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Unraveling OCD: Using Brain Stimulation to Investigate Control

Submission date
15/04/2024

Recruitment status
No longer recruiting

Registration date
03/05/2024

Overall study status
Completed

Last Edited
27/01/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Obsessive-compulsive disorder (OCD) is a serious mental health condition where individuals experience persistent, unwanted thoughts (obsessions) and feel compelled to perform repetitive behaviors (compulsions). These obsessions and compulsions can greatly disrupt daily life. While therapies like counseling and certain medications are successful for about half of patients, others may need alternative options like different medications or deep brain stimulation, which involves surgery and carries risks. Research is ongoing to explore new treatments, such as repetitive transcranial magnetic stimulation (rTMS), which has shown promise in treating OCD. In this study, we will investigate the effectiveness of a specific type of rTMS on reducing OCD symptoms and its impact on brain activity. To accurately assess its effectiveness, we will include a placebo stimulation in the study, where some participants will receive a simulated treatment that we do not expect to have an effect.

Who can participate?
Patients with OCD, 18 to 70 years old with no contraindications for rTMS

What does the study involve?
The participant was assigned by a computer program to one of two groups:
a) receiving active 20Hz ACDC TMS, set at 100% of their motor threshold, consisting of 40 rounds of stimulation with 50 pulses each, lasting 18 minutes, totaling 2000 pulses per session, for 1 session;
b) receiving sham ACDC TMS, where a sham coil was applied to the mPFC for 1 session.
Immediately after the stimulation, the participant underwent EEG testing while performing the Stroop task, and any side effects were assessed.

What are the possible benefits and risks of participating?
If you grant Consent, you will be contributing to the collection of data that will help decide whether TMS is an effective method in the treatment of OCD. At the same time, the conditions for which you are being treated may be improved. There is no honorarium for participating in the research.
The risks of rTMS are generally low, with the main risk being the induction of an epileptic seizure. Even this risk has so far been very rare, usually in people who are predisposed to

seizures. Therefore, people who have or have had epilepsy (even a single seizure) or suspected epilepsy, or who belong to a risk group for epileptic seizures, i.e. people after a serious head injury with unconsciousness, after a stroke, with increased intracranial pressure and, according to individual assessment, with other neurological diseases affecting the brain (brain tumours, multiple sclerosis, Parkinson's disease, etc.), cannot participate in rTMS (and this project). Due to the magnetic field induction, TMS cannot be performed on persons with metallic material in the head area (vascular clips, stimulator, cochlear implants, foreign bodies, etc.) except in the mouth. If any of the conditions and situations described above apply to you, please inform the researcher who will contact you.

Where is the study run from?
National Institute of Mental Health (Czechia)

When is the study starting and how long is it expected to run for?
November 2022 to October 2023

Who is funding the study?
Charles University (Czechia)

Who is the main contact?
Dr Olga Laskov, olga.laskov@nudz.cz

Contact information

Type(s)
Public, Principal investigator

Contact name
Dr Olga Laskov

ORCID ID
https://orcid.org/0000-0002-2856-1024

Contact details
Topolova 748
Klecany
Czech Republic
25067
+420 283 088 148
olga.laskov@nudz.cz

Type(s)
Scientific

Contact name
Dr Monika Klirova

ORCID ID
https://orcid.org/0000-0002-8092-9586

Contact details

Topolova 748
Klecany
Czech Republic
25067
+420 283 088 141
monika.klirova@nudz.cz

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
140223

Study information

Scientific Title
The anterior cingulate double cone transcranial magnetic stimulation (ACDC TMS) as an instrument for the investigation of inhibitory control in patients with obsessive compulsive disorder (OCD)

Acronym
ACDC OCD

Study objectives
A single active ACDC TMS application in a patient population with OCD will lead to:
1. Enhancement of the inhibitory control performance as measured by the Stroop test - decrease in the interference,
2. Lower reaction times to incongruent stimuli (as previous studies showed),
3. Lower error count,
4. Decrease of the ERN, P3, and N2 amplitude in response to errors,
5. Increase of P3 and N2 latencies in response to errors,
6. Reduction of the theta amplitude in resting EEG compared to sham dTMS and
7. At the same time, we expect that the behavioral and electrophysiological changes induced by the application of active dTMS will be positively correlated with Y-BOCS rates and negatively correlated with disease duration.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 04/11/2022, Ethics committee of the Third Faculty of Medicine, Charles University (Ruska 87, Prague, 10000, Czech Republic; +420 267102111; marek.vacha@lf3.cuni.cz), ref: GAUK140223

Study design

Randomized placebo-controlled double-blind study

Primary study design
Interventional

Study type(s)
Other, Treatment

Health condition(s) or problem(s) studied
Inhibitory control in patients with obsessive compulsive disorder

Interventions
The participant was randomly (by computer program) allocated to one of the two groups: a) active 20Hz ACDC TMS, 100% of motor threshold, 40 trains, 50 pulses per train, 18 minutes duration; 2000 pulses per session; 1 session; b) sham ACDC TMS with a sham coil applied either to mPFC; 1 session. Right after the stimulation: EEG with Stroop task and side effect assessment took place.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ACDC TMS was administered using a MagPro R30 stimulator with a cool D-B80 A/P coil

Primary outcome(s)
Inhibitory control measured via the interference effect in the Stroop task, measured as the reaction time to incongruent minus the reaction time to congruent stimuli right after the active and sham ACDC TMS stimulation

Key secondary outcome(s))
Measured right after the active and sham ACDC TMS stimulation:
1. Inhibitory control measured via the reaction times change and error count in the Stroop task (as less sensitive markers)
2. Electrophysiological effect of the active and sham ACDC TMS stimulation measured using EEG

Completion date
31/10/2023

Eligibility

Key inclusion criteria
1. Male and female inpatients or outpatients from the daycare center entering six-week CBT at age 18-70 years
2. Meet DSM-V criteria for OCD as determined by Structured Clinical Interview for DSM-5 (SCID-5)
3. The mental ability to understand and sign Informed Consent Form

4. Being on a stable and adequate dose of antidepressants and/or antipsychotics (monotherapy or combination) for atleast one week prior to enrolment and if clinically appropriate to continue on an unchanged dose of medication during the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Psychiatric comorbidity on axis I and II according to DSM V in six months before enrollment to the study
2. Personality disorder that makes participation in the trial difficult
3. History of substance dependence in the last year except nicotine
4. Contraindications of rTMS (history of epilepsy or any neurologic condition likely to increase risk of seizure, mass brain lesions, cerebrovascular accident, metal in the head, a history of major head trauma with unconsciousness longer than 5 minutes)
5. Pregnancy or breast-feeding
6. Patients with severe somatic disorders (cardiovascular disease, neoplasms, endocrinology disorders etc.)
7. Patients treated with electroconvulsive therapy less than 3 months before enrollment or suffering from neurologic disorder (e.g., epilepsy, head trauma with loss of consciousness) and patients using any treatment which can strongly affect EEG
8. Substantial suicidal risk as judged by the treating psychiatrist
9. Sensory and motor impairment precluding the participation in computer tests

Date of first enrolment
01/12/2022

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
Czech Republic

Study participating centre
National Institute of Mental Health
Topolova 748
Klecany
Czech Republic
25067

Sponsor information

Organisation
Charles University

ROR
https://ror.org/024d6js02

Funder(s)

Funder type
University/education

Funder Name
The Charles University Grant Agency (GA UK)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request rom Dr. Olga Laskov olga.laskov@nudz.cz

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Czech		17/04/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Statistical Analysis Plan			17/04/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes