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Community-Based Kangaroo Mother Care to Prevent Neonatal and Infant Mortality: A Randomized, Controlled Cluster Trial

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What's Known on This Subject

Traditional KMC reduces the incidence of morbidity but not mortality. We successfully adapted KMC for immediate postnatal community-based implementation (CKMC). Our study and a subsequent (as yet unpublished) study in India found that CKMC quickly becomes popular.

What This Study Adds

This is the first study to assess the effect of CKMC on newborn and infant survival. We conclude that additional experimental research ensuring baseline comparability of study groups is needed to determine whether CKMC benefits newborn and infant survival.

ABSTRACT

OBJECTIVE. We adapted kangaroo mother care for immediate postnatal community-based application in rural Bangladesh, where the incidence of home delivery, low birth weight, and neonatal and infant mortality is high and neonatal intensive care is unavailable. This trial tested whether community-based kangaroo mother care reduces the overall neonatal mortality rate by 27.5%, infant mortality rate by 25%, and low birth weight neonatal mortality rate by 30%.

METHODS. Half of 42 unions in 2 Bangladesh divisions with the highest infant mortality rates were randomly assigned to community-based kangaroo mother care, and half were not. One village per union was randomly selected proportionate to union population size. A baseline survey of 39 888 eligible consenting women collected sociodemographic information. Community-based workers were taught to teach community-based kangaroo mother care to all expectant and postpartum women in the intervention villages. A total of 4165 live births were identified and enrolled. Newborns were followed for 30 to 45 days and infants were followed quarterly through their first birthday to record infant care, feeding, growth, health, and vital status.

RESULTS. Forty percent overall and ~65% of newborns who died were not weighed at birth, and missing birth weight was differential by study group. There was no difference in overall neonatal mortality rate or infant mortality rate. Except for care seeking, community-based kangaroo mother care behaviors were more common in the intervention than control group, but implementation was weak compared with the pilot study.

CONCLUSIONS. The extensive missing birth weight and its potential bias render the evidence insufficient to justify implementing community-based kangaroo mother care. Additional experimental research ensuring baseline comparability of mortality, adequate kangaroo mother care implementation, and birth weight assessment is necessary to clarify the effect of community-based kangaroo mother care on survival.

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Key Words
birth weight, kangaroo care, neonatal survival

The opinions expressed herein are those of the authors and do not necessarily reflect the view of the US Agency for International Development.

Abbreviations
LBW—low birth weight
KMC—kangaroo mother care
STS—skin-to-skin
IMR—infant mortality rate
BRAC—Bangladesh Rural Advancement Committee
CKMC—community-based kangaroo mother care
NMR—neonatal mortality rate
BINP—Bangladesh Integrated Nutrition Programme
NNP—National Nutrition Programme
GEE—generalized estimating equations
DSMB—data safety and monitoring board
CI—confidence interval
OR—odds ratio

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Four million newborns die each year, 99% in developing countries. Twenty-eight percent of newborn deaths are attributed to low birth weight (LBW) and prematurity and 26% to severe infections including pneumonia.[1] Kangaroo mother care (KMC) is a method whereby the hospital-born stabilized LBW newborn is placed in skin-to-skin (STS) contact on the mother's breast to promote thermal regulation, breastfeeding, and maternal–infant bonding.[2] Traditional KMC reduces the incidence of morbidity but not mortality in LBW infants, because it is generally applied to clinically stabilized newborns and most neonatal mortality occurs in the first 2 days of life before stabilization.[3–6] A single adequately designed study found a 43% (not statistically significant) lower infant mortality rate (IMR) associated with traditional KMC.[7] Two small African studies of early (as soon as possible after birth) KMC in hospitals with little neonatal intensive care capacity reported reduced mortality within 24 hours of birth[8] and before discharge[9]; however, important differences in study group characteristics were not controlled in analysis. Similarly, a historical improvement in survival of infants who weighed 1000 to 1999 g at birth was associated with early KMC in Zimbabwe.[10] A review was conducted of numerous small and otherwise methodologically challenged studies of early STS care that was provided to term, healthy newborns soon after birth in hospitals.[11] These studies and 3 conducted of preterm infants suggested that under certain conditions, early STS is safe and is as or more effective than standard incubator care in maintaining temperature while improving breastfeeding, maintaining neutral glucose levels, and preventing and treating hypothermia and respiratory problems that commonly are associated with neonatal mortality.[12–14]

Together with the Bangladesh Rural Advancement Committee (BRAC), Mitra and Associates, Ecuadorian and Bangladeshi physicians, nurse-midwives, and KMC experts, the study team adapted KMC so that it can be feasibly implemented as a community-based intervention (CKMC). In low-income countries, most births occur at home, neonatal intensive care is virtually unavailable, and the incidence of LBW and NMR is high. In these circumstances, initiation of CKMC promptly after birth could prove to be an effective means of timely thermal stabilization and early initiation and establishment of breastfeeding and thus potentially reduce the neonatal mortality rate (NMR) and IMR. Unlike hospital-based KMC, CKMC is promoted for all infants, regardless of birth weight, immediately after birth and does not require clinical judgment or birth weight to identify eligible infants. Weight on the day of birth is rarely measured in these countries, because most deliveries do not receive skilled attendance. In Bangladesh, cultural norms also commonly prohibit nonfamily members from entering the birth area in the first few days after delivery. As with traditional KMC with discharge to home in the kangaroo position, CKMC teaches that STS is provided for as long as the infant accepts it.

The government's Bangladesh Integrated Nutrition Programme (BINP), which later became the National Nutrition Programme (NNP), provides advice and supplementation to pregnant women. In a pilot study conducted near but outside the trial area, community nutrition workers from BINP were trained to teach CKMC to all late (≥7 months) gestation and recently postpartum women and their families as frequently as possible.[15] During a single month, mothers and families (35 of whom delivered, all singletons, in the 1-month follow-up period) were taught to hold their infants STS 24 hours a day and to encourage family participation in STS for short periods in which women desire privacy or rest. They were taught to breastfeed promptly, exclusively, and on demand. They were also taught to replace immersion in water with damp or dry cloth cleansing for the first few days of life and thus avoid lowering the infant's temperature, because this is standard hospital practice for LBW KMC infants. They were taught to sleep STS in an inclined position with the infant. As in many KMC programs,[3] mothers were taught to take the infant immediately to a clinic or hospital for perceived illness, specifically when the infant appears pale, blue, cold, or agitated or does not want to breastfeed.

METHODS

We then conducted a randomized, controlled cluster trial in Bangladesh, the country with the highest LBW incidence in the world,[16] where 95% of women deliver at home,[17] to test the effect of teaching community workers to teach CKMC on newborn and infant survival. BRAC implemented the intervention and supervised the collection of birth weight data (a standard duty of the community-based nutrition workers). Bangladesh has a population of 140 000 000 administratively divided into 6 divisions that, combined, contain 64 districts and 496 subdistricts called upazilas, each of which has a capitol city. Each study subdistrict contains 8 to 14 unions, and each union contains 5 to 25 villages. The sample includes the 42 unions that participated in the NNP, all that are supervised by our study partner BRAC in the Dhaka and Sylhet divisions. Dhaka and Sylhet divisions are located in northern Bangladesh, where NMR was 5.2% and 8.2% and IMR was 11.5% and 16.2%, the highest in the nation, when the study was designed.[17] Stratified by union population size and distance to the subdistrict capitol, half of the unions were randomly assigned to receive CKMC and half not. CKMC is a behavioral intervention. To prevent contamination between study groups, only 1 village was randomly selected proportionate to population size (eg, if a village comprised 17% of the union population, then it would have a 17% chance of being included) from each union. This allocation method thus increases the chance of including larger villages. On the basis of $\alpha = .05$ and $1 - \beta = 80\%$, an estimated NMR of 7.25%, and augmenting the sample by 10% and 25% to compensate design effect and for estimated 1- and 12-month loss to follow-up, respectively, a sample of 2000 deliveries per study group was required to test the 1-tailed hypothesis that CKMC would reduce NMR by 27.5% and IMR by 25%.[18] Although birth weight is not normally universally measured, the trial also assessed the effect on birth weight–specific NMR. The sample of 4000 live births is sufficient to test a 30% NMR reduction in LBW (≤2500 g) infants, assuming a 35% incidence of LBW and an 85% NMR concentration in LBW infants given $\alpha = .05$ and $1 - \beta = 80\%$ and a 1-tailed test.

