Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of aromatherapy with essential oil of lavender-bergamot, and counseling based on mindfulness on sexual function, anxiety, and serum level of some bio-markers in postmenopausal women: A randomized controlled trial with factorial design.

Protocol summary

Study aim

Determination of effect of 8 weeks intervention with lavender-bergamot aroma, mindfulness counseling, aroma-mindfulness counseling on sexual function score, anxiety score, and levels of some serum bio-markers in postmenopausal women compared to control group

Design

A randomized controlled clinical trial with a factorial design, stratified by menopause duration. 132 postmenopausal women randomly will be divided into four groups of counseling based on mindfulness and aroma placebo, aromatherapy and routine care, counseling based on mindfulness and aromatherapy, and control group using Random Allocation Software (RAS) with 1:1:1:1 ratio.

Settings and conduct

Eligible women will be selected among health centers and randomly assigned into one of the four groups after giving written informed consent. Aroma and its similar placebo, 3 times daily, 2-3 drops on the skin for 8 weeks and counseling in 45-60 minutes sessions, once a week for 8 consecutive weeks will be administered.The blinding of researcher and participants in terms of counseling will not be possible

Participants/Inclusion and exclusion criteria

Inclusion criteria: Married postmenopausal women; Age between 50-60; Having records in Tabriz Elderly Friendly Centers; Mild to moderate anxiety; Sexual dysfunction score less than 28; PSQI 5 or more; Greene between 15-42. Exclusion criteria: Use of herbal compounds to increase libido in men or women; Sensitivity to any of the herbal remedies; Occurrence of the adverse event within 3 months prior to the study;

Intervention groups

The groups receiving counseling based on mindfulness and aromatherapy, aromatherapy and routine care, counseling based on mindfulness and aromatherapy, or control group (placebo of aroma and routine care)

Main outcome variables

Mean score of sexual function after intervention Mean score of anxiety after intervention Serum level of some bio-markers after intervention

General information

Reason for update

Hi,]t is hereby conveyed that due to the coincidence of the implementation stages of this trial with the corona pandemic and its various peaks, the sampling process was prolonged and sampling was completed with a delay on 2020-11-21 instead of 2020-03-15. Therefore, we want to correct the completion date of sampling. Also, along with the studied variables, due to the importance of sleep quality and menopausal symptoms in menopausal women, these two variables were also considered as a secondary outcome along with other variables. Therefore, please agree with the above amendments. Thank you

Acronym

IRCT registration information

IRCT registration number: **IRCT20131009014957N8**
Registration date: **2019-12-04, 1398/09/13**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-05, 1400/04/14**
Update count: **2**

Registration date

2019-12-04, 1398/09/13

Registrant information

Name

Azizeh Farshbaf-khalili

Name of organization / entity

Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1333 9151

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of aromatherapy with essential oil of lavender-bergamot, and counseling based on mindfulness on sexual function, anxiety, and serum level of some bio-markers in postmenopausal women: A randomized controlled trial with factorial design.

Public title

Effect of aromatherapy and counseling based on mindfulness on sexual function, anxiety, and serum level of some bio-markers in postmenopausal women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Postmenopausal women between the ages of 50-60 Having read and write literacy The Female Sexual Function Score less than 28 Having mild to moderate anxiety based on Beck Anxiety Scale Having sex in the family limit with her permanent spouse Having only one wife for the man Natural menopause Obtaining a score of 15-42 on the Greene scale Having a score of 5 and higher in The Pittsburgh Sleep Quality Index (PSQI)

Exclusion criteria:

Known physical and mental illnesses based on person's self statement (depression, diabetes, cardiovascular disease, olfactory sensations, mental disability, diabetes) Drugs affecting sex (sildenafil, antidepressants, antihistamines, diazepines, barbiturates, amphetamines, antihypertensive drugs, cocaine, thiazide diuretics, narcotics Use of herbal ingredients to increase sexual desire in men or women (ginseng, cinnamon, ginger, etc.) and alergy to any herbal medicine Addiction to the habitual consumption of alcohol and tobacco by women Participate in other similar studies Occurrence of an misadventure within 3 months prior of study (death or acute illness of close relatives) Disorder in the sense of smell according to person's self and other nasal disorders (fracture, aberration, rhinitis) Use of hormotherapy at last 6 month

Age

From **50 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

Postmenopausal women aged 50-60 years will be divided into four groups of aromatherapy and routine care, counseling based on Mindfulness-Based Intervention (MBI) and aromatherapy, counseling based on MBI and placebo of aromatherapy, and control group (placebo of aromatherapy and routine care) using the RAS software with four and eight blocks with a 1: 1: 1: 1 allocation ratio and will be stratified based on menopausal years (less than or greater than 5 years). To conceal the allocated intervention, type of counseling intervention (counseling or routine care) will be written on papers and along with allocated aromas or placebo will be placed in the matte and sealed envelopes numbered from 1 to 132 based on random sequence generated by a non-researcher. The first envelope will be given to the first eligible person and will be continued until the completion of sampling. The participant, researcher and statistical analyst will not be aware of the contents of the package (allocation concealment). In this study, after the random allocation of the individual to the study group, the researcher and participant blindness would not be possible in terms of counseling,

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, outcome assessor and statistical analyst will be kept blind to the specific study groups. So that the combined aroma and its placebo will be poured into identical dark containers and identified only by random code of study. The outcome assessor and the statistical analyst will not be present at the consultation sessions. Questionnaires will not specify the type of intervention and only random code will be written. Also in the statistical software, only the code of the participants and the group number will be written.

Placebo

Used

Assignment

Factorial

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., Golgasht Street., Azadi Avenue
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Approval date
2019-10-14, 1398/07/22
Ethics committee reference number
IR.TBZMED.REC.1398.749

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F41
ICD-10 code description
Other anxiety disorders

2

Description of health condition studied
Sexual dysfunction
ICD-10 code
F52
ICD-10 code description
Sexual dysfunction not due to a substance or known physiological condition

3

Description of health condition studied
Depression
ICD-10 code
F32
ICD-10 code description
Major depressive disorder, single episode

4

Description of health condition studied
Serum levels of some bio-markers
ICD-10 code
ICD-10 code description

5

Description of health condition studied
Menopausal symptoms
ICD-10 code
N95
ICD-10 code description
Menopausal and other perimenopausal disorders

6

Description of health condition studied
Sleep quality
ICD-10 code
G47
ICD-10 code description
Sleep disorders

Primary outcomes

1

Description
Anxiety score in Beck Anxiety Inventory
Timepoint
At baseline and 8 weeks after intervention
Method of measurement
Beck Anxiety Inventory

2

Description
Sexual function score in Female Sexual Function Index
Timepoint
At baseline and 8 weeks after intervention
Method of measurement
Female Sexual Function Index

3

Description
Serum level of cortisol
Timepoint
At baseline and immediately after intervention
Method of measurement
Elisa method by ELISA kits

Secondary outcomes

1

Description
Depression score using Beck Depression Inventory
Timepoint
At baseline and 8 weeks after intervention
Method of measurement
Beck Depression Inventory

2

Description
Serum level of malondialdehyde
Timepoint

At baseline and immediately after intervention

Method of measurement

By spectrophotometric method based on reaction with thiobarbituric acid

3

Description

Serum level of high-sensitivity C-Reactive Protein

Timepoint

At baseline and immediately after intervention

Method of measurement

Complex-based turbidometry based on the reaction between high-sensitivity C-Reactive Protein and specific antiserum

