

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### The effect of mindfulness-based stress reduction on emotion regulation, somatic symptoms and sleep problems in the depressed elderly

#### Protocol summary

##### Study aim

Specific objectives: Determining and comparing the mean scores of emotion regulation in depressed elderly in two groups of stress reduction based on mindfulness and control Determining and comparing the mean score of physical symptoms of depressed elderly in the two groups of stress reduction based on mindfulness and control Determining and comparing the mean score of sleep problems of depressed elderly in two groups of stress reduction based on mindfulness and control

##### Design

The present study is an applied type with experimental methods of pre-test and post-test with a control group. The statistical population of this study includes the elderly referred to the psychiatric clinic of Amin Hospital in Isfahan with a diagnosis of depression, from which 40 people are randomly selected as a sample.

##### Settings and conduct

Psychiatric clinic located in Amin Hospital

##### Participants/Inclusion and exclusion criteria

Entry criteria: Age over 60 years - No simultaneous participation in research or other intervention - No other psychiatric disorders - Lack of neurological disorders - Ability to exercise to perform exercises - Willingness to participate in research Criteria for not entering: Withdrawal from cooperation - absence of more than two sessions - simultaneous infection Other chronic diseases

##### Intervention groups

Consciousness-based stress reduction program training sessions are held in 8 sessions of 90 minutes once a week for the experimental group and the control group does not receive any training. One week after the end of the training sessions, both groups complete the research questionnaires as a post-test.

##### Main outcome variables

Assist in the control and treatment of depression and its associated variables among the elderly; Increasing the psychological and physical well-being of the elderly

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211118053099N1**

Registration date: **2022-01-13, 1400/10/23**

Registration timing: **prospective**

Last update: **2022-01-13, 1400/10/23**

Update count: **0**

##### Registration date

2022-01-13, 1400/10/23

##### Registrant information

##### Name

Nima Javadzade

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3555 2250

##### Email address

nimajavadzade@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-09, 1401/01/20

##### Expected recruitment end date

2022-06-10, 1401/03/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of mindfulness-based stress reduction on emotion regulation, somatic symptoms and sleep problems in the depressed elderly

**Public title**

The effect of MBSR on emotion regulation, physical symptoms and sleep problems in depressed elderly

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age over 60 years Non-simultaneous participation in research or other intervention Absence of other psychiatric disorders Lack of neurological disorders Ability to exercise physically Ability to read and write Willingness to participate in research

**Exclusion criteria:**

Withdrawal from continuing cooperation Absence for more than two sessions Simultaneous infection with other chronic diseases

**Age**

From **60 years** old to **85 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization, Using a table of random numbers and assigning numbers to participants

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

keshavarzi, koche yakhchal, kosar dormitory

**City**

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**Province**

Isfahan

**Postal code**

8174884841

**Approval date**

2021-11-03, 1400/08/12

**Ethics committee reference number**

IR.MUI.MED.REC.1400.612

**Health conditions studied****1****Description of health condition studied**

depression

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Depression score in the geriatric depression scale

**Timepoint**

Measurement of depression at the beginning of the study (before the intervention) and one week after the intervention

**Method of measurement**

Geriatric depression Scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group:

**Category**

Treatment - Other

**2****Description**

Control group:

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

amin hospital

**Full name of responsible person**

Dr omranifar

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Ebne sina

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aminhospital@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Deputy of research and technology  
**Street address**  
Hezar jarib  
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81746-73461  
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mail.mui@yahoo.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Esfahan 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**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Dr fatemeh zargar  
**Position**  
Associate Professor  
**Latest degree**  
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**Other areas of specialty/work**  
Psychology

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Not applicable