

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The role of transcranial direct current stimulation on emotional bias, mind-wandering and affect for patients with depression disorder

Protocol summary

Study aim

The effect of Transcranial direct current stimulation (tDCS) in the dorsolateral prefrontal cortex and ventromedial prefrontal cortex on emotional bias, reduction of mind wandering and improvement of affect in patients with major depressive disorder

Design

In this study, three situations are considered and repeated measures analysis of variance is used. 23 subjects. The order of presenting the sessions to each subject is random and by lot.

Settings and conduct

each subject was intervened in three sessions with an interval of 72 hours. After receiving the consent letter and explaining the steps of the test, electrodes were placed on their head. After 5 minutes from the time of stimulation, the response to the computer tests began. In order to control the effect of learning the tests and to create a controlled experimental method, the order of individuals in each of the stages stimulation was done randomly. The electric current was 1/5mA for 20 min. The study site was the clinic of the School of Behavioral Sciences and Mental Health

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of MDD, Being right-handed, 20 to 40 years
Exclusion criteria: any serious medical conditions, History of seizures, Existence of intracranial implants, Pregnancy, Acute vision problems

Intervention groups

1. the anode is placed on the left DLPFC, which leads to increased neuronal activity in this region, and the cathode is placed on the right vmPFC. 2. the cathode is placed on the DLPFC, which leads to a decrease in neuronal activity in this region, and the anode is placed on the right vmPFC. 3. electrodes are placed on the subject's head for 15 minutes like a real stimulus, but no electric current enters the subject except for the first and the last 30 seconds of the session. This session is considered as control.

Main outcome variables

emotional bias, mind wandering, affect

General information

Reason for update

An error occurred in the design section of the study. In total, there are 23 subjects who are tested in three stages. Each subject acts as its control group. Corrected in the study groups (Cross over). Also in the abstract, the design was modified.

Acronym

IRCT registration information

IRCT registration number: **IRCT20211207053315N1**

Registration date: **2021-12-29, 1400/10/08**

Registration timing: **retrospective**

Last update: **2022-03-03, 1400/12/12**

Update count: **2**

Registration date

2021-12-29, 1400/10/08

Registrant information

Name

Maryam Majidinezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 7753 3296

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2021-08-06, 1400/05/15
Actual recruitment start date
 2021-05-02, 1400/02/12
Actual recruitment end date
 2021-09-05, 1400/06/14
Trial completion date
 2021-09-05, 1400/06/14

Scientific title
 The role of transcranial direct current stimulation on emotional bias, mind-wandering and affect for patients with depression disorder

Public title
 The role of transcranial direct current stimulation on emotional bias, mind-wandering and affect for patients with depression disorder

Purpose
 Other

Inclusion/Exclusion criteria
Inclusion criteria:
 psychiatric diagnosis of depressive disorder Age range 20-40 years Being right-handed
Exclusion criteria:
 any serious medical conditions such as a history of trauma or head surgery History of seizures Existence of intracranial implants Pregnancy acute vision problems

Age
 From **20 years** old to **40 years** old

Gender
 Both

Phase
 0

Groups that have been masked

- Participant

Sample size
 Target sample size: **23**
 More than 1 sample in each individual
 Number of samples in each individual: **3**
 Each participant receives intervention in three different situations. Positions include: 1) Anodal Dlpfc (F3)/ Cathodal Vmpfc (Fp2). 2) Anodal Vmpfc (Fp2)/ Cathodal Dlpfc (F3). 3) Sham
 Actual sample size reached: **23**
 More than 1 sample in each individual
 Actual sample size in each individual: **3**
 Each participant receives intervention in three different situations. Positions include: 1) Anodal Dlpfc (F3)/ Cathodal Vmpfc (Fp2). 2) Anodal Vmpfc (Fp2)/ Cathodal Dlpfc (F3). 3) Sham

Randomization (investigator's opinion)
 N/A

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description
 Participants were unaware of the type of stimulus they received. The order of placement of individuals in each stage of the research was done randomly using a lottery.

Placebo
 Used

Assignment
 Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat Highway, next to Milad Tower

City

Tehran

Province

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Postal code

1449614535

Approval date

2021-03-16, 1399/12/26

Ethics committee reference number

IR.IUMS.REC.1399.1431

Health conditions studied

1

Description of health condition studied

Major depression disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

emotional bias

Timepoint

Simultaneously with the intervention

Method of measurement

the score that the subject has tested in the computer test of emotional faces (Dot-probe)

2

Description

Mind wandering

Timepoint

Simultaneously with the intervention

Method of measurement

the score that the subject has tested in the computer test of SART

3

Description

affect

Timepoint

Before and after each stimulation session

Method of measurement

the score that the subject achieves on the PANAS positive and negative emotion scale.

Secondary outcomes

1

Description

Side effects of tDCS: Headache, dizziness, burning, itching

Timepoint

Immediately after the actual stimulation and sham condition

Method of measurement

TDCS Side Effects Questionnaire

Intervention groups

1

Description

Intervention group: Left anode/Right cathode intervention; In this intervention, the positive electrode (anode) is placed on the left dorsolateral prefrontal cortex (DLPFC) , which leads to increased neuronal activity, and the negative electrode (cathode) is placed on the right ventromedial prefrontal cortex (vmPFC)

Category

Diagnosis

2

Description

Intervention group: Left cathode/Right anode intervention; In this intervention, the negative electrode (cathode) is placed on the left dorsolateral prefrontal cortex (DLPFC) , which leads to a decrease in neuronal activity in this area, and the positive electrode (anode) is placed on the right ventromedial prefrontal cortex (vmPFC)

Category

Diagnosis

3

Description

Intervention group: Sham intervention; In this intervention, the anode and cathode electrodes are placed on the subject's head for 15 minutes like a real stimulus, but no electric current enters the subject except for the first 30 seconds of the beginning and the end of the session. This session is considered as control

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of the Faculty of Behavioral Sciences and Mental Health

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Vice Chancellor for Research of Iran University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Iran 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
Iran University of Medical Sciences
Full name of responsible person
Maryam.Majidinezhad
Position
MSc student
Latest degree
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Person responsible for updating data

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable