Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of aromatherapy with Citrus aurantium essential Oil on sleep quality during pregnancy

Protocol summary

Study aim
Determining the effect of aromatherapy with spring orange essential oil on sleep quality during pregnancy

Design
Clinical trial with control group, without blinding, randomized, phase 3 on 68 patients. Randomization site was used for randomization.

Settings and conduct
This two-group randomized clinical trial study will be performed on 68 pregnant women (first pregnant and multiparous) referred to health centers in Jiroft. After giving the necessary explanations to the research units and obtaining informed consent, sampling will begin as available. After reviewing other inclusion criteria, eligible women will be included in the study and randomly assigned to the intervention and placebo groups. The intervention group used spring orange essential oil and the placebo group used sweet almond oil for one month.

Participants/Inclusion and exclusion criteria
Informed consent Minimum literacy Be a resident of Jiroft. Have a sleep disorder (score of 5 or higher on the Pittsburgh Sleep Quality Questionnaire. From the Depression, Anxiety and Stress Scale - 21 questionnaire, have a depression score of less than 21, an anxiety score of less than 15 and a stress score of less than 26, have a gestational age of 34-28 weeks. Have a singleton pregnancy. No olfactory disorder. Not sensitive to plant odors, herbal essential oils, perfumes and colognes. Do not use tobacco, alcohol or drugs

Intervention groups
Intervention group: for one month, twice a day (once before going to bed at night) and each time pour 5 drops of spring orange essential oil on the mask and inhale it for 20 minutes each time with normal breathing. Control group: for a one month, twice a day (once before going to bed at night) and each time pour 5 drops of sweet almond oil on the mask and and inhale it for 20 minutes each time with normal breathing.

Main outcome variables
sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200512047414N1**
Registration date: **2021-01-16, 1399/10/27**
Registration timing: **prospective**

Last update: **2021-01-16, 1399/10/27**
Update count: **0**

Registration date
2021-01-16, 1399/10/27

Registrant information

Name
Freshteh Mohammadi payandar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 4321 6773

Email address
mohammadipf971@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-19, 1399/10/30

Expected recruitment end date
2021-06-20, 1400/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of aromatherapy with Citrus aurantium essential Oil on sleep quality during pregnancy

Public title
The effect of Citrus aurantium essential oil on sleep quality during pregnancy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Have informed consent to participate in the study. Be at least literate. Have Iranian nationality. Be a resident of Jiroft. From the DASS-21 questionnaire, get a depression score of less than 21, an anxiety score of less than 15, and a stress score of less than 26. Having a gestational age of 34-28 weeks. Have a singleton pregnancy. Get a score of 5 or higher on the Pittsburgh Sleep Quality Questionnaire (PSQI). Not having a cold. Not having allergic to spring orange essential oil or sweet almond oil. Not having a disorder in sense of smell. Not being allergic to plant odors, herbal essential oils, perfumes and colognes. Not having a known sleep disorder before pregnancy. Do not experienced tragic events in the last six months. Not using tobacco, alcohol and drugs. Have a known history of mental illness.

Exclusion criteria:
Do not want to continue the study. Use other techniques for sleep disorders during the study. Experience severe stress during the study. Getting feverish infectious diseases during the study. Being hospitalized during the study. Getting cold or a disorder in sense of smell. Showing allergic to spring orange essential oil or sweet almond oil. Not using spring orange essential oil or sweet almond oil for 2 days or using only once a day for three days.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
By www.randomization.com, a random sequence is determined for 70 people in groups A and B. This sequence is kept in a closed door envelope and each time one of the research units that met the inclusion criteria, the envelope door is opened and according to its code, it enters the intervention group or control group. The selection of codes A and B for the two groups will be done by lottery.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
"Ethics Committee of Mashhad University of Medical Sciences"

Street address
Mashhad, Ibne Sina St., School of Nursing and Midwifery

City
Mashhad

Province
Razavi Khorasan

Postal code
13944-91388

Approval date
2020-11-17, 1399/08/27

Ethics committee reference number
IR.MUMS.NURSE.REC.1399.056

Health conditions studied

1

Description of health condition studied
Sleep disorders in pregnant women

ICD-10 code
G47.9

ICD-10 code description
Sleep disorder, unspecified

Primary outcomes

1

Description
The overall score of sleep disorder

Timepoint
Measurement of sleep quality score at the beginning of the study (before the intervention) and one month after the start of spring orange essential oil consumption "

Method of measurement
Petersburg Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For a month, twice a day (once before going to bed at night) and each time pour 5 drops of spring orange essential oil (prepared from university-approved health centers, soaked in 1: 3 volume ratio in sweet almond oil as a neutral base oil for two weeks) on the mask and inhale it for 20 minutes each time with normal breathing. The most chemical composition of prepared spring orange essential oil was linalool 45-47%.
Category
Treatment - Drugs

2

Description
Control group: For one month, twice a day (once before going to bed at night) and each time pour 5 drops of sweet almond oil (prepared from university-approved health centers) on the mask and inhale it for 20 minutes each time with normal breathing.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Among the health centers of Jiroft, they will be selected randomly through a lottery.
Full name of responsible person
Fereshteh Mohammadi PayAndar
Street address
Ibne Sina St., Mashhad School of Nursing and Midwifery
City
Mashhad
Province
Razavi Khorasan
Postal code
13944-91388
Phone
+98 51 3841 2081
Fax
Email
mohammadipf971@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Fereshteh Mohammadi Pay Andar
Street address
Ibne Sina St., Mashhad School of Nursing and Midwifery
City
Mashhad
Province
Razavi Khorasan
Postal code
13944-91388
Phone
+98 51 3841 2081
Email
mohammadipf971@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Student Research Committee
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
Mashhad University of Medical Sciences
Full name of responsible person
Fereshteh Mohammadi Pay Andar
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Ibne Sina St. School of Nursing and Midwifery
City
Mashhad
Province
Razavi Khorasan
Postal code
13944-91388
Phone
+98 51 3841 2081
Email
mohammadipf971@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person
Dr. Maryam Maryam

Position
Assistant professor of Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
Ibne Sina St. School of Nursing and Midwifery

City
Mashhad

Province
Razavi Khorasan

Postal code
13944-91388

Phone
+98 51 3841 2081

Email
mohammadipf971@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Fereshteh Mohammadi Pai Andar

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Doctor Crossroads, Ibne Sina St., Mashhad School of Nursing and Midwifery

City
Mashhad

Province
Razavi Khorasan

Postal code
13944-91388

Phone
+98 51 3841 2081

Email
mohammadipf971@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
All collected deidentified IPD are to be shareable after the results of study get published on reasonable inquiry.

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Researchers and students from academic institutions

Under which criteria data/document could be used
With citing to the current study and without altering in data.

From where data/document is obtainable
Contact with author responsible for responsiveness with following email/phone mohammadipf971@mums.ac.ir
Tel: 09162436044

What processes are involved for a request to access data/document
Request to access data/document will be assessed with the research team.

Comments