Circuit class training to improve the arm and hand function after stroke

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21297

Source
Nationaal Trial Register

Brief title
Pilot Class Circuit Training

Health condition

Stroke

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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, Visual Analogue Scale (VAS), active minutes (using Actigraph)

Study description

Background summary

Background
After stroke, 69 -88% of the patients have upper limb paresis. Task specific training has proven to be effective to increase upper limb function. However providing individual task specific training is time demanding, expensive and mentally demanding for therapists. To lower the pressure for therapists, it has been proposed to train in groups with different work stations, also known as class circuit training (CCT). The therapist has prepared a set of workstations that are used to train activities of daily living (ADL). In the literature, no studies exist that investigate CCT for the upper extremity using ADL activities.

Main research question
The aim of this pilot is to compare the effectiveness of CCT to usual care (UC) on the improvement of arm/hand function in patients in the subacute phase of stroke. Secondary objectives are to investigate the patient satisfaction, therapist load and active time during therapy sessions.

Design (including population)
Subacute stroke patients, admitted to the rehabilitation ward. Patients should be able to perform finger flexion and have movement in the shoulder.
In this non-randomized pilot, patients will train 4 weeks in either the CCT group or the UC group, based on when they enter the study.
Outcomes are arm function tests, questionnaires about the enjoyment, mental and physical load, satisfaction with therapy, perceived improvement and pain. Once a week, activity is monitored in a session.

Expected results
We expect that patients train more different skills at the same time during CCT and therefore we think that the arm function will improve more in comparison to UC.

Study objective

Patients improve more in upper limb function after CCT in comparison to usual care.
Patients are equally satisfied with both CCT and usual care as therapy.
Patients have more active minutes during CCT in comparison to usual care.

Study design

Patients that enter the rehabilitation center will be checked for eligibility. The patient is

measured before the start of the intervention (pre) and after 4 weeks of intervention (post). The VAS, containing questions regarding pain and perceived improvement of arm function, will be asked daily. The PACES-8, NASA-TLX and Actigraph are measured once a week on Friday. The CSQ-8 will be asked at the end of the study (post)

Intervention

Class Circuit Training (CCT): The therapist has prepared a set of standardized workstations that are used to train activities of daily living (ADL). During CCT, patients train intensive repetitive task specific activities in small groups at the work stations.
Usual care: The therapist and patient have defined goals that are worked on during group therapy. This can be either alone or together with other patients.

Contacts

Public
University Medical Center Groningen
Samantha Rozevink

+31625648829
Scientific
University Medical Center Groningen
Samantha Rozevink

+31625648829

Eligibility criteria

Inclusion criteria

Patients: Adult patients within 4 weeks of first stroke onset, who did not started rehabilitation therapy yet. 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≤20), severe neglect (star cancellation test≤44), severe spasticity (Passive Resistive to Passive

Movement ≥4), severe pain (VAS≥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:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2020
Enrollment:	12
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	24-08-2020
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	NL8844
Other	METC Groningen : METc 2020/413

Study results