Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of education and telephone follow-up on self-care and quality of life in patients with multiple sclerosis

Protocol summary

Study aim
Improving self-care and quality of life in patients with multiple sclerosis

Design
Clinical trial with control group, with parallel groups, One-way blind, randomized by Random number table, on 60 patients

Settings and conduct
The place of association of MS patients of Arak city is through face-to-face training and telephone follow-up. Blindness Statistics Consultant

Participants/Inclusion and exclusion criteria
Inclusion criteria: Definitive diagnosis of the disease by a specialist physician in clinical, laboratory and pathological terms, full knowledge of the patient's diagnosis, age 19-55 years, access to telephone at home, lack of speech and hearing problems, literacy, minimum passing Six months after the doctor's definitive diagnosis, ability to perform self-care activities, satisfaction and interest in participating in the study. Exclusion criteria - History of other chronic diseases from the point of view of a specialist doctor and hospitalization during the study, acute stage of the disease with a specialist doctor, mental retardation, disconnection of telephone for 3 weeks in the 2nd and 3rd months of intervention, unwillingness to Continue cooperation.

Intervention groups
Two sessions of self-care training program (1 - 1.5 hours each session), for 2 weeks by the researcher, in the form of face-to-face training with questions and answers in groups of 5 to 6 people will be performed for members of the control and experimental group by a trained nursing expert. In the experimental group, telephone intervention will be performed for 12 weeks. Thus, telephone calls in the experimental group are made twice a week in the first month and once a week during the second and third months to follow the recommended self-care skills.

Main outcome variables
Self-care

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211128053205N1**
Registration date: **2022-02-04, 1400/11/15**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-04, 1400/11/15**
Update count: **0**

Registration date
2022-02-04, 1400/11/15

Registrant information

Name
leila jamehbozorgi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3222 2003

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-04-19, 1401/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of education and telephone follow-up on self-care and quality of life in patients with multiple sclerosis

Public title
The effect of education and telephone follow-up on self-care and quality of life in patients with multiple sclerosis

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive diagnosis by a specialist physician clinically, laboratory and pathologically the client is fully aware of the diagnosis of his disease age 19-55 years, access to telephone at home, lack of speech and hearing problems literacy at least six months have passed Definitive diagnosis of a physician ability to perform self-care activities satisfaction and interest in participating in the study.

Exclusion criteria:
History of other chronic diseases such as hypertension, diabetes, chronic liver disease (Wilson, primary hemochromatosis, etc.), hyperthyroidism or hypothyroidism, tuberculosis, cardiovascular disorders, respiratory, gastrointestinal, metabolic, cancer acute stage of the disease from the point of view of a specialist, mental retardation

Age
From **19 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients will be selected by available sampling method. In order to assign the samples to the control and intervention groups, the stratified random block method (sex and age) will be used. The size of the blocks will be 4 people according to the number of groups and 4 people will be placed in each group and a random list was created using the online BlockRandomization software (https://www.sealedenvelope.com/simple - randomiser / v1 / lists).

Blinding (investigator's opinion)
Single blinded

Blinding description
Blinding is a statistical expert who will analyze data without knowing the study groups.

Placebo
Not used

Assignment
Single

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
Arak, Basich Square, Payambar Azam (PBUH) University Complex, Vice Chancellor for Research and Technology, Medical Research and Information Management

City
arak

Province
Markazi

Postal code
۳۸۱۹۶۹۳۳۴۵

Approval date
2021-11-24, 1400/09/03

Ethics committee reference number
IR.ARAKMU.REC.1400.213

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
quality of life of patients

Timepoint
(Before the intervention) and 120 days after the intervention

Method of measurement
MSIS-29 Quality of Life Questionnaire

Secondary outcomes

1

Description
Self-Care

Timepoint
Initiation of intervention and 120 days after intervention

Method of measurement
Miller Self-Care Questionnaire

Intervention groups

1

Description
Intervention group: Two sessions of self-care training program (1 - 1.5 hours each session), for 2 weeks by the researcher, in the form of face-to-face training with questions and answers in groups of 5 to 6 about self-care skills of sensory dysfunction, memory loss, fatigue Chronic, muscle cramps, improved nutrition, type of exercise and sexual dysfunction Disorders of urination, stool and constipation for intervention members will be done by a trained nursing expert. In the experimental group, telephone intervention will be performed for 12 weeks

Category
Lifestyle

2

Description
Control group: Two sessions of self-care training program (1 - 1.5 hours each session), for 2 weeks by the researcher, in the form of face-to-face training with questions and answers in groups of 5 to 6 about self-care skills of sensory dysfunction, reduction Memory, chronic fatigue, muscle cramps, improved nutrition, type of exercise and sexual dysfunction Disorders of urination, defecation and constipation for members of the control group will be done by a trained nursing expert.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
MS Arak Association

Full name of responsible person
Moloud Farmahini Farahani

Street address
Arak - Shahid Shiroodi St. - Alam al-Huda St.

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+98 86 3313 6055

Email
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

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?
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
Dr. Moloud Farmahini Farahani

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Assistant Professor

Latest degree
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Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

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Position
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Ph.D.

Other areas of specialty/work
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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