The quality of walking after LOPES II training.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26996

Source
Nationaal Trial Register

Health condition

Stroke
robotic
gait training
quality
Assist-as-needed

CVA
robot
looptraining
kwaliteit
ondersteuning-naar-behoefte

Sponsors and support

Primary sponsor: Roessingh Research and Development
Roessinghsbleekweg 33b
7522 AH Enschede
Source(s) of monetary or material Support: ZonMw and Hersenstichting

Intervention

Outcome measures

Primary outcome

- Quality of gait pattern in terms of symmetry in kinematics and mechanical work

- Individual goals gait:

> Efficiency: Mechanical work derived from COM displacement and movement of body segments.

> 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 foot clearance 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

- Leg motor function

- Walking ability

- Patient’s experience about training in LOPES II

Study description

Background summary

Rationale:

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 clearly 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. In a randomized controlled trial (RCT) the effect of training individually selected impaired subtasks of gait with the LOPES II will be compared to conventional physiotherapy. The main aim is to optimize the quality of the gait pattern.

Objective:

The primary objective of this study is to provide evidence that patient-specific training of impaired subtasks of gait in the LOPES II using AAN algorithms during the subacute phase (1-12 weeks) after stroke can improve the quality of the gait pattern, in terms of less mechanical work and more gait symmetry, more than conventional gait training. Participants will also be evaluated based on individual goal setting (personalized rehabilitation) and walking ability.

Study design:

The study will be conducted as a two-center assessor-blinded randomized controlled trial.

Study population:

Fifty subjects diagnosed with a (sub)acute stroke will be included. They will be recruited from the inpatient rehabilitation program at Roessingh, Centre for Rehabilitation Enschede and Sint Maartenskliniek Nijmegen. The main inclusion criteria for the subjects are: age ≥ 18 years; a first-ever unilateral stroke; having FAC 3 or larger (ability to walk without physical contact of a person), having impaired quality of gait related to the five possible training goals; having stable medical condition; having no intervening cognitive or communicational impairments; having no intervening other medical conditions.

Intervention:

The experimental group will receive six weeks of LOPES II training (aimed at improving individually pre-set goals), three times a week, for a maximum of 30 minutes per session, complemented with maximal two sessions of conventional gait training (physiotherapy). The control group will only receive conventional gait training between three and five times a week. The conventional gait training will be given according to the latest insights in neurorehabilitation.

Main study parameters/endpoints:

The main study parameter is 1) the quality of gait pattern as reflected by the mechanical work done (derived from movements of the Centre of Mass and the body segments relative to the COM) as a composite measure for the quality of gait pattern. Secondary study parameters are 2) leg motor function, 3) walking ability and 4) patient's experience.

Study objective

The LOPES II training will result in less mechanical work and better gait symmetry than conventional gait training.
Individual patient's goals will be better achieved by LOPES II gait training than by conventional gait training.
Improvements on walking ability are larger for LOPES II gait training than for the conventional gait training.

Study design

Subjects will be measured after inclusion (T0), after 6 weeks of training (T1) and at follow up 4 months after the intervention (T3).

Intervention

Experimental group recieves LOPES II training 3 times a week, complemented with maximal 2 times conventional gait training, based on preset goals (determined during gait analysis).

The control group recieves 3-5 times/ week conventional gait training following the latest guide lines of neurorehabilitation.

Contacts

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Eligibility criteria

Inclusion criteria

- adults (> 18 years of age) with a first-ever unilateral ischemic or haemorrhagic supratentorial stroke

- time since stroke between 4 and 6 weeks

- a Functional Ambulation Category (FAC) 3 or larger (walking with or without supervision or walking aid)

- 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 > 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 or interfering disorders

- Depressed mood (Hospital Anxiety and Depression Scale > 7)

- No independent ambulation prior to stroke

- Chronic (joint) pain

- Severe spasticity interfering with robotic support

- Inappropriate or unsafe fit of the robotic trainer due to extreme body size (bodyweight > 140 kg) and/or joint

contractures

- Skin lesions and/or pressure ulcers in areas where the support harness or LOPES II straps are to be fitted

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2015
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-02-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46985
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4954
NTR-old	NTR5060
CCMO	NL50748.044.14
OMON	NL-OMON46985

Study results

Summary results
No publications