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.
**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**

**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, 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**

**Description of health condition studied**
Menopause

**ICD-10 code**
N95.9

**ICD-10 code description**
Menopausal and perimenopausal disorder, unspecified

**Primary outcomes**

**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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**Description**
Sleep quality

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

**Method of measurement**
Pittsburgh Sleep Quality Index

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**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)

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**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

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**Recruitment centers**

1

**Recruitment center**
Health centers of Tabriz city

**Full name of responsible person**
Mehrnaz Shafiee

**Street address**
Faculty of Nursing & Midwifery, South Shariati Street

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Tabriz

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9876065489

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**Email**
mehrnaz.sh1610@gmail.com

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**Sponsors / Funding sources**

1

**Sponsor**
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

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East Azarbaijan

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**Email**
mehrnaz.sh@gmail.com

**Grant name**
Tabriz University of Medical Sciences

**Grant code / Reference number**
100

**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

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**Person responsible for general inquiries**

**Contact**
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**
Midwifery

**Street address**
Faculty of Nursing & Midwifery, South Shariati Street
**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

**Street address**
- Faculty of Nursing & Midwifery, South Shariati Street

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**
- **Justification/reason for indecision/not sharing IPD**: Participant data is confidential

**Study Protocol**
- **Justification/reason for indecision/not sharing IPD**: Participant data is confidential

**Statistical Analysis Plan**
- **Justification/reason for indecision/not sharing IPD**: Participant data is confidential

**Informed Consent Form**
- **Justification/reason for indecision/not sharing IPD**: Participant data is confidential

**Clinical Study Report**
- **Justification/reason for indecision/not sharing IPD**: The results of the clinical study will be published as an article.

**Analytic Code**
- **Justification/reason for indecision/not sharing IPD**: Participant data is confidential

**Data Dictionary**
- **Justification/reason for indecision/not sharing IPD**: Participant data is confidential

**Title and more details about the data/document**
- **Justification/reason for indecision/not sharing IPD**: The results of the clinical study will be published as an article.

**When the data will become available and for how long**
- **Justification/reason for indecision/not sharing IPD**: Immediately after publishing the results

**To whom data/document is available**
- **Justification/reason for indecision/not sharing IPD**: All researchers

**Under which criteria data/document could be used**
- **Justification/reason for indecision/not sharing IPD**: Scientific using with citation to article

**From where data/document is obtainable**
- **Justification/reason for indecision/not sharing IPD**: Email: mirghafourvandm@tbzmed.ac.ir

**What processes are involved for a request to access data/document**
- **Justification/reason for indecision/not sharing IPD**: Up to one week after communication by email

**Comments**