Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of two-different time methods of kangaroo care on anxiety, depression, and general health in mothers of premature infants discharged from the neonatal intensive care unit.

Protocol summary

Study aim

The effect of two-different time methods of kangaroo care on anxiety, depression, and general health in mothers of premature infants.

Design

This study is a randomized, single-blind, clinical trial including: two intervention groups and one control group, (55 participants in each group).The allocation of the neonates to each group will be randomly assigned by using six-block size.

Settings and conduct

Samples will be mothers of discharged premature infants from the neonatal intensive care unit. Before the intervention, Beck Anxiety questionnaire, Edinburgh Postpartum Depression Inventory, General Health Questionnaire (GHQ), and the Mood States Questionnaire will be completed. In the scheduled and unscheduled kangaroo care groups, special coverage for kangaroo care will be provided to the mothers. From them will be asked to record the number and the duration of this care in a special checklist. In control group, will not used kangaroo care cover. After 1 month intervention, all questionnaires will be completed by all mothers. For blinding, researcher will not be aware about the allocation of groups, also all questionnaires will be gathered by the research assistant who will be unaware of projects aims.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Iranian primiparous women, 18-35 years old. Exclusion criteria: No exclusive breast feeding, Psychological disorders in mother.

Intervention groups

Scheduled kangaroo care: This care will be implemented daily in three shifts: in the morning, afternoon, and evening, each time for 30 minutes. Unscheduled kangaroo care: This care will be performed at any time and according to the mother's desire. It will be taken at least 30 minutes for each skin-to-skin contact between the mother and the baby. control group: Kangaroo care cover will not be used in this group.

Main outcome variables

Anxiety, depression and general health of mother

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090810002324N19**
Registration date: **2022-05-10, 1401/02/20**
Registration timing: **prospective**

Last update: **2022-05-10, 1401/02/20**
Update count: **0**

Registration date

2022-05-10, 1401/02/20

Registrant information

Name

Maryam Keshavarz

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-19, 1401/02/29

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two-different time methods of kangaroo care on anxiety, depression, and general health in mothers of premature infants discharged from the neonatal intensive care unit.

Public title

The effect of two-different time methods of kangaroo care on anxiety, depression, and general health in mothers of premature infants.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian primiparous women, age 18-35 year. Wanted and single pregnancy. Gestational age of 32-37 Weeks for neonate. Apgar scores equal or greater than 7 In the 5th minute of neonate birth.

Exclusion criteria:

Psychological disorders (according to personal reporting). Chronic disease of mother (Diabetes / multiple sclerosis / Cardio - vascular disease). Maternal addiction to cigarettes, alcohol and psychotropic substances (according to personal reporting). History of recurrent miscarriage, infertility or infertility treatment. Stressful experiences such as divorce or death of family members in past three months. Congenital anomalies of infants.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **165**

Randomization (investigator's opinion)

Randomized

Randomization description

For one of the two interventions and the control group, will be assigned one of the codes A, B, and C. The allocation of the neonates to each group was randomly assigned by using six-block size. Participants will be placed in one of the two interventions or the control group based on the codes in one of the specified block. For concealment, each block will be placed in an opaque envelope. Each envelope will be randomly selected by a research assistant.

Blinding (investigator's opinion)

Single blinded

Blinding description

Researcher will not be aware about the allocation of groups, also all questionnaires will be gathered by the research assistant who will be unaware of projects aims.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical sciences

Street address

School of Nursing & Midwifery, Rashid Yasemi st., Valiasr St.

City

Tehran

Province

Tehran

Postal code

1996713883

Approval date

2022-01-25, 1400/11/05

Ethics committee reference number

IR.IUMS.REC.1400.987

Health conditions studied

1

Description of health condition studied

The mean score of anxiety, depression and general health

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The mean score of mother's anxiety

Timepoint

Before the intervention and after 1 month intervention

Method of measurement

The anxiety of Beck questionnaire

2

Description

The mean score of mother's depression

Timepoint

Before the intervention and after 1 month intervention

Method of measurement
Postpartum Depression of Edinburgh Questionnaire

3

Description
General Health
Timepoint
Before the intervention and after 1 month intervention
Method of measurement
General Health Questionnaire (GHQ)

Secondary outcomes

1

Description
Depressed mood
Timepoint
Before the intervention and then after 1 month intervention
Method of measurement
Depressed mood in the Profile of Mood States Questionnaire (POMS) (McNair)

Intervention groups

1

Description
Intervention group: The scheduled kangaroo care group. This care will be performed daily in three shifts: in the morning, afternoon, and evening, each time for 30 minutes. Mothers will be taught how to implement kangaroo care. The baby will be placed in a special kangaroo care cover, vertically between the mother's breasts. Skin-to-skin contact will be made, so the mother's chest will be contacted with the front of the baby's body, and turning the baby's head to the sideways. To maintain a body proper temperature may be used for baby a hat, socks or diaper.
Category
Prevention

2

Description
Intervention group: The not scheduled kangaroo care group. This care will be performed at any time and according to the mother's desire. It will take at least 30 minutes for each skin-to-skin contact between the mother and baby. Mothers will be taught how to implement kangaroo care. The baby will be placed in a special kangaroo care cover, vertically between the mother's breasts. Skin-to-skin contact will be made, so the mother's chest will be contacted with the front of the baby's body, and turning the baby's head to the sideways. To maintain a body proper temperature may be used for baby a hat, socks or diaper.
Category
Prevention

3

Description
Control group: Kangaroo care cover will not be used in this group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbar-abadi Hospital
Full name of responsible person
Susan Ahmadi
Street address
Mowlavi st.
City
Tehran
Province
Tehran
Postal code
1168743514
Phone
+98 21 5560 6034
Email
akbarabadihosp@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Kaivani
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway.
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86701
Email
vcm@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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

Iran University of Medical Sciences

Full name of responsible person

Maryam Keshavarz

Position

Associated professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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School of Nursing & Midwifery, Rashid Yasemi st., Valiasr St.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Keshavarz

Position

Associated professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

soosan Ahmadi

Position

Midwife

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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