

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effect of continuous training with rice bran supplementation on selected physical fitness factors, some oxidative stress and hemodynamic indicators of overweight policemen

Protocol summary

Study aim

Determining the interactive effect of continuous training and supplementation of rice bran on selected physical fitness factors, some oxidative stress, and hemodynamic indicators of overweight policemen

Design

A randomized, one-blinded, controlled, semi-experimental with a parallel-group design of 80 overweight males. A lottery will be used for randomization.

Settings and conduct

This research is an applied quasi-experimental study and includes pre-test and post-test with 4 experimental groups in which the effect of independent variables of continuous training and supplementation of rice bran and a combination of the two on selected variables of physical fitness, some pressure indicators Oxidation, some hemodynamic parameters, lipid profile, fasting blood sugar and some inflammatory cytokines and hs-CRP in overweight 20- to 40-year-old police men will be assessed. It will be done in a specialized laboratory. Collaborative researchers will be blind to pre-test and post-test evaluations and the statistical expert will be blind to how individuals are assigned to the groups.

Participants/Inclusion and exclusion criteria

Body mass index 25 to 29.9 Not participating in regular sports activities for 2 years No chronic diseases No respiratory, metabolic, cardiovascular, renal, and hepatic diseases

Intervention groups

Continuous exercise + placebo (20 people), Rice bran supplement (20 people), Combination of Continuous Exercise + Supplement (20 people) placebo (20 people)

Main outcome variables

Aerobic power; Anaerobic power; Body composition; Malonaldehyde; Superoxide dismutase; Glutathione peroxidase; Catalase; Systolic blood pressure; Diastolic

blood pressure; Resting heart rate; Cholesterol; Triglyceride; HDL; LDL; Fasting blood sugar; Interleukin-6; Interleukin-1 beta; hs-CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211023052854N1**

Registration date: **2021-11-27, 1400/09/06**

Registration timing: **retrospective**

Last update: **2021-11-27, 1400/09/06**

Update count: **0**

Registration date

2021-11-27, 1400/09/06

Registrant information

Name

Mojtaba Moazami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3342 1726

Email address

moazami1400@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2021-11-13, 1400/08/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of continuous training with rice bran supplementation on selected physical fitness factors, some oxidative stress and hemodynamic indicators of overweight policemen

Public title

The effect of continuous training and rice bran on oxidative stress and hemodynamic indices of overweight men

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

having a body mass index between 25 and 29.9 Not participating in regular sports activities for 2 years Not having Chronic diseases No respiratory, metabolic, cardiovascular, renal and hepatic diseases

Exclusion criteria:**Age**

From **20 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

80 policemen with overweight will be selected by available sampling method. Through a lottery (participants' names were written on paper and will be divided into 4 groups (3 intervention and 1 control groups) through random lottery)

Blinding (investigator's opinion)

Single blinded

Blinding description

In this research, responsible for collecting and processing the data, the type of intervention, and the participants in the research groups are unaware.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Islamic Azad University -Rasht Branch

Street address

Lakan Blv

City

Rasht

Province

Guilan

Postal code

4147654919

Approval date

2021-09-19, 1400/06/28

Ethics committee reference number

IR.IAU.RASHT.REC.1400.014

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

fat

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

aerobic power

Timepoint

48 hours before intervention and 48 hours after 12 weeks of intervention

Method of measurement

Aerobic power in this study will be measured by a shuttle run test.

2**Description**

anaerobic power

Timepoint

48 hours before intervention and 48 hours after 12 weeks of intervention

Method of measurement

Anaerobic power in this study will be measured by Rast test.

Secondary outcomes**1****Description**

Oxidative stress indices

Timepoint

48 hours before intervention and 48 hours after 12 weeks of intervention

Method of measurement

Measurements will be taken between 7 and 8 in the morning as a 12-hour fast and in the form of a venous blood sample with the help of a syringe while sitting on a chair.

2

Description

blood pressure

Timepoint

48 hours before intervention and 48 hours after 12 weeks of intervention

Method of measurement

Subjects' systolic and diastolic blood pressure will be measured using a Beaur digital sphygmomanometer.

3

Description

Lipid profile

Timepoint

48 hours before intervention and 48 hours after 12 weeks of intervention

Method of measurement

Lipid profiles including LDL, HDL, TG, VLDL and cholesterol are measured enzymatically with the kit of Pars-Azmon Company (made in Iran-Karaj).

4

Description

Fasting blood sugar

Timepoint

48 hours before intervention and 48 hours after 12 weeks of intervention

Method of measurement

It will be tested by laboratory measurements in the blood serum

5

Description

inflammatory cytokines

Timepoint

48 hours before intervention and 48 hours after 12 weeks of intervention

Method of measurement

Measurement of cytokines using special IL-6 and IL-1 β Diaclone kits made in France will be used according to the manufacturer's instructions and ELISA method.

6

Description

hs-CRP

Timepoint

48 hours before intervention and 48 hours after 12 weeks of intervention

Method of measurement

It is measured with the kit of Pars-Azmon Company

(made in Iran-Karaj) and by enzymatic method.

Intervention groups

1

Description

Intervention group1: Medium intensity continuous exercises for 12 weeks, 3 sessions per week will be used. Each session of continuous training for 60 minutes of walking or running on a treadmill includes 10 minutes of warm-up with an intensity of 50 to 60% of maximum heart rate, 45 minutes with 60 to 70% of maximum heart rate and 5 minutes of cooling. Participants will be trained to maintain the intensity of the workout by adjusting the speed or incline of the treadmill. For each session, heart rate, speed and incline will be recorded

Category

Rehabilitation

2

Description

Intervention group 2: Rice bran group will receive 10 gram packages of rice bran supplement of Bijar Quatterm Company 80% extraction for 6 weeks consumption (twice daily). They are asked to consume one packet before breakfast and one packet before dinner, and if desired, pour 10 grams of each packet into their usual yogurt and consume it.

Category

Treatment - Other

3

Description

Intervention group 3: Combining continuous exercise with rice bran supplementation

Category

Treatment - Other

4

Description

Control group: placebo They will receive a placebo for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sports Village

Full name of responsible person

Mojtaba Moazami Goodarzi

Street address

Mallard Road, Marlik Road, next to Mellat Bank, Sports Village

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Alireza Seidavi
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moazami1400@yahoo.com
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
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
Islamic Azad University
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Mojtaba Moazami Goodarzi
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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

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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available