei paesi industrializzati. Ad oggi, le strategie di intervento nei pazienti con patologia age-related (come le demenze) sono risultate inefficaci. Solo le strategie che modificano contemporaneamente i diversi fattori di rischio (approccio multimodale) sembrano essere in grado di modificare l'evoluzione delle patologie del soggetto anziano. La frailty (fragilità), considerata come condizione di rischio per patologia dell'anziano, è divenuta un importante target per la detezione precoce delle malattie dell'anziano, in particolare per le malattie caratterizzate da deficit cognitivo, sia per il trattamento precoce delle condizioni di rischio.

Il progetto my-AHA si pone come obiettivo la costruzione di una piattaforma tecnologica che permetta di **rilevare precocemente, in modo non intrusivo, le diverse condizioni di fragilità (cognitiva, fisica, emotiva,** sociale) di individui anziani a rischio per programmare interventi di stimolazione multimodale che riducano il rischio di conversione a malattia. I soggetti fragili verranno coinvolti, infatti, in attività di stimolazione fisica, cognitiva e sociale per ottenere un controllo significativo dei fattori di rischio per patologia.

B.5 **Scopi e Obiettivi**

Il progetto my-AHA ha un duplice obiettivo:

A. assemblare una piattaforma tecnologica che possa in modo non intrusivo rilevare precocemente le condizioni di frailty del soggetto anziano

B. attivare precocemente strategie di stimolazione fisica, cognitiva, emotiva e sociale che possano ridurre il rischio di malattie correlate all'invecchiamento

Per raggiungere tali obiettivi, nella prima fase verranno testate le diversi componenti della piattaforma (smartphone con applicazioni dedicate, fit-band, MEME glasses, istopFalls, etc.) e, una volta stabilizzata la stessa si provvederà a valutarne l'efficacia in rapporto alle attuali condizioni di "standard of care".

B.6 **Metodologia impiegata**

I soggetti verranno reclutati e seguiti presso il Dipartimento dell'Università di Torino. L'alpha wave prevede una fase di run-in (**piano dello studio - allegato 8**) con la raccolta delle informazioni demografiche, una fase di valutazione delle frailties (T1 – 1 mese da T0) con successiva consegna dei device oggetti di studio, e due controlli mensili a T2 e T3. I test che verranno effettuati in tali occasioni sono presentati nello assessment timepoint.

Ai soggetti reclutati verranno consegnati al tempo T1:

1. Smartphone (modello attualmente testato Lenovo Moto G4 con giroscopio – vedasi allegato). Tale modello potrà fornire in via indiretta informazioni sulla mobilità del paziente. Sulla tastiera dello smartphone verrà, innanzitutto, installata il programma **Smart Companion** che permetterà un utilizzo semplificato del cellulare. Da questo vi sarà il collegamento a diverse app. Nelle fasi iniziali sarà disponibile l'app per **Dashbord** un software sviluppato dall'Istituto Superiore Mario Boella di Torino, che permette di quantificare il rischio di evoluzione della patologia. Sullo stessa APP sono disponibili 3 esercizi di stimolazione cognitiva (exergames) dedicati alle funzioni attentive ed alla working memory
2. Bracciale tipo "fit band" (modello attualmente testato Fit Band Samsung - vedasi allegato)che permetterà di monitorizzare l'attività fisica del paziente tramite connessione diretta con smartphone

Al tempo T2 i risultati dei test di screening delle diverse frailties verranno esaminati in rapporto alle informazioni fornite dallo smartphone. In caso di significativo rischio per frailty fisica o cognitiva, verranno indicate le strategie di stimolazione tramite exergames o tramite schemi di stimolazione fisica. Per le altre frailties verranno indicate strategie personalizzate. Ai tempi T3 e T4 si valuteranno, nel singolo soggetto, le variazioni dei parametri di fragilità così come le caratteristiche di funzionalità degli strumenti utilizzati. Con il proseguire della sperimentazione potrà essere valutato l'uso di altri devices (IStopp Falls, Beddit, Meme Glasses, etc) previa nuova richiesta specifica al Comitato di Bioetica.

B.7 **Risultati attesi**

La fase *pilot* del protocollo my-AHA permetterà di valutare:

1. La portabilità di smartphone e Fit band
2. La sensibilità e la specificità delle informazioni derivate
3. La possibilità di monitorare le strategie di stimolazione cognitiva (exergames) e di stimolazione fisica suggerite ai soggetti coinvolti nella sperimentazione
4. L'eventuale presenza di effetti collaterali della strumentazione utilizzata

B.8 **Rilevanza scientifica**

Nel 2015, la pubblicazione dello studio FINGER su Lancet ha significativamente modificato l'approccio concettuale alla prevenzione delle demenze. Un vasta popolazione di 2600 soggetti che presentavano fattori di rischio per demenza è stata allocata, in modo random, in un gruppo di controllo (general health advice) ed in un gruppo che ha trattato, con approccio multimodale, i fattori di rischio tramite dieta, esercizio fisico e stimolazione cognitiva. I soggetti sottoposti a stimolazione multimodale hanno presentato, dopo due anni di trattamento, un declino significativamente inferiore delle funzioni cognitive. Il protocollo my-AHA si è posto l'ambizioso obiettivo di un intervento ancora più precoce cercando di evidenziare condizioni iniziali di rischio per demenza tramite una piattaforma ICT-based e di intervenire con stimolazione fisica e cognitiva controllata.

B.9 **Riferimenti bibliografici**

Choi J, Ahn A, Kim S, Won CW. Global Prevalence of Physical Frailty by Fried's Criteria in Community-Dwelling Elderly with National Population-Based Surveys. Am Med Dir Assoc. 2015;16:548-550.

Kojima G, Iliffe S, Jivraj S, Walters K. Association between frailty and quality of life among community-dwelling older people: a systematic review and meta-analysis. J Epidemiol Community Health 2016;70:716-721.

Shamliyan T, Talley KM, Ramakrishnan R, Kane RL. Association of frailty with survival: a systematic literature review. Ageing Res Rev. 2013;12:719-736.

Gray SL, Anderson ML, Hubbard RA, et al. Frailty and incident dementia. J Gerontol A Biol Sci Med Sci2013;68:1083-1090.

Panza F, Solfrizzi V, Frisardi V, et al. Different models of frailty in predementia and dementia syndromes. J Nutr Health Aging 2011;15:711-719.

Newman AB, Gottdiener JS, Mcburnie MA, et al. Associations of subclinical cardiovascular disease with frailty. J Gerontol A Biol Sci Med Sci. 2001;56:158-166.

Chen WT, Chou KH, Liu LK, et al. Reduced cerebellar gray matter is a neural signature of physical frailty. Hum Brain Mapp 2015;36:3666-3676.

Kojima G, Taniguchi Y, Iliffe S, Walters K. Frailty as a Predictor of Alzheimer Disease, Vascular Dementia, and All Dementia Among Community-Dwelling Older People: A Systematic Review and Meta-Analysis. J Am Med Dir Assoc. 2016;17:881-888.

Feng L, Nyunt MS, Gao Q, et al. Physical Frailty, Cognitive Impairment, and the Risk of Neurocognitive Disorder in the Singapore Longitudinal Ageing Studies. J Gerontol A Biol Sci Med Sci. 2016, early on line.

Solfrizzi V, Scafato E, Frisardi V, et al. Italian Longitudinal Study on Aging Working Group. Frailty syndrome and all-cause mortality in demented patients: the Italian Longitudinal Study on Aging. Age (Dordr). 2012;34:507-517.

SEZIONE C: INFORMAZIONI RELATIVE AI PARTECIPANTI

INFORMAZIONI RELATIVE AI PARTECIPANTI

C.1 **Indicare i criteri di inclusione/esclusione dei partecipanti alla ricerca**

Liste dei Criteri di Inclusione ed Esclusione, come da protocollo approvato dalla Commissione Europea, in allegato 8

C.2 **Come verranno reclutati i partecipanti**

I soggetti coinvolti nell'alpha-wave verranno reclutati coinvolgendo care-givers e parenti di primo grado di pazienti affetti da disturbi neuro cognitivi maggiori attualmente seguiti presso l'Aging Brain and Dementia Clinic del Dipartimento di Neuroscienze dell'Università di Torino. I soggetti dovranno essere volontari sani, come specificato dai criteri di inclusione/esclusione, di ambo i sessi e di età compresa tra i 60 e gli 80 anni. La fase pilot dello studio prevede l'inclusione di 5 soggetti.

C.3 **Quali tipologie di partecipanti prenderanno parte alla ricerca?**

Bambini e ragazzi di età inferiore a 18 anni

Adulti (età superiore a 18 anni e in grado di esprimere il loro consenso)

Anziani (età superiore ai 65 anni e in grado di esprimere il loro consenso)

Persone di madrelingua non italiana

Persone con deficit cognitivo/mentale, in grado di esprimere il proprio consenso

Persone con deficit cognitivo/mentale, NON in grado di esprimere il proprio consenso

Altre persone la cui capacità di esprimere consenso possa essere compromessa (indicare per quale motivo)

Persone con disabilità fisica (specificare di quale tipo)

Pazienti e/o clienti segnalati da medici, psicologi o altre categorie di professionisti

Non è possibile determinare la tipologia dei partecipanti (ad es., compilazione via internet)

Altro (specificare)

C.4 **È possibile che alcuni dei partecipanti coinvolti nella ricerca si trovino in una qualunque forma di 'dipendenza' nei confronti del ricercatore o di uno dei suoi collaboratori, tale per cui si possa supporre che l'espressione del consenso a partecipare allo studio non sia del tutto incondizionata, libera e priva da ogni tipo di pressione (ad es., studente/professore, paziente/medico, dipendente/datore di lavoro)? Se si, indicare come si intende provvedere per prevenire la possibilità che il partecipante si senta obbligato a prendere parte alla ricerca**

Verranno reclutati soggetti che hanno già avuto precedenti contatti professionali con il PI ed i suoi collaboratori. Questo permetterà la selezione di soggetti motivati che non presentano particolare rischio di "dipendenza emotiva". Alcuni di questi soggetti hanno già espresso la volontà di partecipare a studi di prevenzione delle patologie neurodegenerative.

C.5 **Motivare la scelta del campione coinvolto**

L'obiettivo dell'alpha wave è quello di testare la portabilità, la specificità e la sensibilità delle diverse componenti della futura piattaforma ICT based. Pertanto, il numero dei centri coinvolti così come il numero di soggetti arruolato è basso e non è stata effettuata alcuna elaborazione statistica dell'alpha-power dello studio trattandosi di studio pilota. Il limitato numero di soggetti coinvolti permetterà agli sperimentatori di effettuare controlli frequenti dei soggetti in studio e di adattare il funzionamento dei diversi devices alle necessità del singolo soggetto.

C.6 **Come verranno diffusi le informazioni e l'invito a partecipare alla ricerca?**

I soggetti verranno reclutati tra i familiari ed i caregivers dei pazienti attualmente seguiti presso l'Aging Brain and Dementia Clinic" del Dipartimento di Neuroscienze dell'Università di Torino. Questo reclutamento permetterà di selezionare per l'alpha wave soggetti che, già sensibilizzati alle patologie neurologiche correlate all'invecchiamento cerebrale, possano garantire a priori un buon grado di compliance verso la sperimentazione.

SEZIONE D: RISCHIO E GESTIONE DEL RISCHIO

D.1 La ricerca prevede

□ Utilizzo di questionari (allegare una copia)
□ Interviste strutturate o semi-strutturate (allegare protocollo dell'intervista oppure (se in caso di definizione) allegare copia delle domande che verranno poste; ove questo non sia possibile, specificare perché e indicare gli argomenti che verranno trattati)
□ **Colloqui (allegare traccia del protocollo)**
□ *Focus group*
□ Narrazioni autobiografiche
□ Raccolta di diari (*diary keeping*)
□ Osservazione del comportamento delle persone a loro insaputa
□ Osservazione del comportamento delle persone
□ Registrazioni audio o video dei partecipanti
□ Somministrazione di stimoli, compiti o procedure e registrazione di risposte comportamentali, opinioni, atteggiamenti, giudizi
□ Somministrazione di stimoli, compiti o procedure che il partecipante potrebbe trovare fastidiosi, stressanti, sia durante sia successivamente la conduzione dello studio
□ Registrazione di movimenti oculari
□ Utilizzo di TMS (*Transcranial Magnetic Stimulation*, o stimolazione magnetica transcranica)
□ Immersione in ambienti di realtà virtuale
□ Registrazione di potenziali evocati
□ Somministrazione di test, questionari o protocolli sperimentali attraverso internet (web, posta elettronica)
□ **Utilizzo di test neuropsicologici**
□ Tecniche di neuroimmagine
□ Messa in atto di comportamenti che potrebbero influenzare l'autostima dei partecipanti, o indurre imbarazzo, dispiacere o un senso di vergogna
□ **Altro (specificare)**

Monitorizzazione dell'attività fisica e cognitiva tramite smartphone e fit band

D.2 **Sintesi del percorso informativo previsto**

Nella fase di screening (T0), verrà effettuato un colloquio preliminare in cui il PI illustrerà tutte le caratteristiche dello studio e raccoglierà le informazioni cliniche. A distanza di un mese (T1), in un secondo colloquio, verranno valutate le diverse frailties del soggetto e, laddove vengano soddisfatti i criteri di inclusione, verrà consegnato il foglio illustrativo, raccogliendo la firma del consenso. Solo successivamente, verranno consegnati lo smartphone con i programmi pre-registrati e la fit band.

Nota: Indicare modalità di presentazione della ricerca, foglio illustrativo firma del consenso, restituzione dei risultati.

D.3 **Foglio informativo per il Paziente, Nota Informativa sulla Privacy e Dichiarazione di Consenso (allegati)**

D.4 **Nel caso si coinvolgano partecipanti non in grado di esprimere il consenso, indicare a chi si chiederà di acconsentire alla partecipazione precisandone il ruolo e i motivi**

Non pertinente

D.5 **Nella ricerca saranno coinvolti individui minorenni?**

❑ sì

❑ **no**

In caso affermativo, gli individui minorenni saranno adeguatamente informati circa le finalità e gli scopi della ricerca nella quale si intende coinvolgerli e/o saranno i loro genitori o tutori dare il consenso informato? (Specificare).

D.6 **Quali modalità saranno adottate per la comunicazione di dubbi e precisazioni da parte dei partecipanti nel corso della ricerca e quali modalità verranno messe in atto per le relative risposte?**

I soggetti coinvolti nell'alpha-wave avranno a disposizione un numero telefonico del PI e di almeno un coPI con accesso H24. In tale modo sarà possibile risolvere in modo tempestivo tutte le problematiche che potranno insorgere nel corso dello studio.

D.7 **Qualora, per la realizzazione della ricerca, non fosse metodologicamente possibile informare i partecipanti prima dell'inizio della sperimentazione sull'obiettivo della stessa, specificare quali saranno le modalità del successivo incontro di chiarificazione e dell'espressione del consenso all'utilizzo dei dati.**

Non pertinente

D. 8 **Come i partecipanti verranno informati circa la possibilità di recedere dal partecipare allo studio o alla sperimentazione in un qualunque momento senza dover dare spiegazioni e giustificazioni della loro scelta al responsabile della ricerca?**

Il foglio illustrativo con il consenso informato esplicita in modo inequivocabile che il soggetto coinvolto nello studio può interrompere la sperimentazione in qualsiasi fase senza necessità di spiegazione alcuna e senza interruzione del rapporto fiduciario con gli sperimentatori.

D.9 **Descrivere la natura degli eventuali rischi o disagi che le procedure utilizzate potrebbero generare.**

L'utilizzo dello smartphone è particolarmente diffuso nella popolazione generale, anche di età senile. L'utilizzo nella videata principale di Smart Companion ha l'obiettivo di facilitare l'uso della strumentazione.

Qualche disagio è prevedibile per l'utilizzo di bracciali tipo fitness band. Il contatto con il PI potrà servire a controllare eventuali disagi.

D.10 **Come si prevede di affrontare gli eventuali rischio o disagi.**

Nel corso dell'alpha wave è previsto un controllo mensile del soggetto arruolato. Tale controllo servirà ad evidenziare precocemente rischi e/o disagi connessi alla sperimentazione

D.11 **Si prevede che vi possano essere benefici per chi prende parte alla ricerca?**

L'evidenziazione precoce delle condizioni di fragilità (fisica, psichica, psicologica o sociale) costituisce una potenziale fonte di beneficio per i soggetti coinvolti nella sperimentazione. Eventuali condizioni cliniche significative verranno affrontate precocemente dal medico di famiglia.

D.12 **Allegare l'informativa relativa al trattamento dei dati personali ai sensi del**

D.Lgs. del 30 giugno2003, n. 196 (Codice in materia di protezione dei dati personali).

D.12 a **Come verrà garantito ai partecipanti l'anonimato?**

All'arruolamento (TO), verrà generato un codice di anomizzazione composto da: progetto di ricerca (my-AHA), numerazione Centro (doppia cifra), numerazione progressiva (doppia cifra) – Es. my-AHA-02-04. Solo il PI del Centro sarà a conoscenza della chiave di interpretazione.

D.12 b **Quali sono le misure di sicurezza che si intendono adottate per assicurarsi che venga rispettata la riservatezza dei dati?**

Il protocollo my-AHA preveda la raccolta di un numero ristretto di dati sensibili, riguardanti essenzialmente le funzioni cognitive e l'attività fisica, che per definizione devono rientrare nel range di norma. I soggetti in cui emergeranno sindromi cliniche significative verranno esclusi dallo studio. La raccolta dei dati dello studio verrà effettuata nell'alpha wave su apposito supporto cartaceo.

D.13 **Conservazione e sicurezza dei dati raccolti e dei risultati della ricerca**

D.13 a **Chi avrà accesso ai dati raccolti e ai risultati (ancorché intermedi) della ricerca?**

Il Principale Investigator del Centro di Torino (Prof. Innocenzo Rainero) ed i suoi co-investigators potranno avere accesso a tutti i dati raccolti ed ai risultati preliminari.

D.13 b **Per quanti anni i dati raccolti verranno conservati dalla conclusione della ricerca?**

Secondo la normativa dei Randomized Controlled Studies i dati verranno conservati per anni 10.

D.13 c **Indicare le modalità di conservazione dei dati sensibili specificando la conservazione e il luogo dove verranno conservati.**

I dati sensibili verranno conservati nell'apposito locale disponibile presso il Dipartimento di Neuroscienze dell'Università di Torino, via Cherasco 15, sottopiano, dove viene attualmente conservata tutta la documentazione cartacea degli studi RCT.

D 13 d **Indicare se i dati raccolti potranno essere utilizzati anche da altri gruppi di ricerca, specificando anche le eventuali modalità di acquisizione del consenso informato a tale fine.**

Il protocollo my-AHA prevede il costante e continuo confronto dei dati raccolti solo tra i diversi Centri attivati. I 4 centri coinvolti nell'alpha-wave potranno scambiare i dati raccolti in forma anonimizzata, secondo la codifica già specificata. Per l'alpha wave non è prevista la condivisione automatica dei dati ma ogni scambio verrà regolato dai rispettivi PI.

Luogo e data

Firma dei responsabili

Torino, 12 gennaio 2017

Alessandro Vercelli – Innocenzo Rainero

ANNEX 2

STUDY ASSESSMENTS BY TIME POINT				
SCREENING Men and woman over age 60 Subjects enrolled in several countries in Europe (Italy, Germany, Great Britain, Spain, Sweden, Belgium, Austria) and non-European countries (Japan, South Korea, Australia) E				
INCLUSION CRITERIA -Subjects are able to stand and walk unassisted -Subjects are free of any acute or unstable medical conditions -Subjects are able to understand directions and participate in the protocol				
EXCLUSION CRITERIA -Subjects cannot stand and ambulate anassisted -Subjects are affected by any kind of dementia -Subjects are experiencing any symptomatic cardiovascular or respiratory disease -Subjects with a myocardical or stroke within 6 months -Subjects with painful arthritis, spinal stenosis, amputation, paintful foot lesions, or neuropathy that limits balance and mobility -Subjects untreated hypertension -Subjects with cardiac pacemaker -Subjects with Parkinson's Disease or other neuromuscular disorder -Subjects with metastatic cancer or immunosuppressive therapy Subjects with significant visual impairment	TIME 30 min			
FRIED FRAILTY CRITERIA - unintentional weight loss - exhaustion - muscle weakness		-FRAILTY STATUS or two of the wing criteria): ght loss/shrinking: eport of =4.5 kg lost entionally in the		

- slowness while walking - low levels of activity		ous 12 months kness: lowest 20% in strength austion: answering "a erate amount" or "most e time" to either of the stions from CES-D vness: time to walk 4 activity: in the past 3 hs, not physical ty and spent setting 4 day			
HEALTH - Demographics, health status, falls history - 12-item WHODAS 2.0 - European Quality of Life – 5 Dimensions - ADL (activities of daily living) - IADL (instrumental activities of daily living scale) - Incontinence - Hospitalisation - Falls	TIME 5 min 5 min 5 min 5 min 5 min 5 min	PHYSICAL: - Short Physical Performance Battery - Time Up and Go test - IPEQ	TIME 10 min 2 min 10 min	PHYSICAL: - Short Physical Performance Battery - Time Up and Go test - IPEQ	PHYSICAL: - Short Physical Performance Battery - Time Up and Go test - IPEQ
NUTRITION - Weight - Height - BMI	TIME 5 min	COGNITION -MMSE - HVLT (Hopskins Verbal Learning Test) - Corsi blocks test (visuo-spatial working memory) - Trail Making Test - Stroop test -Digit Symbol Substitution test	TIME 10 min 20 min 5 min 10 min 10 min 5 min	COGNITION -MMSE - HVLT (Hopskins Verbal Learning Test) - Corsi blocks test (visuo-spatial working memory) - Trail Making Test - Stroop test -Digit Symbol Substitution test	COGNITION -MMSE - HVLT (Hopskins Verbal Learning Test) - Corsi blocks test (visuo-spatial working memory) - Trail Making Test - Stroop test -Digit Symbol Substitution test
		PSYCHOLOGY - GDS (Geriatric Depression Scale) - Self-efficacy	TIME 10 min 5 min	PSYCHOLOGY - GDS (Geriatric Depression Scale) - Self-efficacy - Hospital Anxiety	PSYCHOLOGY - GDS (Geriatric Depression Scale) - Self-efficacy

		- Hospital Anxiety and Depression Scale	10 min	and Depression Scale	- Hospital Anxiety and Depression Scale
		SOCIAL UCLA Loneliness Scale	TIME 10 min	SOCIAL UCLA Loneliness Scale	SOCIAL UCLA Loneliness Scale

ANNEX C

Description of the study and Informed Consent

MODULO DI INFORMAZIONE PER IL PAZIENTE

Gentile Signora/e,

Desideriamo proporLe una nuova ricerca, intitolata "My Active and Healthy Aging – Il mio invecchiamento attivo ed in salute" che ha lo scopo di valutare in modo precoce le eventuali condizioni di rischio per patologie legate al passare degli anni.

Come Lei saprà, le malattie legate all'invecchiamento, in particolare quelle che riguardano l'invecchiamento del cervello, stanno divenendo un problema sanitario drammatico. Quando un soggetto sviluppa, ad esempio, una demenza tipo Alzheimer, non abbiamo a disposizione farmaci che possano rallentare l'evoluzione della malattia stessa.

Negli ultimi anni, alcuni studi hanno dedicato particolare attenzione alle condizioni di fragilità (frailty) che possono predisporre il soggetto a patologie legate all'invecchiamento. Oggi conosciamo diverse forme di frailty (cognitiva, fisica, emotiva, sociale) che predispongono il soggetto, non ancora ammalato, a sviluppare con più facilità specifiche malattie.

Alcuni recenti studi hanno dimostrato che se il soggetto in condizioni di frailty modifica il suo comportamento, effettuando attività fisica, cognitiova e sociale, riduce in modo significativo il rischio di sviluppare malattie cerebrali gravi quali la demenza.

Qual è lo scopo di questo trattamento?

La nostra ricerca ha un duplice scopo:

A. Valutare se lei si trova in una condizione di rischio (frailty) per sviluppare una malattia dell'anziano. In questo scopo ci faremo supportare da particolari strumentazioni tecnologiche
B. Co0nsigliare tecniche di stimolazione fisica e cognitiva pèer ridurre il suo rischio di malattia.

Che cosa implica essere sottoposti a questo trattamento?

Qualora Lei decidesse di partecipare, sarà visitato dal nostro coordinatore. La visita includerà anche una valutazione neurologica approfondita e una raccolta anamnestica approfondita, per essere certi che Lei possegga i requisiti richiesti.

Se verrà ritenuto idoneo, dopo un mese, verrà sottoposto alla valutazione del suo rischio di fragilità (cognitiva, fisica, emotiva, sociale) e le verranno consegnati:

A. Un telefonino (smartphone) di facile uso con alcune applicazioni che serviranno a registrare la sua attività fisica e la sua attività cognitiva. Inoltre, tramite lo stesso telefonino potrà effettuare alcuni esercizi per potenziare la memoria e l'attenzione. Per quanto riguarda la connessione telefonica Lei potrà decidere se inserire la sua SIM personale od utilizzare una SDIM autonoma che provvederemo noi ad attivare.

B. Un braccialetto da polso (fit band) che, connesso al telefonino, permetterà di registrare costantemente la sua attività fisica

Ogni mese, per un periodo di tre mesi, Lei verrà a controllo nel nostro Centro e valuteremo tutte le informazioni raccolte per consigliarle nuove strategie comportamentali di controllo del rischio di fragilità.

Nell'eventualità che Lei decida di interrompere il trattamento, Lei potrà farlo senza alcun problema. Nel caso comparissero problemi particolari verranno presi i provvedimenti terapeutici del caso, garantendole l'assistenza medica necessaria .

Se decide di partecipare, Le sarà richiesto di seguire tutte le procedure descritte precedentemente, sotto indicazione del medico responsabile, collaborando al massimo alle prescrizioni che Le verranno fatte.

Non dovrà sostenere alcuna spesa per le pratiche inerenti e correlate al trattamento in oggetto.

Potenziali rischi del trattamento

Non sono previsti rischi per l'uso del telefonino (numerosi studi hanno dimostrato essere innocuo per la salute) e per il braccialetto da polso, strumento frequentemente utilizzato dagli sportivi per monitorizzare l'attività fisica.

Controindicazioni assolute al trattamento

Non vi sono controindicazioni assolute al trattamento. Prima dell'inizio dello studio bverrà verificata l'eventuale coesistenza di altre malattie che sconsigliano lo studio.

Potenziali benefici terapeutici

Possono esserci dei benefici derivanti dal trattamento che riceverà, in particolare lei potrà:

A. Valutare se alcuni dei suoi parametri fisiologici e comportamentali sono a rischio pe patologia e, pertanto, modificarli
B. Effettuare test di stimolazione delle funzioni cerebrali (memoria, attenzione) che possono avere un ruolo protettivo nei confronti dell'invecchiamento cerebrale

Come sarà tutelata la privacy?

Le informazioni relative al suo stato di salute saranno gestite in maniera strettamente riservata sia dal medico responsabile della ricerca, che dal suo gruppo di collaboratori in accordo alla normativa vigente in materia: d.lgs. 196/2003 e s.m.i. come da Linee Guida del Garante per il trattamento dei dati personali nell'ambito

delle sperimentazioni cliniche di medicinali (G.U. 190 del 14/08/2008) e come da ogni altra prescrizione/autorizzazione del Garante stesso.

Le informazioni saranno utilizzate e divulgate in accordo a quanto stabilito nella "Nota informativa per la tutela dei dati personali" (Allegato 1).

A chi rivolgersi per qualsiasi necessità o chiarimento?

Per maggiori informazioni riguardanti questa ricerca, i suoi diritti o, in caso si verifichino problemi di salute, potrà contattare il Prof. Innocenzo Rainero al numero 011-6334763.

Che cosa fare per partecipare?

Per partecipare a questo studio lei dovrà firmare e datare di suo pugno il modulo di consenso che segue (Allegato 2).

NOTA INFORMATIVA PER LA TUTELA DELLA RISERVATEZZA DEI DATI PERSONALI

Ogni informazione, dato personale comune o sensibile che La riguardi (nome e cognome o loro iniziali, informazioni anagrafiche, dati clinici o altri dati sensibili atti a rivelare lo stato di salute) ed il cui trattamento risulti connesso e indispensabile alla Sua partecipazione al presente studio clinico, sarà trattato con modalità idonee a garantire l'assoluta riservatezza, confidenzialità e sicurezza degli stessi, in conformità alle Norme di Buona Pratica Clinica (D.M. 15/07/97) nonché a quelle per la tutela delle persone e di altri soggetti rispetto al trattamento dei dati personali (D. Lgs. 30/06/03, n. 196).

Il Titolare (la persona fisica, giuridica, la pubblica amministrazione, enti pubblici, associazioni o qualsiasi tipo di organismo cui competono le decisioni in ordine alle finalità e modalità del trattamento dei dati personali compreso il profilo della sicurezza) del trattamento dei Suoi dati personali è l'Università degli Studi di Torino, Dipartimento di Neuroscienze.

Il Responsabile (la persona fisica, giuridica, la pubblica amministrazione, enti pubblici, associazioni o qualsiasi tipo di organismo preposti dal titolare al trattamento dei dati personali) del trattamento è lo Sperimentatore principale, nella persona del professor Innocenzo Rainero.

I Suoi dati personali, comuni e sensibili, saranno raccolti e trattati dallo sperimentatore responsabile dello studio e/o dai suoi collaboratori autorizzati, per le esclusive finalità connesse all'espletamento del presente studio clinico e alla verifica dello stato di avanzamento dello stesso.
I dati personali non saranno resi accessibili e disponibili a terzi, ad eccezione dei membri del gruppo di ricerca, del Comitato Etico locale e delle Autorità sanitarie italiane e/o internazionali; dette Autorità potranno, altresì, richiedere di verificare la Sua cartella clinica, con lo scopo di

valutare la correttezza dei dati raccolti e con modalità tali da garantire la riservatezza e la confidenzialità dei dati.
Il promotore dello studio utilizzerà questi dati a scopo di ricerca, per valutare la sicurezza e/o l'efficacia del trattamento cui si fa riferimento nel modulo per il consenso informato, nonché per meglio comprendere le patologie oggetto dello studio o per migliorare il disegno di studi futuri. I suoi dati potranno essere conservati e processati tramite computer e potranno essere trasferiti anche all'estero, in forma strettamente anonima. In ogni caso, anche l'eventuale diffusione all'esterno dei dati tramite pubblicazioni scientifiche e/o presentazioni in congressi, convegni e seminari, avverrà esclusivamente a seguito di un'elaborazione statistica degli stessi e, quindi, in forma assolutamente anonima.
In qualità di soggetto interessato al trattamento dei dati personali (Art. 4, lettera i) Lei potrà in qualunque momento avvalersi della facoltà e dei diritti a Lei attribuiti ai sensi dell'Art. 7 del D.Lgs. n. 196 del 30/06/2003.

Allegato 2

MODULO DI CONSENSO

Codice sperimentazione_____
Data protocollo_____

Titolo della ricerca: my Active and Healthy Aging – Alpha wave

Medico Sperimentatore: Prof. Innocenzo Rainero

ttoscritto _____
/a a _____
dente a _____
fono _____

Dichiaro

- Di partecipare volontariamente allo studio "my Active and Healthy Aging – Alpha wave" avente lo scopo di evidenziare precocemente condizioni di fragilità.
- Di aver ricevuto dal/dalla Dott/Dott.ssa_____esaurienti spiegazioni in merito alla richiesta di partecipazione alla ricerca, in particolare sulle finalità e procedure
- Di aver avuto a disposizione tempo sufficiente per poter leggere attentamente, comprendere ed eventualmente farmi spiegare quanto contenuto nella scheda informativa allegata e da me sottoscritta per presa visione, e che conferma quanto mi è stato spiegato a voce, in particolare che la sperimentazione sarà condotta nel rispetto dei codici etici internazionali;
- Di aver avuto la possibilità di porre domande e di aver avuto risposte soddisfacenti su tutta la sperimentazione ed in particolare sulle possibili alternative diagnostiche e terapeutiche e sulle conseguenze della mancata esecuzione della procedura proposta;
- Di essere stato informato sui possibili rischi o disagi ragionevolmente prevedibili;
- Di acconsentire/non acconsentire che il medico responsabile informi il mio medico di famiglia;
- Di acconsentire che i monitor, audit, autorità regolatorie nazionali ed estere abbiano accesso diretto alla mia documentazione clinica ai fini di monitoraggio e verifica;
- Di essere consapevole che la partecipazione è volontaria, con l'assicurazione che il rifiuto a partecipare non influirà nel ricevere il trattamento più idoneo;
- Di autorizzare ai sensi dell'Art. 23 del D. Lgs. N. 196 del 30/06/03 il titolare ed il responsabile dei suoi dati relativi alla presente ricerca a sottoporre a trattamento (nel senso specificato dalla legge) i dati personali, comuni e sensibili, che La riguardano in quanto necessari alla sua partecipazione alla ricerca clinica in oggetto.
- Di autorizzare il trasferimento all'estero dei miei dati personali, comuni e sensibili, una volta resi anonimi, nei limiti di cui alla nota informativa (Allegato 1).
- Di essere stato assicurato:

• che potrò ritirarmi dallo studio clinico già iniziato in qualsiasi momento, senza conseguenze negative nel ricevere il trattamento più idoneo e senza l'obbligo da parte mia di motivarne la decisione, a meno che la stessa non derivi dalla comparsa di disturbi o effetti indesiderati e/o non previsti, nel qual caso mi impegno fin da ora a comunicarne tempestivamente al medico sperimentatore natura ed entità;
• che la cartella clinica resterà strettamente riservata e i dati saranno utilizzati con le finalità indicate nello studio;
• che sarò informato di eventuali nuovi dati che possano influenzare i rischi o i benefici, oppure di variazioni di protocollo che possano influenzarli;

• che è mio diritto avere accesso alla documentazione che mi riguarda e alla valutazione espressa dal Comitato Bioetico di Ateneo cui potrò rivolgermi se lo riterrò opportuno;
• che una copia del consenso informato e della documentazione di cui ho preso visione rimarrà in mio possesso;
• che per ogni problema o per eventuali ulteriori informazioni potrò rivolgermi al medico sperimentatore:

Prof. Innocenzo Rainero
Via Cherasco, 15 - 10126 - Torino
Tel. 0116634763

Pertanto, confermo di aver avuto risposte esaurienti a tutti i miei quesiti e, preso atto della situazione illustrata,

□ **ACCONSENTO** LIBERAMENTE, SPONTANEAMENTE E IN PIENA COSCIENZA AL TRATTAMENTO PROPOSTOMI.
Dichiaro inoltre di essere a conoscenza della possibilità di revocare il presente consenso in qualsiasi momento.

□ **NON ACCONSENTO**

NOME E COGNOME (stampatello)	
FIRMA PAZIENTE	
EVENTUALI TESTIMONI (nome, cognome, firma)	
FIRMA SPERIMENTATORE	

Annex 4

Approval of the alpha-wave protocol by Comitato di Bioetica di Ateneo – CBA University of Torino (Italy)

UNIVERSITÀ DEGLI STUDI DI TORINO

COMITATO DI BIOETICA D'ATENEO

Prot. n. 83047 del 20/2/2017

Al Prof. Innocenzo Rainero
Dipartimento di Neuroscienze "Rita Levi Montalcini"
Via Cherasco, 15
10126 Torino

Oggetto: Approvazione Progetto

Si comunica che in data 18 gennaio 2017 il Comitato di Bioetica d'Ateneo ha approvato il progetto di ricerca dal titolo "My Active and Healthy Aging (my-AHA) Alpha wave".

Cordiali saluti

(Segreteria Comitato di Bioetica d'Ateneo)
Cesarina Marretta

Comitato di Bioetica d'Ateneo

Direzione Ricerca e Terza Missione

Via Bogino 9, Torino

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