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Effects of transcranial direct current stimulation (tDCS) in obsessive-compulsive disorder

Submission date
18/03/2022

Recruitment status
No longer recruiting

Registration date
22/03/2022

Overall study status
Completed

Last Edited
23/01/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims:
Obsessive-compulsive disorder (OCD) is a psychiatric disease characterized by obsessions and compulsions. Obsessions are described as recurrent and persistent thoughts or impulses which are perceived by the patients as unwanted and hard to inhibit. Compulsions are defined as repetitive behaviours or mental thoughts which patients are unable to control or inhibit. Hence, a deficit in inhibition is considered as a core characteristic of OCD. Inhibition deficits in OCD have been shown to go along with altered activity in specific regions of the brain. There is mounting evidence indicating that transcranial direct current stimulation (tDCS) (i.e., stimulation of the brain by a very light electric current) improves inhibition performance in healthy subjects but no comparable studies have been performed in patients with OCD up to now. Against this background this study aims to investigate the effects of tDCS on clinical symptoms, behavioral inhibition and brain activation in a group of patients suffering from OCD. A tDCS-related improvement in behavioral inhibition and clinical state would underline the clinical relevance of inhibitory capacities and demonstrate the effectiveness of tDCS for OCD. Moreover, normalized brain activation as a result of tDCS would reveal the mechanisms underlying the associated improvements in behavioral inhibition.

Who can participate?
Patients with a primary diagnosis of OCD according to DSM V.

What does the study involve?
tDCS during magnetic resonance imaging (MRI) for 20 minutes

What are the possible benefits and risks of participating:?
There are no personal benefits of participating, except for reimbursement (i.e., 150 €) and a screening of your brain performed by a neuroradiologist. The risks of participating are incidental findings in the MRI image that may cause subjective worries or might require additional treatment. tDCS risks are minimal and can involve transient symptoms such as warming at the

stimulation site, tingling at the stimulation site, a slight headache or a slight feeling of dizziness. MRI risks are likewise minimal and can also comprise a transient feeling of dizziness or a slight headache.

Where is the study run from?
Klinikum rechts der Isar, München (Germany)

When is the study started and how long is it expected to run for?
November 2020 to December 2023

Who is funding the study?
Deutsche Forschungsgemeinschaft (DFG KO 3744/11-1) (Germany)

Who is the main contact?
Prof. Dr. Kathrin Koch, kathrin.koch@tum.de

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
KO 3744/11-1

Study information

Scientific Title
Effects of transcranial direct current stimulation (tDCS) on response inhibition and neuronal activity in obsessive-compulsive disorder

Acronym
TDCSOCD

Study objectives
1. tDCS as compared to sham stimulation will go along with a significant improvement in response inhibition
2. tDCS as compared to sham stimulation will go along with an increased activation during inhibition in preSMA and vmPFC. This increased activation will be correlated with the improvement in response inhibition

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/03/2022, Ethics Committee of Klinikum Rechts der Isar, Technische Universität München (Ethikkommission der Technischen Universität München, Ismaninger Straße 22, 81675 München, Germany; +49 (0)89/4140-7737; ethikkommission@mri.tum.de), ref: 141/22 S

Study design
Single center interventional double-blinded randomized cross-over trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Effects of transcranial direct current stimulation (tDCS) in patients suffering from obsessive-compulsive disorder

Interventions
tDCS (active condition) vs. sham tDCS (control condition) will be applied in a double-blinded randomized cross-over design. tDCS in the active condition will comprise 20 minutes of anodal tDCS over the preSMA region with a current of 2mA in the MRI. tDCS in the control condition will comprise 20 minutes of sham tDCS (20 sec. fade-in, fade out) over the preSMA region. Participants are randomly assigned to the different arms using a random number generator system.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Transcranial direct current stimulation (tDCS)

Primary outcome(s)
1. Brain activation and connectivity measured during real tDCS and sham tDCS using functional magnetic resonance imaging (fMRI) during two response inhibition tasks. Real tDCS and sham tDCS take place 1 week apart.
2. Inhibition performance measured with two well-established inhibition tasks (Stroop task, Stop-Signal-task) at T0 (i.e., first MRI measurement timepoint) and T1 (i.e., 1 week later).

Key secondary outcome(s))
Clinical symptoms assessed with the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) at T0 (i. e., first MRI measurement timepoint) and T1 (i.e., 1 week later)

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. MRI compatibility, age 18-65 years, right-handedness
2. OCD according to DSM-V
3. At least a score of 8 in the Y-BOCS scale
4. No additional psychopharmacological medication (e.g. antipsychotic medication)
5. No bipolar disorder, no schizophrenia, no schizo-affective disorder, no posttraumatic stres disorder, no substance abuse (apart from nicotine), no personality disorder

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
47

Key exclusion criteria

1. Suicidality
2. Neurological disorder
3. Pregnancy
4. Inability to provide consent
5. No willingness to provide consent after information about the study
6. Medicated with benzodiazepines within the last 24 hours

Date of first enrolment
01/04/2022

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
Germany

Study participating centre
Klinikum Windach am Ammersee, Klinikum rechts der Isar München
Klinikum rechts der Isar
Abteilung für diagnostische und interventionelle Neuroradiologie
Neuroimaging Center (TUM-NIC)
Einsteinstr. 1
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Sponsor information

Organisation
Deutsche Forschungsgemeinschaft

ROR
https://ror.org/018mejw64

Funder(s)

Funder type
Research organisation

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)
German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
Raw data will not be shared

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes