

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The Protective Effect of mothers with premature infants admitted to the neonatal intensive care unit of each other on their²Stress

Protocol summary

Summary

Main objective of the study is the Protective Effect of mothers with premature infants admitted to the neonatal intensive care unit of each other on their role. This study is a randomized control trial. Inclusion Criteria: All mothers could read and speak Persian; who had not had another infant admitted to the NICU. Exclusion criteria: Mother's unwillingness to cooperation.80 Mothers using none- randomized form are divided into intervention and control groups.Thus,40 cases are in each group. Support Program (to support sitting together, talking, comfort and interactions) that led to the sharing of information between the mother and the researcher is done. After 2 weeks later, questionnaires will filled again by patients.In this study we use 2 questionnaires:demographic, Perceived stress scale. At the end, stress in mothers will compared between control group and intensive group before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052034050N1**
Registration date: **2017-08-05, 1396/05/14**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-05, 1396/05/14

Registrant information

Name

maryam taheri

Name of organization / entity

shahid Beheshti University of Medical Sciences,
Tehran

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-04-19, 1395/01/31

Expected recruitment end date

2016-07-20, 1395/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Protective Effect of mothers with premature infants admitted to the neonatal intensive care unit of each other on their²Stress

Public title

Reducing Maternal Stress through Peer Support

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: All mothers could read and speak Persian; who had not had another infant admitted to the NICU. Exclusion criteria: Mother's unwillingness to cooperation

Age

No age limit

Gender

Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 80

Randomization (investigator's opinion)
N/A

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

Shahid Beheshti University of Medical Sciences

Street address

Shahid Arabi Avenue, Velenjak, Shahid Beheshti
University of medical Science

City

Tehran

Postal code

1434875451

Approval date

2016-04-16, 1395/01/28

Ethics committee reference number

ir.sbm.u.retech.rec.1395.122

Health conditions studied

1

Description of health condition studied

preterm infant

ICD-10 code

P07.3

ICD-10 code description

Other preterm infants

Primary outcomes

1

Description

Determination of stress in mothers in two groups before
and after intervention

Timepoint

Two weeks after intervention

Method of measurement

Perceived stress scale

Secondary outcomes

empty

Intervention groups

1

Description

In Intervention Group: Presenting the Parent-Miles and Funk Tension Scale and Support Program (to support sitting together, talking, comfort and interactions) that led to the sharing of information between the mother and the researcher is done. The support program was delivered to inexperienced mothers (mothers who had recently given birth to premature infants and resulted in hospitalization) by experienced moms (mothers who had a history of a baby in the intensive care unit) in three sessions each and every 55 minutes. In the intensive care unit).

Category

Behavior

2

Description

In Control Group: Presenting the Parent-Miles and Funk Tension Scale and without support

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital of Babol

Full name of responsible person

Maryam Taheri

Street address

Ayatollah Rouhani Hospital, Ganjafroz Street

City

Babol

2

Recruitment center

Name of recruitment center

Children's Hospital Decedent Shafi'zadeh Amirkola

Full name of responsible person

Maryam Taheri

Street address

Babol, Amirkola, Children's Hospital Decedent
Shafi'zadeh Amirkola

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vic Chancellor for research, Shahid Beheshti
University Of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Arabi Avenue, Velenjak, Shahid Beheshti
University of medical Science

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vic Chancellor for research, Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Lida Nick Freed

Position

Assistant Professor of Nursing Department

Other areas of specialty/work**Street address**

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Nehzat Shakeri

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Assistant Professor of Statistics Department

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Fax**Email****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