The efficacy of C-Mill training for improving walking ability, walking speed and gait adaptability in people post stroke: a single-centre RCT

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

Summary

ID

NL-OMON40076

Source
ToetsingOnline

Brief title
The efficacy of C-Mill training after stroke

Condition

- Central nervous system vascular disorders

Synonym
CVA, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: This study is part of a larger research program entitled 'Steps to follow and obstacles to avoid in speeding up functional gait rehabilitation' which is conducted at Faculty of Human Movement Sciences

Intervention

Keyword: exercise, gait adaptability, stroke, treadmill

Outcome measures

Primary outcome

The main study parameters are walking speed (10MWT) and gait adaptability

(IWW).

Secondary outcome

Secondary parameters are commonly used gait and balance related clinimetric

measures (i.e. FAC, TUG, BBS) and fear of falling (ABS scale).

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.

Study objective

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 (10m timed walking test [10MWT]) and gait adaptability using an Interactive Walkway (IWW), in persons with stroke. Secondary objective is to assess the efficacy of the two forms of training on

other commonly used gait and balance related clinimetric measures (e.g. Functional Ambulation Categories [FAC], Timed Up-and-Go [TUG] test, Berg Balance Scale [BBS]) as well as on fear of falling (Activities-specific Balance Confidence [ABC] scale).

Study design

This study is a single-centre randomized controlled trial with pre-tests, post-tests, retention tests and a 12 month follow-up.

Intervention

Participants will be allocated to either 5 weeks of C-Mill training, which is treadmill training with a specific emphasis on training gait adaptability, or 5 weeks of the NFP program. Both interventions are provided twice per week and are matched in terms of frequency, duration and therapist-attention. Randomization will be optimized for age, time post stroke and FAC score.

Study burden and risks

In order to improve safe community ambulation after stroke, it is important to gather evidence on the efficacy and underlying design features of intervention programs aimed at improving walking ability, walking speed and gait adaptability. The proposed study therefore aims to examine the relative efficacy of C-Mill gait adaptability training (high intensity, gait adaptability training) compared to the NFP program (lower intensity, gait adaptability training) on walking in persons with stroke. The present study will thus unveil the relative importance of practice intensity as a key design feature for effective intervention programs directed at improving gait adaptability and gait speed as important aspects of community walking after stroke. The risks of participating in the current study are negligible. The intensity of the training is only increased as tolerated by the participant. Persons that participate in this study are reasonably good community walkers. In addition, C-Mill training and the NFP program are frequently used methods in rehabilitation, and both are provided as regular therapy in Reade. The only burden of participating in the current study is the time investment associated with the training program, the pre-test, post-test, retention test. and follow-up test. The test will each take approximately 90-120 minutes and training will be provided twice per week for 90 minutes.

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

First ever stroke > 3 months ago
Clinically diagnosed with hemiparesis
Age >= 18 years
Functional Ambulation Category >= 3
Simple instructions must be understood and executed

Exclusion criteria

Other pre-existing orthopaedic or neurological disorders that influence walking (e.g. Parkinson*s disease)
Moderate or severe cognitive impairment (as indicated by a score below 21 at the Mini Mental State Examination)
Other treatments that could influence the effects of the C-Mill training (e.g. recent Botox treatment of lower extremity)
Contraindication to physical activity or practicing fall techniques (e.g., heart failure, osteoporosis)
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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-09-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	23-04-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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: 26824

Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42461.029.13
OMON	NL-OMON26824