

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The Effectiveness of Mindfulness-Based Stress Reduction (MBSR) Bibliotherapy on Stress, Depression, Individual Performance, Pain severity & Mindfulness in Outpatients with Migraine

Protocol summary

Study aim

The aim of this study was to Evaluating the Effectiveness of Mindfulness Based Stress Reduction (MBSR) bibliotherapy methods on women with migraines.

Design

Random assignment to intervention and control groups

Settings and conduct

women with migraines headache referring to headache clinic in Baqiyatallah Hospital in Tehran from March 2017 to May 2017.

Participants/Inclusion and exclusion criteria

All women with migraines Headache referring to the headache clinic of Baqiyatallah hospital in Tehran from March 2017 to May 2017. Diagnosis of migraines by a specialist doctor based on the International Association of Headache Criteria Age between 20 to 50 years Level of education: minimum diploma Internet access and social networks Exclusion criteria: Severe mental disorder Failure to respond to therapist follow up for two consecutive weeks

Intervention groups

Among them, 30 subjects (including experimental and control groups) were selected by objective sampling method and randomly placed two groups. The experimental group, in addition to the current drug therapy, was treated in a correspondence course for 8 sessions of stress-reduction mindfulness. The control group received only medication.

Main outcome variables

Intensity of pain Frequency of headaches Disabling Distressing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170118032033N4**

Registration date: **2018-06-30, 1397/04/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-30, 1397/04/09**

Update count: **0**

Registration date

2018-06-30, 1397/04/09

Registrant information

Name

Zohreh Naderi

Name of organization / entity

baqiyatallah university of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2018-07-06, 1397/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Mindfulness-Based Stress Reduction

(MBSR) Bibliotherapy on Stress, Depression, Individual Performance, Pain severity & Mindfulness in Outpatients with Migraine

Public title

Mindfulness Bibliotherapy for Female Outpatients with Migraine

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of migraines by a specialist doctor based on the International Association of Headache Criteria Age between 20 to 50 years Level of education: minimum diploma Internet access and social networks

Exclusion criteria:

Severe mental disorder Failure to respond to the therapist for two weeks in a row

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

30 subjects (including the experimental and control group) were selected by objective sampling method and randomly placed in two groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not 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, Mulla Sadra Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2017-04-30, 1396/02/10

Ethics committee reference number

IR.BMSU.REC.1396.374

Health conditions studied**1****Description of health condition studied**

Migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine with aura [classical migraine]

Primary outcomes**1****Description**

Pain severity

Timepoint

Before and after the intervention

Method of measurement

Migraine Disability Assessment Scale (MIDAS)

2**Description**

Frequency of headaches

Timepoint

Before the intervention and after the end of the eight sessions of educational-medical correspondence of mindfulness

Method of measurement

Migraine Disability Assessment Scale (MIDAS)

3**Description**

Disability

Timepoint

Before the intervention and after the end of the eight sessions of educational-medical correspondence of mindfulness

Method of measurement

Migraine Disability Assessment Scale (MIDAS)

4**Description**

Distress

Timepoint

Before the intervention and after the end of the eight sessions of educational-medical correspondence of mindfulness

Method of measurement

Depression Anxiety Stress Scale (DASS-21)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Received Medical Treatment As Usual, in addition followed by a course of 8 sessions of Mindfulness Based Stress Reduction bibliotherapy.

Category

Treatment - Other

2

Description

Control group: The control group received only the Medical Treatment As Usual (MTAU) for migraine.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah University of Medical Sciences

Full name of responsible person

Vahid Tavallaei

Street address

Baqiyatallah hospital, Mollasadra street

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Email

svahidtav@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Personal

Full name of responsible person

Vahid Tavallaei

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Mollasadra Apartment, Kharazmi Street, Mollasadra Street, Vanak Square

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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

Personal

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

Person responsible for general inquiries

Contact

Name of organization / entity

Ardakan University

Full name of responsible person

Vahid Tavallaei

Position

Master of Science

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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Master

Other areas of specialty/work

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