

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The effect of resistance training and sour tea (*Hibiscus sabdariffa*) consumption on leptin and adiponectin adipokines in hypertensive elderly men

Protocol summary

Study aim

The effect of 12 weeks of resistance training and sour tea consumption on body composition variables (weight, waist-to-hip ratio, fat percentage, body mass index), hemodynamic markers (systolic and diastolic blood pressure) and biochemical markers (leptin and adiponectin) is associated with high blood pressure in elderly men.

Design

A clinical trial with a control group, with parallel groups, unblinded, randomized, in four groups: resistance training, sour tea, resistance training + sour tea, control. The research randomizer software (www.randomizer.com) will be used for randomization.

Settings and conduct

The subjects of the resistance training and resistance training+sour tea groups performed the resistance training protocol for 12 weeks (3 days per week). Also, the subjects of the sour tea and resistance exercises + sour tea group will consume sour tea 2 times a day (each time 2 grams in 240 ml of water) for 12 weeks. All sports exercises will be done in the sports club, and Other measurements, such as blood sampling, will be performed in the cardiology clinic under the supervision of a specialist doctor.

Participants/Inclusion and exclusion criteria

Inclusion criteria: male, over 65 years old, suffering from high blood pressure, using controlled blood pressure drugs. Complete the informed consent form. Exclusion: history of cardiovascular surgeries, including balloon surgery, known metabolic and inflammatory diseases, consumption of alcoholic beverages and cigarettes, use of beta blockers, and participation in regular sports activities in the six months leading up to the study.

Intervention groups

Four groups: resistance training, sour tea, resistance training+ sour tea, control

Main outcome variables

Hemodynamic (systolic and diastolic blood pressure), body composition (weight, waist-to-hip ratio, fat percentage, body mass index), and biochemical (adiponectin and leptin) markers.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230131057292N1**

Registration date: **2023-06-19, 1402/03/29**

Registration timing: **prospective**

Last update: **2023-06-19, 1402/03/29**

Update count: **0**

Registration date

2023-06-19, 1402/03/29

Registrant information

Name

Shima Mojtahedi

Name of organization / entity

The University of Tehran

Country

Iran (Islamic Republic of)

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+98 21 6111 8872

Email address

shmojtahedi@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of resistance training and sour tea (Hibiscus sabdariffa) consumption on leptin and adiponectin adipokines in hypertensive elderly men

Public title

Effects of resistance training and sour tea consumption on hypertension

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Men aged between 55 and 70 years Hypertensive Taking hypertension drugs Completion of the informed consent form

Exclusion criteria:

using beta blockers drugs having a history of heart surgery suffering from metabolic diseases alcohol participating in regular physical activities in the six months before the time of the study smoking suffering from inflammatory diseases

Age

From **65 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, subjects are selected by Simple randomization by the random allocation rule. After determining the sample size, they will be equally divided into 4 groups. Using the lottery method, the names of the subjects are written on separate papers and placed in a container, then the names of the subjects are randomly taken out and placed in the intervention groups or placebo, respectively.

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

Ethics Committee in Research, Faculty of Physical Education and Sports Sciences, University of Tehra

Street address

Faculty of Physical Education and Sport Sciences, between 15th and 16th St., North Kargar st., Tehran, Islamic Republic

City

Tehran

Province

Tehran

Postal code

1439813117

Approval date

2022-07-17, 1401/04/26

Ethics committee reference number

IR.UT.SPORT.REC.1401.017

Health conditions studied

1

Description of health condition studied

Hypertension

ICD-10 code

Essential

ICD-10 code description

I10

Primary outcomes

1

Description

systolic an diastolic blood pressure

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of exercise or supplementation

Method of measurement

Sphygmomanometer and stethoscope

2

Description

Serum leptin levels

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of exercise or supplementation

Method of measurement

Using the human ELISA diagnostic kit related to the variable

3

Description

adiponectin

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of exercise or supplementation

Method of measurement

Using the human ELISA diagnostic kit related to the variable

Secondary outcomes

1

Description

Weight changes

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of exercise or supplementation

Method of measurement

scale

2

Description

Waist to hip ratio

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of exercise or supplementation

Method of measurement

tape meter

3

Description

Body mass index

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of exercise or supplementation

Method of measurement

Bioelectrical impedance device

4

Description

Fat index

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of exercise or supplementation

Method of measurement

Bioelectrical impedance device

Intervention groups

1

Description

Intervention group: The training group will do 12 weeks and 3 sessions of resistance training program every

week. Resistance exercises include 9 exercises (2 sets/12-15 repetitions) plus 10 minutes of warm-up and cool-down before and after exercise. The main training phase includes upper body exercises (chest press, latissimus dorsi pulldown, back row, biceps curl), lower body exercises (leg press, leg extension, leg curl) and middle body exercises (abdominal crunch, lower back extension).

Category

Prevention

2

Description

Intervention group: Sour tea group for 12 weeks and daily consumption of 2 grams of sour tea dissolved in 240 ml of water.

Category

Prevention

3

Description

Intervention group: resistance exercises + sour tea for 12 weeks and will do resistance exercises 3 times a week. Resistance exercises include 9 exercises (2 sets/12-15 repetitions) plus 10 minutes of warm-up and cool-down before and after exercise. The main training phase includes upper body exercises (chest press, latissimus dorsi pulldown, back row, biceps curl), lower body exercises (leg press, leg extension, leg curl) and middle body exercises (abdominal crunch, lower back extension). . In addition, every day, 2 servings of sour tea will be consumed in the amount of 2 grams dissolved in 240 ml of water.

Category

Prevention

4

Description

Control group: The control group does not do resistance exercise and does not consume sour tea.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Tehran

Full name of responsible person

Shima Mojtahedi

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North Kargar, Physical Education and Sport Sciences faculty

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Tehran

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?

Yes

Title of funding source

University of Tehran

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

Ferdowsi University of Mashhad

Full name of responsible person

Babak Hoshmand moghaddam

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Physiology

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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