AAL Programme

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AAL Programme

Project - SAfety of elderly people and Vicinity Ensuring - "SAVE"

Deliverable 3 - Test and Validation

3.1. Requirements for pilot sites

Main editor: UniTBv

Contributing partners: INRCA, NIMR, ISS

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1. Requirements for pilot sites

1.1. Summary

The report aimed at assessing the implementation and management of these requirements among the involved European partners. Ethical aspects in Romania, Italy and Hungary are also discussed.

1.2. Introduction

The pilot sites are grouping the primary, secondary and tertiary end users involved in co-design.

The pilot sites require capabilities (access networks for data acquisition and transmission) needed to install the SAVE equipment and to configure the services selected in agreement with the end-users and their caregivers. The remote access to assistive devices required online communication interfaces. Important knowledge transfer for pilot sites configuring came from valuable partners' expertise with intelligent residential environments driven by assistive technologies.

The pilot sites were associated with public institutions (social services, rehabilitation, geriatrics) that have as a main objective to improve the quality of life of older persons.

This association aimed to support the pilot sites in their needs for:

- certified methods for comprehensive assessment of candidate end-users;
- psycho-social assistance, including sustenance in difficult situations and prevention of depression;
- socializing and communitarian reintegration - preventing isolation and combating the risk of exclusion;
- home-care and recovery, re-training of cognitive functions, of manual dexterity and physical abilities;
- promoting the image of an active aging and interaction between generations.

The pilot sites requirements are in accordance with the national regulatory frameworks and with specific conditions that were evaluated in each context. Considering also the pandemic conditions, this assessment profiled these requirements and developed the recruitment strategies.

1.3. Assessment of the national models

The legal reference and regulatory frameworks for the pilot implementations are obeying the base principles of any scientific experimentation protocol, in accordance with the Nuremberg Code, the Helsinki Declaration, the Charter on the Fundamental Human Rights in the EU, the UNESCO Declaration on the responsibilities of the present Generations Towards the Future Generations, Ethics and EU funded research Council Decision 1513/2002/EC on FP6 etc.

The most relevant principles considered are the following:

- User's voluntary consent will be ensured by the means of a "informed-consent form". Voluntary participation implies that the user must not be forced and joined the project on its own initiative.
- Experimentation is aimed at finding solution dedicated to improving the quality of life of users. Testing activities are proportionate to the objectives to be achieved: there are no risks of death or serious injury to users. The project will ensure that the experimentation will be conducted so as not to damage the users (both physically and psychologically)
- Professional and qualified operators will be involved in the project.
- If during the implementation of the project unforeseen ethical concerns arise, it will be the responsibility of the project partners to bring the matter to the attention of the Project Coordinator for an ethics review: the theme in question will be analyzed and, if needed, it will be identified the appropriate solution to avoid any kind of risk to the user
- Users can leave the experiment at any time and testing will be interrupted, if there are reasons to believe that the continuation would violate the principles listed above

Given this perspective, the pilots will be set and implemented according to the European and national regulations. The main European reference is the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation - GDPR).

We have discussed the recruiting process of end-users, the questionnaire evaluation, and the users' interviews with the psychologists. We have identified the best tools for recruiting the end-users and how to implement SAVE testing in the pilot groups until the end of the project.

There were considered the different national models (laws, policies, home care services and regulations) and further local constraints (e.g., need of ethical applications) in order to tackle any possible impact on pilot implementations.

- Elderly Italian people population characteristics over 65 - According to the Annual Report (2019) by ISTAT, in Italy, the percentage of regular Internet users aged 65 and over is 21.7%. The analysis by generation allows a better understanding of the changes that have taken place over time with the same age. Analysing the profiles of use of the network, we observe a very limited regular use of the Internet for men and almost nil for women born before 1934 (who in 2018 are 84 years and older). In contrast to a steady spread of regular Internet use for those born since 1934, a marked gap is observed across generations: younger seniors aged 65-69 in 2018 (born between 1949 and 1953) use the Internet regularly much more than their peers fifteen years earlier. This trend is observed among both men (44.7 versus 5.8 percent of those born between 1934 and 1938) and women (34.9 versus 0.7 percent of those born between 1934 and 1938), with clear gender differences. The device most commonly used to access the Internet is the smart-phone, which has certainly contributed to the spread of the network even among older people: in 2018, the percentage of regular users aged 65 and older who use it is 68.5 percent.
- Elderly Hungarian people population characteristics over 65 – According to the National Media and Infocommunications Authority of Hungary, internet usage of the Hungarian elderly (60+) population shows the highest increasing tendency compared to younger populations. The ratio of internet users in the 60+ population reached 41% in 2017 which is far below the ratio of younger populations (81% for the 40-59 years and 91% for the 14-39 years) but is still significantly higher than in earlier years (25% in 2013 and 33% in 2015). [source: https:// nmhh.hu/dokumentum/194915/tavkozlesi_szolgaltatasok_lakossagi_hasznalata_2017.pdf] Although there are no fresh statistics, the epidemic certainly resulted in further increase of the above ratio.
  Internet usage is highly decreasing with age in the 60+ population: 56% for 60-69 years, 31% for 70-79years and only 13% for the 80+ population.
  64% of the Hungarian 65+ population did not use internet at all, 26% used internet only from PC or tablet and 9% on smartphone too, according to a 2017 survey.
- For instance, many of the elderly Romanian people have mobile telephones, but a fewer are also having home sensors in their houses. Only 44% of Romanian population between 55 and 74 years old are using internet (according to the Romanian Statistical Institute), only 30% of them are using it more than once in four days (in average). A statistics report of 2013 showed that only 16% of the Romanian

population over 65 years had internet at home. Therefore, the human-computer interaction was new for almost all the elderly Romanians included in the project.

3.1.1 Ethical aspects

SAVE (SAfety of elderly people and Vicinity Ensuring) project addresses the theme of exploiting information and communication technology (ICT) to promote psycho-social inclusion of end-users using a familiar environment for as long as possible, while feeling safely and optimally cared for.

As mentioned above, all partners of the SAVE project must respect the ethical guidelines set by the EU Regulation 2016/679 GDPR (General Data Protection Regulation) - "Protection of natural persons with regard to the processing of personal data and the free movement of such data."

General aspects:

- all the European and national regulations will be followed accordingly
- the data are collected and stored in a secure and anonymized database
- all the users involved (end users and informal caregivers) are fully informed about the project involvement.

The SAVE project has defined a set of ethical criteria to drive the project work methodology:

Declaring that all the criteria regarding the objectivity of the study, together with the risks and reservations associated with the listed procedures, which will be carried out in the research, have been fully explained to the users.

Users had the opportunity to receive an answer to any of their questions. Users understand that they may withdraw from this study at any time and that this withdrawal will not be to theirs disadvantage in any way.

Users have been informed that the information we provide will be kept confidential, and they freely express their consent to participate in this study.

If the questionnaire is completed online through the Google Forms platform, the data will be purchased according to Google's privacy policy. For the data to be confidential and anonymous, the email addresses will not be stored.

3.1.2 Ethics in Hungary

The ethics application in Hungary must include information about the following items:

- general description of the product and its intended use:
- the name of the device, its fancy name, its factory model number,

- the unique identifier and serial number of the device to be applied,
- device properties as medical device (as defined),
- device classification and its derivation from the relevant rules,
- intended use,
- list of the factors influencing the achievement of the intended use,
- contradictions to and exclusion factors for the application ,
- application alerts, caution, description of the principle of operation,
- general description of the planned variants and their identification data;
- design, planned production methods, in particular sterilization, part- , sub-assembly- , and wiring / circuit drawings:
  - physical description,
  - technical data,
  - schematic / wiring drawing, image / photo;
- descriptions and explanations necessary for understanding the design and the operation of the device:
- list of standards used in the design of the device,
- list of applicable but for the device not used standards and the description of the solutions that make it possible to meet the specifications set out by the essential requirements differently from the standard,
- methods of checking and approval for the design documentation and the make of the device,
- the terms for its intended connection to another device, technical and safety requirements, other conditions and limitations of use of the device for its intended use;
- results of the risk analysis and the list of nationalized harmonized standards fully or partially applied, as well as the description of the solutions used to meet the requirements of Title 3 of this Regulation where the harmonized nationalized standards have not been applied;
- data of the studies performed for evaluation of the safety, quality and usefulness if a component of a medicament, or a substance considered to be a medicinal product or a human blood derivative is an integral part of the device, taking into account the intended use of the device;

- risk management measures taken to reduce the risk of infection if the device is made using animal tissue;
- results of construction calculations, inspections and technical tests.
- the manufacturer must take all necessary measures to produce products during the manufacturing process which comply with the documentation referred to in this point. The manufacturer must allow the assessment of the effectiveness of these measures and, where appropriate, the verification of these measures.
- the method, the surface, and the time of the contact between parts of the device and the user or the operator in regular usage. The certification of bio compatibility and the safety data sheet of the contacting materials.
- requirements for sterility and sterilization procedures and how to provide them
- draft label
- draft instructions of use
- declaration that the device(s) for clinical evaluation(s), in addition to the criteria under evaluation, meet the essential requirements set out in Annex 1 to the specific medical devices directive and that the manufacturer has made every effort to protect the participants' health and safety
- in case of multi-centre investigations, if any, the approval of the Ethics Committee of the European Economic Area Country
- identifying data of the devices under investigation,
- risk analyses and risk assessment, detailed assessment of the likely risks and side effects, their elimination or mitigation,
- analysis and justification of the acceptability of the planned performance over the likely risks and side effects.

3.1.3. Ethics in Italy

At INRCA, own Bioethics Committee (EC) and a specific pathway to follow

- classification of SAVE is an Observational research study
- every document must be translated into Italian
- required documents from technical partners:

- study synopsis (a brief presentation of the project's objectives, materials, and methods, outcomes, safety and security information about the use of technologies),
- data collection tools e.g. topic-guide interview, questionnaires including all scales and measures which will be adopted during the study
- information letter for the subject participating in the study
- informed consent
- required forms to be signed by the project manager:
- transmission letter requesting the opinion of the committee and the company authorization
- declaration of conformity to the ministry of health decree 17/12/2004
- model of public declaration on the conflict of interests of the experiment
- updated curriculum in European format of the Principal Investigator

Procedural characteristics:

- committee meetings: monthly
- evaluation and response time: usually <3 months

3.1.4. Ethics in Romania

- The e Health system used in the pilots could be used as an add-on to the existent data acquired by caregivers and/or volunteers for gaining a more comprehensive image on their supervised elderly people.
- if we are not using medical devices and we discuss the specific risks for human subjects and / or other implications, we will need the following:
- a brief presentation of the project's objectives, materials and methods, outcomes, safety and security information about the use of technologies,
- information about the category of vulnerable participants
- privacy and anonymity measures (to protect their privacy)
- information about the risks (we should explain if the risks are greater than in everyday life).
- information about the freedom to withdraw from the trial after the initial agreement
- the data collection tools e.g. topic-guide interview, questionnaires including all scales and measures which will be adopted during the study; expected results; procedure.

- the information letter for the subject participating in the study
- the informed consent
- confidentiality agreement
- the researchers involved in the project

3.1.5. Involving users

(The format and the content of the this section follows the form of the Local Ethical Commission of the Transilvania University of Brasov, Romania - approval number: *24/03.03.2021*) **from Annex 1.**

A. Human participants - end-users/caregivers

For the group of primary end users in Romania, their number is between 30 and 40 people. The selection of users will be made in various centers and organizations for the elderly such as the Directorate of Social Services in Brasov, on a voluntary basis. Elderly people with various medical problems suffering from chronic age-related diseases, mild cognitive disabilities after the age of 65 are targeted. The selection procedure is carried out together with the interdisciplinary team from the proposed centers following their availability and the characteristics pursued in the project.

Secondary end users are formal and/or informal caregivers, their number in Romania is between 10-20 participants.

Inclusion criteria:

- Professional caregiver/social worker (nurse, physiotherapist, occupational therapist) or healthy family member of the primary end user
- Spends at least 30 hours a week with primary end user

Exclusion criteria:

- No proven experience related to health care in field (e.g. health-care manager)

Tertiary end users are stakeholders including care providers, public social service, end user organizations, medical and nursing researchers. Their number in Romania is between 2-5 participants.

B. Research Methodology on SAVE

Objective

The “SAVE” project is dedicated to the elderly, who suffer (or are at risk of) chronic age-related illnesses and / or mild cognitive problems / disabilities - “end users” over the age of 65. For these, "SAVE" aims to avoid psycho-social exclusion by "restoring the frame of reference" - generic name for "(re) orientation" in a supportive environment - in terms of location of the position and / or in terms of safety (in homes smart sensors) approached in a broader cognitive and behavioral sense, oriented towards individual tasks in the "personal cloud" of relatives, friends and caregivers.

The objective of the research is to investigate the SAVE prototype from the following aspects:

Based on user’s opinion:

- Usability of the functions
- Utility
- Acceptability
- Reliability
- Convenience aspects

Before tests with users, the following prerequisites are verified:

- Safety
- Technical performance
- Technical reliability

Methods

The method used in this study is real-life testing of the SAVE services 24/7 in a period of 21 consecutive days at the user’s home and the vicinity. Primary end users will test the SAVE services on their own choice and needs. Secondary end users will test the digital monitoring of the services their care recipients use. Secondary end user will test the reporting and logging functions of the SAVE framework. Tertiary end users will test the digital care provision efficiency by monitoring how the primary and secondary end users take advantage of the SAVE services. The research team members will analyse the logs collected from each users service analytics, as well as the poll the end users’ opinion with questionnaires at the entry, at

the middle and at the exit of the test period. The local SAVE research support teams will include experts with medical and technical knowledge, who will install/hand over the SAVE devices to the end users, who will train the end users on the use of the SAVE services, and to whom the recruited participants can turn with any type of request through a dedicated SAVE channel (e.g. by pressing the Emergency button), or through ordinary communication channels like phone, e-mail, or SMS.

C. Tools / questionnaires / other materials

The methodology is based on cross cultural assessment- including quantitative and qualitative indicators (objective items from working with cross cultural questionnaires). There is a unified methodology to run sessions and studies with end-users and caregivers.

The data collection tools are made of the following sections:

Health and Well-being

- The SF-36v2™ Health Survey, a widely used instrument, is a 36-item. It is a brief, reliable measure of overall health status. It is useful in large population health surveys and has been used extensively as a screening tool. It includes 8 dimensions: PF - Physical functioning; RP - Role limitations due to physical health problems; BP - Bodily pain; SF - Social functioning; MH - General mental health, covering psychological distress & well-being; RE - Role limitations due to emotional problems; VT - Vitality, energy or fatigue; GH - General health perceptions.
    - The questionnaire is already translated in Italian, Hungarian and Romanian in different studies.
- EuroQol, EQ-5D-5L - Quality of life associated with health

    The questionnaire is already translated in Italian, Hungarian and Romanian in different studies.
- WHO-5 ITEMS. The World Health Organization – Five Well-Being Index is a short self-reported measure of current mental well-being. Individuals are asked to indicate for each of the five statements how they felt over the past two weeks using a six-point Likert scale ranging from 0= “at no time” to 5 = “all of the time” for a brief assessment (less than 1 minute).
    - The questionnaire is already translated in Italian, Hungarian and Romanian in different studies.

Efficacy in self-health monitoring

General Self-efficacy scale is a self-report measure of self-efficacy. The questionnaire is an well known used instrument for measuring general self efficacy.

- Italian Adaptation - Self-Efficacy Generalizzata - By Lucio Sibilia, Ralf Schwarzer & Matthias Jerusalem, 1995

- Hungarian Adaptation of the General Self-Efficacy Scale - by Maria Kopp (Budapest, Hungary), Ralf Schwarzer & Matthias Jerusalem (Berlin, Germany), 1995

- Romanian Version of the General Self-Efficacy Scale - by Adriana Baban, Ralf Schwarzer & Matthias Jerusalem, 1996

or

Quality of Life Inventory - QOLS is a reliable and valid instrument for measuring quality of life on different ages. QOLS is a short method, yet a comprehensive measure of life satisfaction for following domains Health; Self-esteem; Goals and values; Money; Work; Game; Learning; Creativity; Help; Love; Friends; Children, Relatives; Home; Neighborhood and Community.

Has already Italian and Romanian validity.

Usability and Acceptance:

- Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) Quebec User Evaluation of Satisfaction with Assistive Technology. This is a 12-item outcome measure that assesses user satisfaction with two components, Device and Services
or
UTAUT model (Unified theory of acceptance and use technology)

- User Experience Questionnaire - UEQ. The User Experience Questionnaire allows a fast and immediate measurement of user experience containing 6 scales with 26 items.
- UEQ - is already translated in Italian and Hungarian but not yet in Romanian

Questionnaires characteristics:

Name	Abbrevia-tion	Population	Items Number	Test Period	Internal validity	References
Health Survey	Rand 36	Over 65+	36	8-10 min	.91-.94	Lins & Carvalho, 2016
Five Well-Being Index	Who 5 Items	Over 65+	5	1 min		Sischka et al., 2020
General Self Efficacy	GSE	Over 65+	10	2 minute	.76-.90	Luszczynska et al., 2005

Quality of life inventory	QOLS	Over 65+	32	5 minute	.82-.92	Burckhardt & Anderson, 2003
EQ - 5D - 5L Quality life	EQ - 5D - 5L	Over 65+	5	3 minute	.7-.8	Feng et al., 2020
Quebec User Evaluation of Satisfaction with Assistive Technology	(QUEST 2.0)	Over 65+	12	5-30 minute	.76-.82	Lembres, 2002
Unified theory of acceptance and use technology	UTAUT	Over 65+	31 items	10-15 minute	.76-.86	Chao, 2019
User experience questionnaire	UEQ	Over 65+	26 items	10-15 minute		Solano et al., 2019
System usability scale	SUS	Over 65+	10 items	5 minute		Dekker-van Weering et al., 2017

Stigma and Privacy

- Open questions on users' feelings towards the SAVE system. Two closed questions on privacy and stigmatization (i.e. the risk of being la-belled just for the usage of a technology, for example being la-belled as "older" because one's using the digital coach for well-being).

According to the general objectives of this study, primary and secondary outcomes are described below.

Primary outcomes are:

a) Usability. It is intended as „the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use". This outcome will be measure through the **SUS and UEQ scales**.

b) Learn ability. It is one component of usability - is the degree to which the interface is intuitive and the user can immediately grasp how to interact with the system. This outcome will be measured through the **SUS scale**.

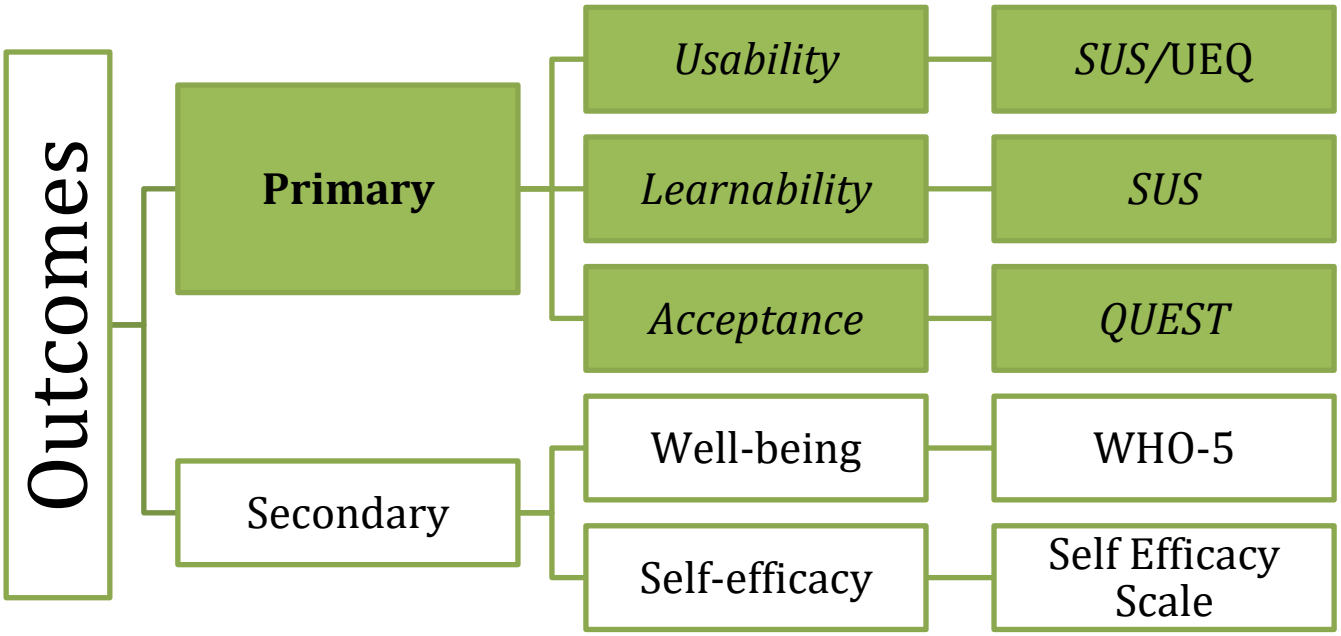
c) Acceptance. It is the degree to which users come to accept and use a **technology.** This outcome will be measured through the **UEQ *questionnaire.***

Secondary outcomes are:

d) Well-being as „a state of complete physical, mental and social wellness and not merely the absence of disease". This outcome will be measured through the WHO-5 scale and EuroQol, EQ-5D-5L scale.

e) Self-efficacy as the set of beliefs held about the own ability to complete a particular task. This outcome will be measured through the General Self Efficacy Scale.

Figure 1 Primary and secondary outcomes and the measures used to evaluate them



The processing of the data from the questionnaires will be performed with the software systems SPSS, Mplus (for performing the confirmatory factor analysis) and AMOS (for performing the exploratory factor analysis) depending on the needs.

D. Procedure

The procedure of the pilot test is demonstrated on the Emergency service.

The local SAVE research support team contacts candidate primary, secondary and tertiary end users. The local SAVE research support team presents the procedure of the SAVE pilot testing to the candidate end users. End users agreeing with the participation in the pilot test sign the informed consent.

Primary end user:

- primary end users test the Emergency service for 21 days
- the local SAVE research support team notifies the primary end user about the date of installation of the SAVE services. The date of installation is the day before the 21 day pilot test period.
- the local SAVE research support team: a technical expert and a medical expert visits the primary end user in his/her home on the day of installation. The technical expert installs the SAVE smart-watch, configures the network settings, hand it over to the primary end user. The technical expert trains the primary end user to use the SAVE smartwatch including the touch and speech interactions, charging, maintenance, and troubleshooting. The medical expert asks the primary end user to fill in the T0 questionnaire.
- the primary end user activates the Emergency service on each day at least two times; one with touching the SAVE smart-watch, another one with telling the SAVE smart-watch: Help. Upon activation of the Emergency service the responsible secondary end user calls the primary end user on his/her SAVE smart-watch, to check the status of the emergency call. If the primary end user activates no or only one emergency call on a test day, the responsible secondary end user calls the primary end user. If the primary end user does not pick up the call on the SAVE smart-watch, the secondary end user calls him/her on a reserve communication line. If the secondary end user cannot verify the status of the primary end user, the secondary end user and the local SAVE research support team visit the primary end user with urgency on the last recorded location of the SAVE smart-watch.
- the local SAVE research support team visits the primary end user on the 11th day of the test period. The local SAVE research support team investigates the status of the SAVE smart-watch and asks the expert asks the primary end user to fill in the T1 questionnaire.
- the local SAVE research support team visits the primary end user on the 21st day of the test period. The local SAVE research support team thanks the primary end user for participating in the pilot testing, receives the SAVE smartwatch, and asks the primary end user to fill in the T2 questionnaire.

Secondary end user:

- secondary end users test the Emergency service for a single or a repeated period of 21 days.
- secondary end users monitor one or more primary end users in the daily use of the Emergency service.
- the local SAVE research support team notifies the secondary end user about the date of installation of the SAVE services. The date of installation is the day before the first day of the pilot test period.
- the local SAVE research support team: a technical expert and a medical expert visits the secondary end user in his/her home/office on the day of installation. The technical expert installs the SAVE smart-phone, configures the network settings, configures the primary end users in the SAVE client software, and hand it over to the secondary end user. The technical expert trains the secondary end user to use the SAVE smart-phone including the touch and speech interactions, charging, maintenance, and troubleshooting. The medical expert asks the secondary end user to fill in the T0 questionnaire. The secondary end user can opt for filling in the electronic version of the questionnaire.
- the secondary end user receives the Emergency service notifications from the primary end users she/he monitors. Right after the receipt of the Emergency service notification the secondary end user calls the primary end user on his/her SAVE smart-phone, to check the status of the primary end user. If the primary end user activates no or only one emergency call on a test day, the secondary end user calls the primary end user. If the primary end user does not pick up the call on the SAVE smart-watch, the secondary end user calls him/her on a reserve communication line. If the secondary end user cannot verify the status of the primary end user, the secondary end user and the local SAVE research support team visit the primary end user with urgency on the last recorded location of the SAVE smart-watch.
- the local SAVE research support team contacts the secondary end user on the midday of the test period. The local SAVE research support team investigates the status of the SAVE smart-phone and asks the secondary end user to fill in the T1 questionnaire. The secondary end user can opt for filling in the electronic version of the questionnaire.
- the local SAVE research support team visits the secondary end user on the last day of the test period. The local SAVE research support team thanks the secondary end user for participating in the pilot testing, receives the SAVE smartphone, and asks the secondary end user to fill in the T2 questionnaire. The secondary end user can opt for filling in the electronic version of the questionnaire.

