

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Assesing the effect of fathers involvement in the care of premature newborns based on developmental care principels on their bonding and self efficacy

Protocol summary

Study aim

Assesing the effect of fathers involvement in the care of premature newborns based on developmental care principels on their bonding and self efficacy

Design

This was a quasi-experimental study, performed on 80 fathers who had preterm infants in neonatal intensive care unit in two groups of control and intervention.

Settings and conduct

Neonatal intensive care units of Arash hospital affiliated to Tehran University of Medical Science

Participants/Inclusion and exclusion criteria

Inclusion criteria: Fathers who have premature baby (gestational age less than 37) in neonatal intensive care unit, the ability to understand and read in Persian, no addiction, not having a premature baby before. Exclusion criteria: The infant gets serious illness during the study (Lung hemorrhage, intraventricular hemorrhage...), mother with post par tum depression (the effect of mother depression on father bonding), hospitalization for more than 4 weeks (the effect of long hospitalization on fathers bonding and self- efficacy), discharge earlier than 1 week

Intervention groups

The control group includes fathers who filled demographic data form,mother to infant bonding scale and perceived parental self efficacy questionnaire in the first three days of application and again one month later. Their baby treat routinely. The intervention group includes fathers who participate in training sessions that researcher performed by using educational movies and medical moulages. In these session care processes, such as positioning, correct movement, feeding, kangaroo mother care, bathing of a swaddling baby, changing diapers, touching the baby, and understanding the behavior of the infant were educated with the participation of fathers and on their infants. Fathers filled

demographic data form,mother to infant bonding scale and perceived parental self efficacy questionnaire in the first three days of application and again one month later

Main outcome variables

By implementing this plan, the level of self-efficacy and transplantation of fathers increased and the development of the baby will be affected

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171010036690N1**

Registration date: **2018-01-31, 1396/11/11**

Registration timing: **retrospective**

Last update: **2018-01-31, 1396/11/11**

Update count: **0**

Registration date

2018-01-31, 1396/11/11

Registrant information

Name

Fatemeh Morovati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-21, 1396/02/31

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

2017-05-21, 1396/02/31

Actual recruitment end date

2017-11-21, 1396/08/30

Trial completion date

empty

Scientific title

Assesing the effect of fathers involvement in the care of premature newborns based on developmental care principels on their bonding and self efficacy

Public title

Assesing the effect of fathers involvement in the care of premature newborns based on developmental care principels on their bonding and self efficacy

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Fathers who have premature baby (gestational age less than 37) in neonatal intensive care unit, the ability to undrestand and read in Persian, no addiction, not having a premature baby before

Exclusion criteria:

Exclusion criteria: The infant gets serious illness during the study (Lung hemorrhage, intra ventricular hemorrhage...), mother with post par tum depression (the effect of mother depression on father bonding), hospitalization for more than 4 weeks (the effect of long hospitalization on fathers bonding and self- efficacy), discharge earlier than 1 week

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

For preventing the information contamination between control and intervention group father will enter the study in succession of 10 people. The random sequence of the control and intervention group is determined by dropping coin. After ending sampling for 10 person and after discharging the last baby 10 father entered to study by the sequence identified.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences

Street address

Enghelab ave

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2017-05-06, 1396/02/16

Ethics committee reference number

IR.TUMS.FNM.REC.1396.2241

Health conditions studied**1****Description of health condition studied**

Assessing bonding and self- efficacy of fathers who have premature baby

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Bonding: The score obtained from the Mother to infant bonding questionnaire.

Timepoint

After 3 days, 4 weeks later

Method of measurement

The questionnaire of Mother to infant bonding scale.

2**Description**

Self efficacy : The score obtained from the Perceived Parental self- Efficacy questionnaire

Timepoint

After 3 days, 4 weeks later

Method of measurement

Perceived Parental self- Efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Fathers have a premature newborn that They are treated in accordance with the routine

Category

N/A

2

Description

Intervention group: Fathers have a newborn in the department that will participate in 4 sessions of evolutionary care education, including positioning, moving, feeding, nursing, bathing with a swaddling baby, changing diapers, touching the baby, understanding the behavior of the baby according to the nature of each infant. . After holding fathers' meetings with the help of the researcher, they performed the lessons learned on the baby's side as needed. During the first meeting with the infant's care department, the characteristics of the premature baby and its needs are taught to parents. During the second session, the philosophy of evolutionary care and how to care for the baby will be provided on the basis of the principles of evolutionary care on the replicate. During the third and fourth session, the care of the infant's bedside and in the presence of the researcher will be done by the fathers in practice.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash hospital

Full name of responsible person

Dr. Ladan Kashani

Street address

Shahid bagheri highway .Baghdarnia avenu

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh morovati

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results will be sent as an article to be printed in internal or external journals

When the data will become available and for how long

Start access after printing the article

To whom data/document is available

All people

Under which criteria data/document could be used

If copyright is observed, mention the available resource

From where data/document is obtainable

fatemehmorovati@yahoo.com An article in the journal has been published

What processes are involved for a request to access data/document

Within a week, an email request will be answered

Comments