

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 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)

Phone

+98 21886553668

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farahani1381@sbmu.ac.ir

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

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+98 11 4221 8018

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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

City

Sari

Province

Mazandaran

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3

Recruitment center

Name of recruitment center

Imam khomeyni hospital

Full name of responsible person

Dr. Misagh Shafizade

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Razi Street

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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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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

<http://nm.sbm.ac.ir/>

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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Shahid Beheshti University of Medical Sciences,
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Person responsible for scientific inquiries

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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@sbm.ac.ir

What processes are involved for a request to access

data/document

About a month

Comments