Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 ≥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

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Iran (Islamic Republic of)

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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

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Tehran

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Tehran

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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
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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