

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effects of music interventions on occupational performance of premature infants hospitalized in the neonatal intensive care unit

Protocol summary

Study aim

Effects of music interventions on occupational performance of premature infants

Design

The study is a single blinded clinical trial in which the samples are selected by convenience sampling and then divided into two groups of experimental and control based on birth weight through stratified randomization. The sample size based on similar studies and formula is 15 for each group.

Settings and conduct

The research will be performed in the neonatal intensive care unit of Akbarabadi Hospital affiliated to Iran University of Medical Sciences in Tehran. With written consent from the infant caregiver or ward manager, first the demographic information questionnaire and then the Test of Infant Motor Performance and Neonatal Behavioral Assessment Scale by the blind assessor to the groups it'll be done. After the interventions, the tests will be repeated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The corrected age of the premature infant should be less than 2 months and more than 36 weeks of the fetal and infants have not any accompanying problems. Exclusion criteria: instability of the infant during the intervention.

Intervention groups

Infants in the control group will receive routine care and in the treatment group, music interventions will be used in addition to routine care that will play through headphones and very simple non-verbal music is used with a frequency of 20-50 Hz and volume about 50 dB. 12 sessions are performed for 3 weeks and 4 times a week, and each session lasts about 20 minutes.

Main outcome variables

Motor performance, Behavioral performance

General information

Reason for update

Acronym

NICU

IRCT registration information

IRCT registration number: **IRCT20191109045380N1**

Registration date: **2021-06-29, 1400/04/08**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-29, 1400/04/08**

Update count: **0**

Registration date

2021-06-29, 1400/04/08

Registrant information

Name

Parinaz Tofighi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3331 3617

Email address

tofigi.p@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of music interventions on occupational performance of premature infants hospitalized in the neonatal intensive care unit

Public title

Effects of music interventions on occupational performance of premature infants hospitalized

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Corrected age less than 2 months and more than 36 weeks of gestation
Satisfaction of the infant's parent
Participating in intervention session by the approval of the ward nurse

Exclusion criteria:

The infant does not feeding by tube
The baby does not connect to the device for breathing
No cerebral hemorrhage of third degree and above
No other accompanying problems including: severe hypoglycemia, seizures, meningitis, encephalitis, asphyxia, sepsis.

Age

From **1 day** old to **60 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be select by the convenience sampling and by stratified randomization in two birth weight floors are 1500 to 2000 grams and 2000 to 2500 grams using quadri-blocks. Then will divide into two experimental and control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Assessors who are allocated to gather data.

Placebo

Not used

Assignment

Parallel

Other design features

Musical interventions are provided in addition to the routine cares.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Faculty of Rehabilitation Iran University of Medical Sciences, Mirdamad St., Madar Sq., Shahid Shahnazari St., Madadkaran St., Farjam St., Faculty of Rehabilitation Sciences

City

Tehran

Province

Tehran

Postal code

1545913487

Approval date

2021-02-06, 1399/11/18

Ethics committee reference number

IR.IUMS.REC.1400.094

Health conditions studied

1

Description of health condition studied

Premature infant over 36 weeks of gestation

ICD-10 code

P07.39

ICD-10 code description

Preterm newborn, gestational age 36 completed weeks

2

Description of health condition studied

Infants weighing 2000 grams to 2500 grams

ICD-10 code

P07.18

ICD-10 code description

Other low birth weight newborn, 2000-2499 grams

3

Description of health condition studied

Babies weighing 1750 grams to 2000 grams

ICD-10 code

P07.17

ICD-10 code description

Other low birth weight newborn, 1750-1999 grams

4

Description of health condition studied

Babies weighing 1500 grams to 1750 grams

ICD-10 code

P07.16

ICD-10 code description

Other low birth weight newborn, 1500-1749 grams

Primary outcomes

1

Description

Motor performance

Timepoint

Before the intervention, the end of the twelfth session in the third week

Method of measurement

Test of Infant Motor Performance

2**Description**

Behavioral performance

Timepoint

Before the intervention, the end of the twelfth session in the third week

Method of measurement

Neonatal Behavioral Assessment Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Receiving music interventions in addition to routine care interventions. Musical interventions are played through headphones, and very simple non-verbal music is used in the frequency range of 20-50 Hz and volume about 50 dB. 12 intervention sessions are performed for 3 weeks and 4 times a week, and each session lasts about 20 minutes.

Category

Rehabilitation

2**Description**

Control group: Infants in the control group will receive routine care, including nursing, medical, and rehabilitation interventions.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Akbarabadi hospital

Full name of responsible person

Dr Majid Kalani

Street address

Bagh Ferdows Station, Molavi Crossroads, Molavi Street

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akbarabadihosp@yahoo.com

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<https://cрта.iums.ac.ir>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Vice-chancellor for Research

Street address

Fifth floor of the headquarters, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

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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

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Parinaz Tofighi

Position

master student

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

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Maddakaran St., Shah Nazari St., Mother Square,
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Full name of responsible person

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Position

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Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr Mitra Khalafbeigi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

Iran University of Medical Sciences

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data that are related to primary outcome will be available.

When the data will become available and for how long

Immediately after publication.

To whom data/document is available

Researchers working in academic institutions.

Under which criteria data/document could be used

Performing similar research

From where data/document is obtainable

Search databases or sending Email to Dr Mitra

Khalafbeigi: khalafbeigi.m@iums.ac.ir

What processes are involved for a request to access data/document

Sending Email to khalafbeigi.m@iums.ac.ir

Comments