Efficacy of Assist-As-Needed (AAN) robotic gait training in sub-acute stroke survivors.

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Primary objective:1) Does individually tailored robotic gait training with the LOPES II result in more reduction of mechanical work during walking and more improvement of gait symmetry than conventional gait training (of similar frequency and...

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

Summary

ID

NL-OMON46985

Source
ToetsingOnline

Brief title
Quality of gait after LOPES II gait training

Condition

- Central nervous system vascular disorders

Synonym
stroke/ CVA

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: ZonMw en Hersenstichting

Intervention

Keyword: Assist-As-Needed, gait training, Robotic, Stroke

Outcome measures

Primary outcome

The primary outcome is the quality of gait pattern as reflected by its mechanical efficiency. The mechanical work during walking can be derived from the movements of the Center of Mass (CoM). Because any improvement in gait symmetry will lead to smoother CoM trajectory, the CoM displacement will be used as a *composite* primary outcome that is applicable in every participant (independent of individual pre-set goals).

The individual pre-set goals are being trained using subtasks. OUcome parameters of the different subtasks are:

- Efficiency; mechanical work derived from CoM displacement

- Stability in Stance: knee and hip angles during single stance, step width and single stance symmetry

- Foot clearance: peak hip, knee and foot angles during swing phase, minimal footclearance during swing phase

- Foot prepositioning: peak knee extension and ankle dorsiflexion angles in terminal swing

- Step length: step length and step length symmetry

Secondary outcome

Secundary parameters are:

- leg motor function, measured with:

> leg score Fugl-Meyer Assessment

> Motricity Index

> Range of Motion hip, knee and ankle

- Walking ability, measured with:

> 10 meter walking test

> 6 minutes walking test

> Timed Up and Go test

> Dynamic Gait Index

- Patients' experience with walking in LOPESII, measured with

> System Usability Scale

> Intrinsic Motivation Inventory

Study description

Background summary

Stroke is a major cause of gait disability. Although regaining a (nearly) normal gait pattern is an important goal for stroke survivors, no exercise therapy has shown to improve the quality of gait after stroke. Robotic gait trainers might provide such an opportunity, but existing robots are based on a *one-size-fits-all* principle and insufficiently promote active learning. Newer generation robotic gait trainers, such as LOPES II, are designed to only assist selected subtasks of gait and promote active participation. These robots might, therefore, be able to support the relearning of an optimal gait pattern in the subacute phase of stroke, avoiding inadequate compensation strategies.

Study objective

Primary objective:
1) Does individually tailored robotic gait training with the LOPES II result in more reduction of mechanical work during walking and more improvement of gait symmetry than conventional gait training (of similar frequency and duration) in stroke subacute survivors who have at least a minimum level of gait independency?

Secondary objectives:
2) What is the effect of gait training in LOPES II on individual patients* goals compared to the conventional gait training?
3) What is the effect of gait training in LOPES II on walking ability (walking speed, walking distance and dynamic balance) compared to conventional gait training?
4) What is the patients* experience with robotic gait training?

Study design

The proposed study is a two-center assessor-blinded Randomized Controlled Trial

Intervention

Subjects will be randomised into two intervention groups:
- the experimental group receives 3 times per week gait training in LOPESII for 30 minutes per session during 6 weeks. The training will be complemented with maximal 2 conventional gait training sessions of 30 minutes per week by a physiotherapist. During the training the focus is on the individual set goals for improvement of gait.
- the control group receives conventional gait training by a physiotherpist 3 to 5 times per week for 30 minutes per session during a 6-weeks training period. The goal of training is also improvement of patients' individual goals for gait.

Frequency of therapies will be equal and controlled for both groups during the study.

Study burden and risks

Gait training is a common therapy during inpatient rehabilitation after stroke. The frequency of the given interventions is not exceeding the frequency of gait training during the rehabilitation program of these patients (FAC=>3). The study is part of the inpatient rehabilitation program. During the study, subjects will receive five gait training sessions a week during a period of six weeks.

The clinical measurements are also common measurements during the rehabilitation of stroke patients. Gait analysis and transcranial magnetic stimulation are frequent used methods in experimental studies. The time for measurements is extensive, so rest is possible for the patients.

The training and the measurements will be accomponied 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 a first-ever or secondary unilateral ischemic or haemorrhagic supratentorial stroke
- Functional Ambulation Category (FAC) <=> 3
- impaired quality of gait related to one of the five possible training goals ((efficiency, stability in stance, foot clearance, foot prepositioning and step length)
- stable cardiopulmonary and general medical condition
- Mini Mental State Examination (MMSE) > 22
- sufficient communication ability (Utrechts Communicatie Onderzoek > 2)
- Signed informed consent

Exclusion criteria

- insufficient mastery of the Dutch language
- serious orthopaedic disorders interfering with gait
- other neurological disorders
- depressed mood (Hospital Anxiety and Depression Scale > 7)
- No independent ambulation prior to stroke
- chronic (joint) pain
- severe spasticity interfering with robotic support

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-12-2015
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	LOPES II robotic gait trainer
Registration:	No

Ethics review

Approved WMO Date:	16-02-2015
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	24-11-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	27-09-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	04-05-2018
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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: 26996
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50748.044.14
OMON	NL-OMON26996