Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of rose water aromatherapy on women's sleep quality in postpartum period

Protocol summary

Study aim
The effect of rose flower aroma on sleep quality of women during the postpartum

Design
A clinical trial with a control group, with parallel groups, without blinding, randomized, phase 3 on 84 people, a random number table was used for randomization.

Settings and conduct
Aromatherapy - Home and self intervention - Three nights of inhalation of a rose that pinned to the pillow. The project was carried out in Arak city and between clients of health clinics.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Lack of severe pain disruptive sleep ; Lack of experience in aromatherapy ; Do not use complementary medicine in the last week ; Awareness (awareness of time, place and person) ; Lack of underlying disease affecting sleep (such as rheumatoid arthritis and migraine) ; No known sleep disorder according to the patient ; No history of asthma and allergies No history of allergies and eczema to flowers and plants and the smell of sweat and their essential oils ; Do not take drugs 6 hours before bedtime ; Not addicted ; Do not take psychiatric drugs ; Lack of care or treatment plan during bedtime ; Lack of orthopnea and respiratory problems ; Baby age 20 to 25 days ; Exclusive breastfeeding ; Criteria for not entering: ; Severe sensitivity to the scent of rosemary during the study. ; The patient's unwillingness to continue participating in the study ; Arbitrary use of sedatives ; Orthopedics and respiratory problems during the study ; The patient becomes ill

Intervention groups
For 3 nights - the napkin is dipped in rose essential and pinned to the pillow. The control group will receive no intervention

Main outcome variables
women's sleep quality during the postpartum

General information

Reason for update
Record sampling date

Acronym

IRCT registration information
IRCT registration number: **IRCT20191013045079N1**
Registration date: **2019-11-05, 1398/08/14**
Registration timing: **prospective**

Last update: **2020-11-26, 1399/09/06**
Update count: **2**

Registration date
2019-11-05, 1398/08/14

Registrant information

Name
hadis fattah

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 66 3340 6516

Email address
hadisfth@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-03, 1398/09/12

Expected recruitment end date
2020-01-20, 1398/10/30

Actual recruitment start date
2019-12-03, 1398/09/12

Actual recruitment end date
2020-03-18, 1398/12/28

Trial completion date
2020-05-19, 1399/02/30

Scientific title
The effect of rose water aromatherapy on women's sleep quality in postpartum period

Public title
The effect of rose aroma on sleep quality

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Lack of severe pain disruptive sleep No experience of aromatherapy until now No use of complementary medicine in recent weeks Being alert (knowing time, place and person) Lack of sleeping conditions (such as rheumatoid arthritis and migraine) No known sleep disorder according to the patient No history of asthma and allergies Not having a history of allergy and eczema to flowers and plants and the smell of sweat and essential oils Do not take drugs 6 hours before bedtime Not being addicted No psychotropic drugs Lack of care or treatment during bedtime Lack of orthopnea and respiratory problems Baby age 20 to 25 days Exclusive Breastfeeding

Exclusion criteria:
Severe sensitivity to the scent of Mohammadi flowers during the study. Patient's unwillingness to continue participating in the study Arbitrary use of sedatives Orthopnea and Respiratory Difficulty During Study Getting sick

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **84**
Actual sample size reached: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Cluster sampling: According to cluster sampling, health centers will be selected by lot from 5 districts of Arak city and then sampling will be done from each of the selected clinics in proportion to the population covered. Random number table: Randomly divide people into two groups of 42 people intervention and control, assign a three-digit code to each person and then create a number table, randomly select three consecutive numbers in a row or column.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Arak University of Medical Sciences., Alam Hoda Street., Shahid Shiroudi Street., Arak

City
Arak

Province
Markazi

Postal code
6819763383

Approval date
2019-09-15, 1398/06/24

Ethics committee reference number
IR.ARAKMU.REC.1398.176

Health conditions studied

1

Description of health condition studied
Poor sleep quality

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
sleep quality

Timepoint
Baseline - After 3 nights inhalation of rose scent

Method of measurement
Petersburg questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Inhaling the scent of Mohammadi flower from 10% essential oil of Mohammadi flower made in by Barij company, Iran, for three consecutive nights and for at least 8 hours every night.

Category
Rehabilitation

2

Description
Control group: they will not receive any intervention
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak Health Centers
Full name of responsible person
Hadis Fattah
Street address
University complex of the Great Prophet., Sardasht
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3814957558
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Katayoon Vakilian
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
All potential data can be shared after unidentifiable people

When the data will become available and for how long
Start accessing 6 months after printing results

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
No more conditions

From where data/document is obtainable
email

What processes are involved for a request to access data/document
Upon request by email

Comments