

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The Effect of the Designed Discharge Planning on the Quality of Life Mothers Premature Infants The Effect of the Designed Discharge Planning on the Quality of Life Mothers Premature Infants The Effect of the Designed Discharge Planning on the Quality of Life Mothers Premature Infants

Protocol summary

Summary

The study was designed to determine the effect of discharge planning is done on the quality of life of mothers with premature infants. Inclusion criteria for infants 30 to 35 weeks gestational age, weighing more than 1200 grams and no obvious abnormalities and genetic disorders. Mothers Inclusion criteria: age 18-35 years, no smoking tobacco, and is not a mental illness. The study population consisted of all mothers with premature infants admitted to the NICU of the hospital research unit have the Bentolhoda Bojnoord that profile and are place in case and control groups by Random sampling. The sample size for each group was determined 30 With the likely loss 10 percent. for intervention groups of discharge planning for 4 Training sessions for mothers (30-45 minutes each session) based on premature infants discharged just two times a week in the break room mother and baby bed Through direct instruction and face-to-face. The first 48 hours of their mother in NICU Held until disarch time. The first meeting of the features of premature infants and cause of infant hospitalization, The second session of maintaining body temperature and control it, the position of the baby, feed and method of feeding and medication to prevent infection, The third meeting of irritation Attention apnea, safe sleeping environment, KMC Kangaroo Mother Care, Fourth session on the growth and development of infants, vaccination and necessity of screening for hearing, vision and ultrasound is. It also offered a booklet about the training given to them. After discharge the telephone counseling once a week for 4 weeks(5-10 Minutes).The intervention was conducted from NOV 2015 to JONE 2016. When discharge and 4 weeks after discharge using the questionnaire World

Health Organization's quality of life and perceived social support can measured in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062922978N1**

Registration date: **2016-07-12, 1395/04/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-12, 1395/04/22

Registrant information

Name

Azam Neyestani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 58 3223 9821

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Recruitment status

Recruitment complete

Funding source

Research funding Research Center.... participation of 80 percent of research funding, contract enforcement and 20% of credit facility evidence-based research center

Expected recruitment start date

2015-11-22, 1394/09/01
Expected recruitment end date
 2016-06-06, 1395/03/17
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 The Effect of the Designed Discharge Planning on the Quality of Life Mothers Premature Infants The Effect of the Designed Discharge Planning on the Quality of Life Mothers Premature Infants The Effect of the Designed Discharge Planning on the Quality of Life Mothers Premature Infants

Public title
 The Effects of Discharge Planning on the Quality of Life of Mothers of Premature Infants

Purpose
 Supportive

Inclusion/Exclusion criteria
 Inclusion criteria for neonatal: Age 30-35 week; weight of 1200 grams; fifth minute Apgar scores of 7 or more; lack of need for mechanical ventilation; no obvious abnormalities and genetic disorders (disorders gastrointestinal, cardiovascular, urinary, reproductive, nervous and trisomy 13,18,21); singletons. mothers inclusion criteria: age 18-35 years; no smoking and tobacco; lack of experience severe stress event 6 months; no history of mental illness; depression and chronic anxiety (according to the mother); Iranian; having the ability to speak Farsi; at least primary education; phone; having to live with his wife and her husband's only wife; In the field of medical science is uneducated; mother does not have a medical problem (heart problems, kidney disease, epilepsy, neurological); lack of disability or debilitating disease in family members; Informed consent to complete; Lack of losing a parent before the age of eleven; demands of pregnancy; Consent of sex; The mother of the baby's bedside
 Exclusion criteria during the study: to be hospitalized for over a month and less than a week; incurable disease risk; newborn baby feet; Maternal disease to medical or psychiatric conditions (depression delivery, breathing problems, kidney, cardiovascular, infectious, neurological); Get the Edinburgh postpartum depression score 13 or and the visit time of discharge and 4 weeks after discharge; anxiety-causing event during the intervention (death of close relatives, spiritual crises, financial crises and divorce); the incidence of disability or debilitating disease in family members (spouse, son)

Age
 From **18 years** old to **35 years** 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
 Mashhad University of Medical Sciences

Street address
 University Of Vice President of Research, University Avenue, Doktora Crossroads

City
 Mashhad

Postal code

Approval date
 2015-08-15, 1394/05/24

Ethics committee reference number
 IR.MUMS.REC.1394.347

Health conditions studied

1

Description of health condition studied
 Quality of life of mothers of premature infants

ICD-10 code
 P07

ICD-10 code description
 Disorders related to short gestation and low birth weight, not elsewhere classified

Primary outcomes

1

Description
 quality of life

Timepoint
 Before the intervention, discharge, four weeks after discharge

Method of measurement
 WHOQOL BREF

2

Description

social support

Timepoint

Before the intervention, discharge and 4 weeks after discharge

Method of measurement

Multidimensional scale of perceived social support

Secondary outcomes

1

Description

Marital Satisfaction

Timepoint

before intervention

Method of measurement

Four ENRICH Couple Scales

2

Description

Postpartum Depression

Timepoint

Before intervention, discharge and 4 weeks after discharge

Method of measurement

Edinburgh Postnatal Depression Scale

Intervention groups

1

Description

for intervention groups of discharge planning for 4 Training sessions for mothers (30-45 minutes each session) based on premature infants discharged just two times a week in the break room mother and baby bed Through direct instruction and face-to-face The first 48 hours of their mother in NICU Held until discharge time. The first meeting of the features of premature infants and cause of infant hospitalization, The second session of maintaining body temperature and control it, the position of the baby, feed and method of feeding and medication to prevent infection, The third meeting of irritation Attention apnea, safe sleeping environment, Kangaroo Mother Care, Fourth session on the growth and development of infants, vaccination and necessity of screening for hearing, vision and ultrasound is. The visits premature infants during the first 48 hours will be at the bedside of their mother. And then the mother timing for the next turn and be given the necessary training. And the last meeting will be 2-1 days before discharge. After discharge the telephone counseling once a week for 4 weeks, in order to continued training and follow-up screening is carried out for a period of 5-10 minutes.

Category

Other

2

Description

The control group received usual care in unit.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Neonatal intensive care unit section
Bentolhoda Bojnord

Full name of responsible person

Soheila Karbndy, MSc, Pediatric Nursing, Coach
Faculty of Nursing and Midwifery, Mashhad

Street address

Bentolhoda Hospital, Sharifvafeqi Alley, West
Taleghani Avenue

City

Bojnord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Doctor Mohsen Tafaghodi

Street address

University Vice President of Research, University
Avenue, Crossroads Doktora.,

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Nursing and Midwifery, Mashhad University

Full name of responsible person

Soheila Karbandi

Position

Master of Nursing Children

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

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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