Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effects of music therapy and aromatherapy with lavender on anxiety in mothers of premature infants hospitalized in the neonatal intensive care unit.

Protocol summary

Study aim
Determining the effect of aromatherapy with lavender on the level of anxiety in mothers of premature infants before and after the intervention Determining the effect of music therapy on the level of anxiety in mothers of premature infants before and after the intervention

Design
A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 96 patients. Block randomization will be used for randomization.

Settings and conduct
The present study was conducted on 96 mothers will be allocated in 3 groups.For the aromatherapy group, the illustrated sponge soaked in three drops of lavender essential oil will be used for 1 week (every day of the week).For the music therapy group, 6 30-minute sessions

Participants/Inclusion and exclusion criteria
Inclusion criteria: Primary mothers, Premature infants (less than 37 weeks gestation), Infant hospitalization in NICU, Mother not taking anti-anxiety and sedative medications during the study. Exclusion criteria: Infant discharged earlier than 2 weeks, Mother's sensitivity to the desired scent, Mother's unwillingness to continue participating in the study.

Intervention groups
The present study is a randomized clinical trial of pretest-posttest type that will be conducted on mothers with premature infants referred to the neonatal intensive care unit. The research samples will be selected on a convenience basis and after reviewing the study entry criteria and obtaining written informed consent, they will be randomly assigned to 3 groups. The first group will receive music, the second group will receive aromatherapy with lavender, and the third group will be the control.

Main outcome variables
Independent variable: In this study, music therapy and aromatherapy are the independent variables. Dependent variable: In this study, anxiety of mothers with premature babies is the dependent variable.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250627066272N1**
Registration date: **2025-07-20, 1404/04/29**
Registration timing: **prospective**

Last update: **2025-07-20, 1404/04/29**
Update count: **0**

Registration date
2025-07-20, 1404/04/29

Registrant information
Name
Marzieh Dadkhahfar
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-08-23, 1404/06/01
Expected recruitment end date
2025-09-11, 1404/06/20
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effects of music therapy and aromatherapy with lavender on anxiety in mothers of premature infants hospitalized in the neonatal intensive care unit.

Public title
Studying the effect of aromatherapy on anxiety/studying the effect of music therapy on anxiety
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Primiparous mothers Having a premature baby (gestational age less than 37 weeks), the baby is hospitalized in the neonatal intensive care unit The mother did not take any anti-anxiety or sedative medications during the study.
Exclusion criteria:
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization, block
Blinding (investigator's opinion)
Single blinded
Blinding description
Single-blind study The research is conducted at a different location and time, separate from the participants.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Mashhad Mirzakuchakkhan Boulevard, Mirzakuchakkhan 28, Khoshnudi 14, Unit 10
City
Mashhad
Province
Razavi Khorasan
Postal code
9158945348
Approval date
2025-07-02, 1404/04/11
Ethics committee reference number
IR.MUMS.NURSE.REC.1404.044

Health conditions studied

1

Description of health condition studied
The level of anxiety
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Anxiety score on the Spielberger Questionnaire
Timepoint
Assessing anxiety levels before, during, and after intervention (aromatherapy and music therapy)
Method of measurement
Spielberger Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First intervention group: The aromatherapy group will use a sponge soaked in three drops of lavender essential oil for 1 week (every day of the week), which will be attached to the mothers' clothes with a magnet, and they will be asked to inhale it for 30 minutes.Second intervention group: For the music therapy group, relaxing, wordless music by Erndstein will be played through an MP3 player and headphones for 6 30-minute sessions (every day of the week for 1 week).
Category
Behavior

2

Description
Control group: No intervention will be performed in this group.

Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr. Ezzat Khodashanas
Street address
Mashhad, Ahmadabad, Bahar Street, Imam Reza Hospital
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Razavi Khorasan
Postal code
9137913316
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Email
br8534@bmi.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Ms. Dr. Fatemeh Hajiabadi
Street address
Mashhad, Azadi Square, East Gate of Ferdowsi University of Mashhad, Shahid Dr. Kharazmi Educational Complex
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Mashhad
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Razavi Khorasan
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9177949025
Phone
+98 51 3882 9278
Email
khm@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
90
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
Mashhad University of Medical Sciences
Full name of responsible person
Marzieh Dadkhahfar
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Mashhad, Mirzakuchakkhan Boulevard, Mirzakuchakkhan 28, Khashnoudi 14, No. 10, Unit 9
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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Data can be shared.

When the data will become available and for how long
Access from 1404 until one year after the results are published.

To whom data/document is available
Research Supervisor and Consulting Professor

Under which criteria data/document could be used
Permission to access information for faculty students

From where data/document is obtainable
Go to Mashhad University of Medical Sciences website

What processes are involved for a request to access data/document
Title approval Proposal approval Thesis approval

Comments