Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

The Effectiveness of 3MA transcranial direct current stimulation (TDCS) on cognitive function, depression, anxiety and severity of obsessive-compulsive symptoms in individuals with OCD: A randomized clinical trial

Protocol summary

Study aim

Determining the effectiveness of applying the 3mA TDCS protocol in the right lower frontal and left supraorbital regions on cognitive functions, depression, anxiety, and severity of obsessive-compulsive symptoms in people with OCD

Design

A controlled, parallel-group, double-blind, randomized clinical trial on 40 patients. Simple randomization was used.

Settings and conduct

This research will be carried out in the Beheshti hospital clinic in Zanjan with direct current transcranial electrical stimulation for 20 sessions in 10 days.

Participants/Inclusion and exclusion criteria

Having the full diagnostic criteria for obsessive-compulsive disorder as diagnosed by a psychiatrist and psychologist based on the diagnostic and statistical manual of mental disorders, age range 18 to 50 years, not receiving psychological treatment two months before the intervention, and simultaneously with the implementation of the intervention until the follow-up period, the same Being the drug group used along with adjusting the dose. Inclusion criteria: psychosis, risk of suicide, presence of electrical objects in the body, history of seizures, pregnancy, Comorbid bipolar disorder

Intervention groups

According to the desired protocol, the patients of the intervention group will receive real stimulation with an intensity of 3 milliamps for twenty sessions of 20 minutes in ten days, with the anode placed in the right area of the lower frontal cortex and the cathode on the left supraorbital area. And the sham group will also receive sham stimulation for the same number of sessions in these areas.

Main outcome variables

Clinical symptoms of obsessive-compulsive disorder, working memory, cognitive inhibition, cognitive flexibility, visual memory, sustained attention, depression, anxiety

General information

Reason for update

Increasing the sample size and adding follow-up three months after treatment

Acronym

IRCT registration information

IRCT registration number: **IRCT20230216057437N1**
Registration date: **2023-03-31, 1402/01/11**
Registration timing: **prospective**

Last update: **2025-03-06, 1403/12/16**
Update count: **1**

Registration date

2023-03-31, 1402/01/11

Registrant information

Name

Atefeh Fatehi chenar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3411 1292

Email address

fatehi.atefe@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-09, 1402/01/20

Expected recruitment end date

2023-10-12, 1402/07/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effectiveness of 3MA transcranial direct current stimulation (TDCS) on cognitive function, depression, anxiety and severity of obsessive-compulsive symptoms in individuals with OCD: A randomized clinical trial

Public title
The Effectiveness of 3MA transcranial direct current stimulation (TDCS) on cognitive function, depression, anxiety and severity of obsessive-compulsive symptoms in individuals with OCD: A randomized clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having complete OCD diagnostic criteria as diagnosed by a psychiatrist and psychologist based on DSM-5 Having at least a third middle school education Age range between 18-50 years Sign the written consent Not receiving psychological treatment two months before the intervention and simultaneously with the implementation of the intervention until the follow-up period The same drug group was used along with dose adjustment
Exclusion criteria:
Risk of suicide psychosis Existence a history of seizures and epilepsy The presence of an electrical or metallic object in the body Diagnosis of any neurological conditions that affects the central nervous system. (like Parkinson's) pregnancy Comorbid bipolar disorder
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples are randomly assigned to the intervention and sham groups. Random allocation is done using Excel software. For this, in the first column, we enter 20 numbers 1 and 20 numbers 2 representing the real intervention group and the sham intervention group, respectively. Then, in the second column, we generate 40 random numbers using the (RAND) function. We sort the data based on column values containing random numbers (ascending or descending). With this sorting, the order of placement of numbers 1 and 2 will also change and be placed randomly. Based on the order of appearance of numbers 1 and 2, the samples are assigned to two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The people under study do not know the type of intervention. Both the researcher and the evaluator are unaware of the type of intervention. The device is set by one of the clinic staff on real or sham intervention and the patient receives a code based on that. The people who analyze the results do not know the nature of the study groups and the evaluation is done by someone other than the researcher.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethnics committee of Zanjan University of Medical Sciences
Street address
Zanjan University of Medical Sciences , Mahdavi Blv, shahrak karmandan
City
Zanjan
Province
Zanjan
Postal code
4513956184
Approval date
2023-02-16, 1401/11/27
Ethics committee reference number
IR.ZUMS.REC.1401.339