Tertiary end user:

- tertiary end users test the Emergency service for repeated period of 21 days.
- tertiary end users receive logs from one or more primary and secondary end users about the daily use of the Emergency service.
- the local SAVE research support team notifies the tertiary end user about the date of installation of the SAVE services. The date of installation is the day before the first day of the pilot test period.
- the local SAVE research support team: a technical expert and a medical expert visits the secondary end user in his/her home/office on the day of installation. The technical expert installs the SAVE smart-phone, configures the network settings, configures the primary end users, the secondary end users in the SAVE client software, and hand it over to the tertiary end user. The technical expert trains the tertiary end user to use the SAVE smart-phone including the touch and speech interactions, charging, maintenance, and troubleshooting. The medical expert asks the tertiary end user to fill in the T0 questionnaire. The tertiary end user can opt for filling in the electronic version of the questionnaire.
- the tertiary end user receives the logs of the Emergency service usage from the primary end users and secondary end users she/he monitors. The tertiary end user can access the analytics of the Emergency service usage at any time.
- the local SAVE research support team contacts the tertiary end user on the midday of the test period. The local SAVE research support team investigates the status of the SAVE smart-phone and asks the tertiary end user to fill in the T1 questionnaire. The tertiary end user can opt for filling in the electronic version of the questionnaire.
- the local SAVE research support team visits the tertiary end user on the last day of the test period. The local SAVE research support team thanks the tertiary end user for participating in the pilot testing, receives the SAVE smart-phone, and asks the tertiary end user to fill in the T2 questionnaire. The tertiary end user can opt for filling in the electronic version of the questionnaire.

In the project pilots will be used Commercial off-the-shelf (COTS) based/integrated products providing real-time feedback for the second targeted users (i.e caregivers) and engaging them in employing them in acting according to their rules and responsibilities in relation with end-user.

Informed consent

Informed consent is a process, devised initially in health care framework in order to obtain and manage permissions before an intervention regarding any person, in order to guarantee total confidentiality and privacy.

Every national pilot site adopts a specific informed-consent form, which will be submitted to, explained to and signed by the selected users before the test's start. An example of Informed consent for users and caregivers is attached in **Annex 2.**

E. Expected results:

The SAVE project envisages the use of questionnaires in order to assess the level of mental and physical adaptation of the elderly participants in the project. The questionnaires described will help the project team to create an objective image of each participant and to use this information for their benefit. The main objective is to maintain the health of the participants and to use the services to their advantage for specific purposes. The services will be modeled based on a deep knowledge of real needs and related areas of opportunity (identified from the answers to the questionnaires).

Discussions during the ethical progress between the partners:

Thinking about the efficiency of the project solutions, we believe that the easiest way is to use devices already suitable for self-management or for home use without any medical implication. According to our ISS partners, in what concerns the e-Health monitoring system proposed and developed by ISS, this is not considered a medical device, nor intended for medical diagnosis, cure, mitigation, treatment, advice or prevention of disease. The e-Health system, as stated by ISS, represents a system for assessing biometric information in terms of measurement and/or statistical analysis of people's unique physical and behavioral characteristics. The e-Health system used in the pilots does not require medical doctors/physicians due to the fact that the biometric information elicited from end-users is not to be used to monitor patients who need accurate medical monitoring, but instead, the biometric info could be used as an add-on to the existent data acquired by caregivers and/or volunteers for gaining a more comprehensive image on their supervised elderly people.

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Annex 1

Application for Approval of Research Projects with Human Participants - UniTBv REPORT

APPLICATION FOR APPROVAL OF RESEARCH PROJECTS WITH HUMAN PARTICIPANTS

- research protocol -

Title - Research Project - SAfety of elderly people and Vicinity Ensuring - "SAVE"	**Destination:** .... publishing .... participating at national/international research competition .... other destination (such as.....) .....
Date collection data started (estimating date) - March 2021	
Research data completion date (estimating date) - July 2022	

Principal Investigator

As a principal investigator, coordinator of a study with human participants, I declare that I am aware of the norms of ethics in social and human scientific research and I will fully respect the rights of the participants. I undertake to inform all participants in the study of the procedures concerning them and to describe in the informed consent, as clearly and completely as possible, the risks to which they are exposed and the benefits of the study. I undertake to

take all necessary measures to ensure that all members of the team involved in carrying out the study comply with the provisions of this statement. I assure the Ethics Commission of the social-human scientific research (CECS) that the entire research will respect the specific regulations from Romania and the Code of Ethics of the Transilvania University of Brasov.

Any changes in the conduct of the research, which concern the person of the principal investigator, the research methodology, as well as unforeseen events, will be reported to the CECS for approval.

Principal Investigator Name

Resume

The aim of the researchers is to help elderly people over 65 years of age who live alone, do not suffer from severe chronic diseases and are willing to learn, and to help their relatives as well. So that the elderly can keep their independent lives in their homes, their lives active and meaningful, and their social relationships can be maintained for as long as possible. This is to be achieved through services based on advanced technologies. The research is carried out under the European Union's Active and Assisted Living programme, SAfety of elderly people and Vicinity Ensuring, shortly known as SAVE (http://www.aal-europe.eu/projects/save/).

1. **Human participants** (anticipated number, selection criteria, socio - demographic data, place of data collection, method of recruitment: procedure, announcements, flyers, letters, etc.)

For the group of primary end users in Romania, their number is between 30 and 40 people. The selection of users will be made in various centers and organizations for the elderly such as the Directorate of Social Services in Brasov, on a voluntary basis. Elderly people with various medical problems suffering from chronic age-related diseases, mild cognitive disabilities after the age of 65 are targeted. The selection procedure is carried out together with the interdisciplinary team from the proposed centers following their availability and the characteristics pursued in the project.

Questionnaires: (fill in, if applicable)

EuroQol, EQ-5D-3L - Health Questionnaire

WHO-5 ITEMS. The World Health Organization - Five Well-Being Index - 5 World Health Organization - 5 Wealth Indices

General Self Efficacy Scale (adapted by Adriana Baban, Ralf Schwarzer & Matthias Jerusalem), 1996

All these questionnaires are "open access" and can be used without prior consent.

Informed consent for end users

Informed consent for members

2. **Ethical implication** / risks to human subjects and / or other implications (if applicable).

+ There are ethical implications ..... There are no ethical implications

sensitive health data will be collected (GDPR)

If there are ethical implications, detail:

2.1 The relations between the participants and the researcher (eg teacher-students, dean-teachers) **and the perception of a possible coercion's**

- there are no participatory relations between the researcher and the respondents
- respondents will be able to participate voluntarily,
- there are no repercussions and the data are anonymous,

2.2 Category of vulnerable participants (If applicable, tick):

- ..... minors participants (participants under 18 year)
- ..... people with disabilities
- .... pregnant women
- .... socio-economically disadvantaged people
- **X** other categories (persons from the age of 65 suffering from chronic age diseases)
- - the project does not take into account the material resources of the participants
- - people from the age of 65 suffering from chronic age diseases
- people with disabilities are not excluded from the project

2.3 Confidentiality and anonymity

X *Participants are identifiable;* *Participants are not identifiable.*

If participants are identifiable, show how they will be protected, how the data will be stored, and who will have access to the data.

Ensuring the anonymity of each participant will be based on an assigned number. Not even initials will be used, only numbers. Only researchers involved in the project will have access to this database. The answers are confidential, and the information in the database will be made based on that code and not by using the name or initials.

Following the text of the request, the agreement of the divided participant will be formulated in specific questions and answers, in order to favor the understanding according to the examples:

I declare that I understand the purpose of the research, the procedure, the risks and the fact that the research is voluntary. I understand that I can withdraw at any time without being penalized in any way.

Yes No

By completing the answers and checking the <Send> option, I agree to participate in this research.

Yes No

I agree that the data provided in this research will be processed and published by the researcher.

Yes No

I declare that all the criteria regarding the objectivity of the study, together with the risks and reservations associated with the listed procedures that will be performed in the research, have been fully explained to me.

Yes No

I declare that I have had the opportunity to receive an answer to any of my questions. I understand that I may withdraw from this study at any time and that this withdrawal will not be to my disadvantage.

Yes No

The questionnaires will be anonymous or signed for all participants regardless of whether they complete them online or in the usual written form (pencil-paper). If the questionnaire is completed online on the Google Forms platform, the data will be purchased in accordance with Google's privacy policy. Email addresses will not be stored.

The questionnaires that will be signed will be ensured their confidentiality according to the rules.

2.4 ***Compensation*** (Specify whether or not participants will be rewarded for participation - money, products, student loans - If credits are obtained, state how those who do not wish to participate in the study will obtain them.)

- There are no financial compensations in this project. Users, as in all AAL projects, will remain in custody of all equipment used (mobile phones, sensors, watches, etc.)

2.5 **Risks**

Show if the risks are higher than in everyday life:

Yes No

If so, describe all possible risks: physical, financial, social, emotional, cognitive, legal, stress.

Health data will be protected. The people involved in the project will be assured the confidentiality of their personal data and image threats to the dignity of participants, etc.

2.6 Benefits for the researcher

a) Describe the benefits of the researchers in this study

Researchers are remunerated for their activity, according to the legislation in force. Researchers can publish, participate in conferences, etc.

Researchers will have the satisfaction of observing the benefits of implementing the project in the lives of the elderly and using this experience in various other projects or research

b) Show the person / institution that commissioned the study (if applicable) and what benefits you anticipate for it

Transilvania University of Brasov is the beneficiary of the grant Euro. The institution that commissioned the study / Funder is: European Union through AAL.

Users' responses to the questionnaires along with the methodology used in the measurement will be materialized by participating in conferences, publishing articles in journals and submitting new project proposals.

c) What are the intentions of using the data

Dissemination of results at various congresses / conferences and publications in various journals.

2.7 Freedom to withdraw from research after initial agreement

Mention the presentation of the participants' right to withdraw at any time

Participation in this study is entirely voluntary. Participants may withdraw from this study at any time without risk. By completing the questionnaire and using the equipment provided according to the project, the participants agree on the data processing. This fact is mentioned in the informed consent for all users as well as for their relatives.

Show the extent to which compensation will be given to those who retire

There is no compensation for those who withdraw from the project.

Show the conditions under which the researcher may interrupt the research to protect a participant.

The research can be stopped at any time when the participant no longer feels comfortable with the actions performed in the project.

3. Research Methodology

3.1 Objective

The “SAVE” project is dedicated to the elderly, who suffer (or are at risk of) chronic age-related illnesses and / or mild cognitive problems / disabilities - “end users” over the age of 65. For these, "SAVE" aims to avoid psycho-social exclusion by "restoring the frame of reference" - generic name for "(re) orientation" in a supportive environment - in terms of location of the position and / or in terms of safety (in homes smart sensors) approached in a broader cognitive and behavioral sense, oriented towards individual tasks in the "personal cloud" of relatives, friends and caregivers.

3.2 Methods (list the methods used)

The method used in this study is the questionnaire survey

3.3 Tools / questionnaires / other materials *(Name - short description)*

The processing of the data from the questionnaires will be performed with the software systems SPSS, Mplus (for performing the confirmatory factor analysis) and AMOS (for performing the exploratory factor analysis) depending on the needs.

Attached to this procedure are the translated questionnaires -

The data collection tools consist of the following sections:

A) Health and well-being

EuroQol, EQ-5D-5L - Quality of life associated with health

WHO-5 ITEMS. The World Health Organization - Five Well-Being Index

B) Efficiency in self-monitoring

General Self Efficacy Scale - adapted by Adriana Baban, Ralf Schwarzer & Matthias Jerusalem, 1996

C) Experience with technology -

a. I feel safe and protected in my environment.

b. Communication with service providers works well and efficiently.

c. The applications are easy to use

d. The time allocated for the commissioning of the sensors was short.

D) Use and acceptance of technology - UTAUT model (Unified theory of acceptance and use technology)

E) Stigma and confidentiality - ad-hoc questions

4.4. Procedure (describe what participants are asked to do, the duration and type of researcher-participant interactions, the different ways of treating some participants, if applicable)

The procedure is simple, as with any completion of a questionnaire and the use of non-invasive devices.

a. Presentation and obtaining informed consent for end users and relatives

b. Knowing the objectives of the study

c. Completion of the questionnaire by the participants

d. The completion of the questionnaires can be done online (using the Google Forms platform) or face to face.

5. Expected results:

The SAVE project envisages the use of questionnaires in order to assess the level of mental and physical adaptation of the elderly participants in the project. The questionnaires described will help the project team to create an objective image of each participant and to use this information for their benefit.

Annex 2

Informed Consent of Users

Project Title: “Psycho-social research” within the “SAVE” grant.

Research field: Improving the quality of life of the elderly

Dear participant,

..... employed at the ....., would like to invite you to participate in the research project on: "Psycho-social research" within the "SAVE" grant. "

This study is conducted under the auspices of the ..... and the results will be processed in order to assess the quality of life of the elderly and their relatives. These data can be published in various journals.

Your participation in this study is entirely voluntary. You are free to withdraw from this study at any time without any repercussions; by completing the questionnaire you give your consent for its processing. You do not have to answer this questionnaire and there is no possibility to identify it.

You will be asked to complete several questionnaires over a period of 15-20 minutes.

1. I declare that all the criteria regarding the objectivity of the study, together with the risks and reservations associated with the listed procedures, which will be carried out in the research, have been fully explained to me.

2. I declare that I have had the opportunity to receive an answer to any of my questions. I understand that I may withdraw from this study at any time and that this withdrawal will not be to my disadvantage in any way.

3. I have been informed that the information I provide will be kept confidential and I freely express my consent to participate in this study.

4. If the questionnaire is completed online through the Google Forms platform, the data will be purchased according to Google's privacy policy. In order for the data to be confidential and anonymous, the email addresses will not be stored.

Any questions about your participation in this project can be addressed to the researcher ..... mail:

Thank you!

Researcher

Name and surname .....Signature …… ..Date .....

Please sign below if you agree to participate in the research project mentioned above.

Participant

Name and surname .... Signature ... …… ..Date .....

Informed Consent relatives/caregivers

Project Title: “Psycho-social research” within the “SAVE” grant.

Research field: Improving the quality of life of the elderly

Dear Relatives/caregivers

..... employed at the ....., would like to invite the person you are caring for to participate in the research project on: “Psycho-research "SAVE" grant "".

The caregiver will be asked to complete several questionnaires over a period of 15-20 minutes.

This study is conducted under the auspices of the ..... and the results will be processed in order to adapt the psychological questionnaires applied in sports. These data can be published in various journals.

The caregiver may be vulnerable only if personal data are associated with the answers provided in the study. If the questionnaire is completed online through the Google Forms platform, the data will be purchased in accordance with Google's privacy policy. I take full responsibility for the protection of personal data (by using a number), for ensuring anonymity and confidentiality. In order for the data to be confidential and anonymous, the email addresses will not be stored.

Participation in this study is entirely voluntary. Mr./Ms. Is free to withdraw from this study at any time without any repercussions; by completing the questionnaire you give your consent for its processing. Mr./Ms. Is not obliged to answer these questionnaires and there is no possibility to be identified.

Any questions about your participation in this project can be addressed to the researcher ....., mail:

Thank you!

Principal Investigator:

Signature …… .. Date .....

Please sign below if you agree with the participation of the person you are caring for in the research project mentioned above.

Mr. / Mrs. in care: (name and surname) ....

Belonging (name and surname) ....

Date ..... Seed ....