Effect van looptraining op het evenwicht na een beroerte

No registrations found.

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

Summary

ID

NL-OMON27894

Source
Nationaal Trial Register

Brief title
Balance capacity in people after stroke

Health condition

Stroke

Sponsors and support

Primary sponsor: Radboud university medical center and
Delft University of Technology
Participating centers include: Sint Maartenskliniek (Nijmegen), Tolbrug Specialistische Revalidatie (Den Bosch), Pieter van Foreest (Delft) and Amstelland Fysiotherapie (Amstelveen).
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Main outcome variables are the frequency response function (feet-in-place test), leg angle at

stepping foot contact (stepping test) and foot placement error (step adjustment test).

Secondary outcome

Secondary outcomes of the feet-in-place test are values for the parameters describing the physics of human balance control. The most important parameters are passive muscle stiffness and damping, reflexive muscle stiffness and damping and time delay. For the stepping test, the secondary outcome variables are step onset, step duration, step length and step velocity. For the step adjustment test, the secondary outcome variables are onset latencies of stepping adjustments and average speed of adjustments. Furthermore, clinical tests (10 meter walking test and mini-BEST test) and activity levels will be evaluated.

Study description

Background summary

People after stroke are at a high risk of falls. Impaired balance and gait are important risk factors for a fall in this population. Previous research has shown that the feet-in-place test, stepping test and step adjustment test were sensitive to evaluate training effects in people after stroke. Despite proven sensitivity, the specificity of test outcomes to various types of training provided is still unknown. More insight in these aspects is definitely needed to determine whether the feet-in-place test, stepping test and/or step adjustment test provide additional information (compared to clinical tests) that is necessary for further improvement and individualization of stroke care.

Study objective

We hypothesize that persons who receive dynamic balance training with visual perturbations (Visual Perturbed intervention) will show larger improvements on the ability to make step adjustments (and thus show a larger difference in foot placement error between pre and post intervention) compared to persons in the Mechanical Perturbed intervention and Inactive Control intervention. Furthermore, we expect that persons receiving the Mechanical Perturbed intervention will show the largest improvements on the stepping test, as shown by a larger difference between pre and post intervention in the leg angle at stepping foot contact.

Study design

Week 1: pre intervention balance assessment and pre intervention activity monitoring

Week 2 – 6: intervention

Week 7: post intervention balance assessment and post intervention activity monitoring

Intervention

• Participants will be randomized in one of the three interventions; two interventions consist of dynamic balance training on the C-mill (treadmill) and one intervention consist of no training (Inactive Control intervention). Participants will receive dynamic balance training during training sessions of 60 minutes, two times a week, during 5 weeks. Dynamic balance training consists of walking on the C-mill with augmented visual context (Visual Perturbed intervention), or walking on the C-mill with mechanical perturbations (Mechanical Perturbed intervention).

Contacts

Public
Jolanda Roelofs
[default]
The Netherlands
Scientific
Jolanda Roelofs
[default]
The Netherlands

Eligibility criteria

Inclusion criteria

-Having sustained a unilateral supratentorial stroke more than 6 months ago with hemiparesis involving the leg.

- Consequences of the stroke were severe enough to get inpatient rehabilitation in a rehabilitation center.

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

- 18 years or older.

Exclusion criteria

- Any other neurological or musculoskeletal conditions affecting balance.

- Current orthopaedic problems; current hip or knee replacement, or limb amputation.

- Severe cognitive problems (Montreal Cognitive Assessment < 24).

- Persistent visuo-spatial neglect (Star-Cancellation Test < 44) .

- Use of psychotropic drugs or other medication negatively affecting balance.

- Behavioural problems interfering with compliance to the study protocol.

- Unable to stand for 15 minutes without orthosis or walking aid.

- Pregnancy.

- Unable to give a personal consent.

- Conditions in which physical exercise is contra-indicated.

- Unable to walk for 10 minutes without walking aid.

- Receiving physiotherapy focusing at balance or gait which cannot be cancelled during participation in this study, except for participants receiving the Inactive Control intervention. (These participants do not have to cancel usual physiotherapy focusing on balance or gait during participation in this study).

- Having received dynamic balance training with visual and/or mechanical perturbations beforehand.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-08-2017
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion
Date: 21-07-2017
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45141
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6373
NTR-old	NTR6557
CCMO	NL53300.091.15
OMON	NL-OMON45141

Study results

Summary results
Not applicable