The effect of a 5-week perturbation-based training on dynamic postural control in people after stroke

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON37268

Source
ToetsingOnline

Brief title
Dynamic balance training after stroke

Condition

- Central nervous system vascular disorders

Synonym
Cerebral Vascular Accident (CVA), Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Balance perturbation, Postural Balance, Stroke, Training program

Outcome measures

Primary outcome

Because this study is designed to provide *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.

Secondary outcome

Secundary outcomes will be foot postioning, leg angle and force during stepping reactions after balance perturbations on the Radboud Falls Simulator. In addition we will compare the intervention and the usual-care group on the following functional tests: Berg Balance Scale, Trunk Impairment Scale, Timed Up&Go, Ten Meter Walking Test en Activity-Balance Confidence Scale.

Study description

Background summary

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.

Study objective

The aim of the proposed *proof-of-principle* study is to assess the feasibility and (preliminary) effectiveness of a newly developed 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.

Intervention

A 5-week perturbation-based training program using the Radboud Falls Simulator (RFS), based on the existing literature on balance perturbations after stroke. This program will train sustaining single translations in eight different directions and at increasing intensities (accelerations) necessitating step reactions. Participants will be forced to step with both the paretic and the nonparetic leg. 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.

Study burden and risks

Participants will spend approximately 10 hours during assessments for this study. Due to a safety harness, fall risk during assessments is very low. As a experimental setup, the balance platform is already in use for several other studies without occurrence of adverse events.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Having sustained a stroke more than 6 months ago and having completed post-acute rehabilitation
- Having the capacity to stand and walk *independently* as defined by a Functional Ambulation Categories (FAC) scores 4 or 5
- Aged 18 till 75 years

Exclusion criteria

- Other neurological or musculoskeletal conditions affecting balance
- Conditions in which physical exercise is contra-indicated
- Use of psychotropic drugs or other medication negatively affecting balance
- Severe cognitive problems (mini mental state examination (MMSE) <24)
- Persistent visuo-spatial neglect (based on the Behavioural Inattention Test / BIT)
- Behavioural problems interfering with compliance to the study protocol

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	10-01-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20002
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42155.091.12
OMON	NL-OMON20002