


REGULAR ARTICLE

Changes in autonomic regulation due to Kangaroo care remain unaffected by using a swaddling device

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Keywords

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ABSTRACT

Aim: To investigate the effects of a swaddling device known as the Hugsy (Hugsy, Eindhoven, the Netherlands) towards improving autonomic regulation. This device can be used both in the incubator and during Kangaroo care to absorb parental scent and warmth. After Kangaroo care, these stimuli can continue to be experienced by infants, while in the incubator. Additionally, a pre-recorded heartbeat sound can be played.

Method: Autonomic regulation was compared in preterm infants before, during and after Kangaroo care with and without the use of a swaddling device in a within-subject study carried out in a level III neonatal intensive care unit. Descriptive statistics and effect sizes were calculated corresponding to changes in heart rate, respiratory rate, oxygen saturation, temperature and heart rate variability on intervention versus control days.

Results: In this study of 20 infants with a median (interquartile range) gestational age of 28.4 (27–29.9) weeks, Kangaroo care was associated with a decrease in heart rate, respiratory rate and heart rate variability on both intervention and control days. There were no differences between intervention and control days.

Conclusion: The use of an alternative swaddling device aimed at facilitating Kangaroo care did not enhance autonomic regulation, as measured by vital signs and heart rate variability.

INTRODUCTION

Preterm infants may be admitted to neonatal intensive care units (NICU) for long periods of time, an environment that is stressful for infants, due to parent–infant separation, bright lights, noise, iatrogenic interventions and other unnatural stimuli (1–3). Over the past decades, it has been suggested that such early life experiences impair long-term neurodevelopmental outcomes (4). Correspondingly, interest in interventions to reduce pain and stress in NICUs has increased.

In addition to pharmacological interventions such as analgesics (5), a Cochrane review has demonstrated that non-pharmacological pain management can have significant benefits as well (6). In that review, different types of

non-pharmacological interventions, including Kangaroo care, swaddling, parental presence and the use of maternal voice were investigated in over 3000 preterm infants. Typically, the effects of interventions are determined by measuring vital signs (7–11) and based on this, the review found evidence to recommend Kangaroo care, sucking-related interventions and swaddling or facilitated tucking (6). Several other studies have also found promising effects of using sounds of parental heartbeat for reducing stress in preterm infants (7–11).

Abbreviations

CI, Confidence interval; ECG, Electrocardiography; NICU, Neonatal intensive care unit; NN-intervals, Normal-to-normal heartbeat intervals; pDec, Percentage of decelerations; RMSSD, Root mean square of successive differences in heartbeat intervals; SDDec, Standard deviation of decelerations; SDNN, Standard deviation of normal-to-normal intervals; SEM, Standard error of the mean.

Key notes

- This study aimed to investigate whether the use of an alternative swaddling device can enhance autonomic regulation in preterm infants.
- This device can absorb parental scent and warmth during Kangaroo care, which are then transferred back to the incubator.
- While Kangaroo care changes heart rate variability, and to a lesser extent vital signs, there is no evidence to suggest that the use of such a swaddling device augments regulation.

In this study, we investigated the effect of a swaddling device designed at the Eindhoven University of Technology termed the Hugsy. It is designed for use, both in the incubator as well as during Kangaroo care (12). During Kangaroo care, the device is wrapped around the parent and infant in a manner such that it folds around the parent's axillary region and is fastened across their back, to optimally absorb scent and warmth. These stimuli are then transferred back into the incubator after Kangaroo care (Fig. 1A,B). Also, the device can play a pre-recorded sound of parental heartbeats. We analysed both vital signs and heart rate variability before, during and after Kangaroo care with and without the use of the swaddling device to identify any potential benefits of augmenting Kangaroo care with the use of such devices.

METHOD

Patient population

All preterm infants admitted to the NICU of Máxima Medical Centre, Veldhoven, the Netherlands, from October 2016 to March 2017 were asked to participate at the earliest appropriate occasion after admission. Infants were deemed eligible after they were determined to be clinically stable by nurses. Exclusion criteria were any serious clinical conditions at the time of inclusion, such as sepsis and necrotising enterocolitis, mechanical ventilation and severe brain pathology defined as intraventricular haemorrhage grade III/IV. Typically, in our hospital, all infants routinely receive Kangaroo care and all parents are encouraged to do so. Since, aside from using an alternative swaddling device, the study was of an observational nature, the medical ethical committee provided a waiver (N16.101) in accordance with the Dutch law on medical research with humans. Written parental consent was obtained corresponding to each participating infant. The study participants are characterised in Table 1.

Study design and swaddling device

This study was of a within-subject design, where intervention days were compared to control days. On intervention days, a swaddling device was used during Kangaroo care

sessions as well as in the incubator (12). Therefore, in the post-Kangaroo care period, infants were swaddled in the same device as during Kangaroo care (Fig. 1A,B). In the post-Kangaroo care period of one hour, the device's speaker played the sound of heartbeats at 30–35 dB and at a pre-recorded frequency of 1–1.5 Hz, corresponding to the resting heart rate of the typical adult. This parental heart rhythm was recorded during the first Kangaroo care session of the study, for a period of 10 minutes. On control days, infants received routine caregiving including Kangaroo care but without using the swaddling device.

The study was designed to last eight days in each infant. Half the infants started with the intervention, while the other half started with routine Kangaroo care (control days). Two intervention days were alternated with two control days, twice in each infant (Fig. 2). Nurses were asked to annotate the start time (placement on parental chest) and end time (placement into incubator) of Kangaroo care. Since the study was of an observational nature, routine caregiving, including the frequency and duration of Kangaroo care remained unaffected.

Measurements; vital signs and heart rate variability

Routine patient monitoring including electrocardiography (ECG, 250 Hz) and the recording of vital signs continued throughout the study. To analyse the potential effects of Kangaroo care on intervention and control days, vital signs and ECG data from the one hour before, during and after Kangaroo care was extracted from a data warehouse (PIIC iX, Data Warehouse Connect; Philips Medical Systems, Andover, MA, USA). The vital signs included heart rate, respiratory rate (using impedance pneumography), oxygen saturation (using pulse oximetry) and diaper-based temperature recorded at a frequency of 1 Hz. ECG data were used to derive heart rate variability—the time intervals between successive heartbeats.

Heart rate variability was calculated using a peak detection algorithm to detect all R-peaks, or heartbeats, in the ECG recordings (13). Artefacts and ectopic beats were removed so that only so-called normal heartbeats remained. Consecutively, beat-to-beat intervals, also known as



Figure 1 (A) illustrates the use of the Hugsy during Kangaroo care. The recording of the heartbeat and the heartbeat module are illustrated elsewhere (12). (B) illustrates the use of the Hugsy as a scented swaddling blanket within the incubator. The speaker playing the heartbeat is positioned in between the Hugsy and the mattress, in close proximity to the infant's head.

Table 1 Median and interquartile ranges (25th–75th percentile) of patient characteristics at birth and during the study

Characteristics	Median	25th percentile	75th percentile
Gestational age (weeks)	28.4	27	29.9
Birth weight (g)	1015	870	1280
No. of KC sessions	5.5	3	7
Duration of KC sessions control days (minutes)	100	77	120
Duration of KC sessions intervention days (minutes)	90	74.5	112
PMA during first KC session	30.6	29.6	31.4
Average PMA for all KC sessions	31	29.9	31.6
PNA during KC (days)	13	9	22
Duration of data collection (days)	8	6.5	8

KC = Kangaroo care; PMA = Post-menstrual age; PNA = Postnatal age. PNA is the number of days after birth. Duration of collection days is the number of days from the first day of the study until the last day of the study.

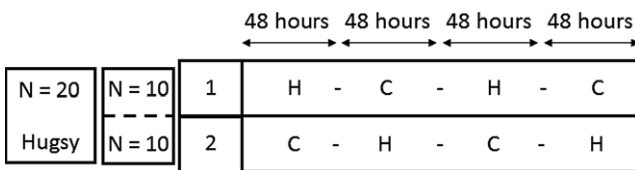


Figure 2 Image of the study design. Odd-numbered participants were part of group 1 and started with two intervention days, while even numbered participants were part of group 2 and started with two control days. H reflects days on which the Hugsy was used (intervention days), and C reflects control days.

normal-to-normal (NN) intervals were determined (13). On the basis of previous research, we calculated four features of heart rate variability: the standard deviation of all NN-intervals (SDNN), the root mean square of the successive difference between NN-intervals (RMSSD), the percentage of NN-intervals corresponding to transient decelerations (pDec) and the standard deviation of the NN-intervals corresponding to transient decelerations (SDDec; 14–16). The feature SDNN is believed to be reflective of overall variability, whereas the RMSSD reflects short-term variability (15). The features pDec and SDDec are reflective of regulatory instability and are specifically designed to capture heart rate decelerations, both transient decelerations as well as prolonged bradycardia (16,17). We calculated the mean value and the standard error of the mean (SEM) for these four features of heart rate variability every minute, using data from the previous five minutes to obtain a time series graph for each heart rate variability feature. Since for these time series we were interested in the effect of Kangaroo care and not absolute values *per se*, a normalisation procedure or baseline removal was carried out by subtracting the mean value of each feature in the first 30 minutes of the pre-Kangaroo care period from the corresponding time series, as detailed in a prior publication (16).

For statistical analyses of heart rate variability and vital signs, representative or stable epochs were defined to enable reliable comparison of differences in absolute values on intervention days versus control days, similar to previous studies (16,18).

In the pre-Kangaroo care period, the first 30 minutes were considered stable, whereas for the periods of during and after Kangaroo care, the epochs corresponding to the 16–45th minute were considered as stable and were used for statistical analyses (see Fig. 3). A detailed discussion motivating this approach is provided in a previous publication (16). Briefly, the first 30 minutes of the pre-Kangaroo care period is a stable period since it is free of routine nursing intervention. The 16–45th minute during Kangaroo care is stable since infants have acclimatised to Kangaroo care after the transition from incubator to the parental chest. Similarly, the 16–45th minute of the post-Kangaroo care period is considered stable since infants have acclimatised to the incubator after the stress of transition from the parental chest to the incubator. The mean values of the heart rate variability features and vital signs were calculated for the stable 30-minute epochs of each pre-Kangaroo care, during Kangaroo care and post-Kangaroo care period. Consecutively, the median and interquartile ranges of these representative values were determined for both the intervention and control arm of the study to analyse the effect of Kangaroo care.

Statistical analyses

Statistical testing for differences in vital signs and heart rate variability features were carried out using two-sided Wilcoxon rank-sum tests. In addition, the effect size of Kangaroo care on both intervention and control days was quantified by determining the difference in means of the individual 30-minute stable periods from the pre-Kangaroo care, during Kangaroo care and post-Kangaroo care periods. Estimates of the 95% confidence intervals (95% CI) of the effect size were obtained by bootstrapping 10 000 times. A p-value ≤0.01 was considered statistically significant.

RESULTS

In this study of 20 preterm infants with a median (interquartile range) gestational age of 28.4 (27–29.9) weeks, 108 and 106 Kangaroo care sessions were analysed corresponding to intervention and control days respectively. With regard to the heart rate and respiratory rate, there were no differences between intervention and control days corresponding to the pre-Kangaroo care, during Kangaroo care and post-Kangaroo care periods (Table 2). However, Kangaroo care, irrespective of whether on intervention or control days, reduced heart rate and respiratory rate compared to the corresponding pre-Kangaroo care periods. This decrease was statistically significant as can be seen in Figure 4A,B since the upper bound of the 95% CI, corresponding to the effect size of Kangaroo care in comparison to the pre-Kangaroo care period is below zero. Notably, though, there is no lasting effect of Kangaroo care on heart

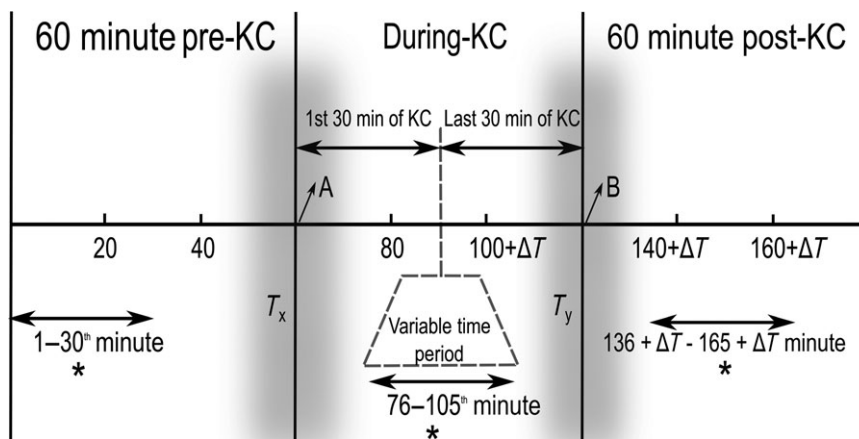


Figure 3 An illustration of the methodology employed in both intervention and control days. The pre-Kangaroo care (KC) and post-KC sessions are 60 minutes long. The duration of KC can vary (first 30 minutes + variable period as indicated with ΔT + last 30 minutes), and thus the first 30 minutes and the last 30 minutes of KC are always used for visualisation. T_x and T_y represent the periods of transfer from the incubator to the parental chest and vice versa. 'A' refers to the first minute on the parent's chest; 'B', to the first minute back in the incubator. Asterisks indicate the stable epochs used for statistical comparisons between intervention and control days and for calculating effect sizes.

Table 2 Median value (interquartile range) of vital signs in the pre-Kangaroo care (KC), during KC and post-KC periods

Vitals	Pre-KC		During KC		Post-KC	
	Intervention	Control	Intervention	Control	Intervention	Control
HR	162 (156–169)	163 (156–170)	160 (154–165)	159 (153–163)	163 (157–167)	162 (157–168)
RR	53 (49–61)	56 (48–65)	50 (45–60)	51 (42–61)	55 (47–62)	56 (47–63)
SpO2	92 (91–95)	93 (91–96)	92 (89–96)	93 (90–95)	94 (91–96)	93 (91–96)
Temp	36.9 (36.7–37.2)	36.9 (36.6–37.2)	36.8 (36.6–37)	36.8 (36.6–37.0)	37 (36.8–37.2)	36.82 (36.6–37.0)

HR = Heart rate; KC = Kangaroo care; RR = Respiratory rate; SpO2 = Oxygen saturation; Temp = Temperature.

There were no statistically significant differences in the vital signs between the intervention and control arms of the study corresponding to these periods.

rate and respiratory rate, since the 95% CI of the effect size corresponding to the effect of intervention measured from the pre-Kangaroo care to the post-Kangaroo care period includes zero.

While Kangaroo care did not affect heart rate and respiratory rate in the post-Kangaroo care period, heart rate variability reduced during Kangaroo care and continued to remain low in the post-Kangaroo care period for both intervention and control days, as can be seen from Table 3 and Figure 5. Figure 5 shows the heart rate variability time series corresponding only to intervention days since heart rate variability was similar in both arms of the study. Note that heart rate variability values were normalised by subtracting the mean value of the first 30 minutes of the pre-Kangaroo care period from the corresponding time series and therefore, in Figure 5, all the time series start around zero. Overall variability (SDNN) changed from 19 ms (13–32) in the pre-Kangaroo care period to 16 ms (10–22) in the post-Kangaroo care period on intervention days, versus from 19 ms (13–28) to 16 ms (12–22) on control days. Values of all features of heart rate variability can be found in Table 3.

With regard to oxygen saturation and temperature, there was no change in response to Kangaroo care (Fig. 4C,D). However, on intervention days, oxygen saturation increased marginally in the post-Kangaroo care period in comparison to the pre-Kangaroo care period. Nevertheless, the effect size was insufficient to create a statistically significant difference between oxygen saturation values in the post-Kangaroo care periods of the intervention and control arms of the study. This can be determined not only from the overlapping 95% CIs in Figure 4C but also from the statistically insignificant difference in the post-Kangaroo care values in Table 2.

DISCUSSION

In this study, we investigated whether an alternative swaddling device used during Kangaroo care, aimed at providing parental scent and heartbeat sounds to preterm infants once back in the incubator, enhanced autonomic regulation as measured by changes in vital signs and heart rate variability on intervention versus control days.

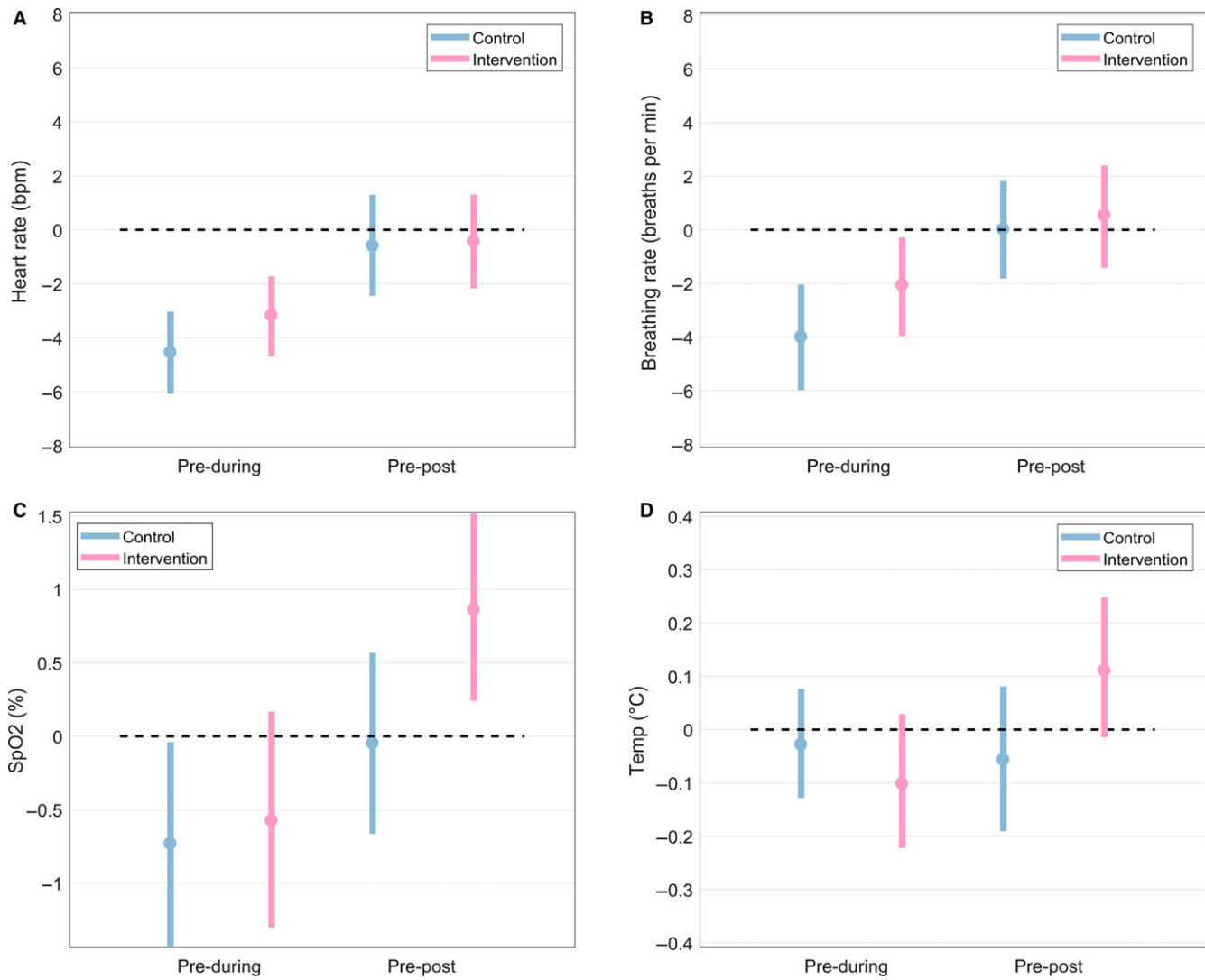


Figure 4 Effect size and confidence interval of vital signs. Differences in heart rate (HR, A), respiratory rate (RR, B), oxygen saturation (SpO2, C) and temperature (D) are illustrated for intervention days (pink) and control days (blue). The effectiveness of Kangaroo care as measured by changes in vital signs from pre-Kangaroo care to during Kangaroo care (pre-during, two left bars) and from pre-Kangaroo care to post-Kangaroo care (pre-post, two right bars) are displayed. When the error bars do not include zero, it points to a statistically significant effect.

Table 3 Heart rate variability in the pre-Kangaroo care, during Kangaroo care and post-Kangaroo care periods

Feature	Pre-KC		During KC		Post-KC	
	Intervention	Control	Intervention	Control	Intervention	Control
SDNN	19 (13–32)	19 (13–28)	16 (11–26)	16 (12–24)	16 (10–22)	16 (12–22)
RMSSD	10 (6–28)	10 (6–23)	9 (6–18)	8 (6–13)	7 (5–13)	7 (5–12)
pDec	46 (41–49)	46 (42–50)	44 (41–48)	46 (42–49)	47 (41–50)	47 (43–50)
SDDec	20 (10–41)	20 (10–36)	19 (9–34)	17 (10–32)	15 (8–28)	15 (10–24)

KC = Kangaroo care; pDec = The percentage of decelerations; RMSSD = Root mean square of successive differences; SDDec = The standard deviation of decelerations; SDNN = The standard deviation of all normal-to-normal intervals.

There were no statistically significant differences in the features of heart rate variability between the intervention and control arms of the study corresponding to these periods.



Figure 5 Time series of the SDNN (A), RMSSD (B), pDec (C) and SDDec (D) during Kangaroo care sessions on intervention days. Normalised mean \pm SEM values are shown for the pre-Kangaroo care period (1–60 minutes), the first and last 30 minutes of Kangaroo care (60–120 minutes) and the post-Kangaroo care period (120–180 minutes). RMSSD = Root mean square of successive differences in heartbeat intervals; SDNN = standard deviation of all normal-to-normal-intervals.

While positive effects of using parental heartbeat and scent in a NICU have been reported previously (7,8,19), this study found no difference in vital signs and heart rate variability during and post-Kangaroo care for intervention and control days, i.e. for Kangaroo care with and without swaddling device. In both arms of the study, Kangaroo care was associated with a reduced heart rate and respiratory rate. In agreement with the literature, these findings may suggest reduced metabolic expenditure during Kangaroo care (20–22). This effect, however, did not remain in the post-Kangaroo care period since both the heart rate and the respiratory rate increased to pre-Kangaroo care values. In contrast, heart rate variability not only reduced during Kangaroo care but remained low in the post-Kangaroo care period on both intervention and control days, suggesting a lasting effect of Kangaroo care. In agreement with previous studies, in this group of preterm infants, decreased heart rate variability also suggests improved autonomic regulation, as demonstrated by a reduction in the extent of decelerations during Kangaroo care (16). Due to immature autonomic regulation, preterm infants are especially prone to transient heart rate decelerations, which remain uncaptured in average measures of heart rate (14,23).

In summary, no changes in vital signs or heart rate variability could be observed in this study where an intervention comprising of the use of a swaddling device during Kangaroo care as opposed to routine Kangaroo care was analysed. In other studies, the sounds of heartbeats were reported to have a calming effect during caregiving procedures as measured by vital signs (8,24). Perhaps the stimuli employed by the swaddling device might have been of an insufficient intensity to overcome the background noise or olfactory stimuli of the NICU (25–27). Furthermore, nasal blockage or the use of masks, tubes and patches meant for respiratory support may hinder the sense of smell in preterm infants. It was not possible to determine whether the olfactory and auditory stimuli provided by the swaddling device were actually sensed by the infant. Another explanation is that the stimuli were of insufficient quality with regard to for instance complexity, dynamicity and synchrony with the infants' rhythm and therefore not effective in affecting regulation. So far, consensus about using pre-recorded heartbeat sounds in NICUs has not been reached. Contrasting findings suggest that the timing, frequency and dynamics of sounds may affect outcomes (28). The swaddling device plays a heartbeat sound that is pre-recorded during Kangaroo care, with the intention to mimic the live

experience. Nevertheless, the simulated heartbeat generated by an oscillating membrane differs substantially from the actual sound of heartbeats and could be a limiting factor in the experience provided to the infant (12). In agreement with a previous study that investigated whether Kangaroo care can be mechanically simulated, this study also suggests that simulating the multisensory experience of Kangaroo care is not easy (18). Whether these limitations in simulating and augmenting Kangaroo care can be attributed to piecewise simulation of Kangaroo care, for instance just mechanical or olfactory stimulation remains an open question. Future work can focus on multisensory stimulation including dynamically titrating the intensity of stimuli in response to the infant's physiological condition. However, until low-cost, safe and reliable approaches for augmenting Kangaroo care can be demonstrated, promoting and facilitating Kangaroo care appears to be the most effective approach to improve autonomic regulation in preterm infants.

CONCLUSION

We investigated the use of an alternative swaddling device that was designed to absorb parental scent and warmth during Kangaroo care and to transfer these stimuli back into the incubator so that they remain available to infants after Kangaroo care. During the post-Kangaroo care period, a pre-recorded heartbeat sound was also played back to the infants. In this study, while Kangaroo care improved regulation, both with and without using the swaddling device, using the device itself showed no evidence of improving regulation as measured by changes in vital signs and heart rate variability.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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