

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 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 , 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

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Sattarkhan St.- Tohid Square Imam Khomeini Hospital Complex

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

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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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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?

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

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Position

Researcher

Latest degree

Master

Other areas of specialty/work

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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