Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation The Effect of Mother's Recorded Voice Compared To Routine Care on Pain Intensity and Physiological Indicators in Children Undergoing Surgery for Congenital Heart Disease

Protocol summary

Study aim
To Determine the Effect of Mother's Recorded Voice on Pain Intensity and Physiological Indicators in Children Undergoing Surgery for Congenital Heart Disease.

Design
Phase III randomized clinical trial with two groups, without blinding, consisted of 72 people, random allocation through PASS 11 software.

Settings and conduct
The location of the study is open heart ICU of Imam Reza Hospital in Mashhad. The study population is children undergoing surgery for congenital heart disease. Blinding is not done in this study.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: the Age of the Child is Between 2 Months and 5 Years and the Child is Undergoing Surgery for Congenital Heart Disease. Exclusion Criteria: Having Neurogenic Developmental Disorders; Hearing Impairment; Previous Surgical History

Intervention groups
In the intervention group, the researcher records the mother's voice (including free conversation with the child or her favorite poems). After the end of the surgery, in addition to the drugs used, the recorded voice is played when the child enters the open heart ICU and then every two hours up to 6 hours and then every four hours up to 24 hours (or until the mother's presence in the ICU)). Routine drugs will be used in the control group.

Main outcome variables
Pain intensity; physiological indicators.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231014059712N1**
Registration date: **2023-11-12, 1402/08/21**
Registration timing: **prospective**

Last update: **2023-11-12, 1402/08/21**
Update count: **0**

Registration date
2023-11-12, 1402/08/21

Registrant information

Name
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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-13, 1402/08/22

Expected recruitment end date
2024-03-12, 1402/12/22

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation The Effect of Mother's Recorded Voice Compared To Routine Care on Pain Intensity and Physiological Indicators in Children Undergoing Surgery for Congenital Heart Disease

Public title
The Effect of Mother's Recorded Voice on Pain Intensity And Vital Signs of Children Undergoing Surgery for Congenital Heart Disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Mother's Consent to Participate in the Research Child Undergoing Surgery for Congenital Heart Disease The Age of the Child is Between 2 Months and 5 Years
Exclusion criteria:
Having Neurogenic Developmental Disorders Hearing Impairment Previous Surgical History
Age
From **1 month** old to **5 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
Random allocation will be done in such a way that people will be divided into two groups through the PASS 11 software using blocks of size four. In this way, after determining the sequence, we put them in the envelopes and number them in order. Mothers take the envelope in the order of their entry into the study and are placed in the intervention or control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Regarding the method of recording the voice, it is explained to the mother that her voice will be recorded at a time of the day in the rooms of the department (open heart surgery in Imam Reza Hospital) which is quiet and appropriate. In this way, the mother is asked to express the words and sentences she uses to calm her child. Audio content can include free conversations with the child or the child's favorite poems. The mother's voice is recorded by the researcher using a mobile recorder for 5 minutes. Then, on the next day, after the end of the surgery, the sound recorded using the researcher's mobile phone is played next to the child's ear at several time points: first, when the child enters the open heart ICU, and then every two hours until 6 hour and then every four hours until 24 hours (or until the mother is in the ICU). Measurement of pain level and physiological indicators (heart rate, breathing, systolic/diastolic blood pressure, SPO2) first at the time of entering the ICU (baseline data), then before the start of each intervention and also 15 minutes after each time playing the sound with FLACC (Face, Legs, Activity, Crying and Consolation) modified behavioral scale of pain is used and the values of physiological indicators are measured and recorded in the relevant form using the monitoring available in the open heart ICU.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Faculty of Nursing and Midwifery - Mashhad University of Medical Sciences
Street address
Educational Complex of Shahid Dr. Kharazmi, University Campus, east gate of Ferdowsi University of Mashhad, Azadi Square, Mashhad, Khorasan Razavi
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Province
Razavi Khorasan
Postal code
9137913199
Approval date
2023-08-15, 1402/05/24
Ethics committee reference number
IR.MUMS.NURSE.REC.1402.079

Health conditions studied

1

Description of health condition studied
Children undergoing surgery for congenital heart disease
ICD-10 code
Q20
ICD-10 code description
Congenital malformations of cardiac chambers and connections

Primary outcomes

1

Description
Intensity of Pain
Timepoint
Pain Intensity is Measured at the Time of Entering the ICU (Baseline Data), Before the Start of each Intervention and also 15 Minutes after each Time the Mother's Voice is Played.
Method of measurement
FLACC Modified Behavioral Pain Scale (Face, Legs, Activity, Cry, Consolability)

2

Description
Heart Rate
Timepoint
Heart Rate is Measured at the Time of Entering the ICU (Baseline Data), Before the Start of each Intervention and also 15 Minutes after each Time the Mother's Voice is Played Using the Monitoring Device in the Ward.
Method of measurement
This variable is recorded as number per minute (heart rate and breathing) using "SADAT" Cardiac Monitoring Device.

3

Description
Respiration
Timepoint
Respiration is Measured at the Time of Entering the ICU (Baseline Data), Before the Start of each Intervention and also 15 Minutes after each Time the Mother's Voice is Played Using the Monitoring Device in the Ward.
Method of measurement
This variable is recorded as numbers per minute using the "SADAT" Cardiac Monitoring device.

4

Description
Systolic/Diastolic Blood Pressure
Timepoint
Systolic/Diastolic Blood Pressure is Measured at the Time of Entering the ICU (Baseline Data), Before the Start of each Intervention and also 15 Minutes after each Time the Mother's Voice is Played Using the Monitoring Device in the Ward.
Method of measurement
This variable is measured and recorded by the Oscillometric Method by tying the Sphygmomanometer Cuff to the child's arm using a Cardiac Monitoring Device, and its unit is Millimeters of Mercury.

5

Description
Oxygen saturation (SpO2)
Timepoint
SPO2 is Measured at the Time of Entering the ICU (Baseline Data), Before the Start of each Intervention and also 15 Minutes after each Time the Mother's Voice is Played Using the Monitoring Device in the Ward.
Method of measurement
This variable is controlled and recorded by connecting the Pulse Oximetry Probe to the child's leg by a Heart Monitoring Device, which is shown as a Percentage.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: in this group, in addition to the routine medical treatment, the mother's recorded voice next to the child's ear using a mobile phone, when the child entered the open-heart ICU, and then every two hours up to 6 hours, and then every four hours. It is played for up to 24 hours (or until the mother is in the ICU). The level of pain and physiological indicators (heart rate, respiration, systolic/diastolic blood pressure, SaO2) at the time of admission to the ICU (baseline data), before the start of each intervention and also 15 minutes after each time playing the sound using a behavioral scale. Adjusted pain FLACC (face, legs, activity, crying and consolation) is measured and the values of physiological indicators are measured using the monitoring available in the open heart ICU department and recorded in the relevant form.
Category
Treatment - Other

2

Description
Control group: In this group, the usual care, which includes routine drug therapy, is performed. These drugs include Dexmedetomidine: 0.2-0.5 mcg/kg/h, Fentanyl: 2-0.5 mcg/kg/h, Midazolam. : 0.5 mcg/kg/min, Ceftazidime: 30-50 mg/kg q8h, Vancomycin: 10mg/kg, Magnesium Sulfate: 15-50mg/kg q4-6h, Potassium Chloride: 0.5meq/kg/h, every 12 hours. Pain scale and physiological indicators are measured at the same time as the intervention group.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Open Heart ICU; Imam Reza Hospital
Full name of responsible person
Zahra Dalir
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Zahra Dalir
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All the data obtained from this research will be shared after completion.

When the data will become available and for how long

Access to the data will be possible 3 months after the results are published.

To whom data/document is available

These data will be used for researchers working in academic and scientific institutions, as well as for parents with children with congenital heart disease.

Under which criteria data/document could be used

The data obtained from this research can be used in other scientific studies.

From where data/document is obtainable

Copying (in any way) either from the full text or from the extracts is possible only with the coordination of the supervisor and the registered author and according to the instructions provided by the Central Library of Mashhad University of Medical Sciences. Details can be accessed through the relevant faculty library. The use of the thesis in articles or any scientific writing is subject to citing the source in compliance with the Mashhad University of Medical Sciences publishing regulations. Zahra Sadegh Al-Hosseini Sadeghhz992@mums.ac.ir

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

The applicant should send an email to the responsible author and register his request. After verifying the correctness of the information of the mentioned person, the required content will be provided to him by mentioning the source.

Comments