

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of supportive program on the stress and anxiety of fathers in the first exposure to premature infant

Protocol summary

Study aim

Investigating the impact of supportive program on the stress and anxiety of fathers in the first exposure to preterm infant

Design

Randomized Clinical trial, sample size=80

Settings and conduct

This study is will be conducted in the public hospital of Shahid Motahari, in Urmia. the researcher invites eligible study units to collaborate. The study units, will be divided into intervention and control groups based on randomization. After filling out State-Trait Anxiety (STAI) Inventory, the first encounter of the father with the infant was established based on the mother's placement, in interventional or control group based on randomization. After intervention, Parental Stressor Scale: Neonatal Intensive Care Unit (PSS-NICU) and STAI Inventories will be filled.

Participants/Inclusion and exclusion criteria

Fathers of preterm infants

Intervention groups

In the intervention group, two albums with the photos of a preterm babies will be shown to the father, and will be trained how to store and transport the breast milk, Then the father will be taken to the infant's bedside and empowered to have a comfortable interaction with the infant, then characteristics of premature infants and equipment around the baby and unit routine will be explained simply. At the end, DVD and pictorial training booklets on preterm infant's characteristics, will be given to the father, and the researcher's telephone number will be given to father to ask any possible question. In the control group, the father goes to the baby's bed and the baby's nurse answers any questions.

Main outcome variables

Stress, anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200120046200N1**

Registration date: **2020-05-11, 1399/02/22**

Registration timing: **prospective**

Last update: **2020-05-11, 1399/02/22**

Update count: **0**

Registration date

2020-05-11, 1399/02/22

Registrant information

Name

Seyedeh saeedeh Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1807

Email address

mousavi.ss@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-20, 1399/03/31

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of supportive program on the stress and anxiety of fathers in the first exposure to premature infant	
Public title	
Effect of supportive program on the stress and anxiety of fathers	
Purpose	
Supportive	
Inclusion/Exclusion criteria	
Inclusion criteria:	
Fathers: Over 18 years of age Literacy Lack of employment in health centers Ability to communicate verbally No stressful events in the past 6 months (such as divorce, separation from spouse, job loss) Lack of any mental illness or history of mental illness, according to the research unit No history of infertility Visitors to the hospital eventually 12 hours after preterm delivery Neonates: Gestational age less than 37 weeks Fifth minute apgar above 5 single pregnancy	
Exclusion criteria:	
Any congenital malformations Any serious disabling conditions: such as grade 3 or 4 intraventricular hemorrhage	
Age	
From 18 years old	
Gender	
Male	
Phase	
N/A	
Groups that have been masked	
No information	
Sample size	
Target sample size: 80	
Randomization (investigator's opinion)	
Randomized	
Randomization description	
Randomization using Quadratic Random Block	
Blinding (investigator's opinion)	
Not blinded	
Blinding description	
Placebo	
Not used	
Assignment	
Parallel	
Other design features	
Secondary Ids	
empty	
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	
Ethics committee of Iran University of Medical Sciences	
Street address	
Fifth floor, Headquarters., Iran University of Medical Sciences., Hemmat Highway between Chamran and Sheikh Fazlullah	
City	Tehran
Province	Tehran
Postal code	۱۴۴۹۶۱۴۵۳۵
Approval date	2020-03-15, 1398/12/25
Ethics committee reference number	IR.IUMS.REC.1398.1361
Health conditions studied	
<u>1</u>	
Description of health condition studied	The effect of supportive program on fathers' stress and anxiety in first exposure to preterm infant
ICD-10 code	
ICD-10 code description	
Primary outcomes	
<u>1</u>	
Description	Father's anxiety
Timepoint	Baseline, day three
Method of measurement	State Trait Anxiety Inventory(STAI)
<u>2</u>	
Description	Stress
Timepoint	Day three
Method of measurement	Parental Stressor Scale: Neonatal Intensive Care Unit (PSS: NICU)
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Intervention group: In the intervention group two albums are shown to the father. One album includes photos of a premature baby from birth to about two years old, and another album includes photos of former premature babies and current and well-to-do children, all born of different weights and ages. By showing these photos, we aim to prepare the father to see our baby with the features of a premature infant (intelligence support), on the one hand, and to provide emotional support for the future on the other, with conversations that show Photographs will be attempted, with the father's beliefs

emphasized on trust, resort, patience, and submission to divine fate (spiritual support), and then the mother's milk storage and transportation will be taught and taught. The device tries, while supporting information, with the hope that our premature infant will eat our milk. There will also be emotional support for the father, at which point the father will be advised to enter the ward and, as he enters, the staff will be introduced to him, followed by the father to the infant's bed, and to engage in sedentary interactions with him. The baby is encouraged and empowered through continuous gentle touch, gentle whispering in the ear, and eye contact. Alongside the baby, the characteristics of the premature baby and the equipment around the premature baby will be explained in a simple, understandable language and will answer any further questions the father has about the baby, the environment and the routine equipment. At the end of the illustrated booklet and DVD, information will be provided to the father on the conditions and characteristics of preterm infants, the needs and alternatives of indirect and indirect nutrition, the general conditions and common problems of preterm infants for the next 3 days and during hospitalization. Their infants can use it and revive it in their minds if they forget to read and observe some topics. The father will also be given a telephone number to answer any questions he may have during these 3 days. On the third day, the father's anxiety questionnaire for the second time and the stress questionnaire for the first time.

Category

Other

2

Description

Control group: In the control group, the father goes to the infant's bed and the infant's nurse answers any questions he may have. On the third day, the control group fathers will be given a second anxiety and stress questionnaire for the second time after completing the anxiety questionnaire and educational DVD and a telephone number will be provided to the father with any possible questions. Respond after reading the book and watching the DVD.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Hospital of Urmia

Full name of responsible person

Paria Jafari

Street address

Not reached the state of Shahid Motahari Hospital, Kashani Street, Urmia

City

Urmia

Province

West Azarbaijan

Postal code

57147

Phone

+98 44 3223 7077

Email

motahari@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

kazem Malakouti

Street address

Area Two, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 9024 6650

Email

malakoutik@yahoo.com

Grant name

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

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

Iran University of Medical Sciences

Full name of responsible person

Seyedeh saeedeh Mousavi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

School of Nursing and Midwifery., Rashid Yasimi
Street., above Vanak Square., Valiasr Street

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1996713883

Phone

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Email

mousavi.ss@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyedeh saeedeh Mousavi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Seyedeh saeedeh Mousavi

Position

Associate professor

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments