Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of self-management program based on virtual group discussion on fatigue, sleep quality and quality of life in patients with multiple sclerosis

Protocol summary

Study aim

Determining the effect of self-management program based on group discussion by virtual method, on fatigue, sleep quality and quality of life in patients with multiple sclerosis referred to MS Urmia Association in 1400

Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, on 60 patients. Randomizer software was used for randomization.

Settings and conduct

Among the patients referred to Urmia MS Association, based on the inclusion criteria, 60 samples were selected by easy sampling method and randomly assigned to a control group and an intervention group using Randomizer web-based software. One-way blinding and the intervention and control groups are not aware of the type of intervention. Sealed consecutive matte envelopes were used to conceal the allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: With multiple sclerosis Age between 50-20 years Having a smartphone No physical or mental illness Being literate Communicate verbally Do not participate in any self-care training courses. Exclusion criteria: Do not attend more than one session Reluctance to participate in the study.

Intervention groups

Patients in the intervention group will receive the educational content of the self-care program through discussion with other members of the group in WhatsApp during 6 one-hour sessions every 5 days for one month. No educational intervention will be performed on patients in the control group.

Main outcome variables

quality of life, sleep and fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211218053443N1**
Registration date: **2022-02-01, 1400/11/12**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-01, 1400/11/12**
Update count: **0**

Registration date

2022-02-01, 1400/11/12

Registrant information

Name

zahra valinasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3386 0087

Email address

zahra.valinasab20@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of self-management program based on virtual group discussion on fatigue, sleep quality and quality of life in patients with multiple sclerosis

Public title
The effect of self-management program based on virtual group discussion on fatigue, sleep quality and quality of life in patients with multiple sclerosis

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
1. Having MS with the approval of a neurologist 2. Having an age between 20-50 years 3. Having a smartphone and being able to work with it 4. No other physical and mental illness 5. Having reading and writing literacy 6. Verbal communication with the researcher 7. Having at least three years of history of MS (almost according to studies after three years the symptoms of fatigue begin) 8. Not attending any self-care training course

Exclusion criteria:
Not attending more than one session and unwillingness to participate in the study

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done in a simple and individual way using Randomizer random allocation software. Individuals are listed according to the national code and then divided into groups 1 (intervention) and group 2 (control) using random allocation software.

Blinding (investigator's opinion)
Single blinded

Blinding description
Only the researcher knows which patient is in the control group and which patient is in the intervention group. Without the patient being aware.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences

Street address
No. 41, Alley 3,Razi Street,Andisheh Town,Urmia

City
Urmia

Province
West Azarbaijan

Postal code
5716138776

Approval date
2021-05-28, 1400/03/07

Ethics committee reference number
IR.UMSU.REC.1400.402

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
fatigue

Timepoint
Before the intervention and two months after the intervention

Method of measurement
Fatigue Impact Scale

2

Description
Sleep Quality

Timepoint
Before the intervention and two months after the intervention

Method of measurement
Pittsburgh Sleep Quality Index

3

Description
Quality of life

Timepoint
Before the intervention and two months after the intervention

Method of measurement
Multiple Sclerosis Quality of Life Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group receive the educational content of their self-care program by discussing with other members of the group in WhatsApp during 6 one-hour sessions, once every 5 days for a month.
Category
Treatment - Other

2

Description
Control group: In this group are MS patients who are not treated.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia MS Patients Association
Full name of responsible person
Dr. Mulla Farajzadeh
Street address
Almas Gharb Building, next to Melli Bank, Danesh Street,
City
Urmia
Province
West Azarbaijan
Postal code
5716138776
Phone
+98 44 3225 7209
Fax
+98 44 3225 7209
Email
infoteam@mssociety.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Madine Jasemi
Street address
Faculty of Nursing and Midwifery, Nazlo Campus,11 km to Sarv Road
City
Urmia
Province
West Azarbaijan
Postal code
5756115335
Phone
+98 44 3275 4961
Fax
+98 44 3275 4921
Email
nursing-college@umsu.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia University of Medical Sciences
Proportion provided by this source
50
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
Oroumia University of Medical Sciences
Full name of responsible person
Dr.Madine Jasemi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Faculty of Nursing and Midwifery, Nazlo Campus,11 km to Sarv Road
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+98 44 3275 4921
Email
Jasemi.m@umsu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Zahra.Valinasab

Position
Graduate student of nursing

Latest degree
Master

Other areas of specialty/work
Nursery

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No. 41,3rd Alley,Razi Street,Andisheh Town

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Person responsible for updating data

Contact

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Graduate student of nursing

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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
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Article

When the data will become available and for how long
2021-2022

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
1- Reference in articles and dissertations 2- Having a code of ethics in your studies 3- Valid academic emails

From where data/document is obtainable
Zahra Vali Nasab, Urmia School of Nursing and Midwifery Zahra.valinasab20@gmail.com

What processes are involved for a request to access data/document
Communication via valid email

Comments