Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

Phone

+98 31 3662 1191

Email address

afsane.sartipzade@yahoo.com

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..
Age
From **18 years** old to **55 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target 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 afterInitial 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 COMMITEE 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
Street address
خیابان طهماسب آباد
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Province
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Postal code
8163867691
Phone
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Email
myazdani@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
dr golparvar
Street address
خیابان ارغوانیه
City
Isfahan
Province
Isfehan
Postal code
8155139998
Phone
+98 31 3535 4001
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 scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohsen Golparvar

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associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

afsaneh sartipzadeh

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Mental health expert

Latest degree

Ph.D.

Other areas of specialty/work

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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