

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation effects of aromatherapy with Rosa Damascena on anxiety of mothers with premature infants admitted to the neonatal intensive care unit (NICU)

Protocol summary

Study aim

Determining effects of aromatherapy with Rosa Damascena on anxiety of mothers with premature infants admitted to the neonatal intensive care unit

Design

A clinical trial with a control group, with factorial groups, non-randomized and without blinding (open-label), phase 3 on 80 mothers who have premature babies

Settings and conduct

After obtaining informed consent from mothers with premature infants, Mahdiah Hospital is randomly divided into two groups of intervention and control. The methodology will be a parallel clinical trial. The subjects in the intervention group received aromatherapy with 10% rosemary essential oil for 10 nights 20 minutes before bedtime as it was poured on 2 * 2 cotton, while the control group did not receive any intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria • Mothers aged 18-45 years • Being able and willing to respond • Satisfaction to participate in the study • Has a premature baby admitted to the neonatal intensive care unit of the hospital • Having anxiety
Exclusion criteria • Whenever a mother gives up from participating in the study after entering the study • Whenever a baby dies for any reason during the study • Headache, infection, and bleeding after the start of the study that requires medical intervention
History of any allergies to Rosa Damascena • History of any drug allergies • Have a history of allergies to herbal medicines • A mother takes medicine to relieve anxiety • A mother uses non-pharmacological methods such as meditation, yoga, acupuncture to relieve anxiety

Intervention groups

Intervention group: Aromatherapy with 10% essential oil of Damask rose, 5 drops, 10 nights + routine recommendations
Control group: Only routine recommendations

Main outcome variables

anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201012049007N1**

Registration date: **2021-07-11, 1400/04/20**

Registration timing: **prospective**

Last update: **2021-07-11, 1400/04/20**

Update count: **0**

Registration date

2021-07-11, 1400/04/20

Registrant information

Name

Fatemeh Hashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 5366

Email address

fatemehashemi2075@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Evaluation effects of aromatherapy with Rosa Damascena on anxiety of mothers with premature infants admitted to the neonatal intensive care unit (NICU)

Public title
Effects of aromatherapy with Rosa Damascena on anxiety of mothers with premature infants

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Mothers aged 18-45 years Ability and willingness to participate in the study Satisfaction to participate in the study Has a premature baby admitted to the neonatal intensive care unit of Mahdieh Hospital in Tehran Having anxiety (with any score)

Exclusion criteria:
Whenever a mother gives up from participating in the study after entering the study Whenever a baby dies for any reason during the study Headache, infection and bleeding after the start of the study that requires medical intervention History of any allergies to Rosa Damascena History of any drug allergies (according to the mother statement) Have a history of allergies to herbal medicines (according to the mother statement) A mother takes medicine to relieve anxiety (according to the mother statement) A mother uses non-pharmacological methods such as meditation, yoga, acupuncture to relieve anxiety (according to the mother statement)

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Not randomized

Randomization description
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 in Research, Vice Chancellor for Research and Technology, Shahid Beheshti University

Street address

Tehran, Vali Asr St., Niayesh intersection, in front of Shahid Rajaei Heart Hospital, School of Nursing and Midwifery

City

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Province

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Postal code

1983963113

Approval date

2021-06-13, 1400/03/23

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.115

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Anxiety score in Spielberger questionnaire

Timepoint

Before the intervention, after 10 days

Method of measurement

Spielberger Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For 10 nights, aromatherapy with 10% Damasak rose essence, 20 minutes before going to bed, 5 drops of it is poured on a piece of 2 * 2 pieces of cotton and inhale for 5-10 minutes. Also, routine recommendations (such as not using electronic devices and cyberspace from 2 hours before bedtime, taking deep breaths, not eating heavy food, ...) will be explained.

Category

Treatment - Drugs

2**Description**

Control group: Only routine recommendations (such as not using electronic devices and cyberspace from 2 hours before bedtime, taking deep breaths, not eating heavy food, ...) will be explained and there is no drug intervention.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tehran Mahdiye Hospital

Full name of responsible person

Fares Najari

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Rasool Choopani

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rasoolchoopani@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fatemeh Hashemi

Position

Msc Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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