

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Investigating the effect of Kangaroo mother care on maternal fatigue of premature infant hospitalized in Neonatal Intensive Care Unit (NICU)

Protocol summary

Summary

The purpose of this study is to investigate the effect of kangaroo mother care on the fatigue of mothers with a premature infant hospitalized in NICU in Kerman Afzalipour Hospital. Participants in this clinical trial will be 100 primiparous mothers. Mothers will be 20-35 years old, have preterm infants with the gestational age of 28-34 weeks hospitalized in NICU. The participants will randomly be divided into experimental and control groups. In each group, 50 couples of mothers and infants participate. In the experimental group, participants will complete the visual analog scale before starting kangaroo mother care and then will do it for 60 minutes. Intervention will be done twice a day in late morning and evening shifts, as the ward is less crowded, for one week. Intervention will be done twice a day in late morning and evening shifts, as the ward is less crowded, for one week. Then, at the end of a week, the visual analog scale is completed again. The control group participants will receive routine cares. They will complete the visual analog scale at the beginning of the study and at the end of it. Data-collection will be done using visual analog scale (VAS-F) and demographic questionnaire. Descriptive and inferential statistics will be used to analyze the data; then, the data will be compared in 2 stages, pretest (before intervention) and post test (after intervention), to evaluate the impact of kangaroo care on fatigue.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017013032307N1**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name

Maryam Khajouei

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5700

Email address

khajoueim1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-08-16, 1396/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Kangaroo mother care on maternal fatigue of premature infant hospitalized in Neonatal Intensive Care Unit (NICU)

Public title

The effect of kangaroo mother care on maternal fatigue

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: primiparous mothers; mothers with the minimum age of 20 and maximums age of 35 years old; mothers with minimum literacy; mothers who their premature infants are hospitalized in NICU and those who breastfeed; the infants who are hospitalized for at least one week; infants must have the gestational age of 28- 34 weeks; single infant; infants without the use of mechanical ventilation and Birth weight>1200 gr and<2000 gr. exclusion criteria: incurable mother's diseases (physically or mentally); infants with anomaly; unwillingness of mothers to participate in the trial.

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

To allocat randomly the participants in two groups with 50 people in each group, permuted block randomizaton method will be used. so that 25 blocks of 4 are used. In this method, the control and intervention groups are divided into two groups A and B. The possible blocks are AABB, ABAB, BAAB, BBAA, ABBA, BABA, and they numberd from 1 to 6 respectively. Then it is extracted from the random numbers table of numbers from 1 to 6. Obviously, in the case of extraction of the zero number and the number 7 to 9 is again taken from the random number table. A block is selected proportional to the number of extracted from random number table, so that 25 blocks are specified. In the sequel, a list of 100 participants will be provided as the 25 blocks will be specified and the participant will be allocated to groups A and B in the same order as the blocks are obtained.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Blvd.

Haftbagh Alavi, Kerman

City

Kerman

Postal code

7616913555

Approval date

2017-01-25, 1395/11/06

Ethics committee reference number

ir.kmu.rec.1395.520

Health conditions studied

1

Description of health condition studied

Fatigue

ICD-10 code

F48.8

ICD-10 code description

Other specified neurotic disorders

Primary outcomes

1

Description

Fatigue

Timepoint

Pre and post intervention (before the intervention and one week after the intervention)

Method of measurement

Visual analoge scale (VAS-F)

Secondary outcomes

1

Description

Depression

Timepoint

Pre and post intervention (before intervention and one week after intervention)

Method of measurement

Edinburgh Postnatal Depression Scale (EPDS)

Intervention groups

1

Description

In intervention group, kangaroo mother care will be performed for 60 minutes in a manner of which the mother, wearing sleeveless, front open gown, will sit on a chair in a comfortable position with an angel of 45 to 60 degrees; then the investigator places the infant, who has been removed from the incubator, under the gown at the mother's cleavage in an upright, chest to chest position.To keep the infant's airway open, their head will be tilted to one side and their neck will slightly be extended. The arms and legs should be flexed in a "frog"

position. The baby, naked except the diaper, a warm hat and socks, will be carried in a kangaroo position secured with a binder. During the whole period of the intervention, the investigator will accompany the mother. Intervention will be done twice a day in late morning and evening shifts, as the ward is less crowded, for one week.

Category

Other

2

Description

In the control group there is no intervention and the control group will receive routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital of Kerman

Full name of responsible person

Maryam Khajouei

Street address

Afzalipour Hospital, Emam Khomeini High way, Kerman

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti, Vice Chancellor for Research Kerman University of Medical Sciences

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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

Vice Chancellor for Research Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Razi Nursing and Midwifery, Kerman University of Medical Sciences

Full name of responsible person

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Position

MS Student in nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty