Improving propulsion of the paretic leg in chronic stroke

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

Summary

ID

NL-OMON46735

Source
ToetsingOnline

Brief title
I-PICS

Condition

- Central nervous system vascular disorders

Synonym
stroke/CVA

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Revalidatiefonds & Stichting Revalidatiegeneeskunde en Wetenschap

Intervention

Keyword: Gait training, Propulsion, Stroke

Outcome measures

Primary outcome

The primary outcome is the propulsion symmetry measured during walking at a comfortable, self-selected walking velocity.

Secondary outcome

Secondary parameters are 1) Walking velocity, 2) mobility at home, 3) determinants for the improvement in PP and 4) the score on the maximal step length test.

Study description

Background summary

Although most stroke survivors regain a (near) normal gait pattern, the walking velocity is slower. A possible explanation for the low walking velocity in stroke survivors is the decreased anterior ground reaction force that is achieved by the paretic leg (*paretic propulsion (PP)*). Interventions aiming to improve the PP in stroke survivors show a large variability in the response to the training. Outcomes suggest that part of the stroke survivors have a relevant, unused residual capacity in PP, which can be addressed by targeted task-oriented training. However, it is yet unknown who responds well to the training.

Study objective

The purpose of this study was to demonstrate that the PP can be improved in chronic stroke survivors using a newly developed, intensive training. The effect of the new training on the PP, walking velocity and mobility at home will be determined. Furthermore, determinants for the improvements in PP will be investigated. We strive to identify stroke survivors who will achieve a minimal gain in PP following the training using the maximal step length test, without the use of a gait laboratory.

Study design

The proposed study is an intervention study with multiple baseline design.

Intervention

Subjects receive two times per week gait training in gait robot LOPES II for 60 minutes per session during five weeks. The training will be complemented with daily home-based exercises, to practice the developed skills and gait strategies. Participants receive an individually tailored exercise program.

Study burden and risks

The gait training in the LOPES II is safe, although some subjects may experience small irritations of the skin due to the attachment to the LOPES II. During the measurements there is a chance that subjects might lose their balance. The chances that performing these tasks will lead to fall are not higher than during daily life. Subjects are allowed to take rest during the training and between the different measurements. The training and the measurements will be accomplished by an experienced physiotherapist who will take care of the patient.

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

- Adults (> 18 years) with an unilateral ischemic of haemorrhagic supratentorial stroke
- Time post stroke > 6 months
- Ability to walk at least 10 meters without the use of a AFO, walking aid or physical assistance from a person (FAC score 3-5, range 0-5)
- Ability to walk at least 5 minutes (assistive devices allowed)
- At least 8% propulsion asymmetry during gait at comfortable speed
- At least 10° passive hip extension and ability to stand with extended knees and plantigrade feet
- Ability to stand on the toes for 3 seconds, with symmetrical weight bearing between legs (MRC-score calf muscles * 3, range 0-5)
- Stable cardiovascular and general medical condition
- Sufficient communication ability (Utrechts Communicatie Onderzoek > 2)
- Signed informed consent

Exclusion criteria

- Insufficient mastery of the Dutch language
- Other disorders interfering with gait, like neurological and orthopaedic disorders, or recent orthopaedic interventions (within 6 months)

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-03-2019
Enrollment:	35
Type:	Actual

Medical products/devices used

Generic name:	LOPES II robotic gait trainer
Registration:	No

Ethics review

Approved WMO

Date:	06-09-2018
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	NL62617.091.17