Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Impact of Peer Education on Breastfeeding Self-Efficacy in Primiparous Women with hospitalized neonate in neonatal ward

Protocol summary

Study aim
Determination of the impact of Peer Education on Breastfeeding Self-Efficacy in Primiparous Women with hospitalized neonate in neonatal ward

Design
Clinical trial with intervention and control group, Randomized using random numbers table, The sample size was 120 people, 60 in the control group and 60 in the intervention group

Settings and conduct
One hundred and twenty samples that sixty people in the control group and sixty in the intervention group are randomized and without blinding and Breastfeeding Education in the Breastfeeding room of the neonatal ward of Amirkola Pediatric hospital and training through peer will be provided to Primiparous Women with hospitalized neonate.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Primiparous Women with a single-term infant (over thirty seven weeks of gestation)؛ Not having a physical or mental illness؛ No structural defects in the breast؛ Mother's desire for Breastfeeding؛ The age range is at least eighteen years and maximum thirty five years؛ Have a reading and writing literacy. Exclusion criteria: The presence of problems requiring admission to the NICU؛ Unwillingness to continue the collaboration of primiparas women؛ The desire not to continue the co-operation of the Peer mothers؛ The death of hospitalized infant؛ Prohibition of breastfeeding by a Neonatalogist during the study

Intervention groups
Control mothers will receive usual and standardized training of the center after delivery.The mothers of the intervention group will receive, in addition to the Center's usual training, two sessions of one hour of other breastfeeding training that will be held by the peer in the first week after the delivery.

Main outcome variables
Mean score Of Breastfeeding Self-Efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180519039708N1**
Registration date: **2018-11-30, 1397/09/09**
Registration timing: **retrospective**

Last update: **2018-11-30, 1397/09/09**
Update count: **0**

Registration date
2018-11-30, 1397/09/09

Registrant information

Name
Safie Rezapour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3220 5537

Email address
s.rezapour@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-06, 1397/05/15

Expected recruitment end date
2018-09-21, 1397/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Impact of Peer Education on Breastfeeding Self-Efficacy in Primiparous Women with hospitalized neonate in neonatal ward

Public title

Impact of Peer Education on Breastfeeding Self-Efficacy

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Primiparous Women with a single-term infant (over thirty seven weeks of gestation) Not having a physical or mental illness No drug use for special disease No structural defects in the breast Having a baby without any Congenital defects Mother's desire for Breastfeeding The age range is at least eighteen years and maximum thirty five years Have a reading and writing literacy No history of smoking, use alcohol and drugs The absence of complications during pregnancy and delivery (such as preeclampsia and bleeding)

Exclusion criteria:

The congenital problems or interruptible problems with breast milk (such as buttocks, cleft palate, respiratory or cardiovascular problems The presence of problems requiring admission to the NICU Unwillingness to continue the collaboration of primiparas women The desire not to continue the co-operation of the Peer mothers The death of hospitalized infant Prohibition of breastfeeding by a Neonatalogist during the study

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Starting from a random point in the random numbers table And from this point we move forward and down the random numbers table And all numbers on this path are selected as sample members and to avoid the unequal number of samples in the intervention and control groups, a random permutation method is used So that for random numbers 0-4, the random permutation AB And for random numbers 5-9, random permutation BA is used. (A = Intervention and B = Control)

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences., Ganj Afrooz Avenue., Babol., Mazandaran

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Approval date

2018-05-05, 1397/02/15

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.012

Health conditions studied

1

Description of health condition studied

Breastfeeding Education

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean score of breastfeeding self-efficacy

Timepoint

The beginning of the study (before the intervention) and the end of the eighth weeks after delivery

Method of measurement

Dennis Breastfeeding Self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Mothers of the intervention group, in addition to the standard and standard breastfeeding training, will have two sessions of one hour of other lactation training that will be held in the first week after the delivery by the peer in the weekly classroom (Saturday, Monday, Wednesday) at 9 o'clock In the morning, they will receive

lactation at the Nursing Department of Amirkola Children's Hospital. Teaching the same mothers to the mothers of the intervention group as a lecture, along with a question and answer, and providing a booklet and educational pamphlet prepared by the researcher.

Category
Behavior

2

Description
Control group: Control mothers will receive only usual breastfeeding education provided by the center.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Amirkola Children's Hospital

Full name of responsible person
Parvin aziznejadroshan

Street address
Babol University of Medical Sciences., Ganj Afrooz Avenue., Babol.,

City
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶-۴۷۷۴۵

Phone
+98 11 3219 9592

Email
aziznejadroshan@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Ghadimi Reza

Street address
Babol University of Medical Sciences., Ganj Afrooz Avenue., Babol., Mazandaran

City
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶-۴۷۷۴۵

Phone
+98 11 3219 9592

Email
rezaghadimi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Babol 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
Babol University of Medical Sciences

Full name of responsible person
Parvin aziznejadroshan

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Babol University of Medical Sciences., Ganj Afrooz Avenue., Babol., Mazandaran

City
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶-۴۷۷۴۵

Phone
+98 11 3219 9592

Email
aziznejadroshan@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Parvin aziznejadroshan

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Babol University of Medical Sciences., Ganj Afrooz Avenue., Babol., Mazandaran

City
Babol
Province
Mazandaran
Postal code
۴۷۱۷۶-۴۷۷۴۵
Phone
+98 11 3219 9592
Email
aziznejadroshan@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Safie rezapour
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Babol University of Medical Sciences., Ganj Afrooz Avenue., Babol., Mazandaran
City
Babol
Province
Mazandaran
Postal code
۴۷۱۷۶-۴۷۷۴۵
Phone
+98 11321995926
Email
safierezapour@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available