

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Aug 2022

Effect of counseling on exclusive breastfeeding continuation in mothers with hospitalized preterm infant using BASNEF model

Protocol summary

Summary

Objective: This study aims at determine the effect of counseling on exclusive breastfeeding continuation in mothers with hospitalized preterm infant is designed, 2014. Exclusion criteria: Singleton pregnancy; Delivery at 37-34 weeks gestation; No abnormalities in the baby at birth. Exclusion criteria: Infant mortality for any cause during the study; infants with severe respiratory distress and infection hospital in need of Nil Per Os; Continued absence of women in training sessions. Methods: This is quasi-experimental study of two groups. The target population of this study consists of all mothers and hospitalized premature infants. Sample size of 62 patients in the intervention group and 62 patients in the control group are determined. Sampling is done by random permutation block. In order to continue exclusive breastfeeding and breastfeeding counseling intervention in preterm infants during the five sessions by the researcher, daily during hospitalization for direct instruction and individual face to face, the theoretical and practical on the steps of reproductive health service (Using the replica, pamphlets, educational compact Disk training) and incentive packages and daily goals chart will be performed. But the control group will performed routine care. Data collection tools included three questionnaires to assess knowledge of mothers about breastfeeding; Training based on structural BASNEF model, demographic characteristics, check list observation and consultation performance breastfeeding mothers, and scales weighing children's model co12000 is made in Iran.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014111013405N6**

Registration date: **2015-01-05, 1393/10/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-05, 1393/10/15

Registrant information

Name

Seyyedeh Zahra Masoumi

Name of organization / entity

Hamedan University of Medical Sciences, School of Nursing and Midwifery

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of counseling on exclusive breastfeeding continuation in mothers with hospitalized preterm infant using BASNEF model

Public title

The effect of counseling on breast feeding in preterm infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Mother are literate; Mother prevention of adduction; Not having a mother with underlying disease and gestational diabetes and preeclampsia; Singleton pregnancy; Delivery at 37-34 weeks gestation; No abnormalities in the baby at birth. Exclusion criteria: Mother's unwillingness to cooperate; Metabolic disorders in newborns; Infant mortality for any cause during the study; infants with severe respiratory distress and infection hospital in need of Nil Per Os; Continued absence of women in training sessions; Mothers taking antidepressant drugs and psychotropic substances; The inability of the breast feeding at the discretion of the physician; Infectious disease of the breast; Unavailability of the mother at the time of completing of questionnaires test and attending breastfeeding education classes during pregnancy.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Hamedan university of Medical Sciences

Street address

Vice Chancellor of Research and Technology,
Hamedan University of Medical Sciences, Shahid
Fahmideh Avenue, Hamedan

City

Hamedan

Postal code

6516645977

Approval date

2014-11-25, 1393/09/04

Ethics committee reference number

16/35/9/4125/پ

Health conditions studied

1

Description of health condition studied

Relationship counseling to exclusive breastfeeding continuation in mothers with hospitalized preterm infant

ICD-10 code

p05-p06-p0

ICD-10 code description

Disorders related to length of gestation and fetal growth

Primary outcomes

1

Description

exclusive breastfeeding continuation

Timepoint

Before then once monthly until 4 months after birth

Method of measurement

Check list

Secondary outcomes

1

Description

Birth weight

Timepoint

Before then once monthly until 4 months after birth

Method of measurement

Weighing Scales babies

Intervention groups

1

Description

Intervention group: breastfeeding counseling for continued exclusive breastfeeding in preterm infants during 5 session by researcher, daily during hospitalization direct instruction and individual face to face, the practical and theoretical will be performed.

Category

Prevention

2

Description

Control group: regular and ongoing training by personnel neonatal unit and after delivery to receive.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research the Technology,
Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeed Bashiriyan

Street address

HVice Chancellor of Research and Technology,
Hamedan University of Medical Sciences, Shahid
Fahmideh Avenue, Hamedan

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for Research the Technology, Hamedan
University of Medical Sciences

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

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Seyedeh Zahra Masoomi

Position

Phd in reproductive health, Vice chancellor for the
School of Nursing and Midwifery

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

Shiler Ahmadi

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Bachelor of Midwifery/ Student of Master in Midwifery
Counselling

Other areas of specialty/work

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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