

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 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

isfahan

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

Street address

Ebne sina

City

Isfahan

Province
Isfahan
Postal code
5314181486
Phone
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81746-73461
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f.zargar@med.mui.ac.ir

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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Email
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
Ph.D.
Other areas of specialty/work
Psychology

Person responsible for scientific inquiries

Contact

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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