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:

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 any 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
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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
Research department, third floor, central construction number 2, Tabriz university of medical sciences, Gogasht 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 intervention

**Method of measurement**
DASS-21 (Depression, Anxiety and Stress Scale-21)

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Sleep quality

**Timepoint**
Before and 6 weeks after the intervention

**Method of measurement**
Pittsburgh Sleep Quality Index

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**Secondary outcomes**

1. Quality of Life
   **Timepoint**
   Before and 6 weeks after the intervention
   **Method of measurement**
   Menopause-specific Quality of Life Questionnaire (MENQOL)

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**Intervention groups**

1. Intervention group will consumed 100 grams of yogurt containing probiotics daily for 6 weeks.
   **Category**
   Treatment - Other

2. Control group will consumed 100 grams of ordinary yogurt daily for 6 weeks.
   **Category**
   Treatment - Other

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**Recruitment centers**

1. Health centers of Tabriz city
   **Full name of responsible person**
   Mehrnaz Shafiee
   **Street address**
   Faculty of Nursing & Midwifery, South Shariati Street
   **City**
   Tabriz
   **Province**
   East Azarbaijan
   **Postal code**
   9876065489

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**Sponsors / Funding sources**

1. **Name of organization / entity**
   Tabriz University of Medical Sciences
   **Full name of responsible person**
   Dr. Mohammad Samiei
   **Street address**
   Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz
   **City**
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   **Grant name**
   Tabriz University of Medical Sciences
   **Proportion provided by this source**
   100
   **Public or private sector**
   Public
   **Domestic or foreign origin**
   Domestic
   **Country of origin**
   empty
   **Type of organization providing the funding**
   Academic

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**Person responsible for general inquiries**

**Contact**

Name of organization / entity
   Tabriz University of Medical Sciences
   Full name of responsible person
   Mehrnaz Shafiee
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Person responsible for scientific inquiries

Contact
- Name of organization / entity: Tabriz University of Medical Sciences
- Full name of responsible person: Dr. Mojgan Mirghafourvand
- Position: PhD of Reproductive Health
- Latest degree: Ph.D.
- Other areas of specialty/work: Midwifery

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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