

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the interactive effect of 8- week combined aerobic-yoga training and quinoa supplementation on serum Irisin levels, lipid profile and body mass index of overweight adult women

Protocol summary

Study aim

Evaluation the interactive effect of eight-week combined aerobic-yoga training and quinoa supplementation on serum Irisin levels, lipid profile and body mass index of overweight adult women in Ardabil

Design

The study design is quasi-experimental and pre-test and post-test with the control group. The study groups will randomly divided into three experimental groups (supplement group, training group and training plus supplement group) and one control group will randomly divided.

Settings and conduct

At ardabil, group supplementation: Quinoa supplement group will consume cooked 25-gram quinoa for 8 weeks and 3 days a week. (Quinoa seed is an organic products of Aman Quinoa in Hamedan). Exercise group will perform 8-week combined aerobic-Yoga training, three session per week, include twenty-minute yoga training and twenty-five minute aerobic exercise, fifteen- minute Recovery and yoga. Exercise plus supplementation group, Exercise plus Supplement group will perform exercise program and use quinoa consumption simultaneously, like exercise group and supplement group.

Participants/Inclusion and exclusion criteria

Inactive and overweight 30-39 years women absence of orthopedic, anatomical and physiological diseases

Intervention groups

Intervention group 1: Quinoa supplement group will consume cooked 25-gram quinoa for 8 weeks and 3 days a week. (Quinoa seed is an organic products of Aman Quinoa in Hamedan). Intervention group 2 will perform 8-week combined aerobic-Yoga training, three session per week, include twenty-minute yoga training and twenty-five minute aerobic exercise, fifteen- minute Recovery and yoga. Intervention group 3: Exercise plus

Supplement group will perform exercise program and use quinoa consumption simultaneously, like exercise group and supplement group.

Main outcome variables

serum Irisin levels, lipid profile and body mass index,

General information

Reason for update

Acronym

AYQSILBW

IRCT registration information

IRCT registration number: **IRCT20200831048570N1**

Registration date: **2020-12-07, 1399/09/17**

Registration timing: **retrospective**

Last update: **2020-12-07, 1399/09/17**

Update count: **0**

Registration date

2020-12-07, 1399/09/17

Registrant information

Name

Nayyer Ghayyem alaei

Name of organization / entity

The University of Mohaghegh ardebili

Country

Iran (Islamic Republic of)

Phone

+98 45 3326 0529

Email address

n.ghayemalaei@student.uma.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the interactive effect of 8- week combined aerobic-yoga training and quinoa supplementation on serum Irisin levels, lipid profile and body mass index of overweight adult women

Public title

Effect of aerobic-yoga training and quinoa supplementation on serum Irisin, lipid profile and body mass index overweight adult women

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range: 30-39 old years Overweight women Inactivity

Exclusion criteria:

Absence of Anatomical, Orthopedic and Physiological disease No addiction

Age

From **30 years** old to **39 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

N/A

Randomization description**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**

Ethics committee of Ardabil University of Medical Sciences

Street address

Ardabil University of Medical Sciences., University Street,

City

Ardabil

Province

Ardabil

Postal code

5618953141

Approval date

2020-01-26, 1398/11/06

Ethics committee reference number

IR.ARUMS.REC.1398.606

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

Overweight and obesity

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Serum levels of irisin

Timepoint

24 hours before the start of the study and 48 hours after the end

Method of measurement

Blood sampling in the amount of 5 cc and using the human ELISA kit of the German Zelbio company

2**Description**

High density lipoprotein

Timepoint

24 hours before the start of the study and 48 hours after the end

Method of measurement

Blood sampling in the amount of 5 cc and using the kit of Pars Azmoon company

3**Description**

Low density lipoprotein

Timepoint

24 hours before the start of the study and 48 hours after the end

Method of measurement

Blood sampling in the amount of 5 cc and using the kit of Pars Azmoon company

4**Description**

Very low density lipoprotein

Timepoint

24 hours before the start of the study and 48 hours after the end

Method of measurement
Using the formula triglyceride / 5

5

Description
Triglyceride

Timepoint
24 hours before the start of the study and 48 hours after the end

Method of measurement
Blood sampling in the amount of 5 cc and using the kit of Pars Azmoon company

6

Description
Total cholesterol

Timepoint
24 hours before the start of the study and 48 hours after the end

Method of measurement
Blood sampling in the amount of 5 cc and using the kit of Pars Azmoon company

7

Description
Body mass index

Timepoint
24 hours before the start of the study and 48 hours after the end

Method of measurement
Weight (KG) / Square height (m).Weight measurement with German Beurer digital scale.Height measurement by calibrated wall with Chinese bar meter

8

Description
Waist to hip ratio

Timepoint
24 hours before the start of the study and 48 hours after the end

Method of measurement
Waist measurement: In the narrowest part of the trunk, ie between the last rib and the crown of the iliac crest, a Chinese tape measure is completely attached to the skin and the size will be recorded without the skin being compressed.Measurement of hip circumference: Place a tape measure in the most voluminous part of the hip circumference, ie under the bulge of the pelvis, and the relevant number will be recorded without squeezing the skin.

9

Description
Percentage of body fat

Timepoint
24 hours before the start of the study and 48 hours after

the end

Method of measurement

Using the three-point model (abdominal, scapular, triceps), Jackson and Pollack will perform a dynamic model caliper.First, the density will be obtained by the following formula: $2 \text{ (sum of three regions)}^2 / (0.00000084) + (\text{sum of three regions}) 000815 / 0.0982 = \text{body density}$.The percentage of fat will be obtained from the following formula: $450 - \text{body density} / 495 = \text{body fat percentage}$

10

Description
Lean body mass

Timepoint
24 hours before the start of the study and 48 hours after the end

Method of measurement
 $\text{Body fat weight} - \text{total body weight} = \text{lean body mass}$

11

Description
Body fat mass

Timepoint
24 hours before the start of the study and 48 hours after the end

Method of measurement
 $\text{body fat mass} = (\text{total weight} \times \text{percentage of body fat}) / 100$

Secondary outcomes

1

Description
Serum levels of irisin

Timepoint
24 hours before the start of the study and 48 hours after the end

Method of measurement
Blood sampling in the amount of 5 cc and using the human ELISA kit of the German Zelbio company

2

Description
Body mass index

Timepoint
24 hours before the start of the study and 48 hours after the end

Method of measurement
Weight (KG) / Square height (m).Weight measurement with German Beurer digital scale.Height measurement by calibrated wall with Chinese bar meter

3

Description
Waist to hip ratio

Timepoint
24 hours before the start of the study and 48 hours after

the end

Method of measurement

Waist measurement: In the narrowest part of the trunk, ie between the last rib and the crown of the iliac crest, a Chinese tape measure is completely attached to the skin and the size will be recorded without the skin being compressed. Measurement of hip circumference: Place a tape measure in the most voluminous part of the hip circumference, ie under the bulge of the pelvis, and the relevant number will be recorded without squeezing the skin.

4

Description

Percentage of body fat

Timepoint

24 hours before the start of the study and 48 hours after the end

Method of measurement

Using the three-point model (abdominal, scapular, triceps), Jackson and Pollack will perform a dynamic model caliper. First, the density will be obtained by the following formula: $2 \text{ (sum of three regions)}^2 / (0.00000084) + (\text{sum of three regions}) 000815 / 0.0982 = \text{body density}$. The percentage of fat will be obtained from the following formula: $450 - \text{body density} / 495 = \text{body fat percentage}$

5

Description

Lean body mass

Timepoint

24 hours before the start of the study and 48 hours after the end

Method of measurement

Body fat weight - total body weight = lean body mass

6

Description

Body fat mass

Timepoint

24 hours before the start of the study and 48 hours after the end

Method of measurement

body fat mass = $(\text{total weight} \times \text{percentage of body fat}) / 100$

7

Description

High-density lipoprotein

Timepoint

24 hours before the start of the study and 48 hours after the end

Method of measurement

Blood sampling in the amount of 5 cc and using the kit of Pars Azmoun Company kit

8

Description

Low density lipoprotein

Timepoint

24 hours before the start of the study and 48 hours after the end

Method of measurement

Blood sampling in the amount of 5 cc and using the kit of Pars Azmoun Company kit

9

Description

Very low density lipoprotein

Timepoint

24 hours before the start of the study and 48 hours after the end

Method of measurement

Using the formula triglyceride / 5

10

Description

Tri glyceride

Timepoint

24 hours before the start of the study and 48 hours after the end

Method of measurement

Blood sampling in the amount of 5 cc and using the kit of Pars Azmoun Company kit

11

Description

Total cholesterol

Timepoint

24 hours before the start of the study and 48 hours after the end

Method of measurement

Blood sampling in the amount of 5 cc and using the kit of Pars Azmoun Company kit

Intervention groups

1

Description

Intervention group 1: Quinoa supplement group will consume cooked 25-gram quinoa for 8 weeks and 3 days a week. (Quinoa seed is an organic products of Aman Quinoa in Hamedan).

Category

Prevention

2

Description

Intervention group 2: 8-week combined aerobic-Yoga training, three session per week, include twenty-minute yoga training and twenty-five minute aerobic exercise, fifteen- minute Recovery and yoga

Category

Prevention

3

Description

Intervention group 3: Exercise plus Supplement group will perform exercise program and use quinoa consumption simultaneously, like exercise group and supplement group.

Category

Prevention

4

Description

Control group: No intervention was made.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardabil city level

Full name of responsible person

Nayyer Ghayyem alaei

Street address

Quds Street

City

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Ardabil

Postal code

5613958917

Phone

+98 45 3326 0529

Email

n.ghayemalayi@student.uma.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mohaghegh Ardabili University

Full name of responsible person

Ghorbani

Street address

Mohaghegh Ardabili University.,University Street,

City

Ardabil

Province

Ardabil

Postal code

5619913131

Phone

+98 45 3351 0136

Email

ghorbani@uma.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mohaghegh Ardabili University

Proportion provided by this source

100

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

The Mohaghegh Ardabili University

Full name of responsible person

Nayyer Ghayyem Alaei

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiology

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Province

Ardabil

Postal code

5619913131

Phone

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Email

n.ghayemalaei@student.uma.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

The university of Mohaghegh

Full name of responsible person

Nayyer ghayyem Alaei

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiology

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Person responsible for updating data

Contact

Name of organization / entity
The University of Mohaghegh ardebili
Full name of responsible person
Nayer Ghayem alaei
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Physiology
Street address
Mohaghegh Ardebili University., Daneshgah Ave
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5619913131
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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

After statistical analysis, the general information of the subjects will be shared in the form of final results and in the article, while preserving the privacy of the subjects and without identifying them.

When the data will become available and for how long

Access started from 1400

To whom data/document is available

Everyone

Under which criteria data/document could be used

Everyone

From where data/document is obtainable

n.ghayemalaei@student.uma.ac.ir

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

Irlandac tracking code

Comments

The printer magazine is currently unknown