

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Investigating the Effect of Functional Edible Powders Enriched with Probiotics, Curcumin, or Their Combination on Quality of Life, Depression, anxiety, and Stress in Overweight or Obese Individuals with Metabolic Syndrome: a Randomized, double-blind, controlled clinical trial

#### Protocol summary

##### Study aim

Determination of the effect of functional edible powder enriched with curcumin, probiotics, and their combination on quality of life, depression, anxiety, and stress in overweight or obese individuals with metabolic syndrome

##### Design

A randomized, double-blinded, phase 3 controlled clinical trial with four parallel groups. 32 individuals (a total of 128) randomly enter the groups using random blocks.

##### Settings and conduct

128 eligible individuals referred to Imam Reza clinic in Shiraz, after informing and obtaining informed consent, are randomly assigned to 4 study groups. Participants along with a low-calorie diet, receive their group powders to dissolve in water and consume for 8 weeks daily. Powders are named as same as the groups with the letters A, B, C, and D to blind the participants, researchers, and assessors. Quality of life, depression, anxiety, and stress will be assessed before and after the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: overweight or obese individuals aged 30 to 65 with metabolic syndrome based on ATP III criteria; not suffering from metabolic, endocrine, or chronic diseases, covid-19, or any kind of infection; Not hospitalized, has not used antibiotics, curcumin, and probiotic supplements or supplements for 3 months before the study. Exclusion criteria: pregnancy or lactation.

##### Intervention groups

Participants dissolve and consume powders in water daily for 8 weeks powders which include edible functional powders enriched with 1000 mg curcumin (Group I),  $10^9$  CFU probiotics (Group II), and 1000 mg curcumin with  $10^9$  CFU Probiotics (Group III), and placebo powder

(Group IV). Also, all participants will receive a low-calorie diet with a reduction of 500 kcal according to their weight.

##### Main outcome variables

Quality of life, depression, anxiety, and stress

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220315054289N2**

Registration date: **2023-02-18, 1401/11/29**

Registration timing: **prospective**

Last update: **2023-02-18, 1401/11/29**

Update count: **0**

##### Registration date

2023-02-18, 1401/11/29

##### Registrant information

##### Name

Mohammad Ali Mohsenpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-06, 1401/12/15

**Expected recruitment end date**

2023-06-20, 1402/03/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the Effect of Functional Edible Powders Enriched with Probiotics, Curcumin, or Their Combination on Quality of Life, Depression, anxiety, and Stress in Overweight or Obese Individuals with Metabolic Syndrome: a Randomized, double-blind, controlled clinical trial

**Public title**

Effect of probiotic, curcumin, and curcumin-probiotic on quality of life, anxiety, stress, and depression

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Aged 30 - 65 years Overweight (BMI between 25 to 29.9) or obese (BMI over 30) individuals with metabolic syndrome based on ATP III criteria Not suffering from metabolic, endocrine, or cardiovascular disease (except diabetes, dyslipidemia, and hypertension) at baseline Not suffering from kidney, liver, or systemic diseases at the beginning of the study Not infected with Covid-19 or any other infections for 3 months before the study No history of hospitalization for 3 months prior to the study Has not used antibiotics for 3 months before beginning the study Has not taken curcumin and probiotic supplements, or supplements for 3 months before the study

**Exclusion criteria:**

Pregnancy Lactating

**Age**From **30 years** old to **65 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**Target sample size: **128****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will perform using the random block method (1: 1: 1: 1 ratio) for four groups (one control and three intervention groups). In this method, blocks of four will be created. Then, a block will be randomly selected to determine the groups assigned to the first four participants. The random-blocks selection process will be

repeated to determine the random allocation for the entire sample size. This process will be performed by an out-of-study person using a web page (sealedenvelope.com). For allocation concealment, after determining the random sequence, these sequences will be placed in numbered sealed opaqued envelopes for each participant. An out-of-study person familiar with randomization will perform this process. During the study, by entering any participant in the study, based on the sequence, an envelope will be opened and the allocated group will be revealed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the produced edible functional powders (including 3 types of powders) and the placebo are the same in color, odor, and taste. The sachets of all four types of powder will be quite similar in appearance, color, and size. Sachets will be named A, B, C, and D. The process of filling and naming the sachets will be done by an out-of-study person. Also, study groups will be named in accordance with the letters on the sachets. Therefore, in this study, participants and the research team (Including the principal investigator, investigators, clinical caregiver, and outcome assessor) will be blinded to the type of powder consumed by each participant until the end of the data analysis process.

**Placebo**

Used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research ethics committee of Shiraz University of Medical Sciences

**Street address**

Shiraz University of Medical Sciences, Zand st.

**City**

Shiraz

**Province**

Fars

**Postal code**

۱۴۳۳۶ - ۷۱۳۴۸

**Approval date**

2022-12-04, 1401/09/13

**Ethics committee reference number**

IR.SUMS.REC.1401.592

**Health conditions studied**

## 1

### Description of health condition studied

Metabolic Syndrome

### ICD-10 code

E88.81

### ICD-10 code description

Metabolic syndrome

## Primary outcomes

## 1

### Description

Quality of Life

### Timepoint

At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)

### Method of measurement

SF-36 questionnaire

## 2

### Description

Depression, Anxiety and Stress

### Timepoint

At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)

### Method of measurement

DASS-21 questionnaire

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group 1: Dissolve and receive curcumin-enriched edible functional powder containing 1000 mg of curcumin (Karen Pharma and Food Supplement Co.) in water daily for 8 weeks. They also follow a low-calorie diet with a reduction of 500 kcal during the study.

### Category

Treatment - Other

## 2

### Description

Intervention group 2: Dissolve and receive probiotic-enriched edible functional powder containing  $10^9$  CFU of Lactobacillus rhamnosus and Lactobacillus acidophilus (Parsilact Co.) in water daily for 8 weeks. They also follow a low-calorie diet with a reduction of 500 kcal during the study.

### Category

Treatment - Other

## 3

### Description

Intervention group 3: Dissolve and receive curcumin-probiotic-enriched edible functional powder containing 1000 mg of curcumin (Karen Pharma and Food Supplement Co.) and  $10^9$  CFU of Lactobacillus rhamnosus and Lactobacillus acidophilus (Parsilact Co.) in water daily for 8 weeks. They also follow a low-calorie diet with a reduction of 500 kcal during the study.

### Category

Treatment - Other

## 4

### Description

Control group: Dissolve and receive placebo powder in water daily for 8 weeks. They also follow a low-calorie diet with a reduction of 500 kcal during the study.

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Reza clinic

#### Full name of responsible person

Mohammad Hassan Eftekhari

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## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

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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**  
Shiraz University of Medical Sciences  
**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**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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