NON-PHARMACOLOGICAL MANAGEMENT OF ACUTE PAIN SYMPTOMS IN PEDIATRIC PATIENTS

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They say it takes a village to raise a child; it took a village to raise this project! To Jeff, Mom, Dad, Jimmy, Tommy, Kay Kay, Michael and Mark; there is no better family. To Heather, I thank you for always being a champion of my causes. Thank you to every person who found it in their hearts to help and support me. This is dedicated to you.

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ABSTRACT

Acute pain is a complex experience of physiological and psychological symptoms. Pediatric acute pain is often undertreated and undermanaged due to a lack of fast acting and cost effective pain management interventions. The aims of this study were to demonstrate the feasibility of implementing a fast acting non-pharmacological pain management intervention in a clinical pediatric setting, and to measure the physiological, behavioral, and psychological outcomes of the interventions. The physiological and psychological outcome measures are the primary components of the "acute pain phenomenon" established by Humprey et al. in 1992.

Forty outpatients from a major metropolitan pediatric hospital participated in this study. Study participants were referred to the Laboratory Medicine Clinic for a routine blood draw from various outpatient clinics in the hospital. Participants in the treatment group completed a non-pharmacological pain management intervention: a mandala art therapy intervention. Participants in the control group received standard of care treatment during needle stick procedures. The physiological outcomes of heart rate and blood oxygen saturation were measured with a pulse oximeter machine. The stress behaviors recorded through observation were fidgeting, crying, screaming, and the need for physical restraint. Subjective anxiety and subjective pain were recorded through self-report surveys as outcome measures for psychological indicators of stress.

Results indicated high feasibility in both the treatment and control groups. Participants in the treatment group experienced less physiological stress and psychological stress in the time

leading up to the needle stick and during the needle stick procedure, including a decrease in anxiety during the procedure. There was no significant difference in subjective pain between the two groups, though self-reported pain was low for the majority of the participants.

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TABLE OF CONTENTS

LIST OF TABLES

Table

LIST OF ILLUSTRATIONS

Figure

CHAPTER 1

INTRODUCTION

Pain management is a critical aspect of patient care, and has become a nationwide standard of care issued by the Joint Commission on Accreditation for Healthcare Organizations (JCAHO, 1999). Pain is a common experience for pediatric and adult patients during hospitalization. Many health care facilities across the nation are implementing a systems approach to pain management based on recommendations set forth by the American Pain Society. Hospitals and medical schools using the systems approach to pain management are developing practice guidelines, policies, and procedures to better address and manage pain during treatment (American Society of Anesthesiologists Committee on Standards and Practice Parameters, 2011; Bellande et al., 2012; Gordon et al., 2005; Meghani et al., 2012; Murinson, Mezei, Kozachik, Buenaver, De Silva, 2012). However, patients and doctors are still reporting undermanaged pain during hospital stays and outpatient procedures (Avansino, Peters, Stockfish, Walco, 2012; Ellis, O'Connor, Cappelli, Goodman, Blouin, Reid, 2002; Kirsh, Passik, Rich, 2013; Pyati, Gan, 2007).

Undertreated pain can be the result of inadequate pain assessments, patients' inability to properly report pain, the lack of appropriate therapies to treat pain, the complexity of pain, and other factors (Breivik et al., 2008; Herr et al., 2006; Resnik, Rehm, 2001; Sinatra, 2010; Stalnikowicz, Mahamid, Kaspi, Brezis, 2005). Improvements in pain management and proper treatment of pain are important for all patient populations. Pediatric patients specifically, suffer from undertreated pain due to an inability to properly articulate their pain experiences which can have negative developmental consequences (Bartholomeusz, Callister, Hodgson, 2013; Cohen et. al, 2007; Perry, Pollard, Blaicley, Baker, Vigilante, 1995). Children who do not receive adequate pain management interventions may experience residual physiological and psychological effects of pain-related trauma (Avansino, Peters, Stockfish, Walco, 2012; Cohen, 2008; Howard, 2003; Lander, Hodgins,

Fowler-Kerry, 1992; Manuck, Cohen, Rabin, Muldoon, & Bachen, 1991; Noel, McMurtry, Chambers, McGrath, 2011; Rutter, 1981).

Patients and parents frequently cite ineffective pain management as a primary source of dissatisfaction in pediatric patient care, and a reason for changing care providers (Kennedy, Luhmann, Zempsky, 2008; Kozlowski et al., 2012; McNeill, Sherwood, Starck, 2004; Press Ganey, 2011). Children who are frequently hospitalized consider procedure-related pain the worst part of being ill (Blount, Piira, Cohen, Cheng, 2006; Fradet, McGrath, Kay, Adams, Luke, 1990; Kennedy, Luhmann, Zempsky, 2008, McMurtry, Noel, Chambers, McGrath, 2011). Procedural pain is not only experienced during major medical procedures, but during small procedures like blood draws, or venpunctures, as well.

Venipuncture Needle Stick Procedures

Venipunctures are needle stick procedures that occur quickly and frequently and are an aversive treatment experience. Patients commonly report that venipunctures cause a great deal of pain, but that pain is not well managed (Blount, Piira, Cohen, Cheng, 2006; Cohen, Blount, Jansevics Cohen, Ball, McClellan, Bernard, 2001; Hedstrom, Haglund, Skolin, Von Essen, 2003; Kennedy, Luhmann, Zempsky, 2008; Press Ganey, 2011). Needle stick procedures receive some of the highest patient-reported pain scores during hospitalization (Anson, Edmundson, Teasley, 2010; Cohen, Blount, Jansevics Cohen, Ball, McClellan, Bernard, 2001; Eichenfield, Funk, Fallon-Friedlander, Cunningham, 2002; Kennedy, Luhmann, Zempsky, 2008; Press-Ganey, 2011; Rutter, 1981; Windich-Biermeier, Sjoberg, Conkin Dale, Eshelman, Guzzetta, 2007). Needle sticks are often performed without anesthetics because these procedures are time sensitive and must be performed immediately and quickly (Humphrey, Boon, Chiquit van Linden van den Heuvell, van de Wiel, 1992, Windich-Biermeier, Sjober, Conkin Dale, Eshelman, Guzzetta,

2007). Topical anesthetics such as EMLA and ELA-Max must be applied at least 30-60 minutes prior to a venipuncture procedure in order to reach full effectiveness (Eichenfield, Funk, Fallon-Friedlander, Cuningham, 2002; Koh, Harrison, Myers, Dembinski, Turner, McGraw, 2004). This 30-60 minute delay in onset of action is too long in the fast-paced hospital environment. Patients often endure venipuncture pain without any additional fast-acting and/or effective pain management tools (Kennedy, Luhmann, Zempsky, 2008; Press Ganey, 2011). Topical anesthetics like EMLA and ELA-Max can also cause skin irritation, and in extreme cases, fatalities due to absorption through the skin ("Lidocaine topical", 2013).

Components of Pediatric Pain

Pediatric pain is not limited to the physical experience of pain, but also includes an emotional and psychological component. Children often describe the pain they feel during needle sticks as something more than physical hurt, and include feelings of fear and anxiety (Bird, McMurtry, 2012; Blount, Piira, Cohen, Cheng, 2006; Broome, 1990; Cohen, Blount, Jansevics Cohen, Ball, McClellan, Bernard, 2001; Kennedy, Luhmann, Zempsky, 2008; McGrath, McAlpine, 1993; McMurtry, Noel, Chambers, McGrath, 2011; Noel, McMurtry, Chambers, McGrath, 2010; Windich-Biermeier, Sjoberg, Conkin Dale, Eshelman, Guzzetta, 2007). Children have indicated in previous studies that venipunctures are "unacceptable" because these procedures are the most feared aspect of hospitalization (Duff, 2003; Humphrey, Boon, Chiquit van Linden van den Huevell, van de Weil, 1992). A child's fear of the unknown procedure or the memory of a previously unpleasant one can cause a more intense pain experience during a needle stick procedure (Broome, 1990; Cohen, Blount, Jansevics Cohen, Ball, McClellan, Bernard, 2001; Kennedy, Luhmann, Zempsky, 2008; McGrath, McAlpine, 1993; McMurtry, Noel, Chambers, McGrath, 2011; Noel, Chambers, McGrath, Klein, Stewart, 2012; Noel, McMurtry, Chambers, McGrath,

2010; Windich-Biermeier, Sjoberg, Conkin Dale, Eshelman, Guzzetta, 2007).

Pediatric patients undergoing needle stick procedures exhibit considerable stress behaviors immediately before the procedure takes place. Studies have found that the psychological distress experienced before and during a procedure is strongly correlated with reported subjective pain (Cohen, Blount, Jansevics Cohen, Ball, McClellan, Bernard, 2001; Fradet, McGrath, Kay, Adams, Luke, 1990; Gondo, Moriguchi, Kodama, Sato, Sudo, Kubo, Komaki, 2012; McMurtry, Noel, Chambers, McGrath, 2011; Noel, McMurtry, Chambers, McGrath, 2010; Sullivan, 1995). Pediatric patients experience anxiety associated with the visual presentation of a needle, even with the use of EMLA topical anesthetic (Du, Champion, Yap, 2008; Noel, McMurtry, Chambers, McGrath, 2010; Schechter, Blankson, Pachter, Sullivan, Costa, 1997). Pediatric patients' sense of control is threatened by the physical and psychological distress associated with venipunctures (Bird, McMurtry, 2012; Cohen, Blount, Jansevics Cohen, Ball, McClellan, Bernard, 2001; Duff, 2003; Eichenfield, Funk, Fallon-Friedlander, Cunningham, 2002; Humphrey, Boon, Chiquit van Linden van den Huevell, van de Weill, 1992; McMurtry, Noel, Chambers, McGrath, 2011; Rutter, 1981; Windich-Biermeier, Sjoberg, Conkin Dale, Eshelman, Guzzetta, 2007). Children can be overwhelmed when these biological and psychological interactions of the pain process are not adequately managed with interventions (Anson, Edmundson, Teasley, 2010; Chambers, Craig, Bennett, 2002; Duff, 2003; Fradet, McGrath, Kay, Adams, Luke, 1990).

The "acute pain phenomenon" was a term developed to describe the interaction of psychological and physical distress experienced during short medical procedures like needle sticks (Duff, 2003; Humphrey, Boon, Chiquit van Linden van den Huevell, van de Weil, 1992). The phenomenon establishes that the pain of the procedure, as well as the negative emotions

associated with it affect a patient's sense of pain (Duff, 2003; Graeff, 1994; Humphrey, Boon, Chiquit van Linden van den Huevell, van de Weil, 1992; Uman, Chambers, McGrath, Kisely, 2008). Patients who receive topical anesthetics are assisted with the physical pain of a venipuncture, but still experience fear and anxiety which can increase the subjective feeling of pain (Duff, 2003). Children who experience a great deal of anxiety and distress during needle stick procedures can have residual fear and anxiety during subsequent needle sticks based on negative memories of the previous procedure (Cohen, Blount, Jansevics Cohen, Ball, McClellan, Bernard, 2001; Kennedy, Luhmann, Zempsky, 2008; McMurtry, Noel, Chambers, McGrath, 2011; Noel, Chambers, McGrath, Klein, Stewart, 2012; Noel, McMurtry, Chambers, McGrath, 2010). Topical anesthetics do not address psychological needs, are costly and often inconvenient, can be a severe skin irritant, and therefore are difficult to use as a standard of care method ("Lidocaine Topical, 2013; Landier, Tse, 2010; McMurtry, Noel, Chambers, McGrath, 2011; Noel, McMurtry, Chambers, McGrath, 2010; Terndrup, 1996). Children who undergo needle stick procedures need pain management interventions that also address the anxiety, fear, and distress associated with the procedure

Non-Pharmacological Pain Management Interventions

Non-pharmacological pain management interventions such as behavior modification strategies, distraction, hypnosis, and suggestion have all proven to be effective in addressing anxiety experienced during venipunctures (Chambers, Craig, Bennett, 2002; Duff, 2003; Fradet, McGrath, Kay, Adams, Luke, 1990; Humphrey, Boon, Chiquit van Linden van den Huevell, van de Weil, 1992; Chiaretti, Pierri, Valentini, Russo, Gargiullo, Riccardi, 2013; Uman, Chambers, McGrath, Kisely, 2006; Uman, Chambers, McGrath, Kisely, 2006; Windich-Biermeier, Sjoberg, Conkin Dale, Eshelman, Guzzetta, 2007). These non-pharmacological interventions produce a

21% reduction in reported pain when used alone, while pharmacological numbing agents produce a 20%-50% pain reduction (Uman, Chambers, McGrath, Kisely, 2008; Shah, Rieder, Taddio, 2008). A twenty-one percent reduction in pain suggests that non-pharmacological pain management interventions are a good resource in the absence of pharmacological pain management interventions. Most of the research into non-pharmacological pain management interventions has been done in an adult population. Much less of this research has been done in a pediatric population. The non-pharmacological pain interventions researched in children are those labeled distractions.

"Distraction" techniques, such as video games, books, and virtual reality glasses are non-pharmacological interventions that have consistently proven to reduce pain and distress during venipunctures in children (Duff, 2003; Chiaretti, Pierri, Valentini, Russo, Gargiullo, Riccardi, 2013; Uman, Chambers, McGrath, Kisely, 2006; Windich-Biermeier, Sjoberg, Conkin Dale, Eshelman, Guzzetta, 2007). Non-pharmacological distraction interventions were found to be the only intervention to reduce both observer- and self-reported pain during needle stick procedures in pediatric patients in a study by Uman, Chambers, McGrath and Kisely (2006). Distraction techniques that are "interactive, varied in technique, and involve more active processing and motor responses" are effective in reducing patients' subjective pain (Uman, Chambers, McGrath, Kisely, 2008). Distraction-based pain management interventions provide a diversion for children who might otherwise undergo venipunctures without any pain management interventions (Fradet, McGrath, Kay, Adams, Luke, 1990).

Complementary and alternative medicine [CAM] practices, such as mind-body therapies, are another form of fast-acting non-pharmacological pain management interventions. Mind-body therapies are defined by the National Center for Complementary and Alternative Medicine

as CAM interventions "that focus on the interactions among the brain, mind, body, and behavior, and on the powerful ways in which emotional, mental, social, spiritual, and behavioral factors can directly affect health" (Mind-Body Medicine, 2007). Mind-body therapies such as meditation, mindfulness-based stress reduction, qi gong, yoga, cognitive behavioral therapy, guided imagery and hypnosis can be used to manage pain. These therapies have been shown to reduce anxiety and distress in hospitalized populations, and instead induce the relaxation response. Inducing the relaxation response counteracts the negative effects of anxiety and distress on subjective pain, and assists with pain management (Mind-Body Medicine, 2007; Astin, 2004; Wente, 2013; Elkins, Johnson, Fisher, Sliwinski, 2013; Kabat-Zinn, 1982; Landier, Tse, 2010; Tacon, McComb, Caldera, Randolph, 2003; Taylor, Goehler, Galper, Innes, Bourguignon, 2010). However, in a literature review of pediatric CAM studies spanning 2006 to 2010, it was found that of the 152 eligible studies, CAM treated pain was an understudied treatment option (Surette, Vanderjagt, Vohra, 2013).

Non-Pharmacological Art Therapy Intervention

Randomized controlled trials examining the effects of non-pharmacological mind-body therapies on acute pain management are greatly needed in a pediatric population. This study proposes the use of a fast-acting mind-body therapy to provide pain management to children undergoing needle stick procedures. The mind-body therapy that will be used is art therapy. Art therapy has been used as a pain management intervention in adult populations, and was found to reduce patient-reported symptoms of pain, anxiety, and distress (Bar-Sela, Atid, Danos, Gabay, Epelbaum, 2007; Favara-Scacco, Smirne, Schiliro, Di Cataldo, 2001; Nainis, Paice, Ratner, Wirth, Lai, Shott, 2006; Sandmire, Gorham, Rankin, Grimm, 2012; van der Vennet, Serice, 2012). The art therapy intervention that will be used is the mandala, a drawing technique that

provides focus, engagement, and relaxation to participants (Councill, 2003; Malchiodi, 1999; Sandmire, Gorham, Rankin, Grimm, 2012; van der Vennet, Serice, 2012). The mandala focuses on actively engaging patients in repetitive movements to color in a blank circle template, and reduces the effects of distress and anxiety (Councill, 2003; Sandmire, Gorham, Rankin, Grimm, 2012; van der Vennet, Serice, 2012).

The mandala art therapy technique is meant to be accessible to patients of all ages and ability levels, however some patients may have a difficult time grasping drawing instruments like pencils, markers, or crayons (Malchiodi, 1999; Malchiodi, 2005). To avoid excluding patients due to fine motor movements, the mandala circle template will be provided to patients on the Apple touch tablet, the iPad (Figure 1). Using a "Sketch" coloring and drawing application on the iPad, the patient can use a gentle touch from any finger to create color on the mandala template (Figure 2). Presenting the mandala art therapy directive in this manner will allow for patients of all ability and cognitive levels to engage in the intervention.

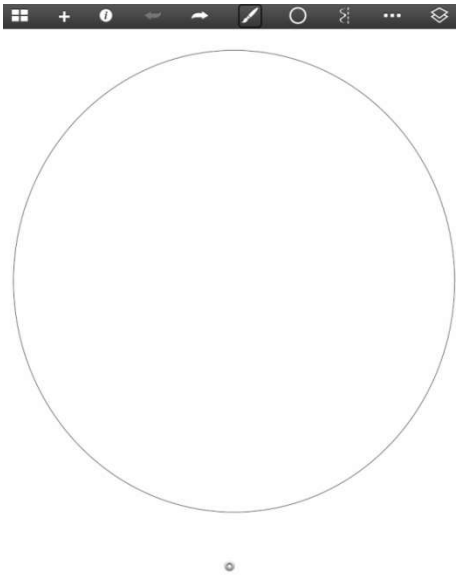

Figure 1. A Mandala Template as it Appears on an Apple iPad Touch Tablet Screen.

Figure 2. Drop-down menu of the "Sketch" Coloring and Drawing Application on the Apple iPad.

Study Aims

The first of two aims of this study is to establish the feasibility of administering the non-pharmacological mind-body pain management intervention in a clinical setting. Feasibility is defined as demonstration of high participant enrollment rate, high retention rate, and minimal interruption to clinical operations. The second aim of this study is to describe the outcome trends of a non-pharmacological pain management intervention on the physiological and psychological symptoms of acute pain affiliated with venipuncture. Physiological symptoms of acute pain and distress are defined as change in heart rate and blood oxygen level (Graeff, 1994). Psychological indicators of acute pain and distress are defined as stress behaviors like crying, screaming, fidgeting, and physical struggle. Crying is defined as vocal crying accompanied by the production of tears. Screaming is defined as a vocal outburst. Fidgeting is defined as significant movement which requires verbal redirection of the Participant by the phlebotomy technician. Physical struggle is defined as struggle significant enough to require physical restraint by family

members or additional phlebotomy technicians. Subjective anxiety and pain will also be measured as psychological indicators of acute pain and distress. It is predicted that providing this non-pharmacological mind-body intervention will affect physiological measures, observed patient behavior, and patient-reported anxiety and subjective pain scores.

CHAPTER 2

METHODS

This study was reviewed and approved by the American University Institutional Review Board and the Institutional Review Board and Nursing Research Assistance Committee at Children's National Health Systems in Washington, D.C.

Participants

Participants were recruited through the laboratory medicine unit at a major metropolitan children's hospital. Participants were male and female between the ages of 7 and 18. Twenty female patients between the ages of 7 and 18 participated in this study, with a mean age of 13.7 years . Twenty male patients between the ages of 8 and 17 participated in this study, with a mean age of 11.75 years. Patients were referred to the laboratory medicine clinic for a venipuncture procedure from the following hospital outpatient clinics: Adolescent Medicine, Cardiology, Children's Medicine, Diabetes, Developmental Medicine, Endocrinology, Gastroenterology, Genetics, Hematology, Infectious Disease, Neurology/Neuroscience, Nephrology, Orthopedics, Psychiatry, Pulmonary, Special Immunology, General Medical. Patients under the age of 7 were excluded from the study population. Non-English-speaking patients were also excluded because all information sheets and intervention materials were presented in English.

Materials

The art therapy directive used in this experiment is called the mandala. A mandala is a drawing technique in which a patient uses repetitive motions to color in a blank circle template. The mandala focuses on actively engaging a patient in repetitive kinesthetic movements, which induces the relaxation response and a state of mindfulness. (Councill, 2003, Sandmire, Gorham, Rankin, Grimm, 2012; van der Vennet, Serice, 2012). These effects of relaxation and mindfulness are not compatible with a state of stress or anxiety. Participants were asked to

create art in and/or around the mandala circle. The mandala was presented on an Apple iPad digital tablet, and participants used their fingers as a stylus for drawing.

The art therapy mandala template was created by the Principal Investigator in the Sketchbook Pro 2.8 app designed by Autodesk for the iPad digital tablet. "Autodesk SketchBook Pro for Tablets is a professional-grade paint and drawing application….. SketchBook Pro delivers a complete set of sketching and painting tools through a streamlined and intuitive user interface designed for the Tablet experience" (http://www.sketchbook.com/sketchbooktablet, 2013).

Design and Procedure

Potential participants in this study were referred to the laboratory medicine clinic of a major metropolitan area children's hospital. The laboratory medicine clinic performs all venipuncture procedures referred from the hospital's outpatient clinics. Laboratory medicine staff were informed that a study was being conducted on the unit, but were blind to the conditions of the study. The study team observed the laboratory medicine team for two weeks to take notes on the timing of venipuncture procedures. The enrollment phase of the study began the following week.

The Principal Investigator acquired written informed consent and assent from potential participants and their parents before the venipuncture procedure. Patients and parents typically waited for 20 minutes after delivering the venipuncture order to the laboratory medicine unit and prior to receiving the venipuncture. This wait period allowed the Principal Investigator to provide a thorough description of the study to the patients and parents and time for asking and answering questions. Of the 44 subjects approached, 40 agreed to participate and 4 declined. The 40 subjects who decided to participate then signed the consent and assent forms. This method of study enrollment allowed parents to be present to provide consent and avoided any interruption in the

typical venipuncture routine. All subjects were informed that they could withdraw from the study at any time. Participants were also informed that if they felt the need to speak with anyone after completion of the study, they could contact the Principal Investigator for a follow up discussion. The Principal Investigator made arrangements with the laboratory medicine unit's attending physician, fellow, and nursing staff, to be available for referral in case of any adverse physical or psychological effects of the study. This was never necessary during the duration of the study. After enrollment in the study the Principal Investigator used a random number generator to assign the Participant to the treatment or control condition of the study. Thirty-nine of the forty participants provided blood samples from a needle stick in the inner crook of their elbows. One participant provided a blood sample from the back of the hand after a failed attempt in the inner crook of the elbow.

Participants randomly assigned to the Control Group were connected to the Masimo Radical 7 pulse oximeter to record the Participant's heart rate and blood oxygen saturation each minute. The pre-procedure measurements were administered at this time. Control subjects waited in the laboratory medicine waiting room where a television is used as a distraction method. The recording of physiological indicators continued during the venipuncture procedure, and for five minutes post-procedure. When the venipuncture procedure was complete, the Principal Investigator administered the post-procedure measurement tools.

Participants randomly assigned to the Treatment Group were also connected to the Masimo Radical 7 pulse oximeter to record heart rate and blood oxygen saturation. These participants were also asked to complete pre-procedure measurements. Treatment subjects also waited in the laboratory medicine unit's waiting room. These subjects received the Apple iPad art therapy pain management intervention five minutes prior to the venipuncture procedure. Participants were

instructed to draw any image they desired during the five-minute period prior to the venipuncture procedure and during the venipuncture procedure. The iPad was sanitized with the use of FDA approved Chef Sleeve protective plastic coverings. These plastic sleeves are one-time use, disposable sleeves that easily slide over the iPad to prevent soiling and were changed with each participant. After completion of the venipuncture procedure, participants in the Treatment Group were asked to complete the post-procedure measurements.

Participants were not required to hold a drawing tool; rather the slightest touch generated color and line on the digital tablet screen. The pulse oximeter machine continued recording the Participant's physiological indicators for the full duration of the venipuncture procedure and for five minutes post-procedure.

When subjects in the Control and Treatment Groups completed the study, the Principal Investigator ensured that the Participant was not in any physical danger. The Principal Investigator reminded each parent and Participant of the contact information on the Information Sheet in case of any additional questions. The study session was then considered complete and the Principal Investigator provided the Participant with a complementary pack of crayons and a coloring sheet as compensation.

Measures

After completion of Participant enrollment and Study Group assignment, the Principal Investigator connected participants to a Masimo Radical 7 pulse oximeter machine to record heart rate and blood oxygen saturation. The Principal Investigator recorded the participants' heart rate and blood oxygen saturation every minute for the duration of the study. The Principal Investigator also administered a one-question self-report measure regarding procedure anxiety. This measure of anxiety is a validated visual analogue scale from the Hospital Fears Rating Scale

which measures situational anxiety related specifically to the hospital experience. The reliability and validity of the Hospital Fears Rating Scale are both high; when visual analogue scales of anxiety were compared with fully recognized scales, the VAS version demonstrated a greater ability to "detect statistically important changes over time" (Bringuier, S., Dadure, C., Raux, O., Dubois, A., Picot, M-C., Capdevila, X., 2009). After completing the study, subjects were asked to complete a post-procedure Hospital Fears Rating Scale. Additionally, a self-report visual analogue scale (VAS) pain instrument was administered post-procedure to measure patient pain levels. The VAS is a highly reliable self-report measure of acute patient pain, with a higher validity rating than the Verbal Rating Scale, as well as higher reliability and validity than simple numerical rating scales (Bijur, Silver, Gallagher, 2001; Ohnhaus, Adler, 1975; Price, Bush, Long, Harkins, 1994). Visual analogue scales like the VAS pain scale and the Hospital Fears Rating Scale have been found to be successfully and accurately completed by children age 6 and older (Shields, Palermo, Powers, Grewe & Smith, 2003).

Statistical Analysis

The Welch t-test, Pearson chi-square test, and Fisher's exact test were performed on demographic data to determine a random sample of pediatric patients. The Welch t-test, Mann-Whitney Wilcoxon test, and Wilcoxon Rank Sum test were used to analyze heart rate, blood oxygen saturation, and subjective anxiety changes. The Mann-Whitney Wilcoxon test was performed on subjective pain scores.

The Shapiro-Wilk test for normality was performed on all data sets to determine normality. Normal data underwent parametric data testing using the Welch t test, while non-normal data was transformed by taking the natural log. In the event that transformed data maintained non-normality,

non-parametric tests such as the Mann-Whitney Wilcoxon test and the Wilcoxon Rank Sum test were performed. An alpha level of .05 was used for all statistical tests.

CHAPTER 3

RESULTS

Subject Characteristics

Forty-four patients were approached to participate in this study. Of those forty-four, four male patients declined. The forty patients who agreed to participate in the study all completed the study procedure, demonstrating a retention rate of 100%. The mean age of the participants was 12.3 years (SD=2.9), the mean age of those in the Treatment Group was 12.0 years (SD=2.9), the mean age of the Control Group was 12.7 years (SD=2.8). There was a relatively even distribution of ages among all participants. Eleven of the 20 participants in the Treatment Group were male, nine were female. Nine of the 20 participants in the Control Group were male, eleven were female. Medical reasons for needle stick procedures were varied; all participants were referred from outpatient clinics. Participant experience with needle stick procedures was diverse: first time (4), one-time a year or less (16), multiple times a year (16), one-time a month or more (4). Table 1 shows there are no significant differences in demographic characteristics between Treatment and Control Groups. Furthermore, comparison across referring clinics revealed no significant difference.

Table 1

Demographic Characteristics of Treatment and Control Groups

	Treatment Group n (%)	Control Group n (%)	Total n (%)	p-value
Age, years				
Mean ± SD	12.0 (2.9)	12.7 (2.8)	12.3 (2.8)	0.4398[1]
Gender				0.527[2]
Male	11 (55)	9 (45)	20 (50)	
Female	9 (45)	11 (55)	20 (50)	
Needle Stick Freq.				0.683[3]
1st Time	3 (15)	1 (5)	4 (10)	
Rarely (1x/yr or less)	8 (40)	8 (40)	16 (40)	
Regularly (Mult. times/yr	8 (40)	8 (40)	16 (40)	
Very Frequently (1x/mo or more)	1 (5)	3 (15)	4 (10)	

Notes: [1] P-value result of Welch t-test, [2] p-value result of Pearson chi-square test, [3] p-value result of Fisher's exact test.

Physiological Indicators of Stress Outcomes

Change in Heart Rate from Minute One to Needle Stick Procedure at Minute Seven

The change in heart rate from Minute One to the needle stick at Minute Seven was calculated by subtracting the value at Minute One from the value at Minute Seven. Table 2 shows the delta value for each participant. For example, Participant One in the Treatment Group had a decrease in heart rate of four beats per minute, while Participant One in the Control Group had a decrease of nineteen beats per minute. Participant Two in the Treatment Group had a decrease in heart rate of seven beats per minute, while Participant Two in the Control Group had an increase in heart rate of twenty-six beats per minute. Calculating the change in heart rate over time removes the confounding variables of age and/or medical condition by showing the raw change in value.

The Shapiro-Wilk test for normality was performed on the data for the change in heart rate from Minute One to the needle stick at Minute Seven. The results showed a non-normal distribution of scores. Data for both groups was transformed taking the natural log of the variable heart rate. The transformed data showed a normal distribution. The transformed data of the control and Treatment Groups was tested for significance using a Welch t test. Table 2 shows the change in heart rate from Minute One to Minute Seven was not significantly different between the two groups, $p = 0.06$.

Table 2

Change in Heart Rate from Minute 1 to Needle Stick

	Treatment Group	Control Group	p-value
Change in HR[1]	-4	-19	0.06[2†]
	-7	26	
	-13	0	
	-3	-17	
	10	9	
	-21	2	
	-1	5	
	5	1	
	25	10	
	-4	31	
	27	-2	
	5	0	
	-11	27	
	10	43	
	30	90	
	14	25	
	-6	44	
	0	2	
	13	27	
	14	32	

Note: [1]Raw data points, [2]p-value result of Welch t-test performed on transformed data, [†]trending toward significance at $p \leq 0.1$ level.

Change in Heart Rate from Needle Stick Procedure to Final Minute Twelve

Table 3 shows the change in heart rate from Minute Seven to Minute Twelve. Table 3 shows the delta value for each participant. The change in heart rate from the needle stick at

Minute Seven to Minute Twelve was calculated by subtracting the value at Minute Seven from the value at Minute Twelve. The Shapiro-Wilk test for normality was performed on the data for the change in heart rate from the needle stick at Minute Seven to Minute Twelve. The results showed a non-normal distribution of scores. Data for both groups was transformed taking the natural log of the variable heart rate. The transformed data showed a normal distribution. The transformed data of the Control and Treatment Groups was tested for significance using a Welch t test. The change in heart rate from Minute Seven to Minute Twelve was not significantly different between the two groups, $p = 0.1$.

Table 3

Change in Heart Rate from Needle Stick at Minute Seven to Minute 12

	Treatment Group	Control Group	p-Value
Change in HR[1]	-5	15	0.1[2†]
	-2	-33	
	10	7	
	-1	2	
	-13	-20	
	7	-12	
	0	-7	
	-11	-8	
	-27	-10	
	-14	-25	
	-31	12	
	6	-1	
	2	-16	
	-6	-29	
	-36	-83	
	-9	-19	
	1	-52	
	-1	-4	
	-12	-28	
	-16	-44	

Note: [1] Raw data points, [2]p-value result of Welch t-test performed on transformed data, [†]trending toward significance at $p \leq 0.1$ level.

Change in Blood Oxygen Saturation from Minute One to Needle Stick Procedure

The change in blood oxygen saturation from Minute One to the needle stick at Minute Seven was calculated by subtracting the value at Minute One from the value at Minute Seven. Table 4 shows the delta value for each participant. For example, Participant One in the Treatment Group had a decrease in blood oxygen saturation of eight percent, while Participant One in the Control Group had an increase of two percent. Participant Two in the Treatment Group had a decrease in blood oxygen saturation of two percent, while Participant Two in the Control Group had an increase one percent. Calculating the change in blood oxygen saturation over time removes the confounding variables of age and/or medical condition by showing the raw change in value.

The Shapiro-Wilk test for normality was performed on the data for the change in heart rate from Minute One to the needle stick at Minute Seven. The results showed a non-normal distribution of scores. Data for both groups was transformed taking the natural log of the variable heart rate. The transformed data showed a normal distribution. The transformed data still demonstrated a non-normal distribution. To test the independence of these variables, a Mann-Whitney Wilcoxon test was performed on the non-transformed data. The Mann-Whitney Wilcoxon test does not assume normal distribution in the data set, and is a parametric statistic often used on non-normal data in place of the Welch t test. There was no statistical difference in change in blood oxygen saturation between the two groups from Minute One to the needle stick procedure, $p=0.09$. Table 4 shows the change in blood oxygen level from Minute One to Minute Seven, as well as the statistical outcome of the Mann-Whitney test.

Table 4

Change in Blood Oxygen from Minute 1 to Needle Stick

	Treatment Group	Control Group	p-Value
Change in BO2	- 8	2	0.09[1†]
	-2	1	
	8	2	
	3	-13	
	-1	0	
	1	-21	
	1	0	
	1	0	
	1	-2	
	2	1	
	0	0	
	2	1	
	-4	0	
	3	1	
	0	1	
	-2	-1	
	0	0	
	0	-1	
	1	0	
	2	0	

Note: [1]P-value result of Mann-Whitney Wilcoxon test,
[†]trending toward significance at $p \leq 0.1$ level.

Change in Blood Oxygen Saturation from Needle Stick Procedure to Final Minute Twelve

The change in blood oxygen saturation from the time of the needle stick at Minute Seven to Minute Twelve was calculated by subtracting the value at Minute Seven from the value at Minute Twelve.

The Shapiro-Wilk test for normality was performed on the data for the change in heart rate from the needle stick at Minute Seven to the Minute Twelve. The results showed a non-normal distribution of scores. Data for both groups was transformed taking the natural log of the variable heart rate. The transformed data still demonstrated a non-normal distribution. To test the independence of these variables, a Mann-Whitney Wilcoxon test was performed on the non-transformed data. The Mann-Whitney Wilcoxon test does not assume normal distribution in the

data set, and is a parametric statistic often used on non-normal data in place of the Welch t test. Table 5 shows there was no statistical difference in change in blood oxygen saturation between the two groups from the needle stick procedure at Minute Seven to the final Minute Twelve, p=0.62.

Table 5

Change in Blood Oxygen from Needle Stick to Minute 12

	Treatment Group	Control Group	p-Value
Change in BO2	1	-1	0.62[1]
	3	-1	
	0	0	
	-1	13	
	1	0	
	-1	21	
	-1	0	
	-1	0	
	1	2	
	-1	0	
	0	-2	
	0	0	
	1	0	
	5	-3	
	0	-1	
	0	1	
	-1	0	
	0	-4	
	-1	-1	
	-1	-1	

Note: [1]P-value result of Mann-Whitney Wilcoxon test.

Stress Behavior Outcomes

Behaviors indicating stress were recorded during the needle stick procedure. These behaviors were fidgeting, defined as movement significant enough to require verbal redirection from the phlebotomy clinician, crying, defined as a verbal outburst accompanied by the production or tears, screaming, defined as a verbal outburst, and physical struggle, defined as struggle significant enough to require physical restraint by additional phlebotomy technicians or parents and family. Table 6 shows the number of participants in the Treatment and Control

Group who exhibited stress behaviors. A Welch t test was conducted, and it showed significantly more participants in the Control Group demonstrated stress behaviors, p=0.03. Table 6 shows the difference between the two study groups by specific behavior, calculated using the Fisher's exact test. The Fisher's exact test was used to manage the small sample size, and because it provided a comparison of categorical data. Though overall, stress behaviors declined in the Treatment Group relative to the Control Group, there was no statistically significant differences between the groups' demonstration of fidgeting, screaming, or need for restraint. Statistically significant differences were observed with significantly more (p = 0.047) participants in the Control Group who demonstrated crying during the needle stick procedure.

Table 6

Presence of Stress Behaviors during Procedure

Any Stress Behavior Present?	Treatment Group	Control Group	p-value
No	18	7	0.03[1*]
Yes	2	13	

Note: [1]P-value result of Welch t-test, *significant at $p \leq 0.05$ level.

Table 7

Stress Behaviors during Procedure

Specific Stress Behavior	Treatment Group	Control Group	p-value
Fidgeting			
No	19	15	0.182[1]
Yes	1	5	
Crying			
No	20	15	0.047[1*]
Yes	0	5	
Screaming			
No	19	18	1.000[1]
Yes	1	2	
Physical Struggle			
No	20	17	0.231[1]
Yes	0	3	

Note: [1]P-value result of Fisher's exact test, [*]significant at $p \leq 0.05$ level.

Impact of Stress Behaviors on Physiological Indicators of Stress

To analyze the impact of stress behaviors on physiological indicators of stress, a robust linear regression model was used to deal with the small sample size. The results are presented in Table 6. Fidgeting behavior significantly correlated with increased heart rate (39.5, p=0.003), but not blood oxygen saturation in the Control Group. The Treatment Group had a significantly lower impact of fidgeting on HR (-37, p=0.007), and no effect on blood oxygen saturation. There was no significant difference in heart rate or blood oxygen saturation found in participants in the Control Group who were crying. None of the participants in the Treatment Group cried during the procedure. The effect of screaming on heart rate and blood oxygen level was significantly lower in the Treatment Group (-4.7, p=0.002; -54, p=0.005) than in the Control Group (56.9, p=0.003). Physical restraint was significantly correlated with elevated heart rate (48.5, p=0.002), but not blood oxygen saturation in the Control Group. None of the participants in the Treatment Group required physical restraint during the procedure.

Table 8

Impact of Stress Behaviors on Physiological Indicators of Stress

Fidgeting on Heart Rate and Blood O2 Sat						
Heart Rate	Coefficient	Std. Err.	t	(95% CI)		p-value
Treatment	-37.01	13.01	-2.84	-63.39	-10.62	0.007[1**]
Control	39.53	12.49	3.16	14.20	64.87	0.003[1**]
Blood O2	Coefficient	Std. Err.	t	(95% CI)		p-value
Treatment	-1.53	1.67	-0.92	-4.91	1.86	0.37[1]
Control	2	1.62	1.23	-1.29	5.29	0.23[1]
Crying on Heart Rate and Blood O2 Sat						
Heart Rate	Coefficient	Std. Err.	t	(95% CI)		p-value
Treatment	(omitted)	(omitted)	(omitted)	(omitted)		(omitted)
Control	25.93	16.23	1.60	-6.96	58.82	0.12[1]
Blood O2	Coefficient	Std. Err.	t	(95% CI)		p-value
Treatment	(omitted)	(omitted)	(omitted)	(omitted)		(omitted)
Control	2.27	1.59	1.42	-0.97	5.50	0.16[1]

Screaming on Heart Rate and Blood O2 Sat						
Heart Rate	Coefficient	Std. Err.	t		(95% CI)	p-value
Treatment	-54.42	18.19	-2.99	-91.31	-17.53	0.005[1**]
Control	56.94	17.82	3.20	20.80	93.09	0.003[1**]
Blood O2	Coefficient	Std. Err.	t		(95% CI)	p-value
Treatment	-4.68	1.43	-3.27	-7.59	-1.78	0.002[1**]
Control	2	1.38	1.45	-0.82	4.80	0.157[1]
Physical Restraint on Heart Rate and Blood O2 Sat						
Heart Rate	Coefficient	Std. Err.	t		(95% CI)	p-value
Treatment	(omitted)	(omitted)	(omitted)		(omitted)	(omitted)
Control	48.53	14.91	3.26	18.33	78.73	0.002[1**]
Blood O2	Coefficient	Std. Err.	t		(95% CI)	p-value
Treatment	(omitted)	(omitted)	(omitted)		(omitted)	(omitted)
Control	2.31	1.41	1.64	-0.54	5.17	0.109[1]

Note: [1]Robust linear regression, [**]significant at $p \leq 0.01$ level.

Self-Reported Anxiety Outcomes

Between Group Change in Self-Reported Anxiety Levels over Time

The Shapiro-Wilk test for normality was performed on the change in anxiety level from pre- to post-procedure in both groups. Participants indicated their level of anxiety on a scale of one to five. Table 10 shows the delta values for each participant. The results showed that the data was not normally distributed. To achieve normality the data was transformed by taking the natural log of the data. The transformed data was still non-normal. To test the independence of these variables, a Mann-Whitney Wilcoxon test was performed on the non-transformed data. The Mann-Whitney Wilcoxon test does not assume normal distribution in the data set. There was no significant difference between groups in change in subjective anxiety over time, p=0.059; however, a trend of decreasing anxiety is identified in the Treatment Group, which is notable in a sample size of twenty participants. Fifty percent of participants in the Treatment Group indicated a two point decrease or greater from pre- to post-procedure anxiety.

Table 10

Between *Groups: Change in Subjective Anxiety Pre-to Post-Procedure*

	Treatment Group	Control Group	*p*-value
Change in Anxiety	0	0	0.059[1†]
	0	0	
	-1	0	
	-1	0	
	-1	0	
	-1	0	
	0	0	
	0	0	
	0	0	
	0	0	
	-1	-1	
	1	0	
	0	0	
	0	1	
	0	0	
	0	0	
	-1	0	
	-1	0	
	0	0	
	0	1	

Note: [1]P-value result of Mann-Whitney Wilcoxon test, [†]trending toward significance at $p \leq 0.1$ level.

Control Group: Change in Self-Reported Anxiety Levels over Time

The Shapiro-Wilk test for normality was performed on the change in anxiety level from pre- to post-procedure in the Control Group. The results showed that the data was not normally distributed. To achieve normality the data was transformed by taking the natural log of the data. The transformed data was still non-normal. A Wilcoxon Rank Sum test was performed on the non-transformed, non-normal data. A Wilcoxon Rank Sum test is a nonparametric statistic used in place of the paired t test to test for significance in non-normally distributed data. There was no significant change in anxiety within the Control Group over time, p=0.77.

Table 11

Control Group: Change in Anxiety Pre-to Post-Procedure

	Pre-Procedure	Post-Procedure	p-value
Change in Anxiety	1	1	0.77[1]
	5	5	
	1	1	
	1	1	
	3	4	
	1	1	
	1	1	
	5	5	
	4	4	
	4	5	
	5	1	
	1	2	
	1	2	
	2	3	
	5	5	
	3	3	
	3	5	
	1	2	
	3	4	
	2	3	

Note: [1]P-value result of Wilcoxon Rank Sum test.

Treatment Group: Change in Self-Reported Anxiety Levels over Time

The Shapiro-Wilk test for normality was performed on the change in anxiety level from pre- to post-procedure in the Treatment Group. The results showed that the data was not normally distributed. To achieve normality the data was transformed by taking the natural log of the data. The transformed data was still non-normal. A Wilcoxon Rank Sum test was performed on the non-transformed, non-normal data. There was a significant decrease in anxiety within the Treatment Group over time, p=0.04.

Table 12

Treatment Group: Change in Anxiety Pre-to Post-Procedure

	Pre-Procedure	Post-Procedure	p-value
Change in Anxiety	3	4	0.04[1*]
	1	1	
	3	1	
	5	2	
	5	1	
	3	2	
	1	1	
	3	4	
	5	4	
	1	1	
	3	1	
	2	4	
	5	3	
	1	2	
	1	2	
	1	1	
	5	2	
	3	1	
	1	2	
	1	1	

Note: [1]P-value result of Wilcoxon Rank Sum test, [*]significant at $p \leq 0.05$ level.

Subjective Pain Outcomes

The self-report pain scale asked participants to rate their experienced pain on a scale of zero to ten, where zero is no pain, and ten is the worst pain. The Shapiro-Wilk test for normality was performed on the self-report pain data in both groups. Table 13 shows the pain score of each participant. The results showed that the data was not normally distributed. Because there were values of zero in the data set, a natural log transformation of the data could not be performed. To test for significant difference between the control and Treatment Groups, a Mann-Whitney Wilcoxon test was performed on the non-normal data. The Mann-Whitney Wilcoxon test does not assume normal distribution in the data set. There was no significant difference between groups in change in subjective pain over time, p=0.97. Table 16 shows that pain scores for both groups were low.

Table 13

Subjective Pain Scores

	Treatment Group	Control Group	p-value
Mean Subjective Pain Scores	2.6	2.4	0.97[1]

Note: [1]P-value result of Mann-Whitney Wilcoxon test

High Anxiety Subset

Change in Heart Rate

A subset of participants from the Control Group, n=10, and the Treatment Group, n=11, provided a pre-procedure anxiety rating of three or higher. This subset of participants was called the High Anxiety Subset. Table 14 shows change in heart rate from Minute One of the intervention to Minute Seven. The change in heart rate from Minute One to the needle stick at Minute Seven was calculated by subtracting the value at Minute One from the value at Minute Seven. Table 14 shows the delta value for each participant. For example, Participant One in the Treatment Group had a decrease in heart rate of four beats per minute, while Participant One in the Control Group had an increase of twenty-six beats per minute. Participant Two in the Treatment Group had a decrease in heart rate of thirteen beats per minute, while Participant Two in the Control Group had an increase in heart rate of nine beats per minute. This data was normally distributed. A Welch t test was run on these values to test significance. Participants in the High Anxiety Subset from the Control Group showed a significant increase in heart rate from the first minute of the intervention to the time of the needle stick at Minute Seven, compared to participants in the Treatment Group, p=0.02. Table 15 shows the change in heart rate from Minute Seven to Minute Twelve. The change in heart rate from the needle stick to Minute Twelve was also calculated. This data was also normally distributed and a Welch t test was

performed to test for significance. Participants in the High Anxiety Subset from the Treatment Group showed a significant decrease in heart rate from the time of the needle stick at Minute Seven to the last minute of the intervention at Minute Twelve, compared to the Control Group, p=0.04.

Table 14

High Anxiety Subset: Change in Heart Rate from Minute 1 to Needle Stick

	Treatment Group	Control Group	*p*-Value
Change in HR	-4	26	0.02[1*]
	-13	9	
	-3	1	
	10	10	
	-21	31	
	5	-2	
	25	90	
	27	25	
	-11	44	
	-6	27	
	0		

Note: [1]P-value result of Welch t-test, [*]significant at $p \leq 0.05$ level.

Table 15

High Anxiety Subset: Change in Heart Rate from Needle Stick to Minute 12

	Treatment Group	Control Group	*p*-Value
Change in HR	-5	-33	0.04[1*]
	10	-20	
	-1	-8	
	-13	-10	
	7	-25	
	-11	12	
	-27	-83	
	-31	-19	
	2	-52	
	1	-28	
	-1		

Note: [1]P-value result of Welch t-test, [*]significant at $p \leq 0.05$ level.

Change in Blood Oxygen Saturation

A subset of participants from the Control Group, n=10, and the Treatment Group, n=11, provided a pre-procedure anxiety rating of three or higher. This subset of participants was called the High Anxiety Subset. The change in blood oxygen saturation from Minute One to the needle stick at Minute Seven was calculated by subtracting the value at Minute One from the value at Minute Seven. Table 16 shows the delta value for each participant. For example, Participant One in the Treatment Group had an increase in blood oxygen saturation of eight percent, while Participant One in the Control Group had an increase of one percent. Participant Two in the Treatment Group had an increase in blood oxygen saturation of eight percent, while Participant Two in the Control Group had no change in saturation. This data was non-normally distributed, and was transformed by taking a natural log of the values. The transformed data was still non-normally distributed. A Mann-Whitney Wilcoxon Test was performed because it does not assume the data is normally distributed. Table 16 shows there was no significant difference between the change in blood oxygen saturation between the two groups, p=0.27. The change in heart rate from the needle stick to Minute Twelve was also calculated, transformed and ultimately tested for significance using the Mann-Whitney Wilcoxon test. Table 17 shows the results of these calculations. There was no significant difference between the two groups, p=0.63.

Table 16

High Anxiety Subset: Change in Blood Oxygen from Minute 1 to Needle Stick

	Treatment Group	Control Group	*p*-Value
Change in BO2	8	1	0.27[1]
	8	0	
	3	0	
	-1	-2	
	1	1	
	1	0	

	1	1
	0	-1
	-4	0
	0	0
	0	

Note: [1]P-value result of Mann-Whitney Wilcoxon Test

Table 17

High Anxiety Subset: Change in Blood Oxygen from Needle Stick to Minute 12

	Treatment Group	Control Group	*p*-Value
Change in BO2	1	-1	0.63[1]
	0	0	
	-1	0	
	1	2	
	-1	0	
	-1	-2	
	1	-1	
	0	1	
	1	0	
	-1	-1	
	0		

Note: [1]P-value result of Mann-Whitney Wilcoxon Test

Between Group Change in Self-Reported Anxiety Levels over Time

A subset of participants from the Control Group, n=10, and the Treatment Group, n=11, provided a pre-procedure anxiety rating of three or higher. This subset of participants was called the High Anxiety Subset. Participants rated their anxiety on a scale of one to five. Table 2 shows the delta value for each participant from pre-procedure anxiety to post-procedure anxiety. The Shapiro-Wilk test for normality was performed on the change in anxiety level from pre- to post-procedure in the High Anxiety Subset for both groups. The results showed that the data was not normally distributed. To achieve normality the data was transformed by taking the natural log of the data however, it was still non-normal. To test for significant difference between the High Anxiety Subset groups, a Mann-Whitney Wilcoxon test was performed on the non-transformed data. The Mann-Whitney Wilcoxon test does not assume normal distribution in the

data set. The High Anxiety Subset of the Treatment Group showed a significant decrease in anxiety from pre- to post-procedure reporting, while the High Anxiety Subset of the Control group remained constant, p=0.02.

Table 18

High Anxiety Subset: Change in Subjective Anxiety Pre-to Post-Procedure

	Treatment Group	Control Group	*p*-Value
Change in Anxiety	1	4	0.02[1*]
	-2	1	
	-3	0	
	-4	0	
	-1	1	
	1	-4	
	-1	0	
	-2	0	
	-2	2	
	-3	1	
	-2		

Note: [1]P-value result of Mann-Whitney Wilcoxon Test, [*]significant at $p \leq 0.05$ level.

CHAPTER 4

DISCUSSION

The first aim of this study was to establish the feasibility of administering a non-pharmacological mind-body pain management intervention in a clinical setting. Feasibility was demonstrated by high enrollment rate, high retention rate, and minimal interruption to clinical operations. Enrollment rate for the study was high; ninety percent of patients who were approached agreed to enroll. One hundred percent of those enrolled participants remained in the study to completion. Administering the pain management intervention did not interrupt the Laboratory Medicine Unit proceedings, nor did it affect provision of patient care. These findings indicate that the non-pharmacological art therapy intervention demonstrates clinical feasibility as a pain management technique in an acute pediatric setting.

The second aim of this study was to describe the physiological and psychological outcome trends of the non-pharmacological pain management intervention. The physiological and psychological outcomes measured in this study are symptoms of the acute pain phenomenon which can be induced by needle stick procedures. The acute pain phenomenon is characterized by signs of physical stress such as elevated heart rate and blood oxygen saturation, and psychological stress like self-reported heightened fear and anxiety, and observed stress behaviors (Bartocci, Begqvist, Lagercrantz, Anand, 2006; Bird, McMurtry, 2012; Blount, Piira, Cohen, Cheng, 2006; Broome, 1990; Cohen, Blount, Jansevics Cohen, Ball, McClellan, Bernard, 2001; Graeff, 1994; Kennedy, Luhmann, Zempsky, 2008; McGrath, McAlpine, 1993; McMurtry, Noel, Chambers, McGrath, 2011; Noel, McMurtry, Chambers, McGrath, 2010; Windich-Biermeier, Sjoberg, Conkin Dale, Eshelman, Guzzetta, 2007). Comparing the outcome measurements of a treatment group using a non-pharmacological pain management intervention to a no-treatment control group, the findings

demonstrated significant differences in some, but not all, of the physiological and psychological symptoms of acute pain.

Heart rate was one of the physiological measurements of the acute pain phenomenon recorded for this study. Heart rate was recorded using a pulse oximeter machine, which was connected to participants by an infrared sensor node secured to participants' fingers. The readings of the machine were recorded every minute from the beginning of the study intervention, through the final minute. The first measure of heart rate variability was calculated by finding the difference between the starting heart rate at Minute One of the intervention, and heart rate during the needle stick procedure at Minute Seven. Calculating this change in heart rate allowed for the control of confounding variables such as patient age and medical condition. The second measure of heart rate variability was calculated by finding the difference between heart rate during the needle stick procedure and the final minute of the intervention, Minute Twelve. Findings indicated no significant difference in change in heart rate between the Treatment and Control Group during the intervention; however the difference, at $p=0.06$, shows a trend in the Treatment Group toward a decrease in symptoms of physical stress and anxiety. It is possible that the decrease in heart rate would have been more significant in the Treatment Group if the pain management intervention had been administered for longer than five minutes prior to the needle stick procedure.

The change in blood oxygen saturation was the other physiological measure recorded during this study. Change in blood oxygen saturation was also calculated by finding the difference in saturation from Minute One to the needle stick at Minute Seven, and from Minute Seven to Minute Twelve. There was no significant change in blood oxygen saturation in either group from Minute One through Minute Twelve of the intervention. The lack of difference between the two groups could be attributed to the short time interval during which the physiological measures were taken.