An independent research organization, Mitra and Associates, conducted a baseline survey of all households in the sample villages to identify eligible women (aged 12–50 years) and obtain their demographic and reproductive health information. Thereafter, consenting women who were identified to be pregnant through quarterly household surveillance were enrolled during 15 months. Consent was obtained at baseline or, for girls living in the surveyed households who became 12 years old during the enrollment period, at quarterly pregnancy identification. As is the norm in Bangladesh, all pregnant participants were married. Study participants received no remuneration for participation. Newborns were followed by Mitra and Associates at 30 to 45 days and infants were followed quarterly through their first birthday to record vital events, reported morbidity, nutritional status, breastfeeding, STS, sleeping contact, contact with the community-based workers and others, and health care use. Infants who were <365 days of age at their fourth follow-up were visited again to follow them through their first birthday. When interviewing in each village, Mitra and Associates measured newborn weight on the subsample of infants who were <8 days old by using uniscales that weighed to the nearest 100 g. Mitra and Associates attempted to obtain NNP or hospital discharge birth weight information when unavailable from BRAC.

At the completion of the baseline survey, a physician who had participated in the pilot study trained 12 BRAC supervisors and, along with 1 supervisor, trained all 63 community nutrition workers and their 25 NNP supervisors serving the intervention group in 5 groups of 6 to 22 people during a 2-month period. Once trained, the community workers (alone or with the supervisors) taught CKMC to expectant mothers and their families in the intervention group villages. All community nutrition workers serving both the intervention and control group villages were responsible for obtaining birth weight using Salter scales that weighed to the nearest 100 g, 1 of their normal duties under NNP. They were standardized monthly in measurement of birth weight separately by study group to avoid contamination. All participating community workers received $7.50 a month, approximately equivalent to their compensation for their normal half-time NNP duties, for attending the monthly standardization sessions and collecting newborn weight within 72 hours of birth. To avoid implementation bias, no additional compensation for teaching CKMC was provided to the nutrition workers. During the study, BRAC monitoring found that the nutrition workers had substantially more duties under NNP than they had under BINP. To meet their originally planned availability and contribution as close to that planned as possible for the remainder of the study, 35 other part-time BRAC community workers with similar qualifications were trained and employed for the last 6 months of the study and paid $7.50 per month to supplement the community nutrition workers in the intervention villages. To partially compensate for their earlier substitution, 2 experienced trainers who participated in the pilot study and were originally intended to conduct the community workers' CKMC training were then also temporarily integrated into the study (1 on a full-time and 1 on a part-time basis for ~4 months) to train the 35 new community workers and lead monthly CKMC refresher training sessions. Variable levels of implementation over time are common in studies of behavioral and rolled-out interventions, as is the case in studies that test dynamic interventions.[19] As did this trial, such studies measure the effectiveness of teaching CKMC, a behavioral intervention, as actually implemented rather than efficacy (ie, effect under ideal conditions).[20]

NMR was reviewed monthly by the principal investigator off-site (in New York) to permit disbanding the study early should intention-to-treat analysis indicate significant reduction of neonatal mortality while masking local knowledge of effect to prevent potential modification of study activities. Data were directly recorded on handheld computers and reviewed for inconsistencies to prompt their resolution before departure from the household. This facilitated monthly data transfer. Intention-to-treat analyses (according to the groups to which the participants' villages and thus the participants were assigned) are presented. Intention-to-treat analyses include all CKMC infants regardless of whether they received the intervention. χ^2 and Student's *t* tests were used to test differences in categorical and continuous variables between the CKMC and comparison groups. Logistic regression models were used for the analysis of mortality. Besides study group, terms were included for stratification variables (population size and distance to the subdistrict capitol) and generalized estimating equations (GEE) with robust variance estimation in adjusted analyses to account for design effect as a result of stratification and clustered allocation.[21] In addition, GEE robust variance logistic regression analyses directly controlling for design effect and study group characteristics (twins, gender, congenital anomalies, and sociodemographic and reproductive health characteristics such as religion, parity, and skilled delivery attendance) were also conducted, replacing missing covariate with sample mean values. GEE robust variance analyses that were adjusted solely for design effect produced the most conservative estimates of effect and significance. No additional adjustment was made for interim review of NMR because no overall NMR difference was observed. There was no interim analysis of birth weight–specific NMR until the data safety and monitoring board (DSMB) meeting 1 month before cessation of enrollment.

The study was approved by the institutional review board of the Population Council, Tufts University Medical Center, Columbia University Medical Center, and the Bangladesh Medical Research Council. The DSMB included a biostatistician, a political scientist, a neonatologist, and a health policy planner.

RESULTS

Baseline Mortality

Of the 39888 age-eligible women (12–50 years of age) who lived in the nearly 25 000 homes in the study villages at the time of the baseline survey, 35 (0.1%) refused participation in the baseline survey and 6 refused interview at follow-up (Fig 1). The stratified allocation of unions resulted in some geographic imbalance between the study groups. Of the 8 study villages in Sylhet division (contributing to 11% of the total sample), only 2 were randomly allocated to the intervention group and the remaining 6 to the control group. Although the sample villages in Dhaka division are similar to each other, they are somewhat sociodemographically

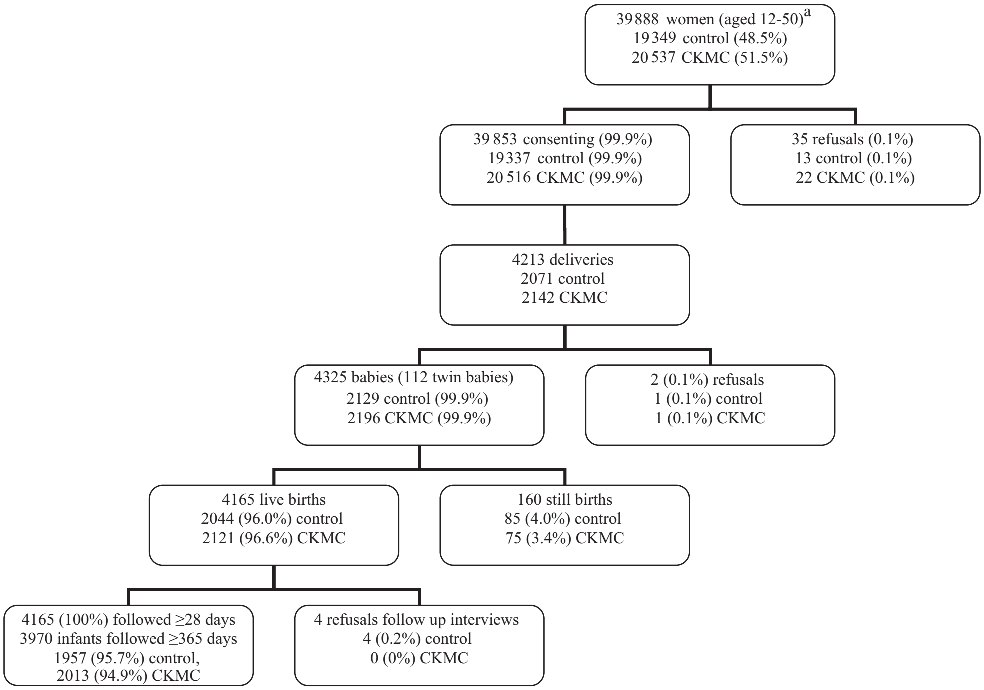

FIGURE 1

Consolidated Standards of Reporting Trials (CONSORT) diagram. [a]Excludes deliveries <14 days after CKMC training was completed in each of 5 CKMC/birth weight standardization training group areas.

