Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Aug 2026

The impact of remote dynamic neuromuscular stabilization exercises on fatigue in individuals with progressive multiple sclerosis

Protocol summary

Study aim

To investigate the effect of a dynamic neuromuscular stabilization exercise program supervised via telerehabilitation on the quality of life, fatigue, mobility level, and spasticity in patients with multiple sclerosis.

Design

This study will be a single-arm with a pre-test and post-test. Due to the nature of the exercise-based telerehabilitation intervention, blinding of participants and therapist is not feasible. however, outcome assessment will be conduct by an independent assessor who is blinded to the intervention details to minimize assessment bias. All participants will undergo the same exercise intervention supervised via remote rehabilitation. Due to the absence of a control group, randomization will not be necessary.

Settings and conduct

All participants will undergo the same exercise intervention supervised via remote rehabilitation. Due to the absence of a control group, randomization will not be necessary.

Participants/Inclusion and exclusion criteria

Men and women with Multiple Sclerosis and moderate disability, diagnosed within the specified time frame, will be selected for this study. All participants will undergo a comprehensive neurological examination by a specialist to determine their level of disability, disease course, medical history, and current medications.

Intervention groups

Men and women with Multiple Sclerosis and moderate disability, diagnosed within the specified time frame, will be selected for this study. All participants will undergo a comprehensive neurological examination by a specialist to determine their level of disability, disease course, medical history, and current medications.

Main outcome variables

Fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240213060998N3**
Registration date: **2026-01-02, 1404/10/12**
Registration timing: **prospective**

Last update: **2026-01-02, 1404/10/12**
Update count: **0**

Registration date

2026-01-02, 1404/10/12

Registrant information

Name

Zahra Salahzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-21, 1404/11/01

Expected recruitment end date

2026-05-21, 1405/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of remote dynamic neuromuscular stabilization exercises on fatigue in individuals with progressive multiple sclerosis

Public title

The impact of remote dynamic neuromuscular stabilization exercises on fatigue in individuals with progressive multiple sclerosis

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 30 and 50 years Moderate disability with an EDSS score between 4 and 7 A minimum score of 21 on the Mini-Mental State Examination (MMSE) Willingness to participate and signing of the informed consent form Minimum education level of high school diploma Absence of other neurological disorder diagnoses No MS relapse in the past month Absence of apraxia Absence of ataxia caused by motor coordination disorder No history of surgery on the lower limbs Absence of severe postural abnormalities in the spine or lower limbs Absence of cardiovascular diseases Absence of uncontrolled diabetes Patients who have received regular physiotherapy or occupational therapy in the past 3 months will be excluded from the study to allow for an independent evaluation of the current intervention's effect. Individuals who occasionally use rehabilitation services (e.g., less than one session per month) are permitted to participate if they adhere to the study protocol. Presence of spasticity of grade 1 or higher based on the Modified Ashworth Scale.

Exclusion criteria:

Desire to withdraw from the study Failure to complete the intervention or occurrence of an incident affecting balance Pregnancy Starting any new physiotherapy or occupational therapy program during the intervention period Change in the dosage of anti-spasticity medications (as per the neurologist's opinion) during the study.

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

29 Bahman Blvd.

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Tabriz

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East Azarbaijan

Postal code

5166414766

Approval date

2025-12-01, 1404/09/10

Ethics committee reference number

IR.TBZMED.REC.1404.665

Health conditions studied

1

Description of health condition studied

MS, Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Fatigue based on MFIS questionnaire

Timepoint

Pre-intervention (Pre-test): One day before starting the exercise program.- Post-intervention (Post-test): One day after the end of the tenth week.- Follow-up: 3 months after the end of the intervention (to assess the sustainability of effects).

Method of measurement

this outcome will be assessed using the Modified Fatigue Impact Scale (MFIS).This 21-item questionnaire evaluates fatigue in three domains: cognitive, physical, and psychosocial. Its validity and reliability have been confirmed in numerous studies (Cronbach's alpha 0.8). Patients will complete the questionnaire online (via Google Forms or a filled-out PDF) or during video sessions (Google Meet) under the assessor's supervision. Physical presence is not required, and the location of implementation will be the patients' homes with internet access .

Secondary outcomes

1

Description

Health-Related Quality of Life

Timepoint

The initial assessment will be conducted one day before starting the treatment, and the final assessment will be conducted one day after receiving the last treatment session. Due to the lack of in-person access for participants, all questionnaires will be provided in a single PDF file and will be filled out under the supervision of an assessor. To evaluate the sustainability of the treatment effects, another assessment will be conducted three months after the second assessment

Method of measurement

Since MS is a chronic disease, improving quality of life is a primary goal of rehabilitation interventions. To measure this variable, the Multiple Sclerosis Quality of Life-54 (MSQoL-54) questionnaire will be used. This questionnaire consists of 54 items across two sections: physical health and mental health. Its content and construct validity have been confirmed in MS patients (Cronbach's alpha 0.89-0.95). It will be administered electronically via PDF, and the location will be the patients' homes

2

Description

Mobility

Timepoint

The initial assessment will be conducted one day before starting the treatment, and the final assessment will be conducted one day after receiving the last treatment session. Due to the lack of in-person access for participants, all questionnaires will be provided in a single PDF file and will be filled out under the supervision of an assessor. To evaluate the sustainability of the treatment effects, another assessment will be conducted three months after the second assessment

Method of measurement

Gait and mobility impairments are common problems in MS patients. The Multiple Sclerosis Walking Scale-12 (MSWS-12) has been selected as a valid tool to assess this outcome. This 12-item questionnaire focuses on walking limitations. Its reliability has been reported with a Cronbach's alpha of 0.94. Patients will record their responses during video calls or by filling out the online form. For objective assessment, patients may be asked to video record their walking. The location will be a safe space in the patient's home (such as a hallway or empty room)

3

Description

Balance

Timepoint

The initial assessment will be conducted one day before starting the treatment, and the final assessment will be conducted one day after receiving the last treatment session. Due to the lack of in-person access for participants, all questionnaires will be provided in a single PDF file and will be filled out under the supervision of an assessor. To evaluate the sustainability of the treatment effects, another assessment will be conducted three months after the second assessment

Method of measurement

To assess this outcome, the Activities-specific Balance Confidence Scale (ABC) will be used. This is a 16-item questionnaire with high reliability (Cronbach's alpha 0.96) and good validity for MS patients. It will be conducted online or during video sessions with the assessor's guidance, in the patient's home

4

Description

Spasticity

Timepoint

The initial assessment will be conducted one day before starting the treatment, and the final assessment will be conducted one day after receiving the last treatment session. Due to the lack of in-person access for participants, all questionnaires will be provided in a single PDF file and will be filled out under the supervision of an assessor. To evaluate the sustainability of the treatment effects, another assessment will be conducted three months after the second assessment

Method of measurement

this outcome will be assessed using the Multiple Sclerosis Spasticity Scale-88 (MSSS-88). Patients without spasticity will score low in this section, which helps in data differentiation. This 88-item questionnaire has confirmed validity and reliability (Cronbach's alpha 0.92-0.95). It will be conducted online or during video sessions with the assessor's guidance, in the patient's home

Intervention groups

1

Description

Intervention group: At the beginning of the study, participants and their caregivers will receive comprehensive education about the importance of physical therapy exercises for the participants and the necessity of maintaining long-term adherence. This educational session will be held via Google Meet to ensure greater accessibility and interaction. Additionally, participants or their caregivers will be taught how to modify their home environment to reduce the risk of falls.Participants will carry out a 10-week home-based physical therapy exercise program, consisting of two sessions per week. The duration of each session will be determined and recorded based on the severity of the participants' symptoms and individual abilities. The intensity of the exercises and rest periods will be adjusted to each participant's condition to ensure optimal safety and effectiveness. All sessions will be held in the morning, and participants will be advised to empty their bladder before starting each session.All exercises will be performed on a mat or chair. To ensure a suitable

environment for exercise, participants will be encouraged to choose a cool, quiet, and distraction-free space in their homes. Rest periods at pre-determined intervals based on individual needs will be included to prevent excessive fatigue. The program will follow a progressive structure.A physiotherapist with five years of experience in neurological rehabilitation will remotely supervise the physical therapy exercise program. Supervision and guidance will be conducted via Google Meet video calls, allowing for direct monitoring, feedback, and progress assessment. The physiotherapist will adjust the intensity and duration of the exercises based on each participant's physical capacity and will carefully monitor their physical and emotional state.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
MS TAVANMAND Charity

Full name of responsible person
Laleh abadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Tabriz 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
University of social welfare and rehabilitation sciences

Full name of responsible person
Laleh Abadi Marand

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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

Title and more details about the data/document
1. The data file of the participants will be designed and collected without mentioning the name and with ID definition. 2. The study protocol will be published in the form of an article after the start of data collection. 3. The statistical analysis map will be prepared in SPSS file format after data collection. 4. The informed consent form of this study was designed and will be available to the participants. 5. The clinical study report will be prepared and published in the form of six-month reports and the final report.

When the data will become available and for how long
Access to data begins three months after publication of study results

To whom data/document is available
The study protocol and final study results will be available to the public after publication. Access to other data is done upon request.

Under which criteria data/document could be used
In order to design other research projects in this field, data will be sent.

From where data/document is obtainable
To receive the data and documents of this study, the scientific officer of this project can be contacted via e-mail. email address: mahboobgh1380@gmail.com

What processes are involved for a request to access data/document
After sending and reviewing the request for access to the data, in accordance with the principle of confidentiality of the personal information of the study participants, the data will be sent within a few days to a few weeks.

Comments