4

Description

Serum level of Total Antioxidant Capacity

Timepoint

At baseline and immediately after intervention

Method of measurement

By Autoanalyzer Abbott (Alcyon 300) using Randox kit

5

Description

Frequency of adverse events

Timepoint

While intervention

Method of measurement

Adverse events checklist

6

Description

Menopausal symptom score using Greene climacteric scale

Timepoint

At baseline and 8 weeks after intervention

Method of measurement

Greene Climacteric Scale

7

Description

The score of Pittsburgh Sleep Quality Index (PSQI)

Timepoint

At baseline and 8 weeks after intervention

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

Intervention groups

1

Description

Intervention group 1: Mindfulness consulting along with placebo of aroma. Mindfulness in-person counseling will be held once per week for eight weeks through the 45-60 minute sessions in a native language. The number of participants in each meeting will be at least eight and up to twelve. The last 15 minutes will be devoted to question and answer. Aroma placebo (probylene glycol) will be rubbed 2 to 3 drops, 2-3 times a day for 8 weeks. The placebo will be made by Goldaru Pharmaceutical Company and packed in 30 ml dark glass.

Category

Treatment - Other

2

Description

Intervention group 2: Aromatherapy with essential oil of lavender-bergamot along with routine care. Lavender-bergamot essential oil will be applied 3 times daily, 2-3 drops each time for 8 weeks on the forearm. The composition of the essential oils will be in the form of 5% lavender and 0.4% bergamot essential oils. The pure essential oils will be provided by the Goldaru Pharmaceutical Company. The analysis of essential oils, blending of them with the desired concentration will be carried out in the Faculty of Pharmacy and will be packed in 30 ml dark glass.Routine care will be carried out in accordance with the Ministry's approved protocol.

Category

Treatment - Other

3

Description

Intervention group 3: Aromatherapy with essential oil of lavender-bergamot along with Mindfulness consulting. Lavender-bergamot essential oil will be applied 3 times daily, 2-3 drops each time for 8 weeks on the forearm. The composition of the essential oils will be in the form of 5% lavender and 0.4% bergamot essential oils. The pure essential oils will be provided by the Goldaru Pharmaceutical Company. The analysis of essential oils, blending of them with the desired concentration will be carried out in the Faculty of Pharmacy and will be packed in 30 ml dark glass. Mindfulness in-person counseling will be held once per week for eight weeks through the 45-60 minute sessions in a native language. The number of participants in each meeting will be at least eight and up to twelve. The last 15 minutes will be devoted to question and answer.

Category

Treatment - Other

4

Description

Control group: Placebo of aroma along with routine care. Aroma placebo (probylene glycol) will be rubbed 2 to 3 drops, 2-3 times a day for 8 weeks. The placebo will be made by Goldaru Pharmaceutical Company and packed in 30 ml dark glass. Routine care will be carried out in accordance with the Ministry's approved protocol.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Elderly-friendly Health Centers

Full name of responsible person
Dr.Mitra Yeganeh

Street address
Nesfrah Square., Tabriz health center

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East Azarbaijan

Postal code
5157665633

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Email
yeghanehm@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mohammad Samiei

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Fax
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research-vice@tbzmed.ac.ir

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
Dr. Azizeh Farshbaf-Khalili

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Physical Medicine and Rehabilitation Research Center, Street, Ground Floor, Imam Reza Hospital, Golgasht Street

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Person responsible for updating data

Contact

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Full name of responsible person

Dr. Azizeh Farshbaf-Khalili
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
Requested data will be provided to researchers for statistical analysis of the submitted proposal (meta-analysis).
When the data will become available and for how long
Starting immediately after publication
To whom data/document is available
Data will be available to researchers as well as to journals
Under which criteria data/document could be used
The data will be available to researchers upon request and submission of a proposal to perform meta-analysis using IPD data after being unidentified. Also, in exceptional cases, data will be made available to journals for checking
From where data/document is obtainable
Refer to the email address (farshbafa@tbzmed.ac.ir)
What processes are involved for a request to access data/document
The requests will be sent by email and data will be available within a week
Comments