

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of Probiotics supplementation and placebo Effect on Physical Performance, Mood and Sleep Quality in Military Students

Protocol summary

Study aim

Determination of the Effect of Probiotic Supplementation on Physical Performance, Sleep Quality and Student's attitudes of Imam Ali (AF) University Students at Army Army

Design

Clinical trial with community-based and pragmatic control group, with parallel, double-blind, randomized.

Settings and conduct

The project is conducted on 150 students of Imam Ali Army officer university with the aim of examining the effect of probiotic supplementation on physical performance, mood and quality of sleep in this university. These 150 sampled individuals are randomly divided into two groups of 75 Which is administered bilaterally to a probiotic supplement and to another placebo group, so that the sample population and the researchers are not aware of the complementary nature of each group.

Participants/Inclusion and exclusion criteria

Students at Imam Ali University Army, Entry criteria: 1. Male students aged 18 to 26 years 2. Students who do not have any injuries or physical illnesses. 3. The all students is in a course and they must be in the same military training and receive the same nutrition. Non-compliance criteria and exclusion criteria: 1. Those who are not Consent with the use of probiotics or placebo 2. Students who have been injured during the course of military exercises 3. Researchers diagnosed with probiotic susceptibility. 4. Scientists who are medically exempt from combat.

Intervention groups

Intervention group: Includes 30 students, that each students taking one probiotic capsule of 500 mg per day for 8 weeks, 30 minute after lunch. (the capsules made in zist takhmir company) Intervention group: Includes 30 students, that each students taking one placebo capsule of 500 mg per day for 8 weeks, 30 minute after lunch. (the capsules made in zist takhmir company)

Main outcome variables

physical performance, mood and quality of sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180201038585N4**

Registration date: **2019-07-11, 1398/04/20**

Registration timing: **retrospective**

Last update: **2019-07-11, 1398/04/20**

Update count: **0**

Registration date

2019-07-11, 1398/04/20

Registrant information

Name

Karim Parastouei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8248 3516

Email address

parastouei@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-05, 1397/12/14

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Probiotics supplementation and placebo
Effect on Physical Performance, Mood and Sleep Quality
in Military Students

Public title

The effect of probiotic supplementation on physical
performance , sleep quality and mood

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Male students 18 to 26 years old Students who have no
visible physical illness or injury The whole of the students
will be from one period and will be under the same
military training and will benefit from the same nutrition.

Exclusion criteria:

Students who are not satisfied with the use of probiotics
or placebo Students injured during the course of military
exercises Students diagnosed as having probiotic
susceptibility Students who are physically unable to work

Age

From **18 years** old to **26 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization to group intervention and control A
stratified randomized permuted block (with block size 4)
will generated by an independent bio-statistician.
Subjects will stratified according to gender and age.
Random assignment will done by the use of table of
random numbers. The enrolling participants, and
assigning participants to the groups will carried out by a
trained nutritionist. Researchers will not informed about
randomization process until completion of data analyses
(concealme

Blinding (investigator's opinion)

Double blinded

Blinding description

All probiotics and its placebo powders will be provided by
Zisttakhmir company in pre-packed boxes and will be
numbered for each patient according to the
randomization sequence. probiotic and its placebos will
be in the same form of package and the patients and
researcher will not aware of the content of the pack until
the end of the trial.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of bahgeyatlah University of
Medical Sciences

Street address

Sheykh bahaei Ave, Molasadra Ave

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2019-01-21, 1397/11/01

Ethics committee reference number

IR.BMSU.REC.1397.133

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

physical performance, mood and sleep quality

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

Physical performance

Timepoint

One day Before and one day after Supplementation

Method of measurement

Sport test (runing 1600 m , runing 4x9m , Barfix , sit-
ups) and cooper test

2**Description**

Mood

Timepoint

One day Before and one day after Supplementation

Method of measurement

Brums questionnaires

3**Description**

Sleep quality

Timepoint

One day Before and one day after Supplementation

Method of measurement

PSQI questionnaires

Secondary outcomes

empty

Intervention groups**1****Description**

Probiotics, one gram, zist takhmir company

Category

Treatment - Drugs

2**Description**

Placebo

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam ali Army university

Full name of responsible person

Jalil Najafi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Bagheiat-allah 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**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Karim Parastoei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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