Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 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
Isfehan
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
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Postal code
5314181486
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aminhopital@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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Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3792 3071
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
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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