

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of music on anxiety in mothers of infants admitted to neonatal intensive care units

Protocol summary

Study aim

. we decided to study the effect of music on the anxiety of mothers of infants admitted to the neonatal intensive care unit. .

Design

This is a clinical trial study on 120 mothers admitted to the neonatal intensive care unit of hospitals of Amir Kola, Bouali Sina in Sari and Rohani in Babol.

Settings and conduct

This is a clinical trial study on 120 mothers who were admitted to the neonatal intensive care unit of hospitals of Amir Kola, Bouali Sina in Sari and Rohani in Babol. The samples are randomly divided into two groups of 60 experimental and control groups. For the experimental group, 10 minutes of soft music is broadcasted through mobile phones and headphones for each mother individually in 10 sessions. There is no intervention for the control group. Both groups of mothers fill the Spielberger anxiety questionnaire before the start of the study and on the 10th day.

Participants/Inclusion and exclusion criteria

the mothers of infants admitted to NICU, whom have a reading and writing literacy, their baby has any kind of chromosomal abnormalities, Their baby is hospitalized for at least 10 days in the NICU

Intervention groups

Mothers who receive music therapy are included in the intervention group. Mothers who do not receive music therapy fall into the control group

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170820035793N2**

Registration date: **2018-05-06, 1397/02/16**

Registration timing: **retrospective**

Last update: **2018-05-06, 1397/02/16**

Update count: **0**

Registration date

2018-05-06, 1397/02/16

Registrant information

Name

Azita Karimi

Name of organization / entity

Babol university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-11, 1396/04/20

Expected recruitment end date

2018-01-10, 1396/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of music on anxiety in mothers of infants admitted to neonatal intensive care units

Public title

Effect of music on anxiety in mothers of infants admitted to neonatal intensive care units

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The samples will be selected from the mothers of infants admitted to NICU. Mothers will enter a research that does not have chronic, physical and psychological illnesses. whom have a reading and writing literacy. Their baby has any kind of chromosomal abnormalities, have no severe critical conditions such as intraventricular hemorrhage and cardiopulmonary arrest at birth. It is their first maternal experience. Their baby is hospitalized for at least 10 days in the NICU.

Exclusion criteria:

. The exit criteria consist of Mothers with history of chronic physical and psychological illness, Have more than one child. Mothers who are not interested in music . whose baby has chromosomal disorders or critical conditions such as intravesical hemorrhage and cardiopulmonary arrest at birth. Mother's lack of cooperation to continue during intervention. Mother-to-be-known addiction to alcohol and addiction and psychotropic drugs. Getting sleepy medications by the mother on the day of the intervention.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

Then, they will be randomly assigned to two groups: experimental (60 people) and control (60 people). The questionnaires are already marketed divided into with or without music, and the mother who randomly takes the music questionnaire will be in the experimental group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Babol University of Medical Sciences

Street address

Ganjafroz AV, Babol University of Medical Sciences, Babol, Mazandaran Province, Iran

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Babol

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Postal code

4717647745

Approval date

2017-07-28, 1396/05/06

Ethics committee reference number

MUBABOL.HRI.REC1396.42

Health conditions studied

1

Description of health condition studied

Anxiety of Mother

ICD-10 code

F06.0

ICD-10 code description

Psychotic disorder with hallucinations due to known physiological condition

Primary outcomes

1

Description

Anxiety

Timepoint

Ten days

Method of measurement

the Spielberger anxiety inventory

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group": Whit Music

Category

Treatment - Devices

2

Description

"Control group": whitout music

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Bouali Hospital

Full name of responsible person

Azita Karimi

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Boali Hospital, Pasdaran boulevadr, Sari, Mazandaran Province, IR Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Azita Karimi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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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

Failure to complete thesis

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available