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1 Summary

This report describes the study procedures for testing and evaluation of the ironHand system in the feasibility study and part 1 of the orthotic study of the ironHand project in the Netherlands, Sweden and Switzerland. All partners of the ironHand project provided input for the trial protocols in order to formulate a structured, standardised protocol suitable to be applied by all partners in the different countries (the Netherlands, Sweden and Switzerland). In addition to the scientific documentation, technical documentation about the newly developed medical device (ironHand system), in accordance with the Medical Device Directive, had to be provided as well (called Investigational Medical Device Dossier, IMDD). A lot of attention and input from all partners of the ironHand project was needed to receive the explicit information needed about the technical specifications of both the hardware and software prototypes to complete the IMDD. After finalizing all documents, the study protocol, IMDD and other ethical documents were submitted to the Dutch Medical Ethical Committee (MEC) in March 2015 (M11). At the moment the study is discussed by the MEC and some small adaptations should be done before the Dutch MEC will approve the trial protocols for the feasibility study and part 1 of the orthotic study. Submission of all revised documents for the feasibility study and part 1 of the orthotic study to the Dutch MEC and approval of the MEC is intended for May 2015 (M13).

Submission of the first version of the trial protocols of part 2 of the orthotic study and the therapeutic study to the Dutch MEC is scheduled for November 2015 (M18).

2 Preface

This report provides information about the protocols that will be used during the feasibility study and the orthotic study to evaluate the first and second prototype of the ironHand system across the Netherlands, Sweden and Switzerland. This document describes the objectives, study design, standardized outcome measures and statistical analyses that will be used in both the feasibility and orthotic study. Additional requirements, involving information about technical aspects and safety issues of the newly developed medical device, the ironHand system, was needed for the ethical procedures in the Netherlands. Bioservo and Hocoma completed this additional document, called Investigational Medical Device Dossier (IMDD), which was submitted together with the trial protocol documents to the Dutch MEC.

The third chapter describes the testing protocol of the feasibility study and part 1 of the orthotic study as submitted to the Dutch MEC. Chapter 4 and 5 provide information about the ethical procedures in Switzerland and Sweden. Both Eskilstuna and terzStiftung will use the trial protocol as submitted to the Dutch MEC as input for their ethical procedures. Eskilstuna and terStiftung will perform the Dutch trial protocol with the same study design, participants, tests, outcome measurements etc. during their feasibility study and orthotic study in Sweden and Switzerland. The standardized outcome measures as described in Chapter 3 are explained and described in detail in Appendix 1 of this document.

3 Dutch ethics protocol

LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

ABR	ABR form, General Assessment and Registration form, is the application form that is required for submission to the accredited Ethics Committee (In Dutch, ABR = Algemene Beoordeling en Registratie)
ADL	Activities of daily living
AE	Adverse Event
AR	Adverse Reaction
BBT	Box and Blocks Test
CA	Competent Authority
CCMO	Central Committee on Research Involving Human Subjects; in Dutch: Centrale Commissie Mensgebonden Onderzoek
CV	Curriculum Vitae
DSMB	Data Safety Monitoring Board
EU	European Union
GCP	Good Clinical Practice
IB	Investigator's Brochure
iH	ironHand
iH AS	ironHand Assistive System
iH TS	ironHand Therapeutic System
IC	Informed Consent
IMDD	Investigational Medical Device Dossier
IMI	Intrinsic Motivation Inventory
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
JTHFT	Jebsen Taylor Hand Function Test
METC	Medical research ethics committee (MREC); in Dutch: medisch ethische toetsing commissie (METC)
NFE	National Foundation for the ElderlY
QoL	Quality of Life

RRD	Roessingh Research and Development
(S)AE	(Serious) Adverse Event
SEM	Soft Extra Muscle
SPC	Summary of Product Characteristics (in Dutch: officiële productinfomatie IB1-tekst)
Sponsor	The sponsor is the party that commissions the organisation or performance of the research, for example a pharmaceutical company, academic hospital, scientific organisation or investigator. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidising party
SUS	System Usability Scale
SUSAR	Suspected Unexpected Serious Adverse Reaction
Wbp	Personal Data Protection Act (in Dutch: Wet Bescherming Persoonsgevens
WMO	Medical Research Involving Human Subjects Act (in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen

3.1 SUMMARY

Rationale: Elderly people frequently experience difficulties with performing activities of daily living (ADL) due to a decline in hand function. They often need personal 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. New technological innovations can support the functional performance of the arms and hands directly by a wearable soft robotic device assisting a person's own function. If people can maintain or increase use of their hands/arms in daily life, this might ultimately even benefit their (unsupported) arm function in ADL.

Objective: The primary objective of this study is to explore user acceptance of the ironHand (iH) system by elderly. Secondary objectives are to examine the direct effect on functional task performance, changes in hand strength and movement execution of such a wearable robotic device in elderly.

Study design: This observational, cross-sectional study will consist of two phases. Phase one will focus on user acceptance and phase two on functional task performance.

Study population: In total, maximal 40 elderly participants, with an age over 55 years, will participate in this study (Phase 1: n=10; Phase 2: n=30).

Intervention (if applicable): In phase 1 of this study, elderly will perform independently a selection of functional tasks with and without the wearable robotic device in a (semi)-controlled environment across two days, after which usability experiences are examined.

In phase two of this study, elderly will perform several hand function tasks with and without the wearable robotic device to assess the direct influence of the device on functional task performance, handgrip and pinch strength, ability to perform functional tasks and user acceptance.

Main study parameters/endpoints: The main study parameters are outcomes related to user acceptance (System Usability Scale) in phase 1 and functional task performance (Jebsen-Taylor Hand Function test) in phase 2.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The iH system might have a beneficial effect on hand function, by directly improving functional task performance. However, the exact benefit cannot be predicted, because this is the topic of the current research.

The risks for the subjects are limited to a minimum. The iH system is a device that facilitates hand grip and opening as initiated by the user him/herself. It provides support only when necessary based on voluntary, active initiation by the person him/herself. Furthermore, the iH system is a so-called soft-robotics device, constructed from soft materials that are comfortable to wear and compliant with human movement. This prevents potential occurrence of pressure points for example. All movements conducted during the study will consist of arm/hand movements that normally occur in ADL and within the abilities of each individual. Additionally, all the evaluation measurements used in these studies are non-invasive and involve no risks for the subjects.

3.2 INTRODUCTION AND RATIONALE

Elderly people frequently have difficulties with performing activities of daily living (ADL) caused by impairments in multiple systems due to ageing, including sensation, cognition, memory and motor control [1]. It is estimated that 20-30% of people over the age of 70 experience difficulties with performing ADL [2]. The hand plays an important role in the performance of many of these functional ADL and occupational tasks [3]. Elderly people experience a decline in hand function due to a reduced muscle mass that causes a deterioration of handgrip strength during aging [3-7]. This loss of muscle mass and function is known as sarcopenia [8]. Many elderly over the age of 65 are suffering from sarcopenia and the amount of elderly with sarcopenia increases with age [9]. All these above mentioned reductions in hand function can lead to a negative effect on the ability to grip and manipulate an object [5]. As a consequence, they can have difficulties with carrying out ADL such as holding a pen, opening buttons on clothing, writing a letter and tying shoelaces [3, 5, 10, 11]. The decline in hand function, accompanied by the deteriorated function in ADL, often has an effect on the participation in society. All this together may impact their quality of life (QoL) [5, 12]. Therefore, it is

essential to improve and maintain hand motor function so the elderly people will experience less deterioration in performing everyday activities and ultimately in QoL.

To overcome limitations in ADL, elderly often need personal 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 independently ADL [13]. There are many assistive devices available that people can use to compensate for the loss of functionality in their upper limb motor function [14]. These assistive devices can range from simple assistive tools (e.g. knife with an adapted handle) to fully robotic systems that can substitute activities performed by people themselves in the case of very severe limitations (e.g. JACO) [15-17]. However, many of these simple assistive tools are only usable for a specific task, while the fully robotic systems allow more functionality, but are not portable (except when mounted on a wheelchair), very expensive and too bulky to use unobtrusively in daily life. Furthermore, these fully robotic systems are completely substitute the function of the person [15, 18, 19].

It is important that (elderly) people will actively initiate and execute movements so that they remain a physically active lifestyle. Physically active elderly are able to recruit additional brain resources, improve their functional performance and will perform better independently in ADL [20, 21]. Therefore, it is important that people are able to use their arms and hands frequently and for prolonged periods during daily life. New technological innovations can support the functional performance of the arms and hands directly by a wearable soft robotic device assisting a person's own function. If people can maintain or increase use of their hands/arms in daily life, this might ultimately even benefit their (unsupported) arm 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 address these issues, an easy to use system based on the concept of a wearable robotic glove (ironHand (iH) system) is developed within the current project that could support elderly with hand function 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 gives only the amount of support that is needed. This will make sure that elderly maintain an active contribution to movements at all time. By adding a personalized computer gaming environment, specific training exercises can be provided as well. Therefore, this study explores whether use of such an assisting glove during functional tasks can enhance ADL performance. Since this device should be usable independently during daily life, both user acceptance and the impact on functional performance are

the main aspects of investigation in the first stage of user testing. If user acceptance and impact on performance are satisfactory, a subsequent stage of user testing will involve the effect of the iH system on ADL during home use at a later time (which is not involved in this METC application).

The first stage of user testing consists of two phases that will use a user centred design method, which integrates users in the early phase of the design and development process to suit the needs of the users better. In both phases, user acceptance and functional task performance will be explored but the focus will be different in both phases. In the first phase, the focus will be on user acceptance of the iH system such as perceived ease of use, motivation, system usability etc. If the results of the first phase are satisfactory, the second phase will focus in more detail on quantifying the impact of the iH system on functional task performance. If necessary, some adaptations will be made to the design of the iH system based on the results of the first testing phase, before the second testing phase will start.

3.3 OBJECTIVES

3.3.1 Primary Objective:

- To explore user acceptance of the iH system

3.3.2 Secondary Objective(s):

- To examine the direct effect of the iH system on functional performance of the most-affected arm and hand
- To examine the direct effect of the iH system on changes in hand strength and movement execution

3.4 STUDY DESIGN

This study consists of two phases, to examine user acceptance of the iH system and the impact of the iH system on functional performance of elderly people in ADL-like situations. Since this study is part of a European project, similar tests will be done in other countries besides the Netherlands (Sweden and Switzerland). The part described in this protocol represents the Dutch part of the study, which involves two sites: Roessingh Research and Development (RRD), Enschede and National Foundation for the Elderly (NFE), Bunnik. Whether participants will be coming to RRD or NFE is largely dependent on the location, for their convenience.

3.4.1 Phase one

The first phase of this 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. First, the

participants will perform a usability test, to obtain insight in perceived ease of use of the iH system. This is done by presenting a few tasks to be performed with the iH system, but without receiving any specific instructions in advance, while being observed by a researcher (see Appendix 1 for more information). During the usability test, two modules of the iH system are tested: the iH Assistive System (iH AS), 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. Next, any additional instructions needed for proper use of the iH system are provided by the researchers.

After the usability test, the participants will use the iH AS independently (with as little directions/instructions as possible) during various functional tasks in a (semi)-controlled environment in a skills-lab setting at RRD or NFE, supervised by the researchers. These tasks will consist of real life situations (see Appendix 2 for more information). The researchers will observe the general performance of these functional tasks (e.g. which hand is used for specific task component such as lifting heavy objects, fluidity, precision, presence of compensatory movements) and performance time for each activity will be measured as well. Each activity will be performed with and without the iH AS to observe the differences between both conditions in functional task performance. The participants will practice the functional tasks with the glove three times and only the last one will be used for analysis. They will perform these tasks on two separate days, the second time will be a few (i.e. 5) weekdays later (see Figure 1), to take potential habituation of the system or tests into account (except for the usability test). After these two sessions, the participants will be asked about their experiences and perceived ability of using the iH system (see Figure 1).

If the results of the phase one are satisfactory (System Usability Scale > 50 points), phase two of this study can start without design adaptations [22, 23]. If that is not the case, some design adaptations will be done to the iH system. After the design adaptations, the System Usability Scale will be assessed again and needs to be > 50 points before the second phase of this study will start.

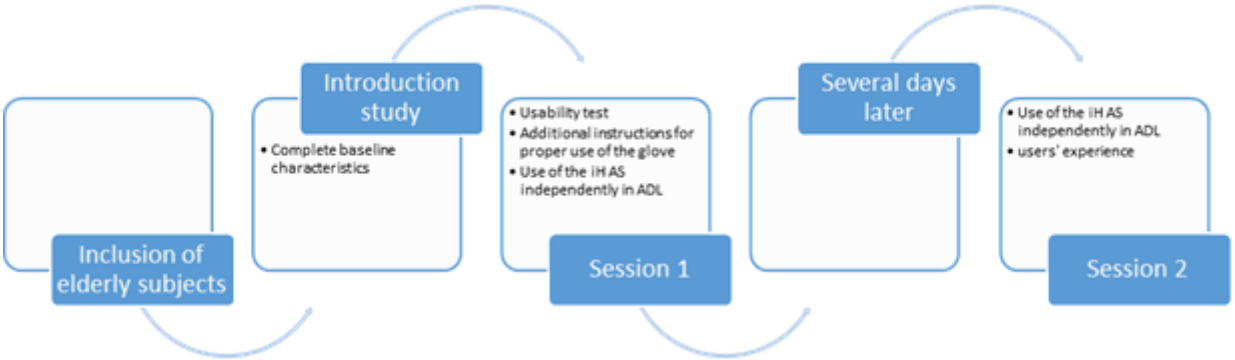

FIGURE 1. FLOWCHART FIRST PHASE OF THE STUDY

3.4.2 Phase two

The second phase of this study will focus on the direct impact of the iH system on functional task performance, but will also include user acceptance. After the first phase of this study, adaptations to the design of the iH system will be made based on the first results of this study, as necessary. A few weeks-months later, the participants will use this updated version of the iH AS during several hand function tests. The participants will perform those hand function tests with and without the glove to assess the direct influence of the iH AS on functional use of the hand, handgrip and pinch strength, ability to perform functional tasks and user acceptance (see Figure 2), during a single session at RRD or NFE.

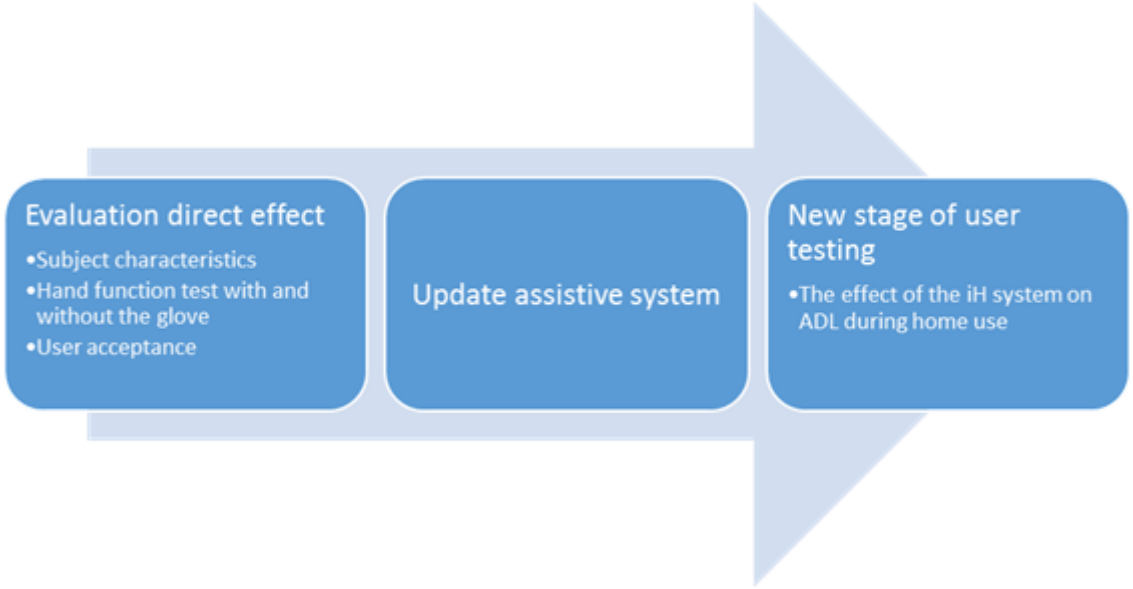

FIGURE 2. FLOWCHART SECOND PHASE OF THE STUDY

3.5 STUDY POPULATION

3.5.1 Population (base)

In this study, NFE and RRD together will recruit 40 elderly participants from their databases or network to participate in this study. For the first phase, a total of 10 elderly participants will be included. In the second phase, 30 elderly will participate. These participants could be the same persons that participated in the first testing phase.

People who are interested to participate in this study will be informed verbally and by letter about the goal of the study and their involvement. All participants will be informed that they can stop at any moment of the study. Even if they give permission to participate in the study, the participants can stop at any time and without giving reasons and without any disadvantages. Prior to the study, all the participants have to submit written informed consent indicating voluntary participation.

3.5.2 Inclusion criteria

In order to be eligible to participate in this study, elderly subjects must meet all of the following criteria:

- Elderly adults over the age of 55 years
- Experience difficulties in performing ADL due to a decline in hand function
- Absence of wounds on their hands that can give a problem when using the glove
- Absence of severe contractures limiting passive range of motion
- Absence of co-morbidities limiting functional use/performance of the arms/hands
- People should have at least 10 degrees of active flexion and extension of the fingers
- Sufficient cognitive status to understand two-step instructions
- Having (corrected to) normal vision
- Living at home
- Provided written informed consent

3.5.3 Exclusion criteria

A potential older subject who meets any of the following criteria will be excluded from participation in the study:

- People with severe sensory problems of the most-affected hand
- People with severe acute pain of the most-affected hand
- Participation in other studies that can affect functional performance of the arm and hand
- People having insufficient knowledge of the Dutch language to understand the purpose or methods of the study

3.5.4 Sample size calculation

The nature of the current study is explorative, to gain understanding about the potential of a wearable robotic glove to support functional abilities and/or improve arm/hand function, in addition to examining users' perspectives of using such technology to support their ability to perform ADL. Therefore, a power calculation is not applicable. The numbers are based on what is believed to be sufficient to gather the intended information and will be feasible to achieve during the course of the study.

3.6 TREATMENT OF SUBJECTS

The researchers involved in the study receive an extensive training about how to handle and operate the iH system by personnel from the technical project partners prior to the start of the study. Also, they are instructed on how to explain use of the iH system to participants, following a standard procedure.

First, participants will perform a usability test (Appendix 1) without prior instruction by the researchers to explore the perceived ease of use of the iH system. Intuitive operation of the iH system (i.e. iH AS and iH TS) is assessed by presenting a selection of assignments, in terms of donning/doffing, turning the glove on/off, using the glove during several functional tasks, play computer-aided exercises, understanding of exercises, flow of therapeutic setting, etc. During these assignments, the researcher observes the actions of the participant closely to identify areas which are in need of further instruction (the session will also be videotaped). Next, the iH AS is tuned for each person. The proper amount of support for grip strength and hand opening has to be set on the iH AS by the researcher. At the end of this test, instructions about all aspects of iH AS use will be given, demonstrated to and practiced with the participant, until the researchers are confident that the participant knows how to use the system properly.
After this usability test, the participants will use the iH AS independently (with as little instructions/help from the researchers as possible) during several functional tasks in a (semi)-controlled environment in a skills-lab setting at RRD or NFE. The performance of these daily tasks will be analysed by the researchers. The participants will receive two sessions on two separate days (the second time a few (i.e. 5) weekdays later). At the end of phase one, participants will be asked about their experiences and perceived ability of using the iH AS and iH TS.

A few weeks-months later, participants will perform a more extensive set of hand function tests with an updated version of the iH system. First, a calibration measurement is performed to assess the proper amount of support to be set in strength and hand opening. The hand function tests will be performed with and without the glove to assess the direct impact of the iH system. At the end of the hand function tests, participants will be asked about their experiences and perceived ability of using the iH AS for support of ADL.

3.6.1 Use of co-intervention (if applicable)

Use of co-intervention is not applicable.

3.6.2 Escape medication (if applicable)

Escape medication is not applicable.

3.7 INVESTIGATIONAL PRODUCT

3.7.1 Name and description of investigational product(s)

The wearable robotic glove is based on an existing grip-enhancing glove, SEM glove [24], which is specifically designed towards the needs of elderly people with declining hand function. The iH system falls under Rule 9 of the Medical device directive, and is considered to be a class IIa.

The iH system is based on the concept of a soft-robotic glove. The main characteristics of the system are:

- A cable-driven glove that can provide assistive force to open and close the hand during everyday activities or therapeutic exercises;
- The assistive force is triggered by an "intention detection" logic that reacts to movement initiation by the user;
- The glove can be connected to an external PC that allows the user to perform specific, computer-game-like exercises tied to functional tasks in order to keep the motivation to remain active.

Furthermore, the iH system can assist clinicians in evaluating changes in motor function over time.

The iH system is composed of two main parts: a iH AS and a iH TS (see Figure 3). The iH AS consists of a (1) Control unit and a (2) Glove. The iH TS consist of a (3) Therapeutic platform and (4) Therapeutic software.

The iH AS can be used by itself, i.e. without the iH TS. In this configuration, the iH system improves *i)* the hand grip strength and endurance following the users grip intention, and *ii)* the agility of the fingers. It can be used when additional grip strength and endurance is desired, for training on everyday activities and to monitor the user's performance.

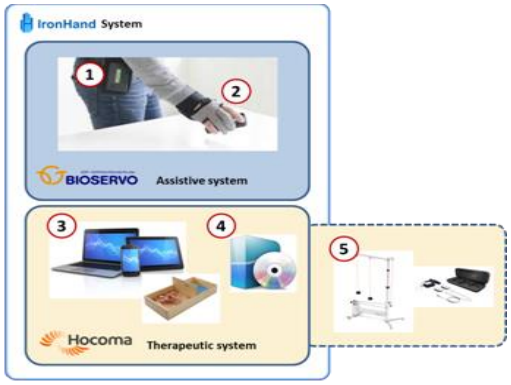

FIGURE 3. IRONHAND SYSTEM

The iH AS can also be used in combination to the iH TS to provide specific hand movement therapy and assessments. In this configuration, the iH system supports specific exercises in order to increase muscle strength, coordination, fine motor skills and range of motion in different joints with the aim to improve or maintain motor function.

The iH system consists of the following parts (Figure 3):

1) Control unit - The control unit contains a battery for power source, one motor for each finger that receives extra force and a microcontroller that controls the iH AS functionality. A cord connects the control unit with the glove and holds the artificial tendons as well as electrical cables for sensors. Close to the glove there is a connection that can be opened, separating the glove from the control unit. This gives the possibility to change between gloves or replace an old glove. An embedded software in the control unit adjusts the amount of assistive force to help the user open or close the hand. When an object is held with the aid of the iH AS, the touch sensors on the finger tips signal to the control unit which pulls the tendons such that the force in the grip becomes larger. The extra force applied by the glove is in proportion to the force applied by the user. Hence, the user can control (increase or decrease) the extra force applied by the iH AS.

2) Glove - The main purpose of the glove is to apply the forces generated by the motors in the control unit and to provide the control unit with sensory input from touch sensors at the fingertips. The forces are applied by artificial tendons that are sewn into the glove along the length of the fingers. The glove works together with the control unit that is placed on the hip or on the back of the user. The glove has a slim design and the same look and feel as a regular glove; therefore, it can be worn as any other glove.

The glove functionality also consists of a hand opening function realized by the use of passive (leaf) springs attached to the top of the hand. The springs cover the fingers and the back of the hand. This

functionality means that the glove should be capable of actively controlling forces for flexion and extension of the fingers.

3) Therapeutic platform - The therapeutic platform refers to a computing system (e.g. PC or tablet) to which the iH AS is connected. This allows the user to train with motivating game-like exercises and visualize his progress through automated reports.

4) Therapeutic software – Additional therapeutic functionality of the iH system is embedded in a therapeutic software. Software development complies with IEC62304:2006 and IEC 60601-1:2005 standards. This software includes the following functionalities: assessments, connectivity, database, exercises, software architecture, safety mechanisms and user interface.

The following configurations will be used during the research studies described in this protocol:

Configuration I - Orthotic mode

The system is considered to operate in *orthotic mode* when the iH AS is not connected to the iH TS. This configuration will be used at both phases during this study. During the first phase of the study, people will use the iH AS in (semi)-controlled environment in a skills-lab setting at RRD or NFE on two separate days, wearing the glove on their most-affected hand during several functional tasks where they perceive this to be beneficial. Each activity will be performed with and without the iH system in orthotic mode to observe the differences between both conditions in functional task performance. After these two days, user acceptance of the iH system will be assessed.

During phase two, participants will perform several hand function tests with and without the glove in orthotic mode, wearing it on their most-affected hand to support their hand as desired and needed. The direct impact of the iH AS will be explored, but also user acceptance will be explored during this phase of the study.

Configuration II - Therapeutic mode

The system is considered to operate in *therapeutic mode* when the iH AS is connected to the iH TS. In this configuration, the user can benefit from additional therapeutic training in a motivating environment. During this study, the iH TS is only used in a controlled and supervised environment as part of the testing of user acceptance.

3.7.2 Summary of findings from non-clinical studies

Findings from non-clinical studies are not applicable in the case of this biomedical device, which is developed for specific interaction with the human body. See IMDD for detailed information about technical testing and product (component) functionality tests.

3.7.3 Summary of findings from clinical studies

While the claimed use of the iH system as a therapeutic device needs further clinical evaluation, which is the topic of the current MEC application, several studies suggest that this approach may be provide therapeutic benefits to the user (see *Literature review references* below). The feasibility study of Nilsson et al. 2013 about the SEM-glove showed already that such a system can be beneficial for participants with impaired hand function. In addition, the Clinical evaluation report of the predicate device SEM™ Glove is considered to provide partial clinical evidence for the iH System when used in *orthotic mode* (see IMDD for more information) [24]. The rehabilitation effects of the use in *orthotic mode* are not covered by the references document, but need further clinical evaluation as described above.

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3.7.4 Summary of known and potential risks and benefits

The iH system might have a beneficial effect on hand function, by directly improving functional task performance. However, the exact benefit cannot be predicted, because this is the topic of the current research.

The risks for the subjects are limited to a minimum. The iH system is a device that facilitates hand grip and opening as initiated by the user him/herself. It provides support only when necessary based on voluntary, active initiation by the person him/herself. Furthermore, the iH system is a so-called soft-robotics device, constructed from soft materials that are comfortable to wear and compliant with human movement. This prevents potential occurrence of pressure points for example. All movements conducted during the study will consist of hand movements that normally occur in ADL and within the abilities of each individual. Additionally, all the evaluation measurements used in these studies are non-invasive and involve no risks for the subjects.
For further information, see IMDD and the associated risk management reports.

3.7.5 Description and justification of route of administration and dosage

The glove applies force to the hand following the same biomechanical constraints as the corresponding muscles. This means that there is no risk that the glove causes unnatural movement of the hand and/or fingers (such as hyperextension). The force to be applied as well as sensitivity of the system will be adjustable to suit the user's needs and limitations by trained personnel. The user will not be able to do any modifications to the configuration. The maximum force of the system is mechanically limited by the motors to a level that is comparable to an average female adult, which means that harmful levels of pressure and/or power can never be reached.

In addition, it is important to remember that the device follows the user's own intention. This means that if the user grasps an object harder the glove will provide more force (up to the limited maximum level) but as soon as the user initiates to release the grasp the force applied by the glove will decrease. This gives good feedback to the user and lowers the risk for harm caused by the using dropping things (coffee cup, hot pot, knife etc.).

The same technology has been successfully used in the CE marked SEM™ Glove for a number of years without leading to incidents and/or causing harm. Furthermore, the feasibility study of Nilsson et al. 2013 [24] showed the potential benefit for participants with impaired hand function when they will use such a device as the SEM-glove. Participants with impaired hand function improved their grip while using the SEM-glove.

3.7.6 Dosages, dosage modifications and method of administration

Not applicable

3.7.7 Preparation and labelling of Investigational Medicinal Product

Not applicable

3.7.8 Drug accountability

Not applicable

3.8 NON-INVESTIGATIONAL PRODUCT

Not applicable

3.9 METHODS

3.9.1 Study parameters/endpoints

3.9.1.1 Main study parameters

Phase 1 (user acceptance):

- System Usability Scale (SUS)

Phase 2 (direct effect):

- Jebsen-Taylor Hand Function Test (JTHFT)

3.9.1.2 Secondary study parameters/endpoints

Phase 1 (user acceptance):

- Qualitative observations about intuitive operation of the system (usability test)
- Intrinsic Motivation Inventory (IMI)
- Semi-structured interview about user's experience
- Performance time of functional tasks
- Qualitative observations of functional task performance (e.g. speed of movement, precision, fluidity, compensatory movements)

Phase 2 (direct effect):

- User acceptance
- Maximal handgrip strength (Jamar dynamometer)
- Handgrip endurance (Jamar dynamometer)
- Maximal pinch force (Jamar pinch Gauge dynamometer)
- Box and Blocks Test (BBT)

For a better understanding of potential mechanisms of hand function changes, additional measurements are performed at RRD only:

- Kinematic data during movement execution of above mentioned functional tasks (e.g. JTHFT, BBT) recorded using a 3D motion analysis system (VICON Vicon MX 13+ motion capture system, Vicon Oxford Metrics, Oxford, United Kingdom)

3.9.2 Other study parameters (if applicable)

Other parameters to be collected are descriptive subject characteristics (see Appendix 3), which will be documented at baseline measurement in both studies:

- Name
- Date of birth
- Sex
- Height
- Weight
- Dominant side before impairment
- Most-effected side
- Metrics of the hand
- Impairment/Pathology

3.9.3 Randomisation, blinding and treatment allocation

There will be no randomisation of participants but only the order of functional tests with and without the glove will be randomized. The numbers 1-10 will be distributed over 10 envelopes. For each participant, the researcher will take one envelope from these 10 envelopes to randomize the order of functional tests with and without the glove. If the researcher will draw first an even number, the participant will perform first all functional tasks with the glove. If the researcher will draw first an odd number, the participant will perform first all functional tasks without the glove. The randomization procedure will take place after the usability test. The study cannot be blinded for the participants or researchers.

3.9.4 Study procedures

First testing phase:

Each participant will have two evaluation sessions during testing phase one of this study. Participants will start the first evaluation session with a usability test followed by additional instructions about how

to use the system. After these instructions, participants will use the iH AS independently in several functional tasks during two sessions on two separate days. The researchers will observe the general performance of these functional tasks. Each activity will be performed with and without the iH AS (see Appendix 2). After both sessions, user acceptance of the iH AS will be assessed. The complete protocol of testing phase one is shown in Table 1.

Table 1: First testing phase protocol

		Activity	Time (min.)
First evaluation	1	Introduction about the study	10
	2	Complete subject characteristics	5
	3	Usability test	15
	4	Explanation of the glove	5
	5	Trying out the glove	10
	6	Session 1	45
	7	System Usability Scale (SUS)	5
Second evaluation	8	Session 2	45
	9	System Usability Scale (SUS)	5
	10	Intrinsic Motivation Inventory (IMI)	15
	11	Semi-structured interview about users' experience	15
		Total:	**175 min**

Second testing phase:

Each participant will have one evaluation session for testing phase two of this study at RRD or NFE. The evaluation session will consist of a short introduction about the iH system followed by an evaluation measurement with different hand function tests with and without the glove to assess the direct influence of the iH AS. Each hand function test will be performed first without the glove. Furthermore, the participants will complete some questionnaires about user acceptance. The complete list of procedures is shown in Table 2.

Table 2: Second testing phase protocol

	Activity	Time (min.)
1	Introduction about the study	10
2	Complete subject characteristics	5
3	Explanation of the iH AS system	10
4	Trying out the iH AS system	5
5	System Usability Scale (SUS)	5
6	Jebsen-Taylor Hand Function Test	25
7	Maximal handgrip strength	15
8	Maximal pinch force	10
9	Handgrip endurance	20
10	Box and Blocks Test (BBT)	10
11	Qualitative interview about the experience of use	15
	Total:	**130 min**

3.9.4.1 Evaluation measurements – Main study parameters

System Usability Scale (SUS) (Appendix 1)

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 will be multiplied by 2.5, so that the maximum score is 100 [25].

Jebsen-Taylor hand function test (JTHFT) (Appendix 1)

The JTHFT is a reliable and valid test to evaluate functional hand motor function in different patient groups and healthy people of various ages [26]. The test consists of 7 different unilateral hand skill tasks related to ADL: (1) writing a letter 24 sentences (2) turning over 7.6- x 12.7-cm cards (3) picking up small, common objects (e.g., paper clips, coins and bottle caps) and move these to a box (4) stacking checkers (test of eye-hand coordination) (5) simulated feeding (e.g. teaspoon with beans) (6) picking up large empty cans (7) moving weighted (450 g) cans. The time of each different task will be recorded in seconds and the different times summed is the total score for the test [26, 27].

3.9.4.2 Evaluation measurements – Secondary study parameters

Usability test (Appendix 1)

At the beginning of testing phase one, a usability test will be performed with the iH system. This is a semi-structured test to evaluate the difficulties of end-users with the use of the iH system. This test will analyse donning and doffing of the glove, a frequent ADL task to explore the ease of use of the device, understanding of exercises and flow of therapeutic setting, when users don't receive any specific instructions about how to use the device (see Appendix 1). This will provide qualitative information based on observations by the researc1hers, supported by video recordings of the task executions.

Intrinsic Motivation Inventory (IMI) (Appendix 1)

The IMI questionnaire is a simple, easy to use, valid and reliable test to assess individuals' intrinsic motivation during any specific exercise activity [28-30]. 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' [29].

Semi-structured interview about users' experience (Appendix 1)

At the end of each phase of this study, a qualitative interview will be performed with open-ended questions about the experience of use such as what do you think about the feasibility of the iH system and ease of use and did you run into any technical problems?. This interview can give us a more in-depth view about subjects' experiences.

Maximal handgrip strength

The maximal handgrip strength will be measured with a Jamar dynamometer [31]. Each participant will sit comfortably with the elbow of the most-affected arm close to their body, flexed 90 degrees, holding the dynamometer in the most-affected hand. The other parts of the body are not allowed to move or help to give more strength. The participant will squeeze the handgrip of the dynamometer maximally, which is maintained for 5 seconds. There will be three attempts and between the different attempts is at least 60 seconds rest. The best of the three attempts will count. This measurement will be done by the less-affected hand as well for reference purposes.

Handgrip endurance

Handgrip endurance will be measured in a static and dynamic situation. In the static situation, the participants will squeeze the Jamar dynamometer maximally for 30 seconds. The formula for analysing fatigue in a static situation is last second / first second, to measure the change in power (N) in percentage [32]. In the dynamic situation, the participants have to squeeze the Jamar dynamometer maximally 12 times in a row. Each contraction has to be held for 3 seconds and between each contraction is a 5 seconds rest period. The formula for analysing fatigue in a dynamic situation is (first peak / last peak) / first peak multiplied by 100, to measure the change in power (N) in percentage [33]. The participant has three attempts in both dynamic and static situation and between the different attempts is at least 60 seconds rest. The best of these three attempts will count.

Maximal pinch strength

The maximal pinch strength will be assessed with a Jamar pinch Gauge dynamometer. The pinch strength will be measured between each of the four fingers and the thumb. The subject will be seated comfortably with the elbow close to their body, flexed 90 degrees and resting on a table. The subject will in all attempts grasp the pinch dynamometer with the distal segment and ventral side of the thumb and finger. In all attempts, the subject will squeeze in the pinch dynamometer maximally with the two fingers for at least 5 seconds. The other fingers are not allowed to give any support. The subject will get 3 attempts for each test and the best one counts. Between all the attempts is at least 60 seconds rest. First, the thumb with the index finger will be tested, followed by the middle finger, ring finger and little finger.

Box and Blocks test (BBT) (Appendix 1)

The BBT is a simple, reliable and valid measurement to measure manual dexterity of elderly people [34]. The participant should grasp blocks with their most-affected hand and has to transfer this from one box to the other adjacent box. The maximum time for this measurement is one minute and the participant has to transfer as much blocks as possible, one at a time. At the end of the measurement, the amount of transferred blocks should be counted and more blocks indicate a better gross manual dexterity [34, 35].

3.9.4.3 Evaluation measurements – laboratory test at RRD

3D kinematics measurement

An additional measurement of 3D kinematics will take place in a subset of participants that are able and willing to come to the research lab of RRD. Participants will perform the different hand function tests (e.g. JTHFT, BBT) at a comfortable speed, during which the hand and arm movement kinematics will be recorded using a 3D motion analysis system, Vicon MX 13+ motion capture system, Vicon Oxford Metrics, Oxford, United Kingdom. This system uses 6 infrared cameras to capture movements of the upper extremity. These cameras will record the positions of reflective markers on the upper extremity. The reflective markers are placed on the joints of the fingers, wrist, arm and trunk (Figure 4/Table 3). This measurement includes different spatial and temporal aspects about movement execution in functional hand performance tasks. This objective measurement provides more sensitive and specific information about hand performance and quality of movement compared to ordinal scales [20].

The 3D positions data of the cameras will be used to calculate the following parameters:

- Movement path
- Movement time (duration of the functional task)
- Velocity
- Acceleration
- Jerk (change of acceleration; smoothness)
- Range of motion of relevant arm and hand joints

FIGURE 4. MARKER POSITIONS OF THE HAND.

3.9.5 Withdrawal of individual subjects

Subjects can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a subject from the study for urgent medical reasons.

3.9.5.1 Specific criteria for withdrawal (if applicable)

The subjects will be withdrawn if the subjects' health is affected or other adverse effects will encounter during the use of the device.

3.9.6 Replacement of individual subjects after withdrawal

If possible within the duration of the study, the subject will be replaced after withdrawal.

3.9.7 Follow-up of subjects withdrawn from treatment

There will be no follow-up for the subjects after withdrawal from the study.

3.9.7.1 Premature termination of the study

The study will be terminated prematurely if there will occur serious adverse events during the study procedures. In such situations, the accredited METC and laboratory manager will be notified and the subjects will be informed as quickly as possible.

Table 3. Overview of marker positions

Body side	Marker position
Hand	*Distal head of the distal phalanx of the thumb*
Hand	*Distal head of the distal phalanx of the index finger*
Hand	*Distal head of the distal phalanx of the middle finger*
Hand	*Distal head of the third metacarpal*
Forearm	*Ulnar styloid (most caudal – medial point)*
Forearm	*Radial styloid (most caudal – lateral point)*
Humerus	*Lateral epicondyle*
Humerus	*Medial epicondyle (via pointer, proximal marker)*
Humerus	*Medial epicondyle (via pointer, distal marker)*
Clavicula	*Acromioclavicular joint (most dorsal point)*
Thorax	*Incisura Jugularis (upper marker in triangular frame)*
Thorax	*Part of triangular frame placed on sternum (pointer)*
Thorax	*Part of triangular frame placed on sternum*
Thorax	*Processus xiphoideus (most caudal point on the sternum*
Thorax	*7^{th} cervical vertebra (processus spinosus)*
Thorax	*8^{th} thoracal vertebra (processus spinosus)*

3.10 SAFETY REPORTING

3.10.1 Section 10 WMO event

In accordance to section 10, subsection 1, of the WMO, the investigator will inform the subjects and the reviewing accredited METC if anything occurs, on the basis of which it appears that the disadvantages of participation may be significantly greater than was foreseen in the research proposal. The study will be suspended pending further review by the accredited METC, except insofar

as suspension would jeopardise the subjects' health. The investigator will take care that all subjects are kept informed.

3.10.2 AEs, SAEs and SUSARs

3.10.2.1 Adverse events (AEs)

Adverse events are defined as any undesirable experience occurring to a subject during the study, whether or not considered related to use of the iH system. All adverse events reported spontaneously by the subject or observed by the investigator or his staff will be recorded.

3.10.2.2 Serious adverse events (SAEs)

A serious adverse event is any untoward medical occurrence or effect that at any dose:

- results in death;
- is life threatening (at the time of the event);
- requires hospitalisation or prolongation of existing inpatients' hospitalisation;
- results in persistent or significant disability or incapacity;
- is a congenital anomaly or birth defect;
- Any other important medical event that may not result in death, be life threatening, or require hospitalization, may be considered a serious adverse experience when, based upon appropriate medical judgement, the event may jeopardize the subject or may require an intervention to prevent one of the outcomes listed above.

The sponsor will report the SAEs through the web portal *ToetsingOnline* to the accredited METC that approved the protocol, within 15 days after the sponsor has first knowledge of the serious adverse events.

SAEs that result in death or are life threatening should be reported expedited. The expedited reporting will occur not later than 7 days after the responsible investigator has first knowledge of the adverse event. This is for a preliminary report with another 8 days for completion of the report.

3.10.2.3 Suspected unexpected serious adverse reactions (SUSARs)

This chapter is not applicable because the iH system is not an investigational medicinal product.

3.10.3 Annual safety report

This chapter is not applicable because the iH system is not an investigational medicinal product.

3.10.4 Follow-up of adverse events

All AEs will be followed until they have abated, or until a stable situation has been reached. Depending on the event, follow up may require additional tests or medical procedures as indicated, and/or referral to the general physician or a medical specialist. SAEs need to be reported till end of study within the Netherlands, as defined in the protocol.

3.10.5 Data Safety Monitoring Board (DSMB) / Safety Committee

Not applicable.

3.11 STATISTICAL ANALYSIS

The data of the outcome measurers will be analysed using IBM SPSS Statistics version 19.0. All the data will be 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 and data of the outcome measures will be shown in mean ± standard deviation (SD) or median and interquartile range (IQR) as applicable. The overall level of significance will be set at $p < 0.05$.

3.11.1 Primary and secondary study parameter (s)

The user acceptance scales (e.g. SUS and IMI) will be presented by descriptive statistics.
In order to assess the direct influence of performance with and without the iH AS, a paired sample t-test or the Wilcoxon signed rank test will be performed for all outcome measures during both phases of the study.

3.11.2 Other study parameters

Descriptive statistics will be used to show the mean ± SD or median and interquartile ranges of the relevant subjects' characteristics.

3.11.3 Interim analysis (if applicable)

Not applicable.

3.12 ETHICAL CONSIDERATIONS

3.12.1 Regulation statement

This study will be conducted according to the principles of the Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013). Other applicable acts and regulations from the involved countries are Wet op Mensgebonden Onderzoek (WMO, the Netherlands).

3.12.2 Recruitment and consent

The researchers of RRD or NFE will select potential subjects based on inclusion and exclusion criteria. When expressing interest in participation, subjects will be provided with written and verbal information about the study by the researchers. The subject has one week to consider their decision for involvement in the study. If the subject decides to participate in the study, the subject has to sign the attached informed consent indicating voluntary participation in this study and satisfactory information provision about all aspects of the study.

3.12.3 Objection by minors or incapacitated subjects (if applicable)

Not applicable.

3.12.4 Benefits and risks assessment, group relatedness

The iH system might have a beneficial effect on hand function, by directly improving functional task performance. However, the exact benefit cannot be predicted, because this is the topic of the current research.

The risks for the subjects are limited to a minimum. The iH system is a device that facilitates hand grip and opening as initiated by the user him/herself. It provides support only when necessary based on voluntary, active initiation by the person him/herself. Furthermore, the iH system is a so-called soft-robotics device, constructed from soft materials that are comfortable to wear and compliant with human movement All movements conducted during the study will consist of hand movements that normally occur in ADL and within the abilities of each individual. Additionally, all the evaluation measurements used in these studies are non-invasive and involve no risks for the subjects.

3.12.5 Compensation for injury

The sponsor/investigator has a liability insurance which is in accordance with article 7, subsection 9 of the WMO.

The sponsor (also) has an insurance which is in accordance with the legal requirements in the Netherlands (Article 7 WMO and the Measure regarding Compulsory Insurance for Clinical Research in Humans of 23th June 2003). This insurance provides cover for damage to research subjects through injury or death caused by the study.

1. € 450.000,-- (i.e. four hundred and fifty thousand Euro) for death or injury for each subject who participates in the Research;
2. € 3.500.000,-- (i.e. three million five hundred thousand Euro) for death or injury for all subjects who participate in the Research;
3. € 5.000.000,-- (i.e. five million Euro) for the total damage incurred by the organisation for all damage disclosed by scientific research for the Sponsor as 'verrichter' in the meaning of said Act in each year of insurance coverage.

The insurance applies to the damage that becomes apparent during the study or within 4 years after the end of the study.

3.12.6 Incentives (if applicable)

Subjects can receive compensation for travelling costs.

3.13 ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

3.13.1 Handling and storage of data and documents

Data will be collected and processed according to the European Data Protection Act (95/46/EC and 93/42/EWG) and the European Clinical Trials Directive (2001/20/EC) on Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use. Data will be collected and used for research purposes only by written permission of the subject, according to their informed consent. The data of the relevant subjects' characteristics, questionnaires, clinical trials and laboratory test will be numerically coded. The information that is concealed by the numeric code is only accessible by the investigators. If necessary, the subject can be linked to the data by a subject identification code list which is safeguarded by the investigators. All the data will be stored anonymously for the next 15 years. When data is transferred between the project partners, this will concern anonymized data only. Furthermore, sensitive data will be protected with an encryption. The researchers can use the data for research purposes, such as presentations in a scientific context and conferences without the names and identities of the subjects.

3.13.2 Monitoring and Quality Assurance

Not applicable.

3.13.3 Amendments

Amendments are changes made to the research after a favourable opinion by the accredited METC has been given. All amendments will be notified to the METC that gave a favourable opinion.

Non-substantial amendments will not be notified to the accredited METC and the competent authority (CA), but will be recorded and filed by the sponsor. Examples of non-substantial amendments are typing errors and administrative changes like changes in names, telephone numbers and other contact details of involved persons mentioned in the submitted study documentation.

3.13.4 Annual progress report

The sponsor/investigator will submit a summary of the progress of the trial to the accredited METC once a year. Information will be provided on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the trial, serious adverse events/ serious adverse reactions, other problems, and amendments.

3.13.5 End of study report

The investigator will notify the accredited METC of the end of the study within a period of 8 weeks. The end of the study is defined as the last patient's last visit. In case the study is ended prematurely, the investigator will notify the accredited METC within 15 days, including the reasons for the premature termination. Within one year after the end of the study, the investigator/sponsor will submit a final study report with the results of the study, including any publications/abstracts of the study, to the accredited METC.

3.13.6 Public disclosure and publication policy

There are no restrictions between sponsor and investigators concerning public disclosure and publication of the research data.

3.14 STRUCTURED RISK ANALYSIS

Potential risks of the iH system prototype to be used in these research studies were identified and evaluated as described in Figure 5. Risk assessment of the iH system operating in in both orthotic mode and therapeutic mode are covered in the IMDD and its appendices in detail (see Figure 5).

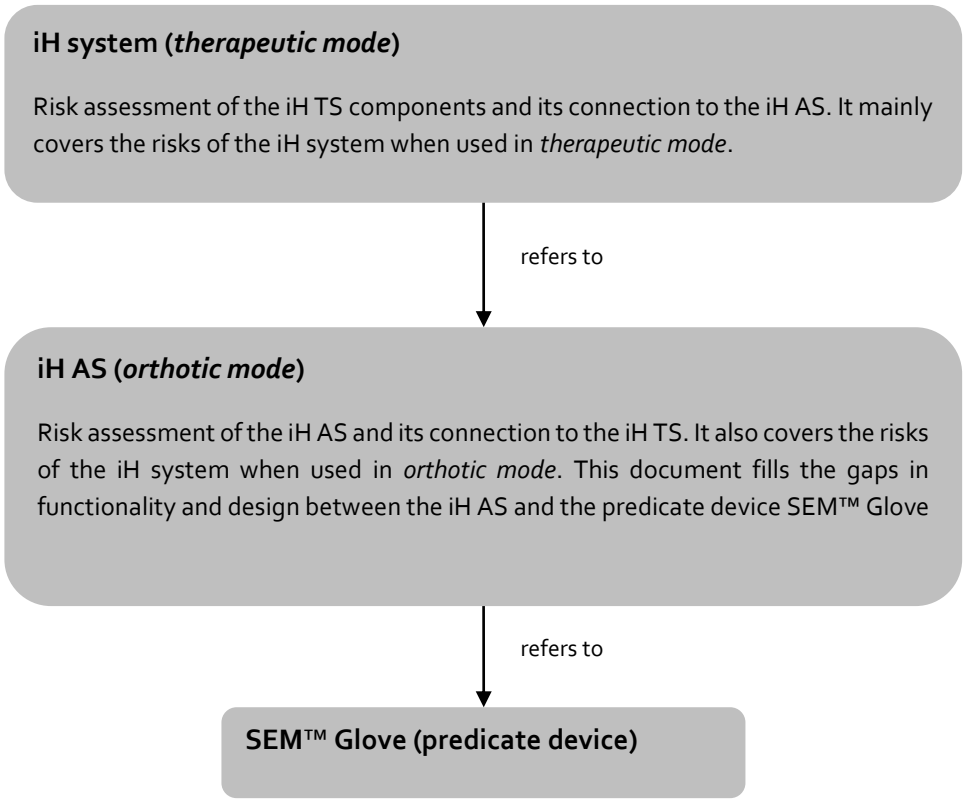

FIGURE 5. OVERVIEW OF THE RISK MANAGEMENT DOCUMENTS FOR THE IH SYSTEM

Risk causes and risk control measures have been reviewed and evaluated in the IMDD and associated documents. The conclusion is, given the intended use of the device, that the overall residual risk is acceptable. There were no identified unacceptable residual risks that may occur in connection with and application of the iH system prototype in this proposed research studies.

Risk management will continue during the development and testing of the iH system prototype. Any feedback from usage of the device during the usability test will be immediately considered in the risk management process.

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4 Swedish ethics protocol

Eskilstuna will submit their ethics application and all the relevant documents to their Ethical Review Board before 27 May 2015. Their application will be raised and judged by the Ethical Review Board 27 May 2015. Eskilstuna will submit the same ethics protocol as RRD (detailed in chapter 3) with the same study design, participants, tests, outcome measurements etc.. However, an important point to note is that there will be a difference in compensation for an injury. The Project participants in Sweden are insured through the liability of the manufacturer of the robotic glove (Bioservo Technologies AB). The liability insurance, including product liability, applies to persons and damage to property throughout the world, excl. US and Canada. Amount of liability insurance is SEK 10,000,000. For property that is processed, installed, assembled, etc. the sum insured is 2 000 000 SEK. Compensation paid to an individual person when inflicted damage is investigated on case by case basis by the insurance company. Deductibles paid by the company Bioservo Technologies. The insurance applies to the damage that becomes apparent during the study.

5 Swiss ethics protocol

terzStiftung and Hocoma will perform the same ethics protocol as RRD (detailed in chapter 3) with the same study design, participants, tests, outcome measurements etc. in Switzerland. However, an important point to note is that there is a difference in ethical procedures between the Netherlands and Switzerland. Therefore, below the ethical aspects regarding advanced technology for old or frail people in Switzerland:

In the following, the Swiss approach for the development and testing of the ironHand glove by terzStiftung and Hocoma regarding ethical aspects is presented.

In Switzerland, the following laws and directives have to be taken in account if personal (medical) data are recorded during field tests:

Art. 13 der Bundesverfassung

(that says that "everyone has the right that his private and family-life, his home, his mail and his telecommunication have to be respected. Everyone is entitled to protection against misuse of his personal data.)

Bundesgesetz über den Datenschutz (Stand 1. Jan. 2014, esp. Art 3c, 2)

Verordnung zum Bundesgesetz über den Datenschutz

Regarding fieldtests with probands the „Bundesgesetz über die Forschung am Menschen" (Humanforschungsgesetz, HFG) has to be considered.

In Switzerland the „Eidgenössischer Datenschutz- und Öffentlichkeitsbeauftragter" in Bern is responsible for all questions of data security. It has to be clarified if especially sensible sensitive (medical) data of identifiable testing persons (probands) will be sent to third persons. If this is the case, the kantonal or the eidgenössische Ethikkommission has to be informed or must be asked for its statement. The president of the kantonal ethic commission in the Kanton Thurgau, Dr. Rainer Andermatten, will be contacted before the tests of May 22.

Every proband in Switzerland has to sign a translation of the letter of informed consent that has been outlined in the logbook. It has to be clarified if a sentence like "Es können besonders schützenswerte Daten weitergegeben werden an ein Forschungsunternehmen, das Mitglied des Konsortiums von

ironHand ist." needs to be included in the informed consent. Thus probands have the possibility to reflect on whom they entrust their data before they take part.

6 Appendix 1

6.1 Usability test

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 (1L) 0,5 meters to the right
5. Open the bottle of water
6. Put some water in a glass
7. Close the bottle of water
8. Take a sip of water

9. Turn on the computer
10. Select the iH software program
11. Start the calibration session
12. Select a game
13. Play the game
14. Close the game
15. Close the iH software program
16. Turn off the computer

17. Turn off the iH system
18. Remove the glove from the hand

6.2 The activities of daily life based on real life situations

- (semi)-controlled environment in the laboratory in a skills lab-setting
- Observation of functional tasks consisting of real life situations
    - 2 sessions
    - Day 1: Usability test, session 1
    - Day 2: session 2, user acceptance
- Supervision of the researchers
    - Time

- Observation by video (e.g. which hand is used for the heavy stuff, movement is performed slow, fluidity, lack of precision, compensatory movements)
- The participants will practise the functional tasks with the glove three times and only the last one will be used for analysis.

- The different functional tasks:
  - Scenario 1 – Eating/drinking
    1. Grab a carton of jus d'Orange (1L)
    2. Take a glass
    3. Open the carton of jus d'Orange
    4. Pour jus d'Orange in the glass
    5. Drink the jus d'Orange
    6. Put the carton of jus d'Orange back on the table
  - Scenario 2 – Eating/drinking
    1. Take out a cucumber
    2. Prepare and cut the food
    3. Eat it
  - Scenario 3 – Household chores
    1. Take down a cloth
    2. Make the cloth (wet)
    3. Wring the cloth
    4. Clean the table
    5. Throw the cloth in the laundry
  - Scenario 4 – Reading and writing
    1. Take down a book from the bookshelf
    2. Open the book
    3. Read 30 seconds in the book
    4. Place the book on the table
    5. Write down the last sentence of the first page
    6. Close the book
    7. Bring the book back to the bookshelf
  - Scenario 5 – Dressing/undressing
    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 and shelf

- Scenario 6 - Open the door
  - 1. Take the key
  - 2. Put the key in the door
  - 3. Open the door
  - 4. Close the door
  - 5. Lock the door

6.3 Subject characteristics - Part 1

Date (of inclusion)		..... - ..... - .....
Name		
Address	Street + nr.	
	Postal code	
	City	
Telephone number		Home: Mobile:
E-mail address		
Subject code		
Bank account number		
Km travel per visit		
Notes		

6.4 Subject characteristics - Part 2

Subject code	
Sex	Male / Female
Date of birth	..... - ..... - .....
Age at inclusion	..... years
Impairment/Pathology	
Time since impairment	..... months
Most-affected body side	left / right
Dominant side before impairment	left / right
Weight	..... kg
Height	..... cm
Notes	

6.5 Subject characteristics - metrics

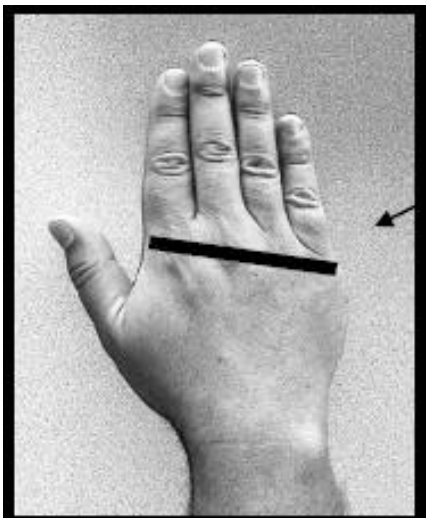
You will need a tape measure to complete this form. Please refer to the measuring instructions below. Measure the metrics below on the most-affected hand.

Subject code: .....

Affected arm: Left / Right

1) Then, lay your hand flat on a table. Place the tape measure **STRAIGHT ACROSS,** just below the knuckles and record the width of the hand **in millimeters**. **DO NOT WRAP THE TAPE AROUND THE HAND.**

Width of the hand.....mm



2) And just to be sure, measure also the complete finger lengths (from MCP to end of finger/thumb):

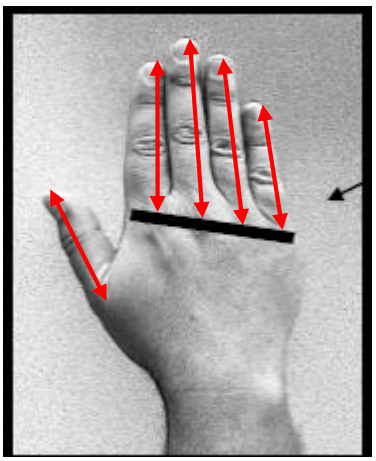
Thumb .....mm

Index .....mm

Middle .....mm

Ring .....mm

Little .....mm



This means the best glove size will be:.....

