

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

Study of effect of an educational program on stress of premature infants' parents hospitalized in neonatal intensive care units

Protocol summary

Summary

This study investigated the effect of the neonatal intensive care unit orientation program on the anxiety of premature infants' mothers in Shahrekord. The study population included all the mothers of the infants who were hospitalized in the NICUs of Shahrekord. The inclusion criteria included the gestational age of 23 to 34 weeks at the time of hospitalization and hospitalization for at least one week. Mothers who their infants were hospitalized more than one month were excluded from the study. In this study, 64 mothers had participated and were divided into two groups of control and intervention. Random sampling was used by tossing. The intervention group received the designed educational program through three 20-minute in-person sessions. The participants of the control group just received the routine care. Study instruments were a questionnaire for gathering demographic variables, the parental stress scale questionnaire and the data collected before and after the intervention. The main outcome of the study was stress.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011631972N1**

Registration date: **2017-07-08, 1396/04/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-08, 1396/04/17

Registrant information

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Name of organization / entity

Kerman University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Kerman University Of Medical Sciences

Expected recruitment start date

2016-02-02, 1394/11/13

Expected recruitment end date

2017-02-07, 1395/11/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of effect of an educational program on stress of premature infants' parents hospitalized in neonatal intensive care units

Public title

The effect of education on stress reduction

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: mothers should be at the age of 18 years or more; Being able to read and write; Not having a history of preterm delivery or giving birth abnormal baby; Not having a history of anxiety or depression disorders; Gestational age between 23 to 34 weeks at the time of hospitalization; hospitalization for at least

one week; no history of stressful events during past 6 months and not having difficult pregnancy. Exclusion criteria: Mothers who their infants were hospitalized over a month.

Age

From **1 year** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

To prevent data exchange between the Control and intervention groups, time Block method will be used. Random sampling will be conducted first for intervention Group and then control group by tossing A coin; Meaning that after the sampling of The intervention group will be completed, the Sampling will be paused for three weeks so that The mothers of the intervention group would Be discharged. Then sampling for the control The group will be conducted through the same Method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor For Research; Kerman University of Medical Sciences

Street address

Haft Baghe Alavi; Kerman

City

Kerman

Postal code

7617949546

Approval date

2016-02-20, 1394/12/01

Ethics committee reference number

IR.KMU.AC.1394013

Health conditions studied

1

Description of health condition studied

Stress

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Stress

Timepoint

Before the intervention - Immediately after the intervention

Method of measurement

The scale of parental stress Miles and Monk

Secondary outcomes

empty

Intervention groups

1

Description

Control group: The participants of the control group just receive the routine care.

Category

Behavior

2

Description

Intervention group: mothers Will receive the designed educational program through three 20-minute in-person sessions. The educational content including introducing the neonatal ward, information about the personnel, the equipment that parents might see at the ward (monitor, respiratory equipment, phototherapy LED, etc.), care conditions (connected intravenous pipes, nasogastric feeding tube , blood transfusion, etc.), information about the infant's appearance, the emotions that mothers may experience.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Borujen Valiasr Hospital

Full name of responsible person

Zeinab Taheri

Street address

Mellat blvd

City

Borujen

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor; for research of Kerman University of Medical Sciences

Full name of responsible person

Dr. Abbas Pardakhti

Street address

Razi School, Haft Baghe Alavi, Kerman

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Kerman

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 of Kerman 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**

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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

