Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of patient-centered empowerment program through tele-nursing on self-management of patients with Multiple sclerosis

Protocol summary

Study aim
The aim of this study will be to determine the effect of patient-centered empowerment program through tele-nursing on self-management of patients with Multiple Sclerosis.

Design
Clinical trial with control group, with parallel groups, double-blind, randomized. we will use the block random allocation method for randomization, which requires 23 blocks of 4.

Settings and conduct
This study will be performed at the Iran MS Society in Tehran. Patients will be divided into intervention and control groups by block randomization method (23 blocks of 4). In order to be blind, a dark envelope will be prepared according to the sample size and the envelopes will be numbered according to the sample size. Random sequences will be recorded on a card and placed inside the envelope. At the time of registration, one of the envelopes will be opened in order based on the order of sample entry and the sample group will be specified.

Participants/Inclusion and exclusion criteria
Definitive diagnosis of MS for at least 6 months, Age range 18 to 60 years, Ability to use phone and smartphone, No other physical or mental illness, and Lack of cognitive and psychological disorders (self-expression and patient record); Reluctance to participate in research

Intervention groups
The intervention group will receive a patient-centered empowerment program to improve self-management in 5 main training sessions over 5 weeks. Patient-centered counseling sessions will be tailored to each patient's needs within 2 weeks. After 8 weeks from the end of the intervention, post-test will be performed and the level of self-management will be analyzed and evaluated using the Multiple Sclerosis Self-Management Scale–Revised. The control group will receive routine care at the Iran MS Society and at the end of the intervention, educational content will be provided to them.

Main outcome variables
Level of self-management

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210824052281N1**
Registration date: **2021-09-13, 1400/06/22**
Registration timing: **prospective**

Last update: **2021-09-13, 1400/06/22**
Update count: **0**

Registration date
2021-09-13, 1400/06/22

Registrant information

Name
Fateme Bayat

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8822 3165

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f-bayat@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-24, 1400/07/02

Expected recruitment end date
2022-01-07, 1400/10/17

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of patient-centered empowerment program through tele-nursing on self-management of patients with Multiple sclerosis

Public title

The effect of empowerment program on self-management of patients with Multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of MS for at least 6 months Age range 18 to 60 years Use of phone and smartphone

Exclusion criteria:

Reluctance to participate in research Other physical or mental illness Cognitive or psychological disorders (self-expression and patient record)

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The allocation of samples to the two groups will be by block random allocation method and will be divided into two groups of intervention and control. Due to the sample size, 23 blocks of 4 are required for random block allocation. The intervention group will be displayed by A and the control group with B. Blocks of size 4 can have six modes 1AABB 2-ABAB 3-ABBA 4-BBAA 5BABA 6-BAAB. Then, we roll the dice, for example, 4 comes, it becomes BBAA. We roll the dice again, and for instance, 5 comes BABA, and ... we repeat and roll the dice until all the samples are allocated. In order to re-hide the random specification from the researcher, we will have a dark envelope with the sample size and number the envelopes as the sample size, in such a way that envelope number one is 1 and so on. Each random sequence created will be recorded on a card, placed inside the envelope, and finally pasted into the envelopes. At the time of enrollment in the study, according to the order of arrival of the samples, one of the envelopes will be opened in order and the group of the sample will be determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

On the one hand, there is blindness to the research community that these people will not find out that they are in the experimental group or in the control group. The allocation for these individuals will be random and they will not be told that they are in the test or control group. The other side that will be blind is the person who will perform the statistical analysis and will not find out whether the data obtained belong to the experimental group or the control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the School of Nursing and Midwifery and the School of Rehabilitation, Tehran Uni

Street address

North Kargar St., 16th St., Alley Complex, Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1439957181

Approval date

2021-07-26, 1400/05/04

Ethics committee reference number

IR.TUMS.FNM.REC.1400.083

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 score on The Multiple Sclerosis Self-Management Scale–Revised

Timepoint

At the beginning of the study (before the start of the intervention) and after 8 weeks from the end of the intervention

Method of measurement
The Multiple Sclerosis Self-Management Scale–Revised

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, individuals in 5 main training sessions over 5 weeks will recieve empowerment program designed in physical dimensions that include: nutrition and diet, sleep, physical activity and exercise, fatigue management, movement problems, pain, body temperature control, vaccination, unhealthy habits (alcohol consumption, smoking) and women's health (menstrual cycle, menopause) in the first and second sessions, topics related to psychological dimensions that include: stress and anxiety management, mood control and management, problem solving skills, promoting resilience and life satisfaction in the third and fourth sessions and finally the topics related to social dimensions that include: employment, participation in society and social performance, lifestyle at home, free time, friendship and relationship, identification of family needs (role structure, responsibilities, goals, etc.) in the fifth session. After these main training sessions, counseling sessions will be held for two weeks according to the needs of each patient. The number of these sessions will vary according to the conditions and needs of each patient. After 8 weeks from the end of the intervention, post-test will be performed and finally the data before and after the intervention will be analyzed and evaluated using the Multiple Sclerosis Self-Management Scale–Revised.
Category
Rehabilitation

2

Description
Control group: Control group: The control group will receive the routine care of the Iran MS Society and at the end of the intervention, educational content will be provided to them.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran MS Society
Full name of responsible person
Seyed Khosrow Sadegh Mousavi
Street address
No. 35, Shahid Mohammad Shams Alley, Tesghani Intersection, Vesal Shirazi St., Enghelab St.
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeian
Street address
No. 8, Unit 5, Alley 7.35, Simetri Niroohavayi St, Damavand St.
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Tehran
Postal code
1748953637
Phone
+98 21 6142 6670
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msahrai@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Fateme Bayat

Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Tohid Square, Dr. Mirkhani St. (Nosrat Sharghi), School of Nursing and Midwifery, Tehran University of Medical Sciences
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Person responsible for scientific inquiries

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Nursery
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Considering that the present study is an academic dissertation and a copy of it is provided to Tehran University of Medical Sciences; Therefore, all data can be shared after being unidentified.
When the data will become available and for how long
Access to the documentation of this study begins three months after the results are published.
To whom data/document is available
Data and documentation of this study will be available for researchers working in academic and scientific institutions.
Under which criteria data/document could be used
All researchers working in scientific and academic centers, including researchers in multiple sclerosis centers, professors, students of nursing, all medical and paramedical degrees, nurses working in hospitals and community health centers, doctors, educational and research officials of multiple sclerosis centers and individuals workers in other paramedical disciplines are allowed to request unidentified data from this study. The use of the documents of this study can be used for all the mentioned groups only by mentioning the source and without any interference in its texts.
From where data/document is obtainable
Considering that a copy of the dissertation will be

provided to the library of the School of Nursing and Midwifery of Tehran University of Medical Sciences; Therefore, clients can visit the library of this center in person at: Tohid Square, Dr. Mirkhani St. (Eastern Nusrat), School of Nursing and Midwifery, Tehran University of Medical Sciences; Phone number: +982166927171; Or visit the library site of Tehran University of Medical Sciences in absentia at http://lib.tums.ac.ir/ to benefit from the documents of this study.

What processes are involved for a request to access data/document

If you visit the library of the School of Nursing and Midwifery of Tehran University of Medical Sciences in person, the client can read the research documents in the library by introducing himself to the librarian and presenting a valid ID card. It should be noted that the client will not be allowed to take the document out of the library and take a photo of it. If you visit the library site of Tehran University of Medical Sciences in absentia, the client will enter a part of the study title in the search box and a summary of the present study will be displayed for him.

Comments