

The OMWaNA Study:
Operationalising kangaroo Mother
care among unstable low birth Weight
Neonates in Africa: a randomised
controlled trial to examine impact on
mortality in Uganda

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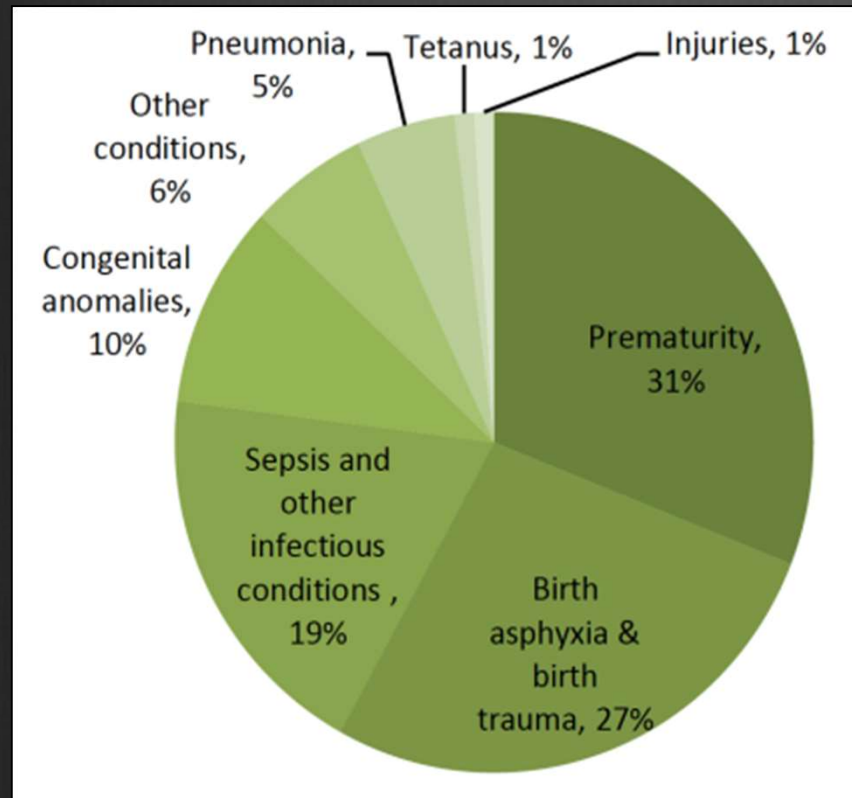
Background

- ⊗ Each year, 15 million babies are born preterm and 1 million deaths occur as a direct result of complications¹⁻³
- ⊗ KMC is associated with decreased mortality, sepsis, hypothermia, and length of stay among *stable* infants^{4,5}
- ⊗ WHO recommends KMC for ‘routine care of newborns weighing ≤ 2000 grams... initiated as soon as newborns are clinically stable’⁶
- ⊗ Only RCT of KMC in unstable infants reported major mortality impact⁷, but methodological issues were present^{7,8}
- ⊗ A well-designed RCT, which includes clear criteria of “stability” is warranted to examine effect on mortality^{9,10}

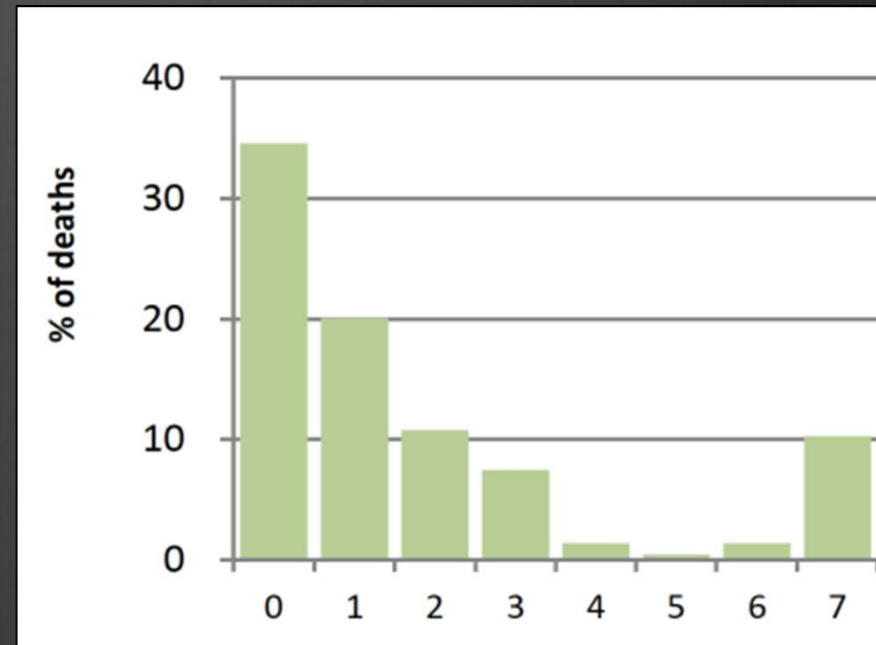
¹Lawn 2014; ²Blencowe 2012; ³Lawn 2013; ⁴Conde-Agudelo 2014; ⁵Boundy 2016; ⁶WHO 2015; ⁷Worku 2005; ⁸Aluvaala 2014; ⁹English 2016; ¹⁰Chan 2016

Neonatal mortality in Uganda

Causes of neonatal deaths



Distribution of neonatal deaths (first 7 days)



Study Site: Jinja Regional Referral Hospital (JRRH), Uganda

- In 2006, Uganda established newborn steering committee, which advised KMC scale-up in facilities¹²
- Jinja Hospital:
 - Catchment area of 4 million
 - ~6,600 deliveries annually
 - Newborn unit has IV fluids, NG tubes, oxygen, pulse oximetry, CPAP, phototherapy, antibiotics, aminophylline, and phenobarbital
 - KMC for stable infants
 - Incubators for small/preterm infants



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Aims

- ⦿ Aim 1: To evaluate the feasibility of a RCT of KMC for clinically unstable infants weighing ≤ 2000 grams admitted to JRRH.
- ⦿ Aim 2: To evaluate the acceptability of KMC for clinically unstable infants weighing ≤ 2000 grams to parents and providers at JRRH.

Feasibility Study Methods

⊗ Part 1: Audit of Admissions

- ⊗ Research Assistant completed data collection form on convenience sample of infants admitted between June 2015 and June 2016
- ⊗ Calculated number meeting proposed eligibility criteria per year

⊗ Part 2: Feasibility of KMC for unstable infants

- ⊗ Enrolled purposive sample of infants admitted between July and October 2016 and meeting proposed trial eligibility criteria
 - ⊗ Counselling mothers/family to provide KMC as close to continuously as possible, goal ≥ 18 hours per day
 - ⊗ Continuous monitoring of oxygen saturation and heart rate
 - ⊗ Calculated duration of KMC per day (defined as skin-to-skin contact) and number of interventions delivered per day
- ⊗ Ethical approval obtained from LSHTM, Makerere University, and Uganda National Council of Science & Technology (UNCST)

