Expanding the Circuit Class Training program for upper limb training for patients in the subacute phase of stroke

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29229

Source
NTR

Brief title
Expanding Circuit Class Training

Health condition

Stroke

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

Approximately 6 new work stations for CCT.
Fugl-Meyer Assessment - Upper Extremity (FMA-UE)

Secondary outcome

Action Research Arm Test (ARAT), ABILHAND, Client Sastisfaction Questionnaire (CSQ-8), Physical Enjoyment Scale (PACES-8), NASA-TLX, Numeric Rating Scale (NRS), active minutes (using Actigraph)

Study description

Background summary

In this research we aim to expand the current circuit class training (CCT) program. Currently, this program consists of 6 work stations which are used for training. To make the program more engaging and fitting to the patient's goals, we aim to include 6 new work stations.

Four steps are planned to get to the new workstations:
1. Focus groups with patients to gather information on training goals. Focus groups with therapists to discuss these training goals and which they think are most important to include in the CCT program
2. Development of the work station. The work stations will be developed according to the Fugl-Meyer Assessment levels.
3. Testing of the work stations. An iterative process of testing the work stations with patients and therapists will be performed.
4. Pilot the work stations in comparison to goal directed training. CCT will be provided for 10 weeks to the patients in the rehabilitation center. Afterwards, 10 weeks of goal directed training will be provided. Patients are asked to participate and fill in questionnaires about their training.

Study objective

We hypothesize that circuit class training will be more enjoyable with the expanded program

Study design

There are four steps to accomplish the new workstations. These steps will be performed within 1,5 years.

Step 1: Focus groups (April to June 2021)
Methods: focus groups are conducting with stroke patients and therapists (separately). During the focus groups, patients are asked about their training goals during rehabilitation therapy. The goal is to identify which training goals may be interesting to include in the circuit training program. The focus groups with patients will be transcribed verbatim. The results will be discussed in focus groups with therapists. Together we will determine which training goals will be used to further be developed.
Outcomes: Three to four verbatim reports and a list of work stations will be the results of this

step.

Step 2: Development of the workstations (July to August 2021)
Methods: Work stations that have been defined in step 1 during the focus groups are developed. The works stations will be shaped according to the Fugl-Meyer Assessment levels. This indicates that first shoulder movements are trained, with increasing difficulty they will work to fine motor movement using the individual fingers. A team of physiotherapists and occupational therapists are involved in the development.
Outcomes: six preliminary drafts of the workstations with approximately 7 levels of difficulty per workstation. Cards are developed which include the instructions per workstation with pictures and text.

Step 3: Testing of the work stations (September to December 2021)
Methods: The first drafts of the workstations are tested in the patient population during 2 test sessions of 2 weeks each. During these test sessions, the patients and therapists have to use the cards of the workstations during therapy. Feedback is gathered during the therapy. Afterwards, a meeting is organized with the therapists to gather overall and specific feedback on the workstations and cards.
Outcomes: Feedback on the work stations and levels and feedback on the workstation cards are gathered and processed. The workstations are now in their final form.

Step 4: Pilot study to compare the work stations to goal directed training(Januari 2022)
Methods: A non-randomized design will be used for this pilot. In the first 10 weeks of the study CCT will be given to the patients. In week 11 to 20, Usual Care (UC) will be provided. Only patients that enter the rehabilitation center in the first 6 weeks of every block (week 1-6 and 11-16) will be eligible to enter the study since they will be able to complete 4 weeks of either CCT or UC.
Patients will receive the assigned therapy for 4 weeks, 5 days a week for 60 minutes. We expect to include 12 patients, 6 patients in both groups. However this is dependent on the number of people that are admitted to the rehabilitation center. Patients who are not eligible or not willing to participate will also follow the current therapy that is provided 5 days a week but do not participate in extra questionnaires or measurements. By providing only one type of therapy, a distinction can be made between CCT and UC for the mental load on the therapists.
Outcomes: Arm function tests: Fugl Meyer Assessment (FMA), Action Research Arm Test (ARAT), ABILHAND, Canadian Occupational Performance Measure. Satisfaction: Client Sastisfaction Questionnaire-8, Physical Activity Enjoyment Scale-8, NASA-Task Load Index (patient), Numeric Rating Scale (NRS) for subjective improvement and physical complaints. Amount of minutes using the affected arm during therapy (Actigraph). NASA-TLX (therapist) to assess the therapist work load.

Intervention

A intervention takes place in step 4 of the study, the patients will either follow CCT or goal directed training.

Contacts

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Eligibility criteria

Inclusion criteria

Patients: Adult patients within 6 weeks of first stroke onset, measured from moment of clinical assessment. Patients should be able to perform finger extension 3 times (FMA extension ≥ 1) and shoulder abduction (Motricity Index > 14). Patients should be able to understand and execute simple instructions, understand the Dutch language and be able to provide informed consent.

Exclusion criteria

Patients: Severe aphasia, severe cognitive problems (Montreal Cognitive Assessment≤18), severe neglect (star cancellation test≤44), severe pain (NRS≥60) and severe sensory problems (Erasmus modification Notthingham Sensory Assessment≤24). Cannot hold attention to task for 2 minutes.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-04-2021
Enrollment:	14
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	30-04-2021
Application type:	First submission

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
NTR-new	NL9471
Other	METc UMCG : METc 2021/216

Study results