

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 than 8, 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4423 2347

##### Email address

tabasir992@mums.ac.ir

##### 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 sealed envelope 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

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9144734756

##### Phone

+98 51 3223 1061

##### Email

royatbc@gmail.com

##### Web page address

<http://www.mums.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Dr. Majid Ghayyur Mobarahan

#### Street address

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

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

917751365

#### Phone

+98 51 3882 5523

#### Email

ghayourM@mums.ac.ir

#### 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

##### Street address

School of Nursing and Midwifery, Crossroads Doctora, Ibne Sina Street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913199

##### Phone

+98 51 3859 1511

##### Email

tabasiR992@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 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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**Name of organization / entity**

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**Full name of responsible person**

Roya Tabasi

**Position**

Master's degree student of midwifery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

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**Phone**

+98 51 3859 1511

**Email**

tabasiR992@mums.ac.ir

## 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 printing

**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**