Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of spiritual care based on Sound Heart Model on Spirituality Experience and tendency to Social Desirability in patients with Multiple Sclerosis

Protocol summary

Study aim
Determining the effect of spiritual care based on Sound Heart Model on Spiritual Experience and tendency to Social Desirability in patients with multiple sclerosis

Design
This study is a clinical trial with two groups (intervention and control), no blinding and randomized (simple random allocation) with 40 patients in each group. SPSS software will be used for randomization.

Settings and conduct
This study, will be performed in Kerman Medical Center for Special Diseases. In the intervention group ,16 sessions of spiritual care based on a healthy heart model will be performed in 8 weeks and two sessions per week and virtually. The variables will be measured before and 1 month after the intervention.

Participants/Inclusion and exclusion criteria
Patients with multiple sclerosis/ Inclusion criteria: Failure to mental illness and use of psychotropic drugs, adult patients over 18 years who are not in the acute stage of the disease, no deafness to communicate, definitive diagnosis of MS according to a neurologist, at least 6 months Onset of illness, at least fifth grade education, access to Android or PC phones and the Internet to attend virtual meetings Exclusion criteria: Hospitalization due to recurrence of the disease, other debilitating diseases, participation in spiritual care training sessions in the past year, unwillingness to continue cooperation and incomplete completion of questionnaires more than 10% of all questionnaire questions.

Intervention groups
Intervention group: 16 virtual sessions of 35 minutes of spiritual care based on Sound Heart Model, virtual and through Skyroom, will receive two sessions per week; While patients in the control group receive routine care.

Main outcome variables
Spiritual experience, Tendency to social desirability

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151107024919N13**
Registration date: **2022-03-19, 1400/12/28**
Registration timing: **prospective**

Last update: **2022-03-19, 1400/12/28**
Update count: **0**

Registration date
2022-03-19, 1400/12/28

Registrant information

Name
Batoul Tirgari

Name of organization / entity
Kerman Medical University of Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the effect of spiritual care based on Sound Heart Model on Spirituality Experience and tendency to Social Desirability in patients with Multiple Sclerosis

Public title
Effect of spiritual care based on Sound Heart Model on Spirituality Experience and tendency to Social Desirability in patients with Multiple Sclerosis

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Failure to mental illness and use of psychotropic drugs Adult patients over 18 years old who are not in the acute stage of the disease No deafness to communicate Definitive diagnosis of MS according to a neurologist At least 6 months after the onset of the disease At least fifth grade education Access to Android phones or computers and the Internet to participate in virtual meetings

Exclusion criteria:
Hospitalization due to recurrence of the disease Having other debilitating diseases Participation in spiritual care training sessions in the past year Unwillingness to continue collaboration and incomplete completion of questionnaires more than 10% of the total questionnaire questions

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients will be selected by available sampling method and will be numbered from 1 to 80. Codes 1 to 80 are entered into SPSS software and the software is instructed to randomly select 40 people who will be placed in the intervention group. In order to assign the subjects to the intervention and control groups, a simple random allocation method will be used. Using SPSS software, half of the subjects will be in the intervention group and the other half in the control group (40 people in each group).

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 Kerman University of Medical Sciences

Street address
Medical Center of the Special Disease, No.78 Alley, Shahid Rajaee Street.

City
Kerman

Province
Kerman

Postal code
7619875994

Approval date
2022-02-07, 1400/11/18

Ethics committee reference number
IR.KMU.REC.1400.644

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
Spiritual Experience

Timepoint
The score of spiritual experience will be measured before and 1 month after the end of the intervention.

Method of measurement
Daily Spiritual Experience Scale (DSES) (Underwood & Teresi)

2

Description
Tendency to Social Desirability

Timepoint
The score of tendency to Social Desirability will be measured before and 1 month after the end of the intervention.

Method of measurement
Social Desirability Scale (Crown & Marlow)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Providing spiritual care based on Sound Heart Model in 16 sessions of 35 minutes for 8 weeks (two sessions per week) virtually through the Sky Room link, by members of the research team in the form of lectures, questions and answers, group discussions, experiences and The use of teaching aids such as PowerPoint, videos and presentation of scenarios, etc. will be implemented for the intervention group. Also, the file of the guide book of patients' spiritual care written by Asad Zandi from the publications of the Academy of Medical Sciences of the Islamic Republic of Iran and the audio and video file of spiritual care training will be provided to them offline via WhatsApp.

Category

Other

2

Description

Control group: Patients in the control group received routine cares.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Medical Center of the Special Diseases

Full name of responsible person
Batool Tirgari

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Medical Center of the Special Disease, No. 78 Alley. Shahid Rajaei Street.

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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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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Batool Tirgari

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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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