

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of teaching attachment behaviors to mothers on the short-term health consequences of premature infants in NICUs.

Protocol summary

Study aim

Determining the effect of attachment behavior training to mothers on short-term health outcomes of preterm infants in neonatal intensive care units

Design

A clinical trial with a blind, randomized, one-way control group, including 80 randomly assigned to two groups

Settings and conduct

The setting of research is Amirkola Children's Hospitals and the Ayatollah Rouhani Hospital in Babol. After obtaining the necessary permissions and obtaining the approval of the Ethics Committee, The researcher explains the goals of the study to the mothers who entered the study. Then, randomly, the eligible subjects in the study are assigned to intervention and control groups. Before the intervention, At first meeting with mothers in the first 48 hours, the checklist for attachment behavior is completed by the researcher's assistance. For intervention group, attachment behaviors are taught by the researcher and the control group receives routine caregivers. Maternal attachment behaviors are re-examined at the time of discharge and the results are analyzed statistically

Participants/Inclusion and exclusion criteria

Mothers with premature infants admitted to Amirkola and Ayatollah Rouhani Children's Hospitals

Intervention groups

The intervention group is a group in which mothers' attachment behaviors are taught. The control group receives routine care

Main outcome variables

Mother's attachment behaviors; Duration of full oral feeding in both groups; Duration of admission

General information

Reason for update

Acronym

neonatal intensive care unit : NICU

IRCT registration information

IRCT registration number: **IRCT20180718040513N1**

Registration date: **2018-12-25, 1397/10/04**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-25, 1397/10/04**

Update count: **0**

Registration date

2018-12-25, 1397/10/04

Registrant information

Name

Mojtaba Qanbari qalesari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 9592

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mojtaba.ghanbari@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of teaching attachment behaviors to mothers on the short-term health consequences of premature infants in NICUs.

Public title

effect of maternal attachment behaviors on the health of premature infants

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Mothers who able to read and write Neonates with birth weight< 1500 neonates with apgar scor>7

Exclusion criteria:

Mothers who are physical and mental ill the prohibition on mothers breastfeeding Mothers addiction to drugs and alcohol neonates with congenital anomalies

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Each of the maternal infants who enter the study is randomly assigned a number, these numbers are randomly distributed among the questionnaires and the units are assigned to the intervention and control groups based on the number received

Blinding (investigator's opinion)

Single blinded

Blinding description

Mothers do not notice the presence of evaluators, and the checklist for the groups is encrypted with a code and the evaluator is blind to the groups. The data analysis is performed by a statistician who has no information about the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National Research Ethics Committee

Street address

Mazandaran, Babol, Babol University of Medical

Sciences, Health Research Cente

City

Babol

Province

Mazandaran

Postal code

۴۱۳۶۷-۴۷۱۷۶

Approval date

2018-08-05, 1397/05/14

Ethics committee reference number

ir.mubabol.hri.rec.1397.113

Health conditions studied**1****Description of health condition studied**

Mother and neonate attachment

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Duration of full oral feeding in both groups;

Timepoint

From admission to full oral feeding

Method of measurement

From the beginning of the first oral feeding of the neonate, according to the physician's order, until the neonate is able to fully nourish it (feeding without gavage)

2**Description**

neonate weight

Timepoint

at the time of admission and discharge

Method of measurement

using the standard digital weighing scale

3**Description**

duration of admission

Timepoint

from admission until discharge

Method of measurement

Calculate the number of days the newborn is admitted to the hospital, from the time of admission to the date of the doctor's order for the discharge of the baby

Secondary outcomes**1****Description**

Mother's attachment

Timepoint

At the time of admission and discharge
Method of measurement
Avant attachment behavior scale

Intervention groups

1

Description

Intervention group: Attachment behaviors are taught to mothers of the intervention group, Maximum 48 hours after admission for 4 sessions, once a day and each session 20 -30 minute, face to face and on the neonate bedside. the content of education are Familiarity with neonatal care environment and equipment for the newborn, appearance and behavioral characteristics of premature neonates and behaviors related to attachment (emotional, Neighborhood, Care)

Category

Behavior

2

Description

Control group: routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Amircola Child Hosital and Ayatolla rouhani Hosital

Full name of responsible person

Afsaneh Arzani

Street address

Faculty of Nursing&Medwifery,Babol University of Medical Sciences, Babol, Iran

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a.arzani@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

Deputy of research and technology, Babol university of medical sciences, Babol, Iran

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Email

rezaghadimi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Mojtaba Qanbari qalesari

Position

Assistant rofessor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The demographic characteristics of the samples, such as age, level of education, etc., Also information on the main outcome of the study are published in the form of a dissertation

When the data will become available and for how long

Immediately after publishing the results in dissertation form

To whom data/document is available

Data is accessible to the general public

Under which criteria data/document could be used

Data is accessible to the general public. The application is submitted electronically only by email: m2ghanbari@yahoo.com

From where data/document is obtainable

E.Mail: m2ghanbari@yahoo.com; arzanaf@gmail.com
nursing and midwifery faculty, Babol University of Medical Sciences

What processes are involved for a request to access data/document

The applicant will be provided electronically about a month after submitting the application

Comments

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mojtaba Qanbari qalesari

Position

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Latest degree

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