Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of combined exercise on plasma levels of alpha-klotho, sirtuin 1, oxidative enzymes, lipid profile and glucose homeostasis in obese men aged 60 to 70 years.

Protocol summary

Study aim

The effect of combined training on alpha-KLOTHO, sirtuin 1, oxidative enzymes, glucose homeostasis and lipid profile in obese men aged 60 to 70 years.

Design

The type of this research is semi-experimental and in this research, the statistical population includes inactive obese elderly men. To determine the size of the sample using G-POWER software, it was equal to 46 and was divided into two groups of 23 people including the experimental group and the control group.

Settings and conduct

The 16-week exercises will be combined endurance and resistance exercises in 3 sessions for 60 minutes. Under the supervision of a trainer and doctor

Participants/Inclusion and exclusion criteria

Entry criteria: Subjects between 60 and 70 years old; people who have the ability to implement the training protocol and tests; stable body weight, and the ability to perform sports intervention. Exclusion criteria: history of orthopedic diseases in the last 5 years and vision problems; having daily sports activities for at least two years; having suspected cases such as cardiovascular disease; having kidney failure and liver disease; coagulation disorders, chronic digestive disorders, pancreatic insufficiency, immunological disease and type 1 and 2 diabetes.

Intervention groups

The intervention group of 60 to 70-year-old men who are able to perform resistance and endurance exercises in this research. The control group of 60 to 70-year-old men go about their daily routine in these 16 weeks

Main outcome variables

SαKl SIRT1, FOXO, oxidative enzymes as well as glucose homeostasis and lipid levels of physical fitness, body composition and blood pressure and heart rate in obese elderly

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230810059112N1**
Registration date: **2023-09-18, 1402/06/27**
Registration timing: **retrospective**

Last update: **2023-09-18, 1402/06/27**
Update count: **0**

Registration date

2023-09-18, 1402/06/27

Registrant information

Name

Maryam Safari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-14, 1401/01/25

Expected recruitment end date

2022-06-15, 1401/03/25

Actual recruitment start date

2022-04-14, 1401/01/25

Actual recruitment end date

2022-06-15, 1401/03/25

Trial completion date

2022-10-22, 1401/07/30

Scientific title
The effect of combined exercise on plasma levels of alpha-klotho, sirtuin 1, oxidative enzymes, lipid profile and glucose homeostasis in obese men aged 60 to 70 years.

Public title
The effect of combined exercise on plasma levels of alpha-glucose, sirtuin 1, oxidative enzymes, lipid profile and glucose homeostasis in obese men aged 60 to 70 years.

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
The subjects were between 60 and 70 years old People who have the ability to implement the training protocol and tests Stable body weight (±5 kg) for at least six months Ability to perform the exercise intervention (exercise capacity) and participants consuming an omnivorous diet

Exclusion criteria:
History of orthopedic diseases in the last 5 years and vision problems Having daily sports activities for at least two years Having suspicious cases such as cardiovascular disease, angina pectoris, myocardial infarction, stroke, peripheral artery occlusion disease Having kidney failure and liver disease, coagulation disorders, chronic gastrointestinal disorders (e.g. Crohn's disease), pancreatic insufficiency, immunological disease (e.g. autoimmune disease) and not taking immunosuppressive drugs or laxatives, heart failure, cardiac arrhythmia, type 1 and 2 diabetes

Age
From **60 years** old to **70 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **46**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment to intervention and control groups The simple random method of the lottery method, each name removed was placed in one of the two study groups

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Islamic Azad University-Rasht Branch (Research Ethics Committee)

Street address
Lakani Street - Azad University, Rasht Branch

City
Rasht

Province
Guilan

Postal code
4147654919

Approval date
2022-07-20, 1401/04/29

Ethics committee reference number
IR.IAU.RASHT.REC.1401.010

Health conditions studied

1

Description of health condition studied
The study subjects are obese

ICD-10 code
E66

ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
levels of klotho

Timepoint
Before and after the end of 16 weeks of training

Method of measurement
ELISA method

2

Description
Sirtuin1

Timepoint
Before and after the end of 16 weeks of training

Method of measurement
ELISA method

3

Description
Catalase enzyme

Timepoint
Before and after the end of 16 weeks of training

Method of measurement
ELISA method

4

Description
Superoxide dismutase enzyme
Timepoint
Before and after the end of 16 weeks of training
Method of measurement
ELISA method

5

Description
Total antioxidant capacity
Timepoint
Before and after the end of 16 weeks of training
Method of measurement
ELISA method

6

Description
FOXO1
Timepoint
Before and after the end of 16 weeks of training
Method of measurement
ELISA method

7

Description
Insulin-like growth factor-1 (IGF-1)
Timepoint
Before and after the end of 16 weeks of training
Method of measurement
ELISA method

8

Description
Insulin
Timepoint
Before and after the end of 16 weeks of training
Method of measurement
ELISA method

9

Description
Fasting blood sugar
Timepoint
Before and after the end of 16 weeks of training
Method of measurement
By photometric enzymic calorimetric

10

Description
Triglyceride
Timepoint
Before and after the end of 16 weeks of training
Method of measurement
Enzymatic calorimetric method

11

Description
High density lipoprotein
Timepoint
Before and after the end of 16 weeks of training
Method of measurement
Enzymatic calorimetric method

12

Description
Low density lipoprotein
Timepoint
Before and after the end of 16 weeks of training
Method of measurement
Through the equation of Friedwald et al(LDL = TC - HDL - TG/0.5

13

Description
Total cholesterol
Timepoint
Before and after the end of 16 weeks of training
Method of measurement
Enzymatic photometric method

14

Description
Ability and capacity to perform basic movements and mobility
Timepoint
Before and after the end of 16 weeks of training
Method of measurement
TUG standing and walking time test

15

Description
Aerobic strength
Timepoint
Before and after the end of 16 weeks of training
Method of measurement
Using Racport

16

Description
Hand and paw strength test(hand grip)
Timepoint
Before and after the end of 16 weeks of training
Method of measurement
Hand and paw strength test(hand grip)with a dynamometer

17

Description
Lower body muscle strength
Timepoint

Before and after the end of 16 weeks of training

Method of measurement

30 second sitting on a chair test

Secondary outcomes

1

Description

Blood pressure and heart rate

Timepoint

Before and after 16 weeks of training

Method of measurement

Variables were measured at rest and after exercise with a sphygmomanometer, systolic and diastolic blood pressure and heart rate

2

Description

Body composition

Timepoint

Before and after 16 weeks of training

Method of measurement

Using weight, body mass index, waist to hip ratio and fat percentage

Intervention groups

1

Description

IntervIn this study, the intervention is sports training, which will be combined training (resistance, endurance) for 16 weeks and 3 sessions per week for 60 minutes. Before the start of the training period, in order to know about the health status and level of preparation of the people, the PARQ physical activity readiness questionnaire will be used. Before starting the main exercises, the subjects are taught exercises for a week. The combined training group has a 16-week training program that consists of three sessions each week and each session lasts 60 minutes. Aerobic and resistance exercises will be held in the morning (6:30 to 7:30). First stage, general warm-up for 10 minutes (walking, soft running, stretching and mobility), performing aerobic exercises for 45 to 60 minutes with an intensity equal to 50 to 70 percent of the reserve heart rate and a training session that gradually It starts from 30 minutes and increases to 60 minutes at the end of the course (Hijazi, 2017). Weight training can be harmful for inexperienced seniors unless it is done under the supervision of a trainer. Therefore, doing resistance exercises with body weight can be more safe and attractive for the elderly, that's why resistance exercises for 10 to 15 minutes with weight bearing to strengthen the muscles of the lower and middle limbs with movements such as squats, lunges, long and Sit-ups, planks and lateral planks (both sides of the body), triceps dip will take place in Lahijan Park (Lahijan Pool). which starts with 2 sets of 10 repetitions in the first weeks and increases to 3 sets of 15 repetitions in the 16th week. At the end of each training session, the body returns to its initial state and cools down for 10 minutes (slow running, walking and stretching exercises). will be done. These exercises will last up to 16 weeks. Anthropometric tests will be done 48 hours before and laboratory tests before the first training session, and after 16 weeks of training, tests and blood tests will be repeated for both groups. It should also be mentioned that at the beginning and after 16 weeks of training, laboratory tests including SαKl, SIRT1, CAT, ROS, SOD, IGF-1, HDL, LDL, cholesterol and triglycerides, FBS, insulin and HOMA-IR blood serum, capacity It is a plasma antioxidant. It should be noted that blood samples are collected 24 hours before training and 24 hours after training for both groups. Sampling will be done between 8 and 10 am in the laboratory, from the vein of the left hand of each subject, while sitting and resting (Hijazi, 2017). Blood samples will be poured into test tubes containing anticoagulant. Then it is centrifuged at 3000 rpm for 10 minutes and the separated plasma is used for analysis. Also, field tests including stand-up and walking time test, Rockport test, consecutive jumps for anaerobic power, hand and paw strength test for upper limb strength, lower limb muscle strength from "sitting on a chair for 30 seconds" test will be used.ention group:

Category

Lifestyle

2

Description

Control group: This group performed field and laboratory tests at the beginning and after 16 weeks, and no intervention was performed.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Aria Clinic

Full name of responsible person

Maryam Safari Sharafshadeh

Street address

Kashif Street, Aria Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Ali delpasand

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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
Islamic Azad 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
Islamic Azad University

Full name of responsible person
Maryam Safari Sharafshadeh

Position
Student of Azad University, Rasht branch

Latest degree
Master

Other areas of specialty/work
Others

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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

In the study of the effect of combined training on the plasma levels of alpha klotho, 1, oxidative enzymes, lipid profile and glucose homeostasis in obese men 60 to 70 years after being unidentifiable, part of the data and the outcome of the type of training can be shared.

When the data will become available and for how long

Beginning of access in the first half of 2024 until 6 months after the publication of the article.

To whom data/document is available

Researchers working in academic and scientific institutions are available.

Under which criteria data/document could be used

The use of data should be within the framework of the laws and should not be misused.

From where data/document is obtainable

To the researcher - Islamic Azad University, Rasht branch

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

Send a message to the researcher's email. Responds as soon as possible.

Comments