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GATE CONTROL THEORY AND ITS APPLICATION IN A PHYSICAL INTERVENTION TO REDUCE CHILDREN'S PAIN DURING IMMUNIZATION INJECTIONS

by

JEAN ELEANOR MENNUTI-WASHBURN

Under the Direction of Lindsey L. Cohen, Ph.D.

ABSTRACT

Vaccinations provide protection against deadly diseases and children are scheduled to receive many immunization injections before the age of six. However, painful procedures, such as immunizations cause negative short- and long-term consequences for children. The Gate Control Theory of Pain suggests that physical interventions may be helpful, but they have not yet been validated as an effective intervention to manage children's acute pain. This randomized trial examined the effectiveness of the ShotBlocker®, a physical intervention designed to decrease children's injection pain, in a sample of 89 4- to 12- year-old children receiving immunizations at a pediatric practice. An ANOVA revealed no significant effect of treatment group (Typical Care Control, Placebo, and ShotBlocker®) on any measure of child distress. Clinical and theoretical implications are discussed.

INDEX WORDS: pediatric pain, Gate Control Theory, pain management intervention, children, immunization

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JEAN ELEANOR MENNUTI-WASHBURN

A Thesis Submitted in Partial Fulfillment of the Requirements for the Degree of

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in the College of Arts and Sciences

Georgia State University

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INTRODUCTION

Childhood immunizations are a priority for public health officials because the vaccinations benefit the child and the public – children are inoculated against fatal illnesses and the public is protected from the spread of diseases. According to the Center for Disease Control and Prevention (CDC), children should receive approximately 28 inoculation injections before they are six years old (CDC, 2004). These routine and brief procedures provide protection against many infectious diseases, such as, polio, measles, diphtheria, whooping cough, rubella, and mumps.

Intramuscular immunizations are typically administered via a needle, which pierces the epidermis, dermis, and subcutaneous layers of the skin, and the vaccination medication is injected into the muscle tissue. Unfortunately, this procedure results in short- and long-term negative repercussions for the pediatric patient. The immediate impact is high levels of fear and anxiety spanning the whole medical visit and intense pain during and briefly following the immunization injection itself. Jacobson, Swan, Adegbenro, Ludington, Wollan, & Poland (2001) found that 45% of 4- to 6-year-old children in their sample showed signs of high distress during vaccinations. The fear of the injection can cause time-consuming struggles between the patients and the office staff (Reis & Holubkov, 1997), and often physical restraint of the child is required to perform the procedure (Fanurik, Koh, Schmitz, & Brown, 1997).

Immunization distress also results in negative long-term outcomes. Children who experience high levels of anxiety and pain during an immunization are more likely to have elevated distress levels for subsequent injections (Fanurik et. al., 1997; Fowler-Kerry & Lander, 1987). The distress of the child might interfere with parent compliance

in bringing the child in for future immunizations, and also might result in physicians withholding subsequent injections during that same visit, thus, increasing the disease risk for that child and others who come in contact with that child (Madlon-Kay & Harper, 1994; Meyerhoff, Weniger, & Jacobs, 2001; Reis, Jacobson, Tarbell, & Weniger, 1998**)**. It is also possible that early painful experiences result in physiological changes, leading to elevated pain responses during later procedures (Taddio, Goldbach, Ipp, Stevens, & Koren, 1995). This is thought to be especially true for premature infants, because the stage of pain receptor neuronal development is particularly vulnerable to detrimental long-term effects (Young, 2005). Along these lines, a retrospective study found that adolescents born prematurely had higher pain sensitivity then their full term peers (Busilka, Nuemann, Zmora, Feldman, & Bolotin, 2003).

In addition, early negative immunization experiences might contribute to avoidance of health care as adults, as well as fear, anxiety, pain, and ineffective coping strategies in adulthood (Pate, Blount, Cohen, & Smith, 1996). Beyond fear and anxiety, Hobbie et al., (2000) found needle pain associated with treatment is correlated with Post Traumatic Stress Disorder symptoms in childhood cancer survivors. Considering there are multiple negative short- and long-term outcomes associated with children's vaccination pain, it is important to fully understand theories of pain, how pain is assessed in children, and what pain management treatments are available.

Theory of Pain

In the 17th Century, the prevailing explanation of pain was the Specificity Theory of pain. This theory proposed that pain impulses traveled directly to the brain; hence, the experience of pain would be directly and linearly related to the injury. In other words,

pain would be proportional to the extent of physical damage done to body tissue. This theory left little room for psychological factors in the experience of pain and greatly influenced how pain was diagnosed, conceptualized, and treated.

In 1965, Melzack and Wall introduced the Gate Control Theory of pain, which is still the dominant theory accepted today (Melzack & Wall, 1965). The Gate Control Theory provides a multi-dimensional understanding of the complex phenomenon of pain and its multiple influences. Melzack and Wall proposed that the pain signal is transmitted from the peripheral nervous system to the central nervous system. In the central nervous system the signal is modulated by a gating system in the dorsal horn of the spinal cord before it reaches the brain; thus, the pain perception can be increased or decreased depending on influences on the gating system. There are two proposed means of impacting the gating mechanism. First, descending nerve impulses from the brain can interfere with the ascending pain signal from the tissue damage. These signals from the brain might include cognitive or emotional factors, such as thoughts, beliefs, emotions, mood, prior experience, expectations, memories, attention, and cultural attitudes. For example, memories of a prior negative experience or anxiety might heighten pain experience, whereas a positive mood or pleasant distraction might decrease the pain.

The second mechanism influences pain perception through ascending signals from the peripheral nerves, which function as competing sensory information. There are two types of nerve fibers that carry the majority of pain signals to the spinal cord: small diameter myelinated and unmyelinated (A-delta) fibers and large diameter myelinated (A-beta) fibers. Physical stimulation such as rubbing, massage, and vibration cause excitation in the A-beta nerve fibers, which conduct the signal more quickly than the A-

delta fibers, where pain due to tissue injury is transmitted. If a pain signal is traveling to the brain via the A-delta fibers and a simultaneous physical stimulation signal is sent via A-beta fiber, the physical stimulation signal will reach the brain first because they moving more quickly then the pain signal. According to the Gate Control Theory, the pain perception will be diminished via interference by the other physical stimulation. Given this complex theory of pain, assessment of pain typically involves a comprehensive battery.

Assessment of Children's Pain

Current views of pain are that it is a multidimensional experience, defined by the International Association for the Study of Pain (IASP) as a negative physical and emotional experience caused by actual or potential tissue damage. IASP also acknowledges that pain is subjective and that, although it is certainly a bodily sensation, it is also an unpleasant emotional experience (Merskey & Bogduk, 1994); therefore, assessing children's pain requires a multi-method approach (McGrath, 1987). Child's self-report, observer's (e.g., parent, nurse) ratings, behavioral measures, and physiological measures are commonly used to assess children's pain.

Child Self-Report

As the Gate Control Theory details, a number of pain factors are personal, internal, and subjective; therefore, self-report is critical to pain assessment in children (Finley & McGrath, 1998; McGrath, 1987). A variety of self-report measures have been developed to measure children's pain including verbal ordinal scales, graphic rating scales, visual analog scales, and pictorial scales. Facial expression scales have advantages. They are developmentally appropriate for younger children because they

make minimal cognitive demands, are not dependent on reading skills, and typically represent a continuum of the universal response to pain (Champion, Goodenough, von Baeyer, & Thomas, 1998).

Some pictorial scales, such as the Oucher Scale (Beyer, 1984), use photographs of children, but most rely on cartoon depictions. It is possible that children may be distracted by age, gender, and race in photographs, which is an advantage of simple cartoon graphics (Champion et al., 1998). One consideration is the depiction of emotion in the image. Some scales use a smiling face for an anchor and a crying face with tears on the distressed end of the continuum, which might influence ratings (e.g., if the child is not crying, the child might not select the face with tears; Chambers & Craig, 1998). To remedy this problem, some scales assess emotion (e.g., anxiety) separately, such as the Children's Anxiety and Pain Scale (Kuttner & LePage, 1989). One of the most widely used and validated child ratings scale of pain is the Faces Pain Scale – Revised (FPS-R; Hicks, von Baeyer, Spafford, van Korlaar, & Goodenough, 2001), which consists of six cartoon faces expressing no pain to extreme pain.

Observer Report

Parents' and medical staffs' perceptions of children's pain are often the deciding factor in whether or not pain management treatment will be employed (Manne, Jacobsen, & Redd, 1992). For this reason, it is important to assess how they rate the pain experience of the child. Another advantage is that observer report provides another source and possibly assesses a different aspect of the child's experience (Manne et al.). Observer ratings are typically done via questionnaires, likert-type ratings, and visual analog scales (Blount et al., 1997). These types of measures are also useful for assessing parents' and

health care providers' own anxiety or other perceptions (e.g., child coping; effectiveness of intervention) concerning the procedure (Cohen, Blount, & Panopoulos, 1997).

Physiological Measures

Physiological measures such as blood pressure, heart rate, respiratory rate, and palmar sweat index are used to measure pain and overall distress in pediatric patients (Blount, Piira, & Cohen, 2003; McGrath, 1987). Although the use of these physiological measures is common in pain research, there is question as to whether they are actually measuring pain. For example, physiological responses can be caused by another number of factors, such as emotional state, movement, or room temperature (Blount et al.; Sweet & McGrath, 1998). Some research has supported the use of heart rate as a physiological measure of pain, showing decreased heart rate when analgesics were administered and decreased heart rate as a result of behavioral interventions. On the other hand, physiological measures may potentially influence anxiety and pain in children if they are invasive and produce discomfort. In addition, measures are not always practical in a clinical setting because they are costly and time consuming (Blount et al; Sweet & McGrath). Although none of the physiological measures are ideal measures of pain, heart rate is promising because of its ease of use and non-invasive nature (Sweet & McGrath).

Observational Measures

Researchers sometimes use measures of observed behaviors in procedural pain because children's overt behaviors serve as the first indicator of pain and they are less susceptible to bias than subjective reports. The child's pain behavior may influence both the child's perception and evaluation of the painful experience. Observational measures are also important because the child's behavior influences their social environment

(McGrath, 1998). The challenge with observational measures is that coding can be a time consuming process that requires many hours of work from well-trained coders. For this reason, observational coding is not consistently used in pain research.

Many observational measures have been developed for use with children undergoing painful medical procedures, such as the Procedural Behavior Rating Scale (PBRS; Katz, Kellerman, & Siegel, 1980), Observational Scale of Behavioral Distress (OSBD; Elliott, Jay, & Woody, 1987), Child-Adult Medical Procedure Interaction Scale (CAMPIS; Blount et al. 1989), and the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS; McGrath, 1998). Scales such as these typically quantify discrete behaviors associated with child pain, such as crying, facial changes, verbal communication, screaming, grimacing, or flailing. Regardless of the modality of the measurement, assessment tools are invaluable to health care professionals in quantifying pain and guiding the initiation and termination of pain management interventions.

Overview of Pediatric Pain Management Strategies

Researchers and clinicians have evaluated various pain management techniques. In general, pain management approaches can be categorized as pharmacological, behavioral, and physical. Pharmacological treatments to reduce procedural pain include medications for sedation and the numbing of pain with and without consciousness. Medical complications are possible, and use of the medications usually requires the presence of personnel with advanced training to handle any possible medical complications. A popular topical anesthetic is Eutectic Mixture of Local Anesthetics (EMLA®), which is a cream composed of lidocaine and prilocaine. Studies on the effectiveness of EMLA® are mixed with some finding it to reduce pain during injections

(Cassidy, et al., 2001) and others finding no benefit (Cohen, 2002; Cohen, Blount, Cohen, Schaen, & Zaff, 1999). A drawback of EMLA® is the delayed onset of the anesthesia effect (60 min) and cost (Reis & Holubkov, 1997; Reis, Jacobson, Tarbell, & Wenieger, 1998). An alternate pharmacological approach is cold spray, which provides a fast acting numbing of the skin. Ethyl chloride and fluoromethane sprays are applied 15 seconds before the injection and have been shown to be as effective as EMLA® (Reis & Holubkov). Unfortunately, some children do not like the sensation or are scared by the spraying sound (Reis & Holubkov), and some studies have indicated that these sprays are not tolerated well by small children (Zappa & Nabors, 1992).

There are practical limitations to pharmacological pain management, such as the time delay, expense, and need for additional medical professional to be present. It is also important to note that pharmacological treatments do not typically treat children's pre-procedural anxiety or address other psychological factors that might impact the intensity of the pain.

Several behavioral strategies have been validated (for a review, see Powers, 1999). Common psychological interventions include relaxation training, distraction, guided imagery, hypnosis, and modeling (Blount et al., 2003; Fanurik, Koh, Schmitz, & Brown, 1997; Piira, Goodenough, & von Baeyer, 2002). The Gate Control Theory suggests that these interventions primarily work by activating descending signals from the brain that interfere and suppress the pain signal. In contrast to pharmacological interventions, there are no negative side effects and these approaches help to reduce both pre-procedural anxiety and procedural pain and anxiety. These techniques usually involve the mastery of a new skill to help cope with a stressful situation. However, training to

develop these skills can be time consuming and costly, making some behavioral interventions difficult to implement in clinical settings (Cohen, Blount, & Panopoulos, 1997).

