

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of family-centered care on the amount of stress, anxiety and depression of mothers of premature infants hospitalized in the Neonatal Intensive Care Unit (NICU)

Protocol summary

Summary

The research is a quasi-experimental research. Research samples include 80 mothers with hospitalized premature infants selected by the gradual sampling method and placed in control and experiment groups. First, samples of the control group are selected. In the first step of family-centered cares, researchers get familiar with nurses and environment and the rest of family-centered care is done in the following three steps with the presence of researcher and mother: 1) At the beginning of taking care of infant by mother, 2) before the fourth day of hospitalization and 3) before the discharge of infant in presence of mother. In the first step, information is provided relating to appearance, behavior, sleep and wakefulness patterns, stress symptoms in infants, and mothers' role in taking care of premature infants. In the second step, the best interaction time with the infant, methods of taking care of premature infants, nutrition, bathing, maintaining the body temperature and taking care of the umbilical cord are provided to mothers. In the final step, the role of mothers in transferring infants from the hospital to house, effective relationship with infants, emphasis on the screening test of vaccination, medicines, and method of communicating with infants are addressed. In order to determine the effect of family-centered care on depression, anxiety and stress of mothers, DASS-21 scale is used at the beginning of mothers' taking care of infants, 4 days after the beginning of intervention and at the day of discharge 1) At the beginning of taking care of infant by mother, 2) before the fourth day of hospitalization and 3) before the discharge of infant with the presence of mother. In the first step, information is provided relating to appearance, behavior, sleep and wakefulness patterns, stress symptoms in infants, and mothers' role in taking care of premature infants. In the second step, the best interaction time with the infant, methods of taking care

of premature infants, nutrition, bathing, maintaining the body temperature and taking care of the umbilical cord are provided to mothers. In the final step, the role of mothers in transferring infants from the hospital to house, effective relationship with infants, emphasis on the screening test of vaccination, medicines, and method of communicating with infants are addressed. In order to determine the effect of family-centered care on depression, anxiety and stress of mothers, DASS-21 scale is used at the beginning of mothers' taking care of infants, 4 days after the beginning of intervention and at the day of discharge by mothers

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012212990N6**

Registration date: **2015-02-14, 1393/11/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-02-14, 1393/11/25

Registrant information

Name

Minoo Mitra Cherhzad

Name of organization / entity

Guilan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 13 1555 5056

Email address

chehrzad@gums.ac.ir

Recruitment status**Recruitment complete****Funding source**

Deputy of Research and Technology, Guilan University of Medical Sciences

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family-centered care on the amount of stress, anxiety and depression of mothers of premature infants hospitalized in the Neonatal Intensive Care Unit (NICU)

Public title

The effect of family-centered care on the amount of stress, anxiety and depression of mothers of premature infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria for infants: Gestational age of 28 to 35 weeks, birth weight of less than 2500 g, being a single infant and lack of congenital malformations. Inclusion criteria for mothers: Age more than 18 years, literacy, predominance in Persian language, not having an infant hospitalized in NICU before, lack of the experience of taking care of a premature infant, lack of a physical illness disturbing daily activities and lack of obvious neurological and psychiatric problems leading to take medicine.

AgeFrom **1 day** old to **30 days** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Samples of the control and experiment groups are

homogenized in terms of some personal characteristics such as mother's age, mother's education, family's income and infant's birth rate

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Guilan University of Medical Sciences Ethics Committee

Street address

Deputy of Research and Technology of University of Guilan, Iran Radiator, Imam Khomeini Blv, Rasht

City

Rasht

Postal code**Approval date**

2014-12-30, 1393/10/09

Ethics committee reference number

2930459716

Health conditions studied**1****Description of health condition studied**

Stress, Anxiety and Depression of mothers of premature infants

ICD-10 code

V- F43.9 ,

ICD-10 code description

Mental and behavioural disorders

Primary outcomes**1****Description**

Stress , Anxiety and Depression

Timepoint

Before intervention , four days after the beginning of the intervention and during the hospital discharge after the last stage of intervention

Method of measurement

DASS-21 scale of stress, anxiety and depression

Secondary outcomes

empty

Intervention groups**1****Description**

In the first step of family-centered care, the experiment

group will get familiar with nurses, environment, facilities, equipment and unit's rule by the researcher and the rest of family-centered care is done in the following three steps with the presence of researcher and mother: 1) At the beginning of taking care of infant by the mother, 2) before the fourth day of hospitalization and 3) before the discharge of infant with the physical presence of mother for taking care of the infant. At any step lasting for one to two hours, first cares are taken by the researcher at the presence of the mother and the feedback is received by the mother. In addition, at the beginning of taking care of the infant by mother, the instructional booklet of family-centered care is provided to parents.

Category

Prevention

2

Description

The control group received usual care

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

17 Shahrivar And Alzahra Remedial Education Centers

Full name of responsible person

Solmaz Pourkhani

Street address

Namjoo Street, Gaz Square, Rasht

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology, Guilan University of Medical Sciences

Full name of responsible person

Doctor Abtin Heidarzadeh

Street address

Deputy of Research and Technolog of University of Guilan, Iran Radiator, Imam Khomeini Blv, Rasht

City

Rasht

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research and Technology, Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Solmaz Pourkhani

Position

Bachelor's Degree in Nursing-Nurse

Other areas of specialty/work

Street address

Razi remedial education Center

City

Rasht

Postal code

Phone

+98 13 3312 9550

Fax

Email

Sogandbosari@YAHOO.COM

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Minoo Mitra Chehrzad

Position

Master of Science in Nursing

Other areas of specialty/work

Street address

Shahid Beheshti Nursing And Midwifery Faculty of Rasht

City

Rasht

Postal code

Phone

+98 13 3355 5056

Fax

Email

chehrzad@gums.ac.ir; mcchehrzad@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Solmaz Pourkhani

Position

Bachelor's Degree in Nursing-Nurse

Other areas of specialty/work**Street address**

Razi remedial education center

City

Rasht

Postal code**Phone**

+98 13 3312 9550

Fax**Email**

SOGANDBOSARI@YAHOO.COM

Web page address**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