

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

The effect of developmental care education using Teach-back method on perceived stress and self- esteem of mothers with hospitalized premature newborn

Protocol summary

Study aim

Determining The effect of developmental care education using Teach-back method on perceived stress and self-esteem of mothers with hospitalized premature newborn

Design

Field trial with control group, with parallel, randomized groups, 70 patients

Settings and conduct

Approval of the research plan in the university ethics committee. At the beginning of the study, complete the demographic characteristics checklist, the Perceived Stress Scale of Cohen et al and Rosenberg Self-Esteem Scale. In the intervention group, mothers individually, during the first 10 days of their newborns' stay in the neonatal intensive care unit, during 4 sessions lasting 45 to 60 minutes based on the same study, are exposed to developmental care education using Teach- back method will be done by the researcher. No training will be given to the control group. immediately after completing the training, complete the Perceived Stress Scale of Cohen et al and Rosenberg Self-Esteem Scale. The place of the training is a room in the neonatal intensive care unit of Imam Sajjad Hospital (AS), in order to preserve the privacy of mothers.

Participants/Inclusion and exclusion criteria

Admission requirements: Willingness and informed consent to participate in the study, mothers with hospitalized premature newborn. Conditions of non-entry: Previous participation in studies similar to the current research.

Intervention groups

Intervention group: In this group, mothers individually, during the first 10 days of their newborns' stay in the neonatal intensive care unit, during 4 sessions lasting 45 to 60 minutes based on the same study, are exposed to developmental care education using Teach- back method will be done by the researcher. Control group: non-

intervention: this training group will not be given.

Main outcome variables

Perceived stress and self- esteem

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230712058758N1**

Registration date: **2023-10-07, 1402/07/15**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-07, 1402/07/15**

Update count: **0**

Registration date

2023-10-07, 1402/07/15

Registrant information

Name

Zeinab Mokhtari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 7253 1080

Email address

zaynabmokhtari792@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of developmental care education using Teach-back method on perceived stress and self- esteem of mothers with hospitalized premature newborn

Public title

The effect of developmental care education using Teach-back method on perceived stress and self- esteem of mothers with hospitalized premature newborn

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The experience of the first premature newborn admitted to the neonatal intensive care unit A mother with a premature newborn with a history of hospitalization in the neonatal intensive care unit single newborn

Willingness and informed consent to participate in the study Gestational age more than 25 and less than 35 weeks Mothers with mild, moderate or severe perceived stress on the Cohen Perceived Stress Scale

Exclusion criteria:

Newborn weight less than 800 grams at birth Newborns suffering from birth defects Previous participation in studies similar to the current research Having a history of depression or other psychiatric disorders in the mother Working in medical science

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of blocks in such a way that blocks of size 2, 4 and 6 will be used. For example, in the case where the block size is 2, we will have two states AB and BA (A and B are the intervention and control groups). In order to create the sequence and concealment, the online software with the following address will be used and a special randomization code will be generated: Sealed Envelope Ltd. 2021. Create a blocked randomization list. [online] Available from: <http://www.sealedenvelope.com/simple-randomizer/v1/lists> [Accessed 16 July 2022]

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 Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2023-08-30, 1402/06/08

Ethics committee reference number

IR.YUMS.REC.1402.093

Health conditions studied**1****Description of health condition studied**

premature newborn

ICD-10 code

P07.3

ICD-10 code description

Preterm [premature] newborn [other]

Primary outcomes**1****Description**

Perceived stress

Timepoint

The level of perceived stress by mothers at the beginning of the study (before the intervention) and immediately after the intervention

Method of measurement

The Perceived Stress Scale of Cohen et al

2**Description**

Self- esteem

Timepoint

The level of self- esteem by mothers at the beginning of the study (before the intervention) and immediately after the intervention

Method of measurement

Rosenberg Self-Esteem Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, mothers individually, during the first 10 days of their newborns' stay in the neonatal intensive care unit, during 4 sessions lasting 45 to 60 minutes based on the same study, are exposed to developmental care education using Teach-back method will be done by the researcher. In this group, the teach-back method with the 5T model will be used. The 5T model is a standard and operational definition of teach-back method that includes 5 steps; triage, tools, take responsibility, tell me and try again. The triage, tool, and take responsibility steps focus on effective comprehension of information and the tell me and try again steps to assess whether the patient has received the information. The Take Responsibility and Tell Me steps are referred to as "Teach Back lead-in." The steps of the teach-back method will include such things; Step 1: The teacher will ensure that he has used simple language and explained the concepts or process to the care recipient. Medical words and terms will be avoided. Step 2: The teacher will ask the care recipient to repeat the content in his own language: How did he understand the concepts or process that the researcher explained? Step 3: The teacher will identify and correct the care recipient's misperception or incorrect performance. Step 4: The instructor will question the care recipient again about what was taught to ensure that the misunderstanding has been corrected. Step 5: The instructor will repeat steps 4 and 5 until he is convinced that the care recipient understands the concepts or has the ability to perform the procedure correctly and safely. In the teach-back method using the same study, after teaching new information, mothers will be asked to explain that information in their own language. Then the level of knowledge of mothers and the adequacy of their explanations will be determined. The mother will repeat the instructions in her own language. In this way, the researcher will be able to evaluate the mother's understanding of the information. If the mother does not repeat the information correctly, the training phase will be completed for that information and progress will be resumed for the new information. However, if there is a defect or error in it, the information will be corrected and repeated by the researcher, and the mother will be asked to express the information in her own language. After completing the cycle, the mother will be asked: "Do you have any other questions?" If possible, open questions will be asked and closed questions will be avoided.

Category

Lifestyle

2

Description

Control group: non-intervention: this training group will not be given.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Sajjad Hospital

Full name of responsible person

Zeinab Mokhtari

Street address

Imam Sajjad Hospital, Next to Hotel Azadi, Yasuj, Kohgiluyeh and Boyerahmad, Islamic Republic of Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Seyed Amin Hossaini Motlagh

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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

Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Zeinab Mokhtari
Position
Msc student in pediatric nursing
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Person responsible for updating data

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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

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