Changes in cerebral activity and connectivity induced by transcranial stimulation of the dorsolateral prefrontal cortex in healthy humans

Published: 18-07-2016
Last updated: 16-04-2024

Here we will test the hypothesis that stimulating DLPFC with either rTMS or tDCS during one single session affects the functional connectivity of the DLPFC, and is associated with an increase of activation in connected areas of the cerebrum and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON42853

Source
ToetsingOnline

Brief title
Aftereffects of transcranial DLPFC stimulation

Condition

- Other condition

Synonym
This study is not aimed at a certain disorder. It is a study with healthy subjects.

Health condition

transcraniale prefrontale stimulatie met gezonde proefpersonen

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: NWO-VICI Grant 453-11-004

Intervention

Keyword: Dorsolateral prefrontal cortex, Magnetic resonance imaging, Transcranial direct current stimulation, Transcranial magnetic stimulation

Outcome measures

Primary outcome

The main study parameters are the changes in blood-oxygenation-level dependent

(BOLD) signal induced by transcranial brain stimulation. We will measure the

BOLD signal at rest and during the performance on two different tasks tapping

executive functions using fMRI.

Secondary outcome

In addition, we will measure cerebral blood flow (CBF) using the arterial spin

labeling technique, and we will record MR spectroscopy data from the dorsal

striatum.

Study description

Background summary

Noninvasive brain stimulation techniques are being explored for the treatment of various neurologic and psychiatric conditions such as depression, schizophrenia, Parkinson disease, dystonia, Alzheimer*s disease, and stroke. The general idea is that by artificially modifying synaptic strength with stimulation it is possible to induce plasticity and long-lasting changes in brain response. Two different techniques are now widely used for this endeavor: repetitive transcranial magnetic stimulation (rTMS) and transcranial direct current stimulation (tDCS). rTMS has been approved as an efficient treatment to

alleviate symptoms of treatment-resistant depression by the Food and Drug Administration as well as by the relevant instances in Europe and Canada. Clinical trials targeting other populations are underway, notably in schizophrenia, with a study conducted in the North of The Netherlands under the lead of Prof. Andre Aleman, and targeting the dorsolateral prefrontal cortex (DLPFC) of patients with schizophrenia with either rTMS or tDCS to try alleviating apathy. Although clinical trials and treatments are underway, we still have very limited knowledge of the neural effects of transcranial brain stimulation as applied in these protocols.

Study objective

Here we will test the hypothesis that stimulating DLPFC with either rTMS or tDCS during one single session affects the functional connectivity of the DLPFC, and is associated with an increase of activation in connected areas of the cerebrum and basal ganglia. We further want to evaluate differences in neural activation induced by the two techniques.

Study design

Participants in the study will be randomly assigned to one of four groups. Two groups will receive real brain stimulation (rTMS or tDCS) and two other groups will receive sham stimulation (sham rTMS or sham tDCS). Before and just after brain stimulation, participants will undergo an MRI scanning session. During the MRI sessions their brain activity will be recorded at rest and during task performance. Prior to the stimulation, participants will also fill in a few questionnaires and perform cognitive tests. The stimulation protocols used for tDCS and rTMS in this study are identical to those used in the ongoing clinical trial (METC 2013-137 * *Randomized controlled trial of neurostimulation treatment for apathy in schizophrenia*), so that the conclusions of the current research can be used to inform the results obtained in patients with schizophrenia after treatment.

Study burden and risks

Participants in the study will go through 4 steps that will take place across two different days less than a week apart. During the first step, participants will undergo a pre-stimulation MRI scanning session. This session will last for 1h. After the MRI, participants will fill out questionnaires and perform cognitive tests assessing executive functions and fluid intelligence. This session will last for about 1h. On the second day, participants will undergo brain stimulation (tDCS, sham tDCS, rTMS, or sham rTMS). The stimulation session will last for about 30 minutes. Just after the stimulation, participants will be brought again in the MRI scanner for the post-stimulation session, which is identical to the pre-stimulation session and lasts for 1h. The total duration of the study for one participant is 4 hours. The experiment

will not involve more than minimal risks for the participants. MRI is a standard brain imaging technique with no known negative effects on health. The only risks are for subjects with cardiac pacemaker and metal implants. These individuals will not be allowed to participate. In terms of burden, MRI involves lying still in a confined environment during one hour. In addition, during data acquisition, the MRI scanner makes a loud noise, and although participants are provided with earplugs, the residual noise can be a burden for some individuals.
During the tDCS procedure participants are exposed to a very low electrical current of 2 mA. The use of tDCS to date has not resulted in significant adverse effects, apart from mild headache or a mild tingling sensation underneath the electrodes. During the rTMS procedure participants are exposed to a magnetic field strength lower than 1.5 Tesla limited to a small brain region at a maximum depth of 2 cm. The application of rTMS is considered safe as long as it follows published safety guidelines. However, the risk of inducing seizure cannot be completely excluded. In consequence, participants with increased risk of seizure will not be allowed in the study, and safety procedures are planned in case such an event should occur.
The study is not intended to benefit the participants directly.
Participants will receive a compensation for their contribution.

Contacts

Public
Universitair Medisch Centrum Groningen

Ant. Deusinglaan 2
Groningen 9713 AW
NL
Scientific
Universitair Medisch Centrum Groningen

Ant. Deusinglaan 2
Groningen 9713 AW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

[1] Healthy males and females,
[2] 18 years old or older,
[3] Normal (or corrected to normal) vision,
[4] Right-handed

Exclusion criteria

[1] (History of) significant medical, psychiatric or neurological conditions,
[2] Metal implants in the body (e.g., pacemaker, heart valves, vascular clips, eye-implants, copper containing intra-uterine devices, non-removable piercing, cerebral implants),
[3] Any risk of having metal particles in the eyes,
[4] Tattoos containing iron oxide,
[5] (Suspected) pregnancy, or breast feeding
[6] Claustrophobia,
[7] Drug or alcohol abuse,
[8] Use of psycho-active medication,
[9] Refusal to be informed about structural brain abnormalities,
[10] Epilepsy or family history of epilepsy,
[11] Use of medication associated with increased epileptic seizure risk,
[12] Neurological problems in the past or present (including brain surgery, infarction, stroke, and the intake of medication that could increase the risk of stroke),
[13] Severe scalp skin lesions.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2016
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	18-07-2016
Application type:	First submission
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	NL57431.042.16