Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

The Effects of Tele-nursing on stress in Mothers with Premature Infants after discharge from Neonatal Intensive Care Unit

Protocol summary

Study aim

This study aims to investigate the effects of Tele-nursing on mothers' level of stress after their infants 'are being discharged from the Neonatal Intensive Care Unit (NICU).

Design

A Quasi experimental research, randomized, two groups of intervention and control, 120 Sample ,

Settings and conduct

This study was conducted in the NICUs of the selected hospitals, affiliated with the universities of medical sciences in Mazandaran Province (the hospitals Imam Khomeni, Razi, Bu-Ali-Sina).In the intervention group Tele-nursing was performed for 4 weeks through Telegram application.The data was gathered in three Stages (the day after discharge, one day after the intervention and four weeks after it. Data collection was done using Barry and Jones' parental stress scale, and the maternal and neonatal demographic questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria included the ability to read and write in Farsi, having a cell phone that supports Telegram application, not taking infertility treatment methods and giving singleton birth; The exclusion criteria included the mother's acute illness; the mother's not being available for more than a week.

Intervention groups

intervention (tele-nursing) included Education, Consultation and follow-ups. Education was provided for mothers in the form videos, photos, instructive texts and Q&A Stages on Telegram installed on their mobile phones , within four consecutive weeks that providing care for the Premature infants. The possibility of phone counseling, provided for the mother 24 hours a day. The follow-ups were done by calling mothers every weekend in order to ask about the content of the previous week's session and create educational feedback. control group received only the care conventionally provided in the ward at the time of discharge.

Main outcome variables

Change in maternal stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161024030474N2**
Registration date: **2019-06-16, 1398/03/26**
Registration timing: **retrospective**

Last update: **2019-06-16, 1398/03/26**
Update count: **0**

Registration date

2019-06-16, 1398/03/26

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)

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+98 21886553668

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-30, 1396/08/08

Expected recruitment end date

2018-06-19, 1397/03/29

Actual recruitment start date

2017-10-30, 1396/08/08

Actual recruitment end date

2018-03-19, 1396/12/28

Trial completion date

2018-06-19, 1397/03/29

Scientific title

The Effects of Tele-nursing on stress in Mothers with Premature Infants after discharge from Neonatal Intensive Care Unit

Public title

The Effects of Tele-nursing on stress in Mothers with Premature Infants

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The ability to read and write in Farsi. Being infant's biological mother. The mother's not having chronic anxiety and stress based on her own statements. Not to be a health care provider. The infant's being hospitalized At least for a week. The infant's being hospitalized only due to prematurity. Having a cell phone that supports Telegram application. Their babies are not discharged with family consent (Leave with personal responsibility). Not taking infertility treatment methods and giving singleton birth Live with their spouse. Their babies having no congenital anomalies and genetic defects.

Exclusion criteria:

Mother's acute illness. Re-admission of the infant before or during the study due to various diseases. The mother's not being available for more than a week. The lack of interest in contributing to the research anymore.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples were randomly assigned to the two groups of intervention and control based on their case reference number: the even numbers were assigned to the control group and the odd numbers to the intervention group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

The samples were randomly assigned to the two groups of intervention and control. the intervention group received the intervention for 4 weeks and there was no intervention in the control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Pharmacy, Nursing and Midwifery Schools. Shahid Beheshti University of Medical S

Street address

no 8, Shams Ally, Tavanir, Vally Asr Blvd

City

Tehran

Province

Tehran

Postal code

193954719

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.SBMU.PHNM.1395.697

Health conditions studied

1

Description of health condition studied

Stress

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Stress score on Barry and Jones' parental stress scale

Timepoint

The day after discharge (before the intervention). 1 and 30 days after the end of the intervention.

Method of measurement

Barry and Jones' parental stress scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tele-Nursing (training, counseling and telephone follow up by the nurse) was conducted for 4 weeks.

Category

Prevention

2

Description
Control group: Receive routine education at discharge
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi hospital
Full name of responsible person
Dr. Mozafar Shabani
Street address
Yoosef Reza Ave
City
Qaemshahr
Province
Mazandaran
Postal code
4765686743
Phone
+98 11 4221 8018
Fax
+98 11 4221 8011
Email
razi-ghh@mazums.ac.ir
Web page address
http://razihospital.mazums.ac.ir/

2

Recruitment center
Name of recruitment center
Boali Sina hospital
Full name of responsible person
Dr. Abdollah Mosavi
Street address
Emam Khomeyni Sq, Pasdaran Blvd
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Sari
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Mazandaran
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Phone
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Fax
+98 11 3334 3017
Email
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Web page address
http://boalihospital.mazums.ac.ir/

3

Recruitment center
Name of recruitment center
Imam khomeyni hospital
Full name of responsible person
Dr. Misagh Shafizade
Street address
Razi Street
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48166-33131
Phone
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+98 11 3336 3754
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imamhospital@mazum.ac.ir
Web page address
http://imamhospital.mazums.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
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1985717443
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farahani1381@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

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Person responsible for updating data

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Other areas of specialty/work
Nursery

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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 (maternal stress) 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 premature infants (mothers-nurses-Physicians)

Under which criteria data/document could be used
Just to reduce the stress of mothers and in the form of university projects

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