Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of the effectiveness of transcranial direct current stimulation (tDCS) and eye movement desensitization and reprocessing (EMDR) on post-traumatic stress disorder symptoms (PTSD)

Protocol summary

Study aim
comparison of the effectiveness of transcranial direct current stimulation and eye movement desensitization and reprocessing on post-traumatic stress disorder symptoms

Design
Clinical trials with control group, with parallel groups, double-blind, randomized. The sample size of this study is 60 individuals: divided into 3 groups of 20 people.

Settings and conduct
After selecting the participants in Baqiyatollah university and Atieh neurosciences center, they are randomly assigned to three intervention 1, intervention 2 and control groups and the researchers, clinical observer and evaluator of outcome are blinded. Participants were also evaluated through post-traumatic stress disorder Inventory, Beck Depression and Anxiety Inventory and Rumination Scale in three stages: pre-test, post-test and follow-up period.

Participants/Inclusion and exclusion criteria
Inclusion criteria: ages of 18 to 60 years, post-traumatic stress disorder, having a PTSD checklist score greater than 50, experienced no change in psychosocial treatments for 2 months before stilmulation, experienced no change in psychotropic medication, either dose or agent for 2 months before stilmulation. Exclusion criteria: comorbidity with other psychiatric disorders, A history of a significant neurological or medical disorders, Changed medications in the 8 weeks prior to commencement of the trial, Implanted medication pumps of any sort that would increase the risk of stilmulation.

Intervention groups
intervention group 1: In this group, the cathode electrode was placed on right prefrontal (F4) and anode electrode was placed on the left prefrontal (F3). They receive a current of 2 mA for 20 minutes in 10 sessions.
intervention group 2: this group also receives 8 sessions for EMDR. placebo group: this group receives sham stimulation for 10 sessions.

Main outcome variables
post-traumatic stress disorder symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180522039775N1**
Registration date: **2018-10-20, 1397/07/28**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-20, 1397/07/28**
Update count: **0**

Registration date
2018-10-20, 1397/07/28

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-29, 1396/11/09

Expected recruitment end date
2018-11-22, 1397/09/01

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

Scientific title
Comparison of the effectiveness of transcranial direct current stimulation (tDCS) and eye movement desensitization and reprocessing (EMDR) on post-traumatic stress disorder symptoms (PTSD)

Public title
Effectiveness of transcranial direct current stimulation in treatment post-traumatic stress disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 60 years Sign the informed consent form Post-traumatic stress disorder Having a PTSD checklist version (PCL-5) greater than 50 Experienced no change in psychosocial treatments for 2 months before tDCS Experienced no change in psychotropic medication
Exclusion criteria:
Axis 1 psychiatric disorders or personality disorders. A history of a significant neurological or medical disorder such as seizure, brain tumors, traumatic brain injury , stroke, Parkinson’s disease, dementia, Huntington’s chorea, multiple sclerosis Changed medications in the 8 weeks prior to commencement of the trial Implanted medication pumps of any sort that would increase the risk of tDCS The risk of Seizure with any reasons, high Intracranial pressure, The history of epilepsy or Seizure in the first relatives, any metal in Head, brain trauma, history of loss of consciousness for more than 5 minutes Pregnancy, breastfeeding High risk of Suicide
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
After determining the sample size (60 people), by random allocation rule, 20 patients were assigned to the intervention group 1, 20 to the intervention group 2 and 20 to the control group. For this purpose, 20 balls for the intervention group 1, 20 balls for the intervention group 2 and 20 balls for the control group are placed inside the lottery container, and then the balls are removed from the container without randomize replacement and the resulting sequence is recorded
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, participants, researchers, caregivers, and evaluators are blind. The initial stimulation and appearance of the tDCS device for the target group and the placebo group are quite similar. In the placebo group, after initial stimulation, the tDCS device turns off without notice to the patient, and the device is turned on at the end of the stimulation. Furthermore, patients refer to the clinic at a 90-minute interval in order to reduce the possibility of infiltration of information between them. The researcher is also unaware of the grouping of participants because the allocation of individuals to groups and the referral to the caregiver is done by a statistician. Also, the implementation and evaluation of the outcome is done by a separate individual Caregiver and assessing the outcome of the proposal, hypothesis, and type of patients are unaware. Furthermore, in this study, the placebo group also receives a special type of stimulation (primary and secondary), which makes it makes it difficult to diagnose the target group from the placebo for caregivers and evaluators. In other words, the placebo group does not end the treatment sessions without stimulation. Therefore, the identification of the placebo and target group is difficult
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
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Behavioral Science Research Center, Baqiyatallah University of Medical Sciences, Sheykh Bahaei Ave, Molla Sadra Ave, Vanak square
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1435916471
Approval date
2017-12-11, 1396/09/20
Ethics committee reference number
IR.BMSU.REC.13960519

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
Score of PTSD on post-traumatic stress index (PCL-5)
Timepoint
Before intervention, Final session, one month after intervention
Method of measurement
Post-traumatic stress index (PCL-5)

Secondary outcomes

1

Description
Score of anxiety
Timepoint
Before intervention, final session ,one month after intervention
Method of measurement
Beck Anxiety Inventory

2

Description
Score of depression
Timepoint
Before intervention, final session ,one month after intervention
Method of measurement
Beck Depression Inventory (BDI-II)

3

Description
Score of rumination
Timepoint
Before intervention, final session ,one month after intervention
Method of measurement
Ruminative Response Scale (RRS)

Intervention groups

1

Description
Intervention group 1: In this group, direct current stimulation was delivered from a battery-driven (Neurosoft, Russia), constant current stimulator and transferred by a pair of 5×7 (35cm2) electrodes. Electrodes were standard carbonic, covered with a normal saline socked sponge cases. In this study, intervention group 1 received real transcranial direct current stimulation (tDCS). In this case, based on the 10-20 system the cathode electrode was placed on right dorsolateral prefrontal cortex (rdLPFC) and anode electrode was placed on the left dorsolateral prefrontal cortex (ldLPFC). 2 mA current for 20 minutes was passed from patient's brain at 10 session.
Category
Treatment - Devices

2

Description
Intervention group 2: In this group, eye movement desensitization and reprocessing (EMDR) is applied during 45minutes in 5 sessions. For this purpose, EMDR is performed in eight steps: Patient history and treatment planning, preparation, assessment, desensitization, Installation, body scan, clousr and reevaluation
Category
Behavior

3

Description
control group: This group received sham transcranial direct current stimulation (tDCS). For sham stimulation, the same methods of placing anode and cathode were used, however, the stimulator was ramped-up to 2 mA in 30s, then gradually ramped-down to 0 mA over the period of 1 minute, and then turned off. The electrodes were on the scalp for 20 minutes and subjects were not informed that the device is turned off.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
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2

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Baqiyatallah 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
Vice Chancellor for Research, Baqiyatallah 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

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Position
researcher

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
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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The total potential data can be shared after unidentifiable people

When the data will become available and for how long
Start the access period 7 months after publishing the results

To whom data/document is available
Data will be available to researchers working in universities and academic institutions

Under which criteria data/document could be used
for scientific use only

From where data/document is obtainable
Mehdi Rezaei- Tel: 00989383354916- E-mail: Rezaee.mehdi15@yahoo.com

What processes are involved for a request to access data/document
The applicant will receive the data within a maximum of one week by explaining the reason for requesting

Comments