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Passive versus Active Distraction Methods to Reduce Vaccination Associated Pain and Anxiety in Children

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Abstract: **Immunizations are a common source of iatrogenic pain in children which can cause long-term psychologically detrimental effects. Measures to reduce needle associated pain among children have been examined with inconclusive evidence.**

Purpose: The current study aimed to compare the effect of non-pharmacological pain control measures in reducing vaccine associated pain and anxiety in pediatric primary healthcare centers in Saudi Arabia.

Methods: A quasi-experimental study was conducted with 100 preschoolers undergoing immunization in three primary healthcare centers in Qasem, Saudi Arabia. The participants were divided into intervention and control groups. The intervention group was subdivided into Therapeutic Toy, Video Games, Role-playing, Comfortable Position, and Wrist Water Toy subgroups. Wong-Baker, Ontario Pain, Anxiety Rating and Visual Facial Anxiety Scales were used to measure pain and anxiety.

Results: Children who received pain control measures while being vaccinated reported less pain and anxiety compared to those who received routine care. The use of interactive distraction methods (e.g. Wrist Water Toy and Video Games) reduced reports of pain, while passive distraction methods (e.g. Therapeutic Toy) reduced reports of anxiety.

Conclusions: Our findings are in support with long standing recommendations to use interactive distraction methods to reduce vaccine associated pain and anxiety.

Keywords**: “Pain”; “Anxiety”; “Children”; “Vaccination”; “Distraction techniques”.**

1. INTRODUCTION

Young children experience a number of routine invasive medical procedures with the most common being vaccinations. Children need immunization against different illness and such vaccines are done worldwide (Marshall et al., 2015). However, the most common source of iatrogenic pain in children is immunizations and that would lead to noncompliance with vaccination (Taddio, Ilersich, Ilersich, & Wells, 2014). Furthermore, pain that experienced in young age can lead to long-term effects on physiological and behavioral responses to vaccinations and medical procedures in general (Thrane, Wanless, Cohen, & Danford, 2016). The distress, the unnecessary pain, and worrying ahead of time during vaccination can causes negative experience (McMurtry et al., 2015). If vaccination pain is not treated fast and effectively, this may lead to long term negative physical and psychological consequences (Sahiner & Bal, 2016). Despite the well documented barriers against utilization of pain control measures during vaccination (Cwynar, Cairns, Eden, Vondracek, & Eller, 2021), healthcare workers need to do an effective assessment of pain and manage it quickly (Cwynar & Osborne, 2019; Viggiano et al., 2015). Various physical, psychological, and pharmacological measures have been evaluated for lessening vaccination associated pain in children (Hall, Ediriweera, Banks, Nambiar & Heal, 2020; Taddio et al., 2015). A recently published clinical practice guideline provides an overall review of the broad range of evidence based approaches to decrease pain during vaccination (Taddio et al., 2015). Nevertheless, the literature examining the use of distraction as a method to control pain among children during routine care procedures is still inconclusive (American Academy of Pediatrics [AAP], Committee on Infectious Diseases, Kimberlin, Brady, Jackson, & Long, 2018; Hillgrove-Stuart et al., 2012).

In addition, several surveys of patients and parents revealed that fear of pain is a contributing factor for vaccine hesitancy and refusal (Miller, Wickliffe, Jahnke, Linebarger, & Humiston, 2014). Therefore, pharmacological and nonpharmacological ways are applied to lessening pain and worry during painful invasive interventions like a venipuncture and vaccinations (Hewida, 2015). The advantage of nonpharmacological methods is that they reduce pain, decrease the use of analgesics, and increase the patient's quality of life (Kim, Jung, Yu, & Park, 2015; Lee, Caillaud, Fong, & Edwards, 2018; Sahiner & Bal, 2016).

Nurses often utilize nonpharmacological pain management strategies because they are simple to apply, cheap and have no side effects (Tercan & Sarıtas, 2017). For example, the use of distraction techniques is one of the nonpharmacological methods that help to reduce pain by shifting the patient's attention to something other than the painful procedure. Distraction methods have been found to reduce pain and anxiety during painful procedures, reduce the number of procedures needed, and provide the opportunity to perform medical procedures in a shorter period of time (Inal & Kelleci, 2012**;** Viggiano et al., 2015). Examples of distraction methods include listening to music, watching television, playing video games, playing with interactive toys, practicing controlled breathing, and guided imagery/relaxation **(**Rezai, Goudarzian, Jafari-Koulaee, & Bagheri-Nesami, 2017**).** Furthermore, involving parents in distraction techniques has been found to successfully decrease child pain or anxiety and is the cornerstone in majority of pediatric procedural pain or distress management methods (Birnie, Noel, Parker, Chambers, Uman, Kisely, & McGrath, 2014). If developmentally age appropriate, such distraction techniques can effectively reduce procedure induced pain in children (Bukola & Paula, 2017; Gorji Taebei, Ranjbar, Hatkehlouei, & Goudarzian 2017; Rezai et al. 2017). Nevertheless, the utilization of pain reduction measures during routine childhood vaccinations is still limited. Many barriers to the use of pain control measures have been reported in the literature such as nurses attitude toward the effect of pain reduction methods, time constraints, and lack of knowledge and recourses. To the extent of our knowledge, reports of needle fears among children undergoing immunization and the specific impact of distraction strategies on reducing the pain and anxiety in Saudi Arabia are limited. The primary objective of this study was to evaluate various pain and anxiety management strategies during vaccinations. We hope that findings from this study can add to the existing literature that supports the incorporation of pharmacological and non-pharmacological pain reduction techniques during routine childhood vaccination as standard of care in primary healthcare centers.

2. METHODS

Study design:

A quasi-experimental study that investigate the effectiveness of the therapeutic toy, video games, role-playing, comfortable position, and wrist water toy on pain and anxiety levels in children undergoing routine immunization.

Setting and samples:

The study was conducted between October and December 2018 in three primary health care centres in the city of Qassim which is located 4 hours away from Riyadh, the capital of Saudi Arabia. The sample consisted of 100 children aged 3-6 years old, randomly selected among those undergoing routine immunization at the day of data collection. Participants came to clinic to take one or more of the following vaccines: diphtheria-tetanus-pertussis (DTaP), oral poliovirus vaccine (OPV), measles, mumps, rubella (MMR) and varicella. The sample was then randomly assigned into a control group

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(those receiving standard care, n=50) and five intervention groups (those receiving any of the non-pharmacological distraction techniques while receiving the vaccine: 1) therapeutic toy, 2) video games, 3) role-playing, 4) comfortable position, and 5) wrist water toy). Children with developmental delay, speech difficulties, those receiving anti-anxiety drugs, analgesics or narcotics, and those who had distress or pain unrelated to the immunizations.

Measurements:

In this study, pain was measured using the following validated tools: 1*) Wong-Baker Faces pain rating scale (FACES).* FACES is a visual-numerical scale. The tool was used to measure self-reported pain immediately after the procedure. The scale presented to the child six faces, each face represents increasing distress level ranging from a neutral (0) to a crying face (10). According to the pain level experienced, the child had to choose among the six faces, the one that reflects his current pain status (Face 0 = no pain at all, face 2= hurts just a little bit, face 4=hurts a little more, face 6= hurts even more, face 8= hurts a whole lot, and face 10= hurts as much as you can imagine). FACES can be used for children older than four years old (Wong & Baker, 1988). *2) Children's Hospital of Eastern Ontario Pain Scale (CHEOPS)*. Unlike FACES, CHEOPS is used to assess pain as observed by healthcare providers in children aged 1-7 years old. The tool includes six categories of pain related behaviors (Cry, facial, verbal, torso, touch, and legs). For each behavior, a score ranging from 0 to 2 or 1 to 3 is assigned and the total composite score is calculated (the possible scores range from 4 to 13) (McGrath et al., 1985).

Anxiety was measured by using the following tools: *1) Visual Facial Anxiety Scale (VFAS).* VFAS consists of six faces representing an increasing level of anxiety (ranging from none=a neutral facial expression to highest = a facial expression displaying extreme fear). The healthcare provider has to ask the patient to choose which of the six facial expressions most accurately reflects their level of anxiety at the current moment of time (Cao, Yumul, Elvir Lazo., Friedman, Durra, Zhang, & White, 2017). *2) Anxiety rating scale.* The anxiety rating scale was used to assess the level of anxiety using 15 statements rated by a 3 points Likert scale ranging from (0) never, (1) sometimes and (2) always. The anxiety rating scale was designed for the purpose of this study and was reviewed for face validity with an area expert in the UQ.

Intervention:

The following distraction techniques were used as non-pharmacological measures of pain relief.

Such measures have been used in many previous studies to relive pain in paediatric procedures such as vaccinations: (1) *Therapeutic toy*, the researchers gave the child a doll and asked her/she to sit comfortably and play with the doll while the nurse administered the vaccine. *(2) Video games:* the games were introduced to the child on an iPad before the vaccination, the child chose the game he/she liked, then the researcher explained how to play the game. While the child is playing the game, the nurse gives the vaccine. *(3) Role-playing*, children were given a mask of Spiderman and were told to imagine that they are Spiderman, talk with them and give some supportive words (e.g. you're strong, you're a hero). While the child is being distracted with the role-play, the nurse gives the vaccine. *(4) Comfortable Position:* the child was asked to set or lay on his/her back (supine) and the parents hold their children while the vaccine is given. (*5) Wrist Water Toy*: the toy was filled with water then placed on the child's wrist and ask him/her to press on the button to spray water and the nurse gave the vaccine while the child was playing.

Data collection:

The data collection and the administration of the intervention was done by 2 researchers while nurses were examining and administering the vaccines to children. All the nurses involved have had a minimum of 5 years' experience in paediatric primary health centres. While the nurse was preparing the scheduled vaccines, the researchers asked the parents for their demographic data. Then, the researchers started the distraction methods for the child. While the child is being distracted, the nurse gave the vaccine and the researchers observed and recorded pain and anxiety scores using the aforementioned tools.

Statistical analysis:

The data were analyzed using Software Package for Social Sciences (SPSS) version 26.0. The continuous study variables were described using means and standard deviation (SD) while the categorical variables were described using frequencies and percentages. Age had 4 categories (1=3-<4, 2=4-<5, 3=5-<6, 4=6-<7), gender was dichotomized as 0=boy and

1=girl, income had three categories (1=5000-10,000, 2=10,000 – 15,000, 3= >15,000/month), and maternal education was dichotomized (0= no college education, and 1= college education and above). The vaccination types were coded as follows: 2 = DTaP, MMR, Varicella, and OPV, 1= MMR, varicella, OPV, 0= others. The distraction strategies were coded as 1= toy, 2=video games, 3=role playing, 4=comfortable position, and 5= wrist water toy.

The study variables were checked for normality, missing data, outliers, and multi-colinearity. There are no missing data and all variables were normally distributed as indicated by values of skewness and kurtosis within acceptable ranges. Bivariate correlation was conducted to assess the level of correlation between the dependent variables. Chi-square was conducted to compare between the control and the intervention groups in relation to the demographic characteristics.

The means of pain and anxiety measures among the study groups were compared using the multivariate analysis of variance and covariance (MANOVA/MANCOVA). The means of Anxiety Rating, Wong-Baker, Ontario, and Facial Affective scales were compared among the control and the intervention groups. The variance of the main study variables was equal across the 5 intervention groups as indicated by a non-significant Leven's test (*p*= 0.266). The means for Anxiety Rating, Wong-Baker, Ontario, and Facial Affective scales were compared across the distraction strategy groups. Leven's test of equality of error variance between the groups was significant for Anxiety and Wong-Baker scales which violates the assumption of MANOVA. However, the assumption of equality of error variance among the dependent variables is robust to violation given that the sample size is larger than 50 and Pillai's Trace test is used to evaluate the results of the MANOVA. Given the issue of multi-colinearity, the analysis was re-ran using separate single analysis of covariance (ANOVA/ANCOVA) for each dependent variable, yet the results remained constant (Appenix.A).

To manage the issue of multi-colineaity, Tabachnic and Field (2009) suggested either collapsing the highly correlated variables into one composite score (a composite score for pain was created using the total score of Wong-Baker, Facial Affective, and Ontario scales), deleting the variables that are highly correlated (the analysis was ran with and without them), or running a separate ANOVA for each dependent variable while adjusting for inflated alpha level by using Bonferoni test. All the previously mentioned steps have been conducted yet the results were invariant (Appendix. A).

To meet the assumption of MANCOVA, the covariates must be correlated with the dependent variables. According to the correlation table in appendix A, income and the number of siblings were not statistically significantly correlated with pain and anxiety. Only maternal education, vaccine type, age, and gender were significantly correlated with pain and anxiety. The effect of the study covariates (age, gender, number of siblings, maternal education, income, and type of vaccine) was tested using MANCOVA and separate ANCOVAs to confirm the results.

Ethical considerations:

The study was approved (IRB Reference number: 15\K/156) by the ethical committee at the College of Nursing, Qassim University (UQ), Qassim, Saudi Arabia. Parents were asked about their willingness to be involved in this study and were informed about their right to refuse or to not continue in this study. The purpose of the study and the study procedure were explained clearly to the parents and the informed consent was obtained.

3. RESULTS

Sample characteristics:

Table.1 represents the demographic characteristics of the intervention and the control groups. In the intervention group, majority (90%) of children were in preschool age with ages ranging from 4 to 7 years old. While in the control group, 22 % of children were below 4 years and the reaming 70 % were preschoolers. The difference in age distribution between the two groups was statistically significant (x^2= 20.563, *p*=.0001). Gender distribution is equal among the intervention and the control group with boys making about 45 % and girls making 57 %.

94 % of the families in both groups resided in urban areas. Due to lack of variability in the place of residence, it was removed from the analysis. The control and the intervention groups were statistically different in relation to their income level (x^2= 6.63, *p*=.036), with a higher proportion of families of middle and higher income level in the intervention group. 62 % of the mothers in the control group while 54 % of the intervention group have college education.

However, the difference in maternal education was not statistically significant. In both groups, about 50 to 60 % came to take the MMR, Varicella, OPV, and DTaP vaccination all together, and only four came to take the MMR alone.

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Mean difference based on control vs. intervention groups:

The means for Wong-Baker, Facial Affective, Ontario, and Anxiety rating scales for the control and the intervention groups is presented in Table.2. Accordingly, children in the intervention group demonstrated slightly lower pain and anxiety scores as measured by Wong-Baker, Facial Affective, and Ontario scales, respectively; with the latter showing the lowest score among the remaining scales. Overall, the means of Anxiety rating scale, Wong-Baker pain scale, Facial Affective anxiety scale, and Ontario pain scales were lower in the intervention group compared to the control group and this difference was statistically significant for all the four scales (Table.2). The highest effect size of the intervention group was reflected on Ontario pain scale with a value of Partial Eta Squared *(partial* η^2) of 0.316, indicating that about 31% of the variance in Ontario pain scores was explained by being in the intervention group (Tables. 3&4).

Mean differences based on distraction strategy:

According to the descriptive statistics of the MANOVA (Table.2), Wrist Water Toy showed the highest reduction in pain as measured by the Wong-Baker Scale, while Comfortable Position did not affect pain. Therapeutic Toy, on the other hand, was associated with the highest reduction in Facial Affective anxiety scale, while Comfortable Position continued to have the lowest effect on Facial Affective anxiety scores. For Ontario pain scale, Video Games showed the highest reduction in pain, while Comfortable Position continued to have the lowest effect. Therapeutic Toys had the highest reduction on anxiety, while Comfortable Position showed the lowest reduction. Nevertheless, the difference in the means of the Anxiety, Facial Affective, Wong-Baker, and Ontario scales based on the distraction strategy group was not statistically significant as indicated by Pillai's Trace value .297, F (12, 135) = 1.234, p= .266. Re-running the analysis without the Facial Affective and Wong-Baker scales; one at a time; produced similar results. Appendix. A represents the results of the multiple separate ANOVA using Ontario scale, Anxiety scale, and the Total Pain Composite as the dependent variable; one at a time; which indicated similar results.

Mean differenced based on demographic variables

Anxiety and pain measured by Wong-Baker, Ontario, and anxiety scores were statistically different as a function of vaccines type, gender, and age (Tables.5). Specifically, measures of pain varied based on the type of vaccine administered (*partial* η^2 = 0.15, & 0.13, respectively) as well as the age of the child (*partial* η^2 = 0.1, & 0.1, respectively), while measures of anxiety varied based on the type of vaccine administered (*partial* η^2 = 0.13) and the gender of the child (*partial* η^2 = 0.1)

When tested using a separate ANCOVA with anxiety as the dependent variable, vaccine type (p= .023) and gender (p=.034) were the only significant covariates indicating that anxiety varied as a function of gender and the type of vaccine administered. When tested using a separate ANCOVA with Ontario Scale as the dependent variable, vaccines type (p= .019, *partial* η^2 =.133) and age (p=.048, *partial* η^2 = 0.1) were the only significant covariates indicating that pain varied as a function of age and the type of vaccine administered.

4. DISCUSSION

Vaccines are one of the most effective methods to prevent infectious diseases in children (Taddio et al., 2014). However, needle phobia or needle-associated pain and anxiety is one of the factors behind parents' hesitancy to adhere to childhood vaccination schedules (McMurtry et al., 2015). Hence, it is important to take extra consideration to reduce this pain as healthcare providers. Many studies across the world have investigated the effect of pharmacological and non-pharmacological pain control strategies. However, as far as we know, this is the first study in Saudi to examine the effect of various pain control strategies on reducing vaccine associated pain and anxiety. Our study aimed at comparing the effect of various distraction strategies to reduce the pain and anxiety among children who come to receive their routine vaccination in three primary healthcare centers in Qassim, Saudi Arabia.

When compared the intervention to the control groups, our findings indicated that vaccine associated pain and anxiety among children who received at least one form of pain control technique were lower than children who received their scheduled vaccine without any form of pain control measures. From a theoretical perspective, using non-pharmacological strategies are suggested to reduce pain and anxiety in children undergoing medical procedures via cognitive behavioral pathway such as diverting attention, cognitive restructuring and altering pain perception (El Geziry, Toble, Al Kadhi,

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Pervais, & Al Nobani, 2018). Our findings are consistent with previous studies reporting similar findings. Sahiner & Bal (2016) compared pain and anxiety reports among 120 children divided into three distraction groups (card games, balloon inflation, music) and a control group. The distraction card group had significantly lower pain levels than the control group while anxiety levels reported by the observer showed a significant difference among the study groups (Sahiner & Bal, 2016).

When compared pain and anxiety across the five distraction groups, pain and anxiety levels were not statistically different. Our findings although not expected, are in accordance with previous studies. Maclaren & Cohen (2005) compared the use of passive, interactive distraction, and standard care and found no significant differences between the groups in pain and anxiety levels among children 1- 7 years old. This lack of difference across the five groups in the current study could be due to the small sample size in each group limiting our ability to find statistical significant difference.

On the other hand, when examined the descriptive statistics of each distraction groups, the use of therapeutic toy, followed by WWT seemed to reduce vaccine associated anxiety the most compared to the rest of the strategies used. The use of WWT and video games showed the highest reduction in vaccine associated pain.

The use of various distraction methods as a way to reduce anxiety and pain perception in children is well explored with many methods showing positive results over one another (Uman et al., 2006). For example, researchers found that the use of interactive distraction methods (e.g. video games) resulted in higher pain tolerance compared to the use of passive distraction methods (e.g. toys) (Dahlquist et al., 2007). Sahiner & Bal (2016) found that in the group of children were distraction cards were used, less pain (self-reported) was reported compared to the control group and the other distraction methods. While the group in which balloon inflation was used, anxiety (observer-reported) was reported to be lower than in the control group and the other distraction methods. In fact, it is suggested that in order for the selected distraction method to be effective, it has to include tasks that has some level of difficulty to sustain the child's attention (Schechter et al., 2007; Razi et al., 2017; Whelan, Kunselman, Thomas, Moore, & Tamburro, 2014). By a similar manner, we expect that due to the interactive nature of the WWT and video games which requires some level of interaction from the child, the distraction resulted has a stronger effect in increasing pain threshold among children in the study.

Of all the methods used, the use of comfortable position showed the least reduction in both pain and anxiety levels. Nevertheless, this lack of effect could be due to the lack of consistency between positions; in one part, and to the small sample size in the group in which comfortable position was used. Although consistency in administering the interventions was assured by having only the researchers provide the distraction measures, the comfortable position to be used was left for the parents/child to decide. However, given that our sample included mostly preschoolers, majority of children preferred the use of upright position while being held by the parents.

Our findings are consistent with recent research that suggests that upright position provides a better sense of control in children, which is expected to play a rule in reducing their vaccine-associated pain and anxiety (Eden, Macintoch, Luthy, & Beckstrand, 2014; Hensel et al., 2013). In addition, other studies found that infants benefited from physical measures such as swaddling, covering with blankets while in supine position, or the use of Kangaroo- Care (Cohen, 2010; Pandita, Panghal, Gupta, Verma, Oillai, Singh, & Naranje, 2018; Yin, Cheng, Yang, Chiu, & Weng, 2017). Nevertheless, evidence in relation to the effect of physical measures such as positioning to reduce pain in this population is still inconclusive (Eden et al., 2014; Hogan, Probst, Wong, Riddell, Katz & Taddio, 2014).

When assessed the differences in pain and anxiety levels across the intervention groups in relation to the demographic and health-related factors, we found that none of the assessed covariates showed a significant effect on pain and anxiety scores. But using test of between subjects' analysis, it appeared that only the type of vaccine, age, and gender showed significant effect on pain and anxiety levels. Particularly, pain levels varied based on the type of vaccine used, yet with a small effect size. It is worth noting that the majority of children in the current study; both in the control and the intervention groups; came to take the combination of MMR, Dtap, Varicella, and OPV (i.e. a total of three injections). As such, it is expected that pain and anxiety levels will be higher among those who took the combination of four vaccines compared to those who took 2 or 1 vaccine only. This finding is consistent with previous research were the number of injections received by infants was found to have a significant effect on pain and anxiety scores; the more injections received, the higher the pain and anxiety scores reported (Yin et al., 2017).

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Moreover, age significantly affected pain yet with a small effect size. Although not statistically significant, participants in the intervention group tended to have larger proportion of children older than 4 years' old who could; due to their age; have higher pain tolerance resulting in less significant differences particularly across the intervention groups. Given the developmental differences in pain threshold, expression, and perception, it is expected that preschool children demonstrate higher pain threshold compared to toddlers.

The findings of this study adds to the literature supporting the utilization of pain control measures during routine vaccine administration in children. Nevertheless, our study has some limitations. First, due to the small sample size among the pain control groups, our ability to detect significant differences between the groups was limited. Second, the same researchers who administered the intervention also did the data collection which could have contributed to assessment bias. Furthermore, due to the nature of the study, a reactivity bias; where participants in the intervention group do better due to being aware that they are in an intervention arm, or due to receiving more attention than the usual care (French & Sutton, 2010); cannot be ruled out.

5. CONCLUSION

Our findings are in support to a long standing recommendations to incorporate the use of pain control measures to reduce vaccination associated pain and anxiety during routine childhood vaccinations. The proper utilization of any or a combination of the various well studied pharmacological and non-pharmacological pain control measures is expected to not only reduce pain and distress of the child, it is also expected to alleviate the stress and anxiety parents go through when their children are being vaccinated. Reducing parents' distress reduces their children's pain perception and level of anxiety during the procedure. Moreover, when parents' anxiety toward their children's next vaccine visit, their vaccine hesitance and non- adherence will be reduced. Furthermore, healthcare providers need to be encouraged to address pain and anxiety during routine medical procedures to prevent the short and the long term impacts it can leave on children and their parents. Moreover, parents need to be educated about the available pain control options and how to choose among them. Future studies should examine the effect of distraction strategies when provided by the parent versus a healthcare provider. In addition, to maximize their benefits, investigators and healthcare providers need to choose developmental-appropriate pain control/distraction methods (Stevens & Marvicsin, 2016). Finally, barriers against the implementation of pain control/distraction strategies such as time constraints, lack of knowledge, and attitude toward the effectiveness of such measures among health care providers in Saudi Arabia need to be assesses and minimized.

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APPENDICES – A

List of table:

Table.1. Sample Characteristics of the Control and the Intervention Groups:

Variables		Intervention		Control		
		Freq.	*%*	*Freq.*	*%*	*Chi-Square*
Age						
	3-<4	2	4%	11	22%	20.651***
	4-<5	11	22%	13	26%	
	5-<6	12	24%	11	22%	
	6-<7	23	50%	15	30%	
Gender	0 = \`boy	24	48%	22	44%	0.161
	1= Girl	26	52%	28	56%	
Siblings	0	0	0%	3	6%	15.948**
	1	11	22%	10	20%	
	2	3	6%	15	30%	
	3	9	18%	9	18%	
	4	27	54%	13	26%	
Income						
	5000-10,000	22	44%	10	20%	6.63*
	10,0001-15,000	20	40%	28	56%	
	>15,000	8	16%	12	24%	
Maternal Education						
	0=<college	23	46%	19	48%	0.657
	1=college or more	27	54%	31	62%	
Vaccine type						
	0=Other	18	36%	14	28%	5.486
	1=MMR, Var, OPV	7	14%	1	2%	
	2=All	25	50%	31	62%	

Note: *= *p*<.05, **=*p*<.01, ***=*p*<.001, MMR=Measles, Mumps, Rubella; Var=Varicella, OPV=oral poliomyelitis virus.

Table. 2: Descriptive Statistics of Pain and Anxiety of the Control and Intervention Groups (MANOVA)

Variable	Therapeutic Toy	Video Gamed	Role Playing	Comfortable Position	Wrist Water Toy	Control	Intervention
Anxiety *M*	19.1667	20.25	21.333	23.222	20	23.58	21
SD	2.714	3.306	3.754	5.517	5.501	3.136	4.252
N	6	12	15	9	8	50	50
Facial Affective *M*	1.167	1.666	1.733	3	1.376	3.2	1.82
SD	1.161	1.23	0.051	1.732	1.767	1.59	1.722
N	6	12	15	9	8	50	50

Wong-Baker *M*	1.666	1.916	2.066	3.444	1.375	2.74	2.12
SD	1.211	1.378	2.12	1.81	1.846	1.139	1.825
N	6	12	15	9	8	50	50
Ontario *M*	8.5833	7.8833	8.9467	10.5778	8.05	11.686	8.798
SD	2.157	1.791	2.881	3.034	2.389	2.58	2.604
N	6	12	15	9	8	50	50

Note: *M*=Mean, *SD*=Standard deviation

Table. 3: Multivariate Test for Pain and Anxiety Scores among the Control and the Intervention Groups (MANOVA)

	Value	*F*	*Sig.*	*Partial* η^2
Pillai's Trace	0.461	20.298	**0.0001*** **	0.461
	Leven's Statistics	*df1*	*df2*	*Sig*
Anxiety	6.325	1	98	**0.012** **
Wong-Baker	12.65	1	98	**0.001** **
Facial Affective	0.006	1	98	0.749
Ontario	16.798	1	98	.890

Note: *= p<.05, **=p<.01, ***=p<.001, *partial* η^2 = Partial Eta Square

Table.4: Test of Between-Subject Effect for Pain and Anxiety Scores among the Intervention Groups (MANOVA)

Intervention Group	*df*	Mean Square	*F*	*Sig.*	*partial* η^2
Anxiety Rating	1	166.41	11.92	0.001**	0.108
Wong-Baker	1	9.61	4.151	0.044*	0.041
Facial Affective	1	47.61	17.32	0.0001***	0.15
Ontario	1	208.514	45.35	0.0001***	0.316

Note: *= p<.05, **=p<.01, ***=p<.001, *df*=degrees of freedom, *partial* η^2 = Partial Eta Square

Table. 5: Test of Between-Subjects Effect of the Demographic Variables on Pain and Anxiety Scores the Intervention Groups (MANCOVA)

Variables		Wong-Baker	Facial Affective	Ontario	Anxiety
Vaccine	Mean Square	14.678	10.438	35.88	88.754
	F	5.516	3.938	6.469	6.424
	Sig.	**0.024***	0.053	**0.015***	**0.015***
	Partial η^2	0.150	0.087	0.133	0.133
Gender	Mean Square	9.557	5.138	5.53	60.318
	F	3.591	1.958	0.997	4.366
	Sig.	0.065	0.169	0.324	**0.043***
	Partial η^2	0.079	0.045	0.023	0.100
Age	Mean Square	11.931	6.295	25.068	55.133
	F	4.483	2.399	4.519	3.991
	Sig.	**0.04** **	0.129	**0.039***	0.052
	Partial η^2	0.100	0.054	0.100	0.087

Note: *= p<.05, **=p<.01, ***=p<.001, Sig.= significance, *partial* η^2 = Partial Eta Square