Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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
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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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Deputy of Research of Kashan University of Medical Sciences
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Dr. Gholam Ali Hamidi
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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

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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