Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of 8 Weeks of High-Intensity Interval Training (HIIT) and Apple Cider Vinegar Consumption on Liver Enzyme Levels in Overweight Women

Protocol summary

Study aim
To investigate the effect of 8-week high-intensity interval training (HIIT) combined with apple cider vinegar consumption on liver enzyme levels in overweight women.

Design
This study is a randomized, four-group, single-blind, parallel quasi-experimental study with a pretest–posttest design. A total of 40 participants were randomly assigned to four groups using sealed, opaque envelopes.

Settings and conduct
This study will be conducted at Farhangian Clinic, Bushehr, Iran. Forty overweight women will be selected via convenience sampling and randomly assigned to four groups after baseline assessment. Outcome assessors and participants will be blinded. Exercise sessions will be supervised by the researcher, and blood analyses will be performed in a certified laboratory.

Participants/Inclusion and exclusion criteria
Participants will be selected based on predefined eligibility criteria. Inclusion criteria include women aged 21–29 years with a body mass index of 25–29.9 kg/m², stable body weight, no recent use of supplements or liver-affecting medications, no history of major chronic diseases, and medical clearance for moderate-to-vigorous physical activity. Exclusion criteria include poor adherence to the intervention, missing training sessions, occurrence of injury or medical conditions preventing continuation, and failure to complete post-intervention assessments or blood sampling.

Intervention groups
Participants will be assigned to four groups: HIIT, apple cider vinegar, combined HIIT plus apple cider vinegar, and control. The HIIT group will perform an 8-week training program (3 sessions/week, 20 minutes per session). The apple cider vinegar group will consume 10 mL daily diluted in water for 8 weeks. The combined group will receive both interventions, while the control group will receive a placebo and maintain usual daily activities.

Main outcome variables
Levels of liver enzymes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251121068065N7**
Registration date: **2026-06-21, 1405/03/31**
Registration timing: **prospective**

Last update: **2026-06-21, 1405/03/31**
Update count: **0**

Registration date
2026-06-21, 1405/03/31

Registrant information
Name
kavoushgaran kavoushgaran
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 915 718 4680
Email address
atiye.hesary@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-07-11, 1405/04/20

Expected recruitment end date
2026-10-07, 1405/07/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of 8 Weeks of High-Intensity Interval Training (HIIT) and Apple Cider Vinegar Consumption on Liver Enzyme Levels in Overweight Women

Public title

The Effect of 8 Weeks of High-Intensity Interval Training (HIIT) and Apple Cider Vinegar Consumption on Liver Enzyme Levels in Overweight Women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 21–29 years. Body mass index (BMI) between 25 and 29.9 kg/m². Residents of Bushehr. Stable body weight during the past 6 months. Stable body weight during the past 6 months. No use of nutritional supplements or drugs affecting liver function in the last 6 months. No history of chronic diseases (e.g., diabetes, cardiovascular, renal, or hepatic diseases). Ability to perform moderate-to-vigorous physical activity based on physician approval and fitness assessment.

Exclusion criteria:

Absence from more than two training sessions. Non-adherence to supplement or placebo regimen. Occurrence of injury or medical condition preventing continuation of the study. Failure to attend post-test assessment or final blood sampling.

Age

From **21 years** old to **29 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

After baseline assessment, participants will be randomly allocated to four groups (HIIT, apple cider vinegar, HIIT plus apple cider vinegar, and control) using a simple randomization method based on a random number table. The allocation sequence will be prepared in advance, and group assignment will be implemented using sequentially numbered, sealed, opaque envelopes to ensure allocation concealment. After enrollment, each participant will be assigned to a group by opening the next available envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is single-blind. Outcome assessors will be blinded to group allocation throughout the study. Participants will also be blinded to the study hypothesis and the comparative objectives of the intervention, while the researchers involved in the intervention delivery will not be blinded due to the nature of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Bushehr University of Medical Sciences

Street address

Bushehr University of Medical Sciences, Cinema Street, Bushehr.

City

Bushehr

Province

Boushehr

Postal code

7518759577

Approval date

2025-09-28, 1404/07/06

Ethics committee reference number

IR.BPUMS.REC.1404.293

Health conditions studied

1

Description of health condition studied

Overweight (Overweight in women)

ICD-10 code

E66.3

ICD-10 code description

Overweight

Primary outcomes

1

Description

Serum alanine aminotransferase (ALT) level

Timepoint

Alanine aminotransferase levels will be assessed at two time points: (1) baseline (before the intervention) and (2) forty-eight hours after completion of the 8-week intervention period.

Method of measurement

Fasting venous blood samples will be collected between 7:00 and 8:00 a.m. A 5 mL blood sample will be drawn from the cubital vein of the left arm by a trained nurse at

each time point. Samples will be allowed to clot at room temperature for 20 minutes, then centrifuged for 10 minutes at 3000–3500 rpm. The separated serum will be aliquoted into microtubes and stored at −80°C. Serum alanine aminotransferase levels will be measured using commercial diagnostic kits (Pars Azmoun, Iran) with a sensitivity of 2–4 IU/L and analyzed by an autoanalyzer using the photometric method.

2

Description
Serum aspartate aminotransferase (AST) level
Timepoint
Aspartate aminotransferase levels will be assessed at two time points: (1) baseline (before the intervention) and (2) forty-eight hours after completion of the 8-week intervention period.
Method of measurement
Fasting venous blood samples will be collected between 7:00 and 8:00 a.m. A 5 mL blood sample will be drawn from the cubital vein of the left arm by a trained nurse at each time point. Samples will be allowed to clot at room temperature for 20 minutes, then centrifuged for 10 minutes at 3000–3500 rpm. The separated serum will be aliquoted into microtubes and stored at −80°C. Serum aspartate aminotransferase levels will be measured using commercial diagnostic kits (Pars Azmoun, Iran) with a sensitivity of 2–4 IU/L and analyzed by an autoanalyzer using the photometric method.

3

Description
Serum alkaline phosphatase (ALP) level
Timepoint
Serum alkaline phosphatase (ALP) level will be assessed at two time points: (1) baseline (before the intervention) and (2) forty-eight hours after completion of the 8-week intervention period.
Method of measurement
Fasting venous blood samples will be collected between 7:00 and 8:00 a.m. A 5 mL blood sample will be drawn from the cubital vein of the left arm by a trained nurse at each time point. Samples will be allowed to clot at room temperature for 20 minutes, then centrifuged for 10 minutes at 3000–3500 rpm. The separated serum will be aliquoted into microtubes and stored at −80°C. Serum alkaline phosphatase (ALP) levels will be measured using commercial diagnostic kits (Pars Azmoun, Iran) with a sensitivity of 2–4 IU/L and analyzed by an autoanalyzer using the photometric method.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: The control group will receive a placebo solution similar in appearance and taste and will not participate in a structured exercise program, maintaining their usual daily activities.
Category
Treatment - Other

2

Description
Intervention group: The first intervention group will perform an 8-week high-intensity interval training program, three sessions per week, with each 20-minute session including warm-up, repeated high-intensity intervals (90–95% HRpeak) interspersed with recovery periods, and cool-down. The subjects' heart rate will be monitored using a Polar heart rate monitor.
Category
Treatment - Other

3

Description
Intervention group: The second intervention group will receive daily intake of 10 mL apple cider vinegar (5% acetic acid) diluted in 250 mL water for 8 weeks.
Category
Treatment - Other

4

Description
Intervention group: The third group will receive a combination of an 8-week high-intensity interval training program and daily consumption of 10 mL of apple cider vinegar.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Farhangian Clinic
Full name of responsible person
Dr. Mollahzadeh
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Shahid Avini Corner, Shahid Ashouri Street, Farhangian Clinic, Bushehr.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Roohollah Ershadi
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Velayat Building (Islamic Azad University, Bushehr Branch), Beginning of Shahid Raees Ali Delvari Boulevard, Municipality Square, Bushehr, Iran
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Boushehr
Postal code
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Phone
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Email
info@bushehr.iau.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University, Bushehr Branch
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
Islamic Azad University, Bushehr Branch
Full name of responsible person
Dr. Elham Dehghan
Position
Assistant Professor
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Person responsible for updating data

Contact
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Master's student
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Bachelor
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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