RESEARCH PAPER

Impact of a Novel Hypothermia Alert Device on Death of Low Birthweight Babies at Four Weeks: A Non-randomized Controlled Community-based Trial

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Objective: To study the effectiveness of a hypothermia monitoring device in reducing neonatal mortality and increasing Kangaroo Mother Care compliance.

Design: Non-randomized controlled trial.

Setting: 3 government Sick Newborn Care Units and 7 Primary Health Centers in Udaipur and Dungarpur districts of Rajasthan for 4 months. The follow-up period was 4 weeks for each baby.

Participants: Total 386 neonates were included in the study. 250 (64.76%) new-borns in the study group (BEMPU bracelet) and 136 (35.23%) enrolled in the control group. Clinically stable babies discharged below 2500 grams, whose parents could be reached by phone, and who could visit the facility for 4 weekly follow-ups were eligible for participation. Infants with complications or those leaving against medical advice were not eligible.

Intervention: The BEMPU Bracelet is a medical device that provides 4 weeks of continuous hypothermia monitoring for new-borns, and emits an audio-visual alarm when the temperature of the newborn is below 36.5°C.

Outcome: Neonatal mortality over the 4-week period.

Results: Mortality data was obtained for 92% (229 babies) of the study group and 91% of the control group (124 babies) at the end of the 4-week period. The intervention group had a significantly lower mortality rate as compared to the control group (6% *vs.* 14%, *P*=0.013). Weight data from 51% of the study group (128 babies) and 32% of the control group (44 babies) did not show a significant difference in weight gain between the groups.

Conclusion: The observed effect on mortality and qualitative feedback on KMC compliance suggest the utility of the device in the community settings.

Keywords: *Body temperature, Kangaroo Mother Care, Neonatal mortality, Community health*.

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Approximately 27 million babies are born in India every year and out of those 8 million are LBW [1], these include over 3.3 million preterm births per year [2]. Such babies are at a high risk of experiencing life-threatening illnesses. Neonatal hypothermia and infection, are among the leading causes of newborn deaths and illness in low-resource settings [3,4]. Infants who are premature and/or low birthweight struggle to regulate their own tempe-rature, which may lead to hypothermia. If untreated, hypothermia may lead to reduced weight gain, which predisposes newborns to sepsis, pneumonia, and even death.

By providing skin-to-skin care, or Kangaroo Mother Care (KMC), caregivers can prevent or correct hypothermia in neonates without the assistance of radiant warmers or incubators [4].The World Health Organization recommends KMC for all low weight babies. However, despite national KMC policies, uptake of the practice has been low due to social and logistic barrier [5].

Accompanying Editorial: Pages 292-93.

The Indian state of Rajasthan has an infant mortality rate of 41 infant deaths per 1000 live births [6], which is comparable to the national average [7]. The National Health Mission (NHM) Rajasthan identified BEMPU bracelet, a hypothermia monitoring device, as an intervention with the potential to address neonatal mortality through hypothermia prevention. This pilot study was done to assess the effectiveness of this device on mortality amongst low birthweight neonates.

METHODS

This non-randomized study was conducted in three government Sick Newborn Care Units (SNCUs) and seven Primary Health Centers (PHCs) in the Udaipur and Dungarpur districts of Rajasthan, India. The approval to conduct the study was sanctioned by the Mission Director of National Health Mission Rajasthan and the Chief Medical and Health Officer, Udaipur, Rajasthan. A team from the product developers trained the site doctors, nurses, data entry operators, and Auxiliary Nurse Midwives (ANMs) on the use of the bracelet, KMC, and data collection procedures. LEHS|WISH (Lord Education and Health Society|Wadhwani Initiative for Sustainable Healthcare) assisted with pilot initiation and oversight of data collection and analysis.

Staff of the facilities enrolled babies from 29 September, 2016 to 10 January, 2017. Clinically stable babies discharged weighing below 2500 grams, whose parents could be reached by phone, and who could come to the facility for 4-weekly follow-ups were eligible for participation. Infants with complications or those leaving against medical advice were not eligible for this study. After obtaining informed consent from parents, SNCU or PHC nurses enrolled the babies. Total 386 babies were enrolled, of which 250 (64.76 %) were in the study (BEMPU bracelet) group, and 136 (35.23%) in the control group (routine care).

Families of babies in both the study and control groups received discharge instructions on hypothermia awareness and prevention, KMC, and swaddling techniques. Parents with babies in the study group also received instructions on how to use the device.

All participants were followed up for 4 weeks. Parents were also given a patient- diary to record hours of KMC. Families were asked to come back for weekly follow-ups for 4 weeks, so staff could collect anthro-pometric measurements on the newborns. Transportation charges for the follow-up visits were reimbursed to ensure regular follow-up.

Parents of newborns enrolled in the study also received three follow-up phone calls to collect information on the health status of their newborn, KMC compliance, and the device usage, if applicable. During this call, they were also reminded weekly about their follow-up appointment. If parents did not answer phone calls, the local ANM was called to gather follow-up data on mortality and encourage parents to attend their weekly follow-up. At the fourth follow-up appointment, parents submitted their patient diary and final anthropometric measurements were taken. Interviews with parents were conducted to gather qualitative evidence on KMC compliance and attitudes towards the device.

Quantitative data on mortality and weight gain from patient diaries were entered by data entry operators. All quantitative data was analyzed using the program tool.

The BEMPU bracelet is a device that provides 4 weeks of continuous temperature monitoring to a preterm or LBW newborn. It emits an audio-visual alarm when a baby's temperature drops below 36.5 degrees, indicating that the infant is hypothermic and prompting caregivers to provide thermal care in the form of KMC (***Web Fig.* 1**). The BEMPU bracelet indicators are explained in ***Web Table* I**. It has a sensitivity of 98.6% and specificity of 95% for detecting neonatal hypothermia [8].

The NHM/WISH pilot was completed in two southern districts of Rajasthan state, Udaipur and Dungarpur. The districts have predominately tribal populations, which represent 47.9% of the population in Udaipur and 70.8% in Dungarpur [9]. These are high-priority districts, having a heavy burden of LBW and neonatal mortality; 49.5% of babies born in Udaipur are LBW and the neonatal mortality rate in the district is 40 per 1,000 live births. In Dungarpur, the rate of LBW is 46.9%, with a neonatal mortality rate of 41 [10].

This pilot study was commissioned by the National Health Mission (NHM) of Rajasthan to assess the feasibility of the innovation, to inform potential adoption through state budgets. While this study was not approved by an Institutional Review Board, the research questions and methods were reviewed and approved by a panel of experts including senior NHM officials and Chief Medical Officers in Rajasthan. The study was conducted as per ethical approval carried out following Helsinki declaration.

RESULTS

Total of 386 newborns were screened for eligibility, enrolled, and assigned to one of the two study groups; 35 of these were lost to follow up after discharge, and 31 died during the 4 weeks of study period (***Fig*.1**). The

Table I Baseline Characteristics of Newborns Discharged From Special Care Neonatal Units in Rajasthan

	Control group (n=136)		*Study group (n=250)*	
	No.	*Mean (SD)*	*No.*	*Mean (SD)*
Birthweight (kg)	132	1.94 (0.43)	243	1.87 (0.38)
Discharge weight (kg)	132	1.88 (0.41)	243	1.89 (0.37)
Gestational age (wk)	94	35.2 (3.1)	74	35 (2.8)

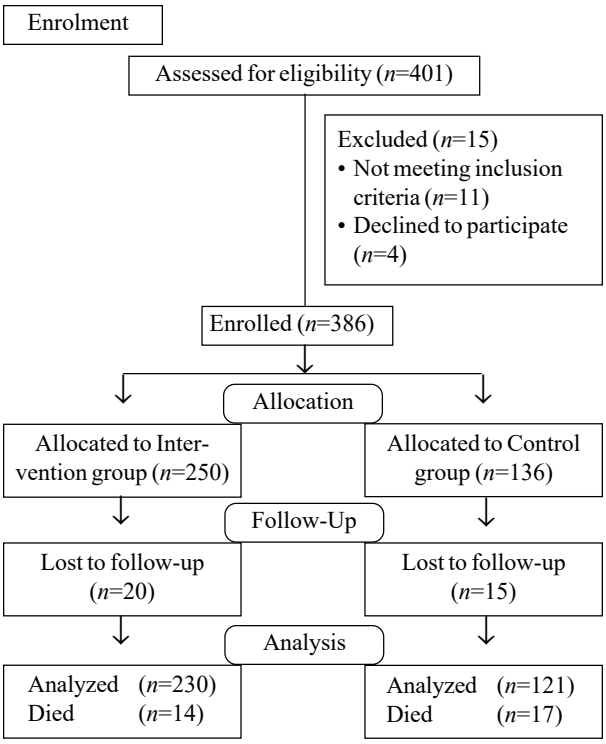

Fig. 1 *Study flow chart.*

baseline characteristics are shown in ***Table* I**. The primary conditions of SNCUs newborns enrolled in the studies are represented in ***Fig.* 1**.

Mortality data was obtained for 92% of the study group (229 babies) and 91% of the control group (124 babies) at the end of the 4-week period. Mortality differences between the groups were statistically significant. The study group had lower mortality rate (6%) than control group (14%) [OR (95%CI) = 2.43, (1.59, 5.13); *P*=0.09]. The characteristics of the newborns that died are shown in ***Fig.* 2**.

Due to the low rate of facility-based follow-up, weight data from only 51% of the study group (128 babies) and 32% of the control group (44 babies) was available for analysis. The weight gain in the two groups was similar [2.79 g, 95% CI (2.64, 2.94) *vs* 2.58 g, 95% CI (2.43, 2.73); *P*= 0.1019].

The KMC tracking charts in patient diaries were inconsistently filled out making them impossible to be reliably analyzed; hence, researchers could not perform further quantitative analysis of this aspect. ***Web box* I** shows the findings of qualitative feedback through semi-structured interview with 11 parents.

The follow-up rate in BEMPU group (59.58 %) was higher than the control group (31.34 %), which indicates that the device promoted a positive behavior change in the parents on newborn care.

DISCUSSION

Providing appropriate thermal care can reduce a newborn's risk of hypothermia-related morbidity and mortality [11]. In this pilot, the study group experienced a statistically significant lower rate of mortality than did the control group. Qualitative data collected from interviews with parents also suggested positive experiences. The follow-up rate of the study group was almost twice as that of the control group, suggesting a favorable behavioral change.

The anthropometric data could not be completely recorded due to various reasons such as high burden on healthcare staff and many families living far from the

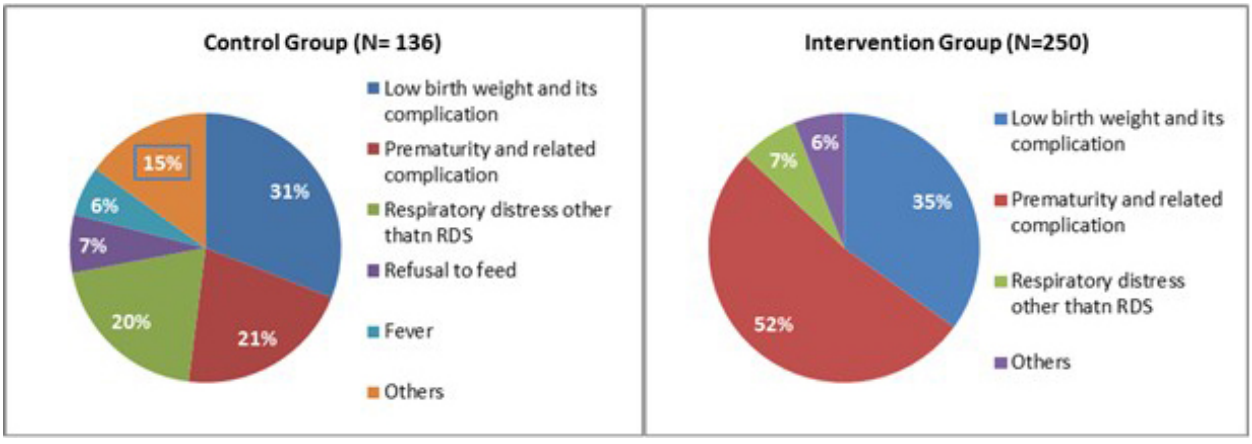

Fig. 1 *Primary conditions of newborns enrolled in the study.*

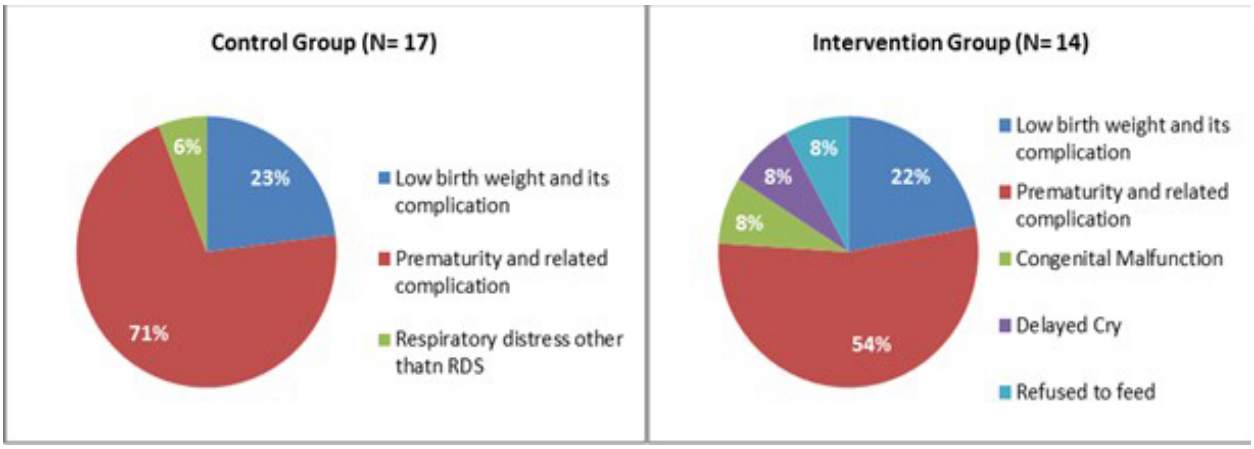

Fig. 2 *Characteristics of the low birthweight newborns who died during the study.*

health facilities; and it was a contributing factor to the loss to follow-up. A larger study is planned to address these limitations. Probably, due to low literacy levels, mothers/family members filled out the KMC tracking chart unsatisfactorily. Other methodologies should be employed in the future to quantitatively evaluate hours of KMC performed with and without the BEMPU Bracelet.

The data for weight gain was difficult to gather and not standardized between centers and nurses. Some newborns were weighed with their clothes on, some nurses rounded information to the nearest half kg, and some centers did not have proper scales.

A device called ThermoSpot, a non-invasive infant hypothermia indicator, that adheres to the skin of and indicates infant hypothermia or a fever by a change of color was studied in the community to understand the impact of behavior change on newborn care [12]. The results of the study revealed that there was an improvements in birth preparedness, hygienic delivery, thermal care (including skin-to-skin care), umbilical cord care, skin care, and breastfeeding [12]. There was little change in care-seeking. Many of the other hypothermia detection devices have not been studied in the community. BEMPU bracelet's simple, easy to understand audio-visual alarm feature distinguish it from other similar interventions. The audio-visual indications can be understood by any mother and family members across all socio-economic groups.

In areas where the risk of neonatal hypothermia is high due to the prevalence of preterm birth and low birth weight, use of the BEMPU Bracelet among these vulnerable babies could result in reduced mortality through provision of thermal care. The observed reduction in mortality and positive parental feedback on KMC promotion in this study supports the BEMPU bracelet's potential to impact neonatal health outcomes. This warrants further research to assess the bracelet's impact on newborn care practices.

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Contributors: MS: conception and design of the study, VM: data analysis, drafting manuscript, MS: conception and design of study; DS: acquisition of data; RDB: implementation of the study, AS: data analysis. All authors approved the final version of manuscript and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Competing interests: All data collection was overseen by the National Health Mission Rajasthan and the WISH Foundation. Data analysis and the authorship of this publication were shared between BEMPU Health and the WISH Foundation. BEMPU Health team conducted the training required for the bracelet use. Staff of the NICUs of the hospitals in the studies carried out the study.

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WHAT THIS STUDY ADDS?

- Using a home-based hypothermia monitoring device among low birthweight neonates positively affects mortality by age of four weeks.

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Web Box I Qualitative Feedback Through Semi-structured Interviews

- One mother with a low birth weight baby mentioned that "*BEMPU showed a red light many times a day, especially in the early morning hours. I used to provide KMC so that BEMPU will not show a red light*." Another mother with a low birth weight baby said, *"BEMPU beeped in the night and early morning hours. Whenever it beeped I provided KMC."* The BEMPU Bracelet's beeping concerned one mother, who told the research team that "*[BEMPU's] beeping alerted me to the baby's temperature and enabled me to perform KMC for my child. The alarm worried me and I would give KMC to stop the beeping."*
- Qualitative responses also revealed that the bracelet encouraged other family members to provide KMC. In one family, the mother, father, and grandmother reported that they performed KMC for an hour each time the bracelet beeped.

Web Fig. 1 *BEMPU bracelet; a hypothermia monitoring device.*

Web Table I BEMPU Bracelet Indicators

State	*Alert*
Normothermia	• Blue light blinks once every 30 seconds • No sound alarm
Hypothermia	Red light blinks once every 5-6 seconds Alarm sounds for 1 minute and repeats every 5-15 minutes • If temperature of the body drops below 0.5 degree with in duration of 5 minutes, then alarm repeats within 5 minutes. • If temperature is not dropping at faster rate, then the alarm repeats after 15 minutes.