Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of inhaling Lavender scent on fatigue and stress of mothers of premature infants admitted to neonatal intensive care unit

Protocol summary

Study aim
Determining the effect of lavender scent inhalation on fatigue and stress of mothers of premature babies
Design
Clinical trial with control group, with parallel groups, randomized, phase 3 on 72 patients, randomization by simple random method in the form of available sampling.
Settings and conduct
Mothers of premature babies in the intervention group inhaled a neck pendant containing cotton soaked with two drops of lavender essential oil at a distance of 20 cm from the nose for 30 minutes three times a week, every other day for 4 weeks. No aromatherapy is done for the control group. Both groups complete questionnaires measuring fatigue and stress before the start of the intervention, two weeks after the start of the intervention and 4 weeks after the start of the intervention.
Participants/Inclusion and exclusion criteria
Entry criteria: having a baby hospitalized in the neonatal intensive care unit; lack of history of neurological and mental illness; No history of allergy and respiratory disorders; No history of drug use (anti-anxiety, anti-stress and anti-depressant); having a baby age between 30 and 37 weeks; Absence of congenital malformation of the baby Exclusion criteria: infant death; causing postpartum depression; The smell of lavender is unpleasant for the mother; causing allergic reactions such as headache, nausea and other allergic symptoms for the mother
Intervention groups
Mothers of premature babies in the intervention group use a neck pendant containing lavender essential oil, with a dose of two drops in 30 minutes, three times a week, every other day for 4 weeks. No aromatherapy is done for the control group. Both groups complete multidimensional fatigue questionnaires (MFI) and parents' stress assessment in the neonatal intensive care unit (PSS:NICU) at different stages.
Main outcome variables
Fatigue, stress

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221026056310N1**
Registration date: **2022-11-21, 1401/08/30**
Registration timing: **prospective**

Last update: **2022-11-21, 1401/08/30**
Update count: **0**
Registration date
2022-11-21, 1401/08/30

Registrant information
Name
Azita آزیتا
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-11-22, 1401/09/01
Expected recruitment end date
2023-01-21, 1401/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
The effect of inhaling Lavender scent on fatigue and stress of mothers of premature infants admitted to neonatal intensive care unit

Public title
Investigating the effectiveness of lavender scent inhalation on fatigue and stress of mothers of premature babies

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having a baby in the neonatal intensive care unit No history of neurological and mental illness No history of allergies and respiratory disorders No history of drug use (anti-anxiety, anti-stress and anti-depressant) willingness to participate in the study Avoid drinking caffeinated beverages one hour before the intervention (due to the close relationship between insomnia and fatigue). The age of the baby is between 30 and 37 weeks Absence of congenital malformation of the baby

Exclusion criteria:
Death of a baby Creating postpartum depression The smell of lavender is unpleasant for the mother Causing allergic reactions such as headache, nausea and other allergic symptoms for the mother

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
First, we put the studied hospitals (Medical Center, Bahrami, Shariati, Valiasr, Yas, Baharlo and Arash hospitals) into two intervention and control groups through lottery. Then, in the mentioned hospitals, based on the entry criteria and exit criteria, we consider a number of mothers of premature babies as the statistical population. In the next step, we assign a unique number to each of the mothers and put the numbers in a bag. Based on the lottery, we draw numbers until we reach the desired sample size in each of the intervention and control groups.

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
Working Group/Committee Ethics in Research Faculty of Nursing and Midwifery and Faculty of Rehabilit

Street address
End of Kargar North, in front of Masjid al-Nabi, Koi Complex for Girls of Medical Sciences, Tehran

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Tehran

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Tehran

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1439957181

Approval date
2022-09-27, 1401/07/05

Ethics committee reference number
IR.TUMS.FNM.REC.1401.078

Health conditions studied

1

Description of health condition studied
Stress and fatigue of mothers of premature babies hospitalized in neonatal intensive care unit

ICD-10 code
F54

ICD-10 code description
Psychological and behavioral factors associated with disorders or diseases classified elsewhere

Primary outcomes

1

Description
Fatigue score in Multidimensional Fatigue Measurement Questionnaire

Timepoint
(before the start of the intervention) and 14 and 28 days after the start of the intervention

Method of measurement
Multidimensional fatigue measurement questionnaire. The Multidimensional Fatigue Measurement Questionnaire is a 20-item self-report tool that provides a deeper and more accurate understanding of a person's fatigue by evaluating 5 dimensions. The multidimensional fatigue measurement questionnaire has 5 areas: general fatigue (4 items), physical fatigue (4 items), mental fatigue (4 items), activity-related fatigue (4 items) and decreased motivation (4 items). In the fatigue questionnaire, people are measured both in the physical dimension and in the mental dimension. The answer range for each question was a 5-point Likert

scale ranging from "yes, completely true" to "no, completely false".

2

Description
Stress score in parental stress questionnaire in neonatal special care unit
Timepoint
(before the start of the intervention) and 14 and 28 days after the start of the intervention
Method of measurement
Parental stress questionnaire in neonatal special care unit. The parental stress questionnaire in the neonatal intensive care unit is a 34-item self-report tool that is used to measure parents' perception of stress in the neonatal intensive care unit. In this questionnaire, there are three subscales that include stress related to: 1- the sights and sounds of the neonatal intensive care unit environment (6 items), 2- the appearance and behavior of the baby and the special treatments performed on the baby (17 items). and 3- parents' relationship with the baby and parental roles (11 items). Answers were scored on a 5-point Likert scale with "1" being "no stress" and "5" being "extremely stressful". A higher score in this questionnaire indicates more stress experience.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, lavender essential oil (Lavandula angustifolia) produced by Zardband Yasouj Company - Iran, which is prepared from the flowering branches of the plant and contains 45% linalool, will be used. This substance is inhaled by mothers of premature babies through a neck pendant. This neck pendant is placed at a distance of 20 cm from the nose and inhaled with a dose of two drops for 4 weeks every other day for 30 minutes.
Category
Other

2

Description
Control group: No aromatherapy is performed in the control group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Batol Pouraboli
Street address
Dr. Gharib Street, at the end of Keshavarz Boulevard, Imam Khomeini Hospital Complex
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2

Recruitment center
Name of recruitment center
Arash Women's General Hospital
Full name of responsible person
Batol Pouraboli
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Corner of 162 Alley (Shahid Abdul Majid), Shahid Bagh Darnia St. (Rashid Shamali), after Shahid Bagheri highway, Resalat highway
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3

Recruitment center
Name of recruitment center
Shariati Hospital, Tehran
Full name of responsible person
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4

Recruitment center
Name of recruitment center
Bharlo Hospital
Full name of responsible person
Batol Pouraboli
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Railway Square, Behadari St
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5

Recruitment center
Name of recruitment center
Yas Hospital
Full name of responsible person
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6

Recruitment center
Name of recruitment center
Bahrami Children's Hospital
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Damavand St, not reaching Mian Imam Hossein, Shahid Kiaei St (Qasim Abad)
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7

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Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotuhi
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Keshavarz Blvd, Qods Corner, Headquarters of Tehran university of medical sciences
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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Azita Ghorbani

Position

Master's student in neonatal special care nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Azita Ghorbani

Position

Master's student in neonatal special care nursing

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

3 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers are allowed to use the results of the data for use in future articles.

From where data/document is obtainable

Azita Ghorbani, contact number 0098 9180857399, E-mail address: Trasib54@gmail.com, North Kargar St., in front of 16th St., Tehran University of Medical Sciences Girls' Dormitory, Postal code 1439957181

What processes are involved for a request to access data/document

The applicant can send his request by e-mail. If you wish, the data will be sent to them after 3 days.

Comments