



ELF@Home

Elderly sELF-care based on sELF-check of health conditions and sELF-fitness at home

D6.2 Trials procedure definition

Lead Authors: Alberto Castaño & Juan Luis Carús (CTIC)

With contributions from: John Waterworth & Eva Waterworth (UMU), Sonia García (CTIC)

Reviewer: Stefanie Erdt (INNO)

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Abstract

This document reports the trials procedure definition. It describes the steps to follow before, during and after the trials that will start in November 2015. This document is the main output of task “T6.2: Specification of field trials and user selection”.

The procedure defined includes getting informed consent and organizing an initial meeting. The variables to collect during the trials are also reported in this document.

Executive Summary

This deliverable outlines the trials procedure definition that will be followed during the field trials of the ELF@Home project. The procedure is described detailing the methodology before the trials, during the trials and after the trials.

Before the trials:

- Users will be recruited taken into account their Barthel Index (20 users from Sweden and 15 users from Spain)
- Information brochure will be given to every user
- Informed consent should be signed by every user
- An initial meeting for users and their relatives will be organized
- The ELF@Home solution will be installed and shown at home
- A fitness test (SPPB) will be done with every user

During the trials:

- Technological feedback will be given
- A half-term meeting will be organized
- Variables about the use and interaction will be collected

After the trials:

- The equipment will be collected
- Users will be interviewed
- A final user meeting will be organized
- Variables collected will be analysed

Document Information

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Authors (Partner)	CTIC – Technology Centre			
Responsible Author	Name	Alberto Castaño	E-mail	alberto.castano@fundacionctic.org
	Partner	CTIC – Technology Centre	Phone	+34 984 29 12 12

Abstract (for dissemination)	<p>This document reports the trials procedure definition. It describes the steps to follow before, during and after the trials that will start in November 2015. This document is the main output of task “T6.2: Specification of field trials and user selection”.</p> <p>The procedure defined includes getting the ethical approval, getting the informed consent and organizing an initial meeting. The variables to collect during the trials are also reported in this document.</p>
Keywords	trials procedure, user involvement, methodology, ethical issues

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1 Introduction

This document describes the main results of the task “T6.2: Specification of field trials and user selection”. All the information related to the trials procedure is described. Section 2 pays attention at the procedure before the trials, Section 3 describes the trials methodology and Section 4 focuses on the variables that will be collected before, after and during the trials.

2 Before the trials

2.1 Planning and timing

According to the DoW, the field trials will start in February 2016 and they will last 2 months. During the 4th Consortium Meeting we have decided to start the trials earlier (about November 2015) to have more time to evaluate the project and to improve the impact.

Two field trials are planned:

- Swedish users: 20 users will evaluate at home the usability and technical feasibility of the ELF@Home solution. Every user will have the prototype for 2 weeks.
- Spanish users: 15 users will evaluate the ELF@Home solution for at least 1 month with medical supervision.

We will have 10 prototypes of the ELF@Home solution: 3 will be sent to Sweden and the other 7 will be used in Spain (3 by MANCOSI¹ and 4 by SGGPA).

2.2 Users' recruitment

The Barthel Scale [2] will be used for selecting which users will take part in the field trials. It is used to measure users' performance in activities of daily living (personal hygiene, dressing, eating...). In this way, if a user has a low index in this scale, he will not be able to use the ELF@Home System because it would be very complex for him, whereas a user with a high index in the Barthel Scale will be able to participate in the field trials

2.3 Ethical aspects

Before the trials start, ethical aspects need to be dealt with, including informed consent procedures. The informed consent form and the procedure about how it is presented and collected to the users will be taken into account at this stage. Annex A and Annex B include the Spanish and Swedish versions of the information brochure and the informed consent that will be used during the project.

In Sweden each user will only participate in the project over a short period (around 15 days) and the trials will be in terms of individual user tests looking at the usability of the system and the technical feasibility of the service. With this focus, we don't need Ethical Approval but, of course, we will get informed consent and take care of confidentiality and security of data.

In Spain, we have contacted with "Comité Ético de Investigación Clínica" in Asturias and with "Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)". They have indicated us that in our case, it is not necessary for a technical approval before the user trials because the ELF@Home solution is not a health product.

2.4 Initial meeting

Just before trials, an initial meeting will be organized. In this meeting, users will be informed in group and the informed consent will be got. Users and their relatives will be invited. We will present the project and what is going to happen during the trials, what data are going to be collected and why, what is expected from the user and what is going to be done with the results.

