Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Iran (Islamic Republic of)

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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, Fatemieh 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, Fatemieh 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 Boulvard 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

Conner- Davidson Resilience Scale

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
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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
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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 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