AAL Programme

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AAL Programme

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

Deliverable 3 - Test and Validation

3.2. Pilot users profile description

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Aim of the study

As explained in D2.1 User Research Report, a great challenge of the SAVE project is to provide a human-centered perspective during the main development cycles of the system. The active involvement of users and a clear understanding of context of use are the key strengths to overcome the main barriers in applying technology for seniors. This strategy represents the core of the User-Centered Design (UCD), a design philosophy which encompasses various methodologies and techniques which seek to involve the end-user in the design process with the end-user being defined as the 'person who will ultimately be using the product'. The goal of UCD is to optimise the usability, human factors and hence the user experience (UX) of a product. The International Standards Organisation standard ISO 9241-210, extended the definition of UCD to "address impacts on a number of stakeholders, not just those typically considered as users", referring to the design approach as Human Centered Design (HCD). The terms HCD and UCD are used synonymously and as such the term UCD will continue to be used throughout this document. Based on the UCD approach, this document presents how the consortium decided to evaluate the system under development.

The general aim of this study is testing the SAVE prototype by assessing its feasibility, usability, learn-ability and acceptance. Moreover, the study will also analyse to what extent it can influence individuals' well-being by motivating older adults to practice a healthy life style.

The study evaluations are set up in three different sites: Italy, Hungary and Romania. This multi-site design will allow evaluating the SAVE system in different social and cultural contexts. Overall, the multinational approach proposed will ensure wide acceptability of the developed technology and prepare the possibility of Europe-wide deployment beyond the initial project life-cycle

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 Methodology - Criteria for selection of test sites

According to WP 2, the pilot site profile and the recruitment strategy, SAVE project is proposing to involve almost 80 end-users. Overall, 80 subjects that match the inclusion criteria shown in table 1 will be enrolled in the study.

Table 1 - Eligibility criteria

	Inclusion Criteria	**Exclusion Criteria**
Older adults 30 users in Romania 25 users in Hungary 25 users in Italy	Signed informed consent, agrees to study Aged 65 years or older Participants feel physically and cognitively fit to participate in the study (self-assessment) They are sufficiently mobile, capable of maintaining, changing their position, manipulating and moving objects, moving in their place of residence, living environment, moving around using transportation)	Not agree to the study, no informed consent Less than 65 years of age Mobility or cognitive abilities are moderately to severely restricted (self-assessment) Suffer from severe chronic illness or severe disability Conditions that make it difficult to use a smart device (e.g. moderate/severe dementia, aphasia)

How SAVE project recruits subjects?

In retirement clubs, elderly organizations, social services, with the help of contact information obtained according to our existing contacts and acquaintances - e.g. telephone, e-mail address.

Potential participants are screened (e.g. by phone) to check the inclusion criteria. The person responsible for recruitment contacts individuals and explains the objectives, methods, procedures and times of the project.

Extending data collection to:

A) Use of a validated health and well-being questionnaire.

B) Efficiency in health monitoring, validated self-efficacy and efficacy questionnaire supplemented by individual questions specific to the study

C) Assessment of general technological experience with individual questions

D) Assessment of usability and acceptance using validated user experience questionnaires.

E) Stigma and data protection assessment using open questions

Each survey is conducted by a trained interviewer verbally, face to face, who records the answers on paper in the approved format.

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

Primary results:

a) usability. This means "to what extent a product can be used by specific users with sufficient efficiency, effectiveness and satisfaction to achieve the specified objectives in a specified use environment".

b) Learning ability. This shows how effectively the connection between the user and the device has been established.

c) Acceptance. The extent to which users can accept, apply and use technology in their lives.

Secondary results:

d) Well-being as „a state of complete physical, mental and social health, and not just a lack of disease", plus the impact of the instruments on this.

e) Self-efficiency as a set of beliefs about the ability to perform a given task.

2. Procedure

Working with elderly, we tried to develop an easy procedure for their evaluation, being easy to understand and to complete. An example of such a procedure:

1. Welcome page

2. SAVE study description, end-user information

3. Informed consent for end-users/caregivers

4. Exclusionary questions (e.g., people living in a social institution, not using a smart device at all), security issues (e.g., intentionally giving false answer)

5. Screening questions (check that respondents meet the selection criteria) + some demographic questions (e.g. gender, number of people aged 65 and over or caring for the elderly, living in a household, has internet access, is it open to new tools)

7. Service / smart device specific warm-up issues later slide

8. Brief description of the services (with the already developed text, graphics)

9. The main part of the questionnaire – The evaluation sheet already agreed, broken down by service

10. Acknowledgments page

3. Cross Sectional Methodology

Table 1

	Italy - Yes	Italy - No	Hungary- Yes	Hungary - No	Romania - Yes	Romania- No
Inclusion Criteria	X		X		X	
Exclusion criteria	X		X		X	
Study design 2-4 months	X		X		X	
Task of participant	Under review		Under review		Under review	
Questionnaires						
SF 36	X		X		X	
WHO	X				X	
EuroQol, EQ-5D-5L	X		X		X	
UTAUT	X				X	
Self Efficacy scale	X				X	
UEQ	X		X			
SUS	X		X			

4. Study design

The field trial runs for 4 months in each site.

The whole study is managed by skilled personnel and researchers that guarantee both the supervision of the tests by specialized staff and the detailed measurement of the first interaction between users and the first system prototype.

The study follows a mixed-methods design in which qualitative and quantitative data will be collected. In order to determine the effects of the SAVE system on the X weeks-

term, three measurements (T0, T1 and T2) will be conducted using standardized tests and open questions domain. Thus, three face-to-face sessions will be scheduled with the participants: one just before the beginning of the study; one at the mid-time, after X/2 weeks of use and one at the end after the total X weeks of use.

In line with the study design, three data collection tools have been drafted, one for every evaluation, i.e. before the testing the system starts (T0), at mid-term (T1) and after the conclusion of the planned timing of usage (T2).

The dimensions explored and monitored by the evaluation study and the measures used for the evaluation are summarized in the table below (Tab 2).

Table 2 Evaluation study dimensions and measures according to the monitoring waves

Main domains	Measure	Baseline (T0)	Mid-term (T1)	Post (T2)
Demographic	-Ad hoc questions	X		
Health condition and well-being	-SF-12 or 36 -WHO-5 items	X	X	X
Self-Efficacy	- General Self-efficacy scale - Quality of Life Questionnaire -ad hoc questions	X	X	X
Experience with technology and Age Well digital coach	-Ad hoc open questions on the usage of technology	X		
Usability and Acceptance	-Short Usability Scale (SUS) - User Experience Questionnaire (UEQ) - UES scale - Acceptance (QUEST)		X	X
Stigma and Privacy	Ad hoc questions	X	X	X

Each instrument will be verbally administered in a face-to-face session by a trained interviewer who filled the response on a paper version of the protocol.

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

6. Risk Management for users test and validation

Pilot project risks have the potential to affect project goals and pilot goals.

The project partners have defined risk as any event which is likely to adversely affect the ability of the project to achieve the defined objectives. Pre-defined procedures will be taken into account in order to minimize the possible occurrence of adverse events in the construction and deployment of the project.

	Risk	Level	Impact	Contingency Plan
End-users enrolment	Drop-outs and the failure to attend the study.	Medium	Medium	A reserve list of potential users that meet the inclusion criteria will be constructed in each site.
Acceptance	The new technological solution does not match to the user's expectations in terms of comfort.	Low	Medium	The previous knowledge and experience of the partners will be used during the pilot evaluations to avoid any problem in respect to the end users. Moreover, during the pilot the participant will be specifically asked about the systems and any feedback provided will be delivered to the technical team for implementation.
Functionality	The system is unable to collect data.	Low	High	During the functional trials, the functionality of the system will be validated long before the system is used with potential users, this to ensure that the system is stable in terms of data collection, data processing and data analysis and presentation.
Feasibility	The participants are unable to use the system alone and unable to operate the system.	Medium	Medium	The participants will require assistance in the beginning and detailed explanation to be able to operate the system alone. Study personnel will explain the operation to the subjects; Participants will also receive a written manual and a video of how to use the system. This video will be placed on their smartphone so that they can view it any time. In addition, during the pilot trials, a researcher will contact the participants by phone or visit them at home once a week to see if they are using the system and if there are no problems.

Usability	The participation of the users is low as participants do not regard the system to be useful for them.	Low	Medium	The validation sites have experience in conducting this kind of activities and they have direct links with end-users and stakeholders. Devoted dissemination campaigns and publicity will be carried out before the start of the validation phase, to ensure a wide participation. Moreover, experts in gerontology, psychology and geriatrics will be involved to motivate the participants and avoid drop-outs.
	The participants do not think they will require such a system and therefore do not intend to use it.	Low	Medium	The system was designed based on user needs as are expressed in the literature and based on WP2 "User requirements". Therefore we do not expect such a scenario. In the case it will occur, the teams will explain the usefulness of the system to the participants and show the many ways it can help in improving daily life.
Ethical Approval	Problems with the approval of the ethics commissions	Low	Medium	Continual communication with the ethical committee, trials preparation under consideration of guidelines for evaluations and eventually re-definition and re-planning of proposed trials based on the committee's feedback
Covid 19	Ongoing / returning Covid-19 pandemic situation and impact on the trial since trials might be difficult to set up	High	High	The consortium will adhere to the practices and measures put in place by ongoing AAL projects (http://www.aal-europe.eu/wp-content/uploads/2021/01/AAL-projects-and-Covid-19-final.pdf).

7. Running a pilot test with smart sensors - usability test in laboratory

The 1st Agile "sprint" completion

We do not focus on developing physical devices, we aimed to develop services by software running on the devices. The creation of an integration software platform enables the user to flexibly configure smart devices according to the needs of the elderly, both in numbers and in services.

1) Location and orientation

For this service it was used a smart-watch together with a smart-phone in order to obtain accurate location and to use a public service for orientation. We tested this service with a Samsung Galaxy Watch and Samsung Galaxy S20 phone for demonstration but the watch and the phone can be chosen from another manufacturer also. These devices demonstrated the possibility of using this service with success. Both, the smart-watch and the smart-phone, have GPS sensors and „share location" can be used for reporting or we can use existing apps like Google maps or a dedicated app for orientation instructions.

2) eHealth – the SAVE project aims to offer eHealth monitoring at home for people over 65 years old, suffering of age-related chronic illnesses, mild cognitive issues/disabilities or cognitive decline. The service implementation alternatives are an Online Health Service (OnHS) and/or Offline Health Service (OffHS), both involving e-Health sensors used on-site at home. As settled at the level of technology, for complying with one of the main requirements of the European AAL perspectives in terms of interoperability and open interfaces for achieving a European market, the eHealth system concept is oriented towards Open-Source Hardware (OSHW) and COTS eHealth Platforms including COTS bio-sensors.

The eHealth system is based on the low-cost eHealth Platform from Libelium, namely MySignals Hardware (HW) Development Platform - eHealth and Medical IoT Development Platform for Arduino. The eHealth system concept, comprises short- and long-range communication protocols as a Wi-Fi and Bluetooth4-enabled therefore scalable base station that offers two services:

- embedded C++ application: offers connection and readout of biometric sensors. It shares data with the cloud via a web-service.

- web application: allows management and configuration for the base station. This option was considered better than OS-dependent smart-phone app (iOS/Android). It will enable configuring the specific sensor, triggering of a certain measurement, displaying the result of the measurement and setting the connection parameters used for cloud interaction, from any device connected to the same network as the base station (PC/laptop/smart-phone).

3) Security – For this service there used for testing a lot of sensors and devices. For sensors we tried a Xiaomi MI kit, but instead that working on smartphone, it can't be integrated with clouds and artificial intelligence so it's better to find other kits.

– For remote access in the situation of non responsive person inside, we tested a Yale Linus system that can be accessed by cloud and artificial intelligence. It seems to fulfill our goals and works also with Google and Alexa assistants. In tests, it opened the gate remotely and also locked the door automatically in order to protect the house. Also in bedtime routine it was inserted a line for locking the door before going to sleep. It is very useful because even the door is already locked, informs that for the peace of mind.

4) Enhancing alert info – The preliminary test of the service was done using a smartwatch that can be used both with smart-phone and by itself. It will be personalized for an emergency app that will connect it with the cloud.

5) Adapting physical exercise and social activities for elderly people, driven by voluntary organizations.

– The smart-watch that we tested will provide alerts and notifications from time to time in order to maintain an active life for the whole day. It tracks physical exercises and can provide small indications for simple movements.

– The Choice Reaction Time (CRT) methodology is based on a visual CRT based on several visual stimuli and two response buttons.

6) Personal (re-) planning service -" TO DO List"

The smart-watch contains an embedded application written in C++, that connects to the Internet via Wi-Fi and can stream automatically data towards the cloud platform (PSRTC16), and receive notifications from it. The platform contains a http server, therefore is accessible from Android and iOS devices (PSRTC4: basically, from any device that has a web-browser application). In addition, the smart-watch contains standard applications, including one that allows answering to incoming calls (PSRTC13) via its wi-fi interface.

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