

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The effectiveness of bilateral transcranial direct current stimulation (tDCS) over dorsolateral prefrontal cortex (dlPFC) on attentional and memory bias and dissociative reactions in patients with post-traumatic stress disorder (PTSD)

Protocol summary

Study aim

Investigation the effect of bilateral transcranial direct current stimulation (tDCS) over dorsolateral prefrontal cortex (dlPFC) on attentional and memory bias and dissociative reactions in patients with post-traumatic stress disorder (PTSD)

Design

This study is a sham-controlled, parallel-group, single-blind, randomized clinical trial including 26 patients with post-traumatic stress disorder (PTSD). The "rand" function of MATLAB software will be used to randomly assign participants.

Settings and conduct

Convenience sampling method will be used to select the participants of the present study. The sample of the current study consists of 26 war veterans diagnosed with PTSD and hospitalized in the psychiatric department of Baqiyat Allah Al-Azam Educational-Therapeutic Center located in Tehran. Each patient should complete a consent form before participating in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Diagnosed with PTSD by a professional psychiatrist Exclusion criteria: 2. History of epilepsy, seizure, traumatic brain injury, and neurological surgery 3. History of other major psychiatric disorders

Intervention groups

Participants will be randomly assigned to two experimental conditions. 1) Receiving real electrical stimulation and psychotropics 2) Receiving sham electrical stimulation and drug therapy. The target brain areas for stimulation will be the left and right dorsolateral prefrontal cortices (F3 and F4 according to the international 10-20 system, respectively), which will be the target of anodal and cathodal stimulation, respectively. The duration of each session will be 20 minutes and the current intensity will be 2 mA. The

number of sessions will be 10 during 5 consecutive days.

The size of the electrodes will be 30 square centimeters.

Main outcome variables

1. Attention bias 2. Memory bias 3. Dissociative reactions

General information

Reason for update

Adjusting the number of patients participating in the study due to significant setbacks in identifying suitable candidates meeting the inclusion criteria and able to continue with the study. Moreover, new information respecting inter-session interval and the follow-up stage of the study was included.

Acronym

IRCT registration information

IRCT registration number: **IRCT20231114060051N1**

Registration date: **2023-11-25, 1402/09/04**

Registration timing: **registered_while_recruiting**

Last update: **2025-01-03, 1403/10/14**

Update count: **1**

Registration date

2023-11-25, 1402/09/04

Registrant information

Name

Reza Estaji

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-11, 1402/09/20

Expected recruitment end date

2024-04-18, 1403/01/30

Actual recruitment start date

2023-11-22, 1402/09/01

Actual recruitment end date

2024-05-19, 1403/02/30

Trial completion date

2024-05-19, 1403/02/30

Scientific title

The effectiveness of bilateral transcranial direct current stimulation (tDCS) over dorsolateral prefrontal cortex (dlPFC) on attentional and memory bias and dissociative reactions in patients with post-traumatic stress disorder (PTSD)

Public title

The effectiveness of brain stimulation on post-traumatic stress disorder (PTSD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed with PTSD by a professional psychiatrist

Exclusion criteria:

Having a history of epilepsy, seizure, traumatic brain injury, and neurological surgery Having a history of other major psychiatric disorders

Age

From **20 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Actual sample size reached: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

Convenience sampling will be conducted, however, we will allocate participants randomly to one of experiment or control groups using statistical softwares.

Blinding (investigator's opinion)

Single blinded

Blinding description

The control group will be undergoing sham stimulation in which the electrode position will be the same as that used for real stimulation; however, the current will ramp up and ramp down at the early seconds of the beginning and end of the session without participants' awareness.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Sciences., South Sheikh Bahai St., Mollasadra St., Vanak Square

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Tehran

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1435916471

Approval date

2023-10-30, 1402/08/08

Ethics committee reference number

IR.BMSU.BAQ.REC.1402.075

Health conditions studied

1

Description of health condition studied

Post-traumatic stress disorder (PTSD)

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description

Attention bias: Attention bias and selective attention to negative and trauma-related stimuli.

Timepoint

Before intervention, Right after intervention, one month after intervention.

Method of measurement

The accuracy and speed of responses in the dot probe and Stroop tasks will be an index of attention bias in the present study.

2

Description

Memory bias: the preference of the memory to recognize and recall negative and trauma-related information.

Timepoint

Before intervention, Right after intervention, one month after intervention.

Method of measurement

Autobiographical memory test

3

Description

Dissociative reactions (flashbacks): One of the symptoms of post-traumatic stress disorder in which the patient acts as if they are re-experiencing the traumatic event.

Timepoint

Before intervention, Right after intervention, one month after intervention.

Method of measurement

Participants' score in the intrusion symptoms subscale (flashbacks) of the PCL-5 rating scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants of the intervention group will be undergoing electrical stimulation. The target brain areas for stimulation will be the left and right dorsolateral prefrontal cortices (F3 and F4 according to the international 10-20 system, respectively), which will be target of anodal and cathodal stimulation, respectively. The duration of each session will be 20 minutes and the current intensity will be 2 mA. The number of sessions will be 10 during 5 consecutive days. The size of the electrodes will be 30 square centimeters.

Category

Treatment - Other

2

Description

Control group: The control group will be undergoing sham stimulation in which the electrode position will be the same as that used for real stimulation; however, the current will ramp up and ramp down at the early seconds of the beginning and end of the session without participants' awareness.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyat Allah Al-Azam Educational-Therapeutic Center

Full name of responsible person

Reza Estaji

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mohsen Saberi

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Web page address

<https://research.bmsu.ac.ir/portal/home/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mohammad Javad Ahmadizadeh

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data file of the participants in a non-identifiable form, the study protocol, the informed consent form, and the clinical study report will be accessible to other researchers and clinicians in the field of mental health after the end of the research and the publication of the article.

When the data will become available and for how long

Accessibility will start after the publication of the results.

To whom data/document is available

Researchers and clinicians in the field of mental health

Under which criteria data/document could be used

The data and protocol of this study will be made available for use in other related research and clinical settings.

From where data/document is obtainable

Dr.Mohammad Javad Ahmadizadeh
mjahmadizadeh@yahoo.com Reza Estaji
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What processes are involved for a request to access data/document

Researchers and clinicians in the field of mental health can submit their request to receive the protocol and data

of the present study by explaining how they are going to use the mentioned items. The data and protocol will be

accessible in a period of less than a week.
Comments