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4 **ABSTRACT**
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6 No research to date has descriptively catalogued what parents of healthy infants are
7 naturalistically doing to manage their infant’s pain over immunization appointments
8 across the first year of life. This knowledge, in conjunction with an understanding of the
9 relationships different parental techniques have with infant pain-related distress, would
10 be useful when attempting to target parental pain management strategies in the infant
11 immunization context. This study presents descriptive information about the pain
12 management techniques parents have chosen, and examines the relationships these
13 naturalistic techniques have with infant pain-related distress over the first year of life. 760
14 parent-infant dyads were recruited from three pediatrician clinics in Toronto, Canada, and
15 were naturalistically followed and videotaped longitudinally over four immunization
16 appointments across the infant’s first year of life. Infants were full-term, healthy babies.
17 Videotapes were subsequently coded for infant pain-related distress behaviours and
18 parental pain management techniques. After controlling for preceding infant pain-related
19 distress levels, parent pain management techniques accounted for, at most, 13% of the
20 variance in infant pain-related distress scores. Across all age groups, physical comfort,
21 rocking, and verbal reassurance were the most commonly used non-pharmacological pain
22 management techniques. Pacifying and distraction appeared to be most promising in
23 reducing needle-related distress in our sample of healthy infants. Parents in this sample
24 seldom used pharmacological pain management techniques. Given the psychological and
25 physical repercussions involved with unmanaged repetitive acute pain and the paucity of
26 work in healthy infants, this paper highlights key areas for improving parental pain
27 management in primary care.
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4 **Naturalistic Parental Pain Management During Immunizations over the First Year**
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7 **of Life: Observational Norms from the OUCH Cohort**
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36 **Summary:** Descriptive information about pain management techniques used in infant
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38 immunizations is provided. The relationship between these techniques and infant pain-
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40 related distress is also examined.
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46 **Number of Text Pages: 40**
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49 **Number of Tables: 9**
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52 **Number of Figures: 6**
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4 Naturalistic Parental Pain Management During Immunizations over the First Year of
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7 Life: Observational Norms from the OUCH Cohort
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9 **1. Introduction**

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11 Generally speaking, pain management strategies in the infant immunization
12 setting fall into two broad categories: pharmacological and non-pharmacological. The
13 uses of sucrose or topical anesthetics are examples of pharmacological approaches, and
14 have been consistently shown to reduce infant pain and distress [4,15,40]. Non-
15 pharmacological techniques consist of parental behaviours used to reduce infant distress,
16 such as distraction [8,13,22], verbal reassurance [5,35], and proximal soothing [3,7,26].
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20 Compared to studies on pharmacological approaches, research pertaining to non-
21 pharmacological techniques has yielded less clear results. In terms of proximal soothing,
22 whereas the majority of studies have found an association or causal relationship with
23 decreased infant pain-related distress [6,7,16,17], one study found that proximal soothing
24 only reduced infant-pain related distress when combined with parent vocalizing [23], and
25 another study found that proximal soothing was related to difficulty with infant distress
26 regulation [3]. However, this latter study measured proximal soothing and distress
27 regulation concurrently, and directionality could not be confirmed. Similarly, research
28 pertaining to distraction has been equivocal, with some studies finding support for
29 distraction [8,10,11] and others not [13,22,25]. On the other hand, research pertaining to
30 verbal reassurance and pacifying has been consistent, with all findings pointing towards a
31 positive relationship between verbal reassurance and infant pain [5,12,32] and a negative
32 relationship between pacifying and infant pain [7].
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4 No research to date has presented the prevalence of parental utilization of these
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6 soothing behaviours in a naturalistic context. To properly address parental pain
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8 management in the immunization context, it is crucial to understand the landscape of
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10 these behaviours. This knowledge, in conjunction with an understanding of the
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12 relationships these behaviours have with infant pain-related distress, would be useful
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14 when attempting to target parental pain management strategies during infant
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16 immunizations.
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21 The level of distress an infant displays is also important to consider, as this has
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23 been linked to what pain management techniques parents use, as well as their efficacy.
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25 For example, higher distress has been related to more proximal soothing [3], and
26
27 breastfeeding and pacifying appear more effective when infant distress is low [23].
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29 Moreover, studies have shown that the strategies parents use during times of high infant
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31 distress (e.g. bouncing, rocking) [6] may not attenuate pain to the extent one would
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33 anticipate [3,6].
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38 The present study had two developmentally-informed objectives: (1) present
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40 descriptive information about what pain management techniques are currently being used
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42 during immunizations across the first year of life, and (2) examine the relationships these
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44 techniques have with infant pain-related distress. No hypotheses were formulated for the
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46 first objective, as this component was descriptive. For the second objective, it was
47
48 hypothesized, based on key reviews to date [30,31,34], that: 1) Pharmacological
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50 interventions would predict lower infant pain-related distress, regardless of age; 2)
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52 Physical comfort, nursing, rocking, and pacifying would predict lower infant pain-related
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54 distress at all ages, while distraction and verbal reassurance would predict lower and
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4 higher infant pain-related distress (respectively), only at higher ages; and 3) Parent pain
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6 management techniques would account for greater variance in infant pain-related distress
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8 during periods of lower distress (i.e., before the needle and 2 minutes post-needle) than
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10 higher distress (i.e. the first minute post-needle).
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13 14 **2. Methods**

15 16 *2.1. Procedure*

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19 Ethical approval was obtained through research ethics review boards at both the
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21 participating university and the associated pediatric hospital. Parents were approached to
22
23 participate, if they expressed interest to a nurse/administrator not directly involved in the
24
25 study. If they agreed to be approached, a research assistant described the study in detail.
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27 Parental consent was obtained in the waiting room prior to the study procedures
28
29 beginning. Immunizations were videotaped with two cameras. The first captured the
30
31 infant's face and the second captured the entire parent-infant interaction. Parent-infant
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33 dyads were observed naturalistically, with no interference from the research assistant
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35 during the immunization period. Videos from each immunization were subsequently
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37 coded for infant pain-related distress and parent pain management techniques. A full
38
39 description of our cohort procedure has been published earlier [28].
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45 46 *2.2. Measures*

47 48 *2.2.1. Demographic questionnaire and pharmacological pain management techniques*

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50 Parents completed a short demographic questionnaire that asked about basic
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52 background information such as their age, self-reported heritage culture, as well as infant
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54 sex and medical conditions since the last time they participated in the study. Parents were
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56 also asked to identify if they had administered pharmacological analgesics to their infants
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4 (i.e., topical anesthetics such as Eutectic Mixture of Local Anesthetics [EMLA] cream or
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7 over-the-counter acetaminophens such as Tylenol or Tempra) prior to the immunization
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9 appointment.

10 11 2.2.2. *Infant pain-related distress*

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14 The Neonatal Facial Coding System (NFCS) [18,19] was used to code infant pain-
15
16 related distress. This measure was designed to measure infants' facial responses to
17
18 painful stimuli and is a well-validated measure of pain. Each of seven facial actions
19
20 included in the analyses (brow bulge, eye squeeze, naso-labial furrow, open lips, vertical
21
22 stretch mouth, horizontal stretch mouth, taut tongue) were coded as present (1) or absent
23
24 (0) for every second within a 10-second epoch during the following four time periods:
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26 immediately before the first needle (Pain Baseline), immediately after the last needle
27
28 (Pain Needle), 1 minute after the last needle (Pain 1) and two minutes after the last needle
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30 (Pain 2). Three of the original facial actions (chin quiver, tongue protrusion, lip purse)
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32 were not included in our analyses because they occurred less than 5% of the time. Our
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34 method is based on published precedents in the literature by our team and the original
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36 author [42,43]. The pain score was obtained for each time period by calculating the
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38 proportion of time facial actions were present. Scores ranged from 0 to 1 and indicate the
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40 proportion of time during each 10-second epoch for which facial actions were present.
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48 Higher scores indicate greater facial pain-related distress expression.
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51 Trained NFCS coders, blind to the study hypotheses, coded the data. Primary
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53 coders to the measure were trained with one of the original scale designers, and
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55 subsequent coders went through a stringent process to attain reliability with trained
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57 coders. Inter-rater reliability was calculated among every permutation of eight coders
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4 (e.g., coder A with B, B with C, A with D, etc.). 20% of the data were coded for
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6 reliability. Reliability was high with percentage agreement scores for all seven pain facial
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8 actions ranging from .85 to .97.
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10 11 2.2.3. *Parent soothing behaviours* 12 13

14 Parent pain management behaviours during the immunization appointment were
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16 coded using the Measure of Adult and Infant Soothing and Distress (MAISD) [9]. The
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18 MAISD is a reliable and valid behavioural observation scale originally developed for use
19
20 during pediatric medical procedures. Each of eight behaviours (Distraction, Offer Toy,
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22 Offer Pacifier, Offer Food [bottle or solid food], Nursing [breastfeeding], Physical
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24 Comfort, Rocking, and Verbal Reassurance) were coded as present (1) or absent (0) for
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26 five-second epochs within three 1-minute periods: one minute before the first needle
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28 (Pre-Needle Parent Behaviours), one minute after the last needle (1-minute Parent
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30 Behaviours), and two minutes after the last needle (2-minute Parent Behaviours). For
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32 each of the eight behaviours, percentage scores ranging from 0 to 1 were calculated for
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34 all three 1-minute phases. These scores represent the percentage of time a behaviour was
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36 present during that minute. Higher scores reflect a greater frequency of behaviour.
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43 Ten trained MAISD coders, blind to the study hypotheses, coded the data.
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45 Primary coders on the measure had training with the scale designer until reliability was
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47 attained. Subsequent coders went through a stringent process to attain reliability with
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49 trained coders. 20% of all data were coded for reliability. Inter-rater reliability on all
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51 eight parent behaviours was calculated among every permutation of coders (e.g., coder A
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53 with B, B with C, A with D, etc.). The intraclass correlations ranged from .67 to .99 for
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55 the analyzed variables (i.e. those that had occurred more than 5% of the time; see below).
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4 *2.3. Analysis plan overview*
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7 To address the first research objective, a mean percentage for each coded epoch
8 (1-minute pre-needle, and 1 and 2 whole minutes post-needle) was calculated for each
9 parental strategy at each age group. For the second objective, correlations were run
10 between the parent behaviour and the subsequent infant pain-related distress score, prior
11 to regressions being run. Because no pharmacological technique was significantly
12 correlated with infant pain-related distress, these planned multiple regressions were not
13 conducted. To test the second hypothesis under the second objective, non-
14 pharmacological behaviours that were significantly correlated with infant pain-related
15 distress were entered as predictor variables in multiple regressions, controlling for
16 previous phases of infant pain-related distress within the immunization, when applicable.
17 Only those parent pain management variables that immediately precede infant pain-
18 related distress variables in a given phase were included in the initial correlations to help
19 us discern directionality (i.e., when measuring infant pain-related distress at 2 minutes,
20 only those parent pain management variables from the first minute post needle were
21 used). Finally, to test the third hypothesis, the percentages of variances accounted for by
22 the soothing behaviours were compared across the four time periods previously
23 described: Pain Baseline, Pain Needle, Pain 1 Minute, and Pain 2 Minute. As all these
24 analyses were conducted at each age, a comparison of results would confirm or
25 disconfirm the developmental aspects of our hypotheses.
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52 **3. Results**

53 *3.1. Study population*
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4 760 parent-infant dyads were recruited into the OUCH (Opportunities to
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6 Understand Childhood Hurt) cohort between October 2007 and June 2012. Parent-infant
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8 dyads were recruited from three pediatrician clinics in the Greater Toronto Area and were
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10 followed longitudinally over the infant's first year of life (at their 2-, 4-, 6-, and/or 12-
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12 month routine immunizations). Infants were recruited at 2-, 4- or 6- months in our
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14 sequential cohort design. Of these 760 dyads, 256 were followed up four times (2, 4, 6,
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16 and 12 months of age), 263 were followed up to three times (2, 6, and 12 months or 4, 6,
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18 and 12 months, or 2, 4, and 6 months), 175 were followed up twice (all two time point
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20 permutations were possible), and 66 were followed up once (2, 4, or 6 months). Analyses
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22 that were conducted were cross-sectional and sample sizes varied across age (2 month n =
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24 497; 4 month n = 592, 6 month n = 601, 12 month n = 531). Eligibility criteria required
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26 that infants were healthy, born at least 37 weeks gestation, had no signs of developmental
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28 delays, had never stayed in a Neonatal Intensive Care Unit, and had parents whose
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30 primary language was English.
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38 Parents' self-identified heritage culture was diverse (35.9% European, 12.6%
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40 Asian, 11.2% Canadian/American, 7.5% Jewish, 5.8% Mixed Canadian, 5.1% South
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42 Asian, 5% African/Middle Eastern, 3.8% South/Latin American, and 13.1% Other). The
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44 majority of parents were married (83.9%) and in dual-income families (89.7%). Using the
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46 Hollingshead Index for socioeconomic status, most parents (45.9%) belonged to the
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48 minor professional social strata (A. B. Hollingshead, 1975, unpublished manuscript), and
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50 were on average 33.46 years old at the time of recruitment. Infants were 50.1% male,
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52 born between 37 and 44 weeks parent-reported gestation, and approximately half
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54 (54.6%) were first- or only-born children.
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4 Across all four ages, mothers most frequently attended the infant's immunization
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6 appointment, followed by both parents together. The breakdown of caregiver attendance
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8 is presented in Table 1. When both parents attended the immunization, mothers were the
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10 primary providers of pain management (65% to 73% of the time). Fathers were the
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12 providers of pain management 15% to 23% of the time, and pain management behaviours
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14 were shared between parents 6% to 15% of the time. When additional caregivers were
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16 present, nannies provided pain management techniques 16% of the time, and
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18 grandparents between 4% and 9% of the time. When the infant was not the only-born
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20 child, at least one other sibling was present, on average, 17% of the time.
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26 Finally, to get a better sense of our sample, parents were asked whether they had
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28 consulted books or websites, participated in parenting classes, or sought guidance from a
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30 professional pertaining to raising their infants. Parents used most resources at 2 months of
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32 age, with numbers dropping over the course of the year. See Figure 1 for details.
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35 36 *3.2. Objective one: Descriptive findings for pain management techniques being used*

37 38 *3.2.1. Pharmacological techniques*

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40 Across all four ages, the use of pharmacological techniques was minimal (with
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42 Tempra/Tylenol use ranging from 6.9% at 2 months to 11.7% at 4 months of age, and
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44 EMLA use less than 1% of the time at all ages). Given the limited use of pharmacological
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46 techniques, they were not included in any subsequent analyses.
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50 51 *3.2.2. Non-pharmacological techniques*

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53 The mean percentages of time each of the eight parent soothing behaviours was
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55 used by parents at the 2-, 4-, 6-, and 12-month appointments are presented in Figures 2
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57 through 5, respectively. Across all ages and 1-minute periods (1 minute pre-needle, 1
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4 minute post-needle, 2 minutes post-needle), Physical Comfort, Rocking and Verbal
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6 Reassurance were the most frequently used behaviours. Examining Figures 2 to 5
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8 concurrently, it was noted that only the frequency of Rocking and Physical Comfort had
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10 notable changes over age, particularly between 2 and 12 months. Specifically, there was
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12 an approximate 10% decrease in Physical Comfort from 2 to 12 months at both 1 and 2
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14 minutes post-needle. There was also an approximate 10% decrease in Rocking from 2 to
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17 12 months at both 2 and 3 minutes post-needle.
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21 Regardless of age, three of the eight parent soothing behaviours (Offer Food,
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23 Offer Toy, and Nursing) occurred extremely infrequently (less than 5% of the time).
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25 Accordingly, data for these behaviours were not presented nor included in our analyses
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27 with infant pain-related distress.
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31 *3.3. Objective two: Relationships between parent pain management behaviours used and* 32 33 *infant pain-related distress* 34

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36 To determine the relationship between parent pain management behaviours and
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38 infant pain-related distress, hierarchical multiple regressions predicting each infant pain-
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40 related distress score (Baseline, Needle, 1 minute, 2 minute) at each age (2, 4, 6, and 12
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42 months) were run separately. Given that research has shown that previous infant pain
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44 predicts subsequent infant pain [1,28], previous infant pain-related distress variables from
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46 within an appointment were entered into the regression models as control variables.
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50 *3.3.1. Bivariate correlations* 51

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53 A total of 164 exploratory correlations (41 for each age group [35 between parent
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55 soothing behaviours and infant pain-related distress; 6 between infant pain-related
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4 distress and previous infant pain-related distress]) were performed, and are presented in
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7 Tables 2 to 5, respectively.

8 9 *3.3.2. Hierarchical regression analyses*

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11 Sixteen hierarchical regressions were planned (4 pain periods [Pre-needle, Needle,
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13 1, and 2 minutes post-needle] x 4 infant ages [2, 4, 6, and 12 months]). However, because
14
15 there were no significant bivariate correlations between any parent pain management
16
17 variable and needle pain at 4 months or at 12 months, only 14 regressions were actually
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19 performed. Intercorrelations between all predictor variables were conducted to ensure
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21 that none of the predictor variables were multicollinear. No intercorrelations exceeded
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23 0.7, a conservative cutoff criterion [36].
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29 At 2 months of age, across the four pain outcomes, parent behaviours accounted
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31 for a maximum of 2.8% (baseline) of the variance in infant pain-related distress (see
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33 Table 6). With the exception of Pacify pre-needle, all other significant predictors
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35 positively predicted subsequent pain scores.
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39 Three sets of regressions were run at 4 months of age (see Table 7). The
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41 predictive utility of parent behaviours was minimal across the three pain outcomes
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43 (baseline, 1-minute, 2-minute), accounting for, at most, 6.3% of the variance in pain
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45 scores (baseline). All significant predictors positively predicted infant pain-related
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47 distress scores.
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51 At 6 months of age, at most 10.2% of the variance in pain scores (baseline) was
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53 accounted for by parent behaviours. See Table 8 for all β weights and p values for the 6-
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55 month regressions. Distraction pre-needle was the only variable across regressions to
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57 negatively predict pain scores immediately following the needle.
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4 At 12 months of age, the maximal amount of variance in pain-related distress
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6 accounted for was 12.9% (baseline), was explained by parent behaviours. All of the
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8 significant predictor variables positively predicted pain scores across all three regressions.
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10 See Table 9 for all β weights and p values.
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14 To clearly contrast, across ages, the amount of variance accounted for (according
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16 to pain phase) by parent behaviours a graph was created using either the adjusted R^2
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18 (predicting baseline) or the change in the adjusted R^2 (predicting 1-minute or 2-minute
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20 pain). Similar trends between pain phases were observed. Specifically, there was more
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22 variability in R^2 values at baseline than any other period and the most variance was
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24 accounted for at baseline. See Figure 6.
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28 **4. Discussion**

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31 To our knowledge, this is the first paper to descriptively catalogue what parents of
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33 healthy infants are naturalistically doing to manage immunization pain over the first year
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35 of life, and how effective their behaviours are at alleviating pain. Given the large sample
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37 size, this study provides important normative data regarding current challenges within the
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39 immunization context.
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43 With respect to the first objective, overall pharmacological techniques are not
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45 being used despite previous research supporting their effectiveness [4,15,40]. In a
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47 previous study investigating parent and physician self-reported determinants of their
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49 utilization of topical anesthetics and over-the-counter acetaminophens [38], mothers
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51 reported that their primary reasons for not using these approaches were unfamiliarity with
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53 these techniques and failure to receive medical advice about using them. Physicians
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55 identified parental factors (i.e. did not request analgesia) and drug factors (i.e. extra cost,
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4 time) as determinants of nonuse. Parents reported they would be willing to pay to reduce
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6 their child's pain and moreover, research has demonstrated that parents can effectively
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8 apply topical anesthetics at home if provided with adequate instruction [38,39]. Other
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10 research has similarly indicated that though many parents are unaware of topical
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12 anesthetics as a strategy, they would be willing to use them if endorsed by their
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14 physicians, who they identify as their primary trusted source of pain management
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16 information [27]. To our knowledge, there were no studies that reported reasons why
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18 parents do not administer sucrose.
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23 Comparatively, parents used non-pharmacological techniques much more often.
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25 Physical Comfort, Rocking, and Verbal Reassurance were used the most, between 18 and
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27 47% of the time. In line with previous research [9], Offer Toy and Offer Food were used
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29 most infrequently. Age-appropriate trends for behaviours were observed. For example,
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31 distraction was used most post-needle for 12-month olds, likely because at this stage of
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33 development, infants are more cognitively capable of entertaining this method. Pacifying
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35 and Physical Comfort were used most post-needle in 2- and 4-month olds, ages at which
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37 infants are likely more responsive to sources of proximal soothing including nonnutritive
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39 sucking. It is important to note, however, that no non-pharmacological strategies were
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41 used for greater than 50% of any of the time periods measured, including the minute
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43 immediately following the needle. Given that significant acute pain persists for at least 2
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45 minutes post-immunization [29], this may suggest that one of the reasons parent soothing
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47 is not a large factor in determining pain scores is that it is prematurely discontinued.
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54 Results pertaining to the second objective, examining the relationships between
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56 pharmacological and non-pharmacological techniques with infant pain-related distress,
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4 were partially in line with hypotheses. The first hypothesis was not possible to test due to
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6 the low frequency usage of pharmacological interventions in our sample, precluding these
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8 variables from being included in the regressions. Pertaining to our other hypotheses
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10 regarding the differential efficacy of parent soothing behaviours and age differences,
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12 findings were partially in alignment with predictions. Specifically, Pacifying and
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14 Distraction was related to decreased pain-related distress at 2 and 6 months, respectively.
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16 These results are in accordance with a recent Cochrane review on non-pharmacological
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18 interventions [30,31], though more research is needed to address additional soothing
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20 behaviours across all ages of infancy. In line with hypotheses, Verbal Reassurance was
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22 positively related to infant pain-related distress across all four ages.
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29 However, with the exception of the two relationships described above, all other
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31 relationships between parent pain management behaviours and infant pain-related distress
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33 were positive, suggesting that the majority of attempts to soothe the infant are actually
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35 predicting *more* distress. Although counter to predictions, this finding is in line with
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37 research showing positive relationships between a parent's behaviour and infant pain-
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39 related distress [3,35]. As suggested by transactional theory [33], a cyclical trajectory
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41 likely exists between infant and parent in the immunization context. Thus, a possible
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43 explanation of this finding could be that it is not the parent behaviours that are directly
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45 predicting more pain but rather, the level of pain-related distress in the infant is so great,
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47 it elicits greater parental soothing.
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53 Findings were again partially in line with predictions for the third hypothesis.
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55 Specifically, the greatest amount of variance in infant pain-related distress accounted for
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57 by parent behaviours was prior to the immunization, when there was little to no distress.
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4 However, findings pertaining to the time period two minutes post-needle (the other time
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6 period when there was less distress) were less in line with predictions such that the
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8 amount of variance accounted for by parent behaviours during this time period was
9
10 similar to that of the high distress periods (pain needle and pain 1 minute post needle).
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14 Despite the lack of direct efficacy on lowering infant pain-related distress, it is
15
16 crucial to continue to underscore the importance of soothing behaviours when an infant is
17
18 in distress. The relationships between parental soothing of infant distress and more
19
20 psychosocial measures (such as the formation of a secure attachment bond) [2,14,24]
21
22 remain imperative to an infant's emotional development, and are important areas of
23
24 future study.
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28 It is important to note that at most, only 13% of the variance in infant pain-related
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30 distress was accounted for by parent behaviours. Moreover, the amount gradually
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32 increased over age and was most clearly seen at Baseline. One explanation of this finding
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34 could be that when an infant is highly distressed from a physically and psychologically
35
36 distressing stimulus, the experience is so overwhelming that the parent-infant attunement
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38 is disrupted, making it more difficult for the infant to be soothed [3]. Whatever pain
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40 management techniques parents might be using at this time may be related to higher
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42 levels of distress solely because the infant feels as though his or her primary concern is
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44 not being addressed [23], leading to more distress.
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50 On a final note, although prior pain-related distress within the immunization
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52 accounts for more of the total variance, there still remains a large amount that is not
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54 explained by previous infant pain-related distress or by parent behaviours.
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58 *4.1. Conclusion*

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4 The present study aimed to present longitudinal descriptive information of what
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6 pain management techniques are naturally occurring during infant immunizations. After
7
8 controlling for previous infant distress scores, parent behaviours appear to minimally
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10 predict infant pain-related distress over the first year of life. The most frequently used
11
12 strategies (e.g. physical comfort, rocking, and verbal reassurance) were not predictive of
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14 reduced infant pain-related distress, and some strategies confirmed to predict diminished
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16 pain (e.g. EMLA, breastfeeding, sucrose) [4,20,21,37,41] were unfortunately the most
17
18 infrequently used strategies. Given these findings are based on a large sample of typical
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20 parent-infant dyads, there now exists a framework in which we can begin to design and
21
22 implement strategies to encourage parents to use the appropriate techniques. It is
23
24 important to use this information for future knowledge mobilization to parents,
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26 pediatricians, and other health professionals, who should be supported in their use of
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28 effective, nationally and internationally recommended strategies to reduce immunization
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30 pain.
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38 *4.2. Limitations and directions for future research*

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41 The current study has some limitations. First, 10-seconds of each time point for
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43 parent behaviours and infant pain-related distress behaviours were coded in both sets of
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45 total scores. Thus, when making inferences about the directionality of the correlations,
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47 this overlap is important to keep in mind.
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51 Secondly, we were unable to control for previous distress when running
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53 regressions with Pain Baseline as the outcome measure. As seen at the other pain phases,
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55 previous pain-related distress accounted for most of the variance in infant pain-related
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4 distress scores. As such, it is unclear if any behavioural distress prior to the immunization
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6 appointment is contributing to the pain-related distress measured before the needle.
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10 Thirdly, although attempts were made at capturing a naturalistic depiction of
11 parent soothing behaviours, videotaping the appointment may have impacted parents'
12 behaviours. Also, it was assumed that the administration of sucrose prior to
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14 immunizations would be apparent through the video; we did not formally ask parents
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16 about their sucrose use.
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21 Finally, given that previous research has shown the effectiveness of specific
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23 pharmacological strategies (e.g. sucrose, topical anesthetics), it could be argued that these
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25 strategies should have been implemented as part of our design. However, the objectives
26
27 of this cohort were to examine what is naturally occurring in immunizations over the first
28
29 year of life as a platform for future research that will implement evidence-based
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31 strategies in reducing pain. We are currently involved in a longitudinal trial examining
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33 the efficacy of pharmacological and non-pharmacological strategies over the first 15
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35 months of life (clinical trial identifier: NCT01503060).
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41 Future research in infant pain management can focus on additional variables to
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43 better explain infant pain-related distress. For example, an examination of variables
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45 pertaining to the infant (e.g. temperament), or the parents (e.g. parent anxiety) may
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47 provide a more comprehensive picture of this paradigm and help elucidate alternative
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49 factors that may exert influence on a highly distressed infant.
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53 Finally, researchers should endeavor to focus on the consistent utilization of
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55 known effective pain management strategies. Now that there exist strategies that have
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57 been repeatedly shown to be efficacious to a highly distressed infant, future directions
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should aim to rectify the gaps elucidated in this paper. It is clear that the translation of efficacy research into effective acute pain management research is still in its infancy.

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Figure Captions

Figure 1. Use of Parent Resources

Figure 2. Mean percentage of every one-minute epoch coded that each parental soothing behaviour was used at 2 months

Figure 3. Mean percentage of every one-minute epoch coded that each parental soothing behaviour was used at 4 months

Figure 4. Mean percentage of every one-minute epoch coded that each parental soothing behaviour was used at 6 months

Figure 5. Mean percentage of every one-minute epoch coded that each parental soothing behaviour was used at 12 months

Figure 6. Percentage of Variance in Pain Scores Accounted for by Naturalistic Parental Soothing Behaviours Across Immunization Appointment

Note. Baseline values refer to Adjusted R^2 values as there were no prior pain scores; Needle, 1 minute and 2 minute values refer to ΔR^2 values, after the prior pain scores were included in the model. Non-significant R^2 values are graphed as 0.

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Summary:

Descriptive information about pain management techniques used in infant immunizations is provided. The relationship between these techniques and infant pain is also examined.

Figure
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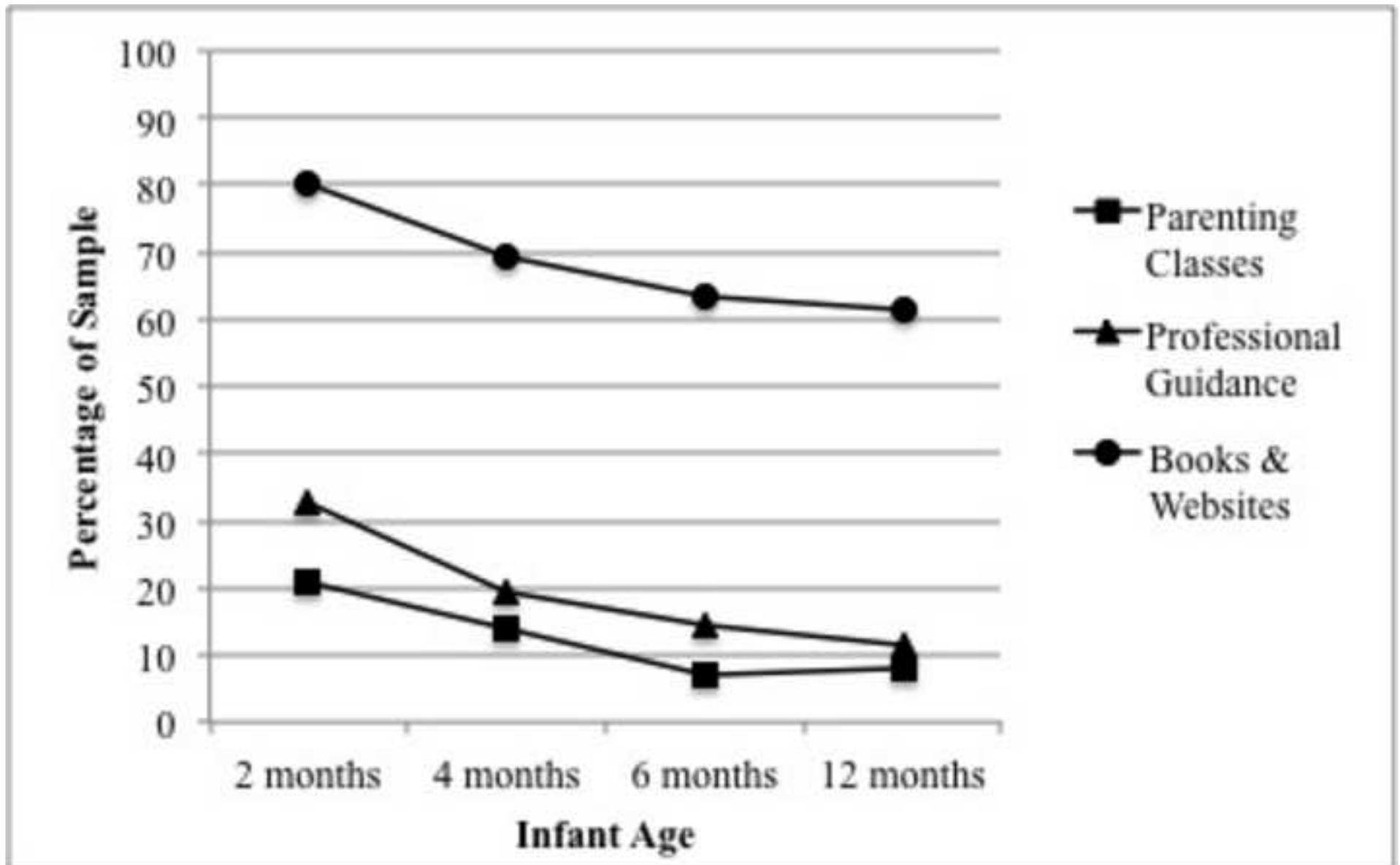


Figure 2
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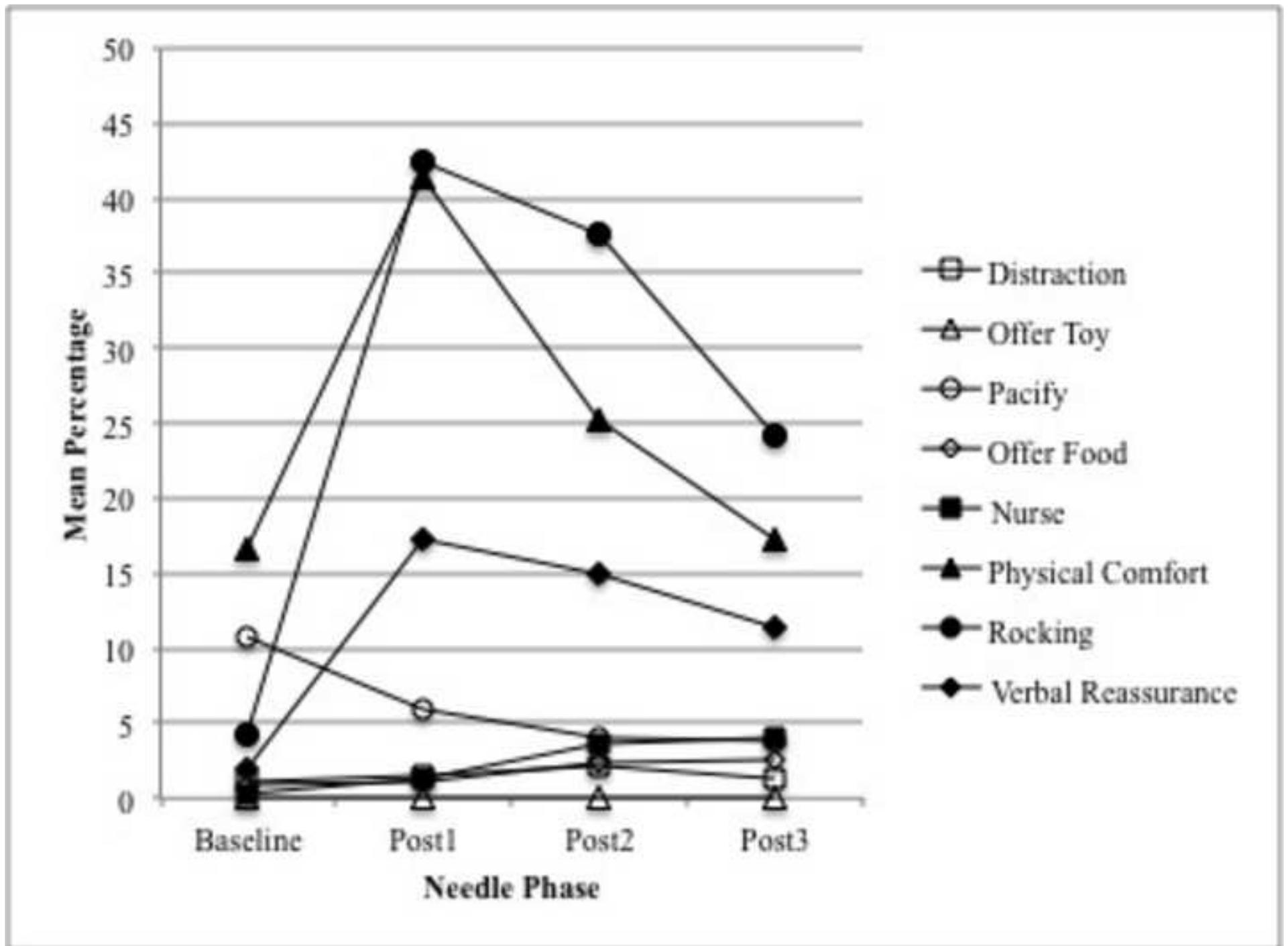


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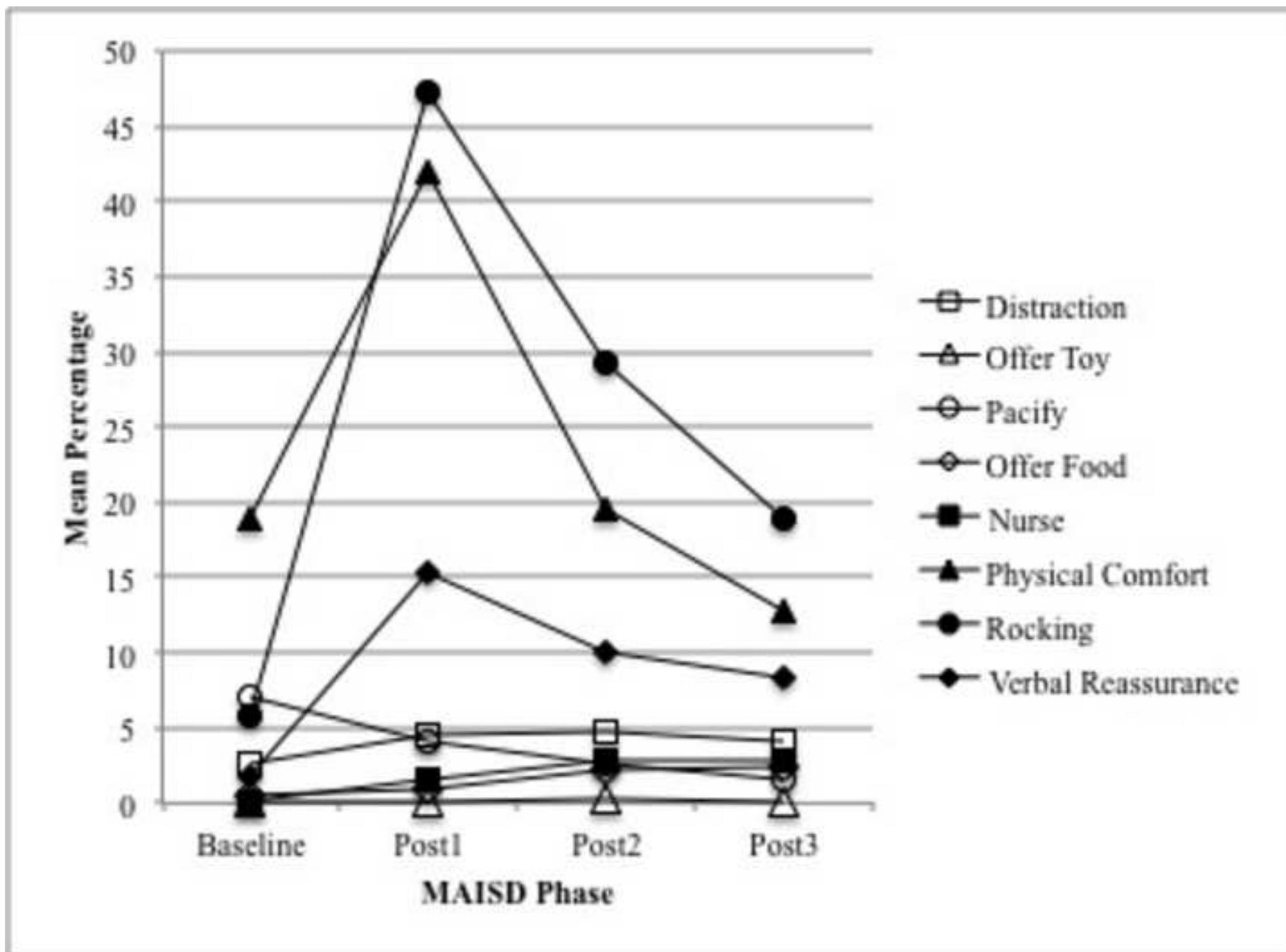


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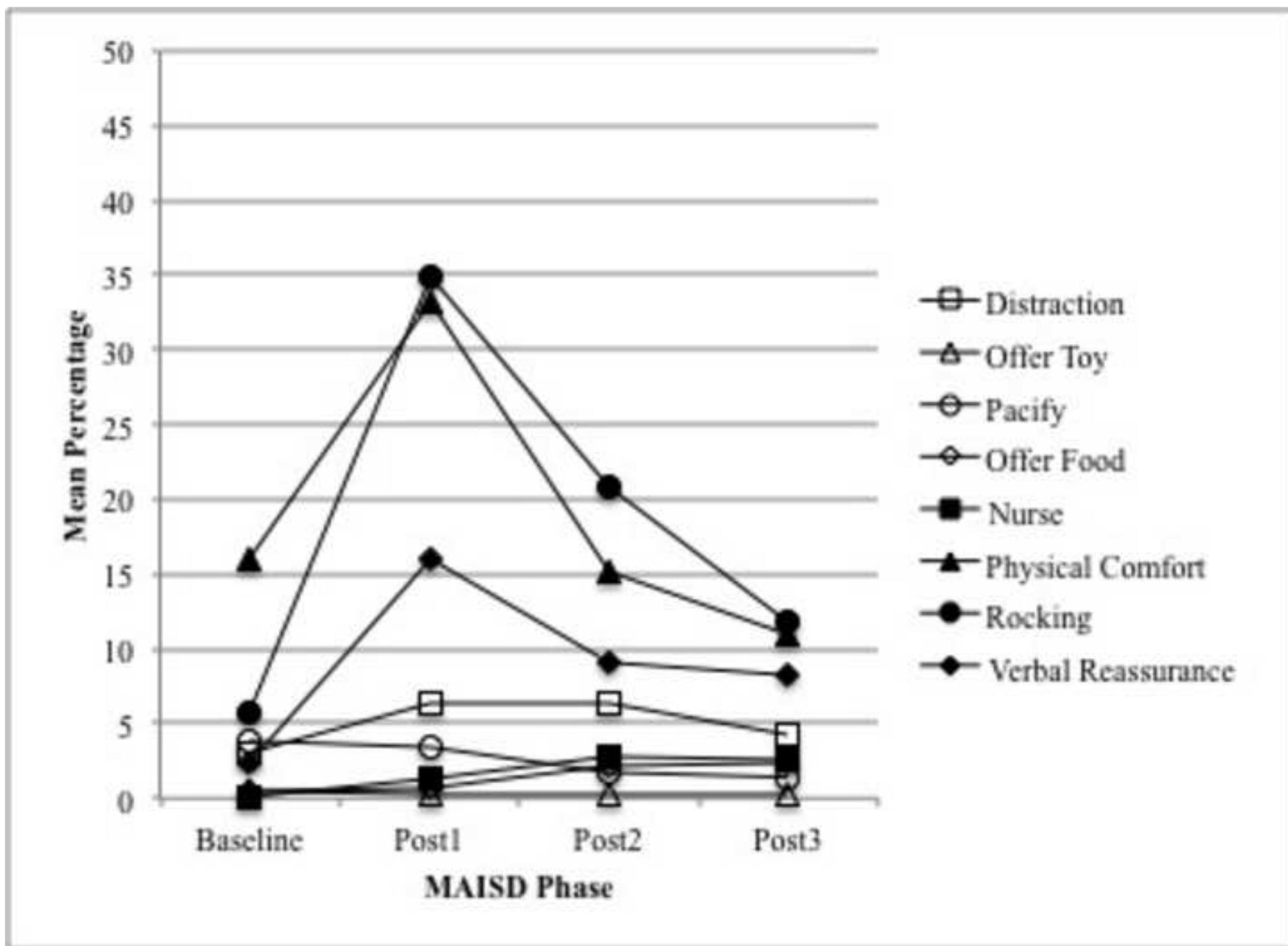


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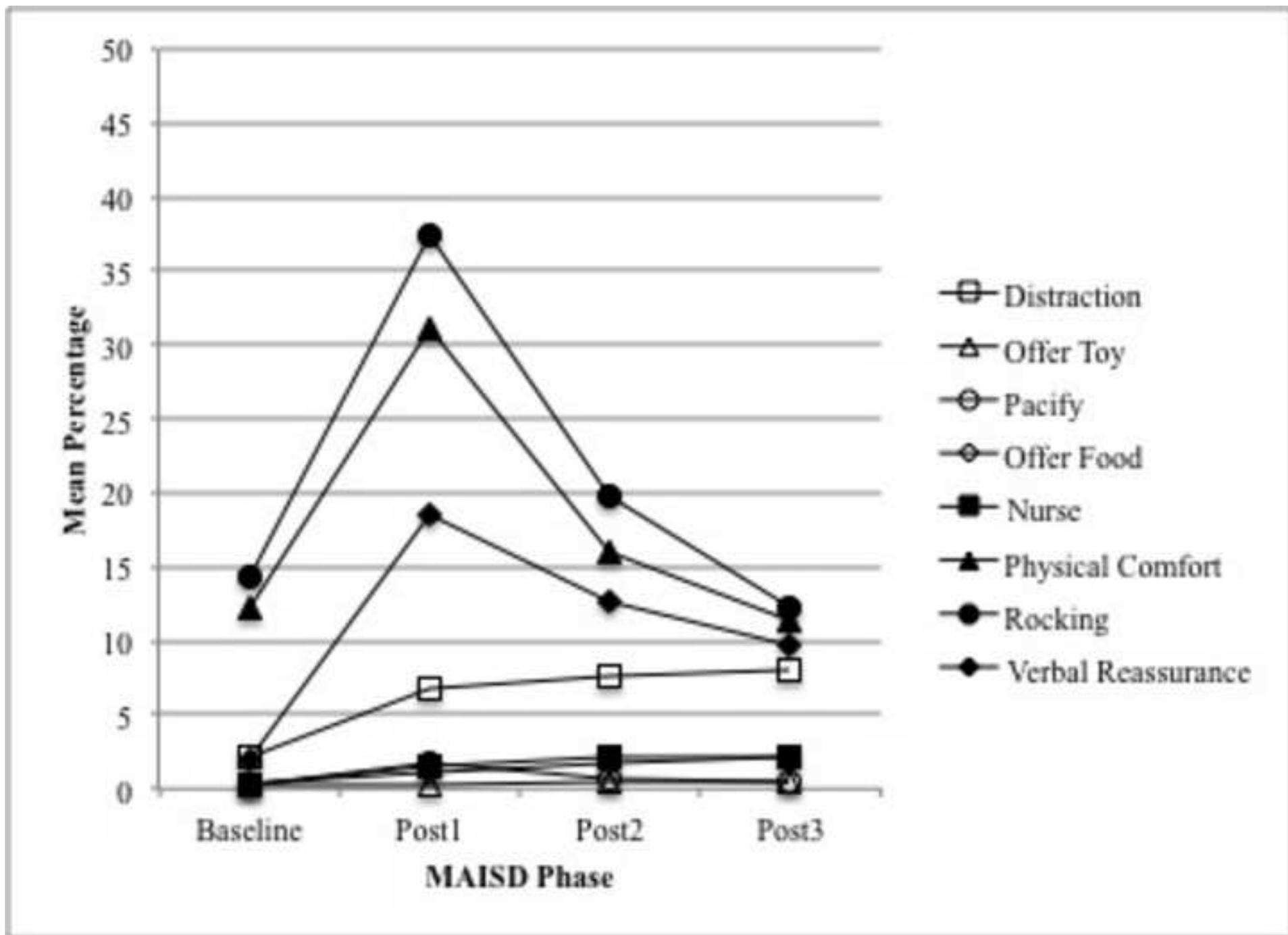


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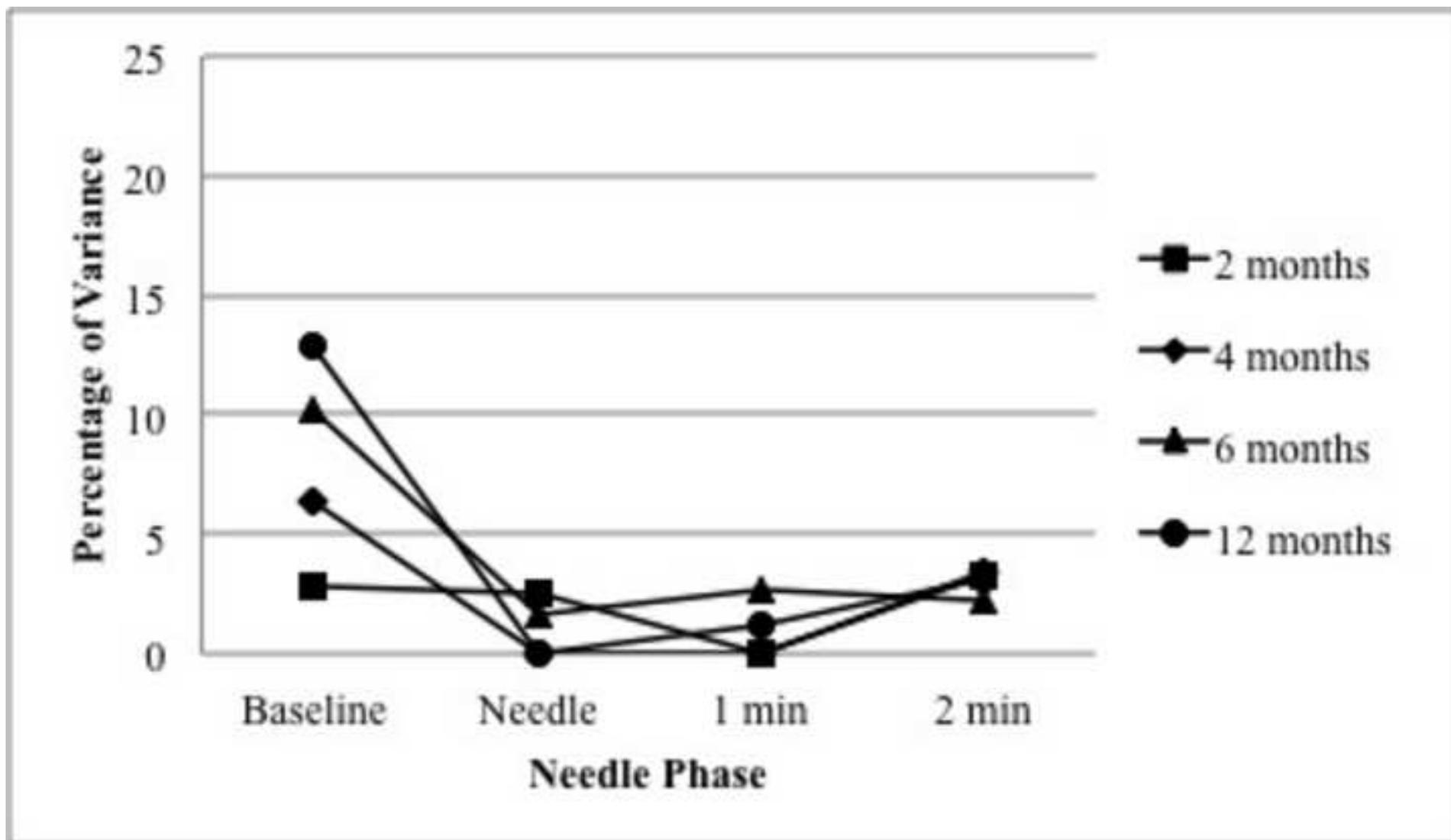


Table 1. Caregiver Attendance Breakdown (%)

	Age of Infant Immunization			
	2 months <i>n</i> = 497	4 months <i>n</i> = 592	6 months <i>n</i> = 601	12 months <i>n</i> = 531
Mother	49.3	58.4	59.4	55.2
Father	0.8	1.2	2	10.2
Mother & Father	40.2	33.6	31.1	27.5
Parent(s) & Nanny	1.2	1	1.3	1.3
Parent(s) & Grandparent(s)	6.4	4.1	4.2	3.6
Parent(s) & Other	2	1.4	2	1.9
Other	0.1	0.3	0	0.3

Table 2. 2-month MAISD Behaviours and their Relations to Pain at Subsequent Time Points

	NFCS Pain Phase			
	Pain Baseline	Pain Needle	Pain 1 Minute	Pain 2 Minutes
Pain Baseline	-	.12* (.009)	.17* (.000)	.14* (.004)
Pain Needle	-	-	.20* (.000)	.18* (.000)
Pain 1 minute	-	-	-	.38* (.000)
Distraction Pre	-.04 (.398)	-.06 (.206)	.00 (1.000)	-.04 (.441)
Pacify Pre	.08 (.091)	-.15* (.001)	.03 (.476)	-.06 (.199)
Physical Comfort Pre	.13* (.003)	-.03 (.496)	.05 (.299)	.01 (.850)
Rock Pre	.11* (.017)	-.02 (.697)	.04 (.411)	.04 (.395)
Verbal Reassurance Pre	.12* (.011)	.02 (.742)	.01 (.778)	.04 (.465)
Distraction 1 Min	-	-	-.06 (.213)	-.02 (.616)
Pacify 1 Min	-	-	-.03 (.562)	-.06 (.241)
Physical Comfort 1 Min	-	-	.04 (.419)	.06 (.180)
Rock 1 Min	-	-	.10* (.038)	.15* (.001)
Verbal Reassurance 1 Min	-	-	.12* (.008)	.05 (.256)
Distraction 2 Min	-	-	-	-.03 (.483)
Pacify 2 Min	-	-	-	-.03 (.509)
Physical Comfort 2 Min	-	-	-	.01 (.842)
Rock 2 Min	-	-	-	.11* (.017)
Verbal Reassurance 2 Min	-	-	-	.13* (.005)

Note. *p* values are in parentheses; * *p* < .05 (two tailed).

NFCS = Neonatal Facial Coding System

Table 3. 4-month MAISD Behaviours and their Relations to Pain at Subsequent Time Points

	NFCS Pain Phase			
	Pain Baseline	Pain Needle	Pain 1 Minute	Pain 2 Minutes
Pain Baseline	-	.17* (.000)	.30* (.000)	.39* (.000)
Pain Needle	-	-	.31* (.000)	.28* (.000)
Pain 1 minute	-	-	-	.39* (.000)
Distraction Pre	-.08 (.060)	-.06 (.145)	.07 (.124)	-.07 (.108)
Pacify Pre	.12* (.004)	-.07 (.085)	.04 (.354)	.04 (.374)
Physical Comfort Pre	.05 (.259)	-.06 (.136)	-.02 (.590)	-.07 (.086)
Rock Pre	.12* (.006)	.06 (.129)	.09* (.040)	.08 (.059)
Verbal Reassurance Pre	.21* (.000)	.08 (.068)	.08 (.059)	.18* (.000)
Distraction 1 Min	-	-	-.09* (.037)	-.06 (.174)
Pacify 1 Min	-	-	-.02 (.701)	-.03 (.459)
Physical Comfort 1 Min	-	-	.07 (.120)	.13* (.002)
Rock 1 Min	-	-	.12* (.006)	.14* (.001)
Verbal Reassurance 1 Min	-	-	.11* (.008)	.12* (.005)
Distraction 2 Min	-	-	-	-.05 (.219)
Pacify 2 Min	-	-	-	.01 (.759)
Physical Comfort 2 Min	-	-	-	.11* (.013)
Rock 2 Min	-	-	-	.09* (.029)
Verbal Reassurance 2 Min	-	-	-	.23* (.000)

Note. *p* values are in parentheses; * *p* < .05 (two tailed).

NFCS = Neonatal Facial Coding System

Table 4. 6-month MAISD Behaviours and their Relations to Pain at Subsequent Time Points

	NFCS Pain Phase			
	Pain Baseline	Pain Needle	Pain 1 Minute	Pain 2 Minutes
Pain Baseline	-	.24* (.000)	.27* (.000)	.25* (.000)
Pain Needle	-	-	.34* (.000)	.23* (.000)
Pain 1 minute	-	-	-	.30* (.000)
Distraction Pre	.05 (.227)	-.14* (.001)	-.01 (.780)	-.02 (.670)
Pacify Pre	.02 (.647)	.01 (.839)	.02 (.617)	.02 (.595)
Physical Comfort Pre	.08 (.060)	.01 (.876)	.08 (.070)	.02 (.632)
Rock Pre	.27* (.000)	.06 (.156)	.11* (.009)	.13* (.002)
Verbal Reassurance Pre	.22* (.000)	.07 (.077)	.06 (.130)	.08 (.068)
Distraction 1 Min	-	-	-.09* (.033)	-.06 (.145)
Pacify 1 Min	-	-	.07 (.096)	.00 (.981)
Physical Comfort 1 Min	-	-	.07 (.088)	.14* (.001)
Rock 1 Min	-	-	.07 (.092)	.12* (.006)
Verbal Reassurance 1 Min	-	-	.11* (.007)	.10* (.015)
Distraction 2 Min	-	-	-	-.03 (.531)
Pacify 2 Min	-	-	-	.04 (.371)
Physical Comfort 2 Min	-	-	-	.10* (.024)
Rock 2 Min	-	-	-	.06 (.199)
Verbal Reassurance 2 Min	-	-	-	.24* (.000)

Note. *p* values are in parentheses; * *p* < .05 (two tailed).

NFCS = Neonatal Facial Coding System

Table 5. 12-month MAISD Behaviours and their Relations to Pain at Subsequent Time Points

	NFCS Pain Phase			
	Pain Baseline	Pain Needle	Pain 1 Minute	Pain 2 Minutes
Pain Baseline	-	.14* (.001)	.21* (.000)	.25* (.000)
Pain Needle	-	-	.32* (.000)	.12* (.007)
Pain 1 minute	-	-	-	.34* (.000)
Distraction Pre	.07 (.110)	-.01 (.916)	.03 (.494)	.01 (.818)
Pacify Pre	.07 (.097)	.02 (.723)	.01 (.778)	-.01 (.818)
Physical Comfort Pre	.26* (.000)	-.03 (.528)	.09 (.052)	.07 (.120)
Rock Pre	.26* (.000)	-.03 (.500)	.16* (.000)	.13* (.003)
Verbal Reassurance Pre	.25* (.000)	-.06 (.190)	.07 (.129)	.00 (.950)
Distraction 1 Min	-	-	-.03 (.484)	-.08 (.076)
Pacify 1 Min	-	-	.03 (.521)	.01 (.828)
Physical Comfort 1 Min	-	-	.02 (.649)	.07 (.134)
Rock 1 Min	-	-	.09 (.043)	.10* (.022)
Verbal Reassurance 1 Min	-	-	.09 (.050)	.13* (.005)
Distraction 2 Min	-	-	-	-.03 (.451)
Pacify 2 Min	-	-	-	-.04 (.330)
Physical Comfort 2 Min	-	-	-	.13* (.005)
Rock 2 Min	-	-	-	.09 (.052)
Verbal Reassurance 2 Min	-	-	-	.21* (.000)

Note. *p* values are in parentheses; * *p* < .05 (two tailed).

NFCS = Neonatal Facial Coding System

Table 6. Linear Regressions Predicting Pain Scores within the 2-month Appointment

Predictor	β	Adj. R^2	R^2	ΔR^2
Pain at Baseline		.028	.034	
Physical Comfort Pre	.110*			
Rocking Pre	.085			
Verbal Reassurance Pre	.091*			
Pain at Needle		.031		.016*
Step 1			.012	.012
Pain Baseline	.108*			
Step 2			.035	.023
Pain Baseline	.120**			
Pacify Pre	-.154***			
Pain at 1 minute		.080		.027***
Step 1			.061	.061
Pain Baseline	.140**			
Pain Needle	.185***			
Step 2			.088	.027
Pain Baseline	.161***			
Pain Needle	.172***			
Rocking 1 min	.082			
Verbal Reassurance 1 min	.137**			
Pain at 2 minutes		.171		.023***
Step 1			.167	.167
Pain Baseline	.075			
Pain Needle	.083			
Pain 1 minute	.367***			
Step 2			.183	.016
Pain Baseline	.088			
Pain Needle	.074			
Pain 1 minute	.357***			
Rocking 1 min	.140**			
Rocking 2 min	-.057			
Verbal Reassurance 2 min	.032			

* $p < .05$ (two tailed); ** $p < .01$ (two tailed); *** $p \leq .001$ (two tailed)

Table 7. Linear Regressions Predicting Pain Scores within the 4-month Appointment

	β	Adj. R^2	R^2	ΔR^2
Pain at Baseline		.063	.068	
Pacify Pre	.106*			
Rocking Pre	.118**			
Verbal Reassurance Pre	.197***			
Pain at Needle				
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Pain at 1 minute		.154		<i>ns</i>
Step 1			.154	.154***
Pain Baseline	.245***			
Pain Needle	.269***			
Step 2			.163	<i>ns</i>
Pain Baseline	.237***			
Pain Needle	.245***			
Rocking Pre	.037			
Distraction 1 min	-.029			
Rocking 1 min	.039			
Verbal Reassurance 1 min	.066			
Pain at 2 minutes		.271		.034***
Step 1			.252	.252***
Pain Baseline	.284***			
Pain Needle	.157***			
Pain 1 minute	.252***			
Step 2			.285	.034***
Pain Baseline	.267***			
Pain Needle	.131***			
Pain 1 minute	.227***			
Verbal Reassurance Pre	.089*			
Physical Comfort 1 min	.048			
Rocking 1 min	.055			
Verbal Reassurance 1 min	-.028			
Physical Comfort 2 min	-.036			
Rocking 2 min	-.021			
Verbal Reassurance 2 min	.136**			

Note. *ns* = not significant

* $p < .05$ (two tailed); ** $p < .01$ (two tailed); *** $p \leq .001$ (two tailed)

Table 8. Linear Regressions Predicting Pain Scores within the 6-month Appointment

	β	Adj. R^2	R^2	ΔR^2
Pain at Baseline		.102	.105	
Rocking Pre	.250***			
Verbal Reassurance Pre	.184***			
Pain at Needle		.075		.025***
Step 1			.054	.054***
Pain Baseline	.232***			
Step 2			.078	.025***
Pain Baseline	.239***			
Distraction Pre	-.157***			
Pain at 1 minute		.154		<i>ns</i>
Step 1			.157	.157***
Pain Baseline	.198***			
Pain Needle	.301***			
Step 2			.161	<i>ns</i>
Pain Baseline	.187***			
Pain Needle	.290***			
Rocking Pre	.040			
Distraction 1 min	-.733			
Verbal Reassurance 1 min	.049			
Pain at 2 minutes		.170		.032**
Step 1			.152	.152***
Pain Baseline	.202***			
Pain Needle	.154***			
Pain 1 minute	.185***			
Step 2			.184	.032**
Pain Baseline	.194***			
Pain Needle	.107*			
Pain 1 minute	.170***			
Rocking Pre	.055			
Physical Comfort 1 min	.105*			
Rocking 1 min	.040			
Verbal Reassurance 1 min	-.044			
Physical Comfort 2 min	-.051			
Verbal Reassurance 2 min	.138**			

Note: *ns* = not significant

* $p < .05$ (two tailed); ** $p < .01$ (two tailed); *** $p \leq .001$ (two tailed)

Table 9. Linear Regressions Predicting Pain Scores within the 12-month Appointment

	β	Adj. R^2	R^2	ΔR^2
Pain at Baseline		.129	.134	
Physical Comfort Pre	.176***			
Rocking Pre	.166***			
Verbal Reassurance Pre	.184***			
Pain at Needle				
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Pain at 1 minute		.152		.012**
Step 1			.145	.145***
Pain Baseline	.193***			
Pain Needle	.301***			
Step 2			.157	.012**
Pain Baseline	.162***			
Pain Needle	.307***			
Rocking Pre	.116**			
Pain at 2 minutes		.188		.031**
Step 1			.172	.172***
Pain Baseline	.213***			
Pain Needle	-.016			
Pain 1 minute	.312***			
Step 2			.203	.031**
Pain Baseline	.192***			
Pain Needle	-.034			
Pain 1 minute	.286***			
Rocking Pre	.024			
Rocking 1 min	.040			
Verbal Reassurance 1 min	.039			
Physical Comfort 2 min	.041			
Verbal Reassurance 2 min	.125*			

* $p < .05$ (two tailed); ** $p < .01$ (two tailed); *** $p \leq .001$ (two tailed)