Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Optimizing Rehabilitation in People with Multiple Sclerosis

Protocol summary

Study aim
General aim: to determine the long-term effects of optimal conditions in square stepping exercises on physical and motor functions (static and dynamic balance and walking speed) and psychological factors (including depressive symptoms), motor and cognitive fatigue, and quality of life in MS patients.

Design
Patients will be randomly divided into intervention (optimal) and control groups by simple randomization method and using Excel software. The research will be single-blind.

Settings and conduct
Participants will be randomly divided into optimal rehabilitation (N = 17) or control rehabilitation (N = 17). For both groups, the square stepping rehabilitation program will be implemented three times a week for eight weeks at Isfahan MS Comprehensive Center. Each session will consist of a five-minute warm-up followed by a 30-minute rehabilitation program.

Participants/Inclusion and exclusion criteria
clinical diagnosis of MS, years of age 30-50, Expanded Disability Status Scale (EDSS): 2.0–4.0, ability to walk without aid (e.g., cane),

Intervention groups
Optimized and control groups

Main outcome variables
Static and dynamic balance, walking speed, depression symptoms, fatigue and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240709062370N1**
Registration date: **2024-07-15, 1403/04/25**
Registration timing: **prospective**

Last update: **2024-07-15, 1403/04/25**
Update count: **0**

Registration date
2024-07-15, 1403/04/25

Registrant information

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Hamid Salehi

Name of organization / entity
The university of Isfahan

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-08-05, 1403/05/15

Expected recruitment end date
2024-09-05, 1403/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Optimizing Rehabilitation in People with Multiple Sclerosis

Public title
Optimizing Rehabilitation in People with Multiple Sclerosis

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
clinical diagnosis of MS years of age 30-50 patients with

a range of disabilities, with scores on the Expanded Disability Status Scale (EDSS) from 2.00 to 4.00 ability to walk without aid (e.g., cane),

Exclusion criteria:

cognitive impairments other neurologic disorders severe contracture in the lower limbs

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method. For this purpose, the participants were listed alphabetically and each participant was assigned numbers one and two from this list. The unit of randomization was individual, and randomization was produced and applied using Excel software and the combination of two commands, SORTBY and ARRAYRAND. By applying this method, each participant will be randomly replaced in the control or optimal group, and the role of all related/unrelated variables in the selection of participants in the two groups will be randomly neutralized.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants of both groups of this study will be told in general that they are going to participate in a course of personalized stepping exercises for MS patients. Permission to use this trial was obtained from the ethics committee. It should be noted that the type of exercises of both groups will be exactly the same and the only difference between the groups is the feedback they receive while performing the movement exercises. All items measured in the pre-test and post-test, the instructions given/not given to perform the tests and movement exercises will be exactly the same for all participants. The participants of both groups will be unaware of the exact purpose of doing the exercises that are included in the specific research hypotheses. However, all participants (MS patients) will be blinded in the study. At the time of allocating the participants to the control and optimal groups, according to the method used for randomization, both the participants and the researcher will be unaware of the allocation of the participants in the study groups and has no role in the allocation. However, due to the nature of the trials that will be applied over 8 weeks, there will be differences in the feedback provided to the groups. To avoid the bias of the evaluators/trainers, one person is used for this purpose for both groups. Therefore, during the experiments, the main researcher (evaluator/trainer) will necessarily know which group each participant belongs to. For this reason, the one-sided blind study option was chosen and it cannot be considered completely double-blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of University of Isfahan

Street address

the University of Isfahan, Azadi square, Isfahan

City

Isfahan

Province

Isfehan

Postal code

۸۱۷۴۶۷۳۴۴۱

Approval date

2023-12-23, 1402/10/02

Ethics committee reference number

IR.UI.REC.1402.122

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis (MS)

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Static and dynamic balance

Timepoint

Pre test, mid test, post test

Method of measurement

Timed Up and Go test

Secondary outcomes

1

Description
Static and dynamic balance
Timepoint
Pre test, Post test
Method of measurement
Timed Up and Go test (TUG)

2

Description
Depression symptoms
Timepoint
Pre test, Post test
Method of measurement
Beck Depression Inventory

3

Description
Walking speed
Timepoint
Pre test, Post test
Method of measurement
25 foot walking

4

Description
Fatigue
Timepoint
Post test
Method of measurement
The Fatigue Scale for Motor and Cognitive Functions, Multiple Sclerosis

5

Description
Quality of life
Timepoint
Post test
Method of measurement
Multiple Sclerosis Impact Scale

Intervention groups

1

Description
The optimal group (intervention): this group will participate in exactly the same pre-tests and post-tests as the control group. The equipment used, the duration of training sessions, and the length of the trial period of this group will be exactly the same as the control group and will be 8 weeks. The only difference will be in the content of the feedback provided during the practice sessions.
Category
Rehabilitation

2

Description
Control group: This group will participate in exactly the same pre-tests and post-tests as the optimal (experimental) group. The equipment used, the duration of training sessions, and the length of the trial period of this group will be exactly the same as the optimal group and 8 weeks. The only difference will be in the content of the feedback provided during the practice sessions.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
M.S Isfahan Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
The University of Isfahan
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
The University of Isfahan
Full name of responsible person
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Associate Professor
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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

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

Analytic Code

Not applicable

Data Dictionary

Not applicable