It is crucial to make a general overview of the tests explaining what we are doing and to give some information about the semi-structured interviews. We will describe how data is stored making clear that the users are anonymous and that they have the right to cancel their participation in any moment without giving any reason.

In this meeting, the information brochure of the project will be given and the informed consent will be signed (one copy for the user and one copy for the consortium).

¹ According to AAL rules in Spain: local, regional and central public administrations can participate as end users but without funding. Thus, MANCOSI has not been included as project partner but as a collaborator.

Finally, we will describe what is going to happen next trying to make an appointment to install the equipment in their homes and start the field trials.

3 Trials methodology

3.1 Install equipment

Before installing the equipment, it is vital to do another introduction meeting in the user's home to present again what is going to be done and conduct the pre-tests and the first interview.

A second visit will be done to install the equipment and demonstrate it. The user should try to handle the prototype themselves before leaving. After 2 days, we will phone and check that the prototype works and that the user remembers how to handle it.

3.2 Start of trials

Fitness tests of users using the Short Physical Performance Battery (SPPB) [3] will be used to evaluate the lower extremity functioning in older persons. The result of this test is highly related to frailty, mortality and cognitive impairment (see Appendix IV for details of the SPPB test). The SPPB test will be used for evaluating their performance in balance and in gait speed. Users will do this test at the start of the field trials and at the end, to determine whether their performance has improved.

3.3 During trials

Users will be monitored during trials evaluating if they are having problems with the ELF@Home solution and trying to solve them as soon as possible. The technological partners of the project will be in charge of solving any detected problem.

After half of the test period, a second meeting will be organized to conduct the half time tests and interviews in user home.

3.4 End of trials

When the trials are finished, we will conduct final tests and interviews and collect the equipment. The SPPB test will be repeated to evaluate the improvements using the ELF@Home solution.

A final group meeting with all users will be organized. The trials will be discussed based on an interview guide and users will be informed about what is happen next. Results will be analyzed and written.

4 Variables to collect

This section sums the variables that we are going to collect before, during and after the trials.

Before the trials:

- Barthel index
- SPPB test
- Guided interview about their technological experience

During the trials:

- Exercises score
- Use of the solution
- Navigation mode (gestures, voice)
- Problems reported

After the trials:

- Barthel index
- SPPB test
- Guided interview about their experiences with the prototype

5 Conclusions

This document defines the trials procedure that will be followed during the field trials of the ELF@Home project. The methodology before, during and after the trials is described in this deliverable.

Before the trials, users will be recruited and the information brochure and the consent form will be given. An initial meeting will be organized and the use of the solution will be explained. During the trials, technological feedback will be given if it is necessary and variables about the user interaction will be gathered. After the trials, the collected variables will be studied and a final user meeting will be organised.

References

- [1] <http://www.elfathome.eu>
- [2] Mahoney F. I & Barthel D. (1965) Functional evaluation: the Barthel Index. *Md State Med J* 14:56–61.
- [3] Guralnik J.M., Simonsick E.M., Ferrucci L, Glynn R.J., Berkman L.F., Blazer D.G. (1994). A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. *J Gerontol.* 1994; 49(2): M85-94.

Annex A Information brochure

A.1 Version for Swedish users

ELF@Home ((elderly sELF-care based on sELF-check of health conditions and sELF-fitness at home) är ett internationellt projekt, som finansieras av AAL Joint Programme. 9 partners i 3 länder (Spanien, Sverige och Tyskland) deltar i projektet. Projektet startade officiellt den 1 juni 2013 och kommer att pågå under 3 år.

ELF@Home's projektidé är att hjälpa äldre människor behålla sin fysiska kondition genom att utveckla ett tekniskt system och hjälpmedel för att hjälpa människor utöva och testa sin fysiska hälsa i hemmet. Systemet föreslår en personlig träningsplan baserad på personens provresultat, och som hjälper och motivera användare att utföra fysisk träning i hemmet. Det fristående systemet är avsett för personer över 65 år som för närvarande bor självständigt hemma.

Den föreslagna lösningen syftar även till att öka medvetenheten om vikten av egenvård och daglig verksamhet. Systemet kontrollera användarens aktivitet och livsstil samt föreslå ändringar om det behövs. Systemet bör bidra till att förhindra svaghet, och minska beroendet och funktionell nedgång hos dess användare. Detta hjälper användarna att hålla formen och leva självständigt hemma och ta itu med sina vanliga dagliga aktiviteter.

För att uppnå dessa mål kommer systemet att inkludera en bärbar fysisk aktivitetssensor, vissa biomedicinska sensorer, ett enkelt TV-gränssnitt för träningspassen och en datorbaserad kamerakomponent som ska användas för att analysera hur övningarna görs.

Systemet kommer att testas av två grupper av användare: användare i Spanien, som kommer att övervakas av professionella gerontologer, och äldre människor som lever i sina egna hem i Sverige utan tidigare erfarenheter med träningsprogram eller enheter för äldre. Den första gruppen kommer att göra det möjligt för validering av det föreslagna systemet i jämförelse med nuvarande metoder. Den andra gruppen kommer att validera spridningen av tekniken och användbarhet i en viktig potentiell marknad. Vi söker volontärer för att hjälpa oss att utveckla en användbar och framgångsrik produkt för denna grupp av användare.

Din lokala representant är:

Namn: -

Organisation: -

Adress: -

Telefon: -

Om du har dig i någon av följande sjukdomar, bör du kontakta din läkare innan du börjar detta träningsprogram: allvarlig sjukdom, hjärt- eller respiratorisk sjukdom, högt blodtryck, svår diabetes, någon smittsam sjukdom, feber eller elakartad tumör.

Om du har drabbats av något av följande problem under de senaste 6 månaderna, bör du inte starta det här programmet: hjärtinfarkt eller kärlkramp, stroke, sjukhusvistelse eller operation.

Om du under genomförandet av detta program har något av dessa symtom, ska du sluta omedelbart och kontakta din läkare: huvudvärk, yrsel, obalans, bröstsmärtor, hjärtklappning, eller andnöd, magsmärtor eller stark smärta i någon del av din kropp

A.2 Version for Spanish users

ELF@Home (elderly sELF-care based on sELF-check of health conditions and sELF-fitness at home) es un proyecto internacional financiado por el Programa Conjunto AAL en el que participan 6 socios de 3 países (España, Suecia y Alemania). El proyecto comenzó oficialmente el 1 de Junio de 2013 y tendrá una duración de 3 años.

La idea del proyecto ELF@Home es ayudar a la gente mayor a mantenerse en un buen estado físico mediante el desarrollo de un sistema técnico y de dispositivos que les ayuden a hacer ejercicio y a comprobar su salud física en su propio hogar. El sistema proporcionará un plan de ejercicio basado en los resultados de las pruebas para que los usuarios estén más motivados en la realización de ejercicio físico, especialmente en el hogar. El sistema auto-contenido está destinado para personas mayores de 65 años que se encuentren actualmente viviendo de forma independiente en su hogar.

La solución propuesta está también destinada a concienciar acerca de la importancia del cuidado personal y de la actividad diaria. Para ello, monitorizará el estilo de vida del usuario y propondrá cambios, si fuera necesario. El sistema debería ayudar al fortalecimiento de los usuarios finales mediante la prevención de la fragilidad y la reducción de la dependencia y del declive funcional, lo cual, a su vez, ayudará a los usuarios a estar en forma, vivir de forma independiente en el hogar y encargarse de las actividades normales del día a día.

Para llevar a cabo estos objetivos, el sistema incluirá un sensor vestible de actividad física, varios sensores biomédicos, una interfaz simple para televisión relativa a las sesiones de ejercicios y un componente basado en una cámara que se usará para analizar la forma en la que se están realizando los ejercicios.

Dos grupos de usuarios evaluarán el sistema: un grupo de usuarios en España que estarán supervisados por gerontólogos profesionales y un grupo de personas mayores en Suecia que viven en sus propios hogares y que no tienen experiencia previa con programas o dispositivos para mantenerse en forma. El primer grupo permitirá la validación del sistema propuesto en comparación con otro tipo de enfoques actuales. El segundo grupo validará el despliegue tecnológico y la usabilidad en un importante mercado potencial. Nuestro objetivo es el de encontrar voluntarios para que formen parte del primer grupo y nos ayuden a desarrollar un producto útil y eficaz para ellos.

Su representante local es:

Nombre: -

Organización: -

Dirección: -

Teléfono: -

Si usted presenta alguna de estas circunstancias, debe consultar con su médico antes de iniciar el programa: enfermedad grave, enfermedad cardíaca o respiratoria, tensión arterial elevada, diabetes mellitus descompensada, enfermedad infecciosa, fiebre o tumor maligno.

Si usted ha presentado en los últimos 6 meses alguno de estos problemas no debería iniciar el programa: infarto agudo de miocardio o angina de esfuerzo, ictus, hospitalización o intervención quirúrgica.

