Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

English title: The Effects of Eight Weeks Aerobic Training Combined with Wheat Germ Extract Supplementation on Serum Levels of some Apoptotic indices BAX, BCL-2, and Caspase-3 in men undergoing methadone treatment.

Protocol summary

Study aim
This study was designed to investigate the combined effect of aerobic exercise combined with the consumption of the NBS superfood dietary supplement on apoptosis factors in men using methadone.

Design
Controlled clinical trial with three non-randomized intervention groups on 60 men using methadone.

Settings and conduct
Male addicts undergoing methadone treatment at the Khane Sepid Addiction Treatment Center located in Mohammad Shahr, Karaj, will be enrolled in the study if they are eligible and will be divided into 4 groups. This study is designed as a double-blind study, with both participants and researchers unaware of the group allocation (supplement/placebo).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Negative urine test for morphine, cannabis, and methamphetamine, need to use methadone maintenance treatment for at least the past three months, no autoimmune diseases, cardiovascular and pulmonary diseases, no muscle and tendon injuries; Exclusion criteria: Unwillingness to participate in the study and being sick

Intervention groups
Intervention group 1: Subjects will perform exercises three times a week for 40 minutes each time for 8 weeks and at the same time, they will receive 4.5 grams of NBS superfood supplement orally in three equal doses daily. Intervention group 2: Subjects will perform exercises three times a week for 40 minutes each time for 8 weeks and at the same time, they will receive 4.5 grams of potato starch orally in three equal doses daily. Intervention group 3: Subjects will receive 4.5 grams of NBS superfood supplement orally (soluble in water) daily in three equal doses for 8 weeks. Control group: Subjects will receive 4.5 grams of placebo (potato starch) orally (soluble in water) daily in three equal doses for 8 weeks.

Main outcome variables
Apoptotic markers BAX, BCL-2, Caspase-3

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141228020465N8**
Registration date: **2026-08-01, 1405/05/10**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-01, 1405/05/10**
Update count: **0**

Registration date
2026-08-01, 1405/05/10

Registrant information
Name
Fatemeh Omidali
Name of organization / entity
University of Ayatollah Boroujerdi
Country
Iran (Islamic Republic of)
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f.omidali@abru.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-07-30, 1405/05/08

Expected recruitment end date
2026-08-16, 1405/05/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
English title: The Effects of Eight Weeks Aerobic Training Combined with Wheat Germ Extract Supplementation on Serum Levels of some Apoptotic indices BAX, BCL-2, and Caspase-3 in men undergoing methadone treatment.

Public title
The effect of aerobic exercise and superfood supplementation on apoptosis
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Negative urine test for morphine, cannabis, and methamphetamine.The need to use methadone maintenance treatment for at least the past three months,Absence of autoimmune diseases,absence of cardiovascular and pulmonary diseasesabsence of muscle and tendon injuries
Exclusion criteria:
Unwillingness to participate in research Being sick
Age
From **25 years** old to **35 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is designed as a double-blind study, so that both participants and researchers will be unaware of the group assignment (supplement/placebo). The supplement and placebo will be provided in identical packaging (in terms of appearance, labeling, and method of administration) and distributed by independent staff of the addiction treatment center who are not involved in other parts of the study.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق در پژوهش دانشکده علوم ورزش و تندرستی دانشگاه تهران
Street address
Tehran, Shahrak Qods (West), between South Flamack and Zarafshan, Simaye Iran Street - Central Headquarters of the Ministry of Health, Treatment and Medical Education, Block A, 13th Floor
City
Tehran
Province
Tehran
Postal code
1417733631
Approval date
2026-07-27, 1405/05/05
Ethics committee reference number
IR.UT.SPORT.REC.1405.056

Health conditions studied

1

Description of health condition studied
Addiction
ICD-10 code
P04.4
ICD-10 code description
Newborn (suspected to be) affected by maternal use of drugs of addiction

Primary outcomes

1

Description
Apoptosis
Timepoint
Before the intervention and 8 weeks after the end of the intervention
Method of measurement
Blood sample, serum separation, ELISA kit, use of ELISA reader

2

Description
Caspase-3
Timepoint
Before the intervention and 8 weeks after the end of the intervention
Method of measurement
Blood sample, serum separation, ELISA kit, use of ELISA

reader

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Aerobic exercise with supplement intake for 8 weeks. Exercise protocol: First, the subjects will warm up for 10 minutes at an intensity of 50% of maximum heart rate. Aerobic exercise will be performed at an intensity of 75% to 85% of maximum heart rate for 40 minutes, three times a week. Finally, the subjects will cool down for 10 minutes at an intensity of 50% of maximum heart rate. The subjects will receive the NBS Superfood supplement at a rate of 4.5 grams per day orally, dissolved in water, and daily in three equal doses: 1.5 grams in the morning, 1.5 grams in the afternoon, and 1.5 grams in the evening. The supplements will be provided by NBS Superfood (NBS Organic Company, Turkey).

Category

Lifestyle

2

Description

Intervention group 2: Aerobic exercise with placebo for 8 weeks. Subjects will first warm up for 10 minutes at an intensity of 50% HRmax. The aerobic exercise groups will perform high-intensity aerobic exercise (75% to 85% HRmax) for 40 minutes each time three times a week. Finally, subjects will cool down for 10 minutes at an intensity of 50% HRmax. The placebo will be 4.5 grams of potato starch orally per day, dissolved in water, in three equal doses: 1.5 grams in the morning, 1.5 grams in the afternoon, and 1.5 grams in the evening.

Category

Lifestyle

3

Description

Subjects will receive 4.5 grams of NBS Superfood supplement orally, dissolved in water, daily in three equal doses for eight weeks: 1.5 grams in the morning (6 am to 12 pm), 1.5 grams in the afternoon (12 pm to 6 pm) and 1.5 grams in the evening. (from 6 pm to 12 am). The supplements will be provided by NBS Superfood (NBS Organic Company, Turkey).

Category

Lifestyle

4

Description

Control group: The control group will receive only placebo for 8 weeks. They will receive 4.5 grams of potato starch orally, dissolved in water, in three equal doses: 1.5 grams in the morning, 1.5 grams in the afternoon, and 1.5 grams in the evening. They will not do any sports activities and will continue their lifestyle.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

White House

Full name of responsible person

sirous ziyarati

Street address

After Jafarabad Martyrs Square - Shams Street - White House Addiction Treatment Center

City

Mohammadshahr

Province

Alborz

Postal code

3194656879

Phone

+98 26 3409 1541

Email

contact@khanesepid.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of Sports and Health Sciences, University of Tehran

Full name of responsible person

Hamed Mousavi

Street address

North Kargar Street (Amirabad), above the intersection with Jalal Al-e Ahmad Expressway, between 15th and 16th Streets, it is located opposite the University of Tehran dormitory complex.

City

tehran

Province

Tehran

Postal code

1439813117

Phone

+98 21 6111 8807

Email

musavihamed@ut.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Faculty of Sports and Health Sciences, University of Tehran

Proportion provided by this source
100
Public or private sector
Public
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
Faculty of Sport and Health Sciences
Full name of responsible person
Arvin aryanpour
Position
Student
Latest degree
Master
Other areas of specialty/work
Exercise physiology
Street address
North Kargar Street (Amirabad), above the intersection with Jalal Al-e Ahmad Expressway, between 15th and 16th Streets, it is located opposite the University of Tehran dormitory complex.
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Postal code
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Phone
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Email
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Sport and Health Sciences
Full name of responsible person
fatemeh shabkhiz
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Exercise physiology
Street address
North Kargar Street (Amirabad), above the intersection with Jalal Al-e Ahmad Expressway, between 15th and 16th Streets, it is located opposite the University of Tehran dormitory complex.
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Person responsible for updating data

Contact
Name of organization / entity
Faculty of Sport and Health Sciences
Full name of responsible person
Arvin aryanpour
Position
Student
Latest degree
Master
Other areas of specialty/work
Exercise physiology
Street address
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Phone
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arvin.aryanpour@ut.ac.ir

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
Not applicable
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
Not applicable
Data Dictionary
Not applicable