



ELF@Home

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

D2.2 Methodological Process Design

**Lead Author: John Waterworth (UMU),
With contributions from: Stefanie Erdt (INNO), Paula
Álvarez (SGPPA), Åke Holmlund (UMU), and others
Reviewer: Paula Álvarez (SGGPA)**

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Abstract

This document is a main output of Task T2.4: Definition of the methodological process, including ethical issues, carried out between November 2013 and February 2014. The report describes the methodological process to be adopted to evaluate design concepts, components and the overall ELF@Home system through involvement of users and experts in Spain, Sweden, and Germany.

The main aim of the evaluations is to ensure that ELF@Home is designed and implemented in a way that is suitable and effective for the target population of users. This includes the overall approach, the component parts, and the overall system. The evaluations are designed to ensure that our users find the system and component devices acceptable, easy and pleasant to use. Furthermore, the effectiveness of using the system over a significant period will be evaluated during the planned full system field trials.

Executive Summary

This deliverable outlines the methodological process to be applied to the evaluation of the ELF@Home system and components, from a user perspective, and a description of the way ethical aspects of user involvement in the project will be dealt with. Ethical aspects covered include steps to be taken to obtain ethical approval, informed consent of users, and the way in which privacy and confidentiality of all user-related data will be protected.

The main aim of the evaluations is to ensure that ELF@Home is designed and implemented in a way that is suitable and effective for the target population of users. This includes the overall approach, the component parts, and the overall system. The evaluations are designed to ensure that our users find the system and component devices acceptable, easy and pleasant to use. Furthermore, the effectiveness of using the system over a significant period will be evaluated during the planned full system field trials. The following table (Table 1) summarises the planned evaluations, including methods to be used, location and schedule for the tests.

Table 1 – Summary of planned evaluations

Evaluation Focus	Location	Methods	Schedule
Conceptual evaluation	Sweden	Focus groups and interviews with semi-structured interviews	From month 3
Component and early prototype tests:	Spain, Sweden, Germany	Component and early prototype tests:	Month 10 to 24
1. Use and acceptability of sensors		1. Focus groups and interviews with semi-structured interviews	
2. TV and Fitness Box a) GUI and Interaction/Navigation b) Activity detection and display		2. a) Initial tests of gestural interaction using Kinect and Heuristic evaluation of interface b) Focus groups and interviews with semi-structured interviews	
3. Fitness assistant		3. Questionnaire	
System prototype tests	Spain, Sweden	Focus groups and interviews with semi-structured interviews User performance data	Before month 30
Field trials	Spain, Sweden	Semi-structured interviews User performance and health data from system Fitness tests of users using Short Physical Performance Battery (SPPB)	Month 30-33

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Authors (Partner)				
Responsible Author	Name	John Waterworth	E-mail	jwworth@informatik.umu.se
	Partner	Umeå University	Phone	+46 738 111 440

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Table of Contents

Executive Summary.....	3
Document Information	4
Table of Contents	5
1 Introduction.....	6
2 Specification of user groups for evaluations	7
2.1 Spain.....	7
2.2 Sweden	7
2.3 Germany	7
3 Definition of the evaluation methodology	8
3.1 Introduction	8
3.2 Conceptual evaluation	8
3.3 Component and prototype tests	8
3.3.1 Methods and Measures	8
3.4 System prototype tests.....	9
3.5 Field trials.....	9
4 Method for handling ethical issues.....	10
4.1 Introduction	10
4.2 Ethical approval process	10
4.3 Consent form definition.....	11
4.4 Privacy and confidentiality of personal data	11
5 Conclusions	12
References	13
Appendix I The Barthel Index.....	14
Appendix II Short Physical Performance Battery	16
Appendix III Heuristic Checklist	17
Appendix IV Usability Evaluation Questionnaire.....	18
Appendix V ELF@Home Informed Consent Form.....	19

1 Introduction

This document is a main output of Task T2.4: Definition of the methodological process, including ethical issues, carried out between November 2013 and February 2014. The report describes the methodological process to be adopted to evaluate design concepts, components and the overall ELF@Home system through involvement of users and experts in Spain, Sweden, and Germany.

The main aim of the evaluations is to ensure that ELF@Home is designed and implemented in a way that is suitable and effective for the target population of users. This includes the overall approach, the component parts, and the overall system. The evaluations are designed to ensure that our users find the system and component devices acceptable, easy and pleasant to use. Furthermore, the effectiveness of using the system over a significant period will be evaluated during the planned full system field trials.

The table below (Table 1), briefly summarises planned evaluation objectives, participation amongst the three countries involved, methods to be used, and schedule. The remaining sections of this document cover these in more detail and are as follows:

Section 2: Specification of user groups

Section 3: Definition of the evaluation methodology

Section 4: Ethical issues study, including consent-form definition.

Table 1 – Summary of planned evaluations

Evaluation Focus	Location	Methods	Schedule
Conceptual evaluation	Sweden	Focus groups and interviews with semi-structured interviews	From month 3
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2 Specification of user groups for evaluations

2.1 Spain

There are two groups of users in Spain: the main user group will be managed by SGGPA and a smaller user group will be managed by the MANCOSI entity.

SGGPA user group consists of 10-15 users (2 women to every man) of average age 80 years. They are independent for all activities of daily living. Users have now a very low activity level profile and they are not used to computers or smart phones. Some of them have easy-to-use mobile phones but only to make and answer calls. All the users are used to TV control and they have LED TVs of 17". They do not have their own Internet connection but in some places a Wi-Fi could be available. They have around 6 chronic diseases and 4 treatments but they do not have cognitive impairments.

In addition to the SGGPA user group, MANCOSI (a public administration in Asturias that takes part in this project as a collaborator) provides another user group for a minor pilot. Only 2 users will take part in this minor pilot, which will be focused on testing the usability and technological deployment of the system. MANCOSI has access to 24 users (23 women and 1 man) with an average age of 85 years: 17 of them are widowed, 2 of them are married and the other 5 are single. Almost all of them live in rural areas and in zones that have contributed to geographical and social isolation. They are independent in the BADLs (Basic Activities of Daily Living) but they have problems with some of the IADLs (Instrumental Activities of Daily Living), such as going shopping, managing bank and administrative documents, using transports and preparing meals. Their health status is good for their age but they have some chronic diseases such as hypertension, rheumatism, bone diseases or diabetes. Most of them live on their own and few of them live with their spouse. Regarding their daily activity level, they are almost completely inactive or they only have a normal domestic activity. None of them suffers from a medium or severe level of cognitive impairment and whereas only 1 or 2 of them suffer from a mild cognitive impairment, they will probably be able to interact with the ELF@Home platform. None of them are used to ICT, as they did not have the opportunity to use computers or new generation TVs. Most of them have changed their TV in recent years, so now they have flat TVs with different kind of connections. Some of them have Internet access in their homes.

In addition, about 5 interaction/elderly experts will take part in some evaluations.

2.2 Sweden

The Swedish user group consists of 12 elderly people, age range 71-85, eight women and four men, living in their own homes. There are two couples but the rest of the group members are living alone. Most of the Swedish users have some experience with using computers, but the degree of computer literacy varies a lot within the group.

In addition, about 5 interaction/elderly experts will take part in some evaluations.

2.3 Germany

There is no defined user group for the ELF@Home project in Munich. The Innovationsmanufaktur will acquire according to the demand and the requirements of each test suitable test persons. Therefore the network of Innovationsmanufaktur can be used, especially contacts to a Munich elderly association.

In addition, about 5 interaction/elderly experts will take part in some evaluations.

3 Definition of the evaluation methodology

3.1 Introduction

The evaluation methodology to be applied covers evaluation of the general approach, design concepts generated for the systems, tests of components of the system, and informal and formal tests of prototypes and the final overall system.

3.2 Conceptual evaluation

Participation of user groups in evaluations: Sweden

Schedule: From month 3

Methods and measures:

Focus groups and individual discussions using semi-structured interviews (see D2.1).

3.3 Component and prototype tests

Participation of user groups in evaluations: Spain, Sweden and Germany

Schedule: Month 10 to month 24

3.3.1 Methods and Measures

1. Use and acceptability of sensors (health status and activity)

Focus groups and individual discussions using semi-structured interviews

Measures: verbal user responses categorised by questions and topics

2. TV and Fitness Box

2a. GUI and Interaction/Navigation

Simple navigation with input by gesture and possibly speech

Initial tests of Kinect interface for games

Measures: user success rates in navigating by gesture

GUI TV interface

Expert heuristic evaluation using the heuristics checklist (see Appendix 1)

Participants: 3-5 experts per country

2b. Activity detection and display

Information displayed – what is useful?

Best method of feedback?

Focus groups and individual discussions using semi-structured interviews

Measures: verbal user responses categorised by questions and topics

3. Fitness assistant

Acceptability of individual exercises

System-collected data from user interactions between exercises

Measures: Ratings obtained from system after each exercise (see 2a above)

Opinions on exercises

View of self

Opinions on interaction with system, and of acceptability of exercise programme as a whole
Specifically designed questionnaire (see Appendix II)
Measures: questionnaire responses

3.4 System prototype tests

Participation of user groups in evaluations: Spain and Sweden

Schedule: before month 30.

Methods and measures:

Focus groups and interviews with semi-structured interviews

User performance data

3.5 Field trials

Participation of user groups in evaluations: Spain and Sweden

Schedule: Month 30-33

Methods and measures:

Semi-structured interviews.

User performance and health data from system.

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 (see Appendix III for details on Barthel Scale).

Fitness tests of users using the Short Physical Performance Battery (SPPB) [4] for evaluating 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 before the beginning of the field trials and at the end, to determine whether their performance has improved.

Note that the main field trials take place in last year of the project and that Task 6.2 covers the specification of trials and user selection, including definition of the trial set-up, the variables to be collected, the methodology used to collect user impressions and the selection of a representative set of users. These will be reported in more detail in D6.2: Trial definition report (due M29).

4 Method for handling ethical issues

4.1 Introduction

ELF@Home raises two main ethical issues: (1) the informed consent of elderly people to participate in the project, (2) the privacy and confidentiality of any personal data collected and/or processed. These ethical issues apply to both the process of implementing the project and to the solutions targeted as results of it.

According to Swedish and Spanish Law we need Ethical approval for the user aspects of the project because of the following facts according to the definition of the information to be stored (page 47 in D2.1):

- User name, email address, date of birth => it is possible to identify a person (although does not in it self require ethical approval)
- Information about chronic diseases, and discrete health status. => need of compulsory ethical approval (in Sweden according to Lag 2003:460 om etikprövning av forskning som avser människor 3§ 1 enligt 13 § PUL (personuppgiftslagen) and in Spain according to Ley Orgánica 15/1999, de 13 de diciembre de Protección de Datos de Carácter Personal (LOPD), Artículo 7)

Whenever necessary, local ethical approval for any user involvement will be obtained, as described in the next section.

The following sections cover the definition of informed consent procedures and steps taken to ensure privacy and confidentiality of personal data.

4.2 Ethical approval process

The following information is needed to make an ethical application to carry out any evaluations involving users;

- Who will have access to data: name, role, institution etc,
- Aim and research questions
- Method
 - When in time are the tests conducted? And for how long?
 - How is it going to be tested?
 - Which methods for data collection are used? Tests? Interviews? Etc.
 - How and where is the data going to be collected?
 - How is the data going to be stored?
 - How is data going to be analysed?
 - How is the result going to be used?
- How is the data stored and saved – data protection
- Description of the user group
- Method to inform about the project/test and how the consent form will be collected
- Possible ethical issues (both positive and negative) and any problems
- How/where is the results going to be presented?
- Possible benefits for the users, society
- How the integrity of the users is taken care of

4.3 Consent form definition

To ensure the voluntary participation and consent of the volunteer participants in the project, an informed-consent form will be provided and explained to participants in any of the work packages (elderly and their caregivers). This informed consent will cover the following issues about the project:

- Description of the project specifying its aims.
- Description of any risks incurred by participating in the project, and how these risks will be minimised.
- Self-determination of the users giving information to turn off the service and to withdraw it at any time.
- Participants will be informed that they will be free to end their participation at any time without giving a reason or incurring costs or other penalties.
- Compensation provided to the primary end-users, if any, will be specified in advance. In this case participants will be informed that if they quit before the end of the study, the compensation will be proportional to their actual involvement in the study.
- Contact person in the project for any question about the system or to solve any problem arising.
- Information about the steps taken to maintain privacy and control of the data collected during the project duration in order to guarantee confidentiality and dignity for the users.

The informed-consent form was designed to be accessible with respect to language and content to guarantee the correct understanding of the users. The aim was write it in an easy way explaining correctly all the specified issues and being transparent for the end-users. Versions in all native languages of the users were created, based on following English-language version specified in Appendix V.

4.4 Privacy and confidentiality of personal data

The system to be developed in this project will collect, process and transmit personal data related to users' health status, physical activity level and fitness exercising patterns. Art. 8 of the European Charter of Fundamental Rights as well as the relevant European directives and national laws will be taken into account to protect data privacy. Data will be used to meet the aims of the project and not for any other reason.

Names and address will not be included with the results of any tests and interviews conducted. As part of the technical solution developed by ELF@Home, data about health status and physical activities will be collected via sensor-based devices. This data will be stored only in anonymised form within secure databases at Explizit AB.

All personal information will be coded and kept completely confidential; that is, it will not be possible to identify individuals without the code key known only to the local project representative. No identifiable personal information about you will be available to anyone beyond local ELF@Home's participants. Users rights concerning their personal data are explained in the native language version of the informed consent information (see above).

5 Conclusions

We have described the methodological process to be applied to the evaluation of the ELF@Home system and components, from a user perspective, and a description of the way ethical aspects of user involvement in the project will be dealt with. Ethical aspects covered include steps to be taken to obtain ethical approval, informed consent of users, and the way in which privacy and confidentiality of all user-related data will be protected.

Applying the evaluation methods outlined in this document will ensure that ELF@Home is designed and implemented in a way that is suitable and effective for the target population of users. This includes the overall approach, the component parts, and the overall system. The methodological process has been designed to ensure that our users find the system and component devices acceptable, easy and pleasant to use. The effectiveness of using the system over a significant period will be evaluated during the planned full system field trials.

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] Nielsen, J. (1994a). Enhancing the explanatory power of usability heuristics. *Proc. ACM CHI'94 Conf.* (Boston, MA, April 24-28), 152-158.
- [4] 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.

Appendix I The Barthel Index

The Barthel Index is a questionnaire hetero-administered with 10 Likert-type items. The items include feeding, moving from wheelchair to bed and return, grooming, transferring to and from a toilet, bathing, walking on level surface, going up and down stairs, dressing, continence of bowels and bladder.

The range of possible values of Barthel Index is between 0 and 100, with intervals of 5 points. Lower score, more dependence, and higher score, more independence. Furthermore, the Barthel Index scores can be used by assigning 1-point intervals between categories. Possible scores for activities are 0, 1, 2, or 3 points - resulting in an overall range between 0 and 20. Suggested cut points by some authors to facilitate interpretation are as follows:

- 0-20 total dependence
- 21-60 severe dependence
- 61-90 moderate dependence
- 91-99 low dependence
- 100 independence

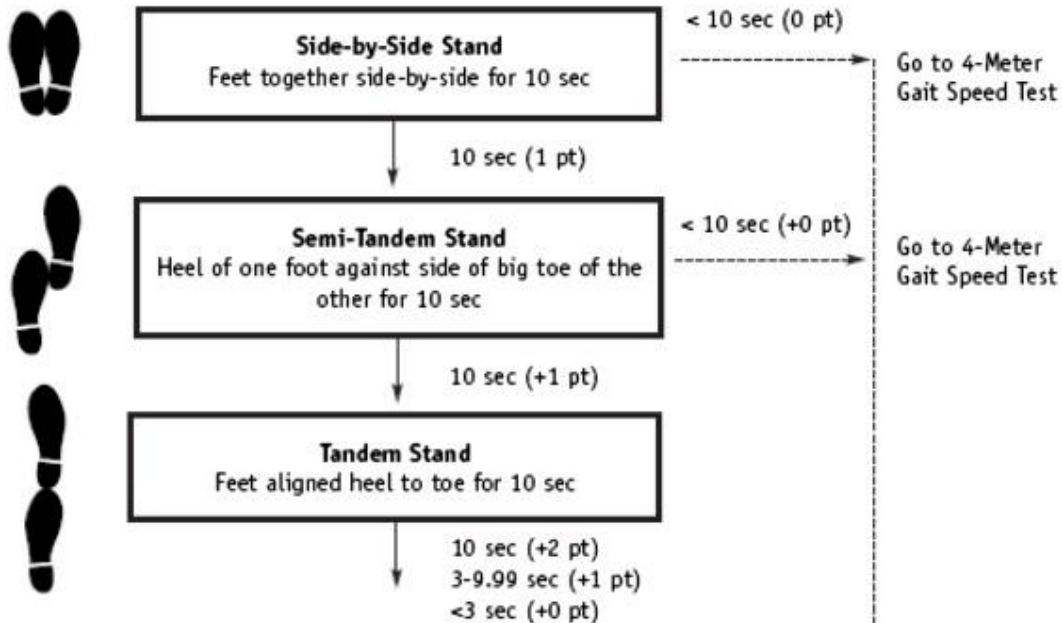
Patient Name: _____ Rater: _____ Date: <u> </u> / <u> </u> / <u> </u> :	
Activity	Score
Feeding 0 = unable 5 = needs help cutting, spreading butter, etc., or requires modified diet 10 = independent	0 5 10
Bathing 0 = dependent 5 = independent (or in shower)	0 5
Grooming 0 = needs to help with personal care 5 = independent face/hair/teeth/shaving (implements provided)	0 5
Dressing 0 = dependent 5 = needs help but can do about half unaided 10 = independent (including buttons, zips, laces, etc.)	0 5 10
Bowels 0 = incontinent (or needs to be given enemas) 5 = occasional accident 10 = continent	0 5 10
Bladder 0 = incontinent, or catheterized and unable to manage alone 5 = occasional accident 10 = continent	0 5 10
Toilet Use 0 = dependent 5 = needs some help, but can do something alone 10 = independent (on and off, dressing, wiping)	0 5 10
Transfers (bed to chair and back) 0 = unable, no sitting balance 5 = major help (one or two people, physical), can sit 10 = minor help (verbal or physical) 15 = independent	0 5 10 15
Mobility (on level surfaces) 0 = immobile or < 50 yards 5 = wheelchair independent, including corners, > 50 yards 10 = walks with help of one person (verbal or physical) > 50 yards 15 = independent (but may use any aid; for example, stick) > 50 yards	0 5 10 15
Stairs 0 = unable 5 = needs help (verbal, physical, carrying aid) 10 = independent	0 5 10
TOTAL (0 - 100)	_____

Appendix II Short Physical Performance Battery

The SPPB is a test that evaluates various aspects of the role of the individual (balance, gait, strength and endurance) by titration of travel (in different positions) and passing a sitting or standing position. The scores range from 0 (worst performance) to 12 (best performance). The SPPB has been shown to have predictive validity showing a gradient of risk for mortality, nursing home admission, and disability.

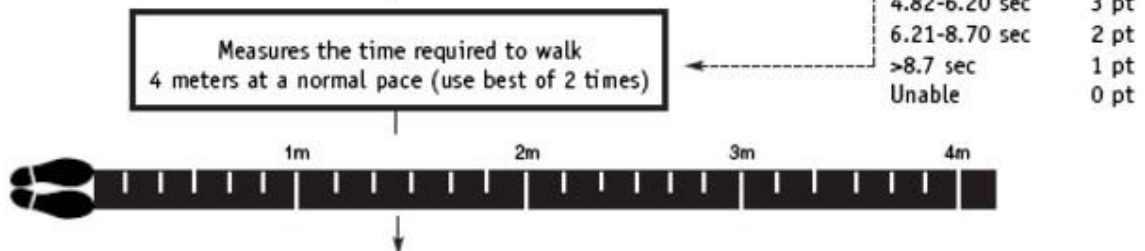
1.

Balance Tests



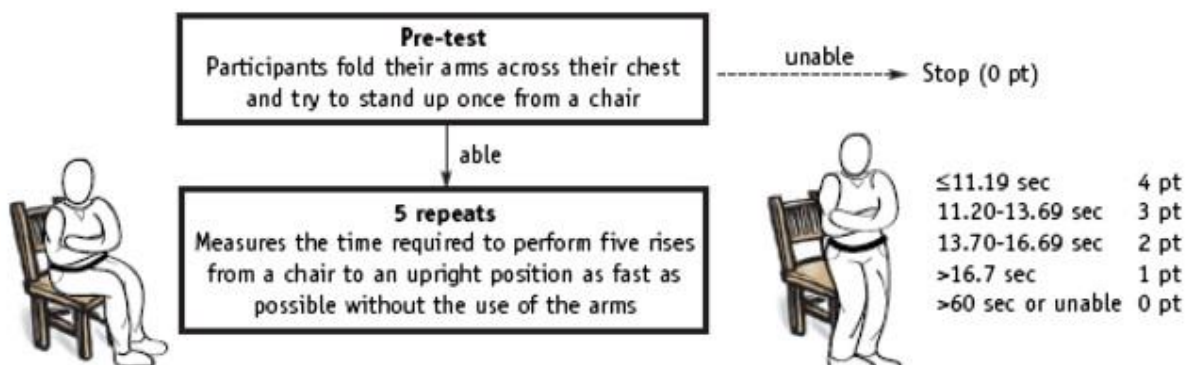
2.

Gait Speed Test



3.

Chair Stand Test



Appendix III Heuristic Checklist

Heuristic evaluation will be used to identify usability problems in the user interface design. A heuristic evaluation specifically involves evaluators (“experts”) examining the interface and judging its compliance with recognized usability principles (the "heuristics"). In this test the heuristic evaluation will be realized on the basis of the ten heuristics by Nielsen [3], which are listed below. These heuristics will be adapted to the ELF@Home system to achieve the best possible results for the project.

Heuristics Checklist

- Visibility of system status: Keeping the users informed about what is going on, through appropriate feedback within reasonable time.
- Match between system and the real world: Speaking the users' language, with words, phrases and concepts familiar to the user, rather than system-oriented terms.
- User control and freedom: Users often choose system functions by mistake and will need a clearly marked "emergency exit" to leave the unwanted state without having to go through an extended dialogue.
- Consistency and standards: Users should not have to wonder whether different words, situations, or actions mean the same thing. Follow platform conventions.
- Error prevention: Even better than good error messages is a careful design which prevents a problem from occurring in the first place. Either eliminate error-prone conditions or check for them and present users with a confirmation option before they commit to the action.
- Recognition rather than recall: Minimize the user's memory load by making objects, actions, and options visible. The user should not have to remember information from one part of the dialogue to another. Instructions for use of the system should be visible or easily retrievable whenever appropriate.
- Flexibility and efficiency of use: Accelerators -- unseen by the novice user -- may often speed up the interaction for the expert user such that the system can cater to both inexperienced and experienced users. Allow users to tailor frequent actions.
- Aesthetic and minimalist design: Dialogues should not contain information which is irrelevant or rarely needed. Every extra unit of information in a dialogue competes with the relevant units of information and diminishes their relative visibility.
- Help users recognize, diagnose, and recover from errors: Error messages should be expressed in plain language (no codes), precisely indicate the problem, and constructively suggest a solution.
- Help and documentation: Even though it is better if the system can be used without documentation, it may be necessary to provide help and documentation. Any such information should be easy to search, focused on the user's task, list concrete steps to be carried out, and not be too large.

Appendix IV Usability Evaluation Questionnaire

We will use a Likert scale questionnaire with users, adapted from the System Usability Scale shown below. SUS is known to be robust and reliable, and is freely available for use in usability assessment as long as any published report acknowledges the source of the measure.

System Usability Scale

© Digital Equipment Corporation, 1986.

	Strongly disagree					Strongly agree
1. I think that I would like to use this system frequently	1	2	3	4	5	
2. I found the system unnecessarily complex	1	2	3	4	5	
3. I thought the system was easy to use	1	2	3	4	5	
4. I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5	
5. I found the various functions in this system were well integrated	1	2	3	4	5	
6. I thought there was too much inconsistency in this system	1	2	3	4	5	
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5	
8. I found the system very cumbersome to use	1	2	3	4	5	
9. I felt very confident using the system	1	2	3	4	5	
10. I needed to learn a lot of things before I could get going with this system	1	2	3	4	5	

Appendix V ELF@Home Informed Consent Form

Information about the ELF@Home project for potential participants

ELF@Home: Elderly sELF-care based in sELF-check of health conditions and sELF-fitness at home

ELF@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 in this second category to help us develop a useful and successful product for this group of users.

Your local representative is:

Name:

Organisation:

Address:

Telephone: ,nnnn , mobile: nnnn

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
- Malignant tumor

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
- Strong pain in any part of your body

INFORMED CONSENT

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 Explizit 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:

The following to be added for Spanish users only:

In view of the above, I do not give my consent to participate in the research project ELF@Home.

Name:

Signature:

Place and Date: