Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of combined training and Nutrition Bio-shield Superfood (NBS) Supplementation on some factors affecting Epigenetic Changes in Obese Men with Type 2 Diabetes

Protocol summary

Study aim

The effect of combined exercise and Nutrition Bio-shield Superfood (NBS) supplementation on some factors affecting epigenetic changes (CD36,DNMT3a, Betaine) and physical performance in obese men with type 2 diabetes

Design

The trial will be conducted in 4 groups, randomized, single-blind, and in Phase 2-3 on 48 patients.

Settings and conduct

The subjects will perform exercises in a gym under the supervision of a specialist. The subjects will also not know whether they are taking the supplement or a placebo.

Participants/Inclusion and exclusion criteria

1. Age range 45 to 55 years. 2. No specific disease 3. No limiting orthopedic conditions. 4. Walk independently and be able to perform daily tasks. 5. Medication dosage has not changed in the past month. 6. No history of regular exercise in the past three months (Yuemin Chen et al., 2015). 7. No smoking 8. Have a medical certificate from a specialist to confirm the ability to perform physical activity. 9. Uncontrolled arrhythmia No insulin injection

Intervention groups

Combined exercises (resistance and aerobic) and Nutrition Bio-shield Superfood (NBS) supplementation. The exercises will be performed three times a week and the supplementation will be taken daily at a rate of 10 drops, equivalent to half a gram. The control group will only receive a placebo, which is similar to the supplement in question.

Main outcome variables

Changes in blood levels of DNMT3a (measured by ELISA), plasma Betaine concentration (measured by enzymatic assay), and CD36 expression/level (measured by ELISA) after 12 weeks of combined exercise training plus NBS supplementation in 48 patients with type 2 diabetes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260607069676N1**
Registration date: **2026-06-20, 1405/03/30**
Registration timing: **prospective**

Last update: **2026-06-20, 1405/03/30**
Update count: **0**

Registration date

2026-06-20, 1405/03/30

Registrant information

Name
Mohammad Khosravi Bakhtiari
Name of organization / entity
Hakim Sabzevari University
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2026-09-22, 1405/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combined training and Nutrition Bio-shield Superfood (NBS) Supplementation on some factors affecting Epigenetic Changes in Obese Men with Type 2 Diabetes

Public title

The effect combined training and NBS Supplementation on Type 2 Diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No specific disease such as acute psychiatric disorders, cardiovascular, respiratory diseases, heart surgery, autoimmune diseases and arthritis. No limiting orthopedic conditions. Walk independently and be able to perform daily tasks. The dose of the medication has not changed in the past month. No history of regular exercise in the past three months No smoking Have a medical certificate from a specialist to confirm the ability to perform physical activity Uncontrolled arrhythmia Severe hearing impairment No insulin injection

Exclusion criteria:

Failure to attend the training program for three consecutive sessions Personal problems Unwillingness to continue the research Injury Engaging in side activities Use of herbal supplements other than those used in the plan or chemical supplements

Age

From **45 years** old to **55 years** old

Gender

Male

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, after selecting the subjects, the subjects will be randomly divided into four groups. Simple Random Assignment is the method used for this purpose. In this method, each subject is assigned independently of the others and with equal probability (25%) to one of the four groups (combined exercise and supplementation, combined exercise and placebo, supplementation, placebo). Random assignment will be done using valid statistical software (such as SPSS, R or Excel) and using a random number generator.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, single-blinding will be used to control for potential bias and increase the validity of the findings. This means that subjects will be unaware of the type of intervention they are receiving (supplement or placebo) throughout the study. To implement this method, the supplement and placebo will be completely similar and indistinguishable in appearance, color, odor, taste, packaging, and method of administration. The products will be distributed by a third party (research collaborator) or using confidential codes so that subjects cannot identify whether they are in the intervention or control group.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hakim Sabzevari University

Street address

Sabzevar, Tohidshahr, Pardis University

City

sabzevar

Province

Razavi Khorasan

Postal code

۹۶۱۷۹۷۶۴۸۷

Approval date

2026-06-07, 1405/03/17

Ethics committee reference number

IR.HSU.REC.1405.005

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

cd36

Timepoint

Before the intervention and 72 hours after the last intervention session

Method of measurement

ELISA laboratory kit

2

Description
Betaine
Timepoint
Before the intervention and 72 hours after the last intervention session
Method of measurement
ELISA laboratory kit

3

Description
DNMT3a
Timepoint
Before the intervention and 72 hours after the last intervention session
Method of measurement
ELISA laboratory kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Combined exercise and NBS supplementation. Perform three sessions of resistance and aerobic exercise and take 10 drops of the supplement daily, equivalent to half a gram.
Category
Treatment - Drugs

2

Description
Intervention group 2: Combined exercise and placebo
Category
Treatment - Devices

3

Description
Intervention group3: NBS supplement. Dosage is the same as in the first group.
Category
Treatment - Drugs

4

Description
Control group: placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Parsian Clinic
Full name of responsible person
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Sponsors / Funding sources

1

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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
Hakim Sabzevari University
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
Hakim Sabzevari University

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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
Yes - There is 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
Some information such as age, gender, weight, medical condition, medications taken
When the data will become available and for how long
12 months after results are published
To whom data/document is available
University professors and students
Under which criteria data/document could be used
Use for scientific activities
From where data/document is obtainable
Send email to: Mohammadkgb79@yahoo.com
What processes are involved for a request to access data/document
Maximum one month
Comments