6.6 System Usability Scale

The System Usability Scale (SUS) is a short questionnaire used for usability research to test the usability of a system. In this case, the usability of the iH system will be tested. Please indicate for each statement below how much you agree with that statement, based on a scale from 1 (strongly disagree) to 5 (strongly agree). Encircle the answer which best suites your opinion. Record your immediate response to each item, rather than thinking about items for a long time.

Subject code:	
Date:	
Measurement (study week):	
Name researcher:	

	STRONGLY DISAGREE				STRONGLY AGREE
1) I think that I would like to use this iH system frequently.	1	2	3	4	5
2) I found the iH system unnecessarily complex.	1	2	3	4	5
3) I thought the iH 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 iH system.	1	2	3	4	5
5) I found the various functions in this iH system were well integrated.	1	2	3	4	5
6) I thought there was too much inconsistency in this iH system.	1	2	3	4	5
7) I would imagine that most people would learn to use this iH system very quickly.	1	2	3	4	5
8) I found the iH system very cumbersome to use.	1	2	3	4	5
9) I felt very confident using the iH system.	1	2	3	4	5
10)I needed to learn a lot of things before I could get going with this iH system.	1	2	3	4	5

6.7 Intrinsic Motivation Inventory

Subject code:	
Date:	
Measurement (study week):	
Name researcher:	

Below are listed 34 items about your experience with the iH system. For each of the following statements, please indicate how true it is for you by putting a cross in the correct square. Use the following scale:

1	2	3	4	5	6	7
Not at all true			*Somewhat true*			*Very true*

A	Question	1	2	3	4	5	6	7
1	The use of the iH system did not hold my attention at all.							
2	I would describe the iH system as very interesting.							
3	While I was using the iH system, I was thinking about how much I enjoyed it.							
4	I enjoyed using the iH system very much.							
5	I thought this was a boring iH system.							
6	I thought the iH system was quite enjoyable.							
7	The training with the iH system was fun to do.							

B	Question	1	2	3	4	5	6	7
1	After using the iH system for a while, I felt pretty competent.							
2	This was a training with the iH system that I couldn't do very well.							
3	I think I did pretty well at using the iH system, compared to other subjects (other stroke patients of my age and same sex).							
4	I think I am pretty good at this training with the iH system.							
5	I am satisfied with my performance at this training with the iH system.							
6	I was pretty skilled at this training with the iH system.							

1	2	3	4	5	6	7
Not at all true			*Somewhat true*			*Very true*

C	Question	1	2	3	4	5	6	7
1	It was important to me to do well at the training with the iH system.							
2	I didn't try very hard to do well at the training with the iH system.							
3	I didn't put much energy into the iH system.							
4	I put a lot of effort into the iH system.							
5	I tried very hard on the training with the iH system.							

D	Question	1	2	3	4	5	6	7
1	I didn't really have a choice about using the iH system.							
2	I believe I had some choice about using the iH system.							
3	I used the iH system because I had to.							
4	I felt like I had to use the iH system.							
5	I used the iH system because I had no choice.							
6	I felt like it was not my own choice to use the iH system.							
7	I used the iH system because I wanted to.							

E	Question	1	2	3	4	5	6	7
1	I was very relaxed in using the iH system.							
2	I felt very tense while using the iH system.							
3	I felt pressured during training with the iH system.							
4	I did not feel nervous at all while using the iH system.							
5	I was anxious while using the iH system.							

F	Question	1	2	3	4	5	6	7
1	I would be willing to use the iH system again because it has some value to me.							
2	I think using the iH system is important.							
3	I believe using the iH system could be beneficial to me.							
4	I believe that the iH system could be of some value to me.							

6.8 Semi-structured interview about user experience - guide

This interview should be video-recorded.

Subject code:	
Date:	
Measurement (study week):	
Name researcher:	

1) What do you think about the ironHand system and the support it delivered?

.....

.....

.....

.....

2) How was it to put on/put out the ironHand system?

- Was it easy or hard?
- Did you manage it by yourself?
- What was it that made it difficult to put the glove on? Suggestions for improvement?

.....

.....

.....

.....

3) What do you think about the ease of use of the system?

.....

.....

.....

.....

4) **What do you think about the technological function and the reliability of the system?**

- Did you run into any technical problems during use of the device?
- If yes:
    - Which problems?
    - How did you experience this? (how was this for you?)
        - e.g. was it very inconvenient?
        - Did technical problems influence the time you spent using the system?

.....

.....

.....

.....

5) **What do you think about the possibility to get support of the ironHand system during activities of daily life at home?**

.....

.....

.....

.....

6) **What do you think about the possibility of performing exercises in a familiar place at home without the presence of your therapist compared with doing the exercises in a clinical setting?**

- Do you think you miss/need the presence of a real person during training?
- What about the scheduling of training: like to prefer to have it scheduled (fixed time) or choose own training time (and duration)?
- Preference of specific day/time to train?

.....

.....

.....

.....

7) **What do you think about the possibility of having the responsibility of the rehabilitation of your hand by yourself, if you could train independently using this system?**

- What do you think about doing exercises on your own (without a therapist present)?
- Do you feel the need to share your results with an health care professional?

.....

.....

.....

.....

8) **Do you have any specific goals that you want to achieve? Could the ironHand system assist you to achieve those goals? In what way?**

.....

.....

.....

.....

9) **Do you think that you need to involve your carer (if you have one) when using the ironHand system? Do they need to assist you in any way? If so/not, could you please explain why?**

.....

.....

.....

.....

10) **Do you think that the ironHand system fits into your physical, personal and social environment?**

.....

.....

.....

.....

11) **Overall, what were the best things about the prototype?**

.....

.....

.....

.....

- The support from the glove

.....

.....

.....

- Games/exercises

.....

.....

.....

12) Overall, what were the worst things about the prototype? So what needs most improvements?

.....

.....

.....

.....

- The glove

.....

.....

.....

- Games

.....

.....

.....

13) Would you like to add anything else to our talk?

.....

.....

.....

.....

6.9 Jebsen-Taylor Hand Function Test

Materials: the JTHFT-kit, stopwatch, table and chair (with backside, preferably without armrests).

In the ironHand project, the JTHFT test will measure a) fine motor skills; (b) weighted functional tasks; and (c) non-weighted functional tasks [36]. The JTHFT consist of the following 7 tasks:

- Writing a short sentence (24 letters, 3rd grade reading difficulty)
- Turning over a 3x5 inch card
- Picking up small common objects (e.g., paper clips, coins and bottle caps)
- Simulated feeding (e.g. teaspoon with beans)
- Stacking checkers (test of eye-hand coordination)
- Picking up large light cans (e.g. empty cans)
- Picking up large heavy cans (450 g)

The JTHFT tasks are performed according to the instructions of Jebsen et al. 1969 [36].

The subject sits close to the table and the trunk must remain in contact with the back of the chair throughout testing. The distance between the subject and the activity should be a comfortable distance. The non-dominant hand will be tested first, followed by the dominant hand.

The time of each different task will be recorded in seconds and all times summed is the total score for the test. The participant will start after the researcher count up to 3 and in the meantime the researcher starts the stopwatch. The researcher stops the stopwatch when the subject finished the activity.

Number	Test	Time (seconds) Non-dominant	Time (seconds) dominant
1	Writing a short sentence		
2	Turning over a 3x5 inch card		
3	Picking up small common objects		
4	Simulated feeding		
5	Stacking checkers		
6	Picking up large light cans		
7	Picking up large heavy cans		
	Total score		

6.10 Box and Block test

Materials: Box and Blocks kit with 150 blocks.

The participant can practice for 15 seconds before the test will start. After practicing, the participant will be instructed by the researcher before the test will start. Before the start of the test, the participant will put his/her hands at one side of the box. The participants needs to transfer as many as possible blocks with his/her dominant hand from one box to the adjacent box. It is only allowed to transport one block at the time. The researcher will count the amount of transferred blocks after one minute. Thereafter, the test will be done with the non-dominant hand [35].

Subject code: _____

Dominant hand: right / left

Dominant Hand: _____ Non-Dominant Hand: _____

Dominant Hand: _____ Non-Dominant Hand: _____

Dominant Hand: _____ Non-Dominant Hand: _____