

Perturbation-based balance training after stroke.

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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.

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

Samenvatting

ID

NL-OMON20002

Bron

Nationaal Trial Register

Aandoening

Stroke
Postural balance
Training program
Balance perturbation

Beroerte
Balanshandhaving
Trainingsprogramma
Balansverstoring

Ondersteuning

Primaire sponsor: Radboud University Medical Centre, Nijmegen, The Netherlands

Overige ondersteuning: n.a.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Mechanical efficacy of stepping responses after support surface translations:

1. Angle of the stepping leg;

2. Step length.

Toelichting onderzoek

Achtergrond van het onderzoek

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 the 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 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Afdeling Revalidatie (898)

UMC st Radboud

Postbus 9101
H. Duijnhoven, van
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3614804

Wetenschappelijk

Afdeling Revalidatie (898)

UMC st Radboud

Postbus 9101
H. Duijnhoven, van

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-11-2012
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	16-01-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37268
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Register

OMON

ID

NL-OMON37268

Resultaten

Samenvatting resultaten

N/A