# 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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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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## 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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**Email**
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
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Nursery
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## Person responsible for updating data

**Contact**
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Tehran University of Medical Sciences
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**Position**
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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**