Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of high-Intensity interval training combined with L-Citrulline supplementation on neuromuscular indices in elderly men with Sarcopenia

Protocol summary

Study aim

Evaluate the effect of high-intensity interval training combined with L-Citrulline supplementation on CAF, balance and muscular performance in elderly men with Sarcopenia

Design

Clinical trial with a control group, with parallel groups, Single blind, randomized. The sample size is 10 people in each group. the randomization will be done using a random numbers table.

Settings and conduct

In this study, 40 elderly men bearing Sarcopenia were randomly selected and in a randomized single-blind design, will allocate into four groups of 10 subjects including training, supplementation, training+supplementation and control. High-intensity interval training performed for 8 weeks, 3 days a week. The supplement and control groups consumes 6 grams of L-citrulline and placebo per main meal. Samples are collected two day before the protocol is executed and 72 hours after the last training session. Concentration of serum CAF, muscle mass, muscle strength and walking speed are measured. The participants will not aware of the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 60-75 Having general physical and mental health Suffering from sarcopenia Man Exclusion criteria: Having a history of chronic disease Inability to exercise Having regular exercise history (3 times a week, more than 30 minutes) Drug use or supplementation

Intervention groups

1. Exercise group : Three sessions of exercise per week for 6 weeks with placebo 2. Supplements group: Take 6 grams of L-citrulline daily 3. Supplement and Exercise Group: 6 grams of L-citrulline supplement per day and three sessions of exercise per week for 8 weeks 4. Control group: no exercise and supplement and with placebo

Main outcome variables

serum CAF; balance; muscular strength, muscular mass, walking speed

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170927036459N3**
Registration date: **2022-09-10, 1401/06/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-10, 1401/06/19**
Update count: **0**

Registration date

2022-09-10, 1401/06/19

Registrant information

Name
Amin Farzaneh Hesari
Name of organization / entity
Sari Azad University
Country
Iran (Islamic Republic of)
Phone
+98 17 3222 8377
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-01, 1401/06/10

Expected recruitment end date

2022-11-11, 1401/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of high-Intensity interval training combined with L-Citrulline supplementation on neuromuscular indices in elderly men with Sarcopenia

Public title

Effects of high-intensity interval training and L-Citrulline supplementation on neuromuscular indices in elders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 60-75 Having general physical and mental health Suffering from sarcopenia Man

Exclusion criteria:

Having a history of chronic disease Inability to exercise Having regular exercise history (3 times a week, more than 30 minutes) Drug use or supplementation

Age

From **60 years** old to **75 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, the subjects will be selected using a simple random method. Then, using a table of random numbers, they are divided into four groups. Therefore, each candidate will be assigned a two-digit number. Equal to the sample size, the same number of digits is determined for the selection of individuals (five-digit numbers whose last two digits are similar to the existing codes) that are randomly assigned to one of the groups It will be given. This will continue until the number of people in each group is completed. Therefore, the researcher will not have the option to change the status of the assignment or predict it. Random hiding will be done by a third party who does not participate in other stages of the intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants will be randomly allocated in to 4 groups and will not aware of the type of treatment. For this purpose, we informed each subject in the form of a confidential letter about all the tasks and their grouping requirements. We reported the status of the subject grouping through the code selected for each group and no group names were recorded in the subjects' letters.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University- Sari branch

Street address

Department of Exercise Physiology, Islamic Azad University of Sari, Farah Abad Road

City

Sari

Province

Mazandaran

Postal code

۱۴۷۷۸۹۳۷۸۰

Approval date

2022-04-17, 1401/01/28

Ethics committee reference number

IR.IAU.SARI.REC.1401.032

Health conditions studied

1

Description of health condition studied

Sarcopenia

ICD-10 code

M62.5

ICD-10 code description

Muscle wasting and atrophy, not elsewhere classified

Primary outcomes

1

Description

Serum C-terminal agrin fragment peptide

Timepoint

Before and after eight weeks of intervention

Method of measurement

ELISA commercial kit

Secondary outcomes

1

Description

Balance

Timepoint

Before and after eight weeks of intervention

Method of measurement

Romberg test

2

Description

Muscular strength

Timepoint

Before and after eight weeks of intervention

Method of measurement

Dynamometer

3

Description

Functional ability

Timepoint

Before and after eight weeks of intervention

Method of measurement

Timed up and go test

Intervention groups

1

Description

Intervention group: Exercise+Placebo: high intensity interval training performed for 8 weeks and 3 sessions per week that included 30 seconds cycling exercise on ergometer (intensity of 85-90% HR reserve). In addition, This group received one capsule similar (placebo) to supplement L-citrulline for 8 weeks.

Category

Placebo

2

Description

Intervention group: Supplement group: L-citrulline supplement consumed in single 6 g-dose daily for 8 weeks.

Category

Other

3

Description

Intervention group: Exercise+supplement group: participants of this group performed high intensity interval training performed for 8 weeks and 3 sessions per week that included 30 seconds cycling exercise on ergometer (intensity of 85-90% HR reserve). In addition, this group received L-citrulline supplement in single 6 g-dose daily for 8 weeks.

Category

Other

4

Description

Control group: This group received one capsule (placebo) similar to supplement L-citrulline for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University of Sari

Full name of responsible person

Amin Farzaneh Hesari

Street address

Department of Exercise Physiology, Sari Branch, Islamic Azad University, Farah Abad Road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Sadegh Salmanpor

Street address

Office of Research and Technology, Sari Islamic Azad University, Farah absd road

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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

Islamic Azad University

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

Full name of responsible person

Amin Farzaneh Hesari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise physiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

A piece of data that contains information about variables that can be shared.

When the data will become available and for how long

Available period from 2022

To whom data/document is available

Researchers

Under which criteria data/document could be used

Statistical analysis on the data is not allowed.

From where data/document is obtainable

Amin Farzaneh Hesari af.hessari@gmail.com

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

The purposes and uses of the data should be clearly stated by the applicant.

Comments