Adaptability training for individuals after stroke

Published: 07-03-2022
Last updated: 05-04-2024

1. To evaluate the efficacy of a gait training program using an instrumented treadmill with virtual and augmented reality for improving gait adaptability in people in the chronic phase after stroke in an RCT. 2. To identify patient characteristics...

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

Summary

ID

NL-OMON50388

Source
ToetsingOnline

Brief title
ATTAINS

Condition

- Central nervous system vascular disorders

Synonym
Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Adaptability, Gait, Rehabilitation, Stroke

Outcome measures

Primary outcome

Time needed to complete the modified Emory Functional Ambulation Profile

obstacle task

Time needed (+ penaly time for errors) to complete the Walking Adaptability

Ladder Task

Secondary outcome

- Gait metrics derived from wearable sensors during the WALT

- Foot placement errors during the Target Stepping Task

- Quantity (number of steps) of daily life gait performance

- Quality of daily life gait performance (activity intensity, dynamic stability)

- Gait stability assessed during treadmill walking with and without

perturbations

Study description

Background summary

After stroke, a major impairment is a decreased ability to adapt gait to meet environmental demands. Rehabilitation programs targeting gait adaptability have gained interest in clinical practice, yet evidence for the efficacy of these interventions is limited to small, pilot trials. Moreover, it is unclear if and how the retention of beneficial effects of the intensive, but short-duration training programs can be maintained in the long run through booster sessions (single training sessions every 3 months) or an unsupervised home exercise program. We hypothesize that treadmill-based training with virtual and augmented reality will improve gait adaptability in post-stroke patients when compared to the standard care provided during a waiting-list control period. We

also hypothesize that providing booster sessions and/or unsupervised home-based practice will yield better retention of training effects at 1 year follow-up as compared to the control arm.

Study objective

1. To evaluate the efficacy of a gait training program using an instrumented treadmill with virtual and augmented reality for improving gait adaptability in people in the chronic phase after stroke in an RCT.
2. To identify patient characteristics that predict a favorable response to training.
3. To evaluate if retention of training-induced gains in gait adaptability can be fostered by providing booster sessions and/or by prescribing unsupervised home-based training.

Study design

We will use a waitlist controlled trial in this study (Study 1), to evaluate the short-term effect of gait adaptability training using augmented reality (on the C-Mill) in individuals in the chronic phase after stroke. Following the post-intervention assessment of Study 1 (S1-T1), all waitlist control participants will enrol in the gait adaptability training. They will undergo an additional assessment after completion of the training period (S1-T2). In the second part of the study, to evaluate the long-term effects of gait adaptability training, the patients who completed the gait adaptability training will be randomized (1:1:1) to one of three arms: booster sessions, home-based exercise program or a control arm. For the group randomized to gait adaptability training in study 1, we will use the post-intervention assessment of study 1 as baseline assessment for study 2 (S1-T1 = S2-T0) . For the wait-list control group, the additional assessment after completion of the training will be used as baseline assessment in study 2 (S1-T2 = S2-T0). Follow-up assessment will be done at 6 (S2-T1) and 12 (S2-T2) months following start of the intervention.

Intervention

Gait adaptability training with instrumented treadmill with augmented reality (C-Mill)

Study burden and risks

Health risks are minimal.
Burden will consist of the effort to do the assessments, training sessions and travel to the Sint Maartenskliniek

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

* >6 months after first unilateral supratentorial stroke (chonic phase)
* No contractures or spasticity requiring other treatments within the duration of the training period of study 1

Exclusion criteria

* any other neurological or musculoskeletal disease affecting gait or balance (e.g. Parkinson*s disease, knee osteoarthritis)
* unable to walk 10min without walking aid
* Has received multiple training sessions on C-Mill of GRAIL in the past 12 months

* severe cognitive or visuo-spatial impairments limiting comprehension of instructions or correct perception of the environments

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-09-2022
Enrollment:	84
Type:	Actual

Ethics review

Approved WMO Date:	07-03-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-01-2023
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

No registrations found.

In other registers

Register	ID
CCMO	NL80178.091.21