

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Effect of combined continues and interval aerobic training on body composition, aerobic power, muscular strength and some serum Biochemistry and hemodynamic indices in males with metabolic syndrome

Protocol summary

2009-07-23, 1388/05/01

Summary

The overall Aim of this study was to determine the Effect of combined continues and interval aerobic training on body composition, aerobic power, muscular strength, and some serum biochemistry and hemodynamic indices of men with metabolic syndrome. Thirty patients with the metabolic syndrome defined according to the Adult Treatment Panel III criteria were selected. The patients were randomized and stratified (by age, Weight and VO2max) into exercise (n15) or control group (n15). Participants in exercise group received combined continues and interval aerobic training with a slope of 2% on a treadmill 3 times a week for 16 weeks. They warmed up for 5 minutes at 50% of maximal heart rate (Hrmax) before performing 20 minutes Continuous at 70% of Hrmax and 4 minutes intervals at 90% of Hrmax with 3 minutes active recovery at 70% of Hrmax between intervals and 5 minutes cool-down period, giving a total exercise time of 55 minutes. The control group followed their routine life activities. Body composition, physical parameters and metabolic indices were measured in both groups at first, middle and the end of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812233565N1**

Registration date: **2009-07-23, 1388/05/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Trbriz University and Tabriz University of Medical Sciences

Expected recruitment start date

2009-07-23, 1388/05/01

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of combined continues and interval aerobic training on body composition, aerobic power, muscular strength and some serum Biochemistry and hemodynamic indices in males with metabolic syndrome

Public title

Effect of physical activity in the treatment of metabolic

syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Male sex, Having sufficient criteria for diagnosing metabolic syndrome (according to ATP III definition), willingness to participate in the study, waist in the thinnest area 107 ± 5 cm, age 50 ± 5 Exclusion criteria: any chronic or severe acute illness, inability to do the physical activity, having orthopedic problems not able to do this physical activity, unwillingness to participate in the study

Age
From **44 years** old to **55 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

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
Tabriz University of Medical Sciences

Street address
Research vice chancellor of Tabriz University of Medical Sciences

City
Tabriz

Postal code

Approval date
2009-10-11, 1388/07/19

Ethics committee reference number
5480/4/5

Health conditions studied

1

Description of health condition studied

Metabolic Syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Determine and compare of some indicators of body composition (thickness of subcutaneous fat, abdominal obesity) in all groups before and after intervention.

Timepoint
Before training - at the end of the eighth week - at the end of the sixteenth week.

Method of measurement
Subcutaneous fat thickness will be achieved using a thickness gauge device (Kalypr) and three point formula (behind the arm, abdomen and above the hip) Faculty of America Sports Medicine (ACSM).

Secondary outcomes

1

Description
levels of insulin resistance and beta cell function

Timepoint
Before training, weeks 8 and 16 after the intervention

Method of measurement
fasting blood glucose and insulin measure by using spectrophotometry and ELISA kit respectively and insulin resistance and beta cell function determined by HOMA-IR and HOMA- β -cell.

2

Description
The thigh muscles power

Timepoint
Before training, weeks 8 and 16 after the intervention

Method of measurement
individuals isometric thigh muscle strength (the length) determined by dynamometer

3

Description
The aerobic power

Timepoint
Before training, weeks 8 and 16 after the intervention

Method of measurement
Aerobic power persons (maximum oxygen consumption) determined by the Bruce treadmill test.

4

Description
levels of lipid profiles (TG, HDL, LDL and TC)

Timepoint
Before training, weeks 8 and 16 after the intervention

Method of measurement

Each variables are measured by a specific biochemical methods. (TC,TG and HDL measured by kit and LDL calculated by this formol $LDL = TC - (HDL - TG/5)$).

5

Description

Blood pressure

Timepoint

Before training, weeks 8 and 16

Method of measurement

Resting blood pressure will be measured by Mercury mannometer

Intervention groups

1

Description

Intervention group: combined continues and interval aerobic training (respectively 70 and 90% of maximum heart rate)with a slope of 2% on a treadmill 3 times a week for 16 weeks. Total exercise time was 55 minutes each session.

Category

Other

2

Description

Control group: routine physical activities

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Hamid Esmaeli

Street address

Golgashat avenue, Tabriz

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences and Tabriz Univesity

Full name of responsible person

Alireza Ostadrahimi

Street address

Research vice-chancellor of Tabriz University of Medical Sciences

City

Tabriz

Grant name

124202- 10506

Grant code / Reference number

124202

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

Yes

Title of funding source

Tabriz University of Medical Sciences and Tabriz Univesity

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University

Full name of responsible person

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Postal code**Phone****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty