

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The effectiveness of Mindful Hypnotherapy on the psychological aspects of depressed patients

#### Protocol summary

##### Study aim

The aim of this study is to evaluate the effectiveness of Mindful Hypnotherapy on depression, Stress, Anxiety, Psychological Flexibility, Emotion Regulation, Rumination, Mental health, Self-Compassion and Resilience in Depressed Patients

##### Design

A randomized clinical trial with a parallel control group, single blind, on 34 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: Depression score higher than 28 in Beck Depression Inventory-II (BDI-II); Having criteria for major depressive disorder according to DSM-5; Age range between 18 and 50 years; Having informed consent to participate in the research and signing the informed consent form At least a diploma educational degree. Exclusion Criteria: 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; serious suicidal thoughts and any plan(s) to attempt suicide.

##### Intervention groups

Mindful Hypnotherapy group

##### Main outcome variables

Main outcome variables includes depression, Stress, Anxiety, Psychological Flexibility, Emotion Regulation, Rumination, Mental health, Self-Compassion and Resilience

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211210053342N1**  
Registration date: **2022-04-08, 1401/01/19**  
Registration timing: **registered\_while\_recruiting**

Last update: **2022-04-08, 1401/01/19**

Update count: **0**

##### Registration date

2022-04-08, 1401/01/19

##### Registrant information

##### Name

Hassan Khazraee

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2293 6346

##### Email address

hassankhazraee@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-03, 1401/01/14

##### Expected recruitment end date

2022-04-20, 1401/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effectiveness of Mindful Hypnotherapy on the psychological aspects of depressed patients

## Public title

En The effectiveness of Mindful Hypnotherapy on depression, Stress, Anxiety, Psychological Flexibility, Emotion Regulation, Rumination, Mental health, Self-Compassion and Resilience in Depressed Patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Depression score higher than 28 in Beck Depression Inventory-II (BDI-II) Having criteria for major depressive disorder according to DSM-5 Age range between 18 and 50 years Having informed consent to participate in the research and signing the informed consent form At least a diploma educational degree

### Exclusion criteria:

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 serious suicidal thoughts and any plan(s) to attempt suicide

## 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: **34**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization will be simple randomization method. the random unit is individuals. 34 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 17 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 Committees of Shahid Beheshti University of Medical Sciences

##### Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

#### Approval date

2022-01-30, 1400/11/10

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1400.880

## Health conditions studied

### 1

#### Description of health condition studied

Major depressive disorder

#### ICD-10 code

F33.2

#### ICD-10 code description

Major depressive disorder, recurrent severe without psychotic features

## Primary outcomes

### 1

#### Description

Depression

#### Timepoint

In the per-intervention and post-intervention stages

#### Method of measurement

Beck Depression Inventory (BDI-II)

### 2

#### Description

Stress

#### Timepoint

In the per-intervention and post-intervention stages

#### Method of measurement

Depression, Anxiety, Stress Scale (DASS-21)

### 3

#### Description

Anxiety

#### Timepoint

In the per-intervention and post-intervention stages

#### Method of measurement

Depression, Anxiety, Stress Scale (DASS-21)

#### 4

##### **Description**

Psychological Flexibility

##### **Timepoint**

In the per-intervention and post-intervention stages

##### **Method of measurement**

The Acceptance and Action Questionnaire (AAQ-2) and The Psychological Flexibility Questionnaire (PFQ)

#### 5

##### **Description**

Emotion Regulation Difficulty

##### **Timepoint**

In the per-intervention and post-intervention stages

##### **Method of measurement**

Emotion Regulation Difficulty Scale (DERS)

#### 6

##### **Description**

Rumination

##### **Timepoint**

In the per-intervention and post-intervention stages

##### **Method of measurement**

Mental rumination questionnaire

#### 7

##### **Description**

Mental health

##### **Timepoint**

In the per-intervention and post-intervention stages

##### **Method of measurement**

The Mental Health Continuum Short Form (MHC-SF)

#### 8

##### **Description**

Self-Compassion

##### **Timepoint**

In the per-intervention and post-intervention stages

##### **Method of measurement**

Self-Compassion Scale (SCS)

#### 9

##### **Description**

Resilience

##### **Timepoint**

In the per-intervention and post-intervention stages

##### **Method of measurement**

Brief Resilience Scale (BRS)

### **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**

Psychology Clinic of Taleghani Hospital

###### **Full name of responsible person**

Hassan Khazraee

###### **Street address**

Talegani Hospital, Arabi St, Tehran

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1111111111

###### **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**

Dr. KianiMogadam

###### **Street address**

Vice-Chancellor of Research Affairs, Shahid Beheshti University of Medical Sciences, Next to Taleghani hospital, Erabi Ave., Chamran highway

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

19839-63113

**Phone**

+98 21 2243 9770

**Email**

Info@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 candidate of clinical psychology

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

Taleghani Educational Hospital, Shahid Beheshti University of medical science, Velenjak Region, Chamran High Way, Tehran, Iran

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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 candidate of clinical psychology

**Latest degree**

Master

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Psychology

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Hassan Khazraee

**Position**

Phd candidate of clinical psychology

**Latest degree**

Master

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**Email**

hassankhazraee@gmail.com

## 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**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Not applicable

**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**

Access to the data will be after the articles are published

**Under which criteria data/document could be used**

The data will be available only to researchers working in academic and scientific institutions

**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**