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
m.samadi@bmsu.ac.ir

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
City
Shiraz
Province
Fars
Postal code
۷۱۵۳۶۷۵۵۰۰
Phone
+98 71 3725 1001
Fax
Email
jafaris@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammadhashem Hashempour
Street address
Zand street, Shiraz
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3230 5410
Email
hashempurm@sums.ac.ir
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
Street address
Namazi street, Shiraz
City
Shiraz
Province
Fars
Postal code
۷۱۵۳۶۷۵۵۰۰
Phone
+98 71 3725 1001
Email
mehran_nouri71@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Mohammad Samadi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
Baqiyatallah Al-Azam Hospital, after Sheikh Bahai, Mulla Sadra Street, Vanak Square
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 81261

Email
samadi.mohammad@yahoo.com

Person responsible for updating data

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

Street address
Namazi street, Shiraz

City
Shiraz

Province
Fars

Postal code
۷۱۵۳۶۷۵۵۰۰

Phone
+98 71 3725 1001

Email
mehran_nouri71@yahoo.com

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