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
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Iran (Islamic Republic of)
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+98 21 86709
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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
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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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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
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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
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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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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

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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
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00
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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
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