

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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

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Ibne Sina St., Mashhad School of Nursing and Midwifery

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

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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

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Person responsible for updating data

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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