Title: Active vs. Passive Distraction and Parent Psychoeducation as pain management techniques during paediatric venepuncture – A Randomized Controlled Trial

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Abstract

Objectives

The aim of this research was twofold: to explore 1) the efficacy of active vs. passive distraction on self-reported pain and distress of children during a venepuncture; and 2) the impact of parental psychoeducation on child and parent outcomes, parental knowledge of distraction procedures and parental engagement in effective pain management strategies.

Methods

This cross-sectional study included 213 children scheduled for a venepuncture, and one of their parents, who were randomly allocated to one of four conditions; interactive distraction, passive distraction, interactive distraction with parent psychoeducation and passive distraction with parent psychoeducation. ANCOVA's were used to investigate the impact of distraction type and the use of parent psychoeducation on child and parent pain related outcome variables.

Results

Statistical analyses revealed no significant differences between groups for child-reported pain and distress. Parents who received parent psychoeducation had a significantly higher level of knowledge than parents who did not receive psychoeducation, but did not engage in more effective pain management behaviour.

Conclusions

The results indicated that passive vs. active distraction does not have a significantly different influence on child pain-related outcome variables. In addition, while psychoeducation was demonstrated to be effective in increasing parental knowledge, it was not sufficient to change parental behaviour.

Keywords: Venepuncture, Distraction, Parent Psychoeducation, Pain, Distress

Medical intervention requiring needle procedures are a common occurrence for most children growing up. In Ireland for example, the Health Service Executive's (HSE) National Immunisation Office recommends six vaccinations for babies before the age of 14 months, two additional vaccinations at 5 years of age, and a further four vaccinations for children aged 12 years [1]. In addition, children who have a diagnosis of an acute or chronic medical condition will require more frequent medical treatment, including needle-related procedures (e.g. intravenous cannulation, venepuncture, injections, lumbar punctures). Pain resulting from needle-related procedures may be considered to be mild; however for some people, needle-related procedures are associated with significant levels of fear and pain [2, 3]. It is important that the pain and distress associated with needle procedures is managed effectively, as negative experiences during needle procedures are associated with increased fear, future avoidance of necessary medical procedures and the potential development of a needle phobia, which may have a pervasive and lasting impact [4]. In addition, blood tests are a crucial diagnostic tool in modern medicine and so a phobia of needles is an important issue in the context of overall public health [5].

Within the research literature on the treatment of acute paediatric needle-related pain, distraction-based interventions have been subject to significant scrutiny. There is however limited tightly controlled clinical research examining the active components of distraction-based interventions, and their relative impact on child reported pain and distress during needle procedures. Research distinguishes between interactive and passive distraction-based interventions. The basic premise is that interactive distraction interventions require active engagement with the distractor stimulus (e.g. playing a videogame), whilst passive distraction interventions do not require a child to interact with the distractor stimulus (e.g. watching a videogame) [6]. Preliminary lab-based research suggests that interactive distraction may be more effective in reducing self-reported pain variables, as it requires a higher degree of cognitive processing [7, 8]. In this lab-based research, the visual and auditory stimuli presented through the head mounted devices in both conditions were identical. Only the child's ability to manipulate the virtual environment varied across the two distraction conditions, through use of a joy stick in the interactive condition and observing only in the passive condition. However, the conclusion on the differential effectiveness of passive vs. active distractive is preliminary, as this has not been evaluated in similarly tightly controlled clinical settings. Clinical research examining

the differential impact of interactive and passive distraction exist [9, 10]. These studies, however, use different stimuli for the interactive and passive distraction treatment groups, making it difficult to discern the reasons for group differences across outcome measures. As a result, further controlled research examining the potential differential impact of interactive and passive distraction-based interventions is warranted.

It is further unclear to what extent involving the parent as an active partner in the child's distraction is beneficial. Evaluations on effective paediatric pain management for acute pain resulting from needle-related procedures has been dominated by studies examining the efficacy of different types of distractor stimuli on child pain related variables with little attention towards the role of social factors. Nevertheless, both theoretical frameworks and growing research evidence point to the notable role of parental responses in explaining child pain experiences [17]. Research examining the impact of parent behaviour on a child's experience of needle-related procedures [11] suggests that there are certain parent behaviours associated with increasing child distress during needle-related procedures, such as providing reassurance, criticizing, and providing the child with procedural related information. Equally, research has shown that there are parent behaviours associated with decreasing child distress such as engaging in distraction, praising good behaviour and using humor[12]. This provides a rationale for looking at ways that we can improve parent engagement in distraction-based behaviours, by providing psychoeducational information on the impact of parent behaviour on child-related pain outcome variables.

In the context of needle pain, a recent study Cohen, Rodrigues [13] examined the impact of parent/child interactions during immunizations by evaluating a computerized parent-training program. This study aimed to establish whether this type of interactive parent training would have an impact on parent knowledge and reported levels of child pain and distress. Children included in this study were between 4 and 6 years of age. Results of this study suggested that while parent knowledge improved, there was no significant impact on child self-reported pain and distress. It is important to note that applied clinical research in this area is just beginning to incorporate social theoretical models into their design [17], and therefore further research in this area is warranted. For instance, research assessing the impact of parent state distress on child procedural distress as well as their ability to engage with

distraction is important to consider in this context. Previous research suggests that high levels of state parental distress at baseline, reduces the efficacy of distraction-based interventions for children [14, 15]. These findings warrant further investigation on how to assist parents to effectively engage in distraction when their child undergoes a painful medical procedure.

Consequently, the aim of the current research is twofold. (1) To extend the existing literature by exploring the efficacy of interactive and passive distraction on child pain and distress during a venepuncture. This systematic comparison of interactive and passive distraction within a paediatric hospital setting will extend the aforementioned laboratory-based research to a clinical setting. It is hypothesized that children in the interactive distraction group will report lower pain and distress than children in the passive distraction group (H1). (2) Additionally, this research aims to examine the additional beneficial impact of parent psychoeducation on pain-related child outcomes, parental knowledge of distraction strategies and parental engagement in distraction. In particular, it is hypothesized that

- children in the parent psychoeducation group will report lower child pain and distress than children in the no parent psychoeducation group (H2),
- parents in the parent psychoeducation group will report less distress than parents in the no parent psychoeducation group (H3).
- parents in the parent psychoeducation group will show more of an increase in parent knowledge scores than parents in the no parent psychoeducation group (H4).
- parents in the parent psychoeducation group will engage in higher levels of distraction coaching than parents in the no parent psychoeducation group (H5).

Materials and Methods

Participants

Inclusion/exclusion criteria. Children and their parents/guardians (herein referred to as parents, meaning the child's biological parent or guardian) who attended the phlebotomy clinic in Our Lady's Children's Hospital, Ireland between November 2015 and May 2016 were invited to take part in the current study. Child and parent dyads were invited to take part in the current study if they met the following inclusion criteria: (a) child between 6-12 years of age, and (b) had a venepuncture scheduled in the hospital. Exclusion criteria in the current study were as follows, and occurred at two time points during the research: Prior to the venepuncture (a) children who have severe hearing/vision impairments which would prevent them from being able to read or understand study materials, (b) children who had a history of neurodevelopmental disability (e.g. autism, attention deficit hyperactivity disorder (ADHD)), (c) children who were identified by the child's medical team as having significant needle related anxiety. At XXXX Hospital these children are not required to queue in the phlebotomy clinic in order to avoid anticipatory anxiety. As a result, there was not sufficient time to complete the pre-procedural measures with these participants. During the venepuncture: (d) children who became distressed during the venepuncture and as a result were unable to have the venepuncture completed.

A G*Power analyses for a power of .80 with a p-value of .05 was conducted for the main analyses (i.e. ANCOVA's) to determine the sample size requirements given the current methodological design, which recommended a sample size of 180 to achieve a moderate effect size [16]. A total of 213 child and parent dyads took part in this study. The recommended sample size was reached before the set deadline to cease data collection was reached. Hence, with permission of the hospital ethics committee and hospital staff, data collection continued past the required number, in an effort to improve the power for the study. Children ranged in age from six to twelve years (86 male, 96 female), with a mean age of 9.01 years (SD = 1.86). Parents ranged in age from 24 to 66 years (45 male, 167 female), with a mean age of 40.94 years (SD = 6.15). The majority of parents who took part in the current study were married (71.8%) and had completed secondary school or higher (90.2%). The Consolidated Standards of Reporting Trials (CONSORT) guidelines were utilized in structuring the write up of the current research article [17].

Procedure

Ethical approval for the current research study was obtained from the ethics committee of the National University of Ireland, Galway (NUIG), as well as by the hospital ethics committee in Our Lady's Children's Hospital. A visual depiction of the procedure is presented in Figure 1 below.

-- Insert Figure 1 about here --

Recruitment and consent. Child and parent dyads who met the inclusion criteria were invited to take part in the current study. Parents were provided with an 'Information Sheet for Parents' and children were provided with an age-appropriate 'Information Sheet for Children,' which was read to them by the researcher. Children and parents were provided with the opportunity to ask questions when necessary and reminded that they were free to withdraw from the study at any time, without penalty or impact on their care at the hospital. The information sheets also functioned as an assent form for children. A parental consent form was provided to the parents. Consent forms and assent forms asked participants to consent/assent to partaking in and being video recorded during the research.

Information for Staff. Staff were also provided with Staff Information Sheets and were asked to complete consent forms prior to commencement of the study. Staff were asked to consent to being video recorded during the study. It was made clear within the information sheet for staff, that video footage would not be utilized to analyse staff behaviour.

Randomization. A block randomization procedure was used in this study, with 24 participants per block: (i) Interactive Distraction (Group 1), (ii) Passive Distraction (Group 2), (iii) Interactive Distraction and Parent Psychoeducation (Group 3) and (iv) Passive Distraction and Parent Psychoeducation (Group 4). The random allocation sequence was generated by the first author prior to the commencement of the study. After providing consent and assent, parent and child dyads were enrolled in groups sequentially, as they presented in the waiting room.

Distraction groups. Children who were allocated to an interactive distraction condition (Group 1) used their nonprocedural arm to play a videogame (minion rush) using an electronic tablet (Lenovo Tab A10). This game was chosen, as informal feedback obtained from children within the designated age range (6-12 years) suggested that it was appealing across this range. Children in Group 1 were given two minutes in the waiting area prior to the procedure to familiarize themselves with

playing the game. Within the passive distraction group (Group 2), participants viewed pre-recorded footage of the same videogame (minion rush) using the same electronic tablet. Similar to the procedure for Group 1, the children in Group 2 watched a 2min clip of pre-recorded game footage game in the waiting room to familiarize themselves with the distractor. Two versions of pre-recorded footage were available so that children viewed different footage prior to the procedure and during the procedure. This was to ensure that the video shown during the procedure was novel, and to avoid the child becoming disinterested in the video**.**

Parent Psychoeducation group. Parents in the parent psychoeducation groups (irrespective of whether the child was assigned to interactive or passive distraction group, see below) were provided with a parent psychoeducation booklet to read in the waiting area prior to their child's procedure. This psychoeducation booklet contained information drawn from previous research to educate parents on techniques that can be used to help engage children in distraction during a venepuncture procedure (e.g. to use distraction, to avoid reassurance). This booklet is available by request from the first author. The techniques advised were adapted to fit a tablet distraction-based intervention procedure.

Data Collection. After group allocation, children were asked to complete the pre-procedural questionnaires, which were read aloud to the child by the researcher to ensure consistency and reliability of responding. During this time parents were asked to complete a demographic questionnaire and the standardized measures. A full list and description of standardized measures is provided below.

When directed to do so by hospital staff, child and parent dyads then proceeded to the clinic room for their venepuncture procedure. At this time, the researcher switched on a Panasonic SDR-SW20 video camera and provided the tablet to the parent. According to earlier randomization, children participated in the relevant intervention condition during their venepuncture procedures. During the procedure, participants' behaviour was recorded using a video camera. During the venepuncture, parents were the only ones interacting with the child; parents were holding the tablet (as the child needed to keep one arm still for the venepuncture) and nurses were by request not interacting with the child.

Following the venepuncture procedure, the researcher asked child and parent dyads to complete self-reported measures of pain and distress. Parents were then asked to provide an estimate of their child's pain during the venepuncture, to

complete post-procedural measures of their own distress and sympathy relating to their child's pain, and the parental knowledge.

Materials

Socio-demographic questionnaire. Parents reported socio-demographic information such as age, sex, level of education, and marital status. Parents were also asked to report if their child had a neuro-developmental disability, hearing difficulties and/or sight problems, in order to determine whether their child met the inclusion/exclusion criteria for the current study.

Child self-reported pain. Immediately following the venepuncture, children were asked to report on their pain using the Faces Pain Scale Revised (FPS-R) (Hicks, von Baeyer, Spafford, van Korlaar, & Goodenough, 2001), which is a self-report measure of pain intensity. This scale is a visual scale, which asks children to rate their pain intensity according to a face and a corresponding metric scale from 0 to 10 with higher scores reflecting higher pain intensity. High test-retest reliability has been demonstrated for the FPS-R ($r = .77$) [18]. Children were asked to point to the face on the faces pain scale. They did not indicate their pain rating verbally, to ensure that they could not be overheard by their parent.

Child self-reported distress. Child self-reported distress was assessed using a Visual Analogue Scale (VAS), with children asked to report their subjective levels of anxiety from 0 (low) to 10 (high), both before and directly after the venepuncture procedure. The VAS has been shown to be a useful and valid measure of anxiety, evidencing a high correlation ($r = .55$) with the State Anxiety Score of the Spielberger State-Trait Anxiety Inventory (STAI) [19].

Parental distress. The Parental Distress and Sympathy Questionnaire (PDSQ) was administered to parents to measure parental distress in response to the venepuncture. A likert scale from 0 (low) to 10 (high) was used to measure parental levels of worry, upset, anxiety, and sadness (combined these adjectives assess distress) as well as understanding, compassion, and, sympathy (combined these adjectives assess sympathy) [20]. Parents were asked to provide a rating prior to the venepuncture and directly following the venepuncture procedure. The PDSQ has been reported to have high levels of internal reliability ($\alpha = .78$) [20]. Total scores for parental distress were calculated by summing the individual scores for each item, with higher scores reflecting higher level of distress. In the current study, the Cronbach's

alpha coefficient for this scale was broadly in line with previous research ($\alpha = .85$ at time 1, and $\alpha = .93$ at time 2).

Parental knowledge on effective responses. The Parent Procedural Behaviour Knowledge Questionnaire (PPBK) [13] was utilized to assess change in parental knowledge on effective behaviour in response to child pain. The PPBK was completed on 2 occasions (i.e., prior to the venepuncture procedure, and directly after the venepuncture procedure) and assesses parent knowledge regarding the types of behaviours that have been shown to decrease and increase child distress. This measure lists eight parent behaviours (for example: distracting, providing information) and asks parents to rate whether each behaviour might increase or decrease child distress. This measure uses a visual analogue scale with 100-mm horizontal lines, with anchors of 'Decreases Child Distress' (0) to 'Increases Child Distress' (100). Responses for the four behaviours that decrease child distress were reverse-scored so that higher scores indicate greater knowledge for all eight behaviours. The total score was computed by adding the eight scores together to get a total parent knowledge score.

As reported by Cohen, Rodrigues [13], the average baseline knowledge Cronbach's alpha score for the PPBK was .36, which increased to .78 post-procedure for the group of parents receiving computer-based parent training but decreased to .22 for the parent group not receiving the training. In the current study, Cronbach's alpha for baseline parent knowledge was .58. The post-procedural Cronbach's alpha for the group who received parent psychoeducation was .64, and was .57 for those who did not receive parent psychoeducation. These data provide preliminary support for the internal consistency of this measure [13].

Engagement with distraction - behavioural measure. Frequency of parental distraction was measured using a modified version of the Distraction Coaching Index (DCI)[21]. This measure was originally intended to assess parent engagement (quality and frequency) in distraction using a range of toys and different objects. As the current study used a tablet computer only, the quality assessment of distraction coaching was not appropriate for use. Quality assessment examined for example, parental choice of distractor, which would not have been appropriate given the current methodology. For the purposes of the current study, only the frequency of distraction coaching was measured. Specifically, using the DCI protocol, video footage of the venepuncture procedure was divided into 10-second intervals, and the number of intervals in which distraction coaching occurred were counted. Specific behavioural

definitions were generated to define the exact meaning of distraction coaching, and what it involved. These definitions were based on the original behavioural definitions specified in the DCI manual and adjusted to be applicable to our specific use of tablet-based distraction. Videos were blind coded to eliminate subjective bias. Training in the coding protocol for this study was conducted by one of the senior authors of this paper (i.e. trainer), who has significant experience in coding this type of data.Training was done using five randomly selected videos, coded independently by the trainer and the two authors responsible for coding the data. Discussions took place to overcome any disagreements in the coding between the trainer and coders before going ahead with the coding of all videos. The overall frequency percentage score was calculated as the ratio of intervals in which distraction coaching occurred to the total number of intervals (e.g. 7 intervals with distraction and 3 intervals without, leads to a frequency score of 70%). Inter-rater reliability was obtained for 10% of the videos in this study, and an interrater reliability analysis using the Kappa statistic was performed to determine consistency among raters,Kappa = 0.68 ($p < .0.001$), indicating substantial agreement between raters.

Treatment Acceptability. Using a Visual Analogue Scale from 0 (did not like) to 10 (liked very much), with 100-mm horizontal lines, children were asked to rate how much they liked the game. Children were also asked whether they would like to use the same distraction method again in the future, if they were having blood taken. The response options provided were *No, Maybe* and *Yes*. To capture treatment acceptability from a parent perspective, parents were asked to rate how distracted their child was by the tablet, using numerical rating scales from 0 (not distracted) to 10 (very distracted). Parents were also asked whether they would use the same method of distraction during future blood draws. The response options provided were *No, Maybe* and *Yes*.

Data Analyses

Data were analysed using the Statistical Package for Social Sciences (SPSS) version 22. To assess the normality of the distribution of the continuous variables in this data set, the skewness and kurtosis values (skewness range = .15 – 1.39; kurtosis range = .17 – 1.61) were examined and, histograms, stem-and-leaf plots, and QQ plots for outliers, were visually inspected. Following the guidelines outlined by Curran, West [22] two variables were transformed (Child post procedural distress and Parent post procedural distress) resulting into skewness and kurtosis

values that fell within the appropriate range. An analysis of missing data was then completed to determine the nature of the missing data using Little's Missing Completely At Random (MCAR) Test [23]. Results of this analysis indicated that the data were not missing at random, resulting in a non-significant chi-square = 339.63 (df = 244, p = .000). As this assumption was violated, pairwise deletion was utilized to manage missing data as recommended by Pallant [24]. A preliminary screening analysis concluded that this data were suitable for parametric analysis using ANCOVA's, as it met the assumptions of normality, homogeneity of variance, interval variables and the assumption of independence [26].

Descriptive statistics were computed for all variables, followed by Chi-square analyses were conducted to analyse differences across groups for categorical variables as follows: topical anesthetic use, number of previous venepunctures and played minion rush previously. Subsequently, 2 (interactive vs. passive distraction) x 2 (parent psychoeducation vs. no parent psychoeducation) univariate or repeated measures analysis of co-variance were conducted to examine differences across groups on child self-reported pain/distress (H1 and H2), parental distress (H3), parent knowledge (H4) and parent engagement with distraction (H5). Child age, child sex, parent age, parent sex, previous number of blood draws, use of topical anaesthetic and whether the child had played minion rush previously were added as covariates if they showed a significant correlation with the outcome variable. In addition, for the analyses with parental outcome, we controlled for child level of pre-procedural distress. Analysis identified positively skewed data for pre-procedural child distress, indicating that a significant proportion of children rated their distress as zero. As a result, for the analyses with parental outcomes, child-reported pre-procedural distress VAS scores were categorized as follows: no/low distress (0-40mm) and distress (40mm–100mm) according to guidelines set out by Joos, Peretz [25].

Results

Sample Characteristics and Descriptive Statistics

Socio-demographic data for the overall sample and other pertinent clinical information are presented in Table 1. The majority of participants 1) opted for topical anesthetic prior to the venepuncture procedure (80.7%), 2) had experience of more than five previous venepuncture (52%) procedures, and 3) had played the game minion rush before (60.8%). Statistics for dependent variables for each of the treatment groups, are presented in Table 2 and Table 3.

--Insert Table 1 here--

--Insert Table 2 here--

--Insert Table 3 here--

A chi-square test of independence was performed to examine group differences for the following variables: topical anesthetic use, number of previous venepunctures and whether the child had played minion rush previously. Results revealed no significant differences across groups for these variables (topical anesthetic use:X^2 (3, N = 170) = 4.24, p = .23, number of previous venepunctures: X^2(15, N = 201) = 15.36, p = .42, played minion rush previously: X^2 (6, N = 204) = 6.79, p = .34.

Treatment Acceptability

Data were gathered to determine the level of treatment acceptability among participants. The majority of children (70.9%) reported that they would like to use the same method of distraction if they were having blood taken in the future, with 23.5% reporting that they would 'maybe' like to use the game again, and only 3.3% of children saying that they would not like to use the same distraction method in the future. This indicates a high rate of treatment acceptability from a child perspective. In terms of parent perspective, 71.3% of parents reported that they would use the same method of distraction with their child during future blood draws. In addition, 63.4% of parents rated the game as being very effective (>=70% effective) in distracting their child during the venepuncture procedure. This indicates a high level of subjective efficacy from a parental perspective, as well as a high rate of social validity.

Child Outcome Variables

Child-Reported Pain

To test H1 and H2, a 2 (interactive vs. passive distraction) x 2 (parent psychoeducation vs. no parent psychoeducation) univariate analysis of covariance (ANCOVA) was conducted to investigate the impact of group assignment on child self-reported pain scores. There was no significant difference observed across groups on child self-reported pain scores (distraction type; $F = .01$, $p = .90$, parent psychoeducation; $F = .82$, $p = .36$). Only the covariates child age ($\beta = -.30$, $F = 9.09$, $p < .005$) and previous number of blood draws ($\beta = -.23$, $F = 4.60$, $p < .05$) showed a significant main effect, indicating that older children and that children who had experienced higher numbers of venepunctures reported lower pain scores.

Child-Reported Distress

To test H1 and H2, a2 (interactive vs. passive) x 2 (parent psychoeducation vs. no parent psychoeducation) repeated measures ANCOVA was conducted to examine the impact of group assignment on child self-reported distress. Child self-reported distress was measured prior to the venepuncture procedure (pre-procedural) and immediately following the venepuncture procedure (post-procedural). The change for pre- to post-procedural distress was not significantly different between the groups (distraction type; $F = 0.06$, $p = .80$, parent psychoeducation; $F = 1.30$, $p = .25$). The covariate child age was the only variable with a significant main effect ($\beta = -2.34$, $F = 4.90$, $p < .05$), indicating that younger children reported higher levels of distress than older children.

Parent Outcome Variables

Parental Distress

To test H3, a 2 (interactive vs. passive) x 2 (parent psychoeducation vs. no parent psychoeducation) repeated measures ANCOVA was conducted to assess the impact of group assignment, on parent-reported distress. Similar to child-reported distress, parent-reported distress was measured prior to the venepuncture procedure and immediately following the venepuncture procedure. There was no significant difference in parental distress observed for group assignment to parent psychoeducation ($F = .00$, $p = .92$). However, a significant main effect was observed for parental distress based on the type of distraction their child received, (distraction type; $F = 4.16$, $p < .05$). The parents of children who received interactive distraction reported significantly higher levels of distress than the parents of children who received passive distraction.

Parent Knowledge

To test H4, a 2 (parent psychoeducation vs. no parent psychoeducation) x 2 (interactive vs. passive distraction) repeated measures ANCOVA was performed. A significant interaction effect was observed ($F = 4.36$, $p < .05$) for level of parent knowledge between parent psychoeducation group and time. This indicates that parents in the parent psychoeducation group had a significantly higher level of knowledge than parents in the no parent psychoeducation group from pre- to post- procedure. Further individual analyses were conducted to determine what specific type of knowledge showed significant changes from pre- to post-venepuncture. Analyses revealed that parent knowledge specifically relating to the provision of reassurance to their child during venepuncture, was significantly different from pre- to post-venepuncture ($F = 4.49$, $p < .05$), with parents in the parent psychoeducation group having a higher mean knowledge regarding the impact of providing reassurance post-venepuncture ($M = 33.37$ parent psychoeducation group, $M = 23.71$ no parent psychoeducation group). The other specific types of knowledge did not differ significantly from pre- to post-venepuncture.

Parent Engagement in Distraction

To test H5, a 2 (parent psychoeducation vs. no parent psychoeducation) x 2 (interactive vs. passive distraction) univariate analysis of co-variance (ANCOVA) was utilized to explore differences in parent distraction percentage score across groups There was no significant difference in parent distraction scores between groups (distraction type; $F = 0.845$, $p = .359$, parent psychoeducation; $F = .027$ $p = .870$). There was no significant difference in parent distraction scores between groups (distraction type; $F = 0.845$, $p = .359$, parent psychoeducation; $F = .027$ $p = .870$). A significant main effect was observed for child age ($\beta = -3.29$, $F = 5.53$, $p < .02$).

Discussion

The aim of this study focused on examining the relative efficacy of interactive and passive distraction on child pain and distress during venepuncture. Furthermore, this study also aimed to determine whether providing parents with psychoeducation regarding effective pain management techniques would reduce child pain and distress as well as parental distress, while improving parent knowledge in this domain, and their engagement in effective pain management behavior.

With regards to child pain and distress and parental distress; results of the current study did not support the original hypotheses regarding changes in pain-related outcome variables. Results demonstrated that group assignment; i.e. allocation to interactive/passive distraction condition, or parent psychoeducation/no parent psychoeducation, did not have a significant influence on child-reported pain and distress (H1-2). This supports preliminary evidence from the most recent Cochrane review [27], which did not report consistent statistically significant differences in levels of child-reported pain and distress, based on the type of distraction intervention employed.

The current findings do not support the original hypotheses within the literature, which suggest that interactive distraction tasks are more effective than passive distraction tasks, due to the greater cognitive processing load placed on participants [8]. It should be noted however that the research which forms the basis for this suggestion is experimental in nature (laboratory based), while the current research was based within a busy paediatric clinical setting. A further factor which requires consideration is that the age range of children included in the current study is relatively wide (6-12 years). Therefore, age as a variable may be preventing the detection of group differences. Additionally, it is important to note that, unexpectedly, our findings indicated that distraction type influenced parental distress. Parents of children who received interactive distraction reported significantly higher levels of distress than parents of children who received passive distraction. This result was not anticipated and thus it is difficult to interpret this finding. However, given previous evidence revealing that parental distress experiences can reduce the efficacy of distraction-based interventions [14, 15], these heightened levels of parental distress during active distraction might have influenced the effectiveness of active distraction. Further research is needed to confirm this outcome, but a potential explanation might be that parents of children in the interactive distraction group felt more distressed due to the added responsibility of engaging their child in the distraction task. Continued efforts to further our

understanding of the experience and role of parental distress during interactive distraction interventions will be crucial.

As hypothesized, findings indicated that parents in the parent psychoeducation group had a significantly higher level of knowledge regarding effective pain management interventions for children (H4). Specifically, a higher level of knowledge regarding the impact of providing reassurance to their child was found for parents who were provided with the booklet. This is an interesting finding, given that the focus of the parent psychoeducation booklet, was on the merits of using distraction, and focused less on the impact of providing reassurance to children. In terms of the level of parent engagement in distraction during the venepuncture procedure, results indicated that there was no significant change in parent behaviour due to receiving the intervention (H5). There might be several explanations as to why no differences were found in parental behaviour. Increasing parent knowledge is undoubtedly an important first step in changing parent behaviour. It is likely however, that a more intensive and dyadic form of parent coaching would be required to provide parents with the necessary skills to achieve a significant change in their behaviour. A study by Cohen, Rodrigues [13] for example, provided parents with a ten-minute interactive computer based training program. The results of this study demonstrated that this intervention did significantly influence parent behaviour, thus supporting the assertion that an interactive parent-led intervention is necessary to have a significant impact on parent behaviour. Interestingly, this study found that parents across all conditions demonstrated a high level of knowledge regarding the benefits of distraction, but only those in the parent intervention condition evidenced a change in behaviour [13]. Furthermore, contrary to our hypotheses, our parental psychoeducation did not reduce parental distress (H3). Given previous evidence indicating that parental distress negatively influences their ability to engage in distraction [13,14], the lack of reducing parental distress might be an alternative explanation as to why our parental psychoeducation did not influence parental behaviours.

Given that needle-related procedures are a source of significant fear and anxiety for some children, it is imperative that phlebotomy clinics and medical personnel are provided with evidence-based interventions to alleviate this anxiety, to prevent refusal of medical treatment by children and to decrease the requirement for additional staff which may be necessary when children present with significant anxiety. During data collection for the current study for example, children who displayed high levels of distress during the venepuncture procedure required two staff members and sometimes three, in an effort to

complete the blood draw. For example, one staff member to hold the equipment, one staff member to support the parent in keeping the child's hands steady and one staff member to complete the blood draw. Extra staff members were required for safety purposes, and in cases where the venepuncture was urgently required for medical investigations. The economic cost of additional staffing, in combination with the benefits of the provision of evidence based psychological intervention, provide a clear rationale for changing how many hospitals currently manage procedural anxiety in a paediatric setting. A move away from reactive management of procedural distress, to a more proactive and preventative approach, certainly appears to make sense, both from an economic perspective as well as from a child well-being perspective. In the current study for example, even an easy to implement passive distraction intervention (i.e. watching a video) could be an important low cost tool, which may be useful in busy paediatric clinic settings.

Parent psychoeducation-based interventions such as that used in the current study have been shown to have a significant influence on parent knowledge. Further development of effective parent-led interventions, which result in parent behaviour change and resulting child behaviour change, is a crucial next step in the paediatric acute pain literature. When fully developed and evaluated, computer based parent training programs, such as the 'Bear Essentials' program developed by Cohen, Rodrigues [13], could provide invaluable training to the parents of high anxiety children in a paediatric context. The provision of this type of parent training could be provided in a cost-effective manner within a hospital setting, without the requirement of additional hospital personnel. This type of evidenced-based intervention has the potential to lead to less refusal by children to have needle-related procedures. Additionally, it is possible that such interventions may lead to a reduction in child and parent distress and an improvement in the overall experience for children and their parents when attending hospital for needle-related procedures.

In developing such interventions, careful consideration needs to be given to how appropriate the intervention is for the child's developmental stage. In the current study, child age showed a significant main effect for each of the pain-related outcome variables. More specifically, it emerged that younger children and their parents expressed significantly more pain and distress than older children and their parents. Previous research has highlighted this finding, emphasizing the important role that the developmental stage of the child can play on the child pain experience [28, 29]. The current study had aimed to curtail the influence of age, by restricting the age group of children (6-12 years) in the current study, as recommended by the StaR guidelines [30]. Results suggest however that

this age range might still be too broad, as age emerged as a significant covariate within the analyses. In light of this finding, perhaps a revision of guidelines for paediatric research is warranted, with more careful consideration given to the specific age grouping categories for research. Future research could benefit from comparing the effectiveness of interventions for children who are at approximately the same developmental stage, with a focus on the development of age specific psychological interventions within an acute paediatric context.

Strengths and Limitations

Results of this study should be considered in the context of its strengths and limitations. A strength of the current research is its tightly controlled and rigorous design within a clinical context, which allowed for an analysis of the effective mechanisms of action within a distraction-based intervention. The study design aimed to address the existing concern within the literature regarding the lack of structured and systematic research exploring distraction efficacy, as highlighted by a recent systematic review [31]. Previous research has for example used a distraction-based intervention which included numerous components such as books, bubbles and music [32, 33]. With this type of research design, it was not possible to isolate the active components of the intervention, where main effects were detected. A further strength of the current study is the size of the sample, which met the power requirements as determined by the G*Power statistical program [16].

A first limitation of the current analyses relates to the absence of an observational measure of child distress and overall child behaviour during the venepuncture procedure. A study by Cohen, Rodrigues [13] for example, examined the impact of parent behaviour change on child behaviour, which is an important factor in understanding the complex social phenomenon of pain expression [34]. Through the use of an observational measure, this study was then able to directly assess the impact of parent behaviour on changes in child behaviour. The addition of an observational measure would also provide an objective and accurate measure of child distress, meaning less of a reliance on self-reported measures of pain, which are flawed in terms of accuracy and reliability [35]. A second limitation associated with the current study is that it did not incorporate a quality measure of distraction, as described in the DCI manual [21]. While the frequency of parent distraction-based behaviour is an important indication of parent engagement with distraction, it does not provide us with information regarding the quality of the distraction provided by the parent. A third limitation relates to the homogenous nature of the current sample (e.g. socio-economic status), which is often an issue with this type of research. Furthermore, the

large quantity of analyses conducted could have led to incorrectly rejecting the null hypothesis. In the current analyses however, a bonferroni correction was deemed too conservative. In addition, a small number of children who became highly distressed and were unable to complete the venepuncture procedure had to be excluded from this study. Qualitative feedback from the parents of these children was that this type of intervention was ineffective for their children, and thus treatment acceptability for this group was low. Further research to identify successful interventions for procedural anxiety for highly distressed children is required. A final limitation associated with the current research relates to the absence of a control group in the study. Following liaison with the nursing staff in the phlebotomy clinic at Our Lady's Children's Hospital, it was established that treatment as usual typically involved nursing staff engaging children with distractor stimuli. In addition, plenty of research has shown that distraction is an effective intervention, whilst the main goal of the current study was to examine the active components of distraction. In light of this information, it was therefore decided that a true control group receiving no intervention was not ethically appropriate.

Considerations for Future Research

Further research is required to develop age specific, cost-effective psychological interventions to specifically target procedural anxiety within a paediatric context. Specific consideration should be given to the developmental stage of the children for whom the intervention is targeted, given the evidence from the current study that age was a significant covariate within the analyses. Further consideration should also be given to the level of pre-procedural anxiety of children who are included in this type of research. Moving forward, it is important to investigate the efficacy of distraction-based interventions for children who present with at least a moderate level of distress. Children who do not present with behavioural symptoms of anxiety during needle-procedures might not necessarily require psychological intervention. Finally, future research should focus on the development of parent directed distraction-based interventions, which directly evaluate parent behaviour change. While psychoeducation was shown to change parental knowledge, further research involving computer based parent training [13] might be required to provoke a significant change in parent behaviour. Further research expanding on this type of intervention should be conducted and may provide a cost-effective method for reducing child and parent procedural related distress.

In summary, the current study provides additional support for the continued development of psychological interventions for the management of paediatric procedural

distress. Despite the fact that the original hypotheses in this study were not supported by the results, the overall profile of results are likely to inform future research into the development of age appropriate psychological interventions for children in an acute pain context. Additional research which addresses the limitations highlighted in the current study is warranted, with a specific focus on developing our understanding of the role of the social process in the paediatric pain experience.

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Table 1
Socio-Demographic information and other clinical information

	Percentage	N	Range	Mean	SD
Child age (years)		212	6-12	9.01	1.86
Child sex (% female)	52.10%	213			
Parent age (years)		206	24-66	40.71	5.92
Parent sex (% female)	78.40%	212			
Marital Status					
Single	10.8%	23			
Married	71.8%	153			
Divorced/Separated	6.1%	13			
Living with partner	8.9%	19			
Widowed	0.5%	1			
Education Level					
Primary School	2.3%	5			
Some Secondary School	7.5%	16			
Completed Secondary School	13.6%	29			
Post-Secondary School	28.2%	60			
University Degree	25.8%	55			
Post-Graduate Degree	19.7%	42			
Previous Blood Draws					
None	12.2%	26			
1-5	31.0%	66			
5-10	14.1%	30			
10-20	11.3%	24			
20-30	6.1%	13			
30+	21.2%	45			
Played Minion Rush					
Yes	61%	130			
No	35.2%	75			
Don’t know	3.8%	8			
Topical Anaesthetic					
Yes	82.6%	176			
No	6.1%	13			
Don’t know	11.3%	24			

Table 2

Descriptive Statistics for Dependent Variables

Dependent Variable	Group 1 – Interactive Distraction	Group 2 – Passive Distraction	Group 3 – Interactive Distraction Plus Parent Psycho-education	Group 4 – Passive Distraction Plus Parent Psycho-education
Child Pre Procedural Distress	N = 54 Mean = 29.31 SD = 29.55	N = 51 Mean = 35.1 SD = 32.55	N = 54 Mean = 27.81 SD = 28.53	N = 50 Mean = 27.36 SD = 24.65
Child Post Procedural Distress	N = 54 Mean = 14.54 SD = 25.84	N = 49 Mean = 16.46 SD = 28.44	N = 52 Mean = 14.48 SD = 28.02	N = 49 Mean = 11.32 SD =
Child Perceived Pain	N = 55 Mean = 2.21 SD = 2.89	N = 49 Mean = 2.24 SD = 3.15	N = 52 Mean = 2.40 SD = 2.93	N = 49 Mean = 2.00 SD = 2.44
Time 1 Parent Distress	N = 45 Mean = 8.42 SD = 9.33	N = 42 Mean = 8.80 SD = 7.17	N = 41 Mean = 9.09 SD = 8.78	N = 43 Mean = 5.39 SD = 6.33
Time 2 Parent Distress	N = 45 Mean = 3.93 SD = 6.71	N = 42 Mean = 5.88 SD = 10.18	N = 38 Mean = 4.52 SD = 6.25	N = 42 Mean = 3.16 5.19
Time 1 Parent Knowledge	N = 43 Mean =507.68 SD = 77.64	N = 40 Mean = 505.30 SD = 51.67	N = 39 Mean = 490.43 SD = 85.39	N = 39 Mean = 508.13 SD = 64.95
Time 2 Parent Knowledge	N = 44 Mean = 474.57 SD = 90.53	N = 37 Mean = 495.27 SD = 58.62	N = 36 Mean = 500.99 SD = 94.03	N = 41 Mean = 531.83 SD =98.01
Parent Distraction Percentage	N = 44 44.33% SD = 35.20	N = 37 44.61% SD = 34.21	N = 40 49.11% SD = 36.04	N = 40 46.05% SD = 34.85

Table 3
Frequency Table for Specific Variables

		Interactive Distraction	Passive Distraction	Interactive Distraction & Parent Psychoeducation	Passive Distraction & Parent Psychoeducation
Age of child	Mean	8.81	8.76	9.09	9.44
	SD	1.78	1.75	2.14	1.70
Gender of child	Male	24	31	25	22
	Female	31	21	29	28
Topical Anesthetic	Yes	42	43	48	41
	No	5	1	2	5
Times blood taken previously	None	7	8	4	7
	1-5 times	16	19	15	16
	6-10 times	4	8	12	5
	11-20 times	3	5		7
	21-30 times	5	3	1	4
	30+ times	15	9	11	9
Played minion rush previously?	Yes	33	27	34	35
	No	19	24	18	14