

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The effects of jump rope interval training and dark chocolate on serum levels of some inflammatory adipokines and cytokines in adolescent males with obesity

#### Protocol summary

##### Study aim

The aim of this study is to investigate the effects of dark chocolate supplementation and rope jump interval training on serum levels of some inflammatory adipokines and cytokines in adolescent males with obesity.

##### Design

Study design: Randomized double-blinded controlled clinical trial. Blinding is carried out for subjects and researchers and randomization will be done using quadratic block. Statistical software (Minitab) will be used to perform randomized block. Population and sample size: 48 sedentary adolescent males with obesity who are not participating in any regular training program for at least 6 months before the study.

##### Settings and conduct

This study will be conducted at Astan Qods Razavi Sports Complex. 48 sedentary adolescent males with obesity will be randomized to 4 groups: 1) interval training + placebo; 2) dark chocolate; 3) interval training + dark chocolate; and 4) Control. blinding will be done for interventions for both researchers and participants. randomization will be done using quadratic block.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: adolescent males with obesity aged 13 to 17 years without participating in any regular training program. Exclusion criteria: recent infections, joint and bone injuries, and symptoms of metabolic disease.

##### Intervention groups

Intervention 1: received 30 grams dark chocolate per day, for six weeks. Intervention 2: exercise training including rope jump interval training, 5 times/wk. Intervention 3: received one capsule containing chickpea flour, for six weeks.

##### Main outcome variables

Body fat, irisin; interleukin-6; leptin; resistin; monocyte chemoattractant protein-1; adiponectin; tumor necrosis

factor-alpha; C-reactive protein; chemerin; retinol binding protein-4; dietary intake

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151025024699N5**

Registration date: **2020-03-19, 1398/12/29**

Registration timing: **retrospective**

Last update: **2020-03-19, 1398/12/29**

Update count: **0**

##### Registration date

2020-03-19, 1398/12/29

##### Registrant information

##### Name

Damoon Ashtary-Larky

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 614436106

##### Email address

ashtary.d@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-06-22, 1398/04/01

##### Expected recruitment end date

2019-10-23, 1398/08/01

##### Actual recruitment start date

2019-07-01, 1398/04/10

**Actual recruitment end date**

2019-11-26, 1398/09/05

**Trial completion date**

2020-03-02, 1398/12/12

**Scientific title**

The effects of jump rope interval training and dark chocolate on serum levels of some inflammatory adipokines and cytokines in adolescent males with obesity

**Public title**

The effects of jump rope interval training and dark chocolate on serum levels of some inflammatory adipokines and cytokines

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

BMI=28.22 or more Without any metabolic disease No smoking No alcoholism Not taking supplements (including vitamins, minerals, ergogenic aids) and medication for at least 2 months before the study Not participating in any regular training program for at least 6 months before the study Interesting in participation in research Age of 13-17

**Exclusion criteria:**

Use of immune system suppressor drugs 6 mounts before research Recent infections Joint and bone injuries Metabolic disease No interesting for participation

**Age**

From **13 years** old to **17 years** old

**Gender**

Male

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **48**

Actual sample size reached: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will done using quadratic block. Statistical software (Minitab) will use to perform randomized block.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, blinding will be done for interventions for both researchers and participants. The chocolates and capsules will be given in the same bottle and will be coded for each groups by someone who are not enroll in the study design .

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Sports Sciences Research Institute

**Street address**

No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1587958711

**Approval date**

2018-12-28, 1397/10/07

**Ethics committee reference number**

IR.SSRI.REC.1397.352

**Health conditions studied****1****Description of health condition studied**

Healthy, Obese

**ICD-10 code**

E66

**ICD-10 code description**

Overweight and obesity

**Primary outcomes****1****Description**

Irisin

**Timepoint**

Before and six weeks after intervention

**Method of measurement**

ELISA

**2****Description**

Interleukin 6

**Timepoint**

Before and six weeks after intervention

**Method of measurement**

ELISA

**3****Description**

Tumor necrosis factor alpha

**Timepoint**

Before and six weeks after intervention  
**Method of measurement**  
ELISA

#### 4

**Description**  
Adiponectin  
**Timepoint**  
Before and six weeks after intervention  
**Method of measurement**  
ELISA

#### 5

**Description**  
C-reactive protein  
**Timepoint**  
Before and six weeks after intervention  
**Method of measurement**  
ELISA

#### 6

**Description**  
Leptin  
**Timepoint**  
Before and six weeks after intervention  
**Method of measurement**  
ELISA

#### 7

**Description**  
Resistin  
**Timepoint**  
Before and six weeks after intervention  
**Method of measurement**  
ELISA

#### 8

**Description**  
Monocyte chemoattractant protein-1  
**Timepoint**  
Before and six weeks after intervention  
**Method of measurement**  
ELISA

#### 9

**Description**  
Chemerin  
**Timepoint**  
Before and six weeks after intervention  
**Method of measurement**  
ELISA

#### 10

**Description**  
Retinol binding protein-4  
**Timepoint**  
Before and six weeks after intervention

**Method of measurement**  
ELISA

### Secondary outcomes

#### 1

**Description**  
Body fat  
**Timepoint**  
Before and six weeks after intervention  
**Method of measurement**  
Body fat Analyzer

#### 2

**Description**  
Dietary intake  
**Timepoint**  
Before and six weeks after intervention  
**Method of measurement**  
Food record questionnaire

### Intervention groups

#### 1

**Description**  
Intervention group: received 30 grams dark chocolate per day, for six weeks  
**Category**  
Lifestyle

#### 2

**Description**  
Intervention group: exercise training including rope jump interval training, 5 times/wk, for six weeks  
**Category**  
Lifestyle

#### 3

**Description**  
Control group: received one capsule containing chickpea flour, for six weeks  
**Category**  
N/A

### Recruitment centers

#### 1

**Recruitment center**  
**Name of recruitment center**  
Private  
**Full name of responsible person**  
Babak Hooshmand Hoghdam  
**Street address**  
Ferdowsi Blvd, Astan Qods Razavi Sports Complex  
**City**  
Mashhad

**Province**  
Razavi Khorasan  
**Postal code**  
9177935176  
**Phone**  
+98 51 3881 0540  
**Email**  
b.hooshmand.m@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Sports Sciences Research Institute  
**Full name of responsible person**  
Babak Hooshmand Hoghadam  
**Street address**  
Faculty of Physical Education and Sport Science of  
Tehran University, Northern Kargar Ave, Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1417466191  
**Phone**  
+98 51 3881 0540  
**Email**  
b.hooshmand.m@gmail.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
Sports Sciences Research Institute  
**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**  
Persons

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
University of Isfahan  
**Full name of responsible person**  
Reza Bagheri  
**Position**  
Researcher  
**Latest degree**  
Master  
**Other areas of specialty/work**

Physiology  
**Street address**  
Isfahan, Azadi square, University of Isfahan  
**City**  
Isfahan  
**Province**  
Razavi Khorasan  
**Postal code**  
8174673441  
**Phone**  
+98 51 3521 4043  
**Email**  
will.fivb@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Damoons Ashtary-Larky  
**Position**  
Researcher  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
Ahvaz Jundishapur University of Medical Sciences,  
Golestan, Ahvaz  
**City**  
Ahvaz  
**Province**  
Khuzestan  
**Postal code**  
1579461357  
**Phone**  
+98 61 3443 6106  
**Email**  
Damoons\_ashtary@yahoo.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
University of Isfahan  
**Full name of responsible person**  
Reza Bagheri  
**Position**  
Researcher  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Physiology  
**Street address**  
Isfahan, Azadi square, University of Isfahan  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**

8174673441

**Phone**

+98 51 3521 4043

**Email**

will.fivb@yahoo.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**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Publication of protocol study in form of the article and also data publication in the original article. The total potential data can be shared after unidentifiable subjects.

**When the data will become available and for how long**

6 months after the publication of results

**To whom data/document is available**

All researchers who have access to clinical trials databases.

**Under which criteria data/document could be used**

The only way for using the data is after the publication of the article in the indexed ISI journal.

**From where data/document is obtainable**

Via database websites such as PubMed and google scholar and via email address:  
damoon\_ashtary@yahoo.com

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

The original article reaches the requestor by email within a maximum of one week.

**Comments**