

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Synbiotic supplementation on the severity of different types of self-reported aggression and anger in healthy adult men.

Protocol summary

Study aim

The effect of Synbiotic Supplementation on the severity of different types of self-reported aggression and anger in healthy adult men.

Design

Randomization is done in the form of random blocks of volume 4. This study is in the third phase of the clinical trial.

Settings and conduct

The present study is a double-blind randomized clinical trial for 8 weeks in healthy adult men aged 18 to 75 years working at Iran University of Medical Sciences. None of the subjects studied, as well as the researcher and colleagues, will be aware of the group in which they are located and the type of intervention received.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Willingness to cooperate. 2- Age 18 to 75 years. 3- Having physical health and no history of cardiovascular diseases and etc. 4- No record of other mental illnesses. 5- Not taking certain medications in the past two months. 6- Not taking any omega-3, multivitamin-mineral supplements for at least the past two months. 7- Absence of severe family conflicts in the past 3 months. Exclusion criteria: 1- The dissatisfaction to continue cooperation. 2- Consume probiotic-containing foods two weeks before and during the study. 3. Antibiotic use during the study. 4. Severe family conflicts during the study. 5- Consume less than 80% of supplements. 6- Occurrence of any disease during the intervention.

Intervention groups

Intervention group: 2 capsules of Femtactic Synbiotic daily. Control group: 2 starch capsules daily.

Main outcome variables

self-reported aggression and anger.

General information

Reason for update

Due to the Corona epidemic and the opposition of the Department of Education, the project could not be implemented for 12- to 18-year-olds. Therefore, the target group of the study was changed to healthy adults (male employees of Iran University of Medical Sciences). According to the change of title, diagnosis of aggression and externalizing behavior problems through the interview by a psychiatrist (according to DSM-5 criteria), Child Behavior Checklist (CBCL), Youth Self-Report (YSR) and Adolescent Physical Activity Questionnaire (PAQ-A)), Which is for people under 18, have been removed. The Spielberger Anger Questionnaire was used to measure anger and the DASS-21 questionnaire was added to measure the severity of depression, stress and anxiety as a confounding factor. The International Physical Activity Questionnaire (IPAQ) was used to assess the level of physical activity. The sample size varied according to similar studies in adults.

Acronym

IRCT registration information

IRCT registration number: **IRCT20091114002709N53**

Registration date: **2020-02-22, 1398/12/03**

Registration timing: **prospective**

Last update: **2021-09-11, 1400/06/20**

Update count: **1**

Registration date

2020-02-22, 1398/12/03

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8862 2755

Email address

shidfar.f@iums.ac.ir

Recruitment status**Recruitment complete****Funding source****Expected recruitment start date**

2021-09-23, 1400/07/01

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Synbiotic supplementation on the severity of different types of self-reported aggression and anger in healthy adult men.

Public title

The effect of Synbiotic on aggression

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to cooperate 18 to 75 years old Having physical health and no history of cardiovascular, gastrointestinal, metabolic, autoimmune disease, allergies, etc. No history of mental disease such as epilepsy, Bulimia nervosa, Anorexia, etc. No anti-depressant, anti-inflammatory, anti-obesity, anti-diabetic medications, and hormone therapy for at least two months ago. Not taking any omega-3, multivitamin-mineral supplements for at least two months ago. lack of severe family conflicts in 3 months ago.

Exclusion criteria:

The dissatisfaction to continue cooperation. Probiotic-containing foods consumption two weeks before and during the study. Antibiotic consumption during the study. Severe family conflicts during the study. consuming Less than 80% of supplements delivered to adolescents. Incidence of any disease during the study.

AgeFrom **18 years** old to **75 years** old**Gender**

Male

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization is done in a randomized, stratified method based on the age and BMI. A randomized list of 100 capsules with codes A and B (randomized blocks of volume 4) is produced by the research consultant and is provided by the researcher.

Blinding (investigator's opinion)

Double blinded

Blinding description

Study subjects and researchers will be blinded to the intervention. Synbiotic and placebo capsules are similar in appearance, odor, weight and packaging and only the code on the package (A or B) is different.

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

Hemat Express way, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-09-30, 1398/07/08

Ethics committee reference number

IR.IUMS.REC.1398.694

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

aggression

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

anger

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

anger from Aggression Questionnaire

Timepoint

Before the intervention and 2 months after the

intervention
Method of measurement
Aggression Questionnaire

Secondary outcomes

1

Description

Aggression

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Aggression Questionnaire

Intervention groups

1

Description

Intervention group: intake of two daily synbiotic of Familact capsule (produced by Bio-Fermentation Company) for 2 months, each capsule being 500 mg containing 7 species of Lactobacillus casei, Lactobacillus acidophilus, Lactobacillus rhamnosus, Lactobacillus bulgaricus, Bifidobacterium breve, Bifidobacterium longum, Streptococcus thermophilus (109 CFU per capsule) with prebiotic fructooligosaccharide (38 mg).

Category

Treatment - Drugs

2

Description

Control group: Intake of 2 Caps daily containing 500 mg of 75% starch.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Sciences

Full name of responsible person

Dr.Farzad Shidfar

Street address

School of Medicine, Crossroads of Shahid Hemmat and Shahid Chamran Expressways,

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

PR@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr.Seyed abbas Motevalian

Street address

Iran University of Medical Science, Hemmat expressway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

amotevalian@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

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

Dr.Farzad Shidfar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

School of health, Iran university of medical science, Shahid Hemmat highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8862 2755

Email

Shidfar.f@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr.Farzad Shidfar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

School of health, Iran university of medical science,
Shahid Hemmat highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8862 2755

Fax

+98 21 8862 2533

Email

Shidfar.f@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Rahele Sadat Montazeri

Position

Ms.c student in Health Sciences in Nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

School of health, Iran university of medical science,
Shahid Hemmat highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 2230 1636

Email

rsmontazeri313@yahoo.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

Some of the data will be shared, such as information about the main consequences and etc.

When the data will become available and for how long

The access period will be 6 months after publication of the results.

To whom data/document is available

The obtained data from the current study will be available only for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Six months after the publication of the papers from this study, the data obtained will be available to the applicant researchers for further analysis.

From where data/document is obtainable

Applicants can be contacted with the corresponding author by e-mail or postal address to receive the requested data. Postal address: Nutrition department, School of Health, Iran University of Medical Sciences, Hemmat expressway, Tehran Phone number:0098 21 8862 2755 E-mail: Farzadshidfar@yahoo.com

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

Applicants will be able to access the obtained data from current study by sending an email to the corresponding author, after a maximum of one week.

Comments