Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

Summary
The aim of this trail 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
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Zahra Behboodi Moghadam
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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-Exlusive 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 certainmedications(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-centeral building-6th floor
City
Tehran
Postal code
Approval date
2013-08-04, 1392/05/13
Ethics committee reference number
130/904/92/ر

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
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2

Recruitment center
Name of recruitment center
Zanjan Health center number 14
Full name of responsible person
Dr Behboodi Moghadam Zahra
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Zanjan Health center number 14-shahrak karmandan street-Zanjan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Science research

Full name of responsible person
Dr Fotoohi Akbar
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Tehran- keshavarz_ghods street-centeral 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
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Person responsible for updating data

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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