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A Randomized Controlled Trial of the ShotBlocker® for Children's Immunization Distress

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ABSTRACT

Objectives: Vaccinations protect children against deadly diseases and approximately 30 immunizations are recommended for children by 6 years of age. However, immunization injections cause negative short- and long-term consequences for children. The Gate Control Theory of Pain suggests that physical interventions (e.g., rubbing the site) may be helpful, but they are not well validated for children's acute pain. This randomized trial examined the effectiveness of the ShotBlocker®, a physical intervention designed to decrease children's injection pain.

Methods: Participants included 89 4- to 12-year-old children receiving immunizations at a pediatric practice. Participants were randomized to ShotBlocker®, placebo control, or typical care control groups. Measures of child distress included self-report, parent report, healthcare provider report, change in heart rate, and observational behavioral coding.

Results: No group differences were evident on any of the measures of child pain or anxiety when controlling for child age, nor were there any significant interactions of treatment condition with child age. On the observational distress measure, ANCOVAs revealed significantly higher distress in the injection than pre- or post-injection phases, and post-injection distress was higher than pre-injection phase distress, irrespective of treatment condition.

Discussion: The data do not support the effectiveness of the ShotBlocker® for acute pediatric pain relief. Clinical and theoretical implications are discussed.

KEY WORDS: ShotBlocker®, Pediatric pain, Gate Control Theory, Pain management intervention, Immunization

INTRODUCTION

Childhood immunizations are a priority for the pediatric patient and the general public; however, pain resulting from these needle injection results in short- and long-term negative repercussions for the child. The immediate impact is high levels of fear, anxiety, and pain during the medical visit; and long-term outcomes include potential elevated distress during upcoming procedures and avoidance of future healthcare.¹

To counter these issues, pain management has included pharmacological (e.g., topical anesthetics), behavioral (e.g., distraction), and physical approaches (e.g., massage). Whereas pharmacological and behavioral treatments have received significant attention, physical approaches have received less attention.¹ Physical interventions, involving direct stimulation of the area near the noxious stimulus, include massage, touching, rubbing, acupuncture, and transcutaneous electrical nerve stimulation (TENS).²

The Gate Control Theory of pain³ offers a theoretical explanation of how physical interventions might reduce pain. The theory suggests that pain is transmitted from the peripheral nervous system to the central nervous system where it is modulated by a gating system in the dorsal horn of the spinal cord. Physical stimulation – such as rubbing, massage, and vibration – activates the fast, large diameter, myelinated nerve fibers (A-beta) and inhibits the transmission (closes the gate) of pain, which travels via the small diameter unmyelinated fibers (A-delta).

One novel and inexpensive physical intervention is the ShotBlocker® (Manufactured by Bionix®; Toldeo, Ohio), a small, flat u-shaped plastic device, measuring approximately 70mm by 50mm across at its widest points and 2mm thick, with rounded nubs to stimulate the skin around the site of the injection (see Figure 1). The device potentially provides more consistent

stimulation than techniques such as pressing, pinching, or stretching. Theoretically, the stimulation by the pressing down of the nubs on the skin should send fast A-beta signals to the brain and interfere with the slow A-delta pain transmission of the injection, consistent with the Gate Control Theory of pain.³

Although conceptually sound, there are few data in support of the manufacturer's claim that the ShotBlocker® "blocks the pain of minor injections without the use of chemical refrigerant sprays or drug based creams."⁴ To date, there are four studies available that have evaluated the ShotBlocker®. Two of these studies, found on the Bionix® website, support the efficacy of the ShotBlocker®.^{5,6} The unpublished study by Gundrum et al. is available only in a brief abstract form. The study enrolled 99 patients over the age of five years (specific ages were not presented), who were randomized to receive immunizations with or without the ShotBlocker®. The authors reported significantly reduced pain in the intervention group; however, specific details of method (e.g., randomization, procedure), statistics, or results were not provided. It appears that child self-report of pain was the exclusive dependent variable. An unpublished study conducted by Guevarra, also presented only in abstract form, included 119 pre-kindergarten students in the Philippines who were receiving intramuscular injections. Participants in the treatment group reported significantly lower pain scores on the Wong-Baker Faces Pain Rating Scale.⁷ Similar to the previous study, no measure of behavioral pain or observer report was examined, no placebo group was included, and additional information about methodology is limited.

The remaining two studies do not provide evidence that the ShotBlocker® is an effective intervention to reduce children's immunization pain. Drago et al.⁸ evaluated the device with 165 2-month- to 17-year-old participants. Parents and nurses rated participants' pain on a 6-point

likert scale and children over 36 months of age provided self-report using the Wong-Baker Faces Pain Rating Scale.⁷ Parents and nurses rated children's pain lower when using the ShotBlocker®; however, there were no significant group differences in children's self-reported pain. Unfortunately, this study was only presented as a conference poster and additional details about design and procedure (e.g., randomization) are not available. The fourth study, printed in a nursing research newsletter⁹, detailed a two-group, randomized, controlled research study that included a diverse sample of 171 children between the ages of 3 months and 17 years. Parents and children old enough to provide self-reported pain ratings rated children's pain using the Faces Pain Scale-Revised (FPS-R).¹⁰ There were no significant differences in pain ratings between the experimental and control group.⁹ Given the paucity and mixed results available and that no data have appeared in a peer-reviewed publication, a more thorough evaluation of the ShotBlocker's® effectiveness is in order.

Summary and Purpose

In summary, immunization injections cause multiple negative short- and long-term consequences for children. The Shotblocker® is an inexpensive and easy-to-use device that might mitigate children's injection pain. Theoretically, the device should stimulate nerve receptors that interfere with pain processing. The purpose of the current study was to provide a thorough evaluation the Shotblocker®. Based on theoretical underpinnings and the results of the two abstracts,^{5,6} it was hypothesized that the ShotBlocker® would result in significantly lower pain scores on child self-report, parent-report, nurse-report, behavioral observation, and physiological measures in comparison to both typical care control and placebo control. A secondary expected finding was that placebo would provide small, but statistically significant, reductions in pain.

MATERIALS AND METHODS

Participants

Participants included 89 parent-child dyads presenting for pediatric 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). Children younger than the age of 4 were not included, because they would not likely be able to provide valid self-report ratings of pain. Children up to 12 years of age were included to increase external validity in applying findings to school-aged children. Using the effects size of 1.18 found in a prior study of the ShotBlocker®,⁵ a power analysis with power of .87 revealed that only 12 participants would be needed to detect differences using a 3-group analysis of variance (ANOVA). However, given the prior mixed findings, a more conservative sample of 30 participants per condition was deemed 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 White (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. 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.

Approximately half of the sample (50.5%) received only one injection, 17 children (18.3%) received two injections, 14 children received three injections (15.1%), and nine children received four injections (10.3%). Researchers did not record the type of immunization or whether the injections were subcutaneous or intramuscular.

Measures

Background information

Parents who agreed to participate in the study completed a questionnaire assessing demographics of both the child and parent in order to provide descriptive information about the sample so that external validity might be assessed and to evaluate whether variables potentially influencing pain experiences and perceptions were equally distributed across the three conditions (i.e., whether randomization was successful). The child's gender, age, race, and family income were included as part of the demographics questionnaire. 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 distress

Children rated their pain both pre- and post-injection using the using the Faces Pain Scale – Revised (FPS-R),¹⁰ which is a modified version of the original Faces Pain Scale¹¹ and contains six cartoon faces expressing no pain to extreme pain and scored from 0-10. The faces are presented to the child, who is told, “These faces show how much pain a child can feel. This face (point to face) shows no pain. The faces show more and more pain up until this one (point to

face). It shows very much pain.” The child is then asked to select a face that represents either their current level of pain or level of pain during the injection. This measure was designed to create minimal cognitive demands on the child, thus making it appropriate for children of young ages. Research has shown that this measure has adequate reliability and validity.¹⁰ However, because the sample included children as young as 4 years old, children who rated their pre-injection level of pain as a 4 or higher were not included in post-injection pain ratings, given that they likely did not understand the measure or were possibly reporting high level of anxiety in addition to physical pain. Ten child post-injection ratings were excluded for this reason.

In addition to the children’s indication of their pain, parents rated their children’s injection pain and anxiety using Visual Analog Scale (VASs). These measures consisted of 100 mm horizontal lines 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?” and anxiety in response to the question, “How much anxiety 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.¹² After the injection, the health-care provider also rated the pain and anxiety of the children using similar VAS’s.

Children’s distress was also assessed via heart rate. 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 interventions¹³. In addition, heart rate is recommended because of its ease of use and non-invasive nature.¹³ That said, it should be noted that heart rate is reactive to emotional state, movement, room temperature, and other factors besides pain.^{13,14} 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 $\pm 5\%$ 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.

Finally, children's distress was coded using three relevant behavioral indicators of distress. The behaviors were consistent with those used and validated in other behavioral scales (e.g., Child-Adult Medical Procedure Interaction Scale;¹⁵ the Observational Scale of Behavioral Distress¹⁶). The behaviors were: crying, screaming, and adult restraint. Initially, coders were trained to code using videotape data from a prior study. Once interrater agreement had been achieved (i.e., Cohen's Kappa of .80), coding of study data commenced. Coders remained blind to study hypotheses and spanned from three minutes prior to the nurse prepping the injection site by wiping it with alcohol until three more minutes after the final needle was removed. In order to examine differences across phases of the procedure, a total observational distress composite (combining all 3 behavioral codes) was calculated, as well as behavioral scores for pre-injection (3 minutes before until cleaning of the site), injection (cleaning of the site until the needle was removed), and post-injection (removal of the needle until 3 minutes later). The behaviors were coded for occurrence in five-second intervals. Ratio of distress behavior was calculated by dividing the number of intervals of distress by the total number of intervals. Interrater reliability for coding in the current study was 93.6% agreement for crying, 98.4% agreement for screaming, and 95.2% agreement for adult restraint of the child.

Procedure

The study procedure and its informed consent form were approved by the Georgia State University Institutional Review Board. This study was designed in accord with, and adheres to

the guidelines detailed in the Consolidated Standards of Reporting Trials (CONSORT) statement^{17,18,19} (see Figure 2 for the CONSORT Flowchart). Eligible 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. The informed consent explained the randomization process for group assignment. Parents and children were told that random assignment, similar to drawing straws, was done by computer ahead of time. In two of the groups a small plastic device would be put on the child's arm and the third group would be the typical care usually administered by the staff. They were also informed that of the two ShotBlocker® groups, one was a placebo group and they would not know until the end of the study which group they were assigned.

With the help of the research assistant, the parent completed the demographics questionnaire. The research assistant also measured the baseline heart rate of both the parent and child. Participants were randomly assigned to either the typical care control (Typical Care Control), the placebo control (Placebo Control), or the ShotBlocker® condition. The randomization was determined prior to the study via a random number table generated by the RanSL computer program.²⁰ Once participants completed all pre-injection measures, the research assistant opened an envelope, which contained the participant condition assignment. Consistent with the explanation provided in the consent form, the parent(s) and child were only told if they were in the typical care group or one of the two ShotBlocker® groups.

After the family had finished visiting with the pediatrician, the researcher re-entered the exam room and set up the video camera, which was used to collect data for observational coding. Before leaving the room, the research assistant began recording, with the video camera focused

on the exam table where injections were administered. The research assistant privately informed the nurse of the assigned condition so that the nurse was aware of the proper group protocol to follow.

ShotBlocker®

Participants in the ShotBlocker® condition received the intervention according to protocol. The nurse used the following script to introduce and describe the ShotBlocker®:

“(Nurse shows 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.)

Once the nurse was prepared to administer the injection, she/he pressed the ShotBlocker® firmly against the child’s skin at the injection site with the raised nubs in direct contact with the child’s skin. The device was placed on the child’s arm for no more than 20 seconds prior to the injection and held in place until the injection was complete.

Placebo control

Participants assigned to the placebo control group received the same scripted introduction to the medical device that was used with the ShotBlocker® condition participants. They were not aware that they were assigned to the placebo control group. The health care provider placed the ShotBlocker® on the child’s arm with the smooth side against the child’s skin, opposite as prescribed. 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).

Typical care control

The typical care control group received treatment as usual and the health care provider 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 health care provider.

In all three conditions and immediately following the injection, the health care provider obtained 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. 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 to the nurse.

RESULTS

In order to ensure that randomization resulted in equivalent groups, an ANOVA was used to compare the three conditions (Typical Care Control, Placebo, and ShotBlocker®) on child age and number of injections received 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 potentially relevant factors across the

three groups.

The next set of preliminary analyses examined bivariate correlations among demographic variables, specifically age, gender, and ethnicity, to determine whether considerations (e.g. covariates or interactions) of these variables would be needed in subsequent analyses. Results revealed inverse correlations between child's age and all ratings of child pain and anxiety (e.g., child-, caregiver-, and nurse-report) and observational coding of child distress (Table 2) except heart rate change. ANOVAs revealed that ethnicity and gender were not related to measures of child distress. Child self-report ratings of injection pain were excluded if the child reported a pre-injection rating of 4 or higher (on a scale of 1-10). Ten child post-injection ratings were excluded for this reason.

Means and standard deviations for all pain scores by condition are presented in Table 3. 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 (Table 4).

A 3 (phase) x 3 (group) repeated measures ANCOVA was used to examine observational distress while controlling for child age and example potential interactions. A similar pattern emerged, with a significant main effect for child age. Additionally, there was a significant main effect for observational distress during the 3 phases of the procedure. The LSD post-hoc test indicating that the injection phase distress was higher than both pre- and post-injection. Further, children had significantly more observational distress during the post-injection than the pre-

injection phase irrespective of condition. There was no main effect of treatment conditions for observational distress, for the phase x condition interaction, or phase x condition x child age interaction (Table 4).

DISCUSSION

Effectiveness of ShotBlocker®

This study evaluated the ShotBlocker®, a physical intervention designed to decrease injection pain in children. The hypotheses of the current study were not supported in that the results revealed no significant differences treatment effects in child distress on self-report, parent-report, nurse-report, heart-rate change, or observational scale indices. Significant phase differences suggest that the behavioral coding was sensitive to pediatric distress.

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 could be that this particular physical intervention did not stimulate the nerves as intended and thus was not sufficiently effective to reduce children's immunization pain. It could also be that this 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 fact, the descending cognitive/emotional factors may have been influenced by discussing the ShotBlocker® device, which might have focused children's attention to the upcoming injection.

Another explanation for the lack of effects is that the nurses or parents might have become overly reliant on the supposed benefits of the ShotBlocker® and foregone distraction or other coaching, which have been shown to be beneficial.²¹ In fact, there are data showing that nurses provide less distraction when a topical anesthetic is used for pediatric pain relief.²²

Previous research evaluating the ShotBlocker® is limited and mixed regarding the effectiveness of the device in reducing children's immunization pain.^{5,6,8,9} Given that the prior studies were not published in peer-reviewed journals and they contain little information about methodology, it is difficult to reconcile any differences. At this point, it is clear that there are not sufficient data to support spending time, money, and energy on the ShotBlocker®. It is important to disseminate information of this sort lest well-intentioned nurses waste resources on an intervention that is not validated and forgo other methods that have considerable support (e.g., distraction).^{1,23}

Limitations and Future Directions

There are several caveats to consider when interpreting the results. The sample was homogenous in terms of class and race, with a primarily White sample and more than half the sample reporting a family income greater than \$90,000 annually. Although a homogeneous sample increases 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.⁵

Another limitation of the study was the wide age range of the sample, 4 to 12 years of age, because there is a great deal of variability in prior immunization experiences in children of different ages, which likely impacts their level of distress. However, analyses suggested age was randomized successfully across treatment conditions. It is possible that the ShotBlocker® might be more effective for children who can understand the purpose of the device more easily, thus reducing their level of anxiety or other cognitive factors that could influence pain perception. Although findings from the current study did not indicate that there is an age interaction, future

researchers should consider comparing effectiveness of the ShotBlocker® within circumscribed age groups.

Another limitation for the study was that both intramuscular and subcutaneous injections were included. Although this factor was randomized across conditions, there remains the possibility that the ShotBlocker® is more effective for one needle injection and not another. Additional research of the ShotBlocker® could answer this question. The potential influence of the nurse script, used in the ShotBlocker® and Placebo conditions, is another important consideration. The script was provided to increase internal validity; however, it might have inadvertently heightened child's focus on the injection.

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 minimized potential placebo effect. On the other hand, the medical setting provided a realistic evaluation of the effectiveness of the ShotBlocker® in a real-life setting.

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 physical interventions for pediatric pain. The current study provided additional evidence that younger children experience high 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 on interventions that do not provide benefit to the patient.

TABLE 1. Continuous and Categorical Demographic Variables of Entire Sample and by Condition

	<i>Entire Sample</i> (<i>n</i> = 89)	Treatment Condition			<i>F</i> (df) or <i>X</i> ² (df)
		<i>Control</i> (<i>n</i> = 31)	<i>Placebo</i> (<i>n</i> = 29)	<i>ShotBlocker</i> [®] (<i>n</i> = 29)	
Child Age (<i>M</i> , <i>SD</i>)	8.46 (2.97)	8.33 (3.21)	8.24 (2.88)	8.80 (2.86)	0.30 (2, 86)
Number of Injections	1.83 (1.05)	1.84 (1.00)	1.71 (0.98)	1.93 (1.18)	0.30 (2, 86)
Child Gender (% Male)	58.4	61.3	51.7	62.1	0.80 (2)
Child Race (% White)	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.

TABLE 2. Bivariate correlations of Child Age with Dependent Variables

	Child Age
Child Pain	
Self-report	-.59**
Parent-report	-.53**
Nurse-report	-.47**
Observational Distress Composite (Pre-Injection)	-.36**
Observational Distress Composite (Injection)	-.61**
Observational Distress Composite (Post-Injection)	-.62**
Heart-Rate Change	-.04
Child Anxiety	
Parent-report	-.41**
Nurse-report	-.39**

** $p < .01$

TABLE 3. Means and Standard Deviations of Dependent Variables by Condition

	<i>Entire Sample</i> (<i>n</i> = 89)	Treatment Condition		
		<i>Control</i> (<i>n</i> = 31)	<i>Placebo</i> (<i>n</i> = 29)	<i>ShotBlocker®</i> (<i>n</i> = 29)
Child Pain				
Self-report (FPS-R)	4.31 (3.79)	4.67 (3.68)	4.00 (4.20)	4.25 (3.55)
Parent-report (VAS)	37.37 (31.27)	37.81 (33.21)	37.44 (34.53)	36.83 (26.73)
Nurse-report (VAS)	36.25 (27.12)	36.03 (26.34)	34.39 (26.94)	38.28 (28.89)
Observational Distress Composite (Pre-Injection)	.09 (.22)	.08 (.18)	.05 (.20)	.14 (.26)
Observational Distress Composite (Injection)	.29 (.42)	.22 (.39)	.26 (.38)	.41 (.46)
Observational Distress Composite (Post-Injection)	.23 (.36)	.20 (.38)	.20 (.33)	.27 (.37)
Heart-Rate Change	1.91 (23.25)	3.14 (17.50)	6.33 (17.92)	-4.78 (32.63)
Child Anxiety				
Parent-report (VAS)	57.15 (36.81)	54.29 (37.90)	57.75 (37.40)	59.62 (36.16)
Nurse-report (VAS)	51.24 (34.07)	50.84 (33.63)	54.93 (29.24)	48.10 (39.31)

Note: No significant group differences.

TABLE 4. ANCOVA Analyses for Treatment Effects with Age as Covariate and Age x Condition Interaction

	<i>Factors</i>	<i>F</i>	<i>Partial eta</i> ²
Child Pain			
Self-report (FPS-R)	Child Age	39.41**	.36
	Condition	.32	.01
	Age x Condition	.42	.01
Parent-report (VAS)	Child Age	36.24**	.31
	Condition	1.78	.04
	Age x Condition	2.21	.05
Nurse-report (VAS)	Child Age	24.87**	.23
	Condition	.64	.02
	Age x Condition	.37	.01
Heart-Rate Change	Child Age	.21	.00
	Condition	1.08	.03
	Age x Condition	1.50	.04
Child Anxiety			
Parent-report (VAS)	Child Age	17.92**	.18
	Condition	.26	.01
	Age x Condition	.12	.00
Nurse-report (VAS)	Child Age	14.85**	.15
	Condition	.58	.01
	Age x Condition	.86	.02
Observational Distress Composite			
	Child Age	61.16**	.44
	Condition	2.71	.06
	Observational Distress	37.17**	.30
	Observational Distress x Condition	.54	.01
	Observational Distress x Condition x Child Age	.27	.00
	Condition x Child Age		

Note: **p<.01

FIGURE 1. The ShotBlocker®

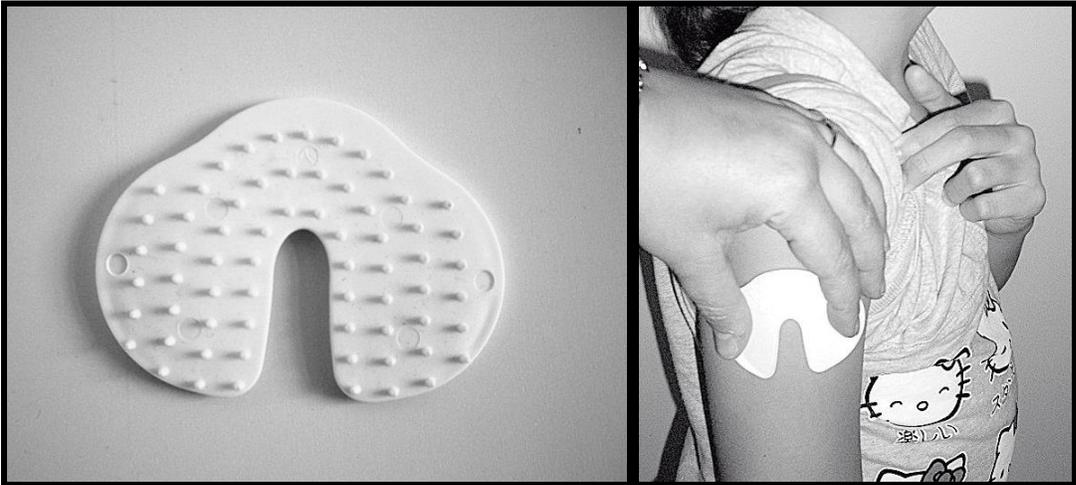
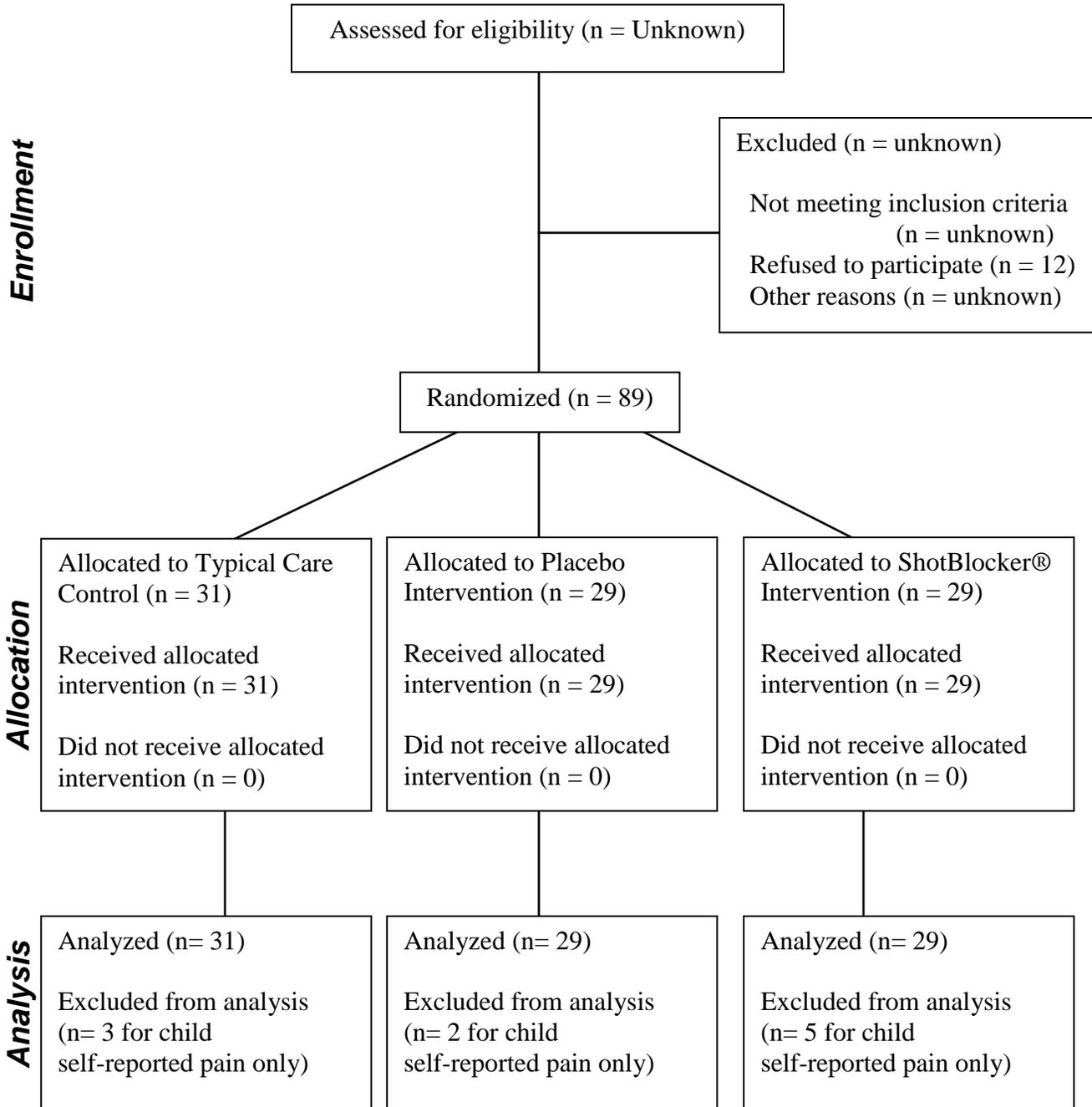


FIGURE 2. CONSORT Diagram Showing the Flow of Participants through Each Stage of a Randomized Trial



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