

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of kangaroo mother care by role-playing method on resilience and breastfeeding self-efficacy 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 resilience and breastfeeding self-efficacy

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 intensive care unit of Fatemieh Hospital

Intervention groups

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. 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

Resilience and self-efficacy of breastfeeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190703044082N4**

Registration date: **2021-04-20, 1400/01/31**

Registration timing: **prospective**

Last update: **2021-04-20, 1400/01/31**

Update count: **0**

Registration date

2021-04-20, 1400/01/31

Registrant information

Name

Fateme Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 4567 8904

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-07-21, 1400/04/30

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 resilience and breastfeeding self-efficacy 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 resilience and breastfeeding self-efficacy in mothers of premature neonates, Fatemeh hospitalized in neonatal intensive care unit, Hamadan, 202

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 The baby has the ability to suck on the mother's breast 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.)

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target 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)
Single 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
Begining of khajeh rashid Boulevard Hamedan University of Medical sciences

City
Hamadan

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
Resilience and self-efficacy of breastfeeding mothers admitted to neonatal intensive care units

ICD-10 code
R09.0

ICD-10 code description
Asphyxia and hypoxemia

Primary outcomes

1

Description
Resilience

Timepoint
Before training, at the time of discharge and one week after discharge

Method of measurement

2

Description

breastfeeding self-efficacy

Timepoint

Before training, at the time of discharge and one week after discharge

Method of measurement

Dennis breastfeeding self-efficacy

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

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh hospital

Full name of responsible person

fateme mohammadi

Street address

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

fateme mohammadi

Street address

Begining 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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Fateme Mohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position

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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