

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

The effectiveness of embrace care combined with the music on attachment of mothers with premature infants in the NICU at the Al-Zahra hospital of Isfahan in 2015

Protocol summary

Summary

This study will be done with aim to investigate the effectiveness of embrace care combined with the music on attachment of mothers with premature infants in the NICU at the Al-Zahra hospital of Isfahan in 2015. This is a non blind clinical trial. The study population would be included all mothers of newborns with gestational age of 30 to 36 weeks that their babies is admission in the neonatal intensive care unit of Al-Zahra hospital in Isfahan, that 64 of them will selected and randomly will be placed in two experimental and control groups. In both groups, at baseline, mothers behavior during breast-feeding by using Avant mother-infant attachment questionnaire is recorded. In the intervention group with the beginning of mother embrace care,for 20 minutes instrumental music during three days (once a day) is played.in the control group just will perform the mother embrace care. Then in both groups by using mother-infant attachment check list, maternal behavior during breastfeeding for 15 minutes is recorded. This 15-minute, each minute is divided into 30 seconds. In first 30 seconds observation and in second 30 seconds behavior are recorded. If the mother contact with her baby is less than 15 minutes, assessment in that turn will not be accepted and will be evaluated in the next turn. Inclusion criteria: Non-mother's addiction to drugs and alcohol and tobacco; No history or current risk of mental illness; The age of 18-40; Training and skills in the field of embrace care. Exclusion criteria: Infant body temperature reduction; Increasing need for oxygen about 10 -20%.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010125601N5**

Registration date: **2016-02-09, 1394/11/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-09, 1394/11/20

Registrant information

Name

Saeideh Aghagoli

Name of organization / entity

Esfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 25366621496

Email address

aqagholi@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Esfahan University of Medical Sciences

Expected recruitment start date

2016-02-05, 1394/11/16

Expected recruitment end date

2016-05-09, 1395/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of embrace care combined with the

music on attachment of mothers with premature infants in the NICU at the Al-Zahra hospital of Isfahan in 2015

Public title

Effectiveness of embrace care combined with the music on attachment of mothers with premature infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Non-mother's addiction to drugs and alcohol and tobacco; No history or current risk of mental illness; The age of 18-40; Training and skills in the field of embrace care. Exclusion criteria: Infants with craniofacial deformities and other clear congenital malformations; Disturbing the stability and the clinical condition of the mother and newborn baby; Infant discharge before the end of the intervention; Infant body temperature reduction; Increasing need for oxygen of 10-20%.

Age

From **7 months** old to **9 months** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomly by tossing coin

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee Ethics, Esfahan University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Esfahan University of Medical Sciences, hezarjarib street

City

Esfahan

Postal code

Approval date

2015-08-23, 1394/06/01

Ethics committee reference number

lr.mui.rec.1394.3.409

Health conditions studied

1

Description of health condition studied

premature babies care

ICD-10 code

Z76.3

ICD-10 code description

Healthy person accompanying sick person

Primary outcomes

1

Description

Mother - infant attachment

Timepoint

Baseline and end of study

Method of measurement

Avant mother-infant attachment questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group with the beginning of mother embrace care, for 20 minutes instrumental music during three days (once a day) is played.

Category

Behavior

2

Description

In the control group just will perform the mother embrace care

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Maryam Vahdati

Street address

School of Nursing & Midwifery, Esfahan University of Medical Sciences, hezarjarib street

City

Esfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mahdi Nematbakhsh

Street address

Vice Chancellor for Research Affairs, Esfahan University of Medical Sciences, hezarjarib street

City

Esfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Esfahan 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

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Vahdati

Position

Student of Ms. Nursing of infant care

Other areas of specialty/work**Street address**

School of Nursing & Midwifery, Esfahan University of Medical Sciences, hezarjarib street

City

Esfahan

Postal code**Phone**

+98 31 3792 2906

Fax**Email**

m.vahdati58@gmail.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Sedigheh Talakoub

Position

Ms.c of Nursing Child

Other areas of specialty/work**Street address**

School of Nursing & Midwifery, Esfahan University of Medical Sciences, hezarjarib street

City

Esfahan

Postal code**Phone**

+98 31 3792 2906

Fax**Email**

talakoub@nm.mui.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Vahdati

Position

Student of Ms. Nursing of infant care

Other areas of specialty/work**Street address**

School of Nursing & Midwifery, Esfahan University of Medical Sciences, hezarjarib street

City

Esfahan

Postal code**Phone**

+98 31 3792 2906

Fax**Email**

m.vahdati58@gmail.com

Web page address

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