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

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

Samenvatting

ID

NL-OMON21661

Bron
NTR

Verkorte titel
ReHab-TOAT

Aandoening

Patients in the chronic stage after a stroke

Ondersteuning

Primaire sponsor: Adelante Zorggroep
Overige ondersteuning: Adelante Zorggroep

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Brunnstrom-Fugl Meyer Test:
The BFMT consists of various separate sections. For this study only the section assessing motor function of the arm, wrist and hand is used. The 33 items assess movements, reflexes and coordination of the shoulder, elbow, wrist and hand.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Stroke patients suffer sensorimotor impairments in the contralateral limb, resulting in a limited use of the affected upper limb. 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. We developed a new task-oriented arm training approach using a 'remote handling concept' (ReHab-TOAT), to manipulate proprioception, aiming at improving arm function, and, ultimately, improvements on the level of activities and participation. We hypothesize that, given the brain's plasticity, proprioception manipulation during task-oriented training may lead to improvements of arm performance in stroke patients. Initial pilot data from patients in either the subacute or chronic stage after a stroke, gathered in 2020 (CCMO study code: NL70014.015.19), revealed both clinically and significant improvements on arm-hand function (AHF) level, and, though to a lesser extent, arm-hand skill performance (AHSP) level, as measured using the Action Research Arm test (ARAT), in both subgroups, who followed a 6 week ReHab-TOAT training regime. The reason for the latter finding may be that the ARAT also focusses on fine, intrinsic hand/finger use, which was not specifically trained on in the ReHab-TOAT concept. However, using the affected arm in (e.g.) stabilizing objects during daily tasks did improve in the aforementioned patients, as corroborated by patients' verbal reports.

Objective:
Based on the aforementioned pilot data, we now aim to perform a Randomized Clinical Trial (RCT), to ascertain the effectiveness of the ReHab-TOAT approach in improving arm function, potentially also leading to improvement in arm skill performance, in patients in the chronic stage after a stroke.

Study design:
The proposed study will be a two-armed randomized clinical trial (RCT). After randomization, the participants will follow one of two study arms featuring either the ReHab-TOAT regime (EXP) or therapy as usual, which, in the case of chronic stroke patients may involve no therapy or regular "maintenance" therapy that these participants may already receive from therapists in their home situation (e.g. "1e-lijns" physiotherapy) (CONTR).

Study population:
Chronic stroke patients suffering from a hemiparesis and arm-hand problems, with an

Utrechtse Arm-hand Test (UAT) score between 1 and 3.

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).

Main study parameters/endpoints:
Brunnstrom-Fugl Meyer Test (BFMT), gauging participants’ arm function. The ARAT, gauging patients' arm and hand skill capacity, will be used as secondary outcome measure, complemented with the so-called Motor Activity Log (MAL) and accelerometry/gyroscopy. Also the EuoQol-5D will be used, and, in the EXP group, the System Usability Scale (SUS) and a questionnaire on user experience of technology used.
Patients’caregiver will be asked to fill out the CarerQoL, gauging caregivers’ perception as to burden of care, care intensity, and quality of life

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
The risks associated with this study do not surpass the risks associated with regular exercise training methods within therapy-as-usual. The remote handling device may assist the execution of 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. 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 more intensely.

Doel van het onderzoek

The primary research questions are:
1. To what extent does a 4 week ReHab-TOAT regime lead to improvement of arm function in chronic stroke patients with either a severely or moderately affected arm-hand?
2. To what extent is any improvement of arm function in chronic stroke patients with either a severely or moderately affected arm-hand maintained up till nine months after treatment has finished?

Additional questions are:
3. To what extent does a 4 week ReHab-TOAT regime lead to improvement of arm skill performance in daily life tasks and perceived quality of life in chronic stroke patients with either a severely or moderately affected arm-hand?
4. To what extent is any improvement of arm skill performance in daily life tasks and perceived quality of life in chronic stroke patients with either a severely or moderately

affected arm-hand maintained up till nine months after treatment has finished?
5. To what extent does a 4 week ReHab-TOAT regime in chronic stroke patients with either a severely or moderately affected arm-hand lead to changes in these patients' perception regarding the usability of the technology used?
6. To what extent does a 4 week ReHab-TOAT regime in chronic stroke patients with either a severely or moderately affected arm-hand lead to changes in quality of life in their caregivers?

