

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effects of transcranial direct current stimulation (TDCS) on improvement of obsessive compulsive symptoms, quality of life, depression, and cognitive functions in patients with obsessive-compulsive disorder: A QEEG-Based Study

Protocol summary

Study aim

Determining the effectiveness of TDCS on improvement of OCD symptoms, quality of life, depression, and cognitive functions in patients with obsessive-compulsive disorder

Design

A randomized (using random numbers table), double-blind, sham controlled clinical trial with a parallel group, 30 patients (15 patients in the sham and 30 patients, 15 in each stimulation group). Both participants and evaluators will be unaware of the allocation of study groups.

Settings and conduct

The statistical population of the present study will include patients with obsessive-compulsive disorder who refer to counseling and psychotherapy centers and psychiatric clinics in Ardabil in 2020. In the stimulation groups (1 mA and 2 mA), the samples will be treated for 10 sessions. Patients will be treated daily for 20 minutes. In the sham group, no therapeutic intervention will be performed with the TDCS device. Patients in both groups will be done pre-tested, post-test and follow up before, after and one month after intervention with Yale Brown, SF-36, Beck-II, Wisconsin cards and QEEG. Control group will be treated with tdcS for 10 sessions after the end of trial.

Participants/Inclusion and exclusion criteria

The research samples will include 45 patients with obsessive-compulsive disorder who will be selected based on the study inclusion/exclusion criteria. Inclusion criteria: Age 18 to 40, literacy to read and write, OCD according to DSM-5 criteria, Willingness to participate in the study Exclusion criteria: Severe mental illness, History of stroke, serious neurologic symptoms including seizures, Brain Surgery, Brain tumor, CSF shunt in the brain, snail planting, physical tools in the body, serious

physical illness,

Intervention groups

15 in the 1 mA group, 15 in the 2 mA group and 15 in the sham group.

Main outcome variables

Improvement of OCD symptoms, quality of life, depression, and cognitive functions in patients with OCD disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200518047492N1**

Registration date: **2020-08-17, 1399/05/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-17, 1399/05/27**

Update count: **0**

Registration date

2020-08-17, 1399/05/27

Registrant information

Name

Behnam Molaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3323 5044

Email address

b.molaei@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of transcranial direct current stimulation (TDCS) on improvement of obsessive compulsive symptoms, quality of life, depression, and cognitive functions in patients with obsessive-compulsive disorder: A QEEG-Based Study

Public title

Effects of TDCS on improvement of obsessive compulsive symptoms in patients with obsessive-compulsive disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 40 literacy to read and write OCD according to DSM-5 criteria Willingness to participate in the study

Exclusion criteria:

severe mental illness, History of stroke, serious neurologic symptoms including seizures, Brain Surgery, Brain tumor, CSF shunt in the brain, snail planting, physical tools in the body, serious physical illness

AgeFrom **18 years** old to **40 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget sample size: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

For small studies, random numbers can be used to sort individuals into groups. Persons participating in the research will be given a code or machine number in order to use the random or random numbers table. Since the number of people we want will be selected from 45 people, so the assigned codes and numbers will be double digits. To select sample people from the table, it will randomly start from a table point in the row or column direction. Subjects are then randomly assigned to one of three study groups (1 mA, 2mA and sham) using the random number table and receive intervention in the same group. Each of the 45 selected individuals will be assigned a code between 01 and 45. Because the volume is two digits, 2 digits out of 5 digits (2 digits to

the right) will be selected from the random number table, excluding numbers greater than 45 and duplicates. After three groups of 15 are formed, they will be randomly replaced in the 1 mA, 2 mA and sham groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the present study, first the objectives of the study and a whole explanation will be described to the participants and informed consent will be obtained from the participants. None of the participants and evaluators will be aware of the type of stimulation (1 mA, 2 mA and dummy stimulation).

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ardabil University of Medical Sciences

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Daneshgah St. Ardabil University of Medical Sciences, Ardabil, Iran

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Ardabil

Province

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Postal code

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Approval date

2020-05-11, 1399/02/22

Ethics committee reference number

IR.ARUMS.REC.1399.102

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**

obsessive compulsive symptoms

Timepoint

Before the intervention, after the intervention and one months after the intervention

Method of measurement

Yale Brown Questionnaire

2

Description

quality of life

Timepoint

Before the intervention, after the intervention and one months after the intervention

Method of measurement

quality of life Questionnaire

3

Description

Depression

Timepoint

Before the intervention, after the intervention and one months after the intervention

Method of measurement

Beck-II Questionnaire

4

Description

cognitive functions

Timepoint

Before the intervention, after the intervention and one months after the intervention

Method of measurement

Wisconsin cards

5

Description

Quantitative Electroencephalographic Changes (QEEG)

Timepoint

Before the intervention, after the intervention and one months after the intervention

Method of measurement

Quantitative Electroencephalographic

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Electrical stimulation for 20 minutes at an intensity of 1 mA.

Category

Treatment - Devices

2

Description

Intervention group: Electrical stimulation for 20 minutes

at an intensity of 2 mA.

Category

Treatment - Devices

3

Description

Control group: Sham stimulation for 20 minutes

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Counseling and psychotherapy centers and psychiatric clinics in Ardabil

Full name of responsible person

Dr Behnam Molaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ardabil 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

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for general inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Dr Behnam Molaei

Position

Assist Prof

Latest degree

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Other areas of specialty/work

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Ardabil University of Medical Sciences

Full name of responsible person

Dr Behnam Molaei

Position

Assist Prof

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Publication of results of the articles in journals with international indexes

When the data will become available and for how long

no limit

To whom data/document is available

no limit

Under which criteria data/document could be used

no limit

From where data/document is obtainable

Dr Behnam Molaei

What processes are involved for a request to access data/document

b.molaei@arums.ac.ir

Comments