Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of 12 weeks of multicomponent training and 8 weeks of follow-up on inflammatory and cardiometabolic markers, physical performance, and body composition in patients with multiple sclerosis

Protocol summary

Study aim

To determine the effects of twelve weeks of multicomponent training and eight weeks of follow-up after the intervention on inflammatory and cardiometabolic markers, physical performance, and body composition in patients with multiple sclerosis.

Design

A controlled clinical trial with intervention and control groups, without blinding, randomized, on 50 patients.

Settings and conduct

Patients with MS referred to the Isfahan MS Center will be enrolled in the study if they meet the entry criteria and will be randomly assigned to two intervention and control groups. No blinding will be performed. The training sessions will be held in a gym at the University of Isfahan.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ability to walk, sit, and stand, Expanded disability status scale (EDSS) between 2 - 4, confirmation of MS by a neurologist; Exclusion criteria: Participation in regular exercise for 6 months prior to the study, pregnancy for women, smoking

Intervention groups

The intervention group will participate in 12 weeks of multi-component training in the form of 3 training sessions per week, each session including endurance, strength, and balance exercises for 40 minutes. The control group will not have any training during the 12 weeks.

Main outcome variables

Tumor necrosis factor alpha; C-reactive protein; Interleukin-6; Adiponectin; Leptin; Cardiometabolic index; Triglyceride; High-density lipoprotein cholesterol; Low-density lipoprotein cholesterol; Total cholesterol; Glucose; Glycosylated hemoglobin (HbA1c); Insulin; Insulin resistance; Blood pressure; Peak oxygen consumption; Aerobic endurance; Mobility; Strength; Walking speed; Balance; Fatigue; Body mass index; Percent Body Fat.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250424065460N1**
Registration date: **2025-06-23, 1404/04/02**
Registration timing: **retrospective**

Last update: **2025-06-23, 1404/04/02**
Update count: **0**

Registration date

2025-06-23, 1404/04/02

Registrant information

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Safa Jabbari

Name of organization / entity

University of Isfahan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-15, 1404/02/25

Expected recruitment end date

2025-06-15, 1404/03/25

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of 12 weeks of multicomponent training and 8 weeks of follow-up on inflammatory and cardiometabolic markers, physical performance, and body composition in patients with multiple sclerosis

Public title
Effects of multicomponent training in multiple sclerosis patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients can walk, sit, and stand up Extensive disability status scale (EDSS) in the low (between 2 and 3) to moderate (between 3 and 4) range Multiple sclerosis confirmed by a neurologist
Exclusion criteria:
Participating in any regular sports activity for 6 months prior to the present study Being pregnant for women Smoking
Age
From **25 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method is simple randomization. The randomization units are patients with MS (individuals). Based on the Cochran formula and the studies conducted, the sample size was determined to be 50 people. First, the randomization units (patients) were numbered from 1 to 50. Then, using the R statistical software, these individuals were randomly assigned to two groups: exercise and control. This study does not have stratified randomization.
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 at University of Isfahan Research Department
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Room 325, 3rd Floor, Main Building, University of Isfahan, Hezar Jerib Street, Azadi Square, Isfahan.
City
Isfahan
Province
Isfehan
Postal code
8174673441
Approval date
2025-03-01, 1403/12/11
Ethics committee reference number
IR.UI.REC.1403.174

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
Tumor necrosis factor alpha (TNF-α)
Timepoint
Pre-intervention (24 hours before the intervention) and post-intervention (24 hours after the final session of the 12-week training program)
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) of fasting blood samples

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Description
Interleukin 6 (IL-6)
Timepoint
Pre-intervention (24 hours before the intervention) and post-intervention (24 hours after the final session of the 12-week training program)
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) of fasting blood samples

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Description

C-reactive protein (CRP)

Timepoint

Pre-intervention (24 hours before the intervention) and post-intervention (24 hours after the final session of the 12-week training program)

Method of measurement

Quantitative CRP diagnostic kit of fasting blood samples

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Description

Leptin

Timepoint

Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after the 8 weeks of follow-up)

Method of measurement

Enzyme-linked immunosorbent assay (ELISA) of fasting blood samples

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Description

Triglycerides (TG)

Timepoint

Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after 8 weeks of follow-up)

Method of measurement

TG quantitative assay kit for fasting blood samples

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Description

Low-density Lipoprotein Cholesterol (LDL-C)

Timepoint

Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after 8 weeks of follow-up)

Method of measurement

LDL-C quantitative determination kit for fasting blood samples

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Description

High-density Lipoprotein Cholesterol (HDL-C)

Timepoint

Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after 8 weeks of follow-up)

Method of measurement

HDL-C quantitative determination kit for fasting blood samples

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Description

Total cholesterol (TC)

Timepoint

Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after 8 weeks of follow-up)

Method of measurement

TC quantitative determination kit for fasting blood samples

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Description

Glucose

Timepoint

Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after 8 weeks of follow-up)

Method of measurement

Glucose oxidase method for fasting blood samlpes

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Description

Glycosylated hemoglobin (HbA1c)

Timepoint

Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after 8 weeks of follow-up)

Method of measurement

HbA1c ELISA kit

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Description

Insulin

Timepoint

Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after 8 weeks of follow-up)

Method of measurement

Human Insulin ELISA Kit

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Description

Insulin resistance (IR)

Timepoint

Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after 8 weeks of follow-up)

Method of measurement

Using the HOMA-IR index with the following formula: (Fasting glucose (milligrams per deciliter) * Fasting insulin (microunits/milliliter)) / 405

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Description

Peak oxygen consumption (VO2peak)

Timepoint
Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after 8 weeks of follow-up)
Method of measurement
By Naughton protocol

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Description
Aerobic endurance
Timepoint
Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after 8 weeks of follow-up)
Method of measurement
Six-minute walk test (6MWT)

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Description
Mobility
Timepoint
Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after 8 weeks of follow-up)
Method of measurement
Timed up and go (TUG) test

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Description
Walking speed
Timepoint
Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after 8 weeks of follow-up)
Method of measurement
Timed 25-foot walk test (T25-FW)

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Description
Strength
Timepoint
Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after 8 weeks of follow-up)
Method of measurement
30-second chair stand test (30-CST)

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Description
Balance
Timepoint
Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after 8 weeks of follow-up)
Method of measurement
Functional reach test (FRT)

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Description
Fatigue
Timepoint
Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after 8 weeks of follow-up)
Method of measurement
Fatigue severity scale (FSS)

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Description
Body mass index (BMI)
Timepoint
Pre-intervention (24 hours before the intervention) and post-intervention (24 hours after the final session of the 12-week training program)
Method of measurement
Using the formula: weight (kilograms) divided by height squared (meters)

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Description
Percent body fat (PBF)
Timepoint
Pre-intervention (24 hours before the intervention) and post-intervention (24 hours after the final session of the 12-week training program)
Method of measurement
Using a digital body composition analyzers device

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Description
Adiponectin
Timepoint
Pre-intervention (24 hours before the intervention) and post-intervention (24 hours after the final session of the 12-week training program)
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) for fasting blood samples

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Description
Blood pressure
Timepoint
Pre-intervention (24 hours before the intervention), post-intervention (24 hours after the final session of the 12-week training program), and post-follow-up (24 hours after 8 weeks of follow-up)
Method of measurement
Digital pressure gauge

24

Description
Cardiometabolic Index (CMI)
Timepoint
Pre-intervention (24 hours before the intervention) and post-intervention (24 hours after the final session of the 12-week training program)
Method of measurement
Calculated by multiplying the waist-to-height ratio (WHtR) by the triglyceride (TG) to high-density lipoprotein cholesterol (HDL-C) ratio. Formula: CMI = (TG / HDL-C) * WHtR.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group will participate in multi-component training with gradual increase in intensity for 12 weeks, three sessions per week, each session lasting 40 minutes. Each session includes five sections: Warm-up, endurance training, resistance training, balance training, and cool-down. The endurance training section lasts 10-15 minutes per session, the intensity of the exercises increases from the first week with an intensity of 55% of the heart rate reserve to the twelfth week with an intensity of 70% of the heart rate reserve. The training volume is 10 minutes in the first week and gradually increases to 15 minutes by the twelfth week. The training method is a stationary bike with lumbar support or walking on a treadmill with the help of a handrail. The resistance training portion lasts 10-15 minutes per session. The intensity of the training is 60% of one repetition maximum. The volume of the training increases gradually and is as follows: Weeks 1 to 3 (one set of 8-10 repetitions), weeks 4 to 6 (one set of 10-12 repetitions), weeks 7 to 9 (two sets of 8-10 repetitions), and weeks 10 to 12 (two sets of 10-12 repetitions). The rest interval between exercises is 60-90 seconds. The training method includes the first session of resistance band training, the second session of light dumbbell exercises, and the third session of bodyweight exercises. The balance training section lasts 5-10 minutes per session. The intensity and volume of the exercises gradually increase from low to moderate. The rest interval between each exercise is 30 seconds, and the training method includes exercises such as standing on one leg, walking heel-to-toe in a straight line, standing and sitting on a chair. Then there will be an eight-week follow-up period without any training.
Category
Rehabilitation

2

Description
Control group: No multi-component training during the twelve-week intervention period and the eight-week follow-up period thereafter.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan MS center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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?
Yes
Title of funding source
University of Isfahan
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
University of Isfahan

Full name of responsible person
Mehdi Kargarfard

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
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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