

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

effect of family-centered care educational program on anxiety and performance of mothers of premature infants hospitalized in neonatal intensive care unit

Protocol summary

Summary

Parents of premature infants in the NICU experience high stress and hopelessness; Who often lack knowledge of how to their parental role And interact with premature infants during hospitalization. Therefore this study the aim of family-centered care impact on the anxiety and performance of mothers of premature infants hospitalized in neonatal intensive care unit In this clinical trial study, 60 mothers with premature infants admitted to the Motahari hospital neonatal intensive care unit Jahrom city were selected arranged to possible sampling and then randomly allocated to intervention and control groups. In the intervention group family-centered care program was conducted in three stages with the researcher and mother near infant and the performance of maternal care was controlled by researcher List .maternal anxiety using the Spielberger state and trait anxiety questionnaire were compared in the two groups. Mothers in the control group received usual care

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021914454N3**

Registration date: **2017-02-20, 1395/12/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-20, 1395/12/02

Registrant information

Name

Fatemeh Nasimi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 72 1222 4259

Email address

nasimif911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Jahrom University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-02-16, 1395/11/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effect of family-centered care educational program on anxiety and performance of mothers of premature infants hospitalized in neonatal intensive care unit

Public title

The effect of family-centered care educational program on anxiety and performance of mothers of premature infants hospitalized in neonatal intensive care unit

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: parental consent; infants age between 37-30 weeks; hemodynamic stability (HR=120-160, RR=30-50, SPO2=85%-95% and keep axillary

temperature range of 37-36 Centigrade degrees); Apgar scores of 7 or more on the first and fifth minutes of birth; spontaneous ventilation and no need for ventilation; lack of congenital malformations. Exclusion criteria: lack of consent to continue working for any reason; ventilation need during the study; infants with recurrent Apnea; seizures during the study.

Age

From **7 months** old to **9 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Jahrom University of Medical Sciences

Street address

Jahrom University of Medical Sciences, Motahari Street, Jahrom

City

Jahrom

Postal code

Approval date

2016-10-05, 1395/07/14

Ethics committee reference number

IR.JUMS.REC.1395.057

Health conditions studied

1

Description of health condition studied

Preterm infants

ICD-10 code

P07.3

ICD-10 code description

Other preterm infants

Primary outcomes

1

Description

Family-centered care

Timepoint

In three stages

Method of measurement

Check list

Secondary outcomes

1

Description

anxiety

Timepoint

Before and after the intervention.

Method of measurement

Spielberg anxiety questionnaire

2

Description

Performance

Timepoint

Before and after the intervention

Method of measurement

Check list

Intervention groups

1

Description

The intervention group of family-centered care program in three phases receive with the researcher and mother near infant

Category

Behavior

2

Description

The control group received usual care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Neonatal Intensive Care Unit, Motahari Hospital

Full name of responsible person

Fatemeh Nasimi

Street address

Neonatal Intensive Care Unit, Motahari Hospital, Motahari Street, Jahrom

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Jahrom University of Medical Sciences

Full name of responsible person

Dr. Kavus Solhjo

Street address

Jahrom University of Medical Sciences, Motahari Street, Jahrom

City

Jahrom

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, Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Fatemeh Nasimi

Position

MSc in Nursing, Neonatal Intensive Care

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