

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Effect of probiotic supplementation on cognitive function and BDNF in patients with type 2 diabetes

#### Protocol summary

##### Study aim

The effect of probiotics supplementation on cognitive function and BDNF in patients with type 2 diabetes

##### Design

double blind randomized controlled trial

##### Settings and conduct

84 patients with type 2 diabetes 45-65 years old referred to Rasoul Akram Hospital and randomly assigned to either intervention or placebo groups (8 weeks). To measure fasting blood sugar, hemoglobin A1C, and serum BDNF, 10 ml of venous blood was collected after 10-12 hours of fasting at the beginning and end of the study. It will also be conducted to assess the cognitive performance of ACE and TMT cognitive tests at the end and end of the intervention.

##### Participants/Inclusion and exclusion criteria

1. Willingness to cooperate and complete informed consent Type 2 diabetes according to the diagnosis of a specialist based on patient records 3. At least 2 years of history of type 2 diabetes 4. No change in the type and dose of medication taken 8 weeks before the intervention 5- Age 45-65 6. No use of probiotic-containing foods for the past 4 weeks 1- Cancer, severe liver and kidney disorders, heart failure and surgery and other endocrine disorders 2-Pregnancy and lactation and hormone-sensitive conditions 3. Use of liver-degrading, anticoagulant, and platelet-derived drugs 4- Use of antidepressants and other drugs that affect the nerves 5. Insulin injection 6- Pregnancy Pills 7. Recent dietary supplements (no case of taking calcium, vitamin D and group B routinely for the past 6 months) 8- Use of antibiotics for the past 1 month 9- Tobacco, drugs and alcohol

##### Intervention groups

Intervention group: 2 capsules of 500 mg Foam Locket daily Control group: 2 capsules daily 500 mg placebo

##### Main outcome variables

cognitive function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20090901002394N44**

Registration date: **2019-11-25, 1398/09/04**

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

Last update: **2019-11-25, 1398/09/04**

Update count: **0**

##### Registration date

2019-11-25, 1398/09/04

##### 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

2019-09-01, 1398/06/10

##### Expected recruitment end date

2020-02-29, 1398/12/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effect of probiotic supplementation on cognitive function and BDNF in patients with type 2 diabetes

## Public title

Effect of probiotic supplementation in patients with type 2 diabetes

## Purpose

Health service research

## Inclusion/Exclusion criteria

### Inclusion criteria:

Willing to participate and signing informed consent  
Having type 2 diabetes based on medical records  
At least 2 years history of type 2 diabetes  
No change in the type and dose of medication taken 8 weeks before the intervention  
Age 45-65  
Not eating probiotic-containing foods for the past 4 weeks

### Exclusion criteria:

Cancer, severe liver and kidney disorders, heart failure and surgery and other endocrine disorders  
Pregnancy and lactation and hormone-sensitive conditions  
Use of liver, anticoagulant, and platelet-degrading drugs  
Use of antidepressants and other drugs that affect the nerves  
Insulin injection  
Contraceptive use  
Recent dietary supplements (no case if calcium - vitamin D and group B supplements are routinely consumed for the past 6 months)  
Use of antibiotics for the past 1 month  
Tobacco, drugs and alcohol  
weight loss diet and weight changes over 5% in the last 3 months

## Age

From **45 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **84**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Subjects will be divided into two groups using block randomization.

## 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, the researcher and statistical consultant and physician will be unaware of this classification. These divisions are based on random number tables

## Placebo

Used

## Assignment

Other

## 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

2019-06-16, 1398/03/26

#### Ethics committee reference number

IR.IUMS.REC.1398.316

## Health conditions studied

### 1

#### Description of health condition studied

Type 2 diabetes mellitus

#### ICD-10 code

E11

#### ICD-10 code description

diabetes (mellitus)(nonobese)(obese): adult-onsetmaturity-onset nonketotic stable non-insulin-dependent diabetes of the young

## Primary outcomes

### 1

#### Description

cognitive function

#### Timepoint

at baseline, and after 2 month

#### Method of measurement

Addenbrooke's Cognitive Examination - Trail Making Test

### 2

#### Description

BDNF

#### Timepoint

at baseline, and after 2 month

#### Method of measurement

Eliza

## Secondary outcomes

## 1

### Description

physical activity

### Timepoint

beginning and end of intervention

### Method of measurement

IPAQ questionnaire

## 2

### Description

energy intake

### Timepoint

beginning and end of intervention

### Method of measurement

Three-day food record

## Intervention groups

## 1

### Description

Intervention group: 2 capsules of 500mg familact daily for 12 weeks

### Category

Treatment - Other

## 2

### Description

Control group: Take 2 placebo capsules daily for 12 weeks

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

hazraterasul hospital

#### Full name of responsible person

Dr amir ziyae

#### Street address

Hemmat Highway next to Milad Tower

#### City

Tehran

#### Province

Tehran

#### Postal code

1449614535

#### Phone

+98 21 8670 4805

#### Email

Jazayeri.sh@iums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Dr Abbas Motevallian

#### Street address

تهران، بزرگراه همت، دانشگاه علوم پزشکی ایران

#### City

Tehran

#### Province

Tehran

#### Postal code

1449614535

#### Phone

+98 21 8670 2503

#### Email

motevalian@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

simakheradmand

#### Position

Master student in nutrition sciences

#### Latest degree

Bachelor

#### Other areas of specialty/work

Nutrition

#### Street address

school of public health, Iran university of medical sciences, Hemmat highway, Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

1449614535

#### Phone

+98 21 8670 4805

#### Email

sima.kherad@yahoo.com

## 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

**Street address**

school of public health, Iran university of medical sciences, Hemmat highway, Tehran, Iran

**City**

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**Postal code**

1449614535

**Phone**

+98 21 8670 4805

**Email**

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**

simakheradmand

**Position**

Master student in nutrition sciences

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

school of public health, Iran university of medical sciences, Hemmat highway, Tehran, Iran

**City**

tehran

**Province**

Tehran

**Postal code**

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**Phone**

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**Email**

sima.kherad@yahoo.com

## 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**