Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Web-based Self-care Program on the Lifestyle of Patients with Multiple Sclerosis

Protocol summary

Study aim
Determining the effect of web-based self-care intervention on the lifestyle of patients with multiple sclerosis

Design
Clinical trial with control group, single blind, randomized, 40 patients in each group

Settings and conduct
First, with the self-care needs assessment questionnaire, the self-care status will be measured in both test and control groups during a two-week period . In this research, there is a program in the form of the ORM conceptual model and based on the educational needs of the multiple sclerosis patients participating in the program, which will be obtained by completing the ORM needs assessment form, and based on the results obtained from the needs assessment, educational content will be designed. For this purpose, a web page will be created and the intervention group will be taught how to work with the defined web page. After the training course and the end of the intervention, the lifestyle questionnaire will be given to both test and control groups again and data will be collected.

Participants/Inclusion and exclusion criteria
• Diagnosis of multiple sclerosis by a neurologist • Not having medical education and not being in medical and paramedical groups • Ability to perform self-care activities • Access to a smart phone or personal computer

Intervention groups
The samples will be distributed to the test and control groups and the content of the intervention will be presented to the test group through the web. In this educational method, text, images and videos will be used to increase access and depth of learning. Self-care assessment is done using questionnaires before and after the intervention. The control group will not receive any intervention by the research team. They will have routine interventions provided by the center.

Main outcome variables
lifestyle of patients with multiple sclerosis

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240811062717N1**
Registration date: **2024-11-24, 1403/09/04**
Registration timing: **retrospective**

Last update: **2024-11-24, 1403/09/04**
Update count: **0**

Registration date
2024-11-24, 1403/09/04

Registrant information
Name
Sara Akbari
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-08-22, 1403/06/01
Expected recruitment end date
2024-11-21, 1403/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Web-based Self-care Program on the Lifestyle of Patients with Multiple Sclerosis

Public title
The Effect of Web-based Self-care Program on the Lifestyle of Patients with Multiple Sclerosis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of Multiple Sclerosis by a Neurologist Willingness to Participate in the Study Being Literate and Older than 18 Years At Least Six Months Have Passed since the Diagnosis of the Disease Not Having Medical Education and not Being in Medical and Paramedical Groups Ability to Perform Self-care Activities Access to a Smart Phone or Personal Computer

Exclusion criteria:
Participation in other educational interventions at the same time as the present study

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants of the study will be selected from among all the people of the research community using the available method and then will be divided into two groups, group A (examination or web-based virtual training group) and group B (control) in the form of random allocation by block method. Since we will have two groups in this study, it is planned to have blocks of four. For example; Block number one may be AABB, which means that the first and second eligible patients are assigned to the intervention group (web-based virtual education). All the possible shapes of the blocks that were determined will be placed in separate envelopes. Envelopes will be randomly numbered for opening order. The random selection of numbers for the envelopes will be done by the project manager and the order of grouping of the patients will be announced to the student.

Blinding (investigator's opinion)
Single blinded

Blinding description
Data analyst: The people who analyze the data collected during the study do not know which study group the data belongs to.

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences

Street address
15, Mehrabad Ave., Hafez Blvd

City
Urmia

Province
West Azarbaijan

Postal code
5714615463

Approval date
2024-08-20, 1403/05/30

Ethics committee reference number
IR.ZUMS.REC.1403.151

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
The lifestyle score in the Walker questionnaire, scores above 150, the lifestyle of the patients is very good

Timepoint
Completing the Walker questionnaire before and after the intervention by both groups of participants

Method of measurement
Walker's lifestyle questionnaire, which has 54 questions in six dimensions (nutrition, exercise, responsibility for health, stress management, interpersonal support, self-actualization) and its purpose is to measure health-promoting behaviors. Its response range is of Likert type (never 1, some 2, often 3, always 4). Its scores range from 54 to 216. If the scores of the questionnaire are between 54 and 62, the lifestyle is poor, between 62 and 150, the average level, scores above 150, the lifestyle of the patients is very good.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The training course will be held in the form of a one-month workshop, and four days a week and Each session averages 30 minutes in the web space for the intervention group. For this purpose, a web page will be created and the intervention group will be taught how to work with the defined web page. The offline training workshop will include familiarization with Multiple Sclerosis, symptom management, possible complications, nutrition, disease control methods and prevention of complications caused by Multiple Sclerosis, which will be provided to patients in simple language along with pictures, videos and messages.

Category

Lifestyle

2

Description

Control group: The control group will not receive any intervention by the research team. They will have routine interventions provided by the center. Routine interventions include outpatient visits to the clinic to receive medication and, if necessary, visits by the treating physician.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
MS Clinic of Waliasr Hospital, Zanjan
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Sara Akbari
Position
Student
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Researchers working in academic and scientific institutions
From where data/document is obtainable
Sara Akbari tel: 0098 09144867303 email: sara.akbari9677@gmail.com
What processes are involved for a request to access data/document
Request to receive data, stating the reason
Comments