Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

Public title
The Impact of Telenursing on level of Anxiety in Parents of Hospitalized Premature Neonates in Neonatal Intensive Care Unit
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The parents' premature neonates that stay at NICU.
Exclusion criteria:
The parents' premature neonates with surgical disease
Age
From **15 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
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.
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
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
19839-63113
Approval date
2015-11-15, 1394/08/24
Ethics committee reference number
IR.SBMU.RAM.REC.1394.352

Health conditions studied

1

Description of health condition studied
Parents' anxiety after their premature neonate hospitalization
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
Parents' anxiety after their premature neonate hospitalization
Timepoint
5-10-15 days later.
Method of measurement
Beck Anxiety Inventory

Secondary outcomes

1

Description
Parents' anxiety after their premature neonate hospitalization
Timepoint
5-10-15 days after start of intervention.
Method of measurement
Beck Anxiety Inventory

Intervention groups

1

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.
Category
Rehabilitation

2

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
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
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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
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
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zarghi@sbmu.ac.ir
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

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Person responsible for updating data

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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