Si durante la realización del programa usted presenta alguno de estos síntomas debería suspenderlo de forma inmediata y consultar con su médico: cefalea o dolor de cabeza, mareos, sensación de inestabilidad, dolor torácico, palpitaciones, disnea o fatiga, molestias gástricas, dolor intenso en cualquier parte del cuerpo.

A.3 Version in English

ELF@Home (elderly sELF-care based on sELF-check of health conditions and sELF-fitness at home) is an international project, funded by the AAL Joint Programme. 9 partners in 3 countries (Spain, Sweden and Germany) are participating in the project. The project started officially on June 1, 2013 and will run for 3 years.

The idea of the ELF@Home project idea is to help elderly people maintain their physical fitness by developing a technical system and devices to assist people to exercise and to test their own physical health in their own home. The system will provide a personalized fitness plan based on the test scores, to help guide and motivate users to carry out physical exercise, especially at home. The self-contained system is intended for people aged over 65 years who are currently living independently at home.

The proposed solution is also intended to increase awareness of the importance of self-care and daily activity. It will monitor the user's activity life-style and propose changes if necessary. The system should help empower end-users by preventing frailty, and reducing dependency and functional decline. This will help users to stay fit and live independently at home and to deal with their regular activities of daily living.

To achieve these goals the system will include a wearable physical activity sensor, some biomedical sensors, a simple TV interface for fitness exercise sessions and a computer camera-based component that will be used to analyse how the exercises are being done.

The system will be tested by two groups of users: users in Spain who will be supervised by professional gerontologists, and elderly people living in their own homes in Sweden with no previous experiences with elderly fitness programmes or devices. The first group will allow the validation of the proposed system in comparison with current approaches. The second group will validate technology deployment and usability in an important potential market. We are seeking volunteers to help us develop a useful and successful product for this group of users.

Your local representative is:

Name: -

Organisation: -

Address: -

Telephone: -

If you find yourself in any of these situations, you must consult your doctor before starting this programme: serious illness, cardiac or respiratory illness, high blood pressure, decompensated diabetes mellitus, infectious illness, fever or malignant tumour.

If you have suffered from any of these problems in the last 6 months, you should not start this programme: heart attack or angina, ictus, hospitalization or operation.

If during the realization of this programme you have any of these symptoms, you should stop straightaway and consult your doctor: cephalaea or headache, dizziness, imbalance, chest pain, palpitations, dyspnea or breathlessness, gastric pain or strong pain in any part of your body

Annex B Informed consent

B.1 Version for Swedish users

Projektet ELF@Home vill att ni lämna vissa uppgifter om dig själv för projektet. Projektet ber att få behandla personuppgifter om dig för att få en bild av hur du använder, upplever och påverkas av användningen av ny teknik för att öka din kondition och förbättra din hälsa. Du bestämmer om du vill lämna information till oss för detta. Ditt namn och adress kommer inte att ingå i resultaten av de tester och intervjuer med dig. Som en del av den tekniska lösningen som utvecklats av ELF@Home, kommer även information om ditt hälsotillstånd och dina fysiska aktiviteter att samlas via sensorbaserade enheter. Dessa data kommer att lagras endast i oidentifierad form inom säkra databaser på CheckUp AB. Dina uppgifter kommer att kodas och hållas helt konfidentiell; det vill säga, det kommer inte vara möjligt att identifiera dig som individ utan kodnyckel som endast din lokala representant har tillgång till. Ingen identifierbar personlig information om dig kommer att vara tillgänglig för någon utanför ELF @ Home deltagare på institutionen för Informatik vid Umeå universitet.

Enligt 26 § personuppgiftslagen (PUL 1998: 204) har du rätt att en gång per år begära ett utdrag om vilka personuppgifter som lagras om dig och hur vi behandlar. Du har också rätt, enligt 28 § personuppgiftslagen (PUL 1998: 204), att begära rättelse av de personuppgifter som lagras om dig.

Jag har fått projektet ELF@Home förklarat för mig och jag har också haft möjlighet att ställa frågor om projektet. Jag har också fått veta att jag kan ställa frågor om projektet och min egen medverkan i projektet när som helst jag vill. Jag har läst informationsbrevet om projekt ELF@Home som jag fått och förstår.

Jag förstår att mitt deltagande i detta projekt är helt frivilligt och att jag kan avsluta mitt deltagande när som helst jag vill utan att behöva ge någon förklaring och utan att ådra sig några negativa konsekvenser.

Jag förstår också att all personlig information som samlas in under projektets gång kommer att behandlas konfidentiellt i all framtid. Jag ger mitt tillstånd till att projektet ELF @ Home's svenska partner, Umeå universitet Informatik, får använda de personuppgifter om mig som specificeras ovan.

Mot bakgrund av ovanstående, jag ger mitt samtycke till att delta i forskningsprojektet ELF@Home.

Namn:

Signatur:

Plats och datum:

B.2 Version for Spanish users

El proyecto ELF@Home necesita que proporcione determinada información sobre su persona para el proyecto. Nos gustaría poseer información personal sobre usted para comprender cómo usa, percibe, o se ve afectado por el uso de las nuevas tecnologías para favorecer su forma física y su salud. Para ello, usted decide si desea facilitarnos algún tipo de información. Su nombre y dirección no se incluirán en los resultados de las pruebas o entrevistas que se lleven a cabo con usted. Además, como parte de la solución técnica desarrollada por ELF@Home, ciertos datos relativos a su estado de salud y actividades físicas se recogerán a través de dispositivos basados en sensores. Estos datos se almacenarán sólo de forma anónima dentro de bases de datos seguras de CheckUp AB. Su información se codificará y se mantendrá completamente confidencial; es decir, no será posible identificarle como persona sin un código que sólo conocerá su representante local. Ningún tipo de información personal identificable sobre usted estará disponible para personas que no pertenezcan al grupo de participantes en el proyecto ELF@Home. Usted tiene el derecho de ser informado una vez al año sobre la información personal que se encuentra almacenada sobre usted, y cómo dicha información es tratada; para ello debe enviarnos una petición firmada. Usted también tiene derecho a solicitar la corrección de los datos personales que se encuentran almacenados sobre usted.

Me han explicado el proyecto ELF@Home y he tenido la oportunidad de hacer preguntas sobre él. También he sido informado de que puedo hacer preguntas sobre el proyecto y sobre mi propia participación en el mismo en cualquier momento que desee. He leído la información relativa al proyecto que el representante de ELF@Home me ha proporcionado y la entiendo.

Entiendo que mi participación en este proyecto es totalmente voluntaria y que puedo cesar mi participación en cualquier momento que desee sin tener que proporcionar ninguna explicación y sin incurrir en ningún tipo de consecuencia negativa.

También entiendo que toda la información personal recogida durante el proyecto se mantendrá confidencial para siempre. Estoy de acuerdo en que el socio sueco del proyecto (Departamento de Informática de la Universidad de Umeå) utilice la información personal sobre mí de acuerdo a lo mencionado anteriormente.

Teniendo en cuenta lo anterior, **doy mi consentimiento** para participar en el proyecto de investigación ELF@Home.

Nombre:

Firma:

Lugar y fecha:

Teniendo en cuenta lo anterior, **no doy mi consentimiento** para participar en el proyecto de investigación ELF@Home.

Nombre:

Firma:

Lugar y fecha:

B.3 Version in English

Project ELF@Home would like you to provide certain information about yourself for the project. We would like to process personal information about you to get a picture of how you use, perceive and are affected by the use of new technologies to increase fitness and health. You decide whether you want to provide any information to us for this. Your name and address will not be included with the results of any tests and interviews conducted with you. As part of the technical solution developed by ELF@Home, data about your health status and physical activities will also be collected via sensor-based devices. This data will be stored only in anonymised form within secure databases at CheckUp AB. Your information will be coded and kept completely confidential; that is, it will not be possible to identify you as an individual without the code key known only to your local representative. No identifiable personal information about you will be available to anyone beyond ELF@Home's participants at Informatics Department at Umeå University. According to 26 § personuppgiftslagen (1998:204) you have the right, after sending a signed request addressed to us, to be told once per year what personal information is stored about you and how we treat it. You also have the right, under 28 § personuppgiftslagen (1998:204), to request correction of the personal data that is stored about you.

I have had the ELF@Home project explained to me and I have also had the opportunity to ask questions about the project. I have also been informed that I can ask questions about the project and my own participation in the project at any time I want to. I have read the project information that the ELF@Home representative has given me and I understand it.

I understand that my participation in this project is entirely voluntary and that I may stop participating at any time I want to without having to give any explanation and without incurring any negative consequences.

I also understand that all personal information collected during the project will be kept confidential in perpetuity. I agree that the project ELF@Home's Swedish partner, Umeå University Informatics, use the personal information about me in accordance with the above.

In view of the above, I give my consent to participate in the research project ELF@Home.

Name:

Signature:

Place and Date: