Randomized controlled trial of skin-to-skin contact from birth versus conventional incubator for physiological stabilization in 1200- to 2199-gram newborns

NJ Bergman¹, LL Linley¹,² and SR Fawcus¹,³
Mowbray Maternity Hospital¹, Mowbray; School of Child and Adolescent Health² and Department of Obstetrics and Gynecology³, University of Cape Town, Cape Town, South Africa

Aim: Conventional care of prematurely born infants involves extended maternal–infant separation and incubator care. Recent research has shown that separation causes adverse effects. Maternal–infant skin-to-skin contact (SSC) provides an alternative habitat to the incubator, with proven benefits for stable prematures; this has not been established for unstable or newborn low-birthweight infants. SSC from birth was therefore compared to incubator care for infants between 1200 and 2199 g at birth.

Methods: This was a prospective, unblinded, randomized controlled clinical trial; potential subjects were identified before delivery and randomized by computerized minimization technique at 5 min if eligible. Standardized care and observations were maintained for 6 h. Stability was measured in terms of a set of pre-determined physiological parameters, and a composite cardio-respiratory stabilization score (SCRIP).

Results: 34 infants were analysed in comparable groups: 3/18 SSC compared to 12/13 incubator babies exceeded the pre-determined parameters \( p < 0.001 \). Stabilization scores were 77.11 for SSC versus 74.23 for incubator (maximum 78), mean difference 2.88 (95% CI: 0.3–5.46, \( p = 0.031 \)). All 18 SSC subjects were stable in the sixth hour, compared to 6/13 incubator infants. Eight out of 13 incubator subjects experienced hypothermia.

Conclusion: Newborn care provided by skin-to-skin contact on the mother’s chest results in better physiological outcomes and stability than the same care provided in closed servo-controlled incubators. The cardio-respiratory instability seen in separated infants in the first 6 h is consistent with mammalian “protest-despair” biology, and with “hyper-arousal and dissociation” response patterns described in human infants: newborns should not be separated from their mothers.

Key words: Hypothermia, prematurity, separation, skin-to-skin contact, stability

Nils Bergman, 8 Francis Road, Pinelands 7405, South Africa (Tel. +27 21 6595543, fax. +27 21 6852991, e-mail. bergman@xsinet.co.za)

Conventional care of low-birthweight neonates involves separation of the mother–infant dyad, with the infant being placed in an incubator. In this environment, technology is provided, when available and indicated. The “necessity” for separating the newborn (premature or not) from its mother has been taken for granted in Western society. Biological research has established that the developing organism’s neurobehavioural programme is determined by its “habitat” (1). For most newborn mammals, that habitat is the “maternal milieu”, in which a parasympathetically mediated “nutrition programme” (2) ensures optimal well-being for further development. This programme is mediated by humoral, autonomic and somatic behaviours, expressed ultimately as innate competency in breastfeeding behaviours (1). This mammalian behaviour in the human is documented and described as “self attachment” (3, 4).

Separation from the mammalian maternal milieu results in “protest-despair” behaviours; “protest” being a sympathetically driven behaviour of activity and crying to return to the mother (1, 5), “despair” being a superimposed parasympathetic response, which lowers heart rate and temperature, possibly for prolonged survival (1). Schore (6, 7), summarizing recent human developmental neuroscience research, describes identical sequences, and refers to protest behaviour as “hyperarousal” and despair behaviour as “dissociation” (a hypometabolic state of disengagement). Anderson provides an evidence-based physiological rationale for separation stress in the newborn: crying is much increased, cortisol levels double (8), with every cry right-to-left shunting leads to increased risk of intraventricular haemorrhage, and delayed adaptation to extra-uterine life and maternal infant attachment (9). The effects of separation may be directly and primarily responsible for making outcomes for premature newborns sub-optimal.
Modern neonatal care relies much on the incubator, which provides humidity and temperature regulation for the newborn. The incubator as an intervention compared with any other method of caring for the newborn has never been subjected to a randomized controlled trial (RCT). Part of the reason for this is the lack of any known and feasible alternative.

Kangaroo Mother Care (KMC) provides an alternative to incubator care, without separation from the mother. KMC has been defined as having three components (10): namely, continuous skin-to-skin contact (SSC), breastfeeding, preferably exclusively, and support. In First World contexts, that support may include ventilation, surfactant and more. In Third World contexts, support may express itself as early discharge from hospital to ambulatory care, which is safe in KMC (11). As originally described from Colombia (12), and as generally practised, only infants stabilized after a period of incubator care have been eligible for KMC, with emphasis on early discharge.

Though SSC from birth for low-birthweight infants has not been studied in larger randomized trials, published reports of its use support its safety and efficacy (13–15), and studies with historical controls in Third World contexts (in the absence of incubators) have shown improved survival (16, 17). Beneficial effects in stabilized low-birthweight infants, taken out of incubators days and weeks after birth, include improved thermal regulation (18, 19), adequate cardio-respiratory stability (20) and improved lactation (21, 22). De Leeuw studied very small and non-stabilized infants just after weaning from ventilation, and found SSC to be safe, with a variety of minor physiological benefits for the newborn, but significant benefits for mothers (23). A review on “kangaroo care (skin-to-skin holding)” with regard to five dimensions of neuro-behavioural development found that, in all dimensions, outcomes for SSC were better: “SSC provides a milieu that supports autonomic stability and fosters improvement in basic physiologic functions” (24). A recent Cochrane review on early skin-to-skin contact for healthy full-term infants showed benefits in breastfeeding and various psychometric measures, and no harmful effects (25).

The purpose of this trial was therefore to compare the effect of two alternative habitats, maternal–infant skin-to-skin contact versus the incubator (= separation), starting from birth for low-birthweight neonates, with all other care being standardized. The primary hypothesis was “SSC from birth is superior to incubator care for low birthweight infants between 1200 g and 2199 g”.

Patients and methods
The study was conducted in two secondary level referral hospitals in Cape Town, South Africa, treating indigent public patients referred from Midwife Obstetric Units according to established protocols. The population low-birthweight rate is 18%, and the Perinatal Mortality Rate 30/1000. The “inborn survival rate” (all neonatal admissions to neonatal ward above 500 g) for Mowbray Maternity Hospital during the study period was 95.1% (500 to 999 g 38%; 1000 to 1499 g 92.8%; 1500 to 1999 g 99.3%); similarly at Karl Bremer Hospital.

The study population consisted of mother–infant dyads. Mothers had to be identified as likely to deliver a low-birthweight infant before the actual birth, with enough time to ensure informed consent to the trial, and to gather basic data.

Mothers were excluded if: (1) delivering outside the unit; (2) having Caesarean section; (3) too severely ill to be able to look after themselves or their infants; (4) known to have positive HIV status; (5) giving their babies up for adoption.

Newborns were excluded if: (1) birth weight below 1200 g or above 2199 g; (2) Apgar score below 6 at 5 min; (3) congenital malformations detected at birth.

Basic data on excluded and refusing mother–infant dyads were collected.

At birth, all infants were delivered on to a theatre cloth on the mother’s abdomen/chest, dried gently, assessed for anomalies and for 1-min Apgar score, resuscitated if needed, and then the cord was tied with tape. Infants were weighed, given eye prophylaxis and vitamin K intramuscularly. Thereafter, they were placed naked on the mother’s naked chest, covered with double layered cotton cloth. The bed was put in semi-Fowlers position.

A computerized minimization method determined allocation in a concealed manner to conventional method of care (CMC, control group) or to skin-to-skin contact (SSC, intervention group) (26). Minimization factors balancing potential confounders for the mother were: gravidity, parity, ethnicity, smoking, alcohol use, gestational age by dates, opiates during labour, oxytocin in labour and hypertension in pregnancy. Factors for the infant were gender, actual birthweight and need for resuscitation in the first 5 min. If adequate, the 5-min Apgar score determined eligibility for randomization, and the allocation determined by the computer was immediately implemented. Initially, randomization was done on a laptop computer by the nurse researcher present at the delivery. When the second hospital started enrolment, one nurse researcher kept the computer permanently, and minimization factors and subsequent allocation by the computer were exchanged by mobile telephone, with no delays.

If allocated to SSC, the infant remained in skin-to-skin contact, and third-stage obstetric care continued. Monitor probes were placed, and Apgar score was repeated at 10 min. The infant was secured to the mother’s chest by means of a metre square cotton theatre towel folded diagonally in two. This passed under the infant’s ear, and under the mother’s axillae, in
such a way as to fix the head and chest of the infant in a
sniffing position on the mother’s chest, ensuring optimal
airway and preventing obstructive apnoea. The hips
were flexed and placed in a “frog position”, arms also
flexed. A shirt with long ties around the mother’s waist
secured the baby below. At 60 min, the mother–infant
dyad was transferred to the observation area of the
neonatal unit, and placed in a comfortable recliner, at an
angle of 30 degrees.

If allocated to CMC, the infant was immediately
transferred to a pre-warmed servo-controlled closed
incubator (Air-Shields Isolite Infant Incubator), which
remained with the mother in the delivery ward for the
first hour. If infant temperature was below 36°C, a cap
and booties were fitted and a heat shield placed over the
infant. If that did not suffice, a sheet of plastic was
framed over the foot end of the heat shield and the outlet
of the warm air funnelled over the infant. At 1 h, the
infant in the incubator was transferred to the same
observation area of the neonatal unit, and the mother
moved to the postnatal ward, as per hospital routine.
The mother was allowed to visit and to spend time next
to the incubator. She was also allowed to hold the infant,
though skin-to-skin contact was not permitted in the
first 6 h, as consented prior to randomization.

Apart from the “habitat” (skin-to-skin or incubator),
all subsequent care and observations were strictly
standardized. All infants were given continuous
intravenous neonatal maintenance solution, 60 ml/kg/
d (4.17 mg dextrose/kg/min), started within 30 min, and
the flow controlled by a volumetric infusion
pump. An orogastric tube was placed within the first
30 min, and a gastric aspirate sent for “bubbles test”,
Gram stain and culture. (Chorioamnionitis is a locally
common cause for premature delivery.) Theophylline
was given through the orogastric tube, 5 mg/kg
loading dose, then 1 mg/kg six hourly. When the
gastric aspirate showed evidence of amnionitis (pus
cells, bacteria), Ceftriaxone 75 mg/kg was com-
enced. When oxygen therapy was required, accord-
ing to routine monitoring, this was given by Argyle
nasal cannulae, such that continuous positive airway
pressure (CPAP) could be given via them if indicated.
If the mother and the baby were well, breastfeeding
opportunities were given at 50 min, 3 h and 5 h of age.

For the intervention group, this required loosening
of the shirt. Breastfeeding instruction and support was the
same for both groups, and was provided in a standard
format by the nurse researcher. After the first 6 h, the
controlled part of the study, infants were monitored
according to ward routines. Both groups of mothers
were encouraged to do SSC beyond this period if their
infants were stable. Gestational age was estimated the
following day.

The physiological observations were provided by two
dedicated and regularly calibrated monitors (Dash
3000), which did not interfere with routine manage-
ment, regardless of the allocation. Apart from the
clinical judgment of medical officers (guided by
objective observations, see below), outcome measures
were based on objective readings not subject to inter-
observer variation. The newborn’s heart rate, respira-
tory rate, oxygen saturation and temperature were
observed continuously throughout the period, and
recorded at 5-min intervals in the first hour, thereafter
15-min intervals. Continuous observations for apnoea
and signs of respiratory distress were made, and blood
sugar was measured by heel prick at 1, 3 and 6 h. Room
temperature, maternal temperature and incubator tem-
peratures were recorded.

“Exceeded parameters” were defined as “physiologi-
cal parameters exceeding normal limits, requiring
medical assessment and or intervention”: (1) skin
temperature remaining below 35.5°C for two consecu-
tive recordings; (2) heart rate below 100, or above 180
beats per minute for two consecutive recordings; (3)
apnoea longer than 20 s; (4) O₂ saturation below 87%
for two consecutive recordings, despite supplementa-
tion with nasal prong oxygen, FiO₂ up to 0.6 and CPAP
up to 5 cm water; (5) blood glucose below 2.6 mmol/l,
reading confirmed by laboratory.

The decision parameters of the medical officer to bail
out of the study could not be standardized: if the
medical officer decided that the infant required inten-
sive or high care, no further research recordings were
done.

Fischer et al. developed a “stability of the cardio-
respiratory system in preterm infants” (SCRIP) score
(20). The values of their score were modified to suit
current local practice in the setting units (see Table 1).

Table 1. Stability of the cardio-respiratory system in preterm infants (SCRIP) score.

<table>
<thead>
<tr>
<th>SCRIP *</th>
<th>2</th>
<th>1</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate</td>
<td>Regular</td>
<td>Deceleration to 80–100</td>
<td>Rate &lt;80 or &gt;200 bpm</td>
</tr>
<tr>
<td>Respiratory rate</td>
<td>Regular</td>
<td>Apnoea &lt;10 s, or periodic breathing</td>
<td>Apnoea &gt;10 s Tachypnoea &gt;80 pm</td>
</tr>
<tr>
<td>Oxygen saturation</td>
<td>Regular &gt;89%</td>
<td>Any fall to 80–89%</td>
<td>Any fall below 80%</td>
</tr>
</tbody>
</table>

* Heart rate, respiratory rate and oxygen saturation is monitored continuously during a 5-min period, and scores allocated accordingly, allowing a maximum of 6 points for the period. To gauge the stabilization during the controlled study time, the (5-min) SCRIP was recorded every 30 min after the first hour, but every 15 min during the 6th hour, giving a maximum possible (composite) SCRIP score of 78. To gauge the final stabilization at 6 h, the four periods of 5 min each in the final hour were analysed separately, for a “last hour score” of 24.
bpm: beats per minute; pm: per minute.
Research hypotheses:

H1a At 6 h, SSC group will have fewer NICU admissions than CMC
H1b During the first 6 h, SSC group will have fewer exceeded parameters than CMC
H2a Composite stabilization score 1–6 h better with SSC than CMC
H2b Composite stabilization score in 6th hour better with SSC than CMC.

The sample size for the first hypothesis was 64 (80% power with two-sided significance of 5%) based on estimates from routine care. With the intention of doing subgroup analysis for different weight categories, a sample of 100 was chosen. In the preparatory pilot phase, only infants between 1500 and 1800 g were selected. Due to difficulty in recruitment, this was widened to include 1200–2199-g infants after repeat ethics approval. NICU admissions were monitored on an ongoing basis to ensure safety.

Four nurse researchers were recruited and trained during a pilot phase, during which time logistics were tested and the detailed care and observational protocols were finalized. Three further nurses were trained at the second hospital. It was obviously not possible to blind the participants or the nurse researchers to the intervention, but after the pilot phase, the principal investigator and data analysis team were blinded.

A standard polygraph patient record was completed on each subject. Data from these records were transferred by one nurse researcher to an Excel spreadsheet, and coded. A statistician, blinded to the allocation, performed the statistical analysis. The t-test was used for continuous variables, and the $\chi^2$ test was used for proportions; the same for subgroup analysis.

Ethical approval was obtained from the University of Cape Town and the Medical Research Council of South Africa.

Results

Patients were recruited between February 2001 and September 2002. The logistics of having a nurse researcher present at the actual birth of potentially eligible mothers were far more difficult than originally anticipated. During this period, there was a major loss of qualified nurses in the two hospitals due to migration to Europe and the Middle East. This meant an increased workload, with a resultant decreased ability and willingness to cooperate from the remaining labour ward staff. By the end of the study period, only one nurse researcher remained, and recruitment came to a standstill. An interim analysis was therefore done, after which recruitment was terminated, based on significant results. The intention had otherwise been to recruit junior doctors to continue the study.

The flow of participants is presented in Fig. 1. Twenty-nine subjects were recruited at Mowbray Maternity Hospital, and six subjects at Karl Bremer Hospital. Twenty-one were randomized to SSC (one excluded after 2 h when the mother required a Caesarean section for a second twin) and 14 to CMC. This difference in group size was not expected, the initial cases were predominantly allocated to SSC.

The baseline characteristics are presented in Table 2 and Fig. 2. The SSC babies were on average 40 g smaller and 1 wk younger, but this was not statistically significant.

The results of the first two hypotheses are presented in Table 3. While there was no statistical difference in NICU admissions, there were significant differences in subjects exceeding physiological parameters; 3/18 SSC compared to 12/13 CMC. Two SSC subjects and one CMC subject did not complete the study period of 6 h; all bailed out within the first 3 h. The three babies who “bailed out” required additional respiratory support. The protocol was that CPAP should be given, when needed. All three warranted CPAP, but night-call
doctors unfamiliar with the study moved them to the NICU. They were nevertheless unstable, and are included as bailouts for the purposes of the study. The two SSC babies received surfactant, and all three subsequently did well.

Eighteen subjects in SSC and 13 in CMC completed the 6-h study period, allowing SCRIP scores to be allocated (see Table 4). The mean score was significantly higher in the SSC group, with 10/18 being fully stable throughout compared to 2/13 of the CMC group. All of the SSC group had perfect stabilization scores after 5 h of skin-to-skin contact, compared with less than half the incubator group.

The mean of the SCRIP score at each recording interval was compared in the two groups (see Fig. 3). It is noteworthy that the SSC group was more stable throughout and was completely stable by 6 h, while the CMC group remained less stable throughout the 6-h period. An exploratory sub-analysis of the SCRIP score of infants between 1200 g and 1799 g was done (see Table 5, Fig. 4). Despite the smaller sample size, the statistically significant differences remain.

The main contributor to exceeded parameters of CMC infants was hypothermia, followed by hypoglycaemia and respiratory problems. A more detailed analysis of the temperatures is shown in Fig. 5. Care

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**Table 2. Baseline demographic and clinical characteristics.**

<table>
<thead>
<tr>
<th></th>
<th>SSC (n = 20)</th>
<th>CMC (n = 14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruited Mowbray</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td>Recruited Karl Bremer</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td><strong>Maternal</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gravidity (mean)a</td>
<td>1.9</td>
<td>1.9</td>
</tr>
<tr>
<td>Parity (mean)a</td>
<td>1.8</td>
<td>1.6</td>
</tr>
<tr>
<td>Race Africana</td>
<td>8</td>
<td>40%</td>
</tr>
<tr>
<td>Race Coloureda</td>
<td>12</td>
<td>60%</td>
</tr>
<tr>
<td>Smoking in pregnancya</td>
<td>7</td>
<td>35%</td>
</tr>
<tr>
<td>Alcohol usea</td>
<td>6</td>
<td>30%</td>
</tr>
<tr>
<td>Opiate in laboura</td>
<td>9</td>
<td>45%</td>
</tr>
<tr>
<td>Hypertensiona</td>
<td>3</td>
<td>15%</td>
</tr>
<tr>
<td>Antepartum steroids</td>
<td>5</td>
<td>25%</td>
</tr>
</tbody>
</table>

**Neonatal**

|                        |              |              |
| Gender baby (male)b    | 12           | 60%          |
| Resuscitation babyb    | 4            | 20%          |
| Mean birthweight (g)a  | 1813 (260)   | 1866 (258)   |
| Mean gestation age (GA)| 34.2 (1.9)   | 35.3 (1.9)   |
| Appropriate for GA     | 13           | 65%          |
| Small for GA           | 7            | 35%          |

|                        |              |              |
| Minimization factors   |              |              |
| No statistical difference for any characteristic. |

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**Table 3. Outcomes of transfers and exceeded parameters.**

<table>
<thead>
<tr>
<th></th>
<th>SSC (n = 20)</th>
<th>CMC (n = 14)</th>
<th>( \chi^2 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>H1a Transferred to NICU</td>
<td>2</td>
<td>1</td>
<td>0.773</td>
</tr>
<tr>
<td>(10%)</td>
<td></td>
<td>(7%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>H1b Exceeded parameters</td>
<td>3</td>
<td>12</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>(17%)</td>
<td></td>
<td>(92%)</td>
<td></td>
</tr>
<tr>
<td>Temperature &lt;35.5°C</td>
<td>1</td>
<td>8</td>
<td>0.006</td>
</tr>
<tr>
<td>Heart rate &lt;100, &gt;180 bpm</td>
<td>0</td>
<td>0</td>
<td>n.s.</td>
</tr>
<tr>
<td>Apnoea &gt;20 s</td>
<td>0</td>
<td>1</td>
<td>n.s.</td>
</tr>
<tr>
<td>Oxygen saturation &lt;89%</td>
<td>1</td>
<td>0</td>
<td>n.s.</td>
</tr>
<tr>
<td>Blood glucose &lt;2.6</td>
<td>1</td>
<td>3</td>
<td>0.02</td>
</tr>
</tbody>
</table>

**Table 4. Outcomes of SCRIP scores.**

<table>
<thead>
<tr>
<th></th>
<th>SSC (n = 18)</th>
<th>CMC (n = 13)</th>
<th>Mean difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCRIP first 6 h (mean)</td>
<td>77.11</td>
<td>74.23</td>
<td>0.031 (2.88)</td>
</tr>
<tr>
<td>(standard deviation)</td>
<td>1.23</td>
<td>4.19</td>
<td></td>
</tr>
<tr>
<td>Number perfect score</td>
<td>10 (56%)</td>
<td>2 (11%)</td>
<td></td>
</tr>
<tr>
<td>(standard deviation)</td>
<td>0</td>
<td>1.22</td>
<td></td>
</tr>
<tr>
<td>SCRIP in 6th hour (mean)</td>
<td>24.0</td>
<td>23.0</td>
<td>0.012 (1.00)</td>
</tr>
<tr>
<td>(standard deviation)</td>
<td>1.23</td>
<td>4.19</td>
<td></td>
</tr>
<tr>
<td>Number perfect score</td>
<td>18 (100%)</td>
<td>6 (46%)</td>
<td></td>
</tr>
</tbody>
</table>

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**Fig. 2.** Gestational age and birthweights of subjects.

**Fig. 3.** Average SCRIP scores through study period.
until randomization was done on the mother, who functioned as a heat source, constant for both groups. The labour ward temperatures were constant throughout the study, and the incubators were pre-warmed, with mean temperature readings of 36.0°C at commencement, increasing thereafter. Despite this, there was a profound and consistent hypothermia in the separated newborns.

There were no adverse events related to the intervention.

<table>
<thead>
<tr>
<th>SCRIP</th>
<th>SSC (n = 9)</th>
<th>CMC (n = 4)</th>
<th>t-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCRIP first 6 h (mean)</td>
<td>76.67</td>
<td>71.75</td>
<td>0.049</td>
</tr>
<tr>
<td>(standard deviation)</td>
<td>1.5</td>
<td>6.65</td>
<td></td>
</tr>
<tr>
<td>Number perfect score (78)</td>
<td>4 (44%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>SCRIP in 6th hour (mean)</td>
<td>24.0</td>
<td>22.25</td>
<td>0.008</td>
</tr>
<tr>
<td>(standard deviation)</td>
<td>0</td>
<td>1.71</td>
<td></td>
</tr>
<tr>
<td>Number perfect score (24)</td>
<td>9 (100%)</td>
<td>1 (25%)</td>
<td></td>
</tr>
</tbody>
</table>

Discussion

This study compared newborns given identical clinical care except for the place or “habitat”, and provides evidence that the habitat of the maternal milieu in skin-to-skin contact immediately after birth is safe, and in fact superior, to the habitat of the incubator, for newborns 1200 g to 2199 g. Newborns receiving skin-to-skin contact from birth were significantly advantaged in two alternative measures of cardio-respiratory stability. Similar temperature differences have been demonstrated in healthy full-term newborns cared for skin-to-skin or in a cot (27). With respect to the underlying scientific rationale, the hypothermia and cardio-respiratory instability seen in this first critical period of life are consistent with effects of maternal–infant separation: the mammalian “protest-despair” (1) and the “hyper-arousal and dissociation” response patterns described in human research (7).

The possibility of selection bias exists: many prematurely born infants delivered quite unexpectedly (without a nurse researcher available), and the aetiology of such premature delivery may differ from those studied. The expected bailout rate in both groups was lower than that predicted, and is possibly a direct result of closer observation and attention to treatment detail, which was strictly controlled. The findings from the stabilization scores, despite the small sample size, can probably be generalized to all infants between 1200 g and 2199 g.

Approximately 96% of the world’s premature infants are born in the Third World (28), with no incubators available. With no known acceptable alternative, many of these infants succumb before they stabilize, the major portion within the first 48 h (29). Skin-to-skin contact from birth has been shown by this study to be a safe alternative, and should therefore be implemented urgently in the Third World. It may be a better alternative in First World settings, also.

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The authors declare they have no conflict of interest.
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