

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 / m2) 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 / m2)
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 / m²)

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

۴۶۹۱۸۴۶۹۴۰

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

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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

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**

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Full name of responsible person

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

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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