

# A Randomized-controlled Trial of Parent-led Tactile Stimulation to Reduce Pain During Infant Immunization Injections

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**Objective:** To determine the effectiveness of parent-led tactile stimulation for pain reduction when added to a combination of evidence-based pain-reducing interventions in infants undergoing immunization injections.

**Methods:** Healthy infants aged 4 to 6 months undergoing routine immunization at a primary care practice were eligible. Infants were randomized to tactile stimulation by a parent or usual care. Parents in the tactile stimulation group rubbed the ipsilateral thigh distal to the site for 15 seconds before, during, and after injections. In addition, all infants received evidence-based pain-relieving interventions including: sucrose solution, holding by a parent, and intramuscular injection without aspiration. The primary outcome was pain, measured by a validated tool, the Modified Behavioral Pain Scale (MBPS), by an observer unaware of treatment allocation using videotapes of the procedure. MBPS scores could range from 0 (no pain) to 10 (maximum pain). Parents, unaware of the study hypothesis, also rated infant pain in real time using a 100mm visual analogue scale.

**Results:** One hundred twenty infants participated. Infant characteristics did not differ ( $P > 0.05$ ) between the tactile stimulation and control groups. Mean MBPS scores and parent visual analogue scale scores did not differ between groups (8.2 [1.1] vs. 8.0 [1.3];  $P = 0.57$ ) and (60 [20] vs. 53 [22] mm;  $P = 0.10$ ), respectively.

**Discussion:** Parent-led tactile stimulation did not reduce pain in infants undergoing immunization injections when combined with other pain-relieving interventions. Potential reasons for the lack of effectiveness are discussed. Investigation of the effectiveness of clinician-led tactile stimulation in this population is recommended.

**Key Words:** immunization, pain management, infants, tactile stimulation

Infant immunization is an accepted and routine preventive health measure. It is also the most frequent source of medical pain for infants and children.<sup>1</sup> In North America and Europe, 5 to more than 20 separate injections can be required in the first year of life alone.<sup>2-4</sup> Current pain management for immunization in infants is not ideal. Despite evidence supporting various single interventions to reduce pain (eg, oral sucrose, topical anesthetics, fast injection with no aspiration),<sup>5,6</sup> none of them reduces pain to zero. Little research has been done to determine the impact of combining interventions in order to achieve pain-free immunizations.<sup>5</sup>

Tactile stimulation is a cost-neutral pain-relieving intervention that requires no advanced preparation, and is easily combined with other interventions. Moreover, it may be suitable for administration by parents due to its simplicity. Evaluating interventions that can be implemented by parents offers an opportunity to increase the number of interventions being used during immunization injections without relying on clinicians to lead the intervention.<sup>7</sup> This may lead to a higher uptake of the intervention.

The proposed mechanism of action for tactile stimulation involves the gate theory of pain, which posits that there is a gate in the spinal cord's dorsal horn that can facilitate or inhibit pain transmission centrally to the brain.<sup>8,9</sup> Briefly, primary afferent neurons, composed of A-delta, A-beta, and C-fibers, carry cutaneous sensory signals to the brain through the spinal cord. A-delta fibers and C-fibers are responsible for the transmission of pain input whereas A-beta fibers transmit touch sensation. A-beta fibers travel at much faster conduction velocities than C-fibers and A-delta fibers.<sup>10</sup> When the skin is touched, either by rubbing or applying pressure, A-beta fibers are stimulated. If A-beta fibers are stimulated at the same time as A-delta and C-fibers, the A-beta signals reach the dorsal horn of the spinal cord first due to their much faster conduction speed, and inhibit, or "close the gate" to pain signals arising from A-delta and C-fibers. This results in a lower pain signal reaching the brain. Importantly, for gating to be successful, overlap must occur in the inputs from nociceptive and touch fibers arriving at the spinal segment that has received the injury, but the relative position for tactile stimulation (ie, distal or proximal to the site of injury) is deemed not to be an important factor (R. Melzack, personal communication, November 20, 2012).

An area of the skin supplied by a single spinal nerve is commonly referred to as a dermatome, and maps are widely available from the internet and text books. However, the exact location of each dermatome varies among sources.<sup>11,12</sup> It is widely accepted that dermatome boundaries vary from person to person and dermatome fields

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overlap.<sup>12,13</sup> In addition, nerve fibers returning from a dermatome send collateral branches to several spinal segments.<sup>13</sup> The overlap of fields and signaling to multiple spinal segments lead to overlap of inputs from both the tactile and noxious stimuli when occurring nearby, even if they do not occur in the same dermatome.

The analgesic effects of tactile stimulation have been demonstrated in adults<sup>14–17</sup> and children<sup>18</sup> undergoing injections and is recommended in our evidence-based clinical practice guideline for reducing childhood immunization pain.<sup>19</sup> Tactile stimulation is not recommended for infants, however, due to an absence of studies in this population.<sup>19</sup> This study was undertaken in order to fill this knowledge gap. The specific objective was to determine the effectiveness of parent-led tactile stimulation for reducing pain in infants undergoing routine immunization injections, within the context of a multimodal pain management strategy.

## METHODS

We conducted a randomized, partially blinded, parallel, 2-group trial in healthy infants aged 4 to 6 months who were attending a primary care practice in Toronto, Canada for their routine immunization injections. The research ethics boards of the study site (Women's College Hospital) and the University of Toronto approved the study. The study was registered with ClinicalTrials.gov (NCT00954499).

Participants were randomized in a 1:1 ratio to the intervention or control group. A computer random number generator was used to create the sequence in random blocks of 4 to 8. The randomization code was created by an individual not directly associated with the study. Treatment allocation was concealed in sequentially numbered opaque sealed envelopes that were not opened until after written consent was obtained from a parent.

All infants aged 4 to 6 months scheduled to receive their routine diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and *Haemophilus influenzae* type B vaccine (DTaP-IPV-Hib) and pneumococcal conjugate vaccine (PCV) vaccines were eligible. Infants were excluded if they had any of the following: impaired neurological development, history of seizures, use of topical local anesthetics at the injection site, use of sedatives or opioids in the preceding 24 hours, fever or illness that would prevent administration of the vaccine, a parent who was unable to use the assessment tools in the study, or a parent who did not speak English. Each infant could participate only once.

Parents of consecutive infants were invited to participate by a research assistant. They were told the study was investigating combinations of several nondrug measures to reduce pain, but they were not informed about the specific intervention being evaluated until after data collection was complete. Hence, parents were blinded to group allocation and study hypothesis. All parents were given an information sheet recommending that, during the injection, they hold their infant close, position their infant upright, and use their voice to distract their infant. Parents in the tactile stimulation group had additional instructions to rub their infant's leg for 15 seconds before, during, and after each injection, using as much pressure as they felt would be suitable without distressing their infant. The site recommended was distal to the injection site, just above the knee on the same side as, and very close to the injection site. The location chosen allowed the nurse to have an area to

administer the vaccine that was not blocked or obscured by the parent's hand. All parents practiced the recommended techniques for a few minutes before the injections. The amount of time allotted for this practice was short, in order to maximize transferability to any practice setting.

Infants were given 2mL of 24% sucrose solution orally, beginning 2 minutes before the first injection. After sucrose administration, parents were instructed to hold their infants in their laps with the infant's legs tucked between the parent's legs, according to usual practice at this site. Then parents initiated the recommended techniques. Infants were administered 2 separate vaccine injections: DTaP-IPV-Hib (Pediacel; Sanofi Pasteur Limited, Toronto, Canada) and PCV. The PCV vaccine supplied by the provincial immunization program was changed from Prevnar (Pfizer Canada Inc., Toronto, Canada) to Synflorix (GlaxoSmithKline Inc., Mississauga, Canada) half way through the study. The clinician administered DTaP-IPV-Hib first and the PCV second in alternate legs, spaced by 1 minute to allow the infant to settle. Each vaccine was administered into the vastus lateralis muscle, on the front of the thigh. The order of injection was maintained to reduce overall pain,<sup>20</sup> but the starting side was chosen by the clinician. Vaccines were administered using a fast injection technique without aspiration.<sup>21</sup> The infant-parent dyad was videotaped during both injections.

