

Kangaroo mother method: randomised controlled trial of an alternative method of care for stabilised low-birthweight infants

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Summary

Because resources for care of low-birthweight (LBW) infants in developing countries are scarce, the Kangaroo mother method (KMM) was developed. The infant is kept upright in skin-to-skin contact with the mother's breast. Previous studies reported several benefits with the KMM but interpretation of their findings is limited by small size and design weaknesses. We have done a longitudinal, randomised, controlled trial at the Isidro Ayora Maternity Hospital in Quito, Ecuador.

Infants with LBW (<2000 g) who satisfied out-of-risk criteria of tolerance of food and weight stabilisation were randomly assigned to KMM and control (standard incubator care) groups (n=128 and 147, respectively). During 6 months of follow-up the KMM group had a significantly lower rate than the control group of serious illness (lower-respiratory-tract disorders, apnoea, aspiration, pneumonia, septicaemia, general infections; 7 [5%] vs 27 [18%], $p < 0.002$), although differences between the groups in less severe morbidity were not significant. There was no significant difference in growth or in the proportion of women breastfeeding, perhaps because the proportion breastfeeding was high in both groups owing to strong promotion. Mortality was the same in both groups; most deaths occurred during the stabilisation period before randomisation. KMM mothers made more unscheduled clinic visits than control mothers but their infants had fewer re-admissions and so the cost of care was lower with the KMM.

Since the eligibility criteria excluded nearly 50% of LBW infants from the study, the KMM is not universally applicable to these infants. The benefits might be greater in populations where breastfeeding is not so common.

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Introduction

Neonatal care of low-birthweight (LBW) infants is costly. In developing countries, resources for perinatal and neonatal care are scarce, nurseries are overcrowded, and staffing is insufficient. The risk of nosocomial infection is high because it is often necessary for infants to share an incubator.

In response to this problem, Dr Edgar Rey and Dr Hector Martinez of the Maternal Child Institute in Bogotá, Colombia,¹ developed a method of ambulatory care of the premature—the kangaroo mother method (KMM). The stabilised LBW infant is placed in an upright position,

in skin-to-skin contact with the mother's breast, which acts as a source of warmth and food.

Since 1983, the KMM has received worldwide attention. Various studies have been done.^{2–13} Survival was the most important endpoint in these studies, but other indices of outcome have included the prevalence, frequency, and duration of lactation, duration (and cost) of hospital stay, temperature, heart rate, respiration frequency of infections, and growth. The studies generally reported greater ability to breastfeed for KMM infants, no substantial difference between them and incubator-treated infants in body temperature, less bradycardia or more regular heart rates, less apnoea or periodic breathing, earlier discharge from hospital, shorter time in incubator, improved growth, no increase in rates of infections, and improved survival. The studies suffer from various weaknesses, notably small sample size, absence of quantification, and design limitations, including the absence of suitable control groups.

The Isidro Ayora Maternity Hospital and the Population Council have carried out a prospective randomised trial in Quito, Ecuador, to compare the effects of the KMM and standard treatment on morbidity, growth, and cost of care for infants weighing less than 2000 g at birth.

Patients and methods

The estimated sample size required to detect a difference of 2.5 vs 7.5% of severe disorders, given an α error = 0.05, $1 - \beta = 0.80$, a two-tailed test, and potential loss to follow up of 25%, was 350 infants per study group. This calculation was based on conservative predictions of the size effect the study might find.

Eligible infants were singleton infants born at the Isidro Ayora Maternity Hospital weighing less than 2000 g, with no serious congenital abnormalities or respiratory, metabolic, or infectious disease.[†] Infants had to be stabilised—temperature between 36.5 and 37.0°C for the 24 h before enrolment; acceptable tolerance of food (sucking reflex or tolerance of nasogastric tube feeding; ability to ingest at least 50% of the desired volume, according to weight, of breastmilk); and stable weight, defined as no decrease for those weighing less than 1750 g at birth for at least 72 h.

Participating infants were assigned by simple randomisation to the experimental (KMM) or standard treatment study group between November, 1991, and December, 1992, and followed up until aged 6 months. Informed consent for the child to participate in the study was obtained from the mother by the study interviewers.

The randomisation codes were kept by the study secretary and statistician, and were not available to the study physicians or nurses. When eligibility was established, a form was submitted to the secretary who gave the infant the next study identification number, which assigned the infant to one or other study group. The study statistician reviewed the assignment of infants each day. All infants were correctly assigned according to this protocol.

*Participants are listed at the end of the article.

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†A table giving detailed criteria is available from *The Lancet*.

	KMM		Control	
	n	Mean (SD) or %*	n	Mean (SD) or %*
Socioeconomic status				
Maternal education (years)*	132	4.6 (1.8)	149	4.4 (1.8)
Marital status				
Married		64.5		73.1
Cohabiting		12.1		18.6
Single		14.5		7.6
Separated		7.3		0.7
Widowed		1.6		0
Living with father of child	132	74.2	149	90.3
Living with parent	123	21.1	143	12.6
Electricity	119	95.0	142	99.31
Radio	119	83.2	142	94.41
Television	119	68.1	142	78.91
Maternal reproductive health				
Age at first interview (years)*	123	24.94 (6.18)	143	24.39 (6.06)
Parity*	121	2.02 (1.75)	142	1.90 (1.59)
Status at birth-eligibility				
Male	130	57.7	152	53.9
Birthweight (g)*		1704 (243)		1704 (248)
Birthweight 1500 g	130	20.8	152	20.4
Gestation (weeks)	129	34.6 (2.5)	152	34.1 (2.4)
Gestation < 37 weeks	129	51.2	152	61.5
Age at eligibility (days)*	127	12.4 (10.5)	148	13.7 (9.9)

*Mean (SD); other values = percentages. $1p \leq 0.05$, $2p \leq 0.01$.

Table 1: Baseline characteristics of study groups

Training in care of LBW infants was provided by hospital nurses in a standard way that reflects current hospital practice. Basic training was the same for both study groups, and included statements informing the mothers that their infants were at high risk because they were small and therefore required special care. Instructions were provided on basic hygiene (washing hands and breasts and rolling up of hair) and immediate notification of the nursing staff if the baby turned blue or pale and showed rapid breathing or feeding problems. After randomisation, additional instruction was provided. Each mother in the control group was instructed about the baby's stay in the incubator or thermal crib, scheduling visits to breastfeed, how to position the baby after feeding to avoid vomiting, how to ensure maintenance of warmth, and how to arrange and maintain a crib at home after discharge. KMM mothers were instructed on how to hold the baby upright, skin-to-skin (diapers allowed) against the breasts to avoid vomiting and provide warmth and nurture, how to breastfeed from inside the blouse, and how to sleep inclined with the baby. The instructions were repeated and infant care demonstrated daily by nursing staff, and to each study group on selected weekdays. Before discharge, the attending nurses and resident physicians reinforced their initial instructions about care of LBW infants. The study then scheduled clinic follow-up visits at 1, 1.5, 2, 3, 4, 5, and 6 months of life.

Household visits were made for those who did not attend within 3 working days of a scheduled visit and for all children who did not attend the final (6 month) follow-up visit, to determine vital status, unless death was known.

At follow-up clinic visits, the nurse interviewer updated information on the extent of skin-to-skin contact, feeding practices, and the infant's condition. The infant was then weighed on Detecto beam-balance scales (to the nearest 20 g), length was measured on locally constructed and calibrated lengthboards, and mid-upper arm and head circumferences were measured with Inser-Tape measures (Ross Laboratories). Medical histories were taken and clinical examinations done.

Analysis

The outcome variables measured were infant growth (weight, length, upper arm and head circumference), morbidity, duration of hospital stay (and re-admission), and costs of care. Indices of morbidity, based on the medical history and clinical examination included diarrhoea, mild illnesses (upper-respiratory-tract disorders, dermatitis, jaundice, hip displacement), moderate illness (urinary infections), and severe illnesses (lower-respiratory-tract disorders, apnoea, aspiration, pneumonia, septicaemia, general infections).

	No (%) of group		p
	KMM (n=131)	Control (n=152)	
Serious illness	7 (5)	27 (18)	0.002
Lower-respiratory-tract disease	6 (5)	19 (13)	0.02
Re-admission	4 (4)	11 (7)	0.13
Signs of alarm	39 (30)	61 (40)	0.08
Moderate illness	9 (7)	10 (7)	0.91
Mild illness	84 (64)	102 (67)	0.31
Diarrhoea	14 (11)	25 (16)	0.18

For definitions see methods, except for signs of alarm = respiratory difficulty, poor movement, poor sucking reflex, paleness, abnormal faeces, fever.

