CHILD-LED EMOTION REGULATION BEHAVIOURS DURING TODDLER VACCINATIONS: BUILDING UNDERSTANDING THROUGH A DYADIC LENS

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ABSTRACT

Vaccination of infants and young children is a routine procedure requiring regulation of high distress. While infants rely heavily on their caregivers for regulating distress, in toddlerhood, children begin to build a repertoire of their own emotion regulation (ER) skills to modulate their distress. The current dissertation consists of three studies to better understand toddler-led ER during vaccination. Study 1 is a published systematic review and meta-analysis (Gennis et al., 2022) aimed at understanding the concurrent relationships between child-led ER behaviours and distress in the first three years of life. Findings indicated that disengagement of attention and physical self-soothing strategies were typically regulatory (i.e., had negative relationships with distress), whereas parent-focused behaviours (e.g., orienting to the caregiver) were associated with more distress, suggesting a signalling function to gain support. With the exception of physical self-soothing, which showed a clear negative association in the first year, relationships between regulatory behaviours and distress were strongest in the second year. Study 2 (Gennis, Flora, Norton et al., submitted) used auto-regressive cross-lagged models to assess the concurrent and predictive relationships between three child-led ER behaviour clusters (disengagement of attention, physical self-soothing, and parent-focused behaviours) and pain-related distress responses during 12- and 18-month vaccinations. Findings indicated that disengagement of attention and physical self-soothing generally had negative relationships with pain-related distress, suggesting a possible regulatory role, whereas parent-focused behaviours were related to higher pain-related distress, suggesting a signalling role for parent support. With the exception of physical self-soothing, relationships were generally stronger at 18 months. Study 3 (Gennis, Flora, McMurtry, et al., submitted) used growth curve modelling to understand the associations between child-led ER behaviours and the change in pain scores across the

appointment (regulation) at 12- and 18- months, after accounting for parent regulatory behaviours and pre-needle distress. Pre-needle distress consistently predicted regulation and parent regulatory behaviours played an increasing role in older toddlers. Findings suggest that after accounting for pre-needle distress and parent regulatory behaviours, child-led parent-focused behaviours predicted less regulation post-needle. Children seek their parent when they are struggling to regulate, suggesting continued need to understand vaccination as a dyadic context.

DEDICATION

This body of work is dedicated to my grandmother, Leona Pinkus. Baba – You supported me every step of the way while you were with us. Sharing program milestones with you was my greatest joy. I dedicate this final milestone in your memory.

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PUBLICATION DISCLOSURE

The works submitted in this dissertation are either published (Chapter 2), accepted pending minor revisions (Chapter 4) or under review for publication (Chapter 6). The manuscript citations are provided below:

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DISSERTATION SYNOPSIS

Emotion regulation (ER) is a critical skill learned in early childhood. Children are not born with the ability to regulate emotions; instead, they learn these skills within the context of the caregiver-child relationship (Kopp 1982, 1989; Sameroff, 2010; Sroufe, 1996). As children near the second year, they have begun to develop cognitive, motor, and social skills that allow them to engage in more sophisticated forms of self-regulation (Kopp, 1982, 1989). Throughout development, there is a shift from reliance on the caregiver to more independent self-regulation based on skills learned through sensitive interactions with their caregiver (Kopp, 1982, 1989; Sameroff, 2010; Sroufe, 1996).

The field is challenged by the fact that most research in this area has used experimental procedures. As Cole et al. (2004) indicated, understanding ER in multiple contexts is important. Therefore, while experimental paradigms have been paramount in our understanding of the development of emotion regulation, they do not allow for an understanding of high levels of distress in naturalistic, dyadic contexts. Vaccination provides such a context. Toddlerhood vaccination was seen as an ideal time to start understanding children's own regulatory strategies and how these reduce or enhance pain-related distress.

To address these issues, three research aims shaped the current dissertation: 1) Systematically review and meta-analyze the literature that included the relationships between distress and child-led ER behaviours in the first three years of life; 2) Using a large sample of toddlers observed during vaccination, assess the concurrent and predictive relationships between child-led ER behaviours and pain-related distress across the vaccination appointment at 12 and 18 months; 3) Understand the relative contributions of these child-led ER behaviours on toddlers' change in pain scores over time (regulation), after accounting for pre-needle distress

and parent regulatory behaviours. These research aims were addressed in three separate studies, all of which are published or submitted for publication (Gennis et al., 2022; Gennis, Flora, Norton, et al., submitted; Gennis, Flora, McMurtry, et al., submitted). While the results will be presented in depth within each of the papers, Appendix A provides a two-page summary of the major results across all papers.

The first study was a systematic review and meta-analysis that synthesized the literature on the concurrent relationships between three clusters of child-led ER behaviours (disengagement of attention, parent-focused behaviours, and physical self-soothing) and distress, separated into the first, second, and third year of life. Key findings were that disengagement of attention (e.g., purposefully distracting oneself) consistently had negative relationships with distress, suggesting a regulatory role, with the strongest associations seen in the second year of life. Physical self-soothing (i.e., physically using one's own body to reduce distress, such as thumb sucking) was seen as regulatory in the first year of life, but either had positive or very weak associations with distress in toddlerhood. Parent-focused behaviours (e.g., orienting to the parent) had positive relationships with distress, which was strongest in the second year. This finding suggests the possibility that children signal to their parent through these behaviours to get support. This behaviour may occur if the distress exceeds their ability to self-regulate. These findings are also understood within the context of substantial heterogeneity across studies.

Study 2 and Study 3 included participants from a longitudinal cohort of caregiver-toddler dyads observed during their 12-month (N=163) and/or 18-month (N=149) vaccinations. Study 2 aimed to examine the concurrent and predictive relationships between the three identified clusters of child-led ER behaviours (disengagement of attention, parent-focused behaviours, and physical self-soothing) and pain-related distress across the three minutes post-needle. Analyses

were run separately at 12- and 18-months, resulting in six models in total. At 18 months, disengagement of attention was significantly negatively associated with pain-related distress one-minute post-needle and pain-related distress one-minute post-needle significantly predicted less disengagement of attention at two minutes post-needle. Parent-focused behaviors had significant positive associations with pain-related distress at both ages, with the strongest association seen at 18 months. Physical self-soothing was significantly related to less pain-related distress at both ages; however, associations were strongest and more frequent at 12 months. Taken together, these findings suggest that disengagement of attention and physical self-soothing support pain-related distress regulation during toddlerhood, whereas parent-focused behaviors again may serve the role of seeking parent support for regulation.

Study 3 aimed to understand the relative contributions of child-led regulatory behaviours on pain-related distress after accounting for parent-led regulatory behaviours (e.g., parent's enactment of distraction as opposed to child's enactment of distraction) and pre-needle distress. Findings suggested that at both ages, child-led parent-focused behaviours were related to slower regulation across the vaccination appointment, after accounting for the important role of pre-needle distress and parent regulatory behaviours. However, at 18 months, only parent-focused behaviours used in the second minute significantly predicted slower regulation. While parent-led distraction was significantly associated with slower regulation post-needle at both ages, there appeared to be a stronger effect of parent regulatory behaviours at 18 months. Parent-led distraction and verbal reassurance significantly predicted slower regulation and parent rocking significantly predicted quicker regulation. Taken together, these findings speak to the importance of understanding both child and parent regulatory behaviours during vaccination, solidifying the need to view distress regulation during vaccination as a dyadic experience.

Chapter 1: Introduction

Defining the Construct of Emotion Regulation

The ability to regulate emotions is seen as a foundational skill learned throughout childhood. Emotion regulation has been linked to psychological outcomes, social outcomes, and school readiness in childhood (e.g., Calkins, 1994; Calkins & Dedmon, 2000; Calkins & Fox, 2002; Eisenberg et al., 2010; Harrington et al., 2020; Hill et al., 2006), as well as outcomes into adulthood (Robson et al., 2020). Thompson (1994) defines emotion regulation as the process of monitoring, evaluating, and modifying the intensity or duration of emotions to accomplish a goal. In his popular definition, Thompson discusses that these processes can be either intrinsic (i.e., self-management of emotions) or extrinsic (e.g., caregiver efforts to modulate their child's emotions). Cole et al. (2004) has added to this conceptualization by explaining that not only can emotions be regulated, as defined above, but emotions themselves can serve to regulate or modify both intrinsic (e.g., physiological responses) or extrinsic (e.g., caregiver behaviour) processes. While other definitions of the construct have come forward, there appears to be increasing consensus that emotion regulation should be viewed as a dynamic, dyadic, and multilevel process that is understood developmentally (Calkins, 2010; Cole et al., 2004).

First, the study of emotion regulation requires an understanding that the reactivity to an emotional event or stimulus and the behaviours or attempts to modify or regulate that response are distinct, and to properly understand their distinct nature, understanding their interactions across time is paramount (Calkins, 2010; Cole et al., 2004). Second, emotion regulation is a biopsychosocial (i.e., multilevel) phenomenon that utilizes behavioural, physiological, neurological, and cognitive processes (Calkins, 2010). Third, among very young children, emotion regulation is a dyadic process involving a caregiver. While a more thorough

understanding of the development of emotion regulation will follow, it is well understood that children's emotion regulation skills develop through interactions with their caregiver in which their caregiver has successfully (or unsuccessfully) used strategies to modify emotions (e.g., Calkins, 2010; Kopp, 1982, 1989; Sameroff, 2010; Sroufe, 1996; Thompson, 1994). Even as children develop into school-age, teachers take on this role (Calkins, 2010). It therefore follows that emotion regulation is best understood in the context of development (Calkins, 2010), and thus developmental periods cannot be ignored.

Understanding Human Development as a Biopsychosocial Phenomenon

Prior to focusing specifically on the development of emotion regulation, a broader understanding of human growth and development is warranted. In his Unified Theory of Development, Sameroff (2010) proposed that human growth can be understood using four models: 1) a contextual model, 2) a personal change model, 3) a regulation model, and 4) a representational model.

Addressing first the contextual component, Sameroff (2010) discusses how child development cannot be understood outside of the social context. Influenced by Bronfenbrenner (1977), the self, which includes psychological and biological processes, is surrounded by the broader social ecology including parents, family, school, peers, community, and the geopolitical context. This ecology in turn supports the notion that child development is a biopsychosocial phenomenon. The personal change component is apparent in the growth of not only the biopsychological components of self, but also the influences of the social ecology over time, from infancy onward, always viewing this process as transactional and interactive.

Perhaps most relevant to the current dissertation on emotion regulation, the regulation model incorporated into the Unified Theory of Development provides an understanding that a

child's ability to self-regulate occurs within the context of "other regulation". Stemming from work by Sameroff and Fiese (2000), there is a transactional relationship between self and other (most often in early childhood, the other is a parent) that works like an "ice-cream-cone-in-a-can". In infancy, self-regulation (i.e., the cone) is heavily reliant on the external environment (i.e., the can); however, across development, the child's skill set expands and they are less reliant on other regulation. As Sameroff (2010) stated, "The capacity for self-regulation arises through the actions of others. This regulation by others provides the increasingly complex social, emotional, and cognitive experiences to which the child must self-regulate and the safety net when self-regulation fails" (p. 15). Lastly, it is understood that a representational model influences all of the above components. That is, past experiences are encoded and become schemas for future experiences (Sameroff, 2010).

The Development of Emotion Regulation

An understanding of the development of emotion regulation as a biopsychosocial phenomenon follows from Sameroff's Unified Theory of Development. Children are not born with the ability to regulate their emotions. Kopp (1982, 1989) has outlined that in the earliest months of an infant's life, emotion regulation is largely driven by innate, physiological mechanisms and is heavily embedded in the caregiving context. As children age, there is a shift from automatic and innate physiological processes that are largely supported by the caregiver to more purposeful and independent regulatory efforts (Kopp, 1982, 1989; Sroufe, 1996). In essence, through experiences of co-regulation with the caregiver in early childhood, regulatory abilities that were more heavily led by caregivers are the foundation for the child's set of self-regulation skills (Calkins, 2010; Sroufe, 1996).

Self-regulation rapidly develops in infancy and into childhood, largely due to the development of neurophysiological systems, motor systems, and attention systems (Kopp, 1982, 1989; Thompson, 1994). In the earliest days of life, infants show evidence of altering distressing states by using reflexive and innate actions (e.g., hand-to-mouth movements, head turning, sucking; Kopp, 1982, 1989). By three months of age, the visual system develops and infants begin to gain more control over their movement, increasing their repertoire of actions (e.g., reaching for objects), which allows for increasing engagement with the environment and disengaging from the distressing stimulus as a potential emotion regulation strategy (Kopp, 1989). However, as Kopp (1989) has explained, the ability to use these behaviours heavily depends on the level of arousal or distress, with higher levels of arousal making certain strategies difficult to utilize, and these strategies remain unplanned, with the infant engaging any possible strategy to reduce distress. This dependency supports the necessity of the caregiver in these early infant years (Kopp, 1982, 1989; Sameroff, 2010; Sroufe, 1996).

From three months to around nine months, infants develop an increasing awareness of their different emotional experiences, as well as an awareness that they or their caregiver can do something to alleviate the distress (Kopp, 1989). However, it has been argued that in the first year, the caregiver remains paramount as many of the distressing situations infants encounter can exceed their ability to regulate their own distress (Kopp, 1989; Sroufe, 1996). Infants appear to use signalling behaviours to their caregivers, such as eye contact, to signal that they need support (Kopp, 1989). There are marked changes in cognitive domains (e.g., memory, spatial discrimination, awareness and recognition of individuals, use of objects), motor skills, and social and communicative abilities that support the increasing repertoire of skills as children develop through infancy to toddlerhood.

Kopp (1982, 1989) has noted that the second year of life is when children begin to show increasing autonomy and self-awareness, which comes with a marked increase in emotion regulation abilities by the end of infancy. They have become more efficient in their motor skills (e.g., they are able to reach and grasp objects), they are able to stroke their body parts purposely, and they have an increasing ability to communicate their needs to their caregivers (Kopp, 1989). As outlined above, the development of these social skills and the caregiver-child relationship is necessary in the context of emerging self-regulatory skills. While there is typically a transition from other-led regulation (e.g., caregiver-led regulation) to more independent self-regulation, the transactional relationship remains important as the toddler's skill set cannot yet meet the demands of each distressing situation. This balance between self- and other-regulation, as well as how a child uses their parent to support distress regulation, can also be understood through the attachment relationship.

Attachment and the Social Context of Emotion Regulation

Given the critical importance of the attachment relationship in early childhood (Bowlby, 1969/1982), particularly the second year of life, discussion of the social context of emotion regulation in more detail is warranted. As described above, in infancy, emotion regulation is a dyadic process rooted in the caregiving relationship (Kopp, 1982, 1989; Sameroff, 2010; Sroufe, 1996). When infants become distressed (such as during vaccination), their attachment system is triggered and they seek proximity to their caregivers with the expectation that caregivers will reduce that distress. Further, caregivers have a parallel caregiving system that supports their response to these signals (Bowlby, 1969/1982). Sroufe (1996) was seminal in helping our understanding that as children develop, they transition from co-regulation of physiological states to self-regulation across childhood.

However, Sroufe (1996) also emphasized the importance of caregiver sensitivity, a concept that is also imperative to the attachment relationship. In essence, when a caregiver is properly attuned to the changing needs of the child and reacts accordingly in both positive and distressing contexts, children learn to use emotion regulation strategies successfully (Sroufe, 1996). It is important to distinguish that while developmental theory and models suggest less of a caregiver role as children develop their self-regulation abilities, toddlers still require caregiver support at times, particularly when task demands exceed their skill set and they are unable to independently regulate (Sroufe, 1996). In line with this need, research has shown an increase in parent signalling behaviours as children develop (Rothbart et al., 1992), which suggests that as the attachment relationship is more established (Ainsworth et al., 1978; Bowlby, 1969/1982), children more readily signal to their parents when task demands exceed their abilities.

Limitations in the Current Study of Emotion Regulation

In their seminal work, Cole and colleagues (2004) put forth recommendations to improve the study of emotion regulation as a construct. Their recommendations included independently measuring emotion and regulatory behaviours, using a dynamic approach (i.e., temporal relations between emotion and regulatory behaviours), use of multiple measures to understand emotion regulation, and using multiple contexts to understand emotion regulation. To address the dynamic or temporal component, studies have used varying longitudinal study designs to better understand how emotion (using both behavioural and physiological indicators) and the regulatory behaviours interact over time to properly assess emotion regulation (e.g., Buss & Goldsmith, 1998; Brooker & Buss, 2010; Chow et al., 2005; Cole et al., 2017; Ekas et al., 2011, 2013; Lougheed et al., 2019; Stifter & Braungart, 1995; Thomas et al., 2017).

However, while there has been research in different experimental contexts to assess the process of emotion regulation in different contexts, few studies have assessed emotion and emotion regulation behaviours separately in naturalistic contexts. With some exception (e.g., Lamb & Malkin, 1986), most research in emotion regulation has been experimental. While this work has allowed a deeper understanding of emotion regulation as a construct, the emotions induced experimentally do not cover the wide array of experiences children have in their daily lives. Further, given ethical considerations of inducing unnecessary distress in children, it is difficult for researchers to study children at their highest levels of distress. High distress is imperative to understanding emotion regulation as it is when children require regulatory strategies the most. Naturalistic distress paradigms which occur outside of experimental contexts provide greater opportunity for observation of such levels of distress.

Pain as a Context for Studying Regulation of High Distress

Pain is defined as "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage" (Raja et al., 2020). An important part of defining pain is that the inability to describe pain verbally does not negate the possibility that an individual, such as a pre-verbal infant or toddler, experiences pain (Raja et al., 2020). Throughout development, the experience of pain is adaptive and inevitable, with healthy children experiencing everyday bumps and bruises or routine medical procedures (e.g., vaccinations). Although variable, children can receive over 20 needles by the time they reach school age (Centers for Disease Control and Prevention, 2022). Given their routine nature, using vaccination as a context to study child emotion regulation can address some of the limitations of the experimental literature – namely, understanding use of child-led emotion regulation strategies in an ecologically valid, naturalistic, and highly distressing context. Vaccinations occur

throughout distinct developmental phases, which allows a developmental understanding of how emotion regulation skills develop from infancy, into toddlerhood, and throughout childhood. Research has established that vaccinations are a highly distressing experience throughout development, with findings suggesting that both infants (Pillai Riddell et al., 2013) and preschoolers (Waxman et al., 2017) struggle to reduce their heightened levels of behavioural distress to a low level.

The DIAPR-R Model

The Development of Infant Acute Pain Responding – Revised (DIAPR-R) model (Pillai Riddell et al., in press) is a framework for understanding the pain experience over the first years of life. Informed by 15 years of longitudinal work in the early childhood vaccination context and influenced by child developmental theorists such as Bowlby (1969/1982), Ainsworth (1978) and Sameroff (2010), the DIAPR-R model pays particular attention to the child's developmental stage. As shown in Figure 1, even prior to the distressing, painful event (e.g., a vaccination), children come with pre-defined schemas from past painful events and therefore their baseline level of distress is an important predictor of how they will respond to the painful stimulus. Once the painful stimulus is given, there is a sequence of events within the infant's peripheral and central nervous system. Initial somatic behaviours and autonomic nervous system (ANS) physiology that define initial reactivity (the initial milliseconds post-painful stimulus) occur concurrently. Following these initial milliseconds, the change in behavioural and physiological responses reflects the young child's return to baseline or pain-related distress regulation. Within the first year of life, given that the child lacks the ability to self-regulate, this acute pain responding sequence, from nociception and perception to initial reactivity and regulation, is largely impacted by the caregiver (Goubert et al., 2021; Pillai Riddell et al., in press).

Starting with their recognition of a painful procedure on their child, the DIAPR-R model suggests that a caregiver's pain schemas and stress-related physiology become engaged as soon as the caregiving process begins. This caregiving cycle involves the caregiver's ongoing processing of the infant's observable behaviours which involve the caregiver's own pain schemas, physiological responses, assessment of the infant's pain-related distress, and management of that pain-related distress. The caregiving cycle represents the ongoing evaluation and responding of the caregiver that occurs when interacting with a young child in pain. This cycle includes both how the caregiver thinks during the painful situation (i.e., pain schemas and assessment) as well as their response (pain management, physiology, emotional reactions). The dyadic feedback loop between infant and caregiver is critical to the understanding the infant pain response, especially once the peak pain response (reactivity) has passed and the regulatory process begins. The regulatory phase is seen as more dependent on this feedback loop than is reactivity, which has been shown to be more dependent on the infant's pain threshold and the specific noxious/painful stimulus itself (Goubert et al., 2021; Pillai Riddell et al., in press).

A large amount of research provides support for the DIAPR-R model and has demonstrated the importance of caregivers during vaccination. It is well documented that particular parent-led regulatory behaviours, such as distraction (Blount et al., 2008; Cohen, 2002; Cohen et al., 2006; Gonzalez et al., 1993; Lisi et al., 2013) and physical soothing (Blount et al., 2008; Campos, 1994; Jahromi et al., 2004), reduce pain-related distress throughout painful procedures, whereas other parent-led behaviours like verbal reassurance (e.g., saying "it's ok") can enhance pain-related distress (Blount et al., 2008; Cohen et al., 2005; Lisi et al., 2013; Pillai Riddell et al., 2018; Racine et al., 2012; Sweet & McGrath, 1998). Further research has shown that caregivers who display more sensitivity during a painful procedure (i.e., follow their child's

displays of distress and modify soothing behaviours accordingly) have children who display less pain-related distress throughout vaccinations (Atkinson et al., 2015; Din et al., 2009; Din Osmun, et al., 2014; Pillai Riddell et al., 2011). More recently, research has demonstrated that caregiver insensitivity may be an even stronger predictor of young children's pain related distress during vaccinations than sensitive behaviours (e.g., Badovinac et al., 2018; Pillai Riddell et al., 2018). Taken together, these findings establish the importance of the caregiver in children's emotion regulation and suggest that there are specific caregiver behaviours and states that influence child pain-related distress regulation.

However, much of the work discussed above that has influenced the development of the DIAPR-R model has studied children in the first year of life, and therefore the model may not fully account for the transactional relationship between other- and self-regulation and how these relationships change throughout the second year of life as the child gains increasing skills to self-regulate during vaccination. While the first year represents marked change in emotion regulation skills, it is not until the end of infancy into toddlerhood when these regulatory behaviours become more purposeful (Kopp, 1982, 1989), coinciding with the attachment relationship between child and primary caregiver becoming reliably measurable. To fully understand early childhood regulation during painful procedures, an understanding of the toddlerhood period is necessary because toddlerhood is approximately when children first independently attempt emotion regulation strategies (Kopp, 1982, 1989).

Further, consistent with the broader emotion regulation literature, most research in early childhood pain has used change in pain intensity or duration to denote the process of regulation (e.g., Pillai Riddell et al., 2013; Waxman et al., 2017), with limited focus on which child-led regulatory strategies are enacted to reduce their pain-related distress. Although the work

described so far has been critical to our understanding of pain processes in early childhood as well as caregiver factors that influence this response, this work is missing a key ingredient to understanding emotion regulation during painful procedures – child-led emotion regulation behaviours. Further, to best understand how child-led emotion regulation behaviours influence pain-related distress, a dynamic approach is needed to understand how child-led emotion regulation behaviours influence pain-related distress over time (Cole et al., 2004).

Although there is evidence of older children using coping or regulatory behaviours to modify pain during vaccination (Campbell et al., 2018), there remains a major gap in our understanding of the behavioural strategies that young children use in the first two years of life. There is a small amount of research on the early childhood period that has tried to disentangle child-led emotion regulation behaviours from pain-related distress in order to understand what children do to successfully reduce their pain-related distress (Blount et al., 2008; Cohen et al., 2005).

Blount and colleagues (2008) demonstrated that use of sucking and object orientation (i.e., distraction or redirecting attention away from procedure) or manipulation was associated with lower levels of crying rather than higher levels of crying at various points across the vaccination appointment. Further, Cohen and colleagues (2005) provided additional evidence for the validity of assessing behaviours such as child-led sucking and disengagement of attention. However, they do not provide evidence for how these behaviours relate to pain-related distress during vaccination. While both studies suggest that children use these types of regulatory behaviours in painful contexts, they collapsed across infancy and toddlerhood, masking the potential for developmental changes in pain-related distress regulation. Given the rapid changes in emotion regulation in infancy, as well as the continued cognitive, motor, and social

developmental changes that occur in toddlerhood, collapsing across these time periods does not allow a full understanding of pain-related distress regulation as it develops in early childhood. Further, consistent with developmental theorizing (Kopp, 1982, 1989; Sameroff, 2010; Sroufe, 1996), the second year marks a transitional period in which children rely less on caregivers and begin to develop the ability to participate in their own distress regulation. Thus, the current dissertation focuses on the toddler period.

Current Dissertation

The overall purpose of the current dissertation is to provide a better understanding of toddler distress regulation in a high distress context (i.e., vaccination) by distinguishing child-led emotion regulation behaviours from pain-related distress and how these relate over time across the vaccination appointment. Further, although there is a shift from reliance on the caregiver to self-regulation as children age beyond infancy, toddlers are still in a period when they need their caregiver, especially when task or emotional demands are beyond their skill level. Given that toddlers may still need their caregivers to support their reduction in pain-related distress, another aim of this dissertation was to understand the relative contributions of parent-led and child-led regulatory behaviours to pain-related distress regulation and how these contributions may shift across toddlerhood.

The current dissertation is a compilation of three studies. The first study was a systematic review and meta-analysis of the relationships between child-led emotion regulation behaviours and distress in the current literature (Chapter 2; Gennis et al., 2022). Given the breadth of this literature, this review focused on concurrent relationships between child-led emotion regulation behaviours and distress in the literature as a starting point for understanding which behaviours

were associated with reductions in distress and how these associations may change across the early childhood period.

Building on limitations of the extant literature elucidated in the systematic review, the second study assessed the concurrent and predictive relationships between child-led emotion regulation behaviours and pain-related distress across the 12- and 18-month vaccination appointments (Chapter 4; Gennis, Flora, Norton, et al., submitted). Lastly, to understand the presence and potential shifts of child-led versus other-led emotion regulation during vaccination, the third study assessed the relative contributions of parent-led regulatory behaviours and child-led regulatory behaviours to toddler's pain-related distress regulation at both the 12- and 18-month vaccination appointments (Chapter 6; Gennis, Flora, McMurtry, et al., submitted). There are brief bridging sections (Chapters 3 and 5) between each of the chapters to articulate the conceptual flow of the papers into each other, as well as a final discussion chapter (Chapter 7).

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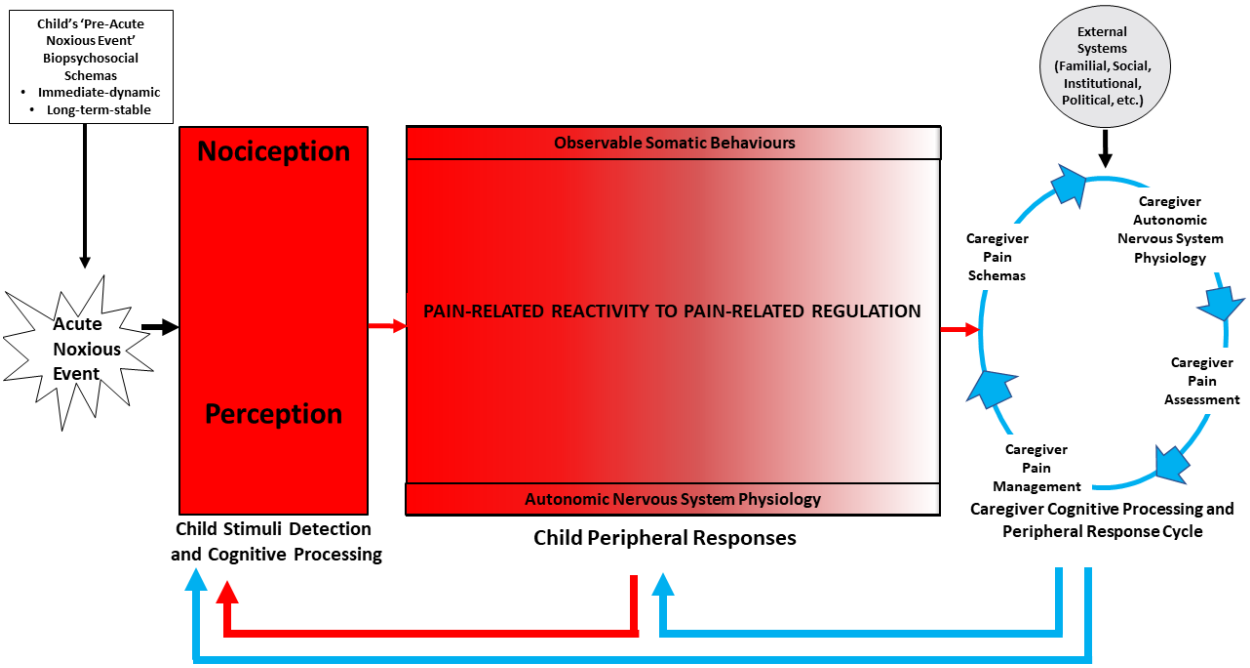
Figure 1

The DIAPR-R 2022 Model



Chapter 2: Child Distress Expression and Regulation Behaviors: A Systematic Review and Meta-Analysis[1]

1. Introduction

The term emotion regulation has been widely used in various social and emotional contexts, as well as across different developmental periods [1]. Emotion regulation reflects one's ability to monitor, evaluate, and modify emotions to attain a goal [2]. Inherent in this definition is that emotions can be regulated, or modified, via different social, behavioral, cognitive, or biological processes [1–3]. The focus of this review will be on behaviors.

There is evidence of self-regulation as early as the first few days of life. Prior to three months, behaviors are largely categorized by unintentional, non-planned motor actions. Neonates lack the cognitive and motor abilities needed to move away from a distressing stimulus, and therefore are speculated to shut out stimulation by closing their eyes, turning their head reflexively, using thumb to mouth actions, sucking, and crying [4,5]. Crying is understood as a reflexive response to distress that draws the caregiver close [6]. In these early months, distress regulation is often required in the context of physiological distress (e.g., hunger or pain). During painful experiences (e.g., vaccination), for example, research has shown that younger infants shut their eyes following a painful stimulus (e.g., a needle), and as infants age, they tend to open their eyes earlier [7]. Sroufe [8] has discussed that by three months, infants show their first "true emotional reactions".

[1] This is the authors' version of the published manuscript
The published paper is cited below:
Gennis, H. G., Bucsea, O., Badovinac, S. D., Costa, S., McMurtry, C. M., Flora, D. B., & Pillai Riddell, R. (2022). *Child distress expression and regulation behaviors: A systematic review and meta-analysis*. *Children*, *9*(2), 174. https://doi.org/10.3390/children9020174

Caregivers are particularly important for distress regulation in the first year, because while infants are developing the ability to enact certain regulatory behaviors, their skill set is inadequate to meet all the novel stressors they encounter or alleviate the stressor itself [5]. An infant's ability to regulate from distress is heavily embedded in co-regulation with the caregiver, and that co-regulation forms the underlying canvas on which self-regulation is learned [4,5,8]. Sameroff [9] describes these developmental processes in terms of a shift from a "other-regulation" (i.e., regulation provided by caregivers) to "self-regulation" that occurs as infants take on an increasing role in managing their own distress beginning in toddlerhood.

Rothbart et al. [10] have outlined developmental trends in self-regulatory behaviors based on observing young infants into their toddler years under several different distressing and non-distressing conditions. Their work has shown that as infants age, they tend to move from more physical regulatory behaviors (e.g., mouthing and sucking) to more active forms of regulatory behaviors. Between 3 and 4 months, there is a hypothesized shift toward disengagement of attention that is solidified by 6 months of age [10]. As the first year progresses, children are considered "true emotional beings" [11], and regulatory efforts become more purposeful. Infants' use of emotion regulation behaviors increases dramatically by the end of the first year due to changes in motor and visual systems, as well as social and emotional domains [4,5].

As children enter toddlerhood (i.e., the second year), emotion regulation strategies are largely social and include signalling to the caregiver for support in regulation [8]. This is consistent with attachment theory [6], which suggests that when infants become distressed, they are innately driven to seek proximity with their caregivers for distress reduction. This process tends to solidify by 12 months of age [6,12,13]. In line with these findings, Rothbart et al. [10] has shown that as children age into their second year (13.5 months in this particular sample),

toddlers' attention becomes increasingly focused on their mothers. Further, continued changes in cognitive and motor processes allow toddlers to shift from more simple methods of attentional control (e.g., gaze aversion) [14,15] to more effortful redirection [16,17]. For example, one study examining the differences in frequency of object orientation during a frustration task found an increase in use of object orientation from four months to 16 months [18].

By the end of the second year, there is evidence of less reliance on the caregiver and more independent methods of emotion regulation, as toddlers begin to develop an understanding of causes of distress and how to use actions to alter or remove the cause [4,5]. It is important to note that while toddlers are able to self-regulate without caregiver intervention, there is still reliance on caregivers, who can serve as a supportive presence that enables the child's self-regulation when demands may be too high [8]. In the third year, toddlers acquire an ability known as mentalization [19]. They begin to understand that their experience of emotion is different from those around them, and with the acquisition of language, begin to talk about their own and other people's feelings [19]. This has important implications for emotion regulation behaviors.

The study of emotions and emotion regulation has been fruitful yet challenged by a difficulty in distinguishing emotional expression from emotion regulation. Independent assessment of emotion expression and regulatory behaviors was deemed to be a key methodological direction needed to advance the study of emotion regulation [1]. With this concept in mind and Thompson's [2] definition of emotion regulation, it is not enough to consider a reduction in distress (i.e., emotional expression) as evidence of emotion regulation. Without looking at the relationship of particular emotion regulation behaviors on the emotional expression, true regulation is not evident. This review provides an analysis of the literature to

date examining the relationship between distress expression and distress regulation behaviors in young children, in order to gain a firm understanding of how particular behaviors impact distress expression across the literature.

Based on our current review of the literature, there appears to be evidence of two distinct types of emotion regulation behaviors in infancy and toddlerhood: caregiver-directed self-regulation behaviors and independent self-regulation behaviors. Caregiver-directed behaviors, defined here as behaviors that solicit parent support to regulate distress, would include behaviors such as orienting to the parent and seeking proximity to the parent. Independent self-regulation behaviors would therefore be those that are not directed at the caregiver or "other". These may include self-directed physical self-soothing (e.g., thumb sucking, auto-manipulative behaviors) or disengagement of attention (e.g., gaze aversion, focusing on a different object). Further, within the category of independent self-regulation behaviors, there appears to be a developmental shift from the use of more physical self-soothing strategies in infancy, to more attention-related strategies in toddlerhood. Thus, these were separated to gain a fuller understanding of these strategies.

The primary goal of this paper was to provide a synthesis of the concurrent relationships between distress expression and three unique clusters of emotion regulation strategies in the first three years of life. These three clusters are: 1. disengagement of attention behaviors, referring to any shift in attention that does not involve the parent (e.g., playing with a toy or object and averting gaze); 2. parent-focused behaviors, referring to any behavior a child does to get the parent's attention or bring the parent close (e.g., gazing at the parent and vocalizations directed at the parent); 3. self-soothing behaviors, referring to the infant's physical attempts to calm down (e.g., thumb sucking). The focus on assessing the relationships between distinct measures of

emotion expression and distinct measures of emotion regulation strategies was based on Cole et al.'s statement of the importance of separating emotional valence and emotion regulation strategies as unique constructs [1].

There is a large body of literature providing data on the relationship between distress expression and distress regulation behaviors; however, there has yet to be a meta-analysis of these findings. Meta-analyses provide an objective, quantitative method to summarize a large literature on a given effect (e.g., mean associations between regulation behaviors and distress expression), while also including methods to understand factors contributing to the heterogeneity of effects across the literature [20]. Another benefit of meta-analyses is that they provide an accessible summary of a particular literature. Given the importance of emotion expression and emotion regulation to a number of scientific areas interested in child development (e.g., health psychology), this is a helpful starting point for researchers in broader research areas.

It is important to state that Cole et al. [1] emphasized additional methodological considerations not directly addressed in this review. These include notably the need to look at temporal or dynamic relationships between these two constructs. While the current review only focused on concurrent relationships to provide a general synthesis of the relationships between emotion expression and regulation behaviors, it does not negate the importance of taking a dynamic, time-based approach. Given the challenges with synthesizing over several time-based or predictive analyses, inclusion of such studies went beyond the scope of this particular review. Assessing the concurrent relationships is seen as an important first step in this synthesis, with temporal relationships needing to be addressed in future studies.

Further, an a priori decision was made to not extend the analyses into the preschool phase of early childhood (i.e., 4–5 years old). This was done for two reasons. First, there is a

substantial shift from guided self-regulation (i.e., caregiver support present) in infancy and toddlerhood to less guided self-regulation in preschool. Second, the types of tasks and expectations (i.e., self-control and self-organization) of preschool [8] are qualitatively different in their demands.

2. Materials and Methods

2.1. Protocol and Registration

This review followed an a priori protocol according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [21]. The review protocol was pre-registered on the International Prospective Register of Systematic Reviews (PROSPERO) [22] prior to data extraction (CRD42020157505; https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=157505; November 6 2019). After examining the quantity of data available, two deviations from the PROSPERO protocol occurred: (1) this study did not analyze the predictive relationships between distress expression and distress regulation behaviors (only concurrent); (2) this study did not analyze relationships that had a physiological distress outcome. See Supplemental File S1 for PRISMA Checklist.

2.2. Eligibility Criteria

Included studies were required to: (1) be English-language observational human cohort or cross-sectional studies; (2) have participants between the ages of 3 months 0 days and 35 months 31 days; (3) include a distressing task; (4) have separate behavioral measures of both distress expression (e.g., facial expressions and crying) and distress regulation behaviors (disengagement of attention, parent-focused, or self-soothing); and (5) report concurrent relationships between the two measures (i.e., measured within the same epochs). Prospective and longitudinal analyses were not considered for this review, due to the heterogeneity in analyses which complicated

obtaining comparable effect sizes. Review articles, dissertations, case studies, commentaries, and conference abstracts were also excluded to focus on published peer-reviewed empirical work.

2.3. Systematic Search

A systematic search was conducted using Medline, Embase, and PsycINFO in December 2020 for English-language references published in the last 30 years. Search terms related to distress, emotion regulation, and infancy or toddlerhood were systematically paired (see Supplemental File S2 for search strategies).

2.4. Study Selection

Four independent coders rated 20% of total abstracts (based on the initial search results of 11,996 abstracts). Percentage agreement of abstract inclusion across pairs of coders ranged from 96.24% to 97.64%. Checks for percentage agreement were continued on subsets of abstracts throughout the remaining screening. Covidence software (www.covidence.org; December 30, 2019) was used for independent abstract rating.

2.5. Data Collection Process

Once full texts were included, all data were extracted by two reviewers using standardized forms. Study authors were contacted if data were missing. Discrepancies were minimal and resolved through discussion.

2.5.1. Data Items

For each article, we recorded the country where the study took place, sample size, participant age in years (First year of life: 3 months 0 days to 11 months 30/31 days; Second year of life: 12 months 0 days to 23 months 30/31 days; and Third year of life: 24 months 0 days to 35 months 30/31 days), distress task, measure of distress expression, measure of distress regulation behaviors, and the correlation between the distress expression measure and the distress regulation measure. Studies were coded as including a fear task, a frustration task, and/or a task

that invoked “other distress” (e.g., a competing demands task or exposure to another child’s or experimenter’s distress). If not explicitly specified as fear or frustration in the article, we coded any task including separation, flattening of affect, or ignoring as fear and coded any task involving a barrier or restraint as frustration. As shown in Table 1, two studies exposed the child to another individual’s distress—either the cry sound of a peer [23], or experimenter distress [24]. These two studies were categorized under fear. One study had a competing demands task [25], which was categorized under frustration. Further, if a study provided several measures of distress regulation behaviors in a particular category, composite measures were prioritized, followed by the behavior that most closely matched other behaviors that would be included in the same analytical category.

2.5.2. Handling of Multiple Effect Sizes

Several studies included multiple effect sizes for one or more of the following reasons: (1) participants of a particular age group underwent two separate distress tasks; (2) there were two or more distress variables; (3) there were separate data from participating in a task with both mother and father; and (4) children participated at multiple ages. Further, several articles presented on the same sample. In these cases, effect sizes were selected from the most distressing task (based on distress scores or reviewing authors consensus), the distress task with the mother, or the effect size that most closely resembled the methodologies of the other included studies to minimize heterogeneity among studies. For example, when effect sizes from multiple ages were provided, we selected the age that was most similar to other studies in the meta-analysis to promote conceptual consistency among the effects meta-analyzed.

2.6. Risk of Bias/Quality Assessment

To evaluate the quality of evidence in the meta-analysis, a modification of the checklists designed by the National Heart, Blood, and Lungs Institute [26], Downs and Black [27], and

Crombie [28] was used. The National Heart, Blood, and Lungs Institute has provided a guideline for assessing the quality of observational cohort and cross-sectional studies [26], and the Downs and Black [27] and Crombie [28] measures were chosen based on a multidisciplinary collaborative review discussing quality in case–control, cohort, and cross-sectional studies [29]. Quality items were scored as Yes, No, or Not applicable. Articles were consensus-coded for quality scores to ensure reliability. Disagreements between two raters were minimal (reliability was 94.8%) and resolved through discussion. There was a total of 16 items on the quality checklist, and a proportion score was calculated for each study based on the number of items endorsed (i.e., scored as Yes) out of the total applicable items (i.e., scored as either Yes or No). See Supplemental File S3 for Quality Measure.

2.7. Data Synthesis

The extracted data were stratified by age (first, second, and third year of life) and cluster of emotion regulation behavior (parent-focused strategies, self-soothing strategies, and disengagement of attention strategies), with a separate meta-analysis conducted for each of the resulting nine datasets.

Meta-Analysis

Correlations between distress expression and distress regulation behaviors were the summary effect size statistic used in the current meta-analysis. In one study [30], the distress expression measure reported was latency to distress (i.e., the amount of time until distress is displayed), for which the direction of the correlation was reversed.

Once correlations were obtained, Fisher's *r*-to-*Z* transformation [31] was used to account for the non-normal sampling distribution of *r*. These *Z* statistics were then meta-analyzed, and the pooled weighted *Z* statistics were returned to *r* values for interpretation. Random-effects models were estimated because it is assumed that the true effect can vary from study to study

(i.e., studies can differ on other factors beyond the random sampling of participants). The meta-analyses were conducted using the metafor package [32] in R, version 4.0.2 [33].

Cochran's Q and I^2 were used to describe heterogeneity among effect sizes (see [34]).

3. Results

3.1. Study Selection

Over three search periods, 13,239 unique abstracts were identified, 295 articles were full-text reviewed, and 31 were included in the final meta-analyses. See Figure 1 for details on exclusion and reasons for exclusion for each stage.

3.2. Study Characteristics

Table 1 shows study characteristics including country of origin, sample size, distress task (specific task used), classification of distress task (fear or frustration), classification of distress regulation behavior, and study quality.

Most studies were from the United States (77%), with the rest coming from Canada, Italy, the Netherlands, Sweden, and Romania. Seven of the studies that assessed an age group in the first year of life provided data for disengagement of attention (43% frustration tasks, 57% fear tasks), 11 provided data for parent-focused strategies (36% frustration tasks, 64% fear tasks), and four provided data for self-soothing strategies (25% frustration tasks, 75% fear tasks). For the second year of life, 11 studies provided data for disengagement of attention (82% frustration tasks, 18% fear tasks), seven provided data for parent-focused strategies (71% frustration tasks, 29% fear tasks), and four provided data for self-soothing strategies (75% frustration tasks, 25% fear tasks). For the third year of life, five studies provided data for disengagement of attention (60% frustration tasks, 40% fear tasks), four for parent-focused strategies (75% frustration tasks, 25% fear tasks), and four for self-soothing strategies (25% frustration tasks, 75% fear tasks).

3.3. Quality Assessment

Across the 31 studies, quality ratings ranged from 43% to 88%, with a mean rating of 62% and a median rating of 60%. Figure 2 outlines the percentage of studies that received credit (i.e., were coded as "Yes") for each of the 16 items in the quality assessment.

Item criteria that were commonly met (i.e., at or above 75% of studies meeting criteria) included using valid and reliable predictor and outcomes variables (i.e., distress expression and distress regulation behaviors), using continuous predictor variables, accounting for relevant confounding variables, specifying the research questions, specifying the statistical methods, and providing gender distributions. Of note, in order to be included in the meta-analysis, all studies were required to provide a correlation or a statistic that could be converted into a correlation, and thus 100% of studies would have met this criterion.

Items that reduced quality ratings across studies (i.e., at or below 25% of studies meeting criteria) included not blinding outcome assessors to hypotheses, not properly defining the study population, neglecting to report or achieve a participation rate of 50% or more eligible participants, neglecting to report or uniformly implement recruitment criteria across participants, and not reporting exact *p*-values associated with the correlations.

3.4. Synthesis of Results: Relations between Distress Expression and Distress Regulation Behaviors

Table 2 summarizes findings from the nine meta-analyses (separate analyses by age and distress regulation behavior). Supplemental Tables S1–S3 provide individual study findings for interested readers.

3.4.1. Meta-Analyses for Disengagement of Attention Regulation Behaviors by Age

First Year of Life

Seven studies were included in the meta-analysis of disengagement of attention in the first year of life [18,35–40] providing a total of 674 participants. The weighted mean effect size was r = −0.28, 95% CI [−0.47, −0.06] indicating a small to moderate negative relationship between distress expression and disengagement of attention behaviors in the first year of life. The heterogeneity of effects among the studies was large (Q = 90.45, $p < 0.001$, $I^2 = 87.18\%$; see Figure 3).

Second Year of Life

Eleven studies were included in the meta-analysis of disengagement of attention in the second year of life [14,16,18,25,30,41–46], providing 1057 participants. The weighted mean effect size was r = −0.44, 95% CI [−0.58, −0.29], indicating a moderate negative relationship. There was substantial heterogeneity of effects among the studies (Q = 106.48, $p < 0.001$, $I^2 = 88.21\%$; see Figure 4).

Third Year of Life

Five studies were included in the meta-analysis of disengagement of attention in the third year of life [16,17,47–49], providing 750 participants. The weighted mean effect size was r = −0.30, 95% CI [−0.54, −0.00], indicating a small to moderate negative relationship between distress expression and disengagement of attention strategies at this age. There was substantial heterogeneity of effects among the studies (Q = 47.72, $p < 0.001$, $I^2 = 92.45\%$; see Figure 5).

3.4.2. Meta-Analyses for Parent-Focused Strategies by Age

First Year of Life

Eleven studies were included in the meta-analysis of parent-focused strategies in the first year of life [14,35,37,38,40,50–55], providing 1809 participants. The weighted mean effect size was r = 0.00, CI 95% [−0.17, 0.17], indicating a lack of a relationship overall between distress

expression and parent-focused strategies. There was large heterogeneity of effects among the studies (Q = 57.52, $p < 0.001$, $I^2 = 88\%$; see Figure 6).

Second Year of Life

Seven studies were included in the meta-analysis of parent-focused strategies in the second year of life [25,42–45,55,56], providing 1573 participants. The weighted mean effect size was r = 0.20, 95% CI [−0.12, 0.49], indicating a weak positive association between parent-focused behaviors and distress expression. There was substantial heterogeneity across studies (Q = 85.53, $p < 0.001$, $I^2 = 96.50\%$; see Figure 7).

Third Year of Life

Four studies were included in the meta-analysis of parent-focused strategies at this age [47–49,55], including data from 1459 participants. The weighted mean effect size was r = 0.11, 95% [−0.16, 0.37], indicating a weak, positive relationship between distress expression and parent-focused strategies. There was large heterogeneity (Q = 33.84, $p < 0.001$, $I^2 = 95.03$; see Figure 8).

3.4.3. Meta-Analyses for Self-Soothing Strategies by Age

First Year of Life

Four studies were included in the meta-analysis of self-soothing strategies in the first year of life [23,35,39,57], providing 437 participants. The overall mean effect size was r = −0.23, 95% CI [−0.46, 0.03] indicating a weak negative relationship between distress expression and self-soothing strategies. There was large heterogeneity of effects among studies (Q = 12.10, $p = 0.007$, $I^2 = 81.67\%$; see Figure 9).

Second Year of Life

Four studies were included in the meta-analysis of self-soothing strategies in the second year of life [25,41,43,46], providing 382 participants. The weighted mean effect size was r =

0.25, 95% CI [0.11, 0.37], indicating a small to moderate positive relationship between distress expression and self-soothing behaviors. Heterogeneity among effects was relatively low (Q =3.38, $p = 0.34$, $I^2 = 41.18\%$; see Figure 10).

Third Year of Life

Four studies were included in the meta-analysis of self-soothing strategies in the third year of life [17,24,48,49], including data from 664 participants. The weighted mean effect size was r = −0.10, [−0.26, 0.06], indicating a weak, negative relationship between distress expression and self-soothing strategies. There was moderate heterogeneity among studies (Q =18.59, $p < 0.001$, $I^2 = 67.37\%$; see Figure 11), which was predominantly driven by a single study.

4. Discussion

The purpose of this paper was to summarize the literature assessing concurrent relationships between child distress expression and child distress regulation behaviors over the first three years of life. Findings were stratified by age (first year, second year, and third year of life), and cluster of emotion regulation behaviors (disengagement of attention, parent-focused, and self-soothing behaviors). This was done given the evidence of developmental shifts in the first three years between caregiver-directed behaviors and independent self-regulation behaviors, as well as a shift in complexity of independent self-regulation behaviors over time. Disengagement of attention strategies consistently had the strongest relationships across each of the years analyzed. Following is a discussion of these findings in greater detail.

4.1. Associations between Distress Expression and Distress Regulation Behaviors

4.1.1. Disengagement of Attention Regulation Behaviors

Over the first three years of life, relationships between distress expression and disengagement of attention were consistently negative, suggesting that greater disengagement of

attention was associated with lower levels of behavioral distress. In the first and third year, the magnitude of the negative relationship was small to moderate. In the second year, the magnitude was moderate, suggesting that disengagement of attention is a particularly strong distress regulation behavior during this developmental period. The increase in the strength of these relationships from the first to second year is consistent with Sameroff's hypothesis [9] that self-led regulatory behaviors become increasingly influential during toddlerhood, and with developmental research that suggests a major shift in attentional capacity throughout the first year, with continued growth across development [4,5,10]. However, the lack of notable increase from the second to third year is less clear. Given that attentional capacity and use of disengagement of attention are expected to increase throughout development, it would be intuitive that the relationship between distress expression and disengagement of attention would be the strongest at three years. While this could be explained by the smaller number of studies available for year three analyses, it is possible that there are more complex cognitive strategies, such as language [19], or other attentional behaviors occurring in the third year that are not captured in the literature summarized here.

4.1.2. Parent-Focused Distress Regulation Behaviors

The relationships between parent-focused distress regulation behaviors and distress expression were consistently small over the first three years of life. Based on the current findings, the strongest relationship is again in the second year of life, with a lack of a relationship in the first year, and a weaker relationship in the third year of life. Findings also suggested that these relationships were positive, indicating that the use of more parent-focused behaviors was related to an increase in distress. This is consistent with early findings of an increase in parent-focused strategies in the second year [10]. The increase in magnitude from the first to second year of life can be understood through Sameroff's work [9], suggesting an increase in use of

more child-directed emotion regulation behaviors from infancy to toddlerhood. The reduction in magnitude from the second to third year is consistent with the shift from more parent-focused strategies to potentially more independently driven strategies as the child develops [4,5,8,9].

The positive direction of these relationship can also be understood as signals from a child to the parent that they need support [6]. Looking across the age groups, in the first year of life, the lack of a relationship may best be understood from an attachment perspective. Parent-focused regulatory behaviors may not be expected to be implemented consistently by children until the attachment relationship between parent and child is more stable, after the first year of life [12,13]. This can help to explain the increase in relationship between parent-focused strategies and distress expression in the second year of life once the attachment relationship and the child's understanding of how the parent will respond has been solidified. However, it is difficult to fully understand the relationships between parent-focused regulation behaviors and distress across development when the parental response and sensitivity to the displayed distress is left unaccounted. It is possible that it is not the actual signal that would result in a reduction in distress, but rather what the parent does with that signal. Enhancing these findings through analyses that account for the caregiver response would allow for a deeper understanding of the association between distress expression and parent-focused regulation behaviors.

4.1.3. Self-Soothing Distress Regulation Behaviors

In the first and third year of life, there were small negative relationships between self-soothing behaviors and distress expression. Although in the expected negative direction, given that in the first year of life distress regulation is heavily influenced by caregiver behavior [4,5,9], and limited by the child's developmental stage, it is understandable that the negative association is small. There was a small to moderate positive relationship between self-soothing behaviors and distress expression in the second year of life, which is consistent with the developmental

trend of movement away from physical self-soothing to other forms of self-regulation [4,5,10]. The findings of this analysis may be showing that these types of behaviors no longer support distress reduction.

Lastly, the small negative relationship in the third year of life warrants attention as this can be puzzling within the developmental context discussed above. Upon further review of the variability of the data in this analysis, it appears that the majority of findings in this area indicate a lack of a relationship, which would be more consistent with the developmental trends discussed above; however, given the small number of studies in this area, less confidence should be attributed to these effect sizes until more work in the area is completed and synthesized.

To summarize across strategies, in line with developmental theorizing [4,5,8,9], our findings reiterate the need for assessing emotion regulation developmentally across the first few years of life. As children age, we expect their use of emotion regulation strategies to become more sophisticated, and we tend to see a shift from relying on a caregiver to regulate distress, to initiating more independent self-regulation strategies. Our work did not necessarily follow this pattern, as arguably the most complex distress regulation could be the disengagement of attention strategies, and this proved to be the most consistently significant effect size from year one to year three. Additionally, it is possible that language accounts for a lack of findings in year three, which was not measured as a regulation strategy in this review. However, our findings do follow particular trends, notably, a peak in the magnitude of the relationship between emotion regulation behaviors and distress expression in the second year of life, across all three clusters of emotion regulation behaviors. This speaks to the second year being a particularly important time for the use of these behaviors, irrespective of whether the behaviors are related to a reduction or increase in distress.

4.2. Heterogeneity across Studies and Methodological Considerations

The above findings need to be understood in the context of substantial heterogeneity among the effect sizes in each analysis. Except for the meta-analysis of self-soothing strategies in the second year of life, there was moderate to large variability across effect sizes included in the various analyses. This finding is important to keep in mind when interpreting the weighted mean effect sizes, because the effect from a given individual study is likely to differ from that mean substantially. Further, an example of how this variability can skew interpretation of findings is seen in the analysis of self-soothing strategies in the third year of life. If one only looked at the mean weighted effect size, it would be concluded that there is a small negative relationship between self-soothing and distress. However, when looking at the spread, a different story suggests that this may be largely affected by one study, with other studies more consistently finding a lack of a relationship.

There was considerable variability in the choice of measures and behaviors included across studies. Distress expression can be measured using several indicators, including crying, fussing, additional facial actions, and body movements. Some studies looked at combinations of these behaviors to indicate distress expression, whereas others examined one in isolation—usually crying or vocal indicators of distress. Regarding the distress regulation behaviors used, how researchers measured different categories of emotion regulation behaviors also varied across studies. Again, some may have only measured one indicator of a particular category, whereas others may have measured numerous behaviors within that category. For example, some studies may have only used visual orientation toward a parent as a parent-focused strategy, whereas other studies may have included visual orientation, gesturing, and vocalizations toward the parent as separate indicators of parent-focused strategies. All of these sources of variability underscore the important topic of how emotion regulation is being studied. Researchers should

conduct psychometric analyses on child distress expression and child distress regulation behaviors and adopt a consistent way of measuring this across distress tasks. Without more consistency in measurement and context, a clear synthesis of this literature will likely evade the field.

In terms of the overall quality of this literature, several factors were found to consistently reduce quality across studies. These included lack of reporting on the study population, recruitment consistency across participants, and low (or lack of reports on) participation rates. Perhaps most notably, the most commonly omitted piece of information that impacted quality ratings was the failure to report blinding of assessors to study hypotheses. Given the risk for subjectivity in coding and potential for bias, this is an extremely important methodological consideration. While it is possible that coders were in fact blind to the hypotheses, and the authors simply did not include this in the Methods section, this is necessary information for critically evaluating research findings and speaks to a larger issue—a need for researchers to use a more structured, consistent method of reporting observational and cohort studies in the field. For example, the Strengthening in the Reporting of Observational Studies in Epidemiology (STROBE) Statement [58,59] provides guidelines that may help strengthen the reporting of observational studies in emotion regulation research. Further, more research assessing the validity and reliability of quality and risk of bias measures based on these reporting standards is required.

4.3. Limitations and Future Directions

First, all studies included in the meta-analyses included experimental distress tasks implemented either at a research laboratory or in participants' homes. Experimental procedures are limited to studying distress regulation behaviors in the context of low to moderate distress, given that it is unethical to keep a child in high distress unnecessarily. Naturalistic procedures

that invoke distress are likely the only context to observe these extreme levels of distress. A common naturalistic procedure that occurs on a routine basis throughout childhood is vaccination. This context provides a naturalistic stressor that invokes high levels of distress but is a routine part of a child's development. With rare exception [60], the associations between behaviors such as child disengagement of attention, parent-focused, and self-soothing and distress in this context have yet to be studied in this age range and remain a fruitful area for future research.

It is important to consider these findings within the sociocultural context of the included studies. The research studies included are almost exclusively from the United States, and therefore the findings in the meta-analyses may not be entirely generalizable to other populations. Future research may wish to understand the impact on sociocultural factors on how different emotion regulation behaviors relate to distress.

Another potential limitation is that our inclusion criteria only allowed for studies that examined disengagement of attention strategies (not including use of parent), parent-focused strategies, and self-soothing strategies as distinct emotion regulation behavior clusters. This decision was driven by our goal of comparing the relative importance of these theoretically distinct behavior clusters; however, as a result, any study that observed self-focused strategies that collapsed across attentional and physical self-soothing strategies was excluded (e.g., [15]). Thus, other research groups may have classified emotion regulation behaviors differently. Further, this review and meta-analysis excluded physiological and biological indices of distress. Given the breadth of papers on this topic, we decided to focus solely on observable emotion expression behaviors. Future studies could explore the biological components of emotional regulation to provide a more complete biopsychosocial perspective.

Another important limitation is the focus on concurrent relationships, which does not allow for an understanding of how distress regulation and distress expression behaviors influence one another in a sequential and interactive manner over time, as recommended by Cole and colleagues [1]. To gain a more nuanced understanding of emotion regulation, more work is needed that examines how distress regulation behavior and distress expression are temporally associated. Analyses such as cross-lagged path models continue to be explored, particularly in naturalistic settings that facilitate observing varying levels of distress (e.g., [61]).

5. Conclusions

Emotion regulation has been an important topic in the developmental psychology literature for decades. This work is the first meta-analysis to examine the association between child distress regulation behaviors and child distress expression. Using an exhaustive search strategy and high standards of synthesis methodology, this review found that the strongest and most consistent relationships in the literature involved disengagement of attention strategies. Small to moderate relationships were found in year 1, 2, and 3. The strongest relationship was seen in the second year. Parent-focused strategies consistently had positive associations with distress, reflecting their function of signalling distress to the caregiver, and peaked in the second year. The associations for self-soothing behaviors were less consistent but support a reduction in usefulness for reducing distress in the second and third year. Heterogeneity of outcome measures and tasks likely contributed to the weaker and inconsistent findings. Efforts to reduce heterogeneity (e.g., consistency in measurement of behaviors) across studies are needed to create a coherent picture regarding the development of child regulation behaviors and distress. This body of work summarizing the overall concurrent relationships between child distress regulation behaviors and child distress expression has also elucidated an important gap in the literature,

specifically, a sparsity of studies assessing these processes in naturalistic high-distress environments that would allow for larger variability in distress. Future research should examine these relationships from a biopsychosocial perspective, within naturalistic distressing situations, to gain a deeper understanding of the development of emotion regulation strategies and their impact on distress.

Supplementary Materials: The following are available online at https://www.mdpi.com/article/10.3390/children9020174/s1, Table S1: Summary of results from studies assessing disengagement of attention separated by age; Table S2: Summary of results from studies assessing parent-focused strategies separated by age; Table S3: Summary of results from studies assessing self-soothing strategies separated by age; File S1. PRISMA checklist; File S2. Systematic search strategies; File S3. Quality assessment measure.

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Table 1

Study Characteristics

Study: First Author Last Name (Year)	Country	Sample Size (Year of Life: N)	Distress Task	Task Classification (Fear/ Frustration)	Distress Regulation Behaviors Measured	Overall Quality (% of Items Rated as 'Yes' out of Applicable Items)
August (2017)	Canada	Y1: 34	Still face	Fear	PF	67%
Beijers (2017)	Netherlands	Y2: 186	Strange situation procedure	Fear	DoA SS	60%
Braungart (1991)	United States	Y2: 80	Strange situation procedure - Reunion	Fear	DoA PF	67%
Braungart-Rieker (1998)	United States	Y1: 94	Still face	Fear	DoA PF SS	57%
Braungart-Rieker (2010)	United States	Y1: 143	Gentle arm restraint	Frustration	DoA	67%

		Y2: 119				
Bridges (1997)	United States	Y2: 62	Parent-Passive Delay with Mother (combines the gift and food delay procedures)	Frustration	DoA PF SS	64%
Buss (1998)	United States	Y1: 48	Y1: Unpredictable Mechanical Dog	Y1: Fear	Y1: PF	60%
		Y2: 103	Y2: Attractive Toy Behind Barrier	Y2: Frustration	Y2: DoA	
Calkins (1998)	United States	Y2: 73	High chair restraint	Frustration	DoA PF	60%
Calkins (1999)	United States	Y3: 65	Combined 2 frustration tasks: high chair task and barrier (toy in a box) task	Frustration	DoA PF	67%
Cole (2011)	United States	Y2: 120	Wait task	Frustration	DoA	60%
		Y3: 120				

Crockenberg (2007)	United States	Y1: 80	Novelty to bumble ball and firetruck	Fear	DoA	57%
Diener (2002)	United States	Y2: 94	Competing demands task with mom	Frustration	DoA PF SS	67%
Ekas (2011)	United States	Y2: 106	Parent-Ignore-Toddler-Situation (PITS) with mother, ignore episode - a modified still face*	Frustration	DoA PF	60%
Frick (2018)	Sweden	Y2: 74	Attractive toy placed behind a barrier	Frustration	DoA	43%
Geangu (2011)	Romania	Y1: 32	Emotional resonance task (cry sound of peer)	Fear	SS	54%
Gill (2003)	United States	Y3: 99	Experimenter Distress	Fear	SS	57%

Graziano (2011)	United States	Y3: 422	Combined 2 frustration tasks: high chair task and prize in a box task	Frustration	DoA PF SS	57%
Grolnick (1996)	United States	Y3: 37	Separation from parent alone	Fear	DoA SS	67%
Gustafsson (2018)	United States	Y1: 68	Arm restraint	Frustration	PF	64%
Haley (2003)	United States	Y1: 43	Modified still-face protocol: Second still face	Fear	PF	60%
Hepworth (2020)	United States	Y2: 186	Mask task	Fear	PF	88%
Kogan (1996)	United States	Y1: 29	Still face reunion	Fear	DoA PF	53%
Mayes (1990)	United States	Y1: 62	Still Face	Fear	PF	53%

Moscardino (2006)	Italy	Y1: 45	Arm Restraint	Frustration	DoA PF	73%
Premo (2014)	United States	Y3: 106	Novelty to Spider	Fear	DoA PF SS	64%
Ross (1999)	United States	Y2: 40	Attractive toy	Frustration	DoA SS	57%
Sheese (2008)	United States	Y1: 50	Mask procedure	Fear	DoA SS	43%
Suurland (2017)	The Netherlands	Y1: 117	Still Face procedure - Reunion	Fear	PF	60%
Swingler (2014)	United States	Y1: 233	Arm Restraint	Frustration	DoA PF	57%

Thomas (2017)	Canada	Y1: 261	8 Frustration Trials collapsed	Frustration	SS	75%
Wu (2020)	United States	Y1: 1036	Y1: Combined arm restraint task, mask task, and barrier task	Frustration	PF	80%
		Y2: 972	Y2: Combined mask task and toy removal task			
		Y3: 866	Y3: Combined mask task and toy removal task			

Note. Y1 = first year of life (3 months to 11 months inclusive), Y2 = second year of life (12 months to 23 months inclusive), Y3 = third year of life (24 months to 35 months inclusive), DoA = disengagement of attention, PF = parent-focused strategies, and SS = self-soothing strategies. * All separation tasks were classified as inducing fear. However, Ekas (2011) described their task as inducing frustration, and therefore it was classified accordingly.

Table 2

Summary of Meta-Analyses

Year of Life	Disengagement of Attention	Parent-Focused	Self-Soothing
Year 1	r = -.28 (k = 7) *	r = .00 (k = 11)	r = -.23 (k = 4)
Year 2	r = -.44 (k = 11) *	r = .20 (k = 7)	r = .25 (k = 4) *
Year 3	r = -.30 (k = 5) *	r = .11 (k = 4)	r = -.10 (k = 4)

Note. Effect estimates (Pearson r) and number of studies included in each effect estimate (k) are presented. *Indicates the 95% Confidence Interval did not cross over 0.

Supplemental Table 1

Summary of Results from Studies Assessing Disengagement of Attention Separated by Age

	Year 1		Year 2		Year 3	
Study	Analysis	Result	Analysis	Result	Analysis	Result
Moscardino (2006)	Correlation	r = -.30				
Bridges (1997)			Correlation	r = -.41		
Swingler (2014)	Correlation	r = -.60				
Beijers (2017)			Correlation	r = -.78		
Premo (2014)					Correlation	r = .25
Ekas (2011)			Correlation	r = -.19		
Braungart (1991)			Correlation	r = -.65		
Diener (2002)			Correlation	r = -.29		
Sheese (2008)	Correlation	r = -.24				
Cole (2011)			Correlation	r = -.30	Correlation	r = -.46
Frick (2018)			Correlation	r = -.21		
Buss (1998)			Correlation	r = -.20		

Braungart-Rieker (2010)	Correlation	r = .29	Correlation	r = -.26		
Braungart-Rieker (1998)	Correlation	r = -.44				
Calkins (1998)			Correlation	r = -.60		
Grolnick (1996)					Correlation	r = -.56
Graziano (2011)					Correlation	r = -.42
Ross (1999)			Correlation	r = -.70		
Calkins (1999)					Correlation	r = -.24
Crockenberg (2007)	Correlation	r = -.18				
Kogan (1996)	Correlation	r = -.41				

Supplemental Table 2

Summary of Results from Studies Assessing Parent-Focused Strategies Separated by Age

	Year 1		Year 2		Year 3	
Study	Analysis	Result	Analysis	Result	Analysis	Result
Moscardino (2006)	Correlation	r = .39				
Bridges (1997)			Correlation	r = .57		
Swingler (2014)	Correlation	r = .14				
Haley (2003)	Correlation	r = -.11				
Premo (2014)					Correlation	r = .06
Ekas (2011)			Correlation	r = .40		
Braungart (1991)			Correlation	r = .39		
Diener (2002)			Correlation	r = .15		
Suurland (2017)	Correlation	r = -.28				
Gustafsson (2018)	Correlation	r = -.26				
August (2017)	Correlation	r = .36				
Braungart-Rieker (1998)	Correlation	r = -.31				

Calkins (1998)			Correlation	r = -.61		
Graziano (2011)					Correlation	r = .39
Buss (1998)	Correlation	r = .38				
Mayes (1990)	Correlation	r = -.19				
Calkins (1999)					Correlation	r = -.26
Wu (2020)	Correlation	r = .11	Correlation	r = .15	Correlation	r = .18
Kogan (1996)	Correlation	r = -.16				
Hepworth (2020)			Correlation	r = .35		

Supplemental Table 3

Summary of Results from Studies Assessing Self-Soothing Strategies Separated by Age

	Year 1		Year 2		Year 3	
Study	Analysis	Result	Analysis	Result	Analysis	Result
Bridges (1997)			Correlation	r = .25		
Beijers (2017)			Correlation	r = .20		
Premo (2014)					Correlation	r = .00
Diener (2002)			Correlation	r = .17		
Geangu (2011)	T Test (Converted)	r = -.47				
Sheese (2008)	Correlation	r = .08				
Thomas (2017)	Correlation	r = -.12				
Gill (2003)					Correlation	r = .05
Braungart-Rieker (1998)	Correlation	r = -.39				
Grolnick (1996)					Correlation	r = .00
Graziano (2011)					Correlation	r = -.32
Ross (1999)			Correlation	r = .47		

Figure 1

PRISMA Flow Diagram

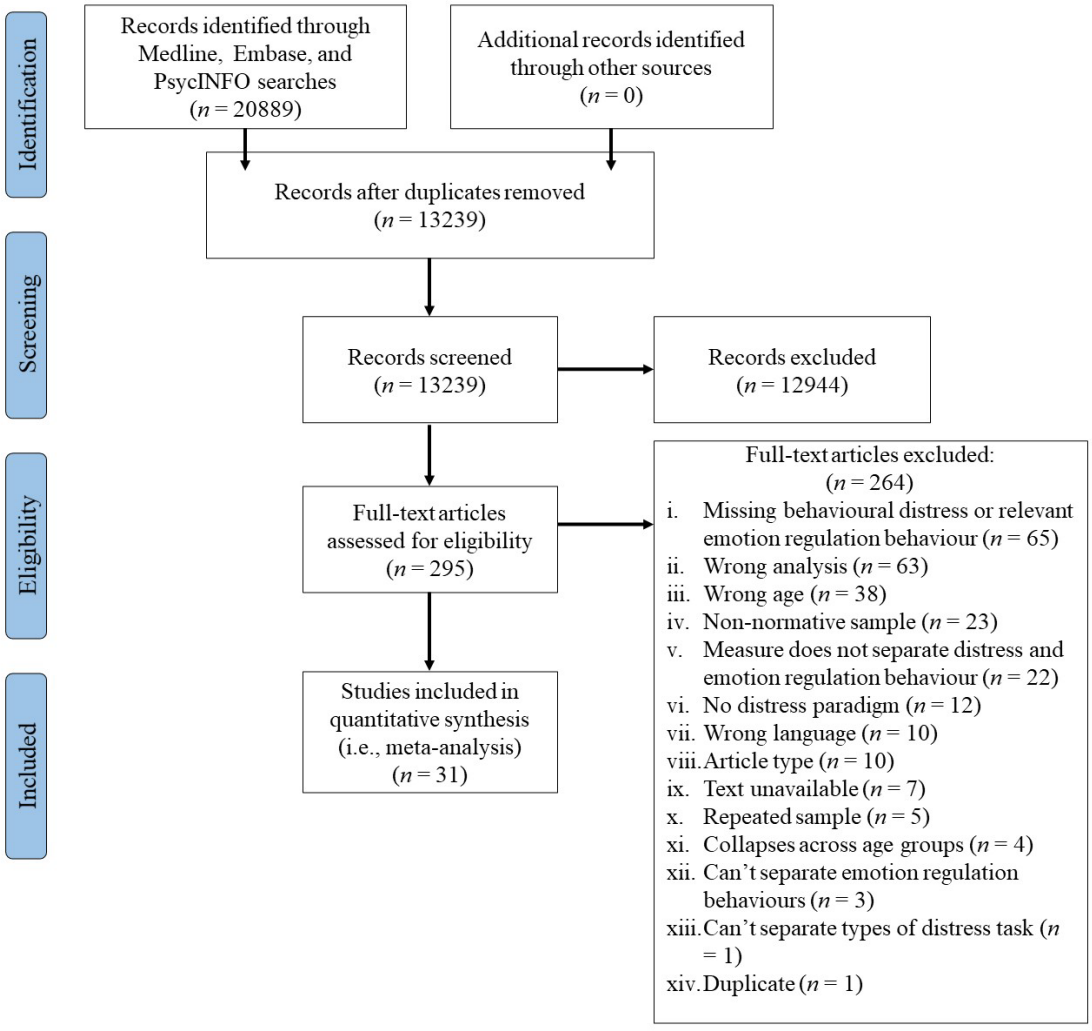
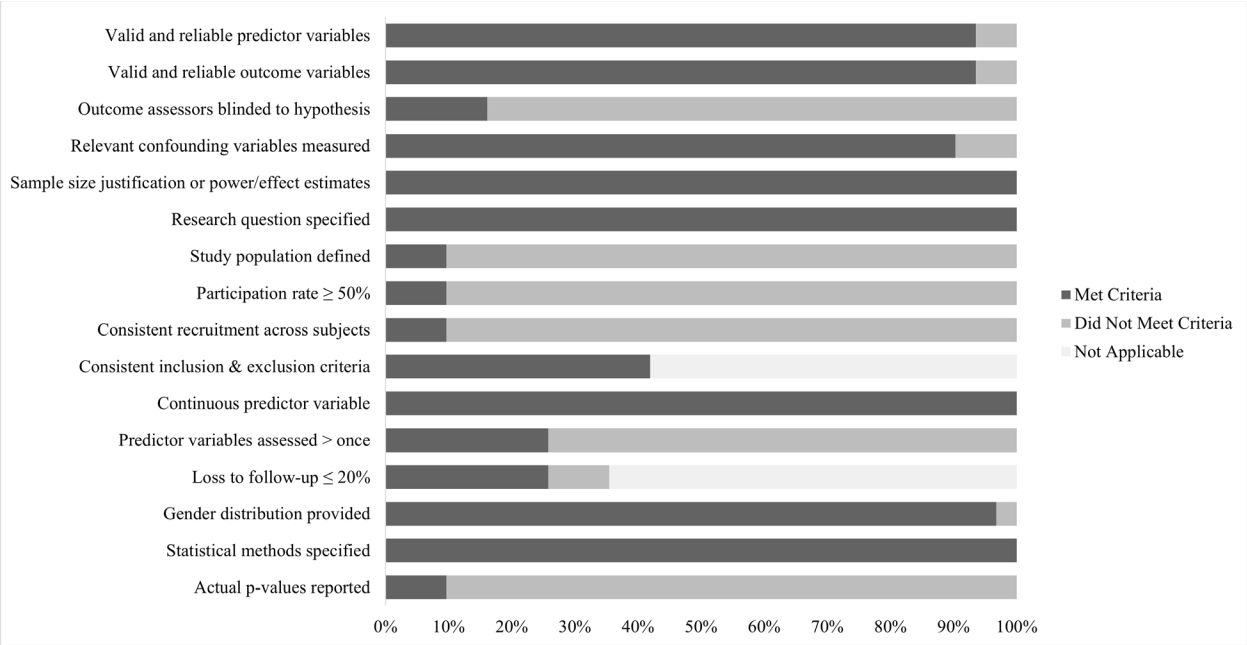


Figure 2

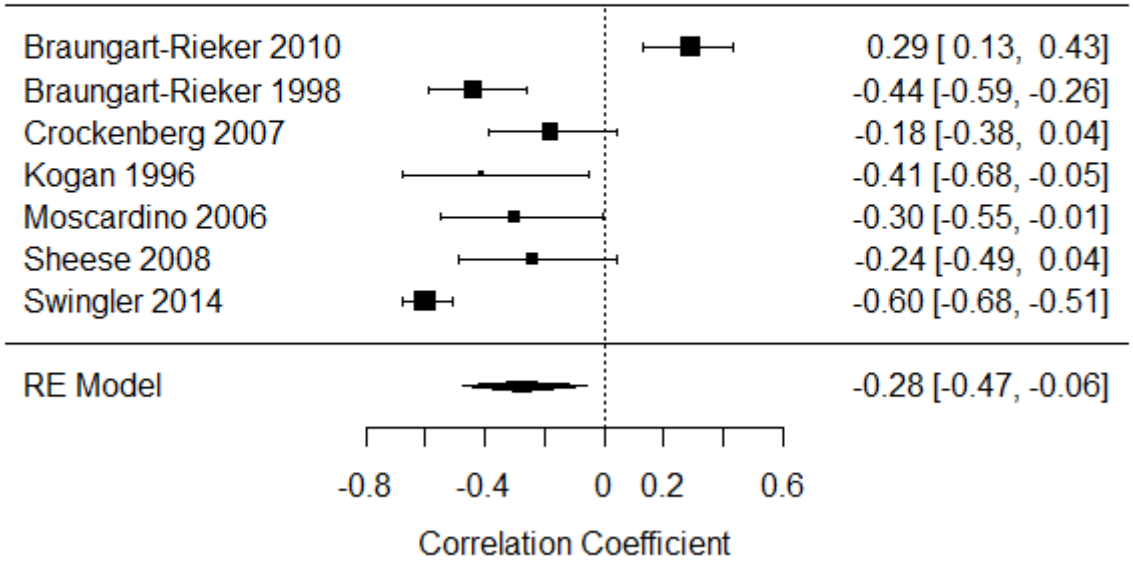
Quality Assessment



Note. Bars represent the percentage of studies (out of 31) that fulfilled each criterion of the quality assessment.

Figure 3

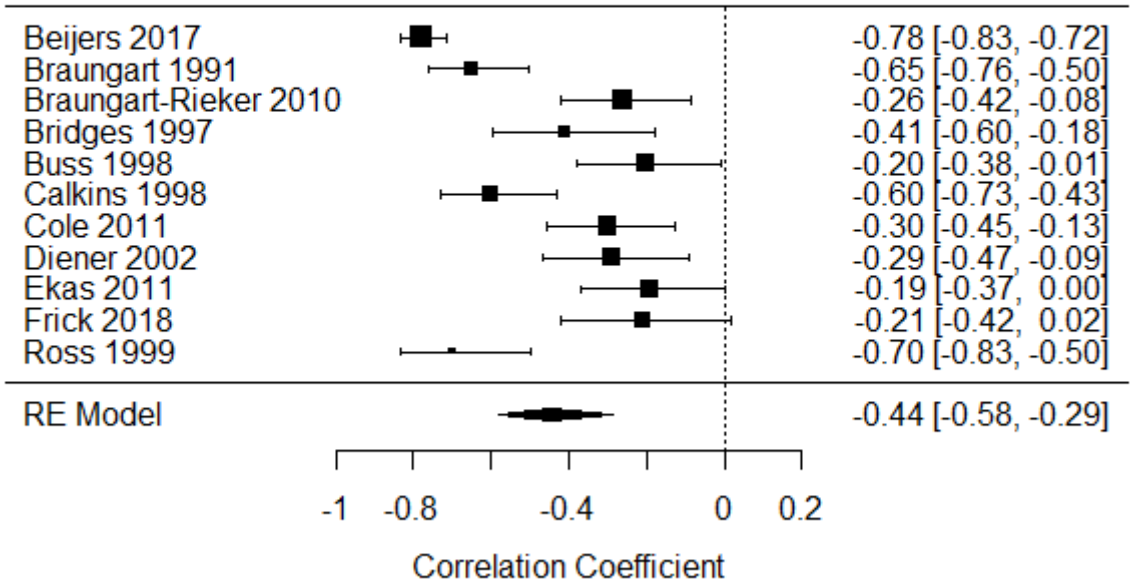
Forest Plot of Year 1 Disengagement of Attention



Note. RE = Random-Effects Model.

Figure 4

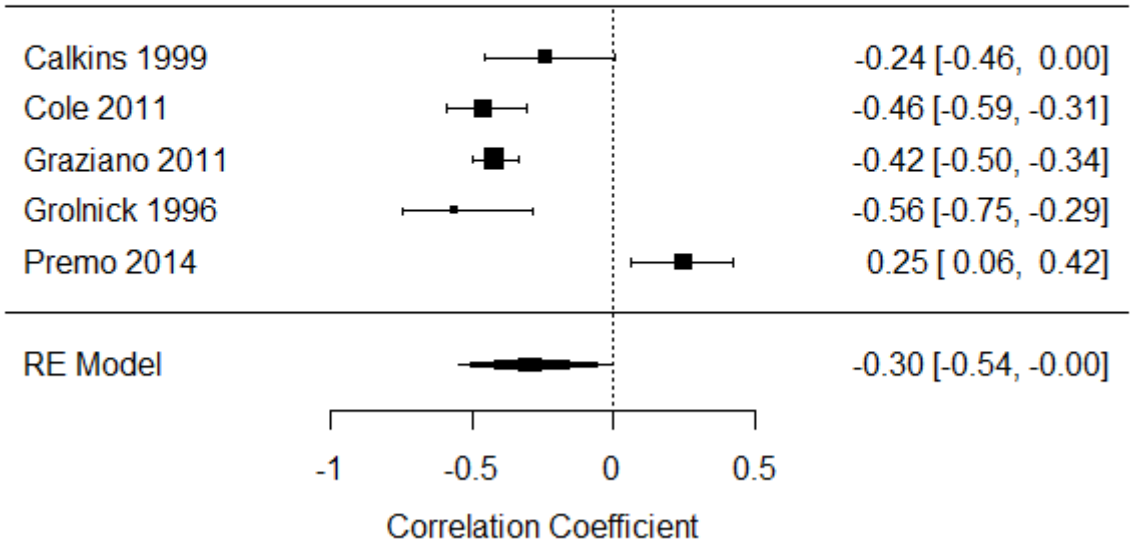
Forest Plot of Year 2 Disengagement of Attention



Note. RE = Random-Effects Model.

Figure 5

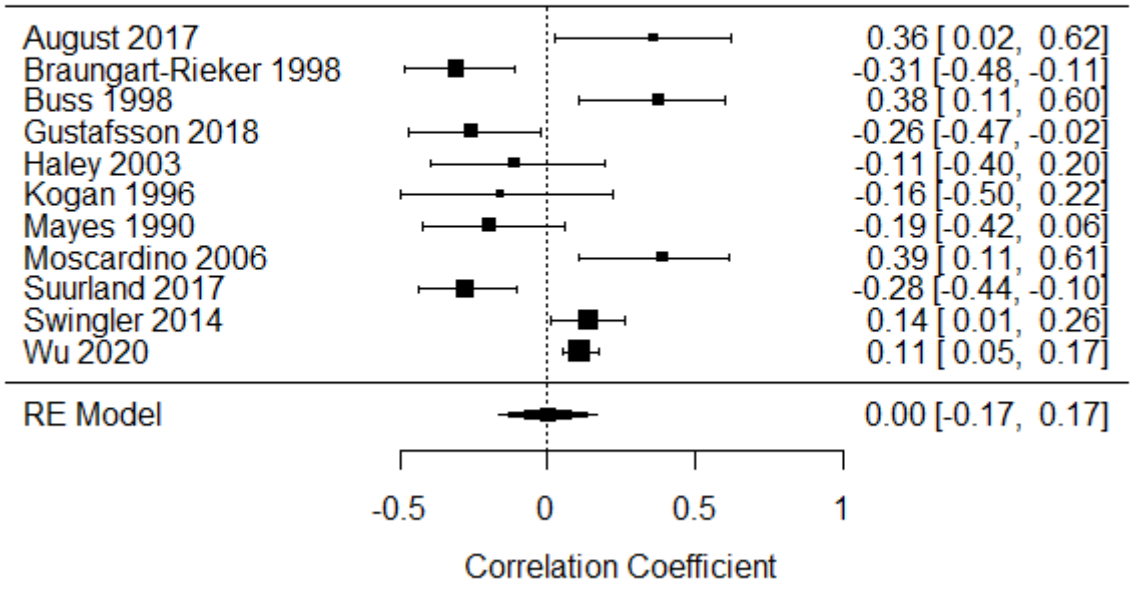
Forest Plot of Year 3 Disengagement of Attention



Note. RE = Random-Effects Model.

Figure 6

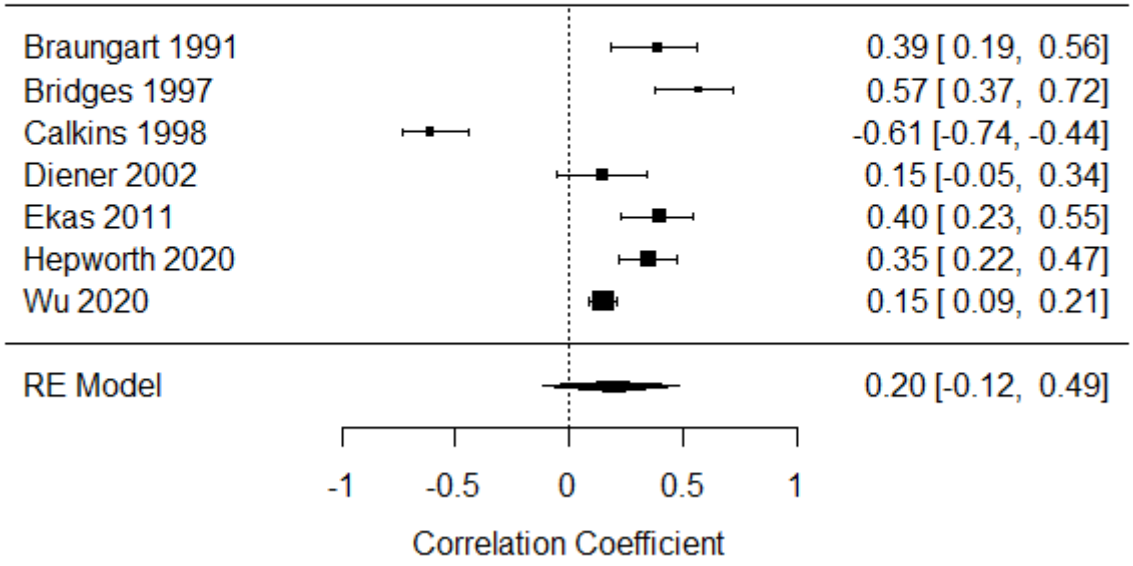
Forest Plot of Year 1 Parent-Focused Strategies



Note. RE = Random-Effects Model.

Figure 7

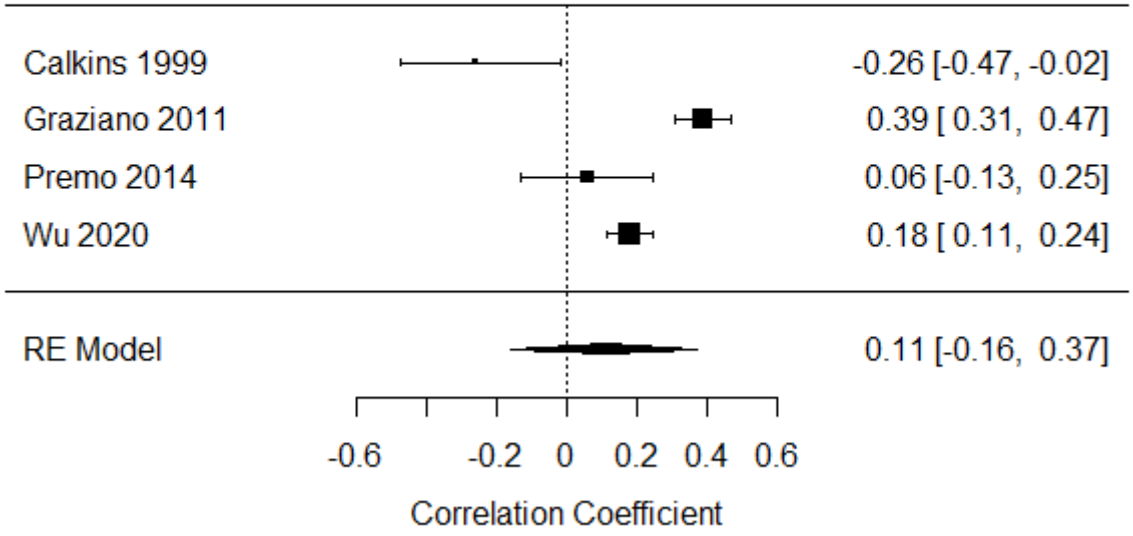
Forest Plot of Year 2 Parent-Focused Strategies



Note. RE = Random-Effects Model

Figure 8

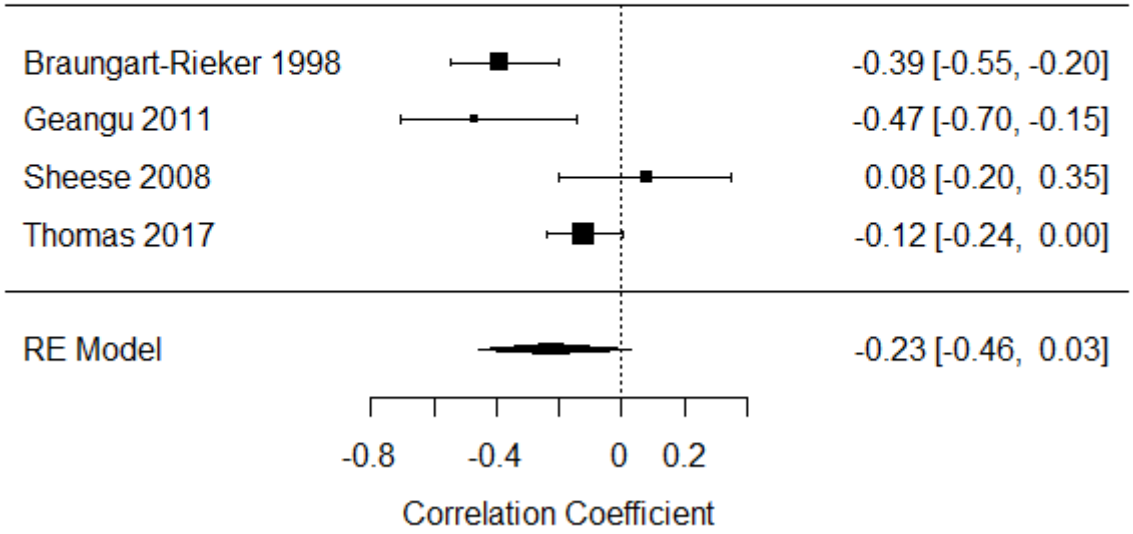
Forest Plot of Year 3 Parent-Focused Strategies



Note. RE = Random-Effects Model.

Figure 9

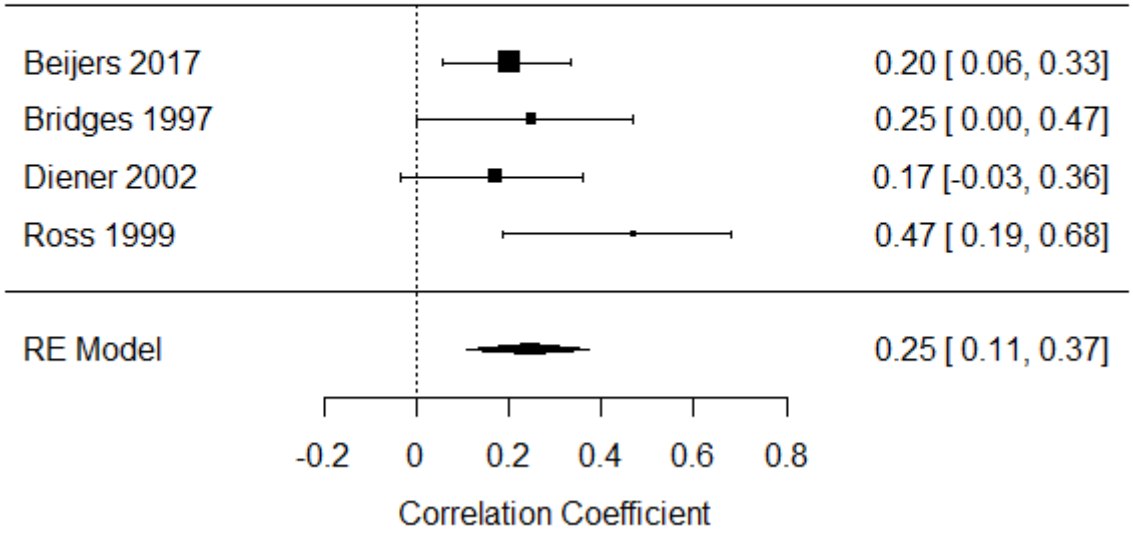
Forest Plot of Year 1 Self-Soothing Strategies



Note. RE = Random-Effects Model

Figure 10

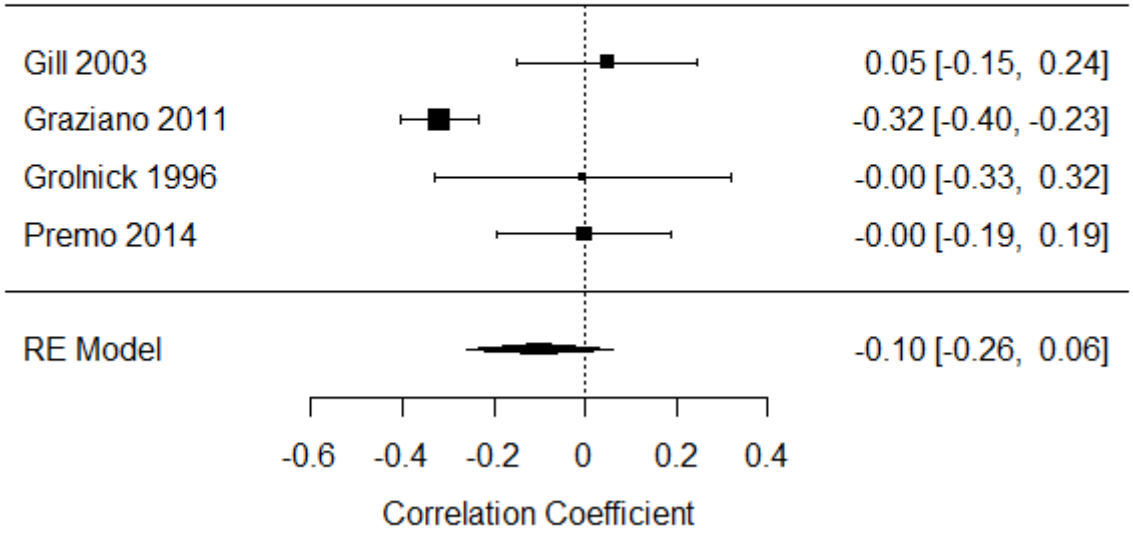
Forest Plot of Year 2 Self-Soothing Strategies



Note. RE = Random-Effects Model

Figure 11

Forest Plot of Year 3 Self-Soothing Strategies



Note. RE = Random-Effects Model

Chapter 3: Bridging Study 1 and Study 2

The goal of the first study of the current dissertation was to gain a deeper understanding of the developmental trends in the literature on child-led emotion regulation, with a particular focus on ascertaining how particular child-led emotion regulation behaviours related to distress. This goal was in line with disaggregating expressed emotion from the behaviours used to modulate them as recommended by Cole et al. (2004) and inherent in key definitions of emotion regulation (e.g., Thompson, 1994). This was a necessary first step in the process of understanding child-led pain-related distress regulation behaviours, to determine which behaviours would warrant study during toddlerhood, potential measures to be incorporated and modified to fit the vaccination context, and to inform hypotheses for the vaccination context.

Key findings from the first study highlighted developmental differences in how child-led emotion regulation behaviours related to developmental distress. Notably, physical self-soothing displayed negative relationships with distress in the first year, while showing near-zero or positive, small relationships in the later two years, suggesting more benefit to distress reduction in infancy. Disengagement of attention showed a negative relationship across all three age points spanning infancy and toddlerhood, with its strongest relationship in the second year, at the beginning of toddlerhood. While the second year also included the strongest relationships between parent-focused behaviours and distress, the relationship was positive. The strength of these relationships in the second year speaks to the importance of assessing these particular behaviours as potential distress-reducing behaviours in the vaccination context. Of note, not one study highlighted in Study 1 included distress paradigms in naturalistic settings; therefore, the above findings, while crucial to framing our understanding of these behaviours, are understood

in the context of low to moderately distressing experimental procedures. The goal of Study 2 was to address this gap in the literature.

As previously noted, vaccination is a highly distressing event that children undergo routinely. Unlike experimental designs, where distress can ethically only be induced to mild or mild-moderate levels (when this threshold is exceeded experimental paradigms are often stopped), naturalistic observation of vaccination allows researchers to observe heightened levels of distress in an ecologically valid setting. Moreover, the developmental literature suggests that toddlerhood is a key phase to assess child-led emotion regulation behaviours and no research to date has assessed these behaviours during vaccination uniquely in this developmental period; thus, it is important to rectify this gap in the literature. In fact, the vaccination literature at this age has fallen prey to methodological challenges highlighted by Cole and colleagues (2004) and has solely looked at a reduction of distress as indication of regulation. While Study 1 did not include a review of the predictive relationships in the literature due to challenges with summarizing over statistical techniques, Study 2 assesses both the concurrent and predictive relationships over time to deepen our understanding of the dynamic relationships between these two constructs. Using the three highlighted clusters of child-led emotion regulation behaviours (i.e., disengagement of attention, parent-focused behaviours, and physical self-soothing), these relationships were assessed at both 12- and 18-months to compare two stages within toddlerhood.

To date, much of the pain management literature has focused on the important role of the parent. In fact, while not the focus at this point, Study 3 incorporates parent-led regulatory behaviours and how they contribute to toddler pain-related distress over time. However, first

Study 2 set out to answer the important question of what toddlers do on their own during vaccination to modify their pain-related distress following a needle.

Chapter 4: Understanding the concurrent and predictive relations between child-led emotion regulation behaviors and pain during vaccination in toddlerhood[2]

Introduction

Pediatric pain researchers have long been interested in understanding and reducing children's pain [1, 34, 37, 45]. Given the importance of parents during painful procedures [20,33] and the developing attachment relationship [5] in infancy and toddlerhood, much of the work in these developmental periods has focused on how parental factors (e.g., soothing behaviors, sensitivity) reduce children's pain-related distress [e.g., 2,3,4,12,23,27-28,31-32], with less focus on child behaviors that may regulate distress [e.g., 4]. Parental sensitivity and soothing does not fully explain children's distress following a painful procedure, with extensive research showing small to moderate effects on acute pain-related distress in infancy and early toddlerhood [28, 31].

To understand emotion regulation, researchers must observe an emotion, behaviors that modify the emotion, and how these relate over time [13,16,44]. In early infancy, strategies to reduce distress are largely led by caregivers; however, as they transition to toddlerhood, children begin a shift from caregiver-led emotion regulation to more active involvement in their own emotion regulation [25-26,40-41]. Child-led emotion regulation behaviors have been coded in experimental contexts [e.g.,10,39,42] and have allowed researchers to understand which child behaviors reduce distress across development. There is clear evidence that in infancy, physical

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self-soothing behaviors (e.g., thumb sucking) reduce distress [e.g., 8,18,42], whereas in toddlerhood, disengagement of attention (e.g., object orientation) [e.g., 6-7,14,22) and parent-focused behaviors (e.g., orienting to parent) [e.g., 6,9,15] appear to be more strongly related to distress. A recent literature review suggests that disengagement of attention is concurrently related to reduced distress whereas parent-focused behaviors are related to increased distress, which may suggest children signal to their parents for support [19].

Vaccination, a routine painful procedure, allow repeated opportunities to better understand the development of child-led emotion regulation in a naturalistic context. This increased understanding may also help researchers expand their understanding of factors that reduce children's pain. Consistent with past research in preschool children [11], the goal of the current paper is to assess both the concurrent and predictive relations between child-led emotion regulation behaviors and pain-related distress immediately following routine vaccination across the second year of life at both 12- and 18-months. Toddlers and their parents were video-recorded during their vaccination visit and videos were subsequently coded for child-led emotion regulation behaviors and pain-related distress.

The following research questions were targeted:

1. How do disengagement of attention, parent-focused strategies, and physical self-soothing strategies relate to pain-related distress concurrently (i.e., within the same timepoint) and predictively (from one timepoint to the next) at 1-, 2-, and 3-minutes post-needle?
2. Do these relations change in magnitude according to child age (i.e., 12 versus 18 months)?

Regarding the first research question, we hypothesized that disengagement of attention and physical self-soothing strategies would show negative relations with pain-related distress following vaccination, while parent-focused behaviors would show a positive relationship. Regarding the second question, based on the aforementioned developmental trends, we hypothesized that the magnitude of relations between pain-related distress and disengagement of attention and parent-focused behaviors would strengthen from one age to the next, whereas the opposite would occur for physical self-soothing behaviors.

Methods

Participants

Data collection for the current analyses occurred between September 2015 and March 2020, as part of a longitudinal cohort study [46]. Caregiver-toddler dyads were recruited from two pediatric clinics in the Greater Toronto Area. The study followed a cohort-sequential design during which dyads were observed at their 12-, 18-, and 24-month vaccination appointments. The current study includes data from the 12- and 18-month vaccinations. Ethics approval was obtained through the research ethics board at the participating university. Caregivers were approached by a research assistant who explained the study and went over informed consent. Toddlers were recruited prior to their 12- or 18-month vaccination appointments and were followed up at subsequent appointments. Figure 1 outlines recruitment and loss of participants. To be included in the current analyses, codable video data was required for each dyad, resulting in a total of 163 caregiver-toddler dyads at 12 months and 149 caregiver-toddler dyads at 18 months. Table 1 outlines key demographic variables, which demonstrates that the sample predominantly included mothers from well-educated, middle-class families.

Procedure

The current study includes only behavioral data. However, at each appointment, dyads were videotaped and connected to equipment to measure their cardiac response. Toddlers and caregivers were recorded for at least three minutes post-needle. Given the naturalistic observation methodology, there was minimal interference from the research team during vaccination appointments, other than the video and physiological recording. Research assistants did not interact with participants during the vaccination window. At each vaccination appointment, caregivers were given an information sheet outlining evidence-based pain management strategies for toddlers [43].

Measures

Demographic information

Prior to the vaccination, caregivers completed a demographic questionnaire that asked for child age, child sex, caregiver age, relationship to the child, and caregiver education. Caregivers also identified their heritage culture and then were asked, how much they identified with that heritage culture (on a scale from 0 to 10) and how much they identified with mainstream Canadian culture (also on a scale from 0 to 10).

Toddler emotion regulation behaviors

Emotion regulation behaviors were coded from video footage using the coding system from the Laboratory Temperament Assessment Battery (Lab-TAB) Locomotor Version 3.1. [21]. The Lab-TAB is a well-established and valid [10,17,35,39] developmental psychology protocol designed to capture a comprehensive repertoire of childhood emotion-related measures through a series of experimental procedures meant to invoke a variety of different emotions in infants and toddlers (e.g., fear). The authors worked with the current Lab-TAB coordinator and trainer (Dr. Jeffrey Gagne, Texas A&M University) to adapt the child-led emotion regulation behaviors

subset to fit the vaccination context. A subset of six behaviors was ultimately included. These behaviors were object orientation, proximity-seeking, caregiver orientation, thumb sucking, other oral behavior, and physical touch. See Table 2 for a description of each behavior and examples. Each behavior was coded as present (1) or absent (0) in 5-second epochs for the one-minute period after the last needle, two-minute period after the last needle, and three-minute period after the last needle.

Scores were calculated representing the proportion of intervals a given behavior was present out of the total number of codable epochs within each one-minute time period. These scores ranged from 0 to 1, with higher scores indicating higher frequency of that behavior. Coding was completed using Noldus Observer. Twenty percent of the 12- and 18-month combined sample was double-coded to assess interrater reliability. Percentage (and kappa) agreement ranged as follows for each behavior: object orientation = .83 to .85 (κ = .58 to .63), proximity-seeking = .87 to .93 (κ = .71 to .81), caregiver orientation = .88 to .91 (κ = .63 to .74), thumb sucking = .98 to .99 (κ = .74 to .91), other oral behavior = .98 to .99 (κ = .94 to .96), physical touch = .92 to .95 (κ = .66 to .82). Coders were blind to study hypotheses. Based on a review of the experimental literature [19], the current analyses combined the six Lab-TAB behaviors into three clusters of self-regulatory behaviors: disengagement of attention (object orientation), parent-focused behaviors (proximity-seeking and caregiver orientation), and physical self-soothing (thumb sucking, other oral behaviors, and physical touch) for 1-minute post-needle, 2 minutes post-needle, and 3 minutes post-needle.

Pain-related distress

The Face, Legs, Activity, Cry, Consolability coding system (FLACC; [30]) was used to measure the degree of behavioral pain-related distress post-immunization. The FLACC was used

to assess five types of pain behaviors in 15-second increments consecutively over the three-minute period of post-needle observation. Within each epoch, each of the five behaviors was scored on a 0 to 2 scale, resulting in a total score from 0 to 10 for each 15s. To get a score for each post-needle minute, the four 15s epochs within that minute were averaged. Coding was also completed using the Noldus Observer. Research has demonstrated moderate to high concurrent validity and item-total and interrater reliability for FLACC scores in the acute pain context [29, 30]. Twenty percent of the current sample was double-coded throughout the coding process to assess interrater reliability between coders at 12- and 18-months, which was strong (ICC= .93 to .96). Coders were blind to study hypotheses.

Analysis Plan

To examine the concurrent and predictive relations among the three clusters of emotion regulation behaviors and pain-related distress at both 12 and 18 months, six separate autoregressive cross-lagged path models [24] (3 emotion regulation behaviors [disengagement of attention, parent-focused behaviors, and physical self-soothing] by 2 ages [12 and 18 months]) were estimated using the *lavaan* package [38] in R [36]. These models were specified so that three types of relations were estimated simultaneously: 1) Predictive Within-Measure, 2) Predictive Between-Measure), and 3) Concurrent (Residual) Between-Measure. First, autoregressive *Predictive Within-Measure* relations assess the prediction of the behavior (either emotion regulation or pain-related distress behavior) from the measure of the same behavior that directly preceded it (e.g., Disengagement of Attention Minute 1 predicting Disengagement of Attention Minute 2). Second, the cross-lagged *Predictive Between-Measure* relations assess the prediction of an emotion regulation behavior from the pain-related distress behavior that directly preceded it (or prediction of the pain-related distress behavior from the directly preceding

emotion regulation behavior; e.g., FLACC Minute 1 predicting Disengagement of Attention Minute 2, and Disengagement of Attention Minute 1 Predicting FLACC Minute 2). Lastly, *Concurrent (Residual) Between-Measure Relations* assess the simultaneous relations between the emotion regulation behavior and pain-related distress behavior at each of the three minutes, controlling the auto-regressive and cross-lagged effects (e.g., concurrent relationship between FLACC Minute 1 and Disengagement of Attention Minute 1). The models were estimated used full-information maximum likelihood to allow the inclusion of incomplete cases and robust model fit statistics and standard errors were used to account for non-normality (see [38]). The comparative fit index (CFI), the Tucker-Lewis index (TLI), and the root mean square error of approximation (RMSEA) were used to assess model fit.

Results

Descriptive Statistics

Mean values and standard deviations (SDs) of all variables in the 12- and 18-month models are in Table 3. Tables 4 to 5 present correlations among the variables included in each 12- and 18-month model, separated by emotion regulation cluster.

Models examining pain-related distress with child-led emotion regulation behaviors

Figures 2 through 7 presented path diagrams, along with standardized estimates, for the six different models estimated. Tables 6 through 11 present the standardized and unstandardized estimates for these models. Each model fit the corresponding data adequately; see Table 12 for the fit statistics of each model.

Disengagement of attention at 12 months. Across the three minutes post-vaccination, use of disengagement of attention at each minute was significantly predicted by use of disengagement of attention in the previous minute (standardized βs = .36 to .49). The same pattern occurred with pain-related distress scores being predicted significantly by scores in the

previous minute (standardized βs = .66 to .69). Use of disengagement of attention did not significantly predict subsequent pain-related distress responses in the post-vaccination period. Similarly, pain-related distress responses did not significantly predict subsequent use of disengagement of attention in the post-vaccination period. There were no significant concurrent residual relations between use of disengagement of attention and pain-related distress behavior.

Disengagement of attention at 18 months. Across the three minutes immediately post-vaccination, use of disengagement of attention at each minute was significantly predicted by use of disengagement of attention in the previous minute (standardized βs = .36 to .60). The same pattern occurred with pain-related distress scores being predicted by scores in the previous minute (standardized βs = .64 to .74). Pain-related distress behavior 1-minute post-needle (FLACC 1) significantly predicted less use of disengagement of attention at 2 minutes post-needle (Disengagement of Attention 2; standardized β = -.23). No other predictive between-measure relations were significant. Finally, there was a significant concurrent negative relationship between use of disengagement of attention and pain-related distress behavior one-minute post-needle (residual r = -.17). No other concurrent relations were significant.

Parent-focused strategies at 12 months. Post-vaccination, use of parent-focused emotion regulation behaviors at each minute was significantly predicted by use of parent-focused behaviors in the previous minute (standardized βs = .53 to .67). Pain-related distress behavior also significantly predicted subsequent pain-related distress (standardized βs = .66 to .68). Use of parent-focused emotion regulation behaviors one-minute post-needle (Parent Focused 1) significantly predicted more pain-related distress behavior two minutes post-needle (FLACC 2; standardized β = .14). No other predictive between-measure relations were significant in this model. Finally, there was a significant positive concurrent relationship between use of parent-

focused emotion regulation behaviors and pain-related distress behaviors at three minutes post-needle (Parent Focused 3 and FLACC 3; residual r = .20). No other concurrent relations were significant.

Parent-focused strategies at 18 months. Use of parent-focused emotion regulation behaviors at each minute post-vaccination was significantly predicted by use of parent-focused behaviors in the previous minute (standardized βs = .62 to .63). Pain-related distress behavior also significantly predicted subsequent pain-related distress (standardized βs = .63 to .74). Use of parent-focused emotion regulation behaviors did not significantly predict subsequent pain-related distress responses. Similarly, pain-related distress responses did not significantly predict subsequent use of parent-focused behaviors. There were significant positive concurrent relations between use of parent-focused emotion regulation behaviors and pain-related distress behavior at one minute post-needle (Parent Focused 1 and FLACC 1; residual r = .38) and two minutes post-needle (Parent Focused 2 and FLACC 2; residual r = .16). The residual relationship at three minutes post-needle was not significant.

Physical self soothing strategies at 12 months. Use of physical self-soothing significantly predicted use of physical self-soothing in subsequent minutes post-vaccination (standardized βs = .59 to .62). Pain-related distress behavior also significantly predicted subsequent pain-related distress (standardized βs = .66 to.70). There were no significant predictive between-measure relations between use of physical self-soothing and pain-related distress. There were significant negative relations between use of physical self-soothing and pain-related distress behavior at one minute (Self-Soothing 1 and FLACC 1; residual r = -.28) and three minutes post-needle (Self-Soothing 3 and FLACC 3; residual r = -.19). The concurrent residual relationship at two minutes post-needle was not significant.

Physical self soothing strategies at 18 months. Use of physical self-soothing significantly predicted use of physical self-soothing in subsequent minutes post-vaccination (standardized βs = .73 to .75). Pain-related distress behavior also predicted subsequent pain-related distress (standardized βs = .62 to.77). There were no significant predictive between-measure relations between use of physical self-soothing and pain-related distress. There was a significant negative relationship between use of physical self-soothing and pain-related distress behavior at one minute (Self-Soothing 1 and FLACC 1; residual r = -.20). The concurrent residual relations at two and three minutes post-needle were not significant.

Discussion

The purpose of this study was to better understand child-led emotion regulation by assessing concurrent and predictive relations between child-led emotion regulation behaviors and pain-related distress in the vaccination context across the second year of life. The toddler period is a key developmental phase in emotion regulation skills [25-26,40-41], and an ideal time to assess the emergence of these behaviors and their role in pain-related distress regulation.

While it has been established in this cohort [46] that at both 12 and 18 months of age, pain-related distress at one-minute post-needle predicted pain-related distress at subsequent minutes, novel relationships were elucidated in relation to the child-led emotion regulation behaviors. For all three child-led emotion regulation behaviors, behavior at one-minute predicted behavior at subsequent minutes. Expanding on the known consistency in pain-related distress responses during toddler vaccinations [46], these results show that the more toddlers use these behaviors early in the appointment, the more they will use them later in the appointment. The next sections discuss the findings regarding the concurrent between-variable relations and the

cross-lagged between-variable relations at both ages, across each of the three child-led regulatory behavior clusters.

The role of child-led disengagement of attention

At 12 months, there were no significant concurrent or predictive relations between disengagement of attention and pain-related distress. This finding suggests that this behavior may not yet serve a regulatory function at this age. In contrast, concurrent and predictive relations were seen at 18 months. Specifically, at one-minute post-needle, there was a significant concurrent negative relationship between disengagement of attention and pain-related distress, which suggests that across the first minute following the needle, greater disengagement of attention is concurrently associated with less pain-related distress. Moreover, when assessing the predictive relations over time, more pain-related distress one-minute post-needle was related to less disengagement of attention the following minute. When children are highly distressed, it is difficult for them to engage with and explore their environment (e.g., orienting toward or manipulating objects). Instead, this high distress is more likely to result in seeking comfort from a caregiver [5]. It is important to understand that although some children may have explored their environment more, other children may have used objects their parents provided them initially to disengage their attention. If the parent was leading the distraction this was not coded as 'child-led'. Future work addressing child-led disengagement of attention strategies in the vaccination context could disentangle the multiple types of distraction that may be co-occurring as children age (i.e., self-led versus parent-led).

The role of parent-focused behaviors

At 12 months, children's use of parent-focused behaviors one minute post-needle predicted greater pain-related distress two minutes post-needle and there was a significant

concurrent relationship between pain-related distress and parent-focused behaviors three minutes post-needle. At 18 months, there were concurrent positive relations between parent-focused behaviors and pain-related distress at one and two minutes post-needle. In line with previous findings [19,39], the magnitude of the concurrent relations increased with age, which suggests that parent-focused behaviors may be more impactful as the attachment relationship develops [5]. These positive relations may indicate that use of parent-focused behaviors do not reduce distress. However, this finding does not necessarily mean that this behavior is not regulatory or does not serve as a strategy for reducing pain. Indeed, these behaviors may serve as a signalling function to show caregivers that children need support. If so, it is not necessarily the act of seeking out their parent that supports distress regulation, but rather that the high distress triggers signalling that in turn triggers parents to support pain-related distress regulation. Past research has shown that when parents respond to their children in a sensitive way, pain-related distress goes down [2,31], whereas when they use insensitive behaviors, distress increases [3-32].

The role of physical self soothing

At 12 months, we found significant negative concurrent relations between physical self-soothing and pain-related distress at one and three minutes post-needle. At 18 months, there was a negative concurrent relationship between physical self-soothing and pain-related distress at one minute post-needle. In contrast to the other two types of child-led emotion regulation behaviors, the magnitude of this association was lower at 18 months than at 12 month, which is consistent with the literature [19,39]. Physical self-soothing may be a particularly helpful regulatory strategy in infancy and early toddlerhood for vaccination, but as the child continues to develop, physical strategies may be less useful, and children begin to rely on others. Like disengagement of attention, some of these strategies (e.g., sucking on a pacifier) are connected to parent

behavior (e.g., the offering of a pacifier). It is important for researchers to demarcate parent pacifying (i.e., placing the pacifier in mouth or holding it in) from self-directed self-soothing (i.e., child keeping the pacifier in their own mouth). Future work is needed to address how parent soothing behaviors and child-led emotion regulation behaviors work together to promote a reduction in pain-related distress.

Limitations and future directions

These findings are understood within the context of some limitations. First, although culturally diverse, the current sample is primarily middle-class and highly educated; thus, these findings may not generalize to higher risk populations. Second, only observable behavior was used as an indicator of pain-related distress post-needle in the current analyses. Previous research has shown that behavioral and physiological indicators of pain may reflect different components of the pain experience [46] and thus future research may set out to understand these relations with physiological distress indicators. Future research may also continue looking at how the relations between child-led regulatory behavior and pain behaviors develop as children begin to reach preschool age of 3 and 4 years.

Conclusions: Implications for research and clinical practice

In conclusion, there is emerging evidence of the role of child-led pain-related distress regulation during the second year of life. Across 12- and 18 months, disengagement of attention and physical self-soothing strategies are related to decreased distress, whereas parent-focused behaviors are related to increased distress. In every model, a number of pathways were not significant reflecting that while toddlers use of self-regulation is emerging, there are a number of other factors at play. This finding suggests that disengagement of attention and physical self-soothing may play more of a direct regulatory role, whereas parent-focused behaviors may play

more of a signalling role, reflective of the child choosing to seek out parent support. Use of disengagement of attention and parent-focused behaviors show stronger relations with pain-related distress at 18 months, suggesting that these skills may be particularly relevant as children continue to develop. In contrast, weaker relations were seen between physical self-soothing behaviors and pain-related distress in older toddlers, suggesting that these emotion regulation strategies may become less useful as children develop.

Taken together, these findings show that emerging emotion regulation skills are seen in routine vaccination appointments. These findings have several research implications, and we recommend that researchers begin to measure both pain-related distress and child-led emotion regulation behaviors to fully understand the construct of regulation. These findings also suggest that toddlers are not passive participants in their routine vaccinations, wholly dependent on caregivers for distress regulation. As these findings do not negate the importance of parents and caregivers, they instead suggest a nuanced developmental interplay of child-led and parent-led regulation strategies interacting and evolving over time. These findings have substantial implications for knowledge translation efforts geared toward reducing pain in children. In conjunction with teaching parents what they can do to support their children's pain, helping them to support the development of independent child-led emotion regulation behaviors for vaccination may have implications for the development of confidence and agency in their own pain management and medical care.

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Table 1

Demographic Information by Age

		12 Month	18 Month
Child Sex	Male	85 (52.8)	86 (58.5)
	Female	76 (47.2)	61 (41.5)
Relationship to Child	Mother	146 (90.7)	127 (85.8)
	Father	14 (8.7)	20 (13.5)
	Other	1 (0.6)	1 (0.7)
Caregiver Education	Graduate School or Professional Training	82 (52.9)	70 (54.3)
	University Graduate (4 years)	47 (30.3)	38 (29.5)
	Partial University (at least 1 year)	3 (1.9)	3 (2.3)
	Trade School/Community College	20 (12.9)	17 (13.2)
	High School Graduate	3 (1.9)	1 (0.8)
Parent Age		35.21 (5.09); 20-59	36.27 (5.97); 22-62
Heritage Culture	Asian	38 (25.2)	34 (23.3)
	European	37 (24.5)	37 (25.3)
	North American	32 (21.2)	33 (22.6)
	Latin, Central and South American	7 (4.6)	4 (2.7)
	Oceanian	3 (2.0)	2 (1.4)
	Caribbean	2 (1.3)	1 (0.7)
	African	1 (0.7)	3 (2.1)
	Mixed	20 (13.2)	21 (14.4)
	Other Ethnic and Cultural Origin	11 (7.3)	11 (7.5)
Acculturation	Lifestyle reflects mainstream Canadian culture	7.7 (2.19); 0-10	7.8 (1.94); 1-10
	Lifestyle reflects heritage culture	6.65 (2.70); 0-10	5.82 (2.49); 0-10

Note. Child sex, relationship to child, caregiver education, and heritage culture are presented as Frequency (Percentage). Parent age and acculturation status are presented as Mean (Standard Deviation); Range.

Table 2

Description of Emotion Regulation Behaviors

Emotion regulation behavior	Description
Object orientation	Child independently orients to or manipulates an object in the environment (e.g., orients to or manipulates a caregiver's cellphone or points to the door)
Caregiver orientation	Child directly looks towards a caregiver (e.g., hears his or her caregiver's voice and turns his or her head towards caregiver)
Proximity-seeking	Child initiates an attempt to get closer to caregiver (e.g., leaning head towards caregiver's chest, verbally saying "Mama," and reaching arms towards mother)
Thumb sucking	Child puts a part of own body (e.g., thumb, finger, fist) in mouth and either sucks or moves it around inside
Other oral behavior	Child uses an object in his or her mouth (e.g., pacifier, bottle) without a caregiver actively feeding it to him or her
Touch body	Child actively touches or rubs a part of own body (e.g., rubbing arm, rubbing belly, rubbing face, wiping eyes) for the purpose of soothing

Table 3

Descriptive Statistics at 12 and 18 Months

	12 months				18 months			
	N	Mean (SD)	Min	Max	N	Mean (SD)	Min	Max
Disengagement of Attention 1	163	.62 (.24)	0	1	149	.66 (.25)	0	1
Disengagement of Attention 2	163	.78 (.26)	0	1	149	.78 (.26)	0	1
Disengagement of Attention 3	163	.82 (.25)	0	1	149	.81 (.27)	0	1
Parent Focused 1	163	.33 (.19)	0	.83	149	.25 (.20)	0	.79
Parent Focused 2	163	.26 (.23)	0	1	149	.24 (.20)	0	.79
Parent Focused 3	163	.24 (.23)	0	1	149	.25 (.23)	0	1
Physical Self Soothe 1	163	.08 (.10)	0	.36	149	.12 (.12)	0	.47
Physical Self Soothe 2	163	.12 (.13)	0	.56	149	.12 (.13)	0	.5
Physical Self Soothe 3	163	.13 (.14)	0	.64	149	.14 (.15)	0	.61
FLACC 1	162	6.69 (1.92)	0.5	10	149	5.48 (2.41)	0	9.19
FLACC 2	162	4.49 (2.66)	0	9	149	3.56 (2.79)	0	8.75
FLACC 3	161	2.97 (2.67)	0	8.75	149	2.83 (2.78)	0	9.75

Note. For all variables, 1, 2, and 3 indicate 1-minute, 2-minute, and 3-minute post-needle, respectively. FLACC (Face, Legs, Arms, Cry, Consolability) represents pain-related distress.

Table 4

Correlations Among Emotion Regulation Behaviors and Pain-Related Distress at 12 Months

	1	2	3	4	5	6	7	8	9	10	11	12
1. Disengagement of Attention 1	-											
2. Disengagement of Attention 2	.36*	-										
3. Disengagement of Attention 3	.18	.49*	-									
4. Parent-Focused 1	-.19	-.25	-.12	-								
5. Parent-Focused 2	-.08	-.29*	-.32*	.54*	-							
6. Parent Focused 3	-.09	-.32*	-.49*	.47*	.68*	-						
7. Physical Self-Soothing 1	.03	.05	.09	-.07	.13	.03	-					
8. Physical Self-Soothing 2	.12	-.04	-.04	.06	.22	.21	.63*	-				
9. Physical Self-Soothing 3	.05	-.06	-.14	.02	.12	.14	.34*	.60*	-			
10. FLACC 1	-.15	-.05	-.03	.16	.10	.10	-.27*	-.28*	-.06	-		
11. FLACC 2	-.14	-.10	-.09	.25	.22	.18	-.19	-.23	-.05	.70*	-	
12. FLACC 3	-.04	-.08	-.12	.21	.15	.23	-.16*	-.14	-.14	.46*	.66*	-

Note. * indicates $p < .001$. Due to concerns with Type 1 error inflation, correlations with higher p values are not indicated.

Table 5

Correlations Among Emotion Regulation Behaviors and Pain-Related Distress at 18 Months

	1	2	3	4	5	6	7	8	9	10	11	12
1. Disengagement of Attention 1	-											
2. Disengagement of Attention 2	.40*	-										
3. Disengagement of Attention 3	.31*	.60*	-									
4. Parent-Focused 1	-.18	-.12	-.22	-								
5. Parent-Focused 2	-.17	-.24	-.24	.65*	-							
6. Parent Focused 3	-.15	-.12	-.32*	.53*	.62*	-						
7. Physical Self-Soothing 1	.06	.14	.14	-.15	-.07	-.11	-					
8. Physical Self-Soothing 2	.06	.09	.15	-.10	-.08	-.08	.73*	-				
9. Physical Self-Soothing 3	.05	.12	.09	-.03	-.07	-.11	.64*	.76*	-			
10. FLACC 1	-.17	-.29*	-.14	.38*	.31*	.24	-.20	-.15	-.12	-		
11. FLACC 2	-.09	-.14	-.06	.26	.30*	.18	-.24	-.18	-.20	.64*	-	
12. FLACC 3	-.07	-.19	-.11	.20	.26	.21	-.10	-.09	-.13	.45*	.76*	-

Note. * indicates $p < .001$. Due to concerns with Type 1 error inflation, correlations with higher p values are not indicated.

Table 6

Estimates for Model of Disengagement of Attention and Pain-Related Distress Behavior at 12 Months

	Standardized estimate	Unstandardized estimate	*z*	*p*
Predictors		FLACC 2 outcome		
FLACC 1	.69	.96	13.89	.00
D of A 1	-.04	-.45	-.77	.44
		Disengagement of Attention 2 outcome		
D of A 1	.36	.39	4.25	.00
FLACC 1	.01	.00	.10	.92
		FLACC 3 outcome		
FLACC 2	.66	.66	12.01	.00
D of A 2	-.02	-.17	-.31	.76
		Disengagement of Attention 3 outcome		
D of A 2	.49	.48	4.66	.00
FLACC 2	-.04	-.00	-.53	.60

Note. FLACC is the measure of pain-related distress. D of A = Disengagement of Attention

Table 7

Estimates for Model of Relations Between Disengagement of Attention and Pain-Related Distress Behavior at 18 Months

	Standardized estimate	Unstandardized estimate	*z*	*p*
Predictors		FLACC 2 outcome		
FLACC 1	.64	.74	11.48	.00
D of A 1	.03	.28	.39	.70
		Disengagement of Attention 2 outcome		
D of A 1	.36	.39	4.70	0.00
FLACC 1	-.23	-.03	-3.42	0.00
		FLACC 3 outcome		
FLACC 2	.74	.74	14.26	0.00
D of A 2	-.09	-.93	-1.32	.19
		Disengagement of Attention 3		
D of A 2	.60	.62	8.30	.00
FLACC 2	.03	.00	.39	.70

Note. FLACC is the measure of pain-related distress. D of A = Disengagement of Attention

Table 8

Estimates for Model of Relations Between Parent-Focused Behaviors and Pain-Related Distress Behavior at 12 Months

	Standardized estimate	Unstandardized estimate	*z*	*p*
Predictors		FLACC 2 outcome		
FLACC 1	.68	.94	13.37	.00
PF 1	.14	1.93	2.57	.01
		Parent Focused 2 outcome		
PF 1	.53	.65	6.98	.00
FLACC 1	.01	.00	.18	.86
		FLACC 3 outcome		
FLACC 2	.66	.66	12.26	.00
PF 2	.00	.02	.04	.97
		Parent Focused 3 outcome		
PF 2	.67	.66	10.00	.00
FLACC 2	.03	.00	.42	.68

Note. FLACC is the measure of pain-related distress. PF= Parent-Focused

Table 9

Estimates for Model of Relations Between Parent-Focused Behaviors and Pain-Related Distress Behavior at 18 Months

	Standardized estimate	Unstandardized estimate	*z*	*p*
Predictors		FLACC 2 outcome		
FLACC 1	.63	.73	9.73	.00
PF 1	.03	.36	.37	.71
		Parent Focused 2 outcome		
PF 1	.63	.63	9.67	.00
FLACC 1	.07	.01	1.02	.31
		FLACC 3 outcome		
FLACC 2	.74	.74	13.47	.00
PF 2	.04	.52	.60	.55
		Parent Focused 3 outcome		
PF 2	.62	.69	9.85	.00
FLACC 2	-.00	-.00	-.05	.96

Note. FLACC is the measure of pain-related distress. PF= Parent-Focused

Table 10

Estimates for Model of Relations Between Physical Self-Soothing and Pain-Related Distress Behavior at 12 Months

	Standardized estimate	Unstandardized estimate	*z*	*p*
Predictors		FLACC 2 outcome		
FLACC 1	.70	.97	14.43	.00
Self Soothing 1	-.00	-.10	-.07	.95
		Self Soothing 2 outcome		
Self Soothing 1	.59	.77	11.54	.00
FLACC 1	-.12	-.01	-1.66	.10
		FLACC 3 outcome		
FLACC 2	.66	.67	12.03	.00
Self Soothing 2	.01	.10	.09	.93
		Self Soothing 3 outcome		
Self Soothing 2	.62	.68	10.19	.00
FLACC 2	.09	.01	1.50	.13

Note. FLACC is the measure of pain-related distress. Self soothing reflects physical self-soothing.

Table 11

Estimates for Model of Relations Between Physical Self-Soothing and Pain-Related Distress Behavior at 18 Months

	Standardized estimate	Unstandardized estimate	*z*	*p*
Predictors		FLACC 2 outcome		
FLACC 1	.62	.71	10.77	.00
Self Soothing 1	-.12	-2.61	-1.92	.05
		Self Soothing 2 outcome		
Self Soothing 1	.73	.78	10.42	.00
FLACC 1	-.01	-.00	-.09	.93
		FLACC 3 outcome		
FLACC 2	.77	.76	14.99	.00
Self Soothing 2	.05	1.01	.84	.40
		Self Soothing 3 outcome		
Self Soothing 2	.75	.83	11.77	.00
FLACC 2	-.07	-.00	-1.17	.24

Note. FLACC is the measure of pain-related distress. Self soothing reflects physical self-soothing.

Table 12

Fit Indices for Models

Model	CFI	TLI	RMSEA
Disengagement of Attention – 12 months	1.00	1.05	0.00
Disengagement of Attention – 18 months	1.00	1.01	0.00
Parent-Focused – 12 months	1.00	0.99	0.03
Parent-Focused– 18 months	0.99	0.96	0.09
Physical Self-Soothing – 12 months	1.00	1.01	0.00
Physical Self-Soothing – 18 months	0.99	0.96	0.09

Note. CFI = comparative fit index; TLI = Tucker-Lewis Index; RMSEA = root mean square error of approximation.

Figure 1

Participant Flow Chart

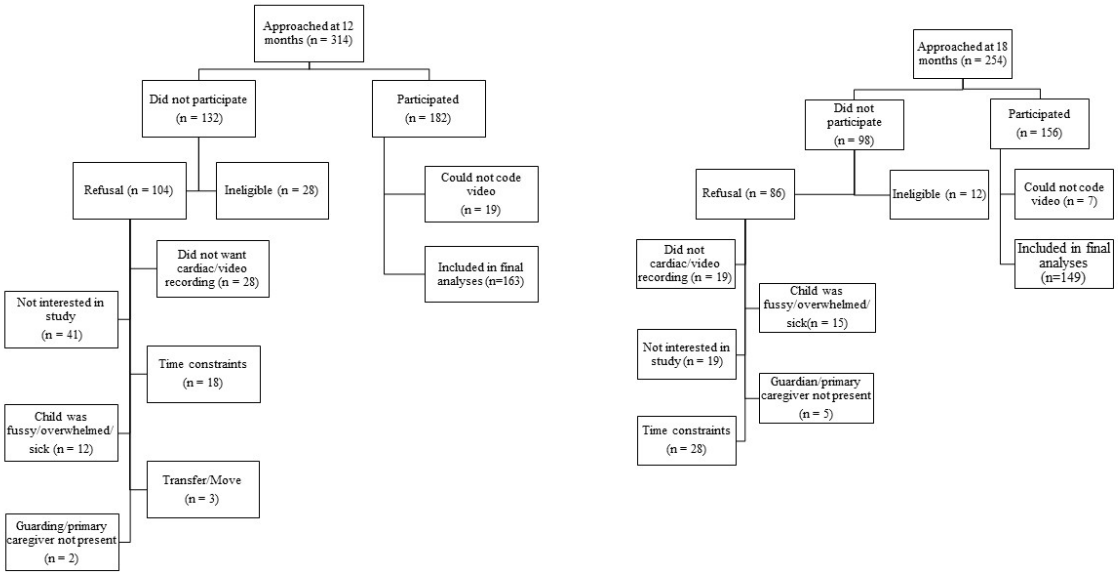
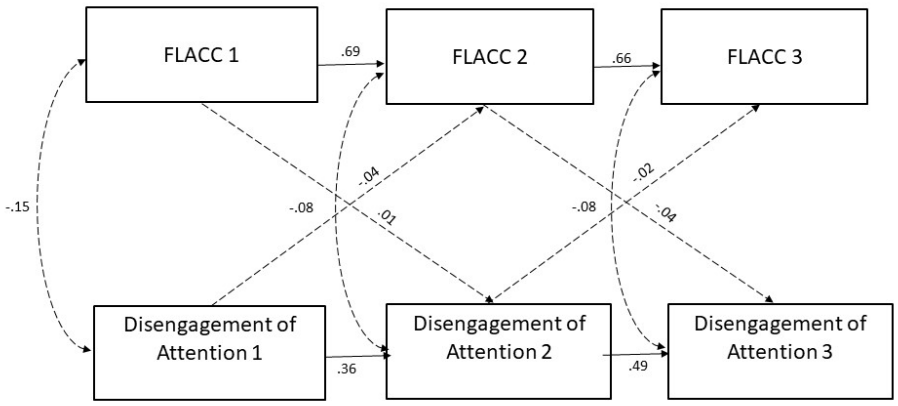


Figure 2

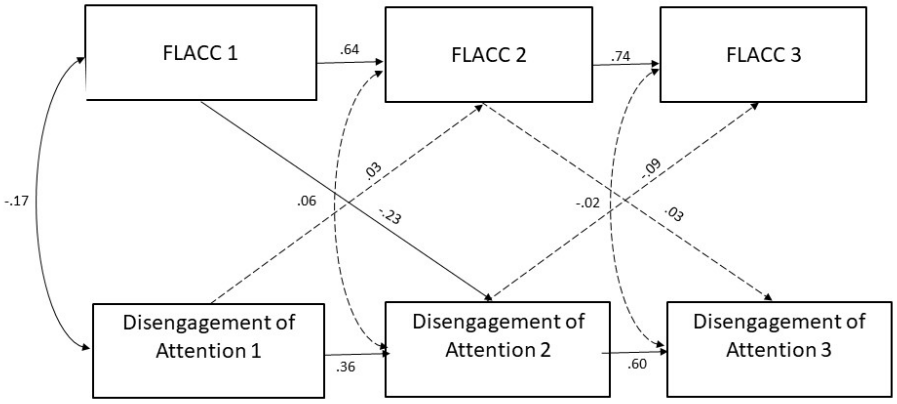
Model of Disengagement of Attention and Pain-Related Distress at 12 Months



Note. Solid paths are significant with $p < .05$. Non-significant paths are dashed.

Figure 3

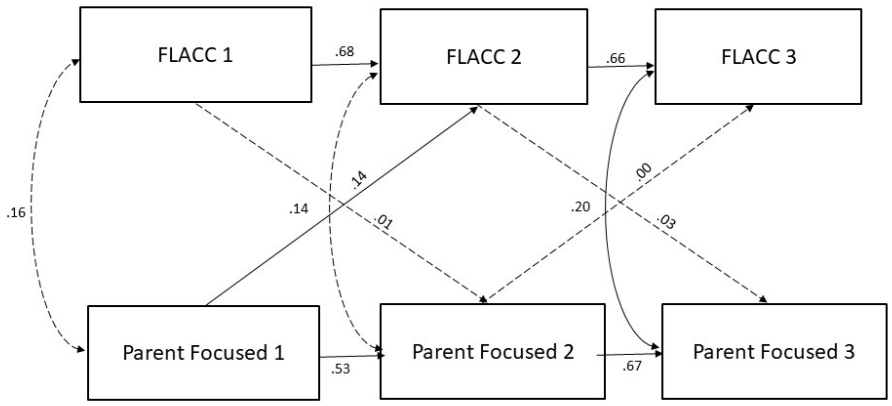
Model of Disengagement of Attention and Pain-Related Distress at 18 Months



Note. Solid paths are significant with $p < .05$. Non-significant paths are dashed.

Figure 4

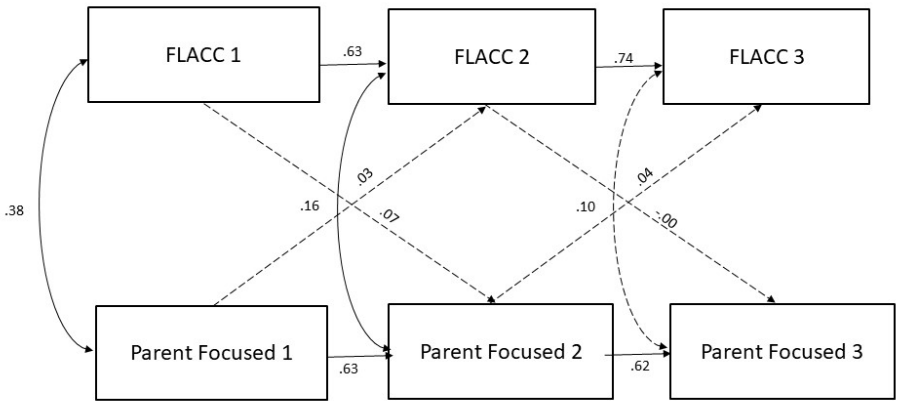
Model of Parent-Focused Behaviors and Pain-Related Distress at 12 Months



Note. Solid paths are significant with p <.05. Non-significant paths are dashed.

Figure 5

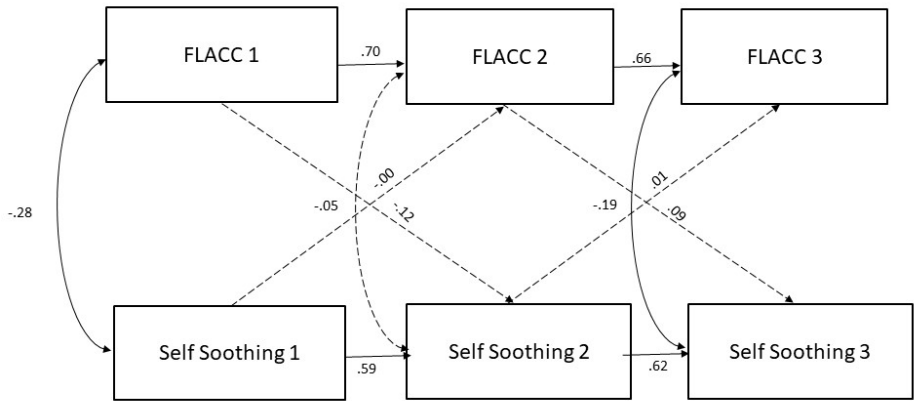
Model of Parent-Focused Behaviors and Pain-Related Distress at 18 Months



Note. Solid paths are significant with $p < .05$. Non-significant paths are dashed.

Figure 6

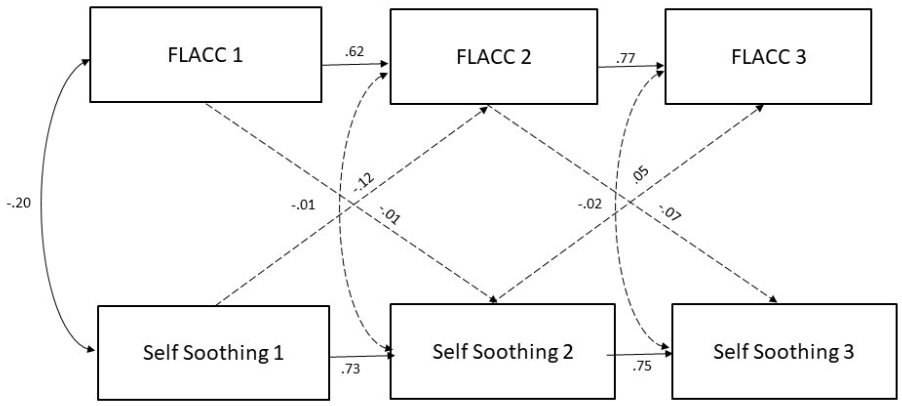
Model of Physical Self-Soothing and Pain-Related Distress at 12 Months



Note. Solid paths are significant with p <.05. Non-significant paths are dashed.

Figure 7

Model of Physical Self-Soothing and Pain-Related Distress at 18 Months



Note. Solid paths are significant with $p < .05$. Non-significant paths are dashed.

Chapter 5: Bridging Study 2 and Study 3

The purpose of Study 2 was to understand the concurrent and predictive relationships between toddlers' pain-related distress and different child-led emotion regulation (ER) strategies. Study 2 provided evidence that toddlers can engage in behaviours that reduce their distress at both 12 and 18 months.

Beginning with disengagement of attention as an ER behaviour, a developmental difference was found in that this behaviour was not significantly related to pain-related distress at 12 months, but disengagement of attention was significantly negatively related to pain-related distress both concurrently and over time at 18 months. While the concurrent association found at Minute 1 does not allow for an understanding of directionality, pain-related distress at Minute 1 predicted less use of disengagement of attention at Minute 2. Taken together, these findings speak to the possible regulatory nature of disengagement of attention; however, heightened pain-related distress levels may hinder use of this potentially regulatory behaviour.

Significant negative concurrent associations between physical self-soothing and pain-related distress were also seen at 12- and 18 months. Although both suggest a potential regulatory role of physical self-soothing, the association was somewhat stronger at 12 months than at 18 months, which suggests that this behaviour becomes less regulatory with development. Further, it is important to note that this behaviour was the least frequently used of all behaviours.

Lastly, there were significant positive concurrent associations between toddlers' use of parent-focused behaviours and pain-related distress at both ages, with stronger magnitudes seen at 18 months, but the predictive association was significant only at 12 months. Given that these behaviours can be seen as signalling to parents (i.e., proximity seeking or maintenance, orienting to parent), an understanding of parent behaviour is warranted to fully understand these findings.

This limitation underscores the importance of Study 3, which considers the roles of both child and parent behaviours.

The purpose of Study 3 was to understand the relative contributions of child-led ER (regulatory) behaviours over and above parent-led regulatory behaviours and pre-needle distress. Given the dyadic nature of vaccination, toddler-led regulatory behaviours should be contextualized within the caregiver relationship. Further, given that pre-needle distress has been well-documented as a critical component of the vaccination experience and the ability of the child to enact child-led regulatory behaviours, it was also important to include to deepen our understanding of child-led regulatory behaviours during toddlerhood.

Chapter 6: It takes two: The relative contributions of parent versus child-led emotion regulation behaviours on toddler vaccination pain[3]

Introduction

There is a significant literature examining the role of parents' support of child distress regulation (Kopp 1982, 1989; Sameroff, 2010), specifically during painful acute procedures like vaccination. Supporting children's pain sensitively (i.e., attuned to their changing needs) is critical (e.g., Badovinac et al., 2018; Din Osmun et al., 2014; Pillai Riddell et al., 2011; Pillai Riddell et al., 2018). Moreover, this work has facilitated an understanding of which parent behaviours support distress reduction, such as physical soothing strategies (e.g., Blount et al., 2008; Campos, 1994; Jahromi et al., 2004), and those that promote distress, such as verbal reassurance (e.g., Cohen et al., 2005; Lisi et al., 2013; Racine et al., 2012; Sweet & McGrath, 1998). Parent use of distraction has mixed findings, with some suggesting it reduces pain post-needle (e.g., Cohen, 2002; Cohen et al., 2006; Gonzalez et al., 1993; Lisi et al., 2013), and others finding it does not (Cramer-Berness & Friedman, 2005; Hillgrove Stuart et al., 2013).

However, with age comes an increasing ability to regulate one's own distress (Kopp, 1982, 1989; Sameroff, 2010). While few studies have tried to understand regulation in early childhood vaccination (e.g., Blount et al., 2008; Cohen et al., 2005), a clear focus on the second year of life is particularly important and absent from the literature. It is arguably when children have developed more stable distress regulation patterns with their caregiver (Ainsworth et al.,

[3] This is the authors' version of the submitted manuscript.
The submitted paper is cited below:
Gennis, H. G., Flora, D. B., McMurtry, C. M., Flanders, D., Weinberg, E., Savlov, D., Garfield, H., & Pillai Riddell R. *It takes two: The relative contributions of parent versus child-led emotion regulation behaviours on toddler vaccination pain*. [Manuscript submitted for publication]. Department of Psychology, York University.

1978; Bowlby, 1969/82). A recent study at this age showed that while behaviours such as child-led disengagement of attention and physical self soothing are related to decreases in distress post-needle, children continue to signal to their parents through gaze or proximity-seeking behaviour (Gennis et al., submitted), likely in attempt to receive additional support. Given the known impact of pre-needle distress on post-needle distress (Campbell et al., 2013; Lisi et al., 2013; Shiff et al., 2022), accounting for its role when exploring parent and child-led regulatory behaviours was seen as important.

The current study was driven by three research questions assessed separately at both 12 and 18 months of child age. **Research Question 1:** What is the role of toddler's pre-needle distress on toddler's pain-related distress regulation? We hypothesized that pre-needle distress would significantly predict toddlers' regulation post-needle. **Research Question 2:** What are the relative contributions of parent and child-led regulatory behaviours on toddler pain-related distress regulation over and above the toddler's pre-needle distress? We hypothesized that parent regulatory behaviours would account for more variance in regulation than baseline distress alone and that child-led regulatory behaviours would account for additional unique variance in regulation. **Research Question 3:** Does the timing of the parent and child-led regulatory behaviours (i.e., Minute 1 or Minute 2 post-needle) affect pain-related regulation? Research question 3 was exploratory and thus no specific hypotheses were made. Additionally, over all research questions, we hypothesized that older toddlers (18 months) would enact regulatory behaviours that accounted for more variance than younger toddlers (12 months).

Methods

Participants

Data collection for the current analyses occurred between September 2015 and March 2020, as part of a longitudinal cohort study (Waxman et al., 2020; Gennis et al., submitted) of caregiver-toddler dyads. Dyads were recruited from two pediatric clinics in the Greater Toronto Area using a cohort-sequential design. The current analyses involve the video-recorded data from the 12- and 18-month waves. Procedures were approved by the research ethics board at the participating university. Caregivers were approached by a research assistant and provided informed consent. The sample consisted primarily of well-educated, middle-class mothers from a wide variety of self-reported cultural backgrounds and their toddlers. As described in Gennis et al. (submitted), after recruitment and attrition, 163 caregiver-toddler dyads were observed at 12 months and 149 dyads were observed at 18 months.

Measures

For all measures, behavioural coding was completed using Noldus Observer. All primary coders were blind to research questions and study hypotheses.

Pain-Related Distress

The Face, Legs, Activity, Cry, Consolability coding system (FLACC; Merkel et al., 1997) was used to measure the degree of behavioural pre-needle distress and pain-related distress post-immunization. The FLACC was used to assess the five namesake pain behaviours in 15-second epochs consecutively for one minute pre-needle and over the three-minute period of post-needle observation. Within each epoch, each of the five behaviours was scored on a 0 to 2 scale, resulting in a total score from 0 to 10 for each 15-second epoch. Research has demonstrated moderate to high concurrent validity and reliability for FLACC scores in the acute pain context

(Merkel et al., 2002). Twenty percent of the current sample was double-coded throughout the coding process to assess interrater reliability between coders at 12- and 18-months, which was strong (ICC= .93 to .96).

For the current analyses, pre-needle distress was based on the full minute prior to the first needle. This score was the mean FLACC score across all available 15-second epochs for a participant within this minute. Post-needle pain-related distress was measured using three variables: FLACC 1 (the first 15-second epoch following the last needle), FLACC 2 (the first 15-second epoch of the second minute post-needle), and FLACC 3 (the first 15-second epoch of the third minute post-needle). Both pain-related distress reactivity and regulation were represented by a latent variable that used the three post-needle FLACC scores, as described below.

Child-Led Regulatory Behaviours

Child-led regulatory behaviours were coded using a modified coding system from the Laboratory Temperament Assessment Battery (Lab-TAB) Locomotor Version 3.1 (Goldsmith & Rothbart, 1999; Gennis et al., submitted). Six behaviours were ultimately included: object orientation (i.e., child orienting to or manipulating non-procedure related objects in the environment), caregiver proximity-seeking (e.g., reaching for parent), caregiver orientation (e.g., looking toward the parent), thumb sucking, other oral behaviour (e.g., independent use of a pacifier), and physical self-touch (e.g., rubbing arm). Dr. J. Gagne (Texas A & M University) consulted in the initial phase of coding to ensure the validity of the measure when applied to the vaccination context.

Each behaviour was coded as present (1) or absent (0) for 12 consecutive 5-second epochs within the first two minutes post-needle. Scores were calculated representing the proportion of intervals a given behaviour was present out of the total number of codable epochs

in each minute, resulting in scores ranging from 0 to 1. Thus, higher scores suggested higher frequency of that behaviour. Percentage (and kappa) agreement ranged as follows for each behaviour: object orientation = .83 to .85 (κ = .58 to .63), caregiver proximity-seeking = .87 to .93 (κ = .71 to .81), caregiver orientation = .88 to .91 (κ = .63 to .74), thumb sucking = .98 to .99 (κ = .74 to .91), other oral behaviour = .98 to .99 (κ = .94 to .96), and physical touch = .92 to .95 (κ = .66 to .82). For parsimony, the six Lab-TAB behaviours were combined into three clusters of ER behaviours: disengagement of attention (object orientation), parent-focused behaviours (average of proximity-seeking and caregiver orientation), and physical self-soothing (average of thumb sucking, other oral behaviours and physical touch) for each minute post-needle. These scores ranged from 0 to 1.

Parent Regulatory Behaviours

Parent regulatory behaviours were coded using the Measure of Adult and Infant Soothing and Distress (MAISD; Cohen et al., 2005). The MAISD is a valid, reliable, and frequently used behavioural coding system for parent regulatory behaviours in the context of infant needle procedures (e.g., Campbell et al., 2013; Lisi et al., 2013; Racine et al., 2012). The measure consists of eight parent regulatory behaviours; however, four behaviours were chosen a-priori due to their relevance and strong research base, and each showed acceptable reliability: distraction (i.e., trying to distract the child when in distress; ICCs = .94 to .98), verbal reassurance (e.g., saying “it’s ok” or “you’re fine”; ICCs = .81 to .95), rocking (e.g., swaying the child while in parent arms; ICCs = .96 to .99), and physical comfort (e.g., kissing the child or rubbing back; ICCs = .80 to .93). Each behaviour was coded as present (1) or absent (0) for 12 consecutive 5-second epochs one-minute and two-minutes post-needle. Composite scores for

each minute were calculated as the number of epochs a behaviour was present out of the total number of codable epochs, with scores ranging from 0 to 1.

Procedure

Prior to the vaccination, dyads were connected to cardiovascular equipment and two cameras were set up in the room. Toddlers and caregivers were recorded and naturalistically observed for at least one minute before the first needle and at least three minutes following the last needle. At each appointment, caregivers were given an information sheet outlining evidence-based pain management strategies for toddlers (Taddio et al., 2010).

Analysis Plan

In the current study, growth curve modeling (GCM; Bollen & Curran, 2006) was used to assess the impact of child regulatory behaviours on pain regulation, after accounting for pre-needle distress and parent regulatory behaviours. At each age, the primary outcome being predicted was the latent variable representing pain-related distress regulation (represented by the slope latent variable, which captured the overall change across FLACC 1, FLACC 2, and FLACC 3). Pain reactivity (i.e., the intercept latent variable, representing the level of FLACC 1) was included as a control, with pre-needle distress also predicting it, because of the importance of immediate pain responding post-needle to understanding regulation and because of the statistical necessity of including an intercept latent variable (see Bollen & Curran, 2006).

Pain reactivity and regulation were first represented in unconditional growth models (one for each of the 12- and 18-month data) to determine whether the FLACC scores showed a linear change over time; the fit of these models was assessed using the Tucker-Lewis Index (TLI), the Comparative Fit Index (CFI), and the Root Mean Square Error of Approximation (RMSEA) (see Bollen & Curran, 2006). All models were estimated with the lavaan package in R (Rosseel,

2012) using direct maximum likelihood estimation (via the "MLR" estimator) to allow the inclusion of incomplete cases; this estimator also produces model fit statistics and estimate standard errors which are robust to non-normality.

An important interpretative note is that the slope latent variable (pain regulation) is negative because acute pain expression decreases over time post-needle. If a predictor has a negative relationship with the slope (pain regulation), higher scores on the predictor are related to a greater decrease in pain scores over time.

In terms of predictors, the same sets of models were estimated separately for each of the 12- and 18-month datasets. With both ages, pre-needle distress was added first as a predictor (Step 1), followed by parent regulatory behaviour (Step 2; either Minute 1 or Minute 2 variables), and then child-led regulatory behaviours (Step 3; either Minute 1 or Minute 2 variables). Therefore, there were two sets of models at each age: One using Minute 1 predictors on regulation and one using Minute 2 predictors. Figure 1 outlines the general structure of the four sets of models.

Results

Descriptive Statistics

See Table 1 for descriptive statistics of key variables. Tables 2 and 3 present correlations among the predictor variables at 12 and 18 months, respectively.

Unconditional Growth Curve Models

The unconditional model for linear growth fit the 12-month pain-related distress data well (TLI = .99, CFI = .99, RMSEA = .03). In contrast, the unconditional model for linear growth did not fit the18-month data adequately, and thus a free-loading model was estimated; as outlined in the means provided in Table 1, there is a much larger reduction in scores between FLACC 1 and

FLACC 2 compared with the change between FLACC 2 and FLACC 3. A free-loading approach allows for exploration of a nonlinear trend across the repeated measures of FLACC (see Bollen & Curran, 2006). The unconditional free-loading model fit the 18-month data well (TLI = 1.00, CFI = 1.00, RMSEA = .02). Tables 4 through 7 provide the findings for each set of models. To aid in subsequent synthesis and interpretation, Table 8 provides a summary of notable findings across all four sets of models.

Predicting Pain-Related Distress Reactivity and Regulation at 12 Months

Minute 1 Parent and Child Regulatory Behaviour Predictors

All estimates are in Table 4. Pre-needle distress alone explained 6% of the variance in pain regulation (unstandardized B = 0.17, p = .01, standardized B* = 0.25). When parent regulatory behaviours from Minute 1 were added as predictors, an additional 4% of the variance was explained (total R^2 = .10). The addition of child regulatory behaviours explained an additional 11% of variance in pain regulation (total R^2 = .21). As shown in Table 4, the child regulatory behaviour with the strongest unique association with pain regulation was parent-focused behaviour, with a standardized regression coefficient of 0.28. In this final model, pre-needle distress (unstandardized B = 0.17, p = .01, standardized B* = 0.27) and parent-led distraction (unstandardized B = 1.62, p = .02, standardized B* = 0.15) were also significant unique predictors of regulation and pre-needle distress significantly predicted pain reactivity (unstandardized B = .11, p = .02, standardized B* = .17).

Minute 2 Parent and Child Regulatory Behaviour Predictors

All estimates are in Table 5. As shown in Tables 4 and 5, the first model (Step 1) remains the same. When parent regulatory behaviours from Minute 2 were added as predictors, they explained an additional 6% of the variance in pain regulation (total R^2 = .12). Child regulatory

behaviours accounted for an additional 9% of the variance in pain regulation (total $R^2 = .21$). The child-led regulatory behaviour with the strongest unique association with pain regulation was parent-focused behaviour (unstandardized B = 1.37, $p = .03$, standardized B* = .23). In this final model, pre-needle distress remained a significant predictor of regulation (unstandardized B = 0.19, $p < .01$, standardized B* = 0.29).

Predicting Pain-Related Distress Reactivity and Regulation at 18 Months

Minute 1 Parent and Child Regulatory Behaviours

All estimates are in Table 6. Pre-needle distress accounted for 3% of the variance in pain-related distress regulation (unstandardized B = 0.09, $p = .03$, standardized B* = 0.17). Parent regulatory behaviours from Minute 1 explained an additional 3% of the variance in regulation (total $R^2 = .06$). Child regulatory behaviours explained an additional 2% of the variance in pain regulation (total $R^2 = .08$). In this final model, none of predictors had significant unique associations with pain regulation. Pre-needle distress remained a significant predictor of reactivity (unstandardized B = 0.27, $p < .01$, standardized B* = .33).

Minute 2 Parent and Child Regulatory Behaviours

Table 7 provides model estimates. As shown in Tables 6 and 7, the first model (Step 1) remains the same. Parent regulatory behaviours from Minute 2 explained an additional 11% of the variance in pain regulation (total $R^2 = .14$). Child regulatory behaviours explained an additional 4% of the variance in pain regulation (total $R^2 = .18$). The child regulatory behaviour with the strongest unique association with pain regulation was parent-focused behaviour (unstandardized B = 1.45, $p = .01$, standardized Beta* = .21). Furthermore, the parent behaviours distraction (unstandardized B = 4.59, $p < .01$, standardized B* = 0.21), rocking (unstandardized B = -0.83, $p = .03$, standardized B* = -0.18), and verbal reassurance (unstandardized B = 1.71, $p =$

.02, standardized B* = 0.16) had significant unique associations with pain regulation. Pre-needle distress remained a significant predictor of reactivity (unstandardized B = 0.27, p <.01, standardized B* = .33).

Discussion

The goal of the current study was to understand the contributions of child-led regulatory behaviours to children's post-needle pain regulation after considering pre-needle distress and parent regulatory behaviours at two different ages within the second year of life (12 and 18 months). This study was driven by three research questions all relating to the timing of and the relation between pre-needle distress, parent regulatory behaviour and child regulatory behaviour when predicting how children regulated post vaccination. We hypothesized that pre-needle distress would significantly predict regulation, parent behaviours would explain further variance in pain regulation over and above pre-needle distress, and that child-led behaviours would further explain the variance in regulation. Lastly, we speculated that across research question 2 and 3, parent and child variables would have stronger associations with regulation in older toddlers (18 months) than younger toddlers (12 months).

Predicting Pain-Related Regulation at 12 months

At 12 months of child age, pre-needle distress significantly predicted regulation, even when parent and child regulatory behaviours were added to the model. Greater distress pre-needle was associated with slower regulation across the vaccination appointment. This finding with pre-needle distress causing longer regulation times confirms findings in separate samples noting the influence of pre-needle distress on increased pain outcomes post-needle (Campbell et al., 2013; Lisi et al., 2013; Shiff et al., 2022). If a child is highly distressed pre-needle, it will

likely impact not only their parents' behaviour, but their own ability to engage in autonomous self-regulation.

At 12 months, both parent and child regulatory behaviours from Minute 1 explained additional variance beyond pre-needle distress. Accounting for all other predictor variables, parent distraction and parent-focused behaviours by children were significant unique predictors of regulation. The positive association between distraction and pain regulation suggested that when parents used more distraction, toddlers were slower to calm down post-needle. This result is consistent with past research showing that distraction may not significantly reduce pain-related distress post-needle (Cramer-Berness & Friedman, 2005; Hillgrove Stuart et al., 2013). Yet, distraction at Minute 2 was not significantly predictive of regulation. An important consideration is that parent distraction was rare in this sample. Further, use of distraction does not necessarily indicate that this behaviour was attuned to the child's needs. It is perhaps for this reason that findings on distraction and pain in early childhood remain mixed. This inconsistency suggests that beyond looking at presence of a parent behaviour, understanding its sensitivity in the context of the child's changing needs remains important (e.g., Badovinac et al., 2018; Din Osmun et al., 2014; Pillai Riddell et al., 2011; Pillai Riddell et al., 2018).

Furthermore, at 12 months, toddlers that maintained proximity or gazed toward their parent during both the first- and second-minute post-needle calmed down more slowly across the vaccination appointment. These findings suggest that at this age, toddlers may struggle to self-regulate across the appointment, and therefore signal to their parent for support or seek comfort. This result is consistent with past findings assessing child-led regulatory behaviours during vaccination (Gennis et al., submitted), as well as attachment theory more broadly (Bowlby, 1969/1982).

Predicting Pain-Related Regulation at 18 months

At 18 months, partially supporting our first hypothesis, pre-needle distress significantly predicted regulation before any other predictors were included in the model. However, when accounting for either Minute 1 or Minute 2 parent and child regulatory behaviours, pre-needle distress no longer significantly predicted regulation.

At this older age, the associations between parent and child behaviours and pain regulation differed according to when these behaviours occurred. When used one-minute post-needle, no individual parent or child behaviour uniquely, significantly predicted pain regulation. However, at two minutes post-needle, both parent and child regulatory behaviours explained substantial additional variance in pain regulation. The largest increase was seen when parent regulatory behaviours were added to the model. Parents' use of distraction was significantly associated with less regulation (i.e., calming down more slowly), akin to findings at 12 months of age. At this age, there were further significant unique associations between parent regulatory behaviours and regulation. Consistent with past literature (e.g., Cohen et al., 2005; Lisi et al., 2013; Racine et al., 2012; Sweet & McGrath, 1998), verbal reassurance (e.g., parents stating "it's ok") was also associated with less regulation.

The only parent behaviour significantly associated with quicker regulation post-needle was parent rocking. This result is consistent with previous literature in younger samples (Campos, 1994; Jahromi et al., 2004). Regarding child-led regulatory behaviours, we again found that toddlers who maintained proximity or gazed toward their parent were slower to calm down at this age. It is possible that as the attachment relationship solidifies (Ainsworth et al., 1978; Bowlby, 1969/1982), parents respond with rocking when children signal that they need

help calming down. However, further research is needed to fully elucidate how these behaviours work together.

Synthesis of Findings and Conclusions

In summary, this study provides several novel insights into toddler pain regulation post-needle. First, findings supported the role of pre-needle distress in predicting regulation. At 12 months, pre-needle distress remained a significant predictor of regulation over and above parent and child regulatory behaviours. At 18 months, while pre-needle distress was a significant predictor of regulation post-needle, once parent and child regulatory behaviours were included, this was no longer a significant predictor. Taken together, this suggests that pain management and support should begin well before the first needle and that age is an important variable.

In general, the inclusion of parent, then child regulatory behaviours explained increasing amounts of variance in pain regulation. However, age, as well as timing of regulatory behaviours, were also important factors in our understanding of the roles of these regulatory behaviours. At 12 months, the largest increase in explaining the variance in regulation occurred when child-led regulatory behaviours were added to the model. Although parent distraction was significantly associated with regulation at this age, the most consistent unique association was that more proximity and gaze toward to the parent were significantly associated with calming down more slowly. At 18 months, the largest increase in explained regulation variance occurred when parent regulatory behaviours in the second minute post-needle were added. Although at Minute 2, the child's parent-focused behaviours showed a similar pattern at 18 months as at 12 months, there were several significant unique associations between parent behaviours and regulation. Both distraction and verbal reassurance were significantly associated with slower regulation, whereas rocking by parent was significantly associated with quicker regulation.

Toddlerhood is a time of both increasing stabilization in the caregiver-child relationship and child autonomy in regulation (Ainsworth et al., 1978; Bowlby, 1969/1982; Kopp, 1982, 1989). At 12 months, caregivers may still be figuring out how to respond appropriately to the signalling of their toddler, which may likely improve by 18 months.

A final point surrounds the finding that the only child-led behaviour significantly associated with regulation was parent-focused behaviour. Inconsistent with past findings (Gennis et al., submitted), more independent behaviours (i.e., disengagement of attention and physical self-soothing) were not significantly associated with quicker regulation over time. While Gennis and colleagues found that both disengagement of attention and physical self-soothing were associated with less distress, these behaviours do not appear to predict quicker regulation across the entire appointment. The fact that parent-focused behaviours were most consistently associated with reduced pain regulation over time suggests the need to understand vaccination as a dyadic context including child signalling and parent response. However, by distinguishing children's more active use of signalling behaviours, such as proximity seeking and gaze, from reactive signals of distress (e.g., crying), we are still able to understand how the child uses their caregiver following vaccination.

Limitations and Future Directions

These findings are understood in the context of some limitations. First, while the current sample is culturally diverse, it represents mid-to-high socioeconomic status, impacting its generalizability to higher risk samples. Further, discrete parent soothing behaviours may not be enough to fully understand the dyadic interaction between parent and child during vaccination, particularly when it comes to their response to the child's signalling through proximity seeking and gaze orientation. Efforts to understand the dyad and the caregiver's sensitivity more

holistically may enhance this understanding. Lastly, given the role of timing (i.e., when regulatory behaviours occurred) in the current study, future research should assess these associations in a sequential manner to fully understand the associations between parent and child regulatory behaviours and pain during vaccination.

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Table 1

Descriptive Statistics of Predictor and Outcome Variables

	12 months				18 months			
	N	Mean (SD)	Min	Max	N	Mean (SD)	Min	Max
Child: Disengagement of Attention 1	163	.62 (.24)	0	1	149	.66 (.25)	0	1
Child: Disengagement of Attention 2	163	.78 (.26)	0	1	149	.78 (.26)	0	1
Child: Parent-Focused Behaviour 1	163	.33 (.19)	0	.83	149	.25 (.20)	0	.79
Child: Parent-Focused Behaviour 2	163	.26 (.23)	0	1	149	.24 (.20)	0	.79
Child: Physical Self Soothing 1	163	.08 (.10)	0	.36	149	.12 (.12)	0	.47
Child: Physical Self Soothing 2	163	.12 (.13)	0	.56	149	.12 (.13)	0	.50
Parent: Distraction 1	164	.06 (.12)	0	.58	148	.03 (.06)	0	.25
Parent: Distraction 2	163	.06 (.13)	0	.83	148	.02 (.07)	0	.42
Parent: Rocking 1	164	.40 (.32)	0	1	148	.25 (.30)	0	1
Parent: Rocking 2	163	.36 (.34)	0	1	148	.24 (.32)	0	1
Parent: Physical Comfort 1	164	.60 (.25)	0	1	148	.52 (.29)	0	1
Parent: Physical Comfort 2	162	.40 (.29)	0	1	148	.37 (.31)	0	1

Parent: Verbal Reassurance 1	158	.22 (.21)	0	.83	146	.21 (.19)	0	.75
Parent: Verbal Reassurance 2	158	.12 (.15)	0	.67	147	.10 (.13)	0	.75
Child: FLACC Pre-Needle Distress	159	1.73 (2.05)	0	9	148	2.66 (2.73)	0	9.75
Child: FLACC 1	162	7.91 (1.31)	2	10	149	7.02 (2.24)	0	10
Child: FLACC 2	161	5.24 (3.15)	0	10	148	3.96 (3.23)	0	9
Child: FLACC 3	158	3.15 (2.98)	0	10	148	2.88 (2.95)	0	10

For all variables, 1 represents one-minute post-needle, 2 represents two-minutes post needle, 3 represents three minutes post-needle.

Table 2

Correlations among Predictor Variables at 12 Months

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1. Child: Disengagement of Attention 1	-														
2. Child: Disengagement of Attention 2	.36	-													
3. Child: Parent Focused 1	-.19	-.25	-												
4. Child: Parent Focused 2	-.08	-.29	.54	-											
5. Child: Physical Self Soothing 1	.03	.05	-.07	.13	-										
6. Child: Physical Self Soothing 2	.12	-.04	.06	.22	.63	-									
7. Parent: Distraction 1	-.00	-.19	-.07	-.13	-.17	-.22	-								
8. Parent: Distraction 2	-.04	-.14	.02	-.13	-.18	-.26	.54	-							
9. Parent: Rocking 1	.05	.10	.04	-.09	-.03	-.07	.22	.19	-						
10. Parent: Rocking 2	-.07	.16	-.01	.01	-.04	-.08	.12	.13	.61	-					
11. Parent: Physical Comfort 1	.08	.03	.22	.10	-.11	-.12	.04	.19	.30	.15	-				
12. Parent: Physical Comfort 2	-.04	.14	.05	.27	.12	.05	-.03	-.02	.17	.37	.37	-			
13. Parent: Verbal Reassurance 1	-.13	-.01	-.01	-.04	.02	-.02	.02	.09	.02	.06	.16	.09	-		
14. Parent: Verbal Reassurance 2	-.06	.07	-.01	.04	-.05	-.19	.15	.17	.05	.15	.09	.10	.55	-	
15. Child: Pre-Needle Distress	-.08	.01	.07	.14	-.09	-.17	-.08	-.04	.03	.09	.03	.10	.04	.01	-

Table 3

Correlations Among Predictor Variables at 18 Months

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1. Child: Disengagement of Attention 1	-														
2. Child: Disengagement of Attention 2	.40	-													
3. Child: Parent Focused 1	-.18	-.12	-												
4. Child: Parent Focused 2	-.17	-.24	.65	-											
5. Child: Physical Self Soothing 1	.06	.14	-.15	-.07	-										
6. Child: Physical Self Soothing 2	.06	.09	-.10	-.08	.73	-									
7. Parent: Distraction 1	-.28	-.35	-.02	.06	-.03	-.06	-								
8. Parent: Distraction 2	-.22	-.18	.09	.14	-.18	-.21	.29	-							
9. Parent: Rocking 1	-.07	-.12	.29	.23	-.09	-.07	.01	.00	-						
10. Parent Rocking 2	-.03	-.02	.33	.31	-.11	-.16	-.02	.07	.70	-					
11. Parent: Physical Comfort 1	-.06	.01	.24	.09	.08	.04	-.17	.00	.20	.16	-				
12. Parent: Physical Comfort 2	-.18	-.01	.07	.13	.09	.03	-.13	.08	.20	.35	.51	-			
13. Parent: Verbal Reassurance 1	.03	.08	.08	-.06	.04	.01	-.01	-.03	-.10	.01	.19	.06	-		
14. Parent: Verbal Reassurance 2	-.06	.02	.25	.11	-.03	-.06	-.01	.08	.13	.14	.28	.24	.49	-	
15. Child: Pre-Needle Distress	.01	-.19	.20	.23	-.09	-.07	.11	.13	.13	.14	.03	-.02	.10	.14	-

Table 4

Predicting 12-Month Pain-Related Distress Regulation Using One-Minute Parent and Child-Led Regulatory Behaviours

Predictor	Standardized Estimate	Unstandardized Estimate	SE	Z	*p*	R^2
Regulation (slope latent variable)						
Step 1 (n = 159)						.06
C: Pre-Needle Distress	**0.25**	**0.17**	0.06	2.72	.01	
Step 2 (n = 153)						.10
C: Pre-Needle Distress	**0.27**	**0.18**	0.06	2.89	<.01	
P: Distraction 1	**0.14**	**1.63**	0.77	2.13	.03	
P: Rocking 1	-0.05	-0.22	0.39	-0.58	.56	
P: Physical Comfort 1	0.09	0.51	0.46	1.13	.26	
P: Verbal Reassurance 1	-0.04	-0.27	0.50	-0.54	.59	
Step 3 (n = 153)						.21
C: Pre-Needle Distress	**0.27**	**0.17**	0.06	2.74	.01	
P: Distraction 1	**0.15**	**1.62**	0.71	2.28	.02	
P: Rocking 1	-0.04	-0.15	0.36	-0.43	.67	
P: Physical Comfort 1	0.00	0.02	0.47	0.04	.97	
P: Verbal Reassurance 1	-0.01	-0.05	0.48	-0.10	.92	
C: Disengagement of Attention 1	0.08	0.43	0.50	0.86	.39	
C: Parent-Focused Behaviour 1	**0.28**	**1.99**	0.57	3.50	<.01	
C: Physical Self Soothing 1	-0.15	-2.03	1.12	-1.81	.07	

Note. C denotes that a variable is a child behaviour, and P denotes that a variable is a parent behaviour. The 1 represents that the behaviour occurred in the first minute post-needle. Bolded values indicate $p < .05$.

Table 5

Predicting 12-Month Pain-Related Distress Regulation Using Two-Minute Parent and Child-Led Regulatory Behaviours

Predictor	Standardized Estimate	Unstandardized Estimate	SE	Z	*p*	R^2
Regulation (slope latent variable)						
Step 1 (n = 159)						.06
C: Pre-Needle Distress	**0.25**	**0.17**	0.06	2.72	.01	
Step 2 (n = 152)						.12
C: Pre-Needle Distress	**0.30**	**0.20**	0.06	3.27	<.01	
P: Distraction 2	0.09	0.98	0.73	1.34	.18	
P: Rocking 2	-0.07	-0.28	0.38	-0.75	.46	
P: Physical Comfort 2	0.07	0.31	0.43	0.72	.47	
P: Verbal Reassurance 2	0.10	0.96	0.73	1.31	.19	
Step 3 (n = 152)						.21
C: Pre-Needle Distress	**0.29**	**0.19**	0.06	2.99	<.01	
P: Distraction 2	0.09	0.90	0.67	1.35	.18	
P: Rocking 2	-0.04	-0.14	0.37	-0.37	.71	
P: Physical Comfort 2	0.02	0.10	0.45	0.21	.83	
P: Verbal Reassurance 2	0.09	0.85	0.69	1.22	.22	
C: Disengagement of Attention 2	-0.12	-0.63	0.54	-1.18	.24	
C: Parent-Focused Behaviour 2	**0.23**	**1.37**	0.63	2.19	.03	
C: Physical Self Soothing 2	-0.10	-0.99	0.91	-1.09	.28	

Note. C denotes that a variable is a child behaviour, and P denotes that a variable is a parent behaviour. The 2 represents that the behaviour occurred in the second minute post-needle. Bolded values suggest $p < .05$.

Table 6

Predicting 18-Month Pain-Related Distress Regulation Using One-Minute Parent and Child-Led Regulatory Behaviours

Predictor	Standardized Estimate	Unstandardized Estimate	SE	Z	*p*	R^2
Regulation (slope latent variable)						
Step 1 (n = 148)						.03
C: Pre-Needle Distress	**0.17**	**0.09**	0.04	2.16	.03	
Step 2 (n = 145)						.06
C: Pre-Needle Distress	**0.18**	**0.09**	0.04	2.17	.03	
P: Distraction 1	0.10	2.50	1.95	1.28	.20	
P: Rocking 1	-0.05	-0.24	0.38	-0.64	.52	
P: Physical Comfort 1	0.08	0.42	0.42	1.00	.32	
P: Verbal Reassurance 1	-0.12	-0.92	0.57	-1.61	.11	
Step 3 (n = 145)						.08
C: Pre-Needle Distress	0.15	0.08	0.04	1.81	.07	
P: Distraction 1	0.10	2.56	2.01	1.28	.20	
P: Rocking 1	-0.08	-0.40	0.40	-1.00	.32	
P: Physical Comfort 1	0.08	0.40	0.40	0.99	.32	
P: Verbal Reassurance 1	-0.12	-0.91	0.58	-1.56	.12	
C: Disengagement of Attention 1	0.00	0.02	0.47	0.04	.97	
C: Parent-Focused Behaviour 1	0.12	0.85	0.67	1.26	.21	
C: Physical Self Soothing 1	-0.10	-1.19	0.79	-1.52	.13	

Note. C denotes that a variable is a child behaviour, and P denotes that a variable is a parent behaviour. The 1 represents that the behaviour occurred in the first minute post-needle. Bold indicates $p < .05$.

Table 7

Predicting 18-Month Pain-Related Distress Regulation Using Two-Minute Parent and Child-Led Regulatory Behaviours

Predictor	Standardized Estimate	Unstandardized Estimate	SE	Z	*P*	R^2
Regulation (slope latent variable)						
Step 1 (n = 148)						.03
C: Pre-Needle Distress	**0.17**	**0.09**	0.04	2.16	.03	
Step 2 (n = 146)						.14
C: Pre-Needle Distress	0.15	0.08	0.04	1.80	.07	
P: Distraction 2	**0.24**	**5.19**	1.09	4.77	<.01	
P: Rocking 2	-0.13	-0.56	0.36	-1.57	.12	
P: Physical Comfort 2	0.10	0.48	0.36	1.35	.18	
P: Verbal Reassurance 2	**0.17**	**1.79**	0.72	2.48	.01	
Step 3 (n = 146)						.18
C: Pre-Needle Distress	0.11	.06	0.05	1.29	.20	
P: Distraction 2	**0.21**	**4.59**	1.14	4.04	<.01	
P: Rocking 2	**-0.18**	**-0.83**	0.37	-2.22	.03	
P: Physical Comfort 2	0.10	0.48	0.36	1.34	.18	
P: Verbal Reassurance 2	**0.16**	**1.71**	0.71	2.40	.02	
C: Disengagement of Attention 2	-0.01	-0.04	0.41	-0.09	.93	
C: Parent-Focused Behaviour 2	**0.21**	**1.45**	0.57	2.57	.01	
C: Physical Self Soothing 2	-0.04	-0.39	0.75	-0.51	.61	

Note. C denotes that a variable is a child behaviour, and P denotes that a variable is a parent behaviour. The 2 represents that the behaviour occurred in the second minute post-needle. Bold indicates $p < .05$.

Table 8

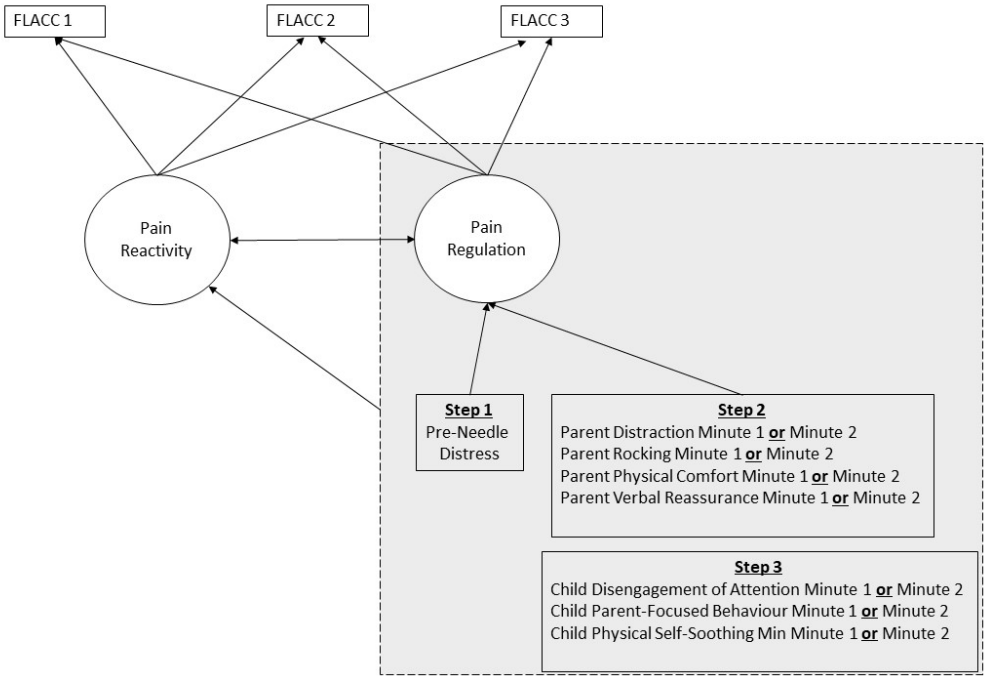
Summary of Notable Findings Across the Final Models (Step 3)

	Step 3 R^2 (Minute 1 Model)	**Child Pre-Needle (Minute 1 Model)**	**Minute 1 Regulatory Behaviours (Parent and Child)**	**Step 3 R^2 (Minute 2 Model)**	**Child Pre-Needle (Minute 2 model)**	**Minute 2 Regulatory Behaviours (Parent and Child)**
12 months	**R^2** = .21	Pre-Needle Distress (Child): B = 0.17 B* = 0.27	Distraction (Parent): B = 1.62 B* = 0.15 Parent Focused Behaviour (Child): B = 1.99 B* = 0.28	**R^2**=.21	Pre-Needle Distress (Child): B = 0.19 B* = 0.29	Parent Focused Behaviour (Child): B = 1.37 B* = 0.23
			Minute 1			**Minute 2**
18 months	**R^2** = .08	*Pre-needle distress did not uniquely predict regulation*	*No significant unique behavioural predictors at Minute 1*	**R^2** = .18	*Pre-needle distress did not uniquely predict regulation*	Distraction (Parent): B = 4.59 B* = 0.21 Rocking (Parent): B = -0.83 B* = -0.18 Verbal Reassurance (Parent): B = 1.71 B* = 0.16 Parent-Focused Behaviour (Child): B = 1.45 B* = 0.21

Note. B = unstandardized regression coefficient; B* = standardized regression coefficient.

Figure 1

General Structure of Growth Curve Models



Note. Focus of current analyses highlighted in the grey box.

Chapter 7: Conclusions

This dissertation research has filled several gaps in the current child pain literature as well as the emotion regulation literature more broadly. Consistent with past theorizing and methodological recommendations (Calkins, 2010; Cole et al., 2004; Kopp, 1982, 1989; Sameroff, 2010; Sroufe, 1996), this work was developed with the understanding that emotion regulation: 1) involves the dynamic relationship between emotion expression and attempts to regulate emotion, 2) is heavily embedded within the caregiving context, and 3) is best understood from a developmental perspective.

First, this dissertation used sophisticated statistical analyses that allow for an understanding of the dynamic associations between child-led emotion regulation behaviors and pain-related distress. Second, it took a psychosocial perspective with emphasis on the dyadic relationship. Third, it took a developmental perspective by examining two stages within the toddlerhood period. Cole et al. (2004) also spoke to the need to understand emotion regulation in varying contexts. This line of work is the first, to our knowledge, that has specifically examined emotion regulation using the tenets discussed above in a naturalistic, highly distress-inducing environment – toddler vaccination.

This dissertation included three studies, all of which are published or currently being considered for publication. Study 1 (Gennis et al., 2022) was a systematic review and meta-analysis aimed at understanding the relationships between different child-led emotion regulation (ER) behaviours and distress in the first three years of life. Nine meta-analyses analysed the associations between distress and three clusters of ER behaviours (disengagement of attention, physical self-soothing, and parent-focused behaviours) separately in infancy (first year of life), early toddlerhood (second year of life), and late toddlerhood (third year of life). This study

supported an understanding of different child-led ER behaviours, how they related to distress, and how these associations may change as a function of developmental period. Study 2 (Gennis, Flora, Norton, et al., submitted) used these findings to inform coding child-led ER behaviours during vaccination and assessed their concurrent and predictive associations with pain-related distress. Again, a developmental perspective was taken. Analyses were separated at 12 and 18 months to ascertain whether there were differences as children developed across the toddlerhood period. Finally, taking the dyadic relationship and toddlers' pre-needle distress into account, Study 3 (Gennis, Flora, McMurtry, et al., submitted) incorporated parent-led regulatory behaviours and pre-needle distress to assess the relative contributions of child-led regulatory behaviours to pain-related distress regulation (change over time) after these primary factors were taken into account.

Each study chapter (Chapter 2, 4, and 6) discussed the results of the study analyses individually. For ease of review of the work in its entirety, the dissertation synopsis provides a 2-page dissertation summary in narrative form and Appendix A provides a brief 2-page summary of objectives and key statistical results for all three studies.

Integrative Synthesis

Informed by findings from the broader experimental emotion regulation literature, the overarching aim of this dissertation was to understand child-led emotion regulation during toddler vaccination. To do so, it was imperative to use a dynamic approach to understanding the relationships between different child-led regulatory strategies and pain-related distress. Further, given the dyadic nature of the vaccination appointment, it was important to consider parent-led regulatory behaviours and the child's distress level before the needle procedure takes place. Taking all three studies together, it is evident that whereas toddlers do show evidence of self-

regulation during vaccination, parent-led regulatory behaviours remain an important contextual factor. Three important contributions to the literature provided by this dissertation follow.

First, there is evidence of child-led ER behaviours during toddlerhood vaccination which varies according to stage of toddlerhood. Study 2 is the first study in the literature to focus on toddlerhood as a developmental period to provide evidence that disengagement of attention and physical self-soothing may be particularly helpful at reducing pain-related distress during vaccination; however, these findings are age dependent. Physical self-soothing appears to be more helpful at 12 months of age, whereas the more complex strategy of disengaging attention is more helpful at 18 months. Further, high levels of distress one-minute post-needle significantly predicted less use of disengagement of attention the following minute, which suggests that it may interfere with successful use of a regulatory strategy in the second minute. It has been well documented that in times of high distress, children engage less with their environment and instead seek closeness to their caregiver (Bowlby, 1969/1982). Although Study 2 showed evidence of disengagement of attention and concurrent physical self-soothing as regulatory, neither behaviour supported regulation across the vaccination appointment as shown in Study 3. It is possible that these two behaviours are more regulatory in the immediate moment, rather than predicting quicker reduction in pain across time.

Further, child-led parent-focused behaviours may be a more indirect strategy for distress regulation when compared to directly disengaging attention or physical self-soothing. The positive associations with pain-related distress seen in Study 2 suggest a signalling function to parents. It is thought that children continue to signal to their parents when the demands or level of distress goes beyond their regulatory skill set. Further supporting this in Study 3, examining change in pain across the entire vaccination appointment, toddlers at both 12 and 18 months who

used more parent-focused behaviours tended to regulate more slowly. As toddlers continue to signal to their parent, we must continue to look toward parent behaviour in response to these signals. Lastly, Study 2 showed that the relationships between child-led parent-focused behaviour and pain-related distress appear to strengthen across toddlerhood, which may reflect the stabilization and predictability of the attachment relationship (Ainsworth et al., 1978; Bowlby, 1969/1982).

This pattern of results leads to the next key finding of this dissertation, which is that understanding child-led ER behaviours in toddlerhood necessitates a dyadic perspective. Given that the most consistent evidence for child-led ER behaviours are parent-focused child behaviours, it follows that an understanding of parent behaviour is necessary. Both Study 2 and Study 3 showed evidence of clear toddler signalling in the presence of heightened distress. However, the ways in which parents responded to these signals may be the key to understanding what supports the reduction in pain over time. At both 12 and 18 months, parent use of distraction was associated with slower regulation across the appointment. Distraction behaviours were rare and the presence of a behaviour does not necessarily suggest that it is attuned or sensitive to the child's needs. This result is further supported at 18 months when the use of verbal reassurance also predicted slower regulation. This finding is consistent with the literature viewing verbal reassurance as a distress-promoting behaviour during vaccination (Cohen et al., 2005; Lisi et al., 2013; Racine et al., 2012; Sweet & McGrath, 1998). These results speak to the need to not only count frequencies of parent behaviour, but also to consider sensitivity when understanding a behaviours' impact on pain post-needle.

Lastly, the dynamic relationships between ER behaviours and emotion expression differ depending on the timing of behaviours, particularly in the context of higher distress pre-needle.

Study 2 took a proximal time-based approach by estimating both concurrent and short-term predictive relationships (i.e., minute to minute) between child-led ER behaviours and level of distress. Study 3 involved predicting change in pain scores across the entire vaccination appointment. Study 3 also accounted for pre-needle distress as well as the difference in when parent and child-led regulatory behaviours occurred in the appointment (i.e., Minute 1 or Minute 2). First, this dissertation showed that these differences in timing can influence whether behaviours are viewed as regulatory. For example, disengagement of attention and physical self-soothing are regulatory when predicting levels of distress at various times post-needle instead of predicting regulation in terms of the change in pain scores across the whole appointment. Second, particular parent and child-led behaviours are associated with regulation depending on when the behaviours occur. For example, at 18 months, regulatory behaviours only significantly predicted regulation when used in the second minute post-needle, after peak distress reduced. Lastly, pre-needle distress was a key predictor of regulation over and above both parent- and child-led regulatory behaviours. While this dissertation provides evidence of all three ER behaviours being associated with pain during vaccination, it provides support for the need to carefully consider the timing of behaviours as well as the need for a dynamic approach to understanding pain regulation.

Research and Clinical Implications

This study provides clear evidence for toddler's use of ER behaviours during vaccination. A challenge in the early childhood pain literature is solely considering a reduction in pain scores in relation to parent regulatory behaviours, without taking into consideration the child-led regulatory behaviours. Further, as Study 1 demonstrated that most of our understanding of emotion regulation comes from experimental procedures, researchers are encouraged to make

use of naturalistic procedures allowing for an ecologically valid understanding of high distress regulation. Another benefit of using a naturalistic procedure like vaccination is that it allows for a more natural understanding of the caregiver-child relationship. The emphasis on understanding emotion regulation within the social context and using a dyadic perspective is of significant benefit to its study.

Perhaps the most important clinical implication stemming from this dissertation is evidence that toddlers are beginning to regulate their own pain-related distress relative to infancy. Although these abilities are still developing, there is certainly evidence that behaviours such as disengagement of attention and physical self-soothing can reduce distress and should be encouraged by caregivers and clinicians alike. Given that early pain experiences influence future pain experiences (e.g., Hermann et al., 2006), building toddlers' confidence and skillset to manage their own pain may support their ability to manage pain later in childhood and into adulthood. Because this dissertation also shows the continued role of the parent, as well as particular behaviours that support or hinder regulation, continued efforts to support parents and provide psychoeducation and coaching remain important. Interventions, such as the ABCD's of pain management (Pillai Riddell et al., 2018), provide evidence-based strategies to parents for soothing their child during vaccination, however; interventions and coaching efforts may wish to also focus on taking a sensitive approach, teaching parents to observe and be with their child's feelings and attempts to self-soothe prior to engaging in soothing strategies to promote self-regulation. Further, a strength of the ABCD's of pain management is that the intervention also prioritizes parent self-regulation prior to supporting their child during vaccination. Future interventions for pain management should include parent emotion regulation strategies, as this

will likely have a positive impact on their ability to be with their child during the vaccination and provide sensitive support.

Further, this work adds to the increasing evidence that pre-needle distress remains one of the most important factors in children's immediate pain response and regulation. Even after accounting for child and parent behaviours, pre-needle distress predicted a higher immediate pain response and less recovery over time. This finding suggests that addressing child distress before the needle is important. Supporting both children and parents to self-regulate prior to the needle so that they are both as calm as possible is imperative.

Limitations and Directions for Future Research

The findings of the current dissertation are understood in the context of limitations. Given the need for parsimony for model fit, particular variables were not focused on in study analyses. For example, child sex was not included as a variable in analyses. This decision was supported by a general lack of sex differences found in seminal research on infant and early toddlerhood emotion regulation (e.g., Rothbart et al., 1992; Stifter & Braungart, 1995) as well as research included in the systematic review and meta-analysis that comprised Study 1 of this dissertation (e.g., Calkins & Johnson, 1998; Ekas et al., 2011; Wu & Feng, 2020). However, given that the current body of work utilized vaccination as a novel context for studying emotion regulation, future studies may consider analyzing sex as a possible factor. For Study 1, the focus on concurrent relationships did not allow a full understanding of the dynamic relationships between the ER behaviours and distress over time. Further, in taking a meta-analytic technique, some of the methodological decisions made (e.g., not including predictive relationships, handling multiple effect sizes, removing repeated populations, excluding samples that crossed two age group) limited the inclusion of several studies. While meta-analysis was considered the most

parsimonious approach to understanding the large literature on ER and distress, future syntheses may wish to use a narrative approach to supplement the current meta-analysis. A limitation of Study 2 and Study 3 is the moderate to high socioeconomic status of the sample, again precluding generalization to lower income families. However, while a noted strength of the sample is its cultural diversity, researchers are encouraged to continue working toward inclusive and diverse samples.

This work is also limited by the fact that it examined two time points in toddlerhood: 12 months and 18 months. Given that toddlerhood spans both the second and third year of life, more work is needed to understand the full spectrum and development of these behaviours throughout the latter half of toddlerhood and how these behaviours transition across childhood development. Another limitation is that although Study 3 assessed the relative contributions of parent and child-led regulatory behaviours, it did not assess how parent and child behaviours interact to promote or hinder pain-related distress regulation. Finally, while parent regulatory behaviours were a natural starting point, this study did not include a broad array of distress-promoting behaviours (beyond verbal reassurance) that are known to have a large impact on pain responses in early childhood and support the use of taking a sensitivity approach as discussed above (e.g., Badovinac et al., 2018; Pillai Riddell et al., 2018).

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Appendix A: Summary of Objectives and Results

STUDY 1: CHILD DISTRESS EXPRESSION AND REGULATION BEHAVIORS: A SYSTEMATIC REVIEW AND META-ANALYSIS

Objective: To provide a synthesis of the concurrent relationships between child distress expression and three unique clusters of child-led emotion regulation strategies (disengagement of attention, physical self-soothing, and parent-focused behaviours) in the first three years of life.

Results:

Year 1	Year 2	Year 3
Disengagement of Attention: r = -.28 (k = 7 articles)	Disengagement of Attention: r = -.44 (k = 11 articles)	Disengagement of Attention: r = -.30 (k = 5 articles)
Physical Self-Soothing: r = -.23 (k = 4 articles)	Physical Self-Soothing: r = .25 (k = 4 articles)	Physical Self-Self Soothing: r = -.10 (k = 4 articles)
Parent-Focused Behaviours: r = .00 (k = 11 articles)	Parent-Focused Behaviours: r = .20 (k = 7 articles)	Parent-Focused Behaviours: r = .11 (k = 4 articles)

STUDY 2: PREDICTING PAIN DURING VACCINATION IN TODDLERHOOD FROM Child Emotion Regulation Behaviours

Objectives/Research Question(s):

1. How do disengagement of attention (DoA), parent-focused strategies (PF), and physical self-soothing (SS) strategies relate to pain-related distress concurrently (i.e., within the same timepoint) and predictively (from one timepoint to the next) at 1-, 2-, and 3-minutes post-needle?
2. Do these relations change in magnitude according to child age (i.e., 12 versus 18 months)?

Results:

- **At both 12 and 18 months**
  - Pain-related distress at one minute predicted subsequent pain-related distress for all three models
  - All three ER behaviours were consistent across the vaccination appointment. Use of one ER behaviour one minute post-needle predicted subsequent use of the same behaviour the follow minute
- **12 Months**
  - Negative concurrent associations were found between physical self-soothing and pain-related distress at Minute 1 (r = -.28) and Minute 3 (r = -.19).
  - Parent-focused behaviours at Minute 1 was positively associated with pain-related distress at Minute 2 (β = .14). There was also a concurrent relationship between parent-focused behaviours and pain-related distress at Minute 3 (r = .20).
- **18 Months**
  - Pain-related distress at Minute 1 negatively predicted use of disengagement of attention at Minute 2 (β = -.23).
  - There was a negative concurrent association between physical self-soothing and pain-related distress at Minute 1 (r = -.20).

There was a positive concurrent association between parent-focused behaviours and pain-related distress at Minute 1 (r = .38). There was also a concurrent association found at Minute 2 (r = .16).

Study 3: RELATIVE CONTRIBUTIONS OF PARENT VS CHILD-LED EMOTION REGULATION BEHAVIOURS ON TODDLER PAIN

Objectives/Research Question(s):

1. What is the role of pre-needle distress on toddlers' pain-related distress regulation?
2. What are the relative contributions of parent and child-led regulatory behaviours on toddler pain-related distress regulation over and above pre-needle distress?
3. Does the timing of the parent and child-led regulatory behaviours (i.e., Minute 1 versus Minute 2) affect pain-related distress regulation?

Results:

	Step 3 R^2 (Minute 1 Model)	**Child Pre-Needle (Minute 1 Model)**	**Minute 1 Regulatory Behaviours (Parent and Child)**	**Step 3 R^2 (Minute 2 Model)**	**Child Pre-Needle (Minute 2 model)**	**Minute 2 Regulatory Behaviours (Parent and Child)**
12 months	**R^2** = .21	Pre-Needle Distress (Child): B = 0.17 B* = 0.27	Distraction (Parent): B = 1.62 B* = 0.15 Parent Focused Behaviour (Child): B = 1.99 B* = 0.28	**R^2**=.21	Pre-Needle Distress (Child): B = 0.19 B* = 0.29	Parent Focused Behaviour (Child): B = 1.37 B* = 0.23
18 months	**R^2 =** .08	*Pre-needle distress did not uniquely predict regulation*	*No significant unique behavioural predictors at Minute 1*	**R^2 =** .18	*Pre-needle distress did not uniquely predict regulation*	Distraction (Parent): B = 4.59 B* = 0.21 Rocking (Parent): B = -0.83 B* = -0.18 Verbal Reassurance (Parent): B = 1.71 B* = 0.16 Parent-Focused Behaviour (Child): B = 1.45 B* = 0.21

Appendix B: Systematic Search Strategies for Study 1

MEDLINE

Database(s): **Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily** 1946 to January 25, 2019
Search Strategy:

#	Searches	Results
1	emotions/ or expressed emotion/ or (emotion or emotions or emotional).tw,kf.	191679
2	stress, psychological/ or (stress or stresses).tw,kf.	751508
3	irritable mood/ or (irritable or irritability).tw,kf.	23335
4	affect/ or (affect or mood or moods or negative reactivity or sad or sadness).tw,kf.	690904
5	anger/ or (tantrum or tantrums or anger*).tw,kf.	17399
6	fear/ or fear*.tw,kf.	83195
7	frustration/ or frustrat*.tw,kf.	17500
8	pain/ or acute pain/ or (pain or pains or distress*).tw,kf.	711933
9	or/1-8	2236871
10	child, preschool/ or exp infant/ or pediatrics/	1527594
11	(infan* or newborn* or "new born*" or perinat* or neonat* or baby or baby* or babies or toddler* or prematur* or pre-term or preterm*).mp.	1563213
12	or/10-11	1987661
13	(regulation or regulatory).tw,kf.	1039331
14	9 and 12 and 13	6674

Embase

Database(s): **Embase Classic+Embase** 1947 to 2019 Week 04
Search Strategy:

#	Searches	Results
1	emotion/ or (emotion or emotions or emotional).tw,kw.	264584
2	mental stress/ or (stress or stresses).tw,kw.	954790
3	irritability/ or (irritable or irritability).tw,kw.	52347
4	affect/ or (affect or mood or moods or negative reactivity or sad or sadness).tw,kw.	885570
5	anger/ or (tantrum or tantrums or anger*).tw,kw.	26078
6	fear/ or fear*.tw,kw.	115395
7	frustration/ or frustrat*.tw,kw.	21682

8	pain/ or (pain or pains or distress*).tw,kw.	1096725
9	or/1-8	3062910
10	child, preschool/ or exp infant/ or pediatrics/	1395661
11	(infan* or newborn* or "new born*" or perinat* or neonat* or baby or baby* or babies or toddler* or prematur* or pre-term or preterm*).mp.	1716033
12	or/10-11	1999185
13	(regulation or regulatory).tw,kw.	1290962
14	9 and 12 and 13	8825

PsycINFO

Database(s): **PsycINFO** 1806 to January Week 3 2019
Search Strategy:

#	Searches	Results
1	emotions/ or (emotion or emotions or emotional).tw,id.	293849
2	psychological stress/ or (stress or stresses).tw,id.	213337
3	(irritable or irritability).tw,id.	8761
4	(affect or mood or moods or negative reactivity or sad or sadness).tw,id.	256250
5	anger/ or (tantrum or tantrums or anger*).tw,id.	30121
6	fear/ or fear*.tw,id.	78467
7	frustration/ or frustrat*.tw,id.	17706
8	pain/ or (pain or pains or distress*).tw,id.	152930
9	or/1-8	844282
10	preschool students/ or pediatrics/	33499
11	(infan* or newborn* or "new born*" or perinat* or neonat* or baby or baby* or babies or toddler* or prematur* or pre-term or preterm*).mp.	147940
12	or/10-11	178212
13	(regulation or regulatory).tw,id.	102997
14	9 and 12 and 13	3208

Appendix C: Information Package for Parents

We need you!

Our new study involves videotaping 12-, 18-, and 24-month-old children during their immunization appointments and completing parent questionnaires. Interested parents will also be given the opportunity to receive a free general developmental assessment at York University after the 24-month immunization. During both the immunizations and the assessment at York University, we would be attaching baby-friendly stickers to the children's and parent's shoulder blades and lower ribs so that equipment can capture their heart's reaction to pain and stress.

Why participate?

You will be helping us understand how kids learn to cope with stress. After every immunization, you will receive a DVD memento and a $10 coffee gift certificate. After participating in the York University assessment, you will receive **a developmental report** using gold standard child development tools. These reports contain valid measures of your child's cognitive, language, and motor development. Reports will help you optimize your child's learning potential.

Want to register?

Please email our Cohort Assessment Coordinator at **cohort@yorku.ca** or call at 416 736-2100, ext. 20177! Please call us before your child's 12-month immunization or let the receptionist know.

Ouch Lab
Opportunities to Understand Childhood Hurt Laboratory

YORK UNIVERSITÉ UNIVERSITY
redefine THE POSSIBLE.

Opportunities to Understand Childhood Hurt Laboratory

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Email: ouchlab@yorku.ca
Website: www.yorku.ca/ouchlab

Have a heart for infants in pain!

Be a Part of Our New Cohort!

Who are we?

The Opportunities to Understand Childhood Hurt Laboratory, is located at York University. It opened in Summer 2004. Since then, under the leadership of Dr. Pillai Riddell, the lab has produced innovative research with infants and how they experience pain, particularly in the context of caregiver interactions.

The old cohort

The O.U.C.H. Lab team has ambitiously followed 760 babies during immunizations over their first year of life in Toronto pediatric clinics.

When the same children were 4 to 6 years of age, approximately 200 families came to the OUCH lab at York University and received a full preschool psychoeducational assessment. This allowed the OUCH lab to better understand how early infant behaviours during immunization relate to their functioning later in childhood.

The new cohort

Now that we understand how babies experience pain in the first year of life, we would like to better understand how infants function during immunizations and in other settings in the second year of life!

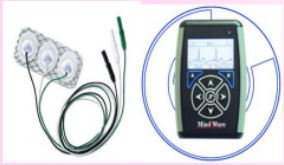
This will tell us how infant behaviours during distressing times relate to their functioning at the end of the second year of life, and what parent behaviours are important in optimizing this functioning.

The most exciting aspect of our study is that we have state-of-the-art technology that can tell how your child's heart is reacting to pain, since they cannot tell us themselves!

This 12-month old is having her heart beats counted!

What can this new technology do?

A wireless device can measure how fast your child's heart is beating through three baby-friendly stickers on your child's shoulder blade and lower ribs!



The wireless device tells us when your child is having strong emotional reactions by looking at how much your child's heart is beating! We use the technology to count parent heart beats too!

Appendix D : Consent Form

Research Consent Form

Title of Research Project:

Physiological and Behavioural Regulatory Processes in Recovering from Distress: Developmental and Contextual Dimensions in Infancy

Investigators:

Primary Investigator: Dr. Rebecca Pillai Riddell, CPsych, PhD

Room 2038 Sherman Health Sciences Research Centre, York University, (416) 736-2100 x20177

Project Co-Investigators:

Dr. Louis Schmidt, PhD, McMaster University

Dr. Karen Mathewson, PhD, McMaster University

Dr. Hartley Garfield

Dr. Dan Flanders, MD

Dr. Eitan Weinberg, MD

Purpose of the Research:

Infants undergo immunization injections, or 'shots' as part of routine medical care. Immunizations are given with a needle, which can be painful. We are doing this study to understand ways that we can help infants when they are experiencing pain. We are interested in how this pain behaviour and physical reaction to pain develops over the second year of life (12, 15, 18, and 24 months), and how it relates to developmental outcomes (cognitive, communication, physical, social/emotional, adaptive) at the end of the second year of life (24 months). We are also interested in how moms' well-being impacts the development of these outcomes. We have already videotaped 2000 immunizations over the first year of life and look forward to learning more about the second year of life.

Description of the Research:

You will be asked to participate at 4 appointments over the course of the year. At your child's 12-month, 15-month, 18-month, and 24-month appointment:

1. We will be videotaping you and your child during their immunizations.
2. Parents will be asked to fill out questionnaires to help us better understand the parent and their child (10-15 minutes) over the phone within one week that is convenient for the parent.
3. We will be connecting your child to equipment that measures their heart rate and stress. Heart rate will be monitored using baby-friendly stickers put on their shoulder blade and lower ribs.
4. Parents will be connected to equipment that measures their heart rate and stress. Heart rate will be monitored using the same baby-friendly stickers put on below their shoulder blade and lower ribs.
5. We will conduct a chart review of your child's health record at your pediatrician's clinic

Videotapes will be viewed later by research assistants that do not know the identity of the children or parents to score their behaviours. Videotaping infants is not part of standard care, however, it does not interfere with the procedures being conducted, and is the usual way we measure pain in research studies.

I agree for my child and myself to be videotaped by research team: ☐ AGREE ☐ DISAGREE

I agree for my child's medical chart to be reviewed by research team: ☐ AGREE ☐ DISAGREE

In addition, I agree or consent for this immunization tape(s)/photograph(s) to be used for:

☐ Other studies on the same topic

☐ Teaching and demonstration at York University

☐ Teaching and demonstration at meetings outside York University

☐ Not to be used for anything else.

Risks and Potential Discomforts or Inconvenience:

The baby-friendly stickers used to measure heart rate and emotional arousal may cause minor discomfort to you or your child's skin. In pilot testing, no children were distressed by removal of the baby-friendly stickers. Additionally, filling out the well-being questionnaires will take about 20 minutes of your time outside of the clinic appointment.

Physiological data will be analyzed later by research assistants that do not know the identity of the parents or children. Putting baby friendly stickers on parents and infants to measure their physical reaction is not part of standard care, however, it does not interfere with the procedures being conducted, and is a common way we measure pain in research studies.

Potential Benefits:

You will receive an electronic copy of your child's immunization, a $10 gift certificate after each immunization, and a $5 gift certificate after each phone interview.

Potential Benefits to Society:

In the future, society may benefit from the results of this study because it will teach us about how regulating from distress during infancy relates to later child development.

Alternatives to Participation:

Participation in research is voluntary. You can choose not to participate or you may withdraw at any time without affecting your child's medical care.

Confidentiality:

We will respect your privacy. No information about who you are will be given to anyone or be published without your permission, unless the law requires us to do this. For example, the law requires Dr. Pillai Riddell to give information about you if a child has been abused, if you have an illness that could spread to others, if you or someone else talks seriously about suicide (killing themselves), or if the court orders us to give them the study papers. You will be contacted if any of these issues have arisen. York University Research Monitors may see your health record to check on the study to ensure we are being compliant. By signing this consent form, you agree to let these people look at your records. We will give you a copy of this research consent form for your files.

The data produced from this study will be stored in a secure, locked location. Only members of the research team (and maybe those individuals described above) will have access to the data. This could include external research team members. Following completion of the research study, the data will be kept as long as required and then destroyed as required by York University policy. Published study results will not reveal your identity. The supervisors of this project are located at York University.

Participation:

It is your choice to take part in this study. You can stop at any time. The care you get at your doctor's office will not be affected in any way whether or not you take part in this study.

New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this new information. And we will ask you again if you still want to be in the study.

During this study we may create new tests, new medicines, or other things that may be worth some money. Although we may make money from these findings, we cannot give you any of this money now or in the future because you took part in this study.

Sponsorship:

This study is paid for through funds allocated to Dr. Pillai Riddell from the Natural Sciences and Engineering Research Council.

Conflict of Interest:

The research team members have no conflict of interest to declare.

Consent:

By signing this form, I agree that:

1) You have explained this study to me. You have answered all my questions.
2) You have explained the possible harms and benefits (if any) of this study.
3) I know what I could do instead of taking part in this study. I understand that I have the right not to take part in the study and the right to stop at any time. My decision about taking part in the study will not affect my health care.
4) I am free now, and in the future, to ask questions about the study.
5) I have been told that my medical records will be kept private except as described to me.
6) I understand that no information about who I am will be given to anyone or be published without first asking my permission.
7) I have read and understood pages 1-4 of this form. I agree, or consent, to take part in this study.

_____	_____
Printed Name of Parent	Parent's signature, date and time
_____	_____
Printed Name of person who explained consent	Signature, date and time
_____	_____
Printed Witness' name (if the subject or legal representative does not read English)	Witness' signature & date

If you have any questions about this study, please call Dr. Rebecca Pillai Riddell at the number on the first page of the consent form. You can also contact the Project Coordinator at ouchlab@yorku.ca. This research has been reviewed by the Human Participants Review Committee in accordance with York's Senate Policy on Research Ethics (York University). This study conforms to the standards of the Canadian Tri-Council Research Ethics guidelines. If you have any questions about this process or about your rights as a participant in the study, please contact Ms. Alison Collins-Mrakas, Manager, Research Ethics, Office of Research Ethics, 5th Floor, York Research Tower, York University (telephone 416-736-5914 or e-mail at acollins@yorku.ca).

Contact Information (RA must check legibility):

Parent Name: _____

Child's Name: _____

Preferred Telephone Number for scheduling appointments (with parent who spends most time with child): _____

Alternative Telephone Number: _____

Best Days and Time to Contact Parent (Please give an approximate 1-2 hour window e.g. 3 to 7pm)?

Monday to Friday_____

Saturday and Sunday_____

Home Mailing Address (To mail Tim Card after phone interview):

_____

_____

_____

_____

Email Address:

_____

Please print clearly!

Future Contact Specifications:

The OUCH lab is often conducting new studies where parents and their children can get involved. We would like to ask you to participate but you can always choose not to participate and ask us to stop contacting you. We would never contact you more than once or twice a year for a new study.

I consent for researchers to contact me via mail, email or phone regarding *(check which statement applies)*:

☐ No further contact (aside from contact directly related to participation in this current study).

☐ Further contact for results of this study.

☐ Further contact for results of this study and opportunities for participation in new future studies.

Video Use in the Media:

- ☐ I consent for my videos to be used for media coverage of the study, which may include print articles, news videos, or publications on websites. We will never release you or your child's identity and will notify you in advance if your video is chosen to be used and which media outlet the video will be using your video. You will always be given the opportunity to withdraw consent.

Appendix E : Participant Information Sheet at 12 Months

PARTICIPANT INFORMATION SHEET – 12 MONTHS

PART 1: PARENT QUESTIONS – *These questions refer to the parent who will be most responsible for **soothing** child during needle.* (*If possible, all questions to be asked by Clinic RA)*

1. **Your birth date** (dd/mm/yyyy)_____

2. **Your relationship to Infant:** Mother Father Other _____

3. **Who is currently the primary caregiver of your infant?**
   Mother Father Equally between Mother & Father Other _____

4. **Time since last fed**: _____Hours _____Minutes

5. **Time since last napped**: _____Hours _____Minutes

6. **Number of Family Members living in your household**: Adults _____ Children_____

7. **For each child in your family please list their age and sex**.
   Age of infant brought in today: _____(months) **Male** **Female**

   Birth date of infant (dd/mm/yyyy): _____

   Ages/genders of your other children:
   Age: _____ Male Female
   Age: _____ Male Female
   Age: _____ Male Female
   Age: _____ Male Female

8. **Which caregivers are present at this immunization?** (circle one number):
   1. Mom only
   2. Dad only
   3. Mom and Dad
   4. Nanny
   5. Grandparents
   6. Parent(s) and Nanny
   7. Parent(s) and Grandparent(s)
   8. Other _____
   9. Parent(s) and Other _____

b) How many other children are present, if any? (do not include child getting the needle) ____

9. Since your child's birth, have you taken any infant parenting classes/workshops? **Yes No**
   If <u>yes</u>, how many? _____

10. Since your child's birth, have you read any infant parenting books/watched videos? **Yes No**
    If <u>yes</u>, how many?_____

11. Since your child's birth, approximately how often do you visit parenting websites?

Never	**Once a day**	**Once a week**	**Once every few weeks**	**Once a month**	**Once a year**

12. Since your child's birth, have you received any guidance from an organization or professional to help with parenting your children (e.g. health unit nurse, midwife, Early Years Centre, Healthy Babies Healthy Children, Hincks-Dellcrest, Jessie's Place)? **Yes No**
    If <u>yes</u>, from how many organizations/professionals? _____

13. Has your child been given EMLA or TYLENOL prior to the appointment?:
    EMLA TYLENOL NONE

14. A) Since your child's birth, has your infant been separated from his/her primary caregiver for longer than 24 hours (e.g. infant hospitalization, parent hospitalization, Children's Aid involvement, parent travel, family emergency)?
    Circle: **YES** **NO**

    ***If you circled YES*:**
    Approximately, how many separations longer than 24 hours have occurred? _____

    How long was the longest period of separation _____(days)

15. **Child's Medical History**

Please check next to any illness or condition that your child has had since birth. When you check an item, also note the approximate date of the illness or your child's age at illness.

Illness or condition	Date(s) or age(s)	Illness or condition	Date(s) or age(s)
□Measles	_____	□Visual problems	_____
□German Measles	_____	□Fainting spells	_____

□Mumps	_____	□Loss of consciousness	_____
		(please specify cause)	
□Chicken Pox	_____	□Lead Poisoning	_____
□Whooping Cough	_____	□Ear Problems	_____
□Diphtheria	_____	□TB	_____
□Scarlet Fever	_____	□Bone or joint disease	_____
□Meningitis	_____	□Anemia	_____
□Pneumonia	_____	□Jaundice/Hepatitis	_____
□Encephalitis	_____	□Cancer	_____
□High fever (>41°C or 105.8°F)	_____	□Heart disease	_____
□Seizure	_____	□Asthma	_____
□Allergy	_____	□Bleeding problems	_____
□Hay Fever	_____	□Eczema or hives	_____
□Injuries to head	_____	□Paralysis	_____
□Broken bones	_____	□Stomach pumped	_____
□Hospitalization	_____	□Thrush	_____
(please specify reason)			
□Operations	_____	□Circumcision	_____
(please specify)			
□Otitis media	_____	□Other	_____

16. Since birth, has your child been diagnosed with any other chronic illnesses not listed above?

Yes No

If <u>yes</u>, which chronic illness and at what age were they diagnosed? _____

_____

17. Since birth, has your child taken any medication long-term (i.e. longer than 2 weeks)?

Yes No

If yes, please list: _____
_____

PART 2: PREGNANCY HISTORY – If child is adopted please check box: ☐

(If so, please fill as much of the following information as you are aware of, which regards to the child's birth mother, her pregnancy, and delivery.)

1. During pregnancy, were you on medication? **Yes☐ No☐**
   If yes, what kind? _____
2. During pregnancy, did you smoke? **Yes☐ No☐**
   If yes, how many cigarettes each day? _____
3. During pregnancy, did you drink alcoholic beverages? **Yes☐ No☐**
   If yes, what did you drink? _____

   Approximately how much alcohol was consumed each day? _____
4. During pregnancy, did you use drugs? **Yes☐ No☐**
   a. If yes, what kind?_____
5. Were there any complications during pregnancy (excessive vomiting, excessive staining/blood loss, threatened miscarriage, infections, toxemia, fainting, dizziness, etc.)
   _____
   _____
6. Duration of pregnancy (weeks):_____
7. Duration of labour (total hours):_____
8. Were there indications of fetal distress during labour or during birth? **Yes☐ No☐**
9. Were forceps used during delivery? **Yes☐ No☐**
10. Was delivery normal? **Yes☐ No☐**
11. Was a Caesarean section performed? **Yes☐ No☐**
12. Was delivery breach? **Yes☐ No☐**
13. Was delivery induced? **Yes☐ No☐**
    If yes on any of the above, for what reason? _____
14. Was your child premature? **Yes☐ No☐**
    a. If so, by how many weeks?_____
15. What was your child's birth weight? (in pounds)_____
16. Were there any birth defects or complications? **Yes☐ No☐**
    a. If yes, please describe: _____
       _____

PART 3: PRIMARY CAREGIVER AND SPOUSE BACKGROUNDS –

(If possible, all questions to be asked by Clinic RA)

1. **Your Highest Education (circle one number):**
   1. Graduate School/Professional Training
   2. University graduate (4 years college)
   3. Partial university (at least 1 year)
   4. Trade School/Community College
   5. High School Graduate
   6. Some high school
   7. Junior high school graduate
   8. Less than 7th grade

   a) **Your Current Occupation** _____

2. **If applicable, your Spouse's Highest Education (circle one number):**
   1. Graduate School/Professional Training
   2. University graduate (4 years college)
   3. Partial university (at least 1 year)
   4. Trade School/Community College
   5. High School Graduate
   6. Some high school
   7. Junior high school graduate
   8. Less than 7th grade

   a) **If applicable, Your Spouse's Current Occupation** _____

3. **What language is spoken most in your home (only put two languages if they are equally spoken)** _____

4. **What country was the primary caregiver born in:**_____

   a) If applicable, what country was your spouse born in:_____

5. **What country was the primary caregiver's parents born in:**_____

   a) If applicable, what country were your spouse's parents born in: _____

6. **How long has the primary caregiver lived in Canada:** _____

   a) If applicable, how long has your spouse lived in Canada: _____

7. **On a scale of 0 to 10, where 0 is "Not at All" and 10 is "Completely", how much do you feel your way of life reflects mainstream North American/Canadian culture?** _____

a) If applicable, how much do you feel your spouse's way of life reflects mainstream North American/Canadian culture: _____

8. **What is your heritage culture (**It may be the culture of your birth, the culture in which you have been raised, or another culture that forms part of your background. Pick the culture that has influenced you *most*. If you do not feel that you have been influenced by any other culture, please try to identify a culture that may have had an impact on previous generations of your family.**): _____**

a) If applicable, what is your spouse's heritage culture: _____

9. **On a scale of 0 to 10, where 0 is "Not at All" and 10 is "Completely", how much do you feel your way of life reflects your heritage culture? _____**

a) If applicable, how much do you feel your spouse's way of life reflects his/her heritage culture: _____

PART 4: PARENT RATINGS (PRE-IMMUNIZATION)

Pre-Immunization **Self-Worry** Rating

*On a scale from 0 to 10, how worried about the needle pain are **YOU**, right now, before the needle, where 0 is "no worry at all" and 10 is "the most worry possible"?*

_____

PART 5: PARENT RATINGS (POST-IMMUNIZATION)

Post-Immunization **Self-Worry** Rating

*On a scale from 0 to 10, how worried about the needle pain are **YOU**, right now, after the needle, where 0 is "no worry at all" and 10 is "the most worry possible"?*

To be done approximately 5 minutes after last needle!

_____

Post-Immunization **Child Pain** Rating

On a scale from 0 to 10, how much pain do you think your child experienced from the needles they just received, where 0 is "no pain at all" and 10 is "the worst pain possible"?

_____

PART 6: VACCINES GIVEN BY IMMUNIZATION NEEDLE

RA to fill out (ask nurse or doctor for vaccine name and trade name)

		Disease it Protects Against
☐	Prevnar	_____
☐	Twinrix	
☐	Bexsero	
☐	Menjugate	
☐	Pediacel	
☐	Menveo	
☐	Nimenrix	
☐	Other (List Name)	
☐	Pneumococcal-13	
☐	NeisVac-C (Menj C)	
☐	MMR	
☐	DPTP/H	
☐	HAB (Hep A / B)	
☐	Varicella	

How many needles total: _____

1. Vaccines in needle #1:_____

2. Vaccines in needle #2:_____

3. Vaccines in needle #3:

Appendix F: Participant Information Sheet at 18 months

PARTICIPANT INFORMATION SHEET – 18 MONTHS

PART 1: PARENT QUESTIONS – *These questions refer to the parent who will be most responsible for **soothing** child during needle.* (*If possible, all questions to be asked by Clinic RA)*

1. **Were you the primary soother at the 12- or 15-month appointment?** Yes No

2. **Your birth date** (dd/mm/yyyy)_____

3. **Your relationship to Infant:** Mother Father Other _____

4. **Who is currently the primary caregiver of your infant?**
   Mother Father Equally between Mother & Father Other _____

5. **Time since last fed**: _____Hours _____Minutes

6. **Time since last napped**: _____Hours _____Minutes

7. **Number of Family Members living in your household**: Adults _____ Children_____

8. **For each child in your family please list their age and sex**.
   Age of infant brought in today: _____(months) **Male** **Female**

   Birth date of infant (dd/mm/yyyy): _____

   Ages/genders of your other children:
   Age: _____ Male Female
   Age: _____ Male Female
   Age: _____ Male Female
   Age: _____ Male Female

9. **Which caregivers are present at this immunization?** (circle one number):
   10. Mom only
   11. Dad only
   12. Mom and Dad
   13. Nanny
   14. Grandparents
   15. Parent(s) and Nanny
   16. Parent(s) and Grandparent(s)
   17. Other _____
   18. Parent(s) and Other _____

b) How many other children are present, if any? (do not include child getting the needle)
____

10. Since we last asked, have you taken any infant parenting classes/workshops? **Yes No**
If <u>yes</u>, how many? _____

11. Since we last asked, have you read any infant parenting books/watched videos? **Yes No**
If <u>yes</u>, how many? _____

12. Since we last asked, approximately how often do you visit parenting websites?

Never	**Once a day**	**Once a week**	**Once every few weeks**	**Once a month**	**Once a year**

13. Since we last asked, have you received any guidance from an organization or professional to help with parenting your children (e.g. health unit nurse, midwife, Early Years Centre, Healthy Babies Healthy Children, Hincks-Dellcrest, Jessie's Place)? **Yes No**
If <u>yes</u>, from how many organizations/professionals? _____

14. Has your child been given EMLA or TYLENOL prior to the appointment?:
EMLA TYLENOL NONE

15. Since we last asked, has your infant been separated from his/her primary caregiver for longer than 24 hours (e.g. infant hospitalization, parent hospitalization, Children's Aid involvement, parent travel, family emergency)?
Circle: **YES** **NO**

***If you circled YES*:**
Approximately, how many separations longer than 24 hours have occurred? _____

How long was the longest period of separation _____(days)

16. **Child's Medical History**

Please check next to any illness or condition that your child has had **<u>since we last asked</u>**. When you check an item, also note the approximate date of the illness or your child's age at illness.

Illness or condition	Date(s) or age(s)	Illness or condition	Date(s) or age(s)

□Measles	_____	□Visual problems	_____
□German Measles	_____	□Fainting spells	_____
□Mumps	_____	□Loss of consciousness	_____
		(please specify cause)	
□Chicken Pox	_____	□Lead Poisoning	_____
□Whooping Cough	_____	□Ear Problems	_____
□Diphtheria	_____	□TB	_____
□Scarlet Fever	_____	□Bone or joint disease	_____
□Meningitis	_____	□Anemia	_____
□Pneumonia	_____	□Jaundice/Hepatitis	_____
□Encephalitis	_____	□Cancer	_____
□High fever (>41°C or 105.8°F)	_____	□Heart disease	_____
□Seizure	_____	□Asthma	_____
□Allergy	_____	□Bleeding problems	_____
□Hay Fever	_____	□Eczema or hives	_____
□Injuries to head	_____	□Paralysis	_____
□Broken bones	_____	□Stomach pumped	_____
□Hospitalization	_____	□Thrush	_____
(please specify reason)			
□Operations	_____	□Circumcision	_____
(please specify)			
□Otitis media	_____	□Other	_____

14. Since we last asked, has your child been diagnosed with any other chronic illnesses not listed above?
Yes **No**

If yes, which chronic illness and at what age were they diagnosed? _____
_____

15. Since we last asked, has your child taken any medication long-term (i.e. longer than 2 weeks)?

Yes No

If yes, please list: _____
_____

PART 2: PREGNANCY HISTORY – If child is adopted please check box: ☐

(If so, please fill as much of the following information as you are aware of, which regards to the child's birth mother, her pregnancy, and delivery.)

Has the primary caregiver answered these questions at 12 months? Yes No

If **yes**, please proceed to Part 3 questions.

If **no**, please proceed to ask questions below.

17. During pregnancy, were you on medication? **Yes☐ No☐**
    If yes, what kind? _____
18. During pregnancy, did you smoke? **Yes☐ No☐**
    If yes, how many cigarettes each day? _____
19. During pregnancy, did you drink alcoholic beverages? **Yes☐ No☐**
    If yes, what did you drink? _____

    Approximately how much alcohol was consumed each day? _____
20. During pregnancy, did you use drugs? **Yes☐ No☐**
    a. If yes, what kind?_____
21. Were there any complications during pregnancy (excessive vomiting, excessive staining/blood loss, threatened miscarriage, infections, toxemia, fainting, dizziness, etc.)
    _____
    _____
22. Duration of pregnancy (weeks):_____
23. Duration of labour (total hours):_____
24. Were there indications of fetal distress during labour or during birth? **Yes☐ No☐**
25. Were forceps used during delivery? **Yes☐ No☐**
26. Was delivery normal? **Yes☐ No☐**
27. Was a Caesarean section performed? **Yes☐ No☐**
28. Was delivery breach? **Yes☐ No☐**

29. Was delivery induced? **Yes□ No□**
    If yes on any of the above, for what reason? _____

30. Was your child premature? **Yes□ No□**
    a. If so, by how many weeks?_____
31. What was your child's birth weight? (in pounds)_____
32. Were there any birth defects or complications? **Yes□ No□**
    a. If yes, please describe: _____
    _____

PART 3: PRIMARY CAREGIVER BACKGROUND – *These questions are to be asked only if this is the first time the parent has participated in the study. (If possible, all questions to be asked by Clinic RA)*

Has the primary caregiver answered these questions at 12 months? Yes No

If **yes**, please proceed to Part 4 questions. If **no**, please proceed to ask questions below.

10. **Your Highest Education (circle one number):**
    1. Graduate School/Professional Training
    2. University graduate (4 years college)
    3. Partial university (at least 1 year)
    4. Trade School/Community College
    5. High School Graduate
    6. Some high school
    7. Junior high school graduate
    8. Less than 7th grade

    a) Your Current Occupation _____

11. **If applicable, your Spouse's Highest Education (circle one number):**
    1. Graduate School/Professional Training
    2. University graduate (4 years college)
    3. Partial university (at least 1 year)
    4. Trade School/Community College
    5. High School Graduate
    6. Some high school
    7. Junior high school graduate
    8. Less than 7th grade

    a) If applicable, Your Spouse's Current Occupation _____

12. **What language is spoken most in your home (only put two languages if they are equally spoken)** _____

13. **What country was the primary caregiver born in:_____**

    a) If applicable, what country was your spouse born in:_____

14. What country was the primary caregiver's parents born in:_____

a) If applicable, what country were your spouse's parents born in: _____

15. How long has the primary caregiver lived in Canada: _____

a) If applicable, how long has your spouse lived in Canada: _____

16. On a scale of 0 to 10, where 0 is "Not at All" and 10 is "Completely", how much do you feel your way of life reflects mainstream North American/Canadian culture? _____

a) If applicable, how much do you feel your spouse's way of life reflects mainstream North American/Canadian culture: _____

17. What is your heritage culture (It may be the culture of your birth, the culture in which you have been raised, or another culture that forms part of your background. Pick the culture that has influenced you *most*. If you do not feel that you have been influenced by any other culture, please try to identify a culture that may have had an impact on previous generations of your family.**): _____**

a) If applicable, what is your spouse's heritage culture: _____

18. On a scale of 0 to 10, where 0 is "Not at All" and 10 is "Completely", how much do you feel your way of life reflects your heritage culture? _____

a) If applicable, how much do you feel your spouse's way of life reflects his/her heritage culture: _____

PART 4: PARENT RATINGS (PRE-IMMUNIZATION)

Pre-Immunization **Self-Worry** Rating

*On a scale from 0 to 10, how worried about the needle pain are **YOU**, right now, before the needle, where 0 is "no worry at all" and 10 is "the most worry possible"?*

_____

PART 5: PARENT RATINGS (POST-IMMUNIZATION)

To be done approximately 5 minutes after last needle!

Post-Immunization **Self-Worry** Rating

*On a scale from 0 to 10, how worried about the needle pain are **YOU**, right now, after the needle, where 0 is "no worry at all" and 10 is "the most worry possible"?*

_____

Post-Immunization **Child Pain** Rating

On a scale from 0 to 10, how much pain do you think your child experienced from the needles they just received, where 0 is "no pain at all" and 10 is "the worst pain possible"?

_____

PART 6: VACCINES GIVEN BY IMMUNIZATION NEEDLE

RA to fill out (ask nurse or doctor for vaccine name and trade name)

		Disease it Protects Against
☐	Prevnar	_____
☐	Twinrix	_____
☐	Bexsero	_____
☐	Menjugate	_____
☐	Pediacel	_____
☐	Menveo	_____
☐	Nimenrix	_____
☐	Other (List Name)	_____
☐	Pneumococcal-13	_____
☐	NeisVac-C	_____
☐	MMR	_____

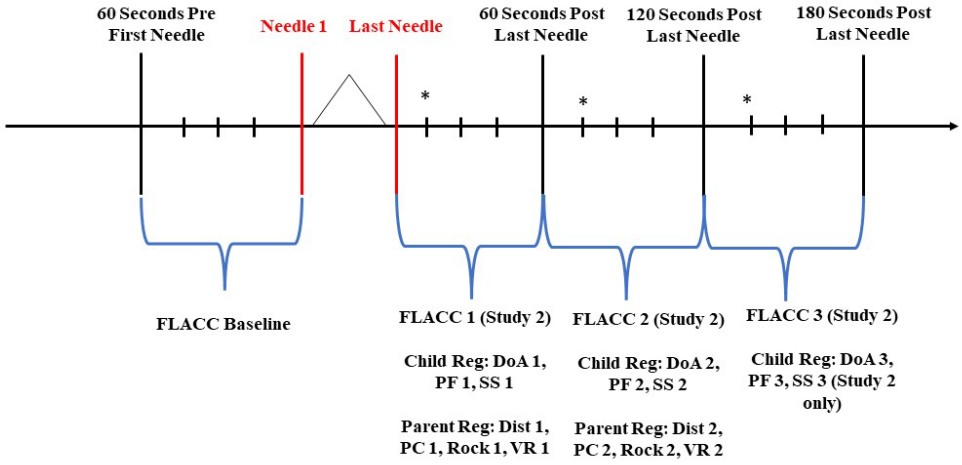
How many needles total: _____

1. Vaccines in needle #1:_____

2. Vaccines in needle #2:_____

3. Vaccines in needle #3:

Appendix G: 12- and 18-Month Vaccination and Measures Timeline



Note. FLACC = Faces, Legs, Arms, Cry, Consolability Scale (measure of pain-related distress); Child Reg = Child-led regulatory (ER) behaviours; Parent Reg = Parent-led regulatory behaviours; DoA = Disengagement of attention; PF = Parent-focused behaviours; SS = Physical self soothing; Dist = Distraction; PC = Physical Comfort; Rock = Rocking; VR = Verbal reassurance.

* For Study 3, FLACC 1 was the first 15s in the Minute 1 period, FLACC 2 was the first 15s in the Minute 2 period, and FLACC 3 was the first 15s in the Minute 3 period.