

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of a combined training session on cardiorespiratory fitness , motor control , cognitive function , balance , walking performance and postural control in active elderly men

Protocol summary

Study aim

The purpose of the present study was to investigate the effect of a combined training session on cardiopulmonary fitness, motor control, cognitive function, balance , walking performance and postural control in elderly active men

Design

In the present study, experimental and control groups, which were divided into simple random sampling, performed their own exercises for 8 weeks.

Settings and conduct

Semi-experimental and in one of the parks of Lahijan city

Participants/Inclusion and exclusion criteria

Entry requirements: 60 to 70 years old men; be healthy based on a health questionnaire and confirmation by a doctor; regular exercise history; BMI between 20 and 29; ability to follow instructions by the examiner and complete the questionnaire. No entry conditions: tobacco and alcohol consumption; failure to attend more than two sessions; having chronic and specific diseases; lack of health approval by a doctor; having mental illness and taking psychotropic drug.

Intervention groups

Intervention group: combined exercise group for eight weeks, three sessions per week. Aerobic exercise with 50 to 70% intensity of maximum heart rate, 15 to 30 minutes, weight-bearing resistance training, 3 sets of 15 repetitions for 10 to 15 minutes, balance training for 5 to 10 minutes. The control group continues its sports activities without the intervention of the researcher.

Main outcome variables

Cardiac readiness, pulmonary function, motor control, cognitive function, balance, walking performance and postural control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150531022498N32**

Registration date: **2020-05-28, 1399/03/08**

Registration timing: **retrospective**

Last update: **2020-05-28, 1399/03/08**

Update count: **0**

Registration date

2020-05-28, 1399/03/08

Registrant information

Name

Ramin Shabani

Name of organization / entity

Islamic Azad University

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-17, 1398/07/25

Expected recruitment end date

2019-12-25, 1398/10/04

Actual recruitment start date

2019-10-17, 1398/07/25

Actual recruitment end date

2019-12-25, 1398/10/04

Trial completion date

2020-01-05, 1398/10/15

Scientific title

The effect of a combined training session on cardiorespiratory fitness , motor control , cognitive function , balance , walking performance and postural control in active elderly men

Public title

Effect of combined exercise training in active elderly men

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

60 to 70 years old men Be healthy based on a health questionnaire and confirmation by a doctor Regular exercise history It has a BMI between 20 and 29 Ability to follow instructions by the examiner and complete the questionnaire

Exclusion criteria:

Tobacco and alcohol consumption Failure to attend more than two sessions Having chronic and specific diseases Lack of health approval by a doctor Having mental illness and taking psychotropic drugs

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: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Forty active elderly were selected as participants in the research process. After the necessary investigations and based on the information of the completed questionnaires, the subjects were divided into two groups of 20 people using a lottery to divide by simple random method.

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 Islamic Azad University, Rasht Branch

Street address

Islamic Azad University Rasht Branch, Taleshan Bridge, Rasht

City

Rasht

Province

Guilan

Postal code

4147654919

Approval date

2020-05-09, 1399/02/20

Ethics committee reference number

IR.IAU.RASHT.REC.1399.015

Health conditions studied

1

Description of health condition studied

Active older men

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Heart rate

Timepoint

Before and after the intervention

Method of measurement

Record blood pressure and heart rate before and immediately after the rockport test

2

Description

Pulmonary function

Timepoint

Before and after the intervention

Method of measurement

A spirometer was used to measure the amount of lung variable volume during respiratory maneuvers.

3

Description

Static motor control

Timepoint

Before and after the intervention

Method of measurement

Static motor control was measured using a stabillometer

4

Description

Static balance

Timepoint

Before and after the intervention

Method of measurement

Static balance was measured using a stabilometer .

5

Description

Static postural control

Timepoint

Before and after the intervention

Method of measurement

Static postural control was measured using a stabilometer .

6

Description

Walking performance

Timepoint

Before and after the intervention

Method of measurement

This test consists of 10 parts. Subjects had to perform a total of 10 items over a distance of 6 meters and a width of 30 centimeters according to the instructions given, which include: 1- Walking level, 2- Change in walking speed, 3- Walking with horizontal rotation of the head, 4- Walking with vertical rotation of the head, 5- Walking and pelvic rotation, 6- Walking so that it is an obstacle in the middle of the road, 7- Walking with a low reliability level, 8- Walking with your eyes closed, 9- Moving backwards, 10- Climbing stairs.

7

Description

Cognitive function

Timepoint

Before and after the intervention

Method of measurement

In this test, 8 cognitive domains were measured through various skills including executive performance, naming, memory, language, abstraction, short-term memory, and awareness of time and place.

Secondary outcomes

1

Description

Body composition

Timepoint

Before and after the intervention

Method of measurement

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

Intervention groups

1

Description

Intervention group: combined exercise group for eight weeks, three sessions per week. Aerobic exercise with 50 to 70% intensity of maximum heart rate, 15 to 30 minutes, weight-bearing resistance training, 3 sets of 15 repetitions for 10 to 15 minutes, balance training for 5 to 10 minutes.

Category

Other

2

Description

Intervention group: This group performs light aerobic exercise three days a week for 8 weeks, including 15 minutes of walking and 10 aerobic movements with 50 to 60% of maximum maximum heart rate

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahan Talent Center

Full name of responsible person

Mina Safari

Street address

Lahijan, Chai Square, Jomhuri St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ali delpasand

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Islamic Azad University, Rasht Branch

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Email

shabani_msn@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Azad University, Rasht Branch

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Azad University, Rasht Branch

Full name of responsible person

Mina Safari

Position

student

Latest degree

Bachelor

Other areas of specialty/work

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to

make this available
Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available