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Kangaroo Mother Care implementation research for accelerating scale-up in Uttar Pradesh, India

Submission date
23/01/2018

Recruitment status
No longer recruiting

Registration date
30/01/2018

Overall study status
Completed

Last Edited
13/02/2024

Condition category
Neonatal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Kangaroo Care (KC) is a scientifically proven low-cost innovation that has the potential to save a quarter of 200,000 newborns that die in Uttar Pradesh (India) annually, reduce morbidity (illness) and improve neurodevelopment outcomes. Despite being a critical intervention, less than 1% of eligible newborns receive KC due to various implementation challenges. As per global guidelines (Every Newborn Action Plan), and guidelines issued by the government of India (India Newborn Action Plan), KC is an essential part of the strategy for caring for low birth weight babies, and is to be implemented by the state governments. This study uses research to improve the effectiveness of the government implementation of the program. The main aim is to ensure that all eligible babies in Uttar Pradesh receive high-quality KC, and use KC to encourage respectful care and foster a climate of collaboration across all stakeholders towards improving newborn survival.

Who can participate?
All babies of birth weight less than 2000g born in health facilities and in the community in the area targeted by the intervention

What does the study involve?
The first part of the study involves understanding the health system and community context for introducing KC, and designing a district-level KC implementation model comprising of infrastructure, systems, processes and people that need to be deployed in order to achieve the desired level of coverage (>80% of all infants with birth weight < 2000g) and quality of KC (>8 hours skin to skin contact per day with exclusive breastfeeding). The evaluation part of the study involves following up all babies born with birth weight <2000g until 28 days of life to measure provision of KC and exclusive breastfeeding. It should be noted that the intervention being evaluated is introduced at the level of the health system, not at the level of individual participants. Therefore, individual participants who are recruited into the study are consented and followed up for data collection only - provision of KC is considered as part of routine standard of care.

What are the possible benefits and risks of participating?
Not provided at time of registration

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

When is the study starting and how long is it expected to run for?
April 2015 to March 2022 (updated 24/03/2021, previously: March 2021; updated 12/05/2020, previously: March 2019)

Who is funding the study?
Bill and Melinda Gates Foundation (USA)

Who is the main contact?
1. Mrs Aarti Kumar (public)
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2. Dr Vishwajeet Kumar (scientific)
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT03098069

ClinicalTrials.gov (NCT)
NCT03419416

ClinicalTrials.gov (NCT)
NCT03506698

Clinical Trials Registry - India (CTRI)
CTRI/2017/07/008988

Protocol serial number
CELIEC/2016009 v1.2

Study information

Scientific Title
Impact of an implementation science driven model on improving coverage and quality of Kangaroo Care at scale

Study objectives
The trialists hypothesize that the model for Kangaroo Mother Care (KMC) implementation developed will lead to more than 80% of babies with birth weight less than 2000g in the study population receiving high quality KMC.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Community Empowerment Lab Institutional Ethics Committee, 20/10/2016, ref: CELIEC/2016009

Primary study design
Interventional

Study design
Interventional non-randomised study

Study type(s)
Other

Health condition(s) or problem(s) studied
Infants with birth weight <2000g

Interventions
This is an implementation research study to understand the health system and community context, and accordingly design a district-level model for KMC implementation and evaluate

whether it is successful in leading to an uptake of high quality KMC in >80% of stable babies with birth weight < 2000g from the study population.

The trialists are currently designing a district-level model for KMC implementation through the health system, which includes the systems, processes, people, infrastructure, etc. that they hypothesize will lead to the desired coverage (>80%) and quality of KC at a population level. The model is being co-designed with health system staff at various levels of administration, health providers, frontline health workers, mothers and community members based on principles of design thinking, systems dynamics and implementation science. The model will be finalized and rolled out by 28/02/2018 - after which, they will start evaluating whether it is leading to the desired primary outcomes, i.e., coverage (>80% of stable babies with birthweight <2000g) and quality of KC (>8 hours skin-to-skin contact and exclusive breastfeeding as measured at discharge and 7 days post discharge).

This implementation research partnership has been set up between Community Empowerment Lab (CEL) and the National Health Mission of Uttar Pradesh state in India, and involves establishment of an incubation lab for KC implementation based on principles of design thinking, systems dynamics and implementation science in 2 districts of Uttar Pradesh. The initial part of the study involves understanding the health system and community context for introducing KC, and co-designing a district-level KC implementation model comprising of infrastructure, systems, processes and people that will need to be deployed in order to achieve the desired level of coverage (>80% of all infants with birth weight < 2000g) and quality of KC (>8hrs skin to skin contact per day with exclusive breastfeeding) at a population level.

The evaluation component of the study involves following-up all babies born with birthweight <2000g in the study population until 28 days of life to measure the study outcomes, i.e., provision of KC, breastfeeding, etc. The primary outcome being measured is the percentage of infants in the study population with birthweight < 2000g who receive KC for at least 8 hours along with exclusive breastfeeding. It should be noted that the intervention that is being evaluated is introduced at the level of the health system, not at the level of individual participants. Therefore, individual participants who will be recruited into the study, will be consented and followed up for data collection only - provision of KC will be considered as part of routine standard of care.

Intervention Type
Other

Primary outcome(s)
Population-level effective coverage of KC, as defined by percentage of infants in the study population with birthweight < 2000g who receive KC for at least 8 hours along with exclusive breastfeeding during the 24-hour period prior to data collection. It will be measured based on participant response to a structured questionnaire administered by an independent data collector at discharge from the KC facility, and at 7 days after discharge. Birth weight will be based on birth weight measured and reported at delivery facilities in cases of institutional delivery, and measured at home and reported by frontline health workers (ASHA) in case of home deliveries.

Key secondary outcome(s)
1. Mean days of KC provided to infants at the population level, i.e., mean number of days that KC was received by infants with birth weight < 2000g during the neonatal period. This will be measured based on participant response to a structured questionnaire administered by an

independent data collector at 28 days of age
2. Percent of infants with birth weight < 2000g receiving any KC (any duration in the last 24 hours) at 28 days of age. This will be measured based on participant response to a structured questionnaire administered by an independent data collector at 28 days of age
3. Percent of infants with birth weight < 2000g who were exclusively breastfed during the 24-hour period prior to data collection, at discharge, 7 days post discharge, and at 28 days of age
4. Neonatal mortality rate (including early neonatal mortality rate) in infants with birth weight < 2000g

Completion date
31/03/2022

Eligibility

Key inclusion criteria
1. All babies of birthweight less than 2000g born in health facilities and in the community in the geographic area targeted by the intervention
2. Newborns who are severely sick according to pre-defined criteria (does not tolerate oral feeds, severe respiratory distress including respiratory rate less than 20 breaths per minute, grunting, central cyanosis, very severe chest in-drawing, convulsions, unconsciousness and severe hypothermia of less than 32 degrees Centigrade) will have the initiation of KMC delayed until they have stabilized

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
2391

Key exclusion criteria
Deaths, referrals, LAMA etc in the first 3 days of life, irrespective of birth weight

Date of first enrolment
01/03/2018

Date of final enrolment
28/02/2019

Locations

Countries of recruitment

India

Study participating centre
Community Empowerment Lab
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Sponsor information

Organisation
The World Health Organization

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Aarti Kumar (aarti.kumar@cel.org.in).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/09/2021	13/02/2024	Yes	No
Protocol article	protocol	21/11/2019	23/10/2020	Yes	No