Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of KMC by mothers and telephone advice on anthropometric indexes and some of the behavioral features in preterm newborns discharged from the neonatal intensive care unit

Protocol summary

Summary

Objectives: Kangaroo mother care (KMC) is least expensive way to human care of babies with low birth weight. Most of studies have investigated the effect of KMC on weight gaining in hospitalized premature infants in intensive care unit and have not reported a significant effect. This result could be due to the short intervention period in the hospital. Few studies focused on KMC at home, so this study will be undertaken to determine if KMC at home has significant effect on anthropometric indexes in preterm newborns. Design: In a single blind randomize controlled trail and, 105 preterm infants who will be discharged from the neonatal intensive care unit (NICU), will be randomly assigned to one of the three groups by a sampler: KMC, KMC with telephone advice and control group (35 in each group). Participants: Iranian singleton preterm infants with gestational age 32-37 weeks; No congenital anomalies; Lack of neonatal resuscitation and intra uterine growth retardation (IUGR). If mother's unwillingness to continue participation in the study; Illness or disability maternal to caring infant; Infant death; Non exclusive breast-feeding; Mother or infant hospitalization during the study; KMC was more than three times a day; KMC less than 2 hours per day, the samples will be excluded from study. Intervention: In the KMC group, the special cover will be given to the mothers. The bare baby will be put in the cover between their breasts for 2-4 hours and maximum for three times every day. Duration of care will be recorded daily in the special checklist. Extra to the above, in the telephone advice group, In order to remind the KMC, will be contacted with mothers twice a week. Before the intervention, in two intervention groups, educational pamphlet about KMC implementation will be given to the mothers. In three groups after the intervention, weight, height, head and chest circumference will be measured by a research assistant in all infants. Main outcome: In three groups after the intervention, weight, height, head and chest circumference will be measured in all infants by a research assistant. In all groups, the number of infant's severe crying, defecation, breast-feeding and sleep that will be recorded daily in special checklist by mother, will be docketed in the data recording sheet by a research assistant. No intervention will be done in control group. Method of blinding: Infant anthropometric measurements and recording of behavioral characteristics of preterm infants in the data recording sheet will be done by by a research assistant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306082324N11**
Registration date: **2014-04-28, 1393/02/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-28, 1393/02/08

Registrant information

Name

Maryam Keshavarz

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1813

Email address

keshavarz@iums.ac.ir

Recruitment status

Recruitment complete

Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2013-09-01, 1392/06/10
Expected recruitment end date
2013-12-01, 1392/09/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of KMC by mothers and telephone advice on anthropometric indexes and some of the behavioral features in preterm newborns discharged from the neonatal intensive care unit

Public title
The effect of kangaroo Mother Care (KMC) by mothers and telephone advice on anthropometric indexes and some of the behavioral features in preterm newborns
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Iranian and singleton preterm infants; Gestational age 32-37 weeks; Lack of neonatal resuscitation and intra uterine growth retardation (IUGR). Exclusion criteria: Mother's unwillingness to continue participation in the study; Illness or inability maternal to caring infant; Neonatal death; Non exclusive breast-feeding; Mother or infant hospitalization during the study; KMC more than three times a day or less than 2 hours per day
Age
From **1 day** old to **1 year** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical commitment of Tehran University of Medical Sciences
Street address
Sixth floor, Central office, Ghods St, Keshavarz Blvd-Tehran, Iran
City
Tehran
Postal code
Approval date
2013-07-01, 1392/04/10
Ethics committee reference number
594/130/92/د

Health conditions studied

1

Description of health condition studied
measurement of anthropometric indexes in preterm infants
ICD-10 code
P07.3
ICD-10 code description
Other preterm infants

Primary outcomes

1

Description
Anthropometric indexes (height, weight, head circumference, chest circumference)
Timepoint
One month after discharge
Method of measurement
Height, head and chest circumference will be measured by the meter and weight will be measured by Seca digital scale

2

Description
severe crying, defecation, sleep and the number of breast-feeding
Timepoint
daily
Method of measurement
will be recorded in special chechlist by mother

Secondary outcomes

empty

Intervention groups

1

Description
In KMC with telephone advice group the special cover will be given to the mothers. The mothers will be put the bare baby in the cover between their breasts for 2-4 hours and maximum for three times every day (during one month). The mothers will be recieved a special check list including infant's severe crying, defecation, sleep and breast-feeding that will be recorded daily. In order to remind the KMC, will be contacted with mothers twice a week.

Category
Prevention

2

Description
In KMC group, the mothers will be put the bare baby in the cover between their breasts for 2-4 hours and maximum for three times every day(during one month).The mothers will be recieved a special check list including infant's severe crying, defecation, sleep and breast-feeding that will be recorded daily

Category
Prevention

3

Description
In control group, the mothers will be recieved a checklist including infant's severe crying, defecation, sleep and breast-feeding that will be recorded daily (during one month).There is no further action.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Akbarabadi treatment & education center

Full name of responsible person
Maryam Keshavarz

Street address
Shahid Akbar Abady, Molavi St. Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sciences vice chancellor for research- Tehran University of Medical Sciences

Full name of responsible person
Dr. Akbar Fotohi

Street address
Sixth floor, Central office, Ghods St, Keshavarz Blvd-
Tehran, Iran

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Sciences vice chancellor for research- Tehran 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
Nursing and Midwifery,Iran University of Medical Sciences

Full name of responsible person
Maryam Keshavarz

Position
Assistant Professor in Midwifery education

Other areas of specialty/work

Street address
Vali-e-Asr Av, Upper Vanak Sq , Rashid Yasami Street-School of Nursing and Midwifery ,Departement of midwifery, Iran University of Medical

City
Tehran

Postal code

Phone
+98 21 6105 4219

Fax

Email
keshavarz.m@iums.ac.ir; m_keshir@yahoo.com

Web page address
www.fnm.iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person
Maryam Keshavarz

Position
Assistant Professor in Midwifery education

Other areas of specialty/work

Street address

Vali-e-Asr Av , Upper Vanak Sq , Rashid Yasami Street- School of Nursing and Midwifery ,Departement of midwifery, Iran University of Medical

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Tehran

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+98 21 6105 4219

Fax

Email

keshavarz.m@iums.ac.ir; m_keshir@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person

Maryam Keshavarz

Position

Assistant Professor in Midwifery education

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+98 21 6105 4219

Fax

Email

Keshavarz.m@iums.ac.ir; m_keshir@yahoo.com

Web page address

www.fnm.iums.ac.ir

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