Effects of transcranial direct current stimulation on cortical asymmetry and behaviour

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To evaluate the effects of tDCS on modulating and stydying frontal brain asymmetry.

Ethical review	Not approved
Status	Will not start
Health condition type	Neurological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON32674

Source
ToetsingOnline

Brief title
tDCS and frontal asymmetry

Condition

- Neurological disorders NEC
- Psychiatric and behavioural symptoms NEC

Synonym
niet van toepassing

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Behaviour, Frontal asymmetry, Physiology, Transcranial direct current stimulation

Outcome measures

Primary outcome

1. 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 (see also Protocol 07-044/O) (page 5-7 of the protocol).

2. 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 7-8 of the protocol).

3. Mood will be monitored using the 20-item Profile of Mood States questionnaire (Shacham, 1983) (duration: 10 min). 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 8 of the protocol).

Secondary outcome

not applicable.

Study description

Background summary

Repetitive transcranial magnetic stimulation (rTMS) is a valuable non-invasive method that employs magnetic fields to induce current densities of ~20 mA/cm2 to investigate frontal brain asymmetries. Alternatively, transcranial direct current stimulation (tDCS) applies weak electrical currents 0.029 mA/cm2 directly to the scalp and is suggested to sort effects similar to rTMS. Importantly, tDCS has several advantages over rTMS which include exposure to weak currents, no physical discomfort, and placebo controlled designs.

Study objective

To evaluate the effects of tDCS on modulating and stydying frontal brain asymmetry.

Study design

Placebo controlled double-blind cross-over design.
The experiment will consist of four sessions of one hour.
Procedure
Session 1: intake: screening, questionnaire, EEG recording, cortical excitability measurement (TMS), attention task
Session 2: test1: questionnaire, tDCS1, questionnaire, EEG recording, cortical excitability measurement (TMS), attention task
Session 3: test2: questionnaire, tDCS2, questionnaire, EEG recording, cortical excitability measurement (TMS), attention task
Session 4: test3: questionnaire, tDCS3, questionnaire, EEG recording, cortical excitability measurement (TMS), attention task

Intervention

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)

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. This technique does not carry any known risk.

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. The main concern when using TMS is its potential to induce a seizure. Safety guidelines, including the limits of stimulation intensity, monitoring of subjects, medical management of induced seizures and contraindications to rTMS as described by the International Federation of Clinical Neurophysiology (Wassermann, 1998) will be followed strictly, to minimize seizure risk. Other potential adverse effects of rTMS include induction of a muscle tension headache. These are generally mild discomforts that respond promptly to common analgesics.

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 an a 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

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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 neurological or psychiatric disorders, medication use (i.e., benzodiazepines, antidepressants and neuroleptica), cardiac pacemaker, pregancy, of 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:	Will not start
Enrollment:	50
Type:	Anticipated

Ethics review

Not approved

Date:	20-01-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL25351.041.08