

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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22517

Bron

NTR

Verkorte titel

SCRIPTSE2

Aandoening

Stroke, Beroerte

Ondersteuning

Primaire sponsor: Roessingh Research and Development b.v.

Overige ondersteuning: European Commission, Seventh Framework Programme

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

Evaluation is based on one baseline measurement pre-training, and one evaluation measurements within one week post-training.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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. $\frac{1}{4}$ 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-04-2014
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	04-04-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register

NTR-new

NTR-old

Ander register

ID

NL4251

NTR4489

: 47904 ABR

Resultaten