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THE EFFECT OF MUSIC THERAPY INTERACTION ON CHILD AND PARENTAL PREOPERATIVE ANXIETY IN PARENTS OF CHILDREN UNDERGOING DAY SURGERY

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THE EFFECT OF MUSIC THERAPY INTERACTION ON CHILD AND PARENTAL PREOPERATIVE ANXIETY IN PARENTS OF CHILDREN UNDERGOING DAY SURGERY

THESIS

A thesis submitted in partial fulfillment of the requirements for the degree of Master in Music Therapy in the College of Fine Arts at the University of Kentucky

By

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Lexington, Kentucky

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Lexington, Kentucky

2015

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ABSTRACT OF THESIS

THE EFFECT OF MUSIC THERAPY INTERACTION ON CHILD AND PARENTAL PREOPERATIVE ANXIETY IN PARENTS OF CHILDREN UNDERGOING DAY SURGERY

Young children who experience high levels preoperative anxiety often exhibit distress behaviors, experience more surgical complications, and are at a higher risk for developing a variety of negative postoperative consequences. A significant factor in pediatric preoperative anxiety is the level of anxiety present in their caregivers. Music therapy interventions addressing a variety of procedural outcomes have been met with success. The purpose of this study was to investigate the comparative effectiveness of two music therapy interventions on reducing preoperative anxiety in young pediatric surgical patients and their caregivers.

A total of 40 pediatric patient and caregiver dyads were included in this study on various days that they were present for ambulatory surgery. Pediatric preoperative anxiety was measured pre- and post-intervention using the modified Yale Pediatric Anxiety Scale, while caregiver anxiety was measured through self-report using the short form Strait-Trait Anxiety Inventory-Y6. Participants received a randomized active or passive preoperative music therapy session. Results indicate a significant reduction in preoperative anxiety for both patients and the caregivers. Neither active, nor passive music therapy interventions were significantly more effective than the other. Future studies should increase sample size and control for various factors such as sedative premedication use.

KEYWORDS: Music Therapy, Ambulatory Surgery, Preoperative anxiety, Pediatrics, Caregivers

Christopher Robert Millett
April 22, 2015
THE EFFECT OF MUSIC THERAPY INTERACTION ON CHILD AND PARENTAL PREOPERATIVE ANXIETY IN PARENTS OF CHILDREN UNDERGOING DAY SURGERY

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April 22, 2015
Date
To my beautiful wife, Taryn,

for loving me with boundless grace,

and to God,

for all the blessings I could never deserve.
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# TABLE OF CONTENTS

Acknowledgements ........................................................................................................ iii

LIST OF TABLES .............................................................................................................. vi

CHAPTER ONE INTRODUCTION .................................................................................. 1
  Operational Definitions ............................................................................................... 3
  Purpose ....................................................................................................................... 4

CHAPTER TWO LITERATURE REVIEW ....................................................................... 5
  Ambulatory Surgery ................................................................................................. 5
  The Pediatric Surgical Patient ................................................................................. 6
  Medical Anxiety in Young Children ......................................................................... 7
  Factors that contribute to preoperative anxiety .................................................... 10
  Measuring Preoperative Anxiety ........................................................................... 13
  Clinical interventions ............................................................................................... 14

CHAPTER THREE METHODOLOGY .............................................................................. 25
  Procedure .................................................................................................................. 27
  Data Analysis ............................................................................................................. 30

CHAPTER FOUR RESULTS ............................................................................................ 32
  Sample Description .................................................................................................... 32
  Comparing Preoperative Anxiety ............................................................................ 33
  Research Question 2 ................................................................................................. 35
  Research Question 3 ................................................................................................. 36

CHAPTER FIVE: DISCUSSION ...................................................................................... 38
  Research Question 1 ................................................................................................. 38
  Research Question 2 ................................................................................................. 39
  Research Question 3 ................................................................................................. 40
  Limitations ................................................................................................................ 41
  Suggestions for Future Research ............................................................................ 43
  Conclusion .................................................................................................................. 44

APPENDIX Appendix A: Letter of Approval from UK IRB ........................................ 45
  Appendix B: Patient Consent and Authorization Form .............................................. 46
  Appendix C: Modified Yale Pediatric Anxiety Scale ................................................ 50
  Appendix D: mYPAS Scoring Guide ....................................................................... 51
  Appendix E: State Trait Anxiety Inventory Y-6 item ................................................ 52
  Appendix F: Sample Music Alternate Engagement Session Plan ............................ 53
  Appendix G: Sample Music-Assisted Relaxation Session Plan ................................ 54

REFERENCES .................................................................................................................. 55

CURRICULUM VITAE ...................................................................................................... 66
LIST OF TABLES

Table 4.1 Results of $t$-test comparing pre-test mYPAS scores between groups............ 34
Table 4.2 Results of $t$-test comparing pre-test STAI-Y6 scores between groups............ 34
Table 4.3 Results of $t$-test comparing pre- and post-mYPAS anxiety scores in patients . 35
Table 4.4 Results of $t$-test comparing pre- and post-STAI anxiety scores in caregivers.. 36
Table 4.5 Results of $t$-test comparing change in mYPAS scores by group.................... 37
Table 4.6 Results of $t$-test comparing change in STAI scores by group....................... 37
CHAPTER ONE

INTRODUCTION

Advances in medical treatments and technology as well as economic trends have reshaped the landscape of United States healthcare in recent decades (Cullen, Hall, & Golosinskiy, 2009). This change is evident when considering the increase in both frequency and use of freestanding ambulatory surgery centers. *Ambulatory surgery*, or day surgery as it is often referred, is defined as “surgical and nonsurgical procedures performed on an outpatient basis in a hospital or freestanding center’s general operating rooms, dedicated ambulatory surgery rooms, and other specialized rooms” (Cullen et al., 2009, p. 1). Due to advances in surgical practices and reimbursement incentives for facilities, an increasing number and range from noninvasive to invasive procedures are conducted in the ambulatory setting.

Surgical experiences often evoke some level of anxiety, and that level is frequently intensified for children whom may have little control over the situation (McCann & Kain, 2001). Young children who experience high preoperative anxiety tend to experience more pain postoperatively (Hubert et al., 1988; Kain et al., 2006). That anxiety can make the procedure stressful not only for the patient but also for the family and medical staff. An anxious child may take control over their situation by displaying distress behaviors such as crying, screaming, avoidance, or physical resistance (Yinger, Walworth, & Gooding, 2014). Further, Pate and colleagues (1996) found a significant correlation between childhood fear, pain, and coping effectiveness in medical situations as a predictor for adult health outcomes including increased avoidance of medical situations.
Blount and colleagues (2000) highlighted the need to address proximal factors that are immediately present and most likely to directly impact the child’s expression of coping or distress behaviors during a medical procedure. Parent and staff behaviors can either promote coping behaviors or elicit distress behaviors (Varni et al., 1995). Several pharmacological and nonpharmacological interventions can be put in place to address preoperative anxiety and increasing coping effectiveness including (a) sedative premedication, (b) including medical play and reinterpretation, (c) distraction-based techniques, and (d) informed parental presence (Banchs & Lerman, 2014; St. Onge, 2012).

*Music therapy* is often described as an adjunctive or complementary medicine practice that can incorporate the above interventions within an individualized approach. The American Music Therapy Association (2012) defines music therapy as the “clinical and evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship by a credentialed professional who has completed an approved program.” Music therapists serve patients across the perioperative process and provide interventions for both noninvasive and invasive procedures (Gooding, Swezey, & Zwischenberger, 2012). Ghetti (2012) defines *music therapy as procedural support* as “the use of music and aspects of the therapeutic relationship to promote healthy coping and decrease distress in individuals undergoing medical procedures” (p. 6). She continues to synthesize music therapy as procedural support approaches into three categories: Music Alternate Engagement (MAE), Music-Assisted Relaxation (MAR), and Integration with the latter receiving the least attention due to the small evidence-base (Yinger et al., 2014). MAE and MAR differ in the focus of active engagement to divert
attention from anxiety-provoking stimuli versus passive interventions that use entrainment to promote gradual reduction in elevated vital signs.

Music therapy intervention immediately prior to, and during, medical procedures has been evidenced as an effective avenue of eliminating the need for sedation in minimally invasive procedures (Walworth 2003; Walworth 2010), teaching coping promoting behaviors to patients and parents (Yinger, 2012), increasing cost effectiveness (Walworth, 2005), increasing affective states, decreasing distress behaviors, increasing the parent’s overall perception of the facility (Gooding, Yinger, & Iocono, In Review), and reducing preoperative anxiety (Chetta, 1981). To date, no music therapy research examines the effect of live music intervention with the child on parent’s preoperative anxiety.

**Operational Definitions**

The following operational definitions are provided to define for the reader the topics related to this study:

*Ambulatory surgery:* is “surgical and nonsurgical procedures performed on an outpatient basis in a hospital or freestanding center’s general operating rooms, dedicated ambulatory surgery rooms, and other specialized rooms” (Cullen et al., 2009, p. 1).

*Music therapy as procedural support:* is “the use of music and aspects of the therapeutic relationship to promote healthy coping and decrease distress in individuals undergoing medical procedures (Ghetti, 2012, p. 6).

*Musical alternate engagement (MAE):* is when “music is used to motivate and structure the patient’s active engagement with music stimuli and therapist in order to reduce the painful or anxiety-provoking stimuli” which differs from distraction “by emphasizing the
active engagement of the individual with musical stimuli and with the therapist,” (Ghetti, 2012).

Music-assisted relaxation (MAR): can be considered “the application of the use of sound or music to reduce pain, anxiety, or a combination of both … through a process of entrainment [where] music is used to promote gradual reduction in elevated vital rhythms which may occur due to injury or anxiety,” (Prensner et al., 2001).

Preoperative Anxiety: is “unpleasant state of uneasiness or tension secondary to disease, hospitalization, the planned use of anesthesia, and surgery,” (Maranets & Kain, 1999).

**Purpose**

The purpose of this study was to investigate the comparative effectiveness of music-assisted relaxation (MAR) and musical alternate engagement (MAE) interventions on reducing preoperative anxiety in young pediatric surgical patients and their caregivers. Specifically, the following research questions were addressed:

1. Does music therapy intervention have an effect on the preoperative anxiety levels in pediatric patients preparing for day surgery?
2. Does music therapy intervention have a subsequent effect on the preoperative anxiety levels in the caregivers of pediatric patients preparing for day surgery?
3. If musical alternate engagement and music-assisted relaxation interventions do have an effect on pediatric patient and caregiver preoperative anxiety, which is more effective?
Ambulatory Surgery

The landscape of healthcare in the United States has experienced many shifts in recent decades and continues to change in response to advances in medical technology and changes in payment arrangements (Cullen, Hall, & Golosinskiy, 2009). One aspect of healthcare that has seen dramatic transformation is the surgical arena, which has migrated from a primarily inpatient experience to a shared equilibrium of inpatient and outpatient, or ambulatory, procedures. Cullen and colleagues (2009) define ambulatory surgery as “surgical and nonsurgical procedures performed on an outpatient basis in a hospital or freestanding center’s general operating rooms, dedicated ambulatory surgery rooms, and other specialized rooms” (p. 1). Ambulatory procedures encompass a variety of settings and a broad spectrum of operations that range from noninvasive procedures that may only require local anesthesia to major surgery under full anesthesia (Kent, Metzner, & Bollag, 2014).

Since the early 1980’s, both the frequency and use of freestanding ambulatory surgery centers has been on the rise with over a 300% increase in the rate of visits from 1996 to 2006 (Cullen et al., 2009). This rise can be attributed to a combination of advances in medical technology, innovative noninvasive and minimally invasive procedure development, and improvements in anesthesia that have allowed procedures traditionally done in an inpatient setting to move towards an outpatient structure. These medical advances coincided with the development of strong financial incentives from Medicare, Medicaid, and private insurance companies (Cullen et al., 2009).
The cost benefits of ambulatory surgery often stem from two factors: ambulatory surgical patients are generally healthier than inpatient surgical patients (Kent et al., 2014) and ambulatory procedures are typically less invasive than those performed during inpatient surgery (Cullen et al., 2009). However much of the cost savings in the ambulatory setting can be lost when a patient experiences an adverse event that disrupts their discharge and the fast-paced flow of patients. All of these factors can combine to reduce the patient’s satisfaction with the surgical experience (Kent et al., 2014).

Although adverse events occur at a much lower frequency, ambulatory surgery patients are still subject to the same risks as inpatients. Modern surgical techniques have reduced extreme adverse events like mortality and lifelong disability, but unexpected admission may still occur (Kent et al., 2014). These unplanned admissions are primarily due to poorly controlled nausea and vomiting, poorly controlled pain, and procedure-related bleeding (Fortier, Chung, & Su, 1998). The highest risk factors for adverse events stem from complications related to obesity and obstructive sleep apnea both individually and combined (Mathis, Naughton, & Shanks et al., 2013).

The Pediatric Surgical Patient

Rabbitts and colleagues (2010) estimated that up to 70% of all pediatric surgeries take place on an outpatient basis. For children under fifteen the most common ambulatory procedures include myringotomy with insertion of tube (draining of fluid in the ear and placing ear tubes), tonsillectomy with or without adenoidectomy, and adenoidectomy with or without tonsillectomy (Cullen et al., 2009). In children, the risk of adverse events during ambulatory procedures is highest for preterm infants, children with upper respiratory tract infections, and those diagnosed with obstructive sleep apnea.
(Collins & Everett, 2010). Fortunately, in healthy children undergoing ambulatory procedures less than 1% experience complications that require unplanned hospitalization (Patel & Hannallah, 1988).

**Medical Anxiety in Young Children**

The low frequency of extreme adverse events in pediatric ambulatory surgery can be offset by noncompliance throughout the perioperative process. Because the expectations among all parties involved in ambulatory surgery are high, a pediatric patient’s noncompliance can have a large impact on the situation and individuals involved. Those impacted include the medical staff, the child’s caregivers, and most importantly the patient (Kent et al., 2014). Children undergoing medical procedures often feel intense uneasiness or anxiety due to a lack of understanding and having little control over their environment, the situation, and their feelings related to the procedure (McCann & Kain, 2001).

Maranets and Kain (1999) define *preoperative anxiety* as an “unpleasant state of uneasiness or tension secondary to disease, hospitalization, the planned use of anesthesia, and surgery,” (p. 1346). Up to 60% of all young children undergoing anesthesia have reported significant anxiety (Fortier & Kain, 2015). Holm-Knudsen, Carlin, & McKenzie (1998) found that preoperative anxiety is similar for elective and emergency procedures and children who are anxious in the holding area and during anesthesia induction experience greater distress during the postoperative period. While waiting in a preoperative holding room children begin to fear the anticipated separation from their parents and pain from the impending surgery (Fortier & Kain, 2015).
More troubling than the presence of preoperative anxiety are its effects on pediatric patients, which may result in immediate and extended consequences. An anxious child may attempt to take control over their situation by displaying distress behaviors such as crying, screaming, avoidance, or physical resistance (Yinger, Walworth, & Gooding, 2014). As noted by Fortier and Kain (2015) due to high preoperative anxiety during the induction, or beginning stage of anesthesia care, up to 25% of children had to be forcibly held down to ensure compliance and safety when they had not received sedative premedication or had no parent present. Further, children who experience high preoperative anxiety have been shown to experience more pain postoperatively (Hubert et al., 1988; Kain et al., 2006).

Children with high preoperative anxiety are also at a greater risk for emergence delirium and increased distress in the immediate postoperative period (Kain et al., 2006). Sikich and Lerman (2004) define emergence delirium as a “disturbance in a child’s awareness of and attention to his/her environment with disorientation and perceptual alterations including hypersensitivity to stimuli and hyperactive motor behavior in the immediate postanesthetic period” (p. 1139). Study estimates suggest an incidence rate of emergence delirium ranging from 5.3% to 50% depending on the metrics used to define and measure the phenomenon (Banchs & Lerman, 2014). During this 5 to 15 minute period the child may injure her or himself, damage the surgical site, or accidentally remove IVs and medical equipment. Children experiencing emergence delirium often require extra attention and supplies from medical staff that further delays discharge. It is currently assumed that a combination of factors combine to cause emergence delirium, with preoperative anxiety and the child’s temperament playing at least a modest role.
The highest risk of developing emergence delirium has been found among children who display withdrawn, impulsive, or emotionally reactive temperaments (Kain, Caldwell-Andrews, & Maranets et al., 2004).

Aside from consequences of preoperative anxiety that directly impact the surgical visit, pediatric patients may experience other maladaptive behavioral changes that can persist for weeks following the procedure (Kain, Caldwell-Andrews, & Maranets et al., 2004; Kain, Mayes, O’Connor, & Cicchetti, 1996). The most commonly experienced negative behaviors include nightmares, waking up crying, separation anxiety, and temper tantrums with a 3.5-fold increase in risk in children with high preoperative anxiety (Kain, Wang, & Mayes et al., 1999). Though less common, new-onset enuresis (bed-wetting) is one of the more problematic behavioral changes that may occur (Kain, Mayes, & O’Connor et al., 1996). Typically these negative behaviors develop shortly after procedures and extinguish after several days, but for 7.8% of children negative behaviors can persist for up to 1 year following surgical procedures (Kain et al., 1999; Kain et al., 1996). Though negative postoperative behaviors do not happen in every child and often span a relatively short amount of time, negative memories of hospitalizations may persist well into adulthood (Vessy, Bogezt, & Dunleavy, 1994).

Children who have experienced high preoperative anxiety and its consequences may demonstrate decreased cooperation during future medical procedures (Mifflin & Hackmann, 2012). Negative associations with previous experiences may result in greater anxiety in the holding area and at separation from parents than previous medical experiences (Kain et al., 1996; Kotiniemi, Ryhanen, & Moilanen, 1996; Lumley, Melamed, & Abeles, 1993). In a 1996 study, Pate and colleagues found a significant
correlation between childhood fear, pain, and coping ineffectiveness in earlier medical experiences as a predictor for poor adult health outcomes including increased avoidance of medical situations. As a result, Banchs and Lerman (2014) have highlighted the need for interventions to reduce preoperative anxiety, or anxiolysis, not only to benefit the current procedure but also all subsequent medical experiences.

Factors that contribute to preoperative anxiety

Many studies have been successful in identifying risk factors for preoperative anxiety in pediatric patients (Banchs & Lerman, 2014; Kain et al., 1996; Kotiniemi et al., 1996; McGraw, 1994). Factors that were correlated with higher levels of preoperative anxiety included (a) age, (b) temperament, (c) perceptions of previous hospital experiences, (d) the type of anesthesia, and (e) the level of parent or caregiver anxiety (Banchs & Lerman, 2014). Recently uncovered areas that warrant further investigation include cultural differences in language and ethnicity (Fortier, Tan, & Mayes et al., 2013). Research has also identified factors that are inconsequential or minimally interactive such as gender (Kain et al., 1996; Kotiniemi et al., 1996;) and the type of surgery (Holm-Knudsen et al., 1998).

Age. The effects of preoperative anxiety and manifestations of problematic behaviors may differ by age, although studies have yielded inconsistent data (Banchs & Lerman, 2014). Younger surgical patients have been shown to exhibit greater distress at parental separation and induction than older children. While older children experience greater anxiety during preoperative waiting periods, they have been found to be generally more cooperative at induction (Kotiniemi, Ryhanen, & Moilanen, 1997). Studies have found conflicting evidence of distress at induction and postoperative behavior changes at
different ages, but Banchs and Lerman (2014) have suggested that this may be due to imprecise metrics for measuring anxiety and small sample sizes.

McGraw (1994) posited that children undergoing medical procedures develop preoperative anxiety based on their stage of development. Whereas infants to age three may exhibit anxiety at separation and induction, children aged four to six may develop anxiety regarding a lack of understanding and control of the environment. Older children may develop anxiety when they are not involved in the decision-making process (McGraw, 1994). Because children experience anxiety in different stage-related ways, they may need age and stage appropriate therapeutic approaches (Banchs & Lerman, 2014).

**Temperament.** Banchs and Lerman (2014) defined temperament as the “behavioral makeup of a child that influences the reaction to surrounding stimuli and stressful environments” (p. 3). Four main components of temperament have been identified including emotionality, activity, sociability, and impulsivity and can be measured using the EASI scale (Buss, Plomin, & Willerman, 1973). Kain and colleagues (1996) noted that lower scores on the EASI scale were predictive preoperative anxiety development similar to that of emergence delirium (Kain, Caldwell-Andrews, & Maranets et al., 2004). However recent findings suggest that cultural differences—such as language and ethnicity—may have caused misattributions to temperament as a causal factor for preoperative anxiety and postoperative recovery behaviors (Fortier et al., 2013). It is recommended that future studies control for cultural factors when measuring temperament as a predictor for preoperative anxiety.
**Previous hospital experiences.** As previously stated, past medical experiences perceived as frightening or anxiety producing can have a disrupting effect on future procedures (Kain et al., 1996; Kotiniemi et al., 1996; Lumley et al., 1993) and potentially persist as medical avoidance into adulthood (Pate et al., 1996). Banchs and Lerman (2014) also noted that a child’s anxiety response to a procedure could be triggered by temporally relevant stressful life events. This would appear to be less relevant in the ambulatory setting than in an emergency procedure.

**Medical indicators.** Holm-Knudsen and colleagues (1998) found that both elective and emergency procedures elicited similar levels of preoperative anxiety, but less certain is whether the type of anesthesia impacts the patient’s anxiety. Currently, there is conflicting evidence of whether inhalational, intravenous (IV), or rectal induction is preferable in reducing anxiety and postoperative negative behaviors and further investigation is warranted. It is however common practice to use midazolam, a conscious form of sedation, as a premedication to reduce preoperative anxiety and increase compliance at anesthetic induction in young children (Banchs & Lerman, 2014).

**Parental Anxiety.** Preparing for pediatric surgery can be equally as, or even more anxiety producing for the parents of the patient. Unfortunately for all parties involved, caregiver anxiety plays a significant role in the overall anxiety level of the child. The child of an anxious parent is more likely to be anxious in the preoperative waiting area and at separation, and 3.2 times more likely to experience postoperative negative behavior changes that persist for up to six months (Kain et al, 1996). Unknowingly, children receive cues from parent and staff interactions that either display coping-promoting or distress-promoting and account for up to a 55% variance in the
patient’s distress behaviors (Frank, Blount, Smith, Manimala, & Martin, 1995).

Conversely, reducing parental anxiety seems to have a similar effect on the reduction of the pediatric patient anxiety (Wang, Gaal, Maranets, Caldwell-Andrews, & Kain, 2005).

Even when a patient is in the care of excellent medical professionals it is natural for parents to experience anxiety when they witness their child in distress. Shirley and colleagues (1998) compiled a list of common concerns parents face that increase their preoperative anxiety including: concerns about how their child reacts to a new environment, concerns about their child’s well-being, concerns on witnessing their child’s loss of consciousness and immobility, and concerns that they are abandoning their child. While under the stress of those concerns it is plausible to see why parents might resort to behaviors that exacerbate anxiety such as repetitive reassurance, excessive talk, apologizing, and using only adult appropriate medical explanations (Blount, Bunke, & Zaff, 2000).

**Measuring Preoperative Anxiety**

Capturing a seemingly subjective experience such as anxiety can prove to be challenging for clinicians and researchers, but Banchs and Lerman (2014) have argued that using appropriate metrics to quantify preoperative anxiety allows for a better understanding of the problem and aids in the development of approaches that decrease risks of complications for the patient. Physiological indicators such as heart rate, blood pressure, and cortisol levels have shown a lack of reliability and validity as well as an overall impractical use in clinical settings. Currently, behavioral observation tools using a Likert-type rating system such as the modified Yale Preoperative Anxiety Scale (mYPAS) developed by Kain and colleagues (1997) are considered the most effective.
means of capturing an accurate assessment of preoperative anxiety in children. In adults, self-report surveys serve as a means of measuring anxiety and the State Trait Anxiety Inventory (STAI) (Spielberger et al., 1983) is considered the gold standard (Banchs & Lerman, 2014). In 1992, Marteau and Bekker developed a six-item short form (STAI Y-6) from the original STAI to measure specifically trait anxiety and it is said to have favorable internal consistency reliability and validity when correlated to the original 20-item scale (Tluczek, Henriques, & Brown, 2009).

**Clinical Interventions**

Reducing both patient and parental preoperative anxiety has been linked to better outcomes for patients in the immediate procedure, postoperative recovery (Kain et al., 1996), and potentially future medical experiences (Banchs & Lerman, 2014) while maintaining the rapid throughput of patients in the ambulatory setting (Kent et al., 2014). Unfortunately, Kain and colleagues (2006) found that when surveyed, a majority of families in the United States stated that they received no treatment to reduce preoperative anxiety. This may be due to a variety of limitations related to current intervention practices and flaws in the ways patients and families receive preoperative information (Fortier & Kain, 2015).

Measures or interventions designed “to reduce a child’s anxiety and decrease the risk of negative postoperative behavioral changes” (Banchs & Lerman, 2014, p. 4) are known as *preoperative anxiolysis*. Currently, strategies that aim to decrease preoperative anxiolysis flow through one of two major lenses of either pharmacological or nonpharmacological interventions. Ahmed, Farrell, Parrish, and Karla (2011) noted a
trend to address pediatric anxiety through a multi-modal effort and consequently have suggested comprehensive, age appropriate preparation of the child and their families.

Pharmacological practices vary depending on a variety of factors, but the most widespread and recommended approach is the use sedative premedication. More specifically the drug midazolam is preferred due to its high track record of safety, effectiveness, and reliability in decreasing preoperative anxiety and subsequent negative consequences (Banchs & Lerman, 2014). There has been some evidence of other medication use, but aside from its bitter taste there are few drawbacks to using midazolam in the preoperative setting.

Nonpharmacological approaches use interventions that do not require medication and have often used behavioral techniques. Popular interventions include parental presence during induction of anesthesia (PPIA), preoperative interviewing and preparation, medical play and re-interpretation, and distraction (Ahmed et al., 2011; St Onge, 2012). The past decade has also focused on nontraditional medical solutions to reduce preoperative anxiety such as the use of (a) music-based interventions, (b) clowns, (c) hypnosis, (d) low sensory stimulation, and (e) handheld video games with the latter displaying significant reductions in anxiety attributed to the enticing and distracting stimulus (Yip, Middleton, Cyna, & Carlyle, 2011).

**Parental presence at the induction of anesthesia (PPIA).** There has been much debate over the effectiveness of PPIA and whether it should still have a place in current preoperative interventions (Banchs & Lerman, 2014). As a response to the natural protective instinct, an overwhelming majority of parents would elect to accompany their child as long as possible through the perioperative process regardless of their level of
anxiety (Ryder & Spargo, 1991). Studies have displayed conflicting data where some have shown a decrease in anxiety while others have shown increased anxiety in parents witnessing induction with no correlation to reduced negative postoperative behavior changes (Bevan, Johnston, & Tousignant, 1990). In fact, for exceptionally anxious parents, separation may alleviate stress (Bevan et al., 1990). Authors have suggested the PPIA’s mixed results may be due to the lack of a distinct role for the parent, the presence not being enough to reduce anxiety, and the lack of interventions put in place to address the parental anxiety (Watson & Visram, 2003).

**Preoperative preparation programs.** Preoperative preparation programs have been shown to vary greatly in their scope and effectiveness, and as such they have experienced a wide range of results (Banchs & Lerman, 2014). Fortier and Kain (2015) have suggested that preoperative preparation programs can achieve success by being: (a) accessible, (b) tailored to the individual’s needs, (c) low cost for families and the surgery centers, (d) evidence-based rather than driven by cost or individual biases, and (e) focus on teaching effective coping mechanisms. More often than not programs lack these qualities and leave patients and families with more of the “overall picture” than giving specific details that would benefits patients and families such as how to cope with postoperative pain (Fortier & Kain, 2015).

Preoperative preparation programs have been delivered using a variety of media including facility tours, group meetings, videotapes, child-appropriate medical play and medical interpretations, and more recently through more accessible means such as websites created for use at home in preparation (Banchs & Lerman, 2014; Fortier & Kain, 2015). The programs with the most significant results have included training of
appropriate provider and caregiver coping techniques such as using empathy, distraction, and assurance (Blount et al., 2000). When effective, these programs can target patient and parental preoperative anxiety while increasing overall satisfaction (Cassady, Wysocki, Miller, Cancel, & Izenberg, 1999; Margolis et al., 1998).

**Distraction and nontraditional interventions.** Distraction based interventions have been embedded within nearly every intervention that addresses preoperative anxiety due to its high effectiveness with young children (Koller, 2008). Techniques using distraction can be implemented by variety of interventionists including (a) medical staff, (b) child life specialists, (c) creative arts therapists, (d) clowns, (e) hypnotists, and (f) parents of patients (Ahmed et al., 2011). Effective tools have included toys (Golden et al., 2006), electronics, and other enticing stimuli that can capture and maintain a young child’s attention (Ahmed et al., 2001). Handheld video games (Denman et al., 2007; Patel et al., 2006) and other electronic devices such as smart phones (Pittaway & Low, 2008) and web-based entertainment (Gomes, 2008) have been effective at reducing preoperative anxiety and increasing cooperation at induction while providing an advantage in their relatively small size and portability.

The use of clowns for distraction has resulted in mixed findings with some studies evidencing a decrease of preoperative anxiety while others showed a lack of significant results at induction and highlighted the lack of acceptance by the medical team (Golan, Tighe, Dobija, Perel, & Keidan, 2009; Vagnoli, Caprilli, & Messeri, 2010). Other complementary and alternative medicine strategies such as (a) hypnosis, (b) acupuncture, (c) music therapy and (d) other music-based interventions have been met with hesitation, but have been shown to display modest to significant results in decreasing anxiety.
Music-based interventions have been noted to produce moderate to significant anxiolytic effect across the age and perioperative spectrum (Gooding, Swezey, & Zwischenberger, 2010), but one study in the anesthesia literature using two music therapists resulted in only a modest reduction in preoperative anxiety for pediatric patients (Kain et al., 2004). This study cautioned the immediate adoption of music therapy practices, but did not clearly report a significant therapist effect that appeared to alter results.

Music-Based Interventions

The therapeutic use of music has been supported by anecdotal evidence that dates back to some of the first written manuscripts and passages in holy texts from a variety of religious institutions (Davis, Gfeller, & Thaut, 2008). In recent centuries much has been discovered about how music interacts with the brain to elicit change in neural pathways and activate regions in both hemispheres to produce physiological changes. Health practitioners have used music’s unique properties as a tool to address various patient needs during medical treatment (Nilsson, 2008). This has been achieved through two distinct therapeutic uses of music, which are typically differentiated as music medicine and music therapy, which share similar properties but differ in both intention and function.

In a Cochrane review of music interventions for preoperative anxiety, Bradt, Dileo, and Shim (2013) defined music medicine as “passive listening to prerecorded music provided by medical personnel” (p. 6) where patients may or may not play a role in the selection of music and typically receive services via headphones and private listening...
Music therapy on the other hand has been defined as “the clinical and evidence-based use of music interventions to accomplish individualized goals for people of all ages and ability levels within a therapeutic relationship by a credentialed professional who has completed an approved music therapy program,” (Certification Board for Music Therapists, 2015). One notable difference is the extent to which a music therapist is able to manipulate specific aspects of music using therapeutic techniques to more precisely target a desirable outcome. Often, but not always, music therapy interventions are implemented using live music with allows for greater flexibility and individualization as the music therapist targets non-musical goals such as decreasing preoperative anxiety. Research suggests that music therapy can be an effective medium to address a variety of emotional, social, physical, cognitive, and spiritual goals (American Music Therapy Association, 2014).

**Music medicine intervention.** The bulk of medical literature on music-based interventions uses a music medicine approach even in cases where it is mislabeled as music therapy or therapeutic music. In most studies music was used as an *audio analgesic* or *audio anxiolytic*, a term used to describe passive music listening in order to reduce pain or anxiety respectively. Several reviews on music interventions as procedural support have been published which evidence decreases in pain compared to control groups (Good, 2010; Klassen, Liang, Tjosvold, Klassen, & Hartlin, 2008), improving patient’s overall experiences during endoscopies (Bechtold et al., 2009), and reducing anxiety in pediatric patients (Klassen et al., 2008). However, a systematic review of 50 music-based interventions found that 84% of all included studies had a high risk of bias and that results should be interpreted with caution due to lack of reporting
transparency in methods (Yinger & Gooding, 2015). This same risk bias was also found in a Cochrane review of 26 studies where pre-recorded music listening was found to produce a moderate decrease in preoperative anxiety (Bradt et al., 2013).

Although the studies contained a high risk of bias, four studies analyzed in the review by Yinger and Gooding (2015) incorporated additional elements of musical distraction (Kristjánsdóttir & Kristjánsdóttir, 2011), guided imagery (Laurio & Fetzer, 2003), therapeutic suggestion (Nilsson et al., 2001), or the visual elements of a music video (Rickert et al., 1994). The included study that yielded the largest decrease in pain and anxiety used passive listening to recorded music where the patient selected the music (Nguyen et al., 2010) and another study reported significant results through recorded listening where a music therapist provided input in the music selection process to the researcher (Hartling et al., 2013). The authors concluded that further research with music listening should be completed with more cautious methodological development to ascertain a more accurate estimate of the effectiveness of music-medicine research and how it can be implemented most successfully (Yinger & Gooding, 2015).

**Procedural support music therapy.** Music therapy research in procedural support has spanned across the perioperative spectrum from noninvasive procedures such as CT scans (Walworth, 2003), MRIs (Walworth, 2010), and ECGs (Loewy et al., 2005; Walworth, 2003); to invasive procedures such as IV starts (Walworth, 2005), extubation (Hunter et al., 2010), immunizations (Yinger, 2012), and wound care (Whitehead-Pleaux et al., 2006). Ghetti (2012) defined procedural support music therapy as “the use of music and aspects of the therapeutic relationship to promote healthy coping and decrease distress in individuals undergoing medical procedures” (p. 6). Procedural support music
therapy uses an evidence-based individualized approach to teach coping skills to pediatric patients (Yinger, 2012), reduce procedural times through increased compliance and successfully eliminate the need for unnecessary sedation for pediatric patients undergoing various noninvasive procedures (Walworth, 2005), and decrease anxiety in adults undergoing chemotherapy treatment (Ferrer, 2007).

Interventions in procedural support music therapy fall into three main categories: musical alternate engagement (MAE), integration, and music-assisted relaxation (MAR) (Ghetti, 2012). These broad intervention approaches use different means to achieve non-musical goals that ultimately aim to facilitate completion of selected procedures and to reach the highest attainable level of patient satisfaction. The intervention approach should be selected based on its appropriateness to fulfill the patient’s needs (Yinger, Walworth, & Gooding, 2014). MAE and MAR techniques are supported by a considerable amount of research both in procedural support music therapy and across the field with various populations. The less researched category of integration interventions serve as an alternate to distraction where music therapists guide patients’ focus through music to focus on physiological and emotional aspects of the pain itself (Loewy et al., 2005). While this may be empowering for patients and certainly has clinical implications, because of the limited body of research on integration techniques, Yinger and colleagues (2014) caution the use of this set of techniques until further research demonstrates its effectiveness across populations and procedures.

In MAE interventions, music therapists use music to motivate and structure active engagement to distract from noxious stimuli such as pain or anxiety. This is often achieved through subinterventions that range in level of active engagement such as (a)
music listening, (b) therapeutic singing, (c) preference expression, (d) songs encouraging compliance, and (e) musical games (Fratianne et al., 2001). Contrastingly, MAR interventions use specific music techniques of entrainment, or iso-principle, to gradually reduce elevated vital rhythms and decrease pain or anxiety through deep breathing, progressive muscle relaxation, and/or imagery (Prensner et al., 2001). Live music is especially effective in MAR interventions due to the therapist’s ability to match the music with the rhythms of the patient.

As opposed to working with other populations where it is possible to develop rapport over weeks, months, and in some cases even years, the procedural support/medical music therapist often must (a) develop rapport, (b) assess the patient’s needs, (c) provide support throughout the procedure as necessary, (d) select appropriate music with or without the patient’s help, (e) provide procedural education through music, and (f) interact with the family and healthcare staff all within the confines of one session (Yinger, Walworth, & Gooding, 2014). Music therapists control for patient’s responses through an ongoing patient assessment, or reflexivity, that is individualized to determine the desired level of engagement and focus of attention (Ghetti, 2012). Ideally the procedural support music therapist engages the patient in a manner that allows the seamless transition through the procedure that supports both the patient and the medical staff performing the procedure.

**Preoperative music therapy.** Preoperative music therapy as a subset of procedural support music therapy has a small but growing body of research that evidences music therapy with pediatric populations as effective in decreasing preoperative anxiety (Chetta, 1981; Robb, 1995), decreasing distress behaviors (Gooding,
Yinger, & Iocono, In Review), increasing affective states (Gooding et al., In Review), and increasing the parent’s overall perception of the facility while agreeing that both they and their child benefitted from receiving services (Gooding et al., In Review). Research suggests that preoperative music therapists most often use age-appropriate interventions with patient preferred music to distract, deliver preoperative preparation, and/or elicit a relaxation response (Yinger, Walworth, & Gooding, 2014). One study out of the anesthesia literature (Kain et al., 2004) found that active music therapy only yielded modest reductions in preoperative anxiety, but due to lack of transparency in intervention reporting and an evident therapist effect those results require further investigation. In an effort to increasing intervention reporting transparency following the guidelines set by Robb and colleagues (2011), Millett, Robinson, and Yinger (2014) developed an intervention tracking tool that was used in the preoperative ambulatory setting with pediatric patients for further use in intervention and research reporting.

Although music therapy researchers have examined the effects of various music therapy inventions on preoperative anxiety in the pediatric patient and on overall patient and family satisfaction, there is a gap in the literature and conflicting research regarding music therapy’s effectiveness in this clinical setting. It is also not known what interventions are most appropriate in this setting with the specific young pediatric population. It is important to fill this gap because if music therapy can simultaneously reduce preoperative anxiety in young pediatric patients and their parents it may lead to increased compliance at induction and better postoperative outcomes for patients. The purpose of this study was to investigate the comparative effectiveness of music-assisted relaxation (MAR) and music-alternate engagement (MAE) interventions on reducing
preoperative anxiety in young pediatric surgical patients and their caregivers.

Specifically, the following research questions were addressed:

1. Does music therapy intervention have an effect on the preoperative anxiety levels in pediatric patients preparing for day surgery?

2. Does music therapy intervention have a subsequent effect on the preoperative anxiety levels in the caregivers of pediatric patients preparing for day surgery?

3. If musical alternate engagement and music-assisted relaxation interventions do have an effect on pediatric patient and caregiver preoperative anxiety, which is more effective?
CHAPTER THREE

METHODOLOGY

Prior to conducting this study, approval was received from the University of Kentucky Institutional Review Board, Office of Research Integrity (Appendix A).

Participants

A convenience sample of pediatric patients and caregiver dyads were solicited for participation in the study on the same day the patients were scheduled for ambulatory surgery. Participants were patients at a university-affiliated healthcare center for advanced surgery undergoing ambulatory surgery services including: (a) urology, (b) ophthalmology, (c) otolaryngology, (d) pediatric surgery, and (e) dentistry. All patients and caregivers were approached for participation in private preoperative waiting rooms after the nurse had completed all preoperative check-in procedures. Because of the age of the patients (0 – 5 years) only caregiver consent was required for participation in the study. Caregivers were defined as biological parents, or legal guardian in the case where the primary guardian was not the biological parent of the patient. The IRB approved informed consent forms are available for review (Appendix B).

Due to the nature of the intervention and instruments used in study sessions, exclusion criteria included (a) patients older than five years of age, (b) those for whom English was not the primary language for the caregiver or child, (c) patients for whom the caregiver was younger than 18 years of age, or (d) those that declined participation.

This study was submitted to the Institutional Review Board (IRB) of the University of Kentucky for expedited, non-medical review. The study was described as having no more than minimal risk to participants. Because music therapy services were
already being delivered with this population in this setting, the PI followed the referral protocol previously established by nursing staff.

**Instrumentation**

**Modified Yale Preoperative Anxiety Scale (mYPAS).** The Modified Yale Preoperative Anxiety Scale (mYPAS) (Kain et al., 1997) was developed by researchers as a tool to assess preoperative anxiety in children (Appendix C). This observational tool consists of five behavioral domains including (a) activity, (b) emotional expressivity, (c) state of apparent arousal, (d) vocalization, and (e) use of parent. A trained observer uses the Likert-type scales to rate each child in the various domains. A separate sheet detailed scoring guide (Appendix D) is available for reference. Total mYPAS scores can range from 23.33 to 100, with higher values indicating higher anxiety. Scores are obtained by dividing each item rating by the highest possible rating, adding all the produced values, dividing by 5, and multiplying by 100. Kain and colleagues (1997) found the mYPAS measure to have strong internal reliability, interrater reliability, and convergent validity.

**State-Trait Anxiety Inventory Y-6 Item (STAI-Y6).** The State-Trait Anxiety Inventory Y-6 Item (STAI-Y6) scale was developed by Marteau and Bekker (1992) in an attempt to shorten the original State Trait Anxiety Inventory (Spielberger, 1983) from 20 items to 6 while maintaining the accuracy of measuring state anxiety. An analysis by Tluczek and colleagues (2009) showed favorable internal consistency reliability and reliability and validity when correlated to the original 20-item STAI in parents of infants with normal or abnormal newborn screens. This also provided a better fitting model than a similar six-item version developed by Chlan and colleagues (2003).
The STAI-Y6 (Appendix E) uses a six-item Likert-type scale to measure state anxiety. Participants rate their anxiety state using the following scale: 1 = Not at all, 2 = Somewhat, 3 = Moderately, and 4 = Very much. The ratings were used for the following questions: I feel calm, I am tense, I feel upset, I am relaxed, I feel content, and I am worried. Positive questions (I feel calm, I am relaxed, and I feel content) are rated at face value (i.e., Not at all = 1, Somewhat = 2, Moderately = 3, and Very much = 4) while negative questions (I am tense, I feel upset, and I am worried) are weighted inversely (i.e., Not at all = 4, Somewhat = 3, Moderately = 2, and Very much = 1). A total score is obtained my adding the weighted ratings of each question for a score that can range from 6 to 24, with higher scores indicating greater state anxiety.

**Procedure**

Prior to any contact with research participants, the PI and three research assistants completed all university and healthcare training requirements related to research integrity and patient confidentiality. Following approval from the university institutional review board, the PI led trainings on the use and administration of the mYPAS and STAI-Y6 measures. Two research assistants practiced using the mYPAS scale by observing video recorded preoperative music therapy sessions with the study population. This was continued until the PI and research assistants came to agreement on the ratings for three separate trials.

Experimental groups were randomized prior to the start of the study using a randomized number generator program. The third research assistant, who had no direct contact with patients and families generated the randomized list, which was concealed from the PI until the time of treatment. Per standard facility protocols, the PI received
referral information from the charge nurse for the center for advanced surgery, which included the age, name, surgery type, and projected surgery start time on the morning patients were scheduled for operations.

A research assistant, blind to the randomized condition, then approached patients and family members with a brief explanation of the study and obtained informed consent in the private preoperative preparation room. Prior to the start of the study, the patient’s primary caregiver was made aware of the potential risks of divulging private health information. After the informed consent was signed, the research assistant collected data using the mYPAS scale and administered the STAI-Y6 to the parent or primary caregiver. The research assistant then left the preoperative waiting room and did not return until the PI exited at the conclusion of the music therapy session. At this point the research assistant re-entered the room, collected an observational measurement of the child with the mYPAS, and administered the STAI-Y6 to the same parent.

The music therapy intervention was delivered by the PI, who is a board-certified music therapist, and included a fifteen-minute session of either passive (live music listening) or active (music alternate engagement). Immediately prior to entering the preoperative waiting room, the PI opened a sealed envelope from research materials that contained the participant’s randomized group assignment. The primary goal of all sessions was to reduce preoperative anxiety, but sessions also ranged in secondary goals as determined by assessment from the PI including: (a) increasing mood, (b) increasing perception of control, (c) increasing relaxation, (d) increasing compliance with preoperative procedures, and (e) increasing normalization of the environment.

The PI began sessions with brief rapport-building questions to the parents and
child followed by the randomly assigned intervention for the protocol period. Sessions focused on the individual patients’ direct needs, but caregivers often engaged in music interventions as well. A stopwatch was used to monitor the fifteen-minute protocol period and immediately following the conclusion of the research period the PI would briefly provide closure to the patient and caregiver for termination of services.

Live music listening sessions, or passive music therapy intervention, consisted of fifteen-minutes of patient and family preferred music or music for relaxation when appropriate. In these sessions, the PI used a parlor-sized guitar and an electronic music storage system. Patient and family preferred music was solicited, and age appropriate music was used when no preference was provided. Patients often sang along or engaged in rhythmic movement to music, but this was not solicited by the PI and was merely a reflection of patient’s response to intervention. Iso-principle techniques were used to elicit relaxation behaviors across the session and distraction techniques were used in appropriate procedural situations such as when various medical staff needed to talk with the patient’s caregiver or the patient was required to ingest preoperative sedative medicines.

Musical alternate engagement sessions, or active music therapy intervention, consisted of fifteen-minutes of patient and family preferred music or age appropriate music when appropriate. In these sessions, the PI used a parlor-sized guitar, an electronic music storage system, and an instrument-carrying cart that contained various small percussion instruments (i.e., egg shakers, lollipop drums with mallets, thunder tube, child-sized ocean drum, wooden percussion frogs) and other age appropriate instruments. Patients were encouraged to select and play instruments and engage in various songs and
musical games. Similar distraction techniques were used in appropriate procedural support situations as the passive music therapy sessions. Sessions began and terminated similarly in both treatment conditions. Sample session plans for music-alternate engagement (Appendix E) and music-assisted relaxation (Appendix F) sessions are available for review.

After the conclusion of the intervention the PI left the preoperative preparatory room and a research assistant returned to administer post-intervention measures. The post-test measures were completed directly following the randomized music intervention. The PI then followed regular music therapy services protocol, infection control policies, and entered documentation of services into the patient’s medical chart. This did not include information regarding the research study.

To ensure patient and caregiver confidentiality and protection of protected health information all data were collected on paper instruments and each participant dyad was assigned a subject number and stored securely. Data collected included the signed informed consent, randomized group information, and completed paper instruments. Following data collection, a secure server was used to input coded subject data and linking paper documents were destroyed after the length of time required by the University of Kentucky Office of Research Integrity passed.

**Data Analysis**

Prior to data analysis, the PI consulted with statisticians from the university affiliated applied statistics laboratory to determine appropriate tests for statistical analyses. Data collected were analyzed using IBM® SPSS® (ver. 22). The patient’s medical chart was used to gather demographic information regarding the patient’s (a) age
in months, (b) surgery service provider, (c) preoperative diagnosis, (d) type of surgical procedure, (e) number of previous operations, (f) use of sedative premedication, (g) notes on induction and surgical complications, (h) music preference, and (i) goals addressed in music therapy session which were analyzed using descriptive statistics. The mYPAS and STAI-Y6 scores were analyzed using independent sample t tests to compare equivalency between treatment conditions for patients and their caregivers and then measured using a paired t test to determine the overall effect of music therapy on preoperative anxiety for both groups. Finally, difference scores from pre- and post-interventions were calculated and analyzed using independent sample t tests used to evaluate whether either intervention was more effective for reducing either patient or caregiver preoperative anxiety.
CHAPTER FOUR

RESULTS

In this study, two specific music therapy interventions—musical alternate engagement and music-assisted relaxation—were examined for effectiveness in reducing preoperative anxiety in pediatric patients and their caregivers while preparing for ambulatory surgery. Demographic and preoperative anxiety data collected were analyzed using IBM® SPSS® (ver. 22) with descriptive and inferential statistics. A total of 42 pediatric patient and caregiver dyads were solicited for participation in the study. At the end of the 10-week study period, a total of $N = 40$ parent and child dyads participated and completed the study measures, for a 95% completion rate.

Sample Description

A total of $N = 40$ patients and caregiver dyads consented to participation in the study with Group 1 receiving the musical alternate engagement intervention ($n = 19$) and Group 2 receiving the music-assisted relaxation intervention ($n = 21$). The age of pediatric participants ranged from 9 to 68 months ($M = 32.58, SD = 17.19$) with more boys (67%) than girls (33%). The majority of patients in the study were Caucasian (87%) with a smaller percentage of African-American (13%). No other ethnicities were identified upon review of patients’ medical charts.

Patients were present for procedures from a variety of services providers including ophthalmology ($n = 13$), otolaryngology ($n = 11$), urology ($n = 9$), pediatric surgery ($n = 6$), and dentistry ($n = 1$). The majority of patients (73%) were present for their first procedure while fewer patients had experienced one (10%), two (10%), or three (7%) previous procedures. No patient had experienced more than three previous
procedures. A post-discharge review of patient’s operative report revealed that no participants experienced post-surgical complications (100%) and of the providers that documented induction notes (13%) all patients were reported as being induced without difficulty. All interventions targeted decreased preoperative anxiety as the primary outcome measure while secondary goals were addressed as appropriate. The list of addressed secondary goals in each session included (a) increased mood (100%), (b) increased perception of control (28%), (c) increased normalization of the environment (25%), (d) increased relaxation (13%), (e) increased procedural compliance (5%), and (f) decreased separation anxiety (3%).

Comparing Preoperative Anxiety

Initial statistical analysis was used to compare the level of preoperative anxiety between experimental groups of pediatric patients and caregivers. Using the totaled pretest mYPAS score, results of an independent-samples t test indicate that there was no significant difference in preoperative anxiety between pediatric patients receiving musical alternate engagement ($M = 47.63, SD = 18.39$) and patients receiving music-assisted relaxation ($M = 45.55, SD = 17.44$); $t (38) = .37, p = .72$. Similarly, the totaled pretest STAI-Y6 score results of an independent-samples t test indicate that there was no significant difference in preoperative anxiety between groups of caregivers of patients receiving music alternate engagement ($M = 14.21, SD = 4.79$) and caregivers of patients receiving music-assisted relaxation ($M = 14.05, SD = 2.80$); $t (28) = .130, p = .90$. These findings suggest that both experimental groups of pediatric patients and their caregivers began the session with similar levels of preoperative anxiety. Given the similarity between the two groups, further analysis was conducted to determine the effects of music.
therapy on parent and caregiver preoperative anxiety. The independent samples \( t \) test source table comparing pre-test anxiety scores between groups of pediatric patients is shown in Table 4.1 and for caregivers in Table 4.2.

Table 4.1

*Results of \( t \)-test Comparing Pre-test mYPAS Scores Between Experimental Conditions*

<table>
<thead>
<tr>
<th>Group</th>
<th>95% CI for Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAE</td>
<td>MAR</td>
</tr>
<tr>
<td>( M )</td>
<td>( SD )</td>
</tr>
<tr>
<td>Pre-test mYPAS</td>
<td>47.63, 18.39</td>
</tr>
</tbody>
</table>

Table 4.2

*Results of \( t \)-test Comparing Pre-test STAI-Y6 scores Between Experimental Conditions*

<table>
<thead>
<tr>
<th>Group</th>
<th>95% CI for Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAE</td>
<td>MAR</td>
</tr>
<tr>
<td>( M )</td>
<td>( SD )</td>
</tr>
<tr>
<td>Pre-test STAI-Y6</td>
<td>14.21, 4.79</td>
</tr>
</tbody>
</table>

**Research Question 1**

*Does music therapy intervention have an effect on the preoperative anxiety levels in pediatric patients preparing for day surgery?*

Before analyzing individual music therapy interventions to compare effectiveness, a paired \( t \) test was used to analyze the overall effectiveness of music therapy intervention on decreasing preoperative anxiety in pediatric patients. There was a significant difference in mYPAS scores in pediatric patients for pre-music therapy intervention levels of preoperative anxiety (\( M = 46.54, SD = 17.70 \)) and post-music therapy intervention levels of preoperative anxiety (\( M = 37.29, SD = 13.36 \)); \( t(39) = 3.62, p = \)__
.001. These results suggest that patients in both experimental groups—those receiving music alternate engagement or music-assisted relaxation interventions—experienced significant reductions in preoperative anxiety following music therapy intervention.

Table 4.3 shows the source data from the paired $t$ test comparing pre- and post-preoperative anxiety scores for pediatric patients.

Table 4.3

Results of $t$-test Comparing Pre- and Post-mYPAS Anxiety Scores in Pediatric Patients

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Before MT treatment</th>
<th>After MT treatment</th>
<th>95% CI for Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome</td>
<td>M</td>
<td>SD</td>
<td>n</td>
</tr>
<tr>
<td></td>
<td>46.54</td>
<td>17.70</td>
<td>37.29</td>
</tr>
</tbody>
</table>

Research Question 2

Does music therapy intervention have a subsequent effect on the preoperative anxiety levels in caregivers of pediatric patients preparing for day surgery?

Similar to the previous research question, analysis was conducted to determine if caregivers of the pediatric patients received subsequent benefit of reduced preoperative from music therapy intervention. Results of a paired $t$ tests analysis found a significant difference in STAI-Y6 scores in caregivers of the pediatric pre-surgical patients for pre-music therapy intervention levels of preoperative anxiety ($M = 14.13, SD = 3.82$) and post-music therapy intervention levels of preoperative anxiety ($M = 12.15, SD = 4.14$); $t(39) = 4.07, p = .000$. These results suggest that caregivers of patients in both experimental groups experienced significant reductions in preoperative anxiety following music therapy intervention. The paired $t$ test source table comparing caregiver preoperative pre- and post-preoperative anxiety scores is shown in Table 4.4.
Table 4.4

Results of t-test Comparing Pre- and Post-STAI Anxiety Scores in Caregivers

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Before MT treatment</th>
<th>After MT treatment</th>
<th>95% CI for Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>SD</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td>14.13</td>
<td>3.82</td>
<td>12.15</td>
</tr>
</tbody>
</table>

Research Question 3

If music alternate engagement and music-assisted relaxation interventions have an effect on pediatric patient and caregiver preoperative anxiety, is one more effective than the other?

Because both experimental groups experienced significant reduction in levels of preoperative anxiety post-music therapy intervention, further analysis was conducted to determine if either of the intervention was more effective than the other. First, difference scores were calculated using the pre- and post-scores from the mYPAS and STAI-Y6 measures and then each was analyzed using an independent-samples t test. Results of the independent-samples t test in pediatric patients indicate no significant difference in preoperative anxiety reduction between the effectiveness of active music therapy intervention ($M = -7.90$, $SD = 19.17$) and passive music therapy engagement ($M = -10.48$, $SD = 13.23$); $t (38) = .50, p = .62$. This is indicated in Table 4.4. In parents of pediatric parents, results of the independent-samples t test of STAI-Y6 difference scores indicate no significant difference in preoperative anxiety reduction between the effectiveness of active music therapy intervention ($M = -2.11$, $SD = 3.60$) and passive music therapy intervention ($M = -1.86$, $SD = 2.57$); $t (38) = -.25, p = .80$. Combined with previous analyses, these findings suggest that though both types of music therapy interventions
resulted in significant reductions of patient and caregiver preoperative anxiety, but neither was found to be more effective than the other. The independent samples t test source table comparing intervention effectiveness in caregivers is shown in Table 4.5.

Table 4.5

*Results of t-test Comparing Change in mYPAS scores by Experimental Condition*

<table>
<thead>
<tr>
<th>Group</th>
<th>MAE</th>
<th>MAR</th>
<th>95% CI for Mean Difference</th>
<th>t</th>
<th>df</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>SD</td>
<td>n</td>
<td>M</td>
<td>SD</td>
<td>n</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in mYPAS</td>
<td>-7.90</td>
<td>19.17</td>
<td>19</td>
<td>-10.48</td>
<td>13.23</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>-7.88, 13.03</td>
<td>.50</td>
<td>38</td>
<td>.62</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4.6

*Results of t-test Comparing Change in STAI scores by Experimental Condition*

<table>
<thead>
<tr>
<th>Group</th>
<th>MAE</th>
<th>MAR</th>
<th>95% CI for Mean Difference</th>
<th>t</th>
<th>df</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>SD</td>
<td>n</td>
<td>M</td>
<td>SD</td>
<td>n</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in STAI-Y6</td>
<td>-2.11</td>
<td>3.60</td>
<td>19</td>
<td>-1.86</td>
<td>2.57</td>
<td>21</td>
</tr>
<tr>
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CHAPTER FIVE:

DISCUSSION

The results of the current study reflect and expand on the trends of current research in procedural support music therapy. More specifically, this study examined the overall effectiveness of music therapy, and the comparative effectiveness of the two different music therapy interventions, to reduce pediatric patient and caregiver preoperative anxiety. Statistical analysis revealed that music therapy intervention significantly decreased preoperative anxiety for both patients and their caregivers. Further comparison found no significant difference in the effectiveness of either musical alternate engagement or music-assisted relaxation interventions. Moreover, analysis of demographic information pulled from patients’ medical charts revealed that many patients involved in this study experienced no difficulty at induction of anesthesia and no patients experienced complications with the surgical process. Though many variables outside of the control of this study factor into a patient’s surgical experience—such as medical staff expertise and the use of sedative premedication—these findings are still noteworthy.

Research Question 1

1. Does music therapy intervention have an effect on the preoperative anxiety levels in pediatric patients preparing for day surgery?

Previous research in procedural support music therapy suggests that music therapy is an effective treatment to address a variety of needs for pediatric patients across a variety of procedures. While music therapy specifically as surgical support is a growing field, results from Gooding and colleagues (In Review) found that pediatric
patients displayed increased affective states and decreased distress behaviors while also using the mYPAS for observational measurements. Two previous studies found reductions in preoperative anxiety (Chetta, 1981; Robb, 1995) while one study from the anesthesia literature found only a minimal effect in reducing preoperative anxiety (Kain et al., 2004). Upon further review the minimal effectiveness of music therapy found in Kain and colleagues study (2004) appears to have a significant variance in therapist effect between the two interventionists.

Of the three research questions addressed in this study, the most evidence supported the use of music therapy to reduce preoperative anxiety in pediatric patients. The results of this study indicate that the pediatric patients did receive a significant benefit from music therapy interaction. Post-hoc examination of the operative report also indicated that no patients involved in the study experienced surgical complications. Related, of the cases that documented patient experience at induction at anesthesia (13%), all patients were reported as being “induced without difficulty”. These findings indicate that brief preoperative music therapy may have longer effects than merely the transition to the operation room.

**Research Question 2**

2. *Does music therapy intervention have a subsequent effect on the preoperative anxiety levels in the caregivers of pediatric patients preparing for day surgery?*

Prior to this study, no research was available on the effectiveness of pre-surgical music therapy to decrease caregiver anxiety while addressing the needs of their child. However, there is some research on preoperative music therapy services with pediatric patients and the subsequent benefits for their caregivers. A recent study by Gooding and
colleagues (In Review) found that caregivers of pediatric patients receiving preoperative music therapy had an increase in their overall perception of the facility and agreed that both they and their child benefitted from receiving services.

While many studies have documented the lack of available services and challenges of reducing preoperative anxiety for patients and their caregivers (Fortier & Kain, 2015; Kain et al., 2006), this study suggests that music therapy may be an effective patient and family-centered treatment. This would be especially useful in surgery centers not already addressing preoperative anxiety in young pediatric patients or their caregivers. When viewing the healthcare landscape through the current evidence base, it seems that music therapy may be an answer to decrease caregiver preoperative anxiety as well as improve the perception of the facility while increasing the patient and family’s overall satisfaction.

**Research Question 3**

3. *If music alternate engagement and music-assisted relaxation interventions do have an effect on pediatric patient and caregiver preoperative anxiety, which is more effective?*

Current theoretical models of music therapy as procedural support provide evidence for three broad intervention categories: (a) musical alternate engagement, (b) music-assisted relaxation, and (c) integration. Much is known about the clinical effectiveness of the first two intervention categories, while less information is available on the latter (Yinger et al., 2014). Chetta (1981) found that active music therapy engagement paired with preoperative education reduced preoperative anxiety, while Robb (1995) found similar results using music-assisted relaxation interventions. Though both
music alternate engagement and music-assisted relaxation interventions have resulted in positive outcomes for a variety of individuals undergoing procedures, it was unclear whether one was clinically preferable to the other with the young pediatric population.

This study found no significant difference between music alternate engagement and music-assisted relaxation interventions, which may be due to a variety of circumstances. Most notably, certain interventions appeared to be more appropriate for patients, and caregivers, exhibiting different manifestations of preoperative anxiety.

Further research would need to expand on assessing situations to determine the most appropriate intervention to support patients and their caregivers. With the current body of research combined with the results of the present study, the researcher recommends both music alternate engagement and music-assisted relaxation based interventions to address preoperative anxiety as well as other ancillary outcome measures.

**Limitations**

As with any study, there were limitations that warrant further investigation to fully understand the nature of music therapy as a solution for preoperative anxiety. First is the relatively small sample size, and as such results must be replicated on a larger scale before widespread generalization. Another limitation for this study was the lack of a no-contact control group for comparison purposes. This decision was made in an effort as to not deny access to services in a facility that has already been receiving music therapy treatment with this population. Although this was followed with ethical intentions in mind, it does limit comparisons to standard medical treatment. However, previous research provides a solid support for procedural support music therapy that was deemed sufficient in designing the present study.
Another constraint was timing of the procedure. In this study, the administering clinician and the research assistants could not approach potential participants until after the nurse had completed all patient check-in procedures. This posed a challenge to enrollment when potential participants were immediately taken to the procedure following the check-in at times when the surgery center was operating at maximum efficiency.

More important than issue of enrollment was that patients received services at various phases—arrival and check-in, waiting period, separation and transition to operative room, induction, etc.—of the preoperative process. Certain patients received music therapy treatment immediately prior to transition to the operating room when they could be supported or distracted from separation anxiety. On days when the surgery center was running less efficiently, patients received music therapy services and then may have had to wait upwards of an hour before their procedure. Patients and caregivers appeared to experience different levels and manifestations of anxiety at these various preoperative phases, and it is probable that post-test results were impacted due to these circumstances. Though beyond the control of the researcher in this study, it would be ideal in future studies to control for the exact preoperative phase services could be delivered.

The final noteworthy limitation of the present study regards interrater reliability of the pre- and post-test measures. Though both research assistants were trained in the use and administration of the mYPAS and STAI-Y6 measures, due to scheduling conflicts the PI was unable to obtain reliability scores. It is highly suggested that future studies obtain and report interrater reliability scores when two or more researchers are
using behavioral rating scales. Other suggestions for future research are as follows.

**Suggestions for Future Research**

In an effort to address gaps in the literature and limitations of previous designs, future studies should utilize experimental designs and randomized controlled trials with no-contact control groups to uncover more information on the overall effectiveness of music therapy with this population. Similarly, as the researcher was unable to control for the use of sedative premedication it would preferable to compare midazolam usage as a separate experimental condition. Controlling for the specific time period of service delivery during the preoperative process and following notes on postoperative recovery patterns would help discover the potential long-term effects of music therapy interaction.

Further, because this study focused on a specific population of young pediatric patients and their caregivers, future studies should focus on various stages of development and appropriate interventions for each. It should be noted that though demographic analysis revealed that participants were overwhelmingly Caucasian (87%) this is in fact representative of the region and facility of the present study. Future studies may want to focus on cultural and gender differences by soliciting a more diverse sample. Ideally, future investigations would be able to increase overall enrollment through multi-site studies from various regions of the United States.

In this study only one clinician administered music therapy interventions for consistency of results, but future studies should acknowledge the potential for therapist effect when using two or more clinicians. This effect was present in Kain and colleagues (2006) study of music therapy to reduce preoperative anxiety, where one therapist elicited significant change while the other did not. Results from the current literature and the
The present study suggest that a board-certified music therapist with training and experience in procedural support and behavioral techniques is best suited to deliver interventions that promote healthy coping skills and decrease distress in individuals undergoing medical procedures.

**Conclusion**

As the evidence base grows, healthcare providers are becoming more aware of the potential of music therapy to address a variety of procedural outcomes through a patient and family centered lens. The present study added to the literature by highlighting the effect of music therapy in reducing both young pediatric patient and caregiver preoperative anxiety. It appears that both active and passive music therapy interventions can be equally effective in reducing anxiety prior to surgical operations. The author suggests that music therapy clinicians should use their best judgment during assessment to determine which interventions would be most effective with particular patients and their caregivers.
APPENDIX

Appendix A: Letter of Approval from UK IRB

UK
KENTUCKY

Initial Review

Approval Date: December 7, 2015
IRB Number: 14-0807-P1S

TO: Christopher Millett
3620 Olympia Circle
Lexington, KY 40517
Phone: (502) 471-7838

FROM: Chairperson/Vice Chairperson
Non-medical Institutional Review Board (IRB)

SUBJECT: Approval of Protocol Number 14-0807-P1S

DATE: December 10, 2014

On December 8, 2014, the Non-medical Institutional Review Board approved your protocol entitled:

The Effect of Music Therapy Intervention on Child and Parental Perinatal Anxiety in Parents of Children Undergoing Day Surgery

Approval is effective from December 8, 2014 until December 7, 2015 and extends to any consent/assent forms, cover letter, and script. It is recommended that the IRB-approved consent/assent document(s) be used when enrolling subjects. Note that subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless a written waiver has been obtained from the IRB. Prior to the end of the period, you will be sent a Continuation Review Report Form which must be completed and returned to the Office of Research Integrity so that the protocol can be reviewed and approved for the next period.

In implementing the research activities, you are responsible for complying with IRB decisions, conditions, and requirements. The research procedures should be implemented as approved in the IRB protocol. It is the principal investigator's responsibility to ensure that the activities of the research are submitted for review and approval by the IRB prior to implementation. Protocol changes made without prior IRB approval to eliminate apparent hazards to the subject(s) should be reported in writing immediately to the IRB. Furthermore, discontinue a study or completion of a study is considered a change in the protocol's status and therefore the IRB should be promptly notified in writing.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research" from the Office of Research Integrity's IRB Survival Handbook web page [http://www.research.uky.edu/ori/IRB-Survival-Handbook.html#responsibilities]. Additional information regarding IRB review, federal regulations, and institutional policies may be found through ORI's web site [http://www.research.uky.edu/ori/]. If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at (859) 257-0428.

[Signature]
Chairperson/Vice Chairperson
Appendix B: Patient Consent and Authorization Form

The Effect of Music Therapy Interaction on Child and Parent Preoperative Anxiety in Parents of Children Undergoing Day Surgery

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study about the effect of different music therapy interventions on parent and child preoperative anxiety. You are being invited to take part in this research study because your child is undergoing surgery in the ambulatory setting where music therapy is currently being used to address patient preoperative anxiety. If you volunteer to take part in this study, you will be one of about 100 people to do so.

WHO IS DOING THE STUDY?

The person in charge of this study is Christopher R. Milette, MT-BC (Principal Investigator, PI) at University of Kentucky, Department of Music Therapy. Christopher is a music therapy graduate student and is being guided in this research by Lori Gooding, PhD, MT-BC (Faculty Advisor). There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to examine and compare the effectiveness of active and passive music therapy interventions with children in the preoperative ambulatory setting and the subsequent levels of parent anxiety.

By doing this study, we hope to learn more about how music therapy interventions with children preparing for surgery impacts their parent(s)/caregiver(s).

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

You should not take part in this study if you are younger than 18 years old, your child is older than 5 years old, or if English is not your primary language.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at University of Kentucky Center for Advanced Surgery. You will need to come to The Center for Advanced Surgery one time during the study. The visit will take about 20 minutes. The total amount of time you will be asked to volunteer for this study is 20 minutes over the next hour.

WHAT WILL YOU BE ASKED TO DO?

If you agree to be in this study, you will be asked to fill out the short-form State-Trait Anxiety Inventory Form Y-6 item before the music therapy session. A research assistant will do a brief observation of your child just before, and just after your child participates in music therapy services. The music therapy session will be approximately 15 minutes where your child will either have the opportunity to play instruments and/or listen to music as determined by chance. Following the music therapy session you will again be asked to fill out the State-Trait...
Anxiety Inventory Form Y-8 item. I will also request that you allow the research team to view your child’s medical records to receive demographic information including age, gender, ethnicity, information on the type of surgical procedure, and previous medical experiences for research purposes.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

To the best of our knowledge, the things you will be doing have no more risk of harm than you would expect in everyday life. A possible risk of participation in this study is that you may be uncomfortable with responding to questionnaires or receiving music therapy services. If this happens, you may stop participation in the study at any time by telling either the PI or a research assistant that you would like to cease your participation.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. However, some people have experienced decreased anxiety from participating in music therapy services and you will gain increased insight into what music therapists do. Your willingness to take part, however, may, in the future, help researchers better understand how children cope with preoperative anxiety through music.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide not to take part in the study, your decision will have no effect on the quality of medical care you receive.

IF YOU DON’T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to take part in the study, there are other choices such as selecting standard care or receiving music therapy services without taking part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep confidential all research records that identify your child to the extent allowed by law.

Your child’s health information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You and your child will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. A research assistant will scan the original paper questionnaires, observation forms, and demographic information obtained from medical records into electronic format for storage in REDCap, a secure web-based application. To ensure de-identification of data, you and your child will be assigned a subject number to be written on the survey and a separate spreadsheet will be created linking the subject numbers to the corresponding name. Once data have been entered into REDCap the linking document, along with the original paper questionnaires, will be destroyed thus making it impossible to link the consent forms back to the surveys.

You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court or to tell authorities if you report information about a child being abused or if you pose a danger to yourself or someone else. Also, we may...
be required to show information which identifies your child to people who need to be sure we have done the research correctly; these would be people from such organizations as the University of Kentucky.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Christopher R. Millert at 502-852-7830. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky between the business hours of 8am and 5pm EST, Mon-Fri at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your child’s health information. The following sections of the form describe how researchers may use your child’s health information.

Your child’s health information that may be accessed, used and/or released includes:

- Demographic information including: age, gender, and ethnicity
- Medical history: Information regarding the type of procedure for this study and the number and types of previous surgical experiences.

The Researchers may use and share your child’s health information with:

- The University of Kentucky’s Institutional Review Board/Office of Research Integrity.
- Law enforcement agencies when required by law.
- University of Kentucky representatives.
- University of Kentucky HealthCare Employees that are directly serving the patient.
- The primary physician will be contacted if researcher in the course of the project learns of a medical condition that needs immediate attention.
The researchers agree to only share your child’s health information with the people listed in this document. Should your child’s health information be released to anyone that is not regulated by the privacy law, your child’s health information may be shared with others without your permission; however, the use of your child’s health information would still be regulated by applicable federal and state laws.

You or your child may not be allowed to participate in the research study. If you decide not to sign the form, it will not affect your:

- Current or future healthcare at the University of Kentucky
- Current or future payments to the University of Kentucky
- Ability to enroll in any health plans (if applicable)
- Eligibility for benefits (if applicable)

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your child’s health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: Christopher R. Milliet at H106 Chandler Hospital, Lexington, KY, 40506-0903 ATTN: Christopher Milliet to inform her of your decision.
- Researchers may use and release your child’s health information already collected for this research study.
- Your child’s protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your child’s information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your and your child’s privacy rights, you should contact the University of Kentucky’s Privacy Officer between the business hours of 8am and 5pm EST, Mon-Fri at: (859) 323-1184.

You are the subject or are authorized to act on behalf of the subject. You have read this information, and you will receive a copy of this form after it is signed.

Signature of research subject or *research subject’s legal representative

Date

Printed name of research subject or *research subject’s legal representative

Representative’s relationship to research subject

Please explain Representative’s relationship to subject and include a description of Representative’s authority to act on behalf of subject:

Name of [authorized] person obtaining informed consent/HIPAA authorization

Date

Signature of Principal Investigator or Sub/Co-Investigator

University of Kentucky

Revised 9/10/14

P1.0160
Mod IRB ICF Template Combined with HIPAA Authorization
## Appendix C: Modified Yale Pediatric Anxiety Scale

**mYPAS**

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<th>Pre-</th>
<th>Post-</th>
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<td><strong>Activity</strong></td>
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<td>□ 1 □ 2 □ 3 □ 4</td>
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<tr>
<td><strong>Vocalizations</strong></td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5 □ 6</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5 □ 6</td>
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<tr>
<td><strong>Emotional Expressivity</strong></td>
<td>□ 1 □ 2 □ 3 □ 4</td>
<td>□ 1 □ 2 □ 3 □ 4</td>
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<tr>
<td><strong>State of apparent arousal</strong></td>
<td>□ 1 □ 2 □ 3 □ 4</td>
<td>□ 1 □ 2 □ 3 □ 4</td>
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<tr>
<td><strong>Use of parents</strong></td>
<td>□ 1 □ 2 □ 3 □ 4</td>
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Subject #:________________
Appendix D: mYPAS Scoring Guide

mYPAS Scoring Guide

Activity
☐ 1. Looks around, curious, playing with toys, reading (or other age-appropriate behavior); moves around the holding area/treatment room to get toys or to go to parents; might move towards operating room equipment
☐ 2. Not exploring or playing, may look down, fidget with hands, or sucks thumb (blanket); may sit close to parent while waiting, or play has a definite manic quality
☐ 3. Moving from toy to parent in unfocused manner, non-activity-derived movements; frenetic/frenzied movement or play; squirming, moving on table; may push mask away or cling to parent
☐ 4. Actively trying to get away, pushes with feet and arms, may move whole body; in waiting room, running around unfocused, not looking at toys, will not separate from parent, desperate clinging

Vocalizations
☐ 1. Reading (nonvocalizing appropriate to activity), asking questions, making comments, babbling, laughing, readily answers questions but may be generally quiet; child is too young to talk in social situations or too engrossed in play to respond
☐ 2. Responding to adults but whispers, “baby talk,” only nodding head
☐ 3. Quiet, no sounds or responses to adults
☐ 4. Whimpering, moaning, grunting, silent crying
☐ 5. Crying or may be screaming “no”
☐ 6. Crying, screaming loudly, sustained (audible through mask)

Emotional expressivity
☐ 1. Manifestly happy, smiling, or concentrating on play
☐ 2. Neutral, no visible expression on face
☐ 3. Worried (sad) to frightened, sad, worried, or tearful eyes
☐ 4. Distressed, crying, extreme upset, may have wide eyes

State of apparent arousal
☐ 1. Alert, looks around occasionally, notices or follows what anesthesiologist does (could be relaxed)
☐ 2. Withdrawn, sitting still and quiet, might sucking on thumb, or have face turned into adult
☐ 3. Vigilant, looking quickly all around, may startle to sounds, eyes wide, body tense
☐ 4. Panicked whimpering, may be crying or pushing others away, turns away

Use of parents
☐ 1. Busy playing, sitting idle, or engaged in age-appropriate behavior and doesn’t need parent; may interact with parent if parent initiates the interaction
☐ 2. Reaches out to parent (approaches parent and speaks to otherwise silent parent), seeks and accepts comfort, may lean against parent
☐ 3. Looks to parent quietly, apparently watches actions, doesn’t seek contact or comfort, accepts it if offered or clings to parent
☐ 4. Keeps parent at a distance or may actively withdraw from parent, may push parent away or desperately clinging to parent and not let parent go

Note: Use of parents is only scored when parent is present.

Scoring: Divide each item rating by the highest possible rating (i.e., 6 for the “vocalizations” item and 4 for all other items), add all the produced values, divide by 5 (or 4 if E is not rated), and multiply by 100.
Appendix E: State Trait Anxiety Inventory Y-6 item

Self-evaluation questionnaire (Y-6 item)  

Pre-test  

A number of statements which people have used to describe themselves are given below. Read each statement and circle the most appropriate number to the right of the statement to indicate how you feel right now, at this moment.

There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

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<tr>
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<th>Not at all</th>
<th>Somewhat</th>
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<td>1. I feel calm</td>
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<td>2. I am tense</td>
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<td>3. I feel upset</td>
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<td>3</td>
<td>4</td>
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<td>4. I am relaxed</td>
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<td>5. I feel content</td>
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<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>6. I am worried</td>
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Please make sure you have answered all the questions.

Post-test  

A number of statements which people have used to describe themselves are given below. Read each statement and circle the most appropriate number to the right of the statement to indicate how you feel right now, at this moment.

There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

<table>
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<tr>
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Please make sure you have answered all the questions.
Appendix F: Sample Music Alternate Engagement Session Plan

Sample Music Alternate Engagement Session Outline

_Approximately Fifteen Minutes_

1) **Introduction**
   i) **Purpose:** To assess patient and caregiver anxiety and activity levels, and increase rapport.
   ii) **Materials:** Not applicable.
   iii) **Intervention example:** Clinical interviewing using counseling techniques to assess and validate patient and caregiver situation while obtaining relevant information on patient musical preferences.
   iv) **Relevant other information:** Not applicable.

2) **Active instrument play**
   i) **Purpose:** To increase the patient’s perception of control, distract from preoperative anxiety, increase mood, and normalize the environment through preferred or familiar music and active intervention.
   ii) **Materials:** Various small percussion, guitar, and music repertoire.
   iii) **Intervention example:** Patient preferred music with instrument play or other age appropriate active interventions (i.e. *Shake your sillies out*).
   iv) **Relevant other information:** Opportunity for patient to exercise control through selecting preferred music and instruments. Also an opportunity for caregivers to engage in interventions through assisting patient, providing preference information, and encouraging the patient.

3) **Musical Game**
   i) **Purpose:** To systematically increase engagement through an intervention requiring a higher focus of attention, increase mood, and increase control through patient taking a leadership role.
   ii) **Materials:** Various small percussion and a guitar.
   iii) **Intervention example:** *Leader of the band*, an intervention where patients must first respond to start-and-stop signals from the therapist and then reverse roles and control the intervention.
   iv) **Relevant other information:** Similarly to the previous intervention, caregivers can exercise their preferred level of engagement in assisting the patient.

4) **Improvisation**
   i) **Purpose:** To increase the patient’s perception of control and mood.
   ii) **Materials:** Three lollipop drums of varying sizes and two soft mallets.
   iii) **Intervention example:** *Drum set*, an intervention where the therapist holds three lollipop drums and encourages free improvisation.
   iv) **Relevant other information:** This can be extended by randomly moving the drums at various points to make the intervention more challenging and engaging. Also, patient preferred or other appropriate songs can be sung a cappella by therapist as an added mood motivation technique.

5) **Extensions and Adaptations (As Necessary)**
   i) **Relevant other information:** Other popular interventions included patient strumming the guitar while being chorded by the therapist, musical rainstorm using the thunder-tube and other percussion, and general instrument selection.

6) **Goodbye and Termination of Services**
   i) **Purpose:** To provide closure.
   ii) **Materials:** Guitar as needed.
   iii) **Intervention example:** *Time to go*, the interventionist’s preferred “goodbye song”.
   iv) **Relevant other information:** This is also a time where patients and caregivers can be encouraged regarding the upcoming procedure as appropriate.
Appendix G: Sample Music-Assisted Relaxation Session Plan

Sample Music-Assisted Relaxation Session Outline

Approximately Fifteen Minutes

1) Introduction
   i) Purpose: To assess patient and caregiver anxiety and activity levels, and increase rapport.
   ii) Materials: Not applicable.
   iii) Intervention example: Clinical interviewing using counseling techniques to assess and validate patient and caregiver situation while obtaining relevant information on patient musical preferences.
   iv) Relevant other information: Not applicable.

2) Live Music Listening
   i) Purpose: To increase the patient’s perception of control, to increase mood, to normalize the environment through preferred or familiar music, and increase relaxation through passive intervention.
   ii) Materials: Guitar and music repertoire.
   iii) Intervention example: Live patient preferred, familiar, or age-appropriate music.
   iv) Relevant other information: Opportunity for patient to exercise control through selecting preferred music. Also an opportunity for caregivers to engage in interventions through providing preference information and encouraging the patient.

3) Extensions and Adaptations (As Necessary)
   i) Purpose: Similar as previous interventions – overall to decrease preoperative anxiety.
   ii) Materials: Guitar and music repertoire.
   iii) Intervention example: Systematic decreases in live music listening to elicit relaxation response (i.e. iso-principle informed decrease in musical activity through softer dynamics, less active picking patterns, and transitioning from higher musical activity to less). Other examples include encouraging deep breathing in patient, lullabies to encourage relaxation, and continuous music.
   iv) Relevant other information: As patients grow more relaxed this could become an opportunity for caregivers to hold the patient in their lap or provide other nurturing techniques.

4) Goodbye and Termination of Services
   i) Purpose: To provide closure.
   ii) Materials: Guitar as needed.
   iii) Intervention example: Time to go, the interventionist’s preferred “goodbye song”.
   iv) Relevant other information: This is also a time where patients and caregivers can be encouraged regarding the upcoming procedure as appropriate.


CURRICULUM VITAE

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Student Member
2012 - Present

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Outstanding Senior Award Recipient
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