Remote handling concept based task-oriented arm training (ReHab-TOAT) in chronic stroke: an RCT

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Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON52340

Source
ToetsingOnline

Brief title
ReHab-TOAT in chronic stroke: an RCT

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: Adelante Zorggroep

Intervention

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

Outcome measures

Primary outcome

The primary outcome measure for this RCT is the Brunnstrom-Fugl Meyer Test (BFMT).

Secondary outcome

The secundary outcome measures for the patiens/participants are:

- Action research ARM Test (ARAT);

- Motor Activity Log (MAL);

- Accelerometry / gyroscopy;

- EuroQoL-5D.

In addition, the following questionnaires are administered to the persons from the EXP group for the purpose of evaluating the technology used:

- System Usability Scale (SUS)

- Questionnaire on experience with the technology used.

All patient participants will also be asked a single question gauging the occurrence of any event over the last 2 weeks that may influence the results of the treatment or the measurements (e.g. the patient having had the flu in the past 2 weeks).

Regarding the caregivers, the CarerQoL questionnaire will be administered.

Also a single question gauging the caregiver's amount of care provided to the

patient will be posed.

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 wel]-being. lmproving 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 function training and arm 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. 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 function and arm skill performance, and, ultimately improvement of quality of life in persons in the chronic stage after a stroke. We also assume that, when patients* arm function improves, they may need less (and less frequent) care from caregivers, which may lead to a lower level of perceived burden and improved quality of life in caregivers.

Study objective

The aim of the proposed RCT is to assess the effectiveness of the ReHab-TOAT approach in improving arm function and arm skill performance in daily life tasks in chronic stroke patients with either a severely or moderately affected arm-hand (i.e. with an Utrechtse Arm test (UAT) score between 1-3). We also want to gauge potential changes in patients* and caregivers* perceived quality of life, and assess the patients* perception regarding the usability of the technology used in ReHab-TOAT.

Study design

This randomized clinical trial features two arms (EXP and CONTR). The EXP group will receive a 4 week ReHab-TOAT regime at a frequency of 3 sessions of 1.5 hours per week. This will be additional to any care the participants may receive outside the research context. The EXP group will also receive 1 additional session to familiarize themselves with the training system, prior to the start of the training phase. The CONTR group will not receive additional arm-hand therapy apart from regular *maintenance* therapy, i.e. therapy participants already may receive from therapists in their current home situation (e.g. *1e-lijns* physiotherapy). For participants in both groups any therapy they may potentially receive, will be inventoried and described. In our protocol, no restrictions will be imposed on any (additional) therapies participants currently receive.

The time and extent of care delivered to patients by their caregiver, as well as quality of life of caregivers are also inventoried longitudinally.

Intervention

Participants in the EXP group receive ReHab-TOAT (Remote Handling Based Task-Oriented Arm Training). ReHab-TOAT contains task-oriented arm training for stroke patients in combination with haptic feedback, generated by a remote handling device. They will train for 4 weeks, 3x per week, 1.5hr per day. Participants in the CONTR group will receive no additional arm-hand therapy apart from regular *maintenance* therapy, i.e. therapy they may already receive from therapists in their current home situation (e.g. *1e-lijns* physiotherapy).

Study burden and risks

The present RCT will investigate the effect of ReHab-TOAT, additionally to any therapy as usual, on improving arm function and arm skill performance in chronic stroke patients with a moderately to severely affected arm-hand function, regarding daily upper extremity tasks. It is hypothesized that provision of enriched proprioceptive information during arm-hand skill training in chronic stroke patients may lead to higher levels of arm function and arm skill performance than a) arm function and arm skill performance levels in the CONTR group, and b) pre-treatment levels of arm function and arm skill performance in subjects in the EXP condition. Furthermore, it is hypothesized that these higher levels of arm function and arm skill performance in the EXP group will be maintained across at least a period of 9 months post-intervention, and will be higher during the follow-up period (of 9 months) relative to arm function and arm skill performance levels in the CONTR group.

The patient may benefit from this RCT because we are able to train his/her arm in a more functional way, thereby increasing the chance of reaching a higher level of functional outcome, enabling him to perform his daily activities

better and improving the patient*s quality of life. We also think that reaching a higher level of functional outcome may lead to the burden caregivers may experience in providing care may decrease and their quality of life may increase. There are already several technology-assisted arm-hand training programs that have been evaluated in clinical trials. None of them reported any side effects. In our own pilot study (CCMO code: NL70014.015.19), involving ReHab-TOAT, no adverse events were observed. Furthermore, given the low net forces that will be exerted by the DexterTM on the patient*s arm (i.e. in the order of 0 N - 20 N) during arm activities also performed in daily life, as well as the many safety features installed, the risks in the present study are estimated to be low. Additionally, all measures used in the present RCT pose no harm to the participant. They are also used as regular clinimetrics in rehabilitation.

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

Regarding 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 older;
- Sufficient cognitive level, i.e. being able to understand the questionnaires and measurement instructions.

Regarding patients' caregivers:
- Age 18 years or older;
- providing informal care to stroke patients from the group mentioned above.

Exclusion criteria

Regarding 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;
- Spasticity in the affected upper limb, i.e. a Modified Ashworth Scale (MAS) score >= 1+;
- Severe cognitive problems that prevent the patient from understanding the tasks;
- No informed consent.

Regarding patients' caregivers:
- No informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	13-09-2021
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO Date:	12-07-2021
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	12-07-2022
Application type:	Amendment
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
Other	Netherlands Trial Register: NL9541
CCMO	NL76382.015.21