Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of supportive educational interventions on stress and adaptation to the role of motherhood in mothers of preterm infants hospitalized in Neonatal Intensive Care Unit

Protocol summary

Study aim

Determining the effect of supportive educational interventions on stress and adaptation to the role of motherhood in mothers of preterm infants hospitalized in Neonatal Intensive Care Unit

Design

The statistical population includes all mothers of premature infants who are referred to the neonatal intensive care unit of Imam Reza Hospital in Kermanshah. After obtaining the necessary permissions, eligible mothers are enrolled in the study. First, control group samples and three weeks after the completion of control groups sampling, the intervention group samples are selected randomly. Intervention takes place in 2-3 sessions. In both groups, at first (before intervention), before discharge and one month after discharge, the level of stress and the degree of adaptation to the role of motherhood are assessed by using the Perceived Stress Scale 4 (PSS-4) and Maternal Role Adaptation Scale (MRAS: NICU).

Settings and conduct

Eligible mothers are selected and entered by referring to the neonatal intensive care unit of Imam Reza Hospital in Kermanshah.

Participants/Inclusion and exclusion criteria

Infant age between 26-26 weeks, fluent in Persian, age over 18, no history of mental disorders and psychoactive drugs use, lack of addiction, lack of known disease in the fetus, being Iranian, non-occurrence of an accident or loss of first class family members in the last three months, have a tendency to participate in the research and two to four days have passed since their baby was admitted.

Intervention groups

This study has an intervention and a control group.Intervention takes place in 2-3 sessions. In both groups, at first (before intervention), before discharge and one month after discharge, the level of stress and the degree of adaptation to the role of motherhood are assessed.

Main outcome variables

Perceived Stress and Maternal Role Adaptation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170305032900N2**
Registration date: **2018-09-10, 1397/06/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-10, 1397/06/19**
Update count: **0**

Registration date

2018-09-10, 1397/06/19

Registrant information

Name

Sousan Heydarpour

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3823 2679

Email address

sheydarpour@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-10, 1397/06/19

Expected recruitment end date

2019-01-09, 1397/10/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supportive educational interventions on stress and adaptation to the role of motherhood in mothers of preterm infants hospitalized in Neonatal Intensive Care Unit

Public title

The effect of supportive educational interventions on stress and adaptation to the role of motherhood in mothers of preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Neonate age between 26 to 36 weeks fluent in Persian language Mother's age over 18 years old Being Iranian Two to four days have passed since the baby was admitted

Exclusion criteria:

Not having a willingness to participate in the study Diagnosis of a known disease in the fetus history of mental disorders, psychotropic drug use and addiction

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study blinding will be performed for the processor. The processor will not be aware of the content of the codes.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kermanshah University of Medical Sciences

Street address

Shahid Beheshti Boulevard; Central Building of Kermanshah University of Medical Sciences

City

kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-02-09, 1396/11/20

Ethics committee reference number

IR.Rec.1396.648

Health conditions studied

1

Description of health condition studied

Pregnancy, childbirth and the puerperium

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

All mothers of premature infants who are referred to Imam Reza Kermanshah Hospital, who are residents of Kermanshah, will be referred.

Timepoint

The intervention involves training the program in 2 to 3 sessions during the hospital stay

Method of measurement

Before discharge and one month after discharge, the level of stress was assessed using the perceived stress questionnaire and the degree of compliance with the maternal role was assessed using a questionnaire adapted to the role of maternal premature infants.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Training the program in 2 to 3 sessions with the help of video tutorials with a tablet and individually. Training includes how to care for a premature baby (previously provided by one of the

researchers in Iran) and a training booklet.

Category
Behavior

2

Description
Control group: Ward routine care

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Fatemeh Tohidi Nezhad

Street address
Nursing Blvd, Sorkhe Ligeh, Kermanshah

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Kermanshah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Sousan Heydarpour

Street address
Kermanshah, Shahid Beheshti Blvd, Central Building

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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
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Sousan Heydarpour

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All participants data can be shared after being unidentified

When the data will become available and for how long

Start the access period after publishing the results

To whom data/document is available

Public

Under which criteria data/document could be used

For use in studies allowed

From where data/document is obtainable

sousan Heydarpour Email: sheydarpour@kums.ac.ir mobile: 00989183366206

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

The application will be sent to the project implementer by email and within 24 hours will receive the necessary items

Comments