Influence of a wearable soft robotic glove on functional ability of the arm/hand in stroke patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON43981

Source
ToetsingOnline

Brief title
A soft robotic glove supporting hand function after stroke

Condition

- Central nervous system vascular disorders

Synonym
cerebrovascular accident, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: eigen financiering

Intervention

Keyword: arm/hand function, robotics, stroke, wearable support

Outcome measures

Primary outcome

The main study parameters are outcomes related to user acceptance (System Usability Scale) in the usability study and functional hand performance in ADL (Action Research Arm Test) in the effect study.

Secondary outcome

Secundary study parameters are related to user acceptance, perceived use, amount of use, changes in hand motor function and impact on quality of life.

Study description

Background summary

The upper limb is one of the most frequently affected parts in stroke patients. Since upper limb function is essential to perform independent activities of daily life (ADL), the recovery of both arm and hand function is an important goal in stroke rehabilitation. To stimulate the recovery of arm and hand function, the rehabilitation of stroke patients should consist of high-intensity, task-specific and functional exercises with active contribution of the patient. New technological innovations can support functional performance of the arms and hands directly by a wearable robotic device assisting a person*s own function, which is expected to enhance functional independence. Even more, with such wearable devices for daily use of the arms and hands, a large variety of functional activities is enabled, turning everyday activities into extensive training, independent from the availability of healthcare providers. In this way, it is even conceivable that arm and hand function may improve after prolonged use of such an assisting device

Study objective

The primary objective of this study is to explore user acceptance of the HiM system in the usability study and to examine changes in functional use of the hand during ADL after prolonged use of a wearable robotic device by stroke

patients in the intervention study.. Secondary objectives are to examine actual use and the impact on quality of life of such a wearable robotic device in stroke patients. Furthermore, we will compare the effect of prolonged use of the device in ADL at home with applying the HiM system as a training tool in a clinical setting.

Study design

The study will consist of both a usability study and a randomized prospective intervention study (clinical trial).

Intervention

In the usability study, the stroke patients 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 the effect study, one group (experimental group 1) will use the wearable robotic device during ADL at home and the other group (experimental group 2) will use the wearable robotic device combined with Inertial Motion Units (IMUs) as a training tool only in a clinical setting, both for 6 weeks. In experimental group 1, chronic stroke patients are recommended to use the wearable robotic device for 180 minutes a week during ADL at home. The chronic stroke patients in experimental group 2 will receive game exercises training for the hand and arm 3 times a week 60 minutes while wearing the robotic device to support hand opening and strength. The glove and IMUs control the hand and arm movements of the game exercises on a screen. Experimental group 2 will also get to opportunity to use the wearable robotic device during ADL at home in the last week (week 6) in addition to their training in-clinic.

Study burden and risks

The wearable robotic device might have a beneficial effect on hand function. It might 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 major research question addressed in this study.
The risks for the subjects are limited to a minimum. The wearable robotic device 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 wearable robotic device 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. Furthermore, in case of the training group,

there will be supervision by a therapist. In case of the home use group, remote monitoring is in place in addition to multiple contact moments between user and researchers, to make sure the participant is doing well. 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

* Patients should be clinically diagnosed with unilateral ischemic or hemorrhagic stroke
* Between 18-80 years of age
* 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 severe contractures limiting passive range of motion.
* Absence of co-morbidities limiting functional use of the arms/hands.
* People should have at least 10 degrees of active flexion and extension of the fingers.
* Absence of wounds on their hands that can give a problem when using the glove.
* Sufficient cognitive status to understand two-step instructions.
* Having (corrected to) normal vision.
* Living at home.
* Provided written informed consent.

Exclusion criteria

* People with severe sensory problems of the affected hand.
* People with severe acute pain of the 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.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-04-2015
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Robot-assisted arm/hand training
Registration:	No

Ethics review

Approved WMO Date:	16-03-2015
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	24-05-2016
Application type:	Amendment
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: 25281
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51270.044.14
OMON	NL-OMON25281