Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Mindfulness Self Compassion Program Training on Severity of Migraine Headache and Quality of Life in Women With Migraine

Protocol summary

Study aim

Studying Mindfulness self compassion program effectiveness on migraine headache severity and quality of life

Design

Controlled Clinical trial, Random number table will be used for randomization

Settings and conduct

A call will be made to female patients of a “family medicine office”, which are diagnosed with migraine and qualified for other Research required specifics. After explaining research conditions, 30 subjects will be chosen from candidates using convenience sampling method. By using randomization, 15 subjects will join control group and 15 remaining subjects will be put in Intervention group. Both groups will continue their medications prescribed by their physician. Intervention group will receive 8 group sessions of Mindful self compassion training, both group will be tested for migraine headache severity and quality of life in pretest and posttest.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Being Female , Having migraine for at least one year , Must be in 20 to 50 years old range, Educational requirement: must have high school diploma , Interested in participating in phycological researches Exclusion Criteria: Suffering from Psychiatric problems , Suffering from physical illnesses that prohibits participating in group therapy sessions

Intervention groups

In the course of 8 sessions the contents of Mindful self compassion program which is based on self compassion training and using mindfulness exercises will be taught to subjects in intervention group. Subjects will not receive any training in control group and just attend the pretest and posttest.

Main outcome variables

McGill Pain Questionnaire Score ; World Health Organization Quality of Life Questionnaire BREF score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220530055023N1**
Registration date: **2022-07-18, 1401/04/27**
Registration timing: **prospective**

Last update: **2022-07-18, 1401/04/27**
Update count: **0**

Registration date

2022-07-18, 1401/04/27

Registrant information

Name
Maryam Kargar
Name of organization / entity
The University of Shiraz
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-21, 1401/04/30

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
The Effectiveness of Mindfulness Self Compassion Program Training on Severity of Migraine Headache and Quality of Life in Women With Migraine

Public title
The Effectiveness of Mindfulness Self Compassion Program in Migraine
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having migraine for at least one year Must be in 20 to 50 years old range Educational requirement: must have high school diploma Interested in participating in phycological researches
Exclusion criteria:
Suffering from psychiatric problems Suffering from physical illnesses that prohibits active participating in group therapy sessions
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: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
30 subjects will be chosen from available candidates using convenience sampling method. Subjects will be split randomly between two groups, control group and intervention group, each group containing 15 persons. For randomizing the splitting process, initially an integer codes between 01 and 30 will be assigned to each person, then we move and stop our finger randomly and blindfolded on a RAND Corporation random number table, we move on that chosen row to find the corresponding random number and consider the last two digits of the random number. If the number is between 01 and 30, a successful random number is generated. The process will continue till 15 random integers in the desired interval is made. 15 selected codes are in the intervention group and the rest are in the control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Seventh floor, Central building of Shiraz University of Medical Sciences, Zand Street
City
Shiraz
Province
Fars
Postal code
71348-14336
Approval date
2022-04-25, 1401/02/05
Ethics committee reference number
IR.SUMS.REC.1401.088

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
G43
ICD-10 code description
Migraine

2

Description of health condition studied
Quality of Life
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
McGill Pain Questionnaire Score
Timepoint
Before intervention and after intervention
Method of measurement
McGill Pain Questionnaire(MPQ)

2

Description
World Health Organization Quality of Life Questionnaire BREF score
Timepoint
Before intervention and after intervention

Method of measurement
World Health Organization Quality of Life Questionnaire BREF(WHOQOL-BREF)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: consisted of 15 female subjects affected with migraine will have weekly group trainings for 8 sessions and each session for two and a half hours long.Training sessions will be held once a week and will last for a total of 2 months. They will continue their medication as prescribed by their physician. Each session has a main topic and a target which will be exercised by discussing more elaborate subtopics and by practicing various trainings. Sessions main topics are: discovering self-compassion, practicing Mindfulness, practicing love-kindness, discovering self-compassionate voice, living deeply, retreating, meeting difficult emotions, exploring challenging relationships, and embracing own life. Examples for the practices are: compassionate listening, forgiveness and embodied listening. During group sessions, the self-compassion basic concepts will be taught to the group by incorporating examples and taking advantage of group training power, and self-compassion will be introduced to the group by using concentration increasing exercises. In the course of sessions, subjects will learn how to be self-compassionate and how to be self-conscious about their feelings and bodily status.
Category
Behavior

2

Description
Control group: consisted of 15 female subjects affected with migraine that will not receive any training and continue their medication as prescribed by their physician. They will join pre-test and post-test, before and after intervention respectively.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
(General Physician) Dr.Ali Mohammad Ahadi’s office
Full name of responsible person
Maryam Kargar
Street address
Upstairs Dr. Rezaei Pharmacy,Enghelab street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Shiraz
Full name of responsible person
Doctor Mohammad Hadi Sadeghi
Street address
5th floor, Shiraz University Central Building, Jomhuri Eslami Boulevard
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viceres@shirazu.ac.ir
Grant name
-
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The University of Shiraz
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 Shiraz
Full name of responsible person
Maryam Kargar
Position
Master Student
Latest degree

Bachelor

Other areas of specialty/work
Psychology

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Person responsible for updating data

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Latest degree
Bachelor

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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
No - There is not a plan to make this available

Informed Consent Form
Yes - There is 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

Title and more details about the data/document
Data (not including participant personal information) consisted of research protocol, questioner’s raw scores, raw forms, raw consent form and general participation protocols is available for fellow researchers via email application, 6 months after first paper publication.

When the data will become available and for how long
6 months after the publication of the article

To whom data/document is available
Mental health researchers and physical health researchers

Under which criteria data/document could be used
Applications: Phycology, chronic headaches, migraine researches

From where data/document is obtainable
Send an email to the researchers

What processes are involved for a request to access data/document
Requests for data will be considered by researchers and in case of being applicable to a mental or physical health research, data will be sent.

Comments