

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

Submission date 18/03/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/03/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/01/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised cross over trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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).

Secondary outcome measures

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)

Overall study start date

01/11/2020

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 stress disorder, no substance abuse (apart from nicotine), no personality disorder

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

44

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

München

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81675

Sponsor information

Organisation

Deutsche Forschungsgemeinschaft

Sponsor details

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Sponsor type

Research organisation

Website

<http://www.dfg.de/en/>

ROR

<https://ror.org/018meiw64>

Funder(s)**Funder type**

Research organisation

Funder Name

Deutsche Forschungsgemeinschaft

Alternative Name(s)

German Research Association, German Research Foundation, DFG

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/03/2025

Individual participant data (IPD) sharing plan

Raw data will not be shared

IPD sharing plan summary

Not expected to be made available