

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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

Fatemeh Moghaddam Tabrizi

Name of organization / entity

Uromia University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

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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**

University of Medical Sciences of urmia

Full name of responsible person

Fateme Mogaddam Tabrizi

Position

Assistant Professor

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City

Urmia

Postal code**Phone**

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Fax**Email****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