

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of eight weeks intense interval training (HIIT) with white tea on inflammatory indices, oxidative stress and muscle damage in overweight and obesity men

Protocol summary

Study aim

The general purpose of this research is to determine the effect of eight weeks of intense interval training with white tea on inflammatory indicators, oxidative stress and muscle damage in men. He is overweight and obese.

Design

This research is applied in terms of goals and semi-experimental in terms of controlling research variables. Also, three groups (HIIT training group, white tea group and HIIT training group with white tea) will be randomly assigned in three groups of 12 people.

Settings and conduct

The statistical population of this study will be healthy middle-aged men aged 40 to 55 years old with overweight and obesity (BMI: 28-35 kg/m²) who are covered by health center number 6 of Urmia city, West Azarbaijan province. Subjects are homogenized based on body mass index, fat percentage and diet. After completing the consent form to participate in the research, health questionnaire, physical activity and 24-hour food diary and three-day record of food intake and making the necessary coordination with them, he helped in the process of assimilation of data and according to the plan for 10 weeks under the supervision of the researcher. They will start a HIIT training program and use white tea.

Participants/Inclusion and exclusion criteria

Not having any chronic diseases such as metabolic syndrome, definite heart disease and hospitalization or congenital history, no history of food allergy, use of drugs affecting inflammatory indicators, oxidative stress and muscle damage in the study

Intervention groups

Three groups (HIIT training group, white tea group and HIIT training group with white tea) will be randomly assigned in three groups of 12 people.

Main outcome variables

HIIT intense interval training; White tea; creatine kinase CK enzyme; LDH lactate dehydrogenase enzyme; interleukin-6 (IL-6); tumor necrosis factor-alpha (TNF-a); Malondialdehyde (MDA)

General information

Reason for update

Acronym

Tabriz HIIT & White Tea Study

IRCT registration information

IRCT registration number: **IRCT20230228057569N1**

Registration date: **2023-12-24, 1402/10/03**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-24, 1402/10/03**

Update count: **0**

Registration date

2023-12-24, 1402/10/03

Registrant information

Name

Mortaza Beirami

Name of organization / entity

The University of Tabriz

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-02-19, 1402/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of eight weeks intense interval training (HIIT) with white tea on inflammatory indices, oxidative stress and muscle damage in overweight and obesity men

Public title

The effect of eight weeks intense interval training (HIIT) with white tea on inflammatory indices, oxidative stress and muscle damage in overweight and obesity men

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Subjects will be selected from people who plan to participate in a sports program for the first time, or those who have been inactive, inactive, or inactive for more than a year. According to the questionnaire, they are medically healthy and do not have any metabolic or other diseases.

Exclusion criteria:

They have not used cigarettes, food supplements and therapeutic drugs in the last 3 months.

Age

From **40 years** old to **55 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

After being informed and invited to participate in the sports plan and among the covered volunteers, after matching in terms of anthropometric characteristics (including fat percentage, body mass index, height and weight), not having any chronic diseases such as metabolic syndrome, disease 36 healthy inactive men with confirmed heart disease and a history of hospitalization or congenital, no history of food allergy, use of drugs affecting inflammatory indicators, oxidative stress and muscle damage, according to the objectives and nature of the research and taking into account previous studies and existing conditions and non-athletes are voluntarily selected from among the men covered by the health center and with the mentioned BMI and randomly assigned to the groups. For random allocation, between 00 and 36 will be our identification numbers. The first number in this domain is placed in group 1, the second number in group 2, the third number in group 3, and so on.

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

Research Ethics Committee of Tabriz University

Street address

Unit 7, Omid Apartment 7, 5 Jannatt Alley, Janet St.,
Matin St., Rodaki St

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West Azarbaijan

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5715653578

Approval date

2023-06-11, 1402/03/21

Ethics committee reference number

IR.TABRIZU.REC.1401.092

Health conditions studied

1

Description of health condition studied

Changes in inflammatory indices, oxidative stress and muscle damage in overweight and obese men

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Changes in inflammatory indices, oxidative stress and muscle damage

Timepoint

Measurement of inflammatory indices, oxidative stress and muscle damage before and after the intervention

Method of measurement

The activity of creatine kinase (CK) and lactate dehydrogenase (LDH) is estimated from the serum sample that was analyzed by ELISA and analyzer. The activity of creatine kinase (CK) and lactate dehydrogenase (LDH) is estimated from the serum sample that was analyzed by ELISA and analyzer. Oxidative stress marker malondialdehyde

(MDA) is expressed by reaction with thiobarbituric acid (TBA).

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: intense interval training group, the whole protocol includes 10 weeks of running training. The first 2 weeks are intended to prepare the participants and the other 8 weeks cover the main course of treatment. The first two weeks start for initial preparation, which is to prepare for heavy training, intense interval training, with an intensity of 50 to 80% of the reserve heart rate. An intense periodic exercise program in the form of running (work) and walking (rest) with 45-second bursts of activity with an intensity of 80 to 90% of the reserve heart rate in the third and fourth weeks and 30-second bursts with an intensity of 90 to 100 The reserve heart rate percentage in the fifth to tenth weeks is considered for three sessions per week.

Category

Lifestyle

2

Description

The second intervention group: white tea group, the groups including white tea should consume bulk Chinese white tea for 10 weeks, three times a day (morning, noon and night) at the same time and one hour before meals. Each serving should include one cup (two grams) of dry white tea in 200 ml of 80 degree water.

Category

Lifestyle

3

Description

The third intervention group: intense interval training group with white tea. the whole protocol includes 10 weeks of running training. The first 2 weeks are intended to prepare the participants and the other 8 weeks cover the main course of treatment. The first two weeks start for initial preparation, which is to prepare for heavy training, intense interval training, with an intensity of 50 to 80% of the reserve heart rate. An intense periodic exercise program in the form of running (work) and walking (rest) with 45-second bursts of activity with an intensity of 80 to 90% of the reserve heart rate in the third and fourth weeks and 30-second bursts with an intensity of 90 to 100 The reserve heart rate percentage in the fifth to tenth weeks is considered for three sessions per week. the groups including white tea should consume bulk Chinese white tea for 10 weeks, three times a day (morning, noon and night) at the same time and one hour before meals. Each serving should include one cup (two grams) of dry white tea in 200 ml of 80

degree water.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Nano Pathobiology Laboratory

Full name of responsible person

Masoum Gholami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Dr. Ramin Amirasan

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4th Floor, Unit 4, Omid Apartment 7, Gannat St. 5, Gannat St., Matin St., At the end of Rudaki St.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iranian academic center for education culture and research

Proportion provided by this source

50

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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Iranian academic center for education culture and research

Full name of responsible person

Morteza Bairami

Position

PhD student

Latest degree

Master

Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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City

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Province

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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