Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Investigating the effect of probiotic supplementation in improving symptoms of depression, anxiety, insomnia, anorexia and cognitive impairment in HIV-positive patients, a three-blind randomized clinical trial with placebo control.

Protocol summary

Study aim

Evaluation the effect of probiotic supplementation on the symptoms of psychiatric disorders such as anxiety and depression, sleep disorder and cognitive disorder in HIV patients and improving their personal and social function.

Design

After the eligibility of the patient is recognized and written informed consent is received, the patients will be assigned to intervention and (placebo) groups by block randomization method with unequal block sizes of 2, 4, and 6. A randomization list is prepared.

Settings and conduct

This is a triple-blind randomized study (patient, outcome measurement researcher, and data analyst). The population is HIV-positive people who meet the inclusion criteria are among outpatients referred to Sabzeh Parvar Center.

Participants/Inclusion and exclusion criteria

Inclusion criteria No past history of treating psychotic disease Over 18 years of age IQ above 70 No ECT in the last two weeks No alcohol ,stimulants and drugs abuse CD4 level above 350 HIV positive patients who refer as outpatients willingness to participate In case of depression disorder, anxiety disorder, sleep disorder, and cognitive disorder start drug treatment Exclusion criteria Prominent neurological or organic disease and cardiovascular disease Another diagnosis in Axis I based on DSM-V IQ less than 70 based Abusing of other substances (except nicotine and caffeine) Taking oral antipsychotics in the past week or long-acting antipsychotics in the past month Receiving ECT in the last two weeks Women will not be accepted without adequate methods of contraception CHF and liver disease

Intervention groups

25 people in the intervention group are treated with one capsule of acidophilus-bifidum and plantarum probiotics (twice a day) and 25 people in the control group are given 1 placebo capsule of starch twice a day.

Main outcome variables

sleep disorder-anxiety-depression-cognitive disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190316043072N3**
Registration date: **2023-05-31, 1402/03/10**
Registration timing: **retrospective**

Last update: **2023-05-31, 1402/03/10**
Update count: **0**

Registration date

2023-05-31, 1402/03/10

Registrant information

Name

Atefeh Zandifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3255 4132

Email address

zandifaratefe@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-30, 1402/02/10

Expected recruitment end date

2023-05-31, 1402/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of probiotic supplementation in improving symptoms of depression, anxiety, insomnia, anorexia and cognitive impairment in HIV-positive patients, a three-blind randomized clinical trial with placebo control.

Public title

The effect of probiotics in improving symptoms of anxiety, depression and appetite in HIV positive patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Over 18 years of age IQ above 70 No consumption of alcohol, drugs and stimulants in the last three months based on the result of the urine test CD4 level above 350 in the last three months HIV-positive patients are outpatients and not hospitalized and in controlled physical conditions with the approval of an infectious disease specialist Voluntary willingness of the individual to participate in the plan

Exclusion criteria:

prominent neurological or organic disease and cardiovascular disease and history of cardiac surgery or any cardiovascular procedure clinical and laboratory examinations and family history Another diagnosis in Axis I based on DSM-V abusing of other substances (except nicotine and caffeine) taking oral antipsychotics in the past week or long-acting antipsychotics in the past month receiving ECT in the last two weeks women of childbearing age will not be accepted without adequate methods of contraception CHF and liver disease

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

After the eligibility of the patient is recognized and written informed consent is received, the patients will be assigned to one of two intervention and comparison (placebo) groups by block randomization method with unequal block sizes of 2, 4, and 6. Prepare a randomization list becomes To prepare the randomization list, from the web-based software to the address https://www.sealedenvelope.com/simple-randomiser/v1/lists will be used. Allocation concealment In order to hide the allocation, the sequence of allocation will be hidden by choosing the size of non-matching blocks. Also, the specific group of each patient will be placed in envelopes and the number of the envelope will match the order of sequence and the order of identification of the patient. At the time of identification of each patient, one of these envelopes will be opened.

Blinding (investigator's opinion)

Triple blinded

Blinding description

A placebo will be used to blind the patient. In this way, materials similar to probiotics in terms of color, taste, shape, and size are sold with the help of the pharmaceutical company. The researcher investigating the outcome and analyzing the data: He is not aware of the patient's random allocation group, and only the researcher who has the random list is aware of this issue.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Ethics Committee Office, 2nd floor, Deputy of Research and Technology, Saffarian Alley, 45 meters from Gol-shahr

City

Karaj

Province

Alborz

Postal code

3198764653

Approval date

2023-04-17, 1402/01/28

Ethics committee reference number

IR.ABZUMS.REC.1402.013

Health conditions studied

1

Description of health condition studied

Human immunodeficiency virus [HIV] disease

ICD-10 code

B20

ICD-10 code description

Human immunodeficiency virus [HIV] disease

2

Description of health condition studied

depressive disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

3

Description of health condition studied

Insomnia

ICD-10 code

F51.0

ICD-10 code description

Insomnia not due to a substance or known physiological condition

Primary outcomes

1

Description

Anxiety

Timepoint

At the beginning of the study, 4th ,8th ,and 12th weeks

Method of measurement

The Beck Anxiety Inventory (BAI)

2

Description

Anorexia

Timepoint

At the beginning of the study, 4th ,8th ,and 12th weeks

Method of measurement

Simple appetite questionnaire

3

Description

sleep quality

Timepoint

At the beginning of the study, 4th ,8th ,and 12th weeks

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

4

Description

cognitive impairment

Timepoint

At the beginning of the study, 4th ,8th ,and 12th weeks

Method of measurement

Montreal cognitive assessment(MoCA)

Secondary outcomes

1

Description

Mild gastrointestinal discomfort

Timepoint

At the beginning of this study, 4th ,8th and 12th weeks

Method of measurement

Medical history

Intervention groups

1

Description

Intervention group: lactobacillus acidophilus capsule twice per day 10 exponent 8 unit daily for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: Starch placebo tablets exactly the same with probiotic capsules for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sabze Parvar Health Care Center

Full name of responsible person

Amirhossein Hajialigol

Street address

Shahid Sabze Paror Health Care Center , Takhti Street,45-meter Kaj (Azeimieh) Street,, Azadegan Square

City

karaj

Province

Alborz

Postal code

3198764653

Phone

+98 26 3252 2415

Email

Ah.hajialigol@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Hatam Godini
Street address
Safarian St , Golshahr Ave, Karaj
City
karaj
Province
Alborz
Postal code
3198764653
Phone
+98 26 3464 3705
Email
Research@abzums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Atefe Zandifar
Position
Assistant professor of psychiatry
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Imam Ali hospital, beginning of Kaj blvd., Karaj
City
karaj
Province
Alborz
Postal code
3198764653
Phone
+98 26 3250 0123
Email
emamali@abzums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Atefe Zandifar
Position
Assistant professor of psychiatry
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Imam Ali hospital, beginning of Kaj blvd., Karaj
City
karaj
Province
Alborz
Postal code
3198764653
Phone
+98 26 3250 0123
Email
emamali@abzums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Atefe Zandifar
Position
Assistant professor of psychiatry
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Imam Ali hospital, beginning of Kaj blvd., Karaj
City
karaj
Province
Alborz
Postal code
3198764653
Phone
+98 26 3250 0123
Email
emamali@abzums.ac.ir

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

We are going to share required data

When the data will become available and for how long

available on March 2023

To whom data/document is available

Public article

Under which criteria data/document could be used

Unconditional

From where data/document is obtainable

Publisher journal or please sent massage to ah.hajialigol@gmail.com

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

sent massage to ah.hajialigol@gmail.com

Comments