# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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**

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Iran (Islamic Republic of)

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**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**
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**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

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Ghadimi Reza

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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**

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

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## Person responsible for updating data

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## 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