Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 2026

Investigation of telenursing in readmission post of discharch in neonate intensive care unit in hospitals, Qazvin University of Medical sciences

Protocol summary

Study aim

The effect of telenursing on newborn readmission rate after discharge from NICU

Design

Randomized Controlled Clinical Trials

Settings and conduct

The research environment was the NICU units of selected hospitals of Qazvin University of Medical Sciences including Kowsar and Qods hospitals. In the intervention group, training was provided through telenursing every 6 days and in 5 stages. The control group only received the ordinary care. One month after the infant's being discharged from the hospital; both groups were surveyed regarding readmission through calling them. Data were collected using Mothers and Infants Demographic Characteristics Form and Mothers' Awareness Assessment checklist.

Participants/Inclusion and exclusion criteria

Mothers are included in the study who: 1. Their infant was admitted to one of the NICU units of the selected hospitals of Qazvin University of Medical Sciences for the first time. 2. They were willing to participate in this study. 3. They had no hearing or speech problems. 4- They spoke Persian (had Persian dialect). 5- Being Single baby Exclusion criteria: 1- Baby's death 2. Permanent transfer of the baby (transfer for more than one shift) to another center 3. No telephone access (more than 3 consecutive times)

Intervention groups

The sample size was 288 cases (144 in the intervention group and 144 in the control group). According to the number of beds in the NICU, 110 patients from Kowsar hospital and 34 from the Qods hospital were included in each of the intervention and control groups.

Main outcome variables

Number of newborn readmission

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161024030474N3**
Registration date: **2020-03-25, 1399/01/06**
Registration timing: **retrospective**

Last update: **2020-03-25, 1399/01/06**
Update count: **0**

Registration date

2020-03-25, 1399/01/06

Registrant information

Name

Azam Shirinabadi Farahani

Name of organization / entity

School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21886553668

Email address

farahani1381@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-09-22, 1394/06/31

Actual recruitment start date

2015-04-21, 1394/02/01

Actual recruitment end date

2015-09-22, 1394/06/31

Trial completion date

2015-09-22, 1394/06/31

Scientific title
Investigation of telenursing in readmission post of discharch in neonate intensive care unit in hospitals, Qazvin University of Medical sciences

Public title
The effect of telenursing on the rate of newborn readmission

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Mothers are included in the study: Their infants were first admitted to the neonatal intensive care unit of the selected hospitals of Qazvin University of Medical Sciences. They were willing to participate in this study. They had no hearing and speech problems They spoke Persian (had Persian dialect). Being single baby

Exclusion criteria:
Infant death Permanent transfer of infant (transfer for more than one shift) to another center No telephone access (more than 3 consecutive times)

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **288**
Actual sample size reached: **288**

Randomization (investigator's opinion)
Randomized

Randomization description
144 cases in the intervention group and 144 in the control group were randomly assigned. Thus, A cards indicated the intervention group and B cards indicated the control group. When the first preterm infant entered the intensive care unit in each of the two hospitals, one of the cards was randomly selected and the intervention or control group was identified. The mother of the next preterm infant was in a group other than her previous group. This work continued one by one until the sampling was completed and the expected sample size was reached.

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
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
School of Nursing and Midwifery, Next to Ayatollah Rafsanjani's crossroads,Valiasr Street,Tehran

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2015-09-28, 1394/07/06

Ethics committee reference number
SBMU2.REC.1394.105

Health conditions studied

1

Description of health condition studied
Newborn readmission

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Newborn Readmission

Timepoint
One month after discharge, mothers of both groups were contacted to determine if the infants had readmitted and to obtain information on the frequency of readmissions.

Method of measurement
Telephone call and questions from the mother about readmission

Secondary outcomes

empty

Intervention groups

1

Description
The mothers in the intervention group were contacted within 2-3 days after their infants' discharge, and then every 6 days and 5 times. Training material was presented during 5 sessions, as follows: 1-Breastfeeding techniques and diet. 2- Changing the infant's position, and its rest and sleep patterns. 3- Skin and perineal care.4- Medications, medicine complications.5- Dressing care (if any), infection control procedures, and the next

visit to the doctor’s. In each session, mothers were questioned on the material discussed during the previous session, first, and their level of awareness was examined by the “Mother’s Awareness Assessment Checklist”, which included 22 phrase on the infant’s general health at home. Then the mothers' questions were answered, and after the elimination of any ambiguity, training was done according to the educational package.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Qods Educational / Therapeutic Center

Full name of responsible person
Farzaneh Moghadam

Street address
Qods Educational / Therapeutic Center,Quds Square,Early East Palestine, Shahid Beheshti Boulevard,Qazvin

City
Qazvin

Province
Qazvin

Postal code
4595-1-34159

Phone
+98 28 3333 4808

Fax
+98 28 3334 4088

Email
hosghods@qums.ac.ir

Web page address
http://hosgods.qums.ac.ir

2

Recruitment center

Name of recruitment center
Kowsar Educational / Medical Center

Full name of responsible person
Farzaneh Moghadam

Street address
Kowsar Educational / Medical Center,Kowsar Alley ,Shahid Taleghani Street,Qazvin

City
Qazvin

Province
Qazvin

Postal code
13176- 34156

Phone
+98 28 3323 6374

Fax
+98 28 3323 6378

Email
hoskosar@qums.ac.ir

Web page address
http://hoskosar.qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Afshin Zarghi

Street address
Shahid Beheshti University of Medical Sciences - Next to Taleghani Hospital - Shahid Abbas Aerebi St. (Parvaneh) - Yemen Street - Shahid Chamran Highway-Tehran

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2243 9780

Fax
+98 21 2243 9780

Email
farahani1381@sbmu.ac.ir

Web page address
http://sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Azam Shirinabadi Farahani

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Shahid School of Nursing and Midwifery, Next to Ayatollah Rafsanjani's crossroads,Valiasr Street,Tehran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Fax
+98 21 8820 2518
Email
farahani1381@sbmu.ac.ir
Web page address
http://nm.sbmu.ac.ir/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Azam Shirinabadi Farahani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Next to Ayatollah Rafsanjani's crossroads,Valiasr Street,Tehran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Fax
Email
farahani1381@sbmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Azam Shirinabadi Farahani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Next to Ayatollah Rafsanjani's crossroads,Valiasr Street,Tehran
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1985717443
Phone
+98 21 8865 5366
Fax
+98 21 8820 2518
Email
farahani1381@sbmu.ac.ir
Web page address
http://nm.sbmu.ac.ir/

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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Information on the main outcome (Newborn Readmission) can be shared
When the data will become available and for how long
Immediately after the publication of the article
To whom data/document is available
Care providers for infants (Mothers-Nurses-Physicians)
Under which criteria data/document could be used
Just to reduce the newborn readmission
From where data/document is obtainable
farahani1381@sbmu.ac.ir
What processes are involved for a request to access data/document
About a month
Comments