Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Otago exercises on some functional characteristics, fear of falling and quality of life in female patients with MS

Protocol summary

Study aim
Determining the effect of 8 weeks of Otago training on static and dynamic balance, cardiorespiratory endurance, neuromuscular function, proprioception, muscle strength, range of motion, fear of falling, fatigue, and quality of life in female patients with MS.

Design
A total of 28 women with MS referred to the Isfahan MS Association, aged 20 to 55 years and with an EDSS score of 4-1, were assigned to two paired experimental and control groups of 14 people. Data analysis was performed using analysis of variance for repeated measures.

Settings and conduct
In the present study, 29 patients were purposively selected as a statistical sample from among the patients who were members of the Isfahan MS Association. The patients were explained that the improvement in their physical condition would be measured after 8 weeks, and blinding was not performed.

Participants/Inclusion and exclusion criteria
1_ MS (according to the diagnosis of a neurologist). 2_ EDSS score between 1 and 4. 3_ Women with MS between the ages of 20 and 55 and not pregnant.

Intervention groups
The control group consisted of 14 female MS patients who did not receive any intervention for two months. The experimental group consisted of 14 female MS patients who received Otago exercises three sessions per week for 8 weeks.

Main outcome variables
The present study showed that Otago exercises improve functional capacity (balance, neuromuscular function, cardiorespiratory endurance) in patients with MS.

General information

Reason for update
Acronym
EOEM
IRCT registration information
IRCT registration number: **IRCT20251111067956N1**
Registration date: **2026-06-20, 1405/03/30**
Registration timing: **retrospective**

Last update: **2026-06-20, 1405/03/30**
Update count: **0**
Registration date
2026-06-20, 1405/03/30

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-10-03, 1403/07/12
Expected recruitment end date
2024-11-07, 1403/08/17
Actual recruitment start date
2024-10-03, 1403/07/12
Actual recruitment end date
2024-11-07, 1403/08/17
Trial completion date
2025-01-04, 1403/10/15

Scientific title
Effect of Otago exercises on some functional characteristics, fear of falling and quality of life in female patients with MS

Public title
Effect of Otago exercises on patients with MS
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
MS (as diagnosed by a neurologist) An Expanded Disability Status Scale (EDSS) score of 1-4 Women with MS aged 20-55 years They are not pregnant They have a history of falling for at least the past two years.
Exclusion criteria:
Having other neuromuscular diseases Pregnant
Age
From **20 years** old to **55 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **28**
Actual sample size reached: **28**
Randomization (investigator's opinion)
Randomized
Randomization description
A total of 28 women with multiple sclerosis referred to the Isfahan MS Association, aged 20 to 55 years and with an Expanded Disability Status Scale (EDSS) score of 4-1, were randomly assigned to two groups of 14 (experimental and control) based on their EDSS scores.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
This study is low-cost and can be performed anywhere for MS patients, improving their quality of life.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the University of Isfahan
Street address
Parvin etesami street, Alley 15
City
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Postal code
8861895711
Approval date
2024-09-14, 1403/06/24
Ethics committee reference number
IR.UI.REC.1403.097

Health conditions studied

1

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

Primary outcomes

1

Description
Static balance
Timepoint
Before the intervention begins and after the intervention ends
Method of measurement
Forward Functional Reach (FFR)

2

Description
Dynamic balance
Timepoint
Before the intervention begins and after the intervention ends
Method of measurement
Timed Up & Go (TUG)

3

Description
Cardiorespiratory endurance
Timepoint
Before the intervention begins and after the intervention ends
Method of measurement
6 minutes walk test

4

Description
Neuromuscular function
Timepoint
Before the intervention begins and after the intervention ends
Method of measurement
30 Seconds Sit To Stand Test

5

Description
Knee proprioception
Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Goniometer

6

Description

Range of motion

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Goniometer

7

Description

Muscular strength

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Dynamometer

8

Description

Fear of falling

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Questionnaire Falls Efficacy Scale- International

9

Description

Fear of movement

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Questionnaire TSK

10

Description

Fatigue

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Questionnaire MFI

11

Description

Quality of life

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Questionnaire Multiple Sclerosis Quality of Life-54 (MSQOL-54)

Secondary outcomes

empty

Intervention groups

1

Description

Experimental group: 14 women with multiple sclerosis referred to the Isfahan MS Association in the age range of 20 to 55 years and with an Expanded Disability Status Scale (EDSS) score of 4-1 were selected as available and then placed in a 14-person (experimental) group based on the EDSS score. The Otago exercise protocol was designed with four levels of difficulty from easy to difficult and was performed by the patients in the experimental group 3 sessions per week for 45 minutes for 8 weeks. These exercises included balance, strengthening, stretching, and aerobic exercises. Aerobic exercises were walking, which was performed once a week for 10 minutes. Before the start of the study, exercises were performed on three patients and the exercises were written in a modified form according to the patients' abilities, and these three patients were excluded from the study and did not enter the experimental group. Some exercises were performed by attaching weights to the feet, and the amount of weights was increased during the two months of performing the exercises. The weights were increased by half a kilo every two weeks, with half a kilo being used in the first and second weeks and two kilos in the seventh and eighth weeks. To increase the load, in addition to adding the amount of weights, the number of times each exercise was performed was increased. Before and after the training intervention, the variables of static balance, dynamic balance, cardiorespiratory endurance, neuromuscular function, range of motion, proprioception, muscle strength, quality of life, fatigue, fear of falling, and fear of movement were evaluated, respectively, through the functional access test, time to get up and go, 6 minutes of walking, and 30 seconds of sitting and getting up from a chair, goniometer, dynamometer, 54-question quality of life questionnaire, MFIS questionnaire, FSI questionnaire, and Tampa questionnaire for patients with multiple sclerosis. Data analysis was performed using analysis of variance for repeated measures. The significance level was accepted at a 95% confidence level.

Category

Rehabilitation

2

Description

Control group: 14 women with multiple sclerosis referring to the Isfahan MS Association, aged 20 to 55 years and with an Expanded Disability Status Scale (EDSS) score of 4-1, were selected through convenience sampling and then placed in a group of 14 (control) based on their

EDSS score. These patients continued their normal lives, including taking medications and daily activities, except for participating in rehabilitation, occupational therapy, and exercise training. Before and after the training intervention, the variables of static balance, dynamic balance, cardiorespiratory endurance, neuromuscular function, range of motion, proprioception, muscle strength, quality of life, fatigue, fear of falling, and fear of movement were evaluated, respectively, through the functional access test, time to get up and go, 6-minute walk, and 30-second sitting and standing from a chair, goniometer, dynamometer, 54-item quality of life questionnaire, MFIS questionnaire, FSI questionnaire, and Tampa questionnaire for patients with multiple sclerosis. Data analysis was performed using analysis of variance for repeated measures. The significance level was accepted at a 95% confidence level.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

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Sponsors / Funding sources

1

Sponsor

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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
The University of Isfahan
Proportion provided by this source
1
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
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only a portion of the data can be shared anonymously.
When the data will become available and for how long
After 6 months
To whom data/document is available
Researchers only
Under which criteria data/document could be used
Repeated measures analysis
From where data/document is obtainable
Researcher conducting research
What processes are involved for a request to access data/document
By sending a request email to raziehamini1996@gmail.com
Comments