Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

The Effect of a Course of High-Intensity Interval Training on NRG-4, Irisin, Asprosin, and Insulin Resistance in Women with Obesity

Protocol summary

Study aim

The primary objective of this study is to investigate the effect of a period of High-Intensity Interval Training (HIIT) on selected biomarkers (NRG-4, irisin, and asprosin) and insulin resistance in women with obesity.

Design

A randomized controlled clinical trial with two parallel groups was conducted on 24 sedentary women with obesity. Participants were allocated to either a 12-week High-Intensity Interval Training (HIIT) group or a control group using stratified block randomization and sequentially numbered opaque sealed envelopes. The study was an open-label (non-blinded) phase II trial.

Settings and conduct

This study will be conducted at the Health and Sports Research Center in Ilam. Following initial assessments, the exercise group will perform a 12-week HIIT protocol under direct supervision. The control group will only be monitored and will not receive any exercise intervention.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having a body mass index (BMI) ≥ 30 kg/m²; being physically inactive for at least the past 6 months; and providing written informed consent to participate in all stages of the study. Exclusion Criteria: Systolic blood pressure >140 / 90 mmHg; use of medications affecting body weight, glucose metabolism, inflammation, or cardiovascular function; and any orthopedic, joint, or muscular problem that limits or contraindicates participation in high-intensity exercise.

Intervention groups

Intervention (HIIT) Group: Participants will complete a 12-week supervised HIIT program (3 sessions/week), consisting of alternating high-intensity intervals (85-95% of max heart rate) with low-intensity recovery periods. Control Group: Participants will maintain their usual physical activity levels and will not receive any structured exercise intervention during the study period.

Main outcome variables

NRG-4؛Irisin؛Asprosin؛HOMA-IR

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251211068287N3**
Registration date: **2026-02-11, 1404/11/22**
Registration timing: **prospective**

Last update: **2026-02-11, 1404/11/22**
Update count: **0**

Registration date

2026-02-11, 1404/11/22

Registrant information

Name

najmeh rezaeinezhad

Name of organization / entity

University of tehran

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-20, 1404/12/01

Expected recruitment end date

2026-02-26, 1404/12/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of a Course of High-Intensity Interval Training on NRG-4, Irisin, Asprosin, and Insulin Resistance in Women with Obesity

Public title
The Effect of Interval Training on Women with Obesity

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having a sedentary lifestyle (defined by IPAQ criteria) for a minimum of 6 months prior to the study Having a Body Mass Index (BMI) ≥ 30 kg/m² Signing an informed consent form to participate in the study.

Exclusion criteria:
Any pre-existing musculoskeletal condition that could limit the ability to perform intense physical training. Use of medications affecting weight, glucose metabolism, or inflammation (such as corticosteroids, anti-obesity drugs, insulin, metformin, etc.) in the past 3 months. History of cardiovascular disease, or uncontrolled hypertension (e.g., systolic blood pressure >140 or diastolic blood pressure >90 mmHg).

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants, after completing baseline assessments, were assigned to either the exercise or control group using a stratified block randomization method via sequentially numbered, opaque, sealed envelopes. This process was administered by an independent coordinator, with outcome assessors being blinded to group allocation

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 Committees of Ilam University

Street address
Ilam, Boulevard-e Pajoohesh, University of Ilam

City
Ilam

Province
Ilam

Postal code
77111-69391

Approval date
2026-02-02, 1404/11/13

Ethics committee reference number
IR.ILAM.REC.1404.46

Health conditions studied

1

Description of health condition studied
Obese Women

ICD-10 code
Z68.53

ICD-10 code description
Body mass index (BMI) pediatric, 85th percentile to less than 95th percentile for age

Primary outcomes

1

Description
Neuregulin-4

Timepoint
Before and after the 12-week exercise intervention

Method of measurement
Enzyme-Linked Immunosorbent Assay (ELISA)

Secondary outcomes

1

Description
Irisin

Timepoint
Before and after the 12-week exercise intervention

Method of measurement
Enzyme-Linked Immunosorbent Assay (ELISA)

2

Description
Asprosin

Timepoint
Before and after the 12-week intervention.

Method of measurement
Enzyme-Linked Immunosorbent Assay (ELISA)

3

Description
Insulin Resistance

Timepoint
Before and after the 12-week intervention.
Method of measurement
Enzyme-Linked Immunosorbent Assay (ELISA)

Intervention groups

1

Description
Intervention group: High Intensity Interval Training
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Sports Club
Full name of responsible person
Maryam Naghibzadeh
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Ilam, Pajoohesh Boulevard, University of Ilam
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ilam University
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
Ilam University
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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
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Kamran Taherpour
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Person responsible for updating data

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Other areas of specialty/work
Exercise physiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Maintaining their confidentiality and privacy

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available