

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the lilt voice of Quran with normal situation, silence, and lullaby music on physiological responses and behavioral measures of premature infant discharged from neonatal intensive care unit

Protocol summary

Summary

Objective: this research planned to compare the effects of holly Quran recitation, with normal situation, silence and lullaby music on physiological responses and behavioral measures of premature infants. Design: a double blind randomized controlled trial will conducted to compare the effects of holly Quran recitation, normal situation, silence, and lullaby music on preterm newborns. All preterm newborns will randomly allocated to either the experimental or control group. Procedure: 120 premature infants who have inclusion criteria of this study, will randomly allocated in four groups: holly Quran recitation, silence, lullaby music and control groups. They will be observed for four dependent variables; oxygen saturation levels, heart rate, respiration rate and behavioral state. Interventions include; 20 minutes Holly Quran recitation (verse 7-23 of Yusuf Quranic chapters, by Shahhat Mohammad Anvar sound) and lullaby music(good night little, the sound of the Islamic Republic of Iran Radio) that will played via headphone with volume range 50-60 dB. Headphone with no sound will be used for silence group. Any group will be observed for physiological responses and behavioral state from 10 minutes before to 30 minutes after intervention and recorded numerous at 5,10 minutes before and 5, 10, 15, 20, 25 and 30 minutes after beginning of intervention, will be used to analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110097746N1**
Registration date: **2011-10-31, 1390/08/09**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-10-31, 1390/08/09

Registrant information

Name

Narges Eskandari

Name of organization / entity

Azad Islamic University, Khalkhal branch

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences

Expected recruitment start date

2011-11-21, 1390/08/30

Expected recruitment end date

2012-05-20, 1391/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the lilt voice of Quran with normal situation, silence, and lullaby music on physiological responses and behavioral measures of premature infant discharged from neonatal intensive care unit

Public title

Comparing the lilt voice of Quran with normal situation,

silence, and lullaby music on physiological responses and behavioral measures of premature infant

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1- Gestational age 28 to 37 weeks 2- Appropriate-for-gestational-age (AGA) 3- APGAR scores from 7 to 10 at one and five minutes after birth 4- Hearing confirmed by OAE 5- Iranian neonate 6- Nutrition by mother milk 7- No current phototherapy 8- No morbidities such as congenital defects, intraventricular hemorrhage (IVH), necrotizing enterocolitis (NEC), sepsis, acute lung disease or neonatal anemia and any acute illness 9- No undergoing mechanical ventilation 10- No receiving sedation medications such as Phenobarbital 11- No documentation of hyper responsiveness to the sound and 12- No history of maternal drug abuse, including alcohol or illegal substances. Only infants, who are clinically stable and physically able to tolerate the stimuli will be included. Exclusion criterias: signs of hyper responsiveness to the sound such as hiccup, facial grimace, finger splay, clenched fingers, crying, vomiting, and heart rate over 200; oxygen saturation lower than 80 and any need to handling.

Age

To 1 year old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 120

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

Qom University of Medical Sciences

Street address

Shahid Lavasani street

City

Qom

Postal code

Approval date

2011-10-02, 1390/07/10

Ethics committee reference number

34/12078/پ

Health conditions studied

1

Description of health condition studied

physiologic and behavioral state

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Oxygen saturation

Timepoint

Q 5 minute from 10 minutes before intervention until 10 minutes after intervention

Method of measurement

Monitor

2

Description

Respiratory rate

Timepoint

Q 5 minute from 10 minutes before intervention until 10 minutes after intervention

Method of measurement

Monitor

3

Description

Heart rate

Timepoint

Q 5 minute from 10 minutes before intervention until 10 minutes after intervention

Method of measurement

Monitor

4

Description

Behavioral state

Timepoint

Q 5 minute from 10 minutes before intervention until 10 minutes after intervention

Method of measurement

Behavioral state instrument scale

Secondary outcomes

empty

Intervention groups

1

Description

4- Control group: natural situation: neonates in this group will receive no intervention and only will be observed for dependent variables for 40 minutes

Category

Treatment - Other

2

Description

1- Holly Quran recitation group: the intervention in this group will include 20 minutes recitation of Yusuf Quranic chapters, verse 7-23, by Shahhat Mohammad Anvar sound that will be played via headphones by volume range 50-60 dB

Category

Treatment - Other

3

Description

3- Silence group: headphones with no sound will be placed on their ears for 20 minutes

Category

Treatment - Other

4

Description

2- Lullaby music group: lullaby music (good night little, the work of the Islamic Republic of Iran radio) include 20 minutes music, will be played via headphones by volume range 50-60 dB for this group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Izadi Medical Center

Full name of responsible person

Street address

City

Qom

2

Recruitment center

Name of recruitment center

Hazrate Zahra Medical Center

Full name of responsible person

Street address

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qom University of Medical Sciences

Full name of responsible person

Ms. Naiieri

Street address

Shahid Lavasani street

City

Qom

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qom 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

Azad Islamic University, Khalkhal branch

Full name of responsible person

Narges Eskandari

Position

Senior lecturer

Other areas of specialty/work

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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