

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effect of 8 weeks WATER RESISTANCE EXERCISE with DARK CHOCOLATE SUPPLEMENTATION on serum MYOSTATIN level, Balance and Appetite in older adults

Protocol summary

Study aim

Evaluation of the effect of eight weeks of water resistance training and supplementation of bitter chocolate on myostatin serum level, balance and appetite of the elderly

Design

Semi-experimental with blind design among elderly and sedentary women, 38 volunteers were selected and after filling out the consent form and health questionnaire and disease risk were randomly divided into four groups: exercise-exercise + supplement-supplement and control. The intervention was eight weeks. The training and practice group + supplement had a week of water resistance training (three sessions per week, each session for one hour) and supplement and training + supplement groups, 30 grams of dark chocolate daily (6 bitter chocolates 83%, 5 g) they received. The control group did not have any sports activities or supplementary consumption during this period. Blood samples were taken before and after the intervention, and it also the Stork balance test by the researcher , as well as filling out the appetite questionnaire in two stages, before and after the intervention.

Settings and conduct

Semi-experimental and not blind and in the field of health services- Sarai Mahalla and the Elderly Center of District 8 of Tehran

Participants/Inclusion and exclusion criteria

History of specific diseases (such as chronic pulmonary disease (COLD); ischemic heart disease (IHD); valvular heart disease (VHD); hypertension (HTN); harmful adipose disease (HLP); hypertrophic heart failure (HCM) and smoking) Mental illness (such as dementia); Musculoskeletal injuries (such as lumbar disc herniation)

Intervention groups

1-Exercise group 2-Control group 3- Exercise group + supplement 4-Supplementary group

Main outcome variables

Myostatin - Balance - Appetite and water resistance exercise

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20200531047612N1**

Registration date: **2020-07-08, 1399/04/18**

Registration timing: **retrospective**

Last update: **2020-07-08, 1399/04/18**

Update count: **0**

Registration date

2020-07-08, 1399/04/18

Registrant information

Name

Maryam Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4432 9092

Email address

mousavi6082068@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 8 weeks WATER RESISTANCE EXERCISE with DARK CHOCOLATE SUPPLEMENTATION on serum MYOSTATIN level, Balance and Appetite in older adults

Public title

Effect of eight weeks of water resistance training and consumption of dark chocolate on serum myostatin Amounts, balance and appetite of the elderly

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy seniors were between the ages of 60 and older and sedentary (not participating in regular sports activities for the past 12 months). 60 - 73 Inactivity (not participating in regular sports activities in the last 12 months)

Exclusion criteria:

Specific diseases such as chronic lung disease Ischemic heart disease Heart valve disease Blood pressure disease Harmful fats Hypertrophic heart disease smoking Do not take supplements or medications for the past month Mental illness (such as dementia) Muscle and joint injuries (such as lumbar disc protrusion)

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)

Randomized

Randomization description

Simple - using a table of random numbers - so that by giving people from 0 to 40 the first number we find in the first intervention group: the practice group is placed, the second number in the second intervention group: the complementary group + practice, The third number in the third intervention group: the complementary group and the fourth number in the fourth intervention group , the control group.

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

Islamic Azad University- Science and Research Branch

Street address

Tehran - End of Shahid Sattari Highway - University Square - Shohadae Hesarak Blvd. - Islamic Azad University, Science and Research Branch .

City

Tehran

Province

Tehran

Postal code

۱۴۷۷۸۹۳۸۵۵

Approval date

2019-10-16, 1398/07/24

Ethics committee reference number

098.IR.IAU.SRB.REC.1398

Health conditions studied

1

Description of health condition studied

Water resistance training - the elderly

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Myostatin

Timepoint

Before the intervention, after eight weeks of intervention

Method of measurement

Blood sample by ELISA by special kit

2

Description

the balance

Timepoint

Before the intervention, after eight weeks of intervention

Method of measurement

Perform spot stain testing

3

Description

Appetite

Timepoint

Before the intervention, after eight weeks of intervention

Method of measurement

Secondary outcomes

1

Description

Water resistance training

Timepoint

Before the intervention, after eight weeks of intervention

Method of measurement

Based on the level of understanding the effort (PRE) is measured.

Intervention groups

1

Description

Intervention group: Exercise group: The subjects of this group performed water resistance training for eight weeks (three sessions per week, one session per hour).

Category

Other

2

Description

Intervention group: Exercise + supplement group: The subjects of this group performed water resistance training for eight weeks (three sessions per week, one session per hour) and in these eight weeks 30 grams of dark chocolate daily (6 bitter chocolates 83% , 5 g) received.

Category

Other

3

Description

Intervention group: Supplementary group: The subjects of this group did not have any sports activities and for eight weeks they received only 30 grams of dark chocolate daily (6 bitter chocolates 83%, 5 g) received.

Category

Other

4

Description

Intervention group: Control group: The subjects of this group did not have any sports activities and supplementation during this period of eight weeks And they went on with their normal lives.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sarai Mahalla and the Elderly Center of District 8 of Tehran

Full name of responsible person

maryam mousavi

Street address

Tehranpars, Damavand St., Shahid Maleki St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

research fellow

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

maryam mousavi

Position

Master of Sports Physiology student

Latest degree

Bachelor

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries

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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)

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