Post-stroke arm/hand training at home.

No registrations found.

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

Summary

ID

NL-OMON29571

Source
Nationaal Trial Register

Brief title
SCRIPTSE1

Health condition

Stroke, CVA, beroerte

Sponsors and support

Primary sponsor: Roessingh Research and Development b.v.
Source(s) of monetary or material Support: The SCRIPT project is partly funded by the European Commission under the 7th Framework Programme.

Intervention

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

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 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.

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).

Study population:

Twenty chronic stroke patients will participate in the study (10 experimental, 10 control). Subjects should have reasonable ability to control the proximal arm, and have some extent of hand function.

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.

Main study parameters/endpoints:

Main study parameters are outcomes related to user acceptance, including usability, satisfaction, motivation and compliance.

Study objective

Patients who will train with the SCRIPT-system will have similar or improved arm and hand function in comparison with the patients who receive conventional arm and hand exercises.

Study design

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.

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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 receive additional therapy of the affected arm/wrist/hand during participation of the study;

2. Patients who are not eligible to join normal rehabilitation (psychological issues, patients with near complete paralysis etc.);

3. 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;

4. Severe sensory deficits from the involved limb;

5. Severe neglect;

6. Visual impairments (that cannot be corrected with glasses or contact lenses to within normal or near normal limits);

7. Cognitive impairment.

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):	01-01-2013
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-10-2012
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	NL3487
NTR-old	NTR3669
Other	ABR : 42483
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A