

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 21 8490 2110

Email address

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

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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 scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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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