Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Sep 2026

High-Intensity Functional Training Combined with Hibiscus sabdariffa Supplementation Improves Cardiovascular Risk Factors in Overweight and Obese Men: A Randomized Controlled Trial

Protocol summary

Study aim

The aim of this study is to evaluate the combined effects of high-intensity functional training (HIFT) and Hibiscus sabdariffa on reducing cardiovascular risk factors such as blood pressure, lipid profile, and inflammation markers in overweight and obese men aged 20 to 25 years.

Design

This is a randomized, double-blind, parallel clinical trial that evaluates the combined effects of high-intensity functional training (HIFT) and Hibiscus sabdariffa on cardiovascular risk factors in overweight and obese men. Randomization will be performed using a random number table.

Settings and conduct

This study will be conducted at the Health Research Center of islamic azad university shahrekord branch . All interventions will be performed in a controlled environment with the use of intervention and control groups. Participants will be randomly allocated to different groups, and randomization and blinding will be used to prevent bias.

Participants/Inclusion and exclusion criteria

Men aged 20 to 25 years Body mass index (BMI) between 25 and 35 kg/m² No history of regular physical activity in the past 12 months No medical conditions that prevent participation in intense physical activity

Intervention groups

This study includes four groups: the HIFT group, the Hibiscus sabdariffa group, the combined HIFT and Hibiscus sabdariffa group, and the control group. Each group receives a specific intervention.

Main outcome variables

The primary outcomes of this study include reduction in blood pressure, improvement in lipid profile (LDL, HDL, total cholesterol, and triglycerides), and reduction in inflammation markers (CRP) in each of the intervention groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241205063953N1**
Registration date: **2025-01-08, 1403/10/19**
Registration timing: **retrospective**

Last update: **2025-01-08, 1403/10/19**
Update count: **0**

Registration date

2025-01-08, 1403/10/19

Registrant information

Name

akram jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 547 9267

Email address

jafari.akm@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-20, 1403/05/30

Expected recruitment end date

2024-11-20, 1403/08/30

Actual recruitment start date

2024-11-20, 1403/08/30

Actual recruitment end date

2024-11-20, 1403/08/30

Trial completion date

2024-11-20, 1403/08/30

Scientific title
High-Intensity Functional Training Combined with Hibiscus sabdariffa Supplementation Improves Cardiovascular Risk Factors in Overweight and Obese Men: A Randomized Controlled Trial

Public title
High-Intensity Functional Training Combined with Hibiscus sabdariffa Supplementation and Cardiovascular Risk Factors

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Men aged 20-25 years with a body mass index (BMI) between 25 and 35 kg/m² No history of regular physical activity in the past 12 months No medical conditions contraindicating intense physical activity (e.g., heart diseases) Willingness to participate in the study and sign an informed consent form

Exclusion criteria:
Individuals allergic to Hibiscus sabdariffa Use of antioxidant drugs or supplements within the past three months

Age
From **20 years** old to **25 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, participants are randomly assigned to different groups, with each group receiving a specific intervention (Hibiscus tea, HIFT, or a combination of both). Random allocation will be performed using a random number table to prevent bias in group assignment.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, blinding was implemented as follows: Participant allocation to groups was performed by an independent statistician using a computer-generated randomization list, and study groups were assigned unique codes. The supplement and placebo capsules, identical in appearance, size, and color, were manufactured by a pharmaceutical company. The labeling of these capsules was conducted by a person unrelated to the study's execution. Participants were unaware of the capsule contents, and the research team, including coaches and outcome assessors, had no access to group allocation information. These measures ensured that any potential bias in data collection or outcome evaluation was minimized.

Placebo
Used

Assignment
Parallel

Other design features
Four groups (HIFT, Hibiscus sabdariffa, combined, and control) are evaluated. HIFT sessions and daily Hibiscus sabdariffa supplementation are administered for 12 weeks.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Islamic Azad University Shahrekord branch

Street address
Rahmatieh- Islamic Azad University Shahrekord Branch

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8817630003

Approval date
2022-04-20, 1401/01/31

Ethics committee reference number
IR.IAU.SHK.REC.1401.021

Health conditions studied

1

Description of health condition studied
Cardiovascular risk factors (Obesity, Hypertension, Dyslipidemia)

ICD-10 code
E66

ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
blood pressure

Timepoint
At baseline (pre-intervention) and after 12 weeks (post-intervention)

Method of measurement
using a mercury sphygmomanometer

2

Description
Lipid Profile: total cholesterol, LDL, HDL, and triglycerides
Timepoint
At baseline (pre-intervention) and after 12 weeks (post-intervention)
Method of measurement
Blood tests using enzymatic methods for total cholesterol, LDL, HDL, and triglycerides

3

Description
CRP
Timepoint
At baseline (pre-intervention) and after 12 weeks (post-intervention)
Method of measurement
Measured using the ELISA method

4

Description
Anthropometric Variables: weight, body mass index (BMI), and body fat percentage
Timepoint
At baseline (pre-intervention) and after 12 weeks (post-intervention)
Method of measurement
Weight: Measured using a digital scale - BMI: Calculated using the formula weight (kg) divided by height (m) squared - Body Fat Percentage: Measured using a Bioelectrical Impedance Analysis (BIA) device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, participants undergo a high-intensity functional training (HIFT) program for 12 weeks. The program consists of three sessions per week, each lasting 45 minutes. The training includes multi-joint movements such as squats, jumps, and resistance exercises targeting the major muscle groups of the body.
Category
N/A

2

Description
Intervention group: In this group, participants consume 450 mg of Hibiscus sabdariffa daily for 12 weeks. The Hibiscus sabdariffa capsules are made from the dried extract of Hibiscus flowers, with each capsule containing 450 mg of the extract.
Category
N/A

3

Description
Intervention group: In this group, participants receive both the high-intensity functional training (HIFT) program and daily supplementation of 450 mg of Hibiscus sabdariffa for 12 weeks.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Islamic Azad University Shahrekord Branch
Full name of responsible person
Ebrahim Rahimi
Street address
Rahmatieh- Islamic Azad University Shahrekord Branch
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8817830003
Phone
+98 38 3336 1001
Email
jafari.akm@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Ebrahim Rahimi
Street address
Rahmatieh- Islamic Azad University Shahrekord Branch
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8817630003
Phone
+98 38 3336 1001
Email
jafari.akm@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Islamic Azad 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
Islamic Azad University
Full name of responsible person
Akram Jafari
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport Medicine
Street address
Rahmatieh- Islamic Azad University Shahrekord Branch
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8817630003
Phone
+98 383361001
Email
jafari.akm@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Akram Jafari
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport Medicine
Street address
Rahmatieh- Islamic Azad University Shahrekord Branch
City
Shahrekord
Province
Chahar Mahaal and Bakhtia
Postal code
8817630003
Phone
+98 38 3336 1001
Email
jafari.akm@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Akram Jafari
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport Medicine
Street address
Rahmatieh- Islamic Azad University Shahrekord Branch
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8817830003
Phone
0098383361001
Email
jafari.shku@yahoo.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
Document Title: Anthropometric data, lipid profile, blood pressure, and inflammation markers (CRP) Further Details: Individual participant data will be shared after de-identification. These data include information related to primary outcomes (weight, BMI, lipid profile, blood pressure, and CRP) and will be available as a dataset for further analysis
When the data will become available and for how long

Access to the data will be available for a period of 6 months following the publication of the study results

To whom data/document is available

Data and documents will be accessible only to academic and scientific researchers working in the health field. Industry professionals involved in health-related research may also request access to the data

Under which criteria data/document could be used

The data and documents are available for scientific and health-related research purposes. Data access requests must include a clear objective for using the data. Commercial use or use outside the scientific framework is not permitted. Access to the data will be granted only after review and approval of the request

From where data/document is obtainable

To request data and documents, please contact the research manager: Name: Akram Jafari Email: Jafari.skm@gmail.com

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

Requests for data access should be submitted to the provided email address. After reviewing the request, an approval confirmation will be sent to the requester, and the data will be shared via a secure link or in digital file format. This process typically takes 2 to 4 weeks.

Comments