Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of kangaroo care for premature infants at home on mothers' resilience, competence and self-efficacy

Protocol summary

Study aim
Determining the effect of kangaroo care for premature infants at home on maternal resilience, competence, and self-efficacy

Design
The clinical trial will be conducted with a sample size of 30 participants in the intervention group and 30 participants in the control group, with participants allocated randomly using block randomization

Settings and conduct
This clinical trial will be conducted at Shahid Rahimi Hospital in Khorramabad. After the infant stabilizes and is transferred from the NICU, mothers in the intervention group will receive face-to-face training and perform kangaroo care with four weeks of follow-up at home, while the control group will receive standard care. Data will be collected through self-efficacy, parenting competence, and resilience questionnaires during the first visit and at the fourth week.

Participants/Inclusion and exclusion criteria
Inclusion: Premature infants 28-37 weeks gestation, birth weight >1000g, stable condition, singleton, mother present with basic literacy, living in Khorramabad, willing and able to perform kangaroo care and phone follow-up.
Exclusion: Congenital anomalies, advanced resuscitation history, maternal psychiatric/addiction issues, severe family stress, infant illness or rehospitalization, chest/abdomen wounds, stressful events, or maternal withdrawal

Intervention groups
After transfer from the NICU, mothers receive kangaroo care training and special clothing before discharge. Follow-ups are conducted weekly for four weeks. Mothers perform kangaroo care twice daily for 30 minutes. The control group receives standard care

Main outcome variables
Mother's resilience; parenting competence; maternal self-efficacy; implementation of kangaroo care

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250722066597N1**
Registration date: **2025-08-08, 1404/05/17**
Registration timing: **prospective**

Last update: **2025-08-08, 1404/05/17**
Update count: **0**

Registration date
2025-08-08, 1404/05/17

Registrant information

Name
Faezeh Kornokar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 66 4323 6285

Email address
faezehkornokar@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-23, 1404/06/01

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of kangaroo care for premature infants at home on mothers’ resilience, competence and self-efficacy

Public title
The effect of kangaroo care of premature infants on mothers
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Premature baby age 28 to 37 weeks, birth weight over 1000 grams, having a mother, The infant's vital signs are stable (oxygen saturation above 85%, respiratory rate between 30-60 breaths per minute, and heart rate between 120-160 breaths per minute) and ready for discharge from the hospital. Being a singleton, Living in Khorramabad, Minimum literacy of the mother (to answer the questionnaires), Mothers' willingness to participate in the study and perform kangaroo care at home and ability to use a telephone/mobile phone
Exclusion criteria:
The presence of congenital abnormalities in the newborn, the presence of a history of advanced resuscitation, The infant's lack of identity, the presence of diagnosed mental disorders and addiction in the mother, the presence of self-reported serious tension with the spouse, The occurrence of an illness in the newborn that requires re-hospitalization, having wounds on the chest and abdomen of the mother and newborn, Stressful event during the study, such as loss or serious illness in a family member and the mother's unwillingness to continue participating in the study
Age
From **1 day** old to **28 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, participants will be enrolled until the sample size is completed, based on the inclusion and exclusion criteria. To standardize the distribution of confounding variables such as gender, birth weight, and infant feeding, strata will be created according to these variables as follows: groups by gender (male/female), birth weight (<2000 g / 2000-2500 g), and feeding method (formula feeding / breastfeeding). Then, using block randomization, participants will be assigned to the intervention and control groups. In the present study, to balance the number of samples allocated to each study group, block randomization will be employed. For this purpose, random blocks of size 4 will be used to allocate participants to the two groups. Six different combinations of 4-sized blocks (AABB, ABAB, ABBA, BBAA, BABA, BAAB) will be created and randomly selected using the Blockrand package in R software. The random sequence will be formed as a series of letters A and B.
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
Research Ethics Committee of Lorestan University of Medical Sciences
Street address
270, 5th East Danesh Alley, Molavi Street, Hashtsad Dastgah
City
Khorram Abad
Province
Lorestan
Postal code
6881755363
Approval date
2025-07-14, 1404/04/23
Ethics committee reference number
IR.LUMS.REC.1404.180

Health conditions studied

1

Description of health condition studied
The effect of kangaroo care for premature infants at home on mothers’ resilience, competence and self-efficacy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Mother's resilience
Timepoint
At the beginning of the study and 4 weeks later
Method of measurement
Connor and Davidson Resilience Questionnaire

2

Description

Mother's parental competence

Timepoint

At the beginning of the study and 4 weeks later

Method of measurement

Johnston and Mash Parental Competency Questionnaire

3

Description

Maternal self-efficacy

Timepoint

At the beginning of the study and 4 weeks later

Method of measurement

Barnes Parenting Self-Efficacy Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the infant's condition stabilizes and they are transferred from the NICU to the neonatal ward, kangaroo care training for the mother will be provided face-to-face by the researcher using pamphlets and videos for the intervention group. To ensure correct maternal performance, practical kangaroo care will be demonstrated by the mother before discharge. The special kangaroo care clothing prepared by the researcher will also be given to the mothers in the intervention group prior to discharge. The intervention will continue at home with weekly virtual and phone follow-ups for four weeks after discharge. Mothers will perform kangaroo care for their infants at home twice daily, at scheduled times after feeding and diaper changes, wearing the special clothing, positioning themselves and the infant properly, and maintaining room temperature to prevent infant hypothermia. Each session will last 30 minutes and continue for four weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahimi Hospital, Khorramabad

Full name of responsible person

Faezeh Kornokar

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270, 5th East Danesh Alley, Molavi Street, Hashtsad Dastgah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr Bahram Kamarei

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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

Khoram-Abad University of Medical Sciences

Proportion provided by this source

70

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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Faezeh Kornokar

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position
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Latest degree
Bachelor

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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
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
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The de-identified personal data file of participants includes maternal and infant demographic information, scores on the resilience, parenting competence, and self-efficacy questionnaires, and kangaroo care outcomes. Only data related to the primary outcomes of the study will be shared after removing any personally identifiable information.

When the data will become available and for how long
Access to data and documentation will begin 6 months after the publication of the study results and the publication of the related article in scientific journals and will be maintained for at least five years.

To whom data/document is available
Researchers working at accredited academic and research institutions, as well as independent researchers pursuing research projects related to maternal and newborn health, can apply to receive data. Applicants must document their scientific identity.

Under which criteria data/document could be used
The data are only allowed to be used for scientific and ethical research purposes. Any commercial or unethical use is prohibited. Applicants must submit their research protocol and sign a confidentiality and non-disclosure agreement.

From where data/document is obtainable
Applicants can apply by sending a formal application via email to faezehkornokar@gmail.com.

What processes are involved for a request to access data/document
Upon receipt, requests will be reviewed by the research team and, if complete and in accordance with ethical and scientific standards, will be responded to within a maximum of 4 weeks. If approved, a data use agreement will be sent and, after signing it, access to the information will be provided.

Comments

All data has been completely de-identified before submission. Data use is subject to compliance with privacy and research ethics laws. Previous applicants will be notified if data release policies change in the future.