

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Investigating the effect of maternal support through telenursing on maternal attachment and quality of life in premature infants under invasive ventilation

Protocol summary

Improving the quality of life and attachment in mothers of babies under invasive ventilation

Study aim

Determining and comparing the effect of maternal support through telenursing on maternal attachment and quality of life in premature infants under invasive ventilation in control and intervention groups.

Design

The clinical trial has two control and intervention groups, the sampling method is accessible and simple random, without blinding, on 40 premature babies

Settings and conduct

The research will be conducted with the participation of 40 mothers of premature babies between 26 and 34 weeks who were under ventilator in Qaim and Imam Reza Hospital of Mashhad. Mothers enter the study on the day of discharge, mothers in the intervention group receive the telenursing program for 4 weeks. Mothers in the control group will receive routine care. Data collection will be done on day 0 and day 30 after discharge, which includes attachment and quality of life questionnaires and scoring based on the mother's answers.

Participants/Inclusion and exclusion criteria

Entry criteria: mother's age between 18 and 35 years, mother's ability and access to a telephone, having a premature baby between 26 and 34 weeks who is ventilated for more than three days, discharge order. Exclusion criteria: the baby has an anomaly, the baby has a history of surgery, the baby's mother is addict, the baby is under invasive ventilation.

Intervention groups

Intervention group: mothers of preterm infants undergoing invasive ventilation with inclusion criteria who receive the intervention of telenursing support over the phone. Control group: mothers of invasively ventilated preterm infants with inclusion criteria receiving routine care

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230708058717N1**

Registration date: **2023-12-17, 1402/09/26**

Registration timing: **prospective**

Last update: **2023-12-17, 1402/09/26**

Update count: **0**

Registration date

2023-12-17, 1402/09/26

Registrant information

Name

mahsa hesari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-12-21, 1403/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of maternal support through telenursing on maternal attachment and quality of life in premature infants under invasive ventilation

Public title
Investigating the effect of maternal support through telenursing on maternal attachment and quality of life in premature infants under invasive ventilation

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Mother's age between 18 and 35 years Firstborn Mother with no known psychiatric illness The mother's ability and access to a landline or mobile phone Having premature babies between 26 and 34 weeks who have been ventilated for more than three days discharge order
Exclusion criteria:
Mother's unwillingness to cooperate in the study
Mother's addiction Having a history of surgery in a baby
A newborn without obvious congenital anomalies

Age
From **182 days** old to **238 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
The random block method with a block size of 4 will be used considering that the final sample size is 20 people in each group and a total of 40 people considering the dropout rate. The start of the study will be provided to the researcher.

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

School of Nursing and Midwifery - Mashhad University of Medical Sciences

Street address

Azadi Square, Ferdowsi University, Khorazmi Building

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Mashhad

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Razavi Khorasan

Postal code

9117941974

Approval date

2023-11-16, 1402/08/25

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.100

Health conditions studied

1

Description of health condition studied

Special conditions that occur in the perinatal period. Including the birth of a baby before the 37th week of intrauterine pregnancy.

ICD-10 code

O60

ICD-10 code description

Preterm labor

Primary outcomes

1

Description

Maternal attachment score in preterm infants with aggressive ventilation

Timepoint

Day zero and thirty after discharge

Method of measurement

Attachment questionnaire

Secondary outcomes

1

Description

Quality of life score in mothers with premature babies under invasive ventilation

Timepoint

On day zero and thirty after discharge

Method of measurement

Quality of life questionnaire

Intervention groups

1

Description

Intervention group: the mothers under study will enter the study on the day of discharge from the hospital, and a summary of the baby's file will be received for

planning. Mothers in the intervention group receive the telenursing program for 4 weeks. The telenursing program is implemented based on the documented care plan that includes two areas of baby care and mother care.

Category

Other

2**Description**

Control group: the mothers under study will enter the study on the day of discharge from the hospital and the summary of the baby's file will be received for planning. Mothers in the control group will receive routine care, i.e. education at the time of discharge.

Category

Other

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

Neonatal Special Care Department of Ghaem Hospital in Mashhad

Full name of responsible person

Mahsa Hesari

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Ghaem Hospital: Dr. Shariati Square

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2**Recruitment center****Name of recruitment center**

Neonatal Special Care Department of Imam Reza Hospital, Mashhad

Full name of responsible person

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Majid Ghayur

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Vakil Abad Blvd., Campus, Science Blvd

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Mahsa Hesari

Position

Nursing Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

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the coach

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available