# 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	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li><li>[X] Protocol</li></ul>
<b>Registration date</b> 19/12/2024	<b>Overall study status</b> Completed	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 17/04/2025	<b>Condition category</b> Pregnancy and Childbirth	<ul><li>[] Individual participant data</li><li>[X] Record updated in last year</li></ul>

#### Plain English summary of protocol

#### Background and study aims

The transition from intrauterine to extrauterine life involves a complex series of energyconsuming 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**

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## 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