

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Effect of eight weeks of aerobic training with and without green coffee consumption on lymphocyte ABCG1 Gene Expression, Apo-B100 and some of the Cardiovascular risk factor in 30 non-Athlete and overweight women

#### Protocol summary

##### Study aim

The effect of eight weeks of aerobic training and green coffee consumption on ABCG1, Apo-B100 gene expression and some cardiovascular risk factors in overweight non-athletic women.

##### Design

A randomized, single-blind, placebo-controlled clinical trial

##### Settings and conduct

During the call at the Shahid Beheshti Club in Mashhad, 30 participants were randomly selected and randomly divided into two groups of green coffee consumption and placebo consumption. And they were told that all the capsules were green coffee.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 35 to 45 years with overweight and BMI ranging from 25 to 29.9 kg / m<sup>2</sup> and not trained. Be physically and mentally healthy and not at all menopausal. During the three days before and after the menstrual cycle, they took no medication at all. They have not used dietary, nutritional, and dietary supplements since two months ago. Do not have a special diet. They did not smoke, and were also obliged to attend meetings and observe conditions set by researchers and educators from beginning to end. Exclusion criteria: Non-compliance, Going on a trip, Non-compliance with diet and illness and absence at training sessions

##### Intervention groups

Exercise group with green coffee intake: start aerobic exercise at 40% intensity (maximum heart rate) / 30 min / three sessions per week and increase to 60 min / 70% intensity / three sessions per week. Aerobic exercise group with placebo: similar to group 1

##### Main outcome variables

ABCG1 gene; ApoB100; HDL; LDL

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191227045907N1**

Registration date: **2020-01-22, 1398/11/02**

Registration timing: **retrospective**

Last update: **2020-01-22, 1398/11/02**

Update count: **0**

##### Registration date

2020-01-22, 1398/11/02

##### Registrant information

##### Name

Ahmad Shajiee

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3833 6796

##### Email address

ahmad.shajie@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-22, 1397/09/01

##### Expected recruitment end date

2018-12-06, 1397/09/15

##### Actual recruitment start date

2018-12-22, 1397/10/01

##### Actual recruitment end date

2018-12-31, 1397/10/10

##### Trial completion date

2020-03-05, 1398/12/15

## Scientific title

Effect of eight weeks of aerobic training with and without green coffee consumption on lymphocyte ABCG1 Gene Expression, Apo-B100 and some of the Cardiovascular risk factor in 30 non-Athlete and overweight women

## Public title

Effect of aerobic training and green coffee consumption in overweight women

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

BMI range between 25 and 29.9 kg / m<sup>2</sup> non-athlete  
Have physical and mental health No disease Do not be menopausal Be in the three days before and after menstruation Do not take any medication They have not used nutritional and nutritional supplements since two months ago Do not have a special diet No smoking If they wish to participate in the research, they are obliged to comply with the conditions set forth from beginning to end. Age range between 35-45 years

### Exclusion criteria:

Non-compliance Disease Having a diet taking medication Being in the menstrual cycle Taking nutritional supplements Go to travel

## Age

From **35 years** old to **45 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **30**

Actual sample size reached: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Note the total names of participants on paper in a container, then randomly withdrawing 30 individuals as sample size from the container containing the names, and then randomly divided into two groups of 15 individuals each with aerobic exercise with and without green coffee.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The green coffee capsules were given to the exercise group with the green coffee and the placebo capsules containing wheat flour to the placebo exercise group. The capsules were similar in appearance, odor, color and taste, and only the subjects were not aware of the contents of the capsules.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Islamic Azad University of Neyshabour Branch

##### Street address

Islamic Azad University, Neyshabur Branch, Imam Mohammad Ghazali Boulevard, Neyshabur

##### City

MASHHAD

##### Province

Razavi Khorasan

##### Postal code

9319797139

#### Approval date

2018-12-13, 1397/09/22

#### Ethics committee reference number

IR.IAU.NEYSHABUR.REC.1397.018

## Health conditions studied

### 1

#### Description of health condition studied

ABCG1 gene

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

ATP-binding cassette Transport G1 gen

#### Timepoint

48 hours before and 48 hours after the first and last aerobic training session

#### Method of measurement

Centrifuge and isolate lymphocytes and then investigate gene expression by RT-PCR method

### 2

#### Description

Apolipoprotein B100

#### Timepoint

48 hours before and 48 hours after the first and last aerobic training session

#### Method of measurement

5 cc of blood sample and ELISA method

### 3

#### Description

High-density lipoprotein

#### Timepoint

48 hours before and 48 hours after the first and last aerobic training session

**Method of measurement**

Spectrophotometry method

**4**

**Description**

Low-density lipoprotein

**Timepoint**

48 hours before and 48 hours after the first and last aerobic training session

**Method of measurement**

Spectrophotometry method

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Aerobic exercise with green coffee intake: 40-70% MHR / three sessions per week / 30-60 minutes per session. 400 mg capsules daily one hour before exercise

**Category**

Prevention

**2**

**Description**

Intervention group: Aerobic exercise with green coffee intake: 40-70% MHR / three sessions per week / 30-60 minutes per session. placebo capsules daily one hour before exercise

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Martyr Beheshti Club of Mashhad

**Full name of responsible person**

Ahmad Shajie

**Street address**

Mashhad Ferdowsi Boulevard Shahid Beheshti Club

**City**

MASHHAD

**Province**

Razavi Khorasan

**Postal code**

918587720

**Phone**

+98 51 3768 3010

**Email**

info@cfu.ac.ir

**Web page address**

<https://pbm.cfu.ac.ir/>

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Ahmad Zendedel

**Street address**

Neyshabour, Research Street, Islamic Azad University, Neyshabour Branch Complex

**City**

Neyshabour

**Province**

Razavi Khorasan

**Postal code**

9319797139

**Phone**

+98 51 4262 1901

**Email**

pajohesh@iau-neyshabur.ac.ir

**Web page address**

<http://iau-neyshabur.ac.ir/>

**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**

1

**Public or private sector**

Public

**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**

Ferdowsi University of Mashhad

**Full name of responsible person**

Amir Rashidlamir

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sport physiology

**Street address**

Ferdowsi University of Mashhad, Faculty of Sport Sciences

**City**  
MASHHAD  
**Province**  
Razavi Khorasan  
**Postal code**  
9117948974  
**Phone**  
+98 51 3880 5000  
**Email**  
pr@um.ac.ir  
**Web page address**  
<https://www.um.ac.ir>

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Ferdowsi University of Mashhad  
**Full name of responsible person**  
Amir Rashidlamir  
**Position**  
Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Sport Physiology  
**Street address**  
Mashhad Ferdowsi University of Mashhad Faculty of Sport Sciences  
**City**  
MASHHAD  
**Province**  
Razavi Khorasan  
**Postal code**  
9117948974  
**Phone**  
+98 51 3880 5000  
**Email**  
pr@um.ac.ir  
**Web page address**  
<https://www.um.ac.ir>

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad Ferdowsi University of Mashhad  
**Full name of responsible person**  
Amir Rashidlamir  
**Position**  
Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Sport Physiology

**Street address**  
Mashhad Ferdowsi University of Mashhad Faculty of Sport Sciences  
**City**  
MASHHAD  
**Province**  
Razavi Khorasan  
**Postal code**  
9117948974  
**Phone**  
+98 51 3880 5000  
**Email**  
amir.rashidlamir@gmail.com  
**Web page address**  
<https://www.um.ac.ir>

## 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

The effect of eight weeks of aerobic exercise and green coffee consumption on ABCG1 lymphocyte, Apo-B100 gene expression and LDL / HDL and CT / HDL ratio in overweight non-athletic women

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

Two months after printing the results

### To whom data/document is available

Researchers and anyone you know in the field of science

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

Protecting Data Security - Use in scientific and research areas

### From where data/document is obtainable

Amir Rashidlamir- 09151514174- Ferdowsi University of Mashhad School of Sport Sciences - amir.rashidlamir@gmail.com Ahmad Shajie- 09155048659- Neyshabour Azad University School of Sport Sciences- ahmad.shajie@gmail.com

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

Two Months After Publishing in Scientific Research Journals

### Comments

Thanks for your kindness