The third category of pain management techniques is physical interventions, which involve direct stimulation of the area near the noxious stimulus. These treatments, such as massage, touching, or rubbing of the tissue, are theorized to travel via the faster A-beta fibers and interfere with the other ascending pain signal, which is transmitted on the slower A-delta fibers. This helps explain of why people commonly rub or squeeze a part of the body immediately after an acute injury.

A classic example of a physical pain intervention is acupuncture, an Eastern medical practice first used over 2,000 years ago (Parris & Smith, 2003). Acupuncture involves very fine needles inserted into the skin on specific areas of the body. The needles are theorized to stimulate the energy flow and restore energy balance in the body. On a biological level, acupuncture has been associated with the release of endorphins that may help to minimize pain. The practice of acupuncture is complex and requires extensive training, thus it might be difficult for parents to find a certified acupuncturist who is trained to work with children. Another disadvantage is that children are likely to be fearful of such a technique because of the use of needles (Zeltzer & Schlank, 2005).

Transcutaneous electrical nerve stimulation (TENS), is a physical intervention grounded in the Gate Control Theory. When using TENS, clinicians place electrodes on the skin and transmit a safe electrical currency. The currency is purported to stimulate the large afferent nerve fibers, which interferes with neurotransmitters and the brain’s ability to receive the pain signal (Sluka & Walsh, 2003). The procedure is safe and effective in

adults with chronic pain, and requires little preparation (Lander & Fowler-Kerry, 1993). Research on the effectiveness of TENS for procedural pain is mixed, and it is still unclear if it is helpful for children and in what capacity (Lander & Fowler-Kerry).

Similar to TENS, physical vibration has been used to reduce pain. Concurrent with the Gate Control Theory vibration is believed to excite A-beta nerve fibers, which inhibit A-delta fiber signals, minimizing the amount of pain signal relayed to the brain (Pantaleo, Duranti, & Bellini, 1986; Smith, Comite, Balasubramanian, Carve, & Liu, 2004). Small and inexpensive commercial vibrating massagers have been found to help reduce injection pain in adults receiving Botox® injections (Smith, Comite, Balasubramanian, Carver, & Liu, 2004). The authors acknowledge that some patients had concerns about the sexual connotation of some vibration devices. This is also likely to be a concern for parents of small children and adolescents. Another disadvantage is that some children may not like the numbing sensation created by the device.

Additional physical techniques that have been found useful in reducing injection pain are pressure, stretching, and pinching at the injection site. Some studies have found that manual pressure prior to the injection at the site reduced pain in adults (Barnhill, Holbert, Jackson, & Erikson, 1996; Chung, Ng, & Wong, 2002). However, when applying manual pressure it is difficult to provide a consistent delivery in the amount of pressure. The z-track technique is an injection procedure where pressure is applied at an angle so that the skin is displaced prior to and during the injection. One study found that when using the z-track technique in adults, the immediate discomfort was higher, but there was less discomfort 3-4 hours later (Keen, 1986). This technique is difficult to standardize and might not be appropriate with children. This is also true for another

technique of pinching. This technique involves pinching a fold skin at the injection site. Fletcher (2005) found that it reduced pain in women receiving intramuscular contraceptive injections.

Although the above physical interventions are viable pain management techniques, none of these have been validated with children. Furthermore, there are limitations to their use in pediatric populations, such as those mentioned above. A possible solution to this dilemma has been presented with the recent development of a physical intervention, intended especially for injection pain management in children. The ShotBlocker® is a u-shaped plastic device with small rounded nubs on one side that should be pressed against the skin at the site of the injection. The device provides a more consistent amount of stimulation then techniques such as pressing, pinching, or stretching. Theoretically, the stimulation of the nubs should send A-beta signals to the brain and interfere with the A-delta pain transmission of the injection.

Although conceptually sound, there is little data in support of the manufacturer's claim that the ShotBlocker® "instantly blocks" needle pain. To date, there are four studies available that evaluate the ShotBlocker®, with contradictory findings. Two studies found that the ShotBlocker® significantly reduced children's immunization pain (Guevarra, 2005; Gundrum, Sherman, & Ruhlman, 2005). The project by Gundrum et al. is only in a brief abstract form and reportedly submitted for publication. The study involved 99 patients over the age of five years, who were randomized to receive immunizations with or without the ShotBlocker® device. The authors report significantly reduced pain in the intervention group; however, specific details of method, statistics, or results were not provided. It appears that child self-report of pain was the exclusive

dependent variable with no use of observational or observer report measures. Communication with one of the authors, Christopher Sherman, revealed little additional information as this author was unable to locate a longer document or additional information (personal communication, November, 11, 2004) about the study. The study conducted by Guevarra is also in abstract form with some tables and figures to present the findings. This study included 119 pre-kindergarten students in the Philippines who were receiving intramuscular injections. Participants randomized to the treatment group reported significantly lower pain scores on the Wong-Baker FACES Pain Scale. Similar to the previous study, no measure of behavioral pain or observer report was examined.

Contradictory to previous finding, the remaining two studies provide some evidence that the ShotBlocker® may not be an effective intervention to reduce children's immunization pain. Drago et al. (2007) presented a poster of their study, which included 165 children aged 2 months to 17 years. Parents and nurses rated the child's pain on a six point likert scale and children over 36 months of age provided self-report using the Wong-Baker FACES Pain Scale. They found that parents and nurses perceived that children experienced less pain when using the ShotBlocker®; however, there were no significant group differences in children's self-reported pain. The fourth study is published in nursing research newsletter by The Children's Hospital in Denver, Colorado (Foster, Eberhart, Zuk, & Finn, 2005). This research group conducted a two-group, randomized, controlled research study that included a diverse sample of 171 children, between the ages of 3 months and 17 years of age. Parents and children old enough to provide self-reported pain ratings, rated their pain using the Faces Pain Scale (Bieri, Reeve, Champion, Addicoat, & Ziegler, 1990). This study found no significant

differences in pain ratings between the experimental and control group (Foster, Eberhart, Zuk, & Finn, 2005). The contradictory findings of these studies indicate that more thorough evaluations of the ShotBlocker's® effectiveness are in order.

Summary and Purpose

In conclusion, despite the value of vaccinations, immunization injections cause multiple negative short- and long-term consequences for children. The Gate Control Theory of pain provides a theoretical framework to understand the complex multidimensional concept of pain and guides the development of pain management interventions (Melzack & Wall, 1965). Although physical interventions are promising, there are currently no validated approaches for children's acute pain. The purpose of the current study is to evaluate the Shotblocker®, a new physical intervention to decrease injection pain in children. It is hypothesized that the ShotBlocker® condition will demonstrate significantly lower pain scores on child self-report, parent-report, nurse-report, and physiological measures in comparison to typical care control and placebo control. An effect is anticipated in the placebo control condition, due to a reduction of the child's pain expectation. Specifically, children in the placebo condition are expected to have lower pain on all measures of pain than children in the control condition.

METHOD

Participants

Participants included 89 parent-child dyads presenting for immunization injections at a southeastern pediatric practice in the Metro-Atlanta area between March, 2006 and July, 2006. The children ranged from 4 to 12 years of age (*M* = 8.46 years, *SD* = 2.97 years) (Table 1). Using the effects size of 1.18 found in a prior study of the ShotBlocker® (Gueverra, 2005), a power analysis with power of .87 revealed that only 12 participants would be needed to detect differences using a 3-group ANOVA. Based on this analysis, it was assumed that 30 participants per condition would be sufficient to find treatment effects. Inclusion criteria included any 4- to 12-year-old English speaking child receiving inoculations at the clinic.

Fifty-two of the child participants were male (58.2%) and 76 were Caucasian (85.4%). Five children were African American (5.6%), one child was Asian American (1.1%), and seven children were reported as “mixed” or “other” by their parents (7.8%). Children primarily came from two-parent homes with 79 parents (88.8%) indicating they were married. Seven parents (7.8%) indicated they were separated or divorced and two parents (2.2%) reported that they were single. For most of the children, injections were not part of their daily routine, as only one parent (1.1%) reported the child having a medical condition that required routine injections, IV’s, or blood draws, and only two children (2.2%) were in the Neonatal Intensive Care Unit as infants. The majority of children were reportedly not on any pain medication (88.8%), and parents reported that most children were their “usual self” (75%) on the day of participation.

All children enrolled in the study were accompanied by either their mother (75, 84.3%) or father (14, 15.7%). Parents ranged in age from 28 to 59 years of age (*M* = 40.2 years, *SD* = 5.7 years); however, three parents chose not to report their date of birth. The parents' years of education ranged from 12 to 23 years (*M* = 15.78 years, *SD* = 1.74 years). The majority of families (78, 60.3%) reported annual income of $90,000 or greater. Twenty-two families (24.8%) reported an annual income between $30,000 and $89,999 and one family (1.1%) reported an annual income between $15,000 and $29,999. Three families chose not to report their annual income.

Measures

Background information

Parents who agreed to participate in the study completed the Family Information Form (Appendix A), a questionnaire assessing demographics of both the child and parent, such as gender, age, race, and income. The parent also answered questions regarding any medical conditions that would require regular injections; any pain-reducing medications the child may have received prior to the procedure (e.g., acetaminophen); and if, when, and how the child was informed of receiving an injection. In addition, the parents were queried as to whether or not the child was born premature, and if so whether the child received neonatal intensive care.

Child pain

Prior to the injection, children rated their baseline level of pain (Child Pre-Injection Form, Appendix B) using the Faces Pain Scale – Revised (FPSR; Hicks, von Baeyer, Spafford, Korlaar, & Goodenough, 2001; Appendix C). After the injection, the children used the same measure to rate their pain experienced during the injection (Child

Post-Injection Form, Appendix D). The Faces Pain Scale – Revised (FPS-R, Appendix C) is a modified version of the original Faces Pain Scale (Bieri, Reeve, Champion, Addicoat, & Ziegler, 1990) and contains six cartoon faces expressing no pain to extreme pain. Children were asked to select a face that represents their level of pain prior to the injection and experienced pain post-injection. The six faces are coded as a pain score of 0, 2, 4, 6, 8, or 10. Unlike other facial pain scales, the FPS-R faces are both race and gender neutral, both variables have been shown to bias report (Chambers & Craig, 1998). Another advantage of this measure is that the faces do not contain confounding expressions of emotion, such as tears or smiling faces, which also has been shown to influence self-report (Chambers & Craig). This measure is designed to create minimal cognitive demands on the child, thus making it appropriate for children of young ages, while generating scores that are comparable to other measures of pain. Research has shown that this measure has adequate reliability and validity (Bieri et al.; Hicks et al.).

In addition to the children's indication of their pain, the parents rated the pain their child experienced during the injection using a Visual Analog Scale (VAS) (Parent Post Injection Form, Appendix E). This measure consisted of a 100 mm horizontal line with anchor descriptors at either end of the continuum (e.g., "no pain" and "severe pain"). Parents were asked to draw a vertical mark on the continuum to rate their child's pain in response to the question, "How much pain did your child experience during the injection?" This measure has been shown to be valid and reliable for both children and adults and is commonly used in pain research (Varni, Walco, & Wilcox 1990). After the injection, the nurse also rated the pain of the children using similar VAS's (Nurse Post Injection Form, Appendix F).

Also, the children's distress was measured with a physiological measure. A small electronic monitor, the Tanita® Cardio (Tanita® Corporation of America, Inc., Arlington Heights, IL) was used to take an electronic reading of the children's heart rate at baseline and then immediately following the injection. The precision is ±5% for pulses between 30-200 beats per minute. Each child's change in heart rate from baseline to post injection served as the physiological measure of distress.

Procedure

The clinical manager identified age-appropriate children who were scheduled to receive immunizations on days when research assistants were able to recruit participants. Participants were typically approached in the exam room between checking in with the nurse and visiting with the pediatrician. Research assistants described the study to parents and obtained parent consent and child assent from those interested in participating.

With the help of the research assistant, the parent completed the Family Information Form (Appendix A). The research assistant provided the parent with instructions to complete the Visual Analog Scales and then administered the Faces Pain Scale-Revised (Appendices B & C) to the child. The research assistant also measured the baseline heart rate of both the parent and child. Once pre-measures were completed, participants were randomly assigned to either the typical care control (Control), the placebo control (Placebo), or the ShotBlocker® (ShotBlocker®) condition. The randomization was determined prior to the study via a random number table generated by the RanSL computer program (Bakeman, 1999). Once participants completed all pre-injection measures the research assistant opened an envelope with the participant ID number, which had been previously generated. Inside the envelope was the participants

randomized condition assignment. The participants were informed that they had been assigned to the typical care group or one of the ShotBlocker® conditions.

After the family had finished visiting with the pediatrician, the researcher re-entered the exam room and set up the video camera. Before leaving the room, the research assistant began recording, with the video camera focused on the exam table where injections were administered. Video recording was done to obtain data for observational coding, which was not included in the analysis for the current study. The research assistant privately informed the nurse of the assigned condition so that the nurse was aware of the proper group protocol to follow.

Typical care control

The typical care control group received treatment as usual and the nurse was asked to administer the intramuscular injection without the use of the ShotBlocker®. No other instructions or guidance about pain management were provided to the nurse.

Placebo control

Participants assigned to the placebo control group received a scripted introduction to the medical device (Appendix G). As was explained to the participants in the informed consent, they were not aware that they were assigned to the placebo control group. The nurse placed the ShotBlocker® on the child's arm with the smooth side against the child's skin, opposite as is prescribed by ShotBlocker®. This prevented the small rounded nubs from contacting the child's skin. The purpose of this condition was to test for any placebo effect (e.g., child or parent expectancy the device might have in reducing the child's experienced pain and anxiety).

ShotBlocker®

Participants in the ShotBlocker® condition received the intervention according to protocol. The nurse used the same provided script as was used in the Placebo condition to introduce the medical device (Appendix G). Once the nurse was prepared to administer the injection, she/he pressed the ShotBlocker® firmly against the child's skin at the injection site and held it in place while administering the injection.

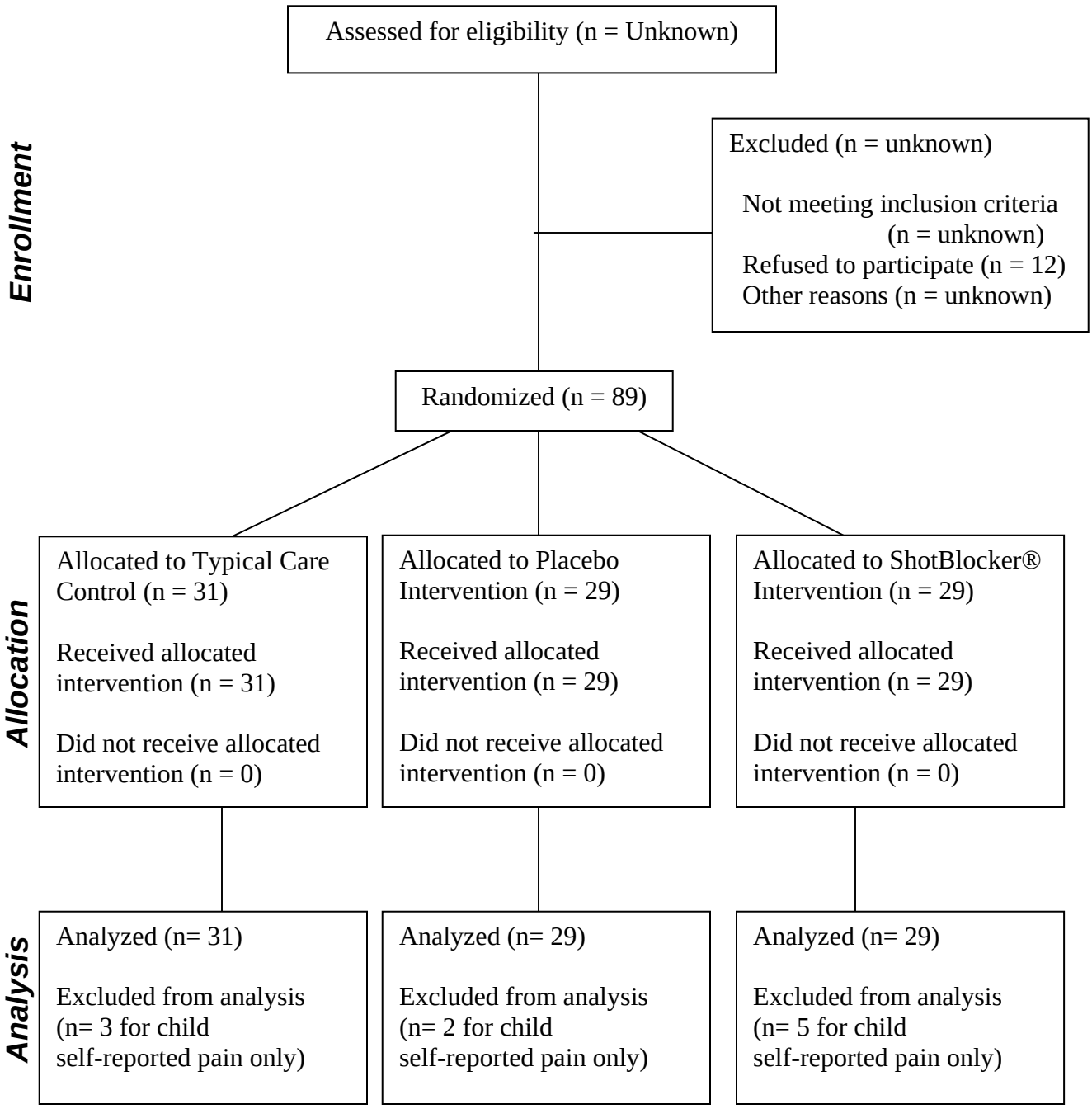
In all three conditions and immediately following the injection, the nurse obtained parent and child heart rate. The research assistant re-entered the exam room after the procedure to turn off the video camera and assist the parent and child with post-injections forms (Appendices C & D; Appendix E). After all forms were completed, children and parents who participated in the Placebo group were debriefed and told that they were part of the placebo control group, and then the research assistant demonstrated the correct use of the ShotBlocker® device with the nubby side against the skin. Participants in the placebo control and ShotBlocker® groups were allowed to keep their ShotBlocker® to use for future injections. All children received a small toy (e.g., small bouncing ball, pencil) to thank them for their participation. The research assistant then administered the post-injection VAS's to the nurse (Appendix F).

RESULTS

Participant Flow

This study was designed in accord with, and adheres to the guidelines detailed in the Consolidated Standards of Reporting Trials (CONSORT) statement (Altman et al., 2001; Moher, Schulz, & Altman, 2001; Stinson, McGrath, & Yamada, 2003) (see Figure 1 for the CONSORT Flowchart and Appendix H for the CONSORT Checklist). Appropriate institutional approval was obtained prior to initiation of data collection. On days when the research assistant was scheduled to collect data the clinical manager of the pediatric practice would identify all 4- to 12-year-olds on the schedule for the hours the research assistant was present. The clinical manager would then check the patients' files to determine if they were likely to receive an immunization during their visit. The number of participants assessed for eligibility is unknown. Prior to enrollment, a number of families were unintentionally excluded for "other reasons," most commonly that the research assistant was occupied with another participant. There were less than five cases when the physician requested that the patient not participate, usually because the patient was either too anxious or was new to the practice. There were a small number (actual number not recorded) of children whose parent elected not to receive the scheduled immunization or the child was sick and the pediatrician chose to delay the immunization.

Figure 1
CONSORT Diagram Showing the Flow of
Participants through Each Stage of a Randomized Trial


Enrollment
Assessed for eligibility (n = Unknown)
Excluded (n = unknown)
Not meeting inclusion criteria (n = unknown)
Refused to participate (n = 12)
Other reasons (n = unknown)
Randomized (n = 89)
Allocation
Allocated to Typical Care Control (n = 31)
Received allocated intervention (n = 31)
Did not receive allocated intervention (n = 0)
Allocated to Placebo Intervention (n = 29)
Received allocated intervention (n = 29)
Did not receive allocated intervention (n = 0)
Allocated to ShotBlocker® Intervention (n = 29)
Received allocated intervention (n = 29)
Did not receive allocated intervention (n = 0)
Analysis
Analyzed (n= 31)
Excluded from analysis (n= 3 for child self-reported pain only)
Analyzed (n= 29)
Excluded from analysis (n= 2 for child self-reported pain only)
Analyzed (n= 29)
Excluded from analysis (n= 5 for child self-reported pain only)

Data Analysis Overview

Preliminary analyses involved several steps. First, an examination of the distributions was conducted to identify outliers. Second, effectiveness of the randomization process was assessed by summarizing demographic characteristics of the entire sample and comparing demographics across conditions (Control, Placebo, ShotBlocker®). Third, associations between the dependent variables and demographic characteristics were examined. The primary analyses were conducted utilizing an ANCOVA to examine a main effect for treatment condition and test for a potential interaction between the child's age and treatment group.

Some data were missing because participants did not complete all measures. In reports of children's pain and anxiety, one child (1.1%) did not report their own post-procedure pain and one parent (1.1%) failed to report their child's procedural pain. The most frequently omitted procedural step was measuring the child's heart rate, and 10 participants (11.2%) were missing either their baseline heart rate, post-procedure heart rate, or both. These data were left as missing data points in analyses and other actions (e.g., inserting a mean value) were not taken.

Preliminary Analysis

Preliminary analyses were conducted for a variety of reasons. The data was first examined for outliers and dependent variable distributions were examined for skewness. Dependent variable z scores ranged from -1.50 to 2.13 indicating that there were no outliers. Skewness was also within normal ranges for all dependent variables, ranging from -.03 to .65. Next, descriptive statistics were conducted to provide information about the sample's demographic characteristics and to ensure that randomization resulted in

equivalent groups. Analyses of variance (ANOVA) was used to compare the three conditions (Typical Care Control, Placebo, and ShotBlocker®) on child age and revealed no significant group differences (Table 1). Chi-square analyses indicated no differences between groups on child gender, race, history of NICU hospitalization, or existing medical condition that requires extra blood draws, injections, or IVs (Table 1). Thus, random assignment successfully balanced demographic factors across the three groups.

Table 1

Continuous and Categorical Demographic Variables of Entire Sample and by Condition

		Treatment Condition			
	Entire Sample *(n = 89)* *M (SD)*	*Control* *(n = 31)* *M (SD)*	*Placebo* *(n = 29)* *M (SD)*	*ShotBlocker®* *(n = 29)* *M (SD)*	*F* (df) or X^2 (df)
Child Age (years)	8.46 (2.97)	8.33 (3.21)	8.24 (2.88)	8.80 (2.86)	0.30 (2, 86)
Child Gender (% Male)	58.4	61.3	51.7	62.1	0.80 (2)
Child Race (% Caucasian)	85.4	93.5	79.3	82.8	11.61 (8)
NICU (% No)	97.7	96.8	100	96.6	0.96 (2)
Medical Condition (% No)	98.8	100	96.3	100	2.17 (2)

Note: No significant group differences.

The next set of preliminary analyses examined bivariate correlations among demographic variables and dependent variables to determine whether considerations (e.g., covariates or interactions) of these variables would be needed in subsequent analyses. Specifically, child age was collapsed across conditions and, as expected, results revealed significant negative correlations between child's age and all ratings of child pain and anxiety (e.g., child-, caregiver-, and health care provider-report) (Table 2). Child,

parent, and healthcare provided reports of the child's pain and anxiety were all significantly negatively correlated with the child's age, indicating that younger children experienced more procedural distress. The physiological measure of the child's heart rate change was not significantly correlated with the child's age.

Table 2

Bivariate correlations of Child Age with Dependent Variables

	Child Age
Child Pain	
Self-report	-.58**
Parent-report	-.53**
HCP-report	-.47**
Heart-Rate Change	-.04
Child Anxiety	
Parent-report	-.41**
HCP-report	-.39**

** *p<.01*

Ethnicity and gender were examined with ANOVA procedures to determine whether child distress differed on these variables. None of the outcome variables were significantly different across child gender or ethnicity. Only one child indicated having a

medical condition that required extra procedures and only two children reported NICU care at birth. Because of the low frequency, the dependent variables for these specific participants were analyzed and none of the data points were outliers relative to the sample (i.e., all z scores for dependent variables were less than 2).

Primary Analyses

An Analysis of Variance (ANCOVA) was used to examine the main effect of treatment condition, while controlling for the child's age and also tested for a potential interaction between treatment condition and child age. Child age continued to predict child pain and anxiety on each dependent variable, except the physiological measure of change in child heart rate; however, treatment condition was not significant for any of the dependent variables, nor were there any significant interactions (see Table 3).

Table 3

ANCOVA Analysis for Treatment Effects with Age as Covariate and Age x Condition Interaction

	Factors	*F*	*Partial eta*^{2}
Child Heart Rate Change	Child Age	.21	.00
	Condition	1.08	.03
	Age x Condition	1.50	.04
Child Pain			
Self-report	Child Age	39.41**	.36
	Condition	.32	.01
	Age x Condition	.42	.01
Caregiver-report	Child Age	36.24**	.31
	Condition	1.78	.04
	Age x Condition	2.21	.05
HCP-report	Child Age	24.87**	.23
	Condition	.64	.02
	Age x Condition	.37	.01
Child Anxiety			
Caregiver-report	Child Age	17.92**	.18
	Condition	.26	.01
	Age x Condition	.12	.00
HCP-report	Child Age	14.85**	.15
	Condition	.58	.01
	Age x Condition	.86	.02

** $p<.01$

DISCUSSION

Effectiveness of ShotBlocker®

This study evaluated the ShotBlocker®, a new physical intervention to decrease injection pain in children. The hypotheses of the current study were not supported in that the results revealed no significant differences in child pain and anxiety as reported by children, their parents, healthcare providers, or heart rate across the ShotBlocker®, Placebo, or Typical Care conditions.

The Gate Control Theory of Pain suggests that the ShotBlocker® should interfere with the ascending pain signal; however, results did not support the hypothesis. It is important to acknowledge that the theory has never been definitively proven and may be an oversimplification of the complex construct of pain. It may simply not have application in a physical intervention to reduce children's immunization pain. It is also possible that the theory is partially accurate in that the pain signals travel through a gating mechanism in route to the brain; however, the Gate Control Theory does not discuss the strength of ascending versus descending signals. In other words, it is possible that the physical intervention does provide a competing ascending signal to the brain, but that the descending cognitive/emotional factors, such as negative expectations or pre-procedural anxiety, override any interference caused by the physical intervention. In the context of an immunization, a child's anxiety may open the gate and negate the effectiveness of a physical intervention such as the ShotBlocker®.

Previous research evaluating the ShotBlocker® is limited, and found mixed support regarding the effectiveness of the device in reducing children's immunization pain (Drago et al., 2007; Foster, Eberhart, Zuk, & Finn, 2005; Guevarra, 2005; Gundrum

et al., 2005). Two of the studies found that the ShotBlocker® was an effective intervention in reducing children's immunization pain. One possible explanation for the discrepancy between these findings with the current study is the potential differences in methodology. Given that they are only poster presentations and there are no detailed reports, little is known about the methodology of these two prior studies. For example, the two previous studies did not include a placebo control group. Thus, if children were provided extensive information about the device or there were other variables present in the treatment condition, the findings may have simply been due to a placebo effect. In comparison, the current study included a placebo condition and also controlled and limited the information that the healthcare professionals provided to the participants about the device. It is also not clear how participants were assigned or randomized to treatment group and there may have been a sampling bias in the previous studies.

Another possible explanation for the discrepancy in findings is that the sample in this study was significantly different demographically from previous studies, which may have impacted the results. For example, the study by Guevarra (2005) was collected in the Philippines and cultural differences may have played a role in the effectiveness of the ShotBlocker®. Demographic information for the study conducted by Gundrum et al., (2005) was not available for comparison.

The study by Drage et al. (2007) found that parents and nurses perceived lower needle pain for children in the ShotBlocker® group than the control group, but there were no significant differences in children's self-reported pain. This might have been the result of a placebo effect for nurses and parents. Similar to the findings of the current study, Foster, Eberhart, Zuk, and Finn (2005) found no significant differences in parent, nurse,

or child self-report pain ratings between the ShotBlocker® condition and the control group. Thus, there are corroborating data to suggest that the ShotBlocker® is not an effective pediatric pain management intervention.

Limitations and Future Directions

There are several limitations to the current study that should be noted. The sample was primarily upper class, with more than half the sample reporting a family income greater than $90,000 annually. The sample was also mostly Caucasian. Although a homogeneous sample such as this one increased internal validity, it raises questions regarding the generalizability of these findings to children of different ethnicities and lower social economical classes. This is especially pertinent given discrepancies in these findings and those with a sample from the Philippines (Guevarra, 2005).

The setting for the study, a group practice pediatric office, had its advantages and disadvantages. For example, given that this was a busy pediatric practice, the staff might have hurried through the explanation of the device to the participants, which may have neutralized any potential placebo effect. On the other hand, the medical setting provided a realistic evaluation of the ShotBlocker®'s effectiveness in a real-life setting.

Finally, the current study may not have adequately assessed the child's pain response to the injection because it relied too heavily on the subjective ratings from the child, parent, and healthcare provider. Subjective ratings of pain might not be as objective as behavioral observation measures. One reason subjective ratings may be less accurate is that research is has found the ratings are influenced by different factors. For example, Manne et al. (1992) found that caregiver ratings were a more accurate reflection of their own anxiety and healthcare providers were found to rate the child based on overt

behavioral distress and using past experiences with other children. Further supporting this argument, previous research has found significant treatment effects of distraction for pediatric pain management with an observational measure when there were no significant differences among caregiver and health care provider ratings (Cohen, 2002).

Additionally, subjective ratings are limited, in that they reflect a global evaluation of a complex procedural experience. For example, children, parents, and caregivers, may base their ratings on specific parts of the procedure, such as anxiety related to the injection, or immediate reaction to the painful stimulus itself, as opposed to how quickly the child recovered from the pain and anxiety in the minutes after the needle has been removed (e.g. Cohen, 2002; Cohen et al., 2006). Observational coding typically measures distress during different phases of a medical procedure and may have been able to identify differences in levels of distress by treatment group if they were present.

The lack of observational data limits the findings, particularly in terms of understanding children's distress during different phases of the procedure, such as anticipatory and recovery. Observational data was collected as part of this study and will be analyzed in the future to help further evaluate the effectiveness of the ShotBlocker®.

Future studies should continue to examine the effectiveness of physical interventions in reducing children's procedural pain. Additional exploration of factors (e.g. child's anticipatory anxiety, verbal explanation of physical intervention) that may facilitate physical interventions should also be explored.

Conclusions

The current study did not support the ShotBlocker® as an effective intervention to reduce children's pain during immunization injections. Despite the lack of significant

findings, the current study contributes to the literature on the Gate Control Theory of Pain. The current study provided additional evidence that younger children experience higher injection distress and might be in greater need for pain reduction interventions. As immunization injections are a common procedure for children and the distress children experience has both short- and long- term consequences, it is important for researchers to continue evaluating and advocating for the implementation of effective pain management interventions. On balance, it is also important that research reveal when interventions are not effective lest practitioners spend time, money, and energy with interventions that do not provide benefit to the patient.

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APPENDIX A

Family Information Form

Family Information Form

Please take a moment to complete the following forms. If you have any questions, please ask. Thanks!

1. **Your** Relation to Child: ___Mother ___Father ___Grandparent If other, describe: ____

2. **Your** Gender: ___Male ___Female

3. **Your** Date of Birth: ____/_____/_____

4. Are **you** Latino? ___Yes ___No

5. **Your** Race: ___White ___Black ___Asian/Pacific Islander ___Mixed
   If other, describe: _____

6. How many years of school have you completed? ___

7. **Your** Marital Status: ___Single ___Married ___Separated ___Divorced ___Widowed

8. How many years of school has your spouse/partner completed? ___

9. Approximate total family income per year: ☐Less than $14,999 ☐$15,000-$29,999 ☐$30,000-$59,999 ☐$60,000-$89,999 ☐$90,000 or more

10. **Child's** Gender: ___Male ___Female

11. **Child's** Date of Birth: ____/____/____

12. Is your child Latino? ___Yes ___No

13. Your child's race: ___White ___Black ___Asian/Pacific Islander ___Mixed
    If other, describe: _____

14. Was your child born premature? ____ Yes _____ No
    If Yes, was your child in the NICU (Neonatal Intensive Care Unit?) ____Yes ____No

15. What, if any pain medication has your child received today (e.g., Tylenol)? _____

16. Is this child his/her usual self today? If not, Why? _____

17. Did you tell your child that they will be getting a shot today? ____ Yes ____ No
    If Yes, when did you tell them? _____

18. Does your child have a medical condition requiring extra blood draws/injections/IVs? If so, what is the condition? _____

APPENDIX B

Child Pre-Injection Form

Child Pre-Injection Form (FPS-R)

For Researcher Use

Show the child the Faces Pain Scale - Revised. Point to the row of faces.

Say:

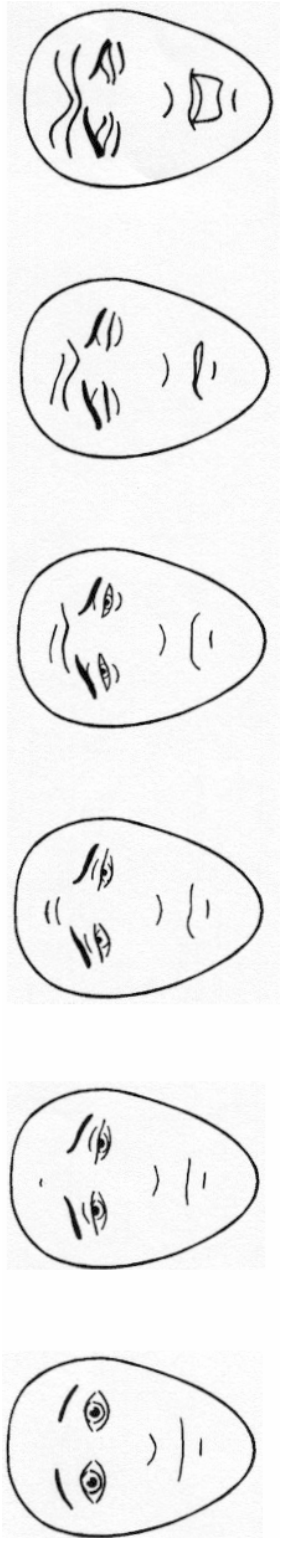
These faces show how much pain a child can feel. This face *(point to the left-most face)* **shows <u>no pain</u>. The faces show more and more pain** *(point to each from left to right)* **up until this one** *(point to the right-most face)* **it shows <u>very much pain</u>.**

1. **Point to the face that shows how much pain you will feel right now**

Child's response: Face # _____

APPENDIX C

Faces Pain Scale – Revised (FPS-R)



APPENDIX D

Child Post-Injection Form

Child Post-Injection Form (FPS-R)

For Researcher Use

Show the child the Faces Pain Scale - Revised. Point to the row of faces.

Say:

Remember these faces? They show how much pain a child can feel. This face *(point to the left-most face)* **shows <u>no pain</u>. The faces show more and more pain** *(point to each from left to right)* **up until this one** *(point to the right-most face)* **it shows <u>very much pain</u>.**

2. **Point to the face that shows how much pain you felt during the injection**

Child's response: Face # _____

APPENDIX E

Parent Post-Injection Form

Parent Post-Injection Form

Please answer the following questions using the lines in the same way you did on the last form. If you have any questions, feel free to ask.

1. How Anxious were you during your child's injection?

Not Anxious _____ Very Anxious

2. How Anxious was **your child** during the injection?

Not Anxious _____ Very Anxious

3. How much Pain did **your child** experience during the injection?

No Pain _____ Severe Pain

APPENDIX F

Nurse Post-Injection Form

Nurse Post-Injection Form

Please answer the following questions using the lines below. Please put a mark so that it intersects the line. If you have any questions, feel free to ask.

1. How Anxious was this **parent** during this child's injection?

Not Anxious _____ Very Anxious

2. How Anxious was this **child** during the injection?

Not Anxious _____ Very Anxious

3. How much Pain did this **child** experience during the injection?

No Pain _____ Severe Pain

4. How Anxious were **you** during this child's injection?

Not Anxious _____ Very Anxious

5. Parent heart rate _____/minute (immediately following the injection)

6. Child heart rate _____/minute (immediately following the injection)

APPENDIX G

Nurse Script – Introduction of ShotBlocker®

Nurse Script - Introduction of ShotBlocker®

Nurse is to use the following script to introduce the medical device to both the treatment group and placebo control group.

(*Show child device*). This is called the ShotBlocker. It is used to help make shots hurt less. I am going to hold it against your arm like this (*nurse demonstrates on own arm**) while I give you your shot. It doesn't hurt at all. Would you like to hold it and see what it feels like? Now I will show you how it feels on your arm (*nurse demonstrates on child's arm**).

*If child is in the ShotBlocker® group, press the device with nubs against skin. If child is in Placebo control, press the device with smooth side against the skin.

APPENDIX H

CONSORT Checklist Items to Include when Reporting a Randomized Trial

PAPER SECTION And topic	Item	Description	Reported on Page #
TITLE & ABSTRACT	1	How participants were allocated to interventions (*e.g.*, "random allocation", "randomized", or "randomly assigned").	i
INTRODUCTION Background	2	Scientific background and explanation of rationale.	1
METHODS Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	14
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	18
Objectives	5	Specific objectives and hypotheses.	13
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors).	15
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	14
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (*e.g.*, blocking, stratification)	17
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	17
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. When relevant, how the success of blinding was evaluated.	17
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	26

RESULTS Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	22
Recruitment	14	Dates defining the periods of recruitment and follow-up.	14
Baseline data	15	Baseline demographic and clinical characteristics of each group.	24
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (*e.g.*, 10/20, not 50%).	24
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (*e.g.*, 95% confidence interval).	27
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	26
Adverse events	19	All important adverse events or side effects in each intervention group.	N/A
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	28
Generalizability	21	Generalizability (external validity) of the trial findings.	28
Overall evidence	22	General interpretation of the results in the context of current evidence.	28