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

No registrations found.

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

Summary

ID

NL-OMON27390

Source
Nationaal Trial Register

Brief title
FIT Stroke

Health condition

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

Sponsors and support

Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

-Stroke Impact Scale (SIS 3.0)/ mobiliteits item
-EuroQoL

Secondary outcome

- Hospital Anxiety and Depression Scale (HADS)

The HADS is a simple measure to determine mood, emotional distress, anxiety, depression and emotional disorder. The HADS is a brief, valid and reliable widely used measure known to give meaningful results as a psychological screening tool. The HADS consists of 14 items (7 anxiety, 7 depression), each with a 4 point rating scale (0-3) and has shown to be responsive to change. The HADS will be assessed at baseline, 12 and 24 weeks post randomisation.

- Fatigue Severity Scale (FSS)

The FSS will be used to assess the impact of fatigue. The FSS consists of nine items and scores of each item range from 1 to 7. The total score of the FSS is the mean of the nine items. The FSS will be assessed at baseline, 12 and 24 weeks post randomisation.

- Motricity Index (MI)

The Motricity Index is a valid and reliable measure and will be used to determine strength of upper (MI arm) and lower paretic limb (MI leg). Scores range from 0 (no activity) to 33 (maximum muscle force) for each dimension. The test has been shown highly reliable and valid (34). The MI will be assessed at baseline, 12, and 24 weeks post randomisation.

- Falls Efficacy Scale (FES)

The FES is an instrument to measure fear of falling, based on the operational definition of this fear as "low perceived self-efficacy at avoiding falls during essential, nonhazardous activities of daily living.". The FES will be assessed at baseline, 12 and 24 weeks post randomisation.

- Six minute walking test

For investigating the effects of functional fitness training on gait performance and endurance, the 6 minute walking test (6-MWT) will be performed. The test will be assessed at baseline, 12 and 24 weeks post randomisation.

- Five meters timed-walk

Gait speed will be measured by the 5 meter comfortable walking speed test (20). In order to reduce measurement error the mean of three repeated walking speed measurements will be calculated. The patient will rest for about one minute between each test. Timing with a digital stopwatch that registered time in 1/100 of a second will be manually initiated at the ‘go’ instruction and stopped when the subject cross the 5 or 10 meter mark. The test will be assessed at baseline, 12 and 24 weeks post randomisation.

- Timed balance test

This instrument consists of 5 different components on an ordinal scale and involves timed balance (i.e., 60 seconds) on progressively diminishing support surfaces. The test has been shown to be reliable and highly related with walking performance. The test will be assessed at baseline, 12 and 24 weeks post randomisation.

- Chair rise test

This test assesses the time it takes to move from a seated position to standing upright and returning to the seated position 5 times as rapidly as possible with subject’s arms across their chest and feet flat on the floor, is recorded to the nearest 0.01 second. The test will be assessed at baseline, 12 and 24 weeks post randomisation.

- Timed up and go test (TUG)

The timed up and go test is a test for basic functional mobility. The participant is asked to rise from an armchair, walk 3 meters as fast as possible, cross a line, turn, walk back and sit down again. The time taken to perform this task is registered. The TUG has been shown to identify patients that have higher risks for falls. The test will be assessed at baseline, 12 and 24 weeks post randomisation.

- Modified stairs test

The modified stairs test is an extended version of the Timed Get up and Go test (TUG). The test includes the same tasks as the TUG, however ascending and descending 5 steps is added. Patients are timed to the nearest 0.01 when they are asked to rise from a chair which is placed 0.5 meter in front of the stair, subsequently, ascend 5 steps, turn and descend the 5 steps and sit again in the chair as safe as possible. The patient will rest for about one minute between each test. The test will be assessed at baseline, 12 and 24 weeks post randomisation.

- Nottingham Extended ADL (NEADL)

The Nottingham Extended ADL scale is based on a self-reported questionnaire on level of activity actually performed. The NEADL consists of 22 items in 4 domains (mobility, kitchen, domestic, leisure). The NEADL is specifically designed for postal use with stroke patients, and has proven to be reliable and valid as an outcome measure in trials and natural history studies. Each item is given one of four responses (able, able with difficulty, able with help, unable). The scale has been shown to have reasonable hierarchical (ordinal) properties in stroke patients. The NEADL will be assessed at baseline, 12 and 24 weeks post randomisation.

Study description

Background summary

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.

Study objective

N/A

Study design

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

Intervention

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.

Contacts

Public
Revant medisch specialistische revalidatie

Ingrid Port, van de
Brabantlaan 1

Breda 4817 JW
The Netherlands
076-5797826
Scientific
Revant medisch specialistische revalidatie

Ingrid Port, van de
Brabantlaan 1

Breda 4817 JW
The Netherlands
076-5797826

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2008
Enrollment:	250
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-11-2008
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	NL1466
NTR-old	NTR1534
Other	ZonMw : 80-82310-98-08303
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A