Spieractiviteit in de Lokomat.

No registrations found.

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

Summary

ID

NL-OMON26453

Source
Nationaal Trial Register

Health condition

Gait disorders; loopvaardigheidsproblemen

Sponsors and support

Primary sponsor: UMCG (Universitait Medisch Centrum Groningen)
Source(s) of monetary or material Support: UMCG (Universitait Medisch Centrum Groningen)

Intervention

Outcome measures

Primary outcome

1. The obtained time normalized data will be used to construct a linear model (see Hof et al. 2002 and den Otter et al. 2004 for a similar approach) in which the relative contributions of (1) gait speed (2) BWS and (3) level of guidance and their mutual two-way interactions will be estimated. This type of analysis will result in plots that represent the changes in so-called neuromuscular gain due to a factor/interaction over the gait cycle. These plot will be used for visual assessment only, and not for statistical analysis;

2. For each muscle, the raw (i.e. not time normalized) data will be rectified (i.e. all measurement values will be made positive) and 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 (µvolt) will be averaged over strides for each participant. This will allow us to conduct a separate repeated measures analysis for each subphase and each muscle;

3. The amplitude of rectified muscle activity will be evaluated for the 4 phases of the gait cycle, and compared between overground walking and walking in the Lokomat , using a oneway repeated measures analysis of variance.

Secondary outcome

N/A

Study description

Background summary

The Lokomat is a recently developed exo-skeleton that is used to retrain gait skills in persons with reduced locomotor skills due to neurological trauma or disease (Colombo et al 2000). As of yet, it is not known which training protocols for the Lokomat will lead to optimal results. In order to optimize training protocols, it is essential to understand how and to what extent the exoskeleton and the main trainings parameters (gait speeds, BWS, and the amount of guidance) affect the gait pattern. One approach to study these effects is to record patterns of muscle activity by means of EMG, and assess how these patterns are altered as a function of the parameters mentioned above.

Therefore, this study has two objectives. First, to determine the effects of (1) the exoskeleton (2) gait speed (3) level of body weight support (BWS), and (4) level of guidance on the patterns of muscle activity in the lower extremities; Second, to establish differences in the muscular control of walking in the Lokomat and walking overground.

Participants (n=10, between 20 and 30 years of age)) will be assessed both during walking in the exoskeleton of the Lokomat, and during walking overground (i.e. outside the exoskeleton/Lokomat). 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 collected EMG data will be assessed by (1) creating a linear model to estimate the relative contributions of body weight support, gait peed, and movement guidance to the observed levels of muscle activity, and (2) statistical comparisons (repeated measures ANOVA) between the integrated levels of muscle activity for 4 subphases of the gait cycle (first double support phase, single support phase, second double support phase, swing phase) to establish the effects of body weight

support, gait peed, and movement guidance on the levels of muscle activity.

Study objective

The Lokomat is a position-controlled exo-skeleton that is used 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 potentially useful approach is to assess how treadmill speed, level of body weight support, and the level of movement guidance affect the neuromuscular control of gait by means of electromyography.

Therefore, the objectives of the study are:
A. To establish the effects of (1) body weight support, (2) treadmill speed, and (3) level of movement guidance provided by the exo-skeleton on neuromuscular control of walking in the Lokomat;

B. To establish the interactions between the above mentioned factors on the neuromuscular control of walking in the Lokomat;

C. To establish whether there are differences in the patterns of muscle activity between overground walking and walking in the Lokomat.

Study design

Testing will be conducted in several phases.

1. Measurements and adjustments will be made (e.g. selection of cuffs, adjustments of the length of the exo-skeleton segments) so as to fit the exo-skeleton to the participant (40 minutes);

2. Preparations will be made to apply EMG-electrodes (in particular, localization of the muscles, preparation of the skin) and fit the EMG amplifier (20 minutes);

3. Testing, including 27 trials of 40 seconds each + time in between trails to adapt to the new condition. In between trials, participants will be allowed to rest (45 minutes);

4. Six trails of overground walking will be conducted (15 minutes).

In total, the experiment is expected to last approximately 2 hours.

Intervention

During testing, participants will be required to walk in the exoskeleton for 27 trials of 40 seconds each. 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). So in total, (3x3x3=) 27 trails of 40 seconds duration will be performed. Because shifts between different conditions may require some time for the participant to adapt, 1 minute acclimation periods will be given between trials. Finally, both prior to testing in the Lokomat and afterwards, participants will produce 3 (i.e. a total of 6) trials of overground walking (10 meters), i.e. without the exoskeleton and treadmill.

Contacts

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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:

Participants should be between 20 and 30 years of age.

Exclusion criteria

Candidate participants that meet any of the following criteria will be excluded from participation in this study:

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;

2. Participants with skin diseases will also be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2013
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion
Date: 22-03-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40057
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3755
NTR-old	NTR3919
CCMO	NL42826.042.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40057

Study results

Summary results
N/A