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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22517

Source
NTR

Brief title
SCRIPTSE2

Health condition

Stroke, Beroerte

Sponsors and support

Primary sponsor: Roessingh Research and Development b.v.
Source(s) of monetary or material Support: European Commission, Seventh Framework Programme

Intervention

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), an adapted version of the Nine Hole Peg Test NHPT) and kinematics).

Study description

Background summary

Rationale:
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.

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 pretraining, and one evaluation measurements within one week post training.

Study population:
Twelve chronic stroke patients will participate in the study. Six will participate in the training study, and 6 participants will only participate in the T01 measurement. Subjects should have reasonable ability to control the proximal arm, and have some extent of hand function.

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.

Main study parameters/endpoints:
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).

Study objective

We hypothesize that the SCRIPT2 training will be accepted, and that the subjects will be able to use the SCRIPT2 system independently. Also, subjects will show improved arm and hand function over the six weeks of training.

Study 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 a 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.

Contacts

Public
Roessingh Research and Development
P.O. Box 310
Sharon Nijenhuis
Roessinghsbleekweg 33b
Enschede 7500 AH
The Netherlands
+31 (0)53 4875766

Scientific
Roessingh Research and Development
P.O. Box 310
Sharon Nijenhuis
Roessinghsbleekweg 33b
Enschede 7500 AH
The Netherlands
+31 (0)53 4875766

Eligibility criteria

Inclusion criteria

1. Patients with an unilateral ischemic or hemorrhagic stroke, between 6 and 12 months post-stroke
2. Between 18 and 80 years of age
3. Clinically diagnosed with central paresis of the arm and/or hand as a result of stroke, but with
A. 15° active elbow flexion
B. ¼ range of active finger flexion (PIP/DIP)
4. Ability to complete measurements and training sessions
5. Discharged from medical centre
6. Living at home and have internet access
7. Having a carer who is co-resident or closely involved in their care
8. A fair cognitive level: ability to read and understand the Dutch language, and ability to understand and follow instructions
9. Patients should fit the device: 5-95% size of hand and body shape
10. Written informed consent to participate in the study

Exclusion criteria

1. Patients who are not eligible to join normal rehabilitation (psychological issues, patients with near complete paralysis etc.)
2. 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
3. Severe sensory deficits from the involved limb
4. Severe neglect
5. Visual impairments (that cannot be corrected with glasses or contact lenses to within normal or near normal limits)
6. Cognitive impairment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2014
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-04-2014
Application type:	First submission

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
NTR-new	NL4251
NTR-old	NTR4489
Other	: 47904 ABR

Study results