# To assess the feasibility of use of Kangaroo Mother Care for transport of neonates in Sub-Saharan Africa

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>			
28/08/2024		[X] Protocol			
Registration date	Overall study status	Statistical analysis plan			
02/09/2024	Completed	[X] Results			
Last Edited	Condition category	[] Individual participant data			
30/12/2024	Other				

## Plain English summary of protocol

Background and study aims

Newborns delivered in the rural and peripheral centres in most Sub-Saharan African countries and transported to the specialised centres usually in the arms of the parents and caregivers and public transport due to the unavailability of dedicated ambulances. A number of these babies arrive cold and unstable which affects their care and survival.

This study aims to assess the feasibility of performing a larger study which compares the outcomes of babies who are transported using kangaroo mother care and those who are transported through the current process in the arms of caregivers from the peripheral birthing centres to a specialised neonatal unit in Sub-Saharan Africa using the available mode of transport

### Who can participate?

Preterm and low birth weight (< 2.5kg) less than 28 days old who are born in the periphery and have to be transported to the specialised centre for continued care

### What does the study involve?

Babies (premature and small for age) to be transported will be identified from 8 different hospital sites. Healthcare workers involved in the study will be trained on the study before the start.

One group of babies will be transported by Kangaroo mother care after initial stabilization and feeding using Kangaroo mother care and the other group of babies will be transported using the already existing process.

Parents and caregivers would use the existing mode of transport without this being altered by the study.

If a health worker is available to accompany the babies, they will be responsible for monitoring and recording the vital signs during the transport, otherwise, the caregiver is advised to closely keep an eye on the breathing, movements and colour of the baby.

What are the possible benefits and risks of participating?

Possible benefits include babies transported by kangaroo mother care arriving with a normal body temperature which will improve their chances of survival

Where is the study run from?
Cape Coast Teaching Hospital (Ghana)

When is the study starting and how long is it expected to run for December 2020 to May 2023

Who is funding the study? Investigator initiated and funded

Who is the main Contact?
Dr Emmanuel Okai, e.okai@uccsms.edu.gh

# **Contact information**

### Type(s)

Public, Scientific, Principal investigator

#### Contact name

Dr Emmanuel Okai

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

Nil known

# Study information

#### Scientific Title

Use of Kangaroo Mother Care in the transfer of preterm and low birth weight infants: a two-arm non-randomized controlled cluster feasibility study of neonatal transport in Cape Coast, Ghana

### Acronym

**FUKMC** 

### **Study objectives**

In the absence of an organised transport system, alongside the limited availability of basic systems of transport, and increasing situations where parents must pay out of pocket for transfer, many newborns particularly preterm and low birth weight (LBW) are transported by less safe methods to higher centres of care. In developing countries Exploring the safe use of Kangaroo Mother Care (KMC) in the transfer of these neonates might go a long way towards reducing the burden of neonatal mortality and morbidity in resource-constrained settings

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 30/07/2021, Cape Coast Teaching Hospital Ethical Review Committee (Cape Coast Teaching Hospital, Cape Coast, CC-070-9967, Ghana; +233 21-340102-14; info@ccthghana.org), ref: CCTHERC/EC/2021 (053)

### Study design

Two arm non-randomized controlled cluster study

### Primary study design

Interventional

## Study type(s)

Other, Quality of life

## Health condition(s) or problem(s) studied

Improving outcomes of transported preterm and low-birth-weight neonates in Sub-saharan Africa

#### **Interventions**

Four primary care/ maternity units with the highest referral/transfer to the neonatal unit of Cape Coast Teaching Hospital (CCTH) were initially recruited following a review of the admission-discharge records over the past 2 years and a 2-month piloting of a designed proforma. Two of these sites were designated as intervention sites and the other two, as control sites with consideration given to optimal balance for socioeconomic status, the size of the maternity unit, ethnic mix, and distance from the neonatal unit in CCTH. Two additional maternity units were added to each arm of the study, 6 months into the study to make up for participant losses. All neonates enrolled in the study had a period of initial stabilisation pre-transfer during which they received conventional care.

## Conventional care (Control group and KMC group)

Conventional care for neonates starts in the delivery room, where the nurse/midwife receives the neonate after delivery, quickly dries and wraps in a towel and provides the necessary resuscitation as prescribed by the Helping Babies Breathe algorithm. A physical examination to check for any anatomical anomalies was performed by the receiving health worker and babies were given vitamin K injection intramuscularly and tetracycline ophthalmic ointment applied. Vital signs (temperature, heart rate, respiratory rate, and oxygen saturation) were checked by the nurse and feeding either at the breast or using expressed breastmilk via cup or nasogastric

tube provided. Participants recruited from control sites received conventional care and their babies were transferred to CCTH using the current established mode of transfer.

Kangaroo Mother Care group (Intervention group)

Neonates at the intervention sites received the same initial stabilization and conventional care as neonates at the control sites. Participants (mother-baby pairs) who were identified by trained health workers at the intervention sites for transfer and who gave consent for participation in the study, were taught the appropriate procedure for KMC and the babies were transferred to the special care baby unit, CCTH with the intervention. The intervention sites assessed women or caregiver's confidence and competence in using KMC and any identified issues were improved before the transfer.

### Intervention Type

Procedure/Surgery

## Primary outcome(s)

Survival and live discharge of preterm and low birthweight neonates measured using data collected from a review of patient records when the babies were eventually discharged from the Unit

### Key secondary outcome(s))

The following secondary outcome variables on the impact of the intervention on improvement in morbidity were measured using a proforma questionnaire for the data collection and populated upon admission of the baby to Cape Coast:

- 1. Thermal stability (hypothermia)
- 2. Glucose control (hypoglycaemia)
- 3. Oxygen saturation (hypoxia)

The qualitative component of the study to assess the acceptability of the use of KMC was measured using semi-structured interviews after the arrival of the babies in Cape Coast

## Completion date

30/05/2023

# **Eligibility**

### Key inclusion criteria

- 1. Newborns <2500 grams and/or 28 to 37 weeks gestation at birth
- 2. Newborns less than 28 days old
- 3. Apgar score of at least 5 in the first and fifth minutes of life
- 4. Not requiring any ventilatory support, intravenous fluids, or vasopressors
- 5. Participants who provide informed consent to take part in the study. Fathers or family members willing to participate in situations where the mother was medically unwell for the transfer.

## Participant type(s)

Health professional, Population, Service user

## Healthy volunteers allowed

No

### Age group

Neonate

### Lower age limit

0 days

### Upper age limit

28 days

### Sex

All

### Total final enrolment

77

### Key exclusion criteria

- 1. Apgar score of less than 5 at 10 minutes of age
- 2. Term neonates or neonates >28 days of age
- 3. Preterm/LBW requiring prolonged resuscitation and oxygen therapy after 4 hours of life
- 4. Newborns with major congenital malformations
- 5. Hypoxic ischaemic encephalopathy/prenatal asphyxia
- 6. Mothers with postnatal complications who were unable to give consent and had no dedicated family member to consent for inclusion in the study

### Date of first enrolment

01/08/2022

### Date of final enrolment

30/04/2023

# Locations

### Countries of recruitment

Ghana

# Study participating centre Cape Coast Teaching Hospital

Cape Coast Cape coast Ghana CC-070-9967

# Sponsor information

## Organisation

University of Cape Coast

### **ROR**

https://ror.org/0492nfe34

# Funder(s)

## Funder type

Other

### Funder Name

Investigator initiated and funded

# **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from (Emmanuel Okai, e.okai@uccsms.edu.gh)

## IPD sharing plan summary

Available on request, Published as a supplement to the results publication

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/12/2024	30/12/2024	Yes	No
Participant information sheet			30/08/2024	No	Yes
Participant information sheet			30/08/2024	No	Yes
Participant information sheet			30/08/2024		Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			30/08/2024	No	No