Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the Effect of Mindfulness Therapy and Aromatherapy with Lavender Essential Oil on Quality of Sleep in Post-Partum Women

Protocol summary

Study aim
The purpose of this research is to compare the effect of mindfulness-based counseling and aromatherapy with lavender essential oil on the sleep quality of postpartum mothers.

Design
A randomized clinical trial study with two intervention groups and one control group, parallel groups, phase 4, on 132 women who have given birth less than 2 weeks. Randomization was done using SPSS software.

Settings and conduct
A randomized clinical trial was conducted in one of the reference hospitals of Isfahan city in women who gave birth.

Participants/Inclusion and exclusion criteria
Age 20-40 years, absence of postpartum depression and lack of completion of sleep questionnaire

Intervention groups
In this study, 3 ژgroups (intervention 1, intervention 2 and control) participated.. Mindfulness counseling group in the form of 8 one-hour WhatsApp sessions and aromatherapy group with lavender essential oil with a volume of 15 ml, which was poured on a napkin between two drops of this oil overnight for two months. and it is inhaled by people before going to bed for ten minutes.In control group was instructed the routine postpartum care via WhatsApp.

Main outcome variables
The quality of sleep

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220706055397N1**
Registration date: **2023-07-06, 1402/04/15**
Registration timing: **retrospective**
Last update: **2023-07-06, 1402/04/15**
Update count: **0**

Registration date
2023-07-06, 1402/04/15

Registrant information

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Zahra Ghalgar
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-31, 1401/03/10

Expected recruitment end date
2022-09-09, 1401/06/18

Actual recruitment start date
2022-06-10, 1401/03/20

Actual recruitment end date
2022-11-11, 1401/08/20

Trial completion date
2023-02-10, 1401/11/21

Scientific title
Comparison the Effect of Mindfulness Therapy and Aromatherapy with Lavender Essential Oil on Quality of Sleep in Post-Partum Women

Public title
Comparison the Effect of Mindfulness Therapy and Aromatherapy with Lavender Essential Oil on Quality of Sleep in Post-Partum Women

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Mothers who passed no more than 2 weeks since their delivery Pittsburgh Sleep Questionnaire score above 5 Not using complementary medicine or psychological counseling during the last six months Lack of underlying disease Lack of pulmonary and respiratory problems such as asthma Having minimum level of reading and writing literacy and mastering the WhatsApp application Access to the Internet and WhatsApp application

Exclusion criteria:

Use of complementary medicine or psychological counseling during the past six months The presence of an underlying disease The presence of lung and breathing problems such as asthma Mother's lack of interest in participating in the research The presence of any problems in the postpartum process, such as the mother or baby being unwell and losing the family Discomfort and dissatisfaction with the smell of fragrances Allergy to lavender

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **132**

Actual sample size reached: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

First, we determine the names and surnames of 132 qualified people who are registered in the above hospital, code them from 1 to 132, and then enter the codes of the people in the SPSS software and use that software. The software that gives us the possibility of simple random selection, we perform a simple random selection and put the subjects under study in each of the groups. For this purpose, after running the random sample of cases, a new column was created in the data whose code 1 indicates the selection for the mindfulness group. Then we delete the selected people of the mindfulness group and execute the command again on other people, and put the code of a new column in the aromatherapy group. The remaining people, who will be coded zero, will be included in the control group.

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 Arak University of Medical Sciences

Street address

Khalige Fars Ave,Arak University of Medical Sciences,Arak town

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2022-05-15, 1401/02/25

Ethics committee reference number

IR.ARAKMU.REC.1401.062

Health conditions studied

1

Description of health condition studied

Postpartum care

ICD-10 code

Z39.2

ICD-10 code description

Encounter for routine postpartum follow-up

Primary outcomes

1

Description

Pittsburgh Sleep Questionnaire score

Timepoint

The sleep score was evaluated at the beginning of the and at the end of the study (8 weeks after the beginning of the study) in 3 groups: mindfulness, aromatherapy with lavender, and the control group.

Method of measurement

Pittsburgh Sleep Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: ´Aromatherapy with lavender with a volume of 15 ml, which is poured on a napkin between two drops of this oil one night for two months, and is inhaled by people for ten minutes before going to bed.

Category

Treatment - Other

2

Description
Intervention group: Mindfulness counseling group in the form of counseling on WhatsApp for 8 one-hour sessions
Category
Treatment - Other

3

Description
Control group: For this group, routine postpartum care, which included breastfeeding, mental health, physical and sexual education, was given by the researcher in a virtual way and in audio and written files. In this group, no counseling was given regarding the improvement of sleep quality.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ascarieh Hospital
Full name of responsible person
Zahra Ghalegar
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
6691
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
Zahra Ghalegar
Position
Master Science student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
We must share with Arak university of medical sciences

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable