The role of the left and right frontal hemisphere on mood and behaviour: A transcranial direct current stimulation study

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The aim of the present double blind cross-over sham controlled study is to study the functional role of the left and right frontal cortex on mood and behaviour in healthy volunteers by applying tDCS to the left and right frontal hemispheres.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON32944

Source
ToetsingOnline

Brief title
tDCS and frontal asymmetry

Condition

- Neurological disorders NEC
- Psychiatric and behavioural symptoms NEC

Synonym
not applicable

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: VIDI 13 2 208 012

Intervention

Keyword: Behavior, Frontal asymmetry, Mood, Transcranial direct current stimulation

Outcome measures

Primary outcome

1. Background electroencephalogram: To monitor changes in electric activity an background electroencephalogram (EEG) will be recorded from 32 scalp locations according to the International 10-20 EEG System using Ag-AgCl-tipped electrodes (sampling rate: 256 Hz) before and immediately after tDCS (page 11-12 of the protocol).

2. Cerebral physiology: Transcranial magnetic stimulation (TMS) will be used to examine brain asymmetry by measuring cortical excitability of the left and right hemisphere, and left-to-right and right-to-left inter-hemispheric connectivity (page 12-13 of the protocol).

3. Behavior: Selective attention for emotional faces will be indexed using an emotional Stroop task comparing colour-naming latencies for neutral, angry, fearful and happy faces (page 13 of the protocol).

4. Mood will be monitored using the 20-item Profile of Mood States questionnaire (Shacham, 1983) (page 14 of the protocol).

Secondary outcome

not applicable

Study description

Background summary

There is evidence from the scientific literature to assume a relationship between a frontal asymmetry in brain activity and cognitive emotional information processes associated with mood. Transcranial direct current stimulation (tDCS) is a non-invasive and safe method that applies weak electrical currents to the scalp that can be used to modulate frontal brain asymmetries to study this assumed relationship. This study will not only broaden our understanding of the functional role of the left and right frontal cortex, but may contribute to the development of alternative ways to treat mood disorders such as depression by way of non-invasive neuromodulation also.

Study objective

The aim of the present double blind cross-over sham controlled study is to study the functional role of the left and right frontal cortex on mood and behaviour in healthy volunteers by applying tDCS to the left and right frontal hemispheres.

Study design

Placebo controlled double-blind cross-over design.
The experiment will consist of one intak (half an hour) and three test sessions of one an a half hour each (total: 5 hours)

The experiment consists of on screening/intake and three experimental sessions. During the first session safety issues and experimental procedures will be explained to the subject and informed consent is obtained. A standard health and safety-screening list is administered to check for contra-indications to non-invasive brain stimulation. Right handedness will be assessed with the Edinburgh handedness inventory (Oldfield, 1971) and subjects will fill out standard lab digital personality questionnaires that include the BIS-BAS (Carver & White, 1994) and BPA questionnaire (Buss & Perry, 1992). Individual motor threshold (MT) from the left and right primary motor cortex using the thumb movement visualization method will be measured to determine TMS intensity (Schutter & Van Honk, 2006). On experimental days participants will be instructed to refrain from taking psychotropic substances, including coffee,

tea and chocolate at least 2 hours prior to experimentation. During the test session a mood questionnaire will be administered (5 min) and a four-minute background EEG recording (15 min including preparation) will be made. Next, participants will be seated in a comfortable chair en receive direct current stimulation to the frontal lobes for 15 min. after which the mood questionnaire (5 min) will be administered and a four-minute background EEG recording (15 min including preparation) will be made for a second time. Then, the excitability of the hemispheres will be measured using transcranial magnetic stimulation (20 min). During this measurement the volunteers has to squeeze his/her hands for a short time prior to the pulse. Finally, an attention tasks will be administered (10 min).

Schematic overview of the procedure:

Session 1: intake: screening, questionnaires, motor threshold determination (TMS)
Session 2: testing day1: questionnaire, background EEG, tDCS1, questionnaire, background EEG, cortical excitability and connectivity (TMS), attention task
Session 3: testng day 2: questionnaire, background EEG, tDCS2, questionnaire, background EEG, cortical excitability and connectivity (TMS), attention task
Session 4: testingday 3: questionnaire, background EEG, tDCS3, questionnaire, background EEG, cortical excitability and connectivity (TMS), attention task

Intervention

MANIPULATION

Transcranial direct current stimulation (tDCS) will be delivered by a battery-driven constant DC current stimulator (Eldith DC Stimulator (CE 0118), Ilmenau) using a pair of electrodes in a 5-7 cm (35 cm2) saline-soaked synthetic sponge at a current intensity of 1 mA for 15 minutes on three separate sessions.

1- Cl-Ar tDCS: Cathodal electrode left frontal cortex - anodal electrode right frontal cortex (1 mA/ 35 cm2, 15 min)

2- Al-Cr tDCS: Anodal electrode left frontal cortex - anodal electrode right frontal cortex (1 mA/ 35 cm2, 15 min)

3- Placebo tDCS: Random montage (0 mA/ 35 cm2, 15 min)

READOUT

Transcranial magnetic stimulation (TMS) will be applied to measure cortical excitability and connectivity between the hemispheres following tDCS. Using a coil that will be placed on the head nerve cells can be activated through

magnetic pulses. Whenever the coil is held over the primary motor cortex the magnetic pulse will cause a thumb twitch (MEP) that can be quantified with a pair of electrodes fixed to the left and right thumb muscle. A series of 72 pulses to the left and 72 pulses to the right hemisphere (stimulatie interval: 5-7s) will provide insights in tDCS-related changes in cortical excitability and connectivity between the hemispheres.

Study burden and risks

Transcranial direct current stimulation (tDCS) is a painless method that applies weak electric currents to the scalp which are able to temporarily modulate brain activity. In some cases tDCS causes an itching senstion under the electrodes or (mild) headache. In rare cases tDCS cause nausea or dizziness. This technique does not carry any other risks.

Transcranial magnetic stimulation (TMS) is a method that applies magnetic pulses to scalp to excite neurons in the motor cortex. This neural excitation causes small hand movements of the muscles that can be recorded using electrodes attached to the hand. Some people report a (mild) headache during stimulation. In rare cases TMS causes nausea and dizziness. In extremely rare cases high frequency TMS (25 Hz or more)can cause an epileptic insult. TMS safety guidelines as published by the journal of the Federation of Clinical Neurophysiology (Wassermann EM Electroencephalography and Clinical Neurophysiology Clinical Neurophysiology 1998 103 1-16). The TMS paramers in the current research proposal are in the low frequency TMS range (0. 2 Hz or less) .

Headache can be treated with standard analgesics, like paracetamol (200mg).

With EEG electric brain activity can be recorded from the scalp using a cap containing electrodes. EEG technique is safe and utilizes gel (salt solution) to make contacts between the scalp en electrode. Some people may experience the cap and gel as a little bit uncomfortable.

Questionnaires and the short attention task will administered to monitor mood and cognitive performance. Neither of these measures carry any significant risk

Procedure will be identical across test sessions (only the applied tDCS varies) and each session will last for maximal 1 hour. Duration of total study is 4 hours.

Notably, volunteers can withdraw from the study at any given time for any given reason or for no reason at all.

Contacts

Public
Universiteit Utrecht

Heidelberglaan 2
3584CS Utrecht
NL
Scientific
Universiteit Utrecht

Heidelberglaan 2
3584CS Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Non-smoking, right-handed, 18-35 years

Exclusion criteria

Skin disease, metal in cranium, use of psychotropic drugs, including cannabis, XTC, amphetamines and cocaine, epilepsy or family history of epilepsy, history of closed-head injury, history of head surgery, history of neurological or psychiatric disorders, medication use (i.e., benzodiazepines, antidepressants and neuroleptica), medication pump, brain infarction, heart disease, cardiac pacemaker, pregnancy or electronic hearing devices.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2009
Enrollment:	54
Type:	Actual

Ethics review

Approved WMO Date:	14-10-2009
Application type:	First submission
Review commission:	METC NedMec

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	NL27082.041.09