Effect van looptraining op het evenwicht na een beroerte

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

Samenvatting

ID

NL-OMON27894

Bron
Nationaal Trial Register

Verkorte titel
Balance capacity in people after stroke

Aandoening

Stroke

Ondersteuning

Primaire 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).
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

• 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).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	07-08-2017
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-07-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45141
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

Not applicable