Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of 12 weeks of high-intensity functional training (HIFT) and Ginkgo biloba consumption on serum levels of inflammatory indicators, antioxidant defense and physical performance in Yazd firefighters.

Protocol summary

Study aim

The general purpose of this study is to investigate the effect of 12 weeks of HIFT and Ginkgo biloba consumption on the serum levels of inflammatory indicators, antioxidant defense and physical performance in Yazd firefighters.

Design

Factorial randomized controlled trial with single-blind treatments on 48 firefighters

Settings and conduct

The current research is a factorial type. It will be done in 2*2 format. Two factors with two levels that will be implemented in four groups. The exercise factor (exercise vs. non-exercise) and the supplement factor (supplement consumption vs. non-supplement consumption) will be implemented as a pre-test and post-test in Yazd city. The data will be collected by laboratory and field method.

Participants/Inclusion and exclusion criteria

The inclusion criteria are: age group 25 to 50 years old, operational post, fire fighting experience of at least 3 years, not taking special and dietary supplements, not having clinical physiological and metabolic diseases. The exclusion criteria are: suffering from certain diseases, consumption of sports and diet supplements during one year before the study, age less than 25 years and more than 50 years, fire fighting experience less than 3 years.

Intervention groups

1. High Intensity Functional Training (HIFT) . 2 HIFT with Ginkgo Biloba 3. Ginkgo Biloba 4. Control

Main outcome variables

Reduction of inflammatory indicators; Increase of antioxidant enzymes; Increasing aerobic fitness, Improving body composition.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230919059465N1**
Registration date: **2024-02-17, 1402/11/28**
Registration timing: **prospective**

Last update: **2024-02-17, 1402/11/28**
Update count: **0**

Registration date

2024-02-17, 1402/11/28

Registrant information

Name

Hamid Sedaghat

Name of organization / entity

Islamic Azad University, Khorasgan branch

Country

Iran (Islamic Republic of)

Phone

+98 912 012 2943

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hsedaghat9194@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-05-09, 1403/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 12 weeks of high-intensity functional training (HIFT) and Ginkgo biloba consumption on serum levels of inflammatory indicators, antioxidant defense and physical performance in Yazd firefighters.

Public title

Investigating the effect of 12 weeks of HIFT and Ginkgo biloba consumption on serum levels of inflammatory indicators and antioxidant defense

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

All firefighters who are in the operational line, have more than 3 years of work experience, age range of 25 to 50 years, not suffering from specific physiological and metabolic diseases, not taking special dietary and sports supplements.

Exclusion criteria:

Work experience of less than 3 years, age less than 25 years and more than 50 years, suffering from a disabling disease from participating in training, taking special dietary and sports supplements

Age

From **1382 years** old to **1352 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

In the current research, the randomization method will be performed using the random sequence generation software method. Random allocation software is one of these software's. In addition to simple randomization, random sequence generation software's are capable of generating random sequences by block method. The randomization unit is individual. In the following, the concealment of random allocation is done by using sealed and opaque envelopes in a random sequence, which is called the SNOSE method. Finally, in the process of randomization in the present study, the person involved in creating the randomization program will be separate from other researchers to reduce possible bias.

Blinding (investigator's opinion)

Single blinded

Blinding description

The training place of the participants who are in the four groups will be separate from each other, the participants will not know the type and content of the supplement consumed. The data analyst will be unaware of the type of data that is related to which group and will not know what type of intervention the data is related to.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University of Isfahan, Khorasgan branch

Street address

University Blvd, Arghwanieh, East J Street, Isfahan, IRAN

City

Isfahan

Province

Isfehan

Postal code

8155139998

Approval date

2023-10-31, 1402/08/09

Ethics committee reference number

IR.IAU.KHUISF.REC.1402.297

Health conditions studied

1

Description of health condition studied

Inflammatory status and antioxidant defense

ICD-10 code

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ICD-10 code description

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Primary outcomes

1

Description

Lipocalin-2

Timepoint

Two stages: before the start of the study and after the end of 12 weeks of interference.

Method of measurement

Valid and standard lipocalin-2 laboratory kit

2

Description

Interleukin-8 (IL-8)

Timepoint

Two stages: before the start of the study and after the

end of 12 weeks of intervention

Method of measurement

Valid and standard IL-8 laboratory kit

3

Description

Interleukin-1beta (IL-1β)

Timepoint

Two stages: before the start of the study and after the end of 12 weeks of intervention

Method of measurement

Valid and standard IL-1β laboratory kit

4

Description

Superoxide desmutase (SOD)

Timepoint

Two stages: before the start of the study and after the end of 12 weeks of intervention

Method of measurement

Valid and standard SOD laboratory kit

5

Description

Catalase (CAT)

Timepoint

Two stages: before the start of the study and after the end of 12 weeks of intervention

Method of measurement

Valid and standard CAT laboratory kit

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention: consists of performing high-intensity functional training (HIFT). The subjects of this intervention (12 people) perform HIFT exercises for 12 weeks and 4 sessions per week based on the principle of overload.. HIFT is a combination of aerobic and resistance training. Aerobic exercise will be performed with an intensity of 60 to 85% of the target heart rate. Resistance training will be performed with 70 to 90% of a maximum repetition. 48 hours before the start of the first training session, the subjects will go to a gym equipped with standard sports equipment to measure anthropometric characteristics, physical and physiological composition. Blood sampling will be done 24 hours before the first training session.

Category

Other

2

Description

The second intervention: consists of performing high-intensity functional training (HIFT) with Ginkgo biloba supplement (80 mg).The subjects of this intervention (12 people) will perform HIFT exercises for 12 weeks and 4 sessions per week based on the principle of overload and will receive Ginkgo biloba (80 mg) in the form of two capsules once a day along with training. Aerobic exercise will be performed with an intensity of 60 to 85% of the target heart rate. Resistance training will be performed with 70 to 90% of a maximum repetition. 48 hours before the start of the first training session, the subjects will go to a gym equipped with standard sports equipment to measure anthropometric characteristics, physical and physiological composition. Blood sampling will be done 24 hours before the first training session.

Category

Other

3

Description

The third intervention: Ginkgo biloba supplement (80 mg). The subjects of this intervention (12 people) will receive gincobiloba supplement (80 mg) on Saturday, Sunday, Tuesday and Wednesday in the form of two capsules per day for 12 weeks. Ginkgo biloba capsule contains 80 mg of standard Ginkgo biloba, including 19.2 mg of flavonoid glycoside (24%), 4.8 mg of terpene lactone (6%) and other substrates such as maltodextrin, microcrystalline cellulose and magnesium stearate.

Category

Other

4

Description

Control :The control group (12 people) does not participate in any intervention and performs its normal daily activities during the study (12 weeks). They will not participate in training programs and physical activities and will follow their normal daily diet. The placebo capsule will also contain microcrystalline cellulose, magnesium stearate and maltodextrin, which will be supplied in the same form and color as the supplement.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fire and Safety Services Organization of Yazd Municipality

Full name of responsible person

Hamid Sedaghat

Street address

Fire Department and Safety Services Organization of Yazd Municipality, Sultanpanah Square, Yazd, IRAN

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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?
No
Title of funding source
Isfahan, Islamic Azad University, Khorasgan branch
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
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Hamid Sedaghat
Position
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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