Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Clinical trial the effect of educational program on the stress of mothers of premature infants

Protocol summary

Study aim
Determining the effect of educational program on the stress of mothers of infants admitted to the neonatal intensive care unit

Design
In this study, 62 mothers of infants admitted to the neonatal intensive care unit will be selected based on entry criteria and the subjects will be randomly assigned into two groups of test and control and each person is assigned a code.

Settings and conduct
This research will be carried out in the neonatal intensive care unit of Vali-e-Asr Hospital in Birjand. After examining the criteria for entering the mothers, they will be divided into two groups of control and intervention and the Parent-Miles and Funk Tests Questionnaire before and one The weeks after the intervention will be completed for the two groups

Participants/Inclusion and exclusion criteria
Mothers of infants weighing less than 2500 grams and immature (uterine age less than 37 weeks)

Intervention groups
The control group will receive no training The intervention group includes an instructional program for handwashing and infective control during contact with the baby, appropriate infant formula, proper physical conditions for the baby in the premature infant, nutrition from the stomach tube, and the teaching of breastfeeding, a suitable measure for weight gain, infant bathing Will receive the importance of hugging and touching the baby and explaining the equipment used for the baby and the condition of breathing and his appearance.

Main outcome variables
Maternal stress score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170902036026N4**
Registration date: **2018-02-01, 1396/11/12**
Registration timing: **retrospective**

Last update: **2018-02-01, 1396/11/12**
Update count: **0**

Registration date
2018-02-01, 1396/11/12

Registrant information

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Fatemeh Taheri
Name of organization / entity
Birjand University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Birjand University of Medical Sciences

Expected recruitment start date
2017-05-26, 1396/03/05

Expected recruitment end date
2017-08-21, 1396/05/30

Actual recruitment start date
2017-05-26, 1396/03/05

Actual recruitment end date
2017-08-21, 1396/05/30

Trial completion date
empty

Scientific title

Clinical trial the effect of educational program on the stress of mothers of premature infants

Public title
The effect of educational program on the stress of mothers of premature infants
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Mothers of infants weighing less than 2500 grams that are immature (uterine age less than 37 weeks) The mother has literacy to read and write
Exclusion criteria:
The baby has no abnormalities Premature birth of a premature baby No history of depression or anxiety
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **62**
Actual sample size reached: **62**
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 of Birjand University of Medical Sciences
Street address
Ghaffari Street, Birjand
City
Birjand
Province
South Khorasan
Postal code
9718863388
Approval date
2017-05-07, 1396/02/17
Ethics committee reference number
ir.bums.REC.1395272

Health conditions studied

1

Description of health condition studied
Estress
ICD-10 code
F43.0
ICD-10 code description
Psychological disorders, stress disorders and physical disorders

Primary outcomes

1

Description
Maternal stress
Timepoint
Before intervention and 10 days after intervention
Method of measurement
Parent-Miles Stress Questionnaire

Secondary outcomes

1

Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
Intervention group: with presence of the mother on the infant's bedside, samples will receive face to face training and practical presentation with practice and repeat in the presence of a researcher during every day 30 to 45 for 3 days, giving minutes and video presentation (45 to 60 minutes). The booklet will be available for participants for reviewing the materials .
Category
Behavior

2

Description
Control group: No intervention will be received
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Neonatal Intensive Care Unit
Full name of responsible person
Ms. Parhiz, Nursing Head-Nurse
Street address
Vali Asr Hospital, Birjand
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Birjand University of Medical Sciences
Full name of responsible person
Kazemi Tuba
Street address
Research & Technology Dept, Third Floor, Education and Research Building, University of Medical Sciences, Birjand
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research, Birjand 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
Valiasr Hospital
Full name of responsible person
Fatemeh Taheri
Position
Nurs
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Birjand University of Medical Sciences
Full name of responsible person
Taheri Fatemeh

Position
Student
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Nursery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not 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
The data for the original outcome is shared
When the data will become available and for how long
One year after the publication of the results
To whom data/document is available
Researchers of academic institutions
Under which criteria data/document could be used
Any analysis on the data is not allowed and is provided only to guide the researchers
From where data/document is obtainable
f.taheri@bums.ac.ir fateme taheri
What processes are involved for a request to access data/document
The researcher will have access to the data once the data is correct, after providing his or her profile and university at work or education, and providing evidence of non-misuse of data.
Comments