Onderzoeksopzet

Measures will be taken at eight different points in time, i.e.:
- at 4 times during the baseline phase (=first month) interspaced by 1 week (Tbl1, Tbl2, Tbl3 and Tbl4) prior to the start of the EXP intervention;
- once at the end of the intervention phase (= second month) (Tfu)
- once every following 3 months for the ensuing 9 months (Tfu3m, Tfu6m, Tfu9m).

(bl = baseline)
(fu = follow-up)
(T = time)
(m = month)

Onderzoeksproduct en/of interventie

The treatment concept investigated in this RCT is the so-called ReHab-TOAT (Remote Handling Based Task-Oriented Arm Training). The remote handling device which is used within this treatment, i.e. the DexterTM (Veolia Nuclear Solutions UK, Didcot, UK) is a means to provide enriched proprioceptive feedback (=sense of movement). This system has already been in use for more than 15 years in nuclear industry in a master-slave robot configuration to sense, at a safe distance, the physical world within a nuclear power plant, and to guide a slave robot in the power plant. DexterTM is a non-investigational product in our study.

General information
Patients in the chronic 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 (proprioceptive) 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 (= sense of movement), especially during (daily) task/skill execution.
The DexterTM device has originally been developed to replicate the flexible, fine motor function of humans in an environment where humans cannot go.

Training session of ReHab-TOAT
The training is split into six phases. The first phase is similar to phase six and contains the performance of daily arm-hand activities patients want to improve on. Phase three and five

are also similar to each other and feature a resting period for the patient while a therapist connects or disconnects the patient to and from the arm-orthosis attached to DexterTM device. Phase four is the main training phase with one resting period in between.

The ReHab-TOAT starts with the patient performing four activities under real life conditions. Two of these four activities may be chosen individually by the patient from a small database. The other two activities are standard activities, chosen by therapists based on their clinical expertise. One of these two standard activities is a dynamic activity, i.e. switching the lights on and off with the affected hand.
The second activity is a stabilizing activity, i.e. stabilizing vegetables with the affected hand, while cutting with the non-affected hand. During the performance of these activities a skill analysis will be done by a physical therapist or an occupational therapist to identify and choose the content of the training later on in the training session, based on the individual needs and impairments of the patient. After finishing each activity, the patient will rate his/her perceived performance on the activity using a visual analogue scale (VAS), only to be used for clinical purposes.

In phase 2 the participant, guided by the therapist, will perform a short number of preparative exercises for the arm and shoulder joints and muscles, aimed at making the arm and shoulder supple before the actual training. These are exercises that are also commonly used in regular therapy.

In the third phase of the treatment session, the patient has a short rest period of five minutes while (s)he is connected to the DexterTM device by a trained physical therapist or a trained occupational therapist used to work with the DexterTM system. Furthermore, the therapist sets the training parameters.

Next, the main training part, i.e. phase 4 of ReHab-TOAT, will start. During the 50 minutes of training with a rest period of ten minutes in between, a remote handling concept device, in this case DexterTM, is used. The patient is seated in front of the DexterTM device, with his affected arm in the arm-orthosis. Different exercises / games are offered to the patient via a screen in front of him/her.

The therapist programs / sets exercises for each patient, based on the individual needs and impairments. This is done via a software-driven interface operated by the therapist. DexterTM is used to generate haptic feedback on the arm of the patient during movements to manipulate proprioception. The haptic feedback provided, should assist, correct and/or give resistance to the movements of the patient while performing parts of activities from daily living. By manipulating proprioception in different ways (e.g. assisting movements or providing resistance to movements) the researchers want to stimulate the patient’s sense of movement, thereby stimulating brain plasticity, which may lead to improvements in motor control and to improvement of arm skill performance.
During the main training part of ReHab-TOAT, the patient will train meaningful movement components of the previously performed activities of daily living, while receiving haptic feedback generated by DexterTM. The method of training parts of the activity is based on so-called ‘task segmentation’, i.e. break-down of skills in meaningful skill components that will be practiced first isolated and later in combinations (chaining). In a previous phase of this

research project important activities from daily living for stroke patients with a limited hand function were investigated by experts. Each activity was segmented into movement components, and the most important movement components and combinations of movement components were identified. During the training using DexterTM the patient will perform different movement components and combinations of movement components, chosen by a physical therapist or an occupational therapist, based on the skill assessment during the activities performed during the first phase of the training session.

Afterwards, the patient again has a short rest period of five minutes, while he is disconnected from the DexterTM device by a physical therapist or an occupational therapist in phase 5.

The ReHab-TOAT ends with phase 6, where the patient has to perform the four activities from the first phase of the training session again. After having finished each activity, the patient will rate his/her perceived performance on the activity on a VAS-scale again, only to be used for clinical purposes.

From a clinical point of view, during the training phase 1 and 6 as described above, the therapist and the patient/participant (in the EXP group) together look for possibilities to facilitate generalisation of training progress towards other daily activities the patient may be able to perform when (s)he is at home. This includes performing the activities together and present tips to the patient on how (s)he can perform the activities more easily and also on how (s)he can perform the activities trained on (as well as similar activities) in his/her home environment. During training phase 4, i.e. when exercising with the DexterTM, the therapist and the patient/participant (in the EXP group) also focus on the arm movements and identify which of those arm movements are useful in other daily activities than those that are focused on during ReHab-TOAT. This approach towards generalisation of (potential) training effects, and stimulating the patient to also try and actually use his affected arm in his daily pursuits is also used in regular arm-hand rehabilitation.

Training parameters
During the RCT the patients in the EXP group will train for 4 weeks, 3x per week, 1.5hr per day. As mentioned above, there are at least 3 resting periods of ten minutes in between training session phases. An occupational therapist or a physical therapist will be present during the training to assist the patient when necessary. ReHab-TOAT combines principles of training physiology (e.g. goal dependent training load) and motor learning (e.g. feedback, and exercise variability) and offers exercises of increasing difficulty levels. The training consists of different levels of difficulty, based on different training principles, i.e.:
● the intensity, determined by the amount of sets, repetitions, and training load;
● the density of training content, as determined by the rate between stimuli and resting periods;
● the training extent, determined by Range-Of-Motion (ROM), support, and feedback;
● the training principles, such as overload, super-compensation and specificity [68]; and
● the content of the training, determined by the variability and task segmentation (including training of movement components) and total skill training (which is called “chaining”);
Based on the patient’s individual needs and impairments, the therapist chooses and adapts the level of difficulty within the ReHab-TOAT session(s). Thereby he sets the training at a certain level of difficulty, which contains enough stimuli to get a training response, but at the

same time preventing overload.

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 related to the upper extremities they may potentially receive, will be inventoried and described. In our protocol, no restrictions will be imposed on any (additional) therapies participants currently receive.

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

For the chronic stroke patients (n=30) to be eligible to participate in this study, they must meet all of the following criteria:
- 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 [41];
- Age 18 years or more;
- Sufficient cognitive level, i.e. being able to understand the questionnaires and

measurement instructions.

Patients' caregivers (n=30) should meet the following inclusion criteria:
- Age 18 years or older;
- providing informal care to stroke patients from the group mentioned above.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients who meet any of the following criteria will be excluded from participation in this study:
- 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+ [65].
- Severe cognitive problems that prevent the patient from understanding the tasks.
- Prior participation in the ReHab-TOAT pilot study (CCMO code: NL70014.015.19).
- No informed consent.

Exclusion criteria for patients' caregivers are:
- No informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	13-09-2021
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	22-06-2021
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	ID
NTR-new	NL9541
Ander register	METC Maxima Medical Centre Veldhoven, the Netherlands : Dutch CCMO code: NL76382.015.21

Resultaten