Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A Comparative Study of the Effect of Reactive and Proactive Exercises on Balance and Balance Confidence in Multiple Sclerosis Patients : A Randomized Clinical Trial

Protocol summary

Study aim
Comparative study of the effect of reactive and proactive exercises on balance and confidence in the balance of patients with multiple sclerosis

Design
In this double-blind trial study, 51 people were randomly assigned to control and experimental groups.

Settings and conduct
This study is performed in the physiotherapy ward of Kashani Hospital in Isfahan on patients with multiple sclerosis.

Participants/Inclusion and exclusion criteria
Patients (male or female) with multiple sclerosis with a disability degree of 5.3 to 5.5 who are not in the acute phase of their disease.

Intervention groups
All patients receive conventional evidence-based treatment for multiple sclerosis rehabilitation. The control group performs only conventional therapy and the two intervention groups, depending on the type of group, perform special balance exercises (reactive and proactive) in addition to conventional therapy.

Main outcome variables
Evaluations include assessing the degree of balance and confidence in balance in patients with multiple sclerosis .The number of patient falls per week is also recorded.

General information

Reason for update

Acronym
MS

IRCT registration information
IRCT registration number: **IRCT20200101045970N8**
Registration date: **2023-01-01, 1401/10/11**
Registration timing: **prospective**
Last update: **2023-01-01, 1401/10/11**
Update count: **0**

Registration date
2023-01-01, 1401/10/11

Registrant information

Name
Ehsan Ghasemi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-21, 1401/11/01

Expected recruitment end date
2023-07-21, 1402/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A Comparative Study of the Effect of Reactive and Proactive Exercises on Balance and Balance Confidence in Multiple Sclerosis Patients : A Randomized Clinical Trial

Public title
The effect of exercise therapy on balance in patients with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of MS by a specialist doctor Age range from 20 to 50 years and being in the remession period At least one year has passed since the diagnosis of the disease having a mild to moderate degree of disability (EDSS=3.5-5.5) determined by a specialist doctor. Being able to stand without assistance for at least 3 minutes

Exclusion criteria:

Lack of regular participation in training sessions Recurrence of the disease during the plan and six months before Excessive fatigue so that it is harmful for her to continue training. Biomechanical or neurological disease or any specific disease in the expert's opinion that affects balance. Participation in a specific exercise program in the 3 months before and during treatment Suffering from other diseases such as cardiovascular, arthritis, respiratory, diabetes, cancer and vestibular system disorders according to the opinion of the relevant expert. A deformity in the lower limb that creates a risk of falling for the person. Use of medicinal agents to control fatigue and sedatives that affect balance. Cognitive disorders and depression and sleep that lead to fatigue.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **51**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients are randomly divided into one of three reactive, proactive and control groups after examining the inclusion and exclusion criteria. In this study, due to the small number of samples, in consultation with a statistician, it was decided to use the random blocking method. Blocking is usually used to balance the number of samples assigned to each of the groups studied. The statistician used the website https://www.sealedenvelope.com/simple-randomiser/v1/lists, Considering that we had 3 groups, they designed 17 two-person blocks. . A person who divides patients into three groups based on this table is unaware of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, because sufficient information about the exercises is given to the participants and it is explained to each of them that they may be randomly placed in one of the three groups, so the participants are not blind. In this study, the evaluator of balance and confidence in balance does not know which group the participant is in, so our evaluator is blind. In addition, the person analyzing the data does not know which person is in which group and only compares the data between the three groups, so they are also blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jrib

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2022-12-28, 1401/10/07

Ethics committee reference number

IR.MUI.NUREMA.REC.1401.128

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

Balance

Timepoint

Before the start of treatment, after the end of treatment and 1 months after the end of the last treatment session

Method of measurement

Use of Mini BES Test

2

Description

Balance Confidence

Timepoint
Before the start of treatment, after the end of treatment and 1 months after the end of the last treatment session
Method of measurement
Use of ABC Scale

Secondary outcomes

1

Description
Number of falls per week
Timepoint
Before the start of treatment, after the end of treatment and 1 months after the end of the last treatment session
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group: Reactive exercises + conventional exercises. The duration of each treatment session for the intervention group is 60 minutes.5 minutes of warm-up, 25 minutes of common balance exercises, 25 minutes of relevant balance exercises (reactive) and 5 minutes of cooling down.
Category
Rehabilitation

2

Description
Intervention group: Proactive exercises + conventional exercises. The duration of each treatment session for the intervention group is 60 minutes.5 minutes of warm-up, 25 minutes of common balance exercises, 25 minutes of relevant balance exercises (Proactive) and 5 minutes of cooling down.
Category
Rehabilitation

3

Description
Control group: Conventional exercises.5 minutes of warm up, 25 minutes of common balance exercises and 5 minutes of cool down.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
kashani Hospital
Full name of responsible person
Ehsan Ghasemi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansour Siavash Dastjerdi
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Vice Chancellor for Research and Technology, Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St.
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Web page address
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Ehsan Ghasemi
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
Physiotherapy
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Because of confidentiality
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
No - There is not a plan to make this available
Title and more details about the data/document
Study protocol, informed consent form and clinical study report
When the data will become available and for how long
The study protocol and consent form are now available in the proposal. The clinical study report will be published after the work is completed.
To whom data/document is available
All researchers working in scientific institutes can access the proposal.
Under which criteria data/document could be used
To be aware of the study conditions and get acquainted with scientific concepts.
From where data/document is obtainable
Contact Dr. Ehsan Ghasemi via email or mobile.
What processes are involved for a request to access data/document
Immediately after sending the email and receiving the request.
Comments