Effect of a training regime featuring the I-Travle system on arm function and skill performance in chronic stroke patients: a single arm trial.

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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-OMON38961

Source
ToetsingOnline

Brief title
I-TRAVLE study

Condition

- Central nervous system vascular disorders

Synonym
obstruction of a bloodvessel or bleeding in the brain, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Adelante Kenniscentrum

Source(s) of monetary or material Support: EU;INTERREG-IV grant

Intervention

Keyword: arm skill performance, robotics, stroke, training

Outcome measures

Primary outcome

Wolf Motor Function Test,

ABILHAND,

Goal Attainment Scaling.

Secondary outcome

Motricity index,

plate tapping task,

active range of motion,

perceived strength,

perceived fatigue.

Study description

Background summary

Approx. 80% of acute stroke patients suffer from acute hemiparesis. Stroke patients have not reached their full potential when they are discharged from hospital. It is proven that extra training opportunities lead to further improvement. To date, new training possibilities, such as robotic techniques for rehabilitation, virtual reality training systems and tele-rehabilitation are being developed to aid in the training of stroke patients.

Study objective

The general aim of this single arm trial (Evans S. Clinical Trial Structures. J Exp Stroke Transl Med 2010, 3(1):8-18) will be to obtain preliminary evidence on the efficacy of an individualised, intensive 6-week technology-assisted

training regime, featuring a robotics-based self-adapting arm training system (I-TRAVLE) in a virtual context, focussed on improvement of arm function and arm skill performance in chronic stroke patients with low to moderate proximal (shoulder/arm) muscle strength.

Study design

single arm prospective cohort study

Intervention

Haptic feedback of the I-TRAVLE robot either supports or challenges the patient to perform movements of the arm, thereby training motor control and co-ordination of the affected arm. Also strength and endurance of arm muscle use may be trained. The I-TRAVLE based training will last 6 weeks. Each week participants will attend training sessions on 3 days, during which they will train 2x 30 minutes, interspaced by at least half an hour to avoid (general) fatigue and overuse.

Study burden and risks

The participants may potentially have direct benefit from the project, i.e. the training may lead to functional improvement of the affected arm. However, this training is still under development. All tests and exercises are pain free, easy to perform, non-intrusive, and not high demanding. Subjects will have to undergo an assessment via a movement protocol as well as clinical outcome tests. In both cases the type of assessment does not differ from the normal assessment at a rehabilitation centre. The training is assisted using a robotic device called the Haptic Master (HM). The participant*s arm is attached to the HM via a gimbal. The HM has a number of safety features to avoid overload on the participant*s arm. Any potential risk for overload is minimised by a) careful build-up of the training regime; b) regular check-ups; and c) checking the participant*s status prior to the next training session.

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

o Age >< = 18 years;
o Clinically diagnosed with a central paresis of the arm/hand at entry in the study, caused by a supratentorial stroke;
o Post-stroke time more than 6 months;
o Having completed their active clinical rehabilitation program
o Hemiparesis featuring a low to moderate proximal (shoulder and arm) muscle strength:
* Motricity Index shoulder/arm item: minimum score of 14 and maximum 25 (out of 33), corresponding to a maximum active shoulder abduction of up to 90 degrees without resistance;
and/or
* a minimum active shoulder anteflexion of 30 degrees and a maximum active range of motion of 120 degrees shoulder joint anteflexion which can actively be maintained for 10 seconds;
o a fair cognitive level, i.e. being able to understand the questionnaires and measurement instructions;
o ability to read and understand Dutch.

Exclusion criteria

o Severe spasticity of the arm, i.e. Modified Ashworth Scale (MAS) score for the elbow and wrist flexors: each * 3;
o Severe visual impairment and/or severe cognitive impairment which may interfere with the execution of the arm-hand tasks or the measurements;

o Severe neglect in the near extra personal space, established by the letter cancellation test and Bell*s test (quantitative evaluation) with a minimum omission score of 15%;
o Broca aphasia, Wernicke aphasia, global aphasia: as determined by the Akense Afasie Test (AAT);
o Severe apraxia as measured by the apraxia test of van Heugten;
o no informed consent.

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):	16-12-2013
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	11-09-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
Other	ClinicalTrials.gov: registratienummer volgt nog
CCMO	NL44523.068.13