Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The impact of spousal support education to fathers on stress and self-efficacy score of mothers in care of premature neonates hospitalized in neonatal intensive care unit of Shiraz University of Medical Sciences 2017.

Protocol summary

Study aim

Determine the effectiveness of spousal support to fathers, stress and self-efficacy scores of mothers in the care of premature infants hospitalized in neonatal intensive care unit

Design

Clinical trial with two groups of control and intervention, 75 samples

Settings and conduct

At each hospital, the control group will be fully sampled. It will be done at sampling days at Hafez Hospital and on coupled days at Namazi Hospital. Then the intervention group will be sampled as mentioned.

Participants/Inclusion and exclusion criteria

Parents have preterm infants with a gestational age of 32-37 weeks that have no major malformations and are not dependent on the ventilator.

Intervention groups

In the control group, routine care is provided, but the fathers of the intervention group will receive an educational support program that includes two 60-minute training sessions using PowerPoint, as well as a training package containing CDs and booklets, and at the end of the first session Fathers also receive the necessary clinical training in the unit. One day after the end of the educational intervention, the parents will have the opportunity to meet and take care of the newborn for 3 days in an hour other than an appointment.

Main outcome variables

The primary outcome is the study of maternal stress and the secondary outcome of maternal self-efficacy, which will be measured by the PSS Stress Questionnaire and the PMP-SE self-efficacy questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171130037691N1**
Registration date: **2018-04-22, 1397/02/02**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-14, 1397/07/22**
Update count: **1**

Registration date

2018-04-22, 1397/02/02

Registrant information

Name

Hamed Gasemloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3366 4762

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stud2900054001@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

2018-03-21, 1397/01/01

Actual recruitment end date

2018-08-22, 1397/05/31

Trial completion date

2018-09-11, 1397/06/20

Scientific title
The impact of spousal support education to fathers on stress and self-efficacy score of mothers in care of premature neonates hospitalized in neonatal intensive care unit of Shiraz University of Medical Sciences 2017.

Public title
The impact of spousal support education to fathers on stress and self-efficacy score of mothers

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Parents with preterm infants born at gestational age of 32-37 weeks of gestation Neonates not being Under the mechanical ventilation The absence of congenital anomalies in the neonate After two days of admission for neonates No history of premature infants hospitalized earlier in pregnancy Parental exposure to other stressful events in the last 6 months Wanting to have a pregnancy No history of taking medications affecting maternal mental health Parents wanting to participate in the study Having at least elementary education Not being twin or upper Dominance in Persian Unemployment to medical group professions

Exclusion criteria:
The baby with major malformations Baby connected to the ventilator Use of anxiety drugs and drugs that affect the mental health of the mother before starting the study The experience of admission of premature infants in the neonatal intensive care unit Parents face a stressor in the last six months Twin being Parental inconvenience to participate in the study mother is illiterate Neonate with gestational age less than 32 weeks of gestation and over 37 weeks of gestation Mother educated from medical science

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **75**
Actual sample size reached: **75**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Factorial

Other design features
In order to prevent transfer of the training content to the control proup, the two groups had to be sampled separately. On the other hand, in order for nurses not to be affected by the intervention and their behavior not to be changed, the control group in each hospital has been sampled, primarily. Thus, the allocation of parents to each group took place after complete sampling of the control group at first place, in each hospital. That is, after the coin toss, sampling was made in Hafez and Nemazee Hospitals on odd and even days, respectively.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
the central building of Shiraz University of Medical Sciences , opposite the Palestine Street, Zand Avenue ,Shiraz

City
Shiraz

Province
Fars

Postal code
71348-14336

Approval date
2017-10-18, 1396/07/26

Ethics committee reference number
IR.SUMS.REC.1396.112

Health conditions studied

1

Description of health condition studied
stress

ICD-10 code
F43.0

ICD-10 code description
Acute stress reaction

Primary outcomes

1

Description
Stress mothers of premature infants

Timepoint
Measuring maternal stress on the second day of admission and the seventh day of admission

Method of measurement
By PSS questionnaire

Secondary outcomes

1

Description
Self-efficacy of mothers of premature infants
Timepoint
On the second day of admission, premature baby and the seventh day of admission
Method of measurement
By PMP-SE questionnaire

Intervention groups

1

Description
Control group: In the control group, the fathers will meet on a routine basis within the specified hours and will not be associated with the research team during the admission.
Category
Other

2

Description
Intervention group:In intervention group, educational interventions will be conducted. This intervention will take place 2 days after the newborn is admitted to the intensive care unit. It includes two 60-minute face-to-face training sessions with fathers of premature infants about the environment, equipment, health care staff and therapeutic care such as vein therapy , Oxygen therapy and ..., and information on premature infants (physical behaviors and symptoms), the role of the father in the protection and care of the baby and the mother, physical and mental changes created in the mother after childbirth, by the researcher using PowerPont will be provided. And questions and answers will be made between the researcher and the fathers about the subjects presented. At the end of the first session, a color booklet with an educational CD containing the educational content provided by the researcher and approved by the professors will be given to the fathers and the method of their use will be taught to the fathers. At the end of the first session, the fathers will visit the section And getting acquainted with the equipment and personnel of the department will be given to the department and the necessary training will be given in the section as well. One day after the end of the educational intervention to provide support for the parent and to exchange ideas and information between parents, the parents have the opportunity to meet for 3 days per hour, other than an appointment (in coordination with the manager and the department manager). Find and take care of the baby.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
Hamed Ghasemloo
Street address
Namazi hospital, Namazai Square, Shirazn Town
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2

Recruitment center
Name of recruitment center
Hafez Hospital
Full name of responsible person
Hamed Ghasemloo
Street address
Hafez Hospital, Chamran Blvd, Shiraz Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Basir Hashemi
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the central building of Shiraz University of Medical Sciences , opposite the Palestine Street, Zand Avenue ,Shiraz
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Hamed Gasemloo
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
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Ph.D.
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Person responsible for updating data

Contact
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Shiraz University of Medical Sciences
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Hamedgasemloo@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available