

# 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

**Age**From **18 years** old to **40 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**Target 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

**Street address**

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

**City**

Ardabil

**Province**

Ardabil

**Postal code**

۵۶۱۸۹۸۵۹۹۱

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

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

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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**

Ardabil University of Medical Sciences

**Full name of responsible person**

Dr Behnam Molaei

**Position**

Assist Prof

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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**Position**

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**Latest degree**

Ph.D.

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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**