MANAGING PREOPERATIVE ANXIETY IN CHILDREN UNDERGOING SURGERY

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LAY ABSTRACT

Preoperative anxiety affects up to 5 million children in North America annually and is associated with many adverse psychological, behavioural, and health effects. These problems not only produce significant distress for children and families, but can have immediate and long-term effects on a child's mental health and development.

Current methods to reduce preoperative anxiety in children (e.g., medications and psychological preparation programs) are limited by their expense and/or time-intensive nature. In an attempt to reduce children's preoperative anxiety and its associated negative outcomes, this work examined the usefulness of audiovisual interventions in reducing children's preoperative anxiety, sought to develop a new instrument to measure children's preoperative anxiety, tested a new tablet-based application to reduce children's preoperative anxiety, and examined the relation between children's temperament and preoperative anxiety. The goal is to improve the surgical experience for children and families, and to reduce psychological and physical problems in children undergoing surgery.

ABSTRACT

Objectives: 1) To examine the effectiveness of Audiovisual (AV) interventions at reducing preoperative anxiety (PA) and its associated outcomes in children undergoing surgery; 2) To assess the psychometric properties of a new scale, the Children's Perioperative Multidimensional Anxiety Scale (CPMAS); 3) To examine the feasibility and acceptability of a novel tablet-based intervention, Story-Telling Medicine (STM), for reducing children's PA; 4) To examine the relation between temperament and PA in the surgical context.

Methods: A systematic review of studies where the primary outcome was children's PA was conducted (Study 1). A study of the reliability and validity of the CPMAS were assessed at preoperative assessment (T1), on the day of surgery (T2), and 1 month postoperatively (T3) was also undertaken (Study 2). The feasibility and acceptability of STM were then examined and compared its effect to Usual Care (UC) (Study 3). Finally, children's temperament was examined using the Colorado Childhood Temperament Inventory at T1 along with the CPMAS assessed at T1 and T2 (Study 4).

Results: Fourteen of the 18 studies led to reductions in children's PA (Study 1). The CPMAS demonstrated good internal consistency, stability and convergent validity across all visits (Study 2). The participant recruitment and study procedures were shown to be feasible and children in the STM group demonstrated greater reductions in CPMAS compared to the UC group (Study 3). Shyness predicted lower PA at T1, while sociability predicted higher PA at T1 and T2 (Study 4).

Conclusions: AV interventions appear useful but full-scale RCTs of these treatments are required to pinpoint those that are most effective. The CPMAS is a promising tool for evaluating children's PA and preliminary evidence suggests that STM is a feasible intervention for reducing children's PA. Finally, our findings highlight the importance of considering individual differences in predicting anxiety in the surgical setting.

Keywords: Audiovisual aids, child, feasibility studies, psychometrics, preoperative anxiety, temperament, systematic review

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LIST OF ABBREVIATIONS AND SYMBOLS

AV: Audiovisual
CCTI: Colorado Childhood Temperament Inventory
CI: Confidence Interval
CPMAS: Children's Perioperative Multidimensional Anxiety Scale
EEG: Electroencephalography
FACES: FACES Rating Scale
GAD: Generalized Anxiety Disorder
M: Mean
MD: Mean difference
MYPAS: Modified Yale Preoperative Anxiety Scale
OR: Operating Room
ORSA: Observer Rating Scale of Anxiety
PD: Panic Disorder
RCT: Randomized Controlled Trial
RR: Relative Risk
Non-Randomized Controlled Studies
SAD: Social Anxiety Disorder
SCARED-C: Screen for Child Anxiety Related Disorders- Child Version
SD: Standard Deviation
SpD: Separation Anxiety Disorder
SSA: Significant School Avoidance
STAI: State-Trait Anxiety Inventory
STAI-C: State-Trait Anxiety Inventory for Children
STM: Story-Telling Medicine
UC: Usual Care
WMD: Weighted Mean difference
VAS: Visual Analog Scale
YPAS: Yale Preoperative Anxiety Scale

DECLARATION OF ACADEMIC ACHIEVEMENT

This thesis is comprised of four studies that were conceptualized and written by the student. She developed all the study design and protocols, collected their data and conducted their analyses, prepared the manuscripts, and made revisions based on the suggestions and feedback received from her co-authors. All of this thesis work was completed between September 5th 2013 and October 1st, 2016. As part of the requirements of a ‘sandwich’ thesis, the co-author contributions in each study will be listed out below.

Study 1 systematically reviewed the literature that has examined the effectiveness of audiovisual (AV) interventions at reducing preoperative anxiety and its associated outcomes in children undergoing elective surgery. It was co-authored by the thesis supervisors, Dr. Louis Schmidt and Dr. Ryan Van Lieshout, and the thesis committee member, Dr. Norman Buckley, who critically reviewed the manuscript and made revisions to improve it for publication. It was also co-authored by a former McMaster graduate student, Ms. Kathleen Dobson, who was consulted for the meta-analytic portion and also critically reviewed the manuscript.

Study 2 assessed the psychometric properties of a newly developed scale, the Children’s Perioperative Multidimensional Anxiety Scale (CPMAS). It was co-authored by Dr. Louis Schmidt, and Dr. Ryan Van Lieshout, who provided guidance on statistical analysis, critically reviewed the manuscript and provided suggestions to improve it for publication. It was also co-authored by Dr. Norman Buckley who provided guidance on participant recruitment and follow-up and critically reviewed the manuscript.

Study 3 examined the feasibility and acceptability of a newly developed tablet-based intervention, Story-Telling Medicine, for reducing children's preoperative anxiety and was co-authored by Dr. Louis Schmidt, Dr. Ryan Van Lieshout, and Dr. Norman Buckley. They critically reviewed the manuscript and provided constructive feedback to improve it for publication.

Study 4 examined the relation between temperament and children's preoperative anxiety one week prior to surgery and the day of surgery. It was co-authored by Dr. Louis Schmidt, Dr. Ryan Van Lieshout, and Dr. Norman Buckley who provided guidance on statistical analysis, critically reviewed the manuscript and made revisions to improve it for publication. It was also co-authored by an undergraduate thesis student, Ms. Nadine Nejati, who was involved in participant recruitment, data collection and critically reviewed the manuscript.

Study 1 (Systematic review of AV intervention on children's preoperative anxiety) served as the foundation of the thesis and revealed research gaps in this area and so provided the framework, rationale, significance and context for conducting Study 2 (Development and validation of the CPMAS), Study 3 (Pilot study), and Study 4 (Role of temperament). Therefore, overlap of some of the materials in the introduction and discussion sections of Study 2, 3, and 4 were inevitable. As I used the same cohort in Study 2, 3 and 4, information pertaining to recruitment and data collection procedures are similar under these method sections.

CHAPTER ONE: GENERAL INTRODUCTION

Preoperative Anxiety: Background

Preoperative anxiety is very common in children receiving elective surgery under general anesthesia. It is estimated that up to 5 million children will undergo elective surgical procedures in North America every year, and that up to 75% of them experience significant preoperative anxiety (Perry, Hooper, & Masiongale, 2012). Preoperative anxiety is the state anxiety experience by children in the surgical context. Based on Spielberger's conceptualization of anxiety (2013), state anxiety is defined as a situational and transitory emotion characterized by physiological arousal and feelings of apprehension, dread, and tension (Endler & Kocovski, 2001).

Psychological Markers of Preoperative Anxiety

Preoperative anxiety typically occurs on the day of surgery and peaks during anesthetic induction. It is often characterized by an increased level of stress, fears of the unknown, excessive worry and nervousness (Wright, Stewart, Finley, & Buffett-Jerrott, 2007). Due to limited cognitive capabilities, a young child is sometimes unable to express their anxiety verbally. As such, many of these children display agitation, increased muscle tone, frequent urination, constant crying, and sometimes even attempt to actively resist the induction of anesthesia (Kain et al., 1996; Lee et al., 2012). These negative reactions stem from the child's fears of separation from one's parents, the loss of a sense of control, and uncertainty regarding the outcome of the surgery (Kain et al., 1996; Litke el, 2012; Vernon et al., 1971).

Children undergoing surgery often also feel overwhelmed by the unfamiliar hospital routines and procedures and the encounters they have with medical staff prior to the operation. Children's adverse reactions are often elicited by what goes on in the busy hospital setting while waiting for their surgery. For example, the combination of the sight of a stretcher, the smell of disinfectant, the sound of crying babies and/or children, and watching other patients and families being transported in and out of the operating room (OR) could cause a child to become anxious and to develop negative schema about what could go wrong during the surgery. Children's distress is usually highest during general anesthetic induction procedures occurring just before the surgery while in the OR, which are potent triggers of the anticipatory anxiety (Wright et al., 2007). Therefore, preoperative anxiety in children and their families can result in emotional distress and trauma if they are not psychologically well-prepared for surgery (Davidson & McKenzie, 2011).

Physiological Markers of Preoperative anxiety

Thus far, only a handful of studies have assessed the biological stress responses correlated with preoperative anxiety. Early studies done in this area used the palmar sweat index to measure children's state anxiety in those undergoing surgery (Johnson & Dabbs, 1967; Melamed & Segel, 1975; Thomson & Sutarman, 1953). Recent research has begun to employ some additional physiological measures of childhood anxiety. Physiologically, anxiety in children is characterized by activation of the sympathetic nervous system as indexed by increased heart rate and blood pressure, as well as hypothalamic–pituitary–adrenal axis arousal (as determined by an increase in cortisol concentrations) (e.g., Beidel, 1991; Carrion et al., 2002; Weems, Zakem, Costa, Cannon, & Watts, 2005).

In the surgical setting, children and adolescents who experience preoperative anxiety are reported to exhibit similar physiological effects such as elevated heart rate (Berger, Wilson, Potts, & Polivka, 2014; Kerimoglu, Neuman, Paul, Stefanov, & Twersky, 2013), increased blood pressure (Berger et al., 2014; Fortier, Martin, Chorney, Mayes, & Kain, 2011), and increased cortisol levels (Kain 1998). Currently, there is a paucity of research on the relationship between behavioral measures of anxiety and its accompanying physiological responses. Thus, it is of significance to further examine the physiological correlates of preoperative anxiety in children undergoing surgery.

Psychological Effects of Preoperative Anxiety

Children with preoperative anxiety are at three and a half times the risk of manifesting adverse postoperative psychological outcomes including separation anxiety, maladaptive behavioral patterns, and increased distress in the recovery phase (Fortier, Del Rosario, Martin, & Kain, 2010; Kain et al., 2004; Kain, Mayes, O'Connor, & Cicchetti, 1996; Kain, Wang, Mayes, Caramico, & Hofstadter, 1999; Litke, Pikulska, & Wegner, 2012). In fact, nearly 50% of youth with elevated preoperative anxiety exhibit postoperative behavioral changes such as aggression toward authority figures, feeding problems, insomnia, nocturnal enuresis, and nightmares, and up to 18% experience postoperative delirium (Kain et al., 2004; Kain, Mayes, Caldwell-Andrews, Karas, & McClain, 2006; Kain et al., 1996; Kain et al., 1999; Litke et al., 2012). Kain and his colleagues (1996) also reported that 54% of children had negative behavioral changes 2 weeks after surgery, 20% manifested these at 6 months, and 7.3% did up to 1 year after their operations.

Physical Effects of Preoperative Anxiety

In addition to these adverse emotional and behavioural reactions, children with high levels of preoperative anxiety also have a more complicated perioperative course, including prolonged anesthesia induction, poorer postoperative recovery, increased postoperative pain and required higher doses of postoperative analgesia (i.e., acetaminophen and codeine) (Fortier et al., 2010; Kain et al., 2006; Kain et al., 1996; Kain et al., 1999). These children are also three times more likely to exhibit postoperative anxiety and require higher doses of propofol for anesthesia induction and maintenance (Kain et al., 1999; Maranets & Kain, 1999). Furthermore, the activation of the neuro-endocrinologic stress response also results in the release of stress hormones (e.g., cortisol and corticotrophin) and causes immunosuppression (e.g., over-activation of natural killer lymphocytes) (Ader et al., 1995; Chrousos & Gold, 1992; Long & Rajagopalan, 2002; Weissman 1990). This leads to prolonged wound healing and a longer postoperative recovery with more medical complications (Chernow et al., 1987; Kain et al., 1999; McCann & Kain, 2001).

Preoperative Anxiety: Existing Interventions & Limitations

Given the myriad potential negative impacts of preoperative anxiety, clinicians and researchers have attempted to apply interventions aimed at reducing its prevalence, severity, and impact. These include the use of preoperative sedative medications, behavioral preparation programs and complementary and alternative therapies (Brewer, Gleditsch, Syblik, Tietjens, & Vacik, 2006; Perry et al., 2012; Tunney & Boore, 2013). Of these, sedative premedication is most frequently used, despite the fact that it is marked by several clinical and practical concerns.

Midazolam, a benzodiazepine, is an anxiolytic and amnestic medication commonly used as a sedative premedicant to reduce preoperative anxiety. It has been shown that more than 80% of anesthesiologists preferred midazolam as a premedication for pediatric patients (Cray, Dixon, Heard, & Selsby, 1996; Kain et al, 1997). Depending on the length of the surgery and the anxiety level of the child, a dosage of oral midazolam ranging from 0.25 mg to 1.0 mg/kg and up to total dose of 20 mg is administered (Coté et al., 2002). While midazolam is effective, research has shown that it can have undesirable side effects including increasing the risk of delirium, higher arousal of distress and increasing pain during recovery (Watson & Visram, 2003; Wright et al., 2007; Viitanen, Annila, Viitanen, & Yli-HankaJa, 1999). When compared to a placebo group, children received premedication midazolam experienced up to 10 minutes of delay in recovery, and an additional 10 minutes of delay in discharge (Viitanen, Annila, Viitanen, & Tarkkila, 1999).

Alternatively, up to 78% of all major U.S. pediatric hospitals also offer behavioral preparation programs as an adjunctive method to usual care for children and families undergoing surgery (Kain, Caldwell-Andrews, & Wang, 2002). Behavioral preparation programs are interventions designed to prepare the child for the impending surgical procedure. These programs generally incorporate one or more empirically supported psychoeducational techniques such as modelling, parental involvement, and/or teaching coping strategies. These exist in various forms such as an OR orientation tour, printed material, a puppet show, play therapy, peer-modelling film, role rehearsal using dolls, the utilization of Child life specialists to teach coping skills, and relaxation training for children and families (Brewer et al., 2006; Kain et al., 2002; Melamed & Ridley-Johnson, 1988; Perry et al., 2012; Tunney & Boore, 2013; Wright et al., 2007).

Kain and his colleagues (2007) have developed and tested a comprehensive behavioral preparation program, ADVANCE (Anxiety-reduction, Distraction, Video modeling and education, Adding parents, No excessive reassurance, Coaching, and Exposure/shaping), which involved a video, anesthetic induction mask practice, and coaching by specialized healthcare support staff. In that study, children in the ADVANCE group exhibited lower anxiety levels than the standard of care group during the preoperative period and anesthetic induction. Unfortunately, despite its potential, the findings showed that these comprehensive preparation programs are less than ideal to be implemented hospital-wide because of their resource intensive nature as more staff and supplies are required to administer them. Interestingly, factors such as a child's age, timing of the administration of the intervention relative to surgery, and a child's previous hospitalization history were suggested to be important consideration when designing for future behavioral preparation program (Wright et al., 2007).

Other complementary and alternative therapies have also been tested in an attempt to reduce children's preoperative anxiety. For example, Kain and colleagues (2004) conducted a study to compare the effectiveness of an interactive music intervention versus midazolam in reducing preoperative anxiety in children aged 3 to 7 years old. The results suggested that the interactive music intervention was effective in reducing anxiety only during separation from one's parents and upon entry into the OR ($F = 2.20$; $P = 0.042$) but not during anesthetic induction which is the most critical, high stress time point for children undergoing surgery. Additionally, a cost analysis revealed that each music therapy session cost up to $125 USD per hour to be carried out by one or more registered music therapist. On average, each child received a minimum of one-hour session (Wright et al., 2007). Thus, the cost and time associated with this and other alternative methods such as hypnosis and acupuncture therapies make them less optimal for use in the hospital setting.

While existing interventions can be effective, there are many barriers to the routine use of these preparation methods because they are very resource intensive and are not readily available. Taking these factors into consideration, it is crucial that efficient and alternative means of managing children's preoperative anxiety be found.

Preoperative Anxiety: Audiovisual Interventions

A recent Cochrane review suggested that non-pharmacological interventions for assisting anesthetic induction in children were as effective as pharmacological treatments in reducing children's preoperative anxiety (Manyande, Cyna, Yip, Chooi, & Middleton, 2015; Yip, Middleton, Cyna, & Carlyle, 2009). In particular, non-pharmacological interventions that contained audiovisual (AV) components such as low sensory stimulation and hand held video games seemed to be efficacious in reducing children's preoperative anxiety, and improving cooperation during general anesthetic induction (Yip et al., 2009). The findings have also led to the suggestion that other AV interventions such as entertainment technology, tablet-based applications, and interactive games or virtual reality programs be explored for their effectiveness in managing children's preoperative anxiety (Ahmed, Farrell, & Parrish, 2011).

Since then, a number of single studies have been conducted to further assess the effectiveness of various forms of AV interventions. More recent studies have focused on using computers and other technologies (i.e., video glasses and smartphone applications) in reducing children's perioperative anxiety and to manage its associated postoperative negative outcomes (Kerimoglu et al., 2013; Klassen, Liang, Tjosvold, Klassen & Hartling, 2008; Lee et al., 2013). Given the promising nature of AV interventions, it is crucial to examine the impacts of these interventions to further our understanding and to help guide future practice in reducing children's preoperative anxiety.

Measuring Preoperative Anxiety in Children: Existing Measures & Limitations

While several measures are currently used to assess anxiety in pediatric surgical settings, existing scales have limitations and have led to their relatively inconsistent use. For example, the modified Yale Preoperative Anxiety Scale [mYPAS], the "gold" standard in the field, (Kain et al., 1997) is an observer-rated scale that is susceptible to observer bias and requires that healthcare staff and research assistants be trained on its administration at multiple assessment points (Wright, Stewart, & Finley, 2013). Unfortunately, from a practical standpoint, the busy hospital setting offers very limited observation time for healthcare and study staff to fully and accurately assess preoperative anxiety (Jenkins et al., 2014). Another disadvantage of the mYPAS is that it also does not allow for the assessment of postoperative anxiety. Other existing scales either have low specificity for children's anxiety (Deloach, Higgins, Stiff, & Caplan, 1998; Wong & Baker, 1998) or are too lengthy (Spielberger et al., 1973) to be used in this medical environment which makes them less optimal, particularly in busy operative areas (Papay & Hedl, 1978; Birmaher et al., 1997).

Thus, in order to properly describe and understand the precursors and sequelae of perioperative anxiety, brief, objective, reliable, and valid tools need to be developed that can accurately measure perioperative anxiety in busy and complex clinical settings. Research has suggested that a multi-item VAS that combines several related constructs should be developed to allow for a more accurate assessment of children's preoperative anxiety (Gift, 1989; Foster & Park, 2012).

Preoperative Anxiety: Risk factors

Research has shown that there are differences in children and their parents in terms of who are likely to respond negatively to surgical procedures (Caldas, Pais-Ribeiro, & Carneiro, 2004; Yuki & Daaboul, 2011). Children who are shy, inhibited and withdrawn, lack good social adaptability, have negative previous medical experiences, and have parents who themselves struggle with high trait anxiety are at risk for elevated levels of preoperative anxiety (Fortier et al., 2010; Kain et al., 2002; Litke et al., 2012). In adolescents, baseline anxiety, depression, somatization, and fearful temperament are significant predictors of anxiety in the preoperative period (Fortier et al., 2011; O'Conner-Von, 2008).

In addition, studies suggest that individual differences in temperament are also associated with adverse psychological outcomes in the surgical setting. For example, Kain and his group (1996) explored temperament as a predictor of preoperative anxiety in children aged 2-10 undergoing elective ambulatory surgeries. They showed that low levels of activity were predictive of increased anxiety in the preoperative holding area, and upon separation from parents immediately prior to surgery. Moreover, high impulsivity in children was found to predict generalized anxiety disorder symptoms (RR= 2.7, 95% CI = 1.1-6.8) and separation anxiety disorder symptoms (RR = 3.5, 95% CI = 1.3-9.6) in children up to 2 weeks after surgery (Kain, et al., 1996).

In a separate set of studies, levels of impulsivity have also been shown to predict anxiety during anesthetic induction procedures for children. In work by Finley and colleagues (2006), children were randomly assigned to receive either midazolam treatment or standard of care without midazolam. Results showed that higher baseline levels of impulsivity were associated with increased rates of anxiety-related behaviors at anesthetic induction for children in the midazolam treatment group but not in standard of care group, suggesting that temperament is not only predictive of preoperative anxiety, but can affect children in such a way that it may inform the use of preoperative anxiolytic medications (i.e., midazolam) in children undergoing surgery (Wright et al., 2013). Therefore, it is of significant clinical interest to be able to identify children who are prone to preoperative anxiety so that the most appropriate interventions aimed at reducing the impact of perioperative anxiety in children undergoing surgery can be designed and applied.

Surgical Setting: An Ecologically-Valid Context

The perioperative surgical setting provides researchers with an ecologically-valid context to study childhood anxiety outside of the traditional laboratory settings. Ecological validity refers to the scientific investigation being carried out in a naturalistic setting and the taking into account of objects, activities and people from everyday life (Bronfenbrenner, 1977).

The current childhood anxiety research is limited by findings that relied heavily on data obtained from the controlled experimental settings (e.g., home, laboratory or school) or using retrospective self-reports (Coll, Kagan, & Reznick, 1984; Kagan, Reznick and Snidman 1986). These findings, although meaningful, might be prone to bias and lack a dimension of ecological validity. Since the surgical setting serves as a naturally threatening and anxiety-provoking situation for children and families undergoing surgery, this context allows for the direct observation of children's behaviors and interactions under a real-life setting. Therefore, research findings derived from this surgical setting can add to the extant literature on the importance of considering ecologically valid contexts when studying individual differences in socioemotional development.

Summary of Findings and Limitations of the Existing Literature

First, despite the high prevalence of preoperative anxiety in pediatric populations, evidence supporting the use of effective AV interventions is lacking. Over the past few years, substantial technological advancements have led to the availability of a large variety of AV interventions in pediatric settings. In general, studies of these suggest that AV interventions can be helpful in preparing children and parents for children's surgeries. However, to our knowledge, there are no existing syntheses or reviews dedicated to elucidating the effects and mechanisms of AV interventions in reducing children's preoperative anxiety (Manyande et al., 2015). Therefore, a systematic review of the literature in this area can help to pinpoint the components (i.e., exact dosage, timing and frequency of administration) of effective AV interventions in pediatric populations, as well as the mechanisms by which they operate, and guide evidence-based practice.

Second, at present, the limitations associated with existing children's anxiety measures may prevent us from rapidly and accurately assessing perioperative anxiety in clinical settings. Ideally, a useful perioperative tool should be short and informative, utilize self-report, and be age-appropriate, as well as specific to perioperative settings. Existing gaps in this area have thus led the development of the Children's Perioperative Multidimensional Anxiety Scale (CPMAS), a tool that uniquely measures children's state anxiety within the surgical setting.

Third, existing interventions aimed at reducing children's preoperative anxiety are not always readily accessible, can be time-intensive, or are associated with undesirable side effects and high costs. Accordingly, an inexpensive, modifiable, multi-sensory interactive tablet-based application: Story-Telling Medicine (STM) was developed to prepare children for complex perioperative and surgical procedures. Recent findings on AV interventions are represented by only a handful of underpowered and small sample size studies. Therefore, a large, adequately powered RCT should be conducted to examine the effects of this more affordable tool, STM, in managing preoperative anxiety and its effects on children. However, before this is undertaken, adequate pilot studies to assess the feasibility, applicability, and the potential effect size of this intervention must be conducted.

Lastly, thus far only a few studies have investigated risk factors for preoperative anxiety in children undergoing surgery. Although recent literature provides some evidence for the link between temperament and anxiety in this context, there is still a paucity of research that can delineate which temperament trait is most predictive of preoperative anxiety and that examines links beyond any one particular temperament style. Given that shyness and sociability are personality traits that predispose an individual to exhibit distinctive patterns of behavior (Schmidt & Buss, 2010), it is important that we attempt to better understand the contribution of individual differences of shyness and sociability to children's anxiety within the clinical surgical context.

An Overview of the Thesis

To address the significant uncertainty that exists in the extant literature on managing preoperative anxiety in children undergoing surgery, I have designed and conducted 4 separate studies to further our understanding of the impact of AV interventions on children's preoperative anxiety (Study 1), to evaluate the usefulness of a newly developed preoperative anxiety measure (Study 2), to test a newly developed AV intervention (Study 3), and to examine the contribution of individual differences within the perioperative context (Study 4). Each of the below studies corresponds to a manuscript that has been recently published and/or submitted for publication.

Study 1 (Chow, Van Lieshout, Schmidt, Dobson, & Buckley, 2015) was a systematic review and meta-analysis that examined the impact of AV interventions on reducing preoperative anxiety and its associated postoperative outcomes in children receiving elective surgery under general anesthesia. Both randomized controlled trials (RCT) and non-randomized controlled studies (NRS) where the primary outcome was children's preoperative anxiety were included in this review. The secondary outcomes included postoperative pain, behavioral changes, recovery, induction compliance, satisfaction and cost-effectiveness. A meta-analytic approach and narrative synthesis of findings were employed to summarize the results of the studies. The risk of bias of each study was assessed.

The findings of the systematic review and meta-analysis revealed that there is a lack of a useful perioperative tool to assess children's preoperative anxiety which led us to develop the Children's Perioperative Multidimensional Anxiety Scale (CPMAS), a tool that uniquely measures self-reports of a child's preoperative state anxiety.

In Study 2 (Chow, Van Lieshout, Buckley, & Schmidt, 2016), I developed and assessed the psychometric properties of the CPMAS. Eighty children aged 7 to 13 years who were undergoing elective surgery at McMaster Children's Hospital were recruited. Children self-completed the CPMAS and the Screen for Childhood Anxiety Related Disorders (SCARED-C) at three time points: at preoperative assessment (T1), on the day of the operation (T2), and 1 month postoperatively (T3). Internal consistency, test-retest reliability and the convergent validity of the CPMAS were assessed across all three visits.

In addition, the primary findings of the systematic review and meta-analysis also suggested that adequately powered RCTs are required to conclusively pinpoint the components and mechanisms of the most effective AV interventions and guide practice. The review suggested that an effective AV intervention should incorporate interactive environments that closely approximate the real surgical experience. Accordingly, a customizable, multi-sensory interactive tablet-based virtual reality application, STM, was developed to prepare children for complex perioperative and surgical procedures. In Study 3 (Chow, Van Lieshout, Schmidt, & Buckley, 2016; submitted to *Journal of Developmental & Behavioral Pediatrics*), I conducted a 3-wave pilot study to examine the feasibility and acceptability of this newly developed STM intervention. One hundred children aged 7-13 years who were undergoing elective surgery were recruited at McMaster Children's hospital. This pilot study comprised 3 waves: Waves 1 (n=30) and 2 (n=30) examined feasibility, and Wave 3 (n=40) examined the acceptability of STM and compared its effect on preoperative anxiety to Usual Care (UC). In Wave 3, children were randomly allocated to receive STM+UC or UC. Change in preoperative anxiety was measured using the CPMAS across all three visits.

Finally, the cumulative findings of the systematic review and pilot study had informed us that a variation of children's stress response as measured by CPMAS exists in the surgical setting. This observation had led me to further examine the role of individual differences in temperament and its relation to preoperative anxiety in children undergoing surgery in Study 4 (Chow, Nejati, Van Lieshout, Buckley, and Schmidt, 2016; submitted to *Clinical Pediatrics*). I chose to examine the contribution of shyness and sociability to children’s anxiety in the clinical surgical settings. I predicted that temperamentally shy children would exhibit more preoperative anxiety, and temperamentally social children would exhibit less preoperative anxiety in the surgical context. Forty children aged 7 to 13 years who were undergoing elective surgery at McMaster Children’s Hospital were recruited. Children self-completed the Colorado Child Temperament Inventory (CCTI; Rowe and Plomin, 1977) at T1 and CPMAS and at all three time points.

In sum, the series of studies in this thesis are presented as follows: Chapter 2 examined the effectiveness of AV interventions at reducing preoperative anxiety and its associated outcomes in children undergoing elective surgery; Chapter 3 assessed the psychometric properties of a newly developed scale, the CPMAS; Chapter 4 examined the feasibility and acceptability of a newly developed tablet-based intervention, STM, for reducing children's preoperative anxiety; Chapter 5 examined the relations between temperament and children’s preoperative anxiety one week prior to surgery and on the day of surgery; and Chapter 6 served as the General Discussion for the thesis in which I summarize the findings from these four studies in relation to the extant literature on understanding and managing children’s anxiety in the surgical setting.

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CHAPTER TWO

STUDY 1

TITLE: Systematic Review: Audiovisual Interventions for Reducing Preoperative Anxiety in Children Undergoing Elective Surgery

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CONTEXT AND IMPLICATIONS OF THIS STUDY: To address the significant knowledge uncertainty that exists in literature, I have designed and conducted this first study of the thesis to further our understanding on the impacts of AV interventions on reducing children's preoperative anxiety. As previously discussed in the introduction, non-pharmacological interventions containing audiovisual (AV) components seemed to be efficacious in reducing children's preoperative anxiety and improving cooperation during general anesthetic induction. To our knowledge, there are no existing syntheses or reviews dedicated to elucidating the effects and mechanisms of AV interventions in reducing children's preoperative anxiety.

This study is the first to systematically review the literature examining the effectiveness of AV interventions at reducing preoperative anxiety and its associated outcomes in children undergoing elective surgery. It reveals the substantial clinical and methodological heterogeneity in the area and identifies shortcomings and limitations of previously conducted studies. This review also highlights the need for large adequately powered RCTs with optimal measurement quality to accurately assess the effects of AV interventions and provides recommendations to guide future evidence-based practice.

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Abstract

The objective of this study was to examine the effectiveness of Audio-Visual interventions at reducing preoperative anxiety and its associated outcomes in children undergoing elective surgery. A systematic review of randomized controlled trials (RCT) and nonrandomized studies where the primary outcome was children's preoperative anxiety was conducted. Secondary outcomes included postoperative pain, behavioral changes, recovery, induction compliance, satisfaction and cost-effectiveness. The risk of bias of each study was assessed. The results showed that 18 studies were identified. A meta-analytic approach and narrative synthesis of findings were employed to summarize the results of the studies. In conclusion, this systematic review suggests that AV interventions can be effective in reducing children's preoperative anxiety. Videos, multi-faceted programs and interactive games appear to be most effective, whereas music therapy and internet program are less effective. While AV interventions appear potentially useful, adequately powered RCTs are required to conclusively pinpoint the components and mechanisms of the most effective AV interventions and guide practice.

Introduction

Exposure to pediatric surgical procedures is a relatively common and significant stressor for children. It is estimated that up to 5 million children undergo elective surgical procedures in North America every year, and nearly 75% of them experience considerable preoperative anxiety (Perry, Hooper, & Masiongale, 2012). This distress is highest during general anesthetic induction procedures during which anticipatory anxiety is provoked (Davidson & McKenzie, 2011). Surgery can produce emotional distress and trauma for children and their families if they are psychologically ill-prepared.

Research has shown that there are individual differences in children and their parents in terms of who are likely to respond negatively to surgical procedures. For example, high trait anxiety and low sociability in children and high anxiety in parents are predictive of elevated levels of perioperative anxiety (Fortier, Del Rosario, Martin, & Kain, 2010; Li & Lopez, 2005). In adolescents, baseline anxiety, depression, somatization, and fearful temperament are significant predictors of anxiety in the preoperative period (Fortier, Martin, Chorney, Mayes, & Kain, 2011).

Preoperative anxiety is predictive of a number of negative clinical outcomes postoperatively including prolonged anesthesia induction, poorer postoperative recovery, and higher doses of postoperative analgesia (Fortier et al., 2010; Kain, Mayes, O'Connor, & Cicchetti, 1996; Kain, Wang, Mayes, Caramico, & Hofstadter, 1999). It has been reported that patients with preoperative anxiety are at 3 times the risk for exhibiting postoperative anxiety and moderate-to-intense pain (Caumo et al., 2000). In one large-scale study, Kain and colleagues showed that anxious young children with high presurgical anxiety had increased postoperative pain and higher analgesic consumption (i.e., acetaminophen and codeine) (Kain, Mayes, Caldwell-Andrews, Karas, & McClain, 2006). Other studies have shown that children with higher levels of preoperative anxiety require increased doses of propofol for anesthesia induction and maintenance (Kain et al., 1999; Maranets & Kain, 1999). Finally, recent research suggests that the prevention of post-operative delirium in preschool children would be aided greatly by managing preoperative anxiety using both psychological approaches and sedative premedication (Dahmani, Delivet, & Hilly, 2014).

Children's emotional and behavioral response to the stress of surgery include separation anxiety, decreased sleep, delirium, behavioral problems, and increased distress in the recovery phase (Kain et al., 2004b; Kain et al., 1996; Kain et al., 1999; Litke, Pikulska, & Wegner, 2012). Preoperative anxiety has also been shown to lead to longer postoperative recovery with more complications and prolonged wound healing (Long & Rajagopalan, 2002; McCann & Kain, 2001). These adverse outcomes can have both transient and long term detrimental effects on a child's growth, development and health (Kain et al., 1996). Furthermore, these negative changes can cause prolonged stays in recovery areas, delays entering the operating room, and increases in healthcare costs (Kain et al., 2007; Lee et al., 2013; McCann & Kain, 2001; Perry et al., 2012).

Current Interventions

Given the potential negative effects of preoperative anxiety, clinicians and researchers have attempted to apply interventions aimed at reducing its prevalence, severity, and impact. These include the use of preoperative sedative medications, psychological preparation programs, and complementary therapies such as reading a story-book, applying age-appropriate teaching interventions, and the utilization of Child Life specialists (Brewer, Gleditsch, Syblik, Tietjens, & Vacik, 2006; Perry et al., 2012; Tunney & Boore, 2013). Although sedative premedication is most routinely used, it has limitations. First, many children experience undesirable side effects such as nausea and vomiting (Sinha et al., 2012). Second, the use of anxiolytic drugs can be limited by a long onset of effect and duration of action, and so it is often difficult to determine the optimal time to administer these drugs in a busy surgical setting. Third, children sometimes refuse to take these medications voluntarily due to their unpleasant aftertaste. They are also likely to resist sedation via intravenous injections due to associated pain and discomfort (Davidson & McKenzie, 2011). Fourth, there are negative postoperative outcomes associated with the use of sedative premedications such as elevated risks of delirium, agitation, and pain (Kain et al., 2004b, 2006). Taking these into consideration, it is crucial that efficient and alternative means of managing children's preoperative anxiety be found.

The most current Cochrane review of non-pharmacological interventions for preoperative anxiety in children was published 6 years ago and was recently updated in 2015. Both reviews concluded that non-pharmacological interventions were as effective as pharmacological treatments (Manyande, Cyna, Yip, Chooi, & Middleton, 2015; Yip, Middleton, Cyna, & Carlyle, 2009). Yip and colleagues concluded that methods such as clown doctors, hypnosis, low sensory stimulation, and hand held video games seemed to be effective in reducing children's anxiety and improving cooperation during general anesthetic induction (Kain, Wang, Mayes, Krivutza, & Teague, 2001; Kuttner , 2012; Patel et al., 2006; Vagnoli, Caprilli, & Messeri, 2010). For example, Vagnoli and colleagues (2010), utilized clowns that interacted with children before entering the operating room and stayed with them along with their parent throughout anesthetic induction procedure. In another study by Calipel et al. (2005), hypnosis, a technique that enables a state of relaxation was used. While effective, unfortunately, there are many barriers to the routine use of these preparation methods because they are extremely resource intensive, costly, and are not readily available. Although the last Cochrane review did not directly discuss the full implications of audio-visual (AV) interventions, it did mention that large RCTs were required to confirm the usefulness of some of the more promising non-pharmacological interventions. Of the 5 non-pharmacological interventions examined, 2 of these contained AV components (Yip et al., 2009). Since then, a number of studies have been conducted to assess the effectiveness of these AV interventions. Because music therapy and other entertainment technologies (e.g. virtual reality) might offer alternative solutions to manage children's preoperative anxiety in a safe and economical way, given the promising nature of AV interventions, and since the term 'non-pharmacological interventions' encompass a broad range of treatments, the current review specifically focuses exclusively on the use of AV interventions in reducing children's preoperative anxiety (Ahmed, Farrell & Parrish, 2011).

The Therapeutic Effects of AV Interventions

There has been a long-standing history of use of AV interventions in both psychology and medicine. Their use in surgical settings can be dated back to the 1970s when preparation programs included procedural information with a sensory component. These programs reported that they reduced anxiety and improved coping skills in children undergoing surgery (Melamed & Siegel, 1975; O'Conner-Von, 2008).

Various forms of AV interventions are now widely used in adult patient populations. One systematic review summarized the benefits of using educational, media-based interventions in reducing preoperative anxiety and in increasing adult patient knowledge and satisfaction. Anxiety levels before anesthesia were reduced in adult patients receiving the video and printed information compared with those receiving no intervention as shown by a weighted mean difference of 3 points (95% CI = 1-5) on the Spielberger State and Trait Anxiety Inventory (Lee, Chui, & Gin, 2003). Another systematic review showed that 30 minutes of slow and flowing non-lyrical music is effective in reducing adult patients' anxiety and pain in perioperative settings. Music interventions were found to have positive effects on reducing patients' anxiety and pain in approximately half of the 42 reviewed RCTs (Nilsson, 2008). Finally, a recent systematic review reinforced the positive effects of preoperative education interventions utilizing audiovisual, visual, and multimedia technologies such as websites in reducing adults' preoperative anxiety (Alanazi, 2014). The collective findings of these systematic reviews suggest that various types of AV interventions are effective in reducing preoperative anxiety and its associated negative postoperative outcomes in adults undergoing surgery.

Despite the high prevalence of preoperative anxiety in pediatric populations, evidence supporting the use of AV interventions is lacking. Over the past few years, substantial technological advancements have led to the use of a large variety of AV interventions in pediatric settings. More recent studies have focused on using computers and other technologies (i.e., video glasses and smartphone applications) in reducing children's perioperative anxiety and to manage its associated postoperative negative outcomes (Kerimoglu, Neuman, Paul, Stefanov, & Twersky, 2013; Klassen, Liang, Tjosvold, Klassen & Hartling, 2008; Lee et al., 2013). In general, these studies suggest that AV interventions can be helpful in preparing children and parents for children's surgeries.

However, to our knowledge, there are no existing syntheses or reviews dedicated to elucidating the effects and mechanisms of AV interventions in reducing children's preoperative anxiety (Manyande et al., 2015). Systematically reviewing the literature in this area can help to pinpoint the effective components (i.e., exact dosage, timing and frequency of administration) and mechanisms of effective AV interventions in pediatric populations, as well as guide practice.

Objective

The objective of the present study was to synthesize and summarize evidence of the effects of AV interventions on reducing preoperative anxiety and its associated postoperative outcomes such as pain, postoperative maladaptive behaviors, recovery (e.g. decrease in discharge time) in children receiving elective surgery under general anesthesia. This systematic review was primarily designed to address the significant knowledge uncertainty that exists in this area. We also examined the acceptability and cost-effectiveness of AV interventions for this indication.

Method

This systematic review is registered with the PROSPERO International prospective register of systematic reviews CRD42014010637 (Chow, Van Lieshout, Schmidt, & Buckley, 2014). The Preferred Reporting items for Systematic Reviews and Meta-Analyses (PRISMA) statement served as a guideline in preparing this systematic review (Moher, Liberati, Tetzlaff, & Altman, 2009).

Selection criteria

The Participants, Interventions, Comparisons, Outcomes & Study design approach was used to generate the research question guiding this systematic review and to establish study inclusion eligibility criteria. We deemed both randomized controlled trials (RCT) and non-randomized controlled studies (NRS) eligible for this review, where studies included children and adolescents under the age of 18 receiving elective surgery under general anesthesia in community, research and University-affiliated hospitals, and where audiovisual (AV) interventions were utilized as experimental treatments. Other study eligibility criteria included a minimum of two comparison arms per study and children's anxiety reported as the primary outcome. Children's anxiety was measured from baseline to the last available follow-up using validated anxiety scales such as the Yale Preoperative Anxiety Scale (Kain et al., 1995), Modified Yale Preoperative Anxiety Scale (mYPAS) (Kain et al., 1997), and Spielberger's State-Trait Anxiety Inventory for Children (STAI-C) (Spielberger, Edwards, Lushene, Montuori, & Platzek, 1973). Secondary outcomes examined included postoperative pain, postoperative maladaptive behavior, recovery, anesthetic induction compliance, satisfaction, and cost-effectiveness.

Audiovisual interventions were defined as involving any audio, visual, or audiovisual components that aimed to reduce preoperative anxiety in children (e.g., videos, video games, internet programs, music, etc.). Comparator groups could be a control group that received standard of care (SC), no-intervention, parental presence, or low doses of sedative pre-medication (e.g., midazolam). The definition of standard of care varied between studies but was generally defined as the routine preparation (i.e., brief explanations of the medical procedures) provided by the nurses and/or physicians during the preoperative period.

Information Sources & Search

A systematic search of electronic databases (MEDLINE, EMBASE, CINAHL, PsycINFO, Web of Science, and The Cochrane Controlled Trials Registry from their inceptions until March 2014) was performed. An electronic search strategy included medical subject heading terms (MeSH) in MEDLINE, where keywords and text words were combined.

The electronic search was based on 4 concepts: i) terms related to anxiety: “anxiet*”, “nervousness”, “fear”, “panic”, “distress”, “emotional stress”, “psychological stress”, “anxious”, “feel* of apprehens*”, “feel* of dread”, “feel* of worry”, “feel* of worried”, “feel* of terror”; ii) terms related to preoperative: “surgical procedures”, “operative”, “preoperative care”, “surgery”, “surgical”, “preop*”, “pre-op*”, “periop*”, “peri-op*”, “preoperat*”; iii) terms related to AV interventions: “distract*”, “cartoon*”, “computer simulation”, “animat*”, “television”, “videodisc recording”, “compact disks”, “cd-I”, “cd-rom”, “videotape recording”, “broadcast”, “software”, “hypermedia”, “video games", "media based", "video-audio media", "media", "audiovisual aids", "multimedia", "tape recording", "visual aid*", "audiovisual aid*", "video*", "*cellular phone", "smartphone", "electronics", "internet", "educational technology"; and iv) terms related to children: "child*", "schoolchild*", "school age*", "preschool*", "kids", "toddler*", "adoles*", "teen*", "boy*", "girl*", "minors*", "pubert*", "pubescen*", "prepubescen*", "pediatric*", "schools", "nursery", "primary school*", "secondary school*", "elementary school*", "high school*".

The search strategy was developed by the reviewers in consultation with a research librarian. The same strategy was used for other databases except with the search terms adjusted to each specific database. Examples of these search strategies are available upon request. Studies were identified and hand searches were conducted on the reference lists of these. There were no search language restrictions. Case studies, studies presented only in abstract form, editorials, and unpublished studies were excluded from our search. The last search was performed on March 3rd, 2014. Ongoing trials were searched on metaregistertrials.com prior to submission.

Study Selection

The screening process was completed independently by two reviewers (C.C. and R.V.L.) based on the study inclusion criteria outlined above. The titles and abstracts of each study were initially screened. Duplicate and non-relevant studies were eliminated. The full text of potentially relevant studies was further examined to determine if inclusion criteria were met. In the case of disagreements, a third author (L.A.S.) was brought in to aid in resolution. The 2 reviewers met and agreed on the final inclusion of studies (n = 18).

Data Extraction

A data extraction form was developed for this review. The form was pilot-tested using two randomly selected studies that met inclusion criteria, and it was refined accordingly. The information extracted from each study included: i) studies' methodological characteristics (i.e., study type, follow-up periods & quality of assessment), ii) population characteristics (i.e., age, gender, setting, & surgery types), iii) details of the interventions (i.e., type, timing, dose, duration and frequency), iv) outcome measures (i.e., children's anxiety levels), and v) summary of results and risk of bias assessments. The primary author extracted data and information was independently verified by the second author. Means and standard deviations were presented as (*M* = mean, *SD* = Standard deviations). All medians and confidence intervals were presented as (*Mdn* = median, 95% CI = lower limits - upper limits).

Risk of Bias in Individual Studies Within and Across Studies

The risk of bias was appraised for each study independently. The Cochrane Collaboration risk-of-bias tool was used to assess each study on 6 evidence-based domains: 1) random sequence generation, 2) allocation concealment, 3) blinding of participants, assessors, and outcome assessments, 4) incomplete outcome data, 5) selective reporting, and 6) other biases.

Each domain was assessed within and across studies. If the study addressed the domain appropriately, low risk of bias was assigned. If the domain was addressed inappropriately, a label of high risk of bias was assigned. If information was unavailable to reach a judgment, then an 'unclear' risk of bias was assigned to that domain (Higgins, Altman & Sterne, 2011; Sterne, Egger & Moher, 2011).

Data Synthesis

In addition to a narrative synthesis of findings, a meta-analytic approach was also used to summarize the results of the studies (Deeks, Higgins, & Altman, 2011). An inverse variance random-effects meta-analysis using mean differences (MD) was undertaken using Review Manager (RevMan) 5.3 software to compute pooled effect estimates of AV interventions on preoperative anxiety. This meta-analysis utilized data from 10 studies. Eight studies were excluded from the meta-analysis (Durst, 1990; Ellerton & Merriam, 1994; Huth, Broome, & Good, 2004; Kain et al., 1998; Kerimoglu et al., 2013; Melamed & Siegel, 1975; Mifflin, Hackmann, & Chorney, 2012; Robinson & Kobayashi, 1991), as the data required for meta-analysis was unavailable in the article or from the study authors.

Data were entered as continuous measures MD for each primary AV intervention and comparison groups. To calculate the mean change within a group, we used the formula, $M = T_2 – T_1$, where T_1 represented mean anxiety score at the time closest to baseline, and T_2 represented the mean anxiety score at the time closest to the operation. To calculate standard deviation values for the mean change, we used the following formula to calculate the standard error, $SE= \sqrt{\frac{SD1^2}{N} + \frac{SD2^2}{N}}$, where SD1 is the standard deviation at T_1, SD2 is the standard deviation at T_2, and N is the number of participants within the arm/group. Individual MDs for each study and an overall weighted mean difference (WMD) for AV interventions included in the analysis were assessed. Heterogeneity was assessed using I^2 values. High heterogeneity was defined as an I^2 value greater than 50% (Higgins & Altman, 2011).

Results

Study Selection

Our search yielded a total of 2514 citations and 4 additional studies were identified from reference lists of retrieved studies and reviews. Of these 2514 citations, 499 duplicate studies were eliminated prior to screening and so 2019 studies were initially screened. Studies were excluded because they did not meet eligibility criteria (e.g., case studies, only presented in abstract form, editorials, etc.). The full text of 129 studies was examined and a total of 18 eligible studies (14 RCTs and 4 NRS) were included in this review (See Figure 1).

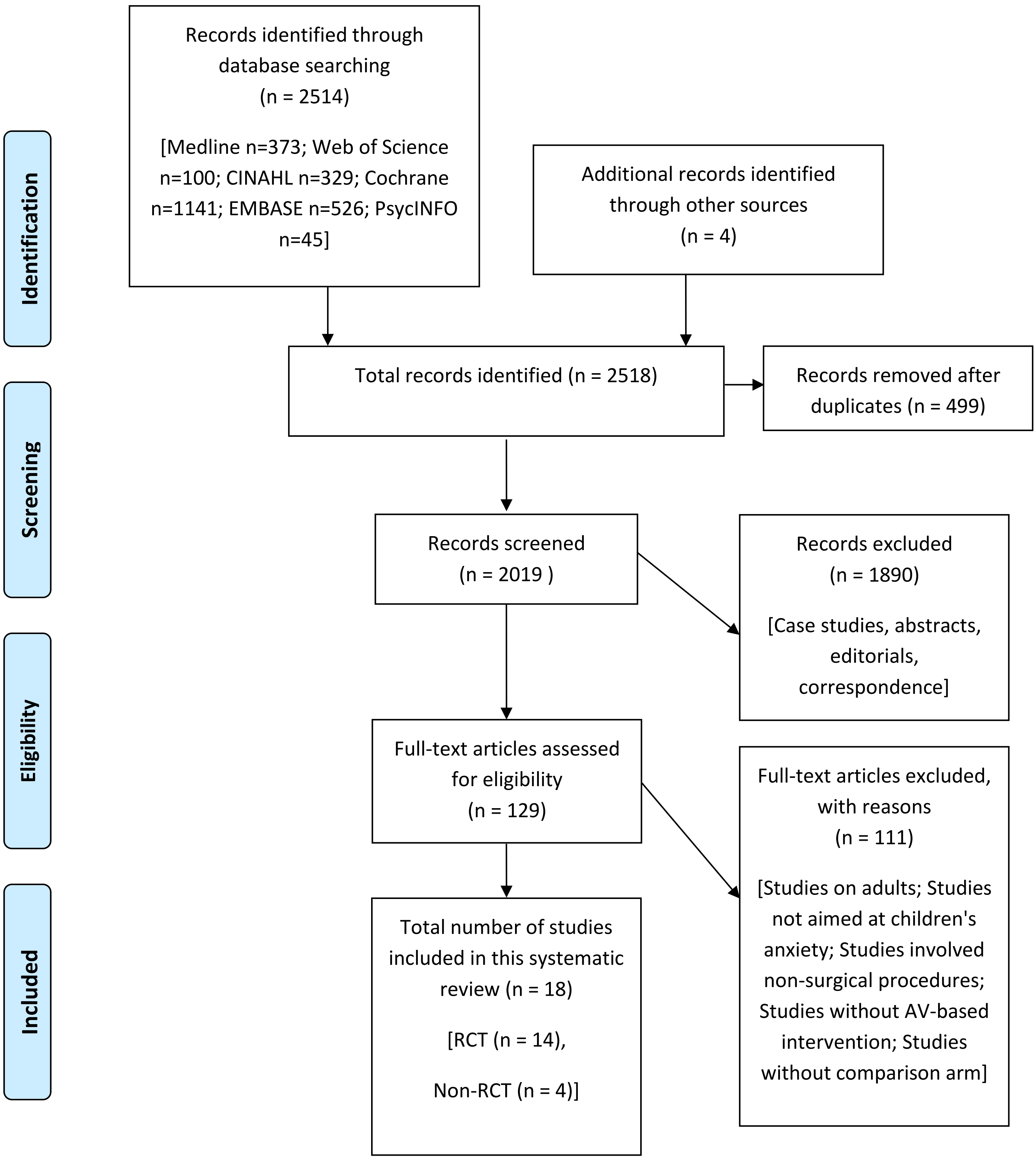
Identification
Screening
Eligibility
Included
Records identified through database searching (n = 2514)
[Medline n=373; Web of Science n=100; CINAHL n=329; Cochrane n=1141; EMBASE n=526; PsycINFO n=45]
Additional records identified through other sources (n = 4)
Total records identified (n = 2518)
Records removed after duplicates (n = 499)
Records screened (n = 2019)
Records excluded (n = 1890)
[Case studies, abstracts, editorials, correspondence]
Full-text articles assessed for eligibility (n = 129)
Full-text articles excluded, with reasons (n = 111)
[Studies on adults; Studies not aimed at children's anxiety; Studies involved non-surgical procedures; Studies without AV-based intervention; Studies without comparison arm]
Total number of studies included in this systematic review (n = 18)
[RCT (n = 14),
Non-RCT (n = 4)]

Figure 1. PRISMA flowchart of study selection process (Moher, Liberati, Tetzlaff, & Altman, 2009).

Study Characteristics

A summary of the baseline characteristics of study participants, AV intervention types, and a description of each individual AV intervention for the 18 eligible studies can be found in Table I.

Table 1. Selected Study Characteristics in the systematic review (N = 18).

Study Authors, Year, Country	Study Design	Population N, Age, Ethnicity	Surgery Types	AV Intervention Type & Intervention to Surgery Period	Intervention Details
VIDEOS					
Meladmed & Siegel (1975) USA	NRS	N = 60, 4-12y, N/S	Elective surgery under general anesthesia	Pre-op preparation video < 1hr prior to admission	A 16min film entitled "Ethan Has an Operation", depicts a 7-year-old male who has been hospitalized for a hernia operation
Pinto & Hollandsworth (1989) USA	RCT	N = 60, 2-12y, 85% White	First-time elective surgery	Pre-op preparation video 1hr prior to admission	A 22min videotape depicts an 8-year-old boy who was being hospitalized for surgery narrated by child (or adult)
Durst (1990) USA	NRS	N = 59, 2-10y, N/S	Elective day surgery	Pre-op preparation video Up to 7d prior to surgery	Videotape depicted 3 children during their perioperative experiences
Robinson & Kobayashi (1991) Australia	RCT	N = 28, 4-13y, N/S	Elective surgery	Pre-op preparation video 7d prior to surgery	A peer-modeling film that followed an 8-year-old Australian girl named Julia through a standard hospital admission for elective surgery + video (child coping skills) + audiotape (child relaxation)

Study Authors, Year, Country	Study Design	Population N, Age, Ethnicity	Surgery Types	AV Intervention Type & Intervention to Surgery Period	Intervention Details
Karabulut & Duygu (2009) Turkey	NRS	N = 90, 9-12y, N/S	Inguinal hernia operation	Pre-op preparation video Same day as surgery	A 12min pre-op preparation video
Wakimizu et al. (2009) Japan	RCT	N = 158, 3-6y, N/S	Elective herniorrhaphy for inguinal hernia and hydrocele testis	Pre-op preparation video 7d prior to surgery	Patient-educational modelling video which introduced the experience of a 5-year-old boy who is hospitalized for hernia and a booklet with regulations and guidelines to use as frequently as they want at home
Lee et al. (2012) South Korea	RCT	N = 130, 3-7y, N/S	General anesthesia for elective surgery	Animated Cartoon using personal computers N/S	Children watched their selected cartoon movie using a notebook or tablet personal computers (PCs)
Mifflin et al. (2012) Canada	RCT	N = 91, 2-10y, N/S	Ambulatory surgery	Online videoclip N/S	An age-appropriate YouTube™ clip for the child to view during induction
Kerimoglu et al. (2013)USA	RCT	N = 96, 4-9y, N/S	Ambulatory surgery	TV program using videoglass N/S	Portable media player of viewing TV program on a magnified scale for a large screen experience
MULTI-FACETED EXTENSIVE PROGRAM					
Ellerton & Merriam (1994) Canada	NRS	N = 75, 3-15y, N/S	Elective day surgery	Day Surgery Program Up to 7d prior to surgery	Pre-op slide show + tour + handouts

Study Authors, Year, Country	Study Design	Population N, Age, Ethnicity	Surgery Types	AV Intervention Type & Intervention to Surgery Period	Intervention Details
Kain et al. (1998) USA	RCT	N = 75, 2-12y, N/S	Elective outpatient surgery	Pre-op preparation Program Up to 10d prior to surgery	OR tour + videotape + Child Life preparation
Kain et al. (2001) USA	RCT	N = 70, 2-7y, N/S	Elective outpatient surgery	Low Sensory Stimuli Prior to anesthetic induction	Low level ligh intensity (200LX) + music + quietness in the room (only 1 attending anesthesiologiest to interact with the child during the induction of anesthesia)
Huth et al. (2004) USA	RCT	N = 73, 7-12y, Majority white	tonsillectomy, adenoidectomy, myringotomy	Imagery video + audiotape Up to 22d prior to surgery	'To Tame the Hurting Thing' (Broome, 1994), included professionally developed imagery booklets for the parent and child, a videotape, and an audiotape for school-age children
Kain et al. (2007) USA	RCT	N = 408, 2-10y, 80 Non-white	Elective outpatient surgery	Pre-op ADVANCE preparation Program Up to 7d prior to surgery	Video, pamphlets, prepare distraction strategy, mask practice, coaching

Study Authors, Year, Country	Study Design	Population N, Age, Ethnicity	Surgery Types	AV Intervention Type & Intervention to Surgery Period	Intervention Details
INTERACTIVE GAME					
Patel et al. (2006) USA	RCT	N = 112, 4-12y, N/S	Elective surgery under general anesthesia	Videogame > 20 min to surgery	A hand-held video game + Parental presence during induction of anesthesia
Lee et al. (2013) South Korea	RCT	N = 120, 1-10y, N/S	Elective surgery under general anesthesia	Smartphone game app > 5 min to surgery	Smartphone game application
INTERNET & MUSIC					
Kain et al. (2004a) USA	RCT	N = 123, 3-7y, N/S	Elective outpatient surgery	Music 30 min prior to surgery	Used instruments and songs as vehicles to encourage expression of anxiety and physical release of that anxiety
O'Conner-Von (2008) USA	RCT	N = 69, 10-16yr, 89% Caucasian	Elective tonsillectomy with or without adenoidectomy	Pre-op prep Internet program < 72hr to surgery	Internet program Titled "Tonsils! Who Needs ‘em?", presented in a conversational format (i.e., peers teaching peers)

NRS = Non-Randomized Controlled Study; RCT = Randomized Controlled Trial; N/S = Not Specified; < = Less than; > = More than.

Baseline Characteristics. A total of 18 studies containing 1897 children and adolescents, ranging in age from 1 to 16 years were eligible. These studies included children that underwent general surgical procedures such as unspecified elective outpatient or ambulatory procedures, (Kain et al., 2007; Lee et al., 2012), herniorrhaphy only (Karabulut & Duygu, 2009; Wakimizu, Kamagata, Kuwabara, & Kamibeppu, 2009), tonsillectomy only (Huth et al., 2004; O'Conner-Von, 2008), and tonsillectomy or herniorrhaphy (Melamed & Siegel, 1975). Only one study focused solely on adolescents (O'Conner-Von, 2008). Overall, there was about a three-to-two ratio of males to females, while one study failed to report sex. Ethnicity was mentioned in only four studies but the majority of participants were Caucasian (Huth et al., 2004; Kain et al., 2007; O'Conner-Von, 2008). None of the 18 studies reported information on socioeconomic status. All studies were conducted in developed countries. The follow-up periods varied greatly, ranged from no post-operative follow-up to 1 month after surgery. Dropout or withdrawal rates were generally low across studies, ranging from 1% to 9%, with an average of 3% among the studies that explicitly described attrition.

Types of Interventions. The majority of eligible AV interventions were preoperative (pre-op) preparation videos (n = 9) (Durst, 1990; Karabulut & Duygu, 2009; Kerimoglu et al., 2013; Lee et al., 2012; Melamed & Siegel, 1975; Mifflin et al., 2012; Pinto & Hollandsworth, 1989; Robinson & Kobayashi, 1991; Wakimizu et al., 2009), followed by multi-faceted extensive AV preparation programs (n = 5) (Ellerton & Merriam, 1994; Huth et al., 2004; Kain et al., 1998; Kain et al., 2007; Kain et al., 2001). Multi-faceted extensive AV preparation programs are defined as those that included a combination of 2 or more interventions (e.g., a program that included the use of imagery booklets, a videotape, and an audiotape). The remaining four studies utilized interactive games (Lee et al., 2013; Patel et al., 2006), and music or internet preparation (Kain et al., 2004a; O'Conner-Von, 2008). AV interventions were compared with: i) standard of care (SC) or no intervention control group in 12 studies, ii) midazolam in two, iii) another AV intervention in two others, and iv) an OR tour and parental presence in the remaining two studies. In addition to the routine preparation, some studies also incorporated guardian presence in the operating room (OR), child life specialists, or an OR orientation tour, as part of standard of care (Kain et al., 1998; Kain et al., 2007; Mifflin et al., 2012). Pre-op preparation videos, multi-faceted extensive AV preparation programs and internet interventions were intended to provide procedural information that would educate children and parents about the perioperative process. Watching a cartoon or an online video clip, playing an interactive game, and interactive music were intended to be used as a distraction tool during the preoperative periods. Table I provides intervention details for individual studies.

Timing, Duration, and Frequency of Intervention Application and Outcome Assessments. Reporting of the timing, duration, and frequency of intervention application and outcome assessments was inconsistent between studies due to variations in time of measurements. The interventions were applied from 22 days up to 5 minutes prior to surgeries. The duration of the AV interventions ranged from 5 to 22 minutes. Most of the participants were exposed to the AV intervention just once preoperatively (n = 14). Participants from four studies were asked to use the intervention more than once (i.e., to listen to mental imagery audiotape as often as needed before and after surgery to manage anxiety and pain (Huth et al., 2004); to watch pre-op preparation video more than twice (Kain et al., 2007); to listen to relaxation audiotape once a day for a week (Robinson & Kobayashi, 1991); and to watch pre-op preparation video and read a booklet as frequently as they want at home (Wakimizu et al., 2009).

Anxiety Scales. Of the 18 studies, 14 showed positive effects on reducing children's preoperative anxiety. The most common instruments used to assess children's preoperative anxiety were the observer-rated Yale Preoperative Anxiety Scale (YPAS) and its modified one added item version (mYPAS); used in nine studies (Kain et al., 1998, 2001, 2004a, 2007; Kain et al., 2007; Kain et al., 2001; Kerimoglu et al., 2013; Lee et al., 2012; Lee et al., 2013; Mifflin et al., 2012; Patel et al., 2006). Clinical significance in terms of reductions in children's anxiety was defined as a 15-point difference or more on the mYPAS in two studies (Kerimoglu et al., 2013; Lee et al., 2012). The child-reported State-Trait Anxiety for Children (STAI-C) (Huth et al., 2004; Karabulut & Duygu, 2009; O'Conner-Von, 2008), the self-report measure FACES comprised of seven anxiety-related facial expressions (Ellerton & Merriam, 1994; Wakimizu et al., 2009), and the Observer Rating Scale of Anxiety (ORSA) (Melamed & Siegel, 1975; Pinto & Hollandsworth, 1989; Robinson & Kobayashi, 1991) were used in the remaining eight studies. One study used a non-validated list of ratings for anxiety-related behaviors (Durst, 1990).

Outcomes

Table II provides an overview and summaries of individual study outcomes including assessment time points, scales used and associated numerical results. The effectiveness of the interventions is presented according to the types of interventions and outcomes as outlined above.

Table 2. The Effectiveness of the interventions (N = 18).

Study Authors, Year, Country	Intervention vs. Comparator group(s)	Scale(s)	Assessment Time point(s)	Study outcome summary Primary Outcome: Children's Preoperative Anxiety
VIDEOS				
Meladmed & Siegel (1975) USA	Ia: Pre-op preparation video entitled "Ethan Has an Operation" (n = 30) Ca: Video entitled "Living Things are Everywhere" (n = 30)	ORSA	Night before surgery	Children who watched pre-op preparation video exhibited lower anxiety than children who watched the control video ($F = 3.33$, $p < 0.02$).
Pinto & Hollandsworth (1989) USA	Ia: Peer-narrated Pre-op preparation video with parents (n = 10) Ib: Peer-narrated Pre-op preparation video without parents (n = 10) Ic: Adult-narrated Pre-op preparation video with parents (n = 10) Id: Adult-narrated Pre-op preparation video without parents (n = 10) Ca: No videotape with parents (n = 10) Cb: No videotape without parents (n = 10)	ORSA	Night before surgery	Children who watched pre-op preparation videotape with their parent present exhibited less preoperative anxiety than children who did not watch the videotape ($F = 7.47$, $p < 0.0001$).
Durst (1990) USA	Ia: Pre-op preparation video (n=29) C: Standard of care (n=30)	N/A	Prior to surgery	No significant difference in behaviors during the observation periods (N/A).
Robinson & Kobayashi (1991) Australia	Ia: Pre-op preparation video + Child coping skills (n = 9) Ib: Pre-op preparation video + Child coping skills + Parent Coping skills (n = 9) Ca: Pre-op preparation video (n = 10)	ORSA		No significant difference in anxiety between all groups ($F = 0.44$, NS).
Karabulut & Duygu (2009) Turkey	Ia: Pre-op preparation VCD (n=30) Ib: Training with booklet (n=30) C: No intervention (n=30)	STAI-C	48 hours before surgery 24 hours before surgery	Children who watched pre-op preparation VCD exhibited lower anxiety than children who received no

				intervention (N/A).
Wakimizu et al. (2009) Japan	Ia: Pre-op preparation video + booklet at home (n = 77) C: Standard of care (Pre-op preparation video) (n = 81)	FACES	Prior to surgery	Children who watched pre-op preparation video at home exhibited lower anxiety than children who watched video at the hospital (F = 2.81, p = 0.038).
Lee et al. (2012) South Korea	Ia: Animated Cartoon (n = 42) Ib: Toy (n = 44) C: Standard of care (n = 44)	mYPAS	Prior to surgery Holding area In the OR	Children who watched animated cartoon exhibited lower anxiety in the OR than children who received standard of care (p < 0.05).
Mifflin et al. (2012) Canada	Ia: Online videoclip (n = 42) C: Usual distraction techniques by anesthesiologists (n = 47)	mYPAS	During induction	Children who watched online videoclip exhibited lower anxiety during anesthetic induction than children who received usual distraction techniques by anesthesiologists (U = 497, p < 0.001).
Kerimoglu et al. (2013) USA	I: Video glasses (n = 32) Ia: Midazolam + Video glasses (n = 32) C: Midazolam (n = 32)	mYPAS	20 min before OR Transport to OR During induction	Children who used video glasses prevented increase in anxiety during anesthetic induction (p = 0.38) than children who received midazolam (p = 0.02). All 3 interventions prevented clinically significant increases (< 15 points) in anxiety from baseline (p = 0.39).
MULTI-FACETED EXTENSIVE PROGRAM				
Ellerton & Merriam (1994) Canada	Ia: Day Surgery Program (Pre-op slide presentation + tour + handouts) (n=23) C: No intervention (n=52)	FACES	Prior to surgery	Fewer children who participated in the day surgery program exhibited high preoperative anxiety than children who received no intervention (Cramer's V= 0.33, p < 0.04).

Kain et al. (1998) USA	Ia: OR tour + videotape + Child Life preparation (n = 24) Ib OR tour + videotape (n = 25) Ca: OR tour (n = 24)	YPAS	Holding area During induction	Children who participated in the pre-op preparation program exhibited lower preoperative anxiety than children who received OR tour only (p = 0.02).
Kain et al. (2001) USA	Ia: Low sensory stimulation group (n=33) C: No intervention (n=37)	mYPAS	Entrance to the OR During induction	Children in the low sensory stimulation group exhibited lower preoperative anxiety than children in the control group (F = 6.3, p = 0.014).
Kain et al. (2007) USA	Ia: ADVANCE (n=96) Ib: PPIA (n=94) Ic: Midazolam (n=98) C: Standard of care (n=99)	mYPAS	Holding area During induction	Children in the ADVANCE group exhibited lower preoperative anxiety in the holding area (Cohen's d = 0.33) and during anesthetic induction (Cohen's d = 0.54) than children in other groups.
INTERACTIVE GAME				
Patel et al. (2006) USA	Ia: Parental Presence + video game (n = 38) Ib: Parental Presence + Midazolam (n = 38) C: Parental Presence (n = 36)	mYPAS	During induction	Children who played video game with parental presence exhibited lower anxiety during anesthetic induction than children who received parental presence (p = 0.04).
Lee et al. (2013) South Korea	Ia: Smartphone App (n = 40) Ib: Midazolam + Smartphone App (n = 40) C: Midazolam (n = 40)	mYPAS	Holding area 5 min after intervention In the OR	Children in the Smartphone APP group exhibited lower preoperative anxiety than children who received midazolam (p < 0.01).
INTERNET & MUSIC				
Kain et al. (2004) USA	Ia: Interactive music therapy (n=51) Ib: Midazolam (n=34) C: Standard of care (n=38)	mYPAS	During induction	No significant difference in preoperative anxiety between children in the music therapy group and children in the standard of care group (p = 0.83).

O'Conner-Von (2008) USA	Ia: Pre-op preparation Internet program (n = 28) C: Standard hospital preparation program (n = 14) Ca: Non-treatment group (n = 24)	STAI-C	Holding area	No significant difference in preoperative anxiety between adolescents in the internet preparation group and children in the standard preparation program group (p = 0.63).

N/A = Not Available; NS = No significant difference; Ia = Intervention; Ib = Comparator I; Ic = Comparator II; Id = Comparator III; C = Standard of care or no intervention; Ca = Control I ; Cb = Control II; ORSA = Observer Rating Scale of Anxiety; FACES = FACES Rating Scale; STAI-C = State-Trait Anxiety Inventory for Children; YPAS = Yale Preoperative Anxiety Scale; mYPAS = modified Preoperative Anxiety Scale

Risk of Bias Within and Across Studies

Cochrane Collaboration's Risk of bias tool was used to assess the biases at the study and outcome level. Within and across studies, all four NRSs demonstrated high risks of biases. Twelve RCTs demonstrated low risks of biases within studies with the exception of two studies (Lee et al., 2012; Lee et al., 2013), that were assessed as unclear risks. No known selective reporting and publication biases were identified across studies.

Primary Outcome: Anxiety

All AV Interventions vs. Comparator groups (N = 18). A total of 18 studies reported children's anxiety as a primary outcome. Nine studies used various forms of video interventions to reduce preoperative anxiety and seven of these nine reported positive effects in reducing anxiety (Karabulut & Duygu, 2009; Kerimoglu et al., 2013; Lee et al., 2012; Melamed & Siegel, 1975; Mifflin et al., 2012; Pinto & Hollandsworth, 1989; Wakimizu et al., 2009). Five studies examined the effects of multifaceted extensive AV intervention programs (Ellerton & Merriam, 1994; Huth et al., 2004; Kain et al., 1998; Kain et al., 2007; Kain et al., 2001). Two studies compared playing interactive video games with other interventions in reducing pre-op anxiety in children (Lee et al., 2013; Patel et al., 2006). Other AV interventions such as interactive music therapy and internet preparation programs were also examined (Kain et al., 2004a; O'Conner-Von, 2008).

Weighted Mean Differences between AV Interventions and Control/SC. Ten studies were pooled to examine the impact of all AV interventions (Figure 2). Data were available for 864 unique participants in these 10 studies (e.g., 4 videos, 2 multi-faceted

AV preparation programs, 2 interactive games, 1 internet and 1 music therapy) (Kain et al., 2007; Kain et al., 2001; Kain et al., 2004a; Karabulut & Duygu, 2009; Lee et al., 2012; Lee et al., 2013; O'Conner-Von, 2008; Patel et al., 2006; Pinto & Hollandsworth, 1989; Wakimizu et al., 2009). The weighted mean difference was calculated by pooling results of the studies. Overall, there was a -11.4 point WMD (95% CI = -17.29 - -5.59, *p* < 0.01) between anxiety scores in AV interventions and control/standard of care groups. This suggests that AV interventions resulted in statistically significant reductions in pre-operative anxiety in children. It should be noted that the standard of care practice varied greatly between different studies (e.g., no intervention, with parental presence and/or with sedative premedication). There was high heterogeneity in this estimate (I^2=97%).

	AV			Control				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Durst 1990	0	0	0	0	0	0		Not estimable
Ellerton & Merriam 1994	0	0	0	0	0	0		Not estimable
Huth et al. 2004	0	0	0	0	0	0		Not estimable
Kain et al. 1998	0	0	0	0	0	0		Not estimable
Kain et al. 2001	0.5	9	33	17	8.6	37	10.4%	-16.50 [-20.64, -12.36]
Kain et al. 2004	18.5	20.8	51	21.6	20.7	38	8.8%	-3.10 [-11.81, 5.61]
Kain et al. 2007	6	27.4	96	16	30.5	99	9.0%	-10.00 [-18.13, -1.87]
Karabulut & Duygu 2009	-17	4.5	30	2.24	8.2	30	10.6%	-19.24 [-22.59, -15.89]
Kerimoglu et al. 2013	0	0	0	0	0	0		Not estimable
Lee et al. 2012	6	9.8	42	30.1	20	44	9.6%	-24.10 [-30.71, -17.49]
Lee et al. 2013	-20.6	18.7	40	8	13.5	40	9.4%	-28.60 [-35.75, -21.45]
Meladmed & Siegel 1975	0	0	0	0	0	0		Not estimable
Mifflin et al. 2012	0	0	0	0	0	0		Not estimable
O'Conner-Von 2008	2.2	10	28	0.3	9.6	14	9.7%	1.90 [-4.35, 8.15]
Patel et al. 2006	4.3	4.7	38	17.2	4.5	36	10.8%	-12.90 [-15.00, -10.80]
Pinto & Hollandsworth 1989	-2.1	3.1	10	-0.2	2.7	10	10.7%	-1.90 [-4.45, 0.65]
Robinson & Kobayashi 1991	0	0	0	0	0	0		Not estimable
Wakimizu et al. 2009	-0.01	2.1	72	0.9	2.3	76	10.9%	-0.91 [-1.62, -0.20]
Total (95% CI)			**440**			**424**	**100.0%**	**-11.44 [-17.29, -5.59]**

Heterogeneity: Tau² = 81.40; Chi² = 342.89, df = 9 (P < 0.00001); I² = 97%
Test for overall effect: Z = 3.83 (P = 0.0001)

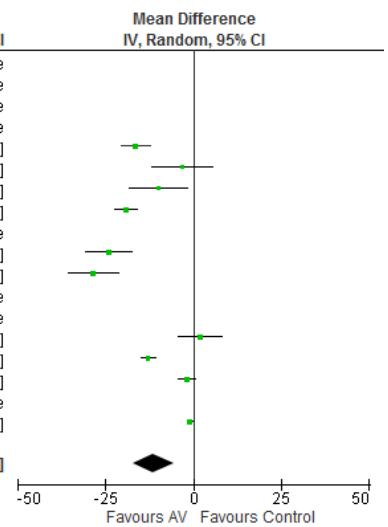

Figure 2. All AV interventions vs. Control/SC for children's preoperative anxiety (WMD= -11.44, 95% CI = -17.29 - -5.59, p<0.01).

Video Interventions vs. Control conditions (n = 5). When compared with control conditions, there seems to be some support for the effectiveness of video interventions in reducing children's preoperative anxiety. The RCT conducted by Pinto et al. (1989) reported that children who watched a 22-minute peer-modeling pre-op preparation videotape one hour prior to admission in the presence of their parent exhibited less preoperative anxiety compared to the control group ($F = 7.47$, $p < 0.0001$) as measured by the ORSA. Similar results was reported in an NRS study by Karabulut et al. (2009) where they reported on a 12-minute pre-op Video Compact-Disc (VCD) training ($M = 23.93$, $SD = 2.92$) given 48-hours before surgery which was found to be significantly more effective in reducing preoperative anxiety than either the control ($M = 40.37$, $SD = 5.68$) or the pre-op booklet training group ($M = 28.6$, $SD = 3.92$) as measured by the STAI-C ($p < 0.01$). In another RCT, Lee et al. (2012) also reported that children who selected and watched an age-appropriate movie from a list using a notebook or tablet personal computer had the lowest mYPAS anxiety scores ($p < 0.01$) in the OR ($M = 31.8$, $SD = 8.8$) compared to children who received standard of care ($M = 57.4$, $SD = 18.1$) or played with their favorite toys ($M = 43.6$, $SD = 16.1$). Finally, in the work of Mifflin and colleagues, children randomized to a video distraction group (i.e., watching an age-appropriate YouTube™ clip) had lower median mYPAS anxiety scores compared to control group at anesthetic induction. The video distraction group also showed a smaller increase in anxiety from holding to induction area than the control ($p < 0.001$) (Mifflin et al., 2012).

Contrary to the above findings, one NRS reported no significant differences in anxiety-related behaviors between a group that received a peer-modeling of a pre-op preparation video and a group receiving preoperative teaching. However, this study failed to include any numerical data (Durst, 1990).

Video Interventions vs. Other Active Intervention(s) (Other Video(s), n = 3; Midazolam, n = 1). In addition to comparing video interventions to control conditions, four studies also compared video interventions alone to videos combined with other interventions. In one RCT, Wakimizu et al. (2009) reported lower anxiety levels on the FACES rating scale ($p < 0.05$) when children were given a peer-modelling pre-op preparation video with an information booklet to use at home as frequently as they wanted ($M = 1.3$, $SD = 1.42$) and compared this to receiving the same video preparation at the hospital ($M = 2.06$, $SD = 1.89$). Similarly, in a NRS by Melamed et al. (1989), state measures of anxiety revealed a significant reduction in preoperative fear arousal in their experimental group that received a 16 minute peer-modeling film pre-op as compared to children assigned to watch a generic film ($F = 3.33$, $p < 0.02$). Furthermore, Kerimoglu's RCT used video glasses with TV program viewing alone (*Mdn* = 33.3, 95% CI = 25-40), midazolam alone (*Mdn* = 45, 95% CI = 32.5-56.7), or both of these in combination (*Mdn* = 47.2, 95% CI = 28.3-56.7). They showed that all interventions were equally effective in preventing significant increase in median mYPAS anxiety scores during induction of anesthesia (Kerimoglu et al., 2013).

On the other hand, one study showed no significant differences between groups that received a peer-modeling video alone, a peer-modeling video along with child coping skills training, and a peer-modeling video along with child and parent coping skills training (Robinson & Kobayashi, 1991). Taken together, these studies suggest that peer-modeling videos are effective in reducing preoperative anxiety in children. Additional research will be required to examine the effects of additional coping skills training in reducing preoperative anxiety in children.

Meta-analysis of the four studies that contained appropriate data on the effectiveness of video interventions was conducted and contained 324 unique participants (Karabulut & Duygu, 2009; Lee et al., 2012; Pinto & Hollandsworth, 1989; Wakimizu et al., 2009). Overall, there was a -8.62 WMD reduction in anxiety scores between video intervention and comparator groups that included both standard of care and other video intervention (95% CI = -15.08 - -2.16, $p < 0.01$; Figure 3). These results suggest that video interventions are more effective than comparator groups at reducing preoperative anxiety. When further examining WMD between video and SC/control interventions only, the mean difference was approximately -11.13 (95% CI = -20.12 - -2.13, $p < 0.01$), indicating that the video interventions were more favorable than standard of care in reducing preoperative anxiety. Examination of the forest plots in Figure 3 suggested that the study of Pinot & Hollandsworth (1989) study accounted for much of the high heterogeneity (I^2=97%) in the pooled estimate. In this work, they reported a mean difference between their peer-narrated video intervention and an adult-narrated video was 0.20 