

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Effect of synbiotic supplementation on reduction of severity of anxiety and depression in women with premenstrual syndrome

#### Protocol summary

##### Study aim

Effect of synbiotic supplementation on reduction severity of anxiety and depression in women with premenstrual syndrome

##### Design

Two arm parallel group randomized trial with blinded

##### Settings and conduct

Girls' dormitories in Iran University of Medical Sciences

##### Participants/Inclusion and exclusion criteria

inclusion criteria: Severe or moderate premenstrual syndrome based on a screening questionnaire; age range between 18-40 years; Body mass index between 25-35 exclusion criteria: Probiotic supplementation from 3 months prior to study; Acute and chronic diseases of depression; Iron deficiency anemia

##### Intervention groups

80 students and medical staff of Iran University of Medical Sciences receive synbiotic supplement with 10 microbial population to 9 colonies per gram, containing (Lactobacillus gassery, Lactobacillus officinalis, Lactobacillus plantarum, Lactobacillus acidophilus) daily 1 in 3 menstrual periods for 10 days before menstruation and 4 days after menstruation. Synbiotic supplement purchased from Zist takhmir company. 80 students and staff of the Iranian University of Medical Sciences received 1 placebo capsule daily (containing lactose, magnesium stearate, talc, silicon dioxide) which is similar to the synbiotic supplement.

##### Main outcome variables

depression

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180425039412N1**

Registration date: **2019-03-10, 1397/12/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-03-10, 1397/12/19**

Update count: **0**

##### Registration date

2019-03-10, 1397/12/19

##### Registrant information

###### Name

Marjan Malakootinejad

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 86709

###### Email address

malakoutinejad.m@tak.iums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2020-03-19, 1398/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of synbiotic supplementation on reduction of severity of anxiety and depression in women with premenstrual syndrome

##### Public title

Effect of probiotic in premenstrual syndrome

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Age range 18-40 years BMI Between 35 and 25 Affection of premenstrual syndrome based on PSST questionnaire The normal duration of bleeding (3-7 days in the 3 months before entering the study) and the regular monthly cycle Lack of chronic systemic diseases and diseases related to the ovary Lack of liver disease, bile duct disease, gastrointestinal and intestinal diseases, kidney disease, parathyroid thyroid and non-hyperphosphatemia Non-use of probiotic and probiotic-based supplements over the past 6 months Not using supplements containing vitamins and minerals supplement W3 or fish oil Non-development of neurological diseases and no use of psychosomatic drugs Non-use of hormonal drugs The desire to participate in the study and written consent written consent Absence of iron deficiency anemia Non-use of steroidal and non-steroidal anti-inflammatory drugs, Anti epileptic drugs, anti cholesterolemic drugs, anti-acid drugs, diuretics and laxatives Not using any medication or dietary supplement that affects weight

**Exclusion criteria:**

Consumption of probiotic supplementation from 3 months before study Affection of acute and chronic diseases of depression Iron deficiency anemia

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**

Target sample size: **160**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

For randomization, the permuted block randomization will be used with quadruple blocks. According to the sample size of 160 identified, 40 blocks will be produced using the online site (www.sealedenvelope.com)

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, producer provides supplements in two groups A and B and similar in appearance to the researcher without identifying the nature of the group. Then, the volunteers participating in the study by the statistician who do not know the type of effective substance in the groups are randomly divided into groups. The researcher, based on the list of counseling statisticians, distributes the supplements to them by explaining the study information and obtaining informed consent from the volunteers.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee Of Iran University Of Medical Sciences

**Street address**

Iran University of Medical Sciences, next to the Milad hospital, the intersection Of sheikh Fazlallah and Shahid Chamran, Hemmat expressway

**City**

tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2018-04-21, 1397/02/01

**Ethics committee reference number**

IR.IUMS.REC.1397.1011

**Health conditions studied**

1

**Description of health condition studied**

premenstrual syndrome

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

depression

**Timepoint**

Before the intervention, 1.2 and 3 months after the intervention

**Method of measurement**

questionnaire

**Secondary outcomes**

1

**Description**

anxiety

**Timepoint**

Before the intervention, 1.2 and 3 months after the intervention

**Method of measurement**

questionnaire Before intervention and 1.2 and 3 months

after the intervention

## 2

### **Description**

BMI

### **Timepoint**

Before the intervention, 1.2 and 3 months after the intervention

### **Method of measurement**

Weight ratio (kg) to squared height (m)

## 3

### **Description**

waist circumference

### **Timepoint**

Before the intervention, 1.2 and 3 months after the intervention

### **Method of measurement**

meter

## 4

### **Description**

Nutritional status

### **Timepoint**

Before the intervention, 1.2 and 3 months after the intervention

### **Method of measurement**

Measurement of energy and nutrients intake using 24-hour dietary recall method and anthropometric measurement using scale and stadiometer

## 5

### **Description**

Physical Activity

### **Timepoint**

Before the intervention, 1.2 and 3 months after the intervention

### **Method of measurement**

IPAQ questionnaire

## 6

### **Description**

quality of life

### **Timepoint**

Before the intervention, 1.2 and 3 months after the intervention

### **Method of measurement**

ququestionnaire

## 7

### **Description**

fat percent

### **Timepoint**

Before the intervention, 1.2 and 3 months after the intervention

### **Method of measurement**

enbody

## **Intervention groups**

### 1

#### **Description**

80 students and medical staff of Iran University of Medical Sciences receive synbiotic supplement with 10 microbial population to 9 colonies per gram, containing (Lactobacillus gassery, Lactobacillus officinalis, Lactobacillus plantarum, Lactobacillus acidophilus) daily 1 in 3 menstrual periods for 10 days before menstruation and 4 days after menstruation. Synbiotic supplement purchased from Zist takhmir company.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: 80 female students and personnel of the University of Medical Sciences each day received 1 placebo capsule (containing lactose, magnesium stearate, talc, silicone dioxide) in 3 menstrual periods for 10 days before menstruation and 4 days after menstruation. The placebo capsule is similar to synbiotic supplementation. A supplement of placebo is purchased from Zist takhmir company.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Girls' dormitories in Iran University of Medical Sciences

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

mitra zarrati

##### **Street address**

Iran University of Medical Sciences, next to the Milad hospital, the intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat expressway

##### **City**

tehran

##### **Province**

Tehran

##### **Postal code**

1449614535

##### **Phone**

+98 21 8670 4814

##### **Email**

zarrati.m@iums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Iran University of Medical Sciences

**Full name of responsible person**

Seyed Ali Javad Moosavi, Assistant of Research and Technology , Iran University of Medical Sciences

**Street address**

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**Phone**

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**Email**

zarrati.m@iums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Zist takhmir company

**Proportion provided by this source**

100

**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**

Other

**Person responsible for general inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Mitra Zarrati

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Faculty of Nutrition, School of Public Health, Iran University of Medical Sciences, next to the Milad hospital, the intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat expressway

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 8670 4814

**Email**

zarrati.m@iums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Mitra Zarrati

**Position**

استادیار

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Faculty of Nutrition, School of Public Health, Iran University of Medical Sciences, next to the Milad hospital, the intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat expressway

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**Phone**

+98 21 8670 4814

**Email**

zarrati.m@iums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

marjan malakooti nejad

**Position**

MS.c student in Nutrition Science

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

Faculty of Nutrition, School of Public Health, Iran University of Medical Sciences, next to the Milad hospital, the intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat expressway

**City**

Tehran

**Province**

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**Postal code**

1449614535

**Phone**

00

**Email**

marjanmalakootinejad.mn@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

The total individual participant data is shared

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

Get started since 1398

### To whom data/document is available

researchers

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

Researcher if permission is granted

### From where data/document is obtainable

marjan malakooti nejad phone number 09123375596

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

After registering the title and publishing the article

### Comments