Transcranial Direct Current Stimulation as treatment for Auditory Hallucinations. A sham-controlled trial

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The present study aims to examine the efficacy of tDCS on the severity of AH.

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

Summary

ID

NL-OMON45026

Source
ToetsingOnline

Brief title
tDCS as treatment for auditory hallucinations

Condition

- Other condition

Synonym
auditory hallucinations, hearing of voices

Health condition

psychiatrische stoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Vidi

Intervention

Keyword: auditory hallucination, psychosis, schizophrenia, transcranial direct current stimulation

Outcome measures

Primary outcome

The severity of the AH as measured with the Auditory Hallucination Rating Scale

(AHRS).

Secondary outcome

Secondary parameters are: the severity of AH as measured with the hallucination

change scale (HCS), schizophrenia symptom severity as measured by the positive

and negative syndrome scale (PANSS), severity of psychotic symptoms as measured

by the questionnaire of psychotic symptoms (QPS), prior expectations regarding

the efficacy of treatment, presence and severity of side-effects of tDCS, and

the motor threshold as determined by transcranial magnetic stimulation (TMS).

Cognitive functioning as measured by the Stroop test and the Trail-Making Test.

The effect of age on the decrease of severity AH as measured with the AHRS.

Study description

Background summary

Auditory hallucinations (AH) are a symptom of several psychiatric disorders, such as schizophrenia. In the majority of patients, these AH respond well to antipsychotic medication. Yet, a significant minority continues to experience frequent AH despite optimal pharmacotherapy and AH severely decrease quality of

life in these patients. The number of alternative treatment options for this medication resistant group is currently low and most of them focus on coping with the hallucinations. Transcranial direct current stimulation (tDCS), in contrast, is a safe, non-invasive technique that is able to directly influence cortical excitability through the application of very low electric currents. This technique has only a few transient side-effects and is cheap and portable. To date, only one randomized controlled trial has been published, suggesting high efficacy of tDCS for the treatment of medication-resistant AH in a relatively small sample. We aim to replicate and extend these findings by investigating the efficacy of this technique in a larger sample.

Study objective

The present study aims to examine the efficacy of tDCS on the severity of AH.

Study design

The objectives are tested in a randomized double blind sham-controlled trial.

Intervention

The participant will receive either 10 tDCS treatments or 10 sham treatments, consisting of 2 mA tDCS or sham stimulation on 5 consecutive weekdays. The anode will be placed over the left dorsolateral prefrontal cortex and the cathode over the left temporo-parietal cortex.

Study burden and risks

Participation includes 8 visits to the UMC Utrecht with a total duration of approximately 20 hours. In these visits the questionnaires and interviews as described above will be conducted four times. The currently proposed tDCS procedure and the motor threshold TMS paradigm do not carry any significant risks. Safety guidelines as acknowledged by the International Federation of Clinical Neurophysiology will be followed strictly. Potential side-effects of tDCS and TMS are itching and tingling sensations, skin irritation and muscle tension and headache. These are generally mild discomforts that respond promptly to common analgesics. Volunteers can withdraw from the study at any time. AH can have a severe impact on an individual*s quality of life and that of his/her surroundings. The proposed technique may offer an alternative therapy for patients who do not respond to antipsychotic medication. It is therefore expected that effects on health and social functioning are high, since a decrease in hallucination severity will decrease fear and social isolation in these patients.

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

- Diagnosis of schizophrenia-spectrum disorder, affective disorder, personality disorder, post-traumatic stress disorder or hearing disorder.
- Age over 18
- Frequent auditory hallucinations (at least 5 times a week as indicated by the screening form).
- Patients are on a stable dose of antipsychotic medication (which can also be zero) for at least 2 weeks
- Mentally competent for informed consent.
- Provided written informed consent.

Exclusion criteria

- Metal objects in or around the head that cannot be removed (i.e. cochlear implant, surgical clips, piercing)
- History of seizures
- History of eye trauma with a metal object or professional metal workers
- History of brain surgery, brain infarction, head trauma, cerebrovascular accident, broken skull, brain tumour, heart disease, cardiac pacemaker.
- Skin disease on the scalp on the position of the tDCS electrodes
- Coercive treatment based on a judicial ruling
- Pregnancy in female patients. A pregnancy test will be used in cases of doubt, e.g. females of childbearing age who are sexually active but do not use any form of contraceptives.
- Participation in TMS research in the previous 6 months
- Mentally incompetent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-05-2014
Enrollment:	102
Type:	Actual

Ethics review

Approved WMO

Date:	24-01-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-03-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	17-05-2017
Application type:	Amendment
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
ClinicalTrials.gov	NCT01977521
CCMO	NL46513.041.13