D4.3 Feasibility study report

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AMBIENT ASSISTED LIVING

JOINT PROGRAMME

AAL-2013-6-134

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1 Preface

In Deliverable 4.3, the feasibility study protocol is described together with the findings of the feasibility study and the overall conclusion and recommendations. After an introduction into the background of the feasibility study in chapter 3, the protocol of the feasibility study is explained in chapter 4 and the results are described in chapter 5. The overall recommendations and conclusions are described in chapter 6 and 7.

The feasibility study was performed during M13-18 with 30 potential end users under supervision of researchers across the Netherlands, Sweden and Switzerland. These tests were performed in a (semi)-controlled environment at National Foundation for the Elderly (NFE), Eskilstuna (ESK) and terzStiftung (TERZ). The objective of the feasibility study was to investigate user acceptance of the second prototype of the ironHand (iH) system and the impact on functional performance.

Responsibility of the feasibility study report was switched from Bioservo (BIO) to Roessingh Research and Development (RRD), as agreed between partners during project meeting PM2.2, because RRD coordinated T4.3 in which the feasibility study was conducted. Furthermore, the originally planned order of testing locations (parallel testing at different sites wasn't possible due to logistics regarding the available iH systems) was adapted. This was needed to accommodate longer duration of ethical procedures than expected for ESK and TERZ. Eskilstuna received their ethical approval on July 6, 2015 and terzStiftung received their ethical approval July 10, 2015 . In the Netherlands, approval from the local ethical committee had been received June 2, 2015. Therefore, the feasibility study started at NFE instead of ESK. In the beginning of the feasibility tests at NFE, there were some problems with the hardware, software and sensors of the wearable soft-robotic gloves that needed repairing by BIO, resulting in shorter time frames for completing the feasibility tests across all three countries. The project partners of the different countries were very flexible which helped to complete the feasibility study in time. The last test of the feasibility study was completed on 5 October 2015 at TERZ, but reporting the collected data (including extensive qualitative information from interviews etc.) required additional time for TERZ and ESK, leading to a slight delay in completing data collection and analysis of all participants by RRD for D4.3.

2 Introduction

Elderly people frequently experience a decline in hand function due to deterioration of handgrip strength during ageing [1-3]. The decline in hand function can lead to a negative effect on the ability to grip and manipulate an object [4]. This results in difficulties in independently performing activities of daily living (ADL) such as holding (heavy) objects, writing and manipulating small objects [5-7]. The decline in hand function, accompanied by the deteriorated function in ADL, often has an impact on elderly's quality of life [8].

To overcome limitations in ADL, elderly often need personal assistance and/or assistive devices to carry out ADL. However, personal assistance will not result in more independence in performing ADL while assistive devices have the potential to provide the assistance that is necessary to perform ADL independently [9]. There are new technological innovations that can support the functional performance of the arms and hands directly by a wearable soft-robotic device assisting a person's own function, which may enhance functional independence. If people can maintain or increase use of their hands/arms in daily life, this might ultimately even benefit their (unsupported) hand function in ADL. Even more, with such wearable devices for daily use of the hands and arms, a large variety of functional activities is enabled.

To allow prolonged use of such an assistive device in everyday activities, an easy to use system based on the concept of a wearable robotic glove (iH system) is developed within the current project that can support elderly people with hand motor problems during ADL. The iH system provides support for grip and hand opening in a natural and intuitive way, but only if the user initiates the movement actively. Furthermore, it will give only the amount of support that is needed. This will make sure that elderly people maintain an active contribution to movements at all time. By adding a personalized computer gaming environment, specific training exercises can be provided as well. As a first step, this study explores whether use of such an assisting glove during functional tasks can enhance performance. Since this device should be usable independently during daily life, not only the impact on functional performance but also user acceptance is a main aspect of investigation in this first stage of user testing. If user acceptance is satisfactory, a subsequent stage of user testing will involve the direct and therapeutic effects of the iH system in ADL during home use at a later time, after potential design adaptations based on the current feasibility findings.

3 Methods/Procedure

3.1 Design

The feasibility study will focus on user acceptance of the iH system while a first indication of the direct influence of the iH system on functional task performance will be explored as well. A cross-sectional study design was used for this feasibility study. The participating individuals were invited for two sessions across one week and the measurements were performed according to an experimental protocol with the second prototype of the iH system (see Figure 1). These tests were performed in a (semi)-controlled environment at NFE, ESK and TERZ supervised by the researchers of NFE, ESK and TERZ and coordinated/supported by RRD.

All individuals received oral and written information about the feasibility study before they decided if they wanted to participate. An informed consent form was signed by both the participating individuals and the researchers before the experiment started.

