

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of home care follow-up program on premature newborns who receive NIDCAP, on mother's anxiety and stress and neonate's Physical growth parameters

Protocol summary

Study aim

Determining The effect of home care follow-up program on premature newborns who receive NIDCAP, on mothers' anxiety and stress and neonates' Physical growth parameters

Design

Randomised, parallel group trial with blinded outcome assessment

Settings and conduct

To reduce the bias, control group data will first be collected. The mothers of the control group will receive regular care trainings during the hospital stay. After discharge the control group In the intervention group, Assessment Program NIDCAP is done by the researcher on the first day of the baby's birth, then every week and after the sustained condition of the newborn, every two weeks until the discharge is done. Its feedback is prepared by a person with an international certificate of NIDCAP and will be provided to the mothers. After one week after the discharge of the baby, the amount of anxiety and stress of the mother and growth parameters of the baby will be assessed. Re-assessment of NIDCAP will be done at home by a physician and a nurse and its developmental feedback will be provided to the mother. after one week, assessment of NIDCAP will be done at home by a nurse.

Participants/Inclusion and exclusion criteria

Mother Lack of known mental disorders in mothers. living in Mashhad. do not have any important or serious problem. did not experience any preterm infant birth. The baby's age is between 26-32 weeks. non anomaly and intracranial hemorrhage 3 and 4 and CLD.

Intervention groups

The study population includes mothers and their premature newborns admitted to the NICU of Omol-Banin Hospital of Mashhad

Main outcome variables

anxiety and stress-For mothers of the two groups, an Initial Spielberger Anxiety and Cohen Stress Questionnaire are completed. After the intervention, the Spielberger and Cohen Stress Anxiety Inventory was completed on the day of discharge and 2 months after discharge in two groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180127038529N1**

Registration date: **2018-05-30, 1397/03/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-30, 1397/03/09**

Update count: **0**

Registration date

2018-05-30, 1397/03/09

Registrant information

Name

Malihe Khoshahang

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3223 1065

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-08-23, 1397/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of home care follow-up program on premature newborns who receive NIDCAP, on mother's anxiety and stress and neonate's Physical growth parameters

Public title
The effect of NIDCAP program on mother's anxiety and stress

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Mother consented to join to the program
Lack of known mental disorders in mothers
Mother is living in Mashhad
Mother is not addicted to drugs based on self-declaration
Mother do not have any important or serious problem
Mother did not have any twin or multiparty delivery
Mother did not experience any preterm infant birth
The baby's age is between 26-32 weeks
Exclusion criteria:
Usage of anti-anxiety drug by mother
Diagnosis of abnormalities in the baby

Age
From **6 months** old to **8 months** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be done in an accessible manner with simple random assignment

Blinding (investigator's opinion)
Double blinded

Blinding description
The intervention and control groups of mothers with preterm infants aged 32-26 who are blind to the purpose of the intervention. Data analysis is also conducted by the unacquainted person in the intervention and control group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Imam Khomeini St., Gonabad

City

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Province

Razavi Khorasan

Postal code

9144734767

Approval date

2018-01-10, 1396/10/20

Ethics committee reference number

IR.GMU.REC.1396.107

Health conditions studied

1

Description of health condition studied

mother's anxiety and stress and neonate's Physical growth parameters

ICD-10 code

F53.0

ICD-10 code description

Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

Primary outcomes

1

Description

Anxiety in mothers of premature infants

Timepoint

Determine mother's anxiety at beginning of study and after execution of the NIDCAP (the day of discharge of baby, before home care and at the end of 2-month period after discharge)

Method of measurement

Spielberger scale

2

Description

Stress in mothers of premature infants

Timepoint

Determine mother's stress at beginning of study and after execution of the NIDCAP (the day of discharge of baby, before home care and at the end of 2-month period after discharge)

Method of measurement

Cohen Perceived Stress Scale

3**Description**

neonant's Physical growth parameters (such as weight, height, Head circumference, Chest circumference)

Timepoint

Determine neonant's Physical growth parameters at beginning of study and after execution of the NIDCAP (the day of discharge of baby, before home care and at the end of 2-month period after discharge)

Method of measurement

Meters and Weight Scales

Secondary outcomes

empty

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

Intervention group: includes the implementation the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) in accordance to the standards of this care program is done by the researcher on the first day of the baby's birth, and then every week and after the sustained condition of the newborn, every two weeks until the discharge is done. Its feedback is prepared by a person with an international certificate of NIDCAP and will be provided to the mothers. After one week after the discharge of the baby, the amount of anxiety and stress of the mother and growth parameters of the baby will be assessed and recorded. Re-assessment of NIDCAP will be done at home by a physician and a nurse and its developmental feedback will be provided to the mother. Then, after one week, assessment of NIDCAP will be done at home by a nurse and necessary trainings will be provided to the mother.

Category

Prevention

2**Description**

Control group: In the control group received routine care

Category

Prevention

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

Om-o-Ibanin Hospital

Full name of responsible person

Malihe Khoshahang

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Om-o-Ibanin Hospital, Behjat 16th , Behjat St., Kamyab Blvd.

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

Gonabad University of Medical Sciences

Full name of responsible person

Ali Sajadi

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

Yes

Title of funding source

Gonabad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Malihe KHoshahang

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Om-o-Ibanin Hospital, Behjat 16th , Behjat St.,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Faculty Member of Gonabad University of Medical
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Ph.D.

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available