

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

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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

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2

Recruitment center

Name of recruitment center
Amir Hamzeh Health Center

Full name of responsible person
Fatemeh Hajibagheri Foroushani

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3

Recruitment center

Name of recruitment center
Fourteen Innocents Health Center

Full name of responsible person
Fatemeh Hajibagheri Foroushani

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Recruitment center

Name of recruitment center
Hazrat Sajjad Health Center

Full name of responsible person
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Recruitment center

Name of recruitment center
Dehno Health Center

Full name of responsible person
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Recruitment center

Name of recruitment center
Rehnan Health Center

Full name of responsible person
Fatemeh Hajibagheri Foroushani

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Hasheminejad St., Rehnan neighborhood, Imam Khomeini Highway

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Latest degree
Master
Other areas of specialty/work
Midwifery
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

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Person responsible for updating data

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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