

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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

City

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Islamic Azad University

Full name of responsible person

Mehran Dukht Nakavand

Street address

Islamic Azad University, Tehran Medical Sciences
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mnakavand@hotmail.com

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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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

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