# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 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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**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.
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**Postal code**
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**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

### 2

**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

### 3

**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

## 4

**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

## 5

**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

## 6

**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

## 7

**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

## 8

**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

## 9

**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

## 10

**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

## 11

**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

## 12

**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

## 13

**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

## 14

**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)

## 15

**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

## 16

**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)

## 17

**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)

## 18

**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)

## 19

**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)

## 20

**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)

## 21

**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

## 22

**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

## 23

**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
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## Sponsors / Funding sources

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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

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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