

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Effect of Synbiotic Supplementation on Symptoms and Brain-derived neurotrophic factor (BDNF) in patients with Schizophrenia

#### Protocol summary

##### Study aim

Effect of symbiotic supplementation on symptoms and brain-derived neurotrophic factor (BDNF) in Schizophrenia Patients

##### Design

double blind randomized controlled trial

##### Settings and conduct

Patients with schizophrenia 18-65 years old referred to psychiatric hospital of Iran and randomly divided into intervention or placebo groups (8 weeks). To measure serum BDNF levels, 10 ml of venous blood is collected after 10-12 hours of fasting at the beginning and end of the study. An evaluation of the symptoms of schizophrenia from the PANSS scale will also be performed at the beginning and end of the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Willingness to collaborate 2-Complete the informed consent form by the patient and the patient's guardian 3-Age range 18-65 years 4-Schizophrenia according to DSM-V criteria 5- Patients with PANSS total score  $\geq 50$  6-Outpatient 7-Duration of illness less than 6 years 8-BMI  $\geq 23$  Exclusion criteria: 1-Pregnancy and lactation 2-A history of drug or alcohol dependence or abuse 3-Diagnosis of mental retardation 4-Diagnosis of major gastrointestinal, renal, heart, cancer, HIV infection, neurological disease or other immunodeficiency problems 5-Having suicidal or homicidal thoughts 6-Sensitivity to probiotics, prebiotic and synbiotic 7-Change the Dose and type of medication used during the last 2 months 8-Receive of Antibiotics in the last month 9-Consumption of probiotics, prebiotic or synbiotic over the last month 10-Consumption of dietary supplements in the last month

##### Intervention groups

Intervention group: 2 daily 500 mg capsules of Lactocar  
Control group: 2 daily 500 mg placebo capsules

##### Main outcome variables

Symptoms of schizophrenia: Brain-derived neurotrophic factor

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20090901002394N46**

Registration date: **2019-12-27, 1398/10/06**

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

Last update: **2019-12-27, 1398/10/06**

Update count: **0**

##### Registration date

2019-12-27, 1398/10/06

##### Registrant information

##### Name

Shima Jazayeri

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8670 4805

##### Email address

sjazayeri@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-27, 1398/09/06

##### Expected recruitment end date

2020-06-09, 1399/03/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effect of Synbiotic Supplementation on Symptoms and Brain-derived neurotrophic factor (BDNF) in patients with Schizophrenia

## Public title

Effect of Synbiotic Supplementation on schizophrenia symptoms

## Purpose

Health service research

## Inclusion/Exclusion criteria

### Inclusion criteria:

Willingness to collaborate Complete the informed consent form by the patient and the patient's guardian Age range 18-65 years Schizophrenia according to DSM-V criteria (By a psychiatrist) Patients with PANSS total score  $\geq 50$  Outpatient Duration of illness less than 6 years BMI  $\geq 23$

### Exclusion criteria:

Pregnancy and lactation A history of drug or alcohol dependence or abuse Diagnosis of mental retardation Diagnosis of major gastrointestinal, renal, heart, cancer, HIV infection ,neurological disease or other immunodeficiency problems Having suicidal or homicidal thoughts Sensitivity to probiotics, prebiotic and synbiotic Change the Dose and type of medication used during the last 2 months Receive of Antibiotics in the last month Consumption of probiotics, prebiotic or synbiotic over the last month Consumption of dietary supplements in the last month

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Subjects will be divided into intervention and placebo groups by stratified randomization based on sex and BMI using 4-sided permutation blocks and randomly selected blocks based on random number table.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Placebo and supplements are similar in appearance And someone other than the researcher encodes them. All investigators, study staff, and participants will be unaware of the allocations

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee, Iran University of Medical Sciences

##### Street address

Shahid Hemmat Highway, next to Milad Hospital, Iran University of Medical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

#### Approval date

2019-10-02, 1398/07/10

#### Ethics committee reference number

IR.IUMS.REC.1398.708

## Health conditions studied

### 1

#### Description of health condition studied

schizophrenia

#### ICD-10 code

F20-F29

#### ICD-10 code description

Schizophrenia

## Primary outcomes

### 1

#### Description

Symptoms of schizophrenia

#### Timepoint

at baseline, and after 2 month

#### Method of measurement

PANSS scale

### 2

#### Description

Brain-derived neurotrophic factor

#### Timepoint

at baseline, and after 2 month

#### Method of measurement

Eliza

## Secondary outcomes

### 1

#### Description

Anxiety and Depression Function

**Timepoint**

at baseline, and after 2 month

**Method of measurement**

Hospital Anxiety and Depression Scale

**2****Description**

Gastrointestinal symptoms

**Timepoint**

at baseline, and after 2 month

**Method of measurement**

GSRS Scale

**3****Description**

physical activity

**Timepoint**

beginning and end of intervention

**Method of measurement**

IPAQ questionnaire

**4****Description**

energy intake

**Timepoint**

beginning and end of intervention

**Method of measurement**

24-hour food recall questionnaire

**Intervention groups****1****Description**

Intervention group: 2 capsules of 500mg Lactocare daily for 8weeks

**Category**

Treatment - Other

**2****Description**

Control group: Take 2 placebo capsules daily for 8 weeks

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Iran Psychiatric Hospital

**Full name of responsible person**

Dr. Fatemeh Hadi

**Street address**

Hemmat Highway, between the intersection of Sheikh Fazlollah noori and Chamran, next to the Milad Hospital, Iran University of Medical Sciences

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**Email**

ccssoommaa@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Abbas Motevallian

**Street address**

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motevalian@iums.ac.ir

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

No

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Somayeh Jamali paghaleh

**Position**

Master student in nutrition sciences

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

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

Iran University of Medical Sciences

**Full name of responsible person**

Dr shima jazayeri

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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sh\_jazayeri@tums.ac.ir

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

Iran University of Medical Sciences

**Full name of responsible person**

Somayeh Jamali paghaleh

**Position**

Master student in nutrition sciences

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

No - There is not 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**

Yes - There is 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

**Title and more details about the data/document**

There is no more information

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

There is no more information

**To whom data/document is available**

There is no more information

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

There is no more information

**From where data/document is obtainable**

There is no more information

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

There is no more information

**Comments**