

**Parental Psychological Distress Moderates the Impact of a
Video Intervention to Help Parents Manage Young Child
Vaccination Pain**

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Abstract

Objective: The current study sets out to conduct a post-hoc analysis of the moderating effect of parent psychological distress on a pediatric pain management intervention.

Methods: Parents of 6-month old infants ($n=64$) and 18-month old toddlers ($n = 64$ each) were randomized to a treatment (The ABCD's of pain management) or control video and videotaped during the vaccination. Parent psychological distress was also measured at the vaccination. Outcomes were children's pain, parent worry, and parent soothing behaviour post-vaccination.

Results: Parent psychological distress only moderated video effect on toddler pain during the regulation phase. Parent psychological distress did not moderate the impact of the video on parent worry nor parent soothing post-needle at either age. The video did increase parent soothing in parents of both infants and toddlers, and reduced worry in parents of toddlers.

Conclusions: To our knowledge, this is the first study to assess a moderating factor on a child pain management intervention. The video's efficacy was moderated for toddlers' pain regulation, such that parents with high psychological distress did not show as much benefit from the intervention. No other moderations were found in either age group for any other outcome. Main effects for the video impacting soothing behaviour of parents of both infants and toddlers were confirmed and a new finding of video efficacy was seen through the significantly lower worry of toddlers' parents post-needle. Given the non-clinical sample, low levels of psychological distress were found. Efforts to replicate this study in a higher risk sample is necessary.

(250 words)

Keywords: Infancy, Toddlerhood, Parent Mental Health, Pain, Soothing

1. Introduction

Parents play a crucial role in children's pain management (Pillai Riddell et al., 2013). Although parents want to manage their child's pain, their use of evidence-based strategies has been limited due to a lack of parental knowledge (Taddio et al., 2009; Taddio et al., 2014). Parent coaching and providing educational content (i.e., pamphlets and videos) are effective ways to increase parents' use of evidence-based pain management/soothing strategies (Taddio et al., 2013; Taddio et al., 2014). These strategies include proximal soothing (physical comfort and rocking) and distraction. Both these strategies are commonly seen in naturalistic observation of parents who are coded as sensitive to their child's needs when they were in pain (e.g., Campbell, Pillai Riddell, Garfield, & Greenberg, 2013; Cohen, 2002; Lisi, Campbell, Pillai Riddell, Garfield, & Greenberg, 2013; Moscardino, Axia, & Altoè, 2006).

However, a lack of knowledge about how to best comfort their child may lead parents to feel anxious and worried during their child's vaccination (e.g., a state of worry that occurs in a particular context). Self-report of parent worry and behaviours that indicate greater parent worry have resulted in more child pain-related behaviours (e.g., Bernard & Cohen, 2006; Bearden, Feinstein, & Cohen, 2012; Racine, Pillai Riddell, Flora, Garfield, & Greenberg, 2012). Thus, educational materials and coaching efforts (e.g., psychoeducational videos) that teach parents how to soothe their child during painful medical procedures could also provide an indirect way to manage parent worry. Parents would have less worry about their child in pain because they can implement those strategies to both reduce their own worry and their child's pain. In terms of direct ways to moderate parent worry during vaccination, one simple evidence-based strategy is deep, diaphragmatic breathing (i.e., belly breathing; Varvogli & Darviri, 2011), which can easily be used during a child's vaccination when a parent would like to regulate their own stress.

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3 An important construct that has scarcely been studied in the field of pediatric pain
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5 outcomes or parental pain management is the role of parent psychological distress. Although the
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7 role of parent mental health and psychological factors have been explored in the adolescent
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9 chronic pain literature (e.g., Crombez, Scotford, Clinch, & Connell, 2004; Jordan, Eccleston, &
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11 Crombez, 2008; Eccleston Palermo & Eccleston, 2009), its role is less understood in the
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13 pediatric acute pain setting (e.g., vaccination). Some research has demonstrated that maternal
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15 psychological distress is associated with greater child pain-related distress during vaccination
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17 (Moscardino, Axia, & Altoè, 2006). Further, more indirect measures of children’s pain, such as
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19 maternal recall of their child’s pain, has been shown to be influenced by parent psychological
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21 distress (Pillai Riddell et al., 2007).
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26 While little is known regarding the role of parent psychological distress on pediatric
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28 acute pain outcomes, even less is known regarding its role in pediatric pain management
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30 intervention efforts. In fact, little is known about any potential moderators on treatment effects in
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32 acute pediatric pain management. When analyzing randomized controlled trials and treatment
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34 efficacy, understanding potential moderators is critical to understanding which individuals may
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36 respond best to treatments, or under which contexts treatment effects differ (Kraemer, Wilson,
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38 Fairburn, & Agras, 2002). Although some work has shown moderating factors in adult chronic
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40 pain management interventions (e.g., Litt, Shafer, & Kreutzer, 2010; Turner, Holtzman, &
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42 Manc, 2007), including somatization, readiness for treatment, and self-efficacy, this work has
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44 been scarce in pediatric pain populations.
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49 Outside of pain research, treatment moderators have been found in parent training
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51 programs for child psychological problems, including level of economic disadvantage (e.g.,
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53 Lundahl, Risser, & Lovejoy, 2006) and parenting self-efficacy (van den Hoofdakker et al.,
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2010). Further work has shown that maternal psychopathology is a particularly relevant factor in terms of parent training treatment outcomes. While the majority of findings have demonstrated a reduction in treatment efficacy in the context of maternal psychopathology, some findings indicate otherwise (see Reyno & McGrath, 2006 for a review). Although these studies are in the area of treatment for psychological disorders in older children, this suggests that parental factors are important to treatment efficacy in pediatric populations.

