Exploring the effects of a restraining force during gait in persons with post-stroke hemiparesis and able-bodied individuals

Published: 20-04-2020
Last updated: 08-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON49478

Source
ToetsingOnline

Brief title
Effects of a restraining force during (hemiparetic) gait

Condition

- Central nervous system vascular 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: impeding force, stroke, walking

Outcome measures

Primary outcome

Ground reaction forces.

Secondary outcome

(1) spatial and temporal gait variables, (2) EMG amplitudes of seven muscles of

both legs, (3) hip, knee and ankle joint angles and (4) perceived exertion.

Study description

Background summary

Gait recovery is a major goal of rehabilitation after stroke [Bohannon 1998]. Propulsion is one aspect of gait that is often affected after a stroke [Awad et al., 2014; Bowden et al., 2006; Chen et al., 2005; Sousa et al., 2013]. Propulsion can be defined as the forward component of the ground reaction force [Hsiao et al., 2016]. In healthy adults, the negative force during heelstrike is compensated by the positive work during toe-off of the contralateral leg. In stroke patients, this negative force during heelstrike is not compensated by the positive work during toe-off. Therefore, paretic propulsion is seen as a limiting factor in functional gait performance [Awad et al., 2014; Bowden et al., 2006; Chen et al., 2005; Sousa et al., 2013].

Improvements in paretic propulsion have shown to go along with improvements in functional balance, walking function (i.e. walking speed and long distance walking ability) and self-perceived participation [Awad et al., 2014; Nadeau et al., 1999]. Therefore, training propulsion is beneficial for stroke patients. However, a strategy that can be broadly applied is not that straightforward. Strategies using functional stimulation [Awad et al., 2014] or assistive devices [Forrester et al., 2016] have shown improvements in paretic propulsion. More simple strategies like body-weight supported treadmill training, however, are unable to show improvements in propulsion [Combs et al., 2012].

Perturbing the forward movement during gait is known to induce a higher

propulsive force [Lewek et al., 2018]. This perturbation can be established by placing a simple pulley-system behind the treadmill. Previous research already showed that such a restraining force during treadmill walking leads to improvements in paretic propulsion [Lewek et al., 2018]. There are several strategies stroke patients can use to increase propulsion during gait. One option is to use the hip muscles during pull-off to increase the trailing limb angle [Nadeau et al., 1999]. Another option is to use the plantarflexor muscles during push-off to increase ankle moment [Nadeau et al., 1999]. These strategies can differ between individuals, but also between legs [Hsiao et al., 2016]. For training purposes, it is informative to know how stroke patients coordinatively solve the problem. In addition, we wish to address if they will use the same strategies as healthy participants to generate a higher propulsive force.

Study objective

The aims of the present study are (1) to assess the immediate effect of a restraining force during treadmill walking on propulsion, (2) to assess what strategy stroke patients use to increase their propulsive force and (3) to assess if stroke patients use a different strategy to increase their propulsive force compared to healthy age-matched adults.

Study design

This is an explorative study with a mixed design with repeated measures and two groups. Participants (15 chronic stroke patients and 15 healthy gender and age-matched controls) will walk on a treadmill during six conditions with a duration of 90 seconds each. The measurement session will have a total duration of approximately two hours. Before participation in the study, each participant will sign a written informed consent form. Travel expenses will be reimbursed and all participants will receive a gift card to compensate for their invested time and effort.

First, participants will walk on the treadmill (Motek, Amsterdam, The Netherlands) at 0.28 m/s and 0.56 m/s (the speed levels will be offered in a randomized order) without the pulley-system. Next, participants will walk on the treadmill with the pulley system attached to their pelvic brim with a load of 5 percent and 10 percent of their body weight attached to the pulley-system at 0.28 m/s and 0.56 m/s (these four conditions will be offered in a randomized order). The acceleration of the weight attached will be measured using a Trigno wireless sensor (bandwidth: 20-450 Hz; Delsys, Natick, MA, USA) to be able to calculate the exact restraining force (according to F=m*a).

Ground reaction forces of both legs will be measured using two force plates that are incorporated into the treadmill. We can infer the propulsive force based on this ground reaction force (primary objective). In addition, with the

ground reaction force, we can calculate the step length, step width and stance/swing durations. These gait variables may help us to say something about the strategy the participant uses to increase his/her propulsive force (first secondary objective).

In addition, to say something about the strategies the participants use to increase the propulsive force (first secondary objective) we will also measure muscle activity and joint angles. During all (six) conditions, muscle activation patterns will be measured bilaterally using surface electromyography (EMG) from: Gluteus Medius, Biceps Femoris, Rectus Femoris, Vastus Medialis, Mediale Gastrocnemius, Soleus and Tibialis Anterior. Joint angles of the hip, knee and ankle will be measured bilaterally using Xsens.

To assess the difference between stroke patients and healthy controls (second secondary objective), we will measure, besides the above mentioned variables, the rate of perceived exertion. The heart rate and the Borg scale will be measured/administered before the experiment and directly after each condition.

Lastly, several characteristics of the participants will, if applicable, be collected for descriptive purposes: score on the *single leg heelrise test*, use of medicine, location of the stroke (left/right and subcortical/cortical), gender, age, time poststroke in months, type of the stroke (haemorrhagic/ischaemic), type of paralysis (spastic or non-spastic), surgery after the stroke with the aim to improve gait ability, history of botulin toxin injections, FAC score, use of walking aids, leg length, body length and body weight.

Intervention

Walking on a treadmill during six conditions (see study design).

Study burden and risks

Because the participant is wearing a harness (similar to a parachute harness) while walking on the treadmill that is attached to a suspension anchored in the ceiling and the treadmill is equipped with hand rests, it is not possible to fall. In the event of unexpected incidents or inconveniences, both the investigator and the participant can press an emergency button that immediately stops the band.

The session will last approximately 2 hours. Of this time, only (6 measurements * 90 seconds =) 9 minutes will be spent walking on a treadmill. In addition, there will be a pause of at least 5 minutes after each measurement. If the subject wants a longer break, this is permitted. Experience shows that stroke patients (and healthy people) tolerate this burden without many problems. In addition, a physical therapist will be present during measurements with

patients who can monitor the well-being of the patient.

If emergencies occur, both the participant and the researcher can immediately stop the treadmill by pressing an emergency button. If walking on the treadmill is uncomfortable for whatever reason (for example due to skin irritation of the electrodes or pain on muscles/tendons) this can be indicated and the measurement will be paused or interrupted in consultation with the participant.

Most of the time the electrodes, sensors and heart rate belt do not cause inconvenience. In view of the low burden and the low risk, it seems justified to carry out such a study because it can provide important information for developing training for the walking ability of stroke 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

Patients:
- A first unilateral stroke (infarction or haemorrhage).
- At least twelve months post onset.
- A unilateral paresis of the leg.
- A Functional Ambulation Categories Score (FAC) of 3 (*is capable of walking when a safer environment with supervision or verbal guidance is provided'*) to 5 (*is independently capable of walking on flat and non-flat surfaces, on slopes and is capable of walking the stairs*).
- Patient should be 18-70 years old at the time of inclusion.
- Written informed consent

Healthy controls:
- Participants should be 18-70 years old at the time of inclusion.
- Participants should match with one of the included patients on gender and age.
- Written informed consent

Exclusion criteria

Patients:
- Severely impaired cognitive functions (Mini Mental State Exam score <25).
- Severe speech, language or communication disorders (it will be left to clinical judgment whether the patient is able to understand instructions and to provide informed consent; in case of doubt the Aachen Aphasia Test will be administered).
- Insufficient working knowledge of the Dutch language to understand instructions and provide informed consent (clinical judgment).
- Severe visual problems (clinical judgment).
- Severe neglect (clinical judgment through observation. In case of doubt, the Star Cancelation Test can be administered).
- Co-morbidity that can affect the results of the study (e.g. pre-existent problems in leg function or a progressive neurological disorder).
- Participation in other scientific studies.
- Use of botulin toxin injections in the lower extremities or oral spasmolytic in a period of two months prior to the measurement.
- Use of an active splint that delivers energy for forward propulsion.

Healthy controls:
- Suffer from neurological, orthopedical, somatosensory, visual, vestibular or other conditions that are known to affect the gait pattern.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-07-2020
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	20-04-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-12-2020
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL73086.042.20