Perturbation-based balance training after stroke.

No registrations found.

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

Summary

ID

NL-OMON20002

Source
Nationaal Trial Register

Health condition

Stroke
Postural balance
Training program
Balance perturbation

Beroerte
Balanshandhaving
Trainingsprogramma
Balansverstoring

Sponsors and support

Primary sponsor: Radboud University Medical Centre, Nijmegen, The Netherlands
Source(s) of monetary or material Support: n.a.

Intervention

Outcome measures

Primary outcome

Mechanical efficacy of stepping responses after support surface translations:

1. Angle of the stepping leg;

2. Step length.

Secondary outcome

Mechanical efficacy of stepping responses after support surface translations:

1. Foot position;

2. Centre of Mass displacement;

3. Force during stepping.

Functional tests:

1. Berg Balance Scale (BBS);

2. Trunk Impairment Scale (TIS);

3. Timed Up&Go test (TUG);

4. 10-m Walking Test (10-MWT) (comfortable speed);

5. Activity-specific Balance Confidence scale (ABC).

Study description

Background summary

Rationale:

In the Netherlands, an estimated 41.000 people sustain a first ever stroke every year. Falls are a common complication after stroke, with balance and gait disorders as its main risk factors. This can be explained by the fact that people after stroke have an impaired capacity to execute quick stepping reactions after a balance perturbation, particularly when de paretic leg is involved. There is some evidence that these stepping reactions can be improved after stroke by a perturbation based training program.

Objective:

The aim of the proposed explorative “proof-of-principle” study is to assess the feasibility and (preliminary) effectiveness of a 5-week perturbation-based training program using the Radboud Falls Simulator (RFS) on dynamic balance capacity in community-dwelling persons in the chronic phase after stroke.

Study design:

This study is designed as a randomized controlled cross over trial. Participants will be randomly allocated to an experimental group receiving the 5-week training program after one week, or to a (waiting list) control group receiving no specific intervention (“usual care”). After a waiting period of 6 weeks, the control group will also receive the experimental training.

Study population:

In this study, twenty participants in the chronic phase after stroke, aged 18 till 75 years, will be included. They will have to have a FAC (Functional Ambulation Categories) score of 4 or more (being able to independently walk on even terrain).

Intervention:

A 5-week perturbation-based training program on the Radboud Falls Simulator (RFS). This program will train sustaining single translations in eight different directions and at increasing intensities (accelerations) necessitating step reactions. In addition, stepping with both the paretic and the nonparetic leg will be stimulated. Participants will receive the training in pairs during training sessions of 90 minutes, two times a week, 5 weeks in a row, under supervision of a trained physiotherapist. The level of difficulty will be increased each session based on a fixed individualized protocol.

Main study parameters/endpoints:

Because this study has an explorative design and aims toprovide “proof of principle”, the primary outcome measure is related to the efficacy of the stepping responses. Centre of mass (CoM) displacement and step length during perturbations on the Radboud Falls Simulator will be compared between the intervention group and the usual care group.

Study objective

The hypothesis is that a 5-week perturbation-based training program using the Radboud Falls Simulator (RFS) will improve the mechanical efficiency of stepping to recover balance in community-dwelling persons in the chronic phase after stroke.

Study design

Experimental group:

T0: Intake;

T1: Pre intervention;

T2: Post intervention (6 weeks);

T3: Follow up (6 weeks);

T4: Follow up (6 weeks).

Control group:

T0: Intake;

T1: Baseline;

T2: Pre intervention (6 weeks);

T3: Post intervention (6 weeks);

T4: Follow up (6 weeks).

Intervention

A 5-week perturbation-based training program on the Radboud Falls Simulator (RFS). This program will train sustaining single translations in eight different directions and at increasing intensities (accelerations) necessitating step reactions. In addition, stepping with both the paretic and the nonparetic leg will be stimulated. Participants will receive the training in pairs during training sessions of 90 minutes, two times a week, 5 weeks in a row, under supervision of a trained physiotherapist. The level of difficulty will be increased each session based on a fixed individualized protocol.

The control group will be put on a waitinglist.

Contacts

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Eligibility criteria

Inclusion criteria

1. Having sustained a stroke more than 6 months ago and having completed post-acute rehabilitation (thereby eliminating spontaneous recovery processes to interact with training effects);

2. Aged 18 till 75 years;

3. Having the capacity to stand and walk ‘independently’ as defined by a Functional Ambulation Categories (FAC) scores 4 or 5.

Exclusion criteria

1. Other neurological or musculoskeletal conditions affecting balance;

2. Conditions in which physical exercise is contra-indicated;

3. Use of psychotropic drugs or other medication negatively affecting balance;

4. Severe cognitive problems (mini mental state examination (MMSE) <24);

5. Persistent visuo-spatial neglect (based on the Behavioral Inattention Test / BIT);

6. Behavioral problems interfering with compliance to the study protocol.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2012
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-01-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37268
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3658
NTR-old	NTR3804
CCMO	NL42155.091.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37268

Study results

Summary results
N/A