

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effects of family-based intervention on stress and coping mechanisms (coping) neonates admitted to the neonatal intensive care unit (NICU).

Protocol summary

Summary

The aim of the study: The effect of family-centered intervention based on verbal communication and stress coping mechanisms (coping) neonates admitted to the neonatal intensive care unit Type of study: This study is a quasi-experimental study with two groups Research environment: Neonatal intensive care unit of a hospital affiliated with the Hamadan University of Medical Sciences Research community: All mothers of infants in the neonatal intensive care unit with age greater than 33 weeks Sampling: The availability and use of neonates admitted to the neonatal intensive care unit and is based on the inclusion criteria. Entry criteria: - Age over 18 years old. - Member of the healthcare team may not. - Top 33 week old baby. Exclusion criteria: Unwillingness to participate in research or tired mother or infant death Sample size: Test and control groups of 50 each. The intervention: Intervention Family-based intervention based on verbal communication with mothers of infants admitted to the NICU nurses in the study and control groups will perform. This form of communication and education to mothers in the intervention groups with mothers who will take delivery of the package (within 4 days). The control group will support the routine. On the fourth day of the questionnaire is completed parenting stress and coping mechanisms (in both groups) and the results of the questionnaires in both groups compared.

General information

Acronym

NICU(neonatal intensive care unit)

IRCT registration information

IRCT registration number: **IRCT201104276316N1**

Registration date: **2015-03-07, 1393/12/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-03-07, 1393/12/16

Registrant information

Name

Zahra Daneshvar Ameri

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-02-08, 1393/11/19

Expected recruitment end date

2015-03-01, 1393/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of family-based intervention on stress and coping mechanisms (coping) neonates admitted to the neonatal intensive care unit (NICU).

Public title

Effects of family-based intervention on stress and coping mechanisms (coping) neonates admitted to the neonatal intensive care unit (NICU).

Purpose

Supportive

Inclusion/Exclusion criteria

Mothers inclusion criteria included the following: 1- Willingness to cooperate. 2- 24 to 48 hours after admission to the baby arrives. 3- Maternal age over 18 years old. 4- The absence of stressful events during the intervention in the family, including children who have a serious illness. 5- No truce with husband. 6- Able to read and write Persian. 7- Member of the healthcare team may not. 8- Avoid the use of anti-anxiety medication. 9- Types of drug addiction is not. 10- Children age greater than 33 weeks. 11- Absence of congenital anomalies of the nervous system disease in infants. Mothers Exclusion criterion: 1- Unwillingness to participate in research or tired mother or infant death.

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

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

Tehran University of Medical Sciences, School of Nursing and Midwifery

Street address

Tehran - tohid Square

City

tehran

Postal code

Approval date

2015-01-21, 1393/11/01

Ethics committee reference number

9011451008-1

Health conditions studied

1

Description of health condition studied

Stress and coping mechanisms

ICD-10 code

F40- 48

ICD-10 code description

Neurotic, stress-related and somatoform disorders

Primary outcomes

1

Description

Coping Mechanisms

Timepoint

On the first and fourth

Method of measurement

Lazarus and Folkman's coping mechanisms questionnaire

2

Description

stress

Timepoint

On the first and fourth days

Method of measurement

Parental Stress Inventory doctor Miles

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Written consent signed by the mother and demographic data sheet ,parental stress questionnaire and coping mechanisms questionnaire on the first day and again on the fourth day will be completed .

Category

Behavior

2

Description

Group test: Mothers after signing informed consent, demographic data sheet, Parental Stress Inventory questionnaire completed adaptation mechanisms and more about the environment, laws, contact phone numbers and information necessary to receive primary and a complete package including all the things that might be controversial for mothers question (the physical space, the physician or physicians baby, named for the section, the baby care, baby pipes connected to the equipment, meeting times, how breastfeeding baby, hold the baby, etc.) are delivered. In the second and third days, the hours designated by the mothers regularly, at least twice a day for half an hour each time and information to meet the psychological needs of mothers will be discussed. On the fourth day, questionnaires

completed by mothers of stress and coping mechanisms.

Category

Behavior

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

Hamadan University of Medical Sciences

Full name of responsible person

Tahereh Sattari

Street address

Hamadan - Fatemiyeh Hospital & Beasat Hospital

City

Hamadan

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

Tehran University of Medical Sciences-Research Administration

Full name of responsible person

Dr. Taghizadeh

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Tehran - Faculty of Nursing and Midwifery

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Tehran

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

Yes

Title of funding source

Tehran University of Medical Sciences-Research Administration

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, Tehran University of Medical Sciences

Full name of responsible person

Zahra Daneshvar Ameri

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Faculty member

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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