

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 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

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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  
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## 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  
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**Province**  
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**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

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#### Province

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## Person responsible for scientific inquiries

#### Contact

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**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
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**Position**  
PHD student of Clinical psychology  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Psychology  
**Street address**  
arabi St, Taleghani Hospital  
**City**  
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**Province**  
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**Phone**  
+98 21 2293 5548  
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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**