Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of cognitive therapy based on mindfulness on the cognitive regulation of emotions, severity of migraine psychosomatic symptoms and stress coping styles among women with migraine.

Protocol summary

Study aim
determine the effectiveness of cognitive therapy based on mindfulness on cognitive regulation of emotions, severity of psycho-physical symptoms of migraine and stress coping styles among women with migraine.

Design
A clinical trial with a control group, with parallel groups, without a blind strain and randomized on 32 patients, rand function of Excel software was used for randomization.

Settings and conduct
After referring to neurologists in Khorramabad city, 32 patients were selected as available and randomly assigned to the test and control groups from among the female patients with migraine who met the criteria for entering the study and willing to cooperate in the research. Cognitive therapy sessions based on mindfulness were conducted by the researcher on the experimental group for 8 sessions of 45 minutes. A post-test was taken before the intervention and after the intervention on both groups.

Participants/Inclusion and exclusion criteria
Entry requirements 1- The age range of women suffering from migraine disease should be from 20 to 50 years. 2- Women suffering from migraine should express their consent to participate in the research. Non-entry conditions 1- Using drugs, alcohol, or suffering from a diagnosed mental disorder, 2- Declaring dissatisfaction with participation in intervention courses,

Intervention groups
In order to improve the effectiveness of cognitive therapy based on mindfulness on the variables of increasing the cognitive regulation of emotions, reducing the severity of psychosomatic symptoms of migraine and improving the coping styles of stress in women with migraine, two groups performed the pre-test. The intervention group was treated during 8 sessions. and the control group was without any training,

Main outcome variables
cognitive regulation of emotions, the severity of migraine psychosomatic symptoms, and stress coping styles

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221218056852N1**
Registration date: **2023-02-19, 1401/11/30**
Registration timing: **retrospective**

Last update: **2023-02-19, 1401/11/30**
Update count: **0**

Registration date
2023-02-19, 1401/11/30

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
2022-10-23, 1401/08/01
Actual recruitment end date
2022-11-11, 1401/08/20
Trial completion date
2022-11-11, 1401/08/20

Scientific title
The effectiveness of cognitive therapy based on mindfulness on the cognitive regulation of emotions, severity of migraine psychosomatic symptoms and stress coping styles among women with migraine.

Public title
The effectiveness of cognitive therapy based on mindfulnessamong on women with migraine.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
1- The age range of women suffering from migraine disease should be from 20 to 50 years 2- Women suffering from migraine should express their consent to participate in the research. 3- Women with migraine do not have a history of suffering from a mental disorder diagnosed by a psychologist or psychiatrist, or a history of addiction to drugs and alcohol. 4- Women with migraine do not have a history of receiving treatment from a psychotherapist
Exclusion criteria:
1- Using drugs, alcohol, or suffering from a diagnosed mental disorder 2- Declaring dissatisfaction with participation in intervention courses 3- Defects in pre-test questionnaires 4- Absence of more than 1 session in the intervention sessions and defects in the post-test questionnaires
Age
From **20 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **32**
Actual sample size reached: **32**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The method of this research is semi-experimental (pre-test - post-test with control group). period. Research design experiment 16 pre-test X post-test Control 16 pre-test - post-test

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Lorestan University of Medical Sciences
Street address
Pardis Kamalvand
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Province
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Postal code
6813833946
Approval date
2022-10-22, 1401/07/30
Ethics committee reference number
IR.LUMS.REC.1401.172

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The percentage of people who have a psychosomatic migraine symptom severity questionnaire score above 25.
Timepoint
Conducting a pre-test before the implementation of the intervention and a post-test review after two months (8 sessions) that the implementation of the intervention takes.November 21 to January 20
Method of measurement
Questionnaire of severity of psychosomatic symptoms of migraine Najarian (1376)

2

Description
Cognitive emotion regulation questionnaire score
Timepoint
Questionnaire of severity of psychosomatic symptoms of migraine Najarian (1376)
Method of measurement
Garnevsky's Cognitive Emotion Regulation Questionnaire (2001)

3

Description
Score of stress coping styles questionnaire
Timepoint
Conducting a pre-test before the implementation of the intervention and a post-test review after two months (8 sessions) that the implementation of the intervention takes. November 21 to January 20
Method of measurement
Billings and Moss (1981) stress coping styles questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Cognitive therapy sessions based on mindfulness were conducted for 8 sessions of 45 minutes. The first session: introduction of the participants and a brief description of the 8 sessions of the raisin eating technique, followed by body scan meditation for 30 minutes. Homework: presence in the moment and expansion. Giving the raisin eating technique to other activities, doing body scan meditation and discussing it. The second session: Homework review, the difference between thoughts and feelings. Do meditation. Task: Mindfulness of a pleasant event, doing sitting meditation and body scan, exercise of seeing and hearing, sitting meditation, third session: discussing homework, doing one of the exercises of mindful movements. Homework: sitting meditation, body scan, exercise 3 One minute breathing space. Fourth session: sitting meditation with attention to breathing, discussion about stress responses and a person's reaction to difficult situations.Practicing mindful walking. Assignments: sitting meditation, body scan or one of the body movements of the conscious mind and 3-minute breathing space practice (in an unpleasant event). Sitting meditation. Fifth session: presenting and performing the movements of the conscious mind. Assignments: sitting meditation, breathing space Three minutes in an unpleasant event and mindfulness of a new daily activity. Three-minute breathing space exercise. Sixth session: Discussion about homework. Presenting an exercise with the title of creating, thinking, separate views. Accepting feelings as feelings. Assignments: Choose a combination of meditations of personal preference plus practice a three-minute breathing space on an unpleasant event and mindfulness of a new daily activity. Seventh session: four-dimensional meditation. Practice session: What is the best way to take care of myself?Teaching acceptance without judgment. Assignments: meditation, three-minute breathing exercise in an unpleasant event, mindfulness of a new daily activity. Eighth session: body scan. Three-minute breathing space exercise. Discussing the methods of dealing with the obstacles of doing meditation. Asking questions about the entire session.
Category
Behavior

2

Description
Control group: 32 people who referred to the office of neurologists were voluntarily and available, whose migraine questionnaire score was above 25, and two questionnaires on cognitive regulation of emotion and coping styles were also implemented on them, then they were randomly divided into two groups of 16 people, and no intervention It was not done on the control group, and then a post-test was taken with the experimental group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Office of Dr. Hamzeh Ali Asadi, Sepenta building
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
student
Proportion provided by this source
100
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
Persons

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
In this research, the data was analyzed at two descriptive and inferential levels. So that in the descriptive part, the frequency, percentage, mean and standard deviation of the findings were displayed, and in the inferential level, the Kolmograf-Smirnov test was first used to check the normality of the research variables, then the research hypotheses. It was analyzed using the statistical method of multivariate analysis of covariance and univariate covariance analysis in the text of multivariate covariance analysis and SPSS version 23 software.

When the data will become available and for how long
Unlimited time

To whom data/document is available
Organizations and licensed professionals

Under which criteria data/document could be used
According to the needs of the applicant

From where data/document is obtainable
Ameneh Shahverdi

What processes are involved for a request to access data/document
Written request

Comments