Invloed van robotische handschoen op functioneren van de arm- en handfunctie van patiënten die een beroerte door hebben gemaakt

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25281

Source
Nationaal Trial Register

Brief title
A soft robotic glove supporting hand function after stroke

Health condition

English: stroke, CVA, arm function, hand function
Nederlands: beroerte, armfunctie, handfunctie

Sponsors and support

Primary sponsor: Roessingh Research and Development (Enschede, the Netherlands)
Source(s) of monetary or material Support: Self financing

Intervention

Outcome measures

Primary outcome

The main study parameters are outcomes related to functional hand performance in ADL.

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

Background of the study:

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

Objective of the study:

The primary objective of this study is to examine changes in functional use of the hand during ADL after prolonged use of a wearable robotic device by stroke patients. We will compare the effect of prolonged use of the device in ADL at home with applying the device as a training tool in a clinical setting. Secondary objectives are to examine user acceptance, actual use and the impact on quality of life of such a wearable robotic device in stroke patients.

Study design:

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

Study population:

In total, maximal ten chronic stroke patients, with an age between 18-80 years, will participate in this study.

Intervention (if applicable):

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 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 3 times a week 60 minutes while wearing the robotic device to support hand opening and strength and to control the game exercises on a screen.

Primary study parameters/outcome of the study:

The main study parameters are outcomes related to functional hand performance in ADL.

Secundary study parameters/outcome of the study (if applicable):

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

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):

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.

Study objective

The expectation is that the wearable robotic device, which assists a person’s own function, will 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 design

There will be 2 evaluations: at baseline (E0) and post-training (E1)

Intervention

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 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 3 times a week 60 minutes while wearing the robotic device to support hand opening and strength and to control the game exercises on a screen.

Contacts

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Eligibility criteria

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
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2015
Enrollment:	10
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 43981
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4600
NTR-old	NTR4854
CCMO	NL51270.044.14
OMON	NL-OMON43981

Study results

Summary results

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