

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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.

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6517838695

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+98 81 3838 0572

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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
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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

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School of Nursing and Midwifery, Hamadan University
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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Dr. Efat Sadeghian

Position

PhD in Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

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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

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