Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+98 21 2293 6346

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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-5Age 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
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Talegani Hospital, Arabi St, Tehran
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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
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Tehran
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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

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

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Person responsible for scientific inquiries

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Position
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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
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