Feasibility of the Supervised Care & Rehabilitation Involving Personal Tele-Robotics active-actuated arm/hand training system at home after chronic stroke

Published: 04-03-2014
Last updated: 20-04-2024

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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-OMON41182

Source
ToetsingOnline

Brief title
Post-stroke active-actuated arm/hand training at home

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: Europese Unie (the 7th Framework Programme)

Intervention

Keyword: Arm/hand function, Robotics, Stroke, Telerehabilitation

Outcome measures

Primary outcome

Main study parameters are outcomes related to user acceptance, including usability, satisfaction, motivation and compliance (Training duration, Intrinsic Motivation Inventory, System Usability Scale, and a semi-structured interview about user experience).

Secondary outcome

Measures to examine general motor function, perceived use and participation (The Action Research Arm Test (ARAT), the upper extremity part of the Fugl-Meyer (FM) test, Motor Activity Log (MAL), the Stroke Impact Scale (SIS), adapted Nine Hole Peg Test (NHPT) and kinematics).

Study description

Background summary

After experiencing a stroke, the majority of people have to cope with impaired arm and hand function. Post-stroke rehabilitation training aims to regain arm and hand motor function, which is essential to perform most activities of daily living (ADL) independently. To stimulate restoration of arm function after stroke, intensive, task-specific training with active contribution of the patient is essential. The application of robotics in rehabilitation to promote this repetitive training is promising. Most research involving robotics so far has demonstrated significant improvement in upper limb motor function by

participants, but limited studies have showed improvements in ADL. In the SCRIPT2 project we are developing robotic technologies for home rehabilitation to enable self-administration of more intense and more frequent exercises, specifically of the hand and wrist with the goal of contributing to the personal independence of stroke patients.

Study objective

The primary objective of this study is to examine user acceptance after technology-supported arm/hand training using the active-actuated orthosis at home by chronic stroke patients. Secondary objectives are to examine whether stroke patients increase their total amount of practice when provided with the opportunity, examine if (additional) training enhances changes in arm/hand function and to explore which factors contribute to this. In addition, we will examine differences in orthotic effect between passive and active versions of arm/hand support on movement performance and motor control.

Study design

This explorative feasibility study has a longitudinal design. Evaluation is based on one baseline measurement pre-training, and one evaluation measurements within one week post training.

Intervention

Subjects will be recommended to exercise 180 minutes per week (6 days, 30 minutes/day) with the SCRIPT2 system at home, during 6 weeks. They will train their arm and hand using games via the patient user interface, while wearing an active-actuated orthosis which supports wrist extension and hand opening, and wearing the SaeboMAS for gravity compensation of the proximal arm. During the six weeks of training, they will be remotely supervised, off-line, by a therapist.

Study burden and risks

Participation in this study can provide an immediate benefit for the subject, in providing the opportunity for additional, self directed rehabilitation of the affected arm and hand. The extent of this benefit cannot be predicted, obtaining these insights is one of the purposes of this study.
The risks for the subjects are minimum, since the movement tasks consist of functional and familiar arm and hand movements and are performed within the ability of the subject, while he/she is seated. During training, subjects will wear the SCRIPT2 active-actuated orthosis. This is an exoskeleton which interacts with the human body by providing forces to the wrist and hand through springs in series with small servo motors in a series-elastic actuation (SEA) configuration. The joint torque is controlled and limited to prevent excessive,

forced movements. The device has several safety stops and it can only operate within safe movement and force range for the individual user. The amount of support can be adjusted to provide more or less offset force to wrist or finger extension. The available power in the actuator is limited, it can produce at most 0.3Nm, which is not sufficient to cause severe injuries. Besides, patients are not able to change the amount of support by themselves. The torque will only be adjusted by an experienced HCP over rehabilitation sessions, based on the patient*s progress as monitored by the system and observed during weekly home visits.
The recommended training sessions will be spread throughout the week to minimise the burden for the subjects. Besides, the subjects will be monitored by a HCP for signs of overloading. In addition, the outcome measurements used in this study during the evaluation measurements (movement analysis, functional scales) are all non-invasive and involve no risk for the subjects.

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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 with an unilateral ischemic or haemorrhagic stroke, between 6 months and 5 years post-stroke
* Between 18 and 80 years of age
* Clinically diagnosed with central paresis of the arm and/or hand as a result of stroke, but with:
- 15° active elbow flexion
- * range of active finger movement (PIP/DIP)
* Ability to complete measurements and training sessions
* Discharged from medical centre
* Living at home and have internet access
* Having a carer who is co-resident or closely involved in their care
* A fair cognitive level: ability to read and understand the Dutch language, and ability to understand and follow instructions
* Patients should fit the device: 5-95% size of hand and body shape
* Written informed consent to participate in the study

Exclusion criteria

* Patients who are not eligible to join normal rehabilitation (psychological issues, patients with near complete paralysis etc.)
* Other severe co-morbidities, like cardiovascular, neurological, orthopaedic or rheumatoid impairments (incl. pain affecting use of the upper extremity) before stroke that may interfere with task performance
* Severe sensory deficits from the involved limb
* Severe neglect
* Visual impairments (that cannot be corrected with glasses or contact lenses to within normal or near normal limits)
* Cognitive impairments

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):	21-08-2014
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	Technology-assisted arm and hand training
Registration:	No

Ethics review

Approved WMO

Date:	04-03-2014
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

No registrations found.

In other registers

Register	ID
CCMO	NL47904.044.14
Other	Volgt na toestemming METC