

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Effect of implementing discharge plan on perceived maternal-parenting self-efficacy in mothers of premature newborns

Protocol summary

Study aim

Determining the effect of the implementation of the discharge plan on the perceived self-efficacy of parent-mother in premature infant mothers

Design

This is a quasi-experimental study. 60 mothers will be selected and will be divided into two groups: intervention and control. Mothers are selected for the intervention and control group on a monthly basis until the samples size is completed.

Settings and conduct

First, the demographic information questionnaire and the self-efficacy questionnaire are completed by all mothers. Then, the discharge plan will be implemented in three sessions for the mothers of the intervention group, in groups of 3 to 4 people. Mothers in the control group receive routine ward training and care. The questionnaire will be completed again at the time of discharge and one month after discharge.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age over 18 years, Literacy, Persian language, No childbirth complications, Birth between 32 and 36 weeks, Single pregnancy, Weight over 1000 grams, No need for mechanical ventilation, No congenital anomalies. Exclusion criteria: mother with mental illness, congenital anomalies, infant need for mechanical ventilation

Intervention groups

The training of mothers of the intervention group of the control group also receives routine training and care

Main outcome variables

Parent-Mother self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200621047861N1**

Registration date: **2020-12-20, 1399/09/30**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-20, 1399/09/30**

Update count: **0**

Registration date

2020-12-20, 1399/09/30

Registrant information

Name

Shabnam Samsami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3402 0142

Email address

shabnam.samsami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of implementing discharge plan on perceived maternal-parenting self-efficacy in mothers of premature newborns

Public title

Implement the discharge plan on the self-efficacy of

mothers of premature newborns

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Newborn entry criteria: Birth between 32 and 36 weeks
Single pregnancy Weight over 1000 grams No need for mechanical ventilation The baby's condition is stable according to the doctor's diagnosis Maternal entry criteria: age over 18 years Reading and writing literacy Persian dialect

Exclusion criteria:

Existence of congenital anomalies The baby needs mechanical ventilation Maternal non-entry criteria: Reluctance to participate in the study Mother's mental illness

Age

From **18 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

Other

Other design features

Mothers will be selected based on inclusion criteria and will be divided into two groups of intervention and control. Mothers are selected for the intervention and control groups on a monthly basis.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Avesta Building, , Nowruz Alley, ShariatSt.

City

Arak

Province

Markazi

Postal code

3819675589

Approval date

2020-05-17, 1399/02/28

Ethics committee reference number

IR.ARAKMU.REC.1399.070

Health conditions studied

1

Description of health condition studied

Preterm infants

ICD-10 code

P07.3

ICD-10 code description

Preterm [premature] newborn [other]

Primary outcomes

1

Description

Self-Efficacy

Timepoint

Data collection is done in three steps. First, the demographic information questionnaire and the self-efficacy questionnaire are completed by all mothers. The self-efficacy questionnaire will be completed again at the time of discharge and one month after discharge.

Method of measurement

Mother's Self-Efficacy Questionnaire in 2007 by Barnes and Adamson-Macedo

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: Education of mothers in the intervention group is based on the presence of the number of qualified mothers in the ward, in groups of 3 to 4 people. First, the demographic information questionnaire and the self-efficacy questionnaire are completed by mothers. Then the discharge plan will be implemented in three sessions (from the second day of the baby's hospitalization, each session lasts about 60 minutes) for the mothers of the intervention group. The questionnaire will be completed again at the time of discharge and one month after discharge. At this time information is collected based on a telephone appointment with the mother or a visit for follow-up. Discharge Program: Teaching the items in the discharge program will be done in three sessions through face to face teaching, written materials, videos and questions and answers. First session: Familiarity and communication with mothers. Explanation about the physical characteristics of the baby (respiration, weight, height), breastfeeding (Time, number and duration of feeding, signs of breastfeeding adequacy, signs of child hunger,

breastfeeding positions)Second Session: Baby sleep (place, duration, position), baby bath, diaper change, baby massage, baby safety, baby stool status. Third session: Common baby problems (hiccups, breastfeeding, colic), danger signs in the baby, infection prevention, special care such as medication. In each session a part of time is assigned for answering mothers' questions. They will also be given a phone number to answer questions after discharge and their mobile number will be obtained to make calls. A training CD and a booklet are also given to mothers at the end of the sessions.

Category

Behavior

2**Description**

Control group: Control group: The mothers of the control group receive routine training and care and complete the questionnaire at the appointed times. Routine care includes breastfeeding training, the time of the next visit to the doctor, the time of visiting the thyroid test, the time and symptoms of jaundice, the occurrence of danger signs in the baby and

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amir Kabir Hospital of Arak

Full name of responsible person

Shabnam Samsami

Street address

Avesta Building, Nowruz Alley, Shariati St.

City

اراک

Province

Markazi

Postal code

3819675589

Phone

+98 86 3402 0142

Email

shabnam.samsami@yahoo.com

2**Recruitment center****Name of recruitment center**

Taleghani Hospital in Arak

Full name of responsible person

Shabnam Samsami

Street address

Avesta Building, Nowruz Alley, Shariati St.

City

Arak

Province

Markazi

Postal code

3819675589

Phone

+98 86 3402 0142

Email

shabnam.samsami@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

sharare khosravi

Street address

Payambar complex -Basij Square- Arak

City

Arak

Province

Markazi

Postal code

76593-38481

Phone

+98 86 3417 3502

Fax

+98 86 3417 3524

Email

Shararehkh2011@yahoo.com

Web page address

<https://arakmu.ac.ir/nursing/fa>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Shabnam Samsami

Position

Student

Latest degree

Bachelor
Other areas of specialty/work
Nursery
Street address
Avesta Building, Nowruz Alley, Shariati St.
City
Arak
Province
Markazi
Postal code
3819675589
Phone
+98 86 3402 0142
Email
shabnam.samsami@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Shabnam samsami
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Avesta building-Noruzi Alley -Shariati Street
City
Arak
Province
Markazi
Postal code
3819675589
Phone
+98 86 3402 0142
Email
Shabnam.samsami@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Shabnam samsami
Position

Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Avesta building- Noruzi Alley-Shariati street -Arak
City
Arak
Province
Markazi
Postal code
3819675589
Phone
+98 86 3402 0142
Email
shabnam.samsami@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All potential data can be shared after people have not been identified

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Everyone

Under which criteria data/document could be used

There is no condition

From where data/document is obtainable

Via email below shabnam.samsami@yahoo.com

What processes are involved for a request to access data/document

After receiving the email, it will finally be answered within a week

Comments