

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of resistance and aerobic training on growth hormones cortisol, insulin-like growth factor 1, and depression in women with relapsing-remitting multiple sclerosis.

Protocol summary

Study aim

Determining the effect of resistance training and aerobic training on growth hormone, insulin-like growth factor-1, cortisol, and depression levels in patients with MS

Design

The clinical trial has a control group and three experimental groups, with parallel groups, unblinded, and randomized (sealed envelopes). It is conducted on 40 patients with MS in Rasht. The sealed envelope method was used for randomization.

Settings and conduct

Forty participants were randomly assigned to three groups (three experimental, one control). All completed the BDI and blood tests for GH, cortisol, and IGF-1 (ELISA). The first group did resistance training, the second did aerobic exercises, and the control group had no training. Post-tests were conducted after the interventions.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 25–50 years; diagnosis of RRMS; EDSS 0.5–5.5; BDI $\geq 14/20$; DPEI 0–5; regular menstrual cycles; no use of antidepressants, cigarettes, or alcohol; no thyroid, renal, or cardiovascular disease; ≥ 2 months since last regular exercise. Exclusion Criteria: Disease relapse; pain or discomfort during exercise; insufficient balance for safe training; participation in physiotherapy, massage, or rehabilitation within the last 3 months; history of cardiovascular disease, epilepsy, or migraine.

Intervention groups

Control group: 10 eligible individuals who do not participate in any training and only take the tests.
Intervention group 1: 10 individuals who participate in resistance training.
Intervention group 2: 10 eligible individuals who participate in aerobic training.
Intervention group 3: 10 individuals who participate in combined aerobic and resistance training.

Main outcome variables

Growth Hormone, Cortisol, Insulin-like Hormone 1, Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250507065634N13**

Registration date: **2026-01-01, 1404/10/11**

Registration timing: **prospective**

Last update: **2026-01-01, 1404/10/11**

Update count: **0**

Registration date

2026-01-01, 1404/10/11

Registrant information

Name

mahnaz shafaei fallah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 930 0704

Email address

articlelab.com@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-08, 1404/10/18

Expected recruitment end date

2026-01-20, 1404/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of resistance and aerobic training on growth hormones cortisol, insulin-like growth factor 1, and depression in women with relapsing-remitting multiple sclerosis.

Public title
The effect of resistance and aerobic training on patients with multiple sclerosis.

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Age range between 25 and 50 years Women with depression in the Beck Depression Inventory range of 21-63 (BDI) Having depressive disorder with a severity of 0-5 on the DPEI scale Having regular menstrual cycles Not using antidepressant medications Disease severity (EDSS) between 0.5 and 5.5 No history of thyroid, renal, cardiovascular, or vascular diseases Having at least a 2-month interval since the last exercise training Non-smoker No alcohol consumption Having a relapsing-remitting type of Multiple Sclerosis (MS)
Exclusion criteria:
Recurrence of the disease Feeling of pain Lack of necessary balance during the exercises Participation in physiotherapy, massage therapy and rehabilitation programs in the last three months History of cardiovascular diseases, epilepsy and migraines

Age
From **25 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
After selecting the sample (40 eligible volunteers), all individuals are numbered. For randomization, opaque, light-tight, and sealed envelopes are used. Before the study begins, 40 envelopes are prepared, inside of which are placed equal numbers of papers labeled "Aerobic Exercise Test Group," "Resistance Exercise Test Group," and "Control Group." The order of the papers in the envelopes is randomized, and the envelopes are then sealed. Upon entering the study, each individual randomly selects an envelope and is assigned to the experimental or control group based on its contents. This process ensures that the assignment of individuals to groups is completely random and that there is no possibility of prediction or interference in the assignment by the researcher or participants.

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

Research Ethics Committee of the Sports Sciences Research Institute

Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2021-09-20, 1400/06/29

Ethics committee reference number

IR.SSRI.REC.1400.1109

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

Depression

Timepoint

Before intervention and immediately after completion of the intervention

Method of measurement

Beck Depression Inventory (BDI)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: 10 participants who meet the inclusion criteria will be randomly assigned to the study as the control group. They will complete a depression questionnaire. ELISA will measure growth hormone, cortisol, and insulin-like growth factor levels before and after the intervention. However, they will not participate in any exercise.

Category

Diagnosis

2

Description

First intervention group: 10 patients with multiple sclerosis referred to Besat Hospital in Rasht, who meet the inclusion criteria and are randomly assigned to participate in the study as the intervention group. They complete a depression questionnaire, and their growth hormone, cortisol, and insulin-like growth hormone levels are measured by ELISA and blood tests before starting the exercises. Then, they are placed in strength training sessions for 30-40 minutes for 24 sessions, 3 sessions per week, over 3 weeks. Before starting the sessions, 6 training sessions will be completed. The exercises are strength-based, and 5-10 minutes are dedicated to warming up (walking and stretching), 25-35 minutes to basic weight-bearing exercises, and 5 minutes to cool down (stretching). After completing the sessions, their growth hormone, cortisol, and insulin-like growth hormone levels are measured again by ELISA and blood tests after the exercises.

Category

Diagnosis

3

Description

Second intervention group: The second intervention group consists of 10 women with relapsing-remitting multiple sclerosis who are referred to Ba'ath Hospital in Rasht and meet the inclusion criteria. Participants are randomly assigned to this group. At baseline, participants complete the Beck Depression Inventory (BDI), and serum levels of growth hormone, cortisol, and insulin-like growth factor 1 are measured before the initiation of the intervention through blood sampling using the Enzyme-Linked Immunosorbent Assay (ELISA) method. Subsequently, participants undergo an aerobic exercise training program for 8 weeks, with two sessions per week, totaling 16 sessions. Before the main intervention, 6 instructional sessions are conducted to familiarize participants with the correct performance of the exercises. Each aerobic exercise session lasts 20 to 40 minutes and consists of three parts to 10 minutes of warm-up (including walking and stretching exercises), 20 to 30 minutes of the main exercise (walking), and 5 minutes of cool-down (stretching exercises). Exercise intensity is individually prescribed and monitored during

the sessions based on the Borg Rating of Perceived Exertion (RPE) scale. After completion of the exercise program, serum levels of growth hormone, cortisol, and insulin-like growth factor 1 are re-measured through blood sampling using the ELISA method.

Category

Diagnosis

4

Description

Intervention group: Third intervention group: 10 people with multiple sclerosis referred to Besat Hospital in Rasht, who meet the inclusion criteria and are randomly assigned to participate in the study as the intervention group. They complete a depression questionnaire and their growth hormone, cortisol, and insulin-like growth hormone levels are measured by ELISA and blood tests before starting the exercises. Then, they participate in combined aerobic and resistance training sessions at each person's home. The duration of the sessions is 28 sessions, 2 sessions per week. After completing the sessions, their growth hormone, cortisol, and insulin-like growth hormone levels are measured again by ELISA and blood tests after the exercises.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Specialized and Subspecialized Clinic

Full name of responsible person

Kourosh Fakhimi

Street address

Besat Specialized and Subspecialized Clinic, Engelab St, next to Tavaf Alley, Rasht, Gilan, Iran

City

Rasht

Province

Guilan

Postal code

4136617865

Phone

+98 13 3326 1451

Email

int@guilan.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Guilan

Full name of responsible person

Ali Bani

Street address

University Complex of Guilan, Km 5 Tehran Road,

Khalij-e Fars Expressway, Rasht, Iran

City

Rasht

Province

Guilan

Postal code

4199613776

Phone

+98 13 3369 0274

Email

int@guilan.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

The University of Guilan

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

The University of Guilan

Full name of responsible person

Faeze Alipour

Position

Master of Physical Education

Latest degree

Bachelor

Other areas of specialty/work

Physical Education

Street address

Ahmadi Sabet, 10th Alley, Jomhouri Street, Lahijan,
Gilan Province, Iran

City

Lahijan

Province

Guilan

Postal code

۴۴۱۹۸۸۵۱۳۶

Phone

+98 937 156 1655

Email

faezealipour2@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Guilan

Full name of responsible person

Payam Saidie

Position

Assistant Professor, University of Guilan

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

University Complex of Guilan, Km 5 Tehran Road,
Khalij-e Fars Expressway, Rasht, Iran

City

Rasht

Province

Guilan

Postal code

4199613776

Phone

+98 911 194 3804

Email

payam.saidie@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

The University of Guilan

Full name of responsible person

Faeze Alipour

Position

Master of Physical Education

Latest degree

Bachelor

Other areas of specialty/work

Physical Education

Street address

Ahmadi Sabet, 10th Alley, Jomhouri Street, Lahijan,
Gilan Province, Iran

City

Rasht

Province

Guilan

Postal code

۴۴۱۹۸۸۵۱۳۶

Phone

+98 937 156 1655

Email

faezealipour2@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic data and the main outcome results of the research can be shared after de-identification and preserving the privacy of individuals.

When the data will become available and for how long

Data can be made available 4 months after the results are published and after personally identifiable information is removed.

To whom data/document is available

The study data and documentation will be available to researchers and scholars working at reputable academic and scientific institutions.

Under which criteria data/document could be used

Research data and documentation may be used for scientific and research purposes. Users must undertake to keep non-identifiable data confidential.

From where data/document is obtainable

If you need data, please contact

What processes are involved for a request to access data/document

After receiving and reviewing the request from the researcher, the request will be responded to as soon as possible.

Comments