The study was approved by the local Medical Ethical Committees (MEC) in the Netherlands, Switzerland and Sweden.

FIGURE 1. IRONHAND SYSTEM

3.2 Experimental protocol

First, the participants performed a usability test, to obtain insight in perceived ease of use of the iH system without prior instructions. During the usability test, two modules of the iH system were tested: the iH Assistive System (iH AS), consisting of the glove and control unit as applied to support functional performance directly; and the iH Therapeutic System (iH TS) with additional computer-game-like exercises to provide a specific training context. In evaluation session 1, the iH AS was tested by presenting a few tasks to be performed with the iH AS, but without receiving any specific instructions in advance, while being observed by a researcher (see Appendix 1 for more information). In evaluation session 2, the participant tested the iH TS by following the protocol of Appendix 2 to obtain insight in perceived ease of use of the system. The participant did not receive any specific instructions in advance for the therapeutic system!

After the usability test, the sensitivity level and maximum force of the iH AS and the amount of leaf springs in the iH AS (opening functionality) were tuned for each person. Furthermore, any additional instructions needed for proper use of the iH system were provided by the researchers, if necessary. Thereafter, the participant was asked to independently perform six functional tasks (consisting of real life situations) with and without the iH AS to compare the performance with and without the iH AS in a (semi)-controlled environment. Each activity was performed three times with and without the iH AS to observe the differences between both conditions in functional task performance. From those three repetitions, the first two were dedicated to getting used to the system, and only the last performance was used to compare the performance time between conditions with and without iH AS. The researchers observed both the general performance of these functional tasks (e.g. which hand is used for handling the heavier objects or performing the most difficult movements, speed of movement, fluidity, precision, presence of compensatory movements) as well as the performance time for each activity. For each participant, the order of functional tasks with and without the glove was randomized. In addition, all measurements were recorded by video, which made it possible to analyse the results in detail afterwards when needed. The following functional tasks were performed by the participants:

1) Scenario 1 – Drinking task (see Figure 2)
    1. Grab a bottle of water (0.5L)
    2. Take a glass
    3. Open the bottle of water
    4. Pour water in the glass
    5. Close the bottle of water
    6. Bring the glass to the mouth
    7. Put the glass back on the table
    8. Return the glass and bottle of water to the starting position on the table

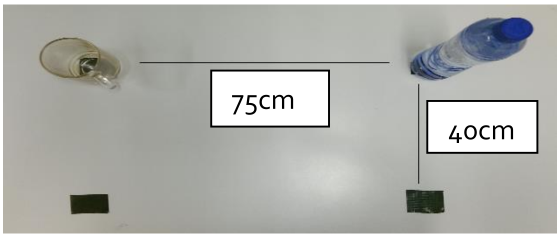

FIGURE 2. SETUP SCENARIO 1

2) Scenario 2 – Eating task (see Figure 3)
    1. Take the cucumber
    2. Take the knife and cutting board
    3. Prepare three slices of cucumber
    4. Return the knife and cucumber to the starting position

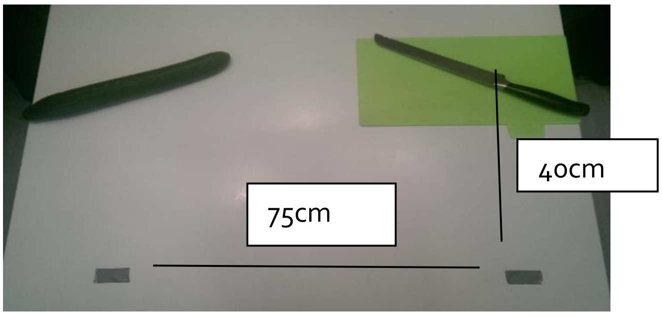

FIGURE 3. SETUP SCENARIO 2

3) Scenario 3 – Household task (see Figure 4)
   1. Take the cloth
   2. Wring the cloth 3 times
   3. Clean the table (start in the left corner and go round)
   4. Return the cloth to the middle

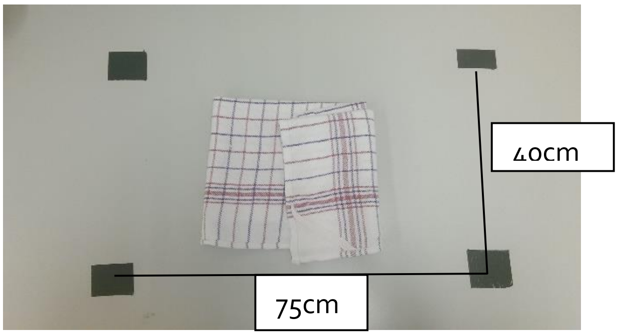

FIGURE 4. SETUP SCENARIO 3

4) Scenario 4 – Reading (and writing) task (see Figure 5)
   1. Take a book from the table
   2. Open the book
   3. Hold the book open for 30 seconds
   4. Place the book on the table (Only if the most affected hand is the writing hand!)
   5. Write down the last word of the open page (Only if the most affected hand is the writing hand!)
   6. Close the book
   7. Return the book to the starting position

