ABSTRACT

Although previous research has examined the relationships between caregiver proximal soothing and infant pain, there is a paucity of work taking infant age into account, despite the steep developmental trajectory that occurs across the infancy period. Moreover, no studies have differentially examined the relationships between caregiver proximal soothing and initial infant pain reactivity and pain regulation. This study examined how much variance in pain reactivity and pain regulation was accounted for by caregiver proximal soothing at four routine immunizations (2, 4, 6, 12 months) across the first year of life, controlling for pre-needle distress. One latent growth model was replicated at each of the four infant ages, using a sample of 760 caregiver-infant dyads followed longitudinally. Controlling for pre-needle infant distress, caregiver proximal soothing accounted for little to no variance in infant pain reactivity or regulation at all four ages. Pre-needle distress and pain reactivity accounted for the largest amount of variance in pain regulation, with this increasing after 2-months. It was concluded that, within each immunization appointment across the first year of life, earlier infant pain behavior is a stronger predictor of subsequent infant pain behavior than caregiver proximal soothing. Given the longer-term benefits that have been demonstrated for proximal soothing during distressing contexts, caregivers are still encouraged to use proximal soothing during infant immunizations.

A Cross-sectional Examination of the Relationships between Caregiver Proximal Soothing and Infant Pain over the First Year of Life

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A Cross-sectional Examination of the Relationships between Caregiver Proximal Soothing and Infant Pain over the First Year of Life

1. Introduction

The archaic view that infants are relatively insensitive to pain has been refuted numerous times over the past three decades. It is now known that pain in early infancy can have lasting consequences [29,32,57-59]. Recognizing the crucial importance of the caregiver to the infant in pain [45], research is beginning to focus on caregiver pain management behaviors during infant immunizations.

Whereas distraction [8,17,20,24] has been associated with decreased pain-related distress and verbal reassurance [8,16,51,55] has been associated with increased pain-related distress, findings pertaining to proximal soothing (e.g., rocking or hugging the infant) have been less clear.

Although several studies have found that proximal soothing is either associated with, or causes, decreased pain-related distress [8,13,25,26], one study found that proximal soothing was only effective when combined with other caregiving behaviors [34], and another study found that proximal soothing was related to prolonged distress regulation [6]. However, this latter study measured distress regulation and proximal soothing concurrently (opposed to the former studies which were all either randomized controlled trials or used lag sequential analysis). Thus, it can be speculated that the timing of proximal soothing might play a role in the direction (positive/negative) of the relationships between proximal soothing and infant pain.

Interestingly, despite the steep developmental trajectory that occurs across the infant's first year [43-45], including that of caregiver-infant interactions [11,14], little research on

caregiver proximal soothing has taken infant age into account. Accordingly, researchers are behooved to make more fine-grained comparisons within this unique period of development.

The differentiation between pain *reactivity* and pain *regulation* as qualitatively different phases of an infant's pain experience has recently been brought into the field [5]. Whereas *reactivity* has been defined as differences in infant initial arousal [5], *regulation* has been defined as differences in infant response modulation [52]. The Development of Infant Actions in Pain Responding (DIAPR) Model [43,47] highlights the importance of differentiating between these two pain phases, given they are hypothesized to be subject to different biopsychosocial influences [30]. Whereas pain reactivity is viewed as more a function of genetic/biological sensory thresholds and previous pain experiences, pain regulation is viewed as a function of broader contextual factors, such as caregiver pain management behaviors [44]. Moreover, the DIAPR model postulates the relationships between caregiver pain management behaviors and infant pain-related distress will differ according to the infant's age, becoming stronger over time as relational patterns within the dyad become more stable [11]. No research on caregiver proximal soothing to date has differentially examined pain reactivity compared to pain regulation within a single study.

The goal of this study was to conduct cross-sectional analyses to examine the relationships between proximal soothing and pain reactivity/regulation at four immunizations (2, 4, 6, 12 months) across the first year of life. Two research questions were posed: (1) at 2, 4, 6, and 12 months, what are the relationships between caregiver proximal soothing and infant pain reactivity/regulation? and (2) do these relationships change over age? It was hypothesized that: (1) caregiver proximal soothing would be more strongly related to pain regulation than to pain

reactivity and (2) the relationships between caregiver proximal soothing and infant pain responding would increase over age.

2. Methods

2.1. Study population

The data from the present study are a part of an ongoing Canadian longitudinal study (The OUCH cohort) that is following caregivers and infants during four immunizations over the first year of life (2, 4, 6, and 12 months of age) and beyond. Caregiver–infant dyads were recruited from three pediatric clinics in the Greater Toronto Area. Infants were recruited beginning at 2 months of age and followed during their 2-, 4-, 6-, and 12-month routine immunization appointments. No previously published [45,51] or planned/submitted manuscripts from this cohort have hypotheses or analyses that overlap with the current study. At the time of the present analysis, the infant waves had been completed and the total sample size is 760. Of these 760 dyads, 256 were followed up 4 times (2, 4, 6, and 12 months of age), 263 were followed up 3 times (2, 6, 12 months or 4, 6, 12 months, or 2, 4, 6 months), 175 were followed up twice (all 2 time point permutations were possible) and 66 were followed up once (2 or 4 or 6 months). To maximize information used in this study's analyses, direct maximum likelihood estimation [3] was used so that all cases, including those without data for all 4 time points, contributed to model estimation.

Caregivers able to speak and read English, whose infants had no suspected developmental delays or impairments, chronic illnesses, and had never been admitted to a neonatal intensive care unit were eligible to participate in the study. Table 1 presents demographic variables for the entire sample. The mean age of caregivers was 33.46 (SD = 5.04). At the 2-, 4-, 6-, and 12-month immunization appointments, infants received an average of 1.92

needles (2 months [mean = 1.95, SD = .27], 4 months [mean = 1.95, SD = .29], 6 months [mean = 1.90, SD = .41], 12 months [mean = 1.91, SD = .47]. 37.6% of caregivers identified their heritage culture as European, 17.7 % as Asian, 11.2% as Canadian/American, 7.5% as Jewish, 5% as African/Middle Eastern, 3.8% as South/Latin American, and 17.2 % as Other.

2.2. Procedure

Research Ethics Boards at both York University and the Hospital for Sick Children have approved the following protocol. Details of the procedure are published elsewhere [45]. Only a brief summary will be provided below. Caregivers and healthy, typically developing infants were recruited during immunization appointments and, depending on when they were recruited, followed for a maximum of 3 subsequent immunization appointments (4, 6, and 12 months). Video recording occurred from the moment the infant entered the examination room up until five minutes after the immunization or when the caregiver and infant had left the clinic room. The current withdrawal rate is 3%, with the most common reason given that caregivers no longer wanted to participate due to lack of interest and second most common reason being that the family was relocating.

2.3. Apparatus

To capture caregiver pain management behaviors and infant pain behaviors, two Canon HD Video Camcorders - HV20 were used. One camera was mounted on a tripod and fitted with a wide-angle lens to capture the caregiver pain management behaviors. The second camera uses a handheld tripod and a research assistant recorded a close-up image of the infant's face in order to capture infant facial expression.

2.4. Measures

2.4.1. Parent demographic information

Caregivers were asked to complete a short demographic questionnaire that asked about their age, relation to the infant, education level, self-reported heritage culture, as well as infant age, gender, and medical conditions since the last time they participated in the study.

For an integrated figure that depicts the timing of all behavioral coding measures (i.e. pain and proximal soothing), see Figure 1. Descriptions of the coding measures follow.

2.4.2. Infant pain-related distress

Infant pain-related distress was measured using the Neonatal Facial Coding System (NFCS) [27], a well-validated assessment tool for acute pain that was designed to measure infants' facial responses to painful stimuli. Based on previous studies [42,49], seven indicators (brow bulge, eye squeeze, naso-labial furrow, open lips, vertical stretch mouth, horizontal stretch mouth, taut tongue) were utilized to create a facial pain score. Each of the NFCS facial actions was coded as "0" (not present) or "1" (present) [28] for every second within a 10-second phase. The facial pain score was obtained for four specific 10-second phases (*Pain Baseline, Pain Needle, Pain 1 Minute, and Pain 2 Minutes)* by calculating the proportion of time the NFCS facial actions were present. *Pain Baseline* was coded during the 10-second phase immediately prior to the first needle, *Pain Needle* was coded during the 10-second phase immediately following the last needle. *Pain 1 Minute* was coded during the first 10-second phase one minute after the last needle. *Pain 2 Minutes* was coded during the first 10-second phase two minutes after the last needle. Scores ranged from 0 to 1 and indicate the proportion of time during the 10-second phase in which the above facial actions were present. Higher scores indicated greater facial pain expression. *Pain Needle, Pain 1 Minute and Pain 2 Minutes* were the variables used to form the main outcomes in our analysis (*Pain Reactivity* and *Pain Regulation*; details in Data Analysis section).

Trained NFCS coders, blind to the study hypotheses, coded the data. Inter-rater reliability was calculated among every permutation of eight coders (e.g., coder A with B, B with C, A with D, etc.). Reliability was high with percentage agreement scores for all 7 pain facial actions ranging from .85 to .97.

2.4.3. Caregiver proximal soothing behavior

Caregiver proximal soothing behavior was coded using the Measure of Adult and Infant Soothing and Distress (MAISD) [16]. The MAISD is a reliable and valid behavioral observation scale that was developed to evaluate the behaviors of infants, parents, and health care professionals during painful pediatric medical procedures [16]. For the purposes of the present research, only caregiver behaviors that subsumed caregiver proximal soothing were utilized. As such, two of the eight MAISD caregiver behaviors were included in the analyses. These behaviors were rocking and physical comfort. Physical comfort was coded when any physical (i.e., nonverbal) behavior was conducted in an attempt to comfort the infant. This included: rubbing, massaging, patting, hugging, or kissing the infant. Rocking was coded when the caregiver swayed, rocked, or bounced the infant.

Rocking and physical comfort were both coded as either present (1) or absent (0) for five-second epochs during the following three phases: (1) the 1 minute prior to the first needle, (2) the 1 minute period following the last needle and (3) the 2 minute period following the last needle. Index scores representing the proportion of time each behavior was present in the total number of epochs available for coding was calculated by adding the total number of five-second epochs during which each behavior was displayed in a phase and dividing by the total number of codable epochs in the phase. The index score for each behavior (rocking and physical comfort) thus ranged from 0 to 1, with higher scores reflecting greater frequency of behavior. To obtain a

composite score of caregiver proximal soothing for each of the three phases, the index scores for rocking and physical comfort for each phase, respectively, were summed. As such, the three composite scores of caregiver proximal soothing were as follows: (1) *Proximal Soothing 1 Minute Pre*; (2) *Proximal Soothing 1 Minute Post*; (3) *Proximal Soothing 2 Minutes Post.*

Seven trained MAISD coders, blind to the study hypotheses, coded the data. Inter-rater reliability on rocking and physical comfort was calculated among every permutation of coders (e.g. coder A with B, B with C, A with D, etc.). The intraclass correlations ranged from .91 to .95 for rocking and from .75 to .88 for physical comfort.

2.5. Data analysis

Structural equation modeling (SEM) techniques were employed to examine the relationships between caregiver proximal soothing and infant pain-related distress at the four immunization appointments. When testing hypotheses pertaining to antecedent-consequence relationships, such as those in the present study, SEM and path analysis are considered the optimal methods of choice [9,38]. Unlike path analysis, however, SEM allows for the assessment of both measured (e.g., *Proximal Soothing 1 minute Pre)* as well as latent variables. Latent variables are constructs that are either challenging or impossible to measure directly because the construct includes multiple dimensions [61].

As previously noted, infant *reactivity* has been defined as differences in initial arousal [5] whereas infant *regulation* has been defined as differences in response modulation [52]. In line with these definitions, each of our models used the *Pain Needle*, *Pain 1 Minute,* and *Pain 2 Minutes* observed variables to form two latent variables: the infant pain intercept factor (set to represent infant initial arousal levels or, in other words, ***Pain Reactivity***) and the infant pain slope factor (representative of ***Pain Regulation*** or, in other words, the infant's rate of response

modulation from *Pain Needle* to *Pain 2 minutes)*. Using slope to represent pain-related distress regulation is consistent with recent research in the field [5, 37] although a more traditional measure of pain regulation that has been used in the past is a summation of pain intensity scores over time [49,50].

As pain scores were expected to become lower over time, negative values for the slope were expected. The more negative the slope value (i.e. further from 0) the steeper the lowering of the pain scores. Figure 2 provides an overview of the model that will be replicated for each age separately.

Within-appointment initial reactions post-immunization needle (*Pain Reactivity),* as well as trajectories of rates of change in post-needle pain-related distress (*Pain Regulation*) were examined as a function of caregiver proximal soothing (controlling for pre-needle pain-related distress [*Pain Baseline*]) using latent growth modeling (LGM) within the SEM framework [10].

Statistical analyses were conducted using four replicated models (see Figure 2), one for each infant age (2, 4, 6, and 12 months). To form the *Pain Reactivity* latent variable, all factor loadings were set to 1.0. Prior to forming the *Pain Regulation* latent variable, an examination of the mean values for *Pain Needle*, *Pain 1 Minute*, and *Pain 2 Minutes* indicated that the overall growth trajectory (pain slope factor) for all 4 ages was not linear. As such, freed-loading models were estimated for all 4 models. Specifically, whereas the *Pain Needle* slope factor loadings were all fixed to .00 and the *Pain 2 minutes* factor loadings were all set to 1.00, all *Pain 1 Minute* slope factor loadings were freely estimated (rather than fixed). This was done in order to reflect linear growth [10]. Factor loadings for all four models are shown in Figure 2. Four predictor variables were used to predict the intercept (*Pain Reactivity*) and slope (*Pain Regulation)* latent variables for all four models. One of the predictor variables was the *Pain Baseline* measure and

the other three predictor variables were the proximal soothing composites for each of the three phases previously described: *Proximal Soothing 1 Minute Pre*; *Proximal Soothing 1 Minute Post*; *Proximal Soothing 2 Minutes Post.* The *Pain Baseline* measure was included as a predictor variable in the models because previous research has shown that behavioral distress prior to a painful procedure is related to an infant's subsequent pain responding to that procedure [1,31]. Given the longitudinal nature of the three proximal soothing predictor variables within each model, the residual error terms for these variables were allowed to covary. These residual error terms are omitted from all figures for graphic simplicity.

All data analysis was conducted using Amos Version 19.0 statistical software [4]. To maximize information used in the analyses, direct maximum likelihood estimation [3] was used so that all cases, including those with incomplete data, contributed to model estimation. Goodness of fit for all models was evaluated using the chi-square significance test $p > .05$, the Comparative Fit Index (CFI) [7] and the Root Mean Square Error of Approximation (RMSEA) [54]. CFI values of 0.95 or higher and RMSEA values of 0.06 or less indicate that a model provides a good fit for the data [33]. CFI values of 0.90 or above and RMSEA values of .08 or below are considered acceptable [39].

2.5.1. Testing of hypotheses

As aforementioned, one model (Figure 2) was replicated at the four ages (Figures 3-6). A synthesis of the results over the four models tested hypotheses, as outlined below.

The R^2 value for the *Pain Reactivity (*or *Pain Regulation)* latent variable was examined for all four models. Subsequently, each of the four models were re-run, however, the proximal soothing predictor variables were removed (leaving only *Pain Baseline* as a predictor of *Pain Reactivity* and *Pain Baseline* and *Pain Reactivity* as predictors of *Pain Regulation*). The new R^2

value generated by the altered model was subtracted from the original R^2 value to yield an "R^2 difference score". This difference score indicated the amount of unique variance in *Pain Reactivity* (or *Pain Regulation*) accounted for by preceding proximal soothing. To test the first hypothesis, that proximal soothing would account for greater variance in pain regulation than pain reactivity, the respective magnitudes of the *Pain Reactivity* "R^2 difference scores" and *Pain Regulation* "R^2 difference scores" were examined for each of the four models. To test the second hypothesis, that the amount of variance in pain reactivity and regulation would increase over age, the respective magnitudes of the *Pain Reactivity* (or *Pain Regulation*) "R^2 difference scores" were examined for each of the four models.

3. Results

Four separate latent growth models were estimated (See Figures 3–6) corresponding to each of the four infant immunization appointments (2, 4, 6, 12 months). Standardized estimates of significant pathways are reported in the figures. All standardized and unstandardized estimates are reported in accompanying tables (see Tables 2-5). Table 6 presents the overall means and standard deviations of all model variables and Tables 7, 8, 9, and 10 present the standard bivariate correlations among all the variables in models 1, 2, 3, and 4, respectively

3.1. Latent growth models

3.1.1. Model 1: Examining the relationships between caregiver proximal soothing and infant pain at the 2 month immunization appointment

Although the χ^2 test of overall model fit was significant ($\chi^2 = 28.70$, $p < .001$), the combination of other fit indices suggested that Model 1 fit the data well (CFI = .92; RMSEA = .06). Figure 3 provides the corresponding model diagram (along with significant standardized

parameter estimates) and Table 2 presents all standardized and unstandardized parameter estimates.

The set of predictors in Model 1 accounted for 2% of the variance (R^2) in the Pain Intercept factor (*Reactivity*) and 45% of the variance (R^2) in the Pain Slope factor (*Regulation*). When the proximal soothing predictor variables were removed from the model, 1% of the variance in the Pain Intercept factor (*Reactivity*) and 41% of the variance in the Pain Slope factor (*Regulation*) was accounted for by the remaining predictor variables (see Table 11).

None of the pathways between the temporal phases of proximal soothing and the Pain Intercept factor (*Reactivity)* were significant. In regards to the pathways between specific temporal phases of proximal soothing and the Pain Slope factor (*Regulation*), only *Proximal Soothing 2 Mins Post* was positively related to *Regulation* ($B = .11$, $p < .05$), such that greater proximal soothing two minutes following the final needle was related to slower rates of regulation.

The Pain Intercept factor (*Reactivity*) negatively predicted the Pain Slope factor (*Regulation*) ($B = -.65$, $p < .05$), such that greater infant pain reactivity predicted steeper rates of regulation (more negative slope values). *Pain Baseline* positively predicted both the Pain Intercept factor (*Reactivity*) ($B = .13$, $p < .05$) and the Pain Slope factor (*Regulation*) ($B = .19$, $p < .001$), such that higher behavioral distress prior to the first needle predicted greater reactivity and slower rates of regulation (less negative slope values).

3.1.2. Model 2: Examining the relationships between caregiver proximal soothing and infant pain at the 4 month immunization appointment

Although the χ^2 test of overall model fit was significant ($\chi^2 = 28.34$, $p < .001$), the combination of other fit indices suggested that Model 2 fit the data adequately (CFI = .94; RMSEA = .08).

Figure 4 provides the corresponding model diagram (along with significant standardized parameter estimates) and Table 3 presents all standardized and unstandardized parameter estimates.

The set of predictors in Model 2 accounted for 3% of the variance (R^2) in the Pain Intercept factor (*Reactivity*) and 76% of the variance (R^2) in the Pain Slope factor *(Regulation*). When the proximal soothing predictor variables were removed from the model, 3% of the variance in the Pain Intercept factor (*Reactivity*) and 74% of the variance in the Pain Slope factor (*Regulation*) was accounted for by the remaining predictor variables (see Table 11).

In terms of the pathways between specific temporal phases of proximal soothing and the Pain Intercept factor (*Reactivity),Reactivity* predicted both measures of subsequent proximal soothing [*Proximal Soothing 1 Min Post* (B = .23, p < .001); *Proximal Soothing 2 Mins Post* (B = .19, p < .001)]. In regards to the pathways between specific temporal phases of proximal soothing and the Pain Slope factor (*Regulation*), none of the pathways were significantly related.

The Pain Intercept factor (*Reactivity*) negatively predicted the Pain Slope factor (*Regulation*) (B = -.88, p < .001), such that greater infant pain reactivity predicted steeper rates of regulation. *Pain Baseline* positively predicted both the Pain Intercept factor (*Reactivity*) (B = .17, p < .001) and the Pain Slope factor (*Regulation*) (B = .33, p < .001), such that higher behavioral distress prior to the first needle predicted greater reactivity and slower rates of regulation.

3.1.3 Model 3: Examining the relationships between caregiver proximal soothing and infant pain at the 6 month immunization appointment

Although the χ^2 test of overall model fit was significant (χ^2 = 25.51, p < .001), the combination of other fit indices suggested that Model 3 fit the data well (CFI = .96; RMSEA =

.05). Figure 5 provides the corresponding model diagram (along with significant standardized parameter estimates) and Table 4 presents all standardized and unstandardized parameter estimates.

The set of predictors in Model 3 accounted for 6% of the variance (R^2) in the Pain Intercept factor (*Reactivity*) and 79% of the variance (R^2) in the Pain Slope factor (*Regulation*). When the proximal soothing predictor variables were removed from the model, these variances remained unchanged (see Table 11).

In terms of the pathways between specific temporal phases of proximal soothing and the Pain Intercept factor (*Reactivity), Reactivity* predicted both measures of subsequent proximal soothing [*Proximal Soothing 1 Min Post* (B = .26, p < .001); *Proximal Soothing 2 Mins Post* (B = .21, p < .001)]. In regards to the pathways between specific temporal phases of proximal soothing and the Pain Slope factor (*Regulation*), none of the pathways were significantly related.

The Pain Intercept factor (*Reactivity*) negatively predicted the Pain Slope factor (*Regulation*) (B = -.92, p < .001), such that greater infant pain reactivity predicted steeper rates of regulation. *Pain Baseline* positively predicted both the Pain Intercept factor (*Reactivity*) (B = .24, p < .001) and the Pain Slope factor (*Regulation*) (B = .21, p < .001), such that higher behavioral distress prior to the first needle predicted greater reactivity and slower rates of regulation.

3.1.4. Model 4: Examining the relationships between caregiver proximal soothing and infant pain at the 12 month immunization appointment

Although the χ^2 test of overall model fit was significant (χ^2 = 45.20, p < .001), the combination of other fit indices suggested that Model 4 fit the data adequately (CFI = .92; RMSEA = .08). Figure 6 provides the corresponding model diagram (along with significant

standardized parameter estimates) and Table 5 presents all standardized and unstandardized parameter estimates.

The set of predictors in Model 4 accounted for 3% of the variance (R^2) in the Pain Intercept factor (*Reactivity*) and 71% of the variance (R^2) in the Pain Slope factor (*Regulation*). When the proximal soothing predictor variables were removed from the model, 2% of the variance in the Pain Intercept factor (*Reactivity*) and 70% of the variance in the Pain Slope factor (*Regulation*) was accounted for by the remaining predictor variables (see Table 11).

In terms of the pathways between specific temporal phases of proximal soothing and the Pain Intercept factor (*Reactivity),Reactivity* predicted both measures of subsequent proximal soothing [*Proximal Soothing 1 Min Post* (B = .14, p < .001); *Proximal Soothing 2 Mins Post* (B = .13, p < .01)]. In regards to the pathways between specific temporal phases of proximal soothing (both pre- and post-needle) and the Pain Slope factor (*Regulation*), *Proximal Soothing Pre* positively predicted *Regulation* (B = .08, p < .05), such that greater proximal soothing prior to the first needle predicted slower rates of regulation and *Proximal Soothing 2 Mins Post* was significantly related to *Regulation* (B = .09, p < .05), such that greater proximal soothing two minutes following the final needle was related to slower rates of regulation.

The Pain Intercept factor (*Reactivity)* negatively predicted the Pain Slope factor (*Regulation*) (B = -.84, p < .001), such that greater infant pain reactivity predicted steeper rates of regulation. *Pain Baseline* positively predicted both the Pain Intercept factor (*Reactivity*) (B = .17, p < .001) and the Pain Slope factor (*Regulation*) (B = .19, p < .001), such that higher behavioral distress prior to the first needle predicted greater reactivity and slower rates of regulation.

4. Discussion

To our knowledge, this was the first study to examine the relationships between caregiver proximal soothing and infant pain over the entire first year of life, as well as the first to differentially examine the relationships between caregiver proximal soothing and infant pain according to pain reactivity versus pain regulation.

For both pain reactivity and pain regulation, proximal soothing only accounted for 4% or less of the variance at all four ages, with preceding pain measurements from within the appointment predicting the majority of the variance. These findings partially conflict with the other study in the literature [5] that found moderate relationships between infant pain and caregiver proximal soothing. However, unlike in the aforementioned study, the present study controlled for infant behavioral distress prior to the injections as well as immediate reactivity post injections. As such, it appears possible that the moderate relationship observed between infant pain and caregiver proximal soothing might have only been found because these two variables were likely related to additional unmeasured variables: pre-needle distress and initial pain reactivity, which the present study, as well as other studies [1,31], have shown are related to pain reactivity and pain regulation, respectively.

Speaking further to the interrelationships between infant pain behaviors, the amount of variance in pain regulation accounted for by preceding pain measurements from within an appointment was dramatic. Whereas pain reactivity variance was accounted for by pre-needle distress to a small extent (between 2 and 6% across ages), pain regulation was largely accounted for by both pre-needle distress and immediate pain reactivity (between 45 and 79%), generally stabilizing to these maximal levels by 4 months of age. Interestingly, it was found that the

higher the pain reactivity, the steeper the rate of regulation. This may be a function of regression toward the mean or could reflect that infants who react strongly to a known painful stimulus regulate more quickly. Infant mental health research suggests that expressing distress commensurate with a stimulus, be that stimulus separation, pain, or otherwise, is reflective of more optimal development [2,11].

Our hypothesis that proximal soothing would account for greater variance in pain regulation than pain reactivity was somewhat supported for 2 and 4 month olds, but not for 6 and 12 month olds. At 2 and 4 months, proximal soothing accounted for greater variance in pain regulation than reactivity. However, at 6 and 12 months, proximal soothing accounted for equal amounts of variance in these two measures. It is important to underscore that the magnitude of the differences between the reactivity and regulation variances at 2 and 4 months were small.

Our hypothesis that the relationships between proximal soothing and infant pain responding would become stronger over age was not supported. Consistently across the four ages, proximal soothing accounted for very little variance in both pain reactivity and pain regulation. In short, while the development of caregiver-infant interactions over the first year of life is considered to undergo rapid and extensive changes [11,14,18,46], these changes do not appear to apply to caregiver-infant interactions relating to proximal soothing and infant pain (in either the reactivity or regulatory phase) within immunizations.

Upon examination of the specific pathways in our models, several interesting findings were noted. First, no relationships were found between pre-needle proximal soothing and infant pain reactivity. however, one important caveat should be offered in relation to this finding. Specifically, given that this study, as well as two other studies [1,31], found that infant behavioral distress prior to an injection predicts greater pain reactivity, it is possible that

proximal soothing pre-needle might be beneficial for certain subsets of infants. More specifically, if pre-needle proximal soothing calms infants who are behaviourally distressed prior to an injection, this, in turn, could indirectly reduce pain reactivity for infants who otherwise may have been behaviorally distressed prior to the injection. This possibility assumes that pre-injection distress is a causal risk factor for increased post-injection pain and distress, a possibility that has yet to be established and systematically examined.

At 12 months, it was found that proximal soothing prior to the first injection predicted (albeit weakly) slower rates of regulation. One possible explanation for this finding could be that, because previous infant pain regulation behavior has been linked to subsequent infant pain regulation behavior across ages [45], caregivers whose infants have shown a history of having difficulty regulating (i.e. at 2, 4, and 6 months) are engaging in proximal soothing proactively at the one year milestone, thus explaining the relationship observed with difficulty regulating at 12 months.

It was also found that higher levels of pain reactivity predicted greater subsequent proximal soothing for the 4, 6, and 12 month infants, suggesting that, at these ages, caregivers are "tuning in" to their infants' distress signals and responding in manners contingent to these distress cues. Contingent responsivity has been linked to optimal future developmental outcomes for infants (i.e. cognitive and social-emotional development, formation of a secure attachment relationship) [2,21,36]. Interestingly, this relationship was not observed at the 2 month appointment and might be partially attributable to the fact that parents are not yet attuned to (or are overwhelmed by) their infant's first example of immunization distress.

4.2. Conclusion

The findings of this study provide support for the DIAPR model assertion of the need to differentiate between infant pain reactivity and regulation. Moreover, findings support that, within immunization appointments at all ages over the first year of life, pain reactivity and especially pain regulation are more a function of infant factors than caregiver proximal soothing, which appears to play a minimal role. Thus, two clinical implications are offered. First, parents are encouraged to use a multitude of pain management strategies with infants to lower pain-related distress during immunizations over the first year of life. Second, given the established longer-term benefits that have been demonstrated for maintaining proximity during distressing contexts (i.e., promoting a secure attachment relationship, enhanced social-emotional and cognitive development) [6,36], caregivers are encouraged to engage in proximal soothing during infant immunizations, despite the minimal discerned effect during infancy. It would also be important to examine whether coaching on proximal soothing from healthcare professionals could increase its effectiveness.

4.3. Limitations

Despite the large sample size, generalizability will be affected by the self-selection bias associated with being a caregiver who agrees to be followed through the first year of immunizations as well as by the high education level of the sample.

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Figure Captions:

Figure 1. Visual Depiction of the Timing of Data Measurement
(consistent over the four ages)

Figure 2. Model Framework and Factor Loadings used for all four Analyses

Figure 3. Model 1: Examining the relationships between caregiver proximal soothing and infant pain at the 2 month immunization appointment. Solid highlighted paths and the corresponding standardized parameter estimates are significant at $p < 0.05$.

Figure 4. Model 2: Examining the relationships between caregiver proximal soothing and infant pain at the 4 month immunization appointment. Solid highlighted paths and the corresponding standardized parameter estimates are significant at $p < 0.05$.

Figure 5. Model 3: Examining the relationships between caregiver proximal soothing and infant pain at the 6 month immunization appointment. Solid highlighted paths and the corresponding standardized parameter estimates are significant at $p < 0.05$.

Figure 6. Model 4: Examining the relationships between caregiver proximal soothing and infant pain at the 12 month immunization appointment. Solid highlighted paths and the corresponding standardized parameter estimates are significant at $p < 0.05$.

***Summary**

25 word summary:

In a longitudinal cohort of 760 caregiver-infant dyads, earlier infant pain behaviour was a stronger predictor of later infant pain responding than caregiver proximal soothing.

Figure1

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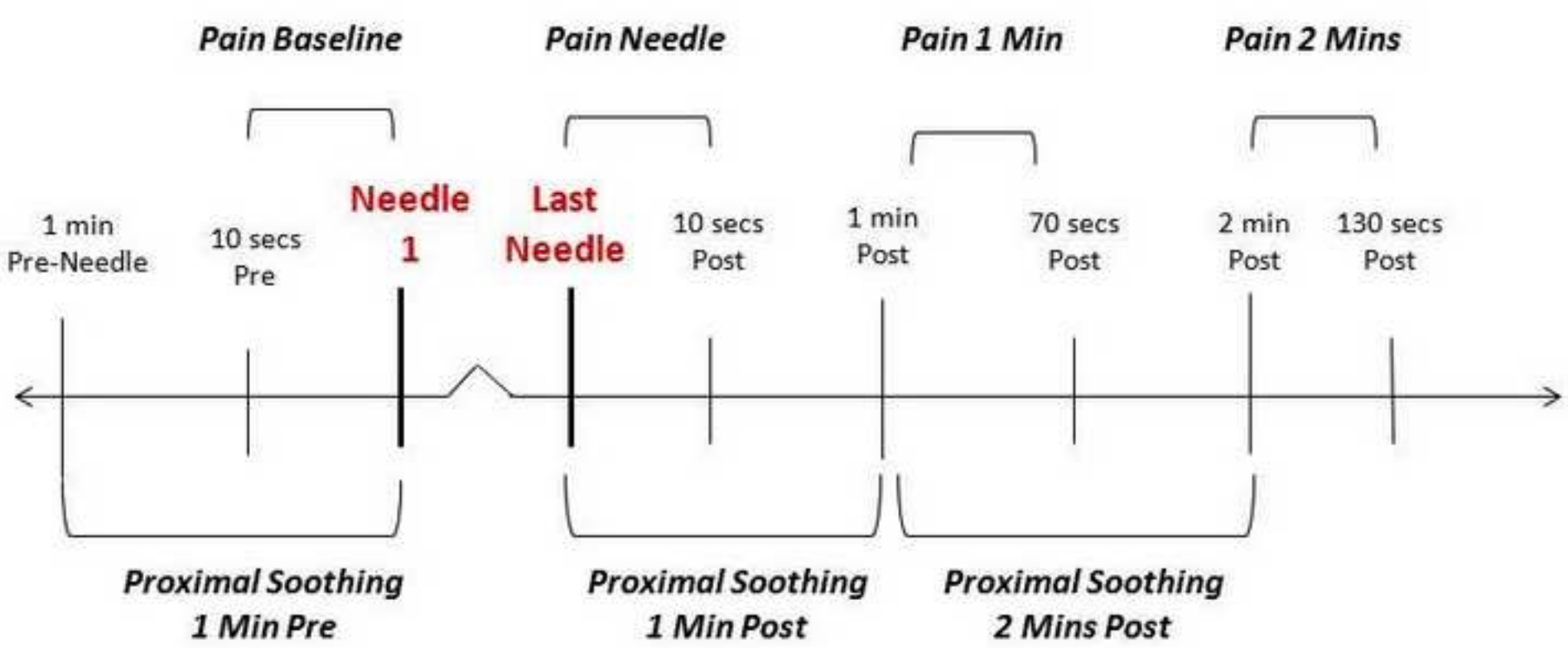

Figure2

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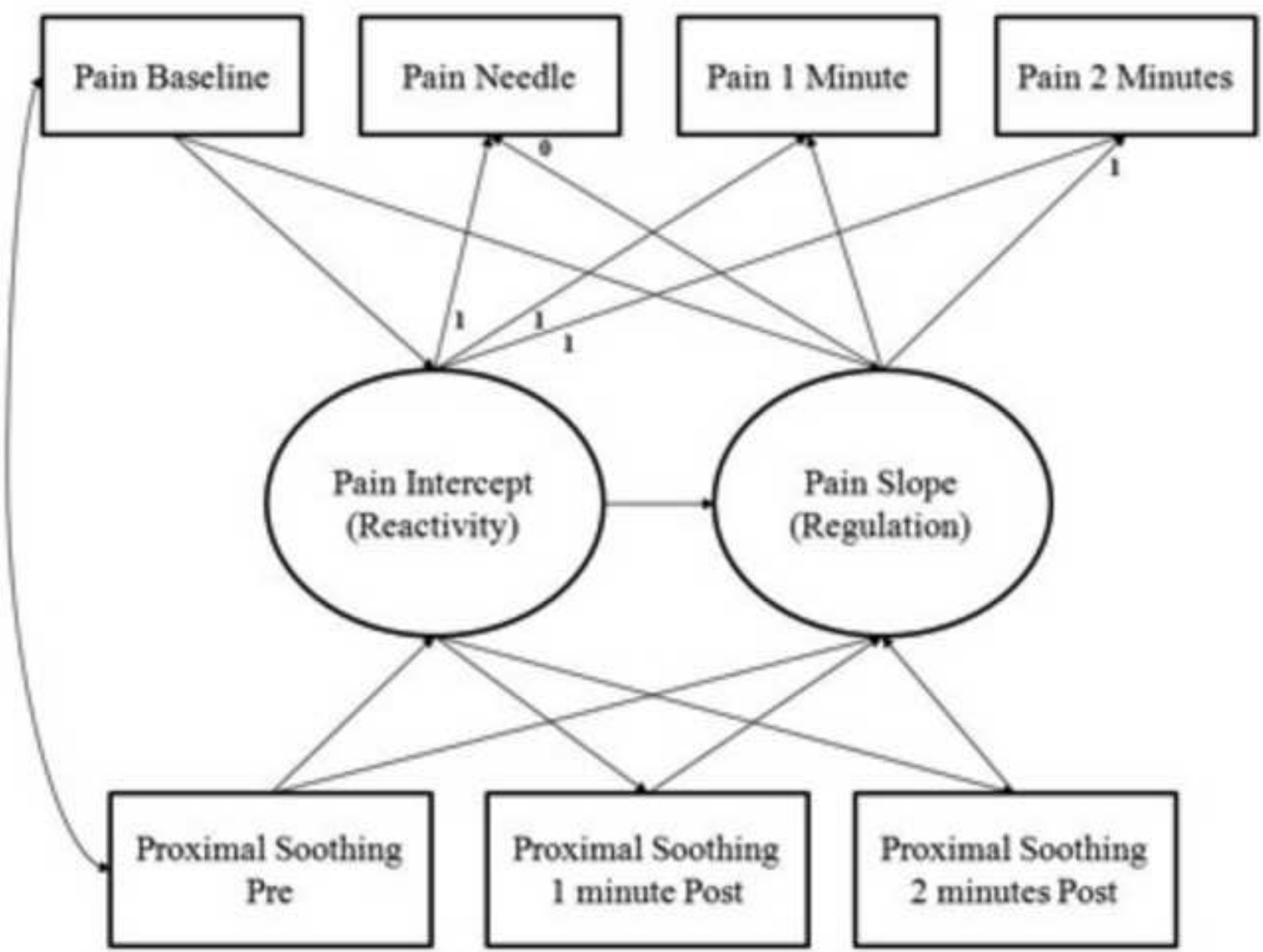

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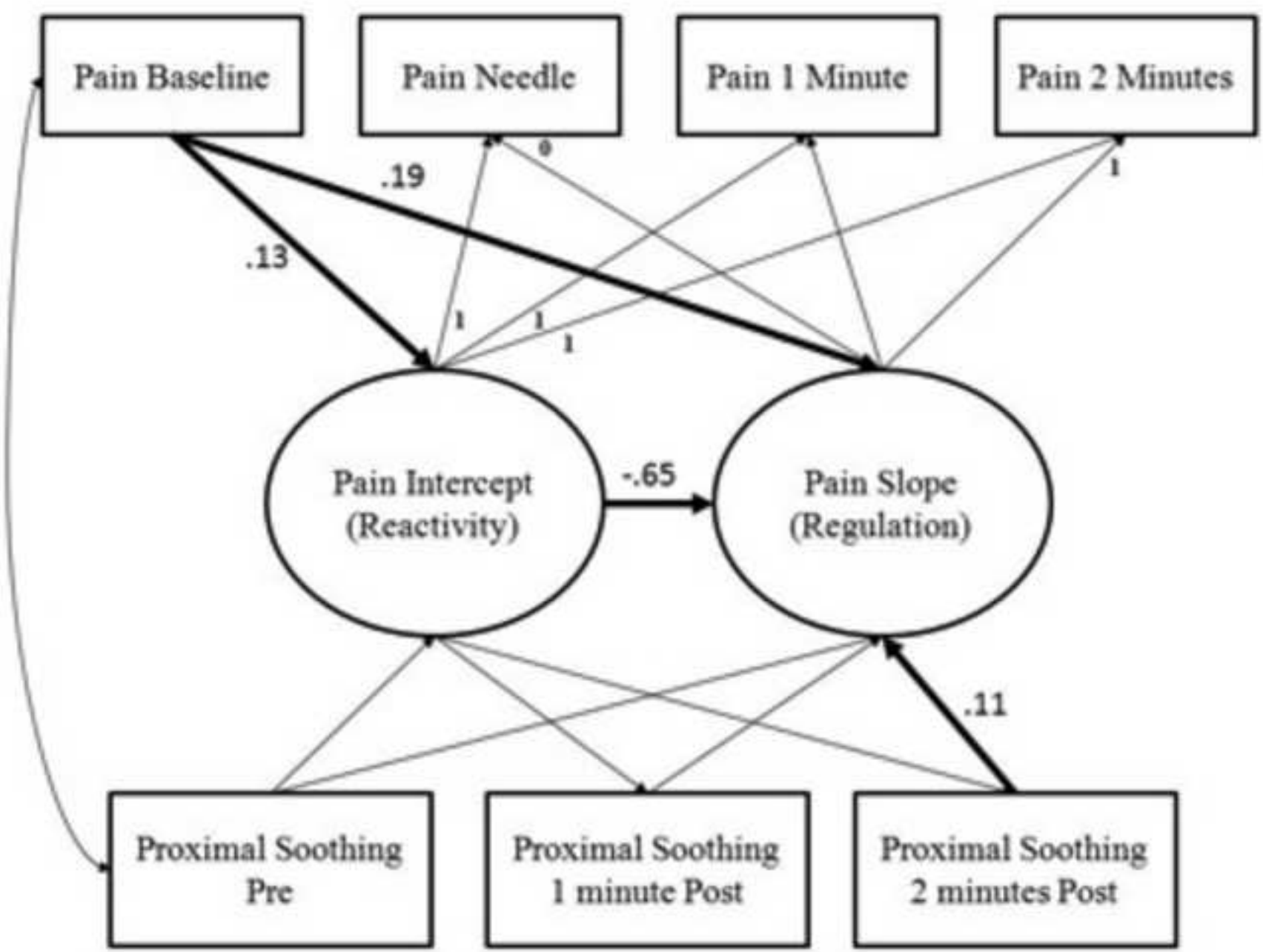

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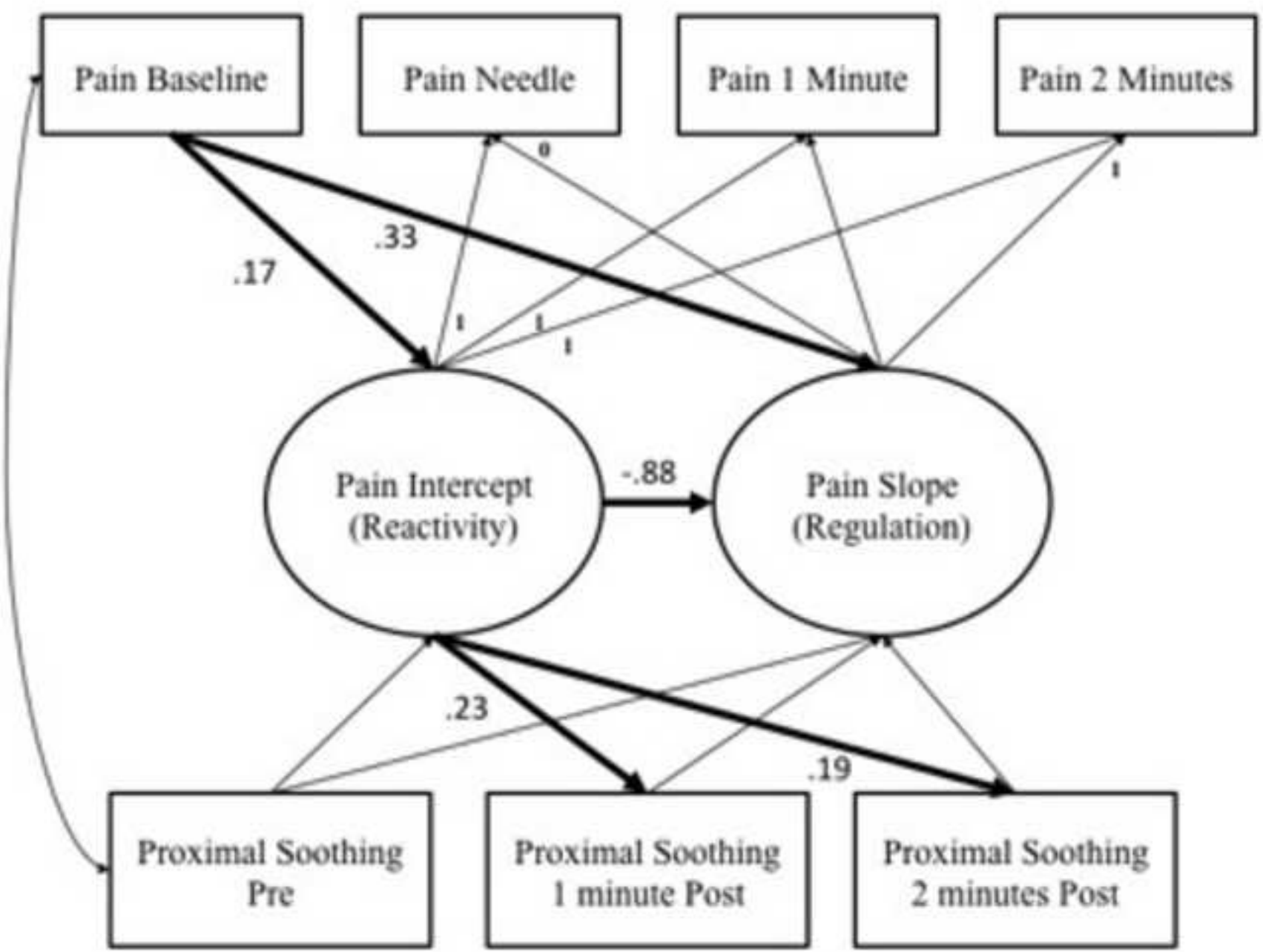

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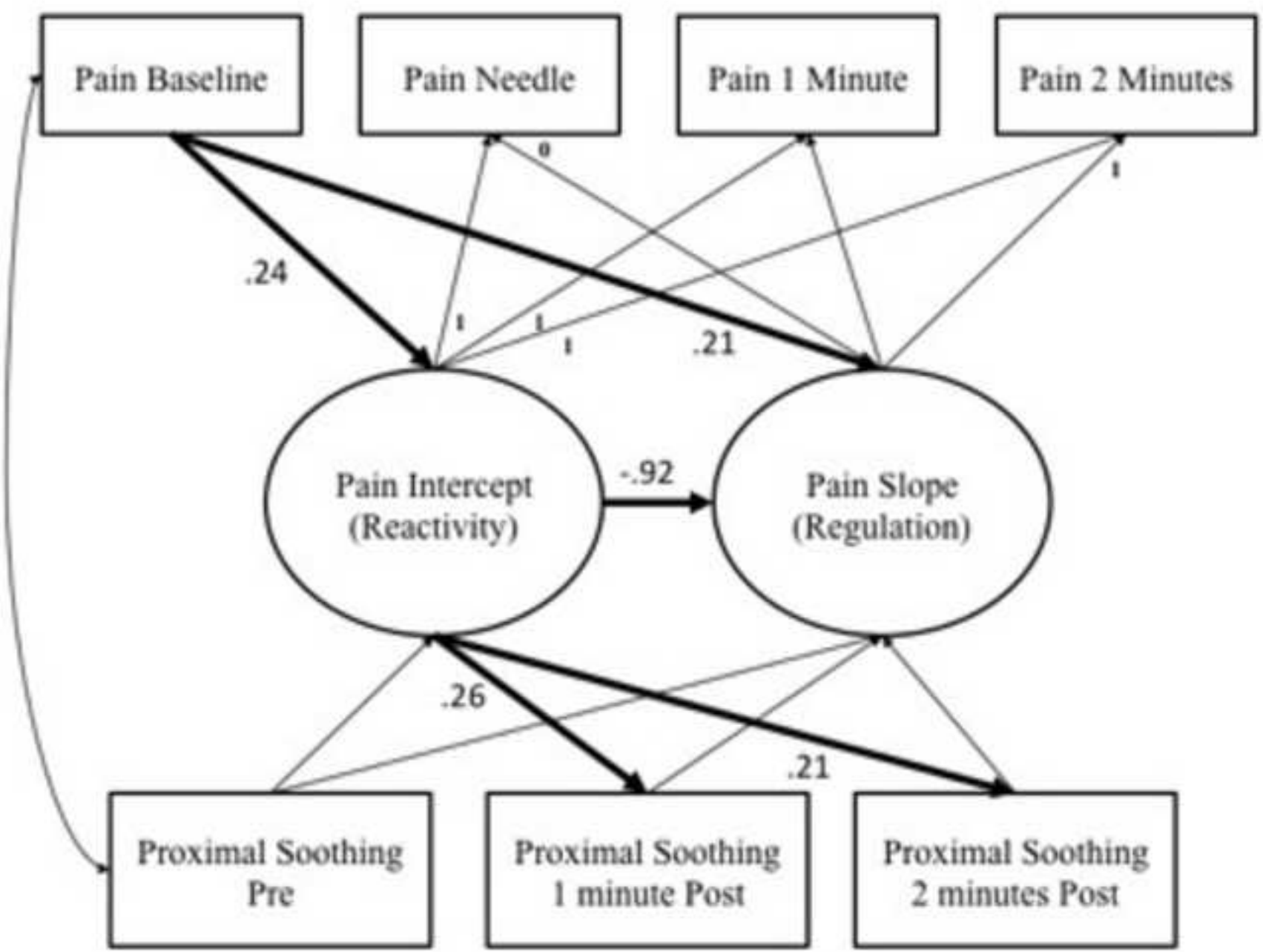

Figure6

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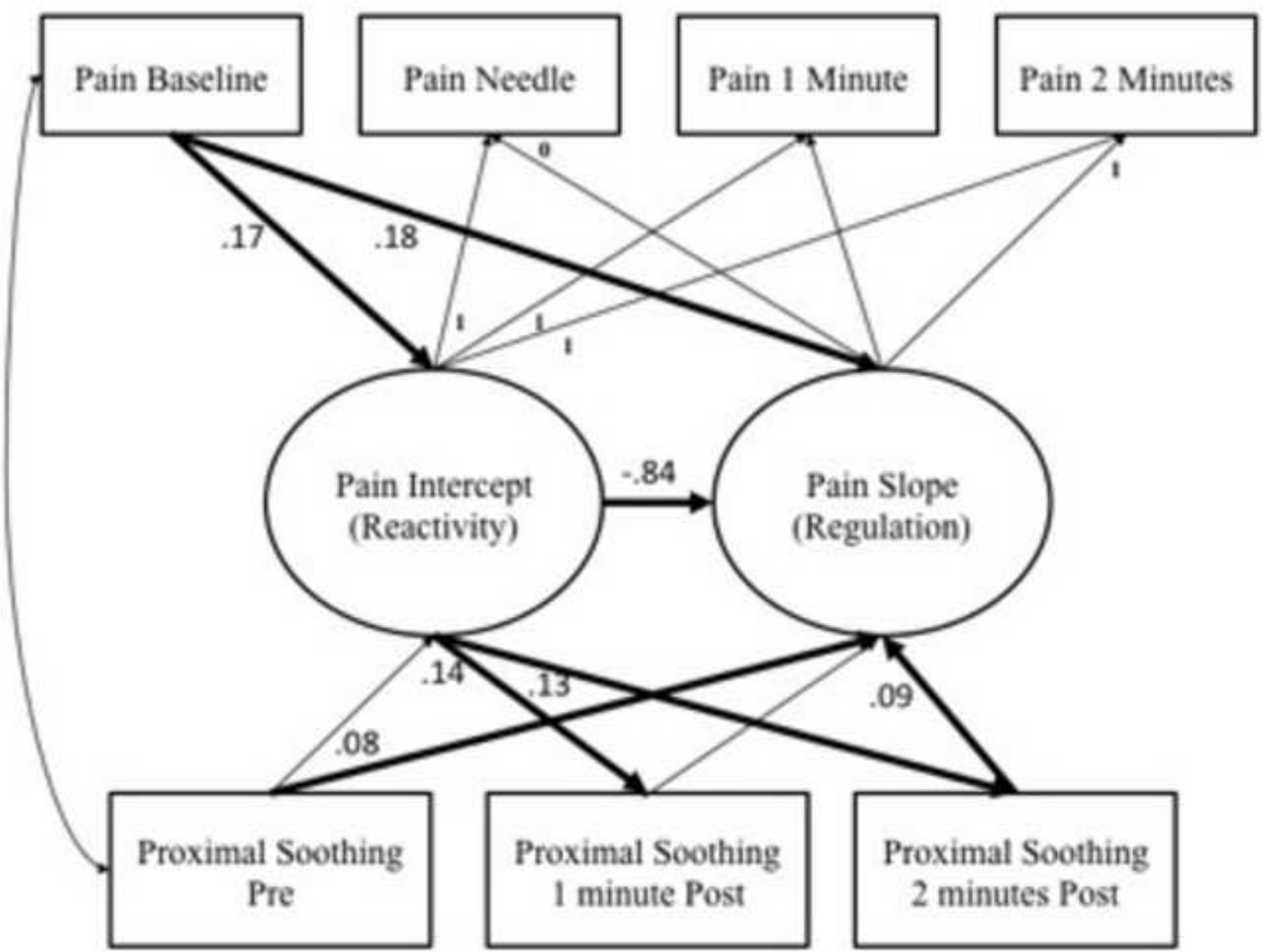

Table1

Table 1
Demographic Characteristics

	2 mos (%)	4 mos (%)	6 mos (%)	12 mos (%)
Caregivers present at immunization				
Mother	49.2	58.5	59.4	55.2
Mother and father	40.5	33.6	31.1	27.3
Father	.8	1.2	2.0	10.4
Parent(s) and grandparent(s)	6.5	4.1	4.3	3.8
Other	3.0	2.6	3.2	3.3
*Education level at recruitment**				
Graduate school or professional training	34.7	30.3	27.3	
University graduate	36.3	41.7	33.3	
Partial university	5.7	4.8	3.0	
Trade school or community college	15.0	16	25.8	
High school graduate	7.3	6.6	9.1	
Did not graduate from high school	1.0	.60	1.5	
*Infant gender at recruitment**				
Male	51.2	46.1	53.7	
Female	48.8	53.9	46.3	

*No infants recruited at 12 mos

Table2

Table 2
Standardized and Unstandardized Estimates for Model 1 (2 month appointment)

	Standardized Estimate	Unstandardized Estimate	Standard Error	Est./S.E.	P-value, 2 tailed
Pain Intercept Factor (Pain Reactivity)					
PS 1 Min Pre	-.00	-.03	.03	-1.15	.249
Pain Slope Factor	-.65	-.70	.05	-13.19	< .001
Pain Baseline	.13	.14	.05	2.77	.006
Pain Needle	1.00	1.00	-	-	-
Pain 1 minute	.65	1.00	-	-	-
Pain 2 minutes	.69	1.00	-	-	-
Pain Slope Factor (Pain Regulation)					
PS 1 Min Pre	.00	.00	.03	.07	.942
PS 1 Min Post	.10	.04	.02	1.83	.07
PS 2 Mins Post	.11	.04	.02	2.06	.04
Pain Baseline	.19	.23	.06	3.88	< .001
Pain Needle	.00	.00	-	-	-
Pain 1 minute	.70	1.12	.03	34.38	< .001
Pain 2 minutes	.83	1.00	-	-	-

Note. PS = Proximal Soothing

Table3

Table 3
Standardized and Unstandardized Estimates for Model 2 (4 month appointment)

	Standardized Estimate	Unstandardized Estimate	Standard Error	Est./S.E.	P-value, 2 tailed
Pain Intercept Factor (Pain Reactivity)					
PS 1 Min Pre	-.03	-.02	.03	-.79	.427
Pain Slope Factor	-.88	-.78	.03	-24.44	< .001
Pain Baseline	.17	.24	.06	4.26	< .001
Pain Needle	1.00	1.00	-	-	-
Pain 1 minute	1.02	1.00	-	-	-
Pain 2 minutes	1.02	1.00	-	-	-
Pain Slope Factor (Pain Regulation)					
PS 1 Min Pre	-.05	-.03	.02	-1.38	.169
PS 1 Min Post	.06	.02	.01	1.57	.116
PS 2 Mins Post	.07	.02	.01	1.78	.075
Pain Baseline	.33	.40	.04	9.62	< .001
Pain Needle	.00	.00	-	-	-
Pain 1 minute	.89	1.02	.02	49.29	< .001
Pain 2 minutes	.91	1.00	-	-	-

Note. PS = Proximal Soothing

Table4

Table 4
Standardized and Unstandardized Estimates for Model 3 (6 month appointment)

	Standardized Estimate	Unstandardized Estimate	Standard Error	Est./S.E.	P-value, 2 tailed
Pain Intercept Factor (Pain Reactivity)					
PS 1 Min Pre	-.00	-.00	.03	-.09	.928
Pain Slope Factor	-.92	-.78	.03	-25.82	< .001
Pain Baseline	.24	.30	.05	5.88	< .001
Pain Needle	1.00	1.00	-	-	-
Pain 1 minute	1.21	1.00	-	-	-
Pain 2 minutes	.98	1.00	-	-	-
Pain Slope Factor (Pain Regulation)					
PS 1 Min Pre	.05	.03	.02	1.41	.158
PS 1 Min Post	-.01	-.00	.02	-.14	.893
PS 2 Mins Post	.02	.01	.02	.43	.668
Pain Baseline	.21	.21	.04	6.00	< .001
Pain Needle	.00	.00	-	-	-
Pain 1 minute	1.02	1.01	.02	42.67	< .001
Pain 2 minutes	.83	1.00	-	-	-

Note. PS = Proximal Soothing

Table5

Table 5
Standardized and Unstandardized Estimates for Model 4 (12 month appointment)

	Standardized Estimate	Unstandardized Estimate	Standard Error	Est./S.E.	P-value, 2 tailed
Pain Intercept Factor (Pain Reactivity)					
PS 1 Min Pre	-.09	-.06	.03	-1.89	.059
Pain Slope Factor	-.84	-.74	.03	-21.65	< .001
Pain Baseline	.17	.19	.05	3.63	< .001
Pain Needle	1.00	1.00	-	-	-
Pain 1 minute	1.03	1.00	-	-	-
Pain 2 minutes	.91	1.00	-	-	-
Pain Slope Factor (Pain Regulation)					
PS 1 Min Pre	.08	.04	.02	1.98	.047
PS 1 Min Post	-.00	-.00	.02	-.09	.931
PS 2 Mins Post	.09	.04	.02	1.97	.049
Pain Baseline	.18	.184	.04	4.68	< .001
Pain Needle	.00	.00	-	-	-
Pain 1 minute	.91	1.19	.03	37.44	< .001
Pain 2 minutes	.95	1.00	-	-	-

Note. PS = Proximal Soothing

Table6

Table 6
Means and Standard Deviations for all Model Variables

	N	Mean	Standard Deviation
2 months			
Pain Baseline	482	.16	.15
Pain Needle	487	.79	.17
Pain 1 Min	460	.36	.26
Pain 2 Mins	435	.32	.25
PS 1 Min Pre	491	.21	.29
PS 1 Min Post	497	.84	.51
PS 2 Mins Post	483	.62	.57
4 months			
Pain Baseline	573	.15	.15
Pain Needle	575	.70	.21
Pain 1 Min	549	.24	.21
Pain 2 Mins	541	.24	.21
PS 1 Min Pre	587	.25	.31
PS 1 Min Post	589	.89	.52
PS 2 Mins Post	581	.49	.51
6 months			
Pain Baseline	565	.17	.19
Pain Needle	566	.66	.23
Pain 1 Min	549	.23	.19
Pain 2 Mins	522	.23	.24
PS 1 Min Pre	589	.22	.30
PS 1 Min Post	595	.69	.48
PS 2 Mins Post	580	.36	.44
12 months			
Pain Baseline	491	.20	.21
Pain Needle	494	.72	.22
Pain 1 Min	493	.33	.23
Pain 2 Mins	471	.26	.27
PS 1 Min Pre	508	.27	.38
PS 1 Min Post	507	.69	.49
PS 2 Mins Post	503	.36	.43

Note. PS= Proximal Soothing

Table7

Table 7
Bivariate Correlations among all Model 1 Variables

	1	2	3	4	5	6	7
1. Pain Baseline	1	.11*	.15**	.15**	.18**	-.09	.006
		(.013)	(.001)	(.002)	(.000)	(.054)	(.900)
2. Pain Needle		1	.20***	.18***	-.04	.04	.06
			(.000)	(.000)	(.388)	(.363)	(.174)
3. Pain 1 Min			1	.384***	.06	.09*	.20***
				(.000)	(.197)	(.045)	(.000)
4. Pain 2 Mins				1	.02	.13**	.07
					(.683)	(.007)	(.169)
5. PS 1 Min Pre					1	.16**	.10*
						(.001)	(.029)
6. PS 1 Min Post						1	.48***
							.000
7. PS 2 Mins Post							1

Note. PS = Proximal Soothing
Note. p values are in parentheses
Note. * $p < .05$. ** $p < .01$,*** $p < .001$ (two tailed).

Table8

Table 8
Bivariate correlations among all model 2 variables

	1	2	3	4	5	6	7
1. Pain Baseline	1	.16***	.28***	.38***	.10*	.03	.08
		(.000)	(.000)	(.000)	(.016)	(.543)	(.063)
2. Pain Needle		1	.31***	.28***	-.02	.23***	.20***
			(.000)	(.000)	(.583)	(.000)	(.000)
3. Pain 1 Min			1	.38***	.02	.12**	.18***
				(.000)	(.584)	(.005)	(.000)
4. Pain 2 Mins				1	-.02	.17***	.11*
					(.695)	(.000)	(.015)
5. PS 1 Min Pre					1	.22***	.18***
						(.000)	(.000)
6. PS 1 Min Post						1	.46**
							(.000)
7. PS 2 Mins Post							1

Note. PS = Proximal Soothing
Note. p values are in parentheses
Note. * $p < .05$. ** $p < .01$,*** $p < .001$ (two tailed).

Table9

Table 9
Bivariate correlations among all model 3 variables

	1	2	3	4	5	6	7
1. Pain Baseline	1	.23***	.26***	.25***	.22***	.14**	.18***
		(.000)	(.000)	(.000)	(.000)	(.001)	(.000)
2. Pain Needle		1	.34***	.21***	.05	.26***	.21***
			(.000)	(.000)	(.269)	(.000)	(.000)
3. Pain 1 Min			1	.32***	.12**	.10*	.14**
				(.000)	(.005)	(.024)	(.002)
4. Pain 2 Mins				1	.10*	.16***	.09*
					(.028)	(.000)	(.037)
5. PS 1 Min Pre					1	.31***	.13**
						(.000)	(.002)
6. PS 1 Min Post						1	.47***
							(.000)
7. PS 2 Mins Post							1

Note. PS = Proximal Soothing
Note. p values are in parentheses
Note. * $p < .05$. ** $p < .01$,*** $p < .001$ (two tailed).

Table10

Table 10
Bivariate Correlations among all Model 4 Variables

	1	2	3	4	5	6	7
1. Pain Baseline	1	.08	.21***	.28***	.33***	.04	.10*
		(.066)	(.000)	(.000)	(.000)	(.433)	(.024)
2. Pain Needle		1	.33***	.15**	-.03	.17***	.17***
			(.000)	(.001)	(.519)	(.000)	(.000
3. Pain 1 Min			1	.36***	.16***	.08	.15**
				(.000)	(.000)	(.081)	(.001)
4. Pain 2 Mins				1	.14**	.11*	.13**
					(.003)	(.020)	(.005)
5. PS 1 Min Pre					1	.27***	.25***
						(.000)	(.000)
6. PS 1 Min Post						1	.55***
							(.000)
7. PS 2 Mins Post							1

Note. PS = Proximal Soothing
Note. p values are in parentheses
Note. * $p < .05$. ** $p < .01$,*** $p < .001$ (two tailed).

Table11

Table 11
R^2 Difference Scores for all Models

	R^2 with PS	R^2 without PS	ΔR^2
2 months			
Reactivity	2%	1%	1%
Regulation	45%	41%	4%
4 months			
Reactivity	3%	3%	-
Regulation	76%	74%	2%
6 months			
Reactivity	6%	6%	-
Regulation	79%	79%	-
12 months			
Reactivity	3%	2%	1%
Regulation	71%	70%	1%

Note. PS = Proximal Soothing

Note. ΔR^2 reflects the amount of unique variance accounted for by proximal soothing