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

Gepubliceerd: 30-04-2021 Laatst bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON29229

Bron
NTR

Verkorte titel
Expanding Circuit Class Training

Aandoening

Stroke

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Approximately 6 new work stations for CCT.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek

Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	30-04-2021
Aantal proefpersonen:	14
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:	30-04-2021
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	NL9471

Register	ID
Ander register	METc UMCG : METc 2021/216

Resultaten