

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The impact of aromatherapy on the quality of sleep in postpartum women

Protocol summary

Summary

The aim of this trial is to determine the impact of aromatherapy on the quality of sleep and anxiety in postpartum women. The study is a randomized clinical trial. 140 eligible women in 3-5 days after delivery randomly will be allocated into an intervention and a control group (placebo). Mothers randomly assign to intervention group inhale Lavender aroma four sessions per week for eight weeks. The process of aromatherapy explains for mothers and Lavender oil will dropped on a piece of cotton pad placed in a small box and mothers are asked to take 10 deep breath first before sleep and then put it near their pillow, within 20 cm distance from themselves. The control group does the same process with placebo instead. All subjects will fill Pittsburgh Sleep Quality Index (PSQI) at baseline (3-5 days after delivery) and 4 and 8 week after initiation of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211179463N8**

Registration date: **2013-09-08, 1392/06/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-09-08, 1392/06/17

Registrant information

Name

Zahra Behboodi Moghadam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

behboodi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of aromatherapy on the quality of sleep in postpartum women

Public title

The impact of aromatherapy on the quality of sleep in postpartum women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Having a singleton live child 2-Literate 3-Uncomplicated vaginal delivery 4-Aged 18 to 35 5-without known physical, mental and psychological illness. 6-Exclusive breast feeding 7-Healthy baby 8-Acquiring Pittsburgh Sleep Quality Index score of 5 or higher
Exclusive criteria: 1-Appearance of physical and psychological illness during study. 2-Using certain medications (such as hypnotics or sedatives) 3-Allergies to the herbs 4-Having depression

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Science

Street address

Tehran-Bolvar Keshavarz near Ghods street-central building-6th floor

City

Tehran

Postal code

Approval date

2013-08-04, 1392/05/13

Ethics committee reference number

130/904/92/>

Health conditions studied

1

Description of health condition studied

Sleep Quality

ICD-10 code

O94, O99

ICD-10 code description

Other Obstetric Conditions, Not elsewhere classified

Primary outcomes

1

Description

sleep quality

Timepoint

before intervention-4 and 8 weeks after initiation of intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

intervention group:the participants will drop lavender oil on a piece of cotton pad placed in a small box before sleep take 10 deep breath and then put it near their pillow, within 20 cm distance from themselves. This process continues for 8 weeks, 4 times a week.

Category

Treatment - Drugs

2

Description

control group(placebo): the participants will drop placebo on a piece of cotton pad placed in a small box before sleep take 10 deep breath and then put it near their pillow, within 20 cm distance from themselves. This process continues for 8 weeks, 4 times a week.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan health center number 9

Full name of responsible person

Dr Behboodi Moghadam Zahra

Street address

Zanjan health center number 9-fateh street-Zanjan

City

Zanjan

2

Recruitment center

Name of recruitment center

Zanjan Health center number 14

Full name of responsible person

Dr Behboodi Moghadam Zahra

Street address

Zanjan Health center number 14-shahrak karmandan street-Zanjan

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science research

Full name of responsible person

Dr Fotoohi Akbar

Street addressTehran- keshavarz_ghods street-central building of
Tehran University of Medical Science**City**

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Science research

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**

tehran university of medical science

Full name of responsible person

Dr Behboodi Moghadam Zahra

Position

phd

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of medical science

Full name of responsible person

Keshavarz Afshar Mahnaz

Position

MA

Other areas of specialty/work**Street address****City**

Zanjan

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*