Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 2026

Investigation the effect of spouse supportive program on stress and coping Strategy of mothers with premature infant in the selected hospital of Isfahan University of Medical Sciences,

Protocol summary

Study aim

Determining the effect of spouse support program on stress and coping strategies of mothers with premature infants in selected hospitals of Isfahan University of Medical Sciences

Design

Samples are available by random sampling and random assignment, in two groups of 36 control and test. For randomization, 72 paper cards with the letters A and the letter B on them will be placed in an envelope where the cards are not visible. Each mother is then asked to randomly select a card until all cards have been removed. Mothers with an A card are in the test group and mothers with a B card are in the control group

Settings and conduct

This research is performed in the neonatal intensive care units of Shahid Beheshti Educational and Medical Center in Isfahan. The researcher will refer to the ward report office and, by accessing the ward report office, will select the admitted and hospitalized infants in the last 24 to 72 hours and with a birth age of less than 37 weeks of gestation and with inclusion criteria by available sampling method. The mothers of the selected infants who meet the inclusion criteria are then selected and randomly assigned to the test and control groups

Participants/Inclusion and exclusion criteria

Absence of child and mother care and support training sessions, absence of mental illness or drug addiction Mothers have not experienced severe stress in the last 12 months. Parents do not have a previous history of neonatal hospitalization in the neonatal intensive care unit. Existence of any problem, absence of spouses for more than one session of training sessions, complication for mother, worsening of infant condition, separation or death of spouse

Intervention groups

3 training sessions are held for the spouses of the test group. The control group receives routine hospital training

Main outcome variables

Reduce stress in mothers with premature babies

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200908048666N1**
Registration date: **2020-09-23, 1399/07/02**
Registration timing: **retrospective**

Last update: **2020-09-23, 1399/07/02**
Update count: **0**

Registration date

2020-09-23, 1399/07/02

Registrant information

Name

Maryam Jalali

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

2019-07-17, 1398/04/26

Actual recruitment end date

2020-04-08, 1399/01/20

Trial completion date

2020-04-18, 1399/01/30

Scientific title

Investigation the effect of spouse supportive program on stress and coping Strategy of mothers with premature infant in the selected hospital of Isfahan University of Medical Sciences,

Public title

Investigation the effect of spouse supportive program on stress and coping Strategy of mothers with premature infant in the selected hospital of Isfahan University of Medical Sciences,

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

1- Parents are interested in participating in the study 2- Be able to speak, read and write in Persian 3- Have not previously participated in sessions on training in infant and mother care and maternal support (any other research project in this field) 4- According to the information recorded in the infants' file, mothers should not have any mental illness or drug addiction and should not take any psychiatric medication 5. Mothers in the last 12 months have not experienced severe stress including: death of spouse, divorce, life apart from spouse, imprisonment, death of a family member and illness (Holmes, Rahe, 1967) which will be determined by asking mothers 6- Parents do not have a previous history of hospitalizing the baby in the neonatal intensive care unit

Exclusion criteria:

1- Existence of any problem so that parents are not able to continue participating in the study 2. Spouses should be absent from more than one training session 3- Mothers after childbirth suffer from postpartum complications such as thrombophlebitis, postpartum infection, pulmonary embolism, severe bleeding 4- The baby's condition deteriorates or dies 5- Separation or death of the spouse occurs

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Actual sample size reached: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Mothers of selected infants who meet the inclusion criteria are randomly divided into control and test groups. To randomize the samples, the number of paper card samples with the letter A (as the test word cipher) and the letter B (as the control cipher) written on the box will be placed in a box (half Cards have the letter A and the other half have the letter B) and mothers are asked to choose a card at random. Then mothers with an A card are in the experimental group and mothers with a B card are in the control group.

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 Isfahan University of Medical Sciences

Street address

Feiz hospital, Modarres Str, Qds Ave

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Province

Isfehan

Postal code

8156756881

Approval date

2018-11-14, 1397/08/23

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.299

Health conditions studied

1

Description of health condition studied

Stress and coping strategies of mothers with premature infants

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Stress and coping strategies using the stress questionnaire of parents of infants admitted to the neonatal intensive care unit and Lazarus and Folkman coping strategies questionnaire

Timepoint

Stress measurement and coping strategies before the intervention and then 5 days after the end of the training

sessions

Method of measurement

questionnaire of parents of infants admitted to the neonatal intensive care unit and Lazarus and Folkman coping strategies questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Demographic profile form, PSS-NICU questionnaire and SCQ questionnaire are completed by all units (mothers). The spouses of the intervention group also fill in the consent form, after which the researcher invites the spouses of the experimental group to participate in the training sessions. The training sessions include 3 one-hour sessions (Karami, Rostami, Ghadirian, 2009 and Hassani Taybi, Kermanshahi, 2013) and will be held in three days, from 13:00 to 14:00, in three days, after selecting the samples, in coordination with the spouses of the research units.Necessary arrangements will be made for the spouses to attend the first visit (at the time of sample selection) and the schedule for the spouses' presence in the hospital will be delivered to them in the form of a tract. The content of the sessions was compiled according to the studies and the principles of NeedCap (Valizadeh, Akbar Begloo, Asadollahi 2009 and Karami, Rostami, Ghadirian, 2009 and Hassani Taybi, Kermanshahi, 2013) and was approved by 10 faculty members.Scheduled training sessions with lectures, questions and answers, role-playing and practical work in the form of group training and face-to-face using PowerPoint, videos, pictures, dolls for spouses by the researcher and in the presence of a psychiatric nurse at the training classes Shahid Beheshti Educational and Medical Center will be held. The content of the educational package includes: Session 1: Explaining the objectives of the study, the benefits of using the educational content, presenting the educational package of baby care using the principles of NeedCup, including: teaching kangaroo care, establishing a suitable position for the baby, controlling pain by non-pharmacological methods, changing clothes and diapers Baby, baby skin care. Also, providing a maternal care training package, including: personal health education, skin and wound care, maternal nutrition and proper breastfeeding. Session 2: Providing training and solutions on emotional support and self-confidence by the researcher in the presence of a colleague Psychiatric nurse.At the end of the sessions, the spouses will be explained that for the next 5 days (5 days after the end of the training classes) once a day (Ghaderi et al., 2013) for one hour (in coordination with the head of the ward) at the time of the hospital visit Find and support mothers using the educational content provided, and then on the fifth day (after one hour of meeting and support of spouses) the researcher will again provide the PSS-NICU questionnaire and the SCQ questionnaire to the mothers of the control group and the experimental group to complete.

Category

Prevention

2

Description

Control group: The control group will receive the support and routine training of the hospital, and after the intervention, each of the mothers in the control group will receive a pamphlet prepared from the educational materials presented in the training sessions for themselves and their spouses to study.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Educational and Medical Center of Isfahan

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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
Esfahan 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

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be 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