

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effect of Spirituality Education Program on Depression and Anxiety in Patients with Multiple Sclerosis

Protocol summary

Study aim

Assess the effect of spirituality educational program on the anxiety and depression in patients with multiple sclerosis

Design

This study is a randomized controlled trial that is designed before and after with control group. Sixty eligible patients will be recruited to the study. They will be randomly allocated to an experimental and a control group using a table of random numbers

Settings and conduct

In the experimental group, patients will receive spirituality educations in eight ninety-minute weekly sessions in the Multiple Sclerosis Association, and in the control group, participants will receive routine illness education. anxiety and depression will be assessed one month after intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: definite diagnosis of multiple sclerosis(MS) for at least one year; having educational level of guidance school or higher; Having the minimum age of 20 and maximum of 50; Obtain score 16 to 28 from Beck Depression Inventory and 12-26 from Beck Anxiety Inventory; Exclusion criteria: having a history of psychotic disorders, dementia, and delirium; having history of using psychiatric medications in the past month; drug addiction; taking psychological therapies

Intervention groups

In the experimental group, patients will receive spirituality education in eight ninety-minute weekly sessions in the multiple sclerosis association, and in the control group, participants will receive routine education

Main outcome variables

Depression and Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170404033212N2**

Registration date: **2018-02-16, 1396/11/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-16, 1396/11/27**

Update count: **0**

Registration date

2018-02-16, 1396/11/27

Registrant information

Name

Siamak Amiri

Name of organization / entity

Alborz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 26 3433 4829

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Alborz University of Medical Sciences

Expected recruitment start date

2018-02-01, 1396/11/12

Expected recruitment end date

2018-05-01, 1397/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Spirituality Education Program on Depression

and Anxiety in Patients with Multiple Sclerosis

Public title

Effect of Spirituality Education Program on Depression and Anxiety

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Definite diagnosis of Multiple Sclerosis based on Patients' Medical Records Having at least one year of history of suffering from multiple sclerosis Having educational level of guidance school or higher Having a minimum age of 20 and maximum of 50 Obtain score 16 to 28 from Beck Depression Inventory (mild to moderate depression) Obtain 12-26 Beck Anxiety Inventory (mild to moderate anxiety)

Exclusion criteria:

History of Psychotic Disorders, Dementia, or Delirium (based on their medical records) Taking psychiatric drugs (Anti-anxiety, Antidepressant, mood stabilizer) in the past month Having psychological therapies Drug Addiction (based on medical records and patients' self-reports)

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Table of random numbers

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**

The Ethics Committee of Alborz University of Medical Sciences,

Street address

North Taleghani st., shahrak edari

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Karaj

Province

Alborz

Postal code

3193914714

Approval date

2015-08-26, 1394/06/04

Ethics committee reference number

abzums.rec.1394.39

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

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes**1****Description**

Depression score in the Beck Depression Inventory

Timepoint

before and after 30 days

Method of measurement

Beck Depression Inventory

2**Description**

Anxiety score in the Beck Anxiety Inventory

Timepoint

Before and After 30 days

Method of measurement

Beck Anxiety Inventory

Secondary outcomes

empty

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

In the experimental group, patients will receive spirituality education in eight ninety-minute weekly sessions

Category

Prevention

2**Description**

Patients in the control group will receive routine multiple sclerosis-related educations

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alborz MS Association

Full name of responsible person

Shahrokh Abadian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mohammad Noori Sepehr

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Email

abzums.research@gmail.com

Web page address

<http://www.abzums.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Siamak Amiri

Position

Faculty member instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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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

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

Statistical Analysis Plan

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

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