Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

“Effect of educational- supportive intervention for fathers of premature newborn on mother-newborn attachment and parents anxiety”

Protocol summary

Summary

Premature birth is a stressful process for families and supportive program can be a viable solution. The purpose of this study was the impact of the fathers of premature newborns participation in intervention-training program on mother-infant attachment and parental anxiety. This study is a randomized clinical trial that fathers of 60 premature infants hospitalized in neonatal intensive care unit Selected with a 1: 1 allocation will be divided into two intervention and control groups. control group fathers will received ward routine care but in intervention group, Two 45-minute training session using the display content and images with PowerPoint will implemented .The intervention group also will received a package contains a CD and a colored manual prepared by the researcher. At the end of the first session, they will visit he neonatal intensive care unit and other part of education will done at the baby's bedside. One day after the intervention, the parents have 3 days non-designated visiting hours for meeting personal needs and baby's care. The mother-infant attachment with Avant checklist and parents anxiety with SpielBerger questionnaire will be measured in both groups in the beginning and end of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080613691N4**
Registration date: **2016-07-27, 1395/05/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-27, 1395/05/06

Registrant information

Name

Mohammad Arshadi Bostanabad

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-12-05, 1395/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

“Effect of educational- supportive intervention for fathers of premature newborn on mother-newborn attachment and parents anxiety”

Public title

“Effect of educational- supportive intervention for fathers of premature newborn on mother-newborn attachment and parents anxiety”

Purpose

Supportive

Inclusion/Exclusion criteria

(Baby Inclusion criteria : premature babies between 37-34 weeks of pregnancy; Apgar score of more than 7

minutes; lack of major congenital anormalies; two days after the adoption of childr; enLack of intubation ; One roll of; Having at least one meeting; the first time؛ Do not use aids fertility; Minimum weight 2000 gr; having oral feeding; wanted pregnancy) (Parents Inclusion criteria: sign the consent and willingness to participate in the study ; there is no known mental problems ; having at least primary education ; living with his wife in Tabriz ; lack of medical staff) (Exclusion criteria: The occurrence of adverse events during treatment (infant death) ; The reluctance of parents to continue reading ;Consumption of anti-anxiety drugs)

Age
To **2 months** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
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
Tabriz University of Medical Sciences

Street address
Daneshgah Ave. Tabriz University of Medical Sciences

City
Tabriz

Postal code
5138947977

Approval date
2016-04-25, 1395/02/06

Ethics committee reference number
IR.TBZMED.REC.1395.99

Health conditions studied

1

Description of health condition studied
maternal-infant attachment

ICD-10 code
Z00.6

ICD-10 code description
Examination for normal comparison and control in clinical research programme

2

Description of health condition studied
anexity

ICD-10 code
f41.1

ICD-10 code description
generalized anexiety disorder

Primary outcomes

1

Description
anexity

Timepoint
before Intervention، post Intervention

Method of measurement
Spielberger questionnaire

Secondary outcomes

1

Description
mother-newborn attachment

Timepoint
before Intervention، post Intervention

Method of measurement
Inventory observation Avant

Intervention groups

1

Description
The intervention group will support educational interventions. The intervention will be done 2 days after admission to the intensive care unit for newborns. Two meetings of a group that includes45-minute face-to-face with the parents of premature infants in the environment, equipment, personnel intensive care unit and medical care such as IV therapy, oxygen therapy, etc., and information on premature babies (behaviors and physical symptoms), the role of parents in protecting and caring for the baby and the mother, physical and emotional changes made to the mother after delivery, will be presented by the researcher using Power Point.And questions and answers between the researcher and fathers topics will be presented.At the end of the first session of the color manual and CD training 40 minutes, with educational content developed by researchers and confirmed by the teachers, the parents and the parents will be taught how to use them.And at the end of the first session, parents to see the facilities

and meet the staff, and training in the sector will be The intervention group will support educational interventions. The intervention 2 days after admission to the intensive care unit for newborns at will Two meetings of a group that includes 60-minute face-to-face with the parents of premature infants in the environment, equipment, personnel intensive care unit and medical care such as IV therapy, oxygen therapy, etc., and information on premature babies (behaviors and physical symptoms), the role of parents in protecting and caring for the baby and the mother, physical and emotional changes made to the mother after delivery, will be presented by the researcher using Power Point

Category

Treatment - Drugs

2

Description

In the control group، Fathers will be visit their infants as ward routine and will be have no accessibility to rsearch team during hospitalization.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

29 Bahman Hospital

Full name of responsible person

Kobra Ravanbakhsh

Street address

29 Bahman Hospital

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ḏr. rashidi

Street address

Daneshgah Ave. Tabriz University of Medical Sciences

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Arshadi Bostanabad Mohammad

Position

Assistant Professor

Other areas of specialty/work

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City

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Postal code

5138947977

Phone

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Fax

Email

arshadi@tbzmed.ac.irarshadi-m@yahoo.com

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty