Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

clinical trial comparing the effect of eight weeks resistance, balance and combined (resistance- balance) training program on balance, gait and quality of life in patients with Multiple Sclerosis

Protocol summary

Summary

Objective: The aim of this study was to compare the efficacy of an 8-week balance, resistance and combined (balance- resistance) exercise program on balance, gait, and quality of life in women with M.S. Design: design of this study was pre test post test and single blind. Setting and conduct: Thirty women with M.S (mean±SD: age 35.33±3.2) were randomely divided into balance, resistance and combined exercise groups. The Berg balance test, gait distance in 6 minutes and MSQOL-54 questionnaire were used respectively evulation of balance, gait and quality of life. Patients underwent a 3 separate intervention protocols for 8 weeks. The one way analysis of variance, Tukey and paired t tests were used for statistical analysis (P<0.05). Participants including major eligibility criteria: To be eligible for inclusion in the study, participants had to have received a laboratory-supported diagnosis of relapsing-remitting, secondary progressive or primary progressive MS. In addition, they had to meet the following criteria: 1) competence to give informed consent, 2) age between 30 and 40 years, 3) ability to walk 25 feet with or without a cane or bracing, and 4) ability to verbalize a willingness to comply with the study's evaluation schedule. The exclusion criteria were as follows: 1) inability to provide informed consent, 2) EDSS score of 7 or higher, 3) inability to walk 25 feet with the use of an assistive device, 4) pregnancy, breastfeeding, or having given birth within 3 months of initiation of the study, and 5) diagnosis of any other neurologic disorder or disability that would affect balance and mobility. Interventions: eight weeks resistance, balance and combined (resistance- balance) training. Main outcome measures: balance, gait and quality of life. Blinnding: traines were learning only their own group and each group was blind about the training protocol of another group. trainers and resercher were blind about effects of these protocols on desired factors.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017053134257N1**
Registration date: **2017-06-15, 1396/03/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-15, 1396/03/25

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

investivator

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-12-19, 1395/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
clinical trial comparing the effect of eight weeks resistance, balance and combined (resistance- balance) training program on balance, gait and quality of life in patients with Multiple Sclerosis

Public title
Comparison the efficacy of eight weeks resistance, balance and combined (resistance- balance) training program on balance, gait and quality of life in patients with Multiple Sclerosis

Purpose
Supportive

Inclusion/Exclusion criteria
To be eligible for inclusion in the study, participants had to have received a laboratory-supported diagnosis of relapsing-remitting, secondary progressive or primary progressive MS. In addition, they had to meet the following criteria: competence to give informed consent; age between 30 and 40 years; ability to walk 25 feet with or without a cane or bracing; ability to verbalize a willingness to comply with the study's evaluation schedule. The exclusion criteria were as follows: inability to provide informed consent; EDSS score of 7 or higher; inability to walk 25 feet with the use of an assistive device; pregnancy, breastfeeding, or having given birth within 3 months of initiation of the study; diagnosis of any other neurologic disorder or disability that would affect balance and mobility.

Age
From **30 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
wemen with a history of MS for at least three years, EDSS between one and four, reffering to Shaygan nejad ' Clinic that were volentire to attend in this research were devided in three groups randomely. Randomization: The patients will be randomly in three groups

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
tehran university ethic committee

Street address
pardis international campus

City
kish

Postal code

Approval date
2016-09-22, 1395/07/01

Ethics committee reference number
489579

Health conditions studied

1

Description of health condition studied
multiple sclerosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
balance, gait and quality of life

Timepoint
balance(Prior to intervention and after 8 weeks intervention); gait (Prior to intervention and after 8 weeks intervention); quality of life(Prior to intervention and after 8 weeks intervention)

Method of measurement
Berg balance test, gait distance in 6 minutes and MSQOL-54 questionnaire

Secondary outcomes

1

Description
none

Timepoint
none

Method of measurement
none

Intervention groups

1

Description
in this study we have 3 Exercise interventions. First intervention group performed 8 weeks of Balance exercise for 3 times in week on the supervision of investigator. 2nd intervention group performed 8 weeks

of resistance exercise for 3 times in week on the supervision of investigator. 3rd intervention group performed 8 weeks of combined balance anr resistance exercise for 3 times in week on the supervision of investigator. Resistance exercise intervention

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
isfahan ms center

Full name of responsible person
Dr Vahid Shayegannezhad

Street address
p 25;felestin Sq;Ferdosi St,Hakim Tower, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
investivator

Full name of responsible person
maryam mohammadzadeh

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university of tehran

City
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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
investivator

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty