

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The Effect of Parental Education Emphasizing the Parental Role on the Stress of Parents with an Infant Admitted to Neonatal Intensive Care Units

Protocol summary

Summary

The main objectives: 1- To determine and compare the stress level of parents in the intervention and control groups on the 3rd day after the admission of the premature infant to the neonatal intensive care unit. 2- To determine and compare the stress level of parents in the intervention and control groups on the 10th day after the admission of the premature infant to the neonatal intensive care unit. 3- To determine and compare the stress level of the intervention group on the 3rd and 10th day after the admission of the premature infant to the neonatal intensive care unit. 4-To determine and compare the stress level of the control group on the 3rd and 10th day after the admission of the premature infant to the neonatal intensive care unit. Design: A single-blind study Methods: Samples are selected in the control and intervention groups. The stress level is compared in both groups after the intervention, which is training. The control group receives the routine clinical care. Inclusion criteria: Literacy, no history of stressful experiences such as divorce, no history of infants' hospitalization in a neonatal intensive care unit, no history of psychiatric medication, no history of drug abuse. Exclusion criteria: Babies who die for any reason or are discharged earlier than 10 days and infants whose parents are not willing to continue cooperating with the researchers. Intervention: Training happens in the intervention group specifically for both parents with a greater emphasis on their parental roles. The main outcome variable: The main variable in this project is parental stress which the researcher is trying to reduce through training them and strengthening their parental role.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201605131788N17**

Registration date: **2016-11-15, 1395/08/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-15, 1395/08/25

Registrant information

Name

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Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, iran University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Parental Education Emphasizing the Parental Role on the Stress of Parents with an Infant Admitted to Neonatal Intensive Care Units

Public title

The Effect of Parental Education on the Stress of Parents with an Infant Admitted to Neonatal Intensive Care Units

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria of the study are as follows: Literacy; having no stressful experience, such as divorce, death of relatives, and so forth in the previous three months; having no history of admitting the infant to NICU; having no history of using psychiatric medications; . Exclusion criteria: infants who died from any cause " babies who were discharged earlier than ten day: infants whose parents do not demonstrate a willingness to continue to cooperate with the investigator.

Age

From **17 years** old to **34 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In the research training of parents as dedicated to each family. Group training is not considered. For training needs analysis in the first fathers of FSS tool has been used.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Iran University of Medical Sciences

Street address

Sidet to the martyr Motahhari Hospital St. martyr Yassami , Vali Asr Ave. City *

City

Tehran

Postal code

1996713883

Approval date

2016-01-06, 1394/10/16

Ethics committee reference number

IR.IUMS.REC.1394.9311451005

Health conditions studied

1

Description of health condition studied

Stress

ICD-10 code

f43.1

ICD-10 code description

Arises as a delayed or protracted response to a stressful event or situation (of either brief or long duration) of an exceptionally threatening or catastrophic nature, which is likely to cause pervasive distress in almost anyone. Predisposing factors, suc

Primary outcomes

1

Description

Stress

Timepoint

The first baby dresses for measuring parental stress is the third day of the second measure is the tenth day hospital stay

Method of measurement

Pss standard tools to help measure the amount of stress that it is done is done validity reliability .

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: from the beginning of July eligible for inclusion in the study 36 parents were selected to participate in the intervention group The full explanation of the study was to parents, then their written consent to participate in the project was completed. On the third day of hospitalization of children in the questionnaire (PSS: NICU) was completed by both parents. The distance between the third and tenth days of hospitalization in infants in the two sessions of face to face training class was held for two hours. This class includes training parents in cases where the stress was more on them. The issues that parents need to know to keep your baby . Finally, a practical class meeting was held with the replica or the baby to bug fixed. The distance between the third and tenth days of hospitalization in infants in a special section for parents by telephone, telegram and email were in contact with the researche.

Category
Behavior

2

Description

Control group : 36 parents for a month and a half has Inclusion criteria were selected for the control group. Authorities first full explanation of the study parents were simple language. After written consent was signed by parents participating in the study, On the third day in the intensive care unit NICU parents were enrolled. In these days of stress questionnaire (PSS: NICU) was completed by them. Then, without intervention and only doing routine infant hospitalized again on the tenth day of this questionnaire (PSS: NICU) was completed.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
AliAsghar hospital
Full name of responsible person
Rabeeh Ghavami
Street address
Street Vahid Dastgerdi, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research and Technology, Iran University of Medical Sciences
Full name of responsible person
Dr Seyed Ali Javad Moosavi
Street address
Besides Milad Tower, Hemmat Highway, Vice Chancellor for Research and Technology
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 and Technology, 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
School of Nursing and Midwifery , Iran University of Medical Sciences
Full name of responsible person
Dr. Leili Borimnejad
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Person responsible for scientific inquiries

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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