FIGURE 5. SETUP SCENARIO 4

5) Scenario 5 – Dressing/undressing task
    1. Take down jacket from the coat hanger
    2. Put jacket on
    3. Close zipper/buttons (functional help to either keep the force in the lower part of the jacket, or to grab the zipper)
    4. Take the jacket off and put back on hanger

6) Scenario 6 - Open the door task
    1. Take the key
    2. Put the key in the lock
    3. Open the door
    4. Close the door
    5. Lock the door
    6. Return the key to starting position (chair next to the door)

Furthermore, the participant was asked about his or her experiences and perceived ability of using the iH system. For this purpose the System Usability Scale (SUS) was assessed for only the iH AS after session 1 and for both the iH AS and iH TS after session 2. Additionally, the Intrinsic Motivation Inventory (IMI) was assessed only after session 2 to investigate participants' motivation during use of the iH system.

3.3 Evaluation

3.3.1 System Usability Scale

The SUS is a simple, valid and reliable assessment for systems usability. It uses a 5- point Likert scale for 10 questions about system usability. The answers can range from 'strongly disagree' till 'strongly agree'. The total score of the questions was multiplied by 2.5, so that the maximum score is 100 [10]. A total score of <50 indicates that the system will almost certainly have usability difficulties in the field; 50-70 is a promising score, but guarantees no high acceptability in the field; >70 indicates high chances for acceptance in the field [11, 12].

3.3.2 Intrinsic Motivation Inventory

The IMI questionnaire is a simple, easy to use, valid and reliable test to assess individuals' intrinsic motivation during any specific exercise activity [13-15]. The items of the IMI questionnaire will be scored by the participant on a 7-point Likert scale in the range from 'not at all true' till 'very true'. A higher score on the IMI means a higher motivation during the use of the iH system [15].

3.4 Data analysis

The data of the outcome measurers were analysed using IBM SPSS Statistics version 23.0. All the data were checked for normal distribution by visual inspection of the q-q plot, the box plot, histogram plot and by the Shapiro-Wilks test, prior to the statistical analyses for the different outcome measures. Descriptive statistics will be used for all outcome measures (functional task performance times, SUS and IMI) and data of the outcome measures will be shown in mean ± standard deviation (SD).
In order to assess the direct influence of performance with and without the iH AS, a Wilcoxon signed rank test or a paired sample t-test was performed, depending on normal distribution of the outcome

measures. The differences between session 1 and 2 for the SUS were evaluated with a paired sample t-test or the non-parametric equivalent if needed. The overall level of significance was set at $p < 0.05$.

4 Results

[Includes confidential information until the results are published in scientific journals.]

5 Discussion and Recommendations

5.1 User acceptance of the iH system

From the current feasibility tests it became clear that the concept of the iH system is well received and appreciated. Many positive features of the iH system have been acknowledged. The main advantages of the assistive glove mentioned by the participants were the support in strength and hand mobility it can provide during functional tasks. In addition, participants were positive about the games and the possibility of performing exercises with fun and in a familiar place at home without the presence of a therapist.

Although some very important aspects for improvement of both the assistive and therapeutic iH system were formulated by the participants, overall the usability was scored high by them. The high score on the SUS showed that there is a good chance for acceptability of the iH system in the field. Although most participants reported that their hand function is too good to be a good candidate for the iH system, they think the iH system can be of value for elderly people with a more affected hand function.

Furthermore, the participants scored high on motivation, measured by the IMI. Remarkably, the individual participants in Sweden scored lower on the IMI compared to the participants in the Netherlands and Switzerland. There may be differences between these countries involved regarding for instance the attitude towards technology, that may have affected the IMI scores. Therefore, it is important to be aware of potential cultural differences during the next testing phases with the iH system, for example by assessing (prior) familiarity with technology, attitudes towards technology, etc.

Despite the positively perceived concept of the iH system, several usability issues have been noted during the feasibility tests, indicating that the current iH prototype could be improved. The most relevant issues are described below, with potential solutions recommended where applicable.

First of all the donning and doffing can be improved by changing the zippers on both the medial and lateral side of the glove. The idea behind using zippers was that the upper part of the glove can be opened so that also patients with minor hand function, are able to put on the iH glove by themselves. Unfortunately this seemed not to be the case, since 40% of the participants had difficulties with donning and doffing of the iH system by themselves. Most of those participants reported difficulties with opening and closing the zippers. Therefore, other solutions need to be found for easier donning and doffing of the iH glove.

Another adaptation that needs to be made is the fabric used for the glove. The current fabric of the glove decreases the sensation of the fingertips when the current glove is used in ADL, which makes it very difficult for participants to perform fine motoric activities. Small objects, like a key or a cap of a bottle, are not sensed in the hand. This loss of proprioceptive input made the glove only suitable for the support of gross motor function. In addition, the glove doesn't fulfil to the wish that the glove is breathable and unobtrusive. In the current prototype, the whole hand is covered by the glove, resulting in a non-comfortable, sweating glove. In addition, participants gave preference to a glove which is water-resistant and washable, which entail some extra material requirements.

Also the current prototype is too clumsy and therefore difficult to use during ADL. It is difficult to perform fine motoric activities and functional tasks such as (un)dressing with this clumsy iH system. Especially the control unit, connection part at the forearm and the glove should be more compact and more lightweight to enable daily usage. Another suggestion to reduce the clumsiness of the iH system is to find another solution to wear the iH system for people that do not use a belt.

With regard to the therapeutic system the participants showed some usability problems. Some buttons were difficult to find and the font size was too small for the participants. Also the instructions for the calibration session were missing and the purpose of the games were difficult to understand without instructions. In addition, the games were too fast and therefore difficult to play for elderly people over the age of 55. In general, this population can have vision problems and/or less experience/affinity with technique. Therefore, a user friendly interface is very much encouraged.

5.2 Functional task performance with iH system

The functional task performance times of session 1 and 2 showed that the participants get experienced in using the glove and that the performance with the glove will probably further improve when using the glove for a longer time period. However, at this moment, almost all functional tasks were performed significantly faster without the glove for the corresponding trials than with the glove during evaluation sessions 1 and 2 ($p<0.05$). Currently, the design of the device could have a negative effect on the performance times because participants had less sensation during the performance of functional tasks with the glove. After design adaptations, the glove would probably have better sensation and will be easier to use for fine motoric tasks which could improve functional task performance times with the glove. On the other hand, some participants mentioned that performing functional tasks with the glove improved their stability and smoothness of the hand instead of performing the functional task faster.

6 Summary and Conclusions

In total, 30 participants were included in the feasibility study across the Netherlands, Sweden and Switzerland. There were two drop outs in the Netherlands as result of too much pain in their fingers/hand.

The results of all 3 countries have been integrated into this feasibility report. The functional performance test showed that the participants performed significantly faster without the glove than with the glove during almost all functional tasks in evaluation sessions 1 and 2. However, participants get experienced in using the glove during both evaluation sessions. Therefore, the performance with the glove could probably be further improved when using the glove for a longer time period and even more after the identified usability issues have been addressed in a next version of the iH system.

The current iH prototype could be improved by making some adaptations to the system suggested by the participants. Suggestions for improvements of the iH system were the zippers of the glove to open and close the glove, the fabric of the glove, the clumsiness of the iH system, the water-resistance of the iH system, the font size of the games and to add some instructions to the calibration session and games. This will make the glove easier to use, comfortable and lightweight to enable daily usage during gross and fine motoric activities. Furthermore, this will give the iH TS a more user friendly interface.

Although some very important aspects for improvement of both the assistive and therapeutic iH system were formulated by the participants, overall the participants scored high on system usability and motivation for using the iH system.

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8 Appendices

8.1 Appendix 1. Overview usability test iH assistive system

	ironHand Assistive System	
	Activity	*Comments*
1	Put the glove of the iH system on the affected hand	
2	Attach the battery to the waist	
3	Turn on the iH system	
4	Move the bottle of water (0.5L) 50cm to the right	
5	Open the bottle of water	
6	Put some water in the glass	
7	Close the bottle of water	
8	Bring the glass to the mouth and put it back on the table	

8.2 Appendix 2. Overview usability test iH therapeutic system

	ironHand Therapeutic System	
	Activity	*Comments*
1	Start the training	
2	Start the calibration session (push next)	
3	Play one game and close this game on 15 seconds	
4	Select another game (e.g. Submarine) and close this game on 15 seconds	
5	Select another game (e.g. Music game) and close this game on 15 seconds	
6	Close the iH software program	
7	Turn off the computer	
8	Turn of the iH system	
9	Remove the glove from the hand	