Roads to recovery

No registrations found.

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

Summary

ID

NL-OMON25043

Source
Nationaal Trial Register

Brief title
ROADS

Health condition

Stroke

Sponsors and support

Primary sponsor: Radboud University Medical Center
Source(s) of monetary or material Support: The Netherlands Organisation for Scientific Research (NWO)

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

The secondary outcome measures of the intervention study will be clinimetric parameters:

Mini-BESTest, the 10-meter walking test and the Activities specific Balance Confidence scale. Furthermore, electrical brain activity will be measured from the participants' scalp to determine cortical activity related to the control of balance and gait before and after training.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

Public
Radboud University Medical Center
Wouter Staring

n.a.
Scientific
Radboud University Medical Center
Wouter Staring

n.a.

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2019
Enrollment:	70
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	14-05-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45932

Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results