Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Plantain Supplementation on exercise-induced Oxidative Stress and Muscle Damage in Overweight Adult Men: A Randomized Controlled Trial

Protocol summary

Study aim

This study aimed to determine the effect of 7-day supplementation with Plantago major extract following a single session of high-intensity functional training(HIFT) on selected oxidative stress and muscle damage blood markers in overweight, untrained men. The exercise session lasted 27 minutes and 30 seconds at 80-85% of the participants' maximum heart rate.

Design

A two-armed parallel-group randomized trial, with a double-blind design. Randomization was performed using the RAND() function in Excel.

Settings and conduct

Location: Laboratory of Faculty of Physical Education and Sports Sciences, Allameh Tabatabai University, Tehran
The participants were randomly assigned to two groups, supplement and placebo, in a double-blind design. After 7 days of supplementation or placebo, they performed an (HIFT) session at 80-85% of their maximum heart rate. the exercise session lasted 27 minutes and 30 seconds. Blood samples were collected at three time points.

Participants/Inclusion and exclusion criteria

A total of 22 sedentary overweight adult men, aged 35 to 50 years, with a BMI between 25 and 29.9 kg/m2, healthy, and non-smokers

Intervention groups

Supplement group (n=11): Received 6 g/day of Plantago extract for 7 days. Placebo group (n=11) Blood samples were collected at: 1. Baseline(T1): Before supplementation. 2. Pre-exercise(T2): After 7 days of supplementation and before exercise. 3. Post-exercise (T3): Immediately after the exercise session.

Main outcome variables

Blood sampling from the serum and indicators of oxidative stress including: superoxide dismutase(SOD); malondialdehyde(MDA); total antioxidant capacity(TAC); Indicators of muscle damage include: lactate dehydrogenase(LDH); and creatine kinase(CK)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241111063676N1**
Registration date: **2025-03-05, 1403/12/15**
Registration timing: **retrospective**

Last update: **2025-03-05, 1403/12/15**
Update count: **0**

Registration date

2025-03-05, 1403/12/15

Registrant information

Name

Neda Rajamand

Name of organization / entity

Allame tabatabaei University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-09, 1402/01/20

Expected recruitment end date

2023-04-27, 1402/02/07

Actual recruitment start date

2023-04-21, 1402/02/01

Actual recruitment end date
2023-04-27, 1402/02/07
Trial completion date
2023-05-04, 1402/02/14

Scientific title
Effect of Plantain Supplementation on exercise-induced Oxidative Stress and Muscle Damage in Overweight Adult Men: A Randomized Controlled Trial

Public title
Effect of Plantain supplementation on oxidative stress and obesity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Abdominal obesity and waist size: above 80 cm No mental disorders No history of regular physical activity in the last 6 months No hormonal treatment Non-smokers Physical ability to attend the protocol No history of surgery in the last 2 years Absence of skeletal and muscular injuries Not taking medicine and nutritional and sports supplements
Exclusion criteria:
Weight loss Consumption of stimulants and energy drinks Not getting enough fluids Alcohol consumption Taking painkillers and anti-inflammatory drugs Having diabetes and high blood pressure Taking medicine Failure to complete exercise Using a diet outside of the researcher's recommendation Failure to participate in two test sessions
Age
From **35 years** old to **50 years** old
Gender
Male

Phase
1-2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **22**
Actual sample size reached: **22**
Randomization (investigator's opinion)
Randomized
Randomization description
This study randomly assigned 22 overweight adult men to either the supplement(Plantago) or placebo group. To control for the potential effect of Body Mass Index(BMI) on the results, participants were first stratified based on their mean BMI and then allocated to one of two study groups using stratified randomization. Random allocation was performed using Microsoft Excel. First, participants' BMI data were entered into the software. Then, the RAND() function was used to generate a random number for each participant. Based on these random values, participants were randomly assigned to one of the two groups(11 per group) in a way that ensured a nearly equal mean BMI across both groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study was conducted in a double-blind manner, meaning that both the participants and the researchers were unaware of the intervention type (supplement or placebo) to minimize bias and ensure the reliability of the results. On the day of the test, all the executive team members, including the coach, the blood sample collector, the laboratory expert, and the statistician, were unaware of the division of the participants until the time of analyzing the results.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Allameh tabatabaei University
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Approval date
2023-01-25, 1401/11/05
Ethics committee reference number
IR.ATU.REC.1401.077

