Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Video Interaction Guidanceof mother-infant interaction on stress in mothers with premature neonates in Neonatal Intensive Care Units".

Protocol summary

Study aim
The assess Video Interaction Guidence of mother- infant interaction in mothers with premature neonates in Neonatal Intensive Care Units".

Design
trial with intervention and control group -80 mother- in acssess

Settings and conduct
Nullipara mothers with preterm infant 34-37 week that hospitalized in NICU in Imam hkomaeini and booalisina hospital in sari depended to Mazandaran University of Medical Sciences.

Participants/Inclusion and exclusion criteria
nullipara mothers with no history in preterm labour- mother with no difficault diseases- Iranian nationality- with lowest literacy of reading and writikg

Intervention groups
intervention group including 34 nullipara mothers who their preterm infant hospitalized in NICU. at first day,they filled pss questionaire(pretest) and then,recieved VIG(Video Interaction Guidence).then, at fourth day,intervention group recieved VIG and then filled pss questionaire(first posttest) and in seventh day, they recieved VIG and then filled pss questionaire (secound posttest).control group including 40 mothers compeleted pss questionaire in first day(pretest),fourth day(first posttest) and seventh day(secound posttest) and they recieved hospital routin care.

Main outcome variables
Mothers stress reducing who their preterm infant hospitalized in NICU

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170220032693N1**
Registration date: **2018-05-31, 1397/03/10**
Registration timing: **retrospective**

Last update: **2018-05-31, 1397/03/10**
Update count: **0**

Registration date
2018-05-31, 1397/03/10

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 4220 3877

Email address
maryambarzegar93@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-24, 1396/10/03

Expected recruitment end date
2018-02-01, 1396/11/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Video Interaction Guidanceof mother-infant interaction on stress in mothers with premature neonates in Neonatal Intensive Care Units".

Public title

The effect of video interaction guidance of mother-infant interaction on stress in mother".

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Nullipara- mothers with the lowest literacy in reading and writing Iranian nationality- married Not addiction with alcohol and extasia material NO associated with difficault diseases

Exclusion criteria:

affected to depression having preterm labour before this reseach

Age

From **21 years** old to **38 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic commitee of iran university of Medical Science

Street address

Shahid beheshti alley,Edalat 41, Rezvan building

City

Ghaemshahr

Province

Mazandaran

Postal code

4765754536

Approval date

2018-03-02, 1396/12/11

Ethics committee reference number

R.IUMS.REC.1395.9311451002.

Health conditions studied

1

Description of health condition studied

The effect of Video Interaction Guidence on preterm infants mother

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

mother stress

Timepoint

The first, fourth and seventh day

Method of measurement

questionaire-Likert

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Recieving Video Interaction Guidence.Intervention group compelete pss quesionaire(pretest) and then recieved Video Interaction Guidence in first day.then,theyrecieved Video Interaction Guidence in fourth day and filled pss questinaire(first posttest).in seventh day,mothers recieved Video Interaction Guidence and then filled pss questionaire(secound post test).

Category

N/A

2

Description

Control group: control group recieved just hospital routin care and filled pss questionaire in first day(pretest) and fourth day(first posttest) and seventh day(secound posttest).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali sina and Imam khomeini hospital

Full name of responsible person

Barzegar ,Maryam

Street address

No41,Edalat 41Alley,Shahid beheshti Street,Ghaemshahr town

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr.Seid Kazem Malakouti.
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Shahid beheshti alley,41 Edalat , Rezvan building
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Web page address
Grant name
20000000Rial
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
50
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
Iran University of Medical Sciences
Full name of responsible person
Maryam Barzegar
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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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
No - There is not a plan to make this available
Title and more details about the data/document
It possible some of data related to outcomes that intersect
When the data will become available and for how long
six month after resaults published
To whom data/document is available
Researcher who employed in association and university
Under which criteria data/document could be used
Useability of data should be with permitting responsible author.
From where data/document is obtainable
access to data by mobile phone
What processes are involved for a request to access data/document
connecting with responsible author by electronic post and mobile
Comments