Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the changes of Tumor necrosis factor-α and Interleukin-10 after 8 weeks of regular Pilates exercise and vitamin D intake in overweight men

Protocol summary

Study aim

Investigating the changes of Tumor necrosis factor-α and Interleukin-10 after 8 weeks of regular Pilates exercise and vitamin D intake in overweight men

Design

The present quasi-experimental study was performed using a pretest-posttest design with control group in a single blind manner. Subjects were randomly divided into four groups: control, Pilates exercise, vitamin D and combination. Pilates and combination training groups perform 8 weeks of Pilates training. Vitamin D and exercise+vitamin D groups will receive 50,000 IU of Vitamin D per week for 8 weeks

Settings and conduct

The statistical population includes sedentry adult men with overweight (body mass index between 25 and 29 kg / m 2), aged 45-55 years, referred to Ghaemshahr sports clubs. Pilates exercises are performed at 50-70% of heart rate reserve and three sessions per week for 8 weeks at the Paya Sports Club in Ghaemshahr. Subjects in the vitamin D and combination groups, vitamin D and exercise and control groups, will receive placebo in a single blind manner.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being a non-athlete, being overweight Exclusion criteria: smoking, use of special drugs, use of any supplements

Intervention groups

Intervention group 1: This group will do 3 sessions of Pilates training for 3 weeks and take placebo weekly. Intervention group 2: receive 50,000 IU of vitamin D weekly. Intervention group 3: In addition to Pilates exercises, they receive 50,000 IU of vitamin D. Control group: will only take placebo weekly.

Main outcome variables

25-Hydroxy vitamin D; tumor necrosis factor-alpha; interleukin 10; C reactive protein ; glucose, insulin, insulin resistance, thyroid-stimulating hormone, lipid profile; liver enzymes; renal enzymes, sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190831044650N2**
Registration date: **2020-03-18, 1398/12/28**
Registration timing: **retrospective**

Last update: **2020-03-18, 1398/12/28**
Update count: **0**

Registration date

2020-03-18, 1398/12/28

Registrant information

Name
Masoumeh Habibian
Name of organization / entity
Qaemshahar Branch, Islamic Azad University
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-31, 1398/10/10

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the changes of Tumor necrosis factor-α and Interleukin-10 after 8 weeks of regular Pilates exercise and vitamin D intake in overweight men

Public title
Effect of 8 weeks of Pilates exercise and vitamin D on Tumor necrosis factor-α and interleukin-10 levels in overweight men
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Being overweight Not having regular exercise for the past six months Ability to perform exercise training Not having cardiovascular disease Not having hypertension
Exclusion criteria:
Use of specific drugs Use of supplement smoking
Age
From **40 years** old to **55 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
The subjects will be divided into four groups of control, exercise, vitamin D and exercise + vitamin D using simple randomization table. First a number is assigned to each person. Then, using the random number table of each selected number, it is assigned to one of the groups at random and will continue until the number of individuals in each group is completed. Therefore, the researcher will have no option to change or predict the status of individuals. Random concealment will be done by a third person who does not participate in other stages of intervention.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants and analysts will be blind. The researcher will administer vitamin D capsules (50,000 units) to vitamin D and exercise + vitamin D individuals as well as placebo to control and exercise groups
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Babol branch, Islamic Azad University
Street address
Department of physical education, Qaemshahr branch, Islamic Azad University, Qaemshahr, Iran
City
Qaemshahr
Province
Mazandaran
Postal code
476516196
Approval date
2020-01-14, 1398/10/24
Ethics committee reference number
IR.IAU.BABOL.REC.1398.088

Health conditions studied

1

Description of health condition studied
Obesity and overweight
ICD-10 code
E66.0
ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Tumor necrosis factor-α
Timepoint
Before and after interventions
Method of measurement
Using the ELISA method

2

Description
25- hydroxy vitamin D
Timepoint
Before and after interventions
Method of measurement
Using the ELISA method

3

Description
Interleukin-10
Timepoint

Before and after interventions

Method of measurement

Using the ELISA method

4

Description

Thyroid Stimulating Hormone

Timepoint

Before and after interventions

Method of measurement

immunochemiluminescence assay

5

Description

C-Reactive Protein

Timepoint

Before and after interventions

Method of measurement

Using the ELISA method

6

Description

insulin

Timepoint

Before and after interventions

Method of measurement

Using the ELISA method

7

Description

insulin resistance

Timepoint

Before and after interventions

Method of measurement

Using the homeostasis model(HOMA-IR)

Secondary outcomes

1

Description

Glucose

Timepoint

Prior and after interventions

Method of measurement

Glucose oxidase assay

2

Description

urea

Timepoint

Prior and after interventions

Method of measurement

Urease method

3

Description

uric acid

Timepoint

Prior and after interventions

Method of measurement

Automatic colorimetric method

4

Description

creatinine

Timepoint

Prior and after interventions

Method of measurement

Jaffe methods

5

Description

Triglyceride

Timepoint

Prior and after interventions

Method of measurement

Enzymatic method

6

Description

low-density lipoprotein cholesterol (LDL-C)

Timepoint

Prior and after interventions

Method of measurement

Enzymatic method

7

Description

high-density lipoprotein cholesterol (HDL-C)

Timepoint

Prior and after interventions

Method of measurement

Enzymatic method

8

Description

total cholesterol

Timepoint

Prior and after interventions

Method of measurement

Enzymatic method

9

Description

Aspartate aminotransferase

Timepoint

Prior and after interventions

Method of measurement

Enzymatic method

10

Description

Alkaline phosphatase

Timepoint
Prior and after interventions
Method of measurement
Enzymatic method

11

Description
Alanine aminotransferase
Timepoint
Prior and after interventions
Method of measurement
Enzymatic method

Intervention groups

1

Description
Intervention group 1: Exercise group will perform 8 weeks of Pilates exercises with 50-55% of heart rate reserve, one set and 10 repetitions in the first week and 65-70% reserve heart rate, 4 sets with 12 repetitions in eighth week (with increase A gradual 5% vigorous exercise, one set and 2 reps every two weeks). They will also take a placebo capsule containing oral paraffin weekly in a single blind manner
Category
Treatment - Other

2

Description
Intervention group II: Vitamin D group, who take 50,000 IU of vitamin D capsules once a week for 8 weeks in a single blind manner
Category
Treatment - Other

3

Description
Intervention group 3: Subjects in this group will have 8 weeks of Pilates exercises similar to the exercise group and will consume 50,000 IU of vitamin D capsules once a week in a single blind manner.
Category
Treatment - Other

4

Description
Control group: There is no intervention in the control group and they are given placebo in a single blind manner.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Paya Sports Club
Full name of responsible person
Fatemeh Eslami Vasmaleii
Street address
Babol Street, Paya Sports Club, Qaemshahr, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qaemshahr branch, Islamic Azad University
Full name of responsible person
Dr Pyman Valipour
Street address
7 kilometers from Allameh Tabari Street, Islamic Azad University of Ghaemshahr Branch, Ghaemshahr, Iran.
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Phone
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habibian_m@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University Qaemshahr Branch
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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Qaemshahr branch, Islamic Azad University

Full name of responsible person
masoumeh habibian

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available