Table 2: Cumulative frequency of morbidity indices

The cost of care was estimated by addition of costs of equipment (incubators, heated cribs) and drugs and supplies by duration of use, professional carers' time (number of episodes of care by doctors or nurses, and the product of number and duration of instructions in child care), and other daily costs of postnatal clinic visits (including transport) or hospital admission (number of visits or duration of stay, respectively).

Adjusted analyses included differences in socioeconomic circumstances, maternal reproductive health, and infant diseases before enrolment, age at measurement, infant's sex, birthweight (or for growth/size analyses only, anthropometric index analogous to that of outcome variable), gestation, number of children under 5 years old living in the household, and indoor plumbing (water), pre-enrolment serious morbidity, respiratory difficulty, or general infections (and for analyses of morbidity only, illnesses similar to those of the outcome variable). We used linear multiple regression analyses for infant growth and cost outcomes and unadjusted Kaplan-Meier survival analyses and Cox's proportional hazards models for infant morbidity. Other analyses were unadjusted χ^2 or t tests.

Enrolment was terminated early because a highly significant difference ($p < 0.02$ at 2 months, $p < 0.005$ at 6 months) in severe morbidity emerged.

Results

There were 603 babies of birthweight less than 2000 g. 51.6% were male. The mean (SD) birthweight was 1605 (322) g, the mean gestational age (known for 594) was 33.6 (2.8) weeks, Apgar scores at 1 min and 5 min were 5.6 (1.8) and 7.8 (1.4), and the mean temperature on admission to the neonatal intensive care unit was 34.5 (1.3)°C. Eligibility for study group assignment was reached at a mean age of 13.0 (10.5, range 0-70) days. 28 (5%) infants died soon after birth and a further 102 (17%) died before they satisfied the eligibility criteria. The mean birthweights of these infants were 1372 (324) g and 1380 (365) g. 282 (47%) of the 603 infants with birthweights below 2000 g were excluded (multiple birth 101, abandoned 6, serious maternal disability 8, severe congenital anomaly 14, perinatal death 28, pre-eligibility death 102, or other 23). The mean birthweight of the excluded infants, apart from those who died perinatally, was 1612 (323, range 660-1985) g compared with 1618 (317, 660-1995) g for the 321 (53%) children eligible for the study.

The parents of 21 (7%) children refused to take part in the study, so 300 babies were randomised, 140 to the KMM group and 160 to the control group.

More than 160 variables were compared to assess the study groups' similarity (table 1; not all data shown). Only 5 (<3%) of these variables showed significant differences between the groups and 6 others suggested important differences. The study therefore observed fewer (<5%) significant differences in baseline status between the study groups than would be expected by chance.

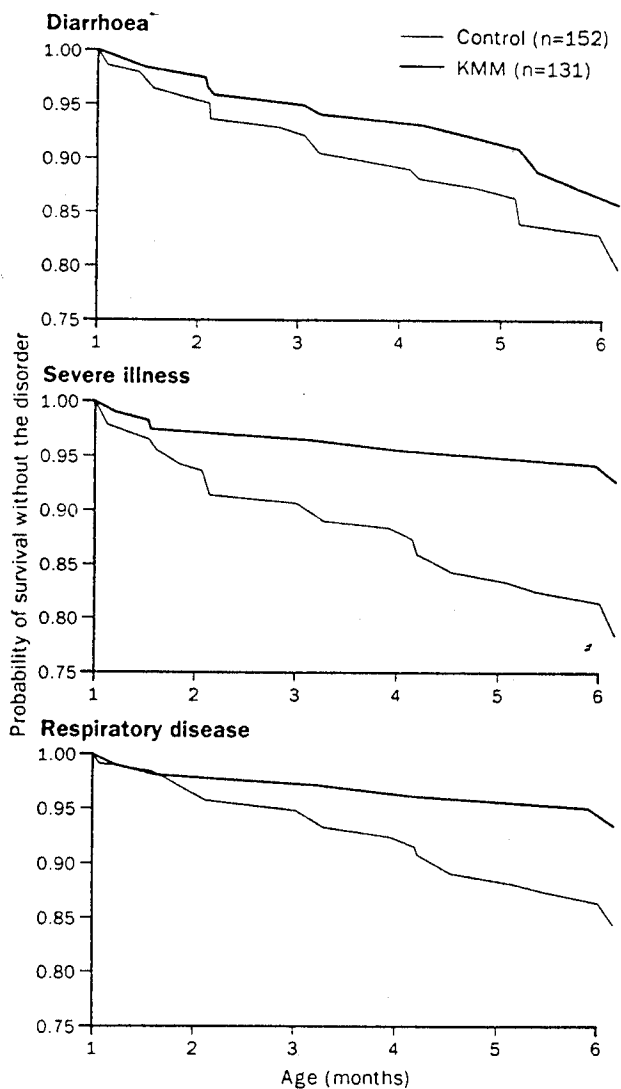


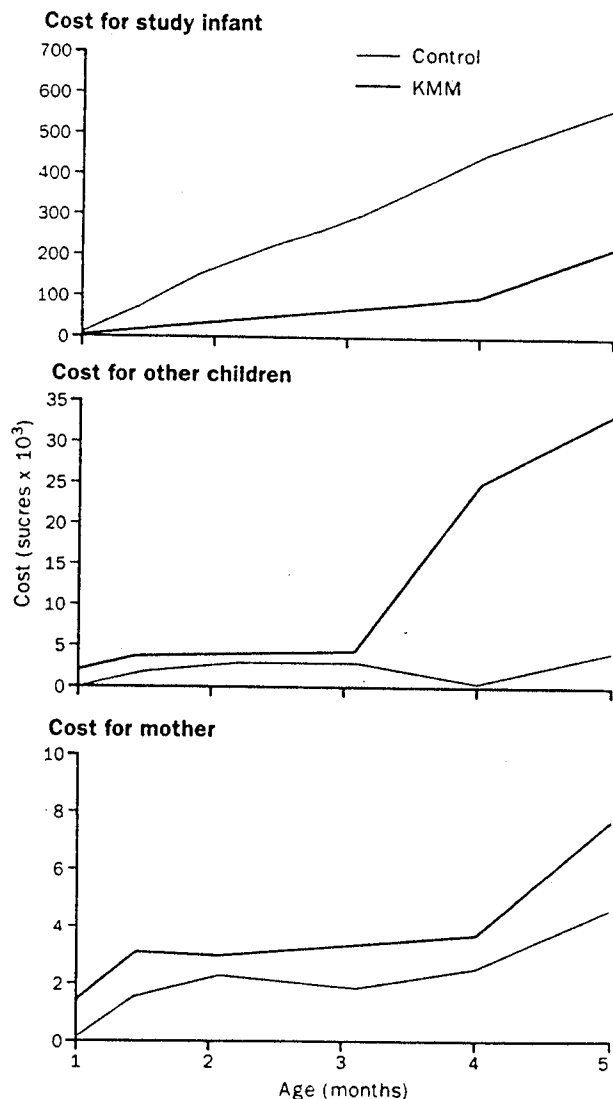
Figure 1: Kaplan-Meier survival analyses of likelihood of diarrhoea, severe illness, and respiratory disease

The KMM group seemed slightly socioeconomically disadvantaged in comparison with the control group but there were no differences in the reproductive health status of mothers, infant size at birth, gestation, or Apgar scores. The KMM group had a slightly larger proportion of male infants, and the mean age at eligibility was 1.5 days younger and that at discharge 0.5 days older.

Skin-to-skin contact was reported only in the KMM group, by 68% at 1 month, 47% at 1.5 months, 20% at 2 months, and 7% at 3 months. Significantly more control than KMM mothers left their children alone in cribs or with other people during the first 2 months of life. Significantly more KMM infants slept with their mothers. Most were held against the breasts until 3 months.

Feeding patterns were very similar in the two groups, probably because of strong promotion of exclusive breastfeeding for all infants. The frequency of breastfeeding was high in both groups throughout follow-up, although few women were still exclusively breastfeeding at 5 months.

We found a moderate, but not significant, difference between the groups in the frequency of diarrhoea (table 2, figure 1). There were no differences in mild or moderate



Dependent variable	Months of follow up					
	0	1	2	3	4	5
Study infant						
KMM	86	69	61	52	47	41
Control	107	84	75	68	61	53
Mother						
KMM	86	69	74	67	64	60
Control	107	84	89	67	81	77

Figure 2: Adjusted cumulative costs of medical care
Median exchange rate during study US\$1 = 1400 sucres.

disorders between the groups but the difference in the cumulative incidence of severe illness was striking—a third lower in the KMM group at 6 months and highly significant from month 2 onwards. Control for pre-eligibility differences in severe morbidity reduced the magnitude and significance of this association only slightly (from $p < 0.002$ to $p < 0.007$). When this difference became apparent recruitment to the trial was halted. There was also a significant difference for disease of the lower respiratory tract. The cumulative incidence of re-admission and signs of alarm was also greater in control than KMM children; these differences were not significant, however. Results of

adjusted Cox's proportional hazards models were similar to those of these unadjusted or linear-adjusted analyses.

There were no significant differences between the groups in growth indices during the 6-month follow-up. As expected, the pattern and frequency of mortality showed no differences; there were 11 post-eligibility deaths in the KMM group and 13 in the control group.

Women in the KMM made more unscheduled clinic visits for the study infants, other children, and themselves than did mothers in the control group; these differences were not significant.

Costs of neonatal care were greater in the control than in the KMM group (figure 2). By chance, KMM infants were 1.5 days younger at eligibility and 0.5 days older at discharge than control infants, so their length of hospital stay was 2.0 days greater (from the point of eligibility) than control infants ($p < 0.05$). However, more control than KMM infants were in incubators after the day of eligibility and the cost of post-eligibility, pre-discharge hospital stay was 475 000 sucres (about US\$340) higher in the control group. The overall cost of post-neonatal care was 561 000 sucres (US\$401) greater for the control than KMM group at 5 months (figure 2). Data were available for only 49 babies (24 KMM, 25 control) at 6-month follow-up.

Additional costs associated with the KMM method arise from the greater time spent in clinic visits for the study children, their siblings, and mothers. This cost can also be viewed as a benefit, since it allows greater interaction between mothers at clinic visits, and between mothers and health-care providers, which could have improved their capacity to take care of their infants. Health-service providers gave advice about child care at every (study and non-study) clinic visit. Because infants in the KMM group were seen more often, they were more likely to be treated in earlier stages of illness, which would prevent more severe sequelae.

Another cost could be maternal morbidity, which varied between the groups. About 50% more mothers in the KMM group than controls made clinic visits, although control mothers returning for clinic visits had almost twice as many multiple illnesses prompting their return visits as did mothers in the KMM group (not significant).

Discussion

Despite the similarity in baseline characteristics and follow-up between the KMM and control groups, substantially lower incidences of severe illnesses, especially lower-respiratory-tract infection were seen with the KMM. Although the differences in method adherence (eg, skin-to-skin contact, sleeping with the infant) were observed in the first few months of life, the difference in morbidity was observed only after 2 months of age.

Although breastfeeding, skin contact, and warmth in the first few months of life may improve bonding between mother and child and lead to longer-term assertiveness to child care, greater use by the KMM mothers of preventive health-care services probably had a significant effect on reducing serious illness. The KMM group had higher expenditures for clinic visits; however, the control group had greater costs for re-admission associated with diarrhoea or serious illness. None of the differences in costs was statistically significant, but they are substantial for families and for the health system of Ecuador.

As expected, the KMM did not reduce neonatal mortality, because most of this mortality (85%) occurred in

the early neonatal period, before infants were eligible for assignment to study groups.

Thus, the benefit of the KMM does not seem to be limited to the three components heat, love, and breastfeeding. The observed benefits are also apparently attributable to greater pre-discharge maturation, better and more instructions in neonatal care, better maternal-infant bonding, which establishes physically and emotionally closer ties that affect infant health and growth even beyond the time when the mother continues skin-to-skin contact, and better use of health care and concern with the infants' health by both parents and health-care providers.

Further studies are needed to elucidate conditions under which the KMM is effective. In this trial, half of the infants weighing less than 2000 g at birth were not eligible because they were not seen as suitable candidates for KMM. The observed reduction in morbidity is consistent with earlier studies. However, the deficiencies (in sample size or design) of these earlier studies do not permit a fair judgment of whether our results can be generalised or to whom. The results may be applicable to LBW infants living in similar climates (high altitude), where lower-respiratory-tract infections are common and where technological limitations are similar (there are shortages of incubators and electricity). The KMM may be more effective in populations where breastfeeding is not so common; incremental benefits due to enhanced breastfeeding could not be observed in this study, since there is a strong breastfeeding policy at the Isidro Ayora Maternity Hospital.

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