Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Quantitative assessment and modeling of balance and gait recovery patterns in patients with Multiple Sclerosis for designing therapeutic protocols based on antigravity treadmill training

Protocol summary

Study aim
To investigate the effects of AlterG treadmill gait training on improving balance, gait patterns and skills, and reducing fatigue in patients with MS

Design
This was a randomized, controlled, parallel-group clinical trial involving 36 patients. The randomization was performed using the RAND() function in Microsoft Excel.

Settings and conduct
Treatment sessions will be conducted at a rehabilitation center in Tehran. The intervention group's treatment program will be administered using the anti-gravity treadmill, while the control group's program will be delivered by an occupational therapist. Evaluation methods: Gait analysis; Analysis of joint mechanical properties; Static balance assessment; Clinical tests All assessments will be performed at 4 distinct time points: Baseline; Mid-point; Post-treatment; Follow-up

Participants/Inclusion and exclusion criteria
Patients with a confirmed diagnosis of MS exhibiting moderate to severe disability. Ability to stand and walk a minimum of 3 steps independently. Provision of signed informed consent to participate in the study. Exclusion : Presence of cardiovascular conditions that would contraindicate physical exercise. Serious knee or hip joint pathologies that would impede the use of the anti-gravity treadmill. Patient non-compliance during the course of the treatment. Occurrence of a severe MS relapse

Intervention groups
The intervention group will participate in a training program using an AlterG treadmill. The program will last for 2 months, comprising 24 sessions held 3 times a week, with each session lasting 20 minutes. The control group will receive conventional occupational therapy exercises for the same duration and frequency.

Main outcome variables
Gait time-space parameters; Dynamic balance; Kinetic and kinematic parameters of the ankle joint; Changes in the center of pressure; Walking endurance; Walking speed; Static balance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250629066292N2**
Registration date: **2025-07-23, 1404/05/01**
Registration timing: **prospective**

Last update: **2025-07-23, 1404/05/01**
Update count: **0**

Registration date
2025-07-23, 1404/05/01

Registrant information

Name
Mohammad Mehdi Mirbagheri

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-08-11, 1404/05/20

Expected recruitment end date
2027-08-11, 1406/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Quantitative assessment and modeling of balance and gait recovery patterns in patients with Multiple Sclerosis for designing therapeutic protocols based on antigravity treadmill training

Public title
Quantitative assessment and modeling of balance and gait recovery patterns in patients with Multiple Sclerosis for designing therapeutic protocols based on antigravity treadmill training
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering from moderate to severe MS Ability to stand and take at least 3 steps independently. Age between 18 and 50 years. Informed consent to participate in the study.
Exclusion criteria:
Heart or vascular problems that do not allow for sports activities. Serious problems in the knee or hip joints that prevent the use of an anti-gravity treadmill. The patient's lack of cooperation during the treatment period. Severe MS attacks that cause disability or hospitalization of the patient.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, simple randomization will be used for patient allocation, and the unit of randomization is the individual patient. A random allocation sequence for 36 patients will be generated using the RAND() function in Microsoft Excel. Each patient will be assigned a random number, and the list will then be sorted based on these numbers. The first 18 patients on the list will be allocated to the intervention group, and the next 18 will be allocated to the control group. For allocation concealment, the allocation result for each patient (intervention or control group) will be written on a card and placed in a sealed, opaque envelope. These envelopes will be sequentially numbered. After a patient meets the inclusion criteria and signs the informed consent form, the corresponding envelope will be opened by an individual not involved in the assessment or treatment process to reveal the patient's group assignment.
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
Tehran University of Medical Sciences Research Ethics Committee
Street address
Tehran university of medical science, Poursina st,
City
Tehran
Province
Tehran
Postal code
1461884513
Approval date
2025-05-13, 1404/02/23
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1404.138

Health conditions studied

1

Description of health condition studied
Multiple sclerosis - MS disease
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Stiffness
Timepoint
Before the start of treatment, After one month of receiving the treatment program, Immediately after completing the treatment program, One month after the end of treatment(Follow-up)
Method of measurement
Neuromuscular rehabilitation robot device

2

Description

Center of pressure fluctuations

Timepoint

Before the start of treatment, After one month of receiving the treatment program, Immediately after completing the treatment program, One month after the end of treatment(Follow-up)

