Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of hypnosis-based mindfulness therapy on psychological aspects and severity of headache in patients with chronic migraine

Protocol summary

Study aim

The aim of this study is to evaluate the effectiveness of hypnosis-based Mindfulness therapy, on the psychological aspects of headache including psychological inflexibility, pain acceptance, pain anxiety, pain catastrophizing, mindfulness, self-compassion, emotion regulation strategies, psychological distress, and headache disability, and the severity of headache in patients with chronic migraine.

Design

A randomized clinical trial with a parallel control group, single blind, on 38 patients. Excel software rand function was used for randomization.

Settings and conduct

Therapeutic intervention will be performed in 8 one-hour individual sessions according to the Elkins protocol in the clinical psychology of Taleghani Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having chronic migraine headaches according to the International Headache Committee (IHS) and the beta version of the Third International Classification of Headache Disorders (ICHD-3 beta); Having informed consent to participate in the research and signing the informed consent form; Age range between 18 and 50 years; At least a diploma degree; Female gender. Exclusion Criteria: Having other chronic pain problems; Have a history of psychotherapy in the last 6 months; Participate in another psychological intervention simultaneously; Recent drugs abuse; Existence of diagnostic indicators or history of borderline personality disorder, psychosis, or schizophrenia due to interference with hypnosis; History of epileptic seizures or facial nerve pain.

Intervention groups

Intervention group: Mindful Hypnotherapy. Control group: routine medical treatment.

Main outcome variables

Psychological inflexibility, pain acceptance, pain anxiety, pain catastrophizing, mindfulness, self-compassion, emotion regulation strategies, psychological distress, headache disability, headache severity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201009048974N2**
Registration date: **2022-01-21, 1400/11/01**
Registration timing: **retrospective**

Last update: **2022-01-21, 1400/11/01**
Update count: **0**

Registration date

2022-01-21, 1400/11/01

Registrant information

Name

Maryam Bakhtiari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2303 1548

Email address

maryam_bakhtiyari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of hypnosis-based mindfulness therapy on psychological aspects and severity of headache in patients with chronic migraine

Public title

The effectiveness of Mindful Hypnotherapy on psychological aspects and severity of headache in patients with chronic migraine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having chronic migraine headaches according to the International Headache Committee (IHS) and the beta version of the Third International Classification of Headache Disorders (ICHD-3 beta) Having informed consent to participate in the research and signing the informed consent form Age range between 18 and 50 years At least a diploma degree Female gender

Exclusion criteria:

Having other chronic pain problems Have a history of psychotherapy in the last 6 months Participate in another psychological intervention simultaneously Recent drugs abuse Existence of diagnostic indicators or history of borderline personality disorder, psychosis or schizophrenia due to interference with hypnosis History of epileptic seizures or facial nerve pain

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be simple randomization method. the random unit is individuals. 38 patients with chronic migraine will be divided into intervention and control groups by Microsoft Excel software using Rand function. In this way, a table of random numbers will be prepared and the Randbetween function will be created and the patients will be divided into two groups of 19 people respectively.

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome assessor in data collection after the intervention and the data analyst will be unaware of the objectives of the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Tehran, Ghods Town (West), between South Flamek and Zarafshan, Iran TV St. - Headquarters of the Ministry of Health, Treatment and Medical Education, Block A, 13th floor

City

Tehran

Province

Tehran

Postal code

11111-11111

Approval date

2022-01-04, 1400/10/14

Ethics committee reference number

IR.SBMU.MSP.REC.1400.651

Health conditions studied

1

Description of health condition studied

Chronic migraine headache

ICD-10 code

G43.701

ICD-10 code description

Chronic migraine without aura, not intractable, with status migrainosus

Primary outcomes

1

Description

psychological inflexibility

Timepoint

In the per-intervention and post-intervention stages for 2 months

Method of measurement

Psychological Inflexibility Pain Scale (PIPS)

2

Description

Pain Acceptance

Timepoint

In the per-intervention and post-intervention stages for 2 months

Method of measurement

Pain acceptance questionnaire (CPAQ)

3

Description

Pain Anxiety

Timepoint

In the per-intervention and post-intervention stages for 2 months

Method of measurement

Pain Anxiety Symptoms Scale (PASS-20)

4

Description

Pain Catastrophizing

Timepoint

In the per-intervention and post-intervention stages for 2 months

Method of measurement

Pain Catastrophizing Scale (PCS)

5

Description

Mindfulness

Timepoint

In the per-intervention and post-intervention stages for 2 months

Method of measurement

Five Facet Mindfulness Questionnaire (FFMQ)

6

Description

Self-Compassion

Timepoint

In the per-intervention and post-intervention stages for 2 months

Method of measurement

Self-Compassion Scale (SCS)

7

Description

Emotion Regulation

Timepoint

In the per-intervention and post-intervention stages for 2 months

Method of measurement

Emotion Regulation Strategies Questionnaire (ERQ)

8

Description

Psychological Distress

Timepoint

In the per-intervention and post-intervention stages for 2 months

Method of measurement

Kessler Psychological Distress Scale (K10)

9

Description

Headache related disability

Timepoint

In the per-intervention and post-intervention stages for 2 months

Method of measurement

Headache related disability questionnaire (HDI)

10

Description

headache intensity

Timepoint

In the per-intervention and post-intervention stages for 2 months

Method of measurement

Visual Analogue Scale (VAS), McGill Pain Questionnaire (MPQ), Blanchard headache diary

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mindful Hypnotherapy. This treatment will be performed in 8 one-hour individual sessions according to the Elkins protocol.

Category

Treatment - Other

2

Description

Control group: At first, the control group does not receive any intervention and only the results of their evaluations, which are done by the relevant questionnaires, will be compared with the intervention group. At the end of the study, for all members of the control group, Mindful hypnotherapy intervention will be performed in 8 one-hour individual sessions according to the Elkins protocol.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaie Tajrish hospitals

Full name of responsible person

Hassan Khazraee

Street address

Tajrish Sq, Tajrish Hospital

City
Tehran

Province
Tehran

Postal code
11111-11111

Phone
+98 912 957 6671

Email
hassankhazraee@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Shahid Beheshti University of Medical Science

Street address
Velenjak St. , Shahid Chamran Highway

City
Tehran

Province
Tehran

Postal code
1111111111

Phone
+98 21 2243 9982

Email
taleghani@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti University of Medical Sciences

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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Hassan Khazraee

Position
PHD student of Clinical psychology

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
arabi St, Taleghani Hospital

City
Tehran

Province
Tehran

Postal code
11111-11111

Phone
+98 21 2293 5548

Email
hassankhazraee@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Hassan Khazraee

Position
PHD student of Clinical psychology

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Arabi St, Taleghani hospital

City
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Province
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+98 21 2293 5548

Email
hassankhazraee@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

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Hassan Khazraee

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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
Yes - There is a plan to make this available
Informed Consent Form
No - There is not 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
Participants' data will be shared in the SPSS file using by code of participants (not using first and last name)
When the data will become available and for how long
Access to the data will be after the articles are published
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
Request from the journals where the articles related to this research intend to be published.
From where data/document is obtainable
By receiving confirmation via email to the main executor or executors of the project
What processes are involved for a request to access data/document
Send an email to the main executor or other executors of the project and receive written confirmation through them
Comments