Clinical Trial Protocol
Iranian Registry of Clinical Trials
31 May 2022

Studying the effect of Telenursing on hope and perceived self-efficacy of mothers with premature infants after discharging from neonatal intensive care unit

Protocol summary

Study aim
Determining the effect of telenursing on hope and perceived self-efficacy of mothers with premature infants after discharging from neonatal intensive care unit of Mahdieh Hospital in 1399

Design
Clinical trial with control and intervention groups as parallel, not blind, non-random assignment to intervention and control groups, 70 samples

Settings and conduct
This study is performed on mothers with premature infants discharged from the NICU of Mahdieh Hospital. The titles of messages will be prepared as follows:

- Experts medical advice if needed
- Screening and vaccination
- Giving medicine
- Routine evaluation of the baby
- Nutrition and nutrition tolerance
- Excretion of feces and urine
- Skin and eye care
- Baby clothes
- Bathing of the baby
- Wrap the baby to move

Participants/Inclusion and exclusion criteria

- Inclusion criteria: Mothers with premature infants without problems and illnesses, without stressful incidents, biological father, access to Instagram, literate, Iranian citizenship
- Exclusion criteria: The baby has a genetic disorder

Intervention groups
After obtaining informed consent, the intervention group will enter the researcher's Instagram account to receive educational files via mobile. In this way, once a day for 4 weeks, the message will be placed in the form of an educational package and in the form of text or photo on Instagram by the researcher. Control group will have a routine treatment and follow-up (clinic visit) which is the usual care of the hospital and is provided by the nurses. The researcher has no role in providing them and will not undergo any intervention during 4 weeks; but for completing the research tools will be entered to researcher's Instagram account.

Main outcome variables
Hope score in the "Scale of expectancy of mothers of premature infants admitted to the intensive care unit" self-efficacy score in the "Perceived self-efficacy questionnaire of maternal parenting"

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20161024030474N5
Registration date: 2021-06-21, 1400/03/31
Registration timing: retrospective

Last update: 2021-06-21, 1400/03/31
Update count: 0

Registration date
2021-06-21, 1400/03/31

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 2188653668

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-20, 1399/11/01
Expected recruitment end date
2021-03-19, 1399/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Studying the effect of Telenursing on hope and perceived self-efficacy of mothers with premature infants after discharging from neonatal intensive care unit

Public title
Studying the effect of Telenursing on hope and perceived self-efficacy of mothers with premature infants after discharging from neonatal intensive care unit

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
- Mothers whose infants were born prematurely (before 37 weeks of gestation) and they are going to be be discharging from the neonatal intensive care unit
- Mothers whose infant has no problems or illnesses other than prematurity
- Mothers who have not had any stressful event in the last six months
- The infant's father is biological
- According to them, they do not have any psychiatric disorders.
- Be literate
- Have access to the Internet and the Instagram social network.
- Have Iranian citizenship
- Not be part of the treatment staff
- Not to have any other previous hospitalized premature infants in neonatal intensive care unit

Exclusion criteria:
The infant has a genetical disorder

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 70

Randomization (investigator's opinion)
Not randomized

Randomization description

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 in Research Schools of Pharmacy, Nursing and Midwifery - Shahid Beheshti University

Street address
Vali Asr Ave., Niayesh Cross Road,Niayesh Complex

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2020-11-01, 1399/08/11

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1399.244

Health conditions studied

1

Description of health condition studied
Premature infant

ICD-10 code
P07.3

ICD-10 code description
Preterm [premature] newborn [other]

Primary outcomes

1

Description
Mothers' Hope

Timepoint
The last day of the baby’s stay in the hospital - immediately after the intervention - 4 weeks after the intervention

Method of measurement
Hope Scale of Mothers of Premature Neonates Admitted to the Intensive Care Unit

2

Description
Percieved Parenting Self-efficacy

Timepoint
The last day of the baby’s stay in the hospital - immediately after the intervention - 4 weeks after the intervention

Method of measurement
Percieved Parenting Self-efficacy Questionnaire

Secondary outcomes
empty
Intervention groups

1

Description
After obtaining informed consent, the intervention group will enter the researcher's Instagram account to receive educational files via mobile. In this way, once a day for 4 weeks, the message will be placed in the form of an educational package, text or photo, by the researcher on Instagram account. If the Instagram social network is filtered, the message will be sent to mothers through an internal messenger such as Soroush Messenger. In addition to subscribing to the Instagram account, mothers will be able to communicate individually with the researcher and ask questions and receive answers by sending a message on the Instagram social network. The researcher will spend the first 10 minutes of each session for reviewing the educational content of the previous session and following up on the fact that mothers have followed the educational content, understood and implemented them. The headings of these messages are prepared as follows and based on valid scientific sources, including instructions for caring of premature infants of the Neonatal Health Department of the Ministry of Health and Medical Education, books and scientific sites, and the validity of the educational package will be approved by experts: Post-discharge follow up, medical advice as needed, screening tests and vaccination, medication, routine neonatal evaluation, feeding and feeding tolerance, defecation and urination, umbilical cord care, skin and eye care, clothing infant, infant bathing, infant wrapping to move, circumcision instructions, emotional communication between infant and parents.

Category
Behavior

2

Description
In the control group, they will have routine treatment and follow-up, referring to clinics for checking, and will not undergo any intervention for 4 weeks.

Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdiye hospital
Full name of responsible person
Fares Najari
Street address
Shishe Gar Khaneh alley, Fadaian Islam Ave, Shoosh Sq, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1185817311
Phone
+98 21 5506 2628
Email
mahdiyeh_hospital@sbmu.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 Behesti University of Medical Sciences, next to Taleghani hospital, Yaman Street, Shahid Chamran highway.
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9780
Email
farahani1381@sbmu.ac.ir
Grant name
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
Azam Shirinabadi Farahani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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
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Other areas of specialty/work
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Phone
+98 21 886553668
Fax
+98 21 8820 2518
Email
farahani1381@sbmu.ac.ir

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 about the main outcome (hope of mothers with premature babies, self-efficacy of mothers with premature babies) 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 increase mothers' hope and self-efficacy 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