

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluating the effectiveness of Creating Opportunities for Parent Empowerment (COPE) program on coping mechanism and mother-preterm infants bonding hospitalized in NICUs.

Protocol summary

Summary

Premature infants compared to natural ones experience several problems, so it is inevitable to hospitalize them in Neonate' Intensive Care Unit (NICU). After, hospitalizing the infants, mothers suffer a high degree of stress. On one hand, inefficient coping leads to a disordered infant-mother attachment. Therefore, supportive programs are needed to support these mothers during the period of hospitalization. This study was implemented in form of a randomized experimental design over 70 mothers with premature infants in Ommolbanin hospital, Mashhad, Iran. In order to avoid exchanging information between the two groups, first, control group was randomly assigned. Having selected the sample, sample selection was stopped for three weeks till mothers participating in the study were discharged from the hospital. Then participants for experimental group were selected. Criteria for enrollment in the study: Age over 18 years, the ability to read and write, babies who were less than 37 weeks of gestational age, or weighed less than 2500 grams. Criteria for discharging: Infant discharging before the program completion, mothers' dissatisfaction to continue. Treatment included four stages: Stage 1: 2 to 4 days after infant hospitalization Stage2: 2 to 4 days after the first stage Stage3: 1 to 3 days before discharging Stage 4: 1 week after discharging In every stage, in the absence of the researcher, the mother listened to an audio file containing information regarding that stage, for 15 minutes. At the same time this information was provided for the mother in the form of a booklet to use during the time of listening. Also, there was a workbook related to that stage at the end of every booklet and mother was required to complete. The completed version was provided for the research.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101519545N1**

Registration date: **2014-11-23, 1393/09/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-23, 1393/09/02

Registrant information

Name

Azam Momenizadeh

Name of organization / entity

Mashhad University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2014-05-06, 1393/02/16

Expected recruitment end date

2014-10-05, 1393/07/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of Creating Opportunities for Parent Empowerment (COPE) program on coping mechanism and mother-preterm infants bonding hospitalized in NICUs.

Public title

Evaluating the effectiveness of Creating Opportunities for Parent Empowerment (COPE) program on coping mechanism and mother-preterm infants bonding

Purpose

Supportive

Inclusion/Exclusion criteria

All mothers older than 18 years of age and who could read and speak Persian; who had not had another infant admitted to the NICU; who According to information obtained from the medical records had not had any; physical illness disrupts daily activities and specific medical problems associated with delivery of as well as mental illness; neurological problems that lead to drug use is clearly. and whose infants met the following criteria were eligible for participation: gestational age of under 37 weeks inclusive; birth weight of less than 2500 grams; no problem is life threatening ; anticipated survival; and There is no physical abnormalities ; Exclusion criteria, mothers whose infants discharged from hospital before the program ends and mothers whose neonate died and. Mother's unwillingness to cooperation

AgeTo **37 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **70****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Parental Empowerment Program (COPE) a educational-behavioural intervention based on the theory of self-regulation and Control is designed by Melyk, in 2001 for parents parents of premature infants

Secondary Ids

empty

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

Vice Chancellor for Research, Mashhad University of Medical Sciences

Street address

Research Assistance, Building Qureshi, Daneshgah Street, Doctora Crossroads, Mashhad

City

Mashhad

Postal code

3316-913791

Approval date

2014-04-29, 1393/02/09

Ethics committee reference number

research/922086/1/827

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**

Coping Strategies with Stress

Timepoint

2 to 4 day after infant hospitalization and 1 days before discharging Stage

Method of measurement

Brief COPE Questionnaire

Secondary outcomes**1****Description**

lenght of stay

Timepoint

The wole of hospitalization from admission day until discharge

Method of measurement

The wole of hospitalization from admission day until discharge

2**Description**

Rate of readmission

Timepoint

One month after discharge from hospital

Method of measurement

Call contact after discharge from hospital

3

Description

Mother-infant bonding

Timepoint

1 days before discharging

Method of measurement

Questionnaire Avant

Intervention groups

1

Description

Treatment included four stages: Stage 1: 2 to 4 days after infant hospitalization Stage2: 2 to 4 days after the first stage Stage3: 1 to 3 days before discharging Stage 4: 1 week after discharging In every stage, in the absence of the researcher, the mother listened to an audio file containing information regarding that stage, for 15 minutes. At the same time this information was provided for the mother in the form of a booklet to use during the time of listening. Also, there was a workbook related to that stage at the end of every booklet and mother was required to complete. The completed version was provided for the research.

Category

Behavior

2

Description

In the control group, the intervention not be; 2_4 day after admitted after infant brife cope questionnaire completed by the mother ; then baby's mother attachment 1 day before discharge by; researchers help blind study assessed ; coping strategies questionnaire was also being used by mother completed

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ommolbanin hospital

Full name of responsible person

Soheila Karbandi

Street address

Ayatollah Behjat Avenue, Ayatollah Behjat 16th, Mashhad-Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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Research Assistance, Building Qureshi, Daneshgah Street, Doctora Crossroads, Mashhad

City

Mashhad

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, 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

AZAM Momenizadeh

Position

MSc in Nursing, Neonatal Intensive Care

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