An important gap in the literature for parent interventions for young child pain is understanding parental factors that may impact treatment efficacy during routine vaccination procedures. Knowing related evidence bases suggest parental psychological distress may be a key factor impacting treatment efficacy and that parents are key agents of pain management during young child vaccination suggests an important direction for the infant pain field to explore. Examining if parent psychological distress moderates the impact of a psychoeducational video on young children's pain response allows the field to move from a simplistic 'does it work?' to exploring more detailed questions relating to 'who does it work for and why?'.
Review

Current Study

The current study conducts secondary post hoc analyses of a double-blind randomized controlled trial (RCT) evaluating the efficacy of a parent psychoeducational video for young child pain management (Treatment Video vs. Placebo Video), at two ages (Infant: 6 months; Toddler: 18 months), on young child pain and parent soothing behaviours immediately following, and in the minutes post-vaccination (Pillai Riddell et al., 2017). The original RCT found that the treatment video was associated with lower pain scores in toddlers (one and two minutes post-needle) but not infants. The original RCT revealed that all parents exposed to the

treatment video demonstrated more soothing behaviours and, regardless of video condition, parents of infants did more soothing behaviours.

The objective of the current study was to examine the moderating effect of parent psychological distress on the efficacy of a psychoeducational pain management video. Of note, it is imperative to study children’s pain at two distinct phases. Pillai Riddell and colleagues (2013) have discussed the differences between pain reactivity (the immediate response to a painful stimulus) and pain regulation (the calming down and return to homeostasis), which are expected to be influenced differently by parental factors (Pillai Riddell et al., 2013). Thus, it is necessary to assess the moderating role of parent distress on the more immediate, and regulatory distress response separately. To our knowledge, this is the first study to look at the way parent psychological distress can impact psychoeducational pain management interventions for infant and toddler vaccination pain.

As this was a post hoc analysis of significant findings, three broad hypotheses were made: 1) Parent psychological distress would moderate the effect of the video on child pain; 2) Parent psychological distress would moderate the effect of the video on parent worry; and 3) Parent psychological distress would moderate the effect of the video on parent soothing behaviours post-needle. Given the limited literature in child pain, as well as mixed findings in the broader child literature, no directional hypotheses were made. Further, due to the lack of literature available, no age-based hypotheses were made.

2. Methods

2.1. Trial Design

This article presents a post hoc analysis contextualizing data from the original double-blind randomized controlled study stratified by age (infants and toddlers; Pillai Riddell et al.,

2017). The initial RCT was multisite (two separate clinics), with balanced randomization (1:1) and parallel groups. The trial protocol was approved by the Research Ethics Board at the participating university and was registered at clinicaltrials.gov (CT Identifier: XXXXXXXXXXXX) prior to recruitment. One hundred and twenty-eight families of young children aged 6 and 18 months were recruited between April 2013 and January 2014 (See Figure 1 for CONSORT participant flow diagram). No participants were lost between recruitment and analyses. The outcome variables of interest for the present study were parent worry, child pain, and parent soothing behaviours, with parent level of psychological distress used as the moderator variable.

2.2. Participants

Families of children receiving their routine 6- (infant) or 18-month (toddler) vaccinations at one of two participating pediatric clinics were assessed for eligibility. Both clinics were located in a large, multi-cultural city in Central Canada. Children were excluded if they had a suspected developmental delay or chronic illness, had been admitted to a neonatal intensive care unit (NICU), were born more than three weeks premature, and/or had a sibling who had already participated in the present study. The mean age of infants was 6.19 months (SD = 0.54 months) in the treatment group, and 6.09 months (SD = 0.39 months) in the control group. The mean age of toddlers was 18.13 months (0.34 months) in the treatment group, and 18.03 months (0.40 months) in the control group.

The parent sample consisted primarily of mothers (88%), who were married (93%), and 95% of all recruited parents self-reported that they were the primary caregivers of the participating child. The sample was highly educated, reporting that they and their spouses had university degrees or higher (83% and 79%, respectively), and was ethnically diverse (see Pillai

Riddell et al., 2017). Mean age of caregivers was 34.42 years (SD=4.19 years) in the treatment group and 34.69 years (SD=4.06) in the control group.

2.3. Interventions

The treatment video instructed parents on the ABCD's (Assess anxiety/worry, **B**elly breathe, **C**alm close cuddle, and **D**istract) of pain management. In terms of the specific instructions provided to parents regarding the ABCD strategies, parents were instructed to, in order: 1) **A**ssess their own worry by self-reflecting on their stress level prior to the vaccination, 2) **B**elly breathe if they are stressed, by putting their hands on their abdomen and breathing in deeply to the count of three and exhaling slowly to the count of three, 3) Use a **C**alm, **C**lose, **C**uddle with their infant before, during, and after the needle until the peak distress has passed, and 4) **D**istract their child once the child's peak distress has passed. Specifically, parents were encouraged to use their normal tone of voice to orient the infant's attention away from the needle pain between 20 seconds and 1 minute after the needle. Parents were told not to distract the infant during the peak period of distress immediately after the needle, as the child would likely become more distressed. In cases where infants remained in peak distress for a longer duration, parents were encouraged to stay in the close, calm, cuddle stage.

The control video was closely matched to the treatment video described above. Parents were provided with neutral information (still in ABCD format). Rather than the evidence-based strategies used in the treatment video, parents were instructed to, in order: 1) **A**ct in their child's best interest, 2) **B**e aware that needles are distressing, 3) **C**arry out what they think is best, and 4) **D**o their best to help their young child.

2.4. Procedure

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3 Parents were provided a study information sheet by the clinic's receptionist in the waiting
4 room. Interested parents were approached by a research assistant (RA) who determined
5 eligibility, described the study, answered questions, and obtained written consent. Following
6 consent, parents were randomly assigned to receive either the 5-minute treatment video or the 5-
7 minute placebo video. The RAs were blinded to which video parents watched prior to the
8 vaccination, and they informed parents that in order to remain blinded they were not allowed to
9 answer any questions about the video. To ensure the RA and immunizing health professionals
10 were blind to treatment condition, parents viewed their assigned video in the waiting room on a
11 portable DVD player, before entering the examination room. Only measures from the original
12 study that related to the current analyses will be described.
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26 Parents were asked to rate on a scale of 0 to 10 how worried they were about the child's
27 needle pain before they watched their randomly assigned video, after they watched their
28 randomly assigned video, and after their child's needle. For the current post hoc study exploring
29 treatment effects, all analyses will focus only on the post-needle ratings. Parents also began
30 filling out a questionnaire pertaining to their psychological distress prior to the appointment,
31 completing the questionnaire following their appointment if time ran out pre-appointment (BSI-
32 18; Derogatis, 2001). The entire vaccination was videotaped by an RA using two cameras. One
33 camera used a wide-angle shot that allowed for coding of the parent-infant interaction, and the
34 other followed the infant's face. Videotaping began the moment the infant-parent dyad entered
35 the examination room and stopped four minutes after the vaccination, or sooner if the dyad left
36 the room. At the moment the infant's skin was punctured by the needle, the RA said "now" to
37 ensure the exact time of the needle was accurately recorded for behavioural coding purposes.
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54 Seventy-two percent and 75% of infants and toddlers received one needle, respectively. Twenty-
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two percent and 28% of infants and toddlers received two needles, respectively. There were two toddlers who received three needles.

2.5. Randomization Procedure

2.5.1. Sequence generation and allocation concealment

Consistent with Consort guidelines, the randomization sequence was generated using an online number generator (<http://www.randomizer.org/form.htm>) by an RA not involved in data collection or analyses. The packages with the randomly assigned DVDs were pre-prepared and sealed, such that the clinic RA would have no knowledge to which video condition the parents were allocated. Health care providers, behavioural coders, and authors were all blinded to participants’ video assignments. The list was not released to the lead author nor did unblinding occur, until the primary analyses were complete. For additional detail on these procedures, see Pillai Riddell et al. (2017). Authors were not blinded for the current analyses, as these were post hoc analyses.

2.6. Measures

2.6.1. Parent Demographic Information

Parents completed a brief demographic questionnaire that asked about basic background information including the caregiver’s relationship to the infant, parent age, education level, marital status, and level of acculturation.

2.6.2. Young Child Pain Behaviours

The Modified Behavior Pain Scale (MBPS; Taddio, Nulman, Koren, & Stevens, 1995) was used to measure children’s pain-related distress. This scale uses the sum of three behaviours: facial expression (scored 0 to 3), cry (scored 0 to 4), and body movement (scored 0-3). The total score ranges from 0 to 10 for each 15-second epoch, with greater scores indicating greater pain-

related distress. At its development, this scale has shown moderate to strong concurrent and construct validity, and item-total and interrater reliability in the vaccination context (Taddio et al., 1995). Based on the pattern of results in the original study (Pillai Riddell et al. 2017) and previous theoretical work by our lab postulating two distinct pain phases (reactivity and regulation, Pillai Riddell et al., 2013), only two pain scores were used in the post hoc analyses to execute more parsimonious analyses. One pain score represented immediate pain reactivity (the initial 15 seconds immediately post-needle) and the second represented pain regulation. The pain regulation score was an average of the first 15-second epoch one-minute post-needle, and the first 15-second epoch two minutes post-needle. In our sample, interrater reliability between two blinded, independent coders was high, with the overall intra-class correlation exceeding .90.

2.6.3. *Parent worry*

Using a validated numerical rating scale (Crandall, Lammers, Senders, Savedra, & Braun, 2007), parents rated their worry after the needle. RAs asked parents, “On a scale from 0 to 10, how worried about your child’s needle pain are you, right now, after the needle, where 0 is “no worry at all” and 10 is “the most worry possible”.

2.6.4. *Parent Soothing Behaviours*

Parent soothing behaviors were coded using the Measure of Adult and Infant Soothing and Distress (MAISD; Cohen et al., 2005). Physical comfort, rocking, and distraction were coded separately as the presence of each behaviour (1) or absence of each behaviour (0) for 5-second epochs over three 1-minute periods: Pain Regulation 1 (one minute after the last needle), Pain Regulation 2 (two minutes after the last needle), and Pain Regulation 3 (three minutes after the last needle). Once again, to achieve parsimony and based on previous findings showing similar trends across soothing behaviours (Pillai Riddell et al., 2017), all three soothing behaviour scores

were averaged at each of the three minutes following the needle for analyses. This resulted in one overall soothing behaviour score, ranging from 0 to 12, for each 1-minute epoch. Greater scores represent greater frequency of the soothing behaviour during that minute. Two coders trained in MAISD, blinded to study hypotheses and treatment conditions, coded the videotapes of the vaccination appointment (interclass correlations > .80 for all three behaviours).

2.6.4. Parent Psychological Distress

The Brief Symptom Inventory – 18 (BSI-18; Derogatis, 2001) is an 18-item scale used to measure psychological distress. The BSI-18 is a valid measure of psychological symptoms (Derogatis, 2001) and demonstrated strong internal consistency within our sample ($\alpha = .81$). Respondents select how much they were distressed by a particular problem on a scale of 0 (not at all) to 4 (extremely) in the past seven days, including the day they participated in the study. The Global Severity Index (GSI) was used to assess broader psychological symptoms and are reported as T-scores (Mean of 50; Standard Deviation of 10). The BSI-18 uses a GSI T score ≥ 63 as a clinical cutoff. Of the current non-clinical sample, 2.4% met the clinical cutoff. Table 1 presents descriptive statistics on all measures for the entire sample.

2.7. Statistical Analyses

All statistical analyses were conducted using SPSS Statistics 22. T-tests and Chi-square analyses were run to compare demographics between both video conditions. The original study showed significant age differences, so analyses were run separately for infants and toddlers. Given the limitations of determining significance solely by p-value (e.g., Halsey, Curran-Everett, Vowler, & Drummond, 2015), effect sizes will be presented (Wilson, n.d.).

To test the hypothesis that parent psychological distress would moderate the effect of video condition on infants’ and toddlers’ pain-related distress post-needle, four moderation

1 regression analyses were run (2 age groups [infant and toddler] X 2 post-needle pain scores
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3 [reactivity and regulation]). Video condition, psychological distress, and the interaction of the
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5 two (moderation term) were predictor variables, and infants' and toddlers' pain scores at the two
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7 post-needle time points were the outcome variables.
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12 To test the hypothesis that psychological distress would moderate the effect of video
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14 condition on parent worry post-needle, two moderation regression models were planned (worry
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16 score [post-needle] for each of the 2 ages [infant versus toddler]). Thus, treatment condition
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18 (treatment versus placebo video), psychological distress, and the interaction of the two
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20 (moderation term) were used as predictors of parental worry post-needle.
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24 Lastly, to test the hypothesis that parent psychological symptoms would moderate the
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26 effect of video condition on parent soothing at both ages, six moderation regression analyses
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28 were run (2 age groups X 3 post-needle epochs [soothing behaviour at 1, 2 and 3 minutes post-
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30 needle]). Video condition, psychological distress, and their interaction (moderation term) were
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32 predictor variables, and the average soothing behaviour over each minute were the outcome
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34 variables.
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38 Prior to analyses, video condition was dummy coded (0 = control, 1 = treatment), the
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40 continuous variables were centered to minimize multicollinearity, and standardized values were
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42 entered in the model to estimate effect sizes. Moderation regression analyses were run using
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44 PROCESS in SPSS (Hayes, 2012). PROCESS runs simple slope analyses and provides the
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46 regression coefficients for the predictor and outcome variable at low (1 SD below mean), high (1
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48 SD above mean), and mean levels of the moderator. If one SD below or above the mean is
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50 outside the range of data, the minimum or maximum value is used.
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54 3. Results

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There were no significant differences on parent marital status, age, relationship to infant, education, and acculturation (data reported in Pillai Riddell et al., 2017). No adverse events were reported during this study.

3.1. The Moderating Effect of Psychological Distress on Infant and Toddler Pain Reactivity and Regulation

The overall models for infant pain reactivity and regulation were non-significant (p 's $\geq .05$), therefore main effects and interactions were not explored further. In parents of toddlers, the overall model for toddler pain reactivity was non-significant ($p > .05$) and was not explored further. However, during the regulatory period, the overall model was significant for toddlers, $R^2 = .20$, $F(3,58) = 4.23$, $p = .01$.

Within this significant model, psychological distress moderated the effect of the treatment video on toddler pain, *standardized* $\beta = 0.63$, $SE = 0.25$, 95% CI [0.12, 1.13], $t = 2.50$, $p = .02$, $d = 1.64$ demonstrating a large effect (see Figure 2). Simple slopes revealed that the treatment video reduced pain in the minutes post-needle, but only when parent psychological distress was below the mean, *standardized* $\beta = -1.35$, $SE = 0.40$, 95% CI [-2.16, -0.55], $t = -3.36$, $p < .01$, and at the mean, *standardized* $\beta = -0.70$, $SE = 0.27$, 95% CI [-1.24, -.16], $t = -2.60$, $p = .01$.

3.2. The Moderating Effect of Parent Psychological Distress on Parent Worry

In infants, the overall model for parent worry post-needle was not significant ($p > .05$), therefore the main effects and interaction were not explored further. In toddlers, the overall model for parent worry was significant, $R^2 = .19$, $F(3,59) = 4.05$, $p = .01$. Within this model, there was a main effect of video condition on parent worry post-needle, *standardized* $\beta = -0.68$

$SE = 0.27$, 95% CI $[-1.22, -0.14]$, $t = -2.51$, $p = .01$, $d = 1.88$, with a large effect size, but no interaction.

3.3. The Moderating Effect of Psychological Distress on Parent Soothing Behaviours

In parents of infants, the overall model for parent soothing one-minute and three minutes post-needle was not significant ($p > .05$), thus the main effects and interactions were not probed further. In the second minute post-needle, the overall model of parent soothing was significant, $R^2 = .16$, $F(3,60) = 3.50$, $p = .02$). Within this model, there was a main effect of video condition on parent soothing behaviours, *standardized* $\beta = 0.78$, $SE = 0.31$, 95% CI $[0.16, 1.39]$, $t = 2.54$, $p = 0.01$, $d = 2.52$, with a large effect size, but no interaction.

In terms of parents of toddlers, the overall model for parent soothing one-minute post-needle was significant, $R^2 = .12$, $F(3,58) = 3.26$, $p = .03$. Within this model, there was an effect of video condition on parent soothing behaviours one-minute post-needle, *standardized* $\beta = 0.49$, $SE = 0.23$, 95% CI $[0.02, 0.95]$, $t = 2.09$, $p = .04$, $d = 1.13$, with a large effect size, but no interaction. The models for parent soothing two- and three minutes post-needle were non-significant (p 's $> .05$).

4. Discussion

For the first time in the literature, this study examined the role of a moderator (psychological distress) on the efficacy of a treatment video designed to improve parents' ability to manage their infant or toddler's pain post-vaccination (Pillai Riddell et al., 2017). Key outcomes for the moderator analyses were child pain reactivity, child pain regulation, parent worry post-needle, and amount of parent soothing behaviour post-needle (minute 1, minute 2, minute 3). The original study showed that the psychoeducational video was shown to be effective at reducing toddler pain following vaccination, and increased parent use of evidence-

based strategies including physical comfort and rocking, regardless of age. The current analyses build on the original findings by examining the moderation of parent psychological distress on these treatment effects and augments the original findings by examining parent worry post-needle. With one exception (toddler pain regulation), moderation hypotheses were not confirmed, but a main effect on parents worry was found in the toddler group.

4.1. *The Moderating Effect of Parental Psychological Distress on Child Pain*

Our first hypothesis was partially confirmed. In infants, there was no effect of video condition or an interaction between video condition and psychological distress on pain reactivity and regulation. However, in toddlers, parent psychological symptoms moderated the impact of the treatment video on toddler pain regulation, demonstrating a large effect. Exposure to the treatment video resulted in less child pain-related distress in the regulatory period, but only when parents reported symptoms at or below the mean. When parents reported a high number of symptoms, the treatment video was no longer effective. The fact that this was not found in infants may speak to important developmental differences between these age groups that are often overlooked, or it may be due to the low levels of psychological distress experienced by our parent sample.

These findings build on previous research studies that have assessed the impact of parent psychological distress on children’s pain outcomes (Moscardino et al., 2006) and maternal recall of children’s pain (Pillai Riddell et al., 2007). Our study has now demonstrated that the impact of a psychoeducational intervention on toddler’s pain responding may also be influenced by parent psychological distress. This builds on past research that has demonstrated important parent factors that moderate parent training effects outside the pediatric pain context (e.g., Lundahl, et al., 2006; Reyno & McGrath, 2006; van den Hoofdakker et al., 2010).

4.2. *The Moderating Effect of Parent Psychological Symptoms on Parent Worry*

Our second hypothesis, that parent psychological symptoms would moderate the effect of video condition on parent worry at both ages throughout the vaccination, was not confirmed. Again, this may be due to the low levels of psychological distress experienced in parents. However, there was a main effect of video condition on toddler parent worry, such that parents in the treatment condition were less worried about their child's pain post-needle which is a novel nuance to our original analysis. This suggests that providing parents of toddlers with psychoeducation on pain management strategies can reduce their worry post-needle. Given our knowledge of the impact of parent worry on their soothing (e.g., Crnic & Low, 2002; Deater-Deckard & Scarr, 1996), reducing worry may lead to use of more evidence based-strategies, thereby reducing young child pain-related distress.

4.3. *The Moderating Effect of Psychological Symptoms on Parent Soothing*

With regards to our final hypothesis, psychological symptoms did not moderate the treatment effect on parent soothing in infants or toddlers. Consistent with findings from the original study (Pillai Riddell et al., 2017), parents of infants and toddlers in the treatment condition did more soothing behaviours post-needle. The novel finding from our original analysis is that parent psychological distress *does not* moderate the impact of the treatment video on parent soothing. There are a number of possible explanations for why psychological distress may not have played a moderating role in parent soothing. One possible explanation is the strength of our video's ability to promote soothing in parents, regardless of their levels of distress. However, this could also be a result of the low levels of psychological distress within our sample.

4.4. *Implications for Clinical Practice*

These findings are the first to examine a moderating factor in pediatric acute pain management efforts with young children. Although parent psychological distress was shown to be a moderating factor in terms of toddler pain regulation, psychological distress did not moderate any of the other treatment effects. It is possible that there are other moderating factors that may be more influential in impacting parent worry and parent soothing that need to be considered. For example, a number of cognitive factors, including attention, memory, and language, may be important moderating factors that would impact parents’ retention of psychoeducational material to promote pain management strategies and reduce parent worry. Further, in line with the adult chronic pain literature (e.g., Litt et al., 2010; Turner et al., 2007) and the parent training literature (Hoofdakker et al., 2010; Lundahl et al., 2006), parenting self-efficacy, socioeconomic factors, and psychological factors including catastrophizing may also play an important moderating role in pediatric pain management efforts.

In conclusion, a novel approach to better understand a parent factor that may moderate the impact of a psychoeducational video was examined. While results in our non-clinical sample showed that parent psychological distress only played a moderating role in toddler pain regulation, this is an important first step in better understanding moderating factors in pain management interventions. Although more work is needed, particularly in parents who suffer from clinical levels of psychological symptomology, these findings indicate that parent psychological distress may be one consideration for the efficacy of pain management interventions. Support of parent psychosocial factors is important for children’s pain outcomes, as well as the general wellbeing of these parents.

4.5. Limitations and Future Directions

It is important to understand these findings in the context of some limitations. The potential for Type 1 error arises due to the number of exploratory post hoc analyses. However, the strength of the toddler pain regulation effect size adds credibility to the potential that parent distress is one important factor to consider. However, given the number of non-significant interaction factors in our models, it must be considered that psychological distress may not be a critical factor impacting treatment efficacy in non-clinical samples.

Further, the non-clinical samples were recruited from relatively low-risk neighborhoods with few parents reporting clinical levels of psychological symptoms. This challenges our findings' generalizability to higher risk populations. Given the low levels of psychological distress in our sample, conducting this study in a sample with a greater proportion of parents reaching the clinical cut-off would be beneficial to our understanding of psychological distress as a moderating factor. Further, the BSI-18 factor structure may not apply equally well to our culturally diverse sample, and thus it is possible that psychological symptoms may be underestimated in some of our sample. In line with this, we also did not ask parents if they were receiving any form of mental health or well-being support, which may influence our findings and would be an important future avenue for research. Finally, the worry and pain regulation scores in infants were somewhat lower than for toddlers. The scores may have been so low that it would not be possible for a treatment to have a significant difference. However, it is noteworthy that no treatment differences were found for pain reactivity in both infants and toddlers despite the high pain scores.

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For Peer Review

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Table 1
Descriptive Statistics for Sample Stratified by Age

	<u>Mean (SD)</u>		<u>Min – Max</u>		<u>Possible</u>
	Infant	Toddler	Infant	Toddler	<u>Range</u>
MBPS: Pain Reactivity	5.98 (2.58)	6.41 (1.74)	2-9	2-9	0-10
MBPS: Pain Regulation	2.65 (1.01)	3.59 (1.50)	2-7	1.5-7	0-10
Parent Worry	1.73 (2.05)	2.39 (2.64)	0-8	0-10	0-10
MAISD: Soothing 1- min Post- Needle	2.48 (2.18)	2.15 (1.92)	0-8	0-8	0-12
MAISD: Soothing 2- min Post- Needle	1.03 (1.72)	0.46 (0.88)	0-7	0-4	0-12
MAISD: Soothing 3- min Post needle	0.64 (1.11)	0.46 (0.85)	0-5.3	0-3.67	0-12
GSI	44.17 (8.41)	43.71 (8.86)	33-63	33-65	33-81

Note. For pain regulation, MBPS scores 1-min post-needle and 2-min post needle were averaged. For soothing scores, MAISD behaviours physical comfort, rocking, and distraction were averaged together to represent a single soothing score for each minute.

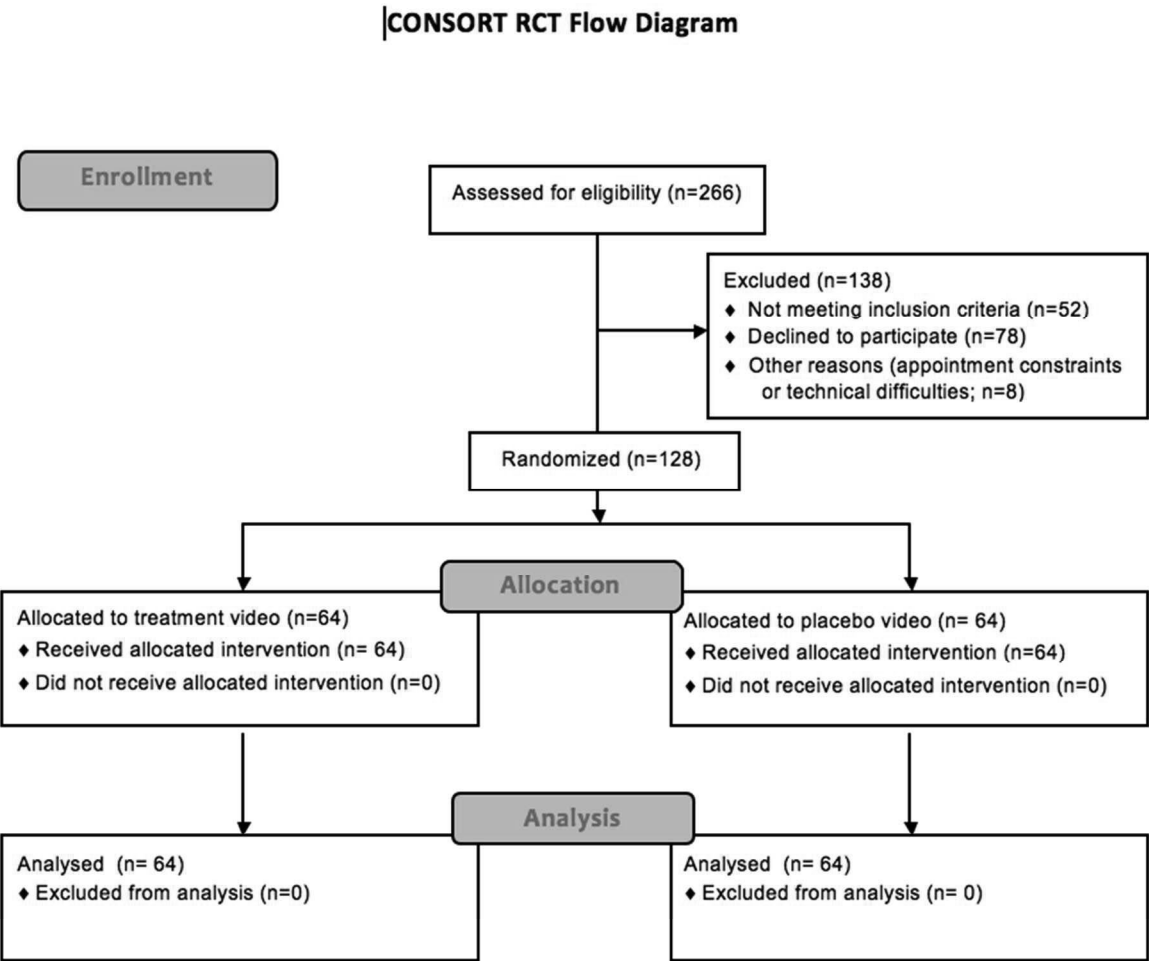


Figure 1. Consort Flow Diagram.

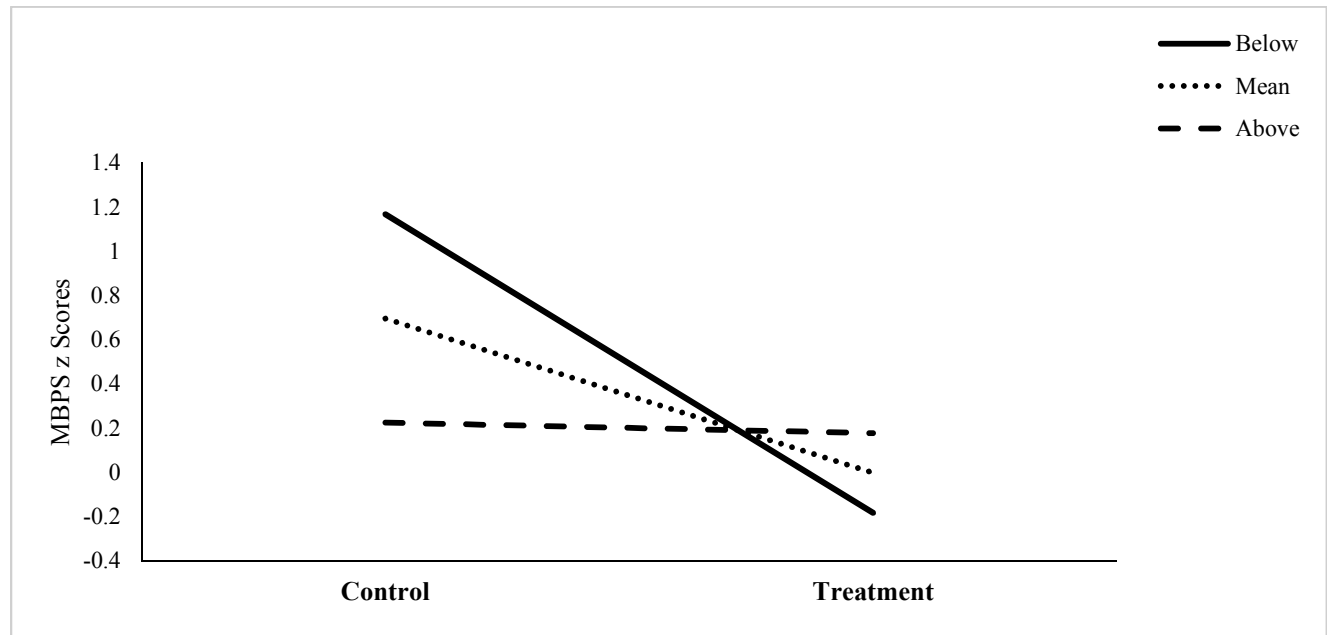


Figure 2. Simple slopes equations of the regression of video condition on pain regulation (toddlers) at three levels of psychological symptoms (using z score values).