

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effectiveness of compassion focus therapy with transdiagnostic treatment on symptoms of migraine , perceived stress ,dark personality and mental toughness in patients with migraine

Protocol summary

Study aim

Effectiveness and comparison of Compassion Focused Therapy and Transdiagnostic Treatment on migraine symptoms, perceived stress, dark personality and mental strength of patients with migraine

Design

At first, 45 migraine patients who were diagnosed with migraine by a neurologist were selected. They were randomly assigned to two experimental and one control groups.

Settings and conduct

This study was conducted at Shahin Shahr Oil Industry Clinic from October to December 2017. During this study, two experimental groups received psychological training and drug therapy, and the control group received only medication. Before the intervention, the pre-test was performed in three groups and after intervention, three groups of post-test were performed and after two months follow up.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of migraine by the neurologist, having at least 3rd grade education, satisfaction with the company's research, and the absence of any acute and psychological illness other than migraine, which leads to the use of medication.
Non-inclusion criteria: receiving psychological treatment in the last 6 months.

Intervention groups

Intervention group 1: Compassion Focused Therapy with drug therapy
Intervention group 2: Transdiagnostic Treatment with drug therapy
Control group: only drug therapy

Main outcome variables

Ahvaz migraine headache questionnaire score; Chohen Perceived stress scale score; Dark Personality Inventory score; Mental Toughness Questionnaire score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180627040263N1**

Registration date: **2018-09-18, 1397/06/27**

Registration timing: **retrospective**

Last update: **2018-09-18, 1397/06/27**

Update count: **0**

Registration date

2018-09-18, 1397/06/27

Registrant information

Name

Mehdi Ashharian dokht

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4525 4625

Email address

a.yarmohammadian@edu.ui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2017-10-07, 1396/07/15

Actual recruitment start date

2017-09-29, 1396/07/07

Actual recruitment end date

2017-10-07, 1396/07/15

Trial completion date

2017-12-22, 1396/10/01

Scientific title

Comparison of the effectiveness of compassion focus therapy with transdiagnostic treatment on symptoms of migraine , perceived stress ,dark personality and mental toughness in patients with migraine

Public title

Comparison of the effectiveness of compassion focus therapy with transdiagnostic treatment on symptoms of migraine

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of migraines by a neurologist having at least 3rd grade education Wiling to participate in the research not having any acute and psychological illness other than migraine

Exclusion criteria:

Psychological treatment in the last 6 months

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Accidental assignment to intervention and control groups which was done through simple randomization. Random numbers table was used to create random sequences. In order to hide the random allocation, non-transparent sealed envelopes were used.

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 on Research, Shahrekord Branch, Islamic Azad University

Street address

Shahrekord Branch, Islamic Azad University,

Rahmateyeh Blvd

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8813733395

Approval date

2018-05-13, 1397/02/23

Ethics committee reference number

IR.IAU.SHK.REC.1397.002

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine without aura [common migraine]

Primary outcomes

1

Description

Ahvaz migraine headache questionnaire score

Timepoint

At the beginning of the study, after the end of the intervention and 2 months after the end of the intervention

Method of measurement

Ahvaz migraine headache questionnaire

2

Description

Chohen Perceived stress scale score

Timepoint

At the beginning of the study, after the end of the intervention and 2 months after the end of the intervention

Method of measurement

Chohen Perceived stress scale

3

Description

Dark Personality Inventory score

Timepoint

At the beginning of the study, after the end of the intervention and 2 months after the end of the intervention

Method of measurement

Johnson & Webster Darkness Personality Questionnaire

4

Description

Mental Toughness Questionnaire score

Timepoint

At the beginning of the study, after the end of the intervention and 2 months after the end of the intervention

Method of measurement

Mental Toughness Questionnaire of Clough & et al

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Compassion focused therapy Protocol (Gilbert, 2014) was performed through 8 90-minute Session, one session a week. Intervention was performed in a group.

Category

Behavior

2

Description

Intervention group 2: The Unified Protocol for Transdiagnostic Treatment (Barlow, 2011) was performed through 8 90-minute Session, one session a week. Intervention was performed in a group.

Category

Behavior

3

Description

Control group: Only taking medication was prescribed by a neurologist.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahin Shahr Oil Industry Clinic

Full name of responsible person

Dr. Ahmad Khatibi

Street address

Oil Industry Clinic, Imam Khomeini Street

City

Shahin Shahr

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Isfahan

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+98 31 4522 9841

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m_eshharian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Rashid Riahy

Street address

Shahrekord Branch, Islamic Azad University, Rahmatyeh Blvd

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Email

riahi.r@iaushk.ac.ir

Web page address

http://research.iaushk.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mehdi Ashharian

Position

Ph.D student

Latest degree

Ph.D.

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

Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments

-