# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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 plasebo 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 4×9m , 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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Imam khomeyni Ave
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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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research@bmsu.ac.ir
**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 Parastouei
**Position**
Associate professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nutrition
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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asistant professor

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**Other areas of specialty/work**

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**Email**

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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