Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

The effect of family-centered training from distance on quality of life and sleep quality in multiple sclerosis patients

Protocol summary

Study aim
The effect of family-centered training from distance on quality of life and sleep quality in multiple sclerosis patients is determined.

Design
A clinical trial with a control group, not blind, randomized, on 70 patients

Settings and conduct
This research is a randomized clinical trial study with a control group. The statistical population is patients with multiple sclerosis referred to the MS Association of Arak city in 1401.

Participants/Inclusion and exclusion criteria
MS patients entry: Completing the consent form, A definite diagnosis of MS for at least 6 months by a neurologist, Age 18-65 years, Living with family, Not having a private nurse, not receiving similar intervention at the same time, Not having hearing, vision, speech problems, Not taking Psychiatric and sleeping drugs, Not having psychological problem, Not suffering from debilitating diseases. family member: Completing the consent form, Age over 18 years, having minimum literacy to read and write, Living with the patient and being a member of the patient's family and access to smart phones, internet and the ability to work with them; Exit: Death of the patient or active family member, long-term hospitalization, Failure to complete questionnaires or filling them incompletely, Unwillingness to continue cooperation and death a family member in the last 6 months

Intervention groups
The members of the intervention group (active family members) will be members of WhatsApp and Telegram groups managed by the researcher and Educational content is provided to members twice a week for 6 weeks. The researcher will call them once a week

Main outcome variables
Quality of life, Sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221211056774N1**
Registration date: **2022-12-15, 1401/09/24**
Registration timing: **prospective**

Last update: **2022-12-15, 1401/09/24**
Update count: **0**

Registration date
2022-12-15, 1401/09/24

Registrant information

Name
Fatemeh Hashemi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-11, 1401/10/21

Expected recruitment end date
2023-01-28, 1401/11/08

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of family-centered training from distance on quality of life and sleep quality in multiple sclerosis patients

Public title

The effect of family-centered training from distance on quality of life and sleep quality

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Completing the consent form of patients to participate in the study A definite diagnosis of multiple sclerosis for at least 6 months by a neurologist Age between 18-65 years Living with family Not having a private nurse Not receiving the same intervention at the same time Not having hearing, vision and speech problems No use of Psychiatric and sleeping drugs Not having a psychological problem Not suffering from other debilitating diseases Entry criteria for an active family member include completing the consent form to participate in the study Age over 18 years Having minimum literacy to read and write Living with the patient and being a member of the patient's family (father, mother, sister, brother, child and spouse) Access to smart phones, internet and social networks and the ability to work with them

Exclusion criteria:

Death of the patient or active family member during the study Long-term hospitalization Failure to complete study questionnaires or filling them incompletely Unwillingness to continue cooperation Death of a family member in the last 6 months

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: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, samples will be selected as available.Then, patients will be divided into two control and intervention groups using permutation block randomization. According to the sample size, blocks with a capacity of 4 units will be considered. By assigning the letter A to the intervention group and the letter B to the control group, there are six states AABB, BBAA, BABA, ABBA, BAAB and ABAB. Then it is randomly selected from among these situations and a list equal to the sample size is prepared for patients before the start of the study .For better randomization, the web software will be used to prepare the randomization list, which creates random permutations for both types of treatment in each block, and according to the change of permutations in each block, concealment is also observed. During the implementation of the study, the predictability of the treatment for each patient is reduced by the researcher. Site used for random permutation block method: https://www.sealedenvelope.com/simple-randomiser/v1/lists

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Management of Research and Medical Information, Deputy of Research and Technology, University Complex of the Prophet (pbuh), Basij Square

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2022-12-10, 1401/09/19

Ethics committee reference number

IR.ARAKMU.REC.1401.214

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Primary outcomes

1

Description

Quality of life

Timepoint

Before the start of the intervention and 30 days after the end of the intervention

Method of measurement

Multiple sclerosis Quality of life questionnaire for MS patients(MSIS-29)

2

Description
Sleep quality
Timepoint
Before the start of the intervention and 30 days after the end of the intervention
Method of measurement
Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The members of the intervention group who are active members of the family will be members of WhatsApp and Telegram groups managed by the researcher, and educational content will be provided to them in the form of text.The researcher will answer the family member's questions in this way or by phone call. During the delivery of educational content, the researcher will ensure that the messages are read and viewed, by calling members and asking a few questions throughout the week. In the intervention group, educational content will be provided to the members twice a week for 6 weeks (generally 12 sessions) and they will be contacted by phone once a week.
Category
Lifestyle

2

Description
Control group: The control group will receive only routine community support. In order to comply with ethical considerations, at the end of the research, the members of the control group will also become its members to use the educational content of social networks.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak MS Association
Full name of responsible person
Fatemeh Hashemi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Fatemeh Hashemi
Position
Nursing master student
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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