

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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

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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

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Kashan University of Medical Sciences

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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

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**

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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