Intra-subject reliability of non-invasive brain stimulation on lower limb motor control

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The objective is to assess the intra-subject reliability of tDCS induced effects on the reaction time in the lower extremities of healthy subjects.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Interventional

Summary

ID

NL-OMON40905

Source
ToetsingOnline

Brief title
Reliability of non-invasive brain stimulation

Condition

- Structural brain disorders

Synonym
nvt

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: ZONMW Neuras

Intervention

Keyword: reaction time, reliability, tDCS

Outcome measures

Primary outcome

The main study parameter is the relative change in reaction time of the ankle

movement at the post measurements compared to the baseline measurement.

Secondary outcome

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Study description

Background summary

Transcranial direct current stimulation (tDCS) is a method that is used in recent studies to increase the excitability of the cortex. This increase in excitability can have a positive effect on the motor control and learning in healthy subjects as well as on the recovery of stroke patients. Although studies have shown large effects of >30% increase in excitability, there is also a large variability between subjects. Moreover, it is not known what the reproducibility of these effects in individual subjects is.

Study objective

The objective is to assess the intra-subject reliability of tDCS induced effects on the reaction time in the lower extremities of healthy subjects.

Study design

This is a double blind and randomised cross-over study. All subjects participate in 5 experimental sessions separated by at least two days. In all sessions both subjects and raters will be blinded to the applied intervention. The order of interventions will be randomized across subjects.

Intervention

In each of the five experimental sessions, one of three types of anodal

stimulation will be applied. The forms involve one time sham (placebo) stimulation, twice conventional anodal continuous tDCS (ac-TDCS) and twice anodal pulsed stimulation (ap-TDCS). The stimulation will be applied for 10 minutes. We will determine the effect of this intervention on the reaction time. The reaction time of ankle movement in response to a visual signal will be assessed before (baseline) and three times after the stimulation (post); after 5 min, 30 min, and 60 min.

Study burden and risks

Participants will have to visit the laboratory five times with a minimum of two days between the different visits. Each of the sessions will take about 1 hour and 45 minutes. The applied technique to modulate motor cortex excitability is generally well tolerated and has only been associated with relatively minor adverse effects in healthy humans and neurological patients, such as mild headache, moderate fatigue, nausea and an itching sensation as well as skin irritation under the electrodes.
The healthy subjects will likely not have any direct benefit from participation. We do not expect that the stimulation results in any long lasting effects. It is of importance to conduct this study to know what the intra-subject reliability of tDCS is and to be able to interpret differences in effects caused by different forms of tDCS. Furthermore, if there is considerable intra-subject variability, the next step will be to try to identify the factors that contribute to this variability.

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

- age >18 years
- able to make ankle movement with both legs
- good vision (on 2 m distance)

Exclusion criteria

- history of skin diseases that could result in irritation of the skin underneath the electrodes
- history of epilepsy or a known case of epilepsy in a first degree relative
- metallic implants in the brain
- presence of cardiac pacemakers, cochlear implant or implanted brain electrodes
- presence of severe or frequent headache
- use of medication that alters the motor cortex excitability
- use of any illegal drugs in the last month
- (possibility of) pregnancy
- had spinal surgery or have drains in their spinal cord or ventricles
- current orthopedic problems
- neurological disorders
- psychiatric disorders
- chronic joint pain
- severe depression

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-12-2014
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	transcranial direct current stimulator _and_ 5-channel electrical stimulator
Registration:	No

Ethics review

Approved WMO Date:	01-12-2014
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL50496.044.14