Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Classical Music and Lullaby on Physiologic Parameters and Sleep/Awake State of Hospitalized Preterm Infants in NICU

Protocol summary

Summary

purpose: determination effect of classical music and lullaby on hospitalized preterm infant's sleep/awake state improvement and physiologic parameters stability. study: RCT, crossover, not blinded, convenient sampling. Inclusion criteria: 1) infant GA in birth between 27w and 6d and 37w and 0d, 2)no congenital abnormality, no heart or neurologic disease, 3) intact hearing,4)no opiate, sedative or anticonvulsive therapy. Exclusion criteria: 1) all situation causes need for oxygen therapy or respiratory support, 2) increased infant distress or hypersensivity to intervention, 3) discharge, 4) parents refuse to continue. sample size: 72. 24 infants for 6 consecutive day in 3 situations, 2days in lullaby situation, 2 days in clossical music situation and 2 days in control situation, are observed.we have 6 groups based on transposition of situations.priority of groups were determined with randomization. outcome: increase o2 saturation, decrease HR and respiration and increase queit sleep in intervention situations.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012081510606N1**
Registration date: **2012-10-08, 1391/07/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-10-08, 1391/07/17

Registrant information

Name

Parisa Rafiei

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Deputy of Research, Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2012-09-21, 1391/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Classical Music and Lullaby on Physiologic Parameters and Sleep/Awake State of Hospitalized Preterm Infants in NICU

Public title

Effect of music therapy on preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1) infant GA in birth between 27w and 6d and 37w and 0d, 2)no congenital abnormality, no heart or neurologic disease, 3) intact hearing,4)no opiate, sedative or anticonvulsive therapy. Exclusion criteria: 1) all situation causes need for oxygen therapy or respiratory support, 2) increased infant distress or hypersensivity to intervention, 3) discharge, 4) parents

refuse to continue.

Age
From **28 years** old to **37 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

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
Tehran Universty of Medical Sciences Ethics Committee

Street address
Tehran, Keshavarz blv, Ghods st.

City
Tehran

Postal code

Approval date
2011-08-20, 1390/05/29

Ethics committee reference number
90/d/130/2598

Health conditions studied

1

Description of health condition studied
physiologic parameters and sleep/awake status

ICD-10 code
XVI

ICD-10 code description
Certain conditions originating in the perinatal period

Primary outcomes

1

Description
respiration rate

Timepoint
every 2 min, for before, simultaneous and after intervention periods

Method of measurement
respiration rate in 1 min,with observation

2

Description
blood pressure

Timepoint
every 5 min for before, simultaneous and after intervention periods

Method of measurement
with osilometric method and bedside monitoring based on mmhg

3

Description
heart rate

Timepoint
every 2 min for before, simultaneous and after intervention periods

Method of measurement
with bedside monitoring

4

Description
o2saturation

Timepoint
every 2 min for before, simultaneous and after intervention periods

Method of measurement
based on saturated Hb percentile, with pulseoximeter

5

Description
sleep/awake status

Timepoint
every 2 min for before, simultaneous and after intervention periods

Method of measurement
includ 6 stages based on Brazelton sleep/awake statuses

Secondary outcomes

empty

Intervention groups

1

Description
This study is crossover and every sample is observed one time as control and two anothrt times as intervention groups. every situation lasts for two days. intervention situations include lullaby and classical music and for every situation two days. observaton time in all situations is 40min every day.it starts 10min before

music in intervention groups and continues for 20min music time and 10min after music. in lullaby situation,0.5 to 1 hr after nutrition we start observation.2 cameras record dependent variables.10 min after start, lullaby is played through 2 speakers, located at incubater corners,with 30 cm of infant's head, in 45-50 dl for 20 min.observation lasts 20 min after music..this situation for every infant includs 2 consecutive days.

Category

Other

2

Description

in classical music situation,0.5 to 1 hr after nutrition we start observation.2 cameras record dependent variables.10 min after start, classical music(Baby Mozzart) is played through 2 speakers, located at incubater corners,with 30 cm of infant's head, in 45-50 dl for 20 min.observation lasts 20 min after music. this situation for every infant includs 2 consecutive days.

Category

Other

3

Description

in control situation.every infant is observed 40 min,start 0/5 to 1 hr after nutrition.2 cameras record dependent variables.this situation for every infant includs 2 consecutive days.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hojar hospital

Full name of responsible person

Parisa Rafiei

Street address

City

Shahre Kord

2

Recruitment center

Name of recruitment center

Imam Ali hospital

Full name of responsible person

Parisa Rafiei

Street address

City

Shahre Kord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research, Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

dr azam baheiraei

Street address

Tehran, tohid sq, Faculty of nursing and midwifery, University of Tehran

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 and Midwifery, Tehran University of Medical Sciences

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 University of Medical Sciences

Full name of responsible person

Prisa Rafiei

Position

MSc student

Other areas of specialty/work

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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