

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The Comparison of the Effectiveness of Combined Medication (Pharmacotherapy and Brief Mindfulness-Based Therapy) and Pharmacotherapy in Improving Migraine Symptoms and Sleep Quality in Women with Migraine

Protocol summary

Study aim

The Comparison of the effectiveness of Combined medication (Pharmacotherapy and brief mindfulness-based therapy) and pharmacotherapy in improving Migraine symptoms and sleep quality in women with migraine

Design

A randomized, single blind clinical trial with a waiting group design of 28 patients, enrolled between July 2018 and October 2018

Settings and conduct

28 people were selected through available sampling method randomly and without being notified, were divided into two groups: Experiment and Waiting. For the experimental group, in addition to the conventional drug therapy, brief mindfulness-based therapy was held that lasted 2 sessions a week, for 2 weeks. But for the waiting group, only the conventional drug therapy was performed. At the end of the research, psychological intervention was also performed for the waiting group for ethical considerations

Participants/Inclusion and exclusion criteria

Inclusion criteria included receiving a diagnosis of migraine according to the psychiatrist's opinion, the age of 18-60, Level of education at least middle school and female gender. Exclusion criteria included any severe psychological disorders such as psychosis, bipolar disorder, severe depression, or personality disorders, a history of drug abuse and dependency on any particular substance, receiving any psychological treatments for migraine over the past two years and changing in drug use during the study

Intervention groups

For the waiting group, only the conventional drug therapy was performed and In the experimental group, in addition to conventional drug therapy, brief mindfulness-

based therapy was performed

Main outcome variables

Migraine symptoms Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190311043018N1**

Registration date: **2019-05-04, 1398/02/14**

Registration timing: **retrospective**

Last update: **2019-05-04, 1398/02/14**

Update count: **0**

Registration date

2019-05-04, 1398/02/14

Registrant information

Name

Hossein Hosseinpour

Name of organization / entity

The university of urmia

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-08-23, 1397/06/01
Actual recruitment start date
2018-07-21, 1397/04/30
Actual recruitment end date
2018-10-22, 1397/07/30
Trial completion date
2018-11-21, 1397/08/30

Scientific title

The Comparison of the Effectiveness of Combined Medication (Pharmacotherapy and Brief Mindfulness-Based Therapy) and Pharmacotherapy in Improving Migraine Symptoms and Sleep Quality in Women with Migraine

Public title

the Effectiveness of Combined Medication (Pharmacotherapy and Mindfulness) in Improving Migraine and Sleep Quality

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Getting Diagnosis of Migraine Based on Psychiatrist's Comment Level of education is at least middle school Not receiving any kind of psychological treatment for migraine over the past two years

Exclusion criteria:

Having any severe psychiatric disorder such as psychosis, bipolar disorder, severe depression or personality disorders History of drug abuse and dependence on any other specific substance Changing in drug dosage

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Actual sample size reached: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random sampling Random unit: person
Randomization Tool: Random Number Tables

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants in the study did not know the allocation of study groups to the experimental and waiting group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences and Health Services, Hezar-Jerib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2018-02-20, 1396/12/01

Ethics committee reference number

IR.MUI.MED.REC.1396.358

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43.0 G43.

ICD-10 code description

Migraine without aura

Primary outcomes

1

Description

Score of participants in Migraine Disability Assessment questionnaire

Timepoint

Migraine Disability Assessment before the intervention and after the intervention

Method of measurement

Migraine Disability Assessment questionnaire

2

Description

Score of participants in Pittsburgh Sleep Quality Index

Timepoint

Sleep Quality Assessment before the intervention and after the intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The MBT intervention, based on Mindfulness-based stress reduction and Mindfulness Based Cognitive Therapy was conducted over a 3-week period involving twice-weekly group classes and daily practice. The program, which included a particular focus on management of headache pain and related psychosocial sequels, and management of stress as a contributing factor to headache, was developed by some of the authors who are psychologists with formal training in mindfulness therapy and extensive teaching, practice and research experience in mindfulness-based meditation. This protocol was first used in a research entitled "Brief Mindfulness-Based Therapy for Chronic Tension-Type Headache". In addition, individuals in the intervention group, along with psychological treatment, followed their drug treatment under the supervision of their psychiatrist.

Category

Treatment - Other

2

Description

Control group: For control group in this study, no psychological treatment was applied and During the study, they only followed their own drug treatment under the supervision of a psychiatrist

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychosomatic Research Center

Full name of responsible person

Dr. Hamid Afshar

Street address

Psychosomatic Research Center, Second Floor, Shahid Mottahari Clinic, Shariati West Street, Hakim Nezami Street

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Sponsors / Funding sources

1

Sponsor

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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

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

The university of Kharazmi

Full name of responsible person

Hossein Hosseinpour

Position

M.A in clinical psychology

Latest degree

Master

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available