Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of aromatherapy and orientation tour on anxiety, stress, and depressed mood in mothers of preterm infants

Protocol summary

Study aim
Comparison of aromatherapy and orientation tour on anxiety, stress and depressed mood in mothers of preterm infants

Design
This study is a semi-experimental, single-blind, three-group trial (two intervention groups and one control group - 42 participants in each group). Continuous sampling will be performed in mothers of pre-term infants who will be admitted to the neonatal intensive care unit (NICU) of Shahid Akbarabadi Hospital. Sampling will be carried out at the beginning of each week by selecting one of the three cards marked Nos. 1 to 3.

Settings and conduct
Orientation tour group: At first, four drops of distilled water, as a placebo, will be dripped on a pad and attached to the mother’s collar of clothes. The mother will typically inhale it for 30 minutes. Then the mother and the researcher will enter into the NICU for the first time. The mother will familiarize with the NICU by brief and understandable explanations about equipment, personnel, rules of the NICU for 30 minutes. The mothers of this group will re-inhale pad, which drips with four drops of distilled water for 30 minutes before bedtime. Aromatherapy and orientation tour group: All steps are similar to the orientation tour group, but instead of using distilled water, four drops of 2% orange essence on a pad, will be inhaled. Control group: The control group will meet their baby for the first time in the usual way, and all schedules for completing the questionnaires for this group will be included.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Iranian primiparous women, gestational age of 30 - 36 weeks; Exclusion criteria: a history of recurrent miscarriage or infertility, mental illness

Intervention groups
Orientation tour; Aromatherapy and orientation tour

Main outcome variables
State anxiety, trait anxiety, stress, depressed mood

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090810002324N16**
Registration date: **2020-06-06, 1399/03/17**
Registration timing: **prospective**

Last update: **2020-06-06, 1399/03/17**
Update count: **0**

Registration date
2020-06-06, 1399/03/17

Registrant information

Name
Maryam Keshavarz

Name of organization / entity
Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 4365 1813

Email address
keshavarz@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-31, 1399/05/10

Expected recruitment end date
2021-01-29, 1399/11/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of aromatherapy and orientation tour on anxiety, stress, and depressed mood in mothers of preterm infants

Public title
Aromatherapy and orientation tour on anxiety, stress and depressed mood

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Iranian primiparous women Single Pregnancy Pregnancy age 30 - 36 weeks First entry into the neonatal intensive care unit Ability to at least read and write Respiratory distress in the newborn

Exclusion criteria:
Substance-abusing (cigarettes, alcohol, and psychotropics) The problem of smell, respiratory diseases, sensitivity to the orange aroma Use of herbal oils and sedatives at least six weeks before the intervention Mental illness (according to the personal reporting) History of recurrent miscarriage or infertility Congenital anomaly in newborn The referred newborn from other hospitals Apgar score of 6 or less at minutes 5

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
All questionnaires at all stages, will be gathered by the research assistant who is unaware of the groups' allocation.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Iran University of Medical sciences

Street address
Iran University of Medical Sciences, Milad Tower, Hemmat Highway, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2020-05-27, 1399/03/07

Ethics committee reference number
IR.IUMS.REC.1399.241

Health conditions studied

1

Description of health condition studied
The state and trait anxiety, stress, depressed mood

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The score of state anxiety

Timepoint
One hour before the mother's first visit to the neonatal intensive care unit (NICU), an hour after leaving the ward, Twenty-four hours after the intervention

Method of measurement
The state anxiety of Spielberger questionnaire

2

Description
The score of trait anxiety

Timepoint
One hour before the mother's first visit to the NICU, an hour after leaving the ward, Twenty-four hours after the intervention

Method of measurement
The trait anxiety of Spielberger questionnaire

3

Description
The score of parental stress

Timepoint
Twenty-four hours after the intervention

Method of measurement
The Parental Stressor Scale: Neonatal Intensive Care Unit (PSS: NICU)

4

Description
The score of depressed mood in the Profile of Mood States Questionnaire (POMS) (McNair)

Timepoint
One hour before the mother's first visit to the NICU, twenty-four hours after the intervention
Method of measurement
Depressed mood in the Profile of Mood States Questionnaire (POMS) (McNair)

Secondary outcomes

empty

Intervention groups

1

Description
Orientation tour: At first, four drops of distilled water, as a placebo, will be dripped on a pad and attached to the mother’s collar of clothes. The mother will inhale it normally for 30 minutes. After removing the pad, the mother and the researcher will enter into the neonatal intensive care unit (NICU) for the first time. Then the orientation tour will be individually held for the mother in a 30- minute section. The mother will be familiarized with the NICU by brief and understandable explanations about equipment such as ventilator, incubator, phototherapy set, pulse oximeter, monitor, warmer and other devices. Employees will be introduced and rules in the NICU will also be explained. At the end of intervention’s day, the mothers of this group will re-inhale pad which drips with four drops of distilled water, for 30 minutes before bedtime.
Category
Prevention

2

Description
Aromatherapy and Orientation tour: At first, four drops of 2% orange essence (made by the Barij Essence Pharmaceutical Company) will be dripped on a pad and attached to the mother’s collar of clothes. The mother will inhale it normally for 30 minutes. After removing the pad, the mother and the researcher will enter into the neonatal intensive care unit (NICU) for the first time. Then the orientation tour will be individually held for the mother in a 30- minute section. The mother will be familiarized with the NICU by brief and understandable explanations about equipment such as ventilator, incubator, phototherapy set, pulse oximeter, monitor, warmer and other devices. Employees will be introduced and rules in the NICU will also be explained. At the end of intervention’s day, the mothers of this group will re-inhale pad, which drips with four drops of 2% orange essence, for 30 minutes before bedtime.
Category
Prevention

3

Description
Control group: The control group will meet their baby for the first time in the usual way, and all schedules for completing the questionnaires in this group will be included. None of the aromatherapy and orientation tour methods will be performed for this group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbar-abadi Hospital
Full name of responsible person
Arash Bordbar
Street address
Mowlavi st, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۱۶۸۷۴۳۵۱۴
Phone
+98 21 5560 6034
Email
akbarabadihosp@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Kazeme Malakouti
Street address
Iran University of Medical Sciences, Milad Tower, Hemmat Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86701
Email
vcm@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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

Iran University of Medical Sciences

Full name of responsible person

Maryam Keshavarz

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

School of Nursing & Midwifery, Rashid Yasemi st., Valiasr St., Tehran, IRAN

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 4365 1813

Email

Keshavarz.m@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Keshavarz

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

School of Nursing & Midwifery, Rashid Yasemi st., Valiasr St., Tehran, IRAN

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 4365 1813

Email

keshavarz.m@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Elham Babaee

Position

Midwife who is working at Shahid Akbar Abadi Hospital

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Moulavi st, Tehran

City

Tehran

Province

Tehran

Postal code

1168743514

Phone

+98 21 5560 6034

Email

babaei.e@iums.ac.ir

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