

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effect of aromatherapy on mood states and resilience of pregnant women

Protocol summary

Study aim

The effect of aromatherapy on mood states and resilience of pregnant women referring to selected health centers in Isfahan, Iran (2021)

Design

Clinical trial, with intervention and control groups, without blinding, randomized, on 70 pregnant mothers, 2 envelopes per package were used for randomization, one of which was selected by the samples.

Settings and conduct

Among pregnant women aged 26-28 weeks referring to selected comprehensive health centers in Esfahan who have the inclusion criteria, 70 people enter the study and are randomly assigned to one of the two intervention or control groups. In the intervention group, Neroli oil is inhaled in 12 one-hour sessions three times a week. The control group also receives routine pregnancy care. The mood states and resilience of the samples were measured before the study, immediately after the intervention and one month after the end and compared in the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: primary gravid and single fetus, gestational age 26-28 weeks with Iranian citizenship and primary and higher education; has a healthy sense of smell. Criteria for not entering: unwillingness and consent to participate in the study; history of allergies and eczema to known flowers and plants and aromatic substances; history of respiratory diseases, psychiatric diseases, hypertension, headache and migraine; unwanted pregnancy; having any midwifery problems during pregnancy that require absolute rest or taking certain medications; using all kinds of complementary and alternative medicine methods during the last month.

Intervention groups

In the aromatherapy group, Neroli oil is inhaled in 12 one-hour sessions three times a week. The control group also receives routine pregnancy care

Main outcome variables

Mood states; resilience

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130525013449N3**

Registration date: **2021-10-29, 1400/08/07**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-29, 1400/08/07**

Update count: **0**

Registration date

2021-10-29, 1400/08/07

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2937

Email address

fahami@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy on mood states and resilience of pregnant women

Public title

The effect of aromatherapy on mood states and resilience of pregnant women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Primary gravid and single fetus Gestational age 28-26 weeks Having Iranian citizenship Primary and higher education Have a healthy sense of smell

Exclusion criteria:

Unwillingness and consent of the mother to participate in the study History of allergies and eczema to known flowers and herbs and aromatic substances History of respiratory diseases such as asthma psychiatric illness Having any obstetric problems during pregnancy that require absolute rest or taking certain medications Unwanted pregnancy Using a variety of complementary and alternative medicine methods during the past month

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Using two numbered envelopes (envelope number one for the intervention group and envelope number two for the control group) and selecting an envelope by research samples)

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 Isfahan University of Medical Sciences

Street address

The deputy of Research and Technology, Building No. 4, Esfahan University of Medical Sciences and Health Services, Hezar Jerib St.

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-07-24, 1400/05/02

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.119

Health conditions studied

1

Description of health condition studied

Normal pregnancy

ICD-10 code

Z34

ICD-10 code description

Supervision of normal pregnancy

Primary outcomes

1

Description

Mood States Score in POMS Mood States Questionnaire

Timepoint

Before the intervention, immediately after the intervention and one month after the intervention

Method of measurement

POMS Mood States Questionnaire

2

Description

Resilience score

Timepoint

Before the intervention, immediately after the intervention and one month after the intervention

Method of measurement

Connor and Davidson Resilience Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Aromatherapy with Neroli essential oil three times a week for a month (12 times in total) by pouring 5 drops of essential oil on a handkerchief each time and attaching it to their collar. Then breathe normally for an hour, then remove the handkerchief. The essential oil is used by Blue Moon brand and with a

concentration of one percent
Category
Behavior

2

Description
Control group: The control group receives routine prenatal care
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Ebne Sina Comprehensive Health Service Center
Full name of responsible person
Fatemeh Hajibagheri Foroushani
Street address
Ebne Sina St., Ebne Sina Health Center, Isfahan
City
Esfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3445 9147
Email
fahami@nm.mui.ac.ir

2

Recruitment center
Name of recruitment center
Amir Hamzeh Health Center
Full name of responsible person
Fatemeh Hajibagheri Foroushani
Street address
Azadi St., Amir Hamzeh Town
City
Esfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3775 7509
Email
fahami@nm.mui.ac.ir

3

Recruitment center
Name of recruitment center
Fourteen Innocents Health Center
Full name of responsible person
Fatemeh Hajibagheri Foroushani
Street address
22 Bahman St., Malekshahr

City
Esfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3344 2583
Email
fahami@nm.mui.ac.ir

4

Recruitment center
Name of recruitment center
Hazrat Sajjad Health Center
Full name of responsible person
Fatemeh Hajibagheri Foroushani
Street address
Golestan St., Esfahan House,
City
Esfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3441 2095
Email
fahami@nm.mui.ac.ir

5

Recruitment center
Name of recruitment center
Dehno Health Center
Full name of responsible person
Fatemeh Hajibagheri Foroushani
Street address
Besat St., University of Technology Square
City
Esfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3385 0196
Email
fahami@nm.mui.ac.ir

6

Recruitment center
Name of recruitment center
Rehnan Health Center
Full name of responsible person
Fatemeh Hajibagheri Foroushani
Street address
Hasheminejad St., Rehnan neighborhood, Imam Khomeini Highway
City
Esfahan

Province
Isfahan
Postal code
8174673461
Phone
+98 31 3331 7091
Email
fahami@nm.mui.ac.ir

Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
School of Nursing and Midwifery, Esfahan University of Medical Sciences and Health Services, Hezar Jerib St.
City
Esfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3792 7513
Email
fahami@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Shaghayegh Haghjoi Javanmard
Street address
The deputy of Research and Technology, Building No. 4, Esfahan University of Medical Sciences and Health Services, Hezar Jerib St.
City
Esfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3668 8138
Email
sh_haghjoo@med.mui.ac.ir
Web page address
<http://research.mui.ac.ir/fa/dr.haghjoo>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Fariba Fahami
Position
Assistant Professor

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Fariba Fahami
Position
Assistant Professor
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
The deputy of Research and Technology, Building No. 4, Esfahan University of Medical Sciences and Health Services, Hezar Jerib St.
City
Esfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3792 3071
Email
fahami@nm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Fariba Fahami
Position
Assistant Professor
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address

The deputy of Research and Technology, Building No. 4, Esfahan University of Medical Sciences and Health Services, Hezar Jerib St.

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3071

Email

fahami@nm.mui.ac.ir

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