The ironHand system integrates both support in ADL and functional training exercises to improve impaired hand function

Published: 09-06-2016
Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43234

Source
ToetsingOnline

Brief title
A robotic glove that supports ADL and therapeutic exercises

Condition

- Other condition
- Neuromuscular disorders
- Age related factors

Synonym
Ageing, Elderly

Health condition

Handfunctie problemen bij veroudering en acute en chronische aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: Ambient Assistant Living Joint Program Call 6

Intervention

Keyword: arm/hand function, Assistive technology, robotics, training device

Outcome measures

Primary outcome

The primary study parameter is the Jebsen-Taylor Hand Function Test

Secondary outcome

Secundairy study parameters are outcomes related to user acceptance, changes in

hand motor function, actual use and potential impact on quality of life (QoL)

Study description

Background summary

Elderly people and patients with acute (e.g. stroke) or chronic (e.g. arthritis) diseases frequently experience difficulties in 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. By integrating both an assistive robotic device with exercise training, performance of ADL can be enhanced directly and/or via an improved arm and hand function after prolonged use of the hands.

Study objective

The primary objective of the present study is to examine the orthotic and therapeutic effect of the ironHand (iH) system, consisting of both an assistive and therapeutic module, by elderly and diagnosed patients with hand function problems, after using the iH system for a four weeks training period at home. Secondary objectives are related to user acceptance, including usability, satisfaction, motivation and compliance.

Study design

A randomized controlled trial design will be conducted, in which both the elderly and patient population will be randomized into three groups; the iH assistive group, the iH therapeutic group and the control group. Evaluation is based on one baseline measurement and one evaluation measurement within one week after the intervention period of four weeks

Intervention

The intervention period for all three groups will last for a period of four weeks. The iH assistive group will use the wearable robotic device during ADL at home and the therapeutic iH group will use the wearable robotic device as a training tool using games via the patient user interface. Participants of the control group do not follow an intervention program. In the iH assistive group, participants are recommended to use the wearable robotic device for 180 minutes a week during ADL at home. The participants in the iH therapeutic group are recommended to train the hand 3 times a week for 60 minutes by performing game exercises while wearing the robotic device to support hand opening and strength and to control the game exercises on a screen. During the four weeks intervention period, all three groups will be monitored by a therapist.

Study burden and risks

The iH system may have a beneficial effect on hand function, by directly improving functional task performance or by using it as a training tool. It may be possible that the functional use of the hand improves, allowing people to be more active in ADL and to maintain or improve their health status. 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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, the elderly population 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;In order to be eligible to participate in this study, the patient population must meet all of the following criteria:
*Patients with hand function problems who are clinically diagnosed by a physician with for example stroke (unilateral ischemic or hemorrhagic stroke) or rheumatoid arthritis
*Patients over the age of 55 years

*Time since onset of disease is at least 6 months
*Discharged from specific arm/hand therapy
*Absence of severe spasticity of the hand (*2 points on Ashworth Scale) ;In order to be eligible to participate in this study, both population groups must meet all of the following criteria:
*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 PIP
*Sufficient cognitive status to understand two-step instructions
*Having (corrected to) normal vision
*Living at home
*Provided written informed consent

Exclusion criteria

A potential subject of either study population who meets any of the following criteria will be excluded from participation in the study in the case of:
* Severe sensory problems of the most-affected hand
* Severe acute pain of the most-affected hand
* Participation in other studies that can affect functional performance of the arm and hand
* Insufficient knowledge of the Dutch language to understand the purpose or methods of the study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-08-2016
Enrollment:	42

Type:	Actual

Medical products/devices used

Generic name:	Robot assisted arm/hand function
Registration:	No

Ethics review

Approved WMO Date:	09-06-2016
Application type:	First submission
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27134
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL56746.044.16
Other	NTR (in aanvraag)
OMON	NL-OMON27134