Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

the effect of spiritual intervention on depression in postmenopausal women

Protocol summary

Summary

This study aimed at analyzing the effect of a spiritual intervention on the depression of the postmenopausal women who have referred to the Healthcare Centers in Isfahan City, Iran, in 2014. Sixty four 45-60-year-old postmenopausal women whose score in Beck Depression Inventory are more than 13 and are willing to participate in this study will consist samples of this clinical trial. They will be excluded if they prefer to discontinue, then they will be divided randomly in two control and experimental intervention groups. spiritual intervention for 8 sessions will be organized for the intervention group in two centers of the Isfahan Health Care Centers. The Beck Depression Inventory (measuring tools of the main variables) will be completed through three phases of pretest, post test and follow-up (1 month) by participants of both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061422733N1**
Registration date: **2015-07-13, 1394/04/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-07-13, 1394/04/22

Registrant information

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Zohre Shafiee
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Isfahan University of Medical Sciences

Expected recruitment start date

2014-11-21, 1393/08/30

Expected recruitment end date

2014-12-31, 1393/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of spiritual intervention on depression in postmenopausal women

Public title

the effect of spiritual intervention on depression in postmenopausal women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: A score higher than 13 from the Beck Depression Inventory; ability to speak and understand the Persian language; believe in Islam; non-smoking; ability to read and write; 45 to 60-year-old; cessation of menstruation for a year; no history of hysterectomy and ovariectomy; free from communication problems; and avoiding participation in other spiritual courses.
Exclusion criteria: Reluctance of subjects to continue participating in the study; absence in more than one session in the training courses; experiencing

psychological crises including death of close relatives; having aphasia; having any known psychological diseases except depression; taking antidepressant drugs; having a disease; hospitalized in a hospital; divorce.

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

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

Isfahan university of medical sciences, Shiraz gateway squar, Isfahan

City

Isfahan

Postal code

Approval date

2014-11-23, 1393/09/02

Ethics committee reference number

393632

Health conditions studied

1

Description of health condition studied

depression

ICD-10 code

F31.3

ICD-10 code description

mild or moderate depression

2

Description of health condition studied

-

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

depression

Timepoint

Pre-intervention, Immediately after intervention,One months after the intervention

Method of measurement

beck questionnaire depression

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: With the agreement of members, a spiritual intervention including eight 60 to 90-minute sessions was held two days a week. The training courses of spirituality were held collectively for the test group members based on some spiritual interventions offered by Richards and Bergin with an Islamic approach and also on Quran verses and narratives of the Infallible Imams in terms of certain principles such as orison, self-consciousness, reliance on God and supplication. At the end of each course, participants were provided with a copy of the session’s discussions.

Category

Behavior

2

Description

For the control group, two training courses, different from the training courses of the test group, with the subject of nutrition and proper movement during the old age were held and they were provided with the training manual at the end of each session.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Navab health center

Full name of responsible person
zohre shafiee
Street address
Ahmadabad sq, Isfahan
City
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2

Recruitment center
Name of recruitment center
Hazrat Ali health center
Full name of responsible person
zohre shafiee
Street address
Sheikh Toosi st,Isfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Isfahan University of Medical Sciences
Full name of responsible person
Peyman Adibi doctor
Street address
Isfahan University of Medical Sciences, Shiraz Gateway Square, Isfahan
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research of Isfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty