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Original Research Article

The ABCDs of Pain Management: A Double-Blind Randomized Controlled Trial Examining the Impact of a Brief Educational Video on Infants' and Toddlers' Pain Scores and Parent Soothing Behavior

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Abstract

Objectives To test the efficacy of a brief behavioral pain management strategy (The ABCDs of Needle Pain Management), delivered via video, on infants' and toddlers' pain scores and on parental soothing behavior. **Methods** This was a double-blind, parallel trial design. Parent–child dyads ($N = 128$) were recruited before their child's 6-month (infant) or 18-month (toddler) vaccination in a pediatric clinic and randomly assigned to watch a 5-min treatment video or a placebo video. The primary outcome was the Modified Behavior Pain Scale (Taddio et al., Journal of Pain and Symptom Management, 10, pp. 456–463, 1995), coded during four epochs (Pain Reactivity, Pain Regulation 1 min, Pain Regulation 2 min, and Pain Regulation 3 min) after the last vaccination needle. Secondary analyses examined parental use of distraction, rocking, and physical comforting over this same time period. **Results** Results demonstrated a treatment effect for toddlers (18-month-olds) for the Pain Regulation 1 ($d = 0.84$) and Pain Regulation 2 ($d = 0.76$) postvaccination scores. Secondary analyses found differences in parental rocking and physical comforting between treatment conditions and between age-groups (d's = 0.37–0.54). **Conclusions** The ABCD pain management strategy delivered via video was an effective way to reduce toddler pain after vaccination and increase parental use of rocking and physical comforting. The treatment effect was not demonstrated with infants.

Key words: children; pain; parents; randomized controlled trial.

Introduction

Parents play a crucial role in supporting their infants during painful contexts (Pillai Riddell & Chambers, 2007; Pillai Riddell, Racine, Craig, & Campbell, 2013), particularly in terms of their efforts to manage or soothe their infant's pain-related distress. Previous research indicates that parents have a desire to reduce their infants' pain but lack specific information about how to do so (Taddio et al., 2014). Although there is a dearth of quality research on parent-targeted interventions for infant pain (Pillai Riddell, Gennis, Taddio, & Racine, 2016), recent research is beginning to focus on this gap.

Specifically, recent studies in the vaccination context (Taddio et al., 2013, 2014) have shown that

parent-directed educational materials such as pamphlets and videos have led to higher use of parent-employed pain management interventions such as breastmilk via feeding, administering sugar water and topical anesthetics, as well as higher use of the non-pharmacological intervention of holding one's infant. Video instruction is considered particularly beneficial in terms of increasing parent knowledge about how to implement pain management strategies (Taddio et al., 2013).

From a parent educational perspective, other forms of interventions worthy of targeting in the vaccination setting include proximal soothing (i.e., physical comfort and rocking) and distraction, both of which are considered the most effective nonpharmacological strategies in the vaccination context (Axia & Bonichini, 2005; Blount, Devine, Cheng, Simons, & Hayutin, 2008; Campbell, Pillai Riddell, Garfield, & Greenberg, 2013; Campos, 1994; Cohen, 2002; Lisi, Campbell, Pillai Riddell, Garfield, & Greenberg, 2013; Moscardino et al., 2006; Stifter & Rovine, 2015). With a few exceptions (Stifter & Rovine, 2015), limited research has investigated the use of multiple parent-led nonpharmacological interventions used concurrently (e.g., distraction and proximal soothing in combination). Moreover, in addition to evoking distress in young children, vaccinations can also be a source of stress for parents themselves. Given that parent stress has been shown to influence parenting behavior (Crnic & Low, 2002; Deater-Deckard & Scarr, 1996; Patterson, 1983), it seems likely that parent worry may have an impact on parents' ability to effectively engage in soothing behaviors. One evidence-based, easy-to-implement strategy for stress reduction (Varvogli & Darviri, 2011) that could be easily used by parents in the vaccination setting is diaphragmatic breathing, also known as "deep" or "belly" breathing.

To our knowledge, no parent-targeted interventions for young child vaccination pain have targeted a combined nonpharmacological approach to young child pain management. The goal of this study was to determine the effectiveness of a brief parent pain management video (The ABCDs of Pain Management) at two distinct developmental stages of young childhood (6 months [infant] and 18 months [toddler]). The primary outcome was behavioral pain scores at four epochs postvaccination (15 s after last needle [Pain Reactivity], 1 min postvaccination [Pain Regulation 1], 2 min postvaccination [Pain Regulation 2], and 3 min postvaccination [Pain Regulation 3]). The video specifically targeted three soothing behaviors—parent use of distraction, physical comforting, and rocking (in addition to raising awareness that parental anxiety can increase young child distress and describing a simple diaphragmatic breathing technique can help to calm oneself down during periods of stress). Secondary analyses examined the impact of the video on the occurrence of the parental soothing behaviors (distraction, physical comforting, and rocking) for the first, second, and third minute postvaccination. For both primary and secondary outcomes, analyses were stratified by age and treatment.

It was hypothesized that the video would result in lower pain scores during the regulation phases post-needle and higher parent use of soothing behaviors. As argued elsewhere (Pillai Riddell et al, 2015), nonpharmacological interventions are not blocking the pain pathways at a cellular level (akin to analgesics and anesthetics), and thus, differences in initial pain reactivity were not hypothesized but differences in pain regulation were expected. The video was hypothesized to change parent behaviors. Thus, more distraction, physical comforting, and rocking were expected to be seen in the treatment group. Finally, it was further hypothesized that age would be a treatment effect modifier. Parent interventions would be more effective for the toddler sample owing to the stability of the parent–infant attachment relationship at that stage compared with earlier in infancy (Pillai Riddell et al., 2013). Thus, parent behaviors would have a stronger impact on toddler distress behaviors than infant distress behaviors.

Methods

Trial Design

This was a multicenter, stratified (6 months and 18 months), with balanced randomization (1:1), double-blind, placebo-controlled, parallel-group study. The research ethics board (Human Participants Review Committee) at the participating university approved the study protocol. The trial was registered in advance at clinicaltrials.gov (CT identifier: NCT01826383). One hundred twenty-eight families were recruited (see Figure 1 for CONSORT Participant flow diagram) from April 2013 to January 2014 and included in the analysis. The primary outcome was 4 behavioral pain scores after last vaccination needle (15 s, 1 min, 2 min, and 3 min after last vaccination needle). The secondary outcomes were distraction, rocking, and physical comforting 1 min, 2 min, and 3 min after last vaccination needle. The last needle was chosen owing to the short interneedle interval (generally <15 s).

Participants

Young children receiving their routine 6- or 18-month routine vaccinations at one of two participating pediatrics clinics were assessed for eligibility. The clinics were in a large multicultural city in

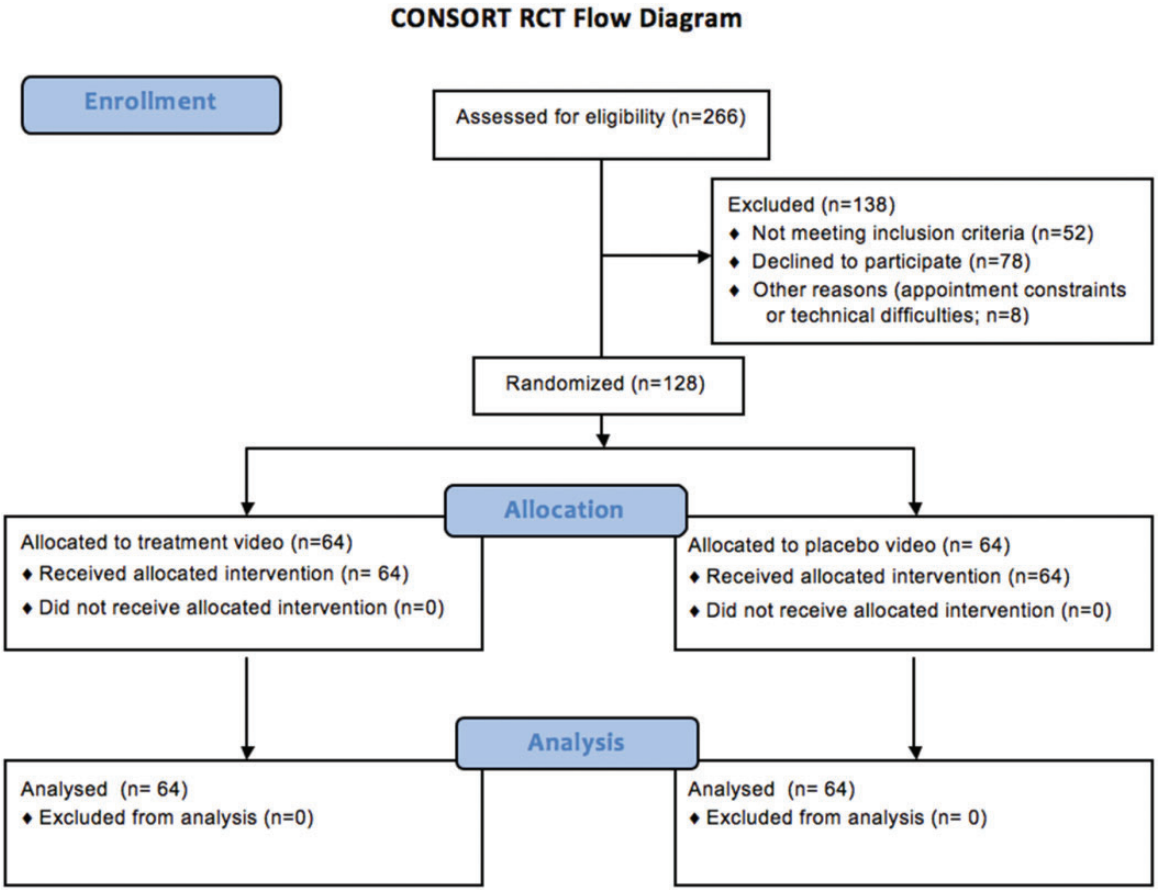

Figure 1. Consort flow diagram.

Central Canada. Parents willing to be approached were asked about exclusion criteria. Young children were excluded if they had a suspected developmental delay or chronic illness, if they had been admitted to a neonatal intensive care unit, if they were born more than three weeks premature, and/or if they had a sibling who had already participated in the present study.

The majority of participants were mothers (88%), who were married (93%) and self-reported they were the primary caregiver of the young child undergoing vaccination (95%). Most caregivers reported that both they and their spouses had a university degree or higher (83% and 79%, respectively). The mean age of caregivers was 34.56 years ($SD = 4.1$). The sample was ethnically diverse with 45 different national or mixed national heritage cultures being self-reported, predominantly from Europe and Asia. In terms of acculturation, the sample reported that their way of life was strongly reflective of both their self-reported heritage culture and mainstream North American/Canadian culture. Twelve families reported the use of Tylenol before the vaccination. They were equally distributed among the four combinations (age by treatment). No families reported use of topical anesthetics. See Table I for demographic characteristics stratified by treatment versus control groups.

Interventions

Parents were provided with a study information sheet by the medical receptionist in the waiting room and asked if they would like to learn more about the study. Parents who indicated interest were approached by a clinic Research Assistant (RA). The RA determined eligibility, described the study in further detail, and obtained written informed consent.

Parents were randomly assigned to receive either a 5-min active treatment video that coached them on how to soothe their young child during the vaccination or a 5-min placebo video that was identical to that of the active video (i.e., same introduction about the importance of pain management in young children with the same health professionals speaking) except that no specific instructions regarding how to soothe their young child during the vaccination were provided. The RAs were blinded to which video version parents watched and therefore were not permitted to watch the video with the parents. The RAs also informed the parents that they would not be able to answer any questions about the video given that they

Table I. *Demographic Variables in the Treatment versus Control Group*

	Number (%)	
	Treatment group ($n = 64$)	Control group ($n = 64$)
Relationship to infant		
Mother	55 (85.9)	57 (89.1)
Father	9 (14.1)	6 (9.4)
Other	0 (0)	1 (1.6)
Marital status		
Married/Common Law	60 (93.8)	59 (92.2)
Never Married	3 (4.7)	1 (1.6)
Other	1 (1.6)	4 (6.3)
Education		
Graduate School/Professional Training	27 (42.2)	29 (45.3)
University Graduate (4 years)	22 (34.4)	28 (43.8)
Partial University (at least 1 year)	5 (7.8)	1 (1.6)
Trade School/Community College	6 (9.4)	3 (4.7)
High School Graduate	3 (4.7)	3 (4.7)
Some High School (Minimum 10th Grade)	1 (1.6)	0 (0)
Age	34.42 (4.19)	34.69 (4.06)
Acculturation status		
Way of life reflects heritage culture	5.89 (2.83)	5.76 (2.33)
Way of life reflects mainstream North American/Canadian culture	7.34 (2.44)	6.91 (2.37)

were not permitted to know anything about the video the parents were watching. Videos were watched in the waiting room on a portable DVD player, before entering the clinic room for their appointment. Thus, health care providers were also blinded to study condition.

The treatment video instructed parents on the ABCDs (**A**ssess anxiety, **B**elly breathe, **C**alm Close Cuddle, **D**istraction) of pain management. These four areas of focus were based on extensive analyses of natural soothing behaviors, objectively coded as sensitive, that parents demonstrated in the Opportunities to Understand Childhood Hurt (OUCH) cohort longitudinal study (e.g., Campbell et al., 2013; Lisi et al., 2013). In regards to the specifics of the ABCDs, parents were encouraged and instructed to, in order, (A) **A**ssess their own anxiety by self-reflecting on their stress level right before the vaccination begins, (B) **B**elly breathe if stressed, by putting their hand on their diaphragm and breathing in deeply counting to three and exhaling slowly counting to three, (C) Use a **c**alm, **c**lose, **c**uddle (before, during, and after the needle) with their young child, and (D) **D**istract their baby when the peak distress has passed. In regards to the distraction component, parents were encouraged to take their baby's attention away from the pain using a normal tone of voice some time within 20 s to 1 min after the needle (e.g., pointing out a window, presenting a toy). It was also highlighted that attempting to distract one's young child when he/she is at peak distress is not advised. In these cases, the video encouraged parents to continue cuddling the young child for a little longer instead of attempting to distract. A 9-min video description of the ABCD's technique, a general primer to the historical neglect of pained infants, and the need for infant pain management are provided at https://www.youtube.com/watch?v=FxGXNYLocWM.

The placebo video provided parents with neutral information (still in an ABCD format) in lieu of the aforementioned ABCDs. In terms of the ABCDs for the placebo video, parents were encouraged and instructed to, in order, (A) Act in their young child's best interest, (B) Be aware that needles are distressing, (C) Carry out what they think is best, and (D) Do their best to help their young child.

Procedure

The entire vaccination was videotaped by a RA using two cameras. The first captured the young child's face and the second captured the entire parent–young child interaction. The RA videotaped from the moment the young child entered the examination room up until 4 min after the vaccination or when the parent and young child had left the clinic room (whichever came first). The RA said "now" at the moment when the young child's skin was punctured by the needle to ensure the exact time of each needle was accurately recorded for coding purposes. Video footage from each vaccination was subsequently coded for young child behaviors and parent soothing behaviors after the last vaccination needle. Seventy-two percent and 75% of 6- and 18-month-olds received one needle, respectively. Twenty-two percent and 28% of 6- and 18-month-olds received two needles, respectively. Two 18-month-olds received three needles. All needles were administered in consecutive sequence, with no

concurrent vaccination. No adverse events were reported during this study.

Randomization

Sequence Generation and Allocation Concealment Mechanism

The first step in generating the random allocation sequence was having a RA blinded to study hypotheses make 64 copies of the treatment video and 64 copies of the placebo video. The blinded RA then used a random number generator (http://www.randomizer.org/form.htm) and obtained 128 sets of randomly generated three-digit numbers. This RA was not involved in data collection or data coding. All sets were generated at once to ensure that no repeated numbers were randomly generated. Going down the list, one at a time, the blinded RA assigned the three-digit numbers to the 64 treatment DVDs and 64 control DVDs, entered the three-digit video ID number onto a master coding sheet that denoted whether it was treatment or control and a second blinded RA labeled the DVD using a black permanent marker. For every DVD, both blinded RAs confirmed that the numbers written on the DVD matched those in the master sheet and were the correct number that was randomly assigned. Subsequently, the treatment video pile and placebo video piles were split by the blinded RAs to make four piles per site (18-month toddlers: 16 treatment, 16 placebo; 6-month infants: 16 treatment, 16 placebo). Afterward, the treatment video piles and placebo video piles for each site and age group were shuffled in a bag and assigned Participant ID numbers. Again, a blinded RA entered the participant ID onto the master coding sheet and a second blinded RA labeled the DVD using black permanent marker. The master list was stored in a locked cabinet that only the blinded RAs would access and the list was not released to the lead author until the analyses were complete.

The aforementioned RAs, pediatric clinic RAs and care providers, behavioral coders, and authors were all blinded regarding participants' assignments to interventions. Unblinding occurred after the primary analyses were completed.

Measures

All behavioral measures (Modified Behavior Pain Scale [MBPS] and Measure of Adult and Infant Soothing and Distress [MAISD]) were trained using manualized procedures and a standard set of training videos to achieve initial reliability over .85. Twenty percent of coding was checked by a primary coder on a biweekly to monthly basis and reports sent to team members. When reliability estimates were below .8, a meeting was set up to discuss discrepancy and the primary coders' scores were used in the data set. All coders were blinded to group assignment and study hypotheses.

Parent Demographic Information

Parents completed a short demographic questionnaire that asked about basic background information such as their relationship to infant, age, education, marital status, and self-reported acculturation level. Parents provided two separate ratings, adapted from the Vancouver Index of Acculturation (Ryder, Alden, & Paulhus, 2000), asking how much they feel their way of life reflects their heritage culture and their mainstream North American/Canadian culture on a scale of 0 (*not at all*) to 10 (*completely*).

Young Child Pain Behaviors (Primary Outcome)

The MBPS (Taddio, Nulman, Koren, Stevens, & Koren, 1995) was used as the primary outcome measure to assess the degree of pain-related distress. This scale uses behavioral indices to determine how much pain the young child is experiencing. There are three subsections of the scale (facial expression, cry, and body movement), each requiring the coder to objectively score based on overt young child behavior during a 15-s epoch. All sections of the measure are summed to get a pain-related distress score out of 10. Moderate to high concurrent and construct validity as well as item-total and interrater reliability have all been demonstrated in the vaccination context (Taddio et al., 1995). Data for this scale were coded immediately after the last needle (Pain Reactivity MBPS; 1–15 s after last needle), as well as at 61–75 s after last needle (Pain Regulation 1), 121–135 s after last needle (Pain Regulation 2), and 181–195 s after last needle.

MBPS was coded by 2 coders who were blind to the study hypotheses and treatment condition. Interrater reliability was high with the overall intra-class correlation exceeding .90.

Parental Behaviors (Secondary Outcomes)

Parent soothing behaviors for each of the first 3 min after the last vaccination needle served as the secondary outcomes.

Frequency of Parent Behaviors

Parent behaviors targeted in the video were coded using the MAISD (Cohen et al., 2005). The MAISD is a reliable and valid behavioral observation scale developed for use during pediatric medical procedures. Only MAISD soothing behaviors viewed as being potentially impacted by the treatment video (i.e., distraction, rocking, and physical comfort) were coded. Each behavior was coded as present (1) or absent (0) for 5-s epochs for four 1-min periods: Pain Reactivity (15 s after the last needle), Pain Regulation 1 (Minute 1 after the last needle), Pain Regulation 2 (Minute 2 after the

last needle), and Pain Regulation 3 (Minute 3 after the last needle). For each of the three behaviors, total scores ranging from 0 to 12 were summed for each of the 1-min phases. These scores represent the frequency that the soothing behavior was present during that minute. Higher scores reflect a greater frequency of behavior. Two trained MAISD coders, blind to the study hypotheses and treatment condition, coded the data. Interrater reliability on all three parent soothing behaviors exceeded .80.

Sample Size

G*Power Statistical Power Analysis Software for Mac was used to determine the required sample size for the present study. An *a priori* analysis was calculated based on an estimated effect size = 0.25, alpha error prob = 0.05, Power = 0.8, and two groups (treatment vs. control). The total sample size required was 128 participants. The effect size was selected based on smallest significant correlational relationships found between parent behavior and pain scores in the OUCH Cohort (Campbell et al., 2013).

Statistical Methods

Chi-square demographic analyses and *t*-tests were run to determine equivalency of the treatment and control conditions. All tests had $p > .05$ and indicated there were no significant differences on parent marital status, age, education, acculturation status, and relationship to infant (see Table I for descriptives).

To compare groups on the primary dependent variables (i.e., the four young child pain outcomes: Pain reactivity, Pain Regulation 1, Pain Regulation 2, Pain Regulation 3), one 2 by 2 multivariate analysis of variance (MANOVA) was conducted. The independent variables were Age (6 vs. 18 months) and Group (treatment vs. control). To compare groups on the secondary outcomes (i.e., the three parent soothing behaviors [distraction, rocking, physical comforting] for Minute 1, Minute 2, and Minute 3 after last needle), three additional 2 by 2 MANOVAs were conducted, one for each of the 3 min. Thus, each secondary outcome MANOVA analyzed physical comforting, distraction, and rocking for a post-needle minute—Minute 1, Minute 2, or Minute 3.

Across MANOVAs, if a significant multivariate result occurred, follow-up post hoc analyses were conducted by 2 by 2 analyses of variance (ANOVAs) for each dependent variable separately. The assumptions of linearity, normality, and multivariate collinearity were examined. Linearity and normality were violated across MANOVAs. Equal sample sizes and using the Pillai's trace allowed for more robust analyses despite violations.

Results

Primary Pain Outcomes Analyses

The multivariate result was significant for both the Age effect and the Age by Group interaction (respectively, Pillai's trace = 0.246, $F = 7.64$, $df = [4, 94]$, $p = .000$; Pillai's trace = 0.121, $F = 3.22$, $df = [4, 94]$, $p = .01$). All means and standard deviations are shown in Table II. The interaction was considered the highest order effect and thus post hoc analyses examined only this effect. Four post hoc ANOVAs examining the interaction effect on all four of the primary outcome-dependent variables were conducted. Significant effects were found only for the Pain Regulation 1 and Pain Regulation 2 epochs (respectively, $F = 12.70$, $df = [1,97]$, $p = .001$; $F = 4.50$, $df = [1, 97]$, $p = .03$). The interaction was graphed and displayed a treatment effect for the 18-month-old group only for both Pain Regulation 1 and Pain Regulation 2 (Figures 2 and 3). The Pain Regulation 1 effect size was $d = 0.84$, while the effect of the treatment on Pain Regulation 2 was $d = 0.76$.

Secondary Outcome Analyses

To compare the groups on parent soothing behavior, three MANOVAs were conducted, one for soothing behaviors during each minute after last vaccination needle. The multivariate result for Minute 1 and Minute 3 indicated no significant overall effects, while significant effects were found for Minute 2. Table III provides the mean values and standard deviations for each of the secondary outcome MANOVA analyses.

For Minute 2, the multivariate result indicated a significant Age effect and a Group effect (respectively, Pillai's trace = 0.06, $F = 2.90$, $df = [3, 120]$, $p = .03$; Pillai's trace = 0.08, $F = 3.46$, $df = [3, 120]$, $p = .01$). Three post hoc ANOVAs examined the differences among rocking, distraction, and physical comforting for age effects at 2 min. Age differences were only

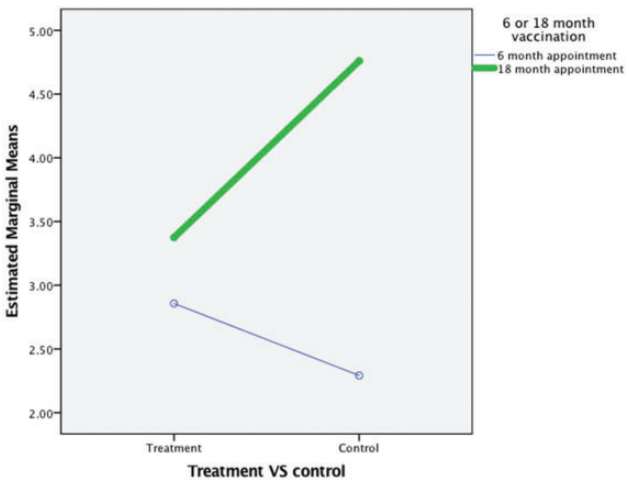

Figure 2. Primary outcome: Signficant interaction effect of age and group for pain regulation 1 score

found for rocking ($F = 7.32$, $df = [1,121]$, $d = 0.48$, $p = .008$). Three post hoc ANOVAs examined the differences among rocking, distraction, and physical comforting for group effects at 2 min. Group effects were only found for physical comforting and rocking (respectively, $F = 4.46$, $df = [1,121]$, $p = .03$, $d = 0.37$; $F = 9.39$, $df = [1, 121]$, $d = 0.54$, $p = .003$).

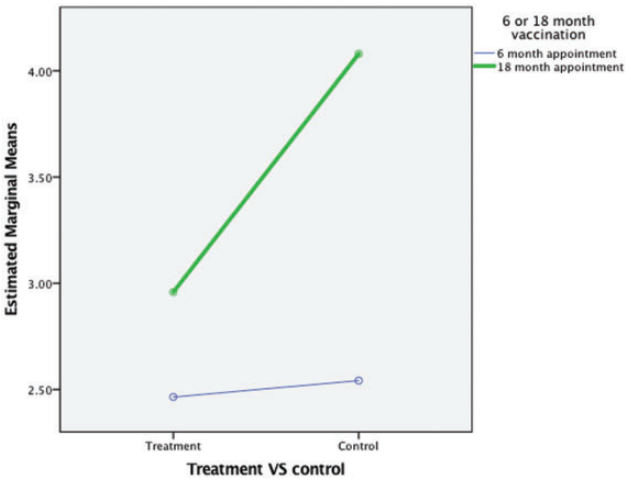

Figure 3. Primary outcome: Significant interaction effect of age and group for pain regulation 2 score

Discussion

To our knowledge, this was the first study on a video intervention for young child pain that focused on an examination of age effects and treatment effects. Treatment groups were stratified according to age (infant [6 months] vs. toddler [18 months]) to determine whether treatment efficacy was impacted by age of child. The primary outcome of interest was young child pain, measured at four different time points to account for the qualitatively different pain experiences of reactivity versus regulation. The secondary outcomes of interest were the parental soothing behaviors targeted in the video. Results partially confirmed hypotheses. An interaction effect was found such that the video only reduced pain in the toddler group (18-month-olds) during the initial regulation phases (1 min and 2 min after last needle). Post hoc analyses suggested both age and group effects for physical comforting and rocking during the second minute after the needle (no interaction). Children in the infant group

Table II. *Means and Standard Deviations for MANOVA Analysis on Primary Outcome (Age by Treatment MANOVA With Dependent Variables Pain Reactivity, Pain Regulation 1, Pain Regulation 2, Pain Regulation 3)*

Primary outcomes	Treatment vs. control	6- or 18-month-olds	Mean	Std. Deviation
Pain Reactivity (15 s after last needle)	Treatment	6	6.25	2.42
		18	5.91	1.74
		Total	6.09	2.12
	Control	6	5.37	2.46
		18	6.72	1.76
		Total	6.06	2.22
	Total age	6	5.84	2.46
		18	6.32	1.78
Pain Regulation 1 (15 s, I min after the last needle)	Treatment	6	2.85	1.26
		18	3.37	1.46
		Total	3.09	1.37
	Control	6	2.29	0.69
		18	4.76	1.80
		Total	3.55	1.84
	Total age	6	2.59	1.07
		18	4.08	1.77
Pain Regulation 2 (15 s, 2 min after the last needle)	Treatment	6	2.46	0.83
		18	2.95	1.36
		Total	2.69	1.12
	Control	6	2.54	1.02
		18	4.08	1.60
		Total	3.32	1.54
	Total age	6	2.50	0.91
		18	3.53	1.58
Pain Regulation 3 (15 s, 3 min after the last needle)	Treatment	6	2.42	0.92
		18	2.70	1.23
		Total	2.55	1.07
	Control	6	2.54	1.17
		18	3.40	1.29
		Total	2.97	1.29
	Total age	6	2.48	1.03
		18	3.06	1.29

Table III. *Means and Standard Deviations for MANOVA Secondary Analysis for Minute 1, 2, and 3 (Age by Treatment MANOVA; Dependent Variables: Distraction, Physical Comforting, and Rocking)*

Parental Behavior	Treatment vs. control	Infant or toddler	Minute 1 Mean (*SD*)	Minute 2 Mean (*SD*)	Minute 3 Mean (*SD*)
Distraction	Treatment	Infant	0.34 (0.97)	0.03 (0.17)	0.21 (0.68)
		Toddler	0.28 (0.85)	0.38 (1.81)	0.30 (1.25)
		Total	0.31 (0.90)	0.20 (1.28)	0.25 (0.97)
	Control	Infant	0.21 (0.94)	0.12 (0.49)	0.04 (0.20)
		Toddler	0.64 (1.40)	0.03 (0.17)	0.19 (0.63)
		Total	0.42 (1.20)	0.07 (0.37)	0.11 (0.47)
	Total age	Infant	0.28 (0.95)	0.07 (0.36)	0.13 (0.52)
		Toddler	0.46 (1.16)	0.20 (1.29)	0.24 (0.96)
		Total	0.37 (1.06)	0.14 (0.94)	0.18 (0.76)
Physical comforting	Treatment	Infant	4.46 (3.56)	2.18 (3.51)	0.67 (1.96)
		Toddler	4.71 (3.66)	0.83 (1.26)	0.95 (2.38)
		Total	4.59 (3.58)	1.52 (2.72)	0.80 (2.14)
	Control	Infant	3.81 (3.02)	0.78 (1.77)	1.08 (1.84)
		Toddler	2.64 (2.65)	0.58 (1.50)	0.73 (1.18)
		Total	3.23 (2.88)	0.68 (1.63)	0.90 (1.53)
	Total age	Infant	4.14 (3.29)	1.48 (2.85)	0.86 (1.90)
		Toddler	3.69 (3.34)	0.70 (1.38)	0.83 (1.82)
		Total	3.92 (3.31)	1.10 (2.27)	0.85 (1.85)
Rocking	Treatment	Infant	3.62 (4.34)	2.62 (3.85)	0.92 (2.41)
		Toddler	3.03 (3.62)	0.58 (1.60)	0.52 (1.90)
		Total	3.32 (3.98)	1.61 (3.12)	0.74 (2.18)
	Control	Infant	2.43 (3.31)	0.43 (1.26)	0.92 (1.60)
		Toddler	1.51 (2.26)	0.32 (0.87)	0.11 (0.43)
		Total	1.98 (2.85)	0.38 (1.08)	0.50 (1.22)
	Total age	Infant	3.03 (3.87)	1.53 (3.05)	0.92 (2.05)
		Toddler	2.28 (3.10)	0.45 (1.28)	0.30 (1.34)
		Total	2.66 (3.52)	1.00 (2.40)	0.62 (1.76)

and children in the treatment group received more soothing behaviors. The following section reviews these results in greater detail.

The Effect of the ABCDs on Pain Scores and Parent Soothing Behavior

The multivariate analysis on pain scores showed an interesting effect of the treatment video on the two age groups over the course of the vaccination appointment. Results indicated significant treatment effects of the video on the toddler group but only during the first two regulatory pain scores (i.e., about 1 min and 2 min after the vaccination). The effect sizes for the toddlers showed an impact of a large magnitude (Cohen, 1988), suggesting an impact of both clinical and statistical significance. Interestingly, a cursory glance at age means *within* a treatment condition (i.e., infant vs. toddler pain scores in the treatment group; infant vs. toddler within control group), suggests that toddlers expressed more pain relative to the infants. This suggests that toddlers have higher pain scores (despite similar vaccinations being administered) and underscores the important need to promote parent soothing behaviors for toddlers.

However, there was no interaction effect seen when analyzing the secondary outcomes or parent soothing behaviors. First, parental soothing only differed during the second minute after vaccination needle. Regardless of treatment condition, there was an age effect. Compared with toddlers, infants received two to three times more rocking and physical comforting during the second minute. This is despite the aforementioned note that toddlers expressed more pain during this same time frame. In addition, regardless of age, treatment effects were seen such that children in the treatment group received two to four times more rocking and physical comforting during the second minute. Taking the results together, perhaps the reason that the video was only effective for the toddlers is because the infants already received more soothing behavior from parents and the video served as an encouragement to prioritize rocking and physical comforting in toddlers. It may be more challenging to proximally soothe a more mobile toddler than an infant; thus, future research may want to explore more specific techniques for toddlers. These findings partially confirmed hypotheses that toddlers would be more impacted by the video and that the video would impact the quantity of parent soothing behaviors in the regulatory phase.

Given the aforementioned significant effects for rocking and physical comforting, the lack of effects for distraction warrant further discussion. At the outset, it was realized that this was likely the most difficult one to teach via brief video because it was nuanced and required judgment as to when to start.

Parents were taught that if distraction is done when distress is high, it would likely have the inverse impact (i.e., increase distress) because it goes directly against the young child's basic attachment need of proximity to primary caregiver when distressed (Bowlby 1969/1982), that is, the child should be pulled into a calm, close cuddle, not oriented away from the parent so the child can engage in a distractor. Finally, although clinical and statistical differences were found for rocking and physical comforting, neither was used extensively according to mean values. Future research may want to explore a practice component in addition to the education component to increase the occurrence even more of parent soothing behaviors such as distraction, rocking, and physical comforting.

Limitations

It is important to address certain limitations of the present study. First, parents who chose to participate in this study were likely already motivated parents to learn strategies to help improve their young child's vaccination pain. We were also unaware of how receptive they were to the content of the video. Accordingly, generalizability of the present study's findings in a less motivated population is unclear. Second, generalizability of our findings may be affected by the high education level or the generally "integrated" acculturation status (ways of life reflecting both their heritage and Canadian/North American culture) of this sample. Third, parents were not given specific instructions in the treatment video about how to assess their anxiety, an opportunity to practice belly breathing, or detailed instruction regarding distraction. In addition, we did not follow them up at another vaccination to see if parents receiving the ABCD intervention used the same techniques. These are all important future areas to consider to increase the impact of the parent video.

Conclusions

A brief video presenting a simple mnemonic derived from naturalistically observing thousands of parents soothe their children postvaccination was found to significantly impact the pain scores of toddlers (but not infants), during the initial pain regulation phases postvaccination (1 min and 2 min after vaccination needle). Regardless of age, treatment effects were seen on rocking and physical comforting during the second minute after vaccination. However, it appears that regardless of treatment condition, younger infants received more soothing and thus the video was particularly important to toddlers' pain management. Toddlers may be more vulnerable to having less parental soothing during vaccination; thus, parents may require even more support in how to soothe their toddlers.

This work underscores the feasibility of supporting parents to help manage their infants' and toddlers' pain after vaccination. Preparing parents from their first well-baby visit and at every visit through videos and brochures, is an important and feasible way to lay a strong foundation for prioritizing pediatric vaccination pain management. Taddio and colleagues offer a variety of educational materials for both health professionals and parents (e.g., http://phm.utoronto.ca/helpinkids/).

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References

Axia, G., & Bonichini, S. (2005). Are babies sensitive to the context of acute pain episodes? Infant distress and maternal soothing during immunization routines at 3 and 5 months of age. *Infant and Child Development*, *14*, 51–62.

Blount, R. L., Devine, K. A., Cheng, P. S., Simons, L. E., & Hayutin, L. (2008). The impact of adult behaviours and vocalizations on infant distress during immunizations. *Journal of Pediatric Psychology*, *33*, 1163–1174.

Bowlby, J. (1969/1982). *Attachment and loss: Vol. 1. Attachment*. New York, NY: Basic Books.

Campbell, L., Pillai Riddell, R., Garfield, H., & Greenberg, S. (2013). A cross-sectional examination of the relationships between caregiver proximal soothing and infant pain over the first year of life. *PAIN*, *154*, 813–823.

Campos, R.G. (1994). Rocking and pacifiers: Two comforting interventions for heelstick pain. *Research in Nursing and Health*, *17*, 321–331.

Cohen, J. (1988). *Statistical power analysis for the behavioral sciences* (2nd ed.). Hillsdale, NJ: Lawrence Erlbaum Associates.

Cohen, L. L. (2002). Reducing infant immunization distress through distraction. *Health Psychology*, *21*, 207–211.

Cohen, L. L., Bernard, R. S., McClelland, C. B., & MacLaren, J. E. (2005). Assessing medical room behavior

during infants' painful procedures: The measure of adult and infant soothing and distress (MAISD). *Children's Health Care*, *34*, 81–94.

Crnic, K., & Low, C. (2002). Everyday stresses and parenting. In *Handbook of parenting. Volume 5: Practical issues in parenting* (p. 242). Mahwah, NJ: Lawrence Erlbaum Associates.

Deater-Deckard, K., & Scarr, S. (1996). Parenting stress among dual-earner mothers and fathers: Are there gender differences? *Journal of Family Psychology*, *10*, 45.

Lisi, D., Campbell, L., Pillai Riddell, R., Garfield, H., & Greenberg, S. (2013). Naturalistic parental pain management during immunizations during the first year of life: Observational norms from the OUCH cohort. *Pain*, *154*, 1245–1253.

Moscardino, U., Axia, G., & Altoè, G. (2006). The role of maternal depressed mood and behavioural soothing on infant response to routine vaccination. *Acta Paediatrica*, *95*, 1680–1684.

Patterson, G.R. (1983). Stress: A change agent for family process. In N. Garmezy, and M. Rutter (Eds.), *Stress, coping, and development in children*. Baltimore, MD: John Hopkins University Press.

Pillai Riddell, R. R., & Chambers, C.T. (2007). Parenting and pain during infancy. In K. J. Anand, B. J. Stevens, & P. McGrath (Eds.), *Pain in neonates and infants* (3rd ed., pp. 289–298). Edinburgh: Elsevier Limited.

Pillai Riddell, R., Gennis, H., Taddio, A., & Racine, N. (2016). Are parents really that important to managing vaccination pain during infancy? *Pain*, *6*, 13–17.

Pillai Riddell, R. R., Racine, N., Craig, K., & Campbell, L. (2013). Psychological theories and biopsychosocial models in pediatric pain. In P. McGrath, B. Stevens, S. Walker, & W. Zempsky (Eds.), *The Oxford textbook of pediatric pain* (pp. 85–94).

Pillai Riddell, R. R., Racine, N. M., Gennis, H. G., Turcotte, K., Uman, L. S., Horton, R. E., & Lisi, D. M. (2015). Non-pharmacological management of infant and young child procedural pain. *The Cochrane Library*, 1–100; 10.1002/14651858.CD006275.pub3

Ryder, A. G., Alden, L. E., & Paulhus, D. L. (2000). Is acculturation unidimensional or bidimensional? A head-to-head comparison in the prediction of personality, self-identity, and adjustment. *Journal of Personality and Social Psychology*, *79*, 49–65.

Stifter, C. A., & Rovine, M. (2015). Modeling dyadic processes using hidden markov models: A time series approach to mother–infant interactions during infant immunization. *Infant and Child Development*, *24*, 298–321.

Taddio, A., Nulman, I., Koren, B.S., Stevens, B., & Koren, G. (1995). A revised measure of acute pain in infants. *Journal of Pain and Symptom Management*, *10*, 456–463.

Taddio, A., Shah, V., Leung, E., Wang, J., Parikh, C., Smart, S. … Jovicic, A. (2013). Knowledge translation of the HELPinKIDS clinical practice guideline for managing childhood vaccination pain: Usability and knowledge uptake of educational materials directed to new parents. *BMC Pediatrics*, *13*, 23.

Taddio, A., Smart, S., Sheedy, M., Yoon, E. W., Vyas, C., Parikh, C., & Shah, V. (2014). Impact of prenatal education on maternal utilization of analgesic interventions at future infant vaccinations: A cluster randomized trial. *PAIN*, *155*, 1288–1292.

Varvogli, L., & Darviri, C. (2011). Stress Management Techniques: Evidence-based procedures that reduce stress and promote health. *Health Science Journal*, *5*, 74–89.