Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effects of premature infant's parent empowerment program in NICU, on their involvement, stress and beliefs in Hospitals of Tehran University of Medical Science.

Protocol summary

Summary

Our goal was to study the effects of premature infant's parent empowerment program in NICU, as a family centered intervention, on their involvement, stress and beliefs. A quasi-experimental, posttest-only design with a comparison group was conducted with 65 families with preterm infants from 2010 to 2011 in NICUs and high risk neonate units in two Hospitals of Tehran University of Medical Science. Parents in experiment group received information and behavioral activities about the appearance and behavioral characteristics of preterm infants and how best to parent them via verbal face to face education, audio taped in CD or Bluetooth and written materials.Both fathers and mothers in the empowerment program group were more involved in their infants' care, and reported significantly less stress in the NICU, as well as, higher beliefs about their parental role and what behaviors and characteristics to expect of their infants during hospitalization, compared with control parents. So, Parent empowerment program can involve parents in their infants' care and reduce parenting stress among both mothers and fathers of preterm infants and improves their beliefs about parental role and what behaviors and characteristics to expect of their infants in NICU.

General information

Acronym

Parental Empowerment Program

IRCT registration information

IRCT registration number: **IRCT138904234372N1**
Registration date: **2011-02-24, 1389/12/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-02-24, 1389/12/05

Registrant information

Name
Roghieh Karimi
Name of organization / entity
Nursing School of Tehran University of Medical Scienses
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Recruitment status

Recruitment complete

Funding source
Tehran university of medical science

Expected recruitment start date

2010-06-05, 1389/03/15

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of premature infant's parent empowerment program in NICU, on their involvement, stress and beliefs in Hospitals of Tehran University of Medical Science.

Public title

Parental Empowerment Program, on their Involvement, Stress & Beliefs

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: All mothers and fathers were above 18 years of age, who could read and speak persian, and did not consume antianxiety drugs, Whitout stressful event in family, And whose infants born at the study sites, below 37 weeks of gestational age and singelton birth. exclusion criteria:situation that cause Neonatal death.
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **65**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Ethical Review Committee of Tehran University of Medical Sciences
Street address
Floor 6, Central Building of Tehran University ,Intersection of Ghods & Keshavarz Blv.
City
Tehran
Postal code
Approval date
2010-01-05, 1388/10/15
Ethics committee reference number
433/130/89/د

Health conditions studied

1

Description of health condition studied
parental Stress
ICD-10 code
Z75.8
ICD-10 code description
Other problems related to medical facilities and other health care

2

Description of health condition studied
Parental Involvement
ICD-10 code
Z76.3
ICD-10 code description
Healthy person accompanying sick person

3

Description of health condition studied
parental Belief
ICD-10 code
Z63.9
ICD-10 code description
Problem related to primary support group, unspecified

Primary outcomes

1

Description
parental Involvement in neonatal care in NICU
Timepoint
1-2 day before discharge
Method of measurement
Observational check list of parental involvement in neonatal care in NICU

2

Description
parental Beliefs in NICU
Timepoint
1-2 day before discharge
Method of measurement
parental Beliefs Scale in NICU (PBS:NICU)

3

Description
parental stress in NICU
Timepoint
1-2 day before discharge
Method of measurement
parental stress Scale in NICU (PSS:NICU)

Secondary outcomes

empty

Intervention groups

1

Description
Parents in experiment group received parental

empowerment program that contains information and behavioral activities about the appearance and behavioral characteristics of preterm infants and how best to parent them via verbal face to face education, audio taped in CD or Bluetooth and written materials.

Category

Behavior

2

Description

in admission, hospitalize & discharge time standard care done for both control & intervention group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Mirza kuchak khan Hospital

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Valie Asr Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research of tehran university of medical science

Full name of responsible person

Dr. Yunesiyan

Street address

floor 6, central bulding of university , Ghods, Keshavarz Blv.

City

Tehran

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 of tehran university of medical science

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

nursing school of tehran university of medical science

Full name of responsible person

Mahboobeh Khajeh

Position

Master of Science in nursing

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

nursing school of tehran university of medical science

Full name of responsible person

Roghieh Karimi

Position

Master of Science in nursing/faculty member

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Mahboobeh Khajeh

Position

Other areas of specialty/work

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mkhajeh@tums.ac.ir

Web page address

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