Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Effect of self-care program based on mobile learning and face to face education methods on quality of life and coping skills in patients with multiple sclerosis

Protocol summary

Study aim

Determining and comparing the average score of quality of life and coping skills in research units before and after the intervention Comparison of changes and determination of the effectiveness of intervention in two educational groups

Design

Clinical trials with two parallel training groups and random block allocation are performed using Randomization software, and finally seven four-person blocks are created by this software.

Settings and conduct

56 patients with multiple sclerosis who are referred to Kashani Hospital will be selected by easy sampling method and will be randomly divided into two groups based on mobile education and face training. Then, the questionnaire will be completed by the research units to measure the quality of life and coping skills, and then face-to-face and mobile-based training sessions will be held in the relevant training groups. After completing the training and giving patients a four-week opportunity to perform and practice self-care activities while following them by phone calls during this period, the questionnaires will be completed by two groups.

Participants/Inclusion and exclusion criteria

Entry requirements: Diagnosis should be made by a specialist and they should be willing to participate in the research. Conditions for non-entry: relapse or participation in another training program

Intervention groups

A self-care program for patients with multiple sclerosis will be taught face-to-face with the group. In the mobile-based educational group, the same educational content will be installed on patients' mobile phones or tablets in the form of software.

Main outcome variables

The main variables of this study include quality of life and coping skills.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190712044181N5**
Registration date: **2020-06-17, 1399/03/28**
Registration timing: **prospective**

Last update: **2020-06-17, 1399/03/28**
Update count: **0**

Registration date

2020-06-17, 1399/03/28

Registrant information

Name

shahla Abolhassani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7548

Email address

abolhasani@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of self-care program based on mobile learning and face to face education methods on quality of life and coping skills in patients with multiple sclerosis

Public title
The effect of self-care program on quality of life and coping skills of multiple sclerosis patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
At least six months have passed since the diagnosis The definitive diagnosis of multiple sclerosis is confirmed by a neurologist and the patient has a medical record. Have a desire to participate in the study Ability to work with mobile and the ability to install software on the patient's mobile Be able to understand the questions of the questionnaire

Exclusion criteria:
Having hearing and vision problems The participants will have other training programs at the same time Patients who are in the process of relapse

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the samples will be selected by easy sampling method from patients with multiple sclerosis referred to Ayatollah Kashani Hospital who have the criteria to enter the research.Based on this, the samples will be introduced to the research team at the time of referral, and if they agree to participate in the study, they will be placed in the intervention or control groups based on the randomization framework. Random allocation of individuals in the two groups of e-learning and face-to-face training is based on randomized block allocation. Thus, 56 samples are divided into seven blocks of eight.The size of the blocks is equal to 8 people (4 people in each group). In each block, the members of the intervention and control group are identified by the letters A and B. For those who accept, assigning groups A and B to e-learning and face-to-face training will be unclear. Random allocation by block method is done using Random Allocation Software.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Isfahan University of Medical Sciences, Hezar Jereb Street

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2020-01-27, 1398/11/07

Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.062

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
Quality of life score in standard questionnaire of quality of life in patients with multiple sclerosis(multiple sclerosis impact scale)

Timepoint
Measurement of quality of life before the intervention and one month after the intervention

Method of measurement
Quality of Life Questionnaire in Multiple Sclerosis Patients

2

Description
coping Skills Score in the coping with multiple sclerosis questionnaire

Timepoint
Measure coping skills before the intervention and one

month after the intervention

Method of measurement

coping with multiple sclerosis questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Face-to-face training group.The educational content of the self-care program is provided based on the needs assessment of patients and will be presented in the face-to-face training group individually or in groups of two or three people in four sessions with one week intervals that each session will last 30-45 minutes.

Category

Other

2

Description

Intervention group 2: mobile-based training group. Self-care training content similar to face-to-face training group will be installed in the form of software that can be installed on both iOS and Android operating systems on patients' mobile phones or tablets. Simultaneously with the face-to-face training course for four weeks, the mobile-based training course will run for the same period.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Medical Educational Center

Full name of responsible person

Iman Adibi

Street address

Ayatollah Kashani Ave.Kashani Hospital

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3233 0091

Fax

Email

Kashani@mui.ac.ir

Web page address

https://kashani.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

Street address

Isfahan University of Medical Sciences, Hezar Jereb Street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

Web page address

https://research.mui.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Shahla Abolhassani

Position

Assistant Professor of Nursing Educational

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Isfahan University of Medical Sciences, Hezar Jereb Street

City

isfahan

Province

Isfehan

Postal code
8174673461

Phone
+98 31 3792 7500

Email
abolhassani@nm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shahla Abolhassani

Position
Assistant Professor of Nursing Educational

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Isfahan University of Medical Sciences, Hezar Jereb Street

City
isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 7500

Email
abolhassani@nm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shahla Abolhassani

Position
Assistant Professor of Nursing Educational

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Isfahan University of Medical Sciences, Hezar Jereb Street

City
isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 7500

Email
abolhassani@nm.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available