Effects of robot-assisted treadmill training in combination with resistance exercise on locomotor performance and quality of life as well as cardiovascular and neuromuscular properties in patients after stroke and individuals with spinal cord injury.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32398

Source
ToetsingOnline

Brief title
Lokomat and resistance exercise after stroke and spinal cord injury.

Condition

- Other condition
- Cranial nerve disorders (excl neoplasms)

Synonym

cerebrovascular accident, spinal cord lesion, stroke

Health condition

dwarslaesie

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Nederlandse hartstichting;eventueel aanvulling door nationaal revalidatiefonds

Intervention

Keyword: CVA, gait training, muscles, quality of life

Outcome measures

Primary outcome

The time at the 10m walk test will be used as the primary outcome variable to

assess walking performance.

Secondary outcome

Additional outcome variables for functional performance are time to perform

get-up-and-go test; score at Berg Balance Scale; Functional Ambulation

Categories-score; Rivermead Mobility Index; distance walked at 6-min Walk test.

Scores at the questionnaires SS-QOL, RAND-36/SF-36 will be used for assessment

of quality of life and scores at the SIP68 will be used for assessment of

social participation.

Variables for cardiovascular function are maximal power output, VO2 and heart

rate during a graded exercise test.

Variables of lower limb muscle function include strength and rate of torque

development during maximal voluntary contractions and (submaximal) electrically evoked contractions and fatigue resistance will be assessed with repeated electrically evoked contractions.

Study description

Background summary

Stroke and spinal cord injury (SCI) leads to severe disability. Many patients have difficulties in performing daily life activities, such as walking or climbing stairs, leading to reduced participation (i.e. *involvement in life situations*) and quality of life. Therefore, an important part of rehabilitation programs in persons after stroke and (incomplete) SCI is aimed at restoration of gait function. There is a growing scientific support for the importance of task specific training in patients with neurological disorders. In addition, because muscle strength of the lower limbs seems to be closely associated with locomotor performance in these patients, additional resistance exercise of these muscles may be important. It is hypothesized that a combination of robot-assisted treadmill training with resistance training will lead tot significantly greater improvement of locomotor performance, participation and quality of life of stroke patients and individuals with incomplete SCI than regular occupational and physical therapy care.

Study objective

The primary objective of the SCI and to investigate its effectiveness on locomotor performance, participation and quality of life. The proposed study further aims to assess the time course of effects, not only during the training period, but also during follow-up after cessation of the training. Finally, it aims to assess the underlying proposed study is to construct a specific training program for stroke patients and persons with incomplete cardiovascular and neuromuscular mechanisms which may be associated with these effects.

Study design

A randomized controlled trial

Intervention

Patients will be assigned to either a control group or to one of two experimental groups. All patients (experimental as well as control groups) will receive similar standard occupational and physical therapy care, except for the

gait training module which is part of this rehabilitation program. One experimental group will receive a specific (gait) training program consisting of 2-3 weekly robot-assisted treadmill training sessions with a Lokomat robotic gait orthosis. The second experimental group also will receive the aforementioned lokomat-training, however, interspersed with a weekly bilateral lower limb resistance training session. This treadmill training (with or without additional resistance exercise) will substitute for the regular gait training module the subjects in the control group will receive.

Study burden and risks

Subjects will participate in a 9-months research project executing a 12 week training-program of robot-assisted treadmill training 2-3 days/week, interspersed with a weekly bilateral lower limb resistance training session. Measurements will be performed at maximal 10 different time slots including tests that assess locomotor performance and cardiovascular and neuromuscular function (45 min to 1.5 hours of duration) as well as questionnaires for social participation and quality of life. Subject may experience some discomfort during electrical stimulation and/or muscle soreness after muscle tests. Furthermore, the risks during training and testing sessions are relatively low because of thorough screening prior to participation, use of skilled and licensed therapists and safety precautions throughout training and testing. The expected beneficial training effects in combination with the limited risks would justify execution of the proposed study.

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

CVA
- first ever stroke (ischaemic, hemorarghic)
- hemiparesis (at least lower limb)
- min. age: 18 yrs
SCI
- motor incomplete lesion (ASIA C, D)
- paraplegia (at least lower limb)
- min age: 18 yrs.
All patient must be incapable to walk unaided.

Exclusion criteria

- medical complications such as unstable hypertension-
arrhythmias and unstable cardiovascular problems
- severe skeletal problems such as osteoarthritis of the lower limbs.
- severe cognitive and/or communicative problems, preventing ability to follow verbal instructions
- earlier neurological and/or psychiatric problems
- other problems that would limit the ability to perform the requested tasks
- contra-indications for electrical stimulation (unstable epilepsy, cancer, skin abnormalities, pacemaker).

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2008
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	17-03-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL22052.029.08