

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jul 2026

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

#### Protocol summary

##### Study aim

Determining of the effect of home visit educational program on preterm 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 Valiollahi

##### 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

**Street address**

Babol University of Medical Sciences, Ganj Afroz Avenue

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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**  
Mayam Valiollahibisheh  
**Street address**  
Rouhani Hospital, Ganj Afroz Avenue, Keshavarz Street  
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### 2

**Recruitment center**  
**Name of recruitment center**  
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## Sponsors / Funding sources

### 1

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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**  
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Babol University of Medical Sciences  
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Associate Professor  
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## Person responsible for updating data

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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