

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

effect of postpartum education to mother about breastfeeding position /latch on newborn feeding behavior at discharge

Protocol summary

Study aim

main goal: Identifying the effects of postpartum education on newborn breastfeeding behavior at discharge specific objectives: 1- identifying newborn breastfeeding behavior before positioning/latch on education in intervention and control group 2- comparing newborn breastfeeding behavior before positioning/latch on education between intervention and control group 3- identifying newborn breastfeeding behavior after positioning/latch on education in intervention and control group 4-comparing newborn breastfeeding behavior after face to face education of positioning/latch on, between intervention and control group

Design

after completing the initial questionnaire, mothers will be randomly divided into intervention or control groups using simple random allocation method. For choosing that the first one is in control or intervention, we will draw a coin (tap or line). Participants will be allocated one in between till completion of sample size

Settings and conduct

postpartum and cesarean wards of al-zahra education and treatment center of Rasht city

Participants/Inclusion and exclusion criteria

inclusion criteria: women with singleton pregnancy and vaginal or cesarean delivery exclusion criteria: pregnancies with medical or surgical complications, history of prolonged or complicated deliveries, anatomical abnormalities or breast surgeries which prevent breastfeeding, newborn APGAR score below 7, newborn admission in NICU, cleft lip or palate or other abnormalities that act as barrier for newborn feeding

Intervention groups

women with singleton pregnancies and vaginal or cesarean delivery who have inclusion criteria of study

Main outcome variables

newborn feeding behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190111042321N1**

Registration date: **2019-02-16, 1397/11/27**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-16, 1397/11/27**

Update count: **0**

Registration date

2019-02-16, 1397/11/27

Registrant information

Name

Zahra Gholipour Soleymani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3333 7106

Email address

elahe.gholipour20@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effect of postpartum education to mother about breastfeeding position /latch on newborn feeding behavior at discharge

Public title

effect of postpartum education to mother about breastfeeding position /latch on newborn feeding behavior at discharge

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

woman with singleton term pregnancy who had vaginal birth or cesarean birth

Exclusion criteria:

pregnancies with medical complications prolonged obstructed labors anatomical defects in breast which an obstacle for breastfeeding APGAR score below 7 newborn admission in NICU cleft lip/palate or other anomalies cause disorder in newborn feeding

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

More than 1 sample in each individual

Number of samples in each individual: **2**

pregnancies with medical complications.prolonged obstructed labors.anatomical defects in breast which an obstacle for breastfeeding.APGAR score below 7.newborn admission in NICU.cleft lip/palate or other anomalies cause disorder in newborn feeding.

Randomization (investigator's opinion)

Randomized

Randomization description

After completing the initial questionnaire , mothers are randomly divided in to two intervention method for choosing than the first client is belonged to intervention or control group , we will draw a coin (tap or line).then for choosing the first one sampling will continue and participants will be allocated one in

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Azad university

Street address

pooltaleshan street,rasht

City

Rasht

Province

Guilan

Postal code

4147654919

Approval date

2017-09-19, 1396/06/28

Ethics committee reference number

IR.IAU.RASHT.REC.1396,165

Health conditions studied

1

Description of health condition studied

newborn breastfeeding behavior

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

newborn breastfeeding behavior

Timepoint

at beginning of study and at discharge

Method of measurement

with IBFAT instrument

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Individuals who have been admitted to the study who received face-to-face education about lactation and then had their baby's milking behavior checked. Control group:

Category

Behavior

2

Description

Control group: Individuals who have been admitted to the study who did not receive face-to-face training and their baby's milking behavior were checked during discharge.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital of Rasht

Full name of responsible person

Zahra Gholipour Soleimani

Street address

Namgo street,alzahra hospital

City

Rasht

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2345987554

Phone

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Fax

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr.Mirfallah

Street address

pooltaleshan street,Rasht

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Zahra Gholipour

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Marzieh Masjodi

Position

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4147092163

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Education

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Email

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