

## ORIGINAL ARTICLE

# Integrative Care Therapies and Physiological and Pain-related Outcomes in Hospitalized Infants

整合护理疗法与住院婴儿的生理指标和疼痛相关指标

Tratamientos integradores de atención y resultados fisiológicos y relacionados con el dolor en lactantes hospitalizados

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## Citation

Global Adv Health Med. 2015;4(4)32-37. DOI: 10.7453/gahmj.2015.029

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## Disclosures

The authors completed the ICMJE Form for Potential Conflicts and had no conflicts to disclose.

## Funding

This work was supported by the Division of Child Life and Integrative Care, Cincinnati Children's Hospital Medical Center and the University of Cincinnati Center for Integrative Health and Wellness, Ohio.

## ABSTRACT

**Background:** Pain management is a frequent problem in the neonatal intensive care unit (NICU). Few studies examining effects of integrative care therapies on pain-related outcomes in neonates have included physiological outcomes or investigated the use of such therapies in a practice-based setting.

**Objective:** The purpose of this practice-based retrospective study was to examine the associations between integrative care therapies, particularly massage and healing touch, and pain-related outcomes among hospitalized infants.

**Methods:** We conducted a retrospective review of a clinical database from a level III NICU regularly delivering integrative care therapies. Paired-samples *t*-tests were used to examine associations between integrative care therapies and 4 pre-post outcome measures: therapist-rated pain and presentation (ranging from asleep to agitated) and neonates' heart rate and oxygen saturation.

**Results:** Of 186 patients ( $M_{age}=68$  days), 58% were male and 67% were Caucasian. Sixty-two percent received both massage and healing touch; the remainder received a single therapy. From pre-post therapy, statistically significant changes were observed in infants' heart rate ( $M_{pre}=156$  vs  $M_{post}=140$  per minute;  $P<.001$ ), oxygen saturation ( $M_{pre}=95.0\%$  vs  $M_{post}=97.4\%$ ;  $P<.001$ ), and therapist-reported pain ( $M_{pre}=2.8$  vs  $M_{post}=0.2$ ;  $P<.001$ ) and presentation ( $M_{pre}=3.2$  vs  $M_{post}=1.0$ ;  $P<.001$ ).

**Conclusion:** Observed improvements in pain-related outcomes suggest that massage and healing touch

may be useful integrative therapies to consider as pain management options in the NICU.

## 摘要

背景：疼痛控制是新生儿重症监护室 (NICU) 经常遇到的一个难题。在评估整合护理疗法对新生儿疼痛相关指标之影响的研究中，几乎没有研究探讨生理指标或评估此类疗法在诊所环境中的应用情况。

目的：这项基于实践的回顾性研究旨在分析整合护理疗法，特别是按摩和康复性抚触，与住院婴儿的疼痛相关指标之间的关系。

方法：我们对经常实施整合护理疗法的 III 级 NICU 的临床数据库进行了回顾性审核。我们采用配对样本 *t* 检验分析了整合护理疗法与以下 4 个治疗前-治疗后评估指标的关系：治疗师评定的疼痛、新生儿的疼痛表现（从睡眠到烦躁不等）、新生儿的心率和血氧饱和度。

结果：在 186 名患儿中（平均年龄 = 68 天），有 58% 为男婴，67% 为白种人。62% 接受了按摩联合康复性抚触，其余仅接受了单一疗法。从治疗前到治疗后，婴儿的心率（治疗前均值 = 156 次/分，治疗后均值 = 140 次/分； $p<0.001$ ）、血氧饱和度（治疗前均值 = 95.0%，治疗后均值 = 97.4%； $p<0.001$ ）、治疗师评定的疼痛（治疗前均值 = 2.8，治疗后均值 = 0.2； $p<0.001$ ）以及疼痛表现（治疗前均值 = 3.2，治疗后均值 = 1.0； $p<0.001$ ）均观察到了有统计显著性的改变。

结论：疼痛相关指标的改善表明，按摩和康复性抚触是有效的整合疗法，可考虑作为疼痛控制方案用于 NICU 中。

## SINOPSIS

**Antecedentes:** El tratamiento del dolor es un problema frecuente en la unidad de cuidados intensivos neonatales (UCIN). Pocos de los estudios que examinan los efectos de los tratamientos integradores sobre los resultados relacionados con el dolor en neonatos han incluido los resultados fisiológicos o investigado el uso de este tipo de tratamientos en un entorno basado en la práctica.

**Objetivo:** El objetivo de este estudio retrospectivo basado en la práctica fue examinar la asociación entre los tratamientos integradores de atención, especialmente el masaje y el toque sanador, y los resultados relacionados con el dolor entre los lactantes hospitalizados.

**Métodos:** Realizamos una revisión retrospectiva de una base de datos clínica de una UCIN de nivel III que proporcionaba regularmente tratamientos integradores de atención. Se utilizaron pruebas *t* de muestras pareadas para examinar las asociaciones entre los tratamientos integradores de atención y cuatro medidas de resultados anteriores y posteriores: dolor puntuado por el terapeuta y presentación (desde dormido hasta sueño agitado) y frecuencia cardíaca y saturación de oxígeno de los neonatos.

**Resultados:** De 186 pacientes (Medad = 68 días), el 58 % eran hombres y el 67 % eran de raza caucásica. El 62 % recibió tanto masajes como toque sanador; el resto recibió un solo tratamiento. A partir del tratamiento anterior y posterior, se observaron cambios estadística-

mente significativos en la frecuencia cardíaca de los lactantes (Manterior = 156 frente a Mposterior = 140 por minuto;  $P < 0,001$ ), saturación de oxígeno (Manterior = 95,0 % frente a Mposterior = 97,4 %;  $P <$

0,001) y dolor notificado por el terapeuta (Manterior = 2,8 frente a Mposterior = 0,2;  $P < 0,001$ ) y presentación (Manterior = 3,2 frente a Mposterior = 1,0;  $P < 0,001$ ).

**Conclusión:** Las mejoras obser-

vadas en los resultados relacionados con el dolor sugieren que el masaje y el toque sanador podrían ser tratamientos integradores útiles a considerar como opciones de tratamiento del dolor en la UCIN.

## BACKGROUND

Pain management is a common challenge in the neonatal intensive care unit (NICU), with infants in the NICU undergoing an average of 12 to 14 painful procedures each day.<sup>1,2</sup> As repeated painful procedures during infancy have been associated with long-term hyperalgesia and negative effects on cognition, learning, and motor functioning,<sup>3,4</sup> a research-driven affirmation of basic, compassionate motives for seeking effective pain management strategies is warranted. Depending on the type of procedure being performed, both nonpharmacological and/or pharmacological pain management options may be appropriate.

Given the importance of managing neonatal pain in a comprehensive manner, studies have explored the use of non-pharmacological integrative health therapies such as massage therapy for neonatal pain.<sup>5-7</sup> Integrative health and medicine is a large and growing medical trend, reflecting the evidence-based integration of complementary treatments such as natural products (eg, fish oil, Co-Q10) and mind and body practices (eg, yoga, relaxation techniques) with conventional therapies.<sup>8</sup> Evidence for biofield therapies is more limited, with studies reporting mixed findings and insufficient evidence for their recommendation.<sup>9-11</sup> An integrative approach to care has been shown to improve a wide range of health problems for both children and adults,<sup>8</sup> and a growing number of studies support the use of integrative care therapies for managing neonatal pain,<sup>12</sup> stress,<sup>13,14</sup> and other issues such as weight, sleep, and immune function.<sup>15-17</sup>

Previous studies of integrative care therapies for pain-related outcomes in neonates have focused on massage therapy, with most of the studies being randomized controlled trials (RCTs). Studies have reported a range of benefits including shorter hospital stays,<sup>18</sup> less observed stress,<sup>14</sup> greater weight gain,<sup>15,17,19</sup> neurological maturation,<sup>20</sup> and relaxation-related physiological changes such as lower cortisol levels,<sup>21</sup> though therapy duration and techniques varied. Studies incorporating vital signs are limited, but one small observational study found lower pulse and respiratory rate and higher oxygen saturation for infants receiving the M technique, a relaxation method involving comforting touch.<sup>22</sup> Still other studies have reported inconsistent results regarding clinical outcomes and/or physiological functioning.<sup>6,23,24</sup>

The evidence supporting integrative therapies in infants has been used to formulate treatment recommendations for managing pain in neonates. For example, massage therapy and related techniques have been rec-

ommended as first-line or standard pain management techniques for neonates and preterm infants in several review articles,<sup>25-27</sup> with a review for nurses even providing specific guidance on kinesthetic movements and techniques.<sup>28</sup> In actual clinical practice, however, such pain management techniques are often underutilized<sup>1,2</sup>; some NICUs have actually implemented restrictive “minimal touch” policies in order to minimize the potential for unpleasant or overstimulating sensations.<sup>29</sup> In a study of 90 California NICU nurses, fewer than half surveyed felt that newborn pain was well managed within their NICU.<sup>30</sup> Thus, despite clinical recommendations for the use of integrative care therapies for pain management in neonates, there remains a lack of integration of these therapies into clinical practice.<sup>1,2,26</sup>

Translation of research findings into clinical practice in the NICU setting is limited by similar factors observed in other areas of health research, including the limited external validity of RCTs, lack of communication and collaboration between researchers and clinicians, and practical and financial considerations.<sup>31</sup> In order to aid these translation efforts, the National Institutes of Health (NIH) has implemented the NIH Roadmap, a federal initiative aimed at enhancing the application of evidence-based treatments into real-world clinical settings.<sup>32</sup> One strategy that the NIH Roadmap supports is the use of practice-based research, which involves systematically examining the effects of clinical interventions in natural clinical settings, helping to bridge from efficacy in controlled trials to effectiveness in actual clinical practice.<sup>31</sup> Despite the various controlled trials of massage and other integrative care therapies in neonates, few studies have examined these therapies in a real-world clinical setting, limiting our understanding of the impact of these therapies and potentially impeding their clinical utilization.

Thus, the purpose of the current study was to examine the relationship between the use of integrative care therapies and pain-related outcomes among infants in a level III NICU using a practice-based study design. Specifically, we used a retrospective review of data collected during real-time clinical encounters to investigate the relationship between the delivery of integrative therapies, in particular massage therapy and healing touch, and both objective (ie, neonatal heart rate and oxygen saturation) and subjective (ie, clinician-reported neonatal pain and presentation) pain-related outcomes. We hypothesized that these integrative care therapies would be associated with reduced pain, improved presentation, decreased heart rate, and increased oxygen saturation among infants in the NICU.

## METHODS

### Participants

Participants included 186 infants who received an integrative care therapy while hospitalized at a large Midwestern pediatric teaching hospital's level III NICU during the 2009 calendar year. In order to enhance the generalizability of the results, participation was not limited to preterm infants; thus, the sample is representative of the NICU population and the standard clinical practice of the integrative care team. As this was a retrospective chart review, inclusion and exclusion criteria are not tied to analytical decisions but instead are clinically-driven and relate to which infants were eligible for integrative care therapies, reflecting the real-world nature of the study. Standard practice guidelines of the integrative care team precluded massage treatment of any infants who were less than 3 lbs or 32 weeks postmenstrual age. Additional massage exclusion criteria per standard practice guidelines included behavioral avoidance cues, vital sign instability (eg, an inability to maintain appropriate temperature during therapy), and medical or anatomic contraindications to massage, as with conditions such as gastroschisis, omphalocele, hemophilia, malignancy, or recent surgical incision sites.<sup>28,33</sup> Since healing touch is an energy-based therapy with light hand placement on the body or hands held slightly above the body, there were no contraindications for delivering this therapy.

### Procedure

All infants in the current study were seen during their hospitalization by a holistic health specialist (HHS), a nurse dedicated to providing integrative therapies in the NICU, from the hospital's Division of Child Life and Integrative Care. The HHS, who provided massage therapy and/or healing touch, had a background that included massage therapist licensure after at least 500 classroom hours and certifications such as Baby's First Massage and/or certification through the Healing Touch Program.<sup>34,35</sup> Referrals for treatment came from other care providers or HHS observations of infants presenting with anxiety, pain, or distress. Due to the critical condition of participating infants, the type of massage therapy offered incorporated non-manipulative touch and gentle stroking, with specific modalities including passive touch, stroking, kneading, joint movement, and fascial stretch as appropriate. Healing touch encompassed both energy work and non-manipulative touch. The HHS also recorded the infants' heart rate and oxygen saturation, as well as their own (ie, therapist-reported) perceptions of infants' pain and presentation (see Measures section below), immediately before and after each integrative care visit. As previously described, the data collected were entered into a network-secured clinical database, along with standard demographic patient information, reason for integrative care referral, the type of integrative

care therapy received, and the duration of the intervention.<sup>36</sup> Approval for this retrospective chart review was obtained from the hospital's institutional review board, and ethical standards were maintained throughout the research process.

Initial data cleaning was conducted on the full clinical database as described in our previous paper<sup>36</sup>; the full database also contained child and adolescent data, while this investigation included only those assessed using the Neonatal Infant Pain Scale to create a previously unreported and distinct sample of 213 patients seen in the NICU. While the full clinical database included multiple interventions and even multiple hospitalizations for some patients, only the first intervention during the first hospitalization in the study period was included in analysis to limit potential effects from patients acclimating to therapies over time. To ensure completeness of data, only those patients who had both pre- and post-intervention scores for one of the outcomes studied (pain, presentation, oxygen saturation, or heart rate) were included, leading to the final sample of 186 patients who had received integrative therapies in the NICU.

### Outcome Measures

#### *Pain*

Integrative care therapists used the Neonatal Infant Pain Scale (NIPS) to provide pre-post neonatal pain ratings. The NIPS is a behaviorally-based clinician-reported outcome measure that assesses 6 pain-related characteristics: facial expression, crying, breathing patterns, arm movement, leg movement, and state of arousal.<sup>37</sup> All characteristics other than crying are rated as 0 or 1; crying is rated as 0, 1, or 2. Per hospital protocol, a total score of three or greater reflects pain levels that require therapist intervention. The NIPS was selected for use based on hospital guidelines and appropriateness for patient developmental and clinical status. The NIPS scale has demonstrated interrater reliability, internal consistency, and concurrent and construct validity.<sup>37,38</sup>

#### *Presentation*

Treating therapists observed and recorded patients' level of presentation/comfort on a 6-point ordered categorical scale: 0=asleep, 1=very relaxed/drowsy, 2=calm/comfortable, 3=slight tension/restless, 4=tense/agitated, or 5=extreme tension/agitated/inconsolable, with a lower score indicating a less agitated presentation based on therapist judgment. This rating scale was created by the integrative care team based on treating therapists' clinical experience. No psychometric data are currently available for this measure.

#### *Heart Rate and Oxygen Saturation*

Treating therapists recorded patients' heart rate and oxygen saturation pre-post therapy based on readings from General Electric continuous bedside monitors typical of a NICU setting.

**Table 1** Demographic and Clinical Sample Characteristics

Variable	Result
N	186
Age in days, mean (SD)	68 (79)
Sex, no. (%)	
Male	108 (58)
Missing	3 (2)
Ethnicity, no. (%)	
Caucasian/White	125 (67)
African-American/Black	39 (21)
Asian	2 (1)
Other	13 (7)
Unknown/Missing	7 (4)
Therapy type, no. (%)	
Massage and healing touch/energy work	116 (62)
Massage alone	45 (24)
Healing touch alone	23 (12)
Other single therapy <sup>b</sup>	1 (1)
Supplemental education for family <sup>a</sup>	30 (16)
With additional emotional support for family <sup>a</sup>	1 (1)
Missing	1 (1)
Length of hospital stay in days, mean (SD)	54 (62)
Intervention duration in minutes, mean (SD)	35 (16)

<sup>a</sup> When indicated, the holistic health specialist supplemented the integrative therapy with family education or support. Teaching family the progression of touch in massage and how to watch for responses helps them provide pain management, comfort, and advocacy for their infant.

<sup>b</sup> Data entered as "Other" in the clinical database; no additional information is available.

**Data Analysis**

Descriptive statistics were calculated for demographic and clinical variables of interest. Bivariate correlations were examined between study variables at pre- and post-therapy. Paired-samples *t*-tests were used to compare mean pain scores, presentation scores, heart rate, and oxygen saturation from pre- to post-therapy. McNemar's chi-square test for within-subjects designs was used to compare the percentage of patients

with normal oxygen saturation, defined as greater than or equal to 95%, from pre- to post-therapy.

**RESULTS**

**Demographics and Clinical Sample Characteristics**

Sample characteristics (N=186) are presented in Table 1. Patients had a mean (SD) age of 68 (79) days. One-hundred eight (58%) were male, and 125 (67%) were Caucasian. One-hundred sixteen patients (62%) received both massage and healing touch or other energy work. The remainder received a single therapy, mostly massage (24%) or healing touch (12%). Of the 89 patients with a gestational age at birth recorded, 83% were born at a gestational age of less than 37 weeks, reflective of the makeup of this NICU population. Among the 102 patients who had a recorded referral source, referrals came most often from pediatric nurses (n=70), followed by the HHS (n=24).

**Bivariate Correlations**

See Table 2 for bivariate correlations between study variables. Before the intervention, pain was significantly correlated with presentation ( $r=.69, P<.01$ ) and heart rate ( $r=.41, P<.01$ ). Presentation was significantly correlated with both heart rate ( $r=.29, P<.05$ ) and oxygen saturation ( $r=.29, P<.05$ ). Heart rate and oxygen saturation were also significantly correlated with one another ( $r=.16, P<.05$ ). After the intervention, pain was significantly correlated with presentation ( $r=.55, P<.01$ ), as well as with heart rate ( $r=.16, P<.05$ ), though none of the other variables were significantly correlated with one another post-intervention.

**Physiological Outcomes**

From pre-post intervention, infants' heart rate significantly decreased ( $M_{pre}=156$  vs  $M_{post}=140$  per min;  $t(159)=16.6, P<.001$ ) and oxygen saturation significantly increased ( $M_{pre}=95.0\%$  vs  $M_{post}=97.4\%$ ;  $t(160)=-10.4, P<.001$ ); see Table 3. The percentage of infants with normal oxygen saturation, greater than or equal to 95%, significantly increased from 60% to 86% pre-post intervention ( $P<.001$ ). Notably, all infants who had normal oxygen saturation prior to initiation of the therapy remained within the normal range afterwards; the only shifts were infants with oxygen saturation

**Table 2** Bivariate Correlations Between Study Variables<sup>a</sup>

	Pain	Presentation	Heart Rate	Oxygen Saturation
Pain	—	.69 <sup>b</sup>	.41 <sup>b</sup>	-.11
Presentation	.55 <sup>b</sup>	—	.29 <sup>c</sup>	.29 <sup>c</sup>
Heart Rate	.16 <sup>c</sup>	.12	—	-.16 <sup>c</sup>
Oxygen Saturation	-.04	-.13	-.07	—

<sup>a</sup> e Table XX for bivariate correlations between study variables.

<sup>b</sup> Correlations between variables before the intervention are presented above the diagonal line formed by dashes; correlations after the intervention are presented below the diagonal line formed by dashes.

<sup>c</sup>  $P<.01$

<sup>d</sup>  $P<.05$



**Table 3** Clinical Outcome Measures

Outcome	N	Mean <sub>pre</sub> (SD)	Mean <sub>post</sub> (SD)	Range <sub>pre</sub>	Range <sub>post</sub>	t
Heart rate	160	156 (20)	140 (17)	84-230	84-184	16.6 <sup>a</sup>
Oxygen saturation (%)	161	95.0 (4.9)	97.4 (3.1)	69-100	80-100	-10.4 <sup>a</sup>
Pain <sup>b</sup>	171	2.8 (3.0)	0.2 (0.7)	0-7	0-5	11.9 <sup>a</sup>
Presentation <sup>c</sup>	73	3.1 (1.3)	1.0 (1.0)	0-5	0-4	14.5 <sup>a</sup>

<sup>a</sup>  $P < .001$

<sup>b</sup> Pain assessed with the Neonatal Infant Pain Scale. Higher scores indicate greater levels of pain.

<sup>c</sup> Presentation assessed with a hospital-generated scale. Lower scores indicate greater levels of relaxation.

<95% prior to the start of therapy who increased to the normal range post-therapy.

### **Pain and Presentation Outcomes**

Therapist-reported pain ( $M_{pre}=2.8$  vs  $M_{post}=0.2$ ;  $t(170)=11.9$ ,  $P<.001$ ) and presentation ratings significantly decreased pre-post intervention ( $M_{pre}=3.1$  vs  $M_{post}=1.0$ ;  $t(72)=14.5$ ,  $P<.001$ ); see Table 3.

### **DISCUSSION**

While results from RCTs support the safety and efficacy of integrative therapies, particularly massage therapy, in neonates, the impact of these therapies in real-world clinical settings is not well understood. The current study utilized a retrospective database review of practice-based data to examine the association between delivery of select integrative care therapies and pain-related outcomes in infants. As hypothesized, we found significant improvements in observed pain, presentation, and vital signs (ie, a slower heart rate and greater oxygen saturation) for infants in the NICU after receiving select integrative care therapies, namely massage and/or healing touch. Results from this study build on the results of previous studies supporting the efficacy of massage therapy and comforting touch in controlled trials and extend these data to provide preliminary support for the effectiveness of massage therapy and healing touch in real-world clinical settings. In keeping with the initiatives outlined in the NIH Roadmap,<sup>31</sup> the current findings in combination with previous literature advance the field with evidence-based support for the integration of these therapies into the NICU.

Of interest is the directional agreement between therapist reports and objective measures of neonatal pain. We found that both subjective (ie, therapist-reported pain and presentation) and objective outcome measures (ie, heart rate and oxygen saturation) demonstrated statistically significant shifts toward a less stressed state. Given that infants are unable to verbally report their pain or distress levels, it is an important finding that therapist reports of infants' pain are reliable and consistent with objective measures of stress. The congruence between these findings also allows for a more holistic assessment of neonatal pain, as it reflects improvements across both behavioral and physiological domains. The closest correlations in out-

come measures were between the subjective metrics of pain and presentation, likely because these were both based on assessment of the infant's observable state. However, statistically significant correlations were also observed between subjective and objective ratings, particularly pre-intervention.

Despite clinician awareness of the importance of pain management in the NICU, consistent application of pain management techniques remains a challenge in real-world practice. Restraint in analgesia use may stem from a conservative risk-benefit assessment of pharmacological pain treatments for the vulnerable NICU population. For example, when pain medication is administered, it may not always provide adequate pain relief and may carry the risk of adverse side effects, complications, tolerance, and withdrawal.<sup>4,25</sup> However, even nonpharmacological methods of pain management are underutilized<sup>1,2,26</sup>; one recent NICU study of oral sucrose for pain management during heel lances found that a clinician education intervention increased the use of this therapy by over 80%, with an accompanying statistically significant reduction in assessed infant pain.<sup>39</sup>

As with any study, there are limitations worth noting. All patients came from the same level III NICU in a Midwestern academic medical center, which limits generalizability of the results to other populations (eg, NICUs of different levels that treat different types of patients or pediatric wards). Second, there may be potential bias from therapist-reported pain and presentation outcomes. Assessment of outcome measures by a researcher other than the therapist would be preferable, though would require thoughtful planning and implementation in real-world settings where it would be unexpected for individuals not involved in the patient's care to be recording their vital signs. The physiological measures also vary over short time spans, creating the possibility for bias in these measures if values were selected at more preferable points. Thus the limitation of bias in the subjective measures is only partially mitigated by the supporting physiological data. Finally, given that this was a real-world practice-based study, we are unable to control for variables such as research-driven inclusion and exclusion criteria, and a time- and attention-matched control group. This limitation reflects the inherent difficulty in finding a balance between internal and external validity in prac-

tice-based research studies.<sup>40</sup> Future studies should explore measuring the same outcomes in samples of patients who did not receive the therapies. It is important to remember, however, that many of these limitations are inherent and intentional aspects of practice-based research that serve to answer questions of effectiveness rather than efficacy and thus can also be viewed as valuable characteristics of the study design.

Future studies could address a variety of questions. While this study investigated initial effects after a single therapeutic interaction, effects over time and multiple therapist visits could be considered in future efforts. Assessment of broader health outcomes, such as level of functioning, over a longer duration and with clear tracking of adverse events would also bring future studies into closer alignment with formal criteria for effectiveness studies.<sup>40</sup> A study with a randomized design would be more appropriate for determining whether specific treatments differentially influence outcomes and providing guidance on the optimal integrative care therapies for use in a NICU setting. Investigating longer-term outcomes and the downstream impact on the potential cost savings of these services would help build support for more robust integrative care service delivery systems from administrative and insurance stakeholders. Finally, more complete patient data for gestational age in future studies would enable separate analysis of outcomes in preterm and full-term infants. While the current study provides preliminary support for the evidence-based incorporation of massage therapy and healing touch into the NICU setting as part of an overall pain management strategy, future research is needed to establish effectiveness and determine clinical best practices.

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