

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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

##### Email address

af.hessari@gmail.com

##### 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

۱۴۷۷۸۹۳۷۸

#### 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  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4816119318  
**Phone**  
+98 11 3317 5333  
**Email**  
af.hessari@gmail.com

## 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  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4816119318  
**Phone**  
+98 11 3317 5333  
**Email**  
sadeghsalmanpour@gmail.com  
**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  
**Street address**  
Department of Exercise Physiology, Sari Branch,  
Islamic Azad University, Farah Abad road  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4816119318  
**Phone**  
+98 11 3317 5333  
**Email**  
af.hessari@gmail.com

## Person responsible for scientific 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  
**Street address**  
Department of exercise physiology, Sari Branch,  
Islamic Azad University, Farah abad road  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4816119318  
**Phone**  
+98 11 3317 5333  
**Email**

af.hessari@gmail.com  
**Person responsible for updating data**

**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  
**Street address**  
Department of exercise physiology, Sari Branch,  
Islamic Azad University, Farah abad road  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4816119318  
**Phone**  
+98 11 3317 5333  
**Email**  
af.hessari@gmail.com

## 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**