distinct from those in Sylhet division, where villages are generally smaller, the population is less literate, and slightly more Hindus live. This imbalance is reflected in small differences in previous NMR. The baseline survey found that NMR and IMR in the previous 2 years were 5.9% and 7.1%, respectively, lower than expected, and was somewhat (not statistically) lower in the comparison than in the intervention group (NMR: CKMC 6.1% vs control 5.6% [$P = .68$]; IMR: CKMC 7.5% vs control 6.5% [$P = .09$]). The incidence of stillbirth in the previous 2 years was 2.8% overall and in the intervention group and 2.9% in the control group ($P = .65$).

Study Group Comparability

For consenting women, 4213 births of 4325 infants (112 were twin births) were prospectively encountered, 4165 of which were live births and 160 (3.7%) of which were reported as stillbirths (Fig 1). The baseline geographic imbalance in study group allocation led to small differences in sociodemographic and reproductive health indices between the study groups, many statistically significant as a result of the large sample (Tables 1 and 2). For example, 32.0% of women in the control group were assisted by skilled attendants at delivery compared with 36.6% of women in the CKMC group, a difference of only 4.6% but highly significant ($P = .002$). The largest differences were observed for religion (86.1% control vs 95.8% CKMC were Muslim; $P < .001$), attendance at school (66.5% control vs 73.1% CKMC; $P < .001$), and speaking another language (7.3% control vs 0.5% CKMC spoke Sylheti, a dialect spoken in addition to Bengali in the Sylhet division; $P < .001$).

Birth Weight

Weight was measured in live-born infants within 7 days of birth for 59.0% of CKMC and 54.2% of control group infants ($P = .002$). Newborn weight was significantly less available for infants who were born outside their own home (missing weight: 68.6% born away from home vs 25.4% born in own home; $P < .001$). A high incidence of missing birth weight for those who died is expected because it is culturally unacceptable in rural Bangladesh to measure infants who are born at home after death, and 55.7% of neonatal mortality occurred on the first day of life. Weight was measured on the day of birth for 23.8% of CKMC and 18.5% of control infants ($P < .001$). For those who died on the day of birth, birth weight was missing for more control (82.2% of 45 infants) than CKMC (76.0% of 50 infants; $P = .46$) infants. For infants who died in the neonatal period, weight was measured within 7 days of birth for 33.0% of CKMC infants compared with 38.6% of control infants ($P = .42$). Weight measured within 7 days of birth was modeled by using internal data to adjust for initial weight loss and subsequent weight gain typical after birth and consistent with the significant cubic association of weight and age at measurement found in this study.[22] This was calculated as the difference in average weight for infants whose weight was measured on the day of birth and those whose weight was measured at a subsequent age. The modeled weight change was minimal: 1.5%, 2%, 3%, and 1.5% loss at the respective ages of 2, 3, 4, and 5 days of life and 1% and 2% gain at age 6 and 7 days of life. This is consistent with the observations from developed and developing countries that

TABLE 1 Demographic, Maternal, and Household Characteristics According to Study Group

Characteristic	Control		CKMC		*P*
	n	% or Mean ± SD	*n*	% or Mean ± SD	
Division, district, subdistrict (upazila)	2003		2080		<.001
Sylhet, Moulvibazar, Rajnagar		18.17		4.28	
Dhaka, Narsingdi, Manohardi		8.09		27.79	
Dhaka, Narsingdi, Narsingdi Sadr		56.27		60.43	
Dhaka, Narsingdi, Shibpur		17.47		7.50	
Kilometers to upazila capitol	2003	11.06 ± 6.93	2080	11.54 ± 8.82	.540
Ever attended school	1995	66.47	2072	73.07	<.001
Illiterate (cannot read)	1995	45.01	2072	39.82	.089
Husband's occupation	1846		1889		
Agricultural worker		27.25		22.02	<.001
Professional		5.04		7.04	.010
Other[a]		67.71		70.94	.033
Own occupation housewife	1995	84.56	2073	84.42	.900
Receive wages/income	1995	7.82	2074	6.36	.070
Sylheti spoken	1995	7.32	2073	0.53	<.001
Religion	1995		2074		<.001
Islam		86.07		95.81	
Hindu		13.93		4.19	
Woman's age, y	2002	23.16 ± 5.91	2080	23.08 ± 5.96	.680
Gravidity	1995	2.00 ± 1.96	2074	1.86 ± 1.89	.017
Nulliparous	1994	27.33	2073	29.72	.092
Parity ≥5	1994	8.88	2073	8.10	.380
No. usually in household	1995	5.87 ± 2.85	2074	5.60 ± 2.63	.001
Has children <5 y of age	1995	66.82	2074	62.63	.001
Past neonatal loss	1419	18.04	1435	18.95	.530
Home birth (own or others)	1897	87.14	1959	85.76	.210
Institutional delivery	1893	12.47	1953	13.93	.180
Skilled birth attendant	1893	31.96	1953	36.61	<.002

Includes 1 response per eligible woman (regardless of multiple gestation or subsequent pregnancies).

[a] Includes numerous other occupations that were not different between the study groups (landlord ~1.5%, retired ~0%, nonagricultural worker 53% in both groups), etc.

TABLE 2 Neonatal Characteristics

Characteristic	Control		CKMC		*P*
	n	% or Mean ± SD	*n*	% or Mean ± SD	
Infant's age at newborn assessment, d	2010	51.36 ± 36.64	2060	57.32 ± 36.36	.970
Twins	2129	2.72	2196	2.46	.580
Infant's gender (male)	2129	48.33	2196	50.45	.006
Congenital abnormality	2012		2056		.410
Major		0.25		0.15	
Minor		2.78		2.24	
Stillbirth	2129	3.99	2196	3.42	.320
Birth weight measured (measured/live-born infants)	1107/2044	54.48	1252/2121	59.14	.003
Modeled birth weight, g	1107	2701 ± 453	1252	2690 ± 468	.570
Modeled birth weight ≤ 2500 g	1107	30.08	1252	32.59	.190
Modeled birth weight ≤ 2000 g	1107	6.41	1252	7.59	.270
Modeled birth weight ≤ 1500 g	1107	1.99	1252	1.44	.300
Measured birth weight within 7 d of birth ≤2000 g	1107	8.40	1252	10.38	.101
Gestation (days since LMP)	1895	285 ± 22	1974	285 ± 21	.350
Gestation < 37 wk	1895	12.08	1974	11.35	.480
Gestation < 35 wk	1895	6.33	1974	6.43	.900
Gestation < 33 wk	1895	3.64	1974	3.70	.930
Maternal death (cases)[a]	2003	(3)	2080	(1)	.300

LMP indicates last menstrual period.

[a] Includes 1 response per eligible woman (regardless of multiple gestation or subsequent pregnancies).

LBW, preterm, and breastfed infants lose a much smaller portion or none of their birth weight in the early postnatal period than term infants and those who are not breastfed.[4,23–26] Modeled weight is presented unless stated otherwise. Analysis of weight as measured during the first 7 days of life is also presented where specified.

