Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Holly Quran Recitation on physiologic responses of premature infants in neonatal intensive care unit, Shahid Akbarabadi treatment & education center, 2009

Protocol summary

Summary

Background: Investigators have demonstrated that providing appropriate complementary and alternative therapy is necessary to developmental outcomes in preterm infants and pleasant sound of holly Quran recitation can be used as a useful and effective procedure to decrease the anxiety and affects on physiological and neurobehavioral functioning in patients. The aim of this research is to study effects of holly Quran recitation on physiological responses in premature infants. Materials and methods: In a double blind randomized control trail, 120 premature infants who will be admitted to the NICU of Shahid Akbarabadi hospital in Tehran, and have inclusion criteria of this study, will randomly assigned to two groups: control group and holly Quran recitation group, and will be observed for three dependent variables; oxygen saturation levels, heart rate and respiration rate. Intervention will be including 20 minutes recitation of Yusuf Quranic chapters, by Shahhat Mohammad Anvar sound that will be played for experimental group via headphone on the morning shift. The volume range will be 50-60 db. Two groups will be observed by monitor for physiological responses from 10 minutes before to 10 minutes after intervention and will be recorded before and 10,20,30 minutes after the beginning of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138806172324N3**
Registration date: **2010-06-24, 1389/04/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-06-24, 1389/04/03

Registrant information

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Maryam Keshavarz
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

School of Nursing and Midwifery, Iran University of Medical Sciences

Expected recruitment start date

2009-07-23, 1388/05/01

Expected recruitment end date

2009-09-21, 1388/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Holly Quran Recitation on physiologic responses of premature infants in neonatal intensive care unit, Shahid Akbarabadi treatment & education center, 2009

Public title

The Effect of Holly Quran Recitation on physiologic responses of premature infants in neonatal intensive care unit, Shahid Akbarabadi treatment & education center, 2009

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Iranian neonate with gestational age 28-36 weeks, birth weight over 1500 gr, 1 and 5-minute APGAR scores from 7 to 10, breast feeding, hearing confirmed by startle reflex, no documentation of hyper responsiveness to the sound, clinically stable infant that are appropriate for gestational age (AGA) and having no operative delivery, anomalies associated with neurological problems, undergoing mechanical ventilation, phototherapy, congenital abnormalities, symptomatic sepsis, acute illness, intraventricular hemorrhage, receiving medications such as Phenobarbital or oxygen and history of drug abuse in mother. Exclusion criteria: hyper responsiveness to the music such as hiccup, facial grimace, finger splay, clenched fingers, crying, vomiting, and heart rate over 200 per min, oxygen saturation lower than 80%, any need to handling or nursing intervention and difficulty in recording of physiological responses.

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
School of Nursing and Midwifery, Iran University of Medical Sciences

Street address
School of Nursing and Midwifery, Iran University of Medical Sciences, Rashid Yasami St. Valiasr Ave, P.P. Box: 19395-4798

City
Tehran

Postal code
19964

Approval date
empty

Ethics committee reference number
1323577

Health conditions studied

1

Description of health condition studied
physiologic responses of premature infants

ICD-10 code
P07.3

ICD-10 code description
Other preterm infants

Primary outcomes

1

Description
improving in physiologic responses of premature infants

Timepoint
every 10 minute

Method of measurement
by monitor

Secondary outcomes

empty

Intervention groups

1

Description
Holly Quran Recitation

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Akbarabadi treatment & education center

Full name of responsible person
Maryam Keshavarz

Street address
Molavi Street

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
School of Nursing and Midwifery, Iran University of Medical Sciences
Full name of responsible person
Maryam Keshavarz
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
School of Nursing and Midwifery, Iran 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

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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