

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of father's education and participation on the success rate of breastfeeding in mothers with preterm infant

Protocol summary

Study aim

Determine of the effect of father's education and participation on the success rate of breastfeeding in mothers with preterm infant

Design

Clinical trial with control group, with parallel groups, three blind, randomized

Settings and conduct

In this study, mothers with preterm infants with less than 37 weeks of gestational age at Imam Reza Hospital of Kermanshah are examined. Infants are randomly divided into two groups: intervention and control. In the intervention group, fathers receive three-session training on breastfeeding and infant feeding while in the control group only routine training is performed. The study is a three-blind study which both mothers and both the assessor and the analyst are not aware of the allocation of groups.

Participants/Inclusion and exclusion criteria

gestational age less than 37 week; non of asphyxia during infant's birth; non of heart problems and serious congenital anomalies; do not use hypnotic drugs by infant; non of congenital malformation and abnormalities in the jaw and mouth

Intervention groups

In the intervention group, infant's fathers will be taught three face-to-face sessions on infant nutrition, lactation problems, and breastfeeding benefits. At the end of the session, a leaflet with the main points of the session was provided to the fathers. In the control group, training sessions were not provided and only routine training was given to fathers.

Main outcome variables

The frequency of breastfeeding; the number of correct breastfeeding; the success rate of the mother in breastfeeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151220025619N3**

Registration date: **2018-03-16, 1396/12/25**

Registration timing: **prospective**

Last update: **2018-03-16, 1396/12/25**

Update count: **0**

Registration date

2018-03-16, 1396/12/25

Registrant information

Name

Leila Mohammadi Pirkashani

Name of organization / entity

Esfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of father's education and participation on the success rate of breastfeeding in mothers with preterm infant

Public title

The effect of father's education and participation on the success rate of breastfeeding in mothers with preterm infant

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

gestational age less than 37 week

Exclusion criteria:

Asphyxia during infant's birth Heart problems and serious congenital malformations of the infant Use hypnotic drugs Congenital malformation and abnormalities in the jaw and mouth

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the newborns were randomly assigned to two random groups using a random number table. A random numbered table is a collection of numbers that are generated without a specific pattern or order and in a completely random manner. To use the random number table, the researcher must first determine the number of the table to read (for example: up, down, left or right), the second assumption is that the researchers will consider the numbers for different groups, in this study paired numbers will be assigned to the intervention group in the random numbers table and the individual numbers will be assigned to the control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

For blinding, for mothers not to understand, the fathers of both groups are trained, The difference is that the fathers of the control group receive only routine training. The evaluator, also helping the researcher, is not aware of the allocation of the groups and the analyst is not aware of the allocation of groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Imam Reza Hospital., Nurse Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6715838316

Approval date

2018-02-28, 1396/12/09

Ethics committee reference number

IR.KUMS.REC.1396.692

Health conditions studied

1

Description of health condition studied

Breastfeeding in mothers with preterm infant

ICD-10 code

O92.7

ICD-10 code description

Other and unspecified disorders of lactation

Primary outcomes

1

Description

The success rate of breastfeeding in mothers with preterm infants

Timepoint

End one month, three months and six months

Method of measurement

Researcher made questionnaire

Secondary outcomes

1

Description

Maternal Satisfaction Score from Breastfeeding

Timepoint

6 months

Method of measurement

Researcher made questionnaire

Intervention groups

1

Description

Intervention group: The fathers of the intervention group were interviewed and offered a face-to-face, 40-minute session about infant feeding and the difficulties sometimes associated with breastfeeding, such as fear of milk insufficiency; hand expression breast milk; teaching of feeding methods in preterm infants such as feeding by cup; return to outside employment in working mothers; and problems such as breast engorgement, mastitis, sore and inverted nipples or flat nipples and breast refusal. They were taught how problems with lactation can occur and how it is possible to prevent and manage them. Moreover, attention was paid to the concerns that a father might have in relation to breastfeeding, and the fathers were helped to recognize and accept their unique and vital role in the success of breastfeeding especially in mothers with preterm infants. At the end of the session, a leaflet with the main points of the session was provided to the fathers. The nurse who conducted the intervention was trained through the training course.

Category

Behavior

2

Description

Control group: In the control group, training sessions were not provided and only routine training was given to fathers.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital Kermanshah

Full name of responsible person

Leila Mohammadi Pirkashani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research of Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farid Najafi

Street address

Imam Reza Hospital., Nurse Blvd

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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

Deputy of Research of Kermanshah University of Medical Sciences

Proportion provided by this source

5

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

Kermanshah University of Medical Sciences

Full name of responsible person

Leila Mohammadi Pirkashani

Position

Master of Science in Neonatal Intensive Care Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available