The influence of surgical correction of foot deformity on the effect of gait training on gait capacity in chronic stroke patients

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The primary objective of this study is to compare the effect of gait training on gait capacity (stepping performance, gait adaptability and dynamic balance) before and after surgical correction of post-stroke foot deformity.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON50562

Source
ToetsingOnline

Brief title
Window of trainability in relation to surgical correction of foot deformity

Condition

- Central nervous system vascular disorders

Synonym
Cerebrovascular accident (CVA), Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

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

Intervention

Keyword: Foot deformity, Gait training, Stroke, Surgical intervention

Outcome measures

Primary outcome

Primary outcomes will be gait adaptability as measured with the Emory Function Ambulation Profile (E-FAP), stepping performance as measured with the Timed-Up-And-Go test (TUG) and dynamic balance as measured with the Margin of Stability (MoS).

Secondary outcome

Concerning gait adaptability:

- Walking Adaptability Ladder Test (WALT)

- Modified Dynamic Gait Index (mDIG)

Concerning dynamic balance:

- Lyapunov exponent

- Foot placement estimator

- Distance between extrapolated center of mass (XCoM) and center of pressure (CoP) in anterior-posterior (AP) and medio-lateral (ML) direction

- Center of mass (CoM) - center of pressure (CoP) inclination angles

- Step width variability

- Step time variability

- Activities-specific Balance Confidence Scale (ABC Scale)

Concerning stepping performance:

- Spatiotemporal gait parameters

- Hip-knee-ankle-foot kinematics

- Peak ankle moment

- Peak ankle power

- Mini-BESTest

Other

- Activity during the training sessions

- Logbook training sessions

Study description

Background summary

Stroke is the leading cause of disability in the western world. In chronic stroke patients, foot deformity such as pes equinovarus is among the most important underlying motor deficits, due to imbalance of muscle strength and activity around the ankle and tarsal joints.

Both nationally and internationally, there is relative underuse of surgical treatment options, although in our clinical experience this often has the best outcome. In addition to positive clinical experiences with surgical interventions, we have experienced that before surgery, there is limited effect of gait training on gait capacity. However, we have experienced that after surgery, the restored normal ankle-foot position creates a new window for training opportunities to further improve gait capacity. Therefore, in this exploratory proof of principle study we aim to investigate the effect of surgical correction of post-stroke foot deformity on the (potential) improvement of gait capacity after gait training. Based on clinical experiences, we expect that after surgery, gait training results in a larger improvement in gait capacity compared to before the surgical intervention due to the increased possibilities to improve balance control.

Study objective

The primary objective of this study is to compare the effect of gait training on gait capacity (stepping performance, gait adaptability and dynamic balance) before and after surgical correction of post-stroke foot deformity.

Study design

Exploratory proof of principle study with repeated-measures.

Intervention

All patients will receive two gait training interventions, each consisting of twelve one hour training sessions. The training sessions will be focussed on improving gait capacity.

Study burden and risks

There are no serious risks associated with participating in this study. All training sessions will be given by experienced physiotherapists and the difficulty of the training sessions will be adjusted based on the patient*s capacity and performance. Furthermore, appropriate safety precautions will be taken during the training sessions when needed. For the measurement in the Gait Real-time Analysis Interactive Lab (GRAIL), the risk is also estimated as negligible, since the measurements will be performed by experienced and certified GRAIL operators. Moreover, patients will wear a safety harness to prevent falling. The assessment of the overground gait capacity outcomes will also be performed by experienced therapists and researchers. In addition, appropriate safety measures will be taken when necessary, such as therapists that are walking next to the patient to prevent falling.
The gait capacity training program will take place at the Sint Maartenskliniek in Nijmegen and consists of twelve training sessions of one hour per training session. Each patient will participate twice in the training program. Before and after each training program, measurements will be performed. The measurements will take approximately two hours. Hence, it will take the participants approximately 32 hours to participate in this study, excluding travel time.

Contacts

Public
Sint Maartenskliniek

Niek Engelschmanlaan 128
Nijmegen 6532CT
NL

Scientific
Sint Maartenskliniek

Niek Engelschmanlaan 128
Nijmegen 6532CT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Stroke patients with ankle-foot deformity
- > 6 months post onset
- 18 years or older
- Functional Ambulation Classification (FAC) => 3: the patient is able to walk without physical support

Exclusion criteria

- suffers from any other disorder that seriously affects gait capacity

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-10-2021
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

No registrations found.

In other registers

Register	ID
CCMO	NL78999.091.21