

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of lavandula and citrus aurantium on depression and sleep quality in menopausal women

Protocol summary

Summary

The aim of this study is to compare the effect of lavandula and citrus aurantium on depression and sleep quality in menopausal women. This study is a randomized clinical trial, triple-blind, controlled with placebo. The samples are postmenopausal women aged 45 to 60. The sample size is 156 women and the intervention period is 8-weeks. These women randomly were allocated into 3 groups (citrus aurantium, lavender and placebo) based on 3 and 6 blocks randomization method. The same capsules contain 500 mg citrus aurantium and lavender flower's powder and placebo (starch) prepared by Yashil drug Sahand Pharmaceutical Company. For allocation concealment, drugs and placebo were placed in the same closed opaque envelopes that serial numbered according to allocation sequence. Block scheduling and preparing envelopes were performed by a person not involved in the sampling and data analysis. They will enter to study by the order number on the envelope. For reminding, 2 and 6 weeks after the start of the study phone call with participants will be taken by the researcher. Sleep quality and depression in all three groups before and after intervention will be measured by Pittsburgh and Beck questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504236582N11**

Registration date: **2015-10-09, 1394/07/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-09, 1394/07/17

Registrant information

Name

Mahin Kamalifard

Name of organization / entity

Tabriz University of Medical Sciences and Health Services

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-04-18, 1395/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of lavandula and citrus aurantium on depression and sleep quality in menopausal women

Public title

Comparison of the effect of lavandula and citrus aurantium on depression and sleep quality in menopausal women

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria: 45-60 years old; 1 to 6 years after

the last menstrual period which start by natural menopause; getting more than 5 score from Pittsburgh Sleep Quality Index (PSQI);getting between4-28 score from Beck depression score; not taking hypnotic and anti depressant drugs; not taking tobacco and alcohol; having phone number for follow-up; without history of asthma and allergy to specific plants or citrus; Lack of acute gastrointestinal problems declared by herself; Living in Urmia; the desire to participate in the study Exclusion Criteria: Having travel or home change during intervention; Having a history of severe physical and mental disease that causes sleep disorders and depression; Death of a relative in the past three months, encounter with the events that caused sleep disorders and depression; Regular weekly or professional exercise; The use of other methods of traditional medicine

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **156**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**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

Tabriz University of Medical Sciences Research Administration

City

Tabriz

Postal code**Approval date**

2015-05-11, 1394/02/21

Ethics committee reference number

TBZMED.REC.1394.98

Health conditions studied**1****Description of health condition studied**

sleep quality

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

2**Description of health condition studied**

depression

ICD-10 code

F32.0

ICD-10 code description

Depressive episode

Primary outcomes**1****Description**

sleep quality

Timepoint

before and 8 week after intervention

Method of measurement

Pittsburgh Sleep Quality Index

2**Description**

depression

Timepoint

before and 8 week after intervention

Method of measurement

Beck Depression Questionnaire

Secondary outcomes**1****Description**

Satisfaction of postmenopausal women

Timepoint

8 weeks after intervention

Method of measurement

Checklist

2**Description**

Anxiety

Timepoint

Before and 8 weeks after intervention

Method of measurement

(STAI) questionnaire

3

Description

Adverse events

Timepoint

8 weeks after intervention

Method of measurement

Checklist

4

Description

Personal and social characteristics associated with depression and sleep quality scores in the groups studied

Timepoint

Before intervention

Method of measurement

Demographic questionnaire

Intervention groups

1

Description

The citrus aurantium group will receive capsules containing 500 mg Citrus aurantium flower's Powder twice a day after breakfast and dinner for 8 weeks.

Category

Treatment - Drugs

2

Description

The lavender group will receive capsules containing 500 mg of Lavender flower's Powder twice a day after breakfast and dinner for 8 weeks.

Category

Treatment - Drugs

3

Description

The control group will receive capsules containing 500 mg starch twice a day after breakfast and dinner for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Mahsa Namadian

Street address

City

Urmia

2

Recruitment center

Name of recruitment center

Fatemie Hospital

Full name of responsible person

Mahsa Namadian

Street address

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mahin Kamalifard

Street address

Nursing and Midwifery, Tabriz University of Medical Sciences

City

Tabriz

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mahin Kamalifard

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Master Sciences of Midwifery

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty