Reactive foot placement in balance control during standing and walking in healthy young adults and stroke survivors.

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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-OMON44237

Source
ToetsingOnline

Brief title
Reactive foot placement in balance control

Condition

- Central nervous system vascular disorders

Synonym
motor control, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente

Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Balance control, Reactive stepping, Standing, Walking

Outcome measures

Primary outcome

The main parameters under study are stepping location (length, width) and swing time (time between toe-off and heel strike).

Secondary outcome

Secondary endpoints are the distance between center of mass and center of pressure, ground reaction forces of the stance leg(s), joint angles and joint torques, body momentum, body sway in the frontal plane, and muscle (reflexive) activity as resulting from an externally applied perturbation and during the balance recovery thereof, as well as their relation to the primary study parameters.

The study parameters will be incorporated in a mathematical explanatory model that describes the relations between the main and secondary study parameters, both for healthy subjects and stroke survivors. This way, human-like stepping behavior might be predicted given the observed related quantities. Furthermore, data collected in experiments done with and without the balance device, will be compared in order to evaluate the contribution of the inertial flywheel actuator in helping subject to keep balance.

Study description

Background summary

In daily life the upright human body is continuously challenged by external disturbances, such as gravitational forces and forces originating from interactions with the environment. These disturbances can lead to a loss of balance, which must be acted upon accordingly to prevent a fall. Following a disturbance, proper foot placement is crucial for maintaining balance during both standing and walking. However it is unclear why humans place their foot at a certain location at a certain time following an unexpected balance disturbance. A model based prediction of a suitable foot placement location to maintain balance and prevent falls can have great value in both clinical and robotics fields of research. Investigating foot placement in stroke patients can lead to a better understanding how stroke related complications affect foot placement, and how these might be compensated using supportive devices such as exoskeletons or balance keeping devices. The latter are wearable and portable robotic devices developed with the aim of detecting the subject*s loss of balance and of providing corrective actions to avoid or delay the risk of falling. An open research topic related to the development of these devices deals with assessing their effectiveness by evaluating how human balance performance changes by using supportive devices.

Study objective

The goal of the research is to apply balance perturbations during standing and walking, and capture the resulting stepping responses. These data will be used to develop and verify predictive models of foot placement. Such models might eventually be incorporated in rehabilitation or balance assisting devices. Another aim of this study is to assess how the balance keeping performance of subjects changes by using a supportive device. An inertial flywheel actuator has been designed at UT to assist subjects in keeping balance in the frontal plane. The effectiveness of the device will be evaluated by comparing the balance keeping performance of subjects when they wear and when they do not wear the inertial flywheel actuator.

Study design

The study is designed as a non-invasive cross-sectional intervention study to assess foot placement for the control of balance during standing and walking. The effectiveness of the inertial flywheel actuator in supporting subjects to keep balance in the frontal plane will be also evaluated. It consists of two main experiments, one in standing and one in walking, each consisting of one or more sessions. The test conditions within a session will be randomized. Healthy subjects might be asked to participate in an additional session with altered conditions that were not captured in the main session. Stroke survivors will only participate in the main session.

Intervention

Balance will be perturbed during standing and/or walking by applying sudden forces of various magnitudes and duration at the pelvis, and by sudden movements of different magnitude and speed of the belts of the treadmill..
These perturbations are applied using two external devices: the pelvis perturbator and the treadmill. The disturbances are sub-maximal. They challenge the subject to make a corrective step, but do not have the goal to make them fall.

Study burden and risks

All experiments are non-invasive procedures involving disturbances similar to those that could occur in daily life. A single experiment will require approximately 45 minutes of active participation for healthy subjects, and approximately 12 minutes for stroke patients. This is not expected to put extensive load on the subjects. All subjects can take rests during the experiment and participate on their own pace. Risks leading to injury of the subject are low, given the safety precautions. The study does not lead to any direct benefits for the subject, but may lead to a better understanding of stepping responses in human balance control and it may prove that the inertial flywheel actuator improves the human balance performance. This knowledge might be applied in both clinical and robotics fields of research.
Stroke survivors will be included to characterize balance control specifically related to the complications occurring after stroke. Understanding in which way these complications hamper balance control might lead to better methods of support, e.g. during rehabilitation.

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

Healthy:
Subjects of age 18-40 years;Stroke:
Between 18 and 70 years of age
Diagnosed with a hemiparesis as the result of a first ever ischemic stroke
>6 months post-stroke (chronic stage)
functional ambulation category (FAC) 4: walk independently on level surfaces
physical condition allows independent walking for at least 3 consecutive minutes
stable medical condition
sufficient cognitive abilities (MMSE><=22)
sufficient communication abilities (UCO ><= 3);Both:
Body weight<100 kg
Written informed consent

Exclusion criteria

Healthy:
current lower extremity problems or deficiencies (e.g. problems with walking)
(history of) neurological or balance related disorders;Stroke:
(history of) neurological or balance related disorders not related to stroke;Both:
using medication that can affect balance control
pregnancy
chronic joint pain
orthopedic problems
(history of) cardiac conditions that interfere with physical load
(history of) skin diseases

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-10-2014
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	Inertial Flywheel Actuator
Registration:	No

Ethics review

Approved WMO Date:	06-11-2014
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	15-12-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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: 25102
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50450.044.14
OMON	NL-OMON25102