

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

Name

Fatemeh Taheri

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3245 0499

Email address

f.taheri@bums.ac.ir

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

2017-05-07, 1396/02/17

Ethics committee reference number

ir.bums.REC.1395272

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

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

City

Birjand

Province

South Khorasan

Postal code

9718863388

Email

f.taheri@bums.ac.ir

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

City

Birjand

Province

South Khorasan

Postal code

9718863388

Email

drtooba.kazemi@gmail.com

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

Latest degree

Master

Other areas of specialty/work**Street address**

Vali Asr Hospital, Ghafari St, Birjand

City

Birjand

Province

South Khorasan

Postal code

9718863388

Phone

+98 56 3245 0499

Fax**Email**

f.taheri@bums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Vali Asr Hospital

Full name of responsible person

Fatemeh Taheri

Position

Nursing expert

Latest degree

Master

Other areas of specialty/work**Street address**

Plaques 69, Tohid 7, Birjand

City

Birjand

Province

South Khorasan

Postal code

9718863388

Phone

+98 56 3245 0499

Fax**Email**

f.taheri@bums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Taheri Fatemeh

Position

Student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Ghaffari Street, Birjand University of Medical Sciences

City

Birjand

Province

South Khorasan

Postal code

9718863388

Phone

+98 56 3245 0499

Email

f.taheri@bums.ac.ir

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