The Effect of Skin-to-Skin Contact (Kangaroo Care) Shortly After Birth on the Neurobehavioral Responses of the Term Newborn: A Randomized, Controlled Trial

Sari Goldstein Ferber, PhD*, and Imad R. Makhoul, MD, DSc‡

ABSTRACT. *Background.* **The method of skin-to-skin contact (kangaroo care [KC]) has shown physiologic, cognitive, and emotional gains for preterm infants; however, KC has not been studied adequately in term newborns.**

Aims. **To evaluate the effect of KC, used shortly after delivery, on the neurobehavioral responses of the healthy newborn.**

Study Design. **A randomized, controlled trial using a table of random numbers. After consent, the mothers were assigned to 1 of 2 groups: KC shortly after delivery or a no-treatment standard care (control group).**

Subjects. **Included were 47 healthy mother-infant pairs. KC began at 15 to 20 minutes after delivery and lasted for 1 hour. Control infants and KC infants were brought to the nursery 15 to 20 and 75 to 80 minutes after birth, respectively.**

Results. **During a 1-hour-long observation, starting at 4 hours postnatally, the KC infants slept longer, were mostly in a quiet sleep state, exhibited more flexor movements and postures, and showed less extensor movements.**

Conclusions. **KC seems to influence state organization and motor system modulation of the newborn infant shortly after delivery. The significance of our findings for supportive transition from the womb to the extrauterine environment is discussed. Medical and nursing staff may be well advised to provide this kind of care shortly after birth.** ***Pediatrics*** **2004;113:858–865;** ***skin-to-skin contact, kangaroo care, birth, neurobehavior, newborn infant.***

ABBREVIATIONS. KC, kangaroo care; C-section, cesarean section; ANOVA, analysis of variance; CNS, central nervous system.

The transition from fetal to neonatal life represents one of the most dynamic and potentially hazardous events in the human life cycle. The initial postnatal period is characterized by high levels of stress, as exemplified by levels of catecholamines and cortisol secretion[1–3] and comparatively labile neurobehavioral regulation.[4] Therefore, methods that may enhance stabilization of neural, behavioral, and state regulation and facilitate the adaptation of the infant to the outside world might be clinically useful. The current study was designed to test the effect of a behavioral method known as skin-to-skin contact (kangaroo care [KC]), used as a postdelivery facilitation of the neurobehavioral self-regulatory responses of the term infant.

The 5 key dimensions of neurobehavioral adaptation described in the literature[5–8] are autonomic, motor, state, attention/interaction, and self-regulation, each regarded as a subsystem interacting with the other, all of which the infant aims to regulate. The degree of a newborn's effectiveness to modulate behavior at a given moment reflects the degree of differentiation and quality of modulation of interaction among the different subsystems. Eventually, the subsystems achieve a relative degree of stable integration and work as a modulated ensemble, which in turn serves as an index for maturation[9,10] and the basis for the next step of differentiation. For example, Ludington et al[11] found increased frequency of quite sleep and reduced activity level during skin-to-skin contact compared with pre- and posttreatment periods, suggesting a better energy conservation as a result of a modulated interplay between the 2 subsystems in the treated preterm infants.

Self-regulation, the index for differences in the level of the neurobehavioral organization in newborns, is expressed in the observable strategies the infant appears to use. This is aimed to maintain a balanced, relatively effective equilibrium of subsystem integration; otherwise, the infant persists in more labile subsystem imbalance and fluctuation that is considered more costly both autonomically and interactively.[4,10,12,13] The term "self-regulation" is widely used to identify infant adaptation to various internal and external stimuli and to unstable situations. The development of infant self-regulation involves the regulation of physiologic systems,[14] information processes,[15] and the formation of attachment bonds[16] and ultimately determines how the infant responds cognitively and social-affectively to the environment. Self-regulation develops in the newborn within the womb and throughout the birth process, and it is especially challenged during the first hours and days after delivery.[13]

Skin-to-skin contact, the normal mammalian postnatal condition,[17–23] has been found to improve infant state organization, thermal regulation, respiration, and oxygen saturation, reduce apnea and

From the *Department of Nursing, Faculty of Social Welfare and Health Studies, University of Haifa, Haifa, Israel; and ‡Department of Neonatology, Meyer Children's Hospital, Rambam Medical Center, and B. Rappaport Faculty of Medicine, Technion, Haifa, Israel.

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Address correspondence to Sari Goldstein Ferber, PhD, Department of Nursing, Faculty of Social Welfare and Health Studies, University of Haifa, Mount Carmel Haifa 31905, Israel. E-mail: sarig@research.haifa.ac.il

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bradycardia, increase milk production, accelerate weight gain, and quicken hospital discharge. Since the KC method was first introduced for preterm infants in Bogota, South America,[24] this form of skin-to-skin contact has been found furthermore to improve state regulation, neurobehavioral status, and autonomic maturation in preterm infants surviving to term age.[25–34]

KC is supposed to help the newborn regulate himself/herself in the presence of incoming information from the outside world,[32,35–37] suggesting that maternal contact could establish a protective function by raising the infant's regulatory threshold for aversive stimuli in the environment. This protective function in turn seems to promote attention and exploration. In support of this view, Feldman et al[32] found that preterm infants, treated with KC before term, by 3 months of age cried only during the more aversive stimuli as compared with controls who did not experience KC.

The effects of KC seem to persist beyond the time period of KC provision. After KC, preterm infants slept longer, their sleep was better organized and restful,[38] and the sleep-wake cyclicity was more mature at term age.[32] Infant alertness was also improved,[39] which is rather important for the development of attention processes and intake of outside information in infancy. In addition, longer duration of breastfeeding was found in KC dyads.[40]

Few studies have reported the use of KC shortly after birth, and it is not being widely used with term infants. Compared with controls who were not held after birth, newborn infants treated with KC shortly after birth had their temperature more readily well maintained,[40–43] had higher blood glucose levels while none of the subjects were fed,[43] and significantly decreased crying 60 minutes postbirth.[43] It was also found that KC functioned as an analgesic intervention in term newborns during the heel-lance procedure.[44] Studies from another laboratory have shown that maternal touch by massage rather than by holding in the postnatal period also was beneficial in terms of improved weight gain in preterm infants[45] and in maturation of circadian rhythms and melatonin secretion in term infants.[46]

In a recent review and meta-analysis on KC,[47] it was concluded that KC after birth has a positive effect on long-term breastfeeding in term dyads and that the temperature of the healthy, newly delivered infant will remain in a safe range, provided ventral-to-ventral KC is uninterrupted and the infant is thoroughly dried and covered across the back.

To date, self-regulation and neurobehavioral responses in the term newborn infant after KC in the early postnatal period have not been reported yet. We hypothesized that KC would be superior to standard care in terms of neurobehavioral responses of newborns after birth. Thus, the aim of this study was to investigate the effect of KC experienced shortly after birth on self-regulation and neurobehavioral expression of the term newborn during the first postnatal hours.

METHODS

Participants

Design

Fifty successively born infants and their mothers were recruited at a large urban medical center in northern Israel and were assigned randomly as dyads to 1 of 2 groups: a treatment group (KC) and a control group of standard care. We calculated that a sample size of 28 mother-infant dyads is sufficient to show a significant effect of the intervention with a power of 80% and 5% risk of type α error.[48] This calculation was based on the effect size found in temperature regulation between term infants held in KC postbirth and controls who were put in cots ($P < .001$).[43] Because the present study is innovative in terms of its outcome measures, we used the variable, which was in maximum proximity to our outcome measures to calculate the projected sample size. We opted to increase the sample size to 50 by taking into consideration a possible refusal rate, exclusion of subjects due to cases of developing fetal distress, and the fact that this study included investigation of infant regulation in >1 facet within 1 model, as compared with the research that served for the basic calculations of the sample size.

Randomization Process

After obtaining consent from mothers at admission to the delivery room, they subsequently were assigned to either study or control groups. Randomization was accomplished by using a table of random numbers. The generator of the study was a different person than executor of group assignment. Mothers were blind to each other's group assignments, because they spent all delivery stages' time in separate delivery rooms.

Inclusion Criteria

Inclusion criteria included healthy mothers with singleton pregnancies and documented prenatal care who were admitted at term (38–42 weeks' gestation) to the hospital delivery room with early uterine contractions and entering stage 1 of an anticipated spontaneous vaginal delivery.

Exclusion Criteria

Exclusion criteria included mothers who showed signs of fetal distress during labor, required cesarean (C)-section, or had fetuses with estimated weights <10th percentile for gestational age. There were no instances of exclusion from the study on the basis of decision to perform C-section. Three of the mothers assigned to the control group were drawn from the study later due to the development of fetal distress. The study population consisted of the remaining 47 mothers who met the study-selection criteria: 25 in the treatment group and 22 in the control group. The research protocol was fully approved by the institutional review board for research with human subjects.

Procedure

Shortly after birth, all newborns were placed on their mother's chest for 5 to 10 minutes while the umbilical cord was cut and the placenta was delivered. All infants then were taken out of the delivery room, dried, put on a scale naked, and then dressed. The experimental group infants then were brought back to their mothers (15–20 minutes after birth), who remained in the delivery room for the intervention period. The control group infants were taken to the newborn nursery while their mothers were offered to rest in the recovery room for 1 hour. Two hours after delivery, all mothers were taken to their postpartum rooms. The treated infants were taken to the nursery after conclusion of the treatment.

Treatment

In the intervention condition the treated infants were undressed and placed between the mothers' breasts, with the infant's head close to mother's neck and the infant's feet on her abdomen. Mothers were bedded comfortably in a fully recumbent position on the delivery bed in the delivery room. The room was a labor-delivery room designed and equipped for all stages of delivery until birth but not equipped for C-sections, which were conducted in a different room. In case of urgent decisions about C-sections (which were not apparent in this study), the mother was brought

to the operation room. The mother was regularly in the labor-delivery room from the time of admission until her infant was born. Near her delivery bed, an armchair was placed for the father, who could share with her all stages of delivery. Recovery time was spent in a different, near-by room. Room temperature was kept steady at 25°C. The room was maintained at a calm, low sound level throughout skin-to-skin holding. Mother and infant were lightly covered with blankets across the infant's back for the duration of KC to assure maintenance of infant body temperature. Mother and infant remained thus in KC in the delivery room for 1 hour. Fathers were allowed to stay in the delivery room for the duration of the study.

Preobservation Pathway

All infants were brought to the newborn nursery (15–20 minutes after birth in the controls and 75–80 minutes after birth in the treatment group). They were placed under a warmer set to 37°C for ~5 to 10 minutes, bundled, and laid in their bassinets covered with a blanket and a warm sheet. This warming and dressing procedure took place for all experimental group infants after conclusion of the KC phase. During the 4 hours after birth, all infants were given routine care including bathing and vaccinations in both thighs: vitamin K and hepatitis B virus. Temperature was measured rectally, and infants were examined by a pediatrician. None of the infants was fed before initiation of the experimental intervention and subsequent observations (the nursery's policy consists of providing the first feed 6 hours postnatally). All were brought to their mothers' rooms 5 hours postnatally.

Observation

The assessment of outcome took place for all infants, the control and experimental group, 4 hours after delivery and consisted of one 60-minute behavioral observation. All observations were conducted by 2 trained researchers who had established an interrater reliability of 98% per behavioral category and per 2-minute sampling block with the research coordinator, who in turn had been trained formally by one of the established training centers for the methodology employed in the United States. Interrater reliability was maintained by co-observation of 10 nonstudy infants evenly distributed throughout the data-acquisition phase.

The observers were blind to the group assignment of the infant at the time of observation. Staff members in the nursery were also blind to group assignment at the time of observation. The methodology used derived from the Naturalistic Behavioral Observation of the Newborn Infant, which is an ingredient of the Newborn Individualized Developmental Care and Assessment Program.[4,9,49,50] In the present study, the observation methodology was used as a behavioral recording tool. The method provides a comprehensive list of specific behaviors spanning all neurobehavioral subsystems of autonomic, motor, state, and attentional regulation in their simultaneity as exhibited by the infant at the time of observation. The recording sheet consists of 74 items including autonomic behaviors such as respiration and skin color; tremors, startles, and twitches; visceral functions such as spit-up and burp, sigh, gasp, and hiccough; motor system behaviors representing muscle tonus and position including tucked versus extended movements and positions, squirms, arching, and stretches; facial behaviors such as tongue extension, hand on face, gape face, mouthing, sucking, and grimacing; and observation of sleep states including restful levels of sleep and their disorganized unsteady counterparts as well as attention-related behaviors such as yawn, open face (eye brow raising), averting, locking look, and frowning. Six state levels are defined according to Brazelton and Nugent,[51] with 6 additional analogous states of diffuse disorganized nature[4,46] as follows: quiet sleep (state 1), active sleep (state 2), drowsy (state 3), alert wakefulness (state 4), actively aroused wakefulness (state 5), and very upset/crying (state 6). Each observation sheet accommodates 10 minutes of observation time, organized in five 2-minute continuous sampling columns.[4]

The behavioral observations, conducted for 60 minutes, thus yielded a maximal frequency count of 30 per behavior. All infants were observed in prone position on a warmer. The infant's legs were uncovered, and the upper body was dressed in an open shirt, allowing the infant to move freely and the observer to identify closely gestures and small movements.

Statistical Analysis

Behavioral items were first combined into a priori "clusters" according to 1 of the 5 neurobehavioral subsystems underlying the methodology. Within each subsystem they were subgrouped further into regulation and disorganization behaviors. This yielded 10 behavioral categories or clusters. Each behavior's frequency within a cluster was prorated to the length of observation of 60 minutes, (ie, 30 possible observation instances multiplied by the number of behaviors included in a cluster).

The clusters were labeled as follows: 1) optimal respiration measure, defined as the number of regular respiration scores (divided by 30); 2) motor disorganization score, which is the number of tremors, startles, facial twitches, body twitches, and extremities twitches (divided by [30 × the number of motor disorganization types]); 3) visceral stress response, which is the number of spit ups, gags, burps, hiccoughs, bowel movement grunts, sighs, and gasp counts (divided by [30 × 7]); 4) optimal flexed movements score, which is the number of flexed arms and legs, smooth movements of arms, legs, and trunk, hand clasp, foot clasp, hand to mouth, grasping, holding on, and fisting scores (divided by [30 × 11]); 5) extension movement score, which is the number of flaccid arms and legs, stretch drown, diffuse squirms, arcs, finger splay airplane postures, salute, and sitting on air scores (divided by [30 × 9]); 6) facial movement score, which is the hand on face, mouthing, smile, and sucking scores (divided by [30 × 4]); and 7/8) sleep states scores, including the length of time in each state. In case there was no scoring for a particular state, the score of zero was given. The time in sleep states and the time in transitional, fussy, and crying states then were combined into a nonawake state score and diffuse state score: 9) positive attention signs, the face open, cooing, and speech movements counts (divided by [30 × 3]); and 10) negative attention signs, the fuss, yawn, sneeze, eye floating, ooh face, frown, avert, and locking counts (divided by [30 × 8]). Multivariate analysis of variance (ANOVA) was used to compare the global profiles between the 2 groups. Posthoc analyses used ANOVA to compare the resultant prorated cluster scores between groups.

RESULTS

Tables 1 and 2 show the sample description. There were no significant differences in any of the variables measured.

Multivariate ANOVA revealed a significant difference between the profiles of the 2 groups (Wilks' λ $F[10,36] = 2.39$; $P = .02$). Table 3 shows means and SDs of each cluster in the 2 groups. ANOVA between the behavioral clusters for the control and experimental groups revealed a significant group difference in sleep states. The treated infants spent more time in sleep states ($F[1,45] = 5.90$; $P = .019$) and less in transitional, fussy, crying, and alert states ($F[1,45] = 6.75$; $P = .019$), as compared with the control newborns (Figs 1 and 2). Posthoc comparisons of the 2 sleep states (quiet and active) separately revealed that the treated infants spent more time in quiet sleep ($F[1,45] = 8.96$; $P = .0045$) than the controls. In addition, significant differences were found between groups in the optimal flexed movements score ($F[1,45] = 4.82$; $P = .033$) and the extended move-

TABLE 1. Sample Description and Potentially Intervening Variables: Variables Analyzed by *t* Tests

Variable	Control (Mean ± SD)	Study (Mean ± SD)	*P*
Maternal age, y	28.9 ± 5.75	27.56 ± 5.22	.45
Paternal age, y	33.95 ± 5.25	32.84 ± 7.54	.12
Gestational age, wk	40.0 ± 1.04	40.0 ± 1.24	.98
Length of time at labor, h	0.36 ± 0.27	0.33 ± 0.16	.60
Birth weight, g	3440 ± 0.47	3450 ± 0.42	.94

TABLE 2. Sample Description and Potentially Intervening Variables: Variables Analyzed by χ^2 Test

Variable	Control Group	Study Group	*P*
	n (%)		
Ethnic origin			
European	8 (36.4)	8 (32)	.88
African	4 (18.2)	6 (24)	
Arab	10 (45.5)	11 (44)	
Religion			
Jewish	11 (50)	14 (56)	.92
Moslem	8 (36.4)	8 (32)	
Christian	3 (13.6)	3 (12)	
Type of living			
Village	3 (13.6)	4 (16)	.496
City	16 (72.7)	20 (80)	
Settlement	3 (13.6)	1 (4)	
Maternal education			
Elementary	2 (9.1)	1 (4)	.28
High school	5 (22.7)	11 (44)	
Academic	15 (68.2)	13 (52)	
Socioeconomic status			
Low	2 (9.1)	1 (4)	.70
Medium	11 (50)	12 (48)	
Medium-high	7 (31.8)	11 (44)	
High	2 (9.1)	1 (4)	
Newborn gender			
Male	8 (36.4)	13 (52)	.28
Female	14 (63.6)	12 (48)	

ments score ($F[1,45] = 4.20$; $P = .046$). The treated children exhibited more flexed and less extended movements and postures, compared with the controls (see Figs 3 and 4). The other clusters studied were not significantly different between the KC and control groups.

DISCUSSION

The results of this study show that KC may be beneficial for term infants after delivery. It contributes to the infants' efforts to regulate themselves in terms of motor system balance and sleep organization during the transition from the womb to the extrauterine environment. Treated infants exhibited more flexed and less extended movements and positions and maintained restful sleep longer, when compared with the control group infants, who were more frequently in transient diffuse states including crying and displayed more extended movements and gestures. As noted by others,[32,38–39] even in premature infants, the skin-to-skin effect persisted after contact itself was terminated and was apparent 4 hours later.

For 85% to 90% of newborns, transition from fetal to neonatal life is a time of rapid physiologic change. Much of the work of transition is accomplished in the first 4 to 6 hours after delivery. During that time, most fetal lung fluid is absorbed, a normal functional residual lung capacity is established, and the heart sustains steady cardiac output.[52] The results of this study suggest that, for the healthy newborn infant, much effort in the first 5 hours after delivery in current postpartum settings engenders a high degree of motor activity and arousal as well as state fluctuations. Balanced regulation of motor activity and state control seems to depend more on environmental stimuli than on the cardiac and respiration adjustment only. These domains seem to be very sensitive to maternal facilitation.

Sleep occurs in the newborn for 70% to 80% of the time[33,34,53] and is the normal response after birth. Recent reports addressed the issue of the quiet sleep during the first day after birth and interpreted this state as a newborn adaptive response to the stress of the birth.[54] Thus, maintenance of quiet sleep in the treated infants may suggest that maternal touch during KC may enhance a competent response in the newborn infant, which is an adaptive healthy behavior. Because the sleep-wake cycle of the newborn is characterized by 50% of rapid eye movement sleep (ie, active sleep, state 2),[55] and quiet sleep implies better control of the brainstem,[56] the maintenance of quiet sleep by the treated infants may suggest a tighter, more effective shield in the face of the birth-induced stress and against environmental disturbances. As outlined earlier, this tighter shield or more effective "stimulus barrier"[57] is regarded as a result of maternal touch, which in other studies has been shown to be associated with better cognitive capacities, exploration, and attention in later development.[34,36,37,58,59] The results of this study thus lend additional support for the proposition that links KC to improved state regulation.[32,60]

KC, as a mode of soothing containing maternal touch, seems to result in better central nervous system (CNS) control by reduction in stress experience for the infants, as also reflected in the smoother and more flexed movements. Extensor movements have been demonstrated to indicate less mature CNS control and are observed frequently in preterm infants.[61,62] Their relative disappearance in well-developing, term infants is considered an index of CNS maturation. This index has been variously demonstrated to be brain based and associated with distinct patterns of visual evoked responses during extensor movements at term, which were found to decrease as a function of gestational ages at birth.[63] Thus, we suggest that KC may act to facilitate the first phases of neurologic adaptation after birth to the extrauterine world. The results of the study support those of others who found that KC effects decrease the amount of purposeless movements[64] and that developmental care reduces the degree and amount of extensor responses.[61–62,65]

In addition, the contribution of KC in lowering the stress experienced postpartum seems to be reflected specifically by the increase in active flexor motor responses. This suggestion is in line with the findings of lower levels of cortisol after touch treatment[66] and more extended movements as an expression of pain during invasive procedures likely to evoke distress.[67]

Because touch therapy has been shown to improve motor maturity in preterm infants,[68] it is also possible that maternal touch in the form of skin-to-skin contact in KC may be particularly beneficial to the regulation of motor activity in the newborn period. This is in keeping with the theoretical perspective that the developing organism evolves toward increasingly more controlled and smoother integration of the tension between the 2 basic antagonists underlying all behavioral development (ie, the approach-

TABLE 3. Neurobehavioral Responses in the Treatment (KC) and Control Groups During a 1-Hour Observation in the Fifth Hour Postnatally

Variable	KC Group	Control Group	*P* Value
Optimal respiration measure	0.99 ± 0.008	0.98 ± 0.09	.288
Motor disorganization score	0.05 ± 0.02	0.04 ± 0.03	.590
Visceral stress response	0.002 ± 0.01	0.002 ± 0.005	.887
Optimal flexed movements score	0.38 ± 0.06	0.33 ± 0.09	.034
Extension movement score	0.10 ± 0.06	0.14 ± 0.05	.046
Facial movement score	0.15 ± 0.10	0.75 ± 2.73	.265
Sleep states score	20.96 ± 9.90	14.40 ± 8.38	.019
Drowsy, fussy, and crying states	3.44 ± 6.57	4.18 ± 4.05	.012
Positive attention signs	0.002 ± 0.005	0.002 ± 0.01	.798
Negative attention signs	0.04 ± 0.04	0.05 ± 0.05	.571

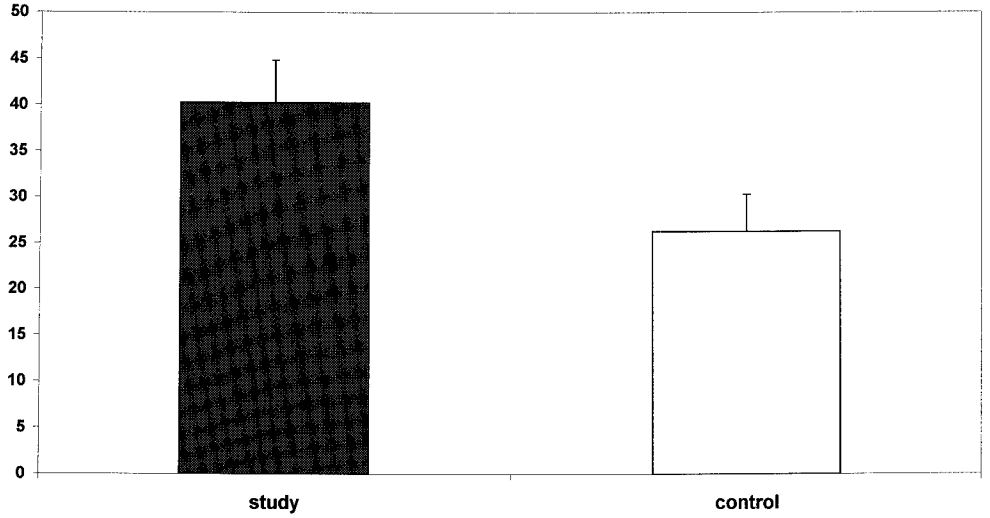


Fig 1. Combined deep and light sleep states score: differences between treated and control infants.

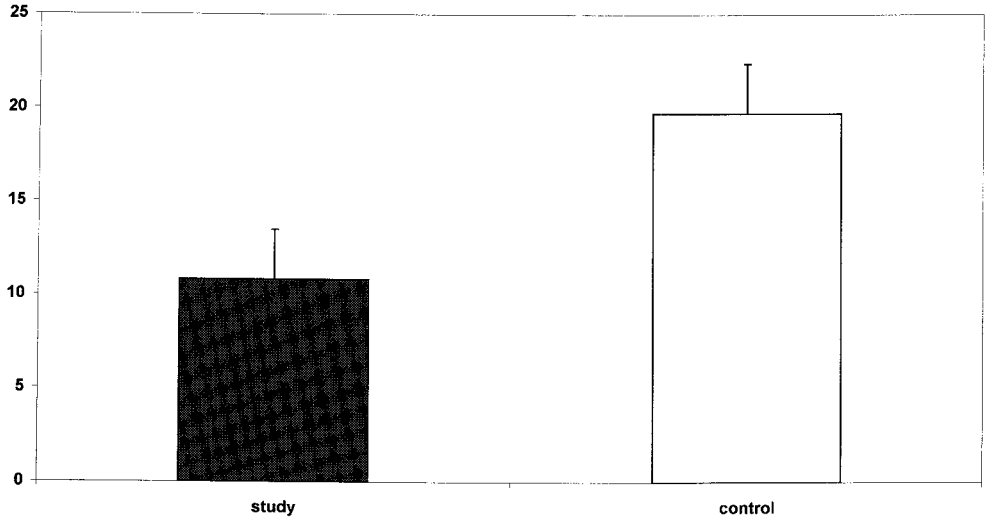


Fig 2. Combined diffuse sleep states (drowsy, fussy, and crying) score: differences between treated and control infants.

ing and withdrawing responses observed in the newborn period). These 2 response poles are, at times, released together and contradict one another, creating the basis for purposeless movements, which appear agitated and restless and are costly for the infant.[4,69,70] Other subsystems such as state organization seem to react in the same manner, with collision among subsystems, which results in the increased probability of poorer state control and more extensor movements.[4] It is possible that, after KC, collision between subsystems may be reduced significantly, as shown by the reduced rate of costly responses such as fussy, transitional, and crying states in our treated infants as well as the lower incidence of extensor purposeless movements. It therefore is contended that the treatment might facilitate the infant's self-regulation and promote more biologically cost-effective use of internal resources.

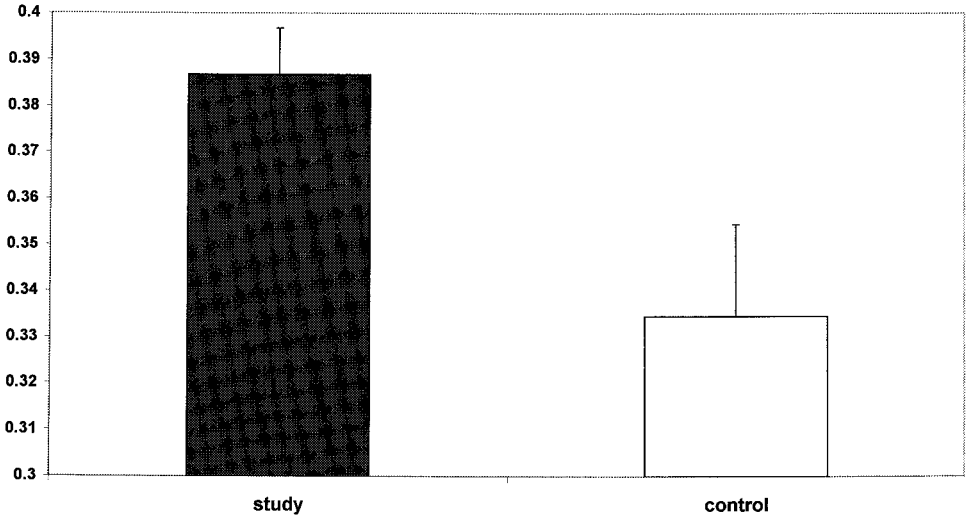


Fig 3. Optimal flexion score: differences between treated and control infants.

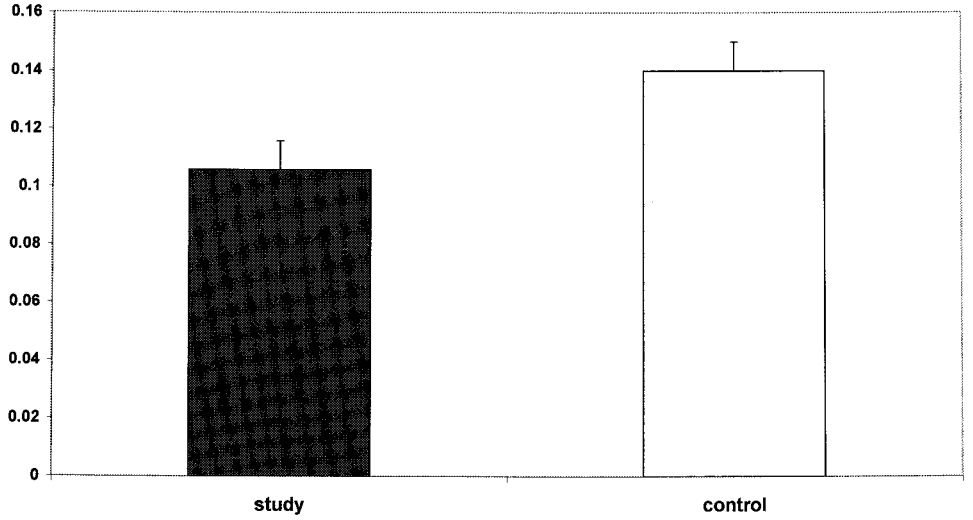


Fig 4. Extended movements score: differences between treated and control infants.

A second key aspect of the theoretical perspective underlying the methodology used views the adaptive task for the newborn in achievement of phase synchrony between periodicities that characterize the subsystems' integration. Although poorly timed stimuli penetrate and disrupt the subsystems, smooth regulation and appropriately timed stimuli seem to maintain and enhance functional integration and support the task of rendezvous with the extrauterine environment.[5–7,71,72] Therefore, providing KC after birth as the first experience of the newborn is an appropriate kind of stimulation. It enhances the initiation of infant regulatory use of adaptation capacities while synchronizing the interrelationship between the motor and state subsystems.

The limitations of this study lie in the modest sample size of participants and the lack of longitudinal measures. However, because for the healthy newborn the first hours after birth, when separated from the mother, may well be the hardest hours, this study may serve as a window to the effect of KC on the emergence of self-regulation in the newborn.

The fact that the treatment effect was not apparent for the autonomic and attention subsystems might be related to the following facts: 1) all infants were healthy and capable of restoring respiration and cardiac regulation; 2) attention is a subsystem that is maintained only briefly during the very first hour after birth, supported by the surge of arousing catecholamines engendered in vaginal deliveries,[73–75] and will become the emergent next developmental agenda in the course of the first 6 weeks after term birth[76–78]; and 3) movement, activity, and state control are of major importance after cardiac activity and independent respiration are established.

CONCLUSIONS

KC shortly after delivery might be used as a beneficial clinical intervention to reduce the stress associated with birth and to pave the pathway for the increasingly independent self-regulation of the newborn in face of the inevitable extrauterine bombardment with environmental stimulus. Medical and nursing staff may be well advised to provide this kind of care shortly after delivery. Additional study might address the issue of continued KC during the

first postnatal weeks and the possible effects on mother-infant interaction, infant temperament, and attention-related skills during early life.

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THE INFORMAL-EXPERIMENT PARADOX

"Innovative therapies not undertaken as part of a study protocol escape the special federal requirements governing informed consent. This arrangement seems paradoxical. Formal study protocols have a number of different safeguards that apply to research activities. In contrast, when physicians use novel procedures or technologies in treating individual patients, they face little supervision of their activities."

Noah L. Informed consent and the elusive dichotomy between standard and experimental therapy. *Am J Law Med*. 2003;28:361–408

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