

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 13 3375 2715

Email address

shabani@iaurasht.ac.ir

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

Street address

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

City

Rasht

Province

Guilan

Postal code

-

Phone

+98 13 3333 3595

Email

sepidehjafarisayadi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ali Delpasand

Street address

Islamic Azad University Rasht Branch, Taleshan
Bredge

City

Rasht

Province

Guilan

Postal code

-

Phone

+98 13 3385 6174

Email

shabani_msn@yahoo.com

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

Street address

Islamic Azad University Rasht Branch, Taleshan
Bridge, Rasht

City

Rasht

Province

Guilan

Postal code

-

Phone

+98 13 3375 2715

Email

sepidehjafarisayadi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Ramin Shabani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

Street address

Islamic Azad University Rasht Branch, Taleshan
Bridge, Rasht

City

Rasht
Province
Guilan
Postal code
-
Phone
+98 13 3375 2715
Email
shabani_msn@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Fatemeh Izaddoust
Position
Ph.D student
Latest degree
Master
Other areas of specialty/work
Exercise Physiology
Street address
Islamic Azad University Rasht Branch, Taleshan
Bridge, Rasht
City
Rasht
Province
Guilan

Postal code
-
Phone
+98 13 3385 6174
Email
fa.izaddoust@gmail.com

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