TABLE 3 CKMC Behaviors

Characteristic	Control		CKMC		*P*
	n	% or Mean ± SD	*n*	% or Mean ± SD	
Ever STS	1927	0.50	2022	77.40	<.001
STS ≥4 h in first 2 d of life	1927	0.10	1985	47.86	<.001
STS within 12 h of birth	1927	0.26	1964	60.85	<.001
STS within 24 h of birth	1927	0.31	1964	66.08	<.001
Average daily hours of STS in first 2 d of life	1927		1985		<.001
0		99.58		29.22	
≤1		0.10		7.98	
1 to ≤7		0.26		39.04	
>7		0.05		23.78	
Breastfed	2042	99.90	2121	100.00	.240[a]
Still breastfeeding at neonatal visit	1920	94.90	1982	94.95	.930
Breastfed within 1 h of birth	1891	41.41	1948	52.39	<.001
Breastfed immediately after birth	1891	3.44	1948	6.06	<.001
Hours after birth first breastfed	1891	8.41 ± 15.13	1948	5.08 ± 11.17	<.001
Consumed something other than breast milk	1927	95.69	1985	89.77	<.001
Bathed on date of birth	1924	72.25	1984	29.28	<.001
Age first bathed, d	1885	2.01 ± 2.41	1985	5.68 ± 5.93	<.001
Slept with infant in first 2 d of life	1921	0.10	1977	38.44	<.001
Took infant to clinic/hospital for well-care check-up in neonatal period	1915	1.10	1969	1.27	.610
Took infant to clinic/hospital for perceived newborn illness	1913	7.74	1970	8.12	.660
Took infant to clinic/hospital for well-care check-up in infancy	2032	1.48	2102	1.90	.290
Took infant to clinic/hospital for perceived infant illness	2032	26.48	2102	25.36	.410

[a] Fisher's exact test where cell $n < 5$.

Too few data were available to estimate birth weight reliably from "birth weight" measurements beyond 7 days of age; however, for those who had missing birth weight, we also estimated their weight at birth as equivalent to their average gender-specific weight-for-age percentile on the basis of the World Health Organization international standards.[27]

CKMC Behaviors

More than three quarters (77.4%; $n = 1565$) of women who delivered in the CKMC group reported giving STS ever compared with 0.50% ($n = 10$) women in the control group ($P < .001$; Table 3). Sixty-one percent of infants in the intervention group received STS within 12 hours of birth; however, only 23.8% received STS >7 hours per day in the first 2 days of life, the most critical period. Including those who never received STS, the average daily hours of STS in the CKMC group was 4.5 ± 4.8 hours in the first 2 days of life, 2.7 ± 3.4 hours in the next 5 days of life, 1.2 ± 2.4 hours in the second week of life, and 0.5 ± 1.4 hours in the remainder of the first month of life. In the CKMC group, 85.9% of women who delivered in their own home gave STS compared with 59.9% who delivered elsewhere ($P \leq .001$). In the CKMC group, the daily duration of STS generally rose since the inception of the study, although fewer mothers provided STS in the seasonally hottest months in June and July. The strongest predictor of STS was contact with the community nutrition worker in the last month of pregnancy; 87.2% of these women reported STS, yet 78.3% of women who reported no contact with the worker in the last month of pregnancy or first month postpartum and reported providing STS had received the CKMC message reminder leaflet. In a subsample of 36 CKMC mothers who provided qualitative interviews, one third reported teaching CKMC to others.

As is customary in rural Bangladesh, virtually all mothers breastfed their infants and gave complementary liquids in the first few days of life. Only 2 live-born infants in the control group were not breastfed. Women in the CKMC group began breastfeeding 3.4 hours sooner after birth ($P < .001$). Few breastfed immediately after birth (6.1% in the CKMC and 3.4% in the control group), and 52.4% of CKMC mothers breastfed within 1 hour of birth compared with 41.4% in the control group (both $P < .001$). Only 29.3% of CKMC infants were bathed by immersion in water on their day of birth compared with 72.3% in the control group ($P < .001$). Although only 38.4% of CKMC mothers slept with their infants, this practice was virtually absent in the control group. As is customary in the study location, only 1% of mothers in both the CKMC and control groups took their newborns to a health care clinic or hospital for well-infant checkups ($P = .62$), and nearly 8% in each group took their newborns for any illness ($P = .66$). Only 1.5% of control and 1.9% CKMC infants were taken to a health care facility for a well-infant checkup in their first year of life ($P = .29$), whereas 26.5% of control and 25.4% of CKMC infants ($P = .41$) had been

TABLE 4 Odds of Neonatal and Infant Mortality Comparing Intervention With Control Group

Parameter	Unadjusted			Adjusted for Design Effect			Adjusted for Covariates[a]		
	OR	95% CI	*P*	OR	95% CI	*P*	OR	95% CI	*P*
Newborn mortality									
NMR (*n* = 4165)	1.065	0.793–1.431	.680	1.060	0.761–1.477	.730	NA[b]	NA	NA
NMR in infants modeled ≤ 2500 g (*n* = 741)	0.892	0.478–1.665	.720	0.869	0.434–1.738	.690	NA	NA	NA
NMR in infants modeled ≤ 2000 g (*n* = 166)	0.360	0.148–0.873	.024	0.371	0.161–0.855	.020	0.325[c]	0.126–0.839	.020[c]
NMR in infants modeled > 2000 g (*n* = 2193)	1.147	0.615–2.138	.670	1.127[d]	0.480–2.652	.690	NA	NA	NA
NMR in infants missing birth weight (*n* = 1806)	1.322	0.910–1.920	.140	1.307	0.938–1.823	.110	NA	NA	NA
Infant mortality									
IMR (*n* = 3970)	1.043	0.813–1.337	.740	1.039	0.770–1.401	.800	NA	NA	NA
IMR in infants modeled ≤ 2500 g (*n* = 714)	1.088	0.650–1.820	.750	1.114	0.648–1.915	.700	NA	NA	NA
IMR in infants modeled ≤ 2000 g (*n* = 158)	0.577	0.270–1.232	.155	0.562	0.301–1.050	.071	NA	NA	NA[c]
IMR in infants modeled > 2000 g (*n* = 2112)	0.997	0.630–1.578	.990	0.992[d]	0.557–1.765	.980	NA	NA	NA
IMR in infants missing birth weight (*n* = 1700)	1.239	0.891–1.723	.980	1.239	0.932–1.648	.140	NA	NA	NA

NA indicates not available.

[a] Covariates entered in the model were literacy; husband engaged as an agricultural worker, farmer, or professional or had no occupation; infant's mother's age and whether she worked outside the home and whether she was nulliparous; number of people and of children younger than 5 years in the household; whether Sylheti was spoken by household members; religion; whether the delivery occurred in a health care facility and whether it was attended by a skilled birth attendant; multiple gestation; infant's gender; whether the infant had a major or minor congenital abnormality; and whether there had been a previous neonatal (for NMR) or infant (for IMR) death.

[b] NA term for study group dropped out of equation, $P < .10$.

[c] Three observations dropped by Stata because of estimability.

[d] A total of 115 observations dropped because of collinearity of NMR and small villages (no cases in small villages).

taken to a health care facility for an illness during their first year of life.

Morbidity and Growth

There was no difference in the infants' weight, head or arm circumference, or reported morbidity at the 30- to 45-day follow-up, except that fewer CKMC than control newborns were reported to have become pale (0.4% vs 1.1%; *P* = .018). More CKMC (43.6%) than control (39.3%) infants were reported to experience diarrhea in their first year of life (*P* = .006).

Newborn Mortality

NMR was nearly the same in the CKMC (4.57%) and control groups (4.31%) in unadjusted (*P* = .68) and adjusted (*P* = .73) analyses (Table 4). NMR was unexpectedly greater in the CKMC than control group in those who were delivered institutionally (NMR odds ratio [OR]: 2.04 [95% confidence interval (CI): 0.98–4.22]; *P* = .055). Although overall NMR was virtually the same, nearly 3 times as many women in the CKMC than control group whose infants died in the newborn period sought care from and delivered in health care facilities (OR: 2.8 [95% CI: 1.15–6.61]; *P* = 025). For those who weighed (modeled weight) ≤2500 g at birth, NMR was 5.4% in the CKMC group compared with 6.0% in the control group (design-adjusted *P* = .69). For those whose modeled weight (adjusted for age at measurement) was ≤ 2000 g at birth, the usual eligibility criteria for hospital-based KMC, NMR was 9.5% in the CKMC group, 64% lower than in the control group 22.5% (adjusted for cluster design effect OR: 0.371 [95% CI: 0.16–0.86]; *P* = .020). These results were identical when missing birth weight was estimated by assigning the gender-specific average percentile weight-for-age from subsequent newborn and infant measurements, because the international standards first percentile at birth is >2 kg for both boys and girls.[27] A cluster design effect adjusted interaction, a more robust statistical measurement of effect, was marginally significant (*P* = .055). The strength and significance of the association increased in analyses that were adjusted for twins, gender, and congenital anomalies in addition to cluster design (OR: 0.316 [95% CI: 0.15–0.66]; *P* = .002). To control directly for potential differences between study group characteristics, we also conducted robust variance GEE backward stepwise logistic regression analyses adjusting for literacy; husband engaged as an agricultural worker, farmer, or professional or had no occupation; infant's mother's age and whether she worked outside the home and whether she was nulliparous; number of people and of children younger than 5 years in the household; whether Sylheti was spoken by household members; religion; whether the delivery occurred in a health care facility and whether it was attended by a skilled birth attendant; multiple gestation; infant's gender; whether the infant had a major or minor congenital abnormality; and whether there had been a previous neonatal (for NMR) or infant (for IMR) death. The sole variables retained as significant in this analysis of NMR were number of children younger than 5 years in the household (OR: 1.69 [95% CI: 1.04–2.73]; *P* = .033), multiple gestation (OR: 4.00 [95% CI: 1.40–11.41]; *P* = .010), institutional delivery (OR: 5.02 [95% CI: 1.58–15.93]; *P* = .006). and CKMC intervention (OR: 0.325; [95% CI: 0.13–0.84]; *P* = .02). Skilled attendance at birth was correlated with whether the birth occurred in a health care facility (0.54; *P* = .001), and although skilled attendance was not correlated with NMR (Pearson product moment correlation = 0.016; *P* = .33), there was a significant positive association between institutional delivery and NMR (Pearson product moment correlation = 0.823; *P* ≤ .001). For those for whom newborn weight was ≤2000 g as measured on the day of

TABLE 5 Age at Death by Study Group and Birth Weight

Parameter	n (Cases)	Control, %	n (Cases)	CKMC, %	P
All newborns	2044	NMR	2121	NMR	
Deaths in first 2 d of life	(54)	2.6	(59)	2.8	.7800
Deaths in days 3 to 7 of life	(19)	0.9	(21)	1.0	.8400
Deaths in days 8 to 28 of life	(15)	0.7	(17)	0.8	.8000
Infant deaths after 28 d of life	(41)	2.0	(41)	1.9	.8700
Newborns weighing ≤2000 g at birth	71		95		
Deaths in first 2 d of life	(5)	7.0	(7)	7.4	.9400
Deaths in days 3 to 7 of life	(6)	8.5	(1)	1.1	.0430[a]
Deaths in days 8 to 28 of life	(5)	7.0	(1)	1.1	.0850[a]
Infant deaths after 28 d of life	(3)	4.2	(7)	7.4	.5190[a]

[a] Fisher's exact test where ≥ cell $n < 5$.

birth (n = 86), NMR was 23.7% in the control group compared with 12.5% in the CKMC group (OR: 0.494 [95% CI: 0.159–1.540]; P = .224). The results were similar (OR: 0.436 [95% CI: 0.19–1.00]; P = .05) in analyses that adjusted for design effect for those whose measured weight was ≤2000 g in the first 7 days of life (n = 223). Most of the difference in NMR for newborns whose weight was ≤2000 g occurred after the first 2 days of life (Table 5). Although data on gestation were more complete than birth weight, gestation was mostly reported in months rather than weeks, and estimates of prematurity are poor. Still, NMR for infants estimated as <37 weeks was also lower, although not statistically so, in the CKMC than in the control group (OR: 0.650 [95% CI: 0.287–1.473]; P = .30). NMR was slightly higher (OR: 1.128 [95% CI: 0.48–2.65]; P = .78), although not significantly so, for intervention than in control group infants who weighed >2000 g at birth and for those with missing birth weight (OR: 1.307 [95% CI: 0.94–1.82]; P = .11). The minimal effect of CKMC on NMR may be estimated by assuming that all newborns who died with missing birth weight weighed ≤2000 g, reducing the OR to 0.675 (95% CI: 0.40–1.13; P = .14, not statistically significant). In the intervention group, NMR was concentrated (58.3%) in those who did not receive STS in the first 2 days of life. In review of the distribution of deaths by daily hours of STS, only 5 (5.2%) of the 97 CKMC newborn deaths occurred in those who received STS >7 hours per day (Table 6). Only 17.4% of newborns who died on the day of birth were held STS compared with 73.3% of those who survived beyond that (P < .001). The dose-response between STS and NMR was smaller but still strong even when infants who died on their day of birth were removed from the analysis (Table 6). There was no interaction of study group and intervention period (ie, before and after taking action to correct training and implementation). Adjustment for intervention period made virtually no difference on NMR ORs (data not shown).

TABLE 6 NMR by Frequency of STS Care in the First 2 Days of Life in the Intervention Group

STS in the First 2 d of Life	NMR of All Newborns (n = 1985), %	NMR of Newborns Who Did Not Die on Their Day of Birth (n = 1939), %
0 h	9.3 (n = 580)	3.0 (n = 542)
>0, ≤1 h/d	5.1 (n = 158)	3.2 (n = 155)
>1, ≤7 h/d	2.5 (n = 775)	1.8 (n = 770)
>7 h/d	1.1 (n = 472)	1.1 (n = 472)

P ≤ .001.

Infant Mortality

IMR was nearly the same in the CKMC (6.86%) and control groups (6.59%) in unadjusted (P = .74) and adjusted (P = .80) analyses (Table 4). Nether skilled attendance at birth nor institutional birth was correlated with IMR; however, the excess CKMC NMR in institutional deliveries was greatly reduced over infancy to insignificant levels for IMR (OR: 1.38 [95% CI: 0.82–2.30]; P = .23). Similarly, the effect of CKMC on IMR for infants who weighed ≤2000 g (modeled) at birth also declined from that observed for NMR (OR: 0.562 [95% CI: 0.30–1.05]; P = .07). The interaction of CKMC and birth weight of ≤2000 g was not statistically significant (P = .19). Adjustment for covariates removed all terms except multiple gestation (OR: 3.58; [95% CI: 1.52–8.45]; P = .004). Assuming that all those who died in infancy and did not have a birth weight measurement weighed ≤2000 g at birth produces a statistically insignificant 26% lower NMR in the CKMC than control group (OR: 0.741[95% CI: 0.44–1.25]; P = .26). More deaths occurred after 28 days in CKMC than control infants who weighed ≤2000 g at birth (Table 5).

Maternal Outcome

As expected, few (7.1% of CKMC and 7.2% of control group) mothers experienced subsequent pregnancy within 1 year of the first study-enrolled pregnancy (OR: 0.97 [95% CI: 0.76–1.23]; P = .80). Slightly more CKMC mothers reported using contraceptives within that period (54.2% CKMC vs 50.0% control; P = .009). Excluding women who used contraception in that time, 4.5% of CKMC and 3.3% of control group mothers experienced subsequent pregnancy within 1 year of the first study-enrolled pregnancy (OR: 1.31 [95% CI: 0.79–2.17]; P = .29).

There were fewer maternal deaths in the CKMC (n = 1) than control (n = 3) group (Fisher's exact P = .37). Unexpected, there was also slightly but significantly less postpartum bleeding reported in CKMC (73.3%) than control births (76.8%; P = .01).

DISCUSSION

Sample

The study groups were very comparable on the individual characteristics, with small differences in characteristics that were statistically significant as a result of the large sample size. The slight geographic imbalance might have been avoided by stratification by subdistrict rather than distance to the subdistrict capitol or using the more complex minimization method of randomization. Adjustment for cluster design effect that mitigates the influence of the study group geographic imbalance produced slightly more conservative effect and significance than no adjustment. Additional adjustment for twins, gender, and congenital anomalies showed larger effect and significance than unadjusted analyses or analyses that were adjusted solely for design effect. Direct adjustment for study group characteristics rendered virtually identical results to those adjusted for cluster design effect. Although skilled attendance at delivery was not associated with outcome, institutional delivery was associated with higher mortality. The slightly higher overall mortality rates in the CKMC group reflects differences in baseline NMR (CKMC 6.1% vs control 5.6%; $P = .68$) and IMR (CKMC 7.5% vs control 6.5%; $P = .09$). There was virtually no relative difference between study groups in NMR change since baseline, but there was a greater reduction in IMR change since baseline (13% CKMC relative reduction compared with a 3% control relative reduction; $P \leq .001$).

Training and Adherence

There was virtually no contamination between study groups; 10 women reported STS in the control group. With the exception of care seeking, incidence of CKMC behaviors was significantly greater in the intervention than control group; however, CKMC implementation fell far short (24%) of that observed in the pilot study, in which 69% of women provided STS >7 hours per day in the first 2 days of life[15] and in which postpartum women still provide CKMC 4 years later. Although women rarely provide round-the-clock STS care, the daily frequency of STS was considerably less than expected.[28] Provision of any STS also was sharply discontinued with few women continuing STS beyond 2 weeks. The training and intervention delivery processes that were used in the pilot study were only partially transferred to the full trial, with unplanned substitution of experienced trainers with individuals who were not trainers, less frequent contact between community workers and mothers in the last month of pregnancy, and unplanned emphasis on CKMC for LBW infants. The nested qualitative study found that >35% of CKMC women were erroneously taught that STS was to be provided to LBW or preterm infants rather than to all infants, and only 30% were correctly taught to hold all infants STS. Less than 40% of CKMC mothers were taught to provide CKMC to infants who were ill, and >25% were erroneously taught to breastfeed on schedule (not on demand). Women had numerous views about the number of hours and days they should provide STS, indicating that they received variable and frequently incorrect messages from the community workers and supervisors. Field visits confirmed that some of those who were employed to conduct the CKMC training believed that CKMC was intended for small infants. Thus, some intervention group mothers may not have provided CKMC because they were mistakenly taught that CKMC is for small infants. CKMC implementation and effect depend on both the quality of CKMC training and the mother's behavior modification, making it difficult to know whether the intervention does not have effect in larger, more mature infants or whether the uptake was suboptimal as a result of insufficient training or poor maternal adherence. Cultural factors are unlikely to explain poor adherence, because adherence was substantially greater in the pilot study with unmodified CKMC training procedures. Average birth weight in the study was 2693 g, and the correlation between perceived size at birth and birth weight was $r = 0.33$, so many small infants may have been considered average in size. CKMC was designed to be implemented by all mothers, rather than mothers of LBW infants, because weight on the day of birth is rarely measured where the incidence of home births and NMR is high and because STS improves breastfeeding behaviors, particularly prompt initiation and theoretically provision of colostrum and avoidance of complementary feeding. Early breastfeeding facilitates the establishment and duration of lactation,[29] critical to infant survival in developing countries.[30,31] The proportion of infants who received STS was similar for those who were born at health care facilities and those who were born in other people's homes; therefore, it is unlikely that the inclusion of the word "community-based" influenced KMC implementation. Rather, it is more likely that primiparous women, who often deliver their first child at relatives' homes in the Indian subcontinent, and those who delivered in health care facilities received less frequent family or clinician support for KMC because relatives and clinicians were unfamiliar with the method. The training guidelines have been expanded to precisely specify CKMC training and to render it less susceptible to modification that diminishes implementation and potentially effect. As suggested by the women in the CKMC group, the guidelines now include instructions to teach other family members and local clinicians.

Potential Bias

NMR may have been underreported, because, contrary to expectation, the stillbirth rate in both groups was greater (although not differentially so) than that reported in the baseline survey. Newborn vital status was assessed at 30 to 45 days after delivery in the trial compared with the baseline survey, which assessed status between 2 and 26 months after delivery. Some respondents may have found it emotionally easier to report an immediate newborn death as a stillbirth when recollection was closer to the time of the loss. Such misclassification would reduce the number of newborn deaths and individuals included in analysis of NMR. With a slightly lower perinatal mortality rate in the CKMC (7.0%) than the control (7.3%) group, this misclassification would tend to reduce the observed associations and statistical significance.

The observed lower NMR in very small infants but absence of effect on overall NMR or IMR may reflect a concentration of CKMC benefit for those who are most likely to be premature, unplanned local emphasis of CKMC for small infants, and/or a higher rate of obstetric complications in the CKMC group. Large impact in a subgroup with no overall impact raises concerns regarding program effect and cost. Although there was no effect on overall NMR, the lower NMR for newborns who were delivered at home and for infants who weighed ≤2500 g (modeled) is clinically important, although the sample did not have adequate power to test these associations. The protective effect on neonatal mortality for infants who weighed ≤ 2000 g (modeled) at birth was large and significant in unadjusted and adjusted analyses but was only marginally significant for infant mortality. Infants who died were less likely to have weight measurement, so deaths are underrepresented in the birth weight–specific analyses, rendering these analyses unrepresentative.

The difference in availability of birth weight data between the study groups may well affect the magnitude of the results. The greater availability of weight for CKMC than control infants in general and on the day of birth and the larger proportion of CKMC infants who weighed ≤2000 g would likely underestimate the NMR effect, whereas the greater availability of weight for control than CKMC infants who died in the newborn period would likely overestimate the effect. We cannot know how many infants whose birth weight was not measured actually weighed ≤2000 g at birth and how many of those died or survived. Similarity of effect for infants who weighed ≤2000 g as measured on the day of birth and in the first 7 days of life and modeled birth weight provides some confirmation. Imputation (modeling) of birth weight may result in some misclassification; however, this would apply to both control and CKMC groups, and misclassification would tend to attenuate and thus underestimate effect. Although the threshold of ≤2000 g was not determined a priori, it is the usual criteria for traditional KMC programs. Still, analyses estimating the minimal effect, which assumed that all infants who died and did not have birth weight were ≤2000 g, reduced the association by almost half, from a significant 63% lower NMR to an insignificant but still large 33% lower NMR and from a marginally significant 44% IMR to an insignificant but still considerable 26% IMR. The interaction of birth weight and CKMC was only marginally significant for NMR and insignificant for IMR and thus not confirmatory.

Dose-Response and Reverse Causality

The nested qualitative study found that 37% of CKMC group mothers whose newborns died did not provide STS care because the infant died too soon after birth (reverse causality), and that certainly contributed to less than the desired frequency and duration of STS.[29,32] Death soon after birth also accounted for 16% of CKMC group mothers whose newborns died providing ≤7 hours of STS care in the first 2 days of life. Similarly, neonatal illness shortly after birth and postpartum maternal illness or weakness deterred from 30% to 50% of mothers who had provided little or no STS from providing STS. Mothers who provided CKMC to sick infants may also have stopped CKMC when their infants became better, theoretically resulting in relapse. Although illness before death clearly accounts for some of the dose-response observed between STS and survival (Table 6), exclusion of infants who died on their day of birth (ie, those least likely to receive STS because of newborn illness) demonstrates that, although reduced, the dose-response relation persists. Reverse causality (illness or death deterring STS) could still account for some of the observed dose-response. When all CKMC behaviors are entered (STS ever or in the first 2 days of life, bathed on day of birth, sleeping with the infant in the first 2 days of life, and when initiated breastfeeding rather than study group) using backward stepwise logistic regression, only STS demonstrated significant reduction of NMR in those who weighed ≤2000 g (OR: 0.774 [95% CI: 0.67–0.90]; $P = .001$) and demonstrated a marginally significant lower overall NMR (OR: 0.943 [95% CI: 0.88–1.01]; $P = .098$). Age when first bathed by immersion in water (instead of “bathed on birthday”) was significantly associated with lower NMR but is difficult to interpret because infants who were not bathed on their date of birth but did not survive their date of birth were excluded from the analysis because of missing age of bathing. Because death within 1 hour of birth is unlikely associated with KMC and those infants are unlikely to benefit from KMC, the study DSMB recommended the exclusion of first-hour deaths from future analogous studies.

Consistency of Results

The study results are consistent with 2 recently published African hospital-based studies. Lincetto et al[8] found an 86% reduction in 24-hour mortality associated with early hospital KMC in a small sample of infants who weighed ≤1800 g at birth. Worku and Kassie[9] found a 33% lower mortality through hospital discharge associated with early KMC; however, mean age at exit from the study and thus the period of observation was nearly 1 day greater in the control than KMC group. In these 2 studies, available newborn services were not well described, and important study-group differences were not controlled in analysis. Although the daily duration of STS in our study was less than desired, the association between STS and NMR is biologically plausible. Anderson et al[28] found the frequency of STS to be considerably less than that promoted. Still, Christensson et al[33] reported that 4 hours of early STS of otherwise stabilized hypothermic neonates with admission weights ≥1500 g sped recovery to normal body temperature; 90% of newborns who received early STS reached normal temperature compared with 60% of control subjects who were maintained in incubators in Zambia, a 50% effect ($P < .001$), similar to their observations with 76 to 85 minutes of immediate postnatal STS for term newborns, also in Zambia.[34] The results are somewhat inconsistent with what is known from a subsequent study of CKMC that included other essential newborn care interventions in India and reported a 50% overall lower NMR in its intervention groups but also reported a 33% lower stillbirth rate in the intervention groups that could represent differences in study group baseline mortality.[35] The magnitude of effect is consistent with the 41% lower IMR observed in the Colombia study of traditional KMC.[4]

Other Effects

Infants who were born in health facilities were 2.7 times less likely to have birth weight available ($P < .001$), and their NMR was twice as high for CKMC than control infants ($P = .055$), although the IMR difference in institutional deliveries was greatly diminished to 38% (not significant). Data on obstetric complications were obtained only in the case of maternal death or institutional delivery that resulted in a newborn death. In the small group of those who were born in health facilities and died in the newborn period, 85.7% of control group and 100% of CKMC group mothers reported having had pregnancy complications ($P = .093$); however, lay reports of obstetric complications where many are illiterate is probably inaccurate. Although there was little difference in the overall mortality, the excess CKMC institutional mortality is explained by the fact that nearly 3 times as many women in the CKMC (24.4%) than control (9.4; $P = .009$) group whose infants died in the newborn period sought care from and delivered in health care facilities. This may reflect better obstetric health-seeking behavior among CKMC mothers.

CKMC infants had a 19% relative significantly greater risk for reported diarrhea than control infants. Had general breastfeeding and supplementary food practices been better in the CKMC group, a lower risk for diarrhea would have been expected. Indeed, holding an unstabilized newborn STS in rural settings similar to this study could potentially increase maternal (or other caregiver)-to-child contamination and infection. Still, the absolute difference in the proportion of infants who were reported to have diarrhea was only 4.3% and may reflect that mothers who hold their infants STS observe and report more occurrences, particularly those that affect their body and cleanliness. Mothers of CKMC infants reported statistically, although only absolutely, 3.5% less postpartum bleeding than control mothers. Although few mothers in either group breastfed immediately, nearly 80% more did so in the CKMC group. Immediate postpartum breastfeeding stimulates production of maternal oxytocin that would inhibit postpartum bleeding. Finally, the use of handheld computers for data collection allowed immediate consistency checks, resulting in fewer than expected inconsistencies at preliminary analysis, and facilitated 100% correct longitudinal linkage of data that minimized attribution well beyond that expected (no cases at 28 days of life and ~5% at 1 year of life).

CONCLUSIONS

This is the first study to demonstrate impact of CKMC, an affordable, pragmatic intervention integrated into an existing community-based program delivered by its community workers, on newborn and infant survival. CKMC implementation fell short of expectation. Theoretically, CKMC should affect overall mortality because conditions such as hypothermia are common in both LBW and normal-weight infants[36] and early initiation of breastfeeding improves survival.[29] The sole effect observed was that for newborns who weighed ≤2000 g (modeled) at birth, a strong, statistically significant, biologically and temporally plausible lower neonatal mortality that is consistent with results from 2 African studies of early ("birth") KMC conducted in hospitals with limited neonatal intensive care capacity was observed; however, the extensive missing birth weight information, that deaths were underrepresented in the birth weight–specific analyses making these analyses unrepresentative, and the differential availability of birth weight in the CKMC and control groups rendered the existing evidence of benefit insufficient to justify implementation of CKMC at this point in time. This conclusion takes into account the results of the 2 randomized trials of birth KMC, the Colombia study (in hospital-born stabilized newborns) and what is known from a subsequent study of CKMC, including other essential newborn care interventions in India.[35] Estimating missing birth weight by statistical modeling of subsequent infant weight-for-age did not help to clarify the results because the first percentile of international standards is > 2000 g and because most infants who died in the newborn period and did not have a birth weight measure did not survive to have subsequent weight measurements. Assuming that all those who died and did not have birth weight measured weighed ≤2000 g at birth greatly reduced the magnitude of effect and rendered it statistically insignificant.

We identified implementation problems and suggestions to overcome them to modify the training guidelines to improve future intervention delivery. Still, it is inappropriate to implement CKMC at this time on the presumption of benefit or assumption of no harm. Currently, the studies of CKMC or birth KMC suffer methodologic challenges that do not answer whether CKMC as promoted—round-the-clock STS given until the infant no longer desires STS, immediate breastfeeding, etc—is sufficient to improve survival or to specify adequate implementation (that which would render benefit). CKMC training at this time is ill-advised. This study demonstrates that suboptimal implementation (whereby infants receive few hours of STS care that is promptly discontinued) results in no overall benefit. Promotion of any unproven intervention may be potentially harmful because it may instill a false sense of confidence that could impair health care–seeking behavior. If CKMC, which quickly becomes popular, is set in place in a manner that is ineffective, then it may be difficult or impossible to improve implementation and effect at a later date. Additional experimental research ensuring baseline comparability of mortality, adequate KMC implementation, and birth weight assessment is necessary to clarify the effect of CKMC on newborn and infant survival before initiation of CKMC programs or inclusion of CKMC in essential newborn care.

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REFERENCES

1. Lawn JE, Cousens S, Zupan J. Lancet Neonatal Survival Steering Team. 4 million neonatal deaths: When? Where? Why? *Lancet.* 2005;365(9462):891–900
2. Rey ES, Martinez HG. *Rational Management of the Premature Infant* [in Spanish]. Bogotá, Colombia: Colombia Universidad Nacional; 1983:137–151
3. Sloan NL, Camacho LW, Pinto Rojas E, Stern C. The kangaroo mother method: a randomised controlled trial of an alternative method of care for stabilised low birthweight infants. Maternidad Isidro Ayora Study Team. *Lancet.* 1994;344(8925):782–785
4. Charpak N, Ruiz-Pelaez JG, Figueroa de CZ, Charpak Y. Kangaroo mother versus traditional care for newborn infants ≤2000 grams: a randomized, controlled trial. *Pediatrics.* 1997;100(4):682–688
5. Cattaneo A, Davanzo R, Worku B, et al. Kangaroo mother care for low birthweight infants: a randomized controlled trial in different settings. *Acta Paediatr.* 1998;87(9):976–985
6. Conde-Agudelo A, Diaz-Rossello JL, Belizan JM. Kangaroo mother care to reduce morbidity and mortality in low birthweight infants [Cochrane Review]. In: *The Cochrane Library*. Issue 4. Chichester, United Kingdom: John Wiley & Sons, Ltd; 2003
7. Charpak N, Ruiz-Pelaez JG, Figueroa de CZ, Charpak Y. A randomized, controlled trial of kangaroo mother care: results of follow-up at 1 year of corrected age. *Pediatrics.* 2001;108(5):1072–1079
8. Lincetto O, Nazir AI, Cattaneo A. Kangaroo mother care with limited resources. *J Trop Pediatr.* 2000;46(5):293–295
9. Worku B, Kassie A. Kangaroo mother care: a randomized controlled trial on effectiveness of early kangaroo mother care for the low birthweight infants in Addis Ababa, Ethiopia. *J Trop Pediatr.* 2005;51(2):93–97
10. Bergman NH, Jurisoo LA. The "kangaroo-method" for treating low birthweight babies in a developing country. *Trop Doct.* 1994;24(2):57–60
11. Anderson GC, Moore E, Hepworth J, Bergman N. Early skin-to-skin contact for mothers and their healthy newborn infants. *Cochrane Database Syst Rev.* 2003;(2):CD003519
12. Bergman NJ, Linley LL, Fawcus SR. Randomized controlled trial of skin-to-skin contact from birth versus conventional incubator for physiologic stabilization in 1200- to 2199-gram newborns. *Acta Paediatr.* 2004;93(6):779–785
13. Ibe OE, Austin T, Sullivan K, Fabanwo O, Disu E, Costello AM. A comparison of kangaroo mother care and conventional incubator care for thermal regulation of infants <2000 g in Nigeria using continuous ambulatory temperature monitoring. *Ann Trop Paediatr.* 2004;24(3):245–251
14. Ludington-Hoe SM, Anderson GC, Swinth JY, Thompson C, Hadeed AJ. Randomized controlled trial of kangaroo care: cardiorespiratory and thermal effects on healthy preterm infants. *Neonatal Netw.* 2004;23(3):39–48
15. Quasem I, Sloan NL, Chowdhury A, Ahmed S, Winikoff B, Chowdhury AMR. Adaptation of kangaroo mother care for community-based application. *J Perinatol.* 2003;23(8):646–651
16. United Nations Children's Fund. *The State of the World's Children 1998*. New York, NY: UNICEF; 1999
17. Niport, Mitra and Associates, ORC Macro. *Bangladesh Demographic and Health Survey 1999–2000*. Calverton, MD: Macro International Inc; 2001:103
18. Cohen J. *Statistical Power Analysis for the Behavioral Sciences.* 2nd ed. New York, NY: Academic Press; 1988:170–214
19. Manandhar DS, Osrin D, Shrestha BP, et al. Effect of a participatory intervention with women's groups on birth outcomes in Nepal: cluster-randomised controlled trial. *Lancet.* 2004;364(9438):970–979
20. Last JM. *A Dictionary of Epidemiology.* 2nd ed. New York, NY: Oxford University Press; 1988:41
21. Diggle P, Heagerty P, Liang KY, Zeger S. *Analysis of Longitudinal Data.* 2nd ed. New York, NY: Oxford University Press; 2002:54–70, 146–160
22. Needlman R. The newborn. In: Behrman RE, Kleigman RM, Jenson HB, eds. *Nelson Textbook of Pediatrics*. 16th ed. Philadelphia, PA: Saunders; 2000:30–32
23. Wright CM, Parkinson KN. Postnatal weight loss in term infants: what is normal and do growth charts allow for it. *Arch Dis Child Fetal Neonatal Ed.* 2004;89(3):F254–F257
24. Enzunga A, Fischer PR. Neonatal weight loss in rural Zaire. *Ann Trop Paediatr.* 1990;10(2):159–163
25. Singhi S, Sood V, Bhakoo ON, Ganguly NK. Effect of intrauterine growth retardation on postnatal changes in body composition of preterm infants. *Indian J Med Res.* 1995;102:275–280
26. Shaffer SG, Quimiro CL, Anderson JV, Hall RT. Postnatal weight changes in low birthweight infants. *Pediatrics.* 1987;79(5):702–705
27. World Health Organization. *WHO Child Growth Standards: Length/Height-for-Age, Weight-for-Age, Weight-for-Length, Weight-for-Height, Body Mass Index-for-Age Methods and Development*. Geneva, Switzerland: World Health Organization; 2006
28. Anderson GC, Chiu SH, Dombrowski MA, Swinth JY, Albert JM, Wada N. Mother-newborn contact in a randomized trial of kangaroo (skin-to-skin) care. *J Obstet Gynecol Neonatal Nurs.* 2003;32(5):604–611
29. Dyson L, McCormick F, Renfrew MJ. Interventions for promoting the initiation of breastfeeding [Cochrane Review]. In: *Cochrane Pregnancy and Childbirth Group Cochrane Database of Systematic Reviews.* Issue 1. Chichester, United Kingdom: John Wiley & Sons, Ltd; 2006

30. WHO Collaborative Study Team on the Role of Breastfeeding on the Prevention of Infant Mortality. Effect of breastfeeding on infant and child mortality due to infectious diseases in less developed countries: a pooled analysis. *Lancet.* 2000; 355(9202):451–455
31. Edmond KM, Zandoh C, Quigley MA, Amenga-Etego S, Owusu-Agyei S, Kirkwood BR. Delayed breastfeeding initiation increases risk of neonatal mortality. *Pediatrics.* 2006;117(3). Available at: www.pediatrics.org/cgi/content/full/117/3/e380
32. Kramer MS, Guo T, Platt RW, et al. Breastfeeding and infant growth: biology or bias? *Pediatrics.* 2002;110(2 pt 1):343–347
33. Christensson K, Bhat GJ, Amadi BC, Eriksson B, Hojer B. Randomised study of skin-to-skin versus incubator care for rewarming low-risk hypothermic neonates. *Lancet.* 1998; 352(9134):1115
34. Christensson K, Bhat GJ, Eriksson B, Shilalukey-Ngoma MP, Sterky G. The effect of routine hospital care on the health of hypothermic newborn infants in Zambia. *J Trop Pediatr.* 1995; 41(4):210–214
35. Kumar V, Darmstadt GL, Yadav R, et al. Weight is not an issue: promotion of skin-to-skin as a life-saving practice in India. Available at: www.icddrb.org/activity/index.jsp?activityobjectID=2481. Accessed March 20, 2008
36. Darmstadt GL, Kumar V, Yadav R, et al. Introduction of community-based skin-to-skin care in rural Uttar Pradesh, India. *J Perinatol.* 2006;26(10):597–604