

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Assessing the effects of creating opportunities for parents empowerment on length of stay and readmission of preterm infants

Protocol summary

Summary

This study was implemented in form of a randomized experimental design over 100 parents with premature infants in Mostfakhomeini and Imamkhomeini hospitals, Ilam, Iran. In order to avoid exchanging information between the two groups, first, control group was randomly assigned. sample selection was stopped for three weeks till mothers participating in the study were discharged from the hospital. Then participants for experimental group were selected.. Treatment included four stages: Stage 1: 2 to 4 days after infant hospitalization Stage2: 2 to 4 days after the first stage Stage3: 1 to 3 days before discharging Stage 4: 1 week after discharging In every stage, in the absence of the researcher, the mother listened to an audio file containing information regarding that stage, for 15 minutes. At the same time this information was provided for the mother in the form of a booklet to use during the time of listening. Also, there was a workbook related to that stage at the end of every booklet and parents was required to complete. The completed version was provided for the research. The length of stay and readmission rate in the two groups were compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090329654N1**

Registration date: **2017-06-21, 1396/03/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-21, 1396/03/31

Registrant information

Name

Zahra Poornajaf

Name of organization / entity

Midwifery&Nursing Faculty The International Branch of Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 84 3223 0047

Email address

zahrapoornajaf@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-10-06, 1395/07/15

Expected recruitment end date

2016-12-05, 1395/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effects of creating opportunities for parents empowerment on length of stay and readmission of preterm infants

Public title

Parents empowerment effect on readmission and length of stay of preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Parents inclusion criteria: biological parents, older than 18 years, ability to write and read, no physical or psychological disorder based on self report and recorded

data. Infants inclusion criteria: gestational age between 26-34 weeks, birth weight less than 2500 grams, singleton pregnancy, no congenital abnormality
Exclusion criteria: Discharge before the end of the program, infant death, absence of parents for more than 4 days.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Parental Empowerment Program (COPE) a educational-behavioural intervention based on the theory of self-regulation and Control is designed by Melyk, in 2001 for parents parents of premature infants

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of The International Branch of Shahid Beheshti University of Medical Sciences

Street address

19 Shahid Abbaspour St. Vali-Asr Ave. Tehran

City

Tehran

Postal code

14155-3693

Approval date

2016-07-18, 1395/04/28

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.112

Health conditions studied

1

Description of health condition studied

Preterm infant

ICD-10 code

po7.3

ICD-10 code description

Other preterm infants

Primary outcomes

1

Description

Length of stay

Timepoint

The wole of hospitalization from admission to discharge

Method of measurement

Day

2

Description

Readmission

Timepoint

One month after discharge

Method of measurement

call contact with parents

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group:Educational-behavioral empowerment program was performed in 4 stages:2-4 days after admission(stage one) 2-4 days after completing the first stage(stage two) 2-4 days after stage two and one week after discharge (stage four).

Category

Behavior

2

Description

Control group: No intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Mostafa Khomeini Hospital
Full name of responsible person
Zahra Poornajaf
Street address
Shahid Keshvari Sq., Modarress Blv,Illam-Iran
City
Illam

2

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Maryam Karami
Street address
Ayatollah Heidari Ave.,Illam-Iran
City
Illam

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Investigator
Full name of responsible person
Zahra Poornajaf
Street address
Abedin Alley, Salehin St. Azadi Blvd. Illam
City
Illam
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Investigator
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
The International Branch of Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zahra poornajaf
Position

NICU Ms Student
Other areas of specialty/work
Street address
Abedin Alley, Salehin St. Azadi Blvd. Illam
City
Illam
Postal code
Phone
+98 84 3223 0047
Fax
Email
ZAHRAPOORNAJAF@YAHOO.COM
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Midwifery&Nursing Faculty of Shahid Beheshti
Full name of responsible person
Fatemeh Alaee Korahroudi
Position
Phd
Other areas of specialty/work
Street address
Vali-Asr Ave, First of Niayesh Highway, Tehran
City
Tehran
Postal code
1985717443
Phone
+98 21 8865 5372
Fax
Email
fatemeha@sbmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
The International Branch of Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zahra Poornajaf
Position
NICU Ms Student
Other areas of specialty/work
Street address
Abedin Alley, Salehin St, Azadi Blvd
City
Illam
Postal code
Phone
+98 84 3223 0047
Fax
Email
zahrapoornajaf@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