

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of “Creating Opportunities for Parents Empowerment” family-centered early intervention program on premature infants and their parents’ occupational performance according to Person-Environment-Occupation Model

Protocol summary

Summary

This is a double-blind clinical trial in which the premature infants and their parents’ occupational performance will be studied. Inclusion criteria for mothers: fluency in Persian; over 18 years of age; residing in Tehran; had not had another premature infant admitted to the NICU; lack of physical and mental chronic diseases. Inclusion criteria for infants: gestational age of 28 to 37 weeks; birth weight of 1000 to 2500 grams; no chromosomal abnormalities; no severe handicapping conditions; singleton birth; apgar score at 5 minutes more than 7; length of hospitalization be more than one week and less than one month. Exclusion criteria: infant and parents suffering from incurable diseases during the study; discharge before finishing defined protocol in NICU; lack of parental consent to continue participation at any stage and for any reason. Three groups of 20 preterm infants and their parents will participate in this study (control group, intervention group, intervention group with supervision). The 5 steps program of "Creating opportunities for parent empowerment" deliver for two intervention groups from infant hospitalization in the neonatal intensive care unit up to 2 months corrected age. The full implementation of the different stages of intervention will follow in intervention group with supervision during the study. At the end of study, effectiveness of this parental training program on infant occupational performance (motor performance, different aspect of infant development) and parents’ performance (participation in caring of infant, satisfaction of parental role) will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040521613N1**

Registration date: **2015-04-10, 1394/01/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-04-10, 1394/01/21

Registrant information

Name

Reihaneh Askary Kachoosangy

Name of organization / entity

Rehabilitation Sciences faculty, Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-05-05, 1394/02/15

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of “Creating Opportunities for Parents Empowerment” family-centered early intervention program on premature infants and their parents’ occupational performance according to Person-Environment-Occupation Model

Public title

Effect of parent training on premature infants and their parents' performance

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria for mothers: ability to read, write, and speak Persian; over 18 years of age; residing in Tehran; had not had another premature infant admitted to the NICU; lack of physical and mental chronic diseases. Inclusion criteria for infants: gestational age of 28 to 37 weeks; birth weight of 1000 to 2500 grams; no chromosomal abnormalities; no severe handicapping conditions including intraventricular hemorrhage; singleton birth; apgar score at 5 minutes more than 7; no congenital abnormalities; no stage 3 and more of retinopathy of prematurity; length of hospitalization be more than one week and less than one month; informed parental consent. Exclusion criteria: infant suffering from incurable diseases during the study; parent suffering from physical and mental diseases; discharge before finishing defined protocol in NICU; lack of parental consent to continue participation at any stage and for any reason

Age

To **2 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat highway , Tehran, Iran.

City

Tehran

Postal code

Approval date

2015-02-14, 1393/11/25

Ethics committee reference number

105/5536/93/3

Health conditions studied

1

Description of health condition studied

preterm infants

ICD-10 code

P07.3

ICD-10 code description

Other preterm infants

Primary outcomes

1

Description

parents' satisfaction

Timepoint

after intervention

Method of measurement

COPM

2

Description

motor performance of infant

Timepoint

before and after intervention

Method of measurement

New Ballard and TIMP

3

Description

parents' participation in infant caring

Timepoint

before and after intervention

Method of measurement

The Index of Participation/Hospitalized Infant

Secondary outcomes

empty

Intervention groups

1

Description

Control group: will receive routine interventions of hospital
Category
Other

2

Description

Intervention group: Parents empowerment program will be expressed for each mother about 20 minutes by direct and face to face training by considering number of mothers. At the end of session, about 15 minutes will be considered for question and answer. Training package consist of booklet, work book with pictures, and audio tape that will be given parents at the certain times.

Category

Other

3

Description

Intervention group with supervision: In addition to parents empowerment program will be followed regular by the researcher

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh hospital

Full name of responsible person

Reihaneh Askary Kachooosangy

Street address

Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Narges Shafaroodi

Street address

Occupational therapy department, Rehabilitation Sciences faculty, Iran University of Medical Sciences, Shahnazari St, Mirdamad, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr. Narges Shafaroodi

Position

faculty member

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr. Nargess Shafaroodi

Position**Other areas of specialty/work****Street address****City****Postal code****Phone**

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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