Feasibility of Supervised Care & Rehabilitation Involving Personal Tele-robotics for arm/hand function of chronic 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-OMON39741

Source
ToetsingOnline

Brief title
Post-stroke 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, Tele-rehabilitation

Outcome measures

Primary outcome

Main study parameters are outcomes related to user acceptance, including usability, satisfaction, motivation and compliance (Intrinsic Motivation Inventory, System Usability Scale, Qualitative interview about experience of use).

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, the Box & Blocks test (BBT), Motor Activity Log (MAL), the Stroke Impact Scale (SIS), kinematics and EMG).

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 SCRIPT 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 and assess changes in arm function by people with chronic stroke following technology-supported arm/hand training at home.
Secondary objectives are to examine whether stroke patients increase their total amount of practice when provided with the opportunity, examine if this additional training enhances changes in arm/hand function and explore which factors contribute to this. We also intend to examine whether technology-supported arm/hand training at home results in comparable improvements to that observed after conventional training.

Study design

This explorative feasibility study has a longitudinal design with an experimental group and a control group. Evaluation is based on one baseline measurement pre-training and two evaluation measurements post-training (within one week and follow-up after two months).

Intervention

During six weeks, the chronic stroke patients will receive either 18 one hour sessions, plus additional training when desired, of technology assisted arm and hand home training (experimental group), or conventional home training (control group). For the experimental group, training consists of arm and hand exercises conducted while undertaking computerised games, wearing the SCRIPT hand device to support hand opening, and wearing the SaeboMAS for gravity compensation of the proximal arm. The training for the control group consists of standard arm and hand exercises.

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. Subjects in the experimental groups will wear a fully passive device with only springs. This is an inherently safe device because the subject cannot be forced into a position he/she cannot achieve by him/herself. 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. This will be based on questions on pain, fatigue, motivation etc. asked after each training session. 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.

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 with an unilateral ischemic or hemorrhagic 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 flexion (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
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-03-2013

Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Technology-assisted arm and hand training
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-01-2013
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	23-05-2013
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

No registrations found.

In other registers

Register	ID
CCMO	NL42483.044.12