Altogether, 13 nurses and 3 medical residents were involved in administering the vaccines. They were not blinded to group allocation; however, they did not speak about the study to parents nor were they involved with data coding or analysis.

Pain was assessed by parents and a research assistant who was present during the injections using a 100 mm visual analogue scale (VAS).<sup>22</sup> After the injections, parents reported their opinion about the feasibility and effectiveness of their interventions using a standardized questionnaire. We observed the injection site for adverse effects due to the intervention, such as skin color changes.

The primary endpoint, infant pain, was assessed from videotapes using the Modified Behavioral Pain Scale (MBPS), a validated tool for measuring immunization pain in infants.<sup>23</sup> The MBPS is a composite measure that rates facial grimacing, crying, and body movements, and varies from 0 (no pain) to 10 (maximum pain). MBPS scores were calculated for 15 seconds before and after each injection. The average postinjection score for both injections was used in the analysis, as in our previous study.<sup>20</sup> We chose to use the mean of both injections as the primary endpoint because parents in our previous studies have consistently reported that they consider the "overall" response of their infants rather than their response to "separate" injections when judging and recalling the event. MBPS preinjection scores were examined to ensure that there were no baseline differences between groups. The research assistant who rated pain using the MBPS was unaware of the study hypothesis. Inter-rater reliability was assessed by rescored 25% of the procedures by a second research assistant.

Secondary endpoints included real-time VAS pain ratings from parents (unaware of the study hypothesis) and the research assistant present at the procedure (aware of the study hypothesis), and duration of infant crying in the first minute after each vaccine injection (obtained from the videorecording and coded by a research assistant blinded to study hypothesis). Cry was defined as an audible vocalization in the presence of facial grimacing.

Fidelity of the allocated intervention (rubbing the leg) was determined by observing parent behavior from video-recordings. In addition, parent soothing behaviors during immunization were coded by a research assistant blinded to the study hypothesis, using the Measure of Adult and Infant Soothing and Distress tool.<sup>24</sup> Behaviors of distraction, offer toy, offer pacifier, offer food, nursing, physical comfort, rocking, and verbal reassurance were coded as present or absent in 5-second increments. Scoring was modified to account for treatment allocation—that is, rubbing the infant’s leg was not coded as physical comfort. The research assistant recorded the number of seconds of a specific behavior for each of 4 epochs (15s before and after each injection) for the 8 behaviors.

### Statistics

A sample of 56 per group was calculated to demonstrate a clinically meaningful change of 15%<sup>25</sup> in MBPS pain scores, assuming a SD of 1.5, 80% power and 2-sided  $\alpha$  level of 0.05. A total of 60 infants per group was planned to account for drop-outs and missing data. MBPS, parent and research assistant VAS scores, and crying time were compared between groups using *t* tests.  $\chi^2$  tests were used to compare categorical data. An  $\alpha$  level of 0.05 was considered significant. Intent-to-treat analysis was used to analyze data, whereby infants were analyzed in the originally assigned group, regardless of treatment received.

## RESULTS

The study was conducted between August 6, 2009 and November 16, 2010. Participant flow is shown in Figure 1. One hundred seventy-nine parents were approached and 120 consented. The most common reason for refusal was parent time constraints (*n* = 26). Sixty infants were

randomized to tactile stimulation and 60 to the control group. There were no significant differences (*P* > 0.05) in baseline characteristics between groups, including postnatal age and sex distribution (Table 1). The overall incidence of parent soothing behaviors was low and did not differ between groups (Table 2). Only 3 behaviors occurred in at least 20% of parent-infant dyads: distraction, physical comfort, and verbal reassurance.

### Fidelity of the Intervention

For the first injection, 56 infants in the tactile stimulation group had their leg rubbed both before and after the injection and 1 infant had their leg rubbed only after the injection. For the second injection, 55 infants in the tactile stimulation group had their leg rubbed before the injection and 51 infants after. Parents rubbed the leg for an average of 12 seconds (SD 4) before and 14 seconds (SD 3) after the first injection; for the second injection, the infant’s leg was rubbed for 14 seconds (SD 3) before and 11 seconds (SD 5) after. Rubbing during the needle penetration time was not coded separately because it represented <1 coding segment (5 s) and was captured in the “after injection” epoch.

In the control group, 2 infants had their leg rubbed before the first injection and 1 infant had his/her leg rubbed after the first injection. No infants in the control group had their leg rubbed before or after the second injection.

### Outcomes

MBPS scores are shown in Table 3. There was no significant difference in the mean MBPS score between the tactile stimulation group and the control group (8.2 vs. 8.0, *P* = 0.57). Similarly, there were no significant differences for parent-rated or research assistant-rated VAS scores, or infant cry duration (Table 3).

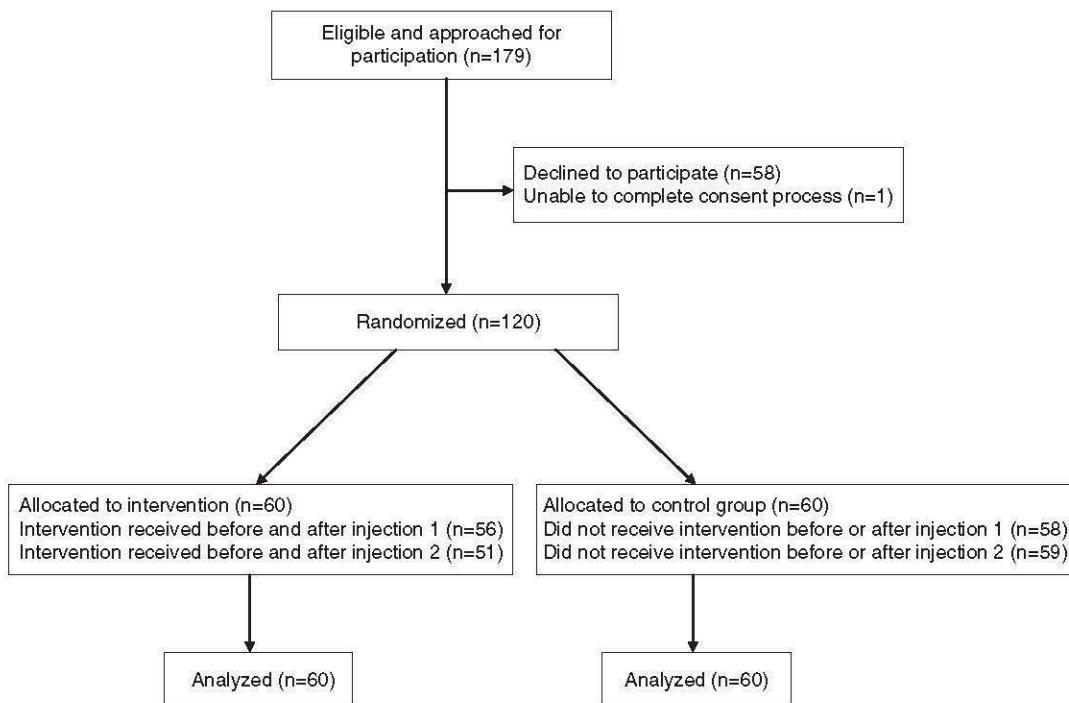


FIGURE 1. Participant flow.

**TABLE 1. Baseline Characteristics**

	Tactile Stimulation, n = 60	Standard Care, n = 60	P
Weight (kg) (SD)	7.4 (1.2)	7.2 (1.2)	0.24
Male sex, n (%)	35 (58)	26 (43)	0.10
Attending for 4 mo visit, n (%)	41 (68)	44 (73)	0.55
White, n (%)	39 (65)	42 (70)	0.56*
Circumcised males, n (% of males)	13 (37)	8 (31)	0.60
Mother attended appointment, n (%)	58 (97)	58 (97)	1.00
First born, n (%)	35 (58)	28 (47)	0.20*
Acetaminophen or ibuprofen before injection, n (%)	13 (22)	17 (28)	0.40
Time since last sleep (h) (SD)	2.1 (1.1)	2.3 (1.1)	0.42
Time since last food (h) (SD)	1.5 (1.9)	1.6 (2.1)	0.94
Time from sucrose administration to first injection (min) (SD)	2.4 (0.7)	2.4 (0.7)	0.93
Synflorix brand of PCV, n (%)†	30 (50)	31 (52)	0.86

\*Versus all others in grouping.

†PCV vaccine supplied by the provincial government changed from Prevnar to Synflorix during the study. Anecdotal reports by the clinicians suggested it had a comparable level of pain response when given to infants. PCV indicates pneumococcal conjugate vaccine.

Most parents in both the intervention and comparison groups found it somewhat or very easy to perform the recommended actions. There were no significant differences between

**TABLE 3. Pain Scores**

	Intervention, n = 60	Control, n = 60	P*
MBPS, mean of both injections (SD)	8.2 (1.1)	8.0 (1.3)	0.57
MBPS, baseline (SD)	3.1 (2.1)†	2.9 (2.0)†	0.70
MBPS, injection 1 (SD)	7.6 (1.8)	7.2 (2.0)	0.30
MPBS, before injection 2 (SD)	4.3 (2.3)	4.9 (2.5)	0.17
MBPS, injection 2 (SD)	8.8 (0.9)	8.9 (0.9)	0.50
VAS, parent, mean of both injections (mm) (SD)	60 (20)	53 (22)	0.10
VAS, research assistant, mean of both injections (mm) (SD)	50 (17)	46 (16)	0.12
Cry % in first minute postinjection, mean of both injections (SD)	51 (25)	48 (25)	0.55

\*t test.

†MBPS score of 2 is a neutral expression, no crying and usual body movements.

MBPS indicates Modified Behavioral Pain Scale (0 to 10, 0 = no pain); VAS, visual analog scale (100 mm scale, 0 = no pain).

groups in any of the responses in the parent questionnaire (Table 4). There were no adverse events in any of the infants.

**DISCUSSION**

To our knowledge, this is the first study to assess parent-led tactile stimulation for pain management during immunization injections in infants. We found that in the

**TABLE 2. Number of Parents Exhibiting MAISD Behaviors\*, †**

	Before Injection (n [%])		After Injection (n [%])	
	Tactile Stimulation, n = 60	Standard Care, n = 60	Tactile Stimulation, n = 60	Standard Care, n = 60
Distraction				
Injection 1	54 (90)	57 (95)	56 (93)	54 (90)
Injection 2	52 (87)	53 (88)	54 (90)	46 (77)
Offer toy				
Injection 1	0	0	0	0
Injection 2	0	0	0	0
Offer pacifier				
Injection 1	1 (2)	1 (2)	3 (5)	1 (2)
Injection 2	0	2 (3)	2 (3)	4 (7)
Offer food				
Injection 1	0	0	0	0
Injection 2	0	0	0	0
Nursing				
Injection 1	0	0	0	0
Injection 2	0	0	0	0
Physical comfort				
Injection 1	2 (3)	4 (7)	9 (15)	8 (13)
Injection 2	6 (10)	4 (7)	8 (13)	17 (28)
Rocking				
Injection 1	0	3 (5)	5 (8)	6 (10)
Injection 2	4 (7)	1 (2)	5 (5)	7 (12)
Verbal reassurance				
Injection 1	4 (7)	0	8 (13)	13 (22)
Injection 2	5 (8)	7 (12)	23 (38)	14 (23)

\*No comparisons were statistically significant using the Bonferroni correction for multiple comparisons.

†Numbers represent parents who exhibited the MAISD behavior for at least one 5-second interval of the coding epoch. MAISD indicates Measure of Adult and Infant Soothing and Distress.

**TABLE 4.** Parent Responses to Questionnaire\*

	n (%)		P†
	Intervention, n = 60	Control, n = 60	
Somewhat or very easy to perform recommended procedures	45 (76)‡	37 (62)	0.12
Parent thought infant benefited from parent's actions	32 (53)	32 (53)	1.00
At future immunizations, parent plans to			
Hold their infant close and upright	60 (100)	60 (100)	1.00
Give oral sucrose	56 (93)	49 (82)	0.10
Distract their infant	51 (85)	52 (87)	0.79
Rub their infant's leg	53 (88)	NA	—

\*All results are represented as n (%).

‡ $\chi^2$  test.

†n = 59 for this question only.

NA indicates not available.

presence of sucrose analgesia, parental holding, parent-led distraction, and injection without aspiration, there was no evidence of a benefit from the addition of parent-led tactile stimulation.

Our finding differs from studies performed in older children and adults that evaluated tactile stimulation led by clinicians or researchers.<sup>14-18,26</sup> A previous study of children aged 4 to 6 years who received immunization injections found that having the leg rubbed by the researcher resulted in less pain than no intervention.<sup>18</sup> Studies in adults undergoing injections<sup>14-17</sup> also demonstrated effectiveness of tactile stimulation. In addition, a study of neonates undergoing heel lance found tactile stimulation reduced pain.<sup>26</sup> There is a major difference in how tactile stimulation was delivered in the present study compared with previous studies<sup>14-18,26</sup> that may, at least partially, explain the discrepant findings. In the present study, parents administered the tactile stimulation. In contrast, previous studies<sup>14-18,26</sup> used either clinicians or researchers to administer the tactile stimulation. It is possible that having parents administer the intervention contributed to the negative findings in several ways. First, it is possible that parents randomized to the tactile stimulation group were focused on rubbing their infant's leg and did not provide usual comforting measures to their infants, negating the benefit of rubbing. Although we did not find a significant difference in parental behaviors, as assessed by the Measure of Adult and Infant Soothing and Distress, the tool does not measure the quality or effectiveness of behaviors,<sup>24</sup> so unmeasured differences in parental behaviors could be contributing to the negative results. Second, it is possible that the technique and location used by parents to rub the skin was ineffective. At present, the best way of delivering tactile stimulation (pressure, rhythm, etc., and proximity to the injection site) is not known and we cannot rule out the possibility that parents may have been too gentle or too rough, or not close enough to the site of injury. Our review of the literature, however, did not suggest any gross errors in the region chosen for tactile stimulation. Furthermore, a study demonstrated the effectiveness of a tactile stimulus when applied distal to a noxious stimulus on the same arm, and conversely, ineffectiveness when administered to the opposite arm.<sup>27</sup> In addition, the positioning of infants (ie,

legs tucked between the parent's legs) and clinicians' injection techniques (ie, handling the injection site before and during immunization) at the primary care practice site may have provided sufficient tactile stimulation to both groups to prevent any additional benefit from the intervention.

Alternatively, it is possible that rubbing is a weak analgesic that, when added to other effective interventions, does not add any appreciable effect. Previous studies that found a pain relieving effect from tactile stimulation did not assess it in the presence of other analgesia, while all infants in the present study received other pain relieving measures. Therefore, it is possible that these measures prevented detection of an effect from tactile stimulation. These results are consistent with a previous study demonstrating no additional benefit from topical lidocaine when added to sucrose analgesia for venipuncture pain management in neonates.<sup>28</sup>

Differences in other design features in the present study when compared with previous studies may account for the differing results. Previous studies lacked blinding of researchers, clinicians, and patients, which may have biased the results in favor of tactile stimulation.<sup>14-18</sup> In the present study, pain was assessed by research assistants (using MBPS) and parents (using VAS) who were blinded to the study hypothesis and group allocation. Consequently, management of bias in evaluation of the outcome may have been more effective in this study.

Treatment fidelity was high for the parents that were randomized to the tactile stimulation group: altogether, 57 (95%) administered the intervention during at least 1 phase of the immunization procedure. We noted that the duration for the tactile stimulation ranged from 11 to 14 seconds, depending on the phase that was examined. There is no evidence that suggests our prescribed time of 15 seconds was either required or optimal for effectiveness, and a duration of <15 seconds was effective in previous studies.<sup>27,29</sup> The 15-second administration time was chosen to give parents sufficient time to establish a motion that was comfortable for them before the injection and not too long after the injection to prevent them from comforting their infant in other ways.

It is noteworthy that at least 85% of parents expressed interest in performing the same pain reduction tactics at future immunizations, even if they did not think their infant had benefited from them. This likely reflects a desire on the part of parents to reduce pain in their infant and highlights that parents are not satisfied with the current care their infants receive at immunization visits. Parent responses also reflect their willingness to use methods recommended to them.

We noticed that pain scores (MBPS and VAS) in this study were higher in both groups than in our other similar immunization pain studies.<sup>20,21</sup> This was surprising, given that all infants in this study received oral sucrose and injection without aspiration, whereas in the earlier studies, the comparison groups received no analgesia.<sup>20,21</sup> We observed a difference in infant position in this study compared with earlier ones.<sup>20,21</sup> Infants in this study sat upright on their parent's laps and had their legs trapped between the parent's legs. In other studies,<sup>20,21</sup> parents held their infant upright in front of them during injection, in a manner that allowed their arms and legs to move freely. It is possible that restraint at the time of the injection (when the infant moved in response to the pain) might have led to additional distress.<sup>6,30,31</sup> These factors might partially explain the high MBPS scores. Future research should evaluate these elements of the immunization procedure.

A limitation of the study was that clinicians were not blinded to group assignment, and therefore, introduction of unintentional bias was possible. However, clinicians did not communicate with parents about the study. In addition, giving injections is a motor skill performed automatically once learned, and it is doubtful that clinicians changed their practice based on knowledge of group assignment.

There are numerous strengths in this study design, including: randomization of infants, concealment of treatment allocation until after recruitment, blinding of parents, blinding of outcome assessors, and using intent-to-treat analysis. The design to “blind” parents to the intervention was important for this study. Because parents could not be blinded to their own actions, concealment of the study hypothesis and group assignment (to help both groups think they were in an intervention group) were suitable ways to reduce bias in parent responses.

In addition, the study design strengthened the generalizability of the findings in the following ways: (1) multiple clinicians administered immunizations, which mirrors real-world practice where clinician habits may vary; (2) participating parents were from a wide variety of ethnic origins, reflecting differences in perspectives and values; (3) parents were briefly trained to administer tactile stimulation and other pain-relieving interventions immediately before immunization injections, during usual waiting times, in order to mimic a feasible approach for the practice setting.

## CONCLUSIONS

In this study, we found no evidence for the effectiveness of parent-led tactile stimulation to reduce pain from immunization injections in infants when added to other pain-relieving interventions. Parent-led tactile stimulation should therefore not be recommended as a method of reducing pain during infant immunization injections. Clinicians who administer the injections may be better suited to administer this intervention. It is recommended that clinician-led tactile stimulation be evaluated in this population in future studies.

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