Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of effect of simulation and educational film on self efficacy of mothers in bathing preterm infant

Protocol summary

Summary

The aim of this study is to compare the effect of simulation and educational film on self-efficacy of mothers in bathing preterm infants. this study is a randomized control clinical trial. the study population of this study includes mothers of preterm infants at (34-37) weeks gestation, who had admission in the neonatal unit and prepare to discharge. participated mothers randomly are divided to 3 groups. socio-demographic and self-efficacy questionnaires will be completed by the mother in 48-72 first hours from admission. in simulation group, baby bathing education will perform using simulation by researcher at a meeting of the group. researcher will teach all steps of infant bathing on model practically. in the film group, baby bathing education with a group of mothers will be provided through the film. the film duration is 15 minutes. mothers in control group will receive routine training in the ward. mothers evaluation in the intervention group will be done in two stages by completion the self-efficacy questionnaire in bathing baby.first post test will take 48 hours after intervention and second post test will be done one week after discharge. in control group first post test will take 48 hours after pretest and second post test will be done one week after neonate discharge.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201408195168N6**
Registration date: **2014-11-12, 1393/08/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-11-12, 1393/08/21

Registrant information

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Maliheh Assadollahi

Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Science

Expected recruitment start date

2014-11-11, 1393/08/20

Expected recruitment end date

2015-02-09, 1393/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of effect of simulation and educational film on self efficacy of mothers in bathing preterm infant

Public title

The effect of education on preterm infant mother's self efficacy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria 1- mothers who have preterm infant in 34 – 37 gestational age and ready to discharge 2- Literacy 3- Mother's tendency to participate in the study. 4- Primiparous 5- Physically and mentally healthy

mothers 6- No drug abuse or any Narcotics 7- No congenital malformation Exclusion criteria: If mothers don't participate less than twice in evaluation times will remove from the study.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
Central Building of Tabriz University of Medical Sciences,Golgasht Avenue, azadi street,Tabriz

City
tabriz

Postal code

Approval date
2014-08-04, 1393/05/13

Ethics committee reference number
9372

Health conditions studied

empty

Primary outcomes

1

Description
Increase in knowledge

Timepoint
Evaluation and assessment of the first 48 hours of training a week after discharge

Method of measurement
mothers evaluation in the intervention group will be done in two stages by completion the self-efficacy questionnaire in bathing baby.

Secondary outcomes

1

Description
Increase self-efficacy in education with film

Timepoint
Pre-test: 48 – 72 first-hours after admission the baby First Post- test: 48 hours after intervention. Second post-test: one week after discharge

Method of measurement
self-efficacy questionnaire in bathing baby

Intervention groups

1

Description
simulation group: baby bathing education using simulation by researcher at a meeting of the group will perform for 15 minutes and researcher will educate all stages of baby bathing on model practically.

Category
Prevention

2

Description
The mothers in control group will receive routine education and no intervention will be performed on them.

Category
N/A

3

Description
film group: In this group baby bathing education with a group of mothers will be provided through the film. the film duration is 15 minutes.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Booali Educational Center Affiliated

Full name of responsible person
Roghayeh karimipoor

Street address
Saheli Street across from Azadi Park

City
ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Science
Full name of responsible person
Malihe Assadollahi
Street address
Department of Pediatrics, School of nursing and Midwifery, Tabriz
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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
Tabriz University of Medical Science
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

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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