Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect and Comparison of Education on Mindfulness-Based Stress Reduction and Combination Method Mindfulness-Based Stress Reduction/ MBSR and transcranial Direct Current Stimulation/ tDCS in the Severity of Stress, Quality of Life and Cognitive Functions of Migraine Sufferers

Protocol summary

Study aim

this study was to evaluate the effect of mindfulness-based stress reduction training and the combination of mindfulness-based stress reduction and brain electrical stimulation on severity

Design

The sample of this study was selected through available sampling method and voluntarily. Finally, all three experimental and control groups, each consisting of 45 subjects, who were completely randomly assigned to the 4-person group, participated in 8 experimental sessions.

Settings and conduct

The present study was performed in Imam Khomeini Hospital in Tehran. In this section, patients were selected as available, and after familiarizing themselves with the aims of the study, volunteered. When large numbers of participants were selected, they were randomly assigned to the groups. The individual assistants received the course training provided by the project administrator and, without knowing that they were in the experimental group or the control, completed the intervention training for 4 sessions. Other assistants then collected the data.

Participants/Inclusion and exclusion criteria

Having the main and predominant diagnosis of migraine disorder Age range from 1 to 2 years Patient presence at Imam Khomeini Hospital in Tehran Alzheimer's, or common psychiatric disorders

Intervention groups

The first group received mindfulness-based stress reduction training. The second group received a combination of mindfulness-based stress reduction techniques combined with electrical stimulation of the brain from the skull using direct electrical current. The control group received the unstructured training program such as time management and review of daily and weekly tasks as a comparison group.

Main outcome variables

Reduction of Mindfulness-Based Stress, Combination of Mindfulness-Based Stress Reduction, Cranial Electrical Stimulation,

General information

Reason for update

Acronym

MBSR و tDCS

IRCT registration information

IRCT registration number: **IRCT20191214045723N1**
Registration date: **2020-02-12, 1398/11/23**
Registration timing: **retrospective**

Last update: **2020-02-12, 1398/11/23**
Update count: **0**

Registration date

2020-02-12, 1398/11/23

Registrant information

Name

Ali Roozbahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 2222

Email address

aliroozbahani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date
2019-05-11, 1398/02/21
Actual recruitment start date
2019-06-21, 1398/03/31
Actual recruitment end date
2019-07-14, 1398/04/23
Trial completion date
2019-12-16, 1398/09/25

Scientific title
The Effect and Comparison of Education on Mindfulness-Based Stress Reduction and Combination Method Mindfulness-Based Stress Reduction/ MBSR and transcranial Direct Current Stimulation/ tDCS in the Severity of Stress, Quality of Life and Cognitive Functions of Migraine Sufferers

Public title
The Effect and Comparison of Education on Mindfulness-Based Stress Reduction and Combination Method Mindfulness-Based Stress Reduction/ MBSR and transcranial Direct Current Stimulation/ tDCS in the Severity of Stress, Quality of Life and Cognitive Functions of Migraine Sufferers
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having the main and predominant diagnosis of migraine disorder Age range from 1 to 2 years Patient presence at Imam Khomeini Hospital in Tehran Alzheimer's, or common psychiatric disorders based on patient records and self-report Minimum diploma literacy
Exclusion criteria:
Existential physical diseases such as epilepsy, cerebral palsy Neurological (except migraine) and psychotic diseases More than two sessions of absenteeism
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **54**
Actual sample size reached: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
The statistical population was all migraine patients aged 18-60 years who were referred to Relaxation Clinic in year 45. Finally, 45 subjects were divided into three groups according to the first group, Mindfulness-Based Stress Reduction training, and the second group Combination Method Mindfulness-Based Stress Reduction/ MBSR and transcranial Direct Current Stimulation/ tDCS and the control group as a comparison group received unstructured training programs such as time management and review of daily and weekly tasks. The pre-test was performed at the end of the post-test and one month after the end of the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, all participants in the study who were available and voluntarily selected were randomly assigned to the experimental and control groups and the research assistants trained for different courses. The control group received a special intervention. Research participants did not know which group they were in, and assistants or clinical caregivers did not know which group they were dealing with.
Placebo
Used
Assignment
Factorial
Other design features
One of the unique features of this intervention is that the control group does not abandon itself, but receives a daily and weekly task management schedule.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences
Street address
Imam Khomeini Hospital, Tohid Square, Sattarkhan Street
City
Tehran
Province
Tehran
Postal code
1445983861
Approval date
2019-01-17, 1397/10/27
Ethics committee reference number
IR.HUMS.REC.1389.304

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
G43.0
ICD-10 code description
G43

Primary outcomes

1

Description
Severity of Stress, Quality of Life and Cognitive Functions
Timepoint
January 1 to February 1
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Education on Mindfulness-Based
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
علی روزبهانی
Street address
Sattarkhan St.- Tohid Square Imam Khomeini Hospital Complex
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Sponsors / Funding sources

1

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Web page address
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Grant name
25 t
Grant code / Reference number
445
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
The researcher himself has funded.
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

2

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?
No
Title of funding source
Bank

Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
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Bandare-abbas University of Medical Sciences
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Ali Roozbahani
Position
Researcher
Latest degree
Master
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Psychology
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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