

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Sep 2026

### Investigation of telenursing in readmission post of discharg 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, Qods 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

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###### Email

farahani1381@sbmu.ac.ir

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##### 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**

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## 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

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School of Nursing and Midwifery, Next to Ayatollah  
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1985717443

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+98 21 8865 5366

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**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**

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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**

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**