The efficacy of C-Mill training after stroke

No registrations found.

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

Summary

ID

NL-OMON26824

Source
Nationaal Trial Register

Brief title
C-Stroke

Health condition

Stroke, gait adaptability, treadmill, exercise
Beroerte, stapaanpassingen tijdens lopen, loopband, oefenen

Sponsors and support

Primary sponsor: MOVE Research Institute Amsterdam, Faculty of Human Movement Sciences, VU University Amsterdam, The Netherlands

Source(s) of monetary or material Support: MOVE Research Institute Amsterdam, Faculty of Human Movement Sciences, VU University Amsterdam, The Netherlands

Intervention

Outcome measures

Primary outcome

The primary outcome measures are walking speed as assessed with the 10 m walk test and gait adaptability as assessed with instrumented 10 m walk tests (i.e., obstacle avoidance and dual task walking).

Secondary outcome

Secondary parameters are commonly used gait and balance related clinimetric measures (e.g., Functional Ambulation Categories , Timed Up-and-Go test, Berg Balance Scale) as well as on fear of falling (Activities-specific Balance Confidence scale).
- gait adaptability as assessed with instrumented 10 m walk tests (i.e., obstacle avoidance and dual task walking).

Study description

Background summary

Almost one third of people with stroke remain unable to walk without supervision in their communities. For most people with stroke, regaining the ability to walk in their communities is of high importance. Community walking, however, requires the ability to adjust gait relative to the environment in order to avoid obstacles for example. Since the ability to adjust gait is often impaired after stroke, improving gait adaptability after stroke might improve safe community walking. The C-Mill, a treadmill that allows for projecting visual obstacles and targets on the belts' surface, has recently shown positive effects in that regard.

The main objective of the proposed study is to examine the relative efficacy of C-Mill gait adaptability treadmill training compared to the Nijmegen Falls Prevention Program (NFP program) for improving walking ability aspects, particularly walking speed and gait adaptability , in persons with stroke.

In this study, walking ability, walking speed and gait adaptability in a group of participants receiving 5 weeks of C-Mill gait adaptability training is compared with that of a group receiving 5 weeks of the lower-intensity, overground NFP program. This study is a single-centre randomized controlled trial with pre-tests, post-tests, retention tests and 12 month follow-up. It is expected that C-Mill gait adaptability training will result in better outcomes than the NFP program as a result of its enhanced training intensity.

Study objective

For most people with stroke, regaining the ability to walk in their communities is of high importance. Community walking, however, requires the ability to adjust gait relative to the environment in order to avoid obstacles for example. Since the ability to adjust gait is often impaired after stroke, improving gait adaptability after stroke might improve safe community walking. The C-Mill, a treadmill that allows for projecting visual obstacles and targets on the belts' surface, has recently shown positive effects in that regard. The main objective of the

current study is to examine the relative efficacy of C-Mill gait adaptability treadmill training compared to the Nijmegen Falls Prevention Program (NFP program) for improving walking ability aspects, particularly walking speed and gait adaptability, in persons with stroke. It is hypothesized that C-Mill training will result in better outcomes than the NFP program as a result of its enhanced training intensity.

Study design

1. Pre-intervention (week 1);

2. Post - intervention (week 6);

3. Retention (4 weeks post-intervention);

4. 12 month follow-up.

Intervention

1. C-Mill gait adaptability training: C-Mill gait adaptability training is treadmill training with a specific emphasis on training gait adaptability. The C-Mill is an instrumented treadmill that was specifically developed to provide task-specific, functional gait training based on individually measured gait characteristics. During C-Mill training, participants practice to control foot positioning on a step-to-step basis during walking by following an imposed step pattern with variation in step length, practice avoidance of real-virtual visual obstacles that are projected on the treadmill, and practice to accelerate and decelerate gait by following a projected walking zone moving in anterior-posterior direction relative to the treadmill. C-Mill gait adaptability training is provided 2 times per week for 90 minutes in groups of 2 participants for 5 consecutive weeks.

2.Nijmegen Falls Prevention (NFP) program: the NFP program is an overground, dose-matched training program developed to reduce the number of falls in community-dwelling elderly. Balance and coordination are practiced and integrated in an obstacle avoidance course that simulates potential challenging situations of daily life. These exercises also have to be performed while cognitive and motor dual tasks are imposed, as well as under visual constraints. In addition, the program incorporates exercises to simulate walking in a crowded environment. The NFP program is provided 2 times per week for 90 minutes in groups of 5 participants for 5 consecutive weeks.

Both intervention programs are matched in therapy duration (15h in total), frequency (2 times per week) and therapist-attention (1 therapist for 2 participants).

- The amount of movement practice (the number of steps taken per session)’ as a process measure. This will be used to examine how the treatment might work if there is a between-

group difference in the primary outcome for the trial. The number of steps taken per therapy session will be registered using the treadmill's inbuilt step counter (C-Mill therapy) and by counting steps from video recordings (FALLS program).

Contacts

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Eligibility criteria

Inclusion criteria

1. First ever stroke > 3 months ago;

2. Clinically diagnosed with hemiparesis;

3. Age ≥ 18 years;

4. FAC ≥ 3;

5. Simple instructions must be understood and executed.
6. walking and/or balance deficits confirmed by a physician

Exclusion criteria

1. Other pre-existing orthopaedic or neurological disorders that influence walking (e.g., Parkinson’s disease);

2. Moderate or severe cognitive impairment (as indicated by a score below 21 at the Mini Mental State Examination [MMSE]);

3. Other treatments that could influence the effects of the interventions (e.g., recent Botox treatment of lower extremity);

4. Contraindication to physical activity or practicing fall techniques (e.g., heart failure, osteoporosis);

5. Severe visual deficits which limit the correct perception of the patient’s direct environment.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	28-06-2013
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-06-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40076
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3842
NTR-old	NTR4030
CCMO	NL42461.029.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40076

Study results

Summary results
N/A