

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of Ocimum Basilicum capsule on postpartum depression symptoms: A Randomized Controlled Trial

Protocol summary

Study aim

Determining the effect of basil capsules on postpartum depression symptoms (primary outcome) and postpartum sleep quality (secondary outcome)

Design

A controlled, parallel-group, double-blind, randomized, phase 2 clinical trial involving 78 participants. To use SAS software will be.

Settings and conduct

Individuals will be selected from Al-Zahra and Taleghani hospitals in Tabriz through face-to-face meetings. Basil and placebo capsules will be provided to the participants in opaque and similar cans. Placebo cans will be scented with basil essential oil. The person who is not involved in the sampling, will be asked to assess the outcome at the end of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having a vaginal term birth or cesarean section, healthy baby, Literacy for reading and writing. Exclusion criteria: Obtaining a score of 13 or higher in the Edinburgh Questionnaire, mental retardation, chronic diseases during pregnancy, the occurrence of a stressful event such as death or diagnosis of an incurable disease in first-degree family members, divorce, during the three months before the start of the study.

Intervention groups

Participants in the intervention group will receive 2 capsules of 500 mg containing dried green basil leaf powder daily for 8 weeks. Participants in the control group will receive 2 capsules of 500 mg containing starch daily, which are blinded They will receive the scented basil essence.

Main outcome variables

The average score of postpartum depression in the intervention and placebo groups after the completion of the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220926056046N2**

Registration date: **2023-02-21, 1401/12/02**

Registration timing: **prospective**

Last update: **2023-02-21, 1401/12/02**

Update count: **0**

Registration date

2023-02-21, 1401/12/02

Registrant information

Name

Solmaz Ghanbari Homaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3524 5181

Email address

homayisolmaz@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-14, 1401/12/23

Expected recruitment end date

2023-10-07, 1402/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Ocimum Basilicum capsule on postpartum depression symptoms: A Randomized Controlled Trial

Public title

The effect of Ocimum Basilicum on postpartum depression

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a vaginal term birth or cesarean section Having a healthy baby Being literate in reading and writing

Exclusion criteria:

Obtaining a score of 13 and above in the Edinburgh Questionnaire Mental retardation Chronic diseases aggravated during pregnancy Occurrence of a stressful event such as death or diagnosis of an incurable disease in first-degree family members, divorce, within three months. Before starting the study

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants were randomly assigned to one of the intervention (basil) and control (placebo) groups using SAS software and by the block method (blocks of six: for example, ABABAB) with a ratio of 1:1 (equal number of participants in intervention and control groups) will be allocated. In order to hide the allocation (Allocation Concealment), the allocation sequence will be done by a person not involved in the study. Basil and placebo capsules will be placed inside sealed opaque bottles that are numbered consecutively.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, researcher, data collector and outcome assessor will be blinded. Basil and placebo capsules are in the same shape and size in both groups and will be placed in similar containers. The person who is not involved in the sampling, will be asked to assess the outcome at the end of the intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz university of medical science, Azadi avenue

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2023-01-23, 1401/11/03

Ethics committee reference number

IR.TBZMED.REC.1401.948

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

postpartum depression

ICD-10 code

F06.31

ICD-10 code description

Mood disorder due to known physiological condition with depressive features

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

Postpartum depression score

Timepoint

Before the start of the intervention and the end of the eighth week after the start of the intervention

Method of measurement

Edinburgh depression questionnaire

Secondary outcomes**1****Description**

Postpartum sleep quality score

Timepoint

The end of the eighth week after the start of the intervention

Method of measurement

Postpartum sleep quality questionnaire

Intervention groups

1

Description

Intervention group: Participants in the intervention group will receive 2 capsules of 500 mg containing dried green basil leaf powder daily for eight weeks.

Category

Prevention

2

Description

Control group: The participants in the control group will receive 2 capsules of 500 mg daily containing starch flavored with basil essential oil. There will be no essential oil inside the capsules. For the purpose of blinding only, the pharmacist will scent the vials containing the placebo with basil essential oil.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Monireh Abdi

Street address

School of Nursing and Midwifery, Shariati street

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3478 5229

Email

m85438a@gmail.com

2

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Monireh Abdi

Street address

Railway Square

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 44 3344 4592

Email

m85438a@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Parviz Shahabi

Street address

Azadi St., Golgosht St., Tabriz University of Medical Sciences, Central Building No. 2, 3rd Floor, Research Vice-Chancellor

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3335 7310

Email

dabir Khanecent@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Monireh Abdi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Shariati Street, Faculty of Nursing and Midwifery

City

Tabriz

Province
East Azarbaijan
Postal code
5138947977
Phone
+98 903 818 5438
Email
m85438a@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Solmaz Ghanbari Homaie
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Nursing and Midwifery school, Shariati street
City
Tariz
Province
East Azarbaijan
Postal code
9876598765
Phone
+98 41 3524 5181
Email
homayisolmaz@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences
Full name of responsible person
Solmaz Ghanbari Homayi
Position
Assestant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing and Midwifery, Shariati Street
City
Tabriz
Province
East Azarbaijan
Postal code
9876598765
Phone
+98 41 3478 5229
Email
homayisolmaz@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participant data is confidential.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available