Patterning of muscle activity in the Lokomat in persons with stroke

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28557

Source
Nationaal Trial Register

Health condition

Gait disorders

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG)
Source(s) of monetary or material Support: D.N.A.

Intervention

Outcome measures

Primary outcome

The rectified and filtered EMG values will be summed for each of the following subphases of the gait cycle: (1) the first double support phase, (2) the single support phase, (3) the second double support phase, and (4) the swing phase. These summed activities will be averaged over strides for each participant. This will result in 4 gait phase values for each unique condition, for each participant. This will allow us to conduct a separate repeated measures ANOVA for each subphase and each muscle, and answer each of the following questions:

1. ‘Are the effects of the main training parameters (treadmill speed, BWS, and guidance) on

muscle activity different for hemiparetic walkers compared to healthy walkers?’

2. ‘Are the effects of the main training parameters (treadmill speed, BWS, and guidance) different for the impaired leg compared to the unimpaired leg in research subjects with hemiparetic stroke ?’ This question concerns the stroke group only.

3. ‘Are the effects of the exo-skeleton on muscle activity different for hemiparetic research subjects compared to healthy walkers, and how does the exo-skeleton affect the effects of BWS and gait speed in both groups?’

The stability of EMG amplitude over the gait cycle will be assessed by calculating the root mean square (RMS) values for the time-normalized EMG pattern of each muscle, for both sessions. Between RMS values of both sessions, intraclass correlation coefficients will be calculated for each muscle and both groups.

Secondary outcome

N/A

Study description

Background summary

The Lokomat is an exoskeleton that is used to retrain gait skills in persons with gait impairments e.g. due to cerebrovascular stroke. As of yet, it is not known which training protocols for the Lokomat will lead to optimal results in this patient population. In order to develop goal-specific and effective protocols, it is essential to understand (1) what the immediate effects are of the training parameters of the Lokomat (treadmill speeds, body weight support (BWS), and movement guidance) on the gait patterns of persons who suffered a stroke, and (2) whether these effects are stable over sessions. A potentially useful approach to answering these questions is to investigate patterns of muscle activity using electromyography (EMG), to determine the immediate effects of the training parameters and establish how stable these effects are over two sessions.

Therefore, this study has three objectives:
(1)To establish the effects of (a) body weight support (b) treadmill speed, and (c) the level of movement support provided by the Lokomat (so called ‘guidance’), on the neuromuscular control of the lower extremities, and to determine whether these effects differ between persons with post-stroke hemiparesis and healthy walkers, and between the impaired and the unimpaired leg in persons with hemiparetic stroke .
(2) To compare the patterns of muscle activity displayed in in the exo-skeleton of the Lokomat, and during walking on the treadmill outside the exo-skeleton, and to determine whether the effects of the exo-skelton differ between persons with hemiparetic stroke and their healthy peers.

(3) To determine the between session stability of muscle activity in the Lokomat, and to compare this between persons with hemiparetic stroke and their healthy peers.

Stroke patients (n=10) and healthy walkers (n=10), with a minimum age 18 years, will be assessed both during walking in the exoskeleton of the Lokomat, and during walking on the treadmill outside the exo-skeleton. When walking in the Lokomat, the following parameters will be varied: (1) gait speed (2) the level of BWS, and (3) the level of guidance. The effects of walking in the exo-skeleton, and the effects of BWS, guidance and speed (and their mutual interactions) will be compared between both study groups, for each of 4 subphases of the gait cycle (first double support phase, single support phase, second double support phase, swing phase).

Study objective

The Lokomat is an exo-skeleton that can be used to retrain gait skills in persons with post stroke hemiparesis. As of yet, it is still not clear what protocols should be used to obtain optimal treatment results in this population. In order to develop goal-specific and effective protocols, it is essential to understand (1) what the immediate effects are of the training parameters of the Lokomat (treadmill speeds, body weight support (BWS), and movement guidance) on the gait patterns of persons who suffered a stroke, and (2) whether these effects are stable over sessions. A potentially useful approach to answering these questions is to investigate patterns of muscle activity using electromyography (EMG), to determine the immediate effects of the training parameters and establish how stable these effects are over two sessions.

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(1)To establish the effects of (a) body weight support (b) treadmill speed, and (c) the level of movement support provided by the Lokomat (so called ‘guidance’), on the neuromuscular control of the lower extremities in , and to determine whether these effects differ between persons with post-stroke hemiparesis and healthy walkers, and between the impaired and the unimpaired leg in persons with hemiparetic stroke .
(2) To compare the patterns of muscle activity displayed in in the exo-skeleton of the Lokomat, and during walking on the treadmill outside the exo-skeleton, and to determine whether the effects of the exo-skelton differ between persons with hemiparetic stroke and their healthy peers.
(3) To determine the between session stability of muscle activity in the Lokomat, and to compare this between persons with hemiparetic stroke and their healthy peers.

Study design

The study involves two testing sessions for both study groups. For stroke patients, an additional session will be organized to make appropriate adjustments to the Lokomat (e.g. selection of cuffs, adjustments of the length of the exo-skeleton segments). For healthy walkers, these adjustments will be made during the first test session.

Test session 1
Prior to testing in the Lokomat exo-skeleton, participants will walk 4 trials outside the

Lokomat exo-skeleton at varying levels of gait speed (1.0, 2.0 km/h) and BWS (0% and 50%). Next, 8 trials will be conducted in the Lokomat. Before testing in the Lokomat will commence, participants are allowed practice time in the Lokomat to get accustomed with the setup. This practice time will also include variations in BWS, gait speed and levels of guidance. When the participant indicates to be comfortable, testing will commence.

During each trial in the Lokomat, a unique combination of gait speed, body weight support, and guidance will be presented to the participant. Gait speed will be varied at 2 levels (1.0, and 2.0 km/h), BWS will be varied at 2 levels (0% and 50% of the participant's body weight), and guidance will be varied at 2 levels (50% and 100%). The latter condition implies that the stepping movements are fully imposed by the exo-skeleton (i.e. the gait movements can be made without active participation of the subject). Because shifts between different conditions may require some time for the participant to adapt, a 1-minute acclimation period will be given between trials. The duration of each trial will depend on the imposed treadmill speed (50 seconds when walking at 2.0 km/h, 120 seconds at 1.0 km/h) to maintain the number of recorded strides approximately constant over gait speed conditions.

In total, test session 1 is expected to last approximately 2 hours for persons with stroke and 3 hours for healthy walkers.

Test session 2
Within one month (but at least one week) after the first session, all participants will be assessed a second time to determine the extent to which walkers display stable (i.e. reproducible) patterns of muscle activity in the Lokomat. To this end, the proocol as used during the first session will be repeated (see above). The second test session will take place within one month, but at least one week after the first session.

Test session 2 is expected to last approximately 2 hour.

Intervention

Both groups of participants will be assessed during two sessions. During session 1, all participants will walk on a treadmill in an exoskeleton (the Lokomat) during 8 trials, in which BWS (2 levels: 0% and 50% of the participants' body weight), guidance (2 levels: 50% and 100%), and gait speed (2 levels: 1.0 km/h and 2.0 km/h) will be varied. During session 1, participants will also walk outside the exoskeleton on the treadmill for 4 trials, in which BWS (2 levels: 0% and 50%) and gait speed (2 levels: 1.0 km/h and 2.0 km/h) will be varied. The duration of each trial will depend on the imposed treadmill speed (50 seconds when walking at 2.2 km/h, and 120 seconds at 0.8 km/h).

During session 2, the stability of muscle activation patterns in the Lokomat will be assessed. To this end, the protocol as used during the first session will be repeated (see above). The second test session will take place between 7 and 14 days the first session.

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

Persons with stroke:
1. A first ever, unilateral stroke (infarction or hemorrhage)
2. At least 3 months post onset
3. Unilateral paresis of the leg
4. A Functional Ambulation Categories Score of 2 (‘ Person needs continuous or intermittent support of one person to help with balance and coordination’) or 3 (‘ Persons requires verbal supervision or stand-by help from one person without physical contact’)
5. Subjects should be older than 18 years

Healthy walkers:
1. Participant should be older than 18 years to be included

Exclusion criteria

Exclusion:
A candidate subject who meets any of the following criteria will be excluded from the study:

Persons with stroke:
1. Severely impaired cognitive functions (Mini Mental State Exam score ≤25)
2. Severe speech, language or communication disorders (it will be left to clinical judgment whether the research subject is able to understand instructions and to provide informed consent; in case of doubt the Aachen Aphasia Test will be administered).
3. Insufficient working knowledge of the Dutch language to understand instructions and provide informed consent (clinical judgment).
4. Severe visual problems (clinical judgment).
5. Severe neglect (clinical judgment through observation. In case of doubt, the Star Cancelation Test can be administered).
6. Co-morbidity that can affect the results of the study (e.g. pre-existent problems in leg function or a progressive neurological disorder).
7. Participation in other scientific studies.

Healthy walkers:
1. The participant suffers from neurological, orthopedic, visual, somatosensory or vestibular disorders, or any other disorder that is known to affect gait behavior or muscle activity.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2014
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 40378
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4245
NTR-old	NTR4390
CCMO	NL46137.042.13
OMON	NL-OMON40378

Study results

Summary results
D.N.A.