Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of exercise training on physical fitness, joint range of motion and quality of life in women patients with multiple sclerosis

Protocol summary

Study aim
Assessing the effect of exercise training on physical fitness, joint range of motion and quality of life in women patients with multiple sclerosis

Design
Randomized clinical trial with control group, non blinded, with parallel groups

Settings and conduct
Among patients with multiple sclerosis that covered by the Welfare Organization, thirty volunteers woman that have expanded disability status scale more than 1.5 and less than 6, will be selected as the study population and will randomly (Lottery) divide into three aerobic-resistance training, aerobic- resistance- balance training and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: women patients suffering from multiple sclerosis, have an expanded disability status scale more than 1.5 and less than 6 Exclusion criteria: have any physical and mental problems that limit their participation in the training. For example: cardiovascular disease and cognitive disorder

Intervention groups
Aerobic-resistance training group: 8- weeks, three times per week, each session include incremental aerobic (at 40-60% of Heart rate reserve) and resistance (at 60-80% of 1RM) training Aerobic-resistance-balance training group: 8- weeks, three times per week, each session include incremental aerobic (at 40-60% of Heart rate reserve) and resistance (at 60-80% of 1RM) training and 15 min balance training Control group: no intervention

Main outcome variables
Physical fitness; joint range of motion; quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150531022498N20**
Registration date: **2018-03-26, 1397/01/06**
Registration timing: **retrospective**

Last update: **2018-03-26, 1397/01/06**
Update count: **0**

Registration date
2018-03-26, 1397/01/06

Registrant information

Name
Ramin Shabani

Name of organization / entity
Islamic Azad University

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-09-21, 1395/06/31

Expected recruitment end date
2016-10-21, 1395/07/30

Actual recruitment start date
2016-09-21, 1395/06/31

Actual recruitment end date
2016-10-21, 1395/07/30

Trial completion date
empty

Scientific title
Effect of exercise training on physical fitness, joint range of motion and quality of life in women patients with multiple sclerosis

Public title
Effect of exercise training in women patients with multiple sclerosis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Have an expanded disability status scale 1.5-6 Have age ranges 28-40 years Be women Patient suffering from multiple sclerosis
Exclusion criteria:
Have any physical and mental problems that limit their participation in the training (including cardiovascular disease and cognitive disorder)
Age
From **28 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Assigning samples using simple random-lottery method
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
Ethics Committee of Islamic Azad University Rasht Branch
Street address
Islamic Azad University Rasht Branch, Taleshan Bridge, Rasht
City
Rasht
Province
Guilan
Postal code
-
Approval date
2016-09-17, 1395/06/27
Ethics committee reference number
IR.IAU.RASHT.REC.1395.27

Health conditions studied

1

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

Primary outcomes

1

Description
Physical fitness
Timepoint
Before and after the end of eight weeks
Method of measurement
Using by measuring muscle strength, aerobic power and balance

2

Description
Joint range of motion
Timepoint
Before and after the end of eight weeks
Method of measurement
Using by goniometer

3

Description
Quality of life
Timepoint
Before and after the end of eight weeks
Method of measurement
Using by quality of life questionnaire (SF-36)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 8-weeks incremental aerobic-resistance training, including three 6-10 min sets at 40-60% of reverse heart rate and three 10 min sets of 60-80% of one repetition maximum
Category
Lifestyle

2

Description

Intervention group: 8-weeks incremental aerobic-resistance training combined with balance training, including three 6-10 min sets at 40-60% of reverse heart rate, three 10 min sets of 60-80% of one repetition maximum and 15 min static and ballistic balance training

Category
Lifestyle

3

Description
Control group: no intervention will be conducted

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
State Welfare Organization of Guilan Province

Full name of responsible person
Sepideh Jafari Sayadi

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State Welfare Organization of Guilan Province, Parastar Street, Rasht, Guilan

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-

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

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?
No

Title of funding source
Personality, Researcher

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Sepideh Jafari Sayadi

Position
MA

Latest degree
Master

Other areas of specialty/work
Exercise physiology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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

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