Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Designed Empowerment Program on Maternal Self Efficacy and Newborn Discharge Preparation from Neonatal Intensive Care Units

Protocol summary

Summary

This trial with pre-post test with a non-parallel control group, Will carried out to determine The Effect of Designed Empowerment Program on Maternal Self Efficacy and Newborn Discharge Preparation from Neonatal Intensive Care Units in Imam Reza (AS), Kermanshah. Inclusion criteria were mothers, after obtaining informed consent, demographic questionnaire, self-efficacy questionnaires and checklist of Discharge readiness will be completed within 1-2 days after admission to the department. Then in addition to usual care intervention to be implemented in the experimental group and the control group will receive usual care. The program also offers educational materials for teaching face to face with writing a manual, a video electronic files through (cd) to native and taught. mathers 1 to 2 days before hospital discharge checklists and questionnaires are completed. The length of baby's hospital stay is recorded in the discharge. Fifteen days after discharge they will be followed by a phone call with her mother about infant’s rehospitalization and Weight gain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604084613N19**
Registration date: **2016-10-31, 1395/08/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-10-31, 1395/08/10

Registrant information

Name

Sousan Valizadeh Dehkharghani

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

vice chancellor of resreach of Tabriz University of Medical Sciences

Expected recruitment start date

2016-10-29, 1395/08/08

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Designed Empowerment Program on Maternal Self Efficacy and Newborn Discharge Preparation from Neonatal Intensive Care Units

Public title

The impact of mother education on Maternal Self Efficacy and Newborn Discharge Preparation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria for mothers: having a minimum of guidance secondary school literacy and more; with Minimum age 20 and more; no history of preterm birth in a previous pregnancy; no history of hospitalization in

previous children in neonatal intensive care unit; not having preeclampsia or other diseases that require needs for long term hospitalization and completed the informed consent. Inclusion criteria for Newborns: birth weight between 2500 to 1000 grams; gestational age between 28 -34 weeks; No anomaly major congenital and major physical illnesses; the absence of neurological defects including seizures; intraventricular hemorrhage with a higher degree of 2 and periventricular Leukomalacia. Exclusion criteria: In case of infant death; In case of infant referring to other centers for treatment continue; Mother withdrew from participation in the study; not mothers participating in the study; mother absence of company training sessions, in case of failure to respond to 20% of questions of the questionnaire.

Age
From **20 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
There was not possibility of random allocation of mothers to groups, due to the possible exchange of educational content between mothers. Therefore, at first, we will choice one of the groups to the desired number by Non Parallel sampling, and then, was selected Group B.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
Vice Chancellor for Research and Vice Chancellor for Research and Technology of Tabriz University of Medical Sciences, Golgasht St,

City
Tabriz

Postal code

Approval date
2016-09-06, 1395/06/16

Ethics committee reference number
58066/16/6/1395 -5/د

Health conditions studied

1

Description of health condition studied
Disorders related to short gestation and low birth weight

ICD-10 code
P07.1, P07

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

Primary outcomes

1

Description
Maternal Self Efficacy

Timepoint
Baseline (within 1-2 days after admission in NICU) and 1 to 2 days before infants hospital discharge (18 days)

Method of measurement
Maternal Self-Efficacy will be measured by Preterm Parenting & Self-Efficacy Checklist That was developed by Pennel and colleagues in 2012. This checklist, will be measured maternal self-efficacy of premature infants in three dimensions the mother's confidence in performing tasks, understand the importance of tasks for mothers and mothers competence (the sense of achievement) with 36 questions. The total range of self-efficacy score will be between: 36-252 and between: 12-84 for each dimension. If score was less than 48, maternal self-efficacy reported as undesirable and if score was more than 48 will be reported as desirable.

2

Description
Preparation discharge

Timepoint
Baseline (within 1-2 days after admission in NICU) and 1 to 2 days before infants hospital discharge (18 days)

Method of measurement
Preparation discharge checklist was measured, that was made by Dashti and colleagues, with review of the literature. This checklist include 28 items with a score of zero and one with 12 questions about the physical condition and general health of the infant at discharge and 16 questions about the training provided to mother.

3

Description
Maternal satisfaction

Timepoint
Baseline (within 1-2 days after admission in NICU) and 1 to 2 days before infants hospital discharge (18 days)

Method of measurement

Mothers' satisfaction, with facilities, nursing care and medical care was measured through a modified pediatric family satisfaction questionnaire (PFSQ), which is modified by Saidi et al. This questionnaire include 13 questions on a Likert scale score (1-5).

Secondary outcomes

1

Description
The rate of hospital readmission
Timepoint
15 days after discharge from the hospital
Method of measurement
Through a phone call with her mother

2

Description
The length of infant' stay (day) at hospital
Timepoint
At the infant discharge from the hospital
Method of measurement
The length of infant' stay in NICU (day) at discharge time will be recorded in the data collection form.

Intervention groups

1

Description
In the control group, usual care (which includes Kangaroo mother care and breast feeding), through face-to-face training will be taught to mothers by department nurses.
Category
Other

2

Description
In the intervention group, mothers in addition to usual care (including learning Kangaroo mother care and breast feeding), the intervention is designed (empowerment program) will be taught by the investigator as step by step by investigator. This program include frequent hand washing with disinfectant solution, touch and infant massage, kangaroo mother care (KMC), preparation and storage of milk, baby sucking practice with pacifier or finger and then with breast, education correct breast feeding and burping the baby, the number of infant feeding, bathing and changing diapers and according to the baby's prematurity or medical conditions; The first time mentioned practices is down by the investigator in the presence mother and along education about how it can be done and next time, if the mother skill for its approved by a colleague, care will be conducted by his mother and under the supervision of a researcher. In addition to face to face training, they are given a training manual booklet and a multimedia electronic files (CD), if it is possible, mothers study at the earliest opportunity before beginning any training.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Shahla Moradi
Street address
Imam Reza (AS) Hospital, next to the Faculty of Medical Sciences, Street Sorkhe Lyzhh, University Square, Kermanshah
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor of Resreach of Tabriz University of Medical Sciences
Full name of responsible person
Doctor Mohammad Rashidi
Street address
Vice Chancellor for Research and Technology of Tabriz University of Medical Sciences, Golgasht St,
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Resreach of Tabriz 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
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Full name of responsible person
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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