Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Selected Recorded Patterned Sound on the Physiologica Responses of Preterm Infants in the NICU , Tabriz. 2012

Protocol summary

Summary

A randomized design with repeated measures is to be used to explore the physiologic responses of preterm infants from 30 to 33 weeks gestation between two intrventional and one control groups to a selection of recorded Bram’s lullaby, mam's lullaby and control ambient noise in a NICU. A 15-minute session lullaby with a relatively constant rhythm, volume and pitch provided at a volume level in the low 65 dBA, 1000 Hertz is the (patterned sound) intervention used. Effects of the patterned/ambient noises measured every 5-minutes before, during, and after the sound condition of mam’s or Bram’s lullaby or ambient noise by observing oxygen saturation, heart rate, respiratory rate of randomely assigned preterm infants in the NICU in relation to a control group in which no patterned sound(only standard NICU care with ambient noise) is to be provided. Recording of 15-minute session(Bram’s lullby in low 65 dBA, 1000 Hertz) saved as a sound file in the iPod touch. Next transducers, acoustic tips and tubing and a dual headphone adapter will be used to connect two earphones to a 8 GB iPod touch. Earphones were lined with cotton to prevent them from sticking to infants' ears. After setting up the equipment, pulse oximeter/monitor recording will be initiated. The patterned sound will be started after 10 minutes and stopped after15 minutes.The pulse oximeter/monitor recordings continued until 20 minutes after sound recording was stopped.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210284617N3**
Registration date: **2012-11-13, 1391/08/23**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2012-11-13, 1391/08/23

Registrant information

Name
Mahnaz Jabraeili
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1479 6770
Email address
jabraeilim@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Council of Tabriz University of Medical Sciences

Expected recruitment start date

2012-11-29, 1391/09/09

Expected recruitment end date

2013-03-18, 1391/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Selected Recorded Patterned Sound on the Physiologica Responses of Preterm Infants in the NICU , Tabriz. 2012

Public title

The Effect of Patterned Sound on the Physiologica Responses of Preterm Infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: cared in cut or incubator; 30-33 week’s gestational age; no need for supported ventilation(ventilator/CPAP/NCPAP/Nasal canula) stabilised; no congenital anomalies; were not receiving pancuronium or other medication to induce muscle paralysis; normal A.B.R and had not undergone surgery. Exclusion criteria: Diagnosis ofIVH, NEC, PDA, sepsis, acute lung disease, or neonatal anemia (Hb<12gm/dL) during intervention; known maternal drug, alcohol, or illegal substance abuse; current overhead phototherapy and currently receiving medications for sedation positive BC.

Age

To **1 year** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences Ethics Committee

Street address

Tabriz. Golgasht street- Rsearch Center of Medical University

City

Tabriz

Postal code

977-5138947

Approval date

2012-10-11, 1391/07/20

Ethics committee reference number

5138/4/5

Health conditions studied

1

Description of health condition studied

Patterned Sound

ICD-10 code

Z00-Z99

ICD-10 code description

Health supervision and care of other healthy infant and child

Primary outcomes

1

Description

o2-saturation

Timepoint

10 minutes before-15 minutes during and 20 minutes after intervention

Method of measurement

oxygen saturation will be obtained through a SAADAT monitoring system and recorded by a coder(research assistant).

2

Description

heart rate

Timepoint

10 minutes before-15 minutes during-20 minuts after intervention

Method of measurement

oxygen saturation, heart rate will be obtained through a SAADAT monitoring system and recorded by a coder(research assistant).

3

Description

respiratory rate

Timepoint

10 minutesbefore-15 minutes during-20 minutes after the intervention

Method of measurement

three chest leads attached to neonates' chest which connected by cable to monitoring system

Secondary outcomes

empty

Intervention groups

1

Description

Recording of15-minute session(Bram’s lullby in low 65 dBA, 1000 Hertz) saved as a sound file in the iPod touch.Next a dual headphone adapter will be used to connect two Bio-logic earphones to a 8 GB iPod

touch.earphones were lined with cotton to prevent them from sticking to infant ears.The decible level transmitted from the iPod through transduer tubing was then tested using an impulse digital sound level meterto ensure maximum sound levels with a volume in the low 60s dBA and the iPod will be locked to prevent any changes in settings.Lastly, the decible level of the room will be measured near the infant's ears within the incubator /crib.After setting up the equipment, pulse oximeter/monitor will be initiated.

Category

N/A

2

Description

Recording of15-minute session(mam's lullby in low 65 dBA, 1000 Hertz) saved as a sound file in the iPod touch.Next a dual headphone will be used to connect two earphones to a 8 GB iPod touch.earphones were lined with cotton to prevent them from sticking to infants' ears.The decible level transmitted from the iPod through transduer tubing was then tested using an impulse digital sound level meterto ensure maximum sound levels with a volume in the low 60s dBA .Lastly, the decible level of the room will be measured near the infant's ears within the incubator /crib.After setting up the equipment, pulse oximeter/monitor will be initiated.

Category

Treatment - Drugs

3

Description

control group cared under standard situation with no additional intervention observed for 45 minutes.the decible level of the room will be measured near the infant's ears within the incubator /crib.After setting up the equipment, pulse oximeter/monitor will be initiated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra center

Full name of responsible person

Sara Moghaddam

Street address

Tabriz, College of nursing

City

Tabriz

2

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Sara Mogadam

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Tabriz University of Medical Sciences

Full name of responsible person

Doctor ostad rahimi

Street address

Research Council of Tabriz University of Medical Sciences, Golgasht street , Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Council of Tabriz 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

tabriz college of nursing

Full name of responsible person

tahmineh-sabet

Position

M.S student

Other areas of specialty/work

Street address

faculty of nursing and midwifery , shariatii street, Tabriz, Iran

City

Tabriz

Postal code

Phone

+98 71 1821 8472

Fax

Email

mlkywy_mn@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz Medical Science University , faculty of nursing and midwifery

Full name of responsible person
Mahnaz Jabraeili

Position
educator, Master of science

Other areas of specialty/work

Street address
faculty of nursing and midwifery , shariati street ,tabriz,iran

City
Tabriz

Postal code
5138947-977

Phone
+98 41 1479 6770

Fax
+98 41 1479 6969

Email
jabraeilim@tbzmed.ac.irjebreilim@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tabriz Medical Science University

Full name of responsible person
Mahnaz Jabraeili

Position
Ms, Educator

Other areas of specialty/work

Street address
Nursing and midwifery of facultuy, shariati street,Tabriz,Iran

City
Tabriz

Postal code

Phone
+98 41 1479 6969

Fax
+98 41 1479 6770

Email
jabraeilim@tbzmd.ac.irjebreilim@yahoo.com

Web page address

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