Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of four-week Water Aerobics training with and without caloric restriction and vitamin D supplementation on body composition, lipid profile and peripheral blood BDNF in adult females with overweight and obesity

Protocol summary

Study aim

the present study aims to determine the effect of four weeks of water aerobic training with 25% caloric restriction and vitamin D supplementation on body composition, lipid profile and peripheral blood BDNF (Brain-derived neurotrophic factor) in adult women with overweight and obesity.

Design

The present study is performed in the semi-experimental, pre- and post-test design, using four homogeneous groups .

Settings and conduct

.Pre-test fasting blood sampling,the physical fitness test and the initial anthropometric measurements will perform on the morning of the eighth day of each woman's menstural cycle on the same day at the University of Tabriz. The training period started on the ninth day of menstural cycle and lasted until the fifth day of other cycle. Some parts of the training were performed in the shallow water and some others in the deep water. Post-test fasting blood sampling and antipropometric measurements was performed 48 hours after the last training session.

Participants/Inclusion and exclusion criteria

Entry criteria: age range 30 to 50 years, body mass index, between 35-30 kg / m2 and having 11-9 times menstural cycle in a year) and Non-entry criteria (having systemic problems such as limited mobility, acute cardiovascular disease, lung disease and other problems, non-compliance with the study protocol and smoking and alcohol consumption)

Intervention groups

4 homogeneous groups including: exercise group, exercise + caloric restriction group, exercise + vitamin D supplementation group, exercise + calorie restriction + vitamin D supplementation group

Main outcome variables

Independent variables: Water Aerobic exercise, a medium caloric restriction, Vitamin D supplementation. Dependent variable: Body composition, Lipid profile,level of peripheral blood BDNF .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200411047036N1**
Registration date: **2020-06-05, 1399/03/16**
Registration timing: **retrospective**

Last update: **2020-06-05, 1399/03/16**
Update count: **0**

Registration date

2020-06-05, 1399/03/16

Registrant information

Name
Negisa Farhangi Zekloje
Name of organization / entity
The University of Tabriz
Country
Iran (Islamic Republic of)
Phone
+98 41 3336 1097
Email address
farhangifarhangi00@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-06, 1397/06/15

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

2018-09-06, 1397/06/15

Actual recruitment end date

2018-11-21, 1397/08/30

Trial completion date

2018-11-21, 1397/08/30

Scientific title

Effect of four-week Water Aerobics training with and without caloric restriction and vitamin D supplementation on body composition, lipid profile and peripheral blood BDNF in adult females with overweight and obesity

Public title

Effect of training, caloric restriction and vitamin D supplementation on body composition, lipid profile and plasma BDNF

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

women between 30 and 50 age group BMI= 30-35 kg/m2
women should be in pre-menopausal period women should have 9 to 11 menstural cycle in year

Exclusion criteria:

Age

From **30 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**
More than 1 sample in each individual
Number of samples in each individual: **2**
pre and post sampling
Actual sample size reached: **80**
More than 1 sample in each individual
Actual sample size in each individual: **2**
pre and post sampling

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, indivitual randomization unit, using random numbers table. Numbers 01-10 for the water exercise group, Numbers 11-20 for the water exercise + calorie restriction group, Numbers 21-30 for the water exercise + Vitamin D supplementation group and Numbers 31-40 for the water exercise + Caloric restriction + Vitamin D supplementation group are considered in the researcher. Then the researcher close her/his eyes and select a number in the random numbers table and reads the first two numbers of that 5 digits number. for selecting other numbers researcher go through the column. The first 10 numbers witch those are smaller than 40 are allocated to the first group and continue this way to determine the samples of all groups. It should be noted that after assigning the samples to 4 groups, the homogeneity of the groups in terms of control variables is examined using SPSS software. Allocation concealment: To this porpuse the sequentially numbered, opaque, sealed envelopes (SNOPE) are used. In this way, after creating a random sequence, based on the sample size of the research (40 people), 40 envelopes with aluminum sheets (using aluminum sheets available in the market) are Prepared and each random sequence created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain random sequencing, numbering on the outer surface of the envelopes is done in the same way. Finally, the lids of the envelopes are pasted and placed inside the box, respectively. At the beginning of the registration process, one of the envelope papers will be opened in order, according to the order in which the eligible participants entered the study, and the assigned group of the partner will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, by using placebo and recieving diet they have assumed that they all received the same intervention Reasercher,without any information and involvement in sample grouping

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

No. A3, Shahid Beheshti Street, Gharebaghiha Ave, second floor of Nour Tower

City

Tabriz

Province

East Azarbaijan

Postal code

5154911468

Approval date

2018-08-27, 1397/06/05

Ethics committee reference number

IR.TBZMED.REC.1397.446

Health conditions studied

1

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

2

Description of health condition studied
Lipid profile (Triglycerides, High-Density Lipoprotein (HDL), Low-Density Lipoprotein (LDL), Total cholesterol
ICD-10 code
E78.5
ICD-10 code description
Hyperlipidemia, unspecified

3

Description of health condition studied
Peripheral blood Brain-Drived Neurotrophic Factor
ICD-10 code
F32
ICD-10 code description
Major depressive disorder, single episode

Primary outcomes

1

Description
Changes in serum Brain-Drived Neurotrophic Factor
Timepoint
Pre-test blood sampling of Brain-Drived Neurotrophic Factor performed on the eighth day of each woman's menstural cycle and Post-test performed on 48 hour after the latest training session (the sixth or eighth day of each woman's menstural cycle)
Method of measurement
Serum Brain-Drived Neurotrophic Factor Concentration measured by the Competitive Sandwich Enzyme-Linked Immunoorbent Assay (ELISA) Test Using Crystal Day Biotech Kit made in China

2

Description
Waist circumference
Timepoint
Pre-test: the eighth day of each woman's menstural cycle
Post-test: 48 hour after the latest training session (the sixth or eighth day of each woman's menstural cycle)
Method of measurement
From the upper abdomen measured by a tape measure and after a normal exhalation.

3

Description
Range of Body Mass Index
Timepoint
Pre-test: the eighth day of each woman's menstural cycle
Post-test: 48 hour after the latest training session (the sixth or eighth day of each woman's menstural cycle)
Method of measurement
By dividing the weight in kilograms by the height of the meter

4

Description
Fat percentage
Timepoint
Pre-test: the eighth day of each woman's menstural cycle
Post-test: 48 hour after the latest training session (the sixth or eighth day of each woman's menstural cycle)
Method of measurement
By caliper tool and using Jackson-Pollock 3Point method

5

Description
Body Fat Mass
Timepoint
Pre-test: the eighth day of each woman's menstural cycle
Post-test: 48 hour after the latest training session (the sixth or eighth day of each woman's menstural cycle)
Method of measurement
By measuring weight and multiplying the percentage of fat by the amount of weight

6

Description
Lean Body Mass
Timepoint
Pre-test: the eighth day of each woman's menstural cycle
Post-test: 48 hour after the latest training session (the sixth or eighth day of each woman's menstural cycle)
Method of measurement
By eliminating the amount of fat mass from the amount of weight

7

Description
Serum triglyceride levels
Timepoint
Pre-test: the eighth day of each woman's menstural cycle
Post-test: 48 hour after the latest training session (the sixth or eighth day of each woman's menstural cycle)
Method of measurement
Using Enzymatic method

8

Description
Serum High-Density Lipoprotein
Timepoint
Pre-test: the eighth day of each woman's menstural cycle

Post-test: 48 hour after the latest training session (the sixth or eighth day of each woman's menstural cycle)

Method of measurement

Using Enzymatic method

9

Description

Serum Ligh-Density Lipoprotein

Timepoint

Pre-test: the eighth day of each woman's menstural cycle
Post-test: 48 hour after the latest training session (the sixth or eighth day of each woman's menstural cycle)

Method of measurement

Friedewald Formula

10

Description

Serum Total Colestrol

Timepoint

Pre-test: the eighth day of each woman's menstural cycle
Post-test: 48 hour after the latest training session (the sixth or eighth day of each woman's menstural cycle)

Method of measurement

Using Enzymatic method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Water Aerobic Training, 12 sessions in 1 to 1.5 hours, three times a week, subjects will intake a Vitamin D placebo everyday without any calorie restriction. In training days they will give a diet plan according their daily energy requirement+ exercise specific energy requirement and in other days a diet plan just according their daily energy requirement.

Category

Other

2

Description

Intervention group: Water Aerobic Training (Training:12 sessions in 1 to 1.5 hours, three times a week)+ Caloric restriction (In training days they will give a 25% restricted diet according their daily energy requirement+ exercise specific energy requirement and in other days a 25% restricted diet just according their daily energy requirement.)They will intake a Vitamin D placebo everyday

Category

Other

3

Description

Intervention group: Water Aerobic Training (Training:12 sessions in 1 to 1.5 hours, three times a week)+ Vitamin D Supplementation (They will intake a 1000 U Vitamin D pearl everyday), without any calorie restriction. In training days they will give a diet plan according their daily energy requirement+ exercise specific energy.

Category

Other

4

Description

Intervention group: Water Aerobic Training (12 sessions in 1 to 1.5 hours, three times a week)+ Caloric Restriction (In training days they will give a 25% restricted diet according their daily energy requirement+ exercise specific energy requirement and in other days a 25% restricted diet just according their daily energy requirement) + Vitamin D Supplementation (They will intake a 1000 U Vitamin D pearl everyday)

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

University Of Tbriz

Full name of responsible person

Negisa Farhangi Zekloje

Street address

No. A3, Shahid Beheshti Street, Gharebaghiha Ave, second floor of Nour Town

City

Tabriz

Province

East Azarbaijan

Postal code

5154911468

Phone

+98 41 3336 1097

Email

farhangifarhangi00@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Tabriz

Full name of responsible person

Dr.Asgar Asghari

Street address

The University of Tabriz, Faculty of Physics

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone
+98 41 3334 4273

Email
asgari@tabrizu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
The University of Tbriz

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
Shahid Beheshti University

Full name of responsible person
Dr.Afshar Jafari

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Others

Street address
Shahid Beheshti University, Tehran Province, Tehran, District 1, Daneshjou Boulevard

City
Tehran

Province
Tehran

Postal code
1983963113

Phone
+98 21 2243 1962

Fax

Email
afshar.jafari@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University

Full name of responsible person
Dr.Afshar Jafari

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Associate Professor

Street address
Shahid Beheshti University, Tehran Province, Tehran, District 1, Daneshjou Boulevard

City
Tehran

Province
Tehran

Postal code
1983963113

Phone
+98 21 2243 1962

Fax

Email
afshar.jafari@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
The University of Tabriz

Full name of responsible person
Negisa Farhangi Zekloje

Position
Graduated Student

Latest degree
Master

Other areas of specialty/work
Student

Street address
No. A3, Second Floor, Nour Town, Gharebaghi ha Alley, Shahid Beheshti Street, Tabriz, East Azerbayjan

City
Tabriz

Province
East Azarbaijan

Postal code
5154911468

Phone
+98 41 3336 1097

Fax

Email
www.farhangifarhangi00@gmail.com

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
Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only part of the data is possible

When the data will become available and for how long

Data will be accessible from september 2020

To whom data/document is available

Only researchers will be able to access the data

Under which criteria data/document could be used

Just to study more and get an idea of the research plan

From where data/document is obtainable

Farhangifarhangi00@gmail.com

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

Send a message to given email

Comments