Roads to recovery

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We hypothesize that perturbation-based training improves the neuromuscular control of balance and gait by normalizing muscle coordination (expressed in terms of muscle synergies), in contrast to conventional physiotherapy.

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

Samenvatting

ID

NL-OMON25043

Bron
Nationaal Trial Register

Verkorte titel
ROADS

Aandoening

Stroke

Ondersteuning

Primaire sponsor: Radboud University Medical Center
Overige ondersteuning: The Netherlands Organisation for Scientific Research (NWO)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure will be the integrity of muscle synergies (i.e., coordinated muscle recruitment) before and after intervention.

Toelichting onderzoek

Achtergrond van het onderzoek

Balance and gait problems are very important aspects of stroke-related disability, for which effective rehabilitation protocols are currently lacking. Preliminary evidence suggests that intensive, perturbation-based balance and gait training is able to improve the neuromuscular control of balance and gait, even in the chronic phase of stroke. Yet, the effects of perturbation-based training on the neuromuscular control of balance and gait remain to be established. This study will provide novel insights into the effects of perturbation-based training, thereby allowing for fine-grain characterization of the trajectories of motor recovery after stroke.

Doel van het onderzoek

We hypothesize that perturbation-based training improves the neuromuscular control of balance and gait by normalizing muscle coordination (expressed in terms of muscle synergies), in contrast to conventional physiotherapy.

Onderzoeksopzet

Week 1. Intake and clinimetric evaluation.
Week 2. Pre-intervention assessment of balance and gait.
Week 3-7. Experimental intervention group: perturbation-based training protocol for balance and gait. Regular care group: conventional physiotherapy.
Week 8. Post-intervention clinimetric evaluation and assessment of balance and gait.
Follow-up: Monthly collection of fall-registration cards for six months.

Onderzoeksproduct en/of interventie

Participants will be randomly assigned to either an experimental intervention or regular care group. The experimental intervention group will receive a perturbation-based training protocol in which an instrumented treadmill will induce reactive balance movements and gait adaptation during walking. The regular care group will receive conventional physiotherapy. Both groups will receive training in sessions of one hour, two times a week, during five weeks.

Contactpersonen

Publiek

Radboud University Medical Center

Wouter Staring

n.a.

Wetenschappelijk

Radboud University Medical Center
Wouter Staring

n.a.

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

To be eligible for participation, an individual must meet the following criteria:
- Having sustained a unilateral supratentorial stroke more than 6 months ago, with mild to moderate impairments.
- Able to stand and walk independently or under supervision (Functional Ambulation Categories ≥ 3).
- Completed inpatient rehabilitation
- Age 18 or older

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Potential participants who meet any of the following criteria will be excluded from participation:
- Conditions in which physical exercise is contra-indicated.
- Unable to walk for 10 minutes without walking aid.
- Receiving physiotherapy focusing on balance or gait that cannot be cancelled during participation in this study.
- Having received perturbation-based training with visual and/or mechanical perturbations in the previous year.
- Any other neurological or musculoskeletal conditions affecting balance.
- Current orthopaedic problems; hip or knee replacement, or limb amputation.
- Severe cognitive problems (Montreal Cognitive Assessment < 24).
- Persistent visuo-spatial neglect (Star-Cancellation Test ≤ 50).
- Use of psychotropic drugs or other medication negatively affecting balance.
- Behavioral problems interfering with compliance to the study protocol.
- Unable to stand for 15 minutes without orthosis or walking aid.

- Pregnancy.
- Unable to give consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2019
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	14-05-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45932

Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7730
CCMO	NL67690.091.18
OMON	NL-OMON45932

Resultaten