Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of postpartum Kangaroo Mother Care on depression in mothers with premature infants

Protocol summary

Study aim
The effect of Kangaroo Mother Care postpartum depression in mothers with premature infants

Design
randomized clinical trial with community-based with parallel groups (pragmatic control group).

Settings and conduct
At the NICU (Neonatal intensive care unit) in hospitals affiliated to Zanjan University of Medical Sciences and on mothers with premature infants. Kangaroo Mother Care was performed practically and mother was requested to place her naked neonate on her bare chest for half an hour three times a day. It will continue for ten days.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Singleton pregnancy, preterm infants between 36-36 weeks of gestation, mothers with reading and writing skills. Exclusion Criteria: The baby needs nutritional supplements, the mother has a known mental illness. baby with a serious illness or congenital or genetic abnormalities, the mother has physical illnesses such as hale syndrome, eclampsia or preeclampsia, hysterectomy, severe bleeding, etc., caused by delivery, requiring special care and treatment. .

Intervention groups
In the 45-person intervention group, mothers with preterm infants, in addition to routine care, were trained the Kangaroo Mother Care method, in which a naked infant was placed on the mother's bosom for ten days. In the control group of 45 people, only regular care was provided. Before and 10 days after the end of the intervention, the Edinburgh Depression List were completed by both groups.

Main outcome variables
Postpartum depression in mothers with preterm infants

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171230038142N6**
Registration date: **2019-02-16, 1397/11/27**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-16, 1397/11/27**
Update count: **0**

Registration date
2019-02-16, 1397/11/27

Registrant information

Name
Khosro Tavakol

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3792 9134

Email address
tavakol@nm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-04, 1397/11/15

Expected recruitment end date
2019-03-06, 1397/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of postpartum Kangaroo Mother Care on depression in mothers with premature infants

Public title

The effect of postpartum Kangaroo Mother Care on depression in mothers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Singleton pregnancy Premature infants between 32-36 weeks of gestation Mother has reading and writing skills.

Exclusion criteria:

The baby needs nutritional supplements. The mother has a known mental illness. The baby has a serious illness or congenital or genetic abnormalities. Mother suffers from physical illnesses such as Hell's syndrome, eclampsia or pre-eclampsia, hysterectomy, severe bleeding, etc., caused by delivery, requiring special care and attention.

Age

No age limit

Gender

Female

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The selection of mothers was by convenience and then simple random method. In this way, 90 questionnaires were prepared, on the top, number one was written on 45 of them and number two on other 45 questionnaires. Then mothers were asked to complete a questionnaire. Number 1 was for control and number 2 was for intervention groups.

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

Deputy of Research of Islamic Azad University of Medical Sciences of Tehran

Street address

Islamic Azad University, Tehran Medical Sciences Branch, Khaghani St., Shariati St.

City

Tehran

Province

Tehran

Postal code

1916893813

Approval date

2019-02-03, 1397/11/14

Ethics committee reference number

IR.IAU.TMU.REC.1397.269

Health conditions studied

1

Description of health condition studied

Postpartum Depression

ICD-10 code

F32.8

ICD-10 code description

Other depressive episodes

Primary outcomes

1

Description

Postpartum Depression

Timepoint

Before the intervention, 24-48 hours after birth and 20 days after the first intervention

Method of measurement

Postpartum Depression Inventory 10th Anniversary of Edinburgh

Secondary outcomes

empty

Intervention groups

1

Description

The group, in addition to the usual care of premature baby, 24 - 48 hours after delivery, performed the method of Kangaroo Mother Care by placing the naked baby on the mother's bare chest for ten days, three times a day , below a linen cover.

Category

Treatment - Other

2

Description

Control group: only received recommendations for the care of preterm infants.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hossein Hospital Zanjan Social Security

Full name of responsible person
Mehran Dukht Nakavand

Street address
Imam Hossein Zanjan Hospital, near Koy Farhang

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Zanjan

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Zanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

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?
Yes

Title of funding source
Islamic Azad University

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
Islamic Azad University

Full name of responsible person
Mehran Dukht Nakavand

Position
Assistant Professor & Research Deputy

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The information can be shared with the coordination of Tehran University of Medical Sciences's research vice after being unidentifiable.
When the data will become available and for how long
Starting the access period two years after the publication of the article.
To whom data/document is available
Students, professors and researchers in nursing, psychology and psychiatric groups.
Under which criteria data/document could be used
To compare the information and the results with a similar clinical approach or psychology or other psychological testing.
From where data/document is obtainable
Firstly, by sending an email to mnakavand@hotmail.com, you will be asked to speak clearly, and then, with the coordination of the research and student affiliation of Tehran University of Medical Sciences, the documentation can be obtained.
What processes are involved for a request to access data/document
Send the request to mnakavand@hotmail.com and then coordinate the research and student affiliation of Tehran University of Medical Sciences.
Comments