

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The effects of synbiotic supplement containing *Bacillus coagulans* and fructooligosaccharide on Quality of life (physical and mental health status) in women with polycystic ovarian syndrome.

#### Protocol summary

##### Study aim

Determining the effects of synbiotic supplement containing *Bacillus coagulans* and fructooligosaccharide on the life quality (physical and mental health status) of women with polycystic ovary syndrome.

##### Design

A controlled, parallel-group, triple-blind, randomized, phase 3 clinical trial on 60 patients. Block randomization method is used for randomization.

##### Settings and conduct

60 women over 18 years old with PCOS will be invited to participate. Then patients are asked to fill PCOSQ-26, SF-12 and PSS-10 questionnaires. Then the patients are randomly assigned to two groups, treatment or control. At the beginning, the set of sachets containing synbiotic supplements or placebo are coded by the factory as A and B so that the researcher, statistical analyst and patients will stay uninformed.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: Having polycystic ovary syndrome according to Rotterdam criteria, At least 2 weeks have passed since the diagnosis and treatment of PCOS, age range of over 18 years, BMI range of 18-5-35 Exclusion criteria: pregnancy, suffering from liver diseases, suffering from kidney failure and heart failure, infectious or inflammatory diseases, suffering from thyroid disorders, diabetes, cancer, hyperprolactinemin, synbiotics or probiotics products in the last month, Use of antibiotics in the last three months, Adherence to special diets or weight loss diets during the last three months and Use of corticosteroids, omega-3

##### Intervention groups

The intervention will be carried out for 12 months on two treatment and control groups, who will receive 2 grams of synbiotic sachets containing *Bacillus coagulans* and fructooligosaccharide or 2 grams of placebo sachets, respectively.

#### Main outcome variables

Emotional, Hirsotism, weight, Infertility and menstrual scores of PCOSQ-26 Physical and mental performance scores (SF12) PSS-10 score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211108053007N1**

Registration date: **2023-02-14, 1401/11/25**

Registration timing: **prospective**

Last update: **2023-02-14, 1401/11/25**

Update count: **0**

##### Registration date

2023-02-14, 1401/11/25

##### Registrant information

##### Name

Zahra Hariri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2235 7483

##### Email address

hariri.nut@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-19, 1401/11/30

##### Expected recruitment end date

2023-05-21, 1402/02/31

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The effects of synbiotic supplement containing Bacillus coagulans and fructooligosaccharide on Quality of life (physical and mental health status) in women with polycystic ovarian syndrome.

**Public title**  
The effects of synbiotic supplement containing Bacillus coagulans and fructooligosaccharide on Quality of life (physical and mental health status) in women with polycystic ovarian syndrome.

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Diagnosed with polycystic ovary syndrome (PCOS) according to Rotterdam criteria At least 2 weeks have passed since the diagnosis and treatment of PCOS Being in the age range of 18-45 years Being in the BMI range of 18.5-35 Willingness to cooperate  
**Exclusion criteria:**  
pregnancy Having liver diseases, kidney failure and heart failure, infectious or inflammatory diseases, thyroid gland disorders, diabetes, types of cancer and hyperprolactinemia. Consuming supplements or products containing synbiotics or probiotics in the last month Adherence to special diets or weight loss diets during the last three months Taking corticosteroids or omega-3

**Age**  
From **18 years** old to **45 years** old

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**  
Target sample size: **30**

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

**Randomization description**  
In order to randomly assign women, stratified block randomization method is used based on BMI, the use of hormonal drugs that regulate the menstrual cycle, and metformin.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
Placebo sachets are completely similar in appearance to synbiotic sachets. In order to carry out this research in a three-blind manner, at the time of the start of the study, the set of sachets containing synbiotic or placebo supplements are coded as A and B by the factory so that

the researcher, statistical analyst and patients are not informed about the type of supplements received by each group.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of vice-chancellor in Research Affairs - Shahd Beheshti University of Med

##### Street address

Ground floor, Building No. 2, Aarabi St., Daneshjoo Blvd., Yaman St., Chamran Hwy.

##### City

Tehran

##### Province

Tehran

##### Postal code

1998743664

#### Approval date

2023-02-12, 1401/11/23

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1401.703

## Health conditions studied

### 1

#### Description of health condition studied

Polycystic Ovary Syndrome

#### ICD-10 code

E28.2

#### ICD-10 code description

Polycystic ovarian syndrome

## Primary outcomes

### 1

#### Description

Emotional domain score of PCOSQ-26

#### Timepoint

At the beginning and 12 weeks after the start of the intervention

#### Method of measurement

PCOSQ-26 form

### 2

#### Description

Hirsotism domain score of PCOSQ-26

### **Timepoint**

At the beginning and 12 weeks after the start of the intervention

### **Method of measurement**

PCOSQ-26 form

## **3**

### **Description**

Weight domain score of PCOSQ-26

### **Timepoint**

At the beginning and 12 weeks after the start of the intervention

### **Method of measurement**

PCOSQ-26 form

## **4**

### **Description**

Infertility Problems domain score of PCOSQ-26

### **Timepoint**

At the beginning and 12 weeks after the start of the intervention

### **Method of measurement**

PCOSQ-26 form

## **5**

### **Description**

Menstrual Problems domain score of PCOSQ-26

### **Timepoint**

At the beginning and 12 weeks after the start of the intervention

### **Method of measurement**

PCOSQ-26 form

## **6**

### **Description**

Physical functioning score

### **Timepoint**

At the beginning and 12 weeks after the start of the intervention

### **Method of measurement**

SF-12 form

## **7**

### **Description**

Physical functioning score

### **Timepoint**

At the beginning and 12 weeks after the start of the intervention

### **Method of measurement**

SF-12 form

## **8**

### **Description**

Perceived Stress scale (PSS-10) score

### **Timepoint**

At the beginning and 12 weeks after the start of the intervention

### **Method of measurement**

PSS-10 form

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: For 12 weeks, they will receive daily one 2 gram sachet of synbiotic containing 10 to the power of 11 CFU/g of Bacillus coagulans, 10 to the power of 10 CFU/g Lactobacillus rhamnus, 10 to the power of 10 CFU/g Lactobacillus heloticus, 500 mg fructo-oligosaccharide and 0.7% orange flavor.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: They will receive a placebo sachet daily containing 2 grams of starch and 0.7% orange flavoring.

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Women's and pcos clinic of Ayatollah Taleghani Hospital

##### **Full name of responsible person**

Zahra Hariri

##### **Street address**

Shahid Aarabi St., Yaman St., Chamran Hwy.

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##### **Postal code**

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##### **Phone**

+98 21 2243 2560

##### **Email**

taleghani@sbmu.ac.ir

##### **Web page address**

<https://taleghani.sbmu.ac.ir/>

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Maryam Rezvani Fard

**Street address**

Ground floor, buliding No. 2, Shahid Aarabi St., Yemen St., Chamran Hwy.

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info@sbmu.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Zahra Hariri

**Position**

MCS Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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**Latest degree**

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## Person responsible for updating data

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Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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## 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**

Only part of the data, such as the main results, will be shared.

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

The beginning of the access period is 12 months after the publication of the results

**To whom data/document is available**

It will be available for researchers working in academic and scientific institutions and industry.

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

The documentation can only be used for more complete studies in this field.

**From where data/document is obtainable**

Zahra Hariri

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

Communication will be possible through the email given in the previous section

**Comments**