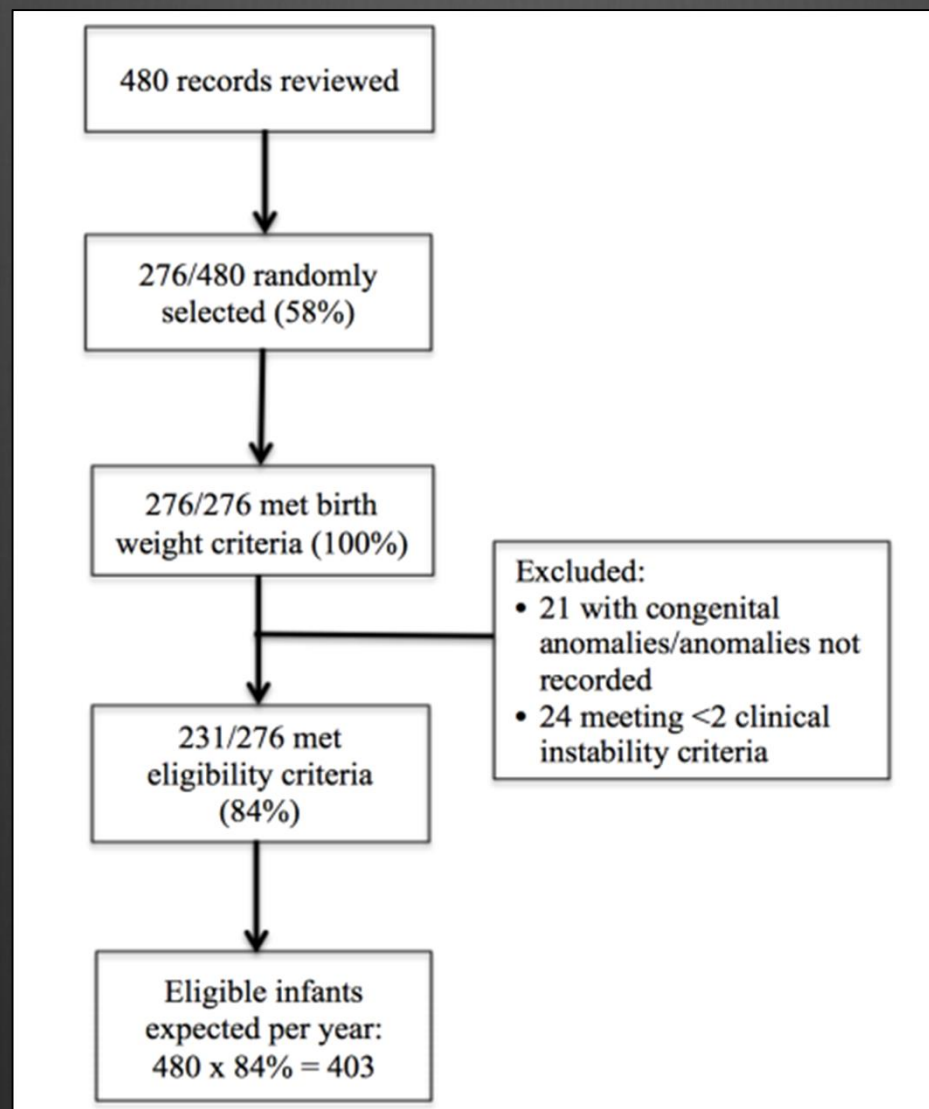
Proposed Enrolment Criteria

- ⊗ Born alive at JRRH
- ⊗ Birthweight ≥ 700 grams and ≤ 2000 grams
- ⊗ Chronological age < 48 hours
- ⊗ No congenital anomalies or severe medical problems
- ⊗ Clinically unstable: defined as requiring ≥ 2 of the following therapies within 48 hours of birth:
 - Oxygen
 - CPAP
 - IV fluids
 - Antibiotics
 - Aminophylline
 - Anti-convulsants
 - Phototherapy
- ⊗ Mother able and willing to participate in KMC

Acceptability Study Methods

- ⦿ Semi-structured interviews
- ⦿ Purposive sample of key stakeholders, which included parents and providers (doctors and nurses/midwives) in newborn unit
- ⦿ Areas explored included:
 - ⦿ Parent/provider-related factors
 - ⦿ Infant-related factors
 - ⦿ Facility-related factors
 - ⦿ Trial participation/randomisation
- ⦿ Data analysed using thematic content approach
- ⦿ Ethical approval obtained from LSHTM, Makerere University, and UNCST

Newborn Audit Flowchart



Characteristics of Infants in Admissions Audit

Characteristics (N = 276)	Number	Percent
Birth weight		
Low (1500-2000 g)	165	60%
Very low (1000-1500 g)	93	34%
Extremely low (700-1000 g)	18	6%
Gender		
Female	150	55%
Clinical instability criteria		
Zero	8	3%
One	16	6%
Two	148	58%
Three	59	23%
Four or more	24	10%

Characteristics of infants in part 2 of feasibility study

Characteristics (N = 9)	Mean (SD)	Range
Birthweight (grams)	1319 (389)	700-1800
Gestational age (weeks)	29 (3.5)	26-35
Length of hospitalisation (days)	10.3 (4.7)	3-19
	Number	Percent
Female	7	78
Discharged	7	78
Died	2	22

Number of concurrent interventions and KMC duration per day

Day of Life	Mean (SD) no. of interventions	Range	Mean (SD) KMC duration (min)	Range
1 (n=9)	4 (0.7)	3-5	164 (173)	60-838
2 (n=9)	3.9 (0.9)	2-5	113 (49)	53-253
3 (n=9)	4 (1.0)	2-5	125 (74)	46-362
4 (n=8)	3.9 (1.0)	2-5	153 (68)	30-318
5 (n=8)	3.9 (1.0)	2-5	146 (140)	20-797
6 (n=8)	3.8 (1.0)	2-5	130 (49)	44-248
7 (n=8)	3.5 (1.2)	1-5	144 (56)	65-260
8 (n=8)	3.5 (1.4)	1-5	139 (57)	56-254
9 (n=7)	3.3 (1.4)	1-5	108 (35)	44-170
10 (n=3)	4 (1.0)	3-5	112 (59)	42-256
11 (n=3)	4 (1.0)	3-5	123 (57)	38-262
12 (n=3)	3.7 (1.2)	3-5	133 (62)	46-276
13 (n=3)	3.7 (1.2)	3-5	130 (50)	59-200
14 (n=3)	3.7 (1.2)	3-5	131 (63)	37-228

Acceptability Study Results

- ⊗ Majority of parents and providers felt KMC could be used in infants concurrently receiving other therapies
- ⊗ A few mothers expressed concern that doing KMC while receiving oxygen/IV fluids could be painful for the baby
 - ⊗ *“I want to be close to him, and I feel like those tubes would hurt him as we are doing KMC.”*
- ⊗ All providers and the majority of parents felt KMC could be used in the first 48 hours after birth
 - ⊗ *“I think it’s a good idea because that skin-to-skin contact will stabilise the baby’s temperature faster than an incubator.”*
- ⊗ Perceived challenges included lack of privacy, beds, education, family support, and staff/resources to monitor infants, and difficulty motivating mothers to devote time to KMC
- ⊗ Staff and peer counselling was the most recommended solution among parents and providers

Summary

- ⊗ Audit showed that 403 infants meeting proposed trial eligibility criteria are admitted each year
- ⊗ Mean KMC duration was ~2 to 2.5 hours per day, with most infants receiving 3-4 concurrent medical therapies as well as continuous monitoring
- ⊗ Majority of parents and providers agree with use of KMC in infants receiving other therapies during the first 48 hours after birth
- ⊗ KMC practice could be improved through staff and peer counselling, more beds/space, and improved availability of devices to help monitor infants in the KMC position

Next steps: planned RCT

- ⊗ **Aim:** To assess early neonatal mortality (at 7 days) with KMC for clinically unstable infants ≤ 2000 grams, compared to conventional incubator care at JRRH
- ⊗ Individually randomised, controlled superiority trial with two parallel groups
- ⊗ Intervention group will receive KMC in addition to conventional therapies
 - ⊗ KMC will be initiated as soon as infants meet eligibility criteria and within 1 hour of randomisation
 - ⊗ Parents will be encouraged to provide KMC ≥ 18 h/day
 - ⊗ Mothers or family members/friends may provide KMC
- ⊗ Control group will receive conventional therapies but incubator care will replace KMC

Discussion

- ⦿ Thoughts on proposed clinical instability criteria
- ⦿ Other approaches to promote near-continuous KMC in the intervention arm
- ⦿ Other comments or questions

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