

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 71 3227 5053

Email address

kargar9574@gmail.com

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 psychological 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

City

Marvdasht

Province

Fars

Postal code

7371778645

Phone

+98 71 4334 1144

Email

ahadi27675@gmail.com

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

City

Shiraz

Province

Fars

Postal code

8447171946

Phone

+98 71 3628 6426

Email

vicerces@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
Street address
No. 2, Sarvenaz Building, Khakshenasi Street, Eram Blvd.
City
Shiraz
Province
Fars
Postal code
7143713386
Phone
+98 71 3227 5053
Email
kargar9574@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
The University of Shiraz
Full name of responsible person
Changiz Rahimi Taghanaki
Position
Full professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Faculty of Psychology and Educational Sciences, Eram University Campus, Eram Square
City
Shiraz
Province
Fars
Postal code
7194684334
Phone
+98 71 3613 4662
Email
crahimi2016@hotmail.com

Person responsible for updating data

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
Street address
No. 2, Sarvenaz Building, Khakshenasi Street, Eram Blvd.
City
Shiraz
Province
Fars
Postal code
7143713386
Phone
+98 71 3227 5053
Email
kargar9574@gmail.com

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