Effects of a task-oriented circuit training to enhance walking competency after stroke.

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N/A

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

Samenvatting

ID

NL-OMON27390

Bron
Nationaal Trial Register

Verkorte titel
FIT Stroke

Aandoening

Stroke, walking competency, task oriented training
CVA, loopvaardigheid, taakgeorienteerde training

Ondersteuning

Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

-Stroke Impact Scale (SIS 3.0)/ mobiliteits item

-EuroQoL

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction:

Most patients with stroke experience reduced walking competency and health-related quality of life (HRQoL). A substantial part of the patients receive individually tailored physiotherapy in the community. However, the effects of face-to-face physiotherapy often given in therapist own practice are unknown. Contrastingly, recent meta-analysis showed that task-oriented circuit training in groups is effective in improving walking competency after stroke. In addition, the cost-effectiveness has never been subject of investigation.

Objectives:
The primary aim is to evaluate the effects of a structured, progressive task-oriented fitness training program applied in a group of 8 to 10 patients on outcome of gait, gait-related ADLs and HRQoL after stroke when compared to individually-tailored physiotherapy in the community. The second objective is to investigate the cost-effectiveness of group fitness training compared to individual physiotherapy within the first 6 months post randomisation (short term evaluation) and beyond 6 months (long term evaluation). Finally, the generalisability of the task-oriented fitness training program on perception of fatigue, anxiety and depression, and HRQoL will be studied.

Study population:
220 stroke patients discharged from a rehabilitation centre to home in the community, but indicated for outpatient rehabilitation, able to communicate and walk at least 10 meters independently.

Study design:
A multicentred, single blinded randomised controlled trial.

Intervention:
Patients in the experimental group will receive fitness training 2 times a week for 12 weeks including a package of home exercises, whereas patients allocated in the control group will receive usual care. For short term evaluation of costs, each patient will be followed for the first 24 weeks after randomisation, whereas for long term evaluation of fitness training, patients will be monthly monitored up to the end of this three year study.

Outcome measures:
Primary outcome will be the mobility part of the Stroke Impact Scale (SIS-3.0) and the EuroQol (EQ-5D). Secondary outcomes are: the other domains of SIS 3.0, muscle strength of lower limbs, walking endurance, gait speed, balance, confidence not to fall, Instrumental ADLs, fatigue, anxiety, depression and health related quality of life in general.

Doel van het onderzoek

N/A

Onderzoeksopzet

Baseline, 6, 12, 18 en 24 weken na randomisatie

Onderzoeksproduct en/of interventie

Experimental intervention:
Patients assigned to the fitness training (i.e, experimental) group (8-10 persons) will receive a structured progressive task-oriented circuit training program twice a week for 12 weeks (24 sessions). The program will contain 4 phases:

1) a warming up (5 minutes)

2) group training (sport & games) (15 minutes)

3) circuit training (60 minutes)

4) cooling down (10 minutes).
The circuit training program contains 8 different work-stations. The workstations are aimed to improve meaningful tasks related to walking competency such as balance control, stair walking, turning, transfers and (speed) walking.
Graded progression will be executed by:
1) increasing the difficulty of the task;
2) adding weights;
3) increasing time or
4) increasing number of repetitions.
The cooling down phase will contain 10 minute stretching exercises and mat activities (plenary applied). The precise compilation of the treatment package for each included patient by appropriate selection of type of workstation, number of repetitions and intensity, will be determined at baseline based on patients' profile of muscle strength, physical fitness and mobility status. Special emphasis will be given in the program to educate patients about the importance of fitness for quality of life and life expectancy during the intervention period. Number of repetitions, speed, accuracy, distance and amount of time spent to home exercises will be registered in a patients' activity log-book. A physical therapist and sport instructor will supervise the training sessions.

Patients who are allocated to the control group will be referred to usual care.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Eligible subjects will meet the following inclusion criteria:

1. Verified stroke following definition of WHO (21)

2. Ability to walk a minimum of 10 meters independently (using an aid or orthotic is allowed)

3. Discharged from a rehabilitation centre to home

4. Need to continue physical therapy in the community to improve walking competency and/or physical condition

5. Informed consent and motivated to participate 24 treatment sessions fitness training within 12 weeks or individual physiotherapy in the community.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients are excluded if they suffer from:

1. Severe cognitive deficits as evaluated by the Mini-Mental State Examination (<24 points)

2. Inability to communicate (i.e. < 4 points on the Utrecht Communication Observation)

3. Living beyond 20 km from the rehabilitation centre. There will be no restrictions with respect to age, ethnicity or social economic status of included patients.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2008
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-11-2008

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	NL1466
NTR-old	NTR1534
Ander register	ZonMw : 80-82310-98-08303
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A