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Integrating Kangaroo mother care for small babies immediately after birth into routine health services in Uttar Pradesh

Submission date
06/06/2023

Recruitment status
Recruiting

Registration date
24/06/2023

Overall study status
Ongoing

Last Edited
15/07/2024

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
This study is a two-phase implementation research study in Uttar Pradesh, India, focusing on integrating immediate Kangaroo Mother Care (iKMC) into routine neonatal care practice within level-2 special newborn care units (SNCUs)/neonatal Intensive Care Units (NICUs). The iKMC intervention is effective and low-cost involving skin-to-skin contact and breastmilk feeding, shown to reduce mortality in preterm and low birth weight infants. The study, part of a multi-country initiative by the WHO, seeks to evaluate the impact of this practice on neonatal mortality within iKMC implementing facilities in Uttar Pradesh, a region with a high neonatal mortality burden. The research is overseen by the WHO, with data managed by the Translational Health Science and Technology Institute and reviewed by multiple ethical committees. The study's findings could pave the way for integrating iKMC into health facilities at scale, based on the latest WHO recommendations for the care of low birth weight and preterm infants from 2022.

Who can participate?
Low birth weight or preterm newborns who are eligible to require care in an SNCU/NICU

What does the study involve? :
Phase I involves developing a healthcare model to achieve high-quality iKMC among participating facilities in a single district, while Phase II evaluates this model's impact across three additional districts using a stepped-wedge cluster randomised controlled design. Collaboration with medical colleges, health departments, and community stakeholders will be vital.

What are the possible benefits and risks of participating?:
Benefits: Since half to two-thirds of deaths among preterm/ <2000 gram infants occur prior to clinical stabilization, the iKMC intervention may improve newborn outcomes of this vulnerable group, as has been suggested by many previous studies and evidence. It will likely result in lowering the mortality and morbidity rates in preterm and low birth weight neonates who take part in the study.

Risks: There is ample evidence supporting the fact that the iKMC intervention itself does not pose any risk to infants receiving Level-2 NICU care, rather it reduces the risk of sepsis and overall neonatal mortality – leading to its inclusion in the revised WHO recommendations for preterm and low birth weight infants. The study team are hence, 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, therefore, less than minimal, with a low likelihood of occurrence. Risks of participation may include a potential breach of confidentiality and embarrassment or discomfort in discussing potentially sensitive issues or during the process of observation.

Where is the study run from?
Community Empowerment Lab (CEL), Uttar Pradesh, India and respective participating centres in Lucknow, Agra, Kanpur Nagar and Varanasi

When is the study starting and how long is it expected to run for?
July 2022 to May 2027

Who is funding the Study?
The World Health Organization (Switzerland)

Who is the Main Contact?
Ms Aarti Kumar (CEO & Co-Principal Investigator), aarti.kumar@celworld.org

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CEL/IEC/202303/001 Dated: March 10, 2023, Version: 3.0

Study information

Scientific Title
Implementation research to develop & evaluate a health system model to integrate immediate Kangaroo Mother Care (iKMC) into the routine care of preterm or low birth weight infants in Uttar Pradesh

Acronym

iKMC

Study objectives
Whether or not the immediate Kangaroo Mother Care (iKMC) implementation model designed and developed as a primary outcome of phase 1 of the study, when scaled will bring a reduction in neonatal mortality

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 11/04/2023, Community Empowerment Lab (CEL) Institutional Ethics Committee (IEC) (A-6/14, Vineet Khand 6, Gomti Nagar, Lucknow, Uttar Pradesh, 226010, India; +91-522-4070395; irb@cel.org.in), ref: CEL/IEC/202304/002

2. Approved 13/05/2023, WHO Research Ethics Review Committee (World Health Organisation, 20, Avenue Appia, Geneva 27, CH-1211, Switzerland; None available; ercsec@who.int), ref: ERC.0003880

3. Approved 06/05/2023, Banaras Hindu University Institutional Ethics Committee (BHU IEC) (Institute of Medical Sciences, Banaras Hindu University, Aurobindo Colony, Bhelupur, Varanasi, Uttar Pradesh, 221005, India; +91-9146814727; dean_med@bhu.ac.in), ref: EC/5052

4. Approved 26/08/2023, Ethics Committee, GSVM Medical College, Kanpur (Room no. 125, 1st Floor, GSVM Medical College, Kanpur, 208002, India; +91 (0)7905966754; ecgsvm@gmail.com), ref: EC/208/Aug/2023

Study design
Mixed methods implementation research with a stepped-wedge cluster randomized study design

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Home, Hospital, Medical and other records

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Disorders of newborn related to short gestation or low birth weight

Interventions

Background
Immediate Kangaroo Mother Care (iKMC) is a simple, cost-effective innovation that involves holding the preterm or low birth weight infant in skin-to-skin contact with the mother or caregiver, together with exclusive breastmilk feeding and other supportive care. When initiated after attaining clinical stability, iKMC has a 40% improved survival when compared to conventional incubator care. Further, when iKMC was initiated prior to attaining clinical stabilization, it was found to hasten the process of clinical stabilization and a further 25% reduction in neonatal mortality as compared to conventional incubator care prior to stabilization.

The revised WHO recommendations on the care of preterm and low birth weight infants released in September 2022 take the latest research findings into account and advise immediate initiation of KMC in all preterm and low birth weight infants, regardless of clinical stability. However, current medical practice involves immediate separation of unstable infants, or infants eligible for care within special newborn care units (SNCU)/neonatal intensive care units (NICU) from their mothers. This limits the potential impact of iKMC, given that half to two-thirds of deaths among preterm /<2000 gram infants would have already occurred prior to clinical stabilization.

This study focuses on integrating iKMC for preterm and/or low birth weight infants requiring admission to an SNCU or level-2 NICU, into existing functional systems of care. It will involve developing an optimized model of care that supports co-habitation of the mother/surrogate caregiver with their newborns eligible for SNCU care, initiation of iKMC within 2 hours of birth or admission to the facility, continuous skin-to-skin contact for at least 8 hours per day, early and exclusive breast milk feeding, and any other medical care (including non-invasive ventilation) to be provided while in skin-to-skin contact. Supporting such care will require space modifications, process modifications, close coordination between the obstetric and paediatric teams, and unlearning/re-learning by care-providing teams.

Study Method: Implementation research; Stepped-wedge cluster randomised trial
The method of randomization for this study will be computer-generated randomization which will assign the order in which each study cluster (out of 3 clusters) transitions from control to intervention at pre-designated time points (every 6 months). Thus, the randomization sequence will identify which of the clusters will transition first, second and third.

Implementation research (IR)
This is IR which is focusing on integrating iKMC for preterm and/or low birth weight infants requiring care in an SNCU or level-2 NICU. WHO has released revised recommendations on the care of preterm and low birth-weight infants recently. So this study is trying to develop a model integrating iKMC for preterm and/or low birth weight infants requiring care to an SNCU or level-2 NICU in 1st phase of the study in one district and then the impact of this model will be evaluated using stepped-wedge cluster randomization in 3 different districts.

Modes of delivery
In a district-level model, medical colleges and district hospital(s) will be selected where SNCU or level-2 NICU is functional. The preterm and/or low birth weight infants requiring admission in SNCU or level-2 NICU will be included as per inclusion criteria to get iKMC along with other supportive care i.e. it will be at SNCU/NICU face-to-face.

Intervention location(s)
This is an IR study that consists of 2 phases: a model development phase and a model evaluation phase. The site for the model development phase will be Kanpur Nagar district, and the proposed sites (treated as study clusters) for the model evaluation phase are Varanasi, Lucknow

and Agra districts. However, this is subject to change prior to the actual initiation of the study phase-2.

The main outcome of the design and optimization phase will be the development of the optimized implementation models that achieve high coverage and quality of iKMC immediate Kangaroo Mother Care) and establish the norm of zero separation between the mother and her newborn; we will measure this through a primary coverage outcome in a tracer indicator that captures the skin-to-skin component of iKMC i.e., initiation and duration of skin-to-skin contact. This will be captured from the hospital records of M-SNCU (Mother-Special Newborn Care Unit) to study case report forms. Skin-to-skin contact is initiated within 2 hours after birth in case of inborn or within 2 hours of reaching the iKMC implementing a facility in case of outborn. Continuous skin-to-skin contact is provided by a mother/surrogate for at least 8 hours per day during the stay in the level 2 M-SNCU hospital (average hours per day for the overall M-SNCU stay).

While in the evaluation phase, we will measure the impact of the scale-up of the optimized model on neonatal mortality, i.e the proportion of preterm or LBW infants who died during the first 28 days of life through a questionnaire that will be asked from the primary caregiver of the newborn on 29th day of infants age; this will be evaluated in a stepped-wedge, cluster-randomized trial design in 3 districts over a duration of 24 months.

Intervention Type
Other

Primary outcome measure
Primary Outcome for Phase I: Model Development
An optimized implementation model that achieves a high coverage and quality of iKMC and establishes the norm of zero separation between the mother and her newborn
The proportion of preterm or LBW newborns (henceforth referred to as 'small newborns') requiring care in level 2 SNCUs either born in or brought to the iKMC implementing facility within 24 hours of birth (denominator), who received iKMC defined as the initiation of iKMC within the first 2 hours of birth (for inborn infants) or first 2 hours of admission (for outborn infants) and received at least 8 hours per day of skin-to-skin contact on average during their stay in the facility.

Primary Outcome for Phase 2: Model Evaluation
The proportion of preterm or LBW infants who died during the first 28 days of life (neonatal mortality rate among the trial participants). The baby will be followed-up just after 28 days (at home or hospital if admitted) to record their current status to record if any mortality.

Secondary outcome measures
Secondary Outcomes for Phase 1 measured using patient medical records at one timepoint:
Quality Outcomes:
1. The proportion of preterm or LBW infants who arrived at an iKMC implementing facility within 24 hours after birth among those born in a health facility who required referral at birth to an iKMC implementing facility
2. The proportion of preterm or LBW infants on respiratory support (any oxygen or CPAP) who received skin-to-skin contact > 8 hours/day in the M-SNCU
3. The proportion of preterm or LBW infants receiving iKMC at discharge (8-24 hours of skin-to-skin contact and exclusively breastfed) in the 24 hours before discharge from the iKMC implementing facility

4. The proportion of preterm or LBW infants who are exclusively breastfed at discharge
5. Median age at putting the baby to the breast for the first time during M-SNCU stay

Implementation Outcomes will be captured from the hospital records of M-SNCU (Mother-Special Newborn Care Unit) to study case report forms at one timepoint:
1. Acceptability: iKMC including transport in skin-to-skin contact from the birthing place to M-SNCU is acceptable to mothers (and/or surrogates). Mothers and caregivers are satisfied with the care received. iKMC is acceptable to health workers (facility and community).
Adoption: The challenges in the adoption of iKMC by mothers, hospital managers and health providers (nurses, midwives, doctors) identified in programme learning are addressed.
2. Adaptation: Modifications to adapt the iKMC intervention to the social and routine health system context are implemented.
3. Cost: what are the costs of implementing iKMC in routine healthcare settings?
4. Fidelity: Quality iKMC care is being provided to mothers and newborns in the level 2 M-SNCUs and iKMC wards and to what extent the mothers are adhering to the recommended practices.

Secondary Outcomes of Phase 2 measured using patient medical records at one timepoint:
Breastfeeding:
1. Proportion of preterm or LBW infants who are exclusively breastfed at discharge from trial facilities
2. Median age at putting the baby to the breast for the first time during M-SNCU/SNCU stay
3. Median age at initiation of breastmilk feeding during the M-SNCU/SNCU stay
4. Proportion of preterm or LBW infants with clinical sepsis: As diagnosed by the attending physician either defined by clinical signs alone or the presence of clinical signs with positive laboratory screening test while in M-SNCU/SNCU
5. Proportion of preterm or LBW infants who has hypoglycaemia: Any blood glucose level of <45 mg per decilitre, measured when clinically indicated during M-SNCU/SNCU stay, as per the SNCU protocol of each study
6. Proportion of preterm or LBW infants who has hypothermia: Any axillary temperature <36°C during M-SNCU/SNCU stay
7. Proportion of preterm or LBW infants receiving iKMC at discharge (8-24 hours of skin-to-skin contact and exclusively breastfed in the 24 hours before discharge) from the trial facility

Overall study start date
15/07/2022

Completion date
15/05/2027

Eligibility

Key inclusion criteria
1. Aged between 0.00 and 27.00 days
2. All genders
3. Preterm (gestational age <37 weeks) or low birth weight (<2.5 kg at birth) requiring care in the SNCU, i.e., who are <1800 g or gestational age <34 weeks (SNCU admission criteria), or those preterm or LBW newborns who are above these cut-offs but are sick and need SNCU admission.

Participant type(s)
Patient

Age group
Neonate

Lower age limit
0 Days

Upper age limit
27 Days

Sex
Both

Target number of participants
3000

Key exclusion criteria
1. Preterm or LBW newborns requiring SNCU care who are critically sick, for example:
1.1. Are unable to breathe spontaneously within the first hour after birth or have congenital malformations that interfere with the intervention, or the intervention interferes with the required care for the congenital malformation (e.g., anencephaly, congenital heart disease, gastroschisis, hydrocephaly, multiple malformations, omphalocele, tracheoesophageal fistula, abdominal detention. etc.)
1.2. Are in shock (in need of inotropes) or
1.3. Are receiving invasive mechanical ventilation in the first 2 hours of birth or admission to SNCU; or
1.4. Liveborn who died in the first 2 hours of birth or first 2 hours of admission or were dead at the time of admission to the iKMC implementing facility

Date of first enrolment
15/08/2024

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
India

Study participating centre
Dr Ram Manohar Lohia Institute of Medical Sciences
Amar Shaheed Path
near Dial100 Police office
Gomti Nagar
Lucknow, Uttar Pradesh
India
226010

Study participating centre
Ganesh Shankar Vidyarthi Memorial Medical College
Hallet Hospital under GSVM Medical College
Swaroop Nagar
Kanpur
Kanpur Nagar, Uttar Pradesh
India
208002

Study participating centre
Institute of Medical Sciences, Banaras Hindu University
Aurobindo Colony
Bhelupur
Varanasi, Uttar Pradesh
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Study participating centre
Sarojini Naidu Medical College
Central Library
Moti Katra
Mantola
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Study participating centre
District Women's Hospital, Gaziabad
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Sponsor type
Government

Website
http://www.who.int/countries/che/en/

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Government

Funder Name
World Health Organization

Alternative Name(s)
, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Switzerland

Results and Publications

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

Intention to publish date
31/12/2027

Individual participant data (IPD) sharing plan

The study protocol and statistical analysis plan will be made freely accessible on a suitable research platform.
The individual participant data that will be shared includes all the raw data that underlie the results reported in this study after de-identification. This includes socio-demographic information, health-related outcomes and data on participation in the intervention.
These data will be available to researchers who provide a methodologically sound proposal for a research question that is in line with the objectives of the original study. Proposals should be directed to the study's principal investigator and will need to be approved by a review committee.
Data will be available beginning 9 months after publication of the main findings from the final dataset.
The data will be shared with researchers for use in individual participant data meta-analysis or for a purpose that is approved by the review committee.
Researchers interested in accessing the data will be required to sign a data access agreement. This agreement will include commitments to using the data only for the approved proposal, securing the data appropriately, and destroying the data after the completion of the approved project.
This initiative is part of our commitment to transparency and accountability in research, and our belief in the potential of shared data to accelerate scientific discovery and improve patient care.

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	For CEL IEC submission version 3.0	10/03/2023	22/06/2023	No	No
Protocol file	For ERC submission version 3.0	09/01/2023	22/06/2023	No	No