A randomised controlled trial of early continuous skin-to-skin contact for hospitalised neonates <2000g in The Gambia

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Why research early STS ?

- 1 million deaths/yr due to complications of preterm birth[1]
- 47% of deaths due to complications of preterm birth are during first day[2]
- Incubator care for preterm/LBW in low resource settings is expensive & impractical
- Urgent need to focus on alternative methods of care during first day
- KMC (including STS) is effective, safe & recommended in “stable” babies <2000g
- Need evidence for different initiation strategies of STS contact to determine optimal mortality impact

1 Liu et al. *Lancet* 2015; 385(9966):430 – 440
2 Sankar et al. *Journal of Perinatology* 2016 36, S1–S11

What is early STS?

Continuous (>20h/day) skin-to-skin contact started within 24h after birth

- Different from initial skin-to-skin care immediately after birth
- Transition from in-utero to ex-utero life
  - Circulation
  - Lungs
  - Intestine
  - Skin
- “Stabilisation” of the preterm/LBW baby takes minutes – hours – days
- Early STS is a method of assisting this stabilisation process?

Mother providing KMC in Nigeria. Photoshare

Cochrane review for KMC (2016)

Reduces	Improves
Mortality by 33 - 40%	Weight/length/OFC gain
Nosocomial infection by 65%	Exclusive Breastfeeding to 3m
Severe infection by 50%	
Hypothermia by 72%	

Evidence for mortality effect in following sub-groups:
Continuous KMC >20h/d
KMC started within 10d
"Unstable"
LMIC

3 Conde-Agudelo A, Díaz-Rossello JL. Cochrane Database of Systematic Reviews 2016, Issue 8

Evidence for early KMC

J Trop Pediatr. 2005 Apr;51(2):93-7.

Kangaroo mother care: a randomized controlled trial on effectiveness of early kangaroo mother care for the low birthweight infants in Addis Ababa, Ethiopia.

Worku B[1], Kassie A.

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Earlier versus later continuous Kangaroo Mother Care (KMC) for stable low-birth-weight infants: a randomized controlled trial

S Nagai, D Andrianarimanana, N Rabesandratana, N Yonemoto, T Nakayama, R Mori

First published: 27 January 2010 Full publication history

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Cochrane
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settings. Further information is required concerning the effectiveness and safety of early-onset continuous KMC in unstabilized or relatively stabilized LBW infants, as well as long-term neurodevelopmental outcomes and costs of care.

Research in The Gambia

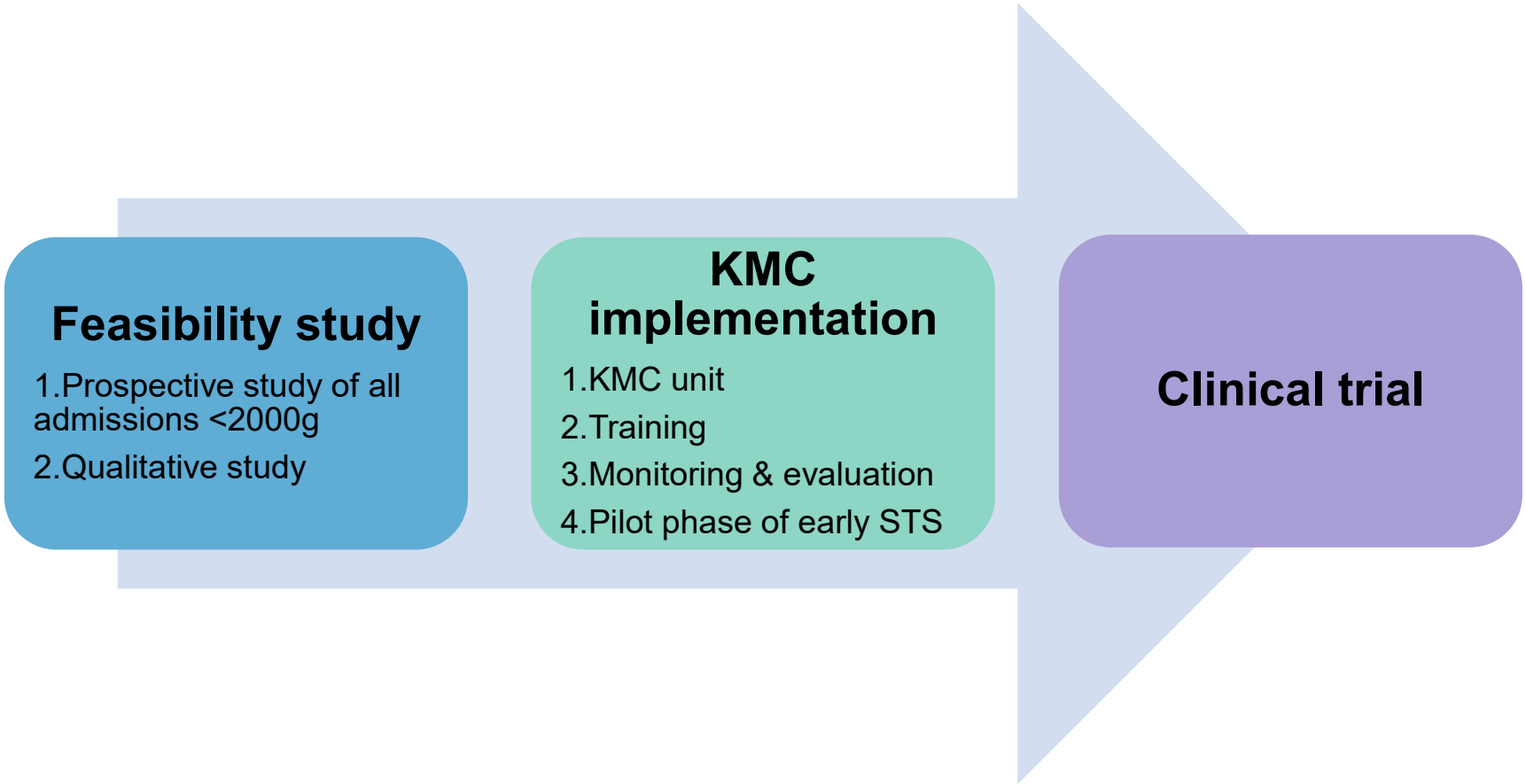
- Population 1.9 million[4]
- NMR 30 / 1000 live births[4]
- 14% preterm birth (2010)[4]
- 10% of births LBW (2013)

- Edward Francis Small Teaching Hospital
- 1400 neonatal admissions/yr[5]
- 350 admissions/yr weigh <2000g[5]
- 34% case fatality rate in <2000g[5]

- Oxygen / IV fluids / IV antibiotics etc
- No KMC programme but KMC unit is identified

4 Healthy newborn network. Sources include UNFPA world population prospects 2015, IGME 2015,
5 Okomo UA et al. Paediatr Int Child Health. 2015 Aug;35(3):252-64

Overview of study



Clinical trial

Aim:	To investigate if early cSTS contact has clinical and microbiological benefits for hospitalised neonates <2000g
Design:	Individually randomised controlled superiority trial Block randomisation, varying block size, wt stratified
Control arm:	Standard care and cSTS at >24h after birth
Intervention arm:	cSTS at <24h after birth
Primary outcome:	All cause mortality at 28d
Secondary outcomes:	ACM at 7d; suspected and confirmed infection; wt/OFC/length gain; time to exclusive breastfeeding; colonisation with GNB; duration of admission;
Sample size:	329 (80% power, 5% alpha). Intention to treat

Target population

1. Inclusion criteria:
    - Weight <2000g
    - Age <20h at time of admission

2. Exclusion criteria:
    - Major congenital malformation (surgery/fatal)
    - Moderate-severe encephalopathy
    - Severely unstable as defined by cardio-respiratory instability:
        - HR <60 or >200 for > 5 mins
        - RR <20 or >100 for > 5 mins
        - Apnoea for >20 seconds or requiring BVM ventilation
        - SPO_2 <85% for 5 mins despite oxygen therapy

Stable, mild and moderately unstable newborns' <2000g and <20h old at time of hospital admission

Safety issues with early cSTS

Midwife doing newborn resuscitation training, South Sudan. Photoshare

- Obstructive apnoea, aspiration, worsening respiratory distress, seizures, cardiac arrest
- Important to monitor and detect quickly
- Pilot phase of early KMC/treatments
- Low-birth weight management protocol
- Maternal education to identify warning signs of severe disease
- Safety monitor and data monitoring board

Summary

- Early cSTS has potential to further reduce neonatal mortality
- Limited published evidence for mortality effect of early cSTS
- RCT of early versus late cSTS in The Gambia
- Including mild-moderately unstable babies
- Results expected 2019

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