Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of probiotic on mood status and sleep quality in menopausal women: A triple-blind randomised controlled trial

Protocol summary

Study aim
The effect of probiotic on mood status and sleep quality in menopausal women:l

Design
A triple-blind randomized controlled trial

Settings and conduct
This trial will be performed on 66 menopausal women who referring to health centers of Tabriz. Menopausal women will be assessed according to the eligibility criteria and if they have criteria and willingness to participate in the study, the written informed consent will obtained and primary evaluations will be conducted. Participants will be assigned into two groups of probiotic yogurt and ordinary yogurt using block randomization method with block sizes of 4 and 6 and allocation ratio of 1:1.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Passing of one year from the last menstrual period after the onset of natural menopause; Age 45-60 years; Women who have been passed lower than 5 years from menopause; Not taking of sleeping drugs and antidepressants, tobacco and alcohol, Having mild, moderate and severe anxiety, depression and stress; Obtaining a score above 5 from the Pittsburgh Questionnaire; Having a contact number to follow up; Being resident in Tabriz; Not having digestive problems, asthma, allergies to certain plants, etc.; Having a file in the health center. Exclusion criteria: Having a history of an y physical or mental illness; Existence of hypothyroidism or hyperthyroidism; Having a habit for caffeine consumption; Experiencing an unfortunate event in the last three months

Intervention groups
The control group will receive 100 gram ordinary yogurt and the intervention group will receive 100 gram probiotic yogurt daily (after lunch) for six weeks.

Main outcome variables
The main outcomes are the mood status and sleep quality.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120718010324N57**
Registration date: **2020-06-30, 1399/04/10**
Registration timing: **prospective**

Last update: **2020-06-30, 1399/04/10**
Update count: **0**

Registration date
2020-06-30, 1399/04/10

Registrant information

Name
Mojgan Mirghafourvand

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-21, 1399/04/31

Expected recruitment end date
2020-11-20, 1399/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of probiotic on mood status and sleep quality in menopausal women: A triple-blind randomised controlled trial

Public title
The effect of probiotic on mood status and sleep quality in menopausal women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Passing of one year from the last menstrual period after the onset of natural menopause Age 45-60 years Women who have been passed lower than 5 years from menopause. Not taking of sleeping drugs and antidepressants, tobacco and alcohol Obtaining anxiety score 8-19 (mild, moderate and severe anxiety), depression score between 10-27 (mild, moderate and severe depression), stress score between 15-35 (mild, moderate and severe stress) from DASS questionnaire and obtaining a score above 5 from the Pittsburgh Questionnaire. Having a contact number to follow up Being resident in Tabriz Not having digestive problems, asthma, allergies to certain plants, etc. according to the person herself Having a file in the health center (SIB system)

Exclusion criteria:
Having a history of any physical or mental illness that causes sleep disorders and depression Existence of hypothyroidism or hyperthyroidism Having a habit for caffeine consumption Experiencing an unfortunate event in the last three months, including the death of a loved one that causes sleep disorders, depression and stress

Age
From **45 years** old to **55 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants will be assigned into the two intervention groups (probiotic yogurt recipient) and control (ordinary yogurt recipient) by stratified block randomization method (stratification based on the time elapsed passed since the onset of natural menopause; less than 5 years and more than 5 years) with block sizes of 4 and 6 and a 1: 1 allocation ratio. Random sequence will be determined by the person not involved in the sampling and data collection. For Allocation Concealment, the code of yogurt will be written on piece of paper and placed inside the serial numbered envelopes. After obtaining informed consent, the relevant envelope will be opened and the intervention type will be determined.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participants, researchers, data analysts, and outcome assessors will be blinded due to the fact that the code of the packages of yogurt will be inserted in sealed envelopes and random allocation will be done by the person not involved in sampling. The shape, weight and appearance of probiotic or ordinary yogurt packages will be same.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue

City
Tabriz

Province
East Azarbaijan

Postal code
5138947977

Approval date
2020-05-18, 1399/02/29

Ethics committee reference number
IR.TBZMED.REC.1399.183

Health conditions studied

1

Description of health condition studied
Menopause

ICD-10 code
N95.9

ICD-10 code description
Menopausal and perimenopausal disorder, unspecified

Primary outcomes

1

Description

Depression, anxiety and stress

Timepoint

Before and 6 weeks after the inervention

Method of measurement

DASS-21 (Depression, Anxiety and Stress Scale-21)

2

Description

Sleep quality

Timepoint

Before and 6 weeks after the intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

1

Description

Quality of Life

Timepoint

Before and 6 weeks after the Intervention

Method of measurement

Menopause-specific Quality of Life Questionnaire (MENQOL)

Intervention groups

1

Description

Intervention group will consumed 100 grams of yogurt containing probiotics daily for 6 weeks.

Category

Treatment - Other

2

Description

Control group will consumed 100 grams of ordinary yogurt daily for 6 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Tabriz city

Full name of responsible person

Mehrnaz Shafiee

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz 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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mehrnaz Shafiee

Position

MSc student of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Participant data is confidential
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The results of the clinical study will be published as an article.
When the data will become available and for how long
Immediately after publishing the results
To whom data/document is available
All researchers
Under which criteria data/document could be used
Scientific using with citation to article
From where data/document is obtainable
Email: mirghafourvandm@tbzmed.ac.ir
What processes are involved for a request to access data/document
Up to one week after communication by email
Comments