Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of aromatherapy with geranium essence on the quality of sleep in the third trimester of pregnant women referring to comprehensive health centers in Rafsanjan \

Protocol summary

Study aim

Determining the effect of aromatherapy with geranium essential oil on sleep quality in the third trimester of pregnant women referring to comprehensive health centers in Rafsanjan in 1403.

Design

A controlled, double-blind, randomized, phase 3 clinical trial with parallel groups on 80 patients. The allocation of subjects to the intervention and control groups will be in a randomized block permutation.

Settings and conduct

In this clinical trial, convenience sampling will be conducted from the research population, which is pregnant women referring to comprehensive health centers who have sleep disorders. The sample size was determined to be 40 people in each group. The allocation of individuals to two intervention and control groups will be block randomization. Demographic information questionnaires, Pittsburgh Sleep Quality Questionnaire will be completed by both groups before and after the intervention. The experimental group will put 2 drops of geranium essence on a towel for three consecutive nights a week for a month and inhale it for ten minutes, and then hang the towel soaked in the desired scent on their clothes or place it near their pillow. The control group will receive placebo (almond oil) in this study.

Participants/Inclusion and exclusion criteria

Iranian nationality؛ gestational age 30 weeks or later؛ score more than 5 on the sleep quality questionnaire؛ having written informed consent

Intervention groups

The intervention group inhaled 2 drops of geranium essential oil for three consecutive nights per week for one month. The control group received placebo in the same manner as the intervention group.

Main outcome variables

quality of sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250504065588N1**
Registration date: **2025-09-24, 1404/07/02**
Registration timing: **prospective**

Last update: **2025-09-24, 1404/07/02**
Update count: **0**

Registration date

2025-09-24, 1404/07/02

Registrant information

Name

Fatemeh Ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3245 4531

Email address

fttm.ebrahimii@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-03-02, 1404/12/11

Expected recruitment end date

2026-03-02, 1404/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of aromatherapy with geranium essence on the quality of sleep in the third trimester of pregnant women referring to comprehensive health centers in Rafsanjan \

Public title
nvestigating the effect of aromatherapy with geranium essence on the quality of sleep in the third trimester of pregnant women

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Iranian nationality gestational age 30 weeks or later score more than 5 on the sleep quality questionnaire having minimal literacy having written informed consent

Exclusion criteria:
absence of pulmonary and respiratory problems such as asthma and migraine not using herbal medicines that affect sleep quality No neurological/psychiatric disorders, no use of narcotics, no use of other sleeping pills, no high-risk pregnancy (such as preeclampsia, diabetes, history of bleeding, placenta previa, etc.), no smell problems no use of narcotics no use of other sleeping pills no high-risk pregnancy (such as preeclampsia, diabetes, history of bleeding, placenta previa, etc.) no smell problems

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The allocation of individuals to the two intervention and control groups will be in the form of a random permutation block. For this purpose, we will use 8 blocks of 10. In each block, 5 cases will be A and 5 cases will be B. In this way, we will first prepare 10 completely identical cards or sheets. The letter A is written on 5 sheets and the letter B is written on the other 5 sheets. Each person who enters the study will be assigned one of the 10 sheets completely randomly, this process will continue until the 10 cards are finished (10 people enter the study), and this process will be carried out for the next ten people and the next ... until the eighth 10 people, in this way, finally, all people will be placed in two groups completely randomly and in equal numbers (40 people).

Blinding (investigator's opinion)
Double blinded

Blinding description
The participant is kept blind to which drug they are using in this study, and the data analyst will also be sent the control and intervention groups as A and B by the researcher.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Rafsanjan University of Medical Sciences

Street address
Birjand-Ghafari30-Pelak43

City
Rafsanjan

Province
Kerman

Postal code
9717934437

Approval date
2024-11-27, 1403/09/07

Ethics committee reference number
IR.RUMS.REC.1403.125

Health conditions studied

1

Description of health condition studied
quality of sleep in the third trimester of pregnant women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
A score of more than 5 on the Pittsburgh Sleep Quality Questionnaire

Timepoint
Immediately after the intervention and two weeks after the end of the intervention, the Pittsburgh Questionnaire (PSQ) will be completed by the participants again.

Method of measurement
Pittsburgh Questionnaire

Secondary outcomes

1

Description
Sleep quality score
Timepoint
Before the intervention, immediately after the intervention, and two weeks after the end of the intervention, the Pittsburgh Questionnaire (PSQ) will be completed by the participants again
Method of measurement
Pittsburgh Sleep Quality Questionnaire, which contains nine questions

Intervention groups

1

Description
Intervention group: Intervention group: The intervention group, for three consecutive nights per week for one month, poured 2 drops of geranium essence (with a concentration of 0.5%) from Tabib Daru Company onto a towel and inhaled it for ten minutes, and then hung the towel soaked in the desired scent on their clothes or placed it near their pillow.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Birjand Comprehensive Health Centers
Full name of responsible person
Fatemeh Ebrahimi
Street address
Kargharan
City
Birjand
Province
South Khorasan
Postal code
9717934437
Phone
+98 992 762 1092
Email
fttm.ebrahimii@gmail.com

2

Recruitment center
Name of recruitment center
Birjand Comprehensive Health Centers
Full name of responsible person
Fatemeh Ebrahimi
Street address
Mahziar
City
Birjand
Province
South Khorasan
Postal code
9717934437
Phone
+98 992 762 1092
Fax
Email
fttm.ebrahimii@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Dr. Maryam Mohseni
Street address
Parastar
City
Kerman
Province
Kerman
Postal code
7716614638
Phone
+98 992 762 1092
Email
Fttm.ebrahimii@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Dr. Maryam Mohseni
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery

Street address
Parastar
City
Rafsanjan
Province
Kerman
Postal code
9717934437
Phone
+98 992 762 1092
Email
Fttm.ebrahimii@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Fatemeh ebrahimi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Parastar
City
Rafsanjan
Province
Kerman
Postal code
9717934437
Phone
+98 56 3245 4531
Email
fttm.ebrahimii@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Fatemeh Ebrahimi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Parastar
City
KERMAN
Province
Kerman
Postal code
9717934437
Phone
+98 56 3245 4531
Email
fttm.Ebrahimii@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available