

Original Article

Touch and Massage for Medically Fragile Infants

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Research investigating the efficacy of infant massage has largely focused on premature and low birth weight infants. The majority of investigations have neglected highly acute patients in academic neonatal intensive care units (NICUs). The current study was developed with two aims: (Phase 1) to develop, implement and demonstrate the feasibility and safety of a parent-trained compassionate touch/massage program for infants with complex medical conditions and (Phase 2) to conduct a longitudinal randomized control trial (RCT) of hand containment/massage versus standard of care in a level III academic Center for Newborn and Infant Critical Care (CNICC). Certified infant massage instructors (CIMIs) taught parents to massage their hospitalized infants. Massage therapy and instruction were performed for seven consecutive days and health outcomes were collected for up to 1 month following treatment. Caregivers, nurses and certified infant massage therapists indicated moderate to high levels of satisfaction and feasibility with the implementation of hand containment/massage in a level III academic center CNICC. In addition, infant behavioral and physiological measures were within safe limits during the massage sessions. All caregivers participating in the massage group reported high levels of satisfaction 7 days into the intervention and at the 1-month follow-up with regards to their relationship with their infant, the massage program's impact on that relationship and the massage program. Due to unequal and small sample sizes, between group analyses (control versus massage) were not conducted. Descriptive infant characteristics of health outcomes are described. Preliminary data from this study indicates feasibility and safety of infant massage and satisfaction among the caregivers, CIMIs and the nurses in the CNICC. An important contribution from this study was the demonstration of the infants' safety based on physiological stability and no change in agitation/pain scores of the infants receiving massage. Massage in a tertiary urban academic NICU continues to be an area of needed study. Future studies examining infant health outcomes, such as weight gain, decreased length of hospitalization and caregiver–infant bonding, would provide greater insight into the impact of massage for medically fragile infants.

Keywords: medically fragile–infant massage–neonatal intensive care–caregiver depression–pediatric psychology–CAM–integrative medicine

Introduction

Over the past 37 years, research investigating the efficacy of infant massage has focused on premature infants (1–3). To date, the majority of these investigations have been performed in community-based neonatal intensive care

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units (NICUs), neglecting highly acute patients in academic (level III) NICUs. Much of the literature on infant massage, or other infant touch such as hand containment (i.e., a gentle form of non-moving touch on key areas of the infant's body in order to establish a physical boundary and to provide safe touch), has been characterized by non-randomized and uncontrolled trials and individual case reports (4–10). In these studies, a diverse range of techniques, methodologies, study populations and clinical settings has led to mixed findings.

A systematic review of the literature revealed 18 randomized controlled trials related to infants and touch or massage (1). These studies demonstrated improvements in infant weight gain (2,3,11–14), behavioral responses (14–16) and decreased length of hospitalization (11–14,17). Additional studies have demonstrated increased bonding and attachment behaviors and decreased parental depression when massage was included in an infant's care (18–21). However, these investigations typically failed to differentiate between infants with complex medical conditions and unstable infants. In 2000, a meta-analysis of 12 randomized controlled trials assessing the impact of massage on infant health reported increased weight gain and a reduced length of hospital stay compared to controls (1).

Caregiver health and satisfaction have also been investigated in relation to infant massage programs. Many anecdotal articles written by healthcare providers and families describe the perceived value of infant massage (5,22–24). Empirical studies have also reported improved parent/infant interaction, increased bonding and attachment behaviors and decreased parental depression when massage was included in the infant's care (18–21). Likewise, a recent study of infant massage in an NICU setting included parent massage training; however, satisfaction was not assessed (2).

There is no clear evidence that infants with medically complex conditions cannot be safely massaged. However, nearly all previous studies carefully exclude possible confounding medical conditions, such as congenital conditions and malformations; gastrointestinal disorders or complications such as necrotizing enterocolitis; and all central nervous system disorders and drug exposure (2,3,11,12,14,17). Some studies even exclude infants requiring basic neonatal support, such as supplemental oxygen or supplemental feeding (14,25,26). On the other hand, even the most recent investigations of massage continue to include premature and low birth weight infants, which the previous literature indicates may not tolerate touch well (14,15,27). Monitoring physiological responses is a critical component of assuring safety in high-risk infant populations. To date, only one group of investigators has published studies that record basic physiological data (i.e. heart rate, respiratory rate, pulse

oximetry) during massage (13,25,26,28). These studies have demonstrated that infants receiving massage do not exhibit extreme or potentially deleterious physiological reactions. In addition, qualitative studies and discussion papers of ongoing massage programs have not reported adverse reactions.

While there is a broad base of articles, case studies and anecdotal accounts of infant massage, clinical research on the NICU population is limited, particularly in the area of medically complex, highly acute infants. Given this dearth of relevant literature to indicate feasibility, safety, or efficacy of hand containment/massage therapy for a diverse neonatal population in a level III NICU setting, our research team investigated the development and implementation of infant massage within a pilot research investigation. The protocol included a broad range of safety, health and satisfaction measures, to explore the value of the intervention to the infant's health or environment of care.

This current research was developed with two aims: (Phase 1) to develop, implement and demonstrate the feasibility and safety of a parent-trained compassionate touch/massage program for infants with complex medical conditions; and (Phase 2) to conduct a longitudinal randomized control trial (RCT) of hand containment/massage versus standard of care, based on previously tested models of massage research (1,11,12,15,16,25,26,29,30), in a level III NICU with medically complex infants. The primary hypothesis for the RCT (Phase II) was that children receiving a 1-week massage program would gain weight compared to the non-massaged infant control group. Secondary exploratory outcomes included infant pain, comfort, heart rate, caregiver depression and satisfaction and bedside nurse ratings of satisfaction. Our work employed a weeklong intensive training model for primary caregivers, conducted by an experienced certified infant massage instructor.

Development of a Hand Containment/Massage Program

The first aim was to develop, implement and assess the feasibility of a parent-trained infant massage program within a level III academic NICU. The study design was selected to integrate parents into their infant's treatment within a family-centered care model. Arguments suggest that an integrative model of palliative care services is optimal (31) and our research is an initial step in that direction. While many studies utilize the expertise of the massage therapist for relieving a patient's pain and anxiety, the current study extended the role of massage instructors to educate and supervise parents on massage techniques. The setting was the NICU at Childrens Hospital Los Angeles (CHLA); this unit was renamed during that period as the Center for Neonatal Intensive and Critical Care (CNICC). CHLA collaborated with

The Heart Touch Project, a Los Angeles based non-profit massage organization, which supplied volunteer massage therapists for program development and implementation. The Heart Touch Project provided training and oversight for their volunteer force in collaboration with a hospital-based physician, who acted as a medical director for the massage program.

Prior to the development of the project, CHLA formed an Integrative Touch Committee to determine the best way to integrate massage therapy into the inpatient hospital setting. The committee consisted of a physical therapist, a volunteer massage therapist, a nurse, a psychologist, a physician, a parent representative, a social worker, administrative personnel and the director of volunteer services. Other members of the hospital staff who were interested in development of a therapeutic massage program were also included. The primary aim of this group was to bring compassionate touch/massage into the hospital setting in a graduated and monitored fashion in order to assure competent and compassionate service.

The Integrative Touch Committee first set out to establish agreed-upon credentialing for the massage therapists to gain privileges within the hospital setting. This process required a literature search of existing published massage programs, a comprehensive search of unpublished massage programs nationally and consultation with other leaders in the field to determine minimum credentialing procedures. At the conclusion of this process, the committee drafted a hospital procedure and policy outlining the necessary licensure and skills mandated for massage therapists to provide direct clinical massage services to the pediatric population at CHLA.

The healthcare team, in collaboration with the Heart Touch Project, developed curricula designed to orient the volunteer massage therapists to the CNICC environment, as well as provide them with hospital privileges for working with patients. This model of care was developed to support the pilot research project in the CNICC and to gather data for future massage program development in the CNICC, as well as other patient populations in both inpatient and outpatient hospital settings. Several pediatric massage approaches have used volunteer massage therapists to provide treatment (32). The first mandated requirement for the massage therapist applicant was city massage therapist licensure. The State of California provides licenses to massage therapists on a city-by-city basis. Massage therapists were also required to attend training sessions to become Certified Infant Massage Instructors (CIMIs) and to take a sensitive touch skills workshop offered by The Heart Touch Project. They were then required to enroll in an orientation/training tailored to the CNICC environment, which was provided by members from the interdisciplinary Integrative Touch Committee and CNICC staff. Once

these requirements were met, the application for privileges was reviewed by the Hospital Committee on Interdisciplinary Practice, which was responsible for approving privileges for the massage therapists to provide services within CHLA. All massage therapist volunteers received full privileges for the study prior to initiation of their participation in the CNICC.

Methodology

Objective

After establishing a standardized program and institutional standards for privileging of massage therapists, the aim was (i) to implement and demonstrate the feasibility and safety of the massage program and (ii) to conduct a 7-day massage protocol with a 30-day follow-up versus standard of care to evaluate infant and caregiver health outcomes. Since this population had not previously been studied, the investigators included careful monitoring of the infant's vital signs during the intervention, including heart rate, pulse oximetry and respiratory rate. The local hospital-based Institutional Review Board approved all research activities.

Recruitment and Inclusion/Exclusion Criteria

Inclusion and exclusion criteria were developed through review of previous literature and in consultation with neonatologists and other clinical care providers. The goal was to include as much of the CNICC population as possible, while excluding those infants who were too immature, or displayed signs or symptoms indicating that they were not medically stable or able to safely receive massage. The CNICC's clinical care coordinator evaluated infants for eligibility based upon a review of their medical charts. Eligible participants had a minimal gestation age of 32 weeks, intact skin and were able to receive massage as determined by the attending neonatologist. The following infants were excluded: infants under 1000 g; infants on a high-frequency ventilator or receiving ventilation with greater than 70% FiO₂; infants receiving inotropic support and infants with septic shock, persistent tachycardia (>180), or persistent bradycardia (<100). Once eligible infants were identified, the clinical care coordinator approached the attending physician to obtain written approval for participation. If approval was successfully obtained, the clinical care coordinator would then notify the principal investigator about the eligible infant and the family would be approached for consent. Due to the potential for rapid change in status prior to intervention, the nurse practitioner or attending neonatologist would confirm the patient's eligibility to receive session-by-session massage. This study was designed with a plan to recruit 52 subjects

in each of the two (massage and control) groups; however, this was not achieved for several reasons, including recruitment challenges and an increasingly acute and medically unstable population.

Randomization

Once families consented to participate, infants were randomized to either a standard of care (control) condition or an infant massage (experimental) condition, based on a predesigned, balanced randomization schedule stratified by two weight groups and two morphine-equivalent groups. Infants who weighed 1500 g or greater were considered 'high weight' whereas those below 1500 g were considered 'low weight'. For randomization, pain medications other than morphine, such as Fentanyl and Methadone, were converted to a morphine-equivalent conversion score (MECS; 33). The MECS conversion system was adopted as a method of indicating infant acuity and pain medication requirements. Infants with a MECS score of 720 or above were considered 'high MECS' whereas those with a MECS score below 720 were considered 'low MECS'. Infants randomized to the standard care group received all usual hospital services including medical care, physical and occupational therapy services and developmentally supportive nursing care.

Instrumentation and Data Collection

The following procedures outline data collected specifically on the enrolled infants by the research investigators and self-report measures provided by caregivers, CIMIs and bedside nurses.

Infants

Medical Chart Review

The following data were obtained by investigators from each participant's medical chart following consent, on the 7th day after consent, and at a 30-day follow-up: age, gestational age, birth weight, current weight, primary diagnosis, medical procedures, ventilation status, days of mechanical ventilation, surgeries/major medical procedures and MECS. Daily enteral intake and output volumes and patient weight were also recorded for the infant's initial assessment and for the subsequent 7 days.

Infant Pain/Agitation Assessment

The Neonatal Pain Agitation and Sedation Scale (N-PASS) score (34) was used for pain assessment. Assessment domains for the N-PASS include crying/irritability, behavior/state, facial expression, extremities/tone and vital signs (heart rate, blood pressure, respiratory rate and pulse oximetry). Two scores are derived from the N-PASS and range from 0 to 10 reflecting

pain/agitation and 0 to -10 reflecting sedation. Initial reliability and validity studies have shown internal consistency ($\alpha=0.73-0.87$). The N-PASS is the standard tool used for pain assessment in the CHLA CNICC. It is administered and recorded every 2 hours by the nurse. The last N-PASS score recorded prior to the massage session was used as data for infants in the massage group. Since massage sessions were generally scheduled in the afternoon or early evening when parents were available, the N-PASS scores for 3:00 p.m. were used for the control subjects to mirror a similar data window as the massage subjects.

Infant Physiological Outcomes

For infants participating in the massage group, physiological outcomes were recorded by a computerized monitoring system (CareVue Chart by Phillips) at 1-minute intervals throughout the intervention. Recorded outcomes included heart rate, respiratory rate and pulse oximetry. Since the monitoring system was calibrated to 1-minute intervals, 20 data points were recorded from massage onset to conclusion. Once the computer recorded the physiological data at the stated intervals, printouts were reviewed for artifact and outliers and entered into the statistical database for evaluation.

Caregiver Measures

Caregiver Satisfaction

At the beginning, all caregivers were asked to fill out a brief self-report questionnaire about their satisfaction with their infant's care up until that moment. Prior to massage instruction, caregivers were also asked to complete a 10-minute questionnaire about their knowledge of touch and massage. At the start of the massage intervention, caregivers in the experimental group were given a massage journal and asked to document the number of massages they provided independently to their child and to qualitatively discuss their experiences related to massage. Upon completing the 7-day massage program and 1 month following intervention, caregivers completed a 10-minute satisfaction questionnaire related to their infant's response and their satisfaction with the CNICC and the massage therapist. All caregiver questionnaires were developed by the interdisciplinary research team based on an evaluation of massage-specific knowledge and experience. Measures of satisfaction were modeled after other satisfaction health outcome measures with highly massage-relevant questions and assessed caregiver satisfaction on a scale from 1 (very dissatisfied) to 4 (very satisfied). Sample statements included 1. 'How satisfied do you feel giving massage to your infant?'

and 2. 'I feel that massage improved my infant's hospital stay.'

Caregiver Depression

The Beck Depression Inventory-II (BDI-II; 35) was administered on day 1 and 7 and 1 month after the caregiver began. The BDI is a 21-item questionnaire that uses a four-point scale (0–3) to indicate the presence or absence and severity of depressed feelings, behaviors and symptoms. Total scores range from 0–60. BDI classification criteria are as follows: 0–13 = minimal depression, 14–19 = mild depression, 20–28 = moderate depression and 29–63 = severe depression. The BDI is a gold standard for measuring depression in an adult population and has well-known and established reliability and validity.

Massage Therapist-Certified Infant Massage Instructor Measures

At each session, the CIMI was asked to complete assessments of the intervention, including qualitative and quantitative information on type of massage administered, areas massaged, the infant's reaction to massage and the presence of family members during instruction. On the fourth day of massage instruction, the CIMI completed a team-developed instrument known as the Caregiver Competency Checklist, which determines whether the caregiver can adequately perform the massage techniques. Following intervention, the CIMI was asked to complete a 10-minute questionnaire that addressed infant, hospital and caregiver satisfaction with massage on a scale from 1 (very dissatisfied) to 5 (very satisfied).

CNICC Bedside Nurse Measures

Prior to the study, nurses were asked to complete a 10-minute survey about their current level of satisfaction with the CNICC environment. Immediately following the study, CNICC nurses were asked to complete a similar satisfaction survey, which included questions regarding satisfaction with the massage intervention. Satisfaction was assessed on a scale from 1 (very dissatisfied) to 5 (very satisfied).

Evaluation of Massage Oil

Several kinds of massage oil were considered. Due to the high-risk population, it was essential to procure advice from the resident pharmacist and CNICC physicians at CHLA. A variety of concerns including potential allergic reactions, systemic effects due to absorption and contaminants such as pesticides guided the decision. Thus the chosen oil should be safely edible, of pharmaceutical

grade for purity and safety, marked with an identified expiration date and available in single doses to decrease the potential for bacterial growth. Soybean oil and a variety of nut oils were ruled out due to an increased potential for allergic responses. Grape seed oil, which is widely used for infant massage, was ruled out based on studies demonstrating the systemic blood-thinning qualities of grapes (36). Apricot oil was considered potentially harmful due to trace amounts of cyanide. In the final analysis, pharmaceutical-grade almond oil with the protein extracted was selected. Almonds, a fruit pit rather than a nut, are not generally associated with allergic responses. Some infants are allergic to protein, thus the investigators felt that using a protein-extracted oil was the best choice.

Hand Containment/Massage Intervention

General Procedure

Infants randomized to the infant massage (experimental) group underwent the same conditions as the control group but also received seven consecutive days of massage therapy. Caregivers of infants assigned to the experimental group attended a 1-hour massage class taught by a nurse who is an infant massage instructor and were subsequently asked to participate in at least three bedside massage instruction sessions taught by a CIMI within the next week. According to design, infants received massage for seven consecutive days, either from the caregiver or the CIMI. On the first day of bedside massage instruction, the CIMI first demonstrated the 20-minute touch procedure with a doll, and then with the infant in the caregiver's presence. After this session, caregivers were invited to conduct the 20-minute touch procedure with their infant in subsequent sessions; however, if the caregiver was unable to do so or did not wish to participate on a particular day, the CIMI would perform the massage to maintain seven consecutive days of therapy. Within the 7-day initial study period, the massage therapist observed the caregiver and completed a multipoint checklist to assure caregiver competence in providing massage techniques. If the caregiver did not satisfactorily complete all items on the Caregiver Competency Checklist within the 7-day period, an additional 1 hour and 10 minutes of bedside massage instruction was offered.

Infant Touch Procedure

The touch procedure included three segments totaling 20 minutes. The first 5-minute segment involved hand containment. For hand containment, typically two areas of the body are covered at a given time—one area is swaddled with each hand (i.e. one hand on the head and

the other on the feet). Therefore, the maximum amount of coverage at a given time is that of two-adult-sized hands. Full contact is provided during hand containment. The middle 10 minutes consisted of infant massage, which included stroking of the skin (arms, legs, stomach, chest, back, face and head) with pharmaceutical-grade protein-extracted almond oil using standard infant massage techniques (37). All surgical incision sites and IV lines were avoided during the massage. The last 5 minutes of touch intervention returned to hand containment.

Many in the field of massage therapy have indicated that a massage protocol defined by a particular sequence of strokes is unrealistic given that massage therapy is not ordinarily practiced in this way. Given this relevant concern, we chose to use a somewhat structured approach that simultaneously allowed for some of the freedoms that would normally be associated with an infant massage session. The touch protocol was followed unless the infant would not tolerate it and showed visible signs of distress. Distress included a significant color change or more than 30 seconds of crying; hyperextension of extremities, trunk, or tongue; frantic activity, squirming, or twitching; tremoring, yawning, clenched fists, or hiccoughs.

Results

Infant Characteristics

Despite vigorous recruitment and review of all infants admitted to the CNICC at CHLA, only 12 infants were successfully recruited over an 11-month period (Table 1). Infants in the control group (four girls, three boys) had a mean age of 13.2 weeks ($SD=9.6$), gestational age of 33.4 weeks ($SD=6.4$), birth weight of 3.1 kg ($SD=2.1$) and baseline weight of 4.1 kg ($SD=1.8$). Infants in the massage group (3 girls, 2 boys) presented with a mean age of 8.2 weeks ($SD=4.7$), gestational age of 38.5 weeks ($SD=3.1$), birth weight of 3.4 kg ($SD=0.6$), and baseline weight of 4.3 kg ($SD=1.1$). Primary diagnoses for the control group included lung disease/breathing complications, cleft palate, bowel obstruction and pneumonia. The experimental massage group included infants with a primary diagnosis of Miller–Dieker syndrome, hernia, a Patent Ductus Arteriosus that failed to close, fetal hydrops and multiple congenital anomalies. Mean length of stay was 35.4 days ($SD=39.1$) for the control group and 56.8 days ($SD=32.2$) for the massage group. Five participants in the control group and one in the massage group were on mechanical ventilation at baseline. Participants in the control group were on mechanical ventilation for a mean of 64.9 days ($SD=84.1$) while those in the massage group averaged 17.2 days ($SD=25.8$). One participant in the control group and three in the massage group were receiving pain medications at baseline. Mean MECS scores at baseline were

Table 1. Patient demographics by treatment group

	Massage Mean (SD) ($n=5$)	Control Mean (SD) ($n=7$)	<i>F</i>
Gender			
Male	2	3	
Female	3	4	
Age (weeks)	8.2 (4.7)	13.2 (9.6)	1.14 ^{NS}
Gestational age (weeks)	38.5 (3.1)	33.4 (6.4)	2.72 ^{NS}
Initial weight (kg)	4.3 (1.1)	4.1 (1.8)	0.017 ^{NS}
Initial MECS	413.3 (493.7)	68.6 (181.4)	2.92 ^{NS}
Initial N-PASS	0 (0)	0 (0)	
Days of MV	17.2 (25.8)	64.9 (84.1)	1.47 ^{NS}
Length of stay (days)	56.8 (32.2)	35.4 (39.1)	0.999 ^{NS}

NS: Non-significant.

68.6 ($SD=181.4$) for the control group and 413.3 ($SD=493.7$) for the massage group. Baseline NPASS scores were 0 for both groups. Additionally, one of the controls expired prior to ending the study (Table 1).

No significant differences emerged between treatment groups in terms of age ($F=1.14$), gestational age ($F=2.72$), initial weight ($F=0.017$), initial MECS score ($F=2.92$), days of mechanical ventilation ($F=1.47$), or length of stay ($F=0.999$).

Caregiver Characteristics

All caregivers who participated were females and all were mothers, except for one case where a grandmother was the identified caregiver.

Infant Physiological Measures

All physiological measures (i.e. heart rate, respiratory rate, oxygen saturation) of the massage group were within normal/safe limits during the sessions and Figure 1 presents the infants' heart rate.

Infant Weight Gain

Infants in the massage group demonstrated weight gain of 5.0 g to 350.0 g ($M=146.0$, $SD=148.0$), while the weight change for infants in the control ranged from a loss of 20.0 g to a gain of 790.0 g ($M=203.6$, $SD=271.4$). Follow-up measures of weight gain were only completed for four of the participants, three of whom were in the massage group. Between-group comparisons could not be conducted based on small and unequal sample sizes.

Caregiver Depression

Caregivers' self-reported depression scores indicated minimal to mild depression at baseline assessment for

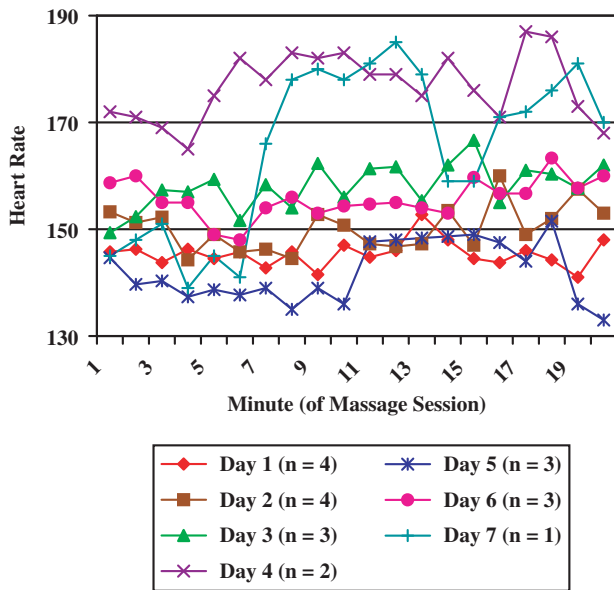


Figure 1. Infant heart rates during 20-minute touch sessions.

both the control ($M=10.2$, $SD=9.6$; $n=6$) and the massage ($M=13.4$, $SD=7.3$; $n=5$) groups. Over 7 days, caregivers in both groups demonstrated a decrease in symptoms, with two caregivers' symptoms from the massage intervention continuing to decline after 1 month (Figs 2 and 3). One caregiver in the control group recorded only a baseline BDI, because her infant died within the 7-day period. BDI scores for the 7th day of intervention were reported by five patients in each group, with a mean of 6.0 ($SD=4.3$) for the control group and a mean of 9.2 ($SD=4.8$) for the massage group. Only one caregiver reported a score for the 1-month follow-up in the control group ($M=13.0$) as opposed to two caregivers in the massage group ($M=6.0$, $SD=1.4$).

Caregiver Satisfaction

All caregivers participating in the massage group reported high levels of satisfaction 7 days into the intervention and at the 1-month follow-up regarding their relationship with their infant and the massage program's impact on that relationship. Slight improvements in satisfaction regarding time the caregiver spent with the infant and involvement in the infant's care were observed between day 7 and the 1-month follow-up. Other measures of satisfaction (e.g. caregiver's comfort while massaging infant, caregiver's comfort while holding infant) remained equally high at day 7 and at the 1-month follow-up.

Caregivers were also highly satisfied with the massage program (e.g. satisfaction with skills learned, teacher's communication) at day 7 and the 1-month follow-up. One Spanish-speaking caregiver noted 'Me encanta, me gusta mucho darle masajes a mi bebe porque me siento más

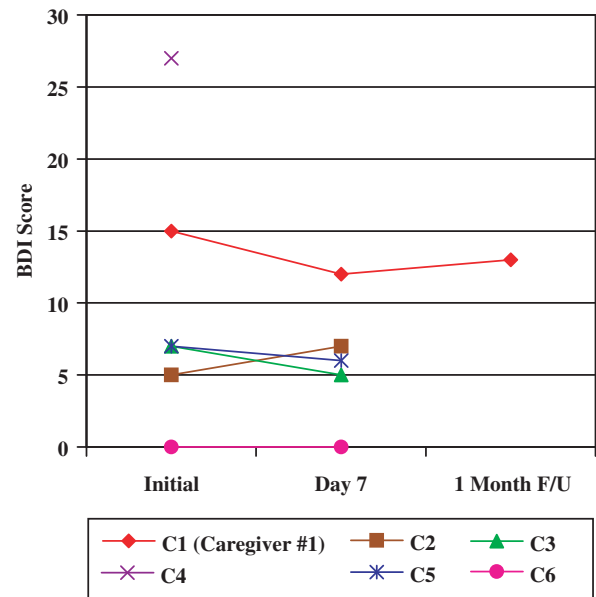


Figure 2. Caregiver-reported depression (control group).

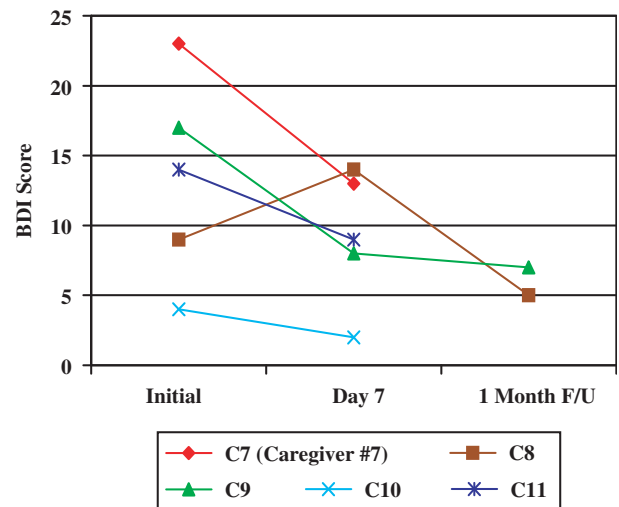


Figure 3. Caregiver-reported depression (massage group).

cerca de ella y a mi bebe le gusta mucha también. Gracias por haberme enseñado.' ('I love it, I love to massage my baby because it makes me feel closer to her, and my baby likes it a lot too. Thank you for teaching it to me.')

Caregivers were assessed on two questions regarding overall satisfaction with medical treatment at baseline and day 7. All caregivers were highly satisfied with the medical treatment their infant received at baseline and day 7. Additionally, caregivers were highly satisfied with the way the medical staff treated them at baseline and on day 7.

Nurse Satisfaction

The CNICC nurses who participated in the massage program indicated moderate to high levels of satisfaction

with regard to the massage program (Fig. 4). Prestudy ($n=32$) and poststudy ($n=13$) nurse reports also indicated a trend toward increased use of hand containment, massage and skin-to-skin contact for non-participating infants in the unit.

CIMI Satisfaction

The CIMIs who participated in the massage program indicated high levels of satisfaction regarding the massage program (Fig. 5).

Discussion

Preliminary data indicates that the development and implementation of a massage program in a tertiary urban academic NICU is feasible. Furthermore, infant behavioral and physiological data indicates good infant tolerance to massage, while caregivers, CIMIs and CNICC nurses reported moderate to high levels of satisfaction to support hand containment/massage as a safe practice for hospitalized infants. In addition, measurable changes in the medical unit culture were noted by CNICC nurses, reflecting an increase in touch and massage practices in the unit.

However, the complexity and acuity of this patient population continues to create tremendous challenges for recruitment, retention and an investigator's ability to conduct clinical massage trials. Compared with previous randomized clinical trials on infant massage (2,3,11,12,14,17,25,26), most of the infants enrolled in this study would have been excluded based on their diagnoses and medical conditions. Nonetheless, we found that the use of carefully trained and supervised volunteer massage therapists, with evidence-based inclusion/exclusion criteria, is a reasonable model for implementation of massage, even in the most complex medical environments.

An important contribution was the demonstration of safety as measured by the infants' physiological stability/reactivity and no documented agitation/pain in their receiving massage. Although some analyses have examined physiological measures (12,25,26), no previous report has undertaken direct, minute-by-minute heart rate, respiratory rate and oxygen saturation measurements to assure physiological stability and safety during the touch procedure. In this modest sample, our findings are consistent with investigations that suggest infants with complex medical conditions may benefit from massage as much or more than infants with fewer complications (13,38). Future investigations of infant massage should refrain from restricting populations to infants whose health status is expected to improve, as this may eliminate infant/caregiver dyads that may benefit from the observed positive health outcomes. Continuing

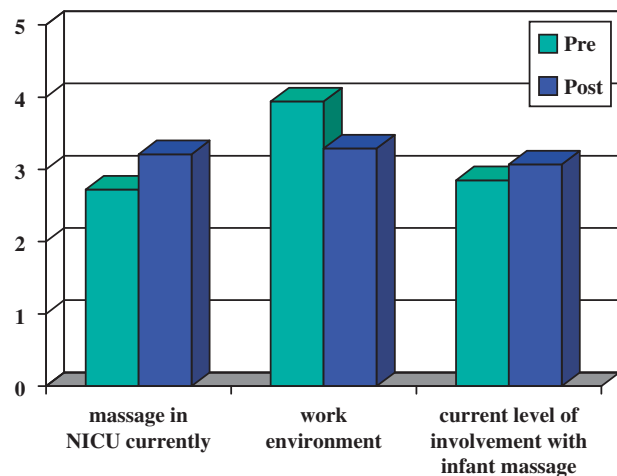


Figure 4. Nurses' satisfaction with massage program.

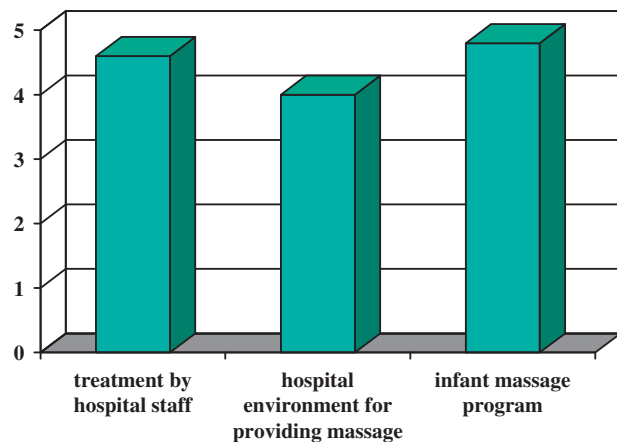


Figure 5. CIMIs' satisfaction with massage instruction.

to analyze this fragile population may highlight important and often overlooked health indices, such as parental bonding, quality of life, palliative care, comfort and the family's sense of participation in their infant's care, all of which are increasingly valued by CNICC staff.

Except in infants under 32 weeks, nearly all previous randomized controlled trials, single case and anecdotal accounts of massage reveal few adverse events or safety concerns. Consistent with these findings, this indicates results hand containment/massage can be safely administered to medically fragile and complex populations.

The primary limitation to the RCT was the small and unequal sample size. This limitation, coupled with recruitment of a heterogeneous infant sample, contributed to our inability to evaluate effects of massage on weight gain or loss. Subject recruitment was a complex process during which a number of factors related to the highly complex nature of the population, as well as other caregiver and environmental (e.g. family, social,

employment) concerns, were identified. All infants admitted to the CNICC were screened and re-screened weekly as their status changed. Less than 5% of patients deemed eligible by criteria were excluded due to physician opinion. During this period, over 70% of the infants admitted to the CHLA CNICC were stabilized and/or received surgical or other procedures, and were returned to the referring hospital, rather than to home. These patients were therefore often in a pre or postoperative state, preparing for transfer, or medically unstable. No parents refused consent due to reservations or concerns about massage for their infant's health. They most often cited their inability to be present to participate in the training due to time and travel constraints and other family obligations, such as other children at home. Due to recruitment difficulties, research efforts in an inpatient setting may achieve better recruitment/retention by focusing on more stable populations, thus reducing the identified medical (e.g., surgical demands) and caregiver/family (e.g., other family and employment demands) factors that restrict participation.

Numerous healthcare researchers have employed measures of satisfaction as an indication of quality of care (39,40). The current study identified high levels of satisfaction among caregivers and nurses alike. This investigation presents complex qualitative data that supports the implementation of a program like massage, where both caregivers and nurses recognize and appreciate the benefits of the intervention. As we continue to integrate adjunctive therapies into inpatient medical settings, therapies like massage provide unique opportunities for caregivers to participate in their children's care. Enhancing family participation may become associated with improved health outcomes for the child and their family, as well as the health provider.

This study demonstrated feasibility and safety of a parent-trained compassionate touch massage protocol for medically fragile infants in a level III neonatal intensive care unit. Our findings indicate that a properly designed and implemented program of infant massage performed by specially trained, volunteer massage therapists can be safely practiced even among the most medically fragile infants.

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