

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of probiotic-enriched kefir compared to regular kefir drinks on stress oxidative and inflammatory markers in elderly overweight and obese participants: a randomized clinical trial

Protocol summary

Study aim

The aim of this study is to evaluate the effect of probiotics-enriched kefir drink on anthropometric indices, oxidative stress, inflammatory markers, lipid profiles, appetite and depression in elderly overweight and obese people.

Design

A parallel randomized double-blind controlled clinical trial of 72 elderly participants, Block randomization with a fixed block size of 4 will be done.

Settings and conduct

Retired elderly men over 65 will be referred to Motahari Clinic in Shiraz and are randomly assigned into 2 study groups. The informed consent form, demographic information, physical activity (IPAQ), 3-day food record, and visual appetite scale (VAS) questionnaires and geriatric depression scale-15 are completed for all individuals before and after the study. Anthropometric measurements, evaluation of total antioxidant capacity, superoxide dismutase, catalase, glutathione peroxidase, c-reactive protein, malondialdehyde, interleukin-6 and lipid profiles are performed before and after the study. The appearance of the kefir drinks is quite similar.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Willingness to participate in the study
Male gender Age over 65 years Body mass index above 25
Absence of chronic liver, kidney, diabetes, cardiovascular diseases, digestive disorders, chronic infectious diseases, severe neurological and psychological disorders and not taking antidepressants medicine
Not taking probiotic supplements within 2 months and antibiotics within the last 3 months
Not taking antioxidant supplements
Not regularly consuming alcohol (more than three units per week) and smoking
Exclusion criteria: Any changes in diet or medications
Unwillingness to continue studying
Unwanted side effects that improve by stopping the intervention, which will

cause participants to withdraw from the study

Intervention groups

Group 1 receives the probiotic-enriched kefir drinks.
Group 2 receives the kefir drink.

Main outcome variables

Total antioxidant capacity, superoxide dismutase, catalase, glutathione peroxidase, c-reactive protein, malondialdehyde and interleukin-6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130227012628N3**
Registration date: **2023-02-21, 1401/12/02**
Registration timing: **prospective**

Last update: **2023-02-21, 1401/12/02**

Update count: **0**

Registration date

2023-02-21, 1401/12/02

Registrant information

Name

Mohammad Samadi

Name of organization / entity

Baqiyatallah University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8248 2407

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotic-enriched kefir compared to regular kefir drinks on stress oxidative and inflammatory markers in elderly overweight and obese participants: a randomized clinical trial

Public title

The effect of probiotic-enriched kefir drinks on elderly overweight and obese participants

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate in the study Male gender Age over 65 years Body mass index above 25 Absence of chronic liver, kidney, diabetes, cardiovascular diseases, digestive disorders, chronic infectious diseases, severe neurological and psychological disorders and not taking antidepressants medicine Not taking probiotic supplements within 2 months and antibiotics within the last 3 months Not taking antioxidant supplements Not regularly consuming alcohol (more than three units per week) and smoking

Exclusion criteria:

Any changes in diet or medications Unwillingness to continue studying Unwanted side effects that improve by stopping the intervention, which will cause participants to withdraw from the study

Age

From **65 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Before beginning the study, an outsider who is familiar with the randomization method prepares 4 blocks of random blocks, then randomly identifies the sequences and groups them in a closed envelope, named A, B, C, and D. After the individuals enter the study, the sealed envelopes containing the assigned group of participants will be opened for each participant based on the sequence determined by the person outside the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

The appearance of the kefir drinks in which they are packaged are quite similar. The drinks will be named with the Latin letters A and B. In the clinical phase of the study, the random allocation sequence is done with the same letters. Therefore, the researcher and all participants will be blinded to the intervention.

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

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

Research Ethic Committee of Bagiyatallah hospital

Street address

Baqiyatallah Al-Azam Hospital, after Sheikh Bahai, Mulla Sadra Street, Vanak Square

City

Tehran

Province

Tehran

Postal code

1435915371

Approval date

2023-02-06, 1401/11/17

Ethics committee reference number

IR.BMSU.BAQ.REC.1401.113

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

Elderly

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

Total antioxidant capacity

Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Calorimetric method with Zelbio (Germany) kit with microplate reader device

2

Description

Superoxide dismutase

Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Calorimetric method with Zelbio (Germany) kit with microplate reader device

3

Description

Catalase

Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Calorimetric method with Zelbio (Germany) kit with microplate reader device

4

Description

Glutathione peroxidase

Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Calorimetric method with Zelbio (Germany) kit with microplate reader device

5

Description

C-reactive protein

Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Enzyme-linked immunosorbent assay (ELISA) method with LDN (Germany) kit

6

Description

Malondialdehyde

Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Spectrophotometry method with Zelbio (Germany) kit

7

Description

Interleukin-6

Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Enzyme-linked immunosorbent assay (ELISA) method with LDN (Germany) kit

Secondary outcomes

1

Description

Weight

Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Scales

2

Description

Height

Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Non stretchable meter

3

Description

Waist Circumference

Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Non stretchable meter

4

Description

Hip Circumference

Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Non stretchable meter

5

Description

Lipid profiles

Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Commercial kits using an automatic autoanalyzer

6

Description

Appetite score

Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Visual appetite scale

7

Description

Depression score

Timepoint

Before the study and 8 weeks after the start of the study

Method of measurement

Geriatric depression scale-15

Intervention groups

1

Description

Intervention group: Group 1 receives the probiotic-enriched kefir drinks. Group 2 receives the kefir drink.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Clinic - Shiraz

Full name of responsible person

Siavash Babajafari

Street address

Namazi Street, Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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7134814336

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mehran Nouri

Position

Ph.D candidate

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

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Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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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