Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The comparison of the effect of in person and virtual evidence based self care training on the self management of patients with Multiple Sclerosis

Protocol summary

Study aim
The comparison of the effect of face to face and virtual evidence based self care training on the self-management of patients with MS

Design
Clinical trial with control group, parallel groups, without blinding, randomized, study on 129 people, for this purpose, random blocks of 4 will be used based on the severity of the disease to assign patients to two groups. There are 6 different combinations of blocks of 4 and (random sequence).

Settings and conduct
The intervention is in two stages, the first stage is qualitative to collect educational content and after that it is approved by a panel of experts, and the second stage is a clinical trial on three intervention groups, in person, virtual and control, and the studied subjects are under the supervision of MS Khorramabad Association.

Participants/Inclusion and exclusion criteria
1- Age above 18 years and less than 60 years. 2- Determining of diagnosis of MS disease by a neurologist (having a medical record and having a membership card of the MS Association), 3- Diagnosis of MS at least two years before entering the study 4- Reading and writing literacy 5- Willingness to participate in the study 6- Lack of cognitive problems and communication difficulties, such as vision and hearing defects. 7- Lack of underlying disease (diabetes, cancer and neurological diseases) and mental illness, 8- Patients should have a similar course in terms of disease activity

Intervention groups
The study subjects will receive evidence based self care training intervention in three face to face training groups. The second group, as the virtual training group, will receive evidence-based self-care training virtually, and the third group, the control group, will receive routine treatment.

Main outcome variables
Self management, age, gender, level of education, marital status, occupation, body mass index, number of rehospitalisations, medications, comorbidities

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240610062077N1**
Registration date: **2025-06-11, 1404/03/21**
Registration timing: **prospective**

Last update: **2025-06-11, 1404/03/21**
Update count: **0**

Registration date
2025-06-11, 1404/03/21

Registrant information

Name
Fatemeh Ahmadi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 66 3326 5631

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fkahmadi93@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-14, 1404/05/23

Expected recruitment end date
2026-01-13, 1404/10/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of the effect of in person and virtual evidence based self care training on the self management of patients with Multiple Sclerosis

Public title
The effect of self care training on the self management of patients with Multiple Sclerosis

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age above 18 years and less than 60 years. Diagnosis of MS disease by a neurologist (having a medical record and having a membership card of the MS Association) Diagnosis of MS at least two years before entering the study Reading and writing literacy Willingness to participate in the study Absence of cognitive problems and communication difficulties, such as vision and hearing Not having any underlying disease (diabetes, cancer and neurological diseases) and mental illness Capability to use smart mobile phone.

Exclusion criteria:
1. Lack of necessary cooperation in conducting meetings and completing questionnaires Patient's migration or death

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **129**

Randomization (investigator's opinion)
Randomized

Randomization description
In the present study, to create a balance in the number of samples assigned to each of the studied groups, the face to face training group (the group for implementing self-care evidence-based training in person) and the virtual training group (the group for implementing virtual self-care evidence-based training) Block randomization method is used. For this purpose, random blocks of 4 will be used to assign patients to two groups based on the severity of the disease. 6 different combinations of 4-blocks (AABB- ABAB- ABBA- BBAA- BABA- BAAB) are created and randomly selected using the Blockrand package of R software, and the random sequence is a sequence of letters. A and B will be formed.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the outcome assessor and data analyst are blinded to the study group allocation.

Placebo
Not used

Assignment
Parallel

Other design features
None

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Lorestan University of Medical Science

Street address
Lorestan, Khorramabad, Moalem St., Shahid Anoushirvan Rezaei Square, University of Medical Sciences

City
Khorramabad

Province
Lorestan

Postal code
6813833946

Approval date
2024-06-30, 1403/04/10

Ethics committee reference number
IR.LUMS.REC.1403.144

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
self management

Timepoint
before intervention

Method of measurement
self-management questionnaire for multiple sclerosis patients

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group receives the virtual educational intervention (via WhatsApp video chat)
Category
Lifestyle

2

Description
Intervention group: The second group receives the in-person educational intervention
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
MS Association in Khorramabad
Full name of responsible person
Shahin Salarvand
Street address
Imam street, Khorramabad
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1234567890
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shsalarvand@lums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
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Street address
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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
0
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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Shahin Salarvand
Position
Associate Professor, Hepatitis Research Center, Faculty of Nursing and Midwifery, Lorestan Universit
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Person responsible for updating data

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MSc nursing student

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identification and will be shared upon reasonable request.

When the data will become available and for how long
After completing this study

To whom data/document is available
Research department, Journals, every researcher or related agency

Under which criteria data/document could be used
participants

From where data/document is obtainable
salarvand60@gmail.com

What processes are involved for a request to access data/document
The applicant can contact the research director directly.

Comments