



Final Report

Improving Uptake of Skin-to-Skin Practice for Babies in Kangaroo Mother Care in Malawi through the Use of a Customized Baby Wrap

September 2017, Malawi – funded by Lærdal foundation.

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Executive Summary

BACKGROUND

With the highest rate of preterm birth globally, Malawi has prioritized implementation of Kangaroo Mother Care (KMC) to improve newborn health and reduce mortality and morbidity. Despite Malawi's success as an early adapter of KMC and in scaling up availability of KMC services in all central and district hospitals, the quality of KMC services is still not up to standard. The success of KMC depends, in part, on ability of mothers and caregivers to practice continuous skin-to-skin. Barriers to skin-to-skin practices reported by mothers in Malawi using traditional chitenje as wraps include: the difficulty to hold baby in the front, concerns about stability of the baby, requirement for two people to tie, thick material that over-heats, and irritation from the large knot at the back from tying the chitenje. In an effort to improve KMC, Lærdal Global Health (LGH) has developed an ergonomic baby carrier, the CarePlus wrap, which has potential to be produced locally at low cost. However, operations research is needed to determine whether the customized CarePlus wrap improves KMC practices.

STUDY OBJECTIVES

To evaluate the acceptability and effectiveness of introducing a custom KMC wrap to improve adherence to skin-to-skin practices within selected hospitals with established KMC programs in Malawi. This study tested the hypothesis that a customized CarePlus wrap will increase the duration of skin-to-skin contact among mother-baby dyads practicing KMC at facility and post-discharge, leading to improved breast-feeding and weight gain.

Alongside the study, we explored the feasibility of local production of the CarePlus wrapper by training and equipping existing hospital-based tailors.

STUDY DESIGN AND METHODOLOGY

This was an operations research study, with a randomized control trial design. The study was conducted in three large hospitals in the southern region of Malawi: Machinga district hospital, Thyolo district hospital, and Queen Elizabeth Central Hospital (Blantyre district). Mother-baby dyads meeting eligibility criteria and providing informed consent were randomized to receive either the CarePlus wrap (intervention group) or a traditional chitenje printed with KMC messages (control group). The primary outcome variable was the average rate of weight gain in g/day among babies enrolled in KMC. A target sample size of 140 mother-baby dyads to be enrolled in each study arm (280 total) was established to detect a 20% difference in average weight gain. Enrolled mother-baby dyads were monitored daily while in facility KMC and 7-10 days post-discharge from KMC through a home visit.

Data were collected from May 2016 to December 2016 by trained staff from Ministry of Health based at the three facilities. Data collection team comprised of Research Officers, Field Workers and Clinical observers. Data collectors were trained for four days by the study PI and Save the Children technical staff. Data were captured using tablets programmed with CS-PRO database. We calculated the difference between intervention and control groups in average rate of weight gain, measured in g/day for two time periods: 1) from the time of KMC admission to the time of discharge from facility and 2) from time of facility discharge to 7-10 days follow-up visit. T-tests were used to determine whether the mean difference in weight gain between the two study groups was statistically significant. All analyses were carried out in Stata® 12 [StataCorp LP, Texas, USA].

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Ethical approval for the study was received in May 2016 from the College of Medicine Research and Ethics Committee (COMREC) national bioethics committee¹.

MAIN RESULTS

A total of 581 babies were assessed for eligibility, of which 318 met the criteria and 301 provided informed consent and were enrolled in the study (152 in the CarePlus wrapper group and 149 in the chitenje group). Of those enrolled, 85% (129) of the intervention group and 77% (114) of the control group completed the study.

There were no significant differences between study arms at enrollment in maternal background or health characteristics or characteristics of babies. Mean maternal age was 25.1 years and less than 60% of mothers had completed primary school. The majority of mothers were married and just over half were unemployed. Most babies were preterm, with close to two-thirds estimated to be between 32 and 36 weeks gestation. Less than 15% of babies were documented to have experienced other complications at birth (in addition to preterm/low birth weight), with asphyxia being the most common. The average age in days at admission to KMC was 1.5 and was similar in both study arms. More than one-third of babies (36%) were less than 1,500g at initiation and about 20% were between 1,800 and 2,000g. Duration of stay in facility KMC was 9.3 days on average, with babies in the intervention arm staying slightly longer on average than control babies, although the difference was not statistically significant. About 20% of babies became sick while in facility KMC, with injections and phototherapy being the most common treatments received; there were no differences between study arms in the proportion of babies receiving phototherapy (4% in both arms).

Primary outcome – rate of weight gain: Data on weight at discharge was available for 276 (96%) of the 287 babies discharged alive from KMC; 143 (98%) of the 146 intervention cases discharged alive from KMC and for 133 (94%) of the 141 control cases discharged alive. Analysis was run using the 266 cases with data on weight at KMC initiation and discharge and data on length of stay in facility KMC. The average rate of weight gain between admission and discharge from hospital in g/day was slightly higher among the babies using the CarePlus wrapper; this difference was not statistically significant. In terms of absolute weight change between KMC admission and discharge from facility, 41% weighed the same or less at discharge compared to admission (38% of CarePlus cases and 45% of chitenje cases).

The average rate of weight gain was significantly higher among babies whose mothers reported practicing 20 or more hours of STS per day (10.4 g/day; 95% CI: 5.9-14.8) compared to those who practiced less (1.0g/day; 95% CI: -2.4 -4.5) (p=0.00). This association was observed both among women using the CarePlus wrapper and women using the chitenje. Baby's birthweight as recorded in maternity register was also significantly associated with average rate of weight gain. Babies born weighing <1,500g had a higher rate of weight gain (10.7 g/day; 95% CI: 7.0-14.3) compared to those born 1,500g or more (1.2 g/day; 95% CI: -2.5-4.8) (p=0.00). The pattern of higher weight gain among those born weighing <1,500g was present in both study arms, but only statistically significant for the control group (p=0.00). The most dramatic difference in average rate of

HIGHLIGHTS OF KEY FINDINGS

- **Women accept KMC:** Women reported high levels of acceptability of KMC regardless of the wrap used.
- **Longer practice results in more weight gain:** Babies held in skin-to-skin for 20 hours or more per day gain more weight regardless of the type of wrap used.
- **Women preferred the Careplus Wrap:** Women using the CarePlus Wrap were more satisfied with KMC and practiced skin-to-skin for more hours every day.
- **Care for preterm babies requires quality improvement and mentorship:** Results varied significantly by study site especially regarding adherence to KMC practices and recorded weight gain indicating other that aspects (beyond the wrap) influenced the outcomes.
- **Follow up care requires more attention:** Only half of mothers returned to the health facility for follow-up within 7-15 days of discharge and critical gaps in counselling on skin-to-skin and feeding practices were noted.

¹ Approval letter received May 19, 2016 (P.11/15/1835).

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weight gain was seen between study sites, with babies at QECH having a much higher rate (17.4 g/day) compared to Thyolo where most recorded weight loss (-13.1 g/day) and Machinga (0.2 g/day) (Table 4b). Maternal HIV status, child becoming sick while in KMC, multiple births, or gestational age were not significantly associated with average rate of weight gain.

Babies at Thyolo appeared to be admitted to KMC earlier, to weigh more at time of admission, and to spend less time in facility KMC than the other two sites. Within each study site, mothers in the CarePlus group had higher average rate of weight gain (or smaller rates of weight loss in the case of Thyolo) compared to mothers in the Chitenje group (QECH: 20.3 vs. 14.8 g/day; $p=0.20$; Thyolo: -10.1 vs. -17.5 g/day; $p=0.15$; Machinga: 1.5 vs -1.1 g/day; $p=0.45$), but the results were not statistically significant due to the small sample size and the relatively small size of the difference between groups, particularly in the case of Machinga.

Follow-up visits were meant to take place within 7-10 days post discharge. However, only 185 of the 287 cases discharged alive completed follow-up within 7-15 days and only 182 had data on follow-up weight and weight at discharge. The findings show that weight at discharge was similar between study groups. The majority of babies (97%) gained weight after discharge, and the rate of weight gain in g/day was markedly higher post-discharge than while in health facility. Three-quarters of babies weighed more than 1,800g by the 7-15 day follow-up visit. There were no differences in weight at the post-discharge visit and the rate of weight gain in g/day between using the CarePlus wrapper and women using the Chitenje. Analysis by study site showed significant differences, with babies discharged from Machinga gaining an average of 45.8g/day compared to 42.3g/day in QECH and 22.7g/day in Thyolo ($p=0.00$).

Skin-to-skin practices: Reported daily duration of skin-to-skin practice while in facility was significantly higher among women using the CarePlus wrapper. Among women using the CarePlus wrapper, 44% of women reported more than 20 hours STS per day and 6% reported 10 hours or less of STS. In comparison, 33% of women using the traditional chitenje reported 20 hours or more of STS per day and 19% reported 10 hours or less per day. Women using the CarePlus wrapper were also more likely to report using the wrapper for nearly all of the day and nearly all or more than half of the night compared to women using the traditional wrapper. Analysis by study site identified statistically significant differences in reported STS duration. At QECH, 61% of mothers from both groups reported more than 20 hours compared to 25% of women in Thyolo and 23% of women in Machinga ($p=0.00$).

Findings show that most women from both study arms were still practicing STS in the community (87% of all those who completed the study, and 93% of those interviewed between 7 and 15 days discharge). Nearly all those continuing STS practice reported daily practice, but contrary to the findings reported while in facility KMC, the proportion reporting practicing STS nearly all the day dropped significantly in both groups. The gains in reported duration of STS among women using the CarePlus Wrapper appeared to disappear by the time of follow-up after facility discharge. The reasons for this are unclear and require further study. Further analysis by study site showed that women from QECH were significantly less likely than women in the other two sites to report going outside the home with their baby in STS position (55% compared to 80% in Thyolo and 63% in Machinga; $p=0.01$). They were also less likely to report keeping the baby in STS position nearly all the day (19% compared to 38% in Thyolo and 31% in Machinga; $p=0.00$) or nearly all the night (49% compared to 89% in Thyolo and 61% in Machinga; $p=0.00$).

Feeding practices: Nearly all babies were able to breastfeed, but most (88%) required use of cup and spoon to support feeding at the time of discharge. There were no differences between study arms in reported use of cup and spoon or type of feeding. Women at QECH and Machinga reported nearly universal use of cup and spoon for feeding (99 and 100%), while in Thyolo only 53% of women reported using cup and spoon to support feeding. Similarly, nearly all mothers in QECH (96%) and Machinga (100%) reported providing breastmilk only, while in Thyolo 81% of mothers were giving exclusive breastmilk, 3% predominately breastmilk and 15% were providing partial breastmilk ($p=0.00$).

Nearly all mothers mentioned receiving support from health facility staff for expressing breastmilk (92%), for feeding position (91%) and reminders for feeding (87%) and levels of supports were similar in both study groups. Analysis by study site showed

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that women in Thyolo were significantly less likely to report receiving support from facility staff for two of the three feeding related areas: expressing breastmilk (68% in Thyolo compared to 98% in QECH and 100% in Machinga; $p=0.00$); and feeding position (75% in Thyolo compared to 98% in QECH and 100% in Machinga; $p=0.00$). Results were similar across sites for feeding reminders (85% in Thyolo compared to 90% in QECH and 92% in Machinga; $p=0.41$).

Acceptability of the CarePlus wrap: While in facility KMC, women were asked about their perceptions of the wrap at two time points – the first within 3 days of admission and the second at the time of discharge. A significantly higher proportion of women using the CarePlus Wrap reported being comfortable to keep baby in skin to skin position (96% vs 71%); being able to tie on the CarePlus Wrap themselves (86% vs 10%); being comfortable to breastfeed while using the CarePlus Wrap (43% vs 12%); and that the CarePlus Wrap would be acceptable for use by fathers and male family members (93% vs 43%). Women using the Care Plus wrapper reported taking less time to become comfortable using the wrap, with 72% comfortable within the first day compared to 40% of those using the chitenje ($p=0.00$). At the time of discharge from KMC, 94% of women who used the CarePlus Wrap were very satisfied with it, compared to 56% of those who used traditional *chitenje*. The results for comfort and ease of use were nearly the same as those at the time of the first interview, with the mothers using the CarePlus wrap reporting significantly higher levels.

Levels of satisfaction with the CarePlus wrap remained high post-discharge and nearly all reported the wrap was suitable for husbands or other male family members to use, would recommend the wrap to other mothers and preferred the KMC wrapper over the *chitenje* for practicing KMC. However, 78% of mothers reported being comfortable going outside the house with the baby in STS position in the wrap, highlighting potential barriers to use, particularly during the daytime when mothers are more likely to move outside the house. This lack of comfort was most pronounced among women from QECH, where only 57% reported being comfortable going outside the home in STS position compared to 87% of women in Thyolo and 93% of women in Machinga ($p=0.00$).

Willingness to recycle and pay for CarePlus wrap: The findings show that: 63% of women who used the CarePlus wrap were willing to return the wrap; 70% would be willing to use a pre-used wrap; an equal number of women would either pay a deposit for the wrap (64%) or buy one (63%) for about \$2 (the estimated cost of local production). There were significant differences between study sites, with women in Thyolo more likely to be willing to pay for a wrap or give a small deposit, to believe that other mothers would purchase a wrap, and to be willing to return the wrap and use a recycled wrap compared to women in the other two sites. Women from Machinga were the least willing to return the wrap while women from QECH were least likely to be willing to use a recycled wrap.

Family and social support: About 63% of women reported another family member was trained in KMC while in facility, usually the mother, sister or mother-in-law. Only 1% reported their husband received training in KMC at the facility. Nearly all women reported receiving some form of help from family members while they were in facility KMC, with the most common support being provision of food, followed by help holding the baby in STS position and caring for children at home. Mothers, husbands, and sisters were the most commonly mentioned family members providing this support. There were no significant differences between women using the CarePlus wrapper and women using the traditional *chitenje*, but there were differences by study site, with women in Thyolo being less likely to report family support (70% compared to 98% in both Machinga and QECH; $p=0.00$).

Following discharge from facility, the reported levels of support from family members in the community were high and similar across study sites (QECH: 90%; Thyolo: 88%; Machinga: 85%; $p=0.56$). More than 80% of mothers reported that family members provided support for holding baby in STS position and results were similar for women in the CarePlus and *chitenje* group. Other frequently mentioned forms of family support were help with food and household chores. A higher proportion of women in the CarePlus group reported receiving support for help with household chores than the *chitenje* group. Levels

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of support from outside the family were similar between study groups and provision of food and help with household chores were the most commonly reported forms of support. Friends were the primary providers of such support from outside the family, followed by women's groups.

Follow-up care and health issues post-discharge: Women are advised to return to the facility for follow-up based on discharge weight, with those less than 1,800g requested to come back weekly until they reach 1,800g and those weighing 1,800g or more requested to come every two weeks until they reach 2,500g. Slightly more than half of women whose babies weighed <1,800g at facility discharge (57%) reported returning to the health facility for their weekly follow-up by the time of the post-discharge visit at 7-10 days; there were no differences by study arm. Levels of follow-up were much lower among women discharged from Machinga (25%) compared to QECH (76%) and Thyolo (71%) ($p=0.00$). Among those returning for follow-up, most babies had their weight measured and temperature taken, but less than half of mother spontaneously reported receiving advice on caring for their baby or were asked about STS and feeding practices. Less than 10% received a home visit from a CHW.

Overall acceptability of KMC: The vast majority of women, regardless of study arm, reported being satisfied with their baby's progress on KMC (94%) and would recommend KMC to others having a preterm baby (99%).

Local production: Results showed that local tailors can produce the wrappers at facility level with necessary materials procured and made available by the facility management team. The five trained tailors managed to produce the wrappers with the help of a construction kit, which guided them on how to cut the patterns and properly connect the different pieces.

STUDY LIMITATIONS

This study had some important limitations, which are summarized below:

- Information on skin-to-skin practices was based on maternal report, and it is possible that women may have misreported the duration of skin-to-skin. The study had planned to observe and record KMC practices, including STS and feeding, on a daily basis and compare that with reported values. However, this did not turn out to be feasible in study sites due to limited staffing resources. Observation data was still being collected by observers and mothers were also providing data on STS but staffing issues made it difficult to have full time observations by clinical observers. Data on skin-to-skin duration were collected by asking mothers to report how long they practiced skin-to-skin at various time points.
- There were important data quality issues that affected the primary outcome. Data on weight at discharge were missing for 4% of babies discharged alive and length of stay for another 4%. As a consequence, analysis of rate of weight change was restricted to 266 of the 287 (93%) babies discharged alive.
- There were limitations to using weight gain as a primary outcome in this study. Day of admission to KMC varied from patient to patient and was significantly different between study sites (although not statistically significant between intervention and control). Data were collected on most infants during the period of physiologic water loss after birth, when both weight gain and weight loss (up to 15% for preterm babies) can be considered safe. Rate of weight gain/loss can change rapidly and suddenly in the first week of life as breastfeeding is established, thus making differences in admission by just a few hours clinically, but perhaps not statistically significant.
- As per study protocol, study follow-up visits were meant to take place between 7-10 days after discharge from facility KMC. However, many visits were completed long after this date, with only 64% of babies

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discharged alive receiving a follow-up visit within this timeframe (67% of intervention and 62% of control; range by facility 25%-76%). Analysis of skin-to-skin practices and follow-up care included all 266 mother-baby dyads with information post-discharge from facility, while analysis on weight change between discharge and follow-up was restricted to 182 cases visited between 7-15 days post-discharge from facility and with complete weight data.

- Data were missing on vital status for 41 enrolled cases (13.6%; 11 who dropped out while in facility and 30 who were lost to follow-up after discharge from facility). As such, it is possible that more babies enrolled in the study died while in facility or in the community after discharge from facility.
- The initial plan was that every mother randomized to the intervention group should receive two wraps each to ensure mothers were that KMC practice could continue even while one wrap was being washed. During the study, mothers received one CarePlus wrap each due to communication failures between the study team and study implementers. This likely limited the ability of the study to demonstrate the potential effect of the effects Laerdal wrap on KMC practices. However, given resource constraints in Malawi, it is likely that during scale up women would only receive one CarePlus wrapper and as such, the results of this study are more generalizable to that scenario.
- Some training materials (e.g. Preemie Natalies and MamaBreast and care at home leaflet) were not delivered to the study sites on time and this may have affected counseling of mothers on KMC, demonstration on expressing breast milk and supporting mothers during breast milk expression.

RECOMMENDATIONS

Findings from this study suggest the following recommendations:

- **Promote the use of a customized wrapper, such as the CarePlus design:** The CarePlus wrapper should be promoted in Malawi as an evidence-based method to improve maternal satisfaction around KMC implementation and to increase adherence to recommended skin-to-skin practices.
- **Incorporate a customized wrapper into district health system planning:** Include a customized wrap, such as the CarePlus wrapper, in the procurement catalogue and district expenditure plans for sustained availability.
- **Produce a customized wrapper locally:** Work with MOH to develop and test approaches for locally producing and financing the CarePlus wrapper.
- **Invest in Quality Improvement:** Reported adherence to KMC practices and recorded weight gain while in facility KMC varied significantly by study site. District hospitals must invest in ongoing mentorship and quality improvement initiatives with attention paid to promotion of appropriate feeding, skin-to-skin practice and providing adequate resources and facilities to encourage such practices.
- **Undertake additional research:** Conduct further investigation to better understand the observed gaps in documentation of KMC services and outcomes and explore underlying barriers to improved quality of care at different sites.
- **Strengthen follow up visits after discharge:** Explore options to address low levels of facility follow-up and home visits by community health workers and improve quality of counselling on skin-to-skin and feeding practices during follow-up visits. Babies discharged from facility-KMC remain highly vulnerable and need regular follow-up and support to reach their growth and developmental potential.

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- **Identify and invest in community-based approaches:** Identify community-based approaches to increase support for mothers and their families to practice KMC in the community.

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Acronyms

COMREC	College of Medicine Research and Ethics Committee
EmONC	Emergency Obstetric and Newborn Care
ENAP	Every Newborn Action Plan
HIV	Human Immunodeficiency Virus
HSA	Health Surveillance Assistant
ICF	Informed Consent Form
IRB	Institutional Review Board
KMC	Kangaroo Mother Care
LBW	Low birth weight
LGH	Lærdal Global Health
PI	Principal Investigator
QECH	Queen Elizabeth Central Hospital
M&E	Monitoring & Evaluation
SCI	Save the Children International
SCiM	Save the Children in Malawi
SNL	Saving Newborn Lives
SOP	Standard Operating Procedures
SSDI	Support for Service Delivery Integration
RHD	Reproductive Health Directorate
WHO	World Health Organization

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1. Background and Rationale

Complications from preterm birth (defined as births occurring before 37 weeks gestation), is a leading cause of under-five mortality worldwide, accounting for an estimated 18% of global deaths¹. Kangaroo mother care (KMC) is an evidence-based approach to reducing mortality and morbidity in low birth weight (LBW) and preterm infants, recommended by the WHO as a priority intervention to address preterm morbidity and mortality². The WHO defines KMC as early, continuous, and prolonged skin-to-skin contact between the mother and the baby; exclusive breastfeeding or breast milk feeding; early discharge after hospital-initiated KMC with continuation at home; and adequate support and follow-up after discharge². KMC has been shown to significantly reduce preterm mortality at 40-41 weeks' corrected gestational age by 40% and to improve other outcomes including severe infection/sepsis and weight gain³. Research from various geographies also suggests that KMC is a cost-effective method for treating preterm infants, and that KMC is acceptable to mothers despite the challenges they face to adhere to the recommended practices⁴.

Malawi has the highest rate of preterm births worldwide, with 18% of live births occurring before 37 weeks of pregnancy⁵. Whilst Malawi has made significant progress toward reducing under-five mortality in the past decade, the neonatal mortality rate has declined at a slower rate than the overall under-five mortality rate with preterm birth complications accounting for one-third of all newborn deaths. Implementation of KMC has been part of the efforts to improve newborn health and KMC was listed as a priority intervention in Malawi's Every Newborn Action Plan (ENAP), which was launched in July 2015⁶. Institutionalization and scale-up of quality care for the most vulnerable small and sick newborns, including establishment of sick newborn care units in all districts and kangaroo mother care (KMC) services throughout Malawi is listed in the Malawi ENAP as a priority⁶. Indeed, KMC services have been expanding across the country since its first introduction at Zomba Central Hospital in 1999. As of August 2016, KMC was available in all central hospitals and most of the lower level hospitals in the country.

Nonetheless, research suggests that Malawi still has challenges with regards to KMC implementation. An in-depth evaluation of 14 healthcare facilities that offered KMC across Malawi in February 2012 found that only 5 (36%) of the facilities were either "on the road to institutionalized KMC practice" or had "evidence of institutionalized [KMC] practice"⁷. Many facilities had poorly trained KMC staff, limited provision of information about KMC to mothers during antenatal care / shortly after birth, and inadequate equipment and supplies for KMC practice. In only half of the facilities visited, mothers were observed to have "diligent compliance in doing KMC"^{7,7}. A comprehensive EmONC assessment in 2014 that covered all hospitals across Malawi found similar results⁸. While 77% of hospitals reported that they provided inpatient KMC services, just 75% of these had the most basic elements for (staff, space for KMC and functional scale) and only 60% had documentation of providing KMC in the last 12 months⁸.

Other studies have noted persistent barriers to uptake of KMC practices by mothers/families. The Boston Consulting Group and Save the Children assessed barriers to KMC practice from the perspective of mothers/families and providers using focus group discussions and interviews in 2013⁹. Barriers to KMC practices include:

- Holding the baby in skin-to-skin position using traditional wraps that have a knot at the back is uncomfortable, particularly when the mother is trying to sleep, and requires frequent breaks.
- Mothers felt it was very difficult to do routine chores with the baby in KMC
- Men did not want to practice KMC because it was perceived to be in the woman's domain
- It is not culturally acceptable to take a preterm infant outside the home
- Mothers did not feel there was a surrogate that could keep the baby in KMC when they needed a break.

Rationale

Despite Malawi's success in scaling up availability of KMC services in all central and district hospitals, the quality of KMC services is not up to standard. Major bottlenecks to effective KMC implementation at scale are poor infrastructure in most of hospitals; shortage of equipment and supplies and inadequate knowledge and skills in caring for the preterm/LBW baby including KMC; poor documentation; and poor reporting and referral systems^{7,8}.

The success of KMC depends on ability of mothers and caregivers to practice continuous skin-to-skin. Barriers to skin-to-skin practices reported by mothers using traditional chitenje as wraps include: the difficulty to hold baby in the front, concerns about stability of the baby, requirement for two people to tie, thick material that over-heats, and irritation from the large knot at the

back from tying the chitenje. Anecdotal reports from a facility in Ekwendeni that introduced custom wraps is that providing a custom wrap for mothers can make practicing skin-to-skin more comfortable for mothers and reduce anxiety and also facilitate uptake to skin-to-skin by other caregivers, alleviating some burden from the mother. In an effort to improve KMC, Lærdal Global Health (LGH) has developed an ergonomic baby carrier (a KMC wrap) that has the potential to be produced locally at low cost. A small scale testing in Malawi in five facilities (Bwaila, QECH, Zomba, Salima, Likoma) in August 2014 suggested that a KMC wrap is a promising approach for improving adherence to skin-to-skin practices. Mothers gave positive feedback on the wraps and were willing to return them at follow-up and also to re-use wraps. Further development and testing of the use of KMC wrappers in Malawi is needed to inform expansion.

The Malawi Government through its Reproductive Health Directorate (RHD), with support from partners, is employing various efforts to improve the quality of KMC and care for small and premature babies. Save the Children, as one of the partners in newborn health, plans to improve quality of KMC services in facilities through quality improvement and routine data use, as well as care at home through the use of new KMC wrappers. The organization aims at documenting and sharing the gains on KMC through the use of these new wrappers.

This study tested the hypothesis that a customized wrap will increase the duration of skin-to-skin contact among Malawian mother-baby dyads practicing KMC at facility and post-discharge, leading to improved breast-feeding and weight gain.

2. Objectives

The primary study aim was to evaluate the acceptability and effectiveness of introducing a custom KMC wrap to improve adherence to skin-to-skin practices within selected hospitals with established KMC programs in Malawi. Specific objectives were to:

- Assess acceptability of the wrap and adherence to skin-to-skin practice with the introduction of a KMC wrap in selected health facilities
- Assess uptake of skin-to-skin practices in the community post-discharge from facility-based KMC

3. Methods

1.1.1 2.1. Study design

This was an operations research study, with a randomized control trial (RCT) design. Mother-baby dyads meeting eligibility criteria and providing informed consent were randomly assigned to receive either the CarePlus KMC wrap (intervention group) or a traditional chitenje (control group).

1.1.2 2.2. Study setting

The study was conducted in three large hospitals in the southern region of Malawi: Machinga district hospital, Thyolo district hospital, and Queen Elizabeth Central Hospital (Blantyre district). Save the Children and Support for Service Delivery Integration (SSDI) were supporting quality improvement efforts of KMC services in these hospitals. The facilities experience high clientele levels of low birth weight and preterm babies. QECH, a government facility, is both a tertiary government referral unit for the Southern region and a district hospital for Blantyre city and its surrounding health centres. In QECH, there are nearly 12,000 deliveries per year (HMIS), many of which are designated high risk. The nursery offers neonatal special care, but no intensive care. A Kangaroo Care inpatient ward was opened in November 2003. It has 35 beds and is run by patient attendants (non-specialist, non-clinical staff with high-school qualifications and on-the-job training) and 2 midwives who are overseen by pediatricians. Data from the HMIS/DHIS2 showed that QECH reported providing KMC to 645 babies between January and June 2015 (~107 cases per month). Mothers carry out all infant care under the support and supervision of the midwives and patient attendants. QECH runs outpatient KMC follow up clinics once every week and these are done by midwives and clinical officers. Thyolo

district hospital is a secondary level hospital providing referral care for Thyolo district. Recent data from the HMIS/DHIS2 shows that Thyolo district hospital reported providing KMC to 104 babies between January and June between January and June 2015 (~17 cases per month). The KMC unit is run by midwives and clinical officers. Machinga district hospital is a secondary level hospital providing referral care for Machinga district. HMIS/DHIS2 data shows that Machinga district hospital reported providing KMC to 194 babies between January and June 2015 (~32 cases per month). The KMC unit is run by midwives.

1.1.3 2.3. Study population

This study involved low birth weight newborns (birth weight less than 2,000g) and their mothers who were admitted to facility-based KMC at the three target hospitals in Malawi (QECH, Thyolo and Machinga).

1.1.4 2.4 Study outcomes

Primary outcome: The primary outcome variable was the average rate of weight gain among babies enrolled in KMC. .

Secondary outcomes: We also evaluated the acceptability and use of the KMC wrap using the quantitative and qualitative indicators outlined by objective below:

- 1) Assess acceptability of the wrap and adherence to skin-to-skin practice with the introduction of a KMC wrap in selected health facilities
 - Proportion of observed time periods in which the mothers were in skin-to-skin position
 - Description of mother's perceptions of and experiences practicing skin-to-skin comparing traditional wrap to KMC wrapper (ease of tying, breast-feeding, sleep, temperature/comfort, security of the wrap for the baby, willingness of surrogates to practice skin-to-skin)
- 2) Assess uptake of skin-to-skin practices in the community post-discharge from facility-based KMC
 - Proportion of mothers reporting practicing skin-to-skin at home post-discharge
 - Description of mother's perceptions practicing skin-to-skin at home comparing traditional wrap to KMC wrapper (ease of use, practice of skin-to-skin by surrogates, going out in public)

Alongside the study, we explored the feasibility of local production of the CarePlus wrapper by training and equipping existing hospital-based tailors. The objectives of this feasibility assessment were to:

- Assess hospital tailor's ability to produce wraps
- Assess quality and cost of locally produced wraps

1.1.5 2.5 Sample size

The sample size for outcome measurement was based on the primary outcome indicator: *average rate of weight gain*. Our study assumption was that the average rate of weight gain, measured in grams (g) per day while in hospital, would be 20% higher among babies of mothers using the KMC wrap compared to those babies whose mothers use the traditional wrap. A 20% difference was considered to be a clinically meaningful increase in the average weight gain and also feasible to detect within the available resources for the study. Considering a significance level of 5%, a power of 90%, a baseline average rate of weight gain of 15 grams/day and a standard deviation of 7g/day, we calculated we would need to enrol 230 mother-baby dyads (115 in each study group) to demonstrate that the average rate of weight gain is 20% or higher among babies of mothers using the KMC wrap. Assuming that ~15-20% will withdraw from the study or be lost to follow-up in each arm, we aimed to enrol 280 mother-baby dyads (140 per arm) to ensure adequate final sample for analysis.

On the local production stream we aimed to reach all hospital tailors in the study sites. Five hospital tailors (1 Tailor from Machinga District Hospital, 1 Tailor from Thyolo District Hospital, 3 Tailors from QECH) and 1 Matron from QECH participated in local production of the wrapper.

1.1.6 2.6 Sampling and Eligibility Assessment

All mother/baby dyads admitted to KMC service at all three study sites, regardless of location in the hospital, were evaluated for eligibility in the study within 24 hours of admission to KMC. The following inclusion and exclusion criteria were applied for the study.

Inclusion criteria

- Low birth weight babies (and their mothers) eligible for facility-based KMC (birth weight less than 2,000g) admitted to one of the three target hospitals (Queen Elizabeth, Machinga or Thyolo)

Exclusion criteria

- Babies already known to have a neurological problem like neural tube defects and hydrocephalus or other congenital abnormalities prior to the onset of the study.
- Babies with major complications in need special care (e.g. severe respiratory problems, severe infections)
- Very small babies with birth weight of less than 800gms
- Babies whose mother died during labor.
- Babies ≥ 7 days at admission to KMC
- Babies who die before discharge from KMC
- Babies referred out for higher level care

1.1.7 2.7 Intervention description

Research has shown that KMC, when practiced as recommended by WHO, is the most effective measure to save underweight and premature babies (2). The KMC method ensures stable body temperature of the child, protects against infection and promotes breastfeeding and contact between mother and child. Lærdal Global Health launched an ergonomic baby carrier (a KMC wrap – see Figure 1 and more details in Annex 1) and teaching materials that make it easier to practice KMC in the facility and also after the mothers are discharged home. The wrap design has been pre-tested in several countries, including Malawi, and shown to be safe for both mother and baby. The wrap should be easy to make locally and at a low cost. To limit costs and enhance sustainability, mothers would take the wrap home and be asked to return the wraps at scheduled KMC follow-up visits so that the wraps could be recycled and used by other mothers. Pilot studies of the KMC wrap were also conducted in Nepal are ongoing in India and Tanzania. The LGH provided funding for this study through Save the Children Norway.



Figure 1. Mother using LGH wrapper - when the mother has been taught, it is easy to tie on by themselves and also to breastfeed.

In each facility, the wrap team enrolled eligible mother-baby dyads who have provided informed consent. At enrollment, mother-baby dyads were randomly assigned to either the intervention arm or the control arm. Facility staff received a brief refresher session on KMC, including continuous counselling for the mothers to ensure they are able to support KMC services as per Malawi's standard protocol. As per standard KMC practice, mothers were oriented on how to practice skin-to-skin and received standard information on how to care for their small baby (covering breastfeeding, cup and spoon feeding, hygiene, and the importance of skin-to-skin position). Mothers received specific instruction on how to use the type of wrap they received (e.g. mothers receiving the LGH wrap were shown how to tie and use the LGH wrap while mothers receiving the chitenje were shown how to tie and use the chitenje).

1.1.8 2.8 Data collection procedures

Data were collected from May 2016 to December 2016 by a team of research assistants based at each of the three study sites, comprising 5 members with the following background and responsibilities:

Team member	Background Requirement	Responsibilities
Research Officer	Clinical Officer or Nurse Midwife	Eligibility assessment, Recruitment of study participants, collecting health facility level data and coordinating follow up visits and data.
Field Workers	Allocated at KMC unit Experience with Health Research especially at community level, Knowledge of KMC	Conducting follow up visits post discharge Administer follow up questionnaire at community level as per protocol.

Clinical Observers	Nurses	Conduct clinical observations and documenting
	Based at KMC units	KMC practices in facility.

Teams were trained by the study PI and Save the Children technical staff for four days and the training covered study protocol, orientation of study tools, orientation on child safeguarding policy as per SCI requirement and finally the training covered data collection using tablets where research assistants had to practice through mock interviews to ensure quality and ethical issues.

Data collectors stationed at each facility completed study tools for all enrolled mother-baby dyads, including information on weight, reported duration of skin-to-skin contact, and mother's perceptions of use of the assigned study wraps. Within 7-10 days following discharge from KMC, the data collectors conducted a home visit to each enrolled mother-baby dyad to collect information on continued skin-to-skin practices, baby's weight, and qualitative information on perceptions of practicing skin-to-skin in the community and use of the assigned study wraps. Detailed information on data collection procedure according to primary and secondary outcomes are given below.

Primary outcome:

Data collectors measured the weight of all enrolled babies upon admission to KMC and at the time of facility discharge using a digital infant scale with 20g accuracy. Birthweight data was extracted from the maternity registers. Data collectors visited each mother-baby dyad discharged from facility at their home within 7-10 days of discharge and weighed the baby using the same type of scale. Average rate of weight gain was calculated in g/day for each study group for the two main periods of interest (admission to facility discharge and discharge to 7-10 day follow-up).

Secondary outcomes:

Adherence to skin-to-skin practice with the introduction of a KMC wrap in selected health facilities and acceptability of the wrap: Mothers were asked to report on the duration of skin-to-skin care while in facility and post-discharge while in the community. Information on mother's perceptions of and experiences practicing skin-to-skin comparing traditional wrap to KMC wrapper (ease of tying, breast-feeding, sleep, temperature/comfort, security of the wrap for the baby, willingness of surrogates to practice skin-to-skin) was collected through brief interviews with mothers at scheduled time periods (upon admission to KMC, on Day 3, and upon discharge).

Uptake of skin-to-skin practices in the community post-discharge from facility-based KMC: Information on continued skin-to-skin practices and use of the wrap was collected 7-10 days post-discharge from the facility. Trained data collectors visited the homes of all enrolled mother-baby dyads discharged from facility to weigh the baby and interview the mother to determine whether the mother is still practicing skin-to-skin and for how much time per day. Information on mother's perceptions practicing skin-to-skin at home and use of traditional or KMC wrap were also collected (ease of use, cleaning/washing, temperature, practice of skin-to-skin by surrogates, going out in public).

Local production: The feasibility of local production of the wrapper was explored by training hospital-based tailors using a construction kit specific for the CarePlus wrapper and assessing the quality and cost of wrappers produced with locally available materials. Technical information (in simple terms) was shared with five hospital-based tailors from the three study sites (three from QECH, and one each from Thyolo and Machinga) to enhance their understanding about low birth weight and prematurity in Malawi and why it is important to have the wrapper produced locally. The wrapper was introduced to five hospital-based tailors who participated in the training with focus on its use and reasons why it is used including details on where it is currently being used in Malawi. The construction kit was discussed in detail, step by step allowing tailors to ask questions and agree how the different patterns need to be connected to create the CarePlus wrapper. After the training, the matron of QECH assessed each wrapper produced by the local tailor to determine its quality.

1.1.9 2.9 Data management and analysis

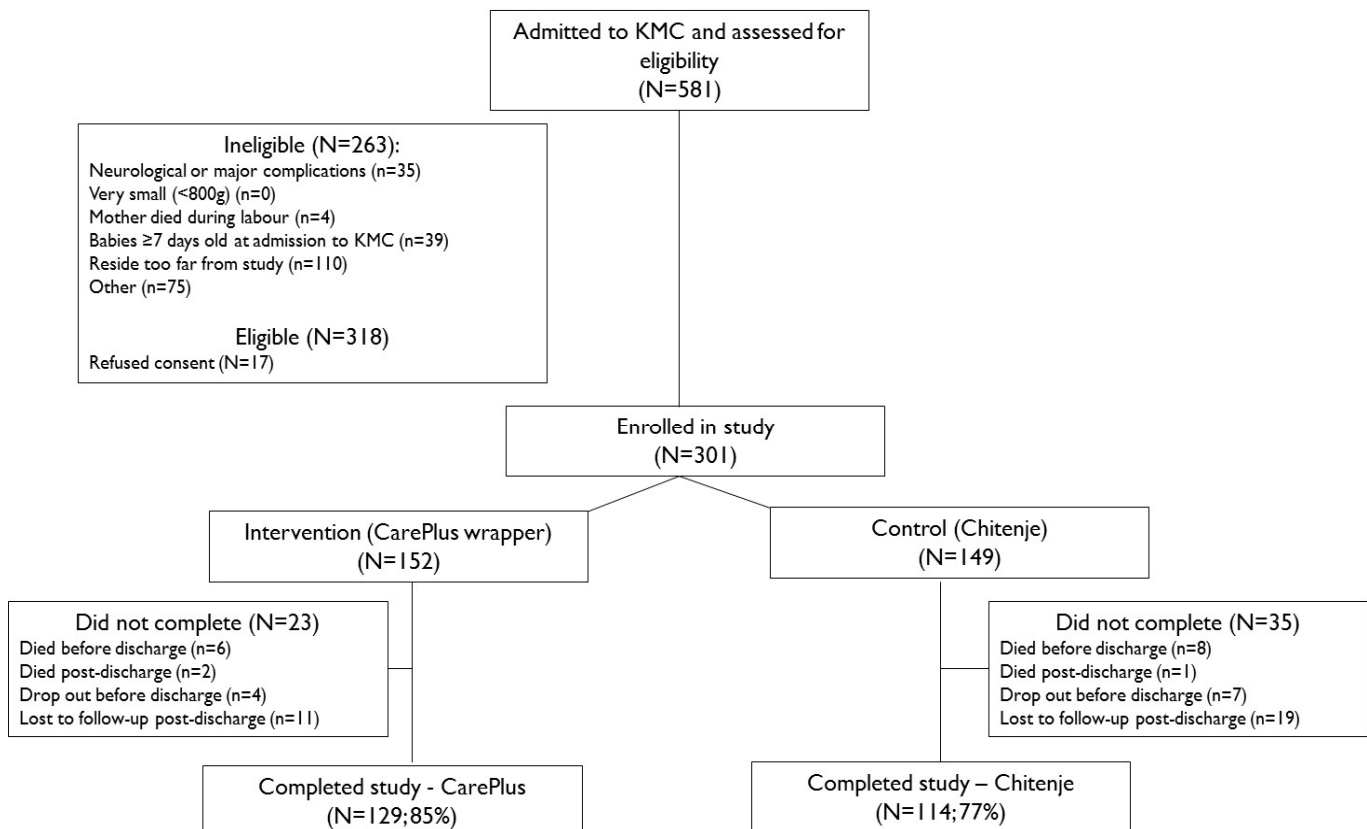
Data were captured using tablets programmed with CS-PRO database. We calculated the difference between intervention and control groups in average rate of weight gain, measured in g/day for two time periods: 1) from the time of KMC admission to the time of facility discharge and 2) from time of facility discharge to 7-10 days follow-up visit. T-tests were used to determine whether the mean difference in weight gain between the two study groups was statistically significant.

1.1.10 2.10 Ethical considerations

Ethical approval for the study was received in May 2016 from the College of Medicine Research and Ethics Committee (COMREC) national bioethics committee (Reference number: P.I I/15/1835). Written informed consent was obtained from every mother/baby dyad who agreed to participate in the study.

3. Study Findings

Data on eligibility were available for 581 babies. Tracking of eligibility was incomplete for QECH in the early stages of the study as the initial research assistant failed to adhere to the protocol. Of the 581 babies assessed for eligibility, 318 met the eligibility criteria and 301 provided informed consent and were enrolled in the study, with 152 in the intervention group and 149 in the control group. Of those enrolled, 85% (129) of the intervention group and 77% (114) of the control group completed the study. The study flow diagram is provided below.



3.1. Characteristics of Mother-Baby Dyads

Table 1 details the background characteristics of enrolled mothers and shows that there were no significant differences between study arms at enrollment. The mean age of mothers was 25.1 years, and nearly one quarter of mothers were less than 20 years of age. Education levels were low, with less than 60% of mothers having completed primary school. The majority of mothers were married and just over half were unemployed. Monthly family income levels were low, with more than 80% of mothers reported less than 30,000 kwacha (about 41.4 USD) per month and 38% reporting less than 10,000 kwacha (about 13.8 USD) per month.

Table 1. Background characteristics of mothers enrolled in the study

Background Characteristics of mothers enrolled in the study	CarePlus (n=152)	Chitenje (n=149)	Total (N=301)	p-value
Study site				
QECH	38.2	40.3	39.2	NA
Thyolo	27.6	26.9	27.2	
Machinga	34.2	32.9	33.6	
Age				
Less than 20 years	21.7	27.5	24.6	0.47
20-29 years	42.8	42.3	42.5	
30+ years	34.9	30.2	32.6	
Education level				
Less than primary	55.3	60.4	57.8	0.45
Completed primary	27.0	20.8	23.9	
Completed some secondary or higher	17.8	18.8	18.2	
Marital status				
Married	75.7	80.5	78.1	0.31
Not married	24.3	19.5	21.9	
Employment status				
None	48.3	57.3	52.7	0.32
Skilled/self-employed	4.2	3.6	3.9	
Salaried	9.8	4.5	7.1	
Agriculture/farmer	15.4	17.4	16.4	
Business	21.7	15.9	18.9	
Other	0.7	1.5	1.1	
Monthly family income				
<10,000 kwacha	37.5	39.6	38.5	0.97
10-30,000 kwacha	44.7	42.3	43.5	
>30,000+ kwacha	17.8	18.1	17.9	

Table 2 summarizes the health characteristics of mothers and babies enrolled in the study as documented in maternity records. No significant differences were seen between study arms. For about two-thirds of mothers, this was not their first child. The majority gave birth within a facility, with about 69% delivering in the study facility and 17% at another facility. An estimated 24% of mothers were known to be HIV+, 75% were known HIV- and 1% had unknown status. Maternal complications were quite common, with close to one quarter of enrolled mothers documented as having experienced at least one maternal complication according to the maternity ward records. Preeclampsia was the most frequently documented complication (10.0%; 30/301), followed by hemorrhage (5.0%; 14/301), prolonged labour (1.3%; 4/301) and other (9.0%; 27/301).

Table 2. Health characteristics of study mothers and babies at enrollment

Health Characteristics of study mothers and babies at enrollment	CarePlus (n=152)	Chitenje (n=149)	Total (N=301)	p-value
Mothers:				
Parity				
First baby	30.9	31.5	31.2	0.91
Second+ baby	69.1	68.5	68.8	
Place of delivery				
Study facility	67.7	71.4	69.4	0.50

Report

Other health facility	15.8	18.1	16.9	
Outside health facility	15.1	9.4	12.3	
Maternal complications				
None	57.9	55.7	56.8	0.42
One or more	25.7	22.2	23.9	
Unknown	16.5	22.2	19.3	
Maternal HIV status				
HIV+	22.7	24.5	23.6	0.77
HIV-	76.7	74.2	75.4	
Unknown	0.7	1.4	1.0	
Babies:				
Sex				
Male	43.3	42.2	42.8	0.84
Female	56.7	57.8	57.2	
Mode of delivery				
Vaginal	84.0	80.3	82.2	0.46
C-section	16.0	19.1	17.5	
Vacuum extraction	0.0	0.7	0.3	
Gestational age (completed weeks)				
<32 weeks	29.0	20.8	24.9	0.17
32-36 weeks	63.2	67.1	65.1	
37+ weeks	7.9	12.1	10.0	
Multiple births				
Singleton	69.7	65.8	67.8	0.59
Twins/Triplets	29.0	31.5	30.2	
Birthweight (as measured in maternity ward)				
<1,500g	38.8	34.9	36.9	0.48
1,500-<2,000g	61.2	65.1	63.1	
Other complications at birth (as recorded in maternity ward)				
None	86.8	85.2	86.1	0.69
Asphyxia	2.0	3.4	2.7	0.46
Sepsis	0	0	0	--
Other	11.2	11.4	11.3	0.95

Most babies were delivered vaginally, while 17.5% were delivered through c-section. Only 10% of enrolled babies were estimated to be term (37+ weeks), with close to two-thirds estimated to be between 32 and 36 weeks gestation. An estimated 63% of babies were born weighing between 1,500 and 2,000g while about 37% were less than 1,500g at birth. Less than 15% of babies were documented to have experienced other complications at birth (in addition to preterm/low birth weight), with asphyxia being the most common.

The average age in days at admission to KMC was 1.5 and was similar in both study arms (Table 3a). The average weight at initiation to KMC was 1,555g and was similar in both study arms. More than one-third of babies (36.2%) were less than 1,500g at initiation and about 20% were between 1,800 and 2,000g. Duration of stay in KMC was 9.3 days on average, with babies in the intervention arm staying slightly longer on average than control babies, although the difference was not statistically significant. Close to 20% of babies became sick while in facility-KMC, with injections and phototherapy being the most common treatments received.

Nearly all babies were discharged from facility alive, with 14 deaths recorded in facility-KMC (6 in intervention and 8 in control). About two-thirds (67.8%) of babies met discharge criteria, while 23.6% left against medical advice and the status of 3.7% was unknown. Weight at discharge from facility was missing for 3.8% of cases, with slightly more chitenje cases missing data compared to women using the CarePlus wrapper. Among those with known weight at discharge (n=276; 96.2% of the 287 discharged alive), average weight was similar between groups, with the difference between average weight at initiation and discharge being 62 g (63g in CarePlus group and 60g in chitenje group). Just over 20% of babies were discharged from facility weighing less than 1,500g.

Table 3a. Summary of KMC experience among enrolled mother and babies by study arm

Summary of KMC experience among enrolled mothers and babies	CarePlus (n=152)	Chitenje (n=149)	Total (N=301)	p-value
Age in days at admission to KMC	1.5	1.6	1.5	0.95
Weight at KMC initiation (mean)	1,547g	1,563g	1,555g	0.58
<1,500g	40.1	32.2	36.2	0.26
1,500-1,799g	39.5	48.3	43.9	
1,800g-<2000g	20.4	19.5	19.9	
Status at discharge from KMC				
Met discharge criteria	66.5	69.1	67.8	0.64
Died	4.0	5.4	4.7	
Referred to higher level	0.0	0.7	0.3	
Left against medical advice	26.3	20.8	23.6	
Unknown	3.0	4.0	3.7	
Weight at KMC discharge for those discharged alive (mean)	1,610g	1,623g	1,617g	0.60
<1,500g	24.7	18.4	21.6	0.17
1,500-1,799g	51.4	58.2	54.7	
>=1,800g	21.9	17.7	19.7	
Missing	2.1	5.7	3.8	
Total number of days in KMC (mean)	9.7	8.9	9.3	0.38
Missing	12 cases	17 cases	29 cases	
Child age in days at time of discharge	11.1	9.7	10.4	0.13
Missing/unknown	21 cases	31 cases	52 cases	
Child became sick while in KMC	22.2	17.4	19.9	0.35
Treatment received while in KMC				
Injections (antibiotics)	13.2	9.4	11.3	0.30
Phototherapy	4.0	4.0	4.0	0.97
Other	1.3	0.7	1.0	0.57

Analysis by study site revealed significant differences across study sites (Table 3b). Babies at QECH tended to be smaller at time of initiation but weight gains were greater and a larger proportion met discharge criteria compared to the other two sites. Babies at Thyolo lost weight on average between admission and facility discharge and only about half of those admitted met discharge criteria; most concerning, 9.8% died while in facility KMC, more than one quarter left against medical advice and status at discharge was 'unknown' for another 9.8%. Weight at discharge was missing for 4.4% of babies discharged alive from QECH, 1.0% of babies at Machinga and 6.8% at Thyolo.

Table 3b. Summary of KMC experience among enrolled mother and babies by study site

Summary of KMC experience among enrolled mothers and babies	QECH (n=118)	Thyolo (n=82)	Machinga (n=101)	p-value
Age in days at admission to KMC	2.2	1.2	1.1	0.01
Weight at KMC initiation (mean)	1,488g	1,602g	1,593g	0.00
<1,500g	44.1	31.7	30.7	0.01
1,500-1,799g	46.6	40.2	43.6	
1,800g-<2000g	9.3	28.1	25.7	
Status at discharge from KMC				
Met discharge criteria	74.6	51.2	73.3	0.00

Report

Died	2.5	9.8	3.0	
Referred to higher level	0.0	1.2	0.0	
Left against medical advice	21.2	28.1	22.8	
Unknown	1.8	9.8	1.0	
Weight at KMC discharge among those discharged alive (mean)	1,637g	1,577g	1,622g	0.15
<1,500g	15.7	32.4	20.4	0.02
1,500-1,799g	63.5	43.2	53.1	
>=1,800g	16.5	17.6	25.5	
Missing	4.4	6.8	1.0	
Total number of days in KMC (mean)	8.9	7.4	10.9	0.01
Missing	8 cases	19 cases	2 cases	
Child age in days at time of discharge	10.9	7.7	11.8	0.00
Missing/unknown	20 cases	21 cases	11 cases	
Child became sick while in KMC	22.5	11.9	22.6	0.20
Treatment received while in KMC				
Injections (antibiotics)	5.8	2.6	9.6	0.01
Phototherapy	5.8	0.9	0.5	0.00
Other	0.7	0.9	0.0	0.44

3.2. Primary outcome – Rate of weight gain

Table 4a summarizes data on average rate of weight gain in g/day between admission and discharge from facility-based KMC for cases that had information on weight at both time points. Data on weight at discharge was available for 276 (96.2%) of the 287 babies discharged alive from KMC; 143 (97.9%) of the 146 intervention cases discharged alive from KMC and for 133 (94.3%) of the 141 control cases discharged alive. Analysis was run using the 266 cases with data on weight at KMC admission and facility discharge and data on length of stay in KMC.

Table 4a. Weight gain while in facility-based KMC (for babies discharged alive) by study arm

Weight gain variables	CarePlus (n=138)	Chitenje (n=128)	Total (N=266)	p-value
Age in days at time of KMC initiation (mean)	1.5	1.6	1.5	0.85
Weight at time of KMC initiation (g)	1,558g	1,589g	1,573g	0.29
Weight at time of KMC initiation				
<1,500g	37.7	26.6	32.3	0.10
1,500-1,799g	41.3	53.1	47.0	
>=1,800g	21.0	20.3	20.7	
Average number of days in facility KMC	9.7	8.8	9.3	0.34
Weight at discharge from KMC (g)	1,614g	1,629g	1,621g	0.56
Weight at discharge from KMC				
<1,500g	24.6	18.8	21.8	0.28
1,500-1,799g	52.9	62.5	57.5	
>=1,800g	22.5	18.8	20.7	
Rate of weight gain between KMC admission and discharge (g/day)	5.7	2.8	4.3	0.30

The average rate of weight gain between admission and facility discharge in g/day was slightly higher among the babies using the CarePlus wrapper; this difference was not statistically significant. In terms of absolute weight change between admission and discharge, 41.4% weighed the same or less at discharge compared to admission (38.4% of CarePlus cases and 44.5% of Chitenje cases).

Further analysis showed that average rate of weight gain was significantly higher among babies whose mothers reported practicing 20 or more hours of STS per day (10.4 g/day; 95% CI: 5.9-14.8) compared to those who practiced less (1.0g/day; 95% CI: -2.4 - 4.5) (p=0.00). This association was observed both among women using the CarePlus wrapper and women using the chitenje. Baby's birthweight as recorded in maternity register was also significantly associated with average rate of weight gain. Babies born weighing <1,500g had a higher rate of weight gain (10.7 g/day; 95% CI: 7.0-14.3) compared to those born 1,500g or more (1.2 g/day; 95% CI: -2.5-4.8) (p=0.00). The pattern of higher weight gain among those born weighing <1,500g was present in both study arms, but only statistically significant for the control group (p=0.00). The most dramatic difference in average rate of weight gain was seen between study sites, with babies at QECH having a much higher rate (17.4 g/day) compared to Thyolo where most recorded weight loss (-13.1 g/day) and Machinga (0.2 g/day) (Table 4b). Maternal HIV status, child becoming sick while in KMC, multiple births, or gestational age were not significantly associated with average rate of weight gain.

Table 4b. Weight gain while in facility-based KMC (for babies discharged alive) by study site

Weight gain variables	QECH (n=110)	Thyolo (n=59)	Machinga (n=97)	p-value
Age in days at time of KMC initiation (mean)	2.1	1.1	1.1	0.00

Report

Weight at time of KMC initiation (g)	1,498g	1,669g	1,599g	0.00
Weight at time of KMC initiation				
<1,500g	42.7	18.6	28.9	0.00
1,500-1,799g	47.3	49.2	45.4	
>=1,800g	10.0	32.2	25.8	
Average number of days in facility KMC	8.9	7.3	10.9	0.01
Weight at discharge from KMC (g)	1,637g	1,590g	1,622g	0.35
(mean)				
Weight at discharge from KMC				
(categorical)				
<1,500g	16.4	33.9	20.6	0.04
1,500-1,799g	66.4	47.5	53.6	
>=1,800g	17.3	18.6	25.8	
Rate of weight gain between KMC	17.4	-13.1	0.2	0.00
admission and discharge (g/day)				

Table 4b shows the full results for the 266 cases by study site. Babies at Thyolo appeared to be admitted to KMC earlier, to weigh more at time of admission, and to spend less time in facility KMC than the other two sites. Within each study site, mothers in the CarePlus group had higher average rate of weight gain (or smaller rates of weight loss in the case of Thyolo) compared to mothers in the Chitenje group (QECH: 20.3 vs. 14.8 g/day; $p=0.20$; Thyolo: -10.1 vs. -17.5 g/day; $p=0.15$; Machinga: 1.5 vs -1.1 g/day; $p=0.45$), but the results were not statistically significant.

Table 5 summarizes weight gain between discharge and follow-up after discharge from facility. Follow-up visits were meant to take place within 7-10 days post discharge. However, only 185 of the 287 cases discharged alive completed follow-up within 7-15 days and only 182 had data on follow-up weight and weight at discharge. The findings show that weight at discharge was similar between study groups. The majority of babies (97%) gained weight after discharge, and the rate of weight gain in g/day was markedly higher post-discharge than while in health facility. Three-quarters of babies weighed more than 1,800g by the 7-15 day follow-up visit. There were no differences in weight at the post-discharge visit and the rate of weight gain in g/day between using the CarePlus wrapper and women using the Chitenje. Analysis by study site showed significant differences, with babies discharged from Machinga gaining an average of 45.8g/day compared to 42.3g/day in QECH and 22.7g/day in Thyolo ($p=0.00$).

Table 5. Weight gain between facility discharge and post-discharge follow-up (for babies discharged alive from facility)

Weight gain variables	CarePlus (n=96)	Chitenje (n=86)	Total (N=182)	p-value
Weight at discharge from KMC (g) (mean)	1,618g	1,641g	1,629g	0.42
<1,500g	24.0	17.4	20.9	0.39
1,500-1,799g	54.2	64.0	58.8	
>=1,800g	21.9	18.6	20.3	
Weight at 7-15 day follow-up visit (g) (mean)	2,012g	1,994g	2,004g	0.77
<1,500g	9.4	4.7	7.1	0.24
1,500-1,799g	14.6	22.1	18.1	
>=1,800g	76.0	73.3	74.7	
Rate of weight gain between KMC discharge and follow-up (g/day)	41.1	36.9	39.1	0.44

3.3. Secondary outcomes

3.3.1 Skin-to-skin practice in facility KMC

Information on reported skin-to-skin practices of mothers while in facility KMC was available for 241 mothers (80% of enrolled cases; 126 intervention and 115 control)². Reported daily duration of skin-to-skin (STS) practice while in facility was significantly higher among women using the CarePlus wrapper (Table 6). Among women using the CarePlus wrapper, 44% of women reported more than 20 hours STS per day and 6% reported 10 hours or less of STS. In comparison, 33% of women using the traditional chitenje reported 20 hours or more of STS per day and 19% reported 10 hours or less per day.

Table 6. Reported STS practices while in facility-based KMC

Skin-to-skin practices reported by mothers while in facility KMC	CarePlus (n=126)	Chitenje (n=115)	Total (N=241)	p-value
Time found easiest to do skin-to-skin				
Day-time	13.5	20.0	16.6	0.38
Night-time	17.5	14.8	16.2	
Both the same	69.1	65.2	67.2	
Usual amount of time in STS during day-time				
Nearly all the day	54.0	40.9	47.7	0.00
More than half the day	43.9	45.2	44.0	
Some of the day (less than half)	3.2	13.9	8.3	
Usual amount of time in STS during night-time				
Nearly all the night	52.4	49.6	51.0	0.00
More than half the night	44.4	33.0	39.0	
Some of the night (less than half)	3.2	17.4	10.0	
Times when took baby off STS				
To rest	1.3	3.4	2.3	0.24
To use bathroom	80.3	77.2	78.7	0.51
To sleep	0.7	2.7	1.7	0.17
For feeding	52.0	40.9	46.5	0.06
For visitors	5.9	8.1	7.0	0.47
When baby was crying/fussy	52.6	57.7	55.2	0.38
Other	27.0	20.1	23.4	0.16
Reported hours/day baby usually placed in STS				
4 hours or less	0.8	0.9	0.8	0.03
5-10 hours	5.6	18.3	11.6	
11-19 hours	46.0	44.4	45.2	
20 or more hours	44.4	33.0	39.0	
Don't know	3.2	3.5	3.3	
Reported day-time STS practice in last 24 hours				
Nearly all the day	54.0	45.2	49.8	0.03
More than half the day	44.4	46.1	45.2	
Some of the day (less than half)	1.6	8.7	5.0	
Reported night-time STS practice in last 24 hours				
Nearly all the night	54.0	45.2	49.8	0.00
More than half the night	43.7	37.4	40.7	
Some of the night (less than half)	2.4	15.7	8.7	
Not at all	0.0	1.7	0.8	

Women using the CarePlus wrapper were also more likely to report using the wrapper for nearly all of the day and nearly all or more than half of the night compared to women using the traditional wrapper. Reported times that the baby was taken off STS were similar between study groups, with the most common times being to use the bathroom, when the baby was crying/fussy and for feeding.

² Data were missing for mothers of babies who died while in facility (n=12/12), for those with unknown status at discharge (n=30/30), for those who left against medical advice (n=15/63); those referred (n=1/1) and those who met discharge criteria (2/195).

Analysis by study site identified statistically significant differences in reported STS duration. At QECH, 61.2% of mothers reported more than 20 hours compared to 25.4% of women in Thyolo and 22.6% of women in Machinga ($p=0.00$). More women using the CarePlus wrapper reported 20 or more hours of STS compared to women using a chitenje in Thyolo (31.4 vs. 16.7%) and Machinga (42.9 vs. 2.4%), whereas in QECH, more women using the chitenje reported 20 or more hours of STS (67.4 vs. 55.1%). Only the differences in Machinga were statistically significant due to the small sample size. The greater proportion of women reporting continuous STS use at QECH is likely to help explain why average rate of weight gain was much higher at that site compared to Thyolo and Machinga.

3.3.2 Feeding practices in facility KMC

Nearly all babies were able to breastfeed (Table 7), but most (88%) required use of cup and spoon to support feeding at the time of discharge. There were no differences between study arms in reported use of cup and spoon or type of feeding. Women at QECH and Machinga reported nearly universal use of cup and spoon for feeding (99.0 and 100%), while in Thyolo only 52.5% of women reported using cup and spoon to support feeding. Similarly, nearly all mothers in QECH (95.9%) and Machinga (100%) reported providing breastmilk only, while in Thyolo 81.4% of mothers were giving exclusive breastmilk, 3.4% predominately breastmilk and 15.4% were providing partial breastmilk ($p=0.00$).

Table 7. Reported feeding practices while in facility-based KMC

Feeding Practices	CarePlus (n=126)	Chitenje (n=115)	Total (N=241)	p-value
Baby able to breastfeed	98.4	100.0	99.2	0.18
Babies using cup and spoon for feeding at time of discharge	88.1	87.8	88.0	0.95
Type of feeding				
Exclusive breastmilk	92.1	95.7	93.8	0.38
Predominantly breastmilk	1.6	1.7	1.7	
Partial breastmilk	6.4	2.6	4.6	

Nearly all mothers mentioned receiving support from health facility staff for expressing breastmilk (92%), for feeding position (91%) and reminders for feeding (87%) and levels of supports were similar in both study groups. Analysis by study site showed that women in Thyolo were significantly less likely to report receiving support from facility staff for two of the three feeding related areas: expressing breastmilk (67.8% in Thyolo compared to 98.0% in QECH and 100% in Machinga; $p=0.00$); and feeding position (74.6% in Thyolo compared to 98.0% in QECH and 100% in Machinga; $p=0.00$). Results were similar across sites for feeding reminders (84.6% in Thyolo compared to 89.8% in QECH and 91.7% in Machinga; $p=0.41$).

1.1.11 3.3.3 Acceptability of the wrap in facility KMC

While in facility KMC, women were asked about their perceptions of the wrap at two time points – the first within 3 days of admission and the second at the time of discharge. Table 8 and 9 show that the majority of women were using their assigned wrap, with just 6/134 not using the Care Plus wrapper at time of interview the first interview and 6/126 at time of discharge. Shortly after initiation, a significantly higher proportion of women using the CarePlus Wrap reported being comfortable to keep baby in skin to skin position (96% vs 71%); being able to tie on the CarePlus Wrap themselves (86% vs 10%); being comfortable to breastfeed while using the CarePlus Wrap (43% vs 12%); and that the CarePlus Wrap would be acceptable for use by fathers and male family members (93% vs. 43%). Women using the Care Plus wrapper reported taking less time to become comfortable using the wrap, with 72% comfortable within the first day compared to 40% of those using the chitenje ($p=0.00$).

Table 8. Acceptability of wrap while in facility at time of first interview (within 3 days of KMC initiation)

Acceptability of wrap at time of first interview	CarePlus (n=134)	Chitenje (n=129)	Total (N=263)	p-value
Proportion of mothers using the assigned wrap	95.5	100.0	97.7	NA
Proportion of mothers at <u>first interview</u> reporting assigned wrap:				
Comfortable to keep baby in STS	96.3	71.3	84.0	0.00
Able to tie herself	85.8	10.1	48.7	0.00
Comfortable to use while breastfeeding	43.3	11.6	27.8	0.00
Comfortable to use while sleeping	97.8	58.9	78.7	0.00
Keeps baby in secure position	95.5	89.2	92.4	0.05
Easy to monitor baby while in wrap	99.3	96.1	97.7	0.09
Acceptable for fathers or male family members to use	93.3	43.4	68.8	0.00
Faced any difficulties using wrap	8.2	31.0	19.4	0.00
Proportion of mothers preferring KMC wrapper over tradition wrap	93.2	NA	NA	NA

At the time of discharge from KMC, 94% of women who used the CarePlus Wrap were very satisfied with it, compared to 56% of those who used traditional *chitenje*. (Table 9). The results for comfort and ease of use were nearly the same as those at the time of the first interview, with the mothers using the CarePlus wrap reporting significantly higher levels. Nearly all mothers (99.6%) reported they intended to practice KMC at home, regardless of which wrap they were assigned.

Table 9. Acceptability of wrap at time of discharge from facility-KMC

Acceptability of wrap at time of discharge	CarePlus (n=126)	Chitenje (n=115)	Total (N=241)	p-value
Proportion of mothers using the assigned wrap at <u>time of discharge</u>	95.2	100.0	97.5	NA
Proportion of mothers at <u>time of discharge</u> reporting assigned wrap:				
Comfortable to keep baby in STS	96.0	68.7	83.0	0.00
Able to tie herself	92.1	10.4	53.1	0.00
Comfortable to use while breastfeeding	54.0	16.5	36.1	0.00
Comfortable to use while sleeping	97.6	56.5	78.0	0.00
Keeps baby in secure position	97.6	88.7	93.4	0.01
Easy to monitor baby while in wrap	99.2	98.3	98.9	0.51
Satisfaction with wrap at time of discharge				
Very satisfied	94.4	55.7	75.9	0.00
Somewhat Satisfied	2.4	26.1	13.7	
Not very satisfied	3.2	18.3	10.4	
Proportion of mothers preferring KMC wrapper over tradition wrap	90.2	NA	NA	NA

1.1.12 3.3.3 Uptake of skin-to-skin practices post-discharge from facility

Data on skin-to-skin practices in the community were available for 243 (84.7%) of the 287 babies discharged alive from facility-based KMC (129 women from the intervention group and 114 from the control group). However, follow-up for many women occurred much later than the 7-10 day women; only 185 women were followed up between 7 and 15 days post-discharge and of these 182 babies were still alive (58/93 at QECH; 44/56 at Thyolo and 80/94 at Machinga). Findings show that most women from both study arms were still practicing STS in the community (87% of all those who completed the study, and 93% of those interviewed between 7 and 15 days discharge) (Table 10). Nearly all those continuing STS practice reported daily practice, but

contrary to the findings reported while in facility KMC, the proportion reporting practicing STS nearly all the day dropped significantly in both groups, but especially among women assigned the CarePlus Wrapper. The gains in reported duration of STS among women using the CarePlus Wrapper appeared to disappear by the time of follow-up after discharge. Women using the traditional wrap were more likely to report practicing STS while doing chores and to go out of the house with the baby in STS position, although these differences were not statistically significant.

Further analysis by study site showed that women from QECH were significantly less likely than women in the other two sites to report going outside the home with their baby in STS position (54.7% compared to 80.4% in Thyolo and 63.4% in Machinga; $p=0.01$). They were also less likely to report keeping the baby in STS position nearly all the day (18.7% compared to 37.5% in Thyolo and 30.5% in Machinga; $p=0.00$) or nearly all the night (49.3% compared to 89.3% in Thyolo and 61.0% in Machinga; $p=0.00$).

Table 10. Reported STS practices post-discharge from facility KMC

Skin-to-skin practices reported by mothers in the community (post-discharge)	CarePlus (n=129)	Chitenje (n=114)	Total (N=243)	p-value
Baby in STS position (observed)	52.7	48.3	50.6	0.49
Still practicing STS (reported)	86.1	88.6	87.2	0.55
Frequency of STS (for those practicing)				
Everyday	94.6	89.5	92.2	0.22
5-6 days/week	3.1	8.8	5.8	
3-4 days/week	1.6	1.8	1.7	
1-2 days/week	0.8	0	0.4	
Practice STS while doing chores	64.9	72.3	68.4	0.25
Go out of house with baby in STS	62.2	68.3	65.1	0.35
Usual amount of time in STS during day-time*				
Nearly all the day	28.8	27.7	28.3	0.66
More than half the day	46.0	48.5	47.2	
Some of the day (less than half)	24.3	20.8	22.6	
Not at all	0.9	3.0	1.9	
Usual amount of time in STS during night-time*				
Nearly all the night	59.5	69.3	64.2	0.07
More than half the night	29.7	18.8	24.4	
Some of the night (less than half)	6.3	10.9	8.5	
Not at all	4.5	1.0	2.8	
Reported day-time STS practice in last 24 hours*				
Nearly all the day	31.5	31.7	31.6	0.77
More than half the day	48.7	47.5	48.1	
Some of the day (less than half)	19.8	19.8	19.8	
Not at all	0.0	1.0	0.5	
Reported night-time STS practice in last 24 hours*				
Nearly all the night	56.8	63.4	59.5	0.78
More than half the night	30.6	24.8	27.8	
Some of the night (less than half)	11.7	10.9	11.3	
Not at all	0.9	1.0	0.9	

*Data available for 212 cases (111 intervention and 101 control; 75 QECH; 55 Thyolo and 82 Machinga) who were still practicing STS at the post-discharge interview

1.1.13 3.3.4 Acceptability of the wrap in the community (post-discharge from facility)

Women in the intervention group were asked about the acceptability of the CarePlus wrapper during the follow-up visit and data were available for 120 of the 129 women (93%) of the women that completed the study. Levels of satisfaction with the wrapper remained high post-discharge and nearly all reported the wrap was suitable for husbands or other male family members to use,

would recommend the wrap to other mothers and preferred the KMC wrapper over the chitenje for practicing KMC (Table 11). However, only 78% reported being comfortable going outside the house with the baby in STS position in the wrap, highlighting potential barriers to use, particularly during the daytime when mothers are more likely to move outside the house. This lack of comfort was most pronounced among women from QECH, where only 56.8% reported being comfortable going outside the home in STS position compared to 87.1% of women in Thyolo and 93.3% of women in Machinga ($p=0.00$).

Table 11. Reported acceptability of the CarePlus wrapper post-discharge

Acceptability of wrap in community	CarePlus (n=120)
Satisfied with wrap in community	93.3
Think wrap is suitable for husband or other male family members	95.0
Used the wrap for anything else (besides putting baby in STS)	4.2
Comfortable going outside house with baby in STS position in wrap	78.3
Would recommend wrap received to other mothers	96.7
Prefer KMC wrapper over chitenje for practicing KMC in the home/community	90.8

3.4 Other findings

1.1.14 3.6.1 Willingness to pay for the wraps or use recycled wrap

The operations research also explored willingness to pay for the wraps and feasibility of establishing a recycling scheme. The findings show that: 63% of women who used the CarePlus wrap were willing to return the wrap; 70% would be willing to use a pre-used wrap; an equal number of women would either pay a deposit for the wrap (64%) or buy one (63%) for about \$2 (the estimated cost of local production; refer to section 4.0). There were significant differences between study sites, with women in Thyolo more likely to be willing to pay for a wrap or give a small deposit, to believe that other mothers would purchase a wrap, and to be willing to return the wrap and use a recycled wrap compared to women in the other two sites. Women from Machinga were the least willing to return the wrap while women from QECH were least likely to be willing to use a recycled wrap.

Table 12. Willingness to pay for CarePlus wrapper

Willingness to pay for wrap	QECH (n=44)	Thyolo (n=31)	Machinga (n=45)	Total (N=120)	p-value
Willing to pay for a wrap (had it not been free)					
Yes	54.6	80.7	60.0	63.3	0.06
No	45.5	19.4	40.0	36.7	
Amount willing to pay for wrap					
Mean	1,000 kw	1,596 kw	1,879 kw	1,508 kw	
(Median)	(1,000kw)	(1,000kw)	(1,500kw)	(1,000kw)	
Range	200- 2000kw	300- 5,000kw	150- 5,000kw	150-5,000kw	
Believes other mothers would purchase wrap					
Yes	9.1	71.0	48.9	40.0	0.00
No	0.0	16.1	22.2	12.5	
Not sure	90.9	12.9	28.9	46.5	
Willing to pay small deposit for wrap that would be returned when wrap was returned					
Yes	56.8	87.1	57.8	65.0	0.00
No	9.1	3.2	24.4	13.3	
Not sure	34.1	9.7	17.8	21.7	
Willing to return the wrap so it could be used by others					
Yes	61.4	90.3	46.7	63.3	0.00
No	38.6	9.7	53.3	36.7	
Willing to use recycled wrap					
Yes	54.6	93.6	68.9	70.0	0.00
No	45.5	6.5	31.1	30.0	

1.1.15

1.1.16 3.6.3 Family and social support for KMC

Women were asked about family and social support for KMC while in facility at the time of discharge from facility and at the post-discharge interview. Table 13 shows that about 63% of women reported another family member was trained in KMC while in facility, usually the mother, sister or mother-in-law. Only 1% reported their husband received training in KMC at the facility. Women in Machinga were more likely to report having a family member trained (88.1%) compared to QECH (52.0%) and Thyolo (44.1%) ($p=0.00$). Nearly all women reported receiving some form of help from family members while they were in facility KMC, with the most common support being provision of food, following by help holding the baby in STS position and caring for children at home. Mothers, husbands, and sisters were the most commonly mentioned family members providing this support. There were no significant differences between women using the CarePlus wrapper and women using the tradition chitenje, but there were differences by study site, with women in Thyolo being less likely to report family support (69.5% compared to 98.0% in both Machinga and QECH; $p=0.00$).

Table 13. Levels of family and social support for KMC while in facility

Family and social support while in facility KMC	CarePlus (n=126)	Chitenje (n=115)	Total (N=241)	p-value
Other family member trained on KMC at facility	60.3	65.2	62.7	0.43
Type of family member involved in training:				
Mother	32.5	36.5	34.4	0.43
Sister	15.1	17.4	16.2	0.63
Mother-in-law	8.7	5.2	7.1	0.29
Husband	1.6	0.9	1.2	0.62
Other	7.9	9.6	8.7	0.65
Received help from family member (either at home or in facility)	91.3	90.4	90.9	0.82
Type of help provided				
Provided food	85.7	89.6	87.6	0.37
Held baby in STS position	38.9	39.1	39.0	0.97
Cared for children at home	32.5	43.5	37.8	0.08
Provided moral support	32.5	34.8	33.6	0.71
Other	15.1	11.3	13.3	0.39
Type of person providing support				
Mother	52.4	46.1	49.4	0.33
Husband	40.5	40.9	40.7	0.95
Sister	35.7	38.3	36.9	0.68
Mother-in-law	19.0	15.7	17.4	0.49
Other	22.2	23.5	22.8	0.82

Table 14 summarizes the reported levels of family and community support after discharge from facility-based KMC. Most women reported help from family members and just over a third reported help from non-family members.

Table 14. Levels of family and social support for KMC in community (post-discharge from facility)

Family and community support for KMC while in community (post-discharge)	CarePlus (n=129)	Chitenje (n=114)	Total (N=243)	p-value
Any family member provided help since returned home	88.4	86.8	87.7	0.72
Type of family member providing help				
Mother	55.8	64.0	59.7	0.19
Husband	47.3	44.7	46.1	0.69
Sister	43.4	41.2	42.4	0.73
Mother-in-law	14.0	14.0	14.0	0.99
Other	19.4	16.7	18.1	0.58
Type of help provided				
Held baby in STS position	81.4	82.5	81.9	0.83
Provided food	78.3	71.9	75.3	0.25
Household chores	79.1	66.7	73.3	0.03
Provided moral support	60.5	53.5	57.2	0.27
Cared for children at home	52.7	43.9	48.7	0.17
Other	0.8	4.4	2.5	0.07
Anyone outside of family providing support	39.5	35.1	37.5	0.48
Type of support provided				
Provided food	30.2	20.2	25.5	0.07
Household chores	27.9	18.4	23.5	0.08
Provided moral support	20.9	18.4	19.8	0.62
Cared for children at home	6.2	6.1	6.2	0.98
Held baby in STS position	4.7	5.3	4.9	0.83
Other	3.1	5.3	4.1	0.40
Type of person providing support				
Friends	34.1	29.0	31.7	0.39
Women's groups	10.1	11.4	10.7	0.74
Village leaders	7.0	5.3	6.2	0.58
Other	0.0	4.4	2.1	0.02

Reported levels of support from family members post-discharge were similar across study sites (QECH: 90.3%; Thyolo: 87.5%; Machinga: 85.1%; $p=0.56$). More than 80% of mothers reported that family members provided support for holding baby in STS position and results were similar for women in the CarePlus and chitenje group. Other frequently mentioned forms of family support were help with food and household chores. A higher proportion of women in the CarePlus group reported receiving support for help with household chores than the chitenje group.

Levels of support from outside the family were similar between study groups and provision of food and help with household chores were the most commonly reported forms of support. Friends were the primary providers of such support from outside the family, followed by women's groups. Women in Thyolo were significantly less likely to report receiving support from non-family members post-discharge (23.2% compared to 44.1% in QECH and 39.4% in Machinga; $p=0.03$).

1.1.17 3.6.4 Follow-up care and health issues post-discharge from facility

Women are advised to return to the facility for follow-up based on weight at the time of discharge from facility, with those less than 1,800g requested to come back weekly until they reach 1,800g and those weighing 1,800g or more requested to come bi-weekly until they reach 2,500g. Slightly more than half of women reported returning to the health facility by the time of the post-discharge visit and there were no differences by study arm or by weight at discharge (Table 15a). Levels of follow-up were much lower among women discharged from Machinga (24.5%) compared to QECH (76.3%) and Thyolo (71.4%) ($p=0.00$). Among those

returning for follow-up, most babies had their weight measured and temperature taken, but less than half of mother reported receiving advice on caring for their baby or were asked about STS and feeding practices.

Table 15a. Follow-up care received by study arm

Follow-up care received	CarePlus (n=129)	Chitenje (n=114)	Total (N=243)	p-value
Returned to health facility for follow-up	54.3	56.1	55.1	0.77
Discharged <1,800g	56.0	57.5	56.7	0.84
Discharged 1,800g or more	48.3	50.0	51.0	0.91
Activities done by health worker at follow-up (<i>among those who went to HF</i>):				
Weighed baby	90.0	98.4	94.0	0.04
Asked about feeding	44.3	40.6	42.5	0.67
Asked about KMC (STS) practices	51.4	45.3	48.5	0.48
Checked baby's temperature	78.6	82.8	80.6	0.55
Gave advice about caring for baby	54.3	42.2	48.5	0.16
Gave vaccination	14.3	4.7	9.7	0.06
Other	0.0	4.7	2.2	0.07
Received home visit from CHW				
Visit from HSA	7.0	3.5	5.4	0.43
Visit from other CHW	4.7	3.5	4.1	
No visit	88.4	93.0	90.5	
Mother experienced fever/malaria post-discharge	3.1	8.8	5.7	0.06
Baby became sick post-discharge	3.9	7.0	5.4	0.28

Among those who received a home visit from a CHW (23 total; 15 in intervention and 8 in control), 87% reported the CHW weighed the baby, 74% gave advice about caring for the baby, 65% asked about STS practices, and 57% asked about feeding.

A total of 13 babies (5 intervention and 8 control; 10 Thyolo; 2 QECH and 1 Machinga) were reported to have experienced an illness between discharge from facility and the follow-up interview. Among these, 12 were kept in STS position while ill. In terms of care seeking, 5 were taken to hospital and 1 to another facility, while 7 did not seek any care. Two babies were admitted to hospital and both reported their baby was given injections and other medicines (amoxicillin, paracetamol).

Analysis by study site highlighted significant differences in follow-up care across facilities, with level of follow-up significantly lower in Machinga than QECH and Thyolo (Table 15b). Among women returning for follow-up care, women from QECH much more likely to report that their baby was weighed and temperature assessed, but less likely to report receiving advice on feeding and STS practices than women returning for follow-up care in Thyolo and Machinga. Levels of home visits by CHWs were higher in Machinga than Thyolo and QECH, but still only a small proportion reported receiving such visits. Mothers of babies discharged from Thyolo were more likely to report their baby experienced illness compared to caregivers from the other two sites.

Table 15b. Follow-up care received by study site

Follow-up care received	QECH (n=93)	Thyolo (n=56)	Machinga (n=94)	p-value
Returned to health facility for follow-up	76.3	71.4	24.5	0.00
Discharged <1,800g	73.4	78.3	23.2	0.00
Discharged 1,800g or more	92.9	40.0	28.0	0.00

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Activities done by health worker at follow-up (*among those who went to HF*):

Weighed baby	100	100	65.2	0.00
Asked about feeding	28.2	65.0	47.8	0.00
Asked about KMC (STS) practices	29.6	80.0	52.2	0.00
Checked baby's temperature	94.4	72.5	52.2	0.00
Gave advice about caring for baby	26.7	80.0	60.9	0.00
Gave vaccination	1.4	0.0	52.2	0.00
Other	0.0	0.0	13.0	0.00
Received home visit from CHW				
Visit from HSA	2.2	5.4	8.5	0.01
Visit from other CHW	0.0	3.6	8.5	
No visit	97.9	91.1	83.0	
Mother experienced fever/malaria post-discharge	6.5	10.7	2.1	0.09
Baby became sick post-discharge	2.2	17.9	1.1	0.00

1.1.18 3.6.5 Overall acceptability of KMC

The vast majority of women, regardless of study arm, reported being satisfied with their baby's progress on KMC and that they would recommend KMC to others having a preterm baby. Responses were similar across study sites.

Table 16. Overall acceptability of KMC

Acceptability of KMC	CarePlus (n=129)	Chitenje (n=114)	Total (N=243)	p-value
Satisfied with baby's progress on KMC	96.9	91.2	94.2	0.06
Would recommend KMC to another women with a preterm baby	99.2	99.1	99.2	0.93

3.4 Feasibility of local production

Each of the hospital-based tailors produced at least one wrapper by the end of the training, and three of the five tailors managed to produce two each. Tailors reported that the construction kit was very helpful and it clearly guided them on how to cut the patterns and properly connect the different pieces of the CarePlus wrapper. The produced wrappers were tested based on guidance from the construction kit and results showed that the wrappers were strong with no loose stitches and joints. The wraps were properly stitched and fit to be used for babies on Kangaroo Mother Care.

The tailors and the matron acknowledged that wrappers can be produced locally, but this will only be possible if management is able to procure the required materials and allocate time for the hospital tailors to produce the wraps. The cost of the local materials required to produce the wrap was estimated to be approximately \$2USD. Based on the assessment of time to produce each wrap and time already allocated for current tailoring responsibilities, each tailor would be capable of producing approximately 2 wraps per day. To meet initial demand for wraps at each hospital in a timely manner, it may be necessary to contract additional local tailors to reach an adequate starting stock of wraps. Assuming that about 60% of wraps would be returned and that wraps would be lost due to wear and tear over time, hospital tailors would need to continually produce replacement wraps.

4. Discussion

This study investigated whether provision of a customized wrapper, the CarePlus wrap, would improve adherence to KMC practices and explored levels of acceptability and the feasibility of local production and recycling scheme. Women enrolled in the study were randomized to receive a CarePlus wrapper or a chitenje printed with KMC messages and followed up while in the facility and then 7-10 days post-discharge from facility KMC.

The results show strong preference among women for the CarePlus wrapper. More than 90% of women assigned the CarePlus wrapper reporting being very satisfied with the wrap compared to only about half of the women assigned to the chitenje group. Women using the CarePlus wrapper were also significantly more likely than women using a chitenje to report that the wrap was comfortable to use, could be tied by themselves, and would be acceptable for male family members to use. More than 95% of women receiving the CarePlus wrapper would recommend the wrap to other mothers and 90% expressed preference for the CarePlus wrapper (over the new chitenje).

The findings also suggest that use of the CarePlus wrap facilitated extended duration of STS practice while in facility, with significantly more women in the CarePlus wrapper group reporting continuous STS (20+ hours) compared to women in the chitenje group. While women still expressed strong satisfaction with and preference for the wrapper after discharge from the facility, there was no significant difference in reported STS duration post-discharge. Some women, particularly those discharged from QECH, reported not feeling comfortable going outside the home with the baby in STS position and this may have contributed to reduced duration of reported STS practice in the community, particularly during the daytime. Women from QECH were

significantly less likely than women in the other two sites to report going outside the home with the baby in STS position and were less likely to report STS practice nearly all the day and nearly all the night. An intensive SBCC campaign aimed at raising awareness around preterm birth and KMC was being implemented in Thyolo and Machinga districts at the same time as the study and could have contributed to reducing stigma in these communities and making women more comfortable practicing KMC openly in the community regardless of which type of wrapper was being used.

The rate of weight gain between admission and discharge from facility-based KMC was slightly higher among women using the CarePlus wrapper, although the results were not statistically significant and important variation was noted by study site. Levels of weight gain were highest among babies enrolled at QECH, regardless of study arm, and were significantly higher among those using the CarePlus wrapper. In contrast, babies enrolled at Thyolo tended to lose weight between admission and discharge, although the rate of weight loss was less among those using the CarePlus wrapper. Babies enrolled in Machinga had very low levels of weight gain and the results were very similar across study arms..

There were several challenges with the use of weight gain as a primary outcome. Measurement of weight during the time of hospitalization can be problematic due to the physiologic early weight loss experienced by newborn infants. Weight loss of 5-6% in term infants and up to 15% in preterm infants during the first week of life is expected and appropriate due to a diuresis of extracellular fluids. What matters with regards to weight for measuring effectiveness of KMC, however, is not necessarily positive or larger weight gain, but *appropriate* weight gain (or in the case of the early days of life, possibly appropriate weight loss). KMC is critical to achieving appropriate weight, but aggregating weight gains and losses across a study population is difficult to interpret given differing gestational ages, day of life on admission, and the fact that there is a range of appropriate weight gain/loss. For example, for a late preterm baby, both a gain of 5 g/day and a loss of 5 g/ day can be appropriate and safe in the first days of life. Although aggregated data on weight gain during the early days of life may be difficult to interpret, weight remains an important indicator in measuring KMC effectiveness for purposes of individualized patient care. Term and preterm infants will only gain weight (or lose weight appropriately) if their nutritional needs are being met, and caloric intake exceeds caloric expenditure.

Ultimately, weight gain (or loss) is determined primarily by the balance between energy intake and expenditure. Energy intake in the first days of life is influenced by intake of colostrum, timing of breast milk let-down, and sufficient breastfeeding. Caloric expenditure is determined by thermal regulation and energy consumed while feeding; both of which can be very high in preterm infants with high surface to body weight ratio, little subcutaneous fat, and reduced glycogen and brown fat stores, as well as poor suck-swallow coordination requiring large expenditure to eat. One study by Nagai et. al. in 2010 did find that early-onset KMC, compared with late-onset KMC, is associated with a significant reduction in body weight loss from birth to 48 hours post birth. Our study was not powered to measure this, however.

While duration of skin-to-skin contact (facilitated by a wrap) is an important determinant to optimizing caloric intake and minimizing caloric expenditure in preterm infants (and thus optimizing weight gain), there are several other factors that can contribute significantly to weight changes. These include recognition and management of special feeding needs (use of cup, spoon, nasogastric tube, supplemented/concentrated feeds), presence of family and health worker support, concurrent illness (infection, respiratory distress syndrome, etc), and insensible water losses in younger preterm infants that may require humidified air, which cannot be provided in STS.

Finally, and importantly, it should be noted that the scale used to measure weight had an accuracy to 20g, and data recorded on birthweight from maternity register appeared to be heaped, with significant rounding. Thus calculating appropriate weight gain as a percentage of gain/loss from birthweight is challenging.

Prior systematic reviews looking at the effect of KMC on a multitude of health outcomes have found weak linkages between weight gain and KMC, likely for similar reasons stated above. A 2014 Cochrane review reported a significant increase in weight gain at the latest follow-up (with significant heterogeneity), but no significant weight gain at discharge, or 6 and 12 months corrected age. A 2016 meta-analysis by Boundy et. al. similarly found no significant difference in weight gain between KMC infants and controls receiving conventional care. The Cochrane and Boundy reviews did find significant differences in mortality, sepsis hypothermia, and hypoglycemia between babies receiving KMC and those receiving conventional care. Using these measures as primary outcomes would require sample sizes that were not feasible for this study. Both reviews did find significant differences in exclusive breastfeeding, which we did examine in this study. However, we were only able to collect limited data on breastfeeding from mothers and more detailed, likely observational data would be required to fully assess feeding practices

Closer examination of weight data reveals only five of all enrolled babies had excessive weight loss during their hospitalization (all at Thyolo hospital). Although this number reflects low levels of unsafe weight loss, it does not reflect the rate of sub-optimal nutrition. Percentage cut-offs for acceptable weight loss as largely based on minimal fluid and growth requirements, not necessarily optimal nutrition for neurodevelopment. Thus the differences in weight gain observed between facilities is clinically significant, even when taking into account differences in time of admission.

The study explored the feasibility of implementing a recycling scheme for the wraps and explored willingness to pay for the wraps. Close to two-thirds of women in the CarePlus group indicated they would be willing to return the wrapper and 70% expressed willingness to use a recycled wrap. Similarly, about 64% of women would either pay a deposit for the wrap or buy one (63%) for about \$2 (the estimated cost of local production). The results varied substantially by facility, suggesting that strategies and approaches will need to be tailored to the setting. Training of tailors showed that it possible to produce the wrappers locally with availability of right materials procured by facility management teams. This suggests the need to work with MoH to develop and test procedures and approaches for financing local production of the CarePlus wrapper in Malawi.

The study also assessed levels of family and social support, which were not anticipated to vary by type of wrapper, but are important to understand potential barriers and facilitators for KMC practices. The results show that about two-thirds of women had another family member (usually mother or sister) involved in the training on KMC at facility and nearly all reported some form of support while in facility KMC from family for providing food and looking after other children. Husbands were only minimally involved in KMC at facility (only 1% were present for KMC training), but about 40% of mothers reported their husbands provided other forms of support while in facility. Most women (>85%) also reported receiving support from family after discharge from facility KMC, with helping to hold the baby in STS position being the most frequently reported form of support, followed by providing food and helping with household chores. More than one-third of women reported receiving support from community members, with friends and women's groups being the most commonly mentioned providers of support.

Women are advised to return to the health facility for follow-up weekly if they weight <1,800g at discharge and biweekly if they weigh 1,800g or more at discharge. Levels of follow-up were lower than expected, with only about half of women reported returning to the health facility by the time of the post-discharge visit, even for those weighing <1,800g at discharge. Among those returning for follow-up, most babies had their weight measured and temperature taken, but less than half of mother reported receiving advice on caring for their baby or were asked about STS and feeding practices, highlighting critical missed opportunities. Levels of follow-up and services received varied significantly by study site. Women from Machinga less likely to return for follow-up, while women at Thyolo who did go for follow-up were less likely to receive advice on STS and feeding. Coverage of home visits by CHWs were very low, with less than 10% receiving a CHW visit by the time of the post discharge follow-up visit.

Study Limitations:

This study had some important limitations, which are summarized below:

- Information on skin-to-skin practices was based on maternal report, and it is possible that women may have misreported the duration of skin-to-skin. The study had planned to observe and record KMC practices, including STS and feeding, on a daily basis and compare that with reported values. However, this did not turn out to be feasible in study sites due to limited staffing resources. Observation data was still being collected by observers and mothers were also providing data on STS but staffing issues made it difficult to have full time observations by clinical observers. Data on skin-to-skin duration were collected by asking mothers to report how long they practiced skin-to-skin at various time points.
- There were important data quality issues that affected the primary outcome. Data on weight at discharge were missing for 4% of babies discharged alive and length of stay for another 4%. As a consequence, analysis of rate of weight change was restricted to 266 of the 287 (93%) babies discharged alive.
- As noted above, there were limitations to using weight gain as a primary outcome in this study. Day of admission to KMC varied from patient to patient and was significantly different between study sites (although not statistically significant between intervention and control). Data were collected on most infants during the period of physiologic water loss after birth, when both weight gain and weight loss (up to 15% for preterm

babies) can be considered safe. Rate of weight gain/loss can change rapidly and suddenly in the first week of life as breastfeeding is established, thus making differences in admission by just a few hours clinically, but perhaps not statistically significant.

- As per study protocol, study follow-up visits were meant to take place between 7-10 days after discharge from facility KMC. However, many visits were completed long after this date, with only 64% of babies discharged alive receiving a follow-up visit within this timeframe (67% of intervention and 62% of control; range by facility 25%-76%). Analysis of skin-to-skin practices and follow-up care included all 266 mother-baby dyads with information post-discharge from facility, while analysis on weight change between discharge and follow-up was restricted to 182 cases visited between 7-15 days post-discharge from facility and with complete weight data.
- Data were missing on vital status for 41 enrolled cases (13.6%; 11 who dropped out while in facility and 30 who were lost to follow-up after discharge from facility). As such, it is possible that more babies enrolled in the study died while in facility or in the community after discharge from facility.
- The initial plan was that every mother randomized to the intervention group should receive two wraps each to ensure mothers were that KMC practice could continue even while one wrap was being washed. During the study, mothers received one CarePlus wrap each due to communication failures between the study team and study implementers. This likely limited the ability of the study to demonstrate the potential effect of the effects Laerdal wrap on KMC practices. However, given resource constraints in Malawi, it is likely that during scale up women would only receive one CarePlus wrapper and as such, the results of this study are more generalizable to that scenario.
- Some training materials (e.g. Preemie Natalies and MamaBreast and care at home leaflet) were not delivered to the study sites on time and this may have affected counseling of mothers on KMC, demonstration on expressing breast milk and supporting mothers during breast milk expression.

1.1.19 4.2 Recommendations

Findings from this study suggest the following recommendations:

- **Promote the use of a customized wrapper, such as the CarePlus design:** The CarePlus wrapper should be promoted in Malawi as an evidence-based method to improve maternal satisfaction around KMC implementation and to increase adherence to recommended skin-to-skin practices.
- **Incorporate a customized wrapper into district health system planning:** Include a customized wrap, such as the CarePlus wrapper, in the procurement catalogue and district expenditure plans for sustained availability.
- **Produce a customized wrapper locally:** Work with MOH to develop and test approaches for locally producing and financing the CarePlus wrapper.
- **Invest in Quality Improvement:** Reported adherence to KMC practices and recorded weight gain while in facility KMC varied significantly by study site. District hospitals must invest in ongoing mentorship and quality improvement initiatives with attention paid to promotion of appropriate feeding, skin-to-skin practice and providing adequate resources and facilities to encourage such practices.
- **Undertake additional research:** Conduct further investigation to better understand the observed gaps in documentation of KMC services and outcomes and explore underlying barriers to improved quality of care at different sites.
- **Strengthen follow up visits after discharge:** Explore options to address low levels of facility follow-up and home visits by community health workers and improve quality of counselling on skin-to-skin and feeding practices during follow-up visits. Babies discharged from facility-KMC remain highly vulnerable and need regular follow-up and support to reach their growth and developmental potential.
- **Identify and invest in community-based approaches:** Identify community-based approaches to increase support for mothers and their families to practice KMC in the community.

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Report

ANNEXES

Annex I – Financial Report