

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of the effectiveness of aromatherapy with *Rosa damascena* Mill. to relieve the symptoms of postpartum depression in primiparous women

Protocol summary

Study aim

Determining the effectiveness of aroma therapy with rose (*Rosa damascena* Mill.) on relieving postpartum depression symptoms in nulliparous women

Design

A clinical trial with a control group, with parallel, non-blind, randomized phase 3 groups on 60 patients, used block method and quadruple blocks for randomization.

Settings and conduct

This clinical trial will be performed by easy sampling method on 60 nulliparous women admitted to the postpartum ward of hospitals under the auspices of Babol University of Medical Sciences. During the first 24 hours after delivery and after the mother has stabilized and obtained written consent and completed the questionnaires, the samples will be divided into two groups of 30 people A and B. Group A or intervention group includes patients receiving rose essential oil and group B or comparison group includes patients receiving base oil as a placebo. According to the type of intervention, only the primary and secondary outcome assessor is unaware of the type of intervention, and also the data is provided to the statistical expert for statistical analysis in a blind and randomized code.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Be literate, age 20-35 years, do not use Drugs and Alcohol, no history of Asthma, Allergies or skin Dermatitis diagnosed, lack of known mental disorders, get a score below 13 according to the Edinburgh Depression Inventory and the birth of a seemingly healthy baby Exclusion criteria: Sensitivity to the oils provided, history of sensitivity to special oils in one of the family members of the subjects

Intervention groups

Group A or intervention group includes patients receiving rose essential oil and group B or comparison group includes patients receiving base oil as a placebo.

Main outcome variables

Depression score in the Edinburgh postpartum depression questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180218038783N1**

Registration date: **2020-11-08, 1399/08/18**

Registration timing: **prospective**

Last update: **2020-11-08, 1399/08/18**

Update count: **0**

Registration date

2020-11-08, 1399/08/18

Registrant information

Name

Fereshteh Behmanesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 0504

Email address

f.behmanesh@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-07, 1399/09/17

Expected recruitment end date

2022-01-07, 1400/10/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of aromatherapy with Rosa damascena Mill. to relieve the symptoms of postpartum depression in primiparous women

Public title

"Effectiveness of Aromatherapy with Rosa damascena Mill. in treatment of postpartum depression"

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Be literate Age 20-35 years Do not use Drugs and Alcohol No history of Asthma, Allergies or skin Dermatitis diagnosed No history of Allergies and Eczema diagnosed to flowers and plants Lack of known mental disorders Do not use Anti-stress and Anti-depressant drugs Having a sense of smell Get a score below 13 according to the Edinburgh Depression Inventory The birth of a seemingly healthy baby

Exclusion criteria:

Sensitivity to the oils provided History of sensitivity to special oils in one of the family members of the subjects

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible individuals are randomly divided into four groups (permuted block randomization) and open table in one of two treatment groups A with a size of 30 and B with a size of 30. The size of the blocks is 4 and in each block, each intervention group will be repeated twice. 15 blocks of 4 will be produced 15 times to create a total of 60 sequences. Group A or intervention group includes patients receiving rose essential oil and group B or comparison group includes patients receiving base oil as a placebo. To hide the random allocation list, a special code will be assigned to each of the intervention groups that only the principal executor (supervisor) is aware of. These codes are written on a piece of paper and placed in a sealed envelope. A single code specific to each patient will be written on this paper as well as on the envelope. All envelopes are placed in a larger box in random order and will be sealed in the box. The evaluator will not know about the allocation of two groups of rose essential oil and placebo. Blinding: According to the type of intervention, only the primary and secondary outcome assessor is unaware of the type

of intervention, and also the data is provided to the statistical expert for statistical analysis in a blind and randomized code.

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**

Babol University of Medical Sciences

Street address

Keshavarz- Babol University Of Medical Sciences

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2020-04-21, 1399/02/02

Ethics committee reference number

IR.MUBABOL.REC.1399.096

Health conditions studied**1****Description of health condition studied**

Postpartum Depression

ICD-10 code

000

ICD-10 code description

Service Temporarily Down

Primary outcomes**1****Description**

Depression score in the Edinburgh postpartum depression questionnaire

Timepoint

Determination of depression score in the first 24 hours after delivery (before intervention), 6 weeks and 12 weeks after starting rose essential oil.

Method of measurement

Edinburgh Postpartum Depression questionnaire

Secondary outcomes

1

Description

Sleep quality score

Timepoint

Determining the quality of sleep in the first 24 hours after delivery (before the intervention), 6 weeks and 12 weeks after starting rose essential oil

Method of measurement

pittsburgh sleep quality index

Intervention groups

1

Description

Intervention group: Mothers who, after discharge, put a cc of rose essential oil on a special cloth and put it on their mouth and nose every night before going to bed for 12 weeks after giving birth, using a dropper, and take 10 deep breaths, and then They put the cloth next to their pillow until morning.

Category

Treatment - Drugs

2

Description

Control group: Mothers who, after discharge, put a cc of distilled water on a special cloth and put it on their mouth and nose every night before going to bed for 12 weeks after giving birth, using a dropper, and take 10 deep breaths, and then They put the cloth next to their pillow until morning.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Postpartum wards of hospitals under the auspices of Babol University of Medical Sciences

Full name of responsible person

Fereshteh Behmanesh

Street address

Babol University of Medical Sciences, Ganj Afrooz St., Babol, Mazandaran

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Phone

+98 11 3219 9592

Fax

+98 11 3219 0181

Email

info@mubabol.ac.ir

Web page address

http://www.mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Reza Ghadimi

Street address

Babol University of Medical Sciences, Ganj Afrooz St., Babol, Mazandaran Province

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Phone

+98 11 3219 9592

Fax

+98 11 3219 0181

Email

info@mubabol.ac.ir

Web page address

http://www.mubabol.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Fereshteh Behmanesh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

School of Midwifery and Nursing, Babol University of Medical Sciences, Ganj Afrooz St., Babol, Mazandaran Province

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Phone

+98 11 3219 9595

Email

f.behmanesh2015@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Fereshteh Behmanesh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

School of Midwifery and Nursing, Babol University of Medical Sciences, Ganj Afrooz St., Babol, Mazandaran Province

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Phone

+98 11 3247 5421

Email

f.behmanesh2015@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Fatemehzahra Hosseini

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Midwifery and Nursing, Babol University of Medical Sciences, Ganj Afrooz St., Babol, Mazandaran Province

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Phone

+98 11 3234 6476

Email

fatemehzahrahosseini3@gmail.com

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Evaluation of the effectiveness of aromatherapy with Rosa damascena Mill. to relieve the symptoms of postpartum depression in primiparus women

When the data will become available and for how long

7 December 2021

To whom data/document is available

Babol University of Medical Sciences research deputy

Under which criteria data/document could be used

Postpartum Depression

From where data/document is obtainable

Postpartum ward of hospitals under the auspices of Babol University of Medical Sciences

What processes are involved for a request to access data/document

Request of the Deputy of Health Research Institute of Babol University of Medical Sciences

Comments