# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

20 Sep 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; Malone dialdehyde; 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**

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**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-1β 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

**City**

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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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**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
**Full name of responsible person**
Mojtaba Moazami Goodarzi
**Position**
PhD student
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Master
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## Person responsible for updating data

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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