Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Siamak Amiri

Name of organization / entity
Alborz University of Medical Sciences

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Iran (Islamic Republic of)

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+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
City
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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Azadegan sq , Karaj
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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Other areas of specialty/work
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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
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