Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of spiritual care versus without spiritual care on death anxiety and self-esteem in multiple sclerosis patients: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of spiritual care versus without spiritual care on death anxiety and self-esteem in multiple sclerosis patients

Design
This is a randomized clinical trial, in which 60 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible multiple sclerosis patients who will refer to the Association for the Support of Multiple Sclerosis Patients in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 65 years; Multiple sclerosis; Acute phase of the disease; At least 6 months past from the begging of the disease Literate; Ability to speak in Persian; Being Shiite Exclusion criteria: Blindness or deafness; Psychological disorders; Cognitive problems

Intervention groups
Intervention group: Routine treatment plus educational session of spiritual care for 60 minutes twice a week for two weeks Control group: Just routine treatment

Main outcome variables
Primary outcome: Assessing the death anxiety Assessing the self-esteem

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N260**
Registration date: **2019-02-09, 1397/11/20**
Registration timing: **retrospective**
Last update: **2019-02-09, 1397/11/20**
Update count: **0**

Registration date
2019-02-09, 1397/11/20

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 81 1838 0090

Email address
poorolajal@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-22, 1397/10/01

Expected recruitment end date
2019-01-21, 1397/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of spiritual care versus without spiritual care on death anxiety and self-esteem in multiple sclerosis patients: a randomized clinical trial

Public title
The effect of spiritual care versus without spiritual care on death anxiety and self-esteem in multiple sclerosis patients

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 65 years; Multiple sclerosis; Acute phase of the disease; At least 6 months past from the begging of the disease Literate; Ability to speak in Persian; Being Shiite
Exclusion criteria:
Blindness or deafness; Psychological disorders; Cognitive problems
Age
From **18 years** old to **65 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
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
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 Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2018-12-01, 1397/09/10
Ethics committee reference number
IR.UMSHA.REC.1397.649

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
Assessing the death anxiety
Timepoint
Before the intervention and 2 weeks after the intervention
Method of measurement
Using the Templer death anxiety questionnaire

2

Description
Assessing the self-esteem
Timepoint
Before the intervention and 2 weeks after the intervention
Method of measurement
Using the Rosenberg self-esteem questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine treatment plus educational session of spiritual care for 60 minutes twice a week for two weeks
Category
Treatment - Other

2

Description
Control group: Just routine treatment
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Association for the Support of Multiple Sclerosis Patients in Hamadan City

Full name of responsible person
Ali Akbari

Street address
Association for the Support of Multiple Sclerosis Patients, Shahid Fahmideh Ave.

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0572

Email
aakbari4973@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr Saeid Bashirian

Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0717

Email
info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Ali Akbari

Position
Nursing Student

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0572

Email
aakbari4973@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Efat Sadeghian

Position
PhD in Nursing

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0572

Email
sadeghianefat@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences
Full name of responsible person
Dr Jalal Poorolajal
Position
Professor of Epidemiology
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Email
poorolajal@umsha.ac.ir

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