

# 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

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**Postal code****Phone**

+98 31 3792 2906

**Fax****Email**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Sedigheh Talakoub

**Position**

Ms.c of Nursing Child

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## Person responsible for updating data

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**Full name of responsible person**

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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**

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**Postal code****Phone**

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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*