Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of Eight Weeks of High-Intensity Interval Training on Inflammatory Markers in Women with Non-Alcoholic Fatty Liver Disease: A Randomized Controlled Trial

Protocol summary

Study aim

This study aimed to evaluate the effects of eight weeks of High-Intensity Interval Training on inflammatory markers including C-Reactive Protein, Interleukin 6, and Cortisol, liver function, anthropometric measures including weight, body mass index, and waist-to-hip ratio, and insulin sensitivity in overweight and obese women with Non-Alcoholic Fatty Liver Disease

Design

This randomized trial included 26 women with Non-Alcoholic Fatty Liver Disease confirmed by sonography, assigned using a closed-envelope method to a control group or an exercise intervention group performing (High-Intensity Interval Training).

Settings and conduct

The study will be conducted as an interventional trial at the gymnasium of Razi University in Kermanshah. All exercises will be supervised by the research team and an experienced trainer, performed in controlled environments with safety standards and accurate evaluation. The intervention will last eight weeks, and assessments will be conducted 48 hours before and after the intervention.

Participants/Inclusion and exclusion criteria

The study included 26 overweight and obese women aged 30 to 50 years, randomly assigned to exercise and control groups. Inclusion criteria were female sex, age 30–50 years, residence in Kermanshah, and body mass index between 25 and 35. Exclusion criteria were regular physical activity in the past three months, physical or musculoskeletal disabilities, use of liver-related or metabolic medications, and severe cardiovascular, pulmonary, renal, or musculoskeletal diseases.

Intervention groups

The study included two groups: a control group and a High-Intensity Interval Training group.

Main outcome variables

The measured outcomes included C-Reactive Protein ,Interleukin-6, Cortisol, liver enzymes, lipid profile, and body composition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250901067078N1**
Registration date: **2025-09-25, 1404/07/03**
Registration timing: **retrospective**

Last update: **2025-09-25, 1404/07/03**
Update count: **0**

Registration date

2025-09-25, 1404/07/03

Registrant information

Name
Zahra Sohrabi
Name of organization / entity
Razi University of Kermanshah
Country
Iran (Islamic Republic of)
Phone
+98 83 3722 0106
Email address
z.sohrabi@stu.razi.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-24, 1403/07/03

Expected recruitment end date

2024-10-26, 1403/08/05

Actual recruitment start date

2022-09-03, 1401/06/12

Actual recruitment end date

2022-11-11, 1401/08/20

Trial completion date

2022-11-21, 1401/08/30

Scientific title

Effects of Eight Weeks of High-Intensity Interval Training on Inflammatory Markers in Women with Non-Alcoholic Fatty Liver Disease: A Randomized Controlled Trial

Public title

The Effect of High-Intensity Interval Training on Health Indicators in Women with Non-Alcoholic Fatty Liver Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female gender Patients with non-alcoholic fatty liver disease (grade 1 or 2, confirmed by ultrasound and a physician) Overweight or obesity (body mass index between 25 and 35) No history of using liver-related or metabolic medications

Exclusion criteria:

Regular physical activity during the past three months Occurrence of medical problems or sports injuries during the study Presence of specific diseases or use of special medications (cardiovascular, respiratory, renal, metabolic diseases, or cancer) Absence from more than three training sessions

Age

From **30 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **26**

Actual sample size reached: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

For the random allocation of participants to the study groups (Control group and High-Intensity Interval Training group), the sealed envelopes method was used. In this method, a random allocation sequence was first generated using random number software. Each allocation number was then assigned to a specific group (Control group or High-Intensity Interval Training group). These numbers were written on paper and placed into opaque, non-transparent envelopes. The envelopes were arranged completely randomly without any particular order. When each participant entered the study, one of the sealed envelopes was randomly selected and opened. Based on the number inside the envelope, the participant was assigned to one of the two groups. This method was implemented to ensure allocation concealment and to prevent bias from both the researchers and the 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

The ethics committee of Razi University of Kermanshah

Street address

Taq Bostan Street

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Approval date

2022-11-09, 1401/08/18

Ethics committee reference number

IR.RAZI.REC.1401.061

Health conditions studied

1

Description of health condition studied

Non-Alcoholic Fatty Liver Disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Interleukin-6 (IL-6)

Timepoint

Pre- and post-intervention

Method of measurement

Serum interleukin-6 (IL-6) concentration was measured using the Immulite IL-6 kit and an immunochemical method based on the Immulite 2000 system.

2

Description

C-Reactive Protein

Timepoint
Pre- and post-intervention
Method of measurement
C-reactive protein (CRP) levels were measured using the CRP-H917-S kit manufactured by Delta Pars Company and the latex immunoturbidimetric method.

3

Description
Cortisol
Timepoint
Pre- and post-intervention
Method of measurement
Cortisol levels were measured using a fully automatic IMMULITE 2000XPi device. This device employs the electrochemiluminescence chemistry method. The kits used were specifically designed for this device and in accordance with international standards.

Secondary outcomes

1

Description
Body composition
Timepoint
Pre- and post-intervention
Method of measurement
Measurements were performed using scales, a stadiometer, the body mass index (BMI), and a body composition assessment device.

2

Description
Lipid profile
Timepoint
Pre- and post-intervention
Method of measurement
Measurements were performed using the respective kits and automated analyzers.

3

Description
Liver enzymes
Timepoint
Pre- and post-intervention
Method of measurement
Measurements were performed using the respective kits and automated analyzers.

4

Description
Fasting blood insulin
Timepoint
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Method of measurement
Fasting insulin levels were measured using a human insulin enzyme-linked immunosorbent assay (ELISA) kit according to the manufacturer’s instructions

5

Description
Fasting blood glucose
Timepoint
Pre- and post-intervention
Method of measurement
Measurements were performed using a glucose kit and automated analyzers.

6

Description
Maximal aerobic capacity
Timepoint
Pre- and post-intervention
Method of measurement
Shuttle Run Test

Intervention groups

1

Description
Control group:The control group did not receive any exercise or training intervention and continued their usual daily activities
Category
N/A

2

Description
Intervention group: The intervention group will perform High-Intensity Interval Training, consisting of aerobic exercises. Sessions will be held three days per week, each lasting 45 minutes, including 5 minutes of warm-up, 30 minutes of high-intensity intervals, and 10 minutes of cool-down. All sessions will be supervised by an experienced trainer and the research team at Razi University gym, with intensity adjusted according to each participant's maximum heart rate.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sports hall of the Faculty of Social Sciences, Razi University
Full name of responsible person
Zahra Sohrabi
Street address
Faculty of Social Sciences, Shahid Beheshti Boulevard, Opposite Taleghani Hospital
City
Kermanshah
Province
Kermanshah
Postal code

6714673175

Phone
+98 83 3836 1370

Email
Zsohrabi635@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research and Technology, Razi University

Full name of responsible person
Keyvan Amini

Street address
Taq Bostan Street

City
Kermanshah

Province
Kermanshah

Postal code
6714414971

Phone
+98 83 3427 7605

Email
info@razi.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for Research and Technology, Razi University

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
Razi University of Kermanshah

Full name of responsible person
Amir Abbas Monazami

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

Street address
Taq Bostan Street

City
Kermanshah

Province
Kermanshah

Postal code
6714414971

Phone
+98 83 3427 7605

Email
MONAZZAMI.AMIRABBAS@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Razi University of Kermanshah

Full name of responsible person
Amir Abbas Monazami

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

Street address
Taq Bostan Street

City
Kermanshah

Province
Kermanshah

Postal code
6714414971

Phone
+98 83 3427 7605

Email
MONAZZAMI.AMIRABBAS@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Razi University of Kermanshah

Full name of responsible person
Zahra Sohrabi

Position
Coach

Latest degree
Bachelor

Other areas of specialty/work
Physiology

Street address
Mosvari Street

City
Kermanshah

Province
Kermanshah

Postal code
6713718699

Phone
+98 83 3722 0106

Email
zsohrabi635@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
Personal data of study participants can be shared after removing identifying information.
When the data will become available and for how long
The access period will begin 6 months after the results are published.
To whom data/document is available
The data will be available only to researchers affiliated with academic and scientific institutions.
Under which criteria data/document could be used
The use of data is permitted only for conducting similar scientific research and must not be used for the personal interests of specific individuals or groups.
From where data/document is obtainable
Zahra Sohrabi, Amir Abbas Monazami
What processes are involved for a request to access data/document
The request should be sent to the provided email address; the applicant's request will be reviewed, and the data will be sent within 5–7 days if the conditions are deemed satisfactory.
Comments