

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### The effect of the educational program on Iranian premature infants' parental stress in neonatal intensive care unit: A double-blind randomized controlled trial.

#### Protocol summary

##### Summary

Birth is one of the important events in the life of each parent and if this matter, since beginning, requires hospitalization in NICU which is full of equipment, tools and supplies and it is noisy, it will put a lot of stress and shock to the parents. As long as the nurses are the primary sources of information to parents and they play a very important role in reducing their stress, we decided to determine the effect of education on the parental stress of the premature infants hospitalized in NICU. Inclusion criteria: 1) age greater than 18 years, 2) mastered in the Persian language and reading and writing ability, 3) a minimum of 1 times to meet the baby and had seen the NICU. Exclusion criteria: 1) The parents want to leave the study, 2) The parents did not participate all of the educational meeting, 3) The parents had another stressor factors moreover than inclusion criteria. Population of study: All of the parents of premature infants that admission in a Neonatal Intensive Care Unit in one of the Hospitals Related to Shiraz University of Medical Sciences. Environmental study: Neonatal Intensive Care Unit in one of the Hospitals Related to Shiraz University of Medical Sciences. In this study, the researcher, attending the Research Environment, selects her samples from the parents of hospitalized infants eligible for inclusion in the study and measured parental stress at three steps: second day after admission, and after intervention and one week after end of intervention, then measured parental stress average numbers in that 3 steps and compared with the same number in control group.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013121515810N1**

Registration date: **2014-07-05, 1393/04/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-07-05, 1393/04/14

##### Registrant information

###### Name

Seyedeh Marzieh Baharlu

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1647 4257

###### Email address

baharlu\_m@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

##### Expected recruitment start date

2013-07-23, 1392/05/01

##### Expected recruitment end date

2013-12-22, 1392/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of the educational program on Iranian

premature infants' parental stress in neonatal intensive care unit: A double-blind randomized controlled trial.

#### Public title

The effect of the educational program on Iranian premature infants' parental stress in neonatal intensive care unit: A double-blind randomized controlled trial.

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: 1) age greater than 18 years, 2) mastered in the Persian language and reading and writing ability, 3) a minimum of 1 times to meet the baby and had seen the NICU, 4) during the past year they didn't have the previous experience stressors, 5) they didn't have the previous precedent of a child had been hospitalized in the neonatal intensive care unit, 6) according to their own statements they were not being treated with certain medications such as tranquilizers, anti-anxiety, 7) according to their own statements they didn't have physical or mental problems which interfere the participation in the study and completion the questionnaire used in the study, 8) during participation in curriculum they were not participate in another program or intervention, 9) they were not one of the medical staff, 10) they were willing to participate in the study in addition they completed a consent form. Exclusion criteria: 1) The parents want to leave the study, 2) The parents did not participate all of the educational meeting, 3) The parents had another stressor factors moreover than inclusion criteria.

#### Age

No age limit

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 120

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Triple 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 Shiraz University of Medical Sciences

#### Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz

#### City

Shiraz

#### Postal code

#### Approval date

2013-12-08, 1392/09/17

#### Ethics committee reference number

926605

## Health conditions studied

### 1

#### Description of health condition studied

Parental Stress Parameters

#### ICD-10 code

Z00,Z01,Z0

#### ICD-10 code description

عوامل مؤثر بر اوضاع سلامتی و مرتبط با خدمات سلامت

## Primary outcomes

### 1

#### Description

Stress

#### Timepoint

2days after admission,after intervention,1week after intervention

#### Method of measurement

Parental Stress Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

intervention group: Parents in the intervention group during four 45-minute sessions of face to face training in a hospital conference room and the baby's bedside are trained by the researcher

#### Category

Prevention

### 2

#### Description

control group: Parents in the control group did not receive any training of researcher and only in times of stress test similar to the intervention group evaluate their stress.

#### Category

Prevention

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Zeinabyeh Hospital

**Full name of responsible person**

Seyedeh Marzieh Baharlu

**Street address**

**City**

Shiraz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Gholamreza Hatam

**Street address**

Shiraz University of Medical Sciences, Zand Street, Shiraz

**City**

Shiraz

**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, shiraz 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**

Shiraz University of Medical Sciences, Hazrate Fatemeh Nursing and Midwifery Faculty

**Full name of responsible person**

Seyedeh Marzieh Baharlu

**Position**

Neonatal Intensive Care Nursing Master of Science Student

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

Nooshin Beheshtipour

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Pediatric Nursing MS, Faculty member

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Seyedeh Marzieh Baharlu

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Neonatal Intensive Care Nursing Master of Science Student

**Other areas of specialty/work**

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**Fax**

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## 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*