Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of two training program and vitamin D supplementation on lipid profile, leptin and body composition in obese adolescents with vitamin D deficiency

Protocol summary

Study aim

Comparison of the effect of two types of exercise programs and vitamin D supplementation on lipid profiles, leptin and body composition in obese adolescents with vitamin D deficiency.

Design

A single-blind randomized clinical trial in the form of pre-test-post-test with a control group in which 48 eligible male volunteers are selected and randomly divided into six groups of 8 people.

Settings and conduct

This study is carried out as a pre and post test in order to compare two methods of aerobic training with vitamin D supplementation on sedentary obese adolescents with vitamin D deficiency in Javanroud city. Eight weeks of training intervention with taking vitamin D supplement and placebo is done on subjects. This study is single-blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being male; being at the age of 13-15 years old; Having an informed consent for participation in the study; 25-OHD serum levels less than 20 ng/ml; body mass index more than 30 kg/m2. Exclusion criteria: having regular exercise in past 3 months; having illness; taking drugs and supplements; drug and alcohol addiction.

Intervention groups

Intervention group 1:running on treadmill + vitamin D, eight weeks training and 2,000 IU/day of vitamin D3 supplementation; Intervention group 2:running on treadmill + placebo, eight weeks training and daily maltodextrin capsule; Intervention group 3:jump rope + vitamin D, eight weeks training and 2,000 IU/day of vitamin D3 supplementation; Intervention group 4:jump rope + placebo, eight weeks training and daily maltodextrin capsule; Intervention group 5: 2,000 IU/day of vitamin D3; Control group: has no activity and does not receive supplements or placebo.

Main outcome variables

Serum leptin level; body fat percentage; high density lipoprotein; low density lipoprotein; Triglyceride; total cholesterol

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240702062312N1**
Registration date: **2024-07-31, 1403/05/10**
Registration timing: **prospective**

Last update: **2024-07-31, 1403/05/10**
Update count: **0**

Registration date

2024-07-31, 1403/05/10

Registrant information

Name
Naser Rostamzadeh
Name of organization / entity
The University of farhangian
Country
Iran (Islamic Republic of)
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+98 87 3371 1530
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-20, 1403/05/30

Expected recruitment end date

2024-08-31, 1403/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of two training program and vitamin D supplementation on lipid profile, leptin and body composition in obese adolescents with vitamin D deficiency

Public title

Leptin response to Training and Supplementation

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Being male Being at the age of 13-15 years old Body mass index (BMI) more than 30 kg/m2 Vitamin D deficiency (less than 20 ng/ml)

Exclusion criteria:

Doing regular exercise in the last 3 months Any illness or acute discomfort Lack of consent of parents or legal guardians Having a medical prohibition to participate in physical activity Taking medicine and supplements in the last 3 months Drug and alcohol addiction

Age

From **13 years** old to **15 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple method of drawing a number randomly from a bag: The researcher assigns a number to each of the samples, then they are selected using the random number table model and randomly assigned to one of the groups. For this, a number will be defined for each of the samples and a number for each of the groups and will be placed in separate bags. The first number that is randomly selected from the bag of samples will be placed in the first group that is selected from the bag of groups, and this will continue until all the samples are placed in the groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Groups that use vitamin D and placebo will use capsules with the same shape, taste, and color, and only the researcher knows which groups will use vitamin D and which groups will use placebo. The jump rope + vitamin D, running on treadmill + vitamin D and vitamin D groups will use 2000 IU of vitamin D in capsule form daily, and the jump rope + placebo and running on treadmill + placebo groups will use one placebo capsule daily in the same way.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Kurdistan

Street address

Pasdaran Blvd.,

City

Sanandaj

Province

Kurdistan

Postal code

6617715175

Approval date

2024-06-08, 1403/03/19

Ethics committee reference number

IR.UOK.REC.1403.022

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

Serum level of leptin

Timepoint

At the beginning of the study and 8 weeks after the start of the study

Method of measurement

Blood sampling

2

Description

Body fat percent

Timepoint

At the beginning of the study and 8 weeks after the start of the study

Method of measurement

Caliper

3

Description

High density lipoprotein (HDL)

Timepoint

At the beginning of the study and 8 weeks after the start of the study

Method of measurement

Blood sampling

4

Description

Low density lipoprotein (LDL)

Timepoint

At the beginning of the study and 8 weeks after the start of the study

Method of measurement

Blood sampling

5

Description

Triglyceride (TG)

Timepoint

At the beginning of the study and 8 weeks after the start of the study

Method of measurement

Blood sampling

6

Description

Total cholesterol (TC)

Timepoint

At the beginning of the study and 8 weeks after the start of the study

Method of measurement

Blood sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 3 sessions per week, 3 × 10 min interval running at 70–85% HRmax separated by 5 min active recovery running on a treadmill, for 8 weeks with 2000 units per day vitamin D supplementation

Category

N/A

2

Description

Intervention group 2: 3 sessions per week, 3 × 10 min interval running at 70–85% HRmax separated by 5 min active recovery running on a treadmill, for 8 weeks with placebo

Category

Placebo

3

Description

Intervention group 3: 3 sessions per week, 30 min of exercise including 1 min of exercise with 30 seconds of rest at 60–90 jump/min jump rope for 8 weeks with 2000 units per day vitamin D supplementation

Category

N/A

4

Description

Intervention group 4: 3 sessions per week, 30 min of exercise including 1 min of exercise with 30 seconds of rest at 60–90 jump/min jump rope for 8 weeks with placebo

Category

Placebo

5

Description

Intervention group 5: Eight weeks of consumption of 2000 units per day vitamin D supplementation

Category

Treatment - Drugs

6

Description

Control group: Non intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Kurdistan

Full name of responsible person

Dariush Sheikholeslami Vatani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Kurdistan

Full name of responsible person

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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

The University of Kurdistan

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

The University of Kurdistan

Full name of responsible person

Dariush Sheikholeslami Vatani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

exercise physiology

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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
A part of the data, such as the information related to the main result or the like, can be shared.

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Researchers

Under which criteria data/document could be used
Research in this field

From where data/document is obtainable
naserrostamzadeh806@gmail.com

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

Comments