

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effects of orange Essential oil and omega 3 in prevention of postpartum depression

#### Protocol summary

##### Study aim

effect of Orange and Omega-3 on prevention of postpartumdepression

##### Design

This is a three-group randomized controlled trial of 150 women in the postpartum period . The selection of study participants is done based on the inclusion criteria and they receive necessary information about the goals and research protocols. Finally, they are randomly divided into three groups: "the aromatherapy", "the omega-3 supplementation" group and the "control" group.

##### Settings and conduct

At first, all participants complete the Edinburgh Depression Questionnaire. if their score are below 12, they complete personal profile, Kasdy's support Social, Eysenck Self-Esteem, Hudson's Marital Satisfaction, and Depression Anxiety and Stress (DASS 21) questionnaires.

##### Participants/Inclusion and exclusion criteria

En: written consent, Living in Mashhad,18 to 35 year old age range, Literacy reading and writing, gestational age 37 to 40 weeks. Ex: Having speech disorders or hearing problems, to have Medical diseasese, depression, severe anxiety and stress, using omega-3 supplementation or Aromatherapy, allergy to the flowers and the plants, Olfactory disorders, having marine foods more than two meals per week, abnormal fetus

##### Intervention groups

Aromatherapy group will receive routine postpartum care and inhale 3 droplets of orange essential oil for ten minutes, two times a day, from the second day after delivery for six weeks. The Omega-3 supplement group will receive routine postpartum care and one gr of omega 3 capsules immediately after lunch from the second day after delivery for six weeks. 3) Control group that receive only routine postpartum care.

##### Main outcome variables

the Incidence of postpartum depression

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170310032993N2**

Registration date: **2018-06-22, 1397/04/01**

Registration timing: **retrospective**

Last update: **2018-06-22, 1397/04/01**

Update count: **0**

##### Registration date

2018-06-22, 1397/04/01

##### Registrant information

##### Name

Afsaneh Mahdizadeh

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 913 041 4362

##### Email address

mahdizadehaf941@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Governmental

##### Expected recruitment start date

2017-05-26, 1396/03/05

##### Expected recruitment end date

2017-08-27, 1396/06/05

##### Actual recruitment start date

2017-05-26, 1396/03/05

##### Actual recruitment end date

2017-09-16, 1396/06/25

##### Trial completion date

empty

## Scientific title

Comparison of the effects of orange Essential oil and omega 3 in prevention of postpartum depression

## Public title

Effect of orange Essential oil and omega 3 in prevention of post partum depression

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Written Consent Resident of Mashhad Literacy reading and writing Age 18-35 years old gestational age 37-41 weeks

### Exclusion criteria:

Depression Severe anxiety and stress history of chronic medical illness history of postpartum depression history of psychiatric disorders sensory disorder flower and plant allergy Use of anticoagulant drugs BMI over 30 Having a speech and audio problem that prevents communication abnormal fetuses use of aroma or supplementation of omega-3 consumption of fish more than two times per week

## Age

From **18 years** old to **35 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **150**

Actual sample size reached: **150**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Based on randomized sequencing that determined by SPSS software, each of the research units will be placed in orange essential oil, omega-3 and control groups

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Not 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

Daneshgah Avenue

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

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#### Approval date

2017-05-20, 1396/02/30

#### Ethics committee reference number

ir.mums.rec.1396.50

## Health conditions studied

### 1

#### Description of health condition studied

post partum depression

#### ICD-10 code

F53.0

#### ICD-10 code description

Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

## Primary outcomes

### 1

#### Description

The incidence of postpartum depression

#### Timepoint

Before the intervention, the tenth day after delivery, 4 weeks after delivery, 6 weeks after delivery

#### Method of measurement

Edinburgh Depression Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Aromatherapy Group In addition to receiving usual post partum care, they inhale 3 drops of orange essential oil prepared by Gorgan Essential Oil Company for 10 minutes every 12 hours (morning and evening).

#### Category

Prevention

### 2

#### Description

Intervention group 2: Omega-3 supplementation group, in addition to receiving routine post-partum care, consumes a single gram of mercury free capsule omega-3.

#### Category

Prevention

### 3

#### Description

Control group: The control group receives routine postpartum care.

#### Category

Prevention

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Ommolbanin Hospital

###### Full name of responsible person

Dr Masoumeh Mirteimouri

###### Street address

Ommolbanin Hospital, Ayatolah Bahjat 16, Zarineh Crossroad

###### City

Mashhad

###### Province

Razavi Khorasan

###### Postal code

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###### Phone

+98 51 3223 1065

###### Fax

###### Email

MirteimouriM@mums.ac.ir

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Full name of responsible person

Dr Mohsen Tafaghodi

###### Street address

Daneshgah street

###### City

Mashhad

###### Province

Razavi Khorasan

###### Postal code

-

###### Email

tafaghodiM@MUMS.AC.IR

###### Grant name

###### Grant code / Reference number

###### 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

Dr Robab Latifnejad

##### Position

Vice President of Research and Faculty of Nursing and Midwifery

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Reproductive Biology

##### Street address

School of Nursing and Midwifery, Ibn Sina Street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

-

##### Phone

+51 38591511

##### Fax

##### Email

latifnejadr@mums.ac.ir

##### Web page address

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mahin Tafazoli

##### Position

Faculty of Nursing and Midwifery

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

##### Street address

School of Nursing and Midwifery, Ibn Sina Street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

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##### Phone

+51 38591511

##### Fax

**Email**

tafazolim@mums.ac.ir

**Web page address****Email**

mahdizadehAF941@mums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Afsaneh Mahdizadeh

**Position**

Midwifery student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

School of Nursing and Midwifery, Ibn Sina Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

-

**Phone**

+51 38591511

**Fax****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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