

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

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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Other areas of specialty/work

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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