Health conditions studied

1

Description of health condition studied
Obsessive-Compulsive Disorder
ICD-10 code
F42
ICD-10 code description
Obsessive-compulsive disorder

Primary outcomes

1

Description
The person's score on the Yale-Brown Obsessive-Compulsive Scale

Timepoint
Measuring the severity of obsessive-compulsive symptoms before the intervention, immediately after the intervention, two weeks, four weeks, and three months after the intervention as follow-up periods

Method of measurement
Yale-Brown Obsessive-Compulsive Scale

2

Description
Individual's score in Beck depression questionnaire

Timepoint
Measurement of depression levels before the intervention, immediately after the intervention, and two-week, four-week, and three-month follow-up periods after the intervention.

Method of measurement
Beck depression inventory

3

Description
Individual's score in Beck's anxiety inventory

Timepoint
Measurement of anxiety levels before the intervention, immediately after the intervention, and two-week, four-week, and three-month follow-up periods after the intervention.

Method of measurement
Beck's anxiety inventory

Secondary outcomes

1

Description
The score of a person's working memory in the task of Spatial Working Memory (SWM) from Cambridge Neuropsychological Test Automated Battery (CANTAB)

Timepoint
Measuring the individual's score in the task of Spatial Working Memory (SWM) before the intervention, Immediately after the end of the intervention, two weeks, four weeks, and three months after the end of the intervention as follow-up periods.

Method of measurement
the Spatial Working Memory (SWM) task from CANTAB

2

Description
A person's cognitive inhibition score in the Stop Signal Task (SST) from CANTAB

Timepoint
Measuring the individual's score in the Stop Signal Task (SST) task before the intervention, Immediately after the end of the intervention, two weeks, four weeks, and three months after the end of the intervention as follow-up periods.

Method of measurement
the Stop Signal Task (SST) from CANTAB

3

Description
The score of the person's cognitive flexibility in the Intra-Extra Dimensional Set Shift (IED) task from CANTAB

Timepoint
Measuring the individual's score in the Intra-Extra Dimensional Set Shift (IED) task before the intervention, Immediately after the end of the intervention, two weeks, four weeks, and three months after the end of the intervention as follow-up periods.

Method of measurement
the Intra-Extra Dimensional Set Shift (IED) task from CANTAB

4

Description
A person's visual memory score in the Paired Associates Learning assignment from CANTAB

Timepoint
Measuring the individual's score in the Paired Associates Learning task before the intervention, Immediately after the end of the intervention, two weeks, four weeks, and three months after the end of the intervention as follow-up periods.

Method of measurement
the Paired Associates Learning assignment from CANTAB

5

Description
The score of a person's sustained attention in the task of Rapid Visual Information Processing from CANTAB

Timepoint
Measuring the individual's score in the Rapid Visual Information Processing task before the intervention, Immediately after the end of the intervention, two weeks, four weeks, and three months after the end of the intervention as follow-up periods.

Method of measurement
the task of Rapid Visual Information Processing from CANTAB

Intervention groups

1

Description
Intervention group: Twenty sessions of 20 minutes in ten days under real stimulation with an intensity of 3 milliamperes, with the anode placed on the right area of the inferior frontal cortex and the cathode on the left supraorbital area.

Category
Treatment - Devices

2

Description
Control group: Twenty sessions of 20 minutes in ten days under sham stimulation with an intensity of 3 milliamperes, with the anode placed on the right area of the inferior frontal cortex and the cathode on the left supraorbital area.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Zanjan Beheshti Hospital Clinic
Full name of responsible person
Atefeh Fatehi chenar
Street address
Ark Square, Shahid Beheshti Therapeutic and Psychiatric Education Center
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Zanjan
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Fax
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Email
fatehi.atefe@zums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Hasan Bakhtiary
Street address
Zanjan University of Medical Science, Mahdavi Blv, Shahrak Karmandan
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Province
Zanjan
Postal code
4513956184
Phone
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Email
hbakhtiary@zums.ac.ir
Web page address
http://zums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Atefeh Fatehi chenar
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Ark Square, Beheshti Hospital
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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Masters student
Latest degree
Bachelor
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atefehfatehi993@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Atefeh Fatehi chenar

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available