

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The effect of kangaroo mother care by role-playing method on mother-infant attachment and sleep quality in mothers of premature neonates, Fatemieh hospitalized in neonatal intensive care unit, Hamadan, 2021

Protocol summary

Study aim

The effect of kangaroo mother care by role-playing method on mother-infant attachment and mothers' sleep quality

Design

Clinical trial with one control group and one intervention group, one-blind, randomized

Settings and conduct

Neonatal Intensive Care Units, Fatemieh Health Services Center, Hamedan the person who will analyze the data will be blinded

Participants/Inclusion and exclusion criteria

All mothers of newborns admitted to the neonatal intensive care unit

Intervention groups

o perform the intervention, the mothers of the experimental group, each mother individually attends two sessions of 30 minutes in the conference room and is taught how to perform cuddle care using the baby model. First, the researcher talks to the mother and answers their questions about how to care for, hug, and caress the baby. It then helps them wear a special blouse designed according to the kangaroo care standard and protocol. These blouses are loose, have sleeves, short buttons with a distance from the front of the dress that can be easily opened and closed. The mother then sits in a comfortable chair in a sitting or half-sitting position that feels comfortable. The baby modeling researcher, who only has a hat and diaper, places it vertically between the mother's two breasts. Closes the bottom buttons of the mother blouse. This model will be placed completely in the mother's breast and in the fabric fence, reducing the possibility of falls and hypothermia. The researcher then stands next to the mother and asks her to try to make eye contact with the model while smiling and caressing and talking to her. Mothers in the intervention group, after training in embrace care by

role-playing method, perform embrace care with the supervision. Mothers in the control group will receive a routine kangaroo mother care training (pamphlet).

Main outcome variables

Mother-Infant Attachment, Mothers' Sleep Quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190703044082N5**

Registration date: **2021-05-07, 1400/02/17**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-07, 1400/02/17**

Update count: **0**

Registration date

2021-05-07, 1400/02/17

Registrant information

Name

Fateme Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 4567 8904

Email address

f-mohammadi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-05, 1400/01/16

Expected recruitment end date

2021-08-19, 1400/05/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of kangaroo mother care by role-playing method on mother-infant attachment and sleep quality in mothers of premature neonates, Fatemeh hospitalized in neonatal intensive care unit, Hamadan, 2021

Public title

The effect of kangaroo mother care by role-playing method on mother-infant attachment and sleep quality in mothers of premature neonates, Fatemeh hospitalized in neonatal intensive care unit, Hamadan, 2021

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Premature infants weighing 1,800 grams or less Have a minimum APGAR score of 5 minutes for births 7 and above Do not undergo photo therapy The baby is 30 weeks old older Single twin babies The baby has not had surgery the infant should have the conditions to leave the incubator and warmer according to the opinion of a specialist doctor Non-use of psychiatric drugs and tobacco by the mother Mothers age 18 years and older Mothers have the ability to read and write Second childbirth onwards The first infant admitted to the intensive care unit Mothers' desire to participate in the study Healthy babies without severe physical disorders

Exclusion criteria:

psychiatric problems in mothers (depression, bipolar, etc.)

AgeFrom **18 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample sizeTarget sample size: **50****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, two neonatal intensive care units are available to researchers. For random allocation of samples in the control and intervention groups, 6 types of 4 blocks will be used as random block allocation by alternative method. Thus, the letter A will be considered for the intervention group and the letter B for the control group. On the pieces of paper, write the following blocks and put them in an envelope and we will randomly place them. Next, according to the possible order, sampling will start as AABB, BBAA, ABBA, BAAB, ABAB, BABA. According to the order of the letters in the blocks, the

mothers of the babies will be assigned to the intervention or control group. The next blocks will then be selected in the same way

Blinding (investigator's opinion)

Double blinded

Blinding description

The person analyzing the data will be blinded to the assignment of individuals in groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics committee of Hamedan University of Medical Sciences

Street address

Beginning of khajeh rashid Boulevard Hamedan University of Medical sciences

City

Hamedan

Province

Hamadan

Postal code

6517838678

Approval date

2021-02-27, 1399/12/09

Ethics committee reference number

IR.UMSHA.REC.1399.1042

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

mother_neonate atachment sleep quality of mothers

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Maternal-Infant Attachment

Timepoint

Before training, At the time of discharge, One week after discharge

Method of measurement

Brackington Attachment Questionnaire

2

Description

Sleep Quality of Mothers

Timepoint

Before training, At the time of discharge, One week after discharge

Method of measurement

Verine Schneider Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

To perform the intervention, the mothers of the experimental group, each mother individually attends two sessions of 30 minutes in the conference room and is taught how to perform cuddle care using the baby model. For this purpose, the researcher first teaches the mothers and helps them to embrace the baby's model and place it between her breast. while the mother's hand is around the baby's model and holds baby's model between her breasts with kindness and look at baby's model and caress baby's model head with the other hand. The mother practices the procedure under the supervision of a researcher to feel ready to perform kangaroo care for her baby. then researcher helps them wear a special blouse designed according to the kangaroo care standard and protocol. These blouses are loose, have sleeves, short buttons with a distance from the front of the dress that can be easily opened and closed. The mother then sits in a comfortable chair in a sitting or half-sitting position that feels comfortable. The researcher then places the baby, who has only a hat and diaper, vertically between the mother's two breasts. The bottom buttons of the mother's blouse will closed, this way the baby will be completely in the mother's breast and in the fabric fence, reducing the possibility of falls and hypothermia. The researcher then stands next to the mother and asks her to try to make eye contact with the model while smiling and caressing and talking to her. Mothers in the intervention group will perform kangaroo mother care for their babies three times a day and each time 30 minutes .

Category

Rehabilitation

2

Description

Control group: Control group: Mothers in the control group will receive a routine kangaroo mother care training (pamphlet)

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh hospital

Full name of responsible person

shima Kamandani

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Unit1, ganjine134 complex, Jalali alley, 13khaneh ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Mohammadi

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Beginning of Ayatollah Kashani boulevard, Hamedan University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

دانشگاه علوم پزشکی همدان

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

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Mohammadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

This is a file-sharing study.

When the data will become available and for how long

After the article was published

To whom data/document is available

Researchers

Under which criteria data/document could be used

In case of the desired effect of hugging care by role playing method on maternal and neonatal attachment and sleep quality of mothers with premature infants, this method can be performed as routine care and education in neonatal intensive care units.

From where data/document is obtainable

Journal Postal Address

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

By contacting the magazine's editor and emailing the author of the article and obtaining permission to receive information

Comments