

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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University complex of the Great Prophet., Sardasht

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3814957558

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Email

Hadisfth@gmail.com

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

Midwifery

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Fax**Email**

hadisfth@gmail.com

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