# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effects of synbiotics supplement on anthropometric indices and body compositions in subjects aged 10-18 years with at least one item of metabolic syndrome

## Protocol summary

**Study aim**
Determination and comparison of mean changes of anthropometric indices and body composition before and after the study between the placebo and synbiotic groups

**Design**
A double-blind randomized clinical trial with randomized block allocation of patients with volume 4 blocks divided into 35 groups of intervention and placebo.

**Settings and conduct**
Individuals 10-18 years old referred to Isfahan University of Medical Sciences, Primary Care Center for Prevention of Non-Communicable Diseases, are referred to the weight control clinic of Isfahan University of Medical Sciences. They will participate if they wish

**Participants/Inclusion and exclusion criteria**
Inclusion criteria are age 10 to 18 years and have at least one item of metabolic syndrome, not participating in weight loss programs for the past 6 months Exclusion Factors Unwillingness to Continue Attending Study, Tobacco Use, Chronic Disease Drug Use

**Intervention groups**
The group receiving two capsules of 0.5 g of synbiotic twice daily and Group receiving two 0.5 g placebo capsules 2 times a day

**Main outcome variables**
Weight BMI Waist circumference WHtR Hip circumference WHR Wrist circumference Neck circumference Fat mass The amount of protein The amount of minerals Whole body water Body muscle mass

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20170501033747N2**
Registration date: **2019-11-28, 1398/09/07**
Registration timing: **prospective**

Last update: **2019-11-28, 1398/09/07**
Update count: **0**

**Registration date**
2019-11-28, 1398/09/07

**Registrant information**

**Name**
Motahar Heidari-Beni

**Name of organization / entity**
Isfahan university of medical sciences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 31 3792 3320

**Email address**
motahar.heidari@nutr.mui.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-01-21, 1398/11/01

**Expected recruitment end date**
2020-11-21, 1399/09/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effects of synbiotics supplement on anthropometric indices and body compositions in subjects aged 10-18 years with at least one item of metabolic syndrome

**Public title**
The effects of synbiotics supplement on item of metabolic syndrome
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age range 10 to 18 years A parent's willingness to participate in the study and sign the informed consent form Has at least one item of metabolic syndrome Failure to participate in weight loss programs for the past 6 months
**Exclusion criteria:**
Unwillingness to continue attending the study Non-compliance with intervention (less than 90% product use) Major change in energy intake and nutrient intake or consumption of less than 800 kcal and more than 4200 kcal during the study based on the 3-day food registration method Start any weight loss or weight gain diet during the study Individual tobacco use during the study Use of antioxidants, multivitamins or any dietary supplements during intervention Antibiotic use during the study People with mental illnesses, cardiovascular, lung, liver, kidney, cancer, thyroid and eating disorders Type 1 diabetic patients with insulin and hypoglycemic drugs People taking drugs that affect appetite, body weight, blood sugar, lipid profile or anti-inflammatory drugs
**Age**
From **10 years** old to **18 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**

- Participant
- Investigator

**Sample size**
Target sample size: **70**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
During Random Allocation, patients are divided into two groups of placebo and placebo with permutation block method with volume 4 blocks. In the permutation block procedure with blocks of volume 4, six blocks are formed, each block containing an equal number of intervention or placebo subjects. These groups include the blocks "ABAB", "BABA", "AABB", "BBAA '," ABBA "and" "BAAB". The blocks are then randomly arranged and numbered with the help of a statistics consultant. Then, participants receive the intervention or placebo according to this arrangement, and this cycle is repeated until the end of the sampling.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
This study is a double-blind randomized clinical trial, in which the participants and the investigator do not know which supplement is placebo and which is synbiotic.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Isfahan University of Medical Sciences
**Street address**
Hezarjrib street, Isfahan University of Medical Sciences,Research Institute for Primordial Prevention of Non-communicable Disease,Child Growth and Development Research Center
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174673461
**Approval date**
2019-11-13, 1398/08/22
**Ethics committee reference number**
IR.MUI.RESEARCH.REC.1398.449

## Health conditions studied

### 1

**Description of health condition studied**
Metabolic syndrome
**ICD-10 code**
E88.9
**ICD-10 code description**
Metabolic disorder, unspecified

## Primary outcomes

### 1

**Description**
Changes in anthropometric indices and body composition
**Timepoint**
The beginning and the end of the study
**Method of measurement**
body composition analysis

## Secondary outcomes

### 1

**Description**

"Abdominal Volume Index" and "Conicity Index" and "A Body Shape Index"

**Timepoint**

The beginning and the end of the study

**Method of measurement**

equation

## Intervention groups

### 1

**Description**

Intervention group: Two 0.5 g capsules of synbiotic twice daily for 8 weeks

**Category**

Prevention

### 2

**Description**

Control group: Two 0.5 g placebo capsules (maltodextrin) 2 times daily for 8 weeks

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Research Institute for Primordial Prevention of Non-communicable Disease

**Full name of responsible person**

Motahar Heidari-Beni

**Street address**

Hezarjrib street, Isfahan University of Medical Sciences,Research Institute for Primordial Prevention of Non-communicable Disease,Child Growth and Development Research Center

**City**

Isfahan

**Province**

Isfehan

**Postal code**

8174673461

**Phone**

+98 31 3792 5284

**Email**

heidari.motahar@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mrs Afshari

**Street address**

Hezarjrib street, Isfahan University of Medical Sciences,Research Institute for Primordial Prevention of Non-communicable Disease,Child Growth and Development Research Center

**City**

Isfahan

**Province**

Isfehan

**Postal code**

8174673461

**Phone**

+98 31 3792 3078

**Email**

heidari.motahar@gmail.com

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Non

**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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Motahar Heidari-Beni

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Hezarjrib street, Isfahan University of Medical Sciences,Research Institute for Primordial Prevention of Non-communicable Disease,Child Growth and Development Research Center

**City**

Isfahan

**Province**

Isfehan

**Postal code**

8174673461

**Phone**

+98 31 3792 5284

**Email**

heidari.motahar@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Esfahan University of Medical Sciences

**Full name of responsible person**
Motahar Heidari-Beni

**Position**
Assistant Professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Nutrition

**Street address**
Hezarjrib street, Isfahan University of Medical Sciences,Research Institute for Primordial Prevention of Non-communicable Disease,Child Growth and Development Research Center

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8174673461

**Phone**
+98 31 3792 5284

**Email**
heidari.motahar@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Esfahan University of Medical Sciences

**Full name of responsible person**
Motahar Heidari-Beni

**Position**
Assistant Professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Nutrition

**Street address**
Hezarjrib street, Isfahan University of Medical Sciences,Research Institute for Primordial Prevention of Non-communicable Disease,Child Growth and Development Research Center

**City**
isfagan

**Province**
Isfehan

**Postal code**
8174673461

**Phone**
+98 31 3792 5284

**Email**
heidari.motahar@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**
Yes - There is a plan to make this available

**Data Dictionary**
Yes - There is a plan to make this available

**Title and more details about the data/document**
All potential data can be shared after unidentifiable people

**When the data will become available and for how long**
Start of access period 6 months after printing results

**To whom data/document is available**
Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**
Any analysis on the data is possible

**From where data/document is obtainable**
heidari.motahar@gmail.com

**What processes are involved for a request to access data/document**
The applicant must email heidari.motahar@gmail.com. It should clearly explain where the data will be used

**Comments**