Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 hospitasl, 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 Sicences

Country

Iran (Islamic Republic of)

Phone

+98 84 3223 0047

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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 psycological 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 comittee of The International Branch of Shahid Beheshti University of Medical Sciences

Street address
19 Shahid Abbasspour 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
Readmision

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:Educatinal-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,Ilam-Iran
City
Ilam

2

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Maryam Karami
Street address
Ayatollah Heidari Ave.,Ilam-Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Investigator
Full name of responsible person
Zahra Poornajaf
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Abedin Alley، Salehin St، Azadi Blvd، Ilam
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Ilam
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
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Person responsible for updating data

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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