Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of educational intervention of self-care behaviors on the quality of life and resilience of multiple sclerosis (MS) patients.

Protocol summary

Study aim

Determining the effect of educational intervention of self-care behaviors on the quality of life and resilience of multiple sclerosis (MS) patients.

Design

A total of 135 patients who meet the criteria for entering the study without blinding will be randomly assigned to intervention and control groups. Random allocation will be done using the random sequence generation method using the table of random numbers in the Excel software

Settings and conduct

With the aim of determining the effect of the educational intervention of self-care behaviors on the quality of life and resilience of multiple sclerosis patients in Shiraz, 135 patients were selected as available sampling. Then, these patients were randomly selected into two intervention groups (experiment) and control group through Randoxel. After that, they will be checked by completing the pre-intervention questionnaires, and in the future, the test group will be trained under the intervention training designed based on the Orem model. After two months, the questionnaires will be completed again and the effect of the intervention will be calculated.

Participants/Inclusion and exclusion criteria

1-Having symptoms of the disease- Do not use a wheelchair unless you are in the acute stage of the disease3- Have a disease for at least 2 to 5 years4- Patients did not participate in self-care training5- Ability to read and write6- The age of the patients should be between 15 and 50 years

Intervention groups

1- The group receiving self-care training (intervention group)2- control group

Main outcome variables

Quality of life and resilience of multiple sclerosis (MS) patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221106056414N1**
Registration date: **2023-01-26, 1401/11/06**
Registration timing: **prospective**

Last update: **2023-01-26, 1401/11/06**
Update count: **0**

Registration date

2023-01-26, 1401/11/06

Registrant information

Name

shohreh afroozeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3353 6316

Email address

mgaziri3000@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2023-04-04, 1402/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational intervention of self-care behaviors on the quality of life and resilience of multiple sclerosis (MS) patients.

Public title
The effect of educational intervention of self-care behaviors on the quality of life and resilience of multiple sclerosis (MS) patients.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
1-Having symptoms of the disease2- Do not use a wheelchair unless you are in the acute stage of the disease3- Have a disease for at least 2 to 5 years4- Patients did not participate in self-care training5- Ability to read and write6- The age of the patients should be between 15 and 50 years
Exclusion criteria:
The patient is suffering from multiple sclerosis (MS) and has no underlying diseases.
Age
From **15 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **135**
Randomization (investigator's opinion)
Randomized
Randomization description
A total of 135 patients who meet the criteria for entering the study without blinding will be randomly assigned to intervention and control groups. Random allocation will be done using the random sequence generation method using the table of random numbers in the Excel software
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
دانشگاه علوم پزشکی شیراز
Street address
Zand Ave-Shiraz university of medical sciences-Shiraz-Iran
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2021-11-29, 1400/09/08
Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1400.098

Health conditions studied

1

Description of health condition studied
Multiple sclerosis (MS) patients
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Determining the effect of educational intervention on the care of multiple sclerosis (MS) patients
Timepoint
Two months after training
Method of measurement
Standard questionnaire of patients' self-care status

Secondary outcomes

1

Description
Determining the effect of self-care training intervention on the resilience of multiple sclerosis (MS) patients
Timepoint
Two months after training
Method of measurement
Resilience questionnaire

2

Description
Determining the effect of self-care training intervention on improving the quality of life of multiple sclerosis (MS) patients
Timepoint
Two months after training
Method of measurement
Quality of life guidelines for MS patients (MSIS-29)

Intervention groups

1

Description
The group receiving training on self-care behaviors who

have received the training intervention course. The training course is designed for 6 sessions of 60 minutes each session will be taught theoretically and practically. Self-care programs are for controlling symptoms such as physical movement disorders, muscle weakness, muscle cramps, fatigue, imbalance while walking, urinary and defecation disorders, and memory and vision problems.

Category

Lifestyle

2

Description

Control group: a group of patients who have received routine training. These patients are thanked in the initial briefing session and are trained by themselves only through pamphlets and booklets.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz MS Association

Full name of responsible person

Hamed Hossaini

Street address

Qasroldasht Ave-Shiraz MS Association-Shiraz-Iran

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MS -SHIRAZ@GMAIL.COM

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Vahid Hossaini

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President_d@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Shohre Afroozeh

Position

University Student

Latest degree

Bachelor

Other areas of specialty/work

Public Health

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Shohre Afroozeh

Position

UNIVERCITY STUDENT

Latest degree

Bachelor

Other areas of specialty/work

Environmental Health

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Person responsible for updating data

Contact
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Full name of responsible person
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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