

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of the Effectiveness of eight weeks of Moderate-Intensity Interval Training With and without spirulina supplementation in Control of Monocyte Chemoattractant Inflammatory Protein-1, Interleukin-10, and lipid profile of overweight women

Protocol summary

Study aim

Comparison of the Effectiveness of eight weeks of Moderate-Intensity Interval Training With and without spirulina supplementation in Control of Monocyte Chemoattractant Inflammatory Protein-1, Interleukin-10, and lipid profile of overweight women

Design

Clinical trial involving three groups: the moderate-intensity interval training group with spirulina supplementation (n = 15) and the moderate-intensity interval training with placebo (n = 15). This is a single-blind, randomized trial.

Settings and conduct

This single-blinded clinical study aims to investigate overweight women in Mashhad. Thirty participants from local sports clubs will be randomly divided into two groups of 15: one receiving moderate-intensity interval training with spirulina and the other with a placebo. Participants won't know if they're getting spirulina or placebo.

Participants/Inclusion and exclusion criteria

Inactivity among women aged 30-35 years, with general physical and mental health and a body mass index greater than 25 kg/m², is the focus of this study. Exclusion criteria include the presence of any physical or orthopedic lesions that interfere with exercise performance or hinder the ability to perform quality exercises.

Intervention groups

Participants in this group will take two 500 mg spirulina capsules daily for eight weeks, provided by Reyhaneh Isfahan Pharmaceutical Company. They'll also perform moderate-intensity interval training for eight weeks (3 sessions/week, 20-40 minutes/session), gradually increasing intensity from 60-65% to 75-80% of maximum heart rate. All training will occur at Mashhad District 3

Municipality Hall.

Main outcome variables

monocyte chemoattractant inflammatory protein-1, interleukin-10, and lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120129008863N11**

Registration date: **2025-07-05, 1404/04/14**

Registration timing: **prospective**

Last update: **2025-07-05, 1404/04/14**

Update count: **0**

Registration date

2025-07-05, 1404/04/14

Registrant information

Name

Keyvan Hejazi

Name of organization / entity

Ferdowsi University of Mashhad

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-07, 1404/04/16

Expected recruitment end date

2025-09-07, 1404/06/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of eight weeks of Moderate-Intensity Interval Training With and without spirulina supplementation in Control of Monocyte Chemoattractant Inflammatory Protein-1, Interleukin-10, and lipid profile of overweight women

Public title

Comparison of the Effectiveness of Moderate-Intensity Interval Training With and without spirulina supplementation in Control of monocyte chemoattractant inflammatory proteins-1

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Inactive Female, aged 30 to 35 In good general physical and mental health Body mass index greater than 25 kg/m²

Exclusion criteria:

Any physical injury or orthopedic issue that interferes with training can hinder its quality.

Age

From **30 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

En This study will employ a simple randomization method. Participants will be randomly assigned to two groups: one intervention group that will engage in moderate-intensity interval training with spirulina supplementation and one group that will engage in moderate-intensity interval training with a placebo. Randomization will occur at the individual level, with each of the 30 participants allocated to one of the two groups. A computerized sequence will be used for this random assignment, ensuring high precision and reproducibility while minimizing selection bias.

Blinding (investigator's opinion)

Single blinded

Blinding description

The present study is a single-blind clinical trial. The single-blinding applies to the spirulina and placebo. Participants will review the research protocol during their

first session. Both the supplement and the placebo are contained in identical capsules. These capsules will be distributed among the participants. Only the researcher will know the contents of the capsules.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Hakim Sabzevari University

Street address

Hakim Sabzevari University, Tohid Shahr, Sabzevar; Department of Sport Sciences

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617976487

Approval date

2025-06-28, 1404/04/07

Ethics committee reference number

IR.HSU.REC.1404.009

Health conditions studied**1****Description of health condition studied**

Overweight and obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes**1****Description**

Monocyte chemoattractant inflammatory proteins-1

Timepoint

Before the intervention and two months following it

Method of measurement

zellBio kit (mmol/l)

2**Description**

interleukin-10

Timepoint

Before the intervention and two months following it

Method of measurement

zellBio kit (mmol/l)

3

Description

Triglyceride

Timepoint

Before the intervention and two months following it

Method of measurement

ParsAzmon Kit (mg/dl)

4

Description

Total Cholesterol

Timepoint

Before the intervention and two months following it

Method of measurement

ParsAzmon Kit (mg/dl)

5

Description

Low lipoprotein

Timepoint

Before the intervention and two months following it

Method of measurement

ParsAzmon Kit (mg/dl)

6

Description

High-lipoprotein

Timepoint

Before the intervention and two months following it

Method of measurement

ParsAzmon Kit (mg/dl)

Secondary outcomes

1

Description

Body Mass Index (BMI) Kg/m²

Timepoint

Before the intervention and two months following it

Method of measurement

The body mass (kg) divided by the square of the body height (cm)

Intervention groups

1

Description

In this group, participants will take two 500 mg spirulina capsules daily (morning and evening) for eight weeks. Reyhaneh Isfahan Pharmaceutical Company is providing the spirulina supplement. Participants will engage in moderate-intensity interval training for eight weeks, with

three sessions per week. Each session will last 20 to 40 minutes. The exercise intensity will start at 60-65% of maximum heart rate in the first week and progressively increase to 75-80% of maximum heart rate by the eighth week. The timing pattern and an additional training principle will be implemented at the Mashhad District 3 Municipality Hall.

Category

Rehabilitation

2

Description

Control group: In this group, participants will consume two 500 mg starch capsules daily for eight weeks. The placebo will be provided by Reyhaneh Isfahan Pharmaceutical Company. Participants will engage in resistance training for eight weeks, with three sessions per week. Each session will last 20 to 40 minutes. The exercise intensity will start at 60-65% of maximum heart rate in the first week and progressively increase to 75-80% of maximum heart rate by the eighth week. The timing pattern and an additional training principle will be implemented at the Mashhad District 3 Municipality Hall.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hakim Sabzevari University

Full name of responsible person

Dr. Keyvan Hejazi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hakim Sabzevari University

Full name of responsible person

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Street address

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Hakim Sabzevari 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**

Hakim Sabzevari University

Full name of responsible person

Dr. Keyvan Hejazi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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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

All data, including the IPD, study protocol, statistical

analysis map, informed consent form, clinical study report, and data dictionary, will be published upon completion of the study. This data will be made available in a valid journal article format.

When the data will become available and for how long

Data will be accessible immediately upon project completion, likely in 1404.

To whom data/document is available

This is intended for researchers at academic and

scientific

Under which criteria data/document could be used

Institutions to support the development of related sciences.

From where data/document is obtainable

Refer to Hakim Sabzevari University

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

Please submit a valid letter from the scientific centers.

Comments