A robotic glove that supports ADL and therapeutic exercises

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27134

Bron
Nationaal Trial Register

Verkorte titel
ironHand

Aandoening

elderly, stroke patients, impaired hand function, assistive technology, robotics, training device

Ondersteuning

Primaire sponsor: Roessingh Research and Development
National Foundation for the Elderly
Overige ondersteuning: This study is partly funded by the Ambient Assisted Living joint programme (grant AAL-2013-6-134) via ZonMw (the Netherlands).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

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.

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.

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.

In total, twenty-seven elderly and fifteen stroke patients, with an age over 55 years, will participate in this study.

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.

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Before the intervention period and within one week after the intervention period an evaluation session will be performed.

Onderzoeksproduct en/of interventie

Participants of both the elderly and patient population (via two separate randomization procedures) will be randomized into three equal groups. Group 1 will use the iH assistive system (AS) during ADL at home (iH assistive group), group 2 will use the iH therapeutic system (TS) as a training tool at home (iH therapeutic group) and group 3 will not perform any intervention at home (control group) during the intervention period of four weeks.

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.

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

- 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

the stroke population must meet all of the following criteria:

- Patients with hand function problems who are clinically diagnosed by a physician with stroke (unilateral ischemic or hemorrhagic stroke)

- 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)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2016
Aantal proefpersonen:	42
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-06-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43234
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5743
NTR-old	NTR5897
CCMO	NL56746.044.16
OMON	NL-OMON43234

Resultaten