

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Evaluation of the effects of probiotics on general mental health in healthy human volunteers of Shahrood city

#### Protocol summary

##### Summary

The aim of this study: Evaluation of the effects of probiotics on general mental health in healthy human volunteers of Shahrood city. Study design: After explaining the purpose of the study and obtaining the informed consent, people will be allocated into A and B groups. The study is double blind, single-center, phase 3 trial. Inclusion criteria: Informed consent. Exclusion criteria: Diabetes; cardiovascular diseases; gastrointestinal diseases; routine use of probiotics. Sample size: 50 people are participated in the study with 25 people in each group. Intervention group: Familact probiotic capsule 10 milion unit oral. Control group: Starch capsule 3 gram oral. Primary outcome: Improve general mental health.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017053034246N1**  
Registration date: **2017-10-10, 1396/07/18**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-10-10, 1396/07/18

##### Registrant information

##### Name

Hadi Sasani

##### Name of organization / entity

Islamic Azad University Of Shahrood

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3522 9652

##### Email address

doctor.hadi.sasani@iau-shahrood.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2017-10-22, 1396/07/30

##### Expected recruitment end date

2017-12-21, 1396/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effects of probiotics on general mental health in healthy human volunteers of Shahrood city

##### Public title

Effect of probiotics on general mental health in healthy human volunteers

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Informed consent Exclusion criteria: Diabetes; cardiovascular diseases; gastrointestinal diseases; routine use of probiotics

##### Age

From **21 years** old to **50 years** old

##### Gender

Both

##### Phase

3

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **50**  
**Randomization (investigator's opinion)**  
Randomized  
**Randomization description**  
**Blinding (investigator's opinion)**  
Double blinded  
**Blinding description**  
**Placebo**  
Used  
**Assignment**  
Parallel  
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**  
Ethics Committee of Islamic Azad University of Shahrood  
**Street address**  
Islamic Azad University of Shahrood, Tehran Blvd, Shahrood City  
**City**  
Shahrood  
**Postal code**  
**Approval date**  
2016-11-10, 1395/08/20  
**Ethics committee reference number**  
IR.IAU.SHAHROOD.REC.1395.7

## Health conditions studied

### 1

#### Description of health condition studied

General mental health  
**ICD-10 code**  
R46.8  
**ICD-10 code description**  
Other symptoms and signs involving appearance and behaviour

### 2

#### Description of health condition studied

Generalized anxiety disorder  
**ICD-10 code**  
F41.1  
**ICD-10 code description**  
Generalized anxiety disorder

## Primary outcomes

### 1

#### Description

General mental health  
**Timepoint**  
Before intervention and one day after intervention  
**Method of measurement**  
Goldberg's general mental health questionnaire

## Secondary outcomes

### 1

#### Description

Generalized anxiety disorder  
**Timepoint**  
One day before intervention, on day after intervention  
**Method of measurement**  
Goldberg's general mental health questionnaire

## Intervention groups

### 1

#### Description

Intervention: Single dose of 10 million unit familact probiotic capsule after breakfast 28 days  
**Category**  
Treatment - Drugs

### 2

#### Description

Control: Single dose of 3 gram placebo starch capsule after breakfast 28 days  
**Category**  
Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**  
Khatam Alanbia Hospital of Shahrood  
**Full name of responsible person**  
Fatemeh Amirkhilili  
**Street address**  
Khatam Alanbia Hospital of Shahrood, Tehran Blvd, Shahrood  
**City**  
Shahrood

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice chancellor for Research and Technology  
**Full name of responsible person**  
Sahebali Manafi  
**Street address**  
Islamic Azad University of Shahrood, Tehran Blvd,

Shahrood  
**City**  
Shahrood  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Vice chancellor for Research and Technology  
**Proportion provided by this source**  
100  
**Public or private sector**  
*empty*  
**Domestic or foreign origin**  
*empty*  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Islamic Azad University of Shahrood  
**Full name of responsible person**  
Hadi Sasani  
**Position**  
Medical Student  
**Other areas of specialty/work**  
**Street address**  
Islamic Azad University of Shahrood, Tehran Blvd,  
Shahrood  
**City**  
Shahrood  
**Postal code**  
4318936199  
**Phone**  
+98 23 3239 0360  
**Fax**  
**Email**  
doctor.hadi.sasanii@gmail.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Islamic Azad University of Shahrood  
**Full name of responsible person**  
Fatemeh Amir Khalili  
**Position**

General Surgeon  
**Other areas of specialty/work**  
**Street address**  
Islamic Azad University of Shahrood, Tehran Blvd,  
Shahrood  
**City**  
Shahrood  
**Postal code**  
4318936199  
**Phone**  
+98 32 3223 3546  
**Fax**  
**Email**  
dr.fatemehamirkhalili@gmail.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University of Shahrood  
**Full name of responsible person**  
Hadi Sasani  
**Position**  
Medical Student  
**Other areas of specialty/work**  
**Street address**  
Islamic Azad University of Shahrood, Tehran Blvd,  
Shahrood  
**City**  
Shahrood  
**Postal code**  
4318936199  
**Phone**  
+98 23 3222 0611  
**Fax**  
**Email**  
doctor.hadi.sasanii@gmail.com  
**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*