Development of a remote handling concept based task-oriented arm training in stroke: a pilot study

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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-OMON48028

Source
ToetsingOnline

Brief title
Development of a technology-assisted task-oriented arm training

Condition

- Central nervous system vascular disorders

Synonym
hemiparesis, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Adelante
Source(s) of monetary or material Support: Interreg Euregio Meuse-Rhine program

Intervention

Keyword: Arm-hand-skill-performance, Propriocepsis, Stroke, Technology-assisted training

Outcome measures

Primary outcome

The Action Research Arm Test (ARAT), gauging patients' arm hand skill capacity,

will serve as primary outcome measure in the pilot study.

Secondary outcome

The Fugl-Meyer test (gauging patients' fucntion level), the ABILHAND (gauging

patients' perceived skill performance), movement extent (measured by the remote

handling concept device) and self-perceived performance of activities trained

on by patients (gauged using a visual analogue scale (VAS)) will serve as

secundary outcome measures for the pilot study.

Study description

Background summary

One of the major deficits after a stroke is sensorimotor impairment in the contralateral limb. A majority of these stroke patients has limited use of the affected upper limb. One year after stroke, motor impairment of the upper limb is associated with anxiety, lower perceived health-related quality of life and a reduced subjective well-being. Improving arm-hand skill performance is a major therapeutic target in stroke rehabilitation. However, treatment time and financial resources are limited. In order to solve these problems, new technology is being used to assist training of patients. By using technology-assisted training, arm-hand function training and arm-hand skill training may be augmented both in amount and duration of training as well as in content richness / variety and task specificity, thus providing optimal conditions for challenging the patient*s brain plasticity regarding sensorimotor (re-)learning, yet, at the same time keep the workload for (para-)medical staff and treatment costs manageable.

We developed a new task-oriented arm training approach using a so-called

remote handling concept, to manipulate proprioception, aiming at improvements on the level of activities and participation. This approach is called *Remote Handling concept based, Task-Oriented Arm Training* (acronym: ReHab-TOAT). We hypothesize that, given the brain*s plasticity, proprioception manipulation during task-oriented training may lead to improvements of arm-hand skill performance in stroke patients.

Study objective

The aim of this study is to gauge the feasibility and potential order-of-magnitude the ReHab-TOAT concept may have on improving arm-hand skill performance in both subacute and chronic stroke patients. These data will be used to a) optimize the training protocols and b) calculate the group sizes needed in an envisioned larger RCT aimed at investigating the effectiveness of ReHab-TOAT, that will be performed after this pilot study.
Also patients' experiences and therapists' experiences in using ReHab-TOAT will be gauged, using questionnaires.

Study design

This study features a) a feasibility study, and b) a clinical pilot study involvong subacute and chronic stroke patients.

In the feasibility study part, 5 patients will train with the ReHab-TOAT concept in 2 therapy sessions. Also, 5 therapists will be involved in using the ReHab-TOAT concept. Results may lead to further fine-tuning of the current protocol and will be reported descriptively.

In the pilot study, featuring a (small) prospective cohort study design with pre-post measurements, 5 subacute stroke patients and 5 chronic stroke patients will receive ReHab-TOAT (additionally to therapy-as-usual, where applicable). these data will serve as input for an estimation of the order-of-magnitude any arm-hand skill performance improvement may have. These data will be used for a group size calculation in a large RCT foreseen after this pilot study.

Intervention

Both the stroke patients in the chronic and in the subacute stage after stroke will receive the so-called ReHab-TOAT (Remote Handling Based Task-Oriented Arm Training). ReHab-TOAT contains task-oriented arm training for stroke patients with a moderately to severely affected arm-hand in combination with haptic feedback, generated by a remote handling device called DexterTM (Veolia Nuclear Solutions UK, Didcot, UK). The task-oriented arm-training is based on the T-TOAT method, developed and clinically evaluated in previous research (TEST-TRACS study: CCMO dossier NL23303.022.08). With the haptic feedback generated by the remote handling device, the researchers will manipulate

proprioception, especially during (daily) task/skill execution.

In the feasibility study part, 5 patients will train with the ReHab-TOAT concept in 2 therapy sessions.
During the clinical pilot studies the patients will train for 6 weeks, 3x per week, 1.5hr per day.

Study burden and risks

The risks associated with this study do not surpass the risks associated with regular exercise training methods that are part of the patients regular rehabilitation process. The skills to be performed are every day skills like eating with knife and fork or combing one's hair. The remote handling device may assist the execution of these daily skills by providing additional proprioceptive information, i.e. information on the 'feeling of movement'. This assistance is in the range of several grams to approx. 2-3 kilograms of force.

Restoring arm function (even if this is partial) is essential for a good quality of life of stroke patients. The recovery mainly depends on proper coordination of the intensity of the offered therapy on the patient*s capacity to perform daily skills. The challenge in rehabilitation is to stimulate brain plasticity in such a way that patients become more skilled. Key ingredients of interventions that constitute such a reorganization are: task-specific, goal-oriented and high-intensity of practice. Technology-assisted rehabilitation offers the possibility to patients to train on improving their daily skills in a motivating way for a longer time.

Contacts

Public
Adelante

Zandbergsweg 111
Hoensbroek 6432CC
NL
Scientific
Adelante

Zandbergsweg 111
Hoensbroek 6432CC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Subacute stroke patients:
- An unilateral stroke (ischemic or haemorrhagic) confirmed by brain imaging;
- Post stroke duration between 6 weeks and 3 months;
- Hemiplegic pattern of arm motor impairment with UAT score 1-3;
- Age 18 years or more;
- Sufficient cognitive level, i.e. being able to understand the questionnaires and measurement instructions.

Chronic stroke patients:
- An unilateral stroke (ischemic or haemorrhagic) confirmed by brain imaging;
- Post-stroke time larger than 12 months;
- Hemiplegic pattern of arm motor impairment with UAT score 1-3;
- Age 18 years or more;
- Sufficient cognitive level, i.e. being able to understand the questionnaires and measurement instructions., Healthy subjects (i.e. therapists):
- degree in physiotherapy or occupational therapy;
- experience in treatment of patients with central nervous system deficits.

Exclusion criteria

Subacute and chronic stroke patients:
- Severe non-stroke related co-morbidity that may interfere with arm-hand function.
- Additional complaints that may interfere with the execution of the measurements.
- Severe cognitive problems that prevent the patient from understanding the tasks

- Spasticity in the affected upper limb, i.e. a Modified Ashworth Scale (MAS) score * 1+.
- No informed consent.
Healthy subjects (i.e. therapists):
- Therapists who are not willing to participate in this study.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-05-2020
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	28-10-2019
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL70014.015.19