Balance capacity in people after stroke

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON45141

Source
ToetsingOnline

Brief title
Balance after stroke

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;IMDI

Intervention

Keyword: Dynamic balance training, Instrumented treadmill, Postural balance, Stroke

Outcome measures

Primary outcome

To assess the balance capacity in people in the chronic phase after a minor stroke, we will conduct a feet-in-place test, stepping test and step adjustment test on the N-Mill-DFP (treadmill with perturbation and measurement options).
In the intervention study, the balance capacity of participants will be assessed pre and post intervention. With regard to the cohort and intervention study, the main study parameters are the Frequency Response Function (FRF; feet-in-place test), the leg angle at stepping foot contact (stepping test) and the foot placement error (step adjustment test). For the cohort study, also the number of falls as registered during the one year follow-up will also be included as main study parameter.

Secondary outcome

With regard to the cohort and intervention study:

The secondary study parameter for the feet-in-place test include a human balance control model which is fit onto the experimentally derived FRF, to estimate parameters with a physiological meaning, for instance ankle joint passive stiffness, reflexive properties and neural time delay.
The secondary study parameters in the stepping test are the spatiotemporal step variables (i.e. step onset, step length, step duration, step velocity).
Furthermore, for stepping in medial lateral direction, the percentage of side steps will be included as study parameter.

For the step adjustment test, onset latencies of stepping adjustments and average speed of adjustments will be calculated as secondary study parameters.

Other secondary study parameters are the scores on the clinical assessment (i.e. Montreal Cognitive Assessment, Motricity Index, Fugl Meyer Lower Extremity Assessment, 10 meter walking test, Activities-specific Balance Confidence scale, Star Cancellation Test and balance test (Mini-BESTest or Berg Balance Scale)) and body sway and reaction forces for unperturbed standing (eyes open and closed). In addition, the daily activity level will be included as secondary parameter.

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. This makes falls and fall prevention of utmost importance for every person involved in stroke care. Currently, balance assessment in clinical settings depends on performance-based tests. These tests do not provide insight into the neurophysiological mechanisms underlying impaired balance, have substantial ceiling effects and are hence insensitive to detect more subtle impairments which still have tremendous impact on functioning in more advanced activities as in daily living. In recent years, several promising experimental tests have been developed that focus on various aspects of our balance capacity. In two of these tests mechanical perturbations during standing were applied to study someone*s feet-in-place responses and stepping responses. In addition, for safe ambulation it is also important to be able to flexibly adjust foot placements in response to environmental demands. This ability can be tested with a step adjustment test. Yet only preliminary evidence suggests that these tests can reveal the underlying mechanisms involved in impaired balance. Stepping responses and step adjustments have previously been used to distinguish people after stroke from healthy controls. However, currently it is still unknown whether the feet-in-place test, stepping test and step adjustment test are also sufficiently sensitive to detect very subtle balance impairments after a minor

stroke. Furthermore, previous research has shown that these balance tests 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

In a cohort of people after a minor stroke, we aim to investigate whether aforementioned balance tests are sensitive enough to detect subtle balance impairments. Secondly, we will investigate whether fall rates differ between people after a minor stroke and healthy controls. Furthermore, in a group of people with stroke with moderate impairments, we aim to investigate whether the outcomes on the tests are specific for the type of dynamic balance training provided.

Study design

This project will include two studies: 1) a cohort study and 2) an intervention study designed as an open-label randomized-controlled study.

Intervention

During the intervention study, participants will be randomized in one of the three interventions; two interventions consist of dynamic balance training on the C-Mill/3NP (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 will consist of walking on the C-Mill/3NP with augmented visual context (Visual Perturbed intervention) or walking on the C-Mill/3NP with mechanical perturbations (Mechanical Perturbed intervention). The level of difficulty will be increased each session based on a fixed individualized protocol.

Study burden and risks

Benefit: Participants in the cohort study will not directly benefit from participation in the study. Participants in the intervention study will possibly receive dynamic balance training. This is expected to translate into improved balance. However, 20 out of 60 participants will not receive training. Information gained from both studies will enhance our understanding of the underlying mechanisms involved in balance in people after stroke and healthy controls.

Burden: Participants in the cohort study will have a balance assessment of two hours. During a one-year follow-up period, daily activities will be monitored four times during a period of one week. In addition, participants will be asked to fill in a fall calendar. Participants in the intervention study will have a pre intervention balance assessment similar to the balance assessment of the cohort study. After the pre intervention balance assessment, daily activity levels will be monitored during one week. In the following 5 weeks, they will receive a training session of one hour, twice a week (except for participants receiving the Inactive Control intervention), resulting in 10 training hours. After the intervention period, participants will perform a post intervention balance assessment, which is similar to the balance assessment of the cohort study. Daily activity levels will also be monitored during one week after the post intervention balance assessment.

Risks: In recent studies, similar balance tests have been performed without occurrence of adverse events. The main risk to consider is that participants lose their balance during the balance assessment or training on a treadmill. However, falling is prevented by a safety harness.

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

In order to be eligible to participate in the cohort study as a participant that had a stroke, a participant must meet the following criteria:
- Having sustained a unilateral minor supratentorial stroke more than 6 months ago with hemiparesis involving the leg.
- Consequences of the stroke were not 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.;In order to be eligible to participate in the cohort study as a healthy participant, a participant must meet the following criteria:
- Not having sustained a stroke.
- Having the capacity to stand and walk *independently* as defined by a Functional Ambulation Categories score 5.
- 18 years or older.;In order to be eligible to participate in the intervention study, a participant must meet the following 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

With regard to the cohort and intervention study, a potential participant who meets any of the following criteria will be excluded from participation:
- 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 < 26).
- 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.;With regard to the intervention study, a potential

participant who meets any of the following criteria will also 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 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)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-02-2017
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	14-04-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-01-2017
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-04-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-05-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-06-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-06-2017
Application type:	Amendment
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: 27894
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL53300.091.15
OMON	NL-OMON27894