

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluating the effectiveness of Creating Opportunities for Parent Empowerment (COPE) program on psychological outcomes and participation of mothers who have preterm infants hospitalized in NICUs.

Protocol summary

Summary

The purpose of this study was to evaluate the effectiveness of Creating Opportunities for Parent Empowerment (C.O.P.E) program on psychological outcomes and participation of mothers who have preterm infants. Method: Randomized, single blind controlled without placebo, in more than one centre in a city, phase 2-3 trial. Main inclusion criteria: older than 18 years of age, ability to read and speak Persian, infants with: gestational age of 26 to 34 weeks, birth weight of less than 2500 grams, singleton birth, no severe handicapping conditions. Main exclusion criteria: mothers who left the program and did not come back to hospital for more than 4 days. Sample size: 90 mothers Intervention, time and primary outcomes: First phase was hold 2-4 days and second phase 4-8 days after NICU admission. Before every intervention phase, assessments tools were completed and the last evaluation was done 6-12 days post NICU admission. In each session mothers listened to 15 minutes audiotaped information, about preterm infant and they could use this information in written form too. Then mothers answered to 10 post test questions. Finally, mothers were asked to complete each phase's workbooks until the next session. Anxiety and stress were assessed three times and participation assessment was done just one time.

General information

Acronym

C.O.P.E

IRCT registration information

IRCT registration number: **IRCT138904214358N1**

Registration date: **2009-09-19, 1388/06/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-09-19, 1388/06/28

Registrant information

Name

Soheila Jafari Mianaei

Name of organization / entity

Shaheed Beheshti Medical University

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2516

Email address

soh_jafari@yahoo.com

Recruitment status

Recruitment complete

Funding source

vice-chancellor for research shaheed beheshti medical university

Expected recruitment start date

2009-09-19, 1388/06/28

Expected recruitment end date

2010-02-19, 1388/11/30

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 psychological outcomes and participation of mothers who have preterm infants hospitalized in NICUs.

Public title

Effectiveness the "Creating Opportunities for Parent Empowerment" program on psychological outcomes and participation of mothers who have preterm infants hospitalized in NICUs.

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 had not had any medical problems related to delivery or sickness, who had not had psychiatric disease and whose infants met the following criteria were eligible for participation: (a) gestational age of 26 to 34 weeks inclusive, (b) birth weight of less than 2500 grams, (c) anticipated survival, (d) singleton birth, (e) no severe handicapping conditions, and (f) born at the study sites. Exclusion criteria: mothers who left the program and didn't come back to hospital for more than 4 days, mothers whose neonate died and mothers whose infants discharged from hospital before the program ends.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

First phase was hold 2-4 days and second phase 4-8 days after NICU admission. Evaluations performed before each phase and 2-4 days after second phase. Control group just used routine NICU's cares.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shaheed Beheshti Medical University

Street address

Tehran, velenjak

City

Tehran

Postal code

Approval date

2010-04-18, 1389/01/29

Ethics committee reference number

88-01-86-6791-1

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

Z63.7

ICD-10 code description

Other stressful life events affecting family and household

2

Description of health condition studied

Stress

ICD-10 code

Z75.8

ICD-10 code description

Other problems related to medical facilities and other health care

3

Description of health condition studied

Participation

ICD-10 code

Z76.3

ICD-10 code description

Healthy person accompanying sick person

Primary outcomes

1

Description

anxiety

Timepoint

2-4 days after infant hospitalization, 2-4 days after first phase, 2-4 days after second phase

Method of measurement

State-Trait Anxiety Inventory

2

Description

stress

Timepoint

2-4 days after infant hospitalization, 2-4 days after first phase, 2-4 days after second phase

Method of measurement

Parental Stressor Scale: Neonatal Intensive Care Unit

3

Description

participation

Timepoint

2-4 days after second phase

Method of measurement

The Index of Participation/Hospitalized Infant

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention had two phases; First phase was hold 2-4 days and second phase 4-8 days after NICU admission. In each session mothers listened to 15 minutes audiotaped information about preterm infant and they could use this information in written form. For the purpose of the evaluation of the education, mothers answered 10 post test questions. Finally mothers were asked to complete each phases work books.

Category

Behavior

2**Description**

Control group just used routine NICU's cares

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shaheed Beheshti hospital

Full name of responsible person

Ms Rezvan

Street address

Shaheed Motahari street

City

Isfahan

2**Recruitment center****Name of recruitment center**

Al Zahra hospital

Full name of responsible person

Ms Sheikh zadeh

Street address

Hakim nezami

City

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice-chancellor for research Shaheed Beheshti Medical University

Full name of responsible person

Vice-Chancellor for research

Street address

Velenjak

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 Shaheed Beheshti Medical University

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**

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Full name of responsible person

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Position

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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