Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effects of Rosa Damascene aromatherapy on sleep quality in menopausal women

Protocol summary

Summary

Objectives: To evaluate the effects of Rosa aromatherapy on sleep quality in menopausal women. The study population: Menopausal women referred to the health centers in Urmia on the intervention and control groups Will be divided randomly into two. Sample size: 60 patients (30 Control, 30 Case). Design: The implementation of the study will be four consecutive nights for 6 week for each person. Rose Aromatherapy will be performed every night for 4 drop and by sleep quality Index Pittsburgh before and after, in both groups ،compare the quality of patients' sleep. Inclusion criteria: Passing at least one year from the last menstrual period; women without diabetes; hypertension; heart and respiratory disease etc. Exclusion criteria: Dissatisfaction to participant in the study. Main outcome measures :sleep quality parameters including subjective sleep quality; sleep latency; sleep duration; habitual sleep efficiency, sleep disturbances; use of sleeping medication; daytime dysfunction initial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111420778N4**
Registration date: **2016-09-02, 1395/06/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-09-02, 1395/06/12

Registrant information

Name

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Name of organization / entity

Uromia University of Medical sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Governmental (University of Medical Sciences of urmia)

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Rosa Damascene aromatherapy on sleep quality in menopausal women

Public title

Aromatherapy effect on sleep quality in menopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Consent to participate in the project; Passing at least one year from the last menstrual period; confirmed menopause; women without diabetes; hypertension; heart and respiratory disease; consumption sleep pills; hormone replacement therapy; mental disorders and Pittsburgh Sleep Quality Index score of 5 or above. Exclusion criteria: Dissatisfaction to participant in the study; Allergic signs and symptoms

while taking aromatherapy; use Rose less than 4 times a week; detection of diabetes and hypertension during intervention; any major stressors.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciences

Street address
Orjhans Street, Resalat Blvd, Urmia

City
Urmia

Postal code
571478334

Approval date
2015-12-01, 1394/09/10

Ethics committee reference number
ir.umsu.rec.1394.293

Health conditions studied

1

Description of health condition studied
Sleep disorder

ICD-10 code
G47

ICD-10 code description
Sleep Disorders

2

Description of health condition studied
Menopause

ICD-10 code
N95

ICD-10 code description
Menopausal and other perimenopausal disorders

Primary outcomes

1

Description
Improve of sleep quality

Timepoint
Before intervention 6 weeks after intervention and 4 weeks after the cessation intervention

Method of measurement
Pittsburgh questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: Rosa Damascene fragrance will be used by participants in the intervention group nightly before sleeping. The fragrance will be dropped on cotton balls, which were placed on a cylindrical container at mothers' disposal. Keeping the container at a projected distance of 20 cm, the participants inhaled 10 deep breaths and then the container was placed beside their pillow until morning. This procedure will be done 4 times a week for 6 weeks.. The instrument for collecting data will be Pittsburgh sleep quality index; which will be completed at the baseline; fourth; and eighth weeks after the intervention. Data Will be analyzed using independent t test and repeated measures analysis of variance calculated by SPSS 16.

Category
Treatment - Drugs

2

Description
Control group: no intervention will be performed in this group.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Urmia city health centers

Full name of responsible person
Somaye rezavand
Street address
Students' dormitory of Urmia University of Medical Sciences
City
Urmia

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Urmia University of Medical Sciences
Full name of responsible person
Iraj mohebbi
Street address
Resalat biv,next to the emergency center، Urmia University of Medical Sciences
City
Urmia
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research,Urmia 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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Fax
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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