

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

A comparison of the effects of 12 weeks walking with two different intensities on the expression of circulating miR-146a and miR-181a and Plasma levels of inflammatory markers IL-6 and TNF- α In Sedentary Aged Women.

Protocol summary

Study aim

A comparison of the effects of 12-week walking with moderate and high intensities on circulating miR-146a and miR-181a, plasma levels of inflammatory markers IL-6, TNF- α , WBC, some performance indicators and cardio-respiratory endurance in sedentary aged women

Design

Randomized clinical trial with control group, non blinded, with parallel groups

Settings and conduct

Among women 60-70 years old and inactive in Karaj, thirty volunteers woman will be selected as the study population and randomly divide into three group: moderate intensity walking, high intensity walking and control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Inactive women aged 60 to 75 years;
Exclusion criteria: have any inflammatory and cardiovascular diseases, certain medication or nutritional status and motor disability

Intervention groups

The first intervention group: 12 weeks walking, 3 sessions per week, with a moderate intensity of 55-50% maximum heart rate reserve(HRRmax) The second intervention group: 12 weeks walking, 3 sessions per week with a high intensity of 75-70% HRRmax The third intervention group: Untrained control group with no intervention

Main outcome variables

Circulating levels of miR-146a and miR-181a, plasma levels of IL-6 and TNF- α , white blood cell counts, static balance, dynamic balance, body composition, cardio respiratory endurance, and the quality of life of elderly women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150531022498N23**

Registration date: **2018-07-06, 1397/04/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-06, 1397/04/15**

Update count: **0**

Registration date

2018-07-06, 1397/04/15

Registrant information

Name

Ramin Shabani

Name of organization / entity

Islamic Azad University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effects of 12 weeks walking with two different intensities on the expression of circulating miR-146a and miR-181a and Plasma levels of inflammatory markers IL-6 and TNF- α In Sedentary Aged Women.

Public title

A comparison of the effects of 12 weeks walking with two different intensities on the expression of circulating miR-146a, miR-181a and Plasma levels of inflammatory markers IL-6 and TNF- α In Sedentary Aged Women.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Women Age range 60 to 75 Inactive

Exclusion criteria:

Having any chronic and inflammatory disease Having any particular diet or medication during the study period Use of auxiliary equipment for walking Motor limitation in the pelvic, hip and knee joints

Age

From **60 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects were divided into 3 groups (one control group and 2 experimental groups) using the random numbers table

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 Rasht Azad University

Street address

Ibn Sina St, District 4, Rasht., Gilan Province.

City

Rasht

Province

Guilan

Postal code

4147654919

Approval date

2017-09-19, 1396/06/28

Ethics committee reference number

IR.IAU.RASHT.REC.1396.93

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

Diseases associated with aging and inflammation

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

Plasma level of miR-146a

Timepoint

Before and after the end of 12 weeks of training

Method of measurement

Using by polymerase chain reaction (PCR)

2**Description**

Plasma level of microRNA-181a

Timepoint

Before and after the end of 12 weeks of training

Method of measurement

Using by polymerase chain reaction (PCR)

3**Description**

Plasma level of Interleukin-6

Timepoint

Before and after the end of 12 weeks of training

Method of measurement

Serum level using ELISA Kit

4**Description**

Plasma level of Tumor necrosis factor alpha (TNF- α)

Timepoint

Before and after the end of 12 weeks of training

Method of measurement

Serum level using ELISA Kit

5**Description**

White blood cell counts

Timepoint

Before and after the end of 12 weeks of training

Method of measurement

Using blood sample

Secondary outcomes

1

Description

Blood pressure variables

Timepoint

Before and after the end of 12 weeks of training

Method of measurement

Rest levels using by measurement of systolic blood pressure, diastolic blood pressure and heart rate

2

Description

Quality of life

Timepoint

Before and after the end of 12 weeks of training

Method of measurement

Using by quality of life questionnaire (SF-36)

3

Description

Body composition

Timepoint

Before and after the end of 12 weeks of training

Method of measurement

Using by measurement of weight, body mass index (BMI), fat percent, fat free mass and waist circumference

4

Description

Physical fitness

Timepoint

Before and after the end of 12 weeks of training

Method of measurement

Using by measurement of dynamic and static balance and maximum oxygen consumption (VO2max)

Intervention groups

1

Description

The first Intervention group: moderate intensity of walking, In this group, the subjects will be walking(55-50% of the target heart rate) for 12 weeks and 3 sessions in a week. The workout time of the first week will begin at 30 minutes and will increase to 45 minutes at the end of the sixth week. The intensity of exercise in the first six weeks will be 50% of the maximum heart rate reserved and in the second six weeks it will be 55%.

Category

Rehabilitation

2

Description

The second Intervention group: High intensity of walking, In this group, the subjects will be walking(70-75% of the target heart rate) for 12 weeks and 3 sessions in a week. The workout time of the first week will begin at 30 minutes and will increase to 45 minutes at the end of the sixth week. The intensity of exercise in the first six weeks will be 70% of the maximum heart rate reserved and in the second six weeks it will be 75%.

Category

Rehabilitation

3

Description

Control group: Without any intervention, subjects in this group will continue their normal routine during the 12-week study period.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Setayesh gym in Alborz Province

Full name of responsible person

Katayon Tehrani

Street address

No. 9, East Baghestan Ave., Shahin Vila Blvd., Karaj Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht Azad University

Full name of responsible person

Farhad Rahmaninia

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Ibn Sina St, District 4, Rasht., Gilan Province.

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Grant name

Grant code / Reference number

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

Title of funding source
Rasht Azad University

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Rasam university of Alborz province

Full name of responsible person
Fateme Falah

Position
Assistant Professor

Latest degree
Master

Other areas of specialty/work
Biochemistry

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Position
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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 more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable