

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### The effect of eight weeks water- based resistance exercise with dark chocolate consumption on serum follistatin level , quality of life and appetite in older adults

#### Protocol summary

##### Study aim

Research in the health care system

##### Design

Semi-experimental experimentation with complete satisfaction of individuals, four intervention groups, simple accident, 38 people, blind and drug-free

##### Settings and conduct

Tehranpars Neighborhood Hall, 48 hours before and after the intervention of blood sampling and filling out the questionnaire by the participants, performed 8 weeks of intervention

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study included healthy elderly people aged 60 to 73 years, sedentary lifestyle (not participating in regular sports activities in the last 12 months) and physical and mental health. Criteria for leaving the study also include: history of specific diseases (such as chronic lung disease; ischemic heart disease; valvular heart disease; hypertrophic heart failure, etc.); Mental illness (such as dementia); muscle and joint injuries (such as lumbar disc herniation)

##### Intervention groups

Exercise, Exercise + Supplement, Supplement, Control

##### Main outcome variables

Independent variable: 8 weeks of practice in water; bitter chocolate  
Dependent variable: Follistatin; Quality of life index; Appetite

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200609047708N1**

Registration date: **2020-07-12, 1399/04/22**

Registration timing: **retrospective**

Last update: **2020-07-12, 1399/04/22**

Update count: **0**

##### Registration date

2020-07-12, 1399/04/22

##### Registrant information

###### Name

Masoumeh Mohamadkhani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7784 7528

###### Email address

mohamadkhni.m@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-17, 1398/07/25

##### Expected recruitment end date

2019-11-16, 1398/08/25

##### Actual recruitment start date

2019-10-17, 1398/07/25

##### Actual recruitment end date

2019-12-11, 1398/09/20

##### Trial completion date

2019-12-11, 1398/09/20

##### Scientific title

The effect of eight weeks water- based resistance exercise with dark chocolate consumption on serum follistatin level , quality of life and appetite in older adults

##### Public title

The effect of water resistance training and consumption of dark chocolate on the plasma level of follistatin,

quality of life index and appetite of the elderly

#### **Purpose**

Basic science

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Healthy elderly people between the ages of 60 and 73 sedentary (not participating in regular sports activities in the last 12 months) physical health mental health

##### **Exclusion criteria:**

History of specific diseases (such as chronic lung disease, ischemic heart disease, etc. smoking Mental illness (such as dementia) Muscle and joint injuries (such as lumbar disc , etc.)

#### **Age**

From **60 years** old to **73 years** old

#### **Gender**

Female

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **40**

Actual sample size reached: **38**

#### **Randomization (investigator's opinion)**

Not randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Factorial

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Islamic Azad University Ethics Committee , Tehran  
Science and Research Branch

###### **Street address**

Hesarak Martyrs Boulevard, University Square,End of  
Shahid Sattari Highway, Tehran

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1477893855

##### **Approval date**

2019-10-16, 1398/07/24

##### **Ethics committee reference number**

IR.IAU.SRB.REC.1398.099

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

The relationship between eight weeks of water resistance training and consumption of dark chocolate on the plasma level of follistatin, the quality of life index and appetite of the elderly

##### **ICD-10 code**

##### **ICD-10 code description**

### **Primary outcomes**

#### **1**

##### **Description**

follistatin

##### **Timepoint**

Before the intervention, after eight weeks of intervention

##### **Method of measurement**

Blood sample by ELISA by special kit

#### **2**

##### **Description**

Life quality index

##### **Timepoint**

Before the intervention, after eight weeks of intervention

##### **Method of measurement**

SF-36 questionnaire

#### **3**

##### **Description**

appetite

##### **Timepoint**

Before the intervention, after eight weeks of intervention

##### **Method of measurement**

Questionnaire for mood swings

### **Secondary outcomes**

#### **1**

##### **Description**

Water resistance training

##### **Timepoint**

Before the intervention, after eight weeks of intervention

##### **Method of measurement**

It is measured based on rating of perceived exertion (RPE)

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: 1 Exercise group: The subjects of this group performed water- based resistance exercise for eight weeks (3 sessions per week, each session for one hour).

**Category**

N/A

**2****Description**

Intervention group: 2 exercises + supplements: The subjects of this group performed water - based resistance exercise in water for eight weeks with the consumption of dark chocolate (eight weeks water-based resistance exercises in water 3 sessions per week with daily consumption of 30 grams of dark chocolate and 6 bitter chocolate 5 g).

**Category**

N/A

**3****Description**

Intervention group: 3 Supplementary groups: The subjects of this group consumed dark chocolate for eight weeks (daily consumption of 30 grams of dark chocolate, 6 bitter chocolate 5 grams).

**Category**

N/A

**4****Description**

Intervention group: 4 control groups: The subjects of this group did not have any additional training and consumption

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

District 8 Health Department, Tehranpars  
Neighborhood Hall, Elderly Center

**Full name of responsible person**

Masoumeh Mohamadkhani

**Street address**

West 108th Alley (Maleki), Dariush Station,  
Damavand St

**City**

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**Province**

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**Postal code**

1651967441

**Phone**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Masoumeh Mohamadkhani

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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**

Masoumeh Mohamadkhani

**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**

Other

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

Islamic Azad University

**Full name of responsible person**

Masoumeh Mohamadkhani

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

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

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**Full name of responsible person**

Farshad GHazalian

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**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