Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of aromatherapy with Damask rose essential oil on postpartum blues in nulliparous women

Protocol summary

Study aim
Determining the effect of aromatherapy with rose essential oil on postpartum grief in nulliparous women

Design
A randomized clinical trial with a control group(placebo), with parallel groups,without blinding,

Settings and conduct
Sampling is done in the Department of Obstetrics and Gynecology of Umm al-Binin Hospital in Mashhad. The researcher will attend at the hospital and based on the selection criteria, eligible mothers were selected as available.Through questions from the research unit and her file, Stein's postpartum blues questionnaire and Paswald's olfactory scale (for entry criteria of not having Impaired sense of smell) and Rosenberg's self-esteem scale (for homogenization of confounding variable) and Rotten's visual fatigue intensity scale in 12 to 24 hours after delivery through questions from The research unit is completed. Subjects are randomly divided into two intervention and placebo group, In both, within 12 to 24 hours after delivery, it is recommended for two weeks after delivery, twice a day(one time when waking up and one time before going to bed at night) and each time 7 drops of rose essential oil or placebo(sweet almond oil)) on the mask and inhale it with deep breathing for 20 minutes each time. Stein's postpartum blues questionnaire on the fourth and fourteenth day after Delivery is completed in person and on the 10th day after delivery by phone.

Participants/Inclusion and exclusion criteria
Inclusion criteria:obtaining informed consent،age range 18-42, postpartum blues score greater than8,having a normal delivery.Exclusion criteria:Allergic to rose essential oil or sweet almond oil

Intervention groups
Intervention group: put 7 drops of rose essential oil on the mask twice a day for 14 days and inhale each time for 20 minutes with deep breathing. Placebo group: sweet almond oil will be used similar with intervention.

Main outcome variables
Postpartum blues score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220606055089N1**
Registration date: **2022-08-08, 1401/05/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-08, 1401/05/17**
Update count: **0**

Registration date
2022-08-08, 1401/05/17

Registrant information

Name
Roya Tabasi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 51 4423 2347

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-16, 1401/04/25

Expected recruitment end date
2022-10-12, 1401/07/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of aromatherapy with Damask rose essential oil on postpartum blues in nulliparous women

Public title
The effect of aromatherapy with Damask rose essential oil on postpartum blues

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having informed consent to participate in the study Being at least literate Having Iranian nationality Being a resident of Mashhad Age ranged 42-18 years Having a postpartum blues disorder (from the Stein postpartum blues questionnaire) scores higher than 8 Being primiparous Having a normal vaginal delivery Not having high-risk pregnancy Having a singleton pregnancy Not having hard and prolonged labor Not having disturbance in the sense of smell Not having major medical conditions Not having experience of tragic events in the last six months Not having known history of mental illness Not using tobacco, alcohol or drugs

Exclusion criteria:
Allergic to rosemary essential oil or sweet almond oil The mother or baby being hospitalized

Age
From **18 years** old to **42 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
The random assignment of the sample in two groups is determined by the permutation block method by the sealedenvelope site, with the explanation that each block has 4 members and the shape of the blocks, for example, can be as follows: [ABAB], [BBAA], [BABA] Codes A and B are assigned randomly to the intervention group and the placebo group. The aforementioned site randomly selects 16 blocks out of all four possible blocks so that all patients can be included in the study.

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
Qureshi Building University Street, Mashhad, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9173595199

Approval date
2022-07-06, 1401/04/15

Ethics committee reference number
IR.MUMS.NURSE.REC.1401.028

Health conditions studied

1

Description of health condition studied
Postpartum Blues

ICD-10 code
O90.6

ICD-10 code description
Postpartum mood disturbance

Primary outcomes

1

Description
Postpartum blues score from Stein's postpartum grief questionnaire

Timepoint
before the start of the intervention and 4،10, 14 days after the start of aromatherapy

Method of measurement
Stein postpartum blues questionnaire

Secondary outcomes

1

Description
Fatigue level

Timepoint
before the intervention and 4, 10 and 14 days after the start of aromatherapy

Method of measurement
visual measure of Roten fatigue intensity

Intervention groups

1

Description

Intervention group: In the intervention group, during the first 12 to 24 hours after delivery, seven drops of Barij rose essential oil, a standardized essential oil based on at least 0.2 mg of nerol per milliliter, prepared by extraction with an organic solvent, will be dripped on a three-layer white disposable surgical mask with drops, and they will breath deeply for twenty minutes each time. It is recommended to repeat this process every morning when you wake up and at night when you go to sleep for 14 days after giving birth.

Category

Treatment - Drugs

2

Description

Control group: Sweet almond oil placebo During the first 12 to 24 hours after delivery, seven drops of sweet almond oil will be dripped on a three-layer white disposable surgical mask with a dropper, and they will breathe deeply for twenty minutes each time. It is recommended to repeat this process every morning when you wake up and at night when you go to sleep for 14 days after giving birth.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Umm al-Binin Hospital

Full name of responsible person

Dr. Farideh Akhlaghi

Street address

Ayatolah Bahjat St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayyur Mobarahan

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Qureshi Building University St., Vice Chancellor for Research and Technology, Mashhad University of Medical Sciences

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Grant name

Grant code / Reference number

4002143

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Roya Tabasi

Position

Master's degree student of midwifery

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 Moradi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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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
Yes - There is 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
Yes - There is 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
Not applicable

Title and more details about the data/document
Publication of research results in the form of scientific article printining

When the data will become available and for how long
data will become available after publication of the article

To whom data/document is available
The general public and all researchers

Under which criteria data/document could be used
To inform the public about the effect of aromatherapy with rose essential oil on postpartum blues in primiparous women and scientific use based on the article.

From where data/document is obtainable
Dr. Maryam Moradi, Assistant Professor, Mashhad School of Midwifery Nursing, e-mail: moradim@mums.ac.ir

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

Comments