

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Assessment of the effect of home visit educational program on prematur infant's mothers anxiety

Protocol summary

Study aim

Determining of the effect of home visit educational program on prematur infant's mothers anxiety

Design

Mothers in this quasi-experimental study will be divided into two intervention and control groups with parallel groups using available sampling method without blindness

Settings and conduct

For this study 70 mothers with preterm infants, Who have the inclusion criteria are selected and divided into two groups of 35. The researcher referred to the homes of these mothers and Anxiety Inventory (Spielberger) is completed by the mother before the beginning of the educational program and the next month

Participants/Inclusion and exclusion criteria

Inclusion criteria: The preterm infants with 28-37 weeks of gestation, The preterm infants without brain disorders, Congenital heart diseases, Metabolic or endocrine diseases, Known genetic and chromosomal disorders and intraventricular hemorrhage, No experience of the hospitalized infant in NICU or the death of infant, Lack of stressful events at the time of intervention in the family including no separation, No death of first-degree relatives in the past six months, The mother is not a member of the healthcare team. Exit criteria: The preterm infants with congenital anomalies and nervous system, The parents have other children with serious illness, Experience of the hospitalized infant in NICU or the death of infant, Presence of stressful events at the time of intervention in the family such as divorce or as losing the job or and death of first-degree relatives in the past six months, The parents cannot read and write in Persian, Use of mother-given anxiety medication, Mother addiction to all kinds of drugs

Intervention groups

Intervention group: Group with educational program: The researcher will arrange a home visit training program with educational contents. Control group: Group without

educational program

Main outcome variables

Anxiety

General information

Reason for update

Acronym

NICU

IRCT registration information

IRCT registration number: **IRCT20180729040621N1**

Registration date: **2018-12-02, 1397/09/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-02, 1397/09/11**

Update count: **0**

Registration date

2018-12-02, 1397/09/11

Registrant information

Name

Maryam Valiollahibisheh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3230 2422

Email address

m.valiollahi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of home visit educational program on preterm infant's mothers anxiety

Public title

The effect of home visit educational program on preterm infant's mothers anxiety

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The preterm infants with 28-37 weeks of gestation The preterm infants without brain disorders, Congenital heart diseases, Metabolic or endocrine diseases, Known genetic and chromosomal disorders and intraventricular hemorrhage Not having a previous experience of the hospitalized infant in NICU or the death Lack of stressful events at the time of intervention in the family including no separation and no death of first-degree relatives in the past six months The mother is not a member of the healthcare team.

Exclusion criteria:

The preterm infants with congenital anomalies and nervous system The parents have other children with serious illness Experience of the hospitalized infant in NICU or the death of infant Presence of stressful events at the time of intervention in the family such as divorce or as losing the job, or death of first-degree relatives in the past six months The parents cannot read and write in Persian The mother uses the anxiolytics and has the history of drug addiction.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **70****Randomization (investigator's opinion)**

Randomized

Randomization description

This study was a quasi-experimental study with two groups of test and control that mothers were divided into two groups of test and control by random block allocation sampling method. In this way, mothers are randomly assigned randomized groups using four random blocks and four in the test and control groups.

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**

Ethics Committee of Babol University of Medical Sciences

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Babol University of Medical Sciences, Ganj Afroz Avenue

City

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Province

Mazandaran

Postal code

4717647745

Approval date

2018-03-03, 1396/12/12

Ethics committee reference number

MUBABOL. HRI. REC.1396.227

Health conditions studied**1****Description of health condition studied**

Mothers anxiety

ICD-10 code

F06.0

ICD-10 code description

Psychotic disorder with hallucinations due to known physiological condition

Primary outcomes**1****Description**

Anxiety

Timepoint

At the beginning of the study (before the intervention), after 2 sessions and 4 weeks after the last training session in the intervention group

Method of measurement

Spielberger STAI

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Educational program
Category
Behavior

2

Description
Control group: Group without educational program
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Rouhani Hospital
Full name of responsible person
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2

Recruitment center
Name of recruitment center
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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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Parvin Aziznejadroshan
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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