ISRCTN14346778 https://doi.org/10.1186/ISRCTN14346778

Exploring the benefits of early Kangaroo Mother Care on breastfeeding and growth in newborns who are 2500 grams or more birth weight

Submission date
18/11/2024

Recruitment status
No longer recruiting

Registration date
19/12/2024

Overall study status
Completed

Last Edited
17/04/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

The transition from intrauterine to extrauterine life involves a complex series of energy-consuming adaptive processes, each crucial for the newborn's survival. These challenges faced by newborns in establishing homeostasis include thermoregulation, metabolic, respiratory, cardiovascular, skin barrier and immune system adaptations. The time required for each adaptive process can vary based on gestational age, birth weight and early care practices that may support or disrupt these processes. The high energy requirements of these adaptive processes compound the energy deficit due to the sudden interruption of continuous nutrient supply through the placenta, potentially contributing to the observed early weight loss. Kangaroo Mother Care (KMC) offers an innovative approach that may mitigate these factors, benefiting newborns of all birth weights and gestational ages. KMC involves close skin-to-skin contact between the newborn infant and the caregiver, typically the mother. It is a comprehensive care strategy centred around continuous skin-to-skin contact between the newborn and their mother or caregiver. This approach encompasses various essential components, including thermal regulation, support for breastfeeding, and the creation of a nurturing and protective environment for the infant. The World Health Organization currently recommends KMC as foundational care for all preterm and low birth weight infants. It is noteworthy that KMC is presently not prescribed for infants with normal birth weight. This study's objective is to generate empirical evidence regarding the efficacy of KMC when initiated within the first 48-72 hours following birth, even for infants born with normal birth weight. Should this intervention prove effective, it could pave the way for the normalisation of KMC as a standard of care for all newborns within healthcare facilities. This, in turn, could lead to enhancements in nutritional and growth outcomes, particularly within settings characterised by inadequate early infant feeding practices. The study aims to show that prolonged KMC (at least 8 hours and ideally >20 hours of daily skin-to-skin contact along with exclusive breastfeeding) in the first 72 hours among normal birth weight infants when compared with standard care, will lead to a 25% reduction in average weight loss (as a proportion of birth weight) during the first 2 days, a 20% improvement in mean weight gain velocity measured during the first 28 days of life, and 50% fewer mother-baby dyads

with moderate-to-poor Bristol Breastfeeding Assessment Tool (BBAT) score (<7 out of 8) (assessed at age 7 completed days).

Who can participate?
All healthy singleton newborns with birth weight >2500 grams, born vaginally and screened and enrolled within 4 hours of birth living in the catchment area

What does the study involve?
Normal birth weight newborns will be randomly assigned to one of two treatment groups i.e. control arm or intervention arm. Both groups will receive the essential newborn practices and the intervention group will additionally receive the KMC component. All enrolled newborns will be followed up for 29 days.

What are the possible benefits and risks of participating?
Benefits to participants: Inadequate breastfeeding practices in the initial week of an infant's life can set the stage for a harmful cycle of insufficient milk production and slowed growth. The initial thermoregulatory and metabolic hurdles experienced during the transition from the womb to the outside world within the first 72 hours may also contribute to early weight loss in newborns. Kangaroo Mother Care (KMC) is an existing recommendation for reducing mortality in low birth weight infants, and it has the potential to enhance nutritional and growth outcomes in infants of regular birth weight when initiated within the first 72 hours of life.
The study includes healthy and normal birth weight newborns in the study. Also, there is ample evidence supporting the fact that the intervention “KMC” itself does not pose any risk to infants, rather it reduces the risk of sepsis and overall neonatal mortality – leading to its inclusion in the revised WHO recommendations. The study is therefore not developing or evaluating any new intervention, but rather developing and evaluating a model to scale up an intervention that is already proven to reduce the risk of neonatal mortality. The risks of participating in the study are thus less than minimal, with a low likelihood of occurrence.

Where is the study run from?
Community Empowerment Lab, Lucknow (India)

When is the study starting and how long is it expected to run for?
February 2024 to May 2025

Who is funding the study?
The Indian Council of Medical Research (ICMR)

Who is the main contact?
Ms. Aarti Kumar (scientific), aarti.kumar@celworld.org
Mr. Vinay Pratap Singh (public), vinaypratap.singh@celworld.org

Contact information

Type(s)
Scientific, Principal Investigator

Contact name
Ms Aarti Kumar

ORCID ID

http://orcid.org/0000-0003-4331-3747

Contact details
A 6/14, Vineet Khand Gomti Nagar
Lucknow
India
226010
+91 9936060009
aarti.kumar@celworld.org

Type(s)
Public

Contact name
Mr Vinay Pratap Singh

ORCID ID
http://orcid.org/0000-0003-1421-8775

Contact details
A 6/14, Vineet Khand Gomti Nagar
Lucknow
India
226010
+91 9818000252
vinaypratap.singh@celworld.org

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Indian Council of Medical Research (ICMR) grant code: IIRP-2023-7329, CTRI/2024/01/062057

Study information

Scientific Title
Can Kangaroo Mother Care (KMC) during the first 72 hours lead to improved breastfeeding and growth among normal birth weight newborns? - A randomised controlled trial

Study objectives
Prolonged KMC (at least 8 hours and ideally >20 hours of daily skin-to-skin contact along with exclusive breastfeeding) in the first 72 hours among normal birth weight infants when compared with standard care, will lead to:

1. a 25% reduction in mean percentage weight loss during the first 2 days, and
2. a 20% improvement in mean weight gain velocity measured during the first 28 days of life, and
3. 50% fewer mother-baby dyads with moderate-to-poor BBAT score (<7 out of 8) assessed at age 7 completed days.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 12/12/2023, Community Empowerment Lab Institutional Ethics Committee (A 6/14, Vineet Khand Gomti Nagar, Lucknow, 226010, India; +91 8810725123; irb@cel.org.in), ref: CEL /IEC/202311/003

2. Approved 23/09/2024, Institutional Ethics Committee King's George Medical University (King Georges Medical University, Shahmina Road, Lucknow, 226003, India; +91 522 4070395; ethics@kgmcindia.edu), ref: 130th ECM IIA/P20

Study design
Multicenter pragmatic individually randomized controlled open-label superiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital

Study type(s)
Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Healthy singleton newborns and their mothers who intend to breastfeed

Interventions
This is an open-label individually randomised controlled study. The study biostatistician will generate a randomisation scheme with random permuted blocks of variable sizes between 2, 4 and 6 using a computer program for each facility. The random allocation file for each facility will be electronically stored in the secure RedCap application database for sequentially use for enrolment.

Mother-to-newborn:
The intervention from the mother to the baby will include continuous and prolonged skin-to-skin contact (SSC) (ideally >=20 hours, but at least >=8 hours daily), along with breastfeeding on demand in the KMC position (on-demand, as initiated by the newborn as per his/her needs while

in SSC) during the first 72 hours of life. Post the first 72 hours and through the newborn period, mothers will be recommended to continue with SSC as per their desire and comfort and be advised to continue to breastfeed in the KMC position to the extent possible.

Counseling and support to the mother:
A team of lay workers trained in KMC support (called the KMC team) will be responsible for providing counselling and support to mothers in KMC during the first 48 hours of facility admission.

Mothers will be counselled on the potential benefits of Kangaroo Mother Care and will be supported in providing prolonged KMC in the facility with the help of a binder. The KMC team will counsel and support the mother in placing the baby appropriately in a skin-to-skin position, teaching her the use of a binder and breastfeeding while the baby is in the KMC position. SSC during the hospital stay will involve the infant and mother remaining bare-chested in the KMC position, with the baby's head covered by a cap, and feet kept warm with socks. All measures will be taken to keep the baby safe in the SSC position. This will include keeping the mother in a semi-reclined position at an angle of 30-45 degrees (or in an ambulatory position when the mother wishes) and securing the baby with a binder firmly to the chest and a shirt that provides containment in the KMC position. All routine care will be provided in SSC. Any interruptions in SSC will be documented to determine the duration for which the intervention was provided per day (dose). The KMC team will take all measures to ensure that mothers provide continuous KMC, with >= 20 hrs of daily SSC without removing the baby for breastfeeding, to the extent possible.

Post 48 hours, the mother-baby dyad will be discharged from the facility in ambulatory KMC (provided there are no signs of complications in either mother or baby that require a longer duration of hospital stay). The KMC team will ensure that the mother-baby dyad is discharged in the KMC position along with counselling on continuing KMC similarly for at least 1 more day at home. The KMC team will remind mothers/ family members telephonically in the morning and afternoon of the day after discharge to encourage the provision of prolonged KMC (ideally >=20 hours, but at least >=8 hours). Post 72 hours, on Day 4, the KMC team will make a final call to mothers and family members to recommend them to continue keeping the baby in SSC for as long as they wish, as per their desire and comfort, and be advised to continue to breastfeed in the KMC position throughout the newborn period.

Intervention Type
Behavioural

Primary outcome measure
1. Newborn weight measured using a calibrated Seca 334 or equivalent digital weighing scale over the first 48 hours after birth
2. The weight gain velocity will be calculated during the newborn period using newborn weight measured using a calibrated Seca 334 or equivalent digital weighing scale from baseline to last follow-up between 28-32 days
3. Quality of breastfeeding measured using the Bristol Breastfeeding Assessment Tool (BBAT) score on Day 8 (i.e. at 7 completed days of age)

Secondary outcome measures
1. Exclusive breastfeeding measured using a 24-hour dietary recall method for exclusive breastfeeding at Day 1, 2, 4, 8, 14 and 28 follow-up visits
2. Early challenges with breastfeeding measured using the Breastfeeding Experience Scale (BES)

reported by the mother on follow-up day 8
3. Possible Serious Bacterial Infection (PSBI) among infants measured by trained and standardised workers using the Integrated Management of Childhood Illness (IMCI) algorithm protocol on days 4, 8, 15 and 29
4. Maternal depression measured using the Edinburgh Postnatal Depression Scale (EPDS) at 15 days after birth
5. Breastfeeding self-efficacy measured using the Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF) on day 29
6. The mother's feelings towards her infant measured using the Mother-to-Infant Bonding Scale (MIBS) on day 29

Overall study start date
20/02/2024

Completion date
17/04/2025

Eligibility

Key inclusion criteria
1. Healthy singleton newborns with birth weight >2500 grams, born vaginally and screened and enrolled within 4 hours of birth.
2. Mothers having singleton vaginal delivery without any complication in the study facility who are further willing to stay in the facility for 48 hours post-delivery and who shall reside in the catchment area near the study facility for the next 28 days.
3. Mother who intend to breastfeed their infants over the first 28 days of life.

Participant type(s)
Healthy volunteer, Service user

Age group
Neonate

Lower age limit
0 Days

Upper age limit
27 Days

Sex
Both

Target number of participants
516

Key exclusion criteria
Newborns:
1. Any condition that will require immediate admission to the neonatal intensive care unit (NICU/ SNCU) such as respiratory distress, birth asphyxia etc
2. Newborns should not be enrolled in any other research study that would interfere with the

intervention and outcomes
3. Having major congenital malformations which are apparent at birth that can interfere with the intervention like anencephaly, hydrocephaly, omphalocele, cleft lip, cleft palate, meningomyelocele, imperforate anus.

Mothers:
1. Maternal Death
2. Multiple births
3. Caesarean section delivery
4. Women with HIV opting for top feeding
5. Any complications e.g. postpartum haemorrhage (PPH), eclampsia, etc. identified within an hour of birth, requiring special or intensive care beyond routine postnatal care
6. Any other problems, such as generalized skin rashes/ infection, that may hinder their ability to provide prolonged KMC

Date of first enrolment
15/11/2024

Date of final enrolment
14/06/2025

Locations

Countries of recruitment
India

Study participating centre
King George's Medical University, Lucknow
Shahmina Road
Lucknow
India
226003

Study participating centre
Veerangana Avanti Bai District Women's Hospital
Veerangana Avanti Bai Mahila Chikbagwalaitsalaya Dufferin Hospital, Hospital Rd, Golaganj, Qaisar Bagh
Lucknow
India
226018

Sponsor information

Organisation

Indian Council of Medical Research

Sponsor details
V. Ramalingaswami Bhawan, P.O. Box No. 4911 Ansari Nagar
New Delhi
India
110029
+91-11-26588895
icmrhqds@sansad.nic.in

Sponsor type
Government

Website
https://www.icmr.gov.in/

ROR
https://ror.org/0492wrx28

Funder(s)

Funder type
Government

Funder Name
Indian Council of Medical Research

Alternative Name(s)
Indian Council of Medical Research, Government of India, Indian Council of Medical Research (ICMR), New Delhi, ICMROrganisation, , Indian Council of Medical Research, New Delhi, ICMR, ICMRDELHI, ...

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
India

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 0.3	18/12/2024	20/01/2025	No	Yes
Protocol file	version 3.0	10/09/2024	20/01/2025	No	No