Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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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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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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Sponsors / Funding sources

1

Sponsor

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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
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Position
Nurse
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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