Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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, Mahdieh 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

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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 Universit

Street address

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

City

Tehran

Province

Tehran

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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No. 19, Shahid Abbaspour Bridge (Tavanir), Vali Asr Ave. Tehran
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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
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Fatemeh Hashemi
Position
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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