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Development of a technology-assisted task-oriented arm training

Submission date
16/03/2022

Recruitment status
No longer recruiting

Registration date
30/03/2022

Overall study status
Completed

Last Edited
14/02/2024

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
One of the major deficits after brain damage caused by a stroke is loss of function in the arm and hand, limiting their use in daily life. One year after stroke, arm-hand function loss is associated with anxiety, lower perceived quality of life, and reduced self-perceived well-being. Improving arm-hand skill performance is a major therapeutic target in stroke rehabilitation. However, treatment time and financial health care resources are limited. In order to solve these problems, new technology is being used to assist training of patients. Technology may assist arm-hand function and arm-hand skill training. It may augment both amount and duration of training as well as richness of training content and task specificity. It may thus provide optimal conditions for challenging the patient's brain in (re-)learning skills, yet, at the same time keep the workload for (para-)medical staff and treatment costs manageable.
We developed a new arm training approach using a so-called 'remote handling concept', to manipulate proprioception i.e. the sense of movement. This training approach aims to improve patients' 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 ability of the brain to adapt/learn, manipulation of the sense of movement during task-oriented training may lead to improvements of arm-hand skill performance in stroke patients.
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. Also, patients' and therapists' experiences in using ReHab-TOAT will be gauged, using questionnaires.

Who can participate?
a) Subacute and chronic stroke patients suffering from loss of arm-hand function;
b) Physiotherapists and occupational therapists treating patients with central nervous system deficits, like stroke.

What does the study involve?
This study features a) a feasibility study, and b) a clinical pilot study, involving subacute and chronic stroke patients with a moderately to severely affected arm-hand. 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 a 6 week programme of ReHab-TOAT. These data will serve as input for the estimation of the order-of-magnitude regarding arm-hand skill performance improvement.
All participants will receive the so-called ReHab-TOAT (Remote Handling Based Task-Oriented Arm Training). ReHab-TOAT contains task-oriented arm training in combination with haptic (i.e. proprioceptive) feedback, generated by a remote handling device called DexterTM (Veolia Nuclear Solutions UK, Didcot, UK). With the haptic feedback generated by the remote handling device, the researchers will manipulate the sense of movement, especially during (daily) task /skill execution.
The upper extremity part of the Fugl-Meyer Assessment, measuring patients' arm-hand performance, will serve as the primary outcome measure. Secondary study parameters of the study will be the Action Research Arm Test, measuring arm-hand skill performance, and the ABILHAND, gauging patients' perceived arm-hand skill performance.

What are the possible benefits and risks of participating?
The risks associated with this study do not surpass the risks associated with exercise training methods used during regular rehabilitation. The skills to be performed are everyday skills, like eating with a knife and fork or combing one's hair. The remote handling device may assist the execution of these daily skills by providing additional proprioceptive feedback, i.e. information on the 'feeling of movement'. This device’s assistance is in the range of several grams to approx. 2-3 kilograms of force.
Restoring arm function (even if this is only partial) is essential for a good quality of life. Recovery mainly depends on proper coordination of the intensity of the therapy offered relative to the patient's capacity to perform daily skills. The challenge in rehabilitation is to stimulate the brain in better coordinating movement in such a way that patients become more skilled. Key ingredients of interventions that constitute such a brain reorganization are task-specific and goal-oriented approach, 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.

Where is the study run from?
The study is performed at Adelante Rehabilitation centre in the Netherlands.

When is the study starting and how long is it expected to run for?
April 2019 to October 2020

Who is funding the study?
This study, as part of the i2-CoRT project (www.i2-CoRT.eu), is co-funded by the Interreg V-A Euregio Meuse-Rhine (EMR) programme under Grant EMR1. (European Union)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ReHab-TOAT JE/CW/HS-07

Study information

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

Study objectives
Aim of the study was to
a) assess the feasibility of the use of the ReHab-TOAT approach in chronic and in subacute stroke patients with either a moderately or severely affected arm-hand from both the patients' perspective and the therapists' perspective
b) to assess the order of magnitude of any potential treatment effect the ReHab-TOAT approach might have on arm-hand skill performance in daily life tasks in chronic and in sub-acute stroke patients with either a severely or moderately affected arm-hand.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/10/2019, Medical Ethics Committee of Maxima Medisch Centrum (Postbus 7777, 5500 MB Veldhoven, the Netherlands; +31 (0)40 888 95 28; metc@mmc.nl), ref: NL70014.015.19

Study design
Single-centre interventional feasibility study and clinical pilot study with a quasi-experimental non-randomized pre-post design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Chronic and subacute stroke patients with either a moderately or severely affected arm-hand

Interventions
All participants receive ReHab-TOAT. ReHab-TOAT is a task-oriented arm training approach for stroke patients with a moderately to severely affected arm-hand (UAT score 1, 2, or 3) . One of ReHab-TOAT's unique ingredients is that the therapists can provide (and instantly change) enriched proprioceptive feedback related to the (daily) task/skill that is trained on, directly during task/skill execution, i.e., the proprioceptive feedback generated by the remote handling device. There are no restrictions on additional treatments or therapy.

Participants of the feasibility study receive 2 sessions of ReHab-TOAT before answering a developed questionnaire.

Participants of the pilot study recieve a 6weeks training program of ReHab-TOAT with pre- and post measurements of arm-hand function and arm-hand skill performance.

Intervention Type
Mixed

Primary outcome measure
1. User satisfaction and experiences from both patients and therapists on different aspects of feasibility like acceptability, demand, practicality and implementation are measured using interviews after receiving the intervention
2. Motor performance of the affected arm-hand is measured pre- and post-intervention by the upper extremity section of the Fugl-Meyer assessment Assessment (FMA)

Secondary outcome measures
1. Arm-hand skill performance measured using ARAT pre- and post intervention
2. Percieved arm-hand skill performance measured using ABILHNAD pre- and post intervention

Overall study start date
01/04/2019

Completion date

12/10/2020

Eligibility

Key inclusion criteria
1. A unilateral stroke (ischemic or haemorrhagic) confirmed by brain imaging;
2. Post-stroke time between 6 weeks and 3 months for subacute stroke patients/Post-stroke time larger than 12 months for chronic stroke patients;
3. Hemiplegic pattern of arm motor impairment with UAT score 1-3;
4. Age 18 years or more;
5. Sufficient cognitive level, i.e. being able to understand the questionnaires and measurement instructions.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
1. Severe non-stroke-related co-morbidity that may interfere with arm-hand function.
2. Additional complaints that may interfere with the execution of the measurements.
3. Spasticity in the affected upper limb, i.e. a Modified Ashworth Scale (MAS) score ≥1.
4. Severe cognitive problems that prevent the patient from understanding the tasks.
5. No informed consent.

Date of first enrolment
25/04/2020

Date of final enrolment
26/08/2020

Locations

Countries of recruitment
Netherlands

Study participating centre
Adelante Zorggroep
Zandbersgwe 111
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Netherlands
6432 CC

Sponsor information

Organisation
Adelante Zorggroep

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
Interreg V-A Euregio Meuse-Rhine (EMR)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/03/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are expected to be made available upon personal and resonable request.
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IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Chronic CVA patients (in Dutch) version 2	20/09/2019	16/03/2022	No	Yes
Participant information sheet	Feasibility study (in Dutch) version 2	20/09/2019	16/03/2022	No	Yes
Participant information sheet	Subacute CVA patients (in Dutch) version 2	20/09/2019	16/03/2022	No	Yes
Results article		20/04/2023	14/02/2024	Yes	No
Results article		24/06/2023	14/02/2024	Yes	No