

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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

Name

Zohre Shafiee

Name of organization / entity

Isfahan University of Medical Sciences

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Email address

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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

Isfahan

2**Recruitment center****Name of recruitment center**

Hazrat Ali health center

Full name of responsible person

zohre shafiee

Street address

Sheikh Toosi st, Isfahan

City

Isfahan

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 addressIsfahan 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 sourceVice 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**

Isfahan University of Medical Sciences

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Position

Student master of science in nursing

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Web page address

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