Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effects of Mother's Lullaby on physiological parameters of premature infants

Protocol summary

Summary

Among infants hospitalized in the neonatal intensive care unit, excessive noise is correlated with increases in heart rate, increase in respiratory rate, and decrease in oxygen saturation. Lullaby is an appropriate auditory stimulation for preterm infants. It is a kind of developmental supportive care and reduces stress responses in autonomic, motor and state systems and neurobehavioral function provide by appropriate infant stimulations. Study assesses effects of lullaby on preterm infants' physiologic parameters. In a randomized control trail and cross over study, in year 2014, 40 premature infants who admitted to the NICU of Vali Asr hospital, Tehran and had inclusion criteria of this study, were randomly assigned to two groups: control group and lullaby group, and observed for three dependent variables; oxygen saturation levels, heart rate, respiration rate. Mother's lullaby was played for experimental group via speaker. The volume range was 50-60 db. The infants in the control group received no intervention. Only variables recorded each infant was considered as the control group. For two consecutive days in each of the control and intervention groups were studied. The observation took 40 minutes each day during which the heart rate and Sao2 was recorded every two minute using pulse oximeter and the respiratory rate was counted every 2 minutes for the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501296316N5**
Registration date: **2015-02-17, 1393/11/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-17, 1393/11/28

Registrant information

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Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-11-16, 1393/08/25

Expected recruitment end date

2015-01-15, 1393/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Mother's Lullaby on physiological parameters of premature infants

Public title

The Effects of Mother's Lullaby on premature infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1-Gestational age infants at birth based

on first trimester ultrasound and LMP between 28 weeks and 36 weeks and 6 days. 2- The birth weight infants between 1500 and 2500 g. 3-Infants with confirmed auditory health with OAE. 4-Any congenital abnormality or neural and cardiac disease has been confirmed on the basis of the records is not. 5-Physiological and behavioral effects of drugs such as anticonvulsants, sedatives and narcotics receive. 6-The family history is not retarded person. 7-Infants are not undergoing phototherapy or mechanical ventilation. 8-Infants, are enrolled from the third day after birth. Exclusion criteria: 1-Each change of status of infants in the days leading to the need for respiratory support. 2-Creation of symptoms of stress and intolerance on the part of nursing interventions include apnea, mottling, flashing, bradycardia, decreased blood oxygen saturation below 80% for more than 2 minutes, uncontrollable crying, hiccups, hypotonia and ... 3- hyperbilirubinemia that need for blood exchange. 4- Discourage parents from continuing to participate in the study. 5- Discharge early infant

Age
From **7 months** old to **9 months** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Tehran University of Medical Sciences

Street address
No.43, 16th Azar st. Keshavarz blvd.

City
Tehran

Postal code

Approval date
2014-11-09, 1393/08/18

Ethics committee reference number
9111451012-125032

Health conditions studied

1

Description of health condition studied
Physiological parameters of premature infants

ICD-10 code
P90-96

ICD-10 code description
Other disorders originating in the perinatal period

Primary outcomes

1

Description
Heart rate

Timepoint
Ten minutes before the lullaby, 20 minutes during lullaby and 10 min after the lullaby

Method of measurement
Puls oximeter

2

Description
Respiratory rate

Timepoint
Ten minutes before the lullaby, 20 minutes during lullaby and 10 min after the lullaby

Method of measurement
Observed and count abdominal movements

3

Description
Arterial oxygen saturation

Timepoint
Ten minutes before the lullaby, 20 minutes during lullaby and 10 min after the lullaby

Method of measurement
Puls oximeter

Secondary outcomes

empty

Intervention groups

1

Description
Experimental group: Mother's lullaby voice recordings is played for twenty minutes

Category
Other

2

Description

control: without intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU Valiasr(aj) hospital

Full name of responsible person

Mis. Abron

Street address

Valiasr hospital, Keshavarz blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research Faculty of Nursing Midwifery

Full name of responsible person

Dr. Ziba Taghizadeh

Street address

Faculty of Nursing Midwifery, Tohid square

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research Faculty of Nursing Midwifery

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Tehran

Full name of responsible person

Elham Shafiei

Position

Masters of students NICU

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty