

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The effects of curcumin supplementation along with pilates training on anthropometric indices, liver enzymes and lipid profile in overweight and obese women

#### Protocol summary

##### Study aim

Determining of the effects of curcumin supplementation along with pilates training on anthropometric indices, liver enzymes and lipid profile in overweight and obese women

##### Design

Clinical trial with control group, with factorial groups, single-blind, randomized, phase 3 on 60 people. For randomization, block design is used.

##### Settings and conduct

Referral to a private clinic in Ramsar in 2021, selection of 60 people based on inclusion criteria, randomization into 4 groups, intervention and pilates training for 8 weeks, completion of the individual consent, physical activity and 24-hour recall questionnaires, receiving 5 Cc of blood before and after the intervention. Blinding of statistical analyzer, coding by a third party who does not know the details.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study Women between 20 to 50 years old Body mass index (BMI) between 25 to 35 (kg / m<sup>2</sup>) Exclusion criteria: Reluctance of patients to participate in the study Use of other dietary supplements, probiotics and anti-inflammatory drugs Use of any antioxidant supplements in the last 3 months Use of immunosuppressive drugs Following of special diets Change of diet or decide to lose weight Pregnancy, lactation Smokers Menopause Metabolic and chronic diseases Having surgical operation to weight loss

##### Intervention groups

1) Supplement: one capsule 500 mg/d (450 mg of turmeric rhizome and 50 mg of turmeric extract), 2) Placebo: (one capsule 500 mg/d containing starch), 3) Pilates training (three times/week, 1 hour each time) and supplement one capsule 500 mg/d (450 mg of turmeric rhizome and 50 mg of turmeric extract), 4) Pilates

training (three times/week, 1 hour each time) and placebo (one capsule 500 mg/d containing starch)

##### Main outcome variables

Liver enzymes, lipid profile and anthropometric indices

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210103049933N2**

Registration date: **2021-05-24, 1400/03/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-05-24, 1400/03/03**

Update count: **0**

##### Registration date

2021-05-24, 1400/03/03

##### Registrant information

##### Name

zeinab porasgari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 5525 1015

##### Email address

porasgarizeynab@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-22, 1400/03/01

##### Expected recruitment end date

2021-07-24, 1400/05/02

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The effects of curcumin supplementation along with pilates training on anthropometric indices, liver enzymes and lipid profile in overweight and obese women

**Public title**  
The effects of curcumin supplementation along with pilates training in overweight and obese women

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Willingness to participate in the study Women between 20 to 50 years old Body mass index (BMI) between 25 to 35 (kg / m<sup>2</sup>)  
**Exclusion criteria:**  
Reluctance of patients to participate in the study Use of other dietary supplements, probiotics and anti-inflammatory drugs Use of any antioxidant supplements in the last 3 months Use of immunosuppressive drugs Following of special diets Change of diet or decide to lose weight Pregnancy, lactation Smokers Menopause Having a history of diabetes, cancer, liver, kidney, thyroid and gastrointestinal diseases Having surgical operation to weight loss

**Age**  
From **20 years** old to **50 years** old

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**  

- Data analyser

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Assignment of people in each of the study groups (supplement, placebo, pilates training and supplement, pilates training and placebo) will be done by "Random allocation software" using classified randomized blocking method (block size: 4). In addition, in order to reduce selection bias error, allocation concealment will be used. This will be done by assigning unit codes (two codes A and B) to each person's capsules. In this way, 60 people will be randomly allocated to supplement (n = 15), placebo (n = 15), pilates training and supplement (15), pilates training and placebo (n = 15) groups. In fact, each person will receive a can containing code A or B, and eventually 30 people will receive cans containing code A and 30 people will receive cans containing code B. Also, 30 people in two groups will receive pilates training in addition to supplement or placebo.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**  
In the present study, the statistical analyst will be blinded to the study groups. Before starting the study, the cans containing the respective capsules will be coded by a person other than the researcher (this person will not aware of the details of the research) to A and B, so that the type of received capsules in each group will be blinded for researcher. Also, placebo and supplement capsules will be similar in terms of color, shape, size and taste. In addition, cans containing the supplement and placebo will be quite similar.

**Placebo**  
Used

**Assignment**  
Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of Sport Sciences  
Research Institute

##### Street address

Velayat University Complex, Shahid Sohani St., Army  
Blvd, Imam Ali highway, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۱۴۸۹۶۳۵۳۷

#### Approval date

2021-04-20, 1400/01/31

#### Ethics committee reference number

IR.SSRC.REC.1400.025

## Health conditions studied

### 1

#### Description of health condition studied

Overweight and obesity

#### ICD-10 code

E66

#### ICD-10 code description

Overweight and obesity

## Primary outcomes

### 1

#### Description

Weight

#### Timepoint

Before the intervention and 1 week after the end of intervention

**Method of measurement**

Seca scale

**2**

**Description**

Body mass index

**Timepoint**

Before the intervention and 1 week after the end of intervention

**Method of measurement**

Weight divided by the square of height in meters (kg / m<sup>2</sup>)

**3**

**Description**

Waist circumference

**Timepoint**

Before the intervention and 1 week after the end of intervention

**Method of measurement**

Tape metre (cm)

**4**

**Description**

Hip circumference

**Timepoint**

Before the intervention and 1 week after the end of intervention

**Method of measurement**

Tape metre (cm)

**5**

**Description**

Lipid profile (HDL-c, LDL-c, TG, total cholesterol and VLDL)

**Timepoint**

Before the intervention and 1 week after the end of intervention

**Method of measurement**

Colorimetric enzymatic method (Pars Azmun)

**6**

**Description**

Alanine transaminase, Aspartate transaminase and Gamma-glutamyltransferase

**Timepoint**

Before the intervention and 1 week after the end of intervention

**Method of measurement**

Colorimetric enzymatic method (Pars Azmun)

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group:1) Supplement: one capsule 500 mg/d (450 mg of turmeric rhizome and 50 mg of turmeric extract) for 8 weeks

**Category**

Lifestyle

**2**

**Description**

Control group: one capsule 500 mg/d containing starch for 8 weeks

**Category**

Placebo

**3**

**Description**

Intervention group: 2) Pilates training (three times/week, 1 hour each time) and supplement one capsule 500 mg/d (450 mg of turmeric rhizome and 50 mg of turmeric extract) for 8 weeks

**Category**

Lifestyle

**4**

**Description**

Intervention group: 3) Pilates training (three times/week, 1 hour each time) and placebo (one capsule 500 mg/d containing starch) for 8 weeks

**Category**

Lifestyle

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Private clinic

**Full name of responsible person**

zeynab porasgari

**Street address**

No. 133, Mehregan Medical Building, Motahari St., Ramsar, Iran

**City**

Ramsar

**Province**

Mazandaran

**Postal code**

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**Phone**

+98 21 8807 4874

**Email**

porasgarizeynab@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Ali Kashi

**Street address**

Tehran, Imam Ali highway, Army Blvd, Shahid Sohani St., Velayat University Complex

**City**

Tehran

**Province**

Tehran

**Postal code**

1148963037

**Phone**

+98 21 8807 4874

**Email**

porasgarizeynab@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Islamic Azad University

**Proportion provided by this source**

1

**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**

Islamic Azad University

**Full name of responsible person**

zeynab porasgari

**Position**

Master of Science

**Latest degree**

Master

**Other areas of specialty/work**

Sports Physiology - Sports Nutrition

**Street address**

No.133, Mehregan Medical Building, Motahari St, Ramsar, Iran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Zeynab Porasgari

**Position**

Master of Sciences

**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Zeynab Porasgari

**Position**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

The person's information will be confidential and the results will be as collective statistics

### 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

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

This clinical trial will be an research article and its protocol, results report and statistical analysis will be published to be used by therapists and researchers.

### When the data will become available and for how long

after the publication of results

### To whom data/document is available

All researchers who have access to clinical trials databases

### Under which criteria data/document could be used

Sometimes for re-analysis or for use in meta-analysis studies

### From where data/document is obtainable

Project manager

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

Mail to porasgarizeynab@yahoo.com

### Comments