# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 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**
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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
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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**
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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

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## Person responsible for updating data

**Contact**

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Mashhad University of Medical Sciences

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Fereshteh Mohammadi Pai Andar

**Position**
Masters student

**Latest degree**
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**Other areas of specialty/work**
Midwifery

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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**