

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy of mindfulness based stress reduction on pain severity, mindful awareness, perceived stress and psychological health in patients with tension headache in Kashan

#### Protocol summary

##### Summary

Mindfulness-based stress reduction (MBSR) is a new psychotherapy that appears to be effective in treating chronic pain and stress. In many disorders and illnesses there are symptoms of headache. This study evaluated efficacy of MBSR in treatment of tension headache. Methods: this study is a randomized clinical trial. Sixty patients with tension type headache according to the International Headache Classification Subcommittee were assigned in treatment as usual (TAU) or experimental group (MBSR) randomly. The MBSR group received eight weekly treatments. Any session was 120-min. The sessions were based on MBSR protocol. Diary scale for measuring headache, Mindful Attention Awareness Scale (MAAS), Brief Symptom Inventory (BSI) and Perceived Stress Scale (PSS) administered in pre and post treatment and at 3 months follow-up in both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014061618106N1**  
Registration date: **2014-07-19, 1393/04/28**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-07-19, 1393/04/28

##### Registrant information

##### Name

Abdollah Omid

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5555 0021

##### Email address

omidi-a@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kashan University of Medical Sciences

##### Expected recruitment start date

2012-06-19, 1391/03/30

##### Expected recruitment end date

2022-09-21, 1401/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of mindfulness based stress reduction on pain severity, mindful awareness, perceived stress and psychological health in patients with tension headache in Kashan

##### Public title

Efficacy of mindfulness based stress reduction on pain severity, mindful awareness, perceived stress and psychological health in patients with tension headache

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Not receiving psychiatric medication and psychotherapy from 6 months up to the study of the experimental group; not receiving psychotherapy from 6 months up to the study in both experimental and control groups; no concurrent psychiatric problems.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 60

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Kashan University of Medical Sciences

**Street address**

Kashan University of Medical Sciences

**City**

Kashan

**Postal code****Approval date**

2012-01-31, 1390/11/11

**Ethics committee reference number**

2615/11/11/90

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

Tension headache

**ICD-10 code**

R51

**ICD-10 code description**

Headache

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

pain

**Timepoint**

pre and post treatment and at 3 months follow-up

**Method of measurement**

Diary scale for measuring headache

**Secondary outcomes****1****Description**

mindful awareness

**Timepoint**

pre and post treatment and at 3 months follow-up

**Method of measurement**

Mindful Attention Awareness Scale

**Intervention groups****1****Description**

mindfulness based stress Reduction The 8 weekly sessions followed the standard MBSR protocol as developed by Kabat-Zinn (1990). Each session was 150 min. The overall content of the sessions were: (a) Theoretical debates about relaxation, meditation, and body-mind connections; (b) train and practice of meditation and yoga both inside and outside the sessions during the day, (c) Resolve obstacles to successful training. In addition, a pamphlet consists of information related to each week's instruction was provided for participants. Daily practice for them determined at least 40 min as homework.

**Category**

Lifestyle

**2****Description**

no psychotherapy

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Kashan Medical University Clinics

**Full name of responsible person**

Abdollah Omid

**Street address**

Kashan Medical University Clinics

**City**

Kashan

**Sponsors / Funding sources****1****Sponsor**

**Name of organization / entity**

Deputy of Research of Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Gholam Ali Hamidi

**Street address**

Kashan University of Medical Sciences

**City**

Kashan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Deputy of Research of Kashan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Abdollah Omid

**Position**

Assistant professor

**Other areas of specialty/work****Street address**

Kashan University of Medical Sciences

**City**

Kashan

**Postal code****Phone**

+98 31 5554 0021

**Fax****Email**

omidi-a@kums.ac.irabomidi20@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Abdollah Omid

**Position**

Clinical psychologist, ph.D.

**Other areas of specialty/work****Street address**

Kashan University of Medical Sciences

**City**

Kashan

**Postal code**

8715988141

**Phone**

+98 31 5555 0021

**Fax**

+98 31555550021

**Email**

omidi-a@kums.ac.ir

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

Kashan University of Medical Sciences

**Full name of responsible person**

Fatemeh Zargar

**Position**

Assistant profesor

**Other areas of specialty/work****Street address**

kashan

**City**

kashan

**Postal code**

8715988141

**Phone**

+98 31 5555 0021

**Fax****Email**

fatemehzargar@gmail.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*