Explaining balance skill levels by cortical and spinal balance control mechanisms

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Primary Objective: To determine if spinal and cortical balance control mechanisms mediate the age-associated decline inbalance skills.Secondary Objective: To determine the reliability of TMS and H-reflex measures in the soleus muscle in different...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39653

Source
ToetsingOnline

Brief title
Corticospinal Balance Control

Condition

- Other condition

Synonym
aging, elderly

Health condition

Veroudering

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: aging, balance, H-reflex, transcranial magnetic stimulation (TMS)

Outcome measures

Primary outcome

The main study parameters are the size of the short-interval intracortical inhibition (SICI), the amount of EMG suppression after subthreshold TMS and Hmax/Mmax ratio. SICI is the inhibition of the test motor evoked potential (MEP), when the suprathreshold TMS pulse (the test stimulus) is preceded by a few milliseconds with a subthreshold TMS pulse (the conditioning stimulus). SICI and EMG suppression are measures of motor cortical inhibition, and can thus be used to examine cortical influences. The Hmax/Mmax ratio, on the contrary, is a measure of the spinal influences.

Secondary outcome

The secondary study parameters is the Multiscale Entropy (MSE) complexity index of the CoP.

Study description

Background summary

Over 1/3 of individuals age 65 and older falls each year. A better understanding of neural, especially cortical and corticospinal, mechanisms of balance control would help to design more accurate balance assessments and treatments. With the combination of H-reflex and transcranial magnectic stimulataion (TMS) measures it is now

possible to determine the role of cortical and spinal control of balance. For example, Tokuno et al. (2009) have shown that motor cortical excitability increases, while the excitability of the spinal motor neuron pool decreases, in normal versus supported standing. We are interested in how age affects cortical and spinal control mechanisms of balance.

Study objective

Primary Objective: To determine if spinal and cortical balance control mechanisms mediate the age-associated decline in balance skills.
Secondary Objective: To determine the reliability of TMS and H-reflex measures in the soleus muscle in different standing postures.

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Study design

The primary objective will be investigated using a cross-sectional design, comparing young versus older adults. Reliability will be investigated with a test-retest design.

Intervention

During the experiment participants undergo TMS and peripheral nerve stimulation, while they are standing in different postures.

These different postures are:
- Leaning forward 80% of the maximum with feedback of the center of pressure position
- Leaning forward 80% of the maximum with support of a wall while contracting the soleus muscle
- Sitting while contracting the soleus muscle
- Standing on a rigid platform with eyes open
- Standing on a rigid platform with eyes closed
- Standing on a platform that gently tilts forward with eyes open
- Standing on a platform that gently tilts forward with eyes closed

Study burden and risks

Subjects have to visit the Center for Human Movement Sciences one or two times within one week (dependent on the study).
One testing session will last for maximal two hours, in which they will have to stand for a total of about one hour. Resting periods

of 2-3 minutes are given as needed. A longer resting period of 10 minutes is built in between the TMS and H-reflex data collection. Participation in this study comprises electrical stimulation of the tibial nerve and magnetic stimulation of the motor cortex during standing. The TMS may cause slight discomfort lasting less than a second on the scalp near the coil. It may also cause some twitching of the muscles, the face and jaw, which may be unpleasant and surprising but not painful. Peripheral nerve stimulation causes the muscles to twitch that can be more surprising than painful. It can cause some momentary burning and tingling sensation. There are no known long-term risks of peripheral nerve or magnetic brain stimulation. Subjects wear a harness that is attached to the ceiling to minimize any risk of falling. Electromyography (EMG) of the soleus and tibialis anterior muscles will be recorded. Therefore the skin underneath the three electrodes will be shaved and cleaned. This may cause some light irritation of the skin.

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

Young group:
(1) Age 18 - 35 years ;Older group:
(1) Age 65 years or older

Exclusion criteria

(1) Neurological disorders
(2) Not able to stand independently for 10 minutes without rest
(3) Pro-epileptogenic medications or medications known to affect balance
(4) Epilepsy
(5) Any metal in the brain/skull
(6) Pregnancy or suspicion of pregnancy (self-reported)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	94
Type:	Anticipated

Ethics review

Approved WMO Date:	24-01-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-03-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-12-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-04-2014
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	NL40988.042.12