The effects of body weight support, guidance, and gait speed on the patterning of muscle activity in the Lokomat

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a. To establish the effects of (1) body weight support (2) treadmill speed, and (3) level of movement guidance provided by the exoskeleton on the neuromuscular control of the lower extremities.b. To establish the interactions between the above...

Ethical review	Approved WMO
Status	Completed
Health condition type	Neuromuscular disorders
Study type	Interventional

Summary

ID

NL-OMON40057

Source
ToetsingOnline

Brief title
Patterning of muscle activity in the Lokomat

Condition

- Neuromuscular disorders

Synonym
cerebrovasculair accident (CVA); Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Gait, Muscle activity, Rehabilitation, Robotics

Outcome measures

Primary outcome

The amplitude of mucle activity in µvolt.

Secondary outcome

Does not apply

Study description

Background summary

The Lokomat is a position controlled exo-skeleton that is utilize for the training of gait skills in (neurological) patients. During training in the Lokomat, a number of relevant parameters can be precisely adjusted by the trainer: (1) treadmill speed (2) the amount of body weight support, and (3) the level of movement guidance delivered by the Lokomat. For the development of effective training programs it is important to understand how settings of these parameters affect the control of gait in the Lokomat. A logical approach is to assess how treadmill speed, level of body weight support, and the level of movement guidance affect the neuromusculair patterns of gait, and how these differ from normal, overground walking.

Study objective

a. To establish the effects of (1) body weight support (2) treadmill speed, and (3) level of movement guidance provided by the exoskeleton on the neuromuscular control of the lower extremities.
b. To establish the interactions between the above mentioned factors on the neuromuscular control of the lower extremities.
c. To establish whether there are differences in the patterns of muscle activity between those obtained during walking in the Lokomat and those obtained during walking overground.

Study design

Participants will be required to walk in the exoskeleton for trials of 40 seconds, while the activity of the following muscles will be measured by means of electromyography (EMG): (1) Gastrocnemius medialis (2) peroneaus longus (3) soleus (4) tibilais anterior (5) rectus femoris (6) vastus medialis (7) Semitendinosus (8) biceps femoris. During each individual trial, a unique combination of gait speed, body weight support, and guidance will be presented to the participant. All independent variables will be varied at 3 levels (gait speed: 1,3, and 5 km/h; body weight support: 0, 15, an 30% of the participants* body weight; guidance: no guidance, moderate guidance, strong guidance). In total, (3x3x3=) 27 trails of 40 seconds duration will be performed. In addition, participants will walk an overground trajectory (10 meters), i.e. without the exoskeleton, a total of six times.

Intervention

Sixteen self-adhesive electrodes will be attached to the skin of each participant.

Study burden and risks

Walking in the exoskeleton may be somewhat fatiguing to some people, when extremely low treadmill speeds (< 2km/h) and high levels of body weight support (> 30% of body weight) are used. Because participants wear a harness, and the treadmill Is equipped with hand rests, participants will not be able to fall.
In case of unexpected calamities, the experimenter as well as the participant can press a *emergency-stop*, which will halt the treadmill and the exo-skeleton immediately. If walking in the Lokomat becomes uncomfortable for some reason (e.g. skin irritation, pain in muscles/tendons), the participant can indicate this and the experiment will be paused or aborted.

The required gait activity of participants is similar to everyday walking. The participant is not likely to experience any burden from the elektrodes of the EMG system.

In the light of the relatively low burden and the small risks associated with this study, it seems justified to conduct this study because it may yield important information that can be used to develop training protocols for neurological patients.

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

Participants should be between 20 and 30 years of age.

Exclusion criteria

Participants suffer from neurological, orthopedic, visual, somatosensory or vestibular disorders, or any other disorder that is known to affect gait behavior or muscle activity. Participants with skin diseases will also be excluded.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	28-06-2013
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	13-06-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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: 26453
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	(is aangevraagd) Candidate number 14576
CCMO	NL42826.042.12
OMON	NL-OMON26453