Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the cost-effectiveness of face-to-face and virtual healthy lifestyle training on the burden of care in caregivers of multiple sclerosis patients

Protocol summary

Study aim
Determining and Comparison of the cost-effectiveness of face-to-face and virtual healthy lifestyle training on the care burden of caregivers of MS patients

Design
A randomized controlled with a parallel group, single-blind, on 60 caregivers of MS patients referring to Ghaem Hospital.

Settings and conduct
The study environment is the MS clinic of Ghaem Hospital. In intervention group, the educational content is taught virtually through the Eitta messenger during 5 weeks in 5 sessions (45-60 minutes). In control group, the same educational content will be presented through lectures, group discussions in face-to-face sessions during 5 weeks in 5 sessions (45-60 minutes). Cost-effectiveness in each group is calculated and analyzed using the incremental cost-effectiveness ratio formula (ICER).

Participants/Inclusion and exclusion criteria
Some important entry criteria: being main caregiver of the patient and a history of at least 3 months of caring the MS patient, A patient suffering from MS for more than six months Important criteria for non-entry: participation in similar educational programs and having uncorrectable visual and hearing problems

Intervention groups
In intervention group, educational content is shared virtually through Eitta messenger. In control group, the same educational content will be presented through lectures, group discussions. Cost-effectiveness in each group is calculated using the incremental cost-effectiveness ratio formula (ICER).

Main outcome variables
Care burden of caregivers of MS patients using Zarit care burden questionnaire; the Cost-effectiveness of training based on caregivers' burden of care

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231212060344N1**
Registration date: **2024-02-25, 1402/12/06**
Registration timing: **prospective**

Last update: **2024-02-25, 1402/12/06**
Update count: **0**

Registration date
2024-02-25, 1402/12/06

Registrant information

Name
Farzaneh Salehi-Tizabi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3189 2105

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salehif992@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-05, 1402/12/15

Expected recruitment end date
2024-06-21, 1403/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the cost-effectiveness of face-to-face and virtual healthy lifestyle training on the burden of care in caregivers of multiple sclerosis patients

Public title
cost effectiveness of healthy lifestyle training on the burden of care in caregivers of multiple sclerosis patients

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 y/o and older Willingness to participate in research Access to mobile phones with Android operating system Being literate At least 3 months of patient care experience Being the main caregiver of the patient The stability of the patient's clinical condition

Exclusion criteria:
Having visual and hearing problems Participate in similar training courses in the last three months A history of mental disorders

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization. First, based on the inclusion criteria, research samples will be selected from the list of MS clinic clients, and then they will be divided into two intervention and control groups using a random number table.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Due to the fact that the data is entered in a coded form in the statistical analysis software, the analyst is unaware of the data of the groups under study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Nursing and Midwifery Mashhad University of Medical Sciences

Street address
Faculty of Nursing and Midwifery, Shahid Kharazmi Building, Azadi Square, Mashhad University of Medical Sciences, Mashhad, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Approval date
2024-02-06, 1402/11/17

Ethics committee reference number
IR.MUMS.NURSE.REC.1402.117

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis

ICD-10 code
G35- Multi

ICD-10 code description
https://icd.who.int/browse10/2010/en#/G35

Primary outcomes

1

Description
burden Care of caregivers of multiple sclerosis patients

Timepoint
4 weeks after the end of 5 training sessions

Method of measurement
Zarit care burden questionnaire

2

Description
The cost-effectiveness of education in two ways, face-to-face or virtual

Timepoint
4 weeks after the end of 5 training sessions

Method of measurement
Incremental Cost Effectiveness Ratio Formula

Secondary outcomes

empty

Intervention groups

1

Description
In intervention group, the educational content is taught virtually through the Eitta messenger during 5 weeks in 5 sessions (45-60 minutes).

Category

Lifestyle

2

Description
In control group, the same educational content will be presented through lectures, group discussions in face-to-face sessions during 5 weeks in 5 sessions (45-60 minutes).
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital affiliated to Mashhad University of Medical Sciences
Full name of responsible person
Mahmoud Bakhshi
Street address
Faculty of Nursing and Midwifery, Shahid Kharazmi Building, Azadi Square, Mashhad University of Medical Sciences, Mashhad, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghghodi - Vice President of Research and Technology
Street address
Research and Technology Vice-Chancellor, University Street, Central Building of Mashhad University of Medical Sciences, Mashhad, Iran
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9138813944
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+98 51 3841 1538
Email
vcresraech@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mahmoud Bakhshi
Position
faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
To maintain data confidentiality

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
The results of the research will be published in the text of the thesis and also through the article.

When the data will become available and for how long
After the completion of the study and defense of the thesis, about the next 7 to 8 months

To whom data/document is available
all people

Under which criteria data/document could be used
without any preconditions

From where data/document is obtainable
Website of Central Library of Mashhad University of Medical Sciences

What processes are involved for a request to access data/document
No special process is needed.

Comments