Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of supervised exercise program via telerehabilitation on gait and quality of life in patients with multiple sclerosis

Protocol summary

Study aim
Assessment of the effect of supervised exercise through telerehabilitation on the quality of life and walking of multiple sclerosis patients

Design
Single-blind controlled clinical trial with two parallel arms 38 multiple sclerosis patients with walking disorder (without using an assistive device and if using a one-sided assistive device such as a cane) and are assigned to two parallel groups using the random sequence generated by the software

Settings and conduct
The intervention group received individualized exercise under the supervision The control group performs exercises with the same exercise protocol in person at the rehabilitation clinic. Exercises are performed 2 days a week for 40 minutes based for 6 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria Diagnosis of multiple sclerosis based on Mc Donalds criteria Expanded Disability Status Scale <6 No recurrence of the disease in the last 30 days Exclusion criteria Patients with severe disease who are unable to walk Active phase of the disease Associated underlying disease Pregnant women

Intervention groups
The intervention group received individualized exercise, including stretching, aerobics, strength exercises) through video calls during 12 sessions (1 month and a half) and under the supervision of a physical medicine and rehabilitation physicians, and all necessary evaluations and tests before and after the intervention are also done remotely and with the cooperation of the telepartner.

Main outcome variables
Timed Up and Go Test; 2 Minute Walk Test; Multiple Sclerosis Impact Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180804040685N5**
Registration date: **2023-04-23, 1402/02/03**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-23, 1402/02/03**
Update count: **0**

Registration date
2023-04-23, 1402/02/03

Registrant information

Name
Hamid Reza Fateh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8490 2110

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hr-fateh@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-15, 1402/01/26

Expected recruitment end date
2023-06-15, 1402/03/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effects of supervised exercise program via telerehabilitation on gait and quality of life in patients with multiple sclerosis

Public title
Effects of telerehabilitation in multiple sclerosis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of multiple sclerosis based on Mc Donalds criteria Expanded Disability Status Scale <6 No recurrence of the disease in the last 30 days
Exclusion criteria:
Patients with severe disease who are unable to walk Active phase of the disease Associated underlying disease Pregnant women
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
The participants are randomly allocated to two parallel groups using the block randomization technique. The block size is six and randomize the allocation of intervention or control within each block can be done by using a random number generator. Once the randomization within each block is completed, assign the participants to their respective intervention or control group based on randomization results to make balance within each block. Then, continue the process for subsequent blocks until all of them are assigned. The blinding and concealment of the randomization process also will be done.
Blinding (investigator's opinion)
Single blinded
Blinding description
Those who evaluate the outcome and those responsible for data collection do not know about the allocation of groups and the information of individuals is given in terms of numbers.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Karger St., Jalal Al Ahmad Street, Shariati hospital
City
Tehran
Province
Tehran
Postal code
14117 13135
Approval date
2023-04-09, 1402/01/20
Ethics committee reference number
IR.TUMS.SHARIATI.REC.1402.006

Health conditions studied

1

Description of health condition studied
Multiple sclerosis rehabilitation, telerehabilitation, walking disabilities, quality of life
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Timed up and go test (TUG), 2-minute walk test (2MWT), multiple sclerosis impact scale-29 (MSIS-29)
Timepoint
Before and immediately after the end of the intervention and after 2 months
Method of measurement
TUG is the time measured with the stopwatch from the time the patient gets up from the chair and walks 3 meters and returns and sits on the chair, and 2MWT is measured with the meter. The distance with maximum amount of walking power in 2 minutes, and the quality of life is measured by MSIS-29 questionnaire.

Secondary outcomes

1

Description
Berg balance scale, muscle force, fatigue severity scale
Timepoint
Before and immediately after the end of the intervention and after 2 months
Method of measurement

Fatigue severity is measured by a questionnaire, static and dynamic balance is measured by a Berg balance questionnaire, and muscle strength is measured by a manual muscle strength test.

Intervention groups

1

Description
Intervention group: The intervention group underwent remote rehabilitation during 12 sessions of 1 month and a half through a designed exercise protocol (including stretching, aerobic, strength exercises) and under the supervision of a physical medicine and rehabilitation doctor via video calls. and all the necessary evaluations and tests before and after the sports intervention are done offline and with the cooperation of the telepartner.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Hamid Reza Fateh
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Shariati Hospital, Jalal Al Ahmad Street, Kargar Street, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hamid Reza Fateh
Street address
Shariati Hospital, Department of Physical Medicine and Rehabilitation, Jalal Al Ahmad St., North Kargar St., Tehran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tehran University of medical Sciences
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hamid Reza Fateh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
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Person responsible for updating data

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable