

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison the Effectiveness of Mindfulness Based Cognitive therapy with Cognitive Behavioral therapy Focused on Isomnia and Fordyce Happiness training on Depression, Pain Self Efficacy. Pain Anxiety, , Resiliency, Affective Capital and Migraine Symptoms in Women with Migraine Headache.

Protocol summary

Study aim

Comparison the Effectiveness of Mindfulness Based Cognitive therapy with Cognitive Behavioral therapy Focused on Isomnia and Fordyce Happiness training on Depression, Pain Self Efficacy. Pain Anxiety, , Resiliency, Affective Capital and Migraine Symptoms in Women with Migraine Headach

Design

clinical trial with control group, with parallel group, One-way blind, Random, Phase one on 72 patients, Excel software rand function was used for randomization

Settings and conduct

This study will be conducted in a quasi-experimental and four groups. After purposeful selection and random assignment of participants in the three treatment groups and the control group, the experimental groups will be trained electronically before the pre-test training, after the post-test training and two months after the training. In this study, blinding will be done unilaterally in such a way that the statistical analyst will be unaware of the interventions provided to the experimental groups and the identification of the control group.

Participants/Inclusion and exclusion criteria

Diagnosis of migraine by a neurologist, Being in the age group of 18 to 55 Female gender, a minimum of secondary education, Not undergoing parallel psychological or psychiatric treatments, Having physical fitness (not having debilitating physical diseases such as MS, muscular and skeletal diseases) to participate in training courses, Determination and desire to participate in research and its continuation No migraine diagnosed by a neurologist, Being under the age of 18 and over 55

Intervention groups

Mindfulness Based Cognitive therapy with Cognitive

Behavioral therapy Focused on Isomnia and Fordyce Happiness training and control group

Main outcome variables

Pain Anxiety; Depression; Pain Self Efficacy; Resiliency; Affective Capital and Migraine Symptoms; Women; Migraine Headache

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200514047442N1**

Registration date: **2021-12-06, 1400/09/15**

Registration timing: **prospective**

Last update: **2021-12-06, 1400/09/15**

Update count: **0**

Registration date

2021-12-06, 1400/09/15

Registrant information

Name

afsaneh sartipzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3662 1191

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2022-04-04, 1401/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effectiveness of Mindfulness Based Cognitive therapy with Cognitive Behavioral therapy Focused on Isomnia and Fordyce Happiness training on Depression, Pain Self Efficacy. Pain Anxiety, , Resiliency, Affective Capital and Migraine Symptoms in Women with Migraine Headache.

Public title

Comparison the Effectiveness of Mindfulness Based Cognitive therapy with Cognitive Behavioral therapy Focused on Isomnia and Fordyce Happiness training on Depression, Pain Self Efficacy. Pain Anxiety, , Resiliency, Affective Capital and Migraine Symptoms in Women with Migraine Headache

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of migraine by a neurologist, Being in the age group of 18 to 55 Female gender, a minimum of secondary education, Not undergoing parallel psychological or psychiatric treatments, Having physical fitness (not having debilitating physical diseases such as MS, muscular and skeletal diseases) to participate in training courses, Determination and desire to participate in research and its continuation.

Exclusion criteria:

No migraine diagnosed by a neurologist, Being under the age of 18 and over 55..

AgeFrom **18 years** old to **55 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample sizeTarget sample size: **72****Randomization (investigator's opinion)**

Randomized

Randomization description

Participants in the study are divided into 4 groups of 18 people and randomly assigned to 3 intervention and control groups. Reminds about how to randomize after initial interview and initial screening, 72 women with the criteria to enter the study were selected, then by coding and using the lottery method, 18 people are divided into four groups by the lottery method into three

experimental groups based on type The intervention and a control group are divided

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyzer does not know the type of actions for the groups

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

IRAN NATION COMMITTEE FOR ETICS IN BIOMEDICAL RESEARCH

Street address

kerman

City

kerman

Province

Kerman

Postal code

8163867691

Approval date

2021-06-02, 1400/03/12

Ethics committee reference number

IR-IAU.KHUISF.REC.1400.057

Health conditions studied**1****Description of health condition studied**

migrain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain Anxiety

Timepoint

pretest-posttest- two months follow up

Method of measurement

Pain Anxiety scale

2**Description**

Pain Self Efficacy

Timepoint

pretest-posttest- two months follow up

Method of measurement

Pain Self Efficacy scale

3**Description**

Depression

Timepoint

pretest-posttest- two months follow up

Method of measurement

Beck Depression scale

4**Description**

resiliency

Timepoint

pretest-posttest- two months follow up

Method of measurement

Conner-Davidson resiliency scale

5**Description**

Affective Capital

Timepoint

pretest-posttest- two months follow up

Method of measurement

Affective Capital scale

6**Description**

Migraine Symptoms

Timepoint

pretest-posttest- two months follow up

Method of measurement

Migraine Symptoms scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Cognitive Behavioral therapy
Focused on Isomnia

Category

Treatment - Other

2**Description**

Intervention group: Mindfulness Based Cognitive therapy

Category

Treatment - Other

3**Description**

Intervention group: Fordyce Happiness training

Category

Treatment - Other

4**Description**

Control group: not intervention

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

کلینیک های روانپزشکی

Full name of responsible person

مدیر کلینیک های روانپزشکی

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

dr golparvar

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Email

info@khuisf.ac.ir

Web page address

http://new.khuisf.ac.ir

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
-

Proportion provided by this source
1

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
Islamic Azad University

Full name of responsible person
Aida Elham

Position
TEACHER

Latest degree
Master

Other areas of specialty/work
Psychology

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Person responsible for updating data

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Sharing plan

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

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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
The results of the analysis of participants' individual data are shared

When the data will become available and for how long
20.4.2022-208.2022

To whom data/document is available
All researchers

Under which criteria data/document could be used
In order to use the results of the analysis in future research

From where data/document is obtainable

From the site of the journals in which the extracted article is published

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

If the article is published in scientific research journals,

the author's email address will be posted on the site and researchers can request the necessary information by sending a request to the author's email address. After reviewing the requests by the author, if approved, the authorized information will be sent to researchers

Comments