Health conditions studied

1

Description of health condition studied
Overweight and Obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Serum levels of Superoxid dismutase

Timepoint
before the start of supplementation, seven days after supplementation, and immediately after the exercise session

Method of measurement
Superoxide dismutase serum level measuring kit made in Germany, ZellBio GmbH by ELISA method

2

Description
Serum levels of malondialdehyde

Timepoint
before the start of supplementation, 7 days after supplementation, and immediately after the exercise session

Method of measurement
Malondialdehyde serum level measuring kit made in Germany, ZellBio GmbH by ELISA method

3

Description
Serum levels of total antioxidantcapacity

Timepoint
before the start of supplementation, 7 days after supplementation, and immediately after the exercise session

Method of measurement
Total antioxidant capacity serum level measuring kit made in Germany, ZellBio GmbH by ELISA method

4

Description
Serum levels of Lactate dehydrogenase

Timepoint
before the start of supplementation, 7 days after supplementation, and immediately after the exercise session

Method of measurement
Measurement of Lactate dehydrogenase using NAC.Kinetic UV enzyme kit by Delta Derman Part Company, Made in Iran.

5

Description
Serum levels of Creatine Kinase

Timepoint
before the start of supplementation, 7 days after supplementation, and immediately after the exercise session

Method of measurement
Measurement of creatine kinase using NAC.Kinetic UV enzyme kit by Delta Derman Part Company, Made in Iran.

Secondary outcomes

empty

Intervention groups

1

Description
Plantain extract, provided from plantain seeds, in the form of capsules. Each capsule contains 600 mg of the extract, with a daily dosage of 12 grams (2 capsules/day) half an hour after having breakfast. The Plantago extract was produced by using an industrial reactor through a step-by-step solvent extraction process involving polar solvents (water and ethanol). The extract was then transformed into a powder using a spray dryer. The resulting powdered extract was accurately weighed using a precision balance (with a sensitivity of 0.01 grams) and then capsulated in edible gelatin capsules with adherence to health protocols and standards. Finally, the capsules were sealed and packaged for use by participants.

Category
Treatment - Drugs

2

Description
For the lacebo group, 14 capsules containing 400 mg of maltodextrin were provided for 7 day. Participants were instructed to take two capsules along with a glass of water 30 minutes after brekfast each day. Aside from teh preparation of the capsules, there was no visible difference in the intervention between the study group and the placebo group.

Category
Placebo

3

Description
Intervention Group: HIFT Training SessionThe training protocol consisted of an 8-minute warm-up, 27:30 minutes of exercise activity, and a 5-minute cool-down for all subjects in both the supplement and placebo groups.The exercise was performed as 10 functional movements in a circuit training system (two circuits, each with three sets). Each movement was performed for 30 seconds, followed by 20 seconds of active rest. After every 10 movements (1 set of exercise), subjects had a one-minute rest period. Each circuit was repeated for three sets.To standardize the activity load among participants, weights equivalent to 5% of each individual's body weight were used. Throughout the protocol, subjects were verbally encouraged to perform the movements with maximum speed and repetition.After each exercise circuit, subjects were asked about their Borg Rating of Perceived Exertion (RPE), and the score was recorded. The intensity of the exercises was performed in the range of 80-85% of maximum heart rate, which was monitored in real-time by a heart rate sensor.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Allameh Tabtabaei University
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Allameh tabatabaei 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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
The University of Allame tabatabaei
Full name of responsible person
Neda Rajamand
Position
Ph.D. Student
Latest degree
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Other areas of specialty/work
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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

No - There is not 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

The data will be available for publication if necessary and upon request from the corresponding author, supervisor, co-supervisor, and participants.

When the data will become available and for how long

within 5 years

To whom data/document is available

Corresponding author, supervisor, consultant, and participants

Under which criteria data/document could be used

Depending on the design and request

From where data/document is obtainable

Corresponding author Neda Rajamand neda.rajamand@gmail.com +989125392434

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

By sending an email and providing a clear explanation of the reason and process of the request, a response will be received within 24 hours.

Comments