Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assessing the effect of Functional Edible Powder Enriched with Probiotics, Curcumin, or Their Combination on Some Inflammatory Markers, Fasting Blood Glucose, and Blood Pressure 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 TNF-a, IL-6, hs-CRP, fasting blood sugar, and blood pressure 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, which are named the same as the groups with the letters A, B, C, and D to blind the participant and the researcher, in water for 8 weeks daily. Inflammatory markers, fasting blood glucose, and blood pressure 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 any medications and supplements for 3 months before the study. Non-inclusion criteria: pregnancy; lactation; having components of the metabolic syndrome that require drug treatment.

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

TNF-a; IL-6; hs-CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220315054289N1**
Registration date: **2022-04-01, 1401/01/12**
Registration timing: **prospective**

Last update: **2022-04-01, 1401/01/12**
Update count: **0**

Registration date

2022-04-01, 1401/01/12

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-06-22, 1401/04/01
Expected recruitment end date
2022-10-22, 1401/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessing the effect of Functional Edible Powder Enriched with Probiotics, Curcumin, or Their Combination on Some Inflammatory Markers, Fasting Blood Glucose, and Blood Pressure in Overweight or Obese Individuals with Metabolic Syndrome: a Randomized, double-blind, controlled clinical trial

Public title
Investigating the effect Functional Edible Powder Enriched with Probiotics, Curcumin, or Their Combination on Some Inflammatory Markers, Fasting Blood Glucose, and Blood Pressure in Overweight or Obese Individuals with Metabolic Syndrome
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, any drugs or supplements for 3 months before the study
Exclusion criteria:
Pregnancy Lactating Suffering from components of the metabolic syndrome (diabetes, hypertension, or dyslipidemia) that require drug treatment
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 with rotation will be created by an out-of-study person. 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. 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
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Schools of Health and Nutrition-Shiraz University of Medical Sciences
Street address
School of Health and Nutrition, Razi Blvd., Shiraz
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Province
Fars
Postal code
7134814336
Approval date

2022-01-16, 1400/10/26

Ethics committee reference number

IR.SUMS.SCHEANUT.REC.1400.085

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

Tumor necrosis factor alpha (TNF-a) blood level

Timepoint

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

Method of measurement

Enzyme-linked immuno_sorbent assay (ELISA)

2

Description

Interleukin 6 (IL-6) blood level

Timepoint

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

Method of measurement

Enzyme-linked immuno_sorbent assay (ELISA)

3

Description

High-sensitivity C-reactive Protein (hs-CRP) blood level

Timepoint

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

Method of measurement

Enzyme-linked immuno_sorbent assay (ELISA)

Secondary outcomes

1

Description

Fasting blood glucose

Timepoint

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

Method of measurement

Standard enzymatic method

2

Description

Systolic blood pressure

Timepoint

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

Method of measurement

Sphygmomanometer

3

Description

Diastolic blood pressure

Timepoint

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

Method of measurement

Sphygmomanometer

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

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza clinic
Full name of responsible person
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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
Shiraz University of Medical Sciences
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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