Influence of a robotic glove on movement execution of stroke patients during reaching and grasping

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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-OMON43175

Source
ToetsingOnline

Brief title
Influence of robotic glove on reaching and grasping in stroke

Condition

- Central nervous system vascular disorders

Synonym
CVA, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: ADL, Assistive Technology, Soft robotics, Stroke, Upper Extremity

Outcome measures

Primary outcome

The main study parameters are outcomes related to (functional) task performance and movement execution. To examine the direct influence of the grasp support system on (functional) performance of the most-affected arm and hand during the different proposed conditions, the following main study parameters will be measured:

* Qualitative observations of functional task performance and movement execution (e.g. speed of movement, precision, fluidity, compensatory movements)
* Quantitative parameters of functional task performance and movement execution (e.g. performance time, kinematics of hand and arm joints, movement path, velocity (profile), acceleration and jerk)

Secondary outcome

To explore user acceptance of the grasp support system and to examine the direct effect of the grasp support system on changes in hand strength and movement execution, the following parameters will be registered during the measurements:

* System Usability Scale (SUS)
* Semi-structured interview about user*s experience
* Action Research Arm Test (ARAT)
* Maximal pinch force (Jamar pinch Gauge dynamometer)

Study description

Background summary

Stroke survivors 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.

Study objective

The primary objective of this study is to examine the direct influence of the grasp support system on (functional) performance and movement execution of the most-affected arm and hand. Secondary objectives are to examine the direct effect of the grasp support system on hand strength and to explore user acceptance of the grasp support system.

Study design

This observational, cross-sectional study will consist of one visit.

Intervention

Stroke survivors will perform several hand function tasks and clinical tasks with and without the wearable robotic device to assess the direct influence of the device on functional task performance, ability to perform functional tasks and user acceptance.

Study burden and risks

The grasp support 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 grasp support 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 grasp support 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

* 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 three months
* 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

* Provided written informed consent

Exclusion criteria

* People with severe sensory problems of the affected upper extremity
* People with severe acute pain of the affected arm
* People who participate 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
* People with severe contractures limiting passive range of motion
* People with co-morbidities limiting functional use of the hand
* People with wounds on their hand that can give a problem when using the system

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):	28-11-2016
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Wearable soft-robotic glove
Registration:	No

Ethics review

Approved WMO Date:	28-10-2016
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: 20620
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL58778.044.16
Other	Wordt nog aangemeld bij NTR
OMON	NL-OMON20789
OMON	NL-OMON20620