Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Zohreh Naderi

Name of organization / entity
baqiyatallah university of medical sciences

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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 migrain.
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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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
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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