

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

The Effect of Family Participation on Mother's Breast Feeding Self-Efficacy and Weight gain of Premature Neonate

Protocol summary

Summary

This research will be random clinical trial in two groups on 60 mothers having premature neonate (gestational age between 32-36 week) bed ridden in the NICU Mashhad University of medical science research and training centers. Sampling will be done based inclusion criteria. Control group will receive the typical unit programs While the intervention group includes families who are family partnership in tendance; as they are trained in premature neonate tendace in the field of basic care, including: the right way of washing hands at the time of entring the unit, before and after of touching the neonate, way of using incubator, changing bedsheet and diapers, way of breastfeeding and infant feeding then the infant will be weighed every morning up to the time of releasing, in two groups, breastfeeding self-efficocy questionnaire (Denis 2003) containing 14 questions this questionnaire will be compeleted in 3 steps. Firstly, in the first 24 hours after child birth; secoundly, before releasing and thirdly, in the eighth weeks. At the end the infant weight will be controlled in the eight week. Inclusion criteria: ages between 32-36 weeks; Hemodynamic stubility; neonate family including first and secound degree relatives. Exclusion criteria: neonate in the ventile; neonate with sepsis; family absence in the unit for more than one third of hospitalization time (intervention groups).

General information

Acronym

Family Centered Care (FCC)

IRCT registration information

IRCT registration number: **IRCT2013081814393N1**

Registration date: **2013-09-21, 1392/06/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-09-21, 1392/06/30

Registrant information

Name

Zahra Askari Hoseini

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1859 1511

Email address

askarihz901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Financial Assistance Mashhad University of Medical Sciences

Expected recruitment start date

2013-09-01, 1392/06/10

Expected recruitment end date

2013-12-31, 1392/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Family Participation on Mother's Breast Feeding Self-Efficacy and Weight gain of Premature Neonate

Public title

The Effect of Family Participation on Mother's Breast Feeding Self-Efficacy and Weight gain of Premature Neonate

Purpose

Supportive

Inclusion/Exclusion criteria

Neonate inclusion criteria: age between 32 - 36 weeks; Hemodynamic stability (HR=120-160, RR = 40-60, SPO2= 85%-95% and baby pink color); Congenital anomaly is not clear; newborn premature infants who are hospitalized; at least seven days to be admitted; be the first child; IUGR not. Family inclusion criteria: they agree to participate in the study; neonate family includes first and second degree relatives; medical personnel are not; minimum education level reading and writing; have a natural physical ability; lack of mood disorders and emotional barriers to effective communication; drug abuse is not; have the possibility to participate in the study (Intervention group); during the first day of admission to attend; have lived in Mashhad. Mother inclusion criteria: be nulliparous mothers; the desire to breastfeed is not a medical condition; there may be a phone call. Neonate exclusion criteria: neonate dies; respiratory disease that has required ventilation; neonatal sepsis is. Family exclusion criteria: withdraw from the study for any reason that is; in unit more than one third of neonates is absent the intervention group; notes do not observe trained and assigned tasks.

Age

From **32 years** old to **36 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not 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

Mashhad University of Medical Sciences

Street address

School of Nursing and Midwifery Mashhad, Four ways

PhD

City

Mashhad

Postal code

Approval date

2013-08-19, 1392/05/28

Ethics committee reference number

research/920541/1/111

Health conditions studied

1

Description of health condition studied

Disorders related to short gestation and low birth weight, not elsewhere classified

ICD-10 code

P07

ICD-10 code description

weight gain of premature neonate

Primary outcomes

1

Description

weight gain of premature neonate

Timepoint

Two months after the start of the intervention

Method of measurement

Weight in grams using a digital scale

2

Description

Mother's breastfeeding self-efficacy

Timepoint

Two months after the start of the intervention

Method of measurement

Dennis questionnaire

Secondary outcomes

1

Description

The rate of weight change

Timepoint

Two months after the start of the intervention

Method of measurement

Weight in grams with a digital scale

2

Description

The rate of mother's breastfeeding self-efficacy

Timepoint

Two months after the start of the intervention

Method of measurement

Dennis self-efficacy questionnaire

Intervention groups

1

Description

Control group will receive the typical unit programs. The intervention group includes families who are family partnership in tendance. they are trained in premature neonate tendace in the field of basic care, including: the right way of washing hands at the time of entring the unit, before and after of touching the neonate, way of using incubator, changing bedsheet and diapers, way of breastfeeding and infant feeding.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU, Educational and Research Center Mashhad
University of Medical Sciences

Full name of responsible person

Mr.Hamidreza Behnam Vashani

Street address

Mashhad School of Nursing and Midwifery

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Mashhad University of Medical
Sciences

Full name of responsible person

Dr.Tafaghodi

Street address

Building Qureshi

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Council of Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Askari Hoseini

Position

MSc in Nursing,neonatal intensive care

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

MSc Nursing,Faculty member of School of Nursing and
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Person responsible for updating data

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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