

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The Impact of Telenursing on level of Anxiety in Parents of Hospitalized Premature Neonates in Neonatal Intensive Care Unit

Protocol summary

Study aim

The Impact of Telenursing on level of Anxiety in Parents of Hospitalized Premature Neonates in Neonatal Intensive Care Unit

Design

A quasi-experimental study on Parents' Premature Neonates stay at Neonatal Intensive Care Unit

Settings and conduct

This before-after Quasi-experimental with control group study was conducted on the parents of hospitalized neonates in NICU of Mofid Children's Hospital affiliated to Shahid Beheshti University of Medical Sciences, Tehran, Iran. Sixty participants were selected through convenience sampling method. Thus 30 parents randomly were selected in each group. In the intervention group, totally five conversations were done during 15 days. The time duration of the conversations was 15 minutes. During these phone contacts, the researcher announced information to one of the parents about recent vital signs of the neonate's respiration, consciousness level, their sleeping rhythm, feeding, and whether or not physical attendance of the parents was necessary. The data were collected through self-report using the Beck Anxiety Inventory and socio-demographics questionnaire before the intervention and after each phone call for five, ten and fifteen days during the intervention. The results in the intervention group were compared with those of the control group.

Participants/Inclusion and exclusion criteria

Parents' Premature Neonates stay at Neonatal Intensive Care Unit; parents' Premature Neonates stay at Neonatal Intensive Care Unit with the surgical candidate

Intervention groups

Parents' Premature Neonates stay at Neonatal Intensive Care Unit

Main outcome variables

anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190617043912N1**

Registration date: **2019-07-16, 1398/04/25**

Registration timing: **retrospective**

Last update: **2019-07-16, 1398/04/25**

Update count: **0**

Registration date

2019-07-16, 1398/04/25

Registrant information

Name

saleheh tajalli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 2030

Email address

saleheh_tajalli@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-01-05, 1397/10/15

Actual recruitment start date

2018-09-23, 1397/07/01

Actual recruitment end date

2019-01-05, 1397/10/15

Trial completion date

2019-01-05, 1397/10/15

Scientific title

The Impact of Telenursing on level of Anxiety in Parents of Hospitalized Premature Neonates in Neonatal Intensive Care Unit		Postal code 19839-63113	
Public title The Impact of Telenursing on level of Anxiety in Parents of Hospitalized Premature Neonates in Neonatal Intensive Care Unit		Approval date 2015-11-15, 1394/08/24	
Purpose Supportive		Ethics committee reference number IR.SBMU.RAM.REC.1394.352	
Inclusion/Exclusion criteria Inclusion criteria: The parents' premature neonates that stay at NICU. Exclusion criteria: The parents' premature neonates with surgical disease		Health conditions studied	
Age From 15 years old to 50 years old		<u>1</u> Description of health condition studied Parents' anxiety after their premature neonate hospitalization	
Gender Both		ICD-10 code F06.4	
Phase N/A		ICD-10 code description Anxiety disorder due to known physiological condition	
Groups that have been masked <i>No information</i>		Primary outcomes	
Sample size Target sample size: 60 Actual sample size reached: 60		<u>1</u> Description Parents' anxiety after their premature neonate hospitalization	
Randomization (investigator's opinion) Randomized		Timepoint 5-10-15 days later.	
Randomization description A simple random sampling was done. so the parents with inclusion criteria to enter the study, and then without prior knowledge, the paired numbers were placed in the intervention group and odd numbers in the control group.		Method of measurement Beck Anxiety Inventory	
Blinding (investigator's opinion) Not blinded		Secondary outcomes	
Blinding description		<u>1</u> Description Parents' anxiety after their premature neonate hospitalization	
Placebo Not used		Timepoint 5-10-15 days after start of intervention.	
Assignment Parallel		Method of measurement Beck Anxiety Inventory	
Other design features		Intervention groups	
Secondary Ids empty		<u>1</u> Description Intervention group: The premature parents, were called each day at a certain hour and with specific phone numbers and specific content based on a standard protocol, gave them information about the conditions of feeding, respiration, sleep and pattern of output.	
Ethics committees		Category Rehabilitation	
<u>1</u> Ethics committee Name of ethics committee Ethics committee of Shahid Beheshti University of Medical Sciences Street address 7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran. City Tehran Province Tehran		<u>2</u> Description Control group: The premature parents, were gave routine care.	

Category

N/A

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

Mofid Children's Hospital affiliated to Shahid Beheshti University of Medical Sciences.

Full name of responsible person

Saleheh Tajalli

Street address

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Grant name

Vice-Chancellor of Research Affairs, Shahid Beheshti university of medical science

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

Yes

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

Saleheh Tajalli

Position

studrnt

Latest degree

Master

Other areas of specialty/work

Nursery

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

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Person responsible for updating data**Contact****Name of organization / entity**

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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)**

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

All of the data was gathered basis ob Beck, questioner.

When the data will become available and for how long

At the end of the study

To whom data/document is available

All of them have aimed secondary research.

Under which criteria data/document could be used

For secondary research.

From where data/document is obtainable

Mofid Children's Hospital affiliated to Shahid Beheshti
University of Medical Sciences-neonatal health research
center- miss saleheh tajalli

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

Requesting by email.

Comments