The psychological measure of anxiety was recorded using a self-report visual analogue scale tool. Participants were invited to answer the one question from the Hospital Fears Anxiety Scale by indicating their level of anxiety on a scale of one to five, where one is no anxiety and five is extreme anxiety. This tool was administered prior to the needle stick procedure and post-procedure. The change in Participant anxiety was then calculated by finding the difference in anxiety from pre-procedure to post-procedure reports. Participants in the Treatment Group demonstrated a significant decrease in anxiety over time, while participants in the Control Group did not show a significant change in self-reported anxiety from pre-procedure ratings to post-procedure ratings. The post-procedure anxiety scores were compared between the Treatment and Control Groups, revealing a p-value of 0.059. These results indicate no statistical significance, but indicate a trending decrease in felt anxiety in the Treatment Group compared to the Control Group. These findings have clinical significance, showing 50% of participants in the Treatment Group had a decrease in anxiety of 20% or more during the intervention. Only 5% of the Control Group experienced a decrease in anxiety. A 15% change in anxiety is considered a medically, or clinically, significant difference (Puhan, Frey, Buchi, Schunemann, 2008). These findings are consistent with other studies that show art therapy, and in particular mandala art therapy, reduces anxiety (Sandmire, Gorham, Rankin, Grimm, 2012; van der Vennet, Serice, 2012).

Stress behaviors such as crying, screaming, fidgeting, and physical struggle are part of the acute pain phenomenon (Duff, 2003; Humphrey, Boon, Chiquit van Linden van den Huevell, van de Weil, 1992). Patients who demonstrate these behaviors in a medical setting are experiencing fear and anxiety about the medical procedure (Bird, McMurtry, 2012; McMurtry, Noel, Chambers, McGrath, 2011; Noel, McMurtry, Chambers, McGrath, 2010). The above-mentioned stress behaviors were observed and recorded for this study. The findings indicated

that significantly more participants in the Control Group demonstrated stress behaviors compared with the Treatment Group. The stress behaviors were then examined individually, and the results showed that crying was significantly higher in the Control Group.

When stress behaviors are exhibited, there are physical implications for the patients who exhibit them in a medical setting. For example, in this study only two participants in the Treatment Group demonstrated stress behaviors. One Participant fidgeted for a moment during the needle insertion, but quickly stopped once the phlebotomy technician verbally addressed the Participant. Another Participant in the Treatment Group gave a quick squeal or scream as the needle was inserted into the back of the hand. The Participant indicated the needle stick in the back of the hand was a first-time experience. Participants in the Control Group who demonstrated stress behaviors often maintained the behavior for an extended period of time. Crying, screaming, fidgeting, and physical struggle were all exhibited in the Control Group. The impact of the stress behaviors on physiological indicators was measured. Results showed that participants in the Control Group who fidgeted had a significantly elevated heart rate when compared with the Participant who fidgeted in the Treatment Group. There was no difference between the blood oxygen saturation of these two groups. Similarly, participants in the Control Group who screamed had a significantly higher heart rate than the Participant in the Treatment Group who demonstrated the same behavior. Again, no difference was found between the blood oxygen levels of either group. Participants in the Treatment Group did not cry or physically struggle, so a comparison could not be made with the Control Group for these two behaviors. However, results showed that physical struggle was correlated with elevated heart rate in the Control Group. These findings support the hypothesis that unaddressed physiological and psychological stress experienced during acutely painful procedures has a negative impact on

participants' experience of the procedure (Bird, McMurtry, 2012; Blount, Piira, Cohen, Cheng, 2006; Broome, 1990; Cohen, Blount, Jansevics Cohen, Ball, McClellan, Bernard, 2001; Kennedy, Luhmann, Zempsky, 2008; McGrath, McAlpine, 1993; McMurtry, Noel, Chambers, McGrath, 2011; Noel, McMurtry, Chambers, McGrath, 2010; Windich-Biermeier, Sjoberg, Conkin Dale, Eshelman, Guzzetta, 2007).

This study also measured subjective pain as a psychological component of the acute pain phenomenon (Bird, McMurtry, 2012; McMurtry, Noel, Chambers, McGrath, 2011; Noel, McMurtry, Chambers, McGrath, 2010). Participants were asked to rate their pain on a scale of zero, no pain, to ten, the most pain. This visual analogue scale was administered after the needle stick procedure. The subjective pain scores were compared across the Treatment and Control Groups, and no significant difference was found. It should be noted that the subjective pain scores reported in both groups were very low. These results are not consistent with previous findings that a heightened level of physiological and psychological stress and anxiety increase subjective pain during a needle stick procedure (Bird, McMurtry, 2012; McMurtry, Noel, Chambers, McGrath, 2011; Noel, McMurtry, Chambers, McGrath, 2010). The results of the subjective pain measure may be uncharacteristically low in both groups because of pressure from parents and medical staff who invalidated participants' suggestions that the procedure is painful. Future studies should consider a more confidential reporting system for subjective pain.

An additional finding in this study pertains to a subset of participants from the Treatment and Control group who reported a pre-procedure anxiety rating of three out of five or higher. An anxiety rating of three or higher indicated that the Participant was feeling "scared", "between scared and really scared, or "really scared". This subset of participants were considered the High Anxiety Subset, and consisted of eleven participants from the Treatment Group and ten from the Control

Group. The data from the High Anxiety Subset was examined in the same manner as the larger sample. The findings indicated that participants from this subset who were in the Treatment Group experienced a significant decrease in physiological stress, as well as psychological stress over time, when compared with the Control Group participants in this subset. The physiological indicator, blood oxygen saturation, did not differ between the two groups; however, there was a very significant decrease in Treatment Group heart rate for the duration of the intervention. The change in heart rate for both groups was calculated using the same formula as previously described. The results showed a statistically significant decrease in Treatment Group heart rate from Minute One to the needle stick at Minute Seven, and an even greater decrease in heart rate from Minute Seven to Minute Twelve. The Treatment Group also showed a statistically significant decrease in psychological stress over time, with a greater decrease in self-reported anxiety. The Treatment Group had significantly lower anxiety post-procedure when compared with the Control Group. These findings indicate the usefulness of non-pharmacological pain management interventions with patients experiencing a great deal of anxiety.

This study had several limitations. First, the location of this study was a working phlebotomy clinic which experienced a high volume of patients every day. The area where study recruitment and the pre-procedure waiting period took place was very noisy and busy. Wait times could be excessive, and it was possible to hear other children crying as a result of the needle stick procedures. All of these factors could have compounded the stress and anxiety participants were already experiencing because of their upcoming venipunctures. Another limitation may have been the amount of time allotted for administering the intervention. It is possible that using an art therapy intervention five minutes prior to a needle stick was not enough time for the anti-anxiety effects of the intervention to take effect. Future studies may want to

consider adjusting the time frame of intervention administration. Finally, as previously mentioned, participants' parents and some medical staff were frequently close by during the pre- and post-subjective anxiety and pain measures. There were several instances when, regardless of study instruction, a parent would suggest the participant was "not scared" or "did not have pain". This projection was frequently reflected in the participant's self-report measure.

Overall, the results of this study support the hypothesis that mind-body pain management interventions, such as art therapy, are a feasible treatment option for pediatric patients undergoing acute venipuncture procedures in a clinical setting. The study findings also show that non-pharmacological mind-body therapies can significantly reduce physiological and psychological stress affiliated with needle stick procedures. While there was no significant difference in subjective pain, the pain scores reported by both groups were quite low. These findings suggest that using non-pharmacological mind-body interventions are a feasible, low cost, fast acting, and effective method for managing both the physiological and psychological symptoms of the acute pain phenomenon.

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