# Roads to Recovery, control of balance and gait after stroke

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| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Central nervous system vascular disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON45932

**Source**
ToetsingOnline

**Brief title**
Roads to Recovery

### Condition

- Central nervous system vascular disorders

**Synonym**
Cerebro vascular accident (CVA), Stroke

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum
**Source(s) of monetary or material Support:** ZonMW vidi grant

## Intervention

**Keyword:** Balance, Recovery, Stroke, Training

## Outcome measures

### Primary outcome

The main outcome of the intervention study is the proportion of individuals with stroke showing normalization of neuromuscular control of balance and gait after the intervention. This is defined as the presence of muscle synergies similar to a reference set of normal muscle synergies. Synergies will be compared pre and post training to determine the effect of DCT.

### Secondary outcome

Secondary outcome measures that will be assessed are clinimetric parameters such as, Mini-BESTest and Trunk Impairment Scale. Cortical activity will be measured to determine whether there is cortical reorganization after training. For an additional assessment of neuromuscular structures we will determine the change in DMC-index pre and post intervention and will compare these to healthy controls as well. Furthermore, patients will have a follow-up time of 6 months to obtain insights in the occurrence of falls after training.

# Study description

### Background summary

Stroke is a leading cause of long-term disability. Balance and gait problems are important aspects of stroke-related disability, for which effective rehabilitation protocols are currently lacking. This is due to a lack of knowledge on normal cortical control mechanisms of balance and gait, on the contributions of *original* and compensatory cortical control to balance and gait after stroke, and on whether exercise therapy has a potential to impact

these control mechanisms. Conventional treatment has been unsuccessful in substantially restore neuromuscular control. However, preliminary evidence suggests that even in the chronic phase of stroke, it is still possible to improve with intensive, task-specific training. This study will answer the key clinical question of whether a new dynamic C-Mill training intervention would be superior to conventional physiotherapy in improving neuromuscular control of balance and gait. In addition, it will permit a fine-grained characterization of balance and gait in terms of coordinated muscle activity and cortical activity for balance and gait control.

## Study objective

The primary objective of this study is to compare the changes in neuromuscular control related to reactive and adaptive movements during balance and gait, following Dynamic C-mill Training to conventional physiotherapy. Furthermore, an additional assessment of healthy participants will provide further insights into neuromuscular parameters of balance control and gait (co-activation of leg muscles and their neural correlates) during functional assessments

A secondary aim of this study is to obtain more insights in the cortical contributions to the recruitment of muscle synergies during balance and gait.

## Study design

This project entails an intervention study designed as an open-label randomized controlled study. Two groups will participate in training therapies. One group will perform DCT, while the other group will receive conventional physiotherapy. Subsequently, both groups will be compared to healthy controls to provide more insights in neuromuscular control after stroke.

## Intervention

The intervention training will be provided on the C-Mill/3NP. The C-Mill/3NP is a treadmill that can deliver mechanical and visual perturbations. Visual perturbations can be projections on the treadmill on which patients have to step. Mechanical perturbaitons can be changes in speed of the treadmill while walking. This training will be conducted twice a week for 5 weeks. Every training session will last approximately an hour. The intensity of the training will be changed based on the progression of the patient.

## Study burden and risks

The burden to participants will be low.
Healthy controls will be performing one measurement of approximately 4 hours. During this measurements there will be no use of invasive methods, since data will be collected by surface EMG, EEG by an EEG cap and forces and movement by

means of force plates and the Vicon motion tracking system.

Participants of the intervention study will visit the Radboudumc 3 times. The first visit will be to familiarize the patients with the environment of the lab and to obtain informed consent. This visit will take approximately 2 hours. Subsequently, participants will participate in two measurements, pre- and post training of approximately 4 hours. The intervention consist of 10 training sessions within the Radboudumc for 5 weeks( 2 per week). During these visits participants will train for an hour on the C-Mill. Participants who will receive physiotherapy, will plan 10 sessions with a physiotherapist of their preference. This can be a physiotherapist in the current environment of the participant. Physiotherapy and DCT could both have a beneficial effect on their balance and gait capacity.

Additionally, for patients who are eligible for an MRI-scan we will plan when the MRI-scan will take place. We will try to be as time-efficient as possible to ascertain minimum burden of time spend for the patient.

Previous studies have shown no adverse effects when balance and gait was assessed in a similar way. The main risk is that participants might lose their balance during the balance tests or during training. However, they will be wearing a safety-harness to prevent falling.

## Contacts

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## Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

The inclusion criteria have been specified for healthy controls and post-stroke survivors separately.
In order to be eligible to participate in the study as a healthy participant, a participant must meet the following criteria:
- No history of stroke
- Having the capacity to stand and walk *independently* as defined by a Functional Ambulation Categories score 5;In order to be eligible to participate in the study as a post stroke participant , a participant must meet the following criteria: ;- Having sustain 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

## Exclusion criteria

People 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 past 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.
- 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.;Additionally, All stroke patients will be checked for

eligibility for a MRI-scan. For this scan additional exclusion criteria are defined. These criteria are specified by guidelines of the Radboudumc Radiology department and are described in document F1f. MRI-controle lijst. Note, participants will still be able to participate in the study regardless of their eligibility for a MRI-scan

# Study design

## Design

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

## Recruitment

NL

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| Recruitment status: | Completed |
| Start date (anticipated): | 15-07-2019 |
| Enrollment: | 130 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 14-03-2019 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25043
Source: Nationaal Trial Register
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL67690.091.18 |
| OMON | NL-OMON25043 |