Method of measurement

Force plate

3

Description

Timed Up and Go Test

Timepoint

Before the start of treatment, After one month of receiving the treatment program, Immediately after completing the treatment program, One month after the end of treatment(Follow-up)

Method of measurement

Stopwatch

Secondary outcomes

1

Description

Step length

Timepoint

Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), Immediately after completing the treatment program (Post-treatment), One month after the end of treatment (Follow-up)

Method of measurement

Using marker positions in the motion capture lab

2

Description

Walking speed

Timepoint

Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), Immediately after completing the treatment program (Post-treatment), One month after the end of treatment (Follow-up)

Method of measurement

Using marker positions in the motion capture lab

3

Description

Ankle joint angles

Timepoint

Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), Immediately after completing the treatment program (Post-treatment), One month after the end of treatment (Follow-up)

Method of measurement

Using marker positions in the motion capture lab

4

Description

Fluctuations in the center of static pressure

Timepoint

Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), Immediately after completing the treatment program (Post-treatment), One month after the end of treatment (Follow-up)

Method of measurement

Force plate

5

Description

Active ankle range of motion

Timepoint

Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), Immediately after completing the treatment program (Post-treatment), One month after the end of treatment (Follow-up)

Method of measurement

Neuromuscular rehabilitation robot displacement recording sensor

6

Description

Maximum voluntary contraction force

Timepoint

Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), Immediately after completing the treatment program (Post-treatment), One month after the end of treatment (Follow-up)

Method of measurement

Torque recording sensor for neuromuscular rehabilitation robot

7

Description

Speed of voluntary joint movement

Timepoint

Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), Immediately after completing the treatment program (Post-treatment), One month after the end of treatment (Follow-up)

Method of measurement

Neuromuscular rehabilitation robot displacement recording sensor

8

Description

10-meter walking test time

Timepoint

Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), Immediately after completing the treatment program

(Post-treatment), One month after the end of treatment (Follow-up)

Method of measurement

Stopwatch

9

Description

6-minute walk test

Timepoint

Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), Immediately after completing the treatment program (Post-treatment), One month after the end of treatment (Follow-up)

Method of measurement

Meter

Intervention groups

1

Description

Intervention group: Participants will undergo a modern skill acquisition rehabilitation program using an anti-gravity treadmill for 30 minutes per session, 3 times a week, for a total of 24 sessions over two months. The anti-gravity treadmill enables the patient to walk actively and voluntarily by reducing their body weight (by up to 80%), thereby enhancing their gait skills. The anti-gravity treadmill consists of a standard treadmill enclosed within an inflatable, pressurized chamber. The individual is positioned inside the device while wearing specialized neoprene shorts, which are then zipped into the chamber. Subsequently, the chamber is inflated with air using built-in pumps. The air pressure generated within the chamber creates a lifting force on the body, which reduces the user's effective body weight. The amount of this weight reduction is controlled by adjusting the pressure inside the chamber. When using the device, the body weight reduction allows the patient to walk more easily and with a more normative gait pattern. Consequently, through intensive and consistent training, the patient can learn and reinforce a more correct walking skill.

Category

Rehabilitation

2

Description

Control group: The control group in this study will receive a standard occupational therapy program for 30 minutes per session, 3 times a week, for a period of 2 months (total of 24 sessions). The primary focus of this program is on improving endurance and balance.In this group, patients will be under the supervision of occupational therapists and will follow an exercise regimen that includes muscle strengthening, balance, and endurance training. The balance exercises are specifically designed to improve both static and dynamic balance and to prevent falls. This program is delivered regularly, adhering to standard occupational therapy practices, and does not involve the use of the specific technology (the anti-gravity treadmill) employed in the intervention group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Fakhre Sadeq Rehabilitation Center

Full name of responsible person

Shahrbanoo Mojtahedi

Street address

No. 42, Mohandes El-Mamalek Bldg., Alipour Karami St., Jomhuri St.

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Province

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mehdi.northwestern@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Ramin Kordi

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Province

Tehran

Postal code

1461884513

Phone

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Email

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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

Tehran University of Medical Sciences

Proportion provided by this source

48

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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Mehdi Mirbagheri
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Engineering
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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

Contact
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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
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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available