

**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 one million deaths occur as a result. WHO guidelines state that kangaroo mother care (KMC) is recommended for “routine care of newborns weighing  $\leq 2000\text{g}$  at birth, and should be initiated in facilities as soon as newborns are *clinically stable*.” However, the majority of deaths occur in babies who are *unstable*. There is uncertainty in the effect of KMC in unstable babies and a need for a well-designed RCT that examines effect on mortality.

**Aim:** To compare the effect of KMC on mortality (at 7, 28 days) to incubator care in unstable infants weighing  $\leq 2000\text{g}$  at Jinja Hospital in Uganda.

**Design:** This will be a parallel group RCT, enrolling 460 infants over 24 months. The trial will include 230 infants per arm, which will provide 80% power to detect a 25% relative reduction in mortality by day 7. Infants randomised to the intervention group will receive KMC along with conventional treatments deemed necessary according to hospital guidelines. Infants randomised to the control group will receive the same conventional treatments with the exception that incubator care will replace KMC. The primary outcome will be the between-group difference in mortality rate at 7d, and the primary analysis will be based on ‘intention-to-treat.’

**Results:** This is a planned trial. Results of studies evaluating the feasibility and acceptability of KMC for unstable infants at Jinja Hospital will also be discussed.

**Conclusion:** This trial will provide important evidence on the effect of KMC among clinically unstable infants.