Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Evaluation of Effect of Telerehabilitation Education on Anxiety in People with Multiple Sclerosis

Protocol summary

Study aim

The purpose of the study is to investigate the effect of telerehabilitation education on the anxiety level of people who have recently been diagnosed with multiple sclerosis.

Design

The clinical trial has a control group, simple randomized, on 70 patients. Random Number Generator will be used for randomization.

Settings and conduct

The study will include telerehabilitation education in the form of education sessions (4 sessions) via Skype, on people visiting the Comprehensive Multiple Sclerosis Center located in Qaem Hospital in Mashhad. People can participate in the sessions at home or other places they prefer. Anxiety will be measured in both intervention and comparison groups before the intervention and 4 weeks after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Between 18-65 years, They have recently been diagnosed with MS, Expanded Disability Status Scale (EDSS) should be 4.0 or less, Able to read and write., have Sufficient knowledge in association with electronic devices and computers, Having a personal computer, laptop or smartphone, Have active internet access., Not participating in MS disease programs at the same time., Not suffering from other acute or chronic physical disorders. Exclusion criteria: Unwillingness to participate in the study.

Intervention groups

The intervention group will receive 4 sessions of telerehabilitation education. In the control group, they will receive their usual treatment before the study and will not receive any education.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230907059371N1**
Registration date: **2023-09-18, 1402/06/27**
Registration timing: **prospective**

Last update: **2023-09-18, 1402/06/27**
Update count: **0**

Registration date

2023-09-18, 1402/06/27

Registrant information

Name
Atieh Sadat Mariani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3768 2740
Email address
atieh.mariani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-21, 1402/06/30

Expected recruitment end date

2024-01-15, 1402/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Evaluation of Effect of Telerehabilitation Education on Anxiety in People with Multiple Sclerosis

Public title
Telerehabilitation Education on Anxiety in People with Multiple Sclerosis
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-65 Have recently been diagnosed with MS (maximum one year) and have been confirmed by a specialist. Expanded Disability Status Scale (EDSS) should be 4.0 or less and be approved by a specialist. Should be able to read and write. In case of not being able to read and write, the companion or caregivers of the person with MS should be able to read and write. Having sufficient knowledge In association with electronic devices and computers, or having a skilled person (caregiver of the patient or her/him first-degree relatives) to provide electronic devices Having a personal computer, laptop or smart phone Have active internet access Not participating in other MS education programs at the same time Not suffering from other acute or chronic physical disorders (debilitating heart, respiratory, liver, skeletal-muscular, renal, metabolic or other neurodegenerative diseases) recorded in the file. Not having severe hearing and cognitive disorders recorded in the file
Exclusion criteria:
Attending other education sessions. Severe auditory and cognitive disorders recorded in the file Suffering from other acute or chronic physical disorders (debilitating heart, respiratory, liver, skeletal-muscular, renal, metabolic or other neurodegenerative diseases) recorded in the file.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples will be assigned into two groups of comparison and intervention by randomization method using Random Number Generator software. In this way, people are coded in the order of entering the study(1,2,3...), then the numbers will be entered into the software in the same order(1-70). Then the sample volume will be entered to the data software. After that, random numbers will be generated by the software. The first 30 numbers will be in the intervention group and the second 30 numbers will be in the comparison group.
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 Iran University of Medical Science
Street address
Iran University of Medical Sciences, 5th floor of the central headquarters, Hemat Highway, next to Milad Tower, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2021-05-02, 1400/02/12
Ethics committee reference number
IR.IUMS.REC.1400.127

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
Anxiety
Timepoint
Measuring the level of anxiety at the beginning of the study (before the intervention) and 4 weeks after the end of the intervention
Method of measurement
Beck Anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Education will be provided by the researcher in 4 sessions, one session per week for 30 to 45 minutes in groups of 4 to 6 people through Skype software.The first session will be an introduction of people, discussion about multiple sclerosis and anxiety and sharing experiences about disease problems. The second session is titled: management of bladder and bowel problems. the third: Fatigue and pain management, and the fourth session will be: communication, physical activity in free time.

Category
Rehabilitation

2

Description
Control group: Does not receive any education

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive MS Center affiliated with Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mehran Beyraghi Tusi

Street address
AhmadAbad Blv, Parastar Ave, Qaem Hospital

City
Mashhad

Province
Razavi Khorasan

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99199-91766

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+98 51 3840 0001

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b.ghaem@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Dr Reza Falak

Street address
Iran University of Medical Sciences, 5th floor of the central headquarters, Hemat Highway, next to Milad Tower, Tehran

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research-m@iums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Atieh Sadat Mariani

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

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Position

student

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Other areas of specialty/work

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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

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Not applicable

Title and more details about the data/document

After de-identifying individuals, demographic and main outcome information will be shared.

When the data will become available and for how long

Access starts two months after the results are published

To whom data/document is available

The data will be accessible to researchers, students, clinicians, professors and patients.

Under which criteria data/document could be used

It will be available to use the data for further studies and increase the level of audience information

From where data/document is obtainable

In order to receive the data, audience can access the data by visiting the Central Library of Iran University of Medical Sciences at the address: Tehran, Hemat Highway, next to Milad Tower, Iran University of Medical Sciences, Central Library. Also, contact the researcher via email: atieh.mariani@gmail.com, contact number: 09383150595 and receive information.

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

The applicant must visit the Central Library of Iran University of Medical Sciences in person and then request access to theses and search for the title of this thesis to access the contents. He/She can also access the information by sending a message through a contact number or email and introducing yourself and the purpose of requesting access to the data in less than 6 hours.

Comments