

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of Synbiotics on the Components of Metabolic Syndrome in Patients with Schizophrenia

Protocol summary

Study aim

The Effect of Symbiotic Supplementation on the Components of Metabolic Syndrome in Schizophrenia Patients

Design

A randomized, double-blind, parallel design trial with one intervention and one control group

Settings and conduct

After obtaining consent, patients were randomly divided into two groups: taking symbiotic supplements (1 g daily) and controls (placebo with similar specifications). Patients receive supplementation for 8 weeks. Placebo and supplements are coded by someone other than the researcher. Participants and the lead researcher will not be informed of supplement and placebo content. At the beginning and end of the study, 10 cc blood samples will be taken to measure biochemical factors.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Having at least 2 metabolic syndrome criteria 2. Age range 18-65 years 3. Willingness to cooperate 4. suffering schizophrenia for at least 1 year 5. BMI ≥ 23 6. Disease of schizophrenia according to DSM-V criteria Inclusion criteria: 1. Endocrine disorders 2. Weight loss medications, Corticosteroids over 10 days 3. History of weight loss surgeries 4. Any conditions that the researcher does not consider appropriate for the study 5. Drug abuse 6. Immune deficiency 7. Pregnant and lactating mothers and women of childbearing age 8. Female participants who plan to become pregnant 9. Change in dosage and type of medication at least 2 months prior to intervention 10. Antibiotic use from 1 month before study 11. Consumption Foods containing symbiotic, prebiotic and probiotic 1 month before intervention

Intervention groups

70 people with schizophrenia will be included in the study according to inclusion criteria. Subjects were randomly divided into two intervention groups (probiotic or placebo)

Main outcome variables

Waist circumference, fasting blood sugar, total cholesterol, high density lipoprotein, triglyceride, hypertension

General information

Reason for update

Two inclusion criteria were corrected because they could not affect the study outcomes. (PANSS and duration of the disease)

Acronym

IRCT registration information

IRCT registration number: **IRCT20090901002394N45**
Registration date: **2019-12-26, 1398/10/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-15, 1402/07/23**

Update count: **2**

Registration date

2019-12-26, 1398/10/05

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

2019-11-11, 1398/08/20

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

Effects of Synbiotics on the Components of Metabolic Syndrome in Patients with Schizophrenia

Public title

Effects of Synbiotics on the Components of Metabolic Syndrome in Patients with Schizophrenia

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) Outpatient Duration of illness more than one year BMI ≥ 23

Exclusion criteria:

Pregnancy and lactation A history of drug or alcohol dependence or abuse Diagnosis of mental retardation Diagnosis of neurological disease or any serious illness that needs treatment Diagnosis of major gastrointestinal, renal, heart, cancer, HIV infection or other immunodeficiency problems Having a history of traumatic brain injury, seizures, epilepsy, Loss of consciousness (LOC) for more than 30 minutes, or other known neurological or organic diseases of the central nervous system Having suicidal or homicidal thoughts or any safety concern by research staff Sensitivity to probiotics, prebiotic and synbiotic Subjects who may require imminent hospitalization Change the Dose and type of medication used during the last 2 months Receive of electricity shock treatment, immunosuppressive medications, stimulants, mood stabilizer during the last 3 months Receive of Antibiotics in the last month Consumption of Food or supplements containing probiotics, prebiotic and synbiotic over the last month such as kefir-yogurt-cheese and ... Consumption of dietary supplements in the last month Any disease or condition in which the researcher does not consider the participants appropriate for the study

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

Patients will be divided into two groups receiving two daily synbiotic capsules or placebo after coding using random codes. Random allocation will be performed using four blocks classified by BMI and gender.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to double-blind the study of total cans containing capsules by a person other than the researcher, they will be divided into two groups in order to observe the researcher not knowing the type of capsules received by each group. Researcher, statistical consultant, and physician unaware of this classification This classification will be based on a random number table

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

Iran University of Medical Sciences-near Milad Hospital-between the intersection of Sheikh Fazlollah Nouri and Shahid Chamran-Shahid Hemmat Highway

City

Tehran

Province

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Postal code

1449614535

Approval date

2018-11-20, 1397/08/29

Ethics committee reference number

IR.IUMS.REC.1398.650

Health conditions studied**1****Description of health condition studied**

schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Waist circumference

Timepoint

8 weeks

Method of measurement

Tape measure

2

Description

Fasting blood sugar

Timepoint

8 weeks

Method of measurement

Enzymatic colorimetric

3

Description

Total cholesterol

Timepoint

8 weeks

Method of measurement

Enzymatic colorimetric

4

Description

HDL

Timepoint

8 weeks

Method of measurement

Enzymatic colorimetric

5

Description

TG

Timepoint

8 weeks

Method of measurement

Enzymatic colorimetric

6

Description

blood pressure

Timepoint

8 weeks

Method of measurement

Mercury barometer

Secondary outcomes

1

Description

LDL

Timepoint

8 weeks

Method of measurement

Enzymatic colorimetric

2

Description

Serum insulin

Timepoint

8 weeks

Method of measurement

Eliza

3

Description

HOMA-IR

Timepoint

8 weeks

Method of measurement

Calculation by formula

4

Description

QUICKI

Timepoint

8 weeks

Method of measurement

Calculation by formula

5

Description

HbA1c

Timepoint

8 weeks

Method of measurement

analyzer

6

Description

hs-CRP

Timepoint

8 weeks

Method of measurement

Eliza

7

Description

Weight

Timepoint

8 weeks

Method of measurement

Standard scales

8

Description

BMI

Timepoint

8 weeks

Method of measurement

Calculation measured by height and weight

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Abbas Motevallian

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Grant name

Grant code / Reference number

100%

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

Poorya Basafaroodi

Position

Master student in nutrition sciences

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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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