Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Study the effectiveness of mindfulness-based stress reduction treatment on anxiety sensitivity, rumination, cognitive avoidance and emotional resilience in women with neurogenic migraine

Protocol summary

Study aim
Study of the effectiveness of mindfulness-based stress reduction therapy on anxiety sensitivity, rumination, cognitive avoidance, and emotional resilience in women with migraine

Design
A controlled clinical trial with parallel groups, without blinding, randomized, on 40 patients. SPSS/27 was used for randomization.

Settings and conduct
In this study, in order to select a representative sample of women with migraine neurosis living in Ahvaz, a stratified random sampling method with proportional allocation was used. The sampling unit in this study was the patient (a woman with migraine neurosis). Using this method allows for examining possible differences between different groups of patients and reducing sampling error.

Participants/Inclusion and exclusion criteria
Research entry criteria: 1- Age range 20 to 50 years for women with migraine 2- Signing a written consent form to participate in the research and adhere to treatment Research exit criteria: 1- Simultaneous participation in other psychological treatments 2- Having diseases such as substance abuse and psychotic disorder

Intervention groups
Mindfulness-Based Stress Reduction: This training session was developed based on the Kabat-Zinn method (2013) and is conducted in 8 90-minute sessions, two sessions per week for 1 month.

Main outcome variables
Mindfulness-based stress reduction in women with migraine

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250624066248N1**
Registration date: **2025-09-08, 1404/06/17**
Registration timing: **retrospective**

Last update: **2025-09-08, 1404/06/17**
Update count: **0**

Registration date
2025-09-08, 1404/06/17

Registrant information

Name
Akram Hosseini

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 5262 2200

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akramhosseiny67@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-08, 1403/11/20

Expected recruitment end date
2025-03-10, 1403/12/20

Actual recruitment start date
2025-02-08, 1403/11/20

Actual recruitment end date
2025-03-10, 1403/12/20

Trial completion date
2025-08-11, 1404/05/20

Scientific title
A Study the effectiveness of mindfulness-based stress

reduction treatment on anxiety sensitivity, rumination, cognitive avoidance and emotional resilience in women with neurogenic migraine

Public title
Mindfulness-based stress reduction treatment for women with migraine headaches.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age range of women with migraines: 20 to 50 years History of headaches for at least the past 6 months
Exclusion criteria:
Concurrent participation in other psychological treatments Having illnesses such as substance abuse and psychotic disorder Unwillingness to participate in research
Age
From **20 years** old to **50 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, participant allocation to study groups was performed using block randomization. The block size was set at block size, 4 participants. To ensure a balanced distribution of participants based on [key characteristic, e.g., migraine severity], stratified randomization was also employed. The unit of randomization was individual. The allocation sequence was generated using statistical software SPSS , and the allocation process was concealed via [concealment method.
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 Islamic Azad University of Ahvaz Branch
Street address
Golestan-Islamic Azad University of Ahvaz
City
AHVAZ
Province
Khouzestan
Postal code
134937333
Approval date
2025-01-15, 1403/10/26
Ethics committee reference number
IR.IAU.AHVAZ.REC.1403.457

Health conditions studied

1

Description of health condition studied
Nervous migraine
ICD-10 code
G43.0
ICD-10 code description
Migraine without aura

Primary outcomes

1

Description
Mindfulness-based stress reduction in women with migraine.
Timepoint
30
Method of measurement
Kabat-Zinn Method (2013)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Mindfulness-Based Stress Reduction Therapy: In this method, with a psychological understanding, the mind-body medicine models of stress are integrated with findings related to how to cope with the challenges of modern life. Therefore, this program includes intensive mindfulness meditation training and participants are trained to apply what they have learned practically in relation to the problems of managing the challenges of daily life. In this design, the subjects were measured before the implementation of the independent variable (pre-test), then the experimental intervention or independent variable was applied. After that, the subjects were measured again. Finally, after one month of the post-test, both groups were measured again to examine the continuity of the effects of the interventions on the experimental group. In the present study, mindfulness-based stress reduction training sessions

were implemented based on the Kabat-Zinn protocol (2013) and were implemented over an 8-week period with 90-minute sessions per week for the experimental group.

Category
Treatment - Other

2

Description
Control group: The control group did not receive any intervention during the study. However, to avoid factors that threatened the internal validity of the study, such as compensatory competition by the control group or demoralization, they were assured that they would receive mindfulness-based stress reduction therapy at the next visit (after data collection).

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
All neurologist clinics

Full name of responsible person
Akram Hoseini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

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
Islamic Azad University

Proportion provided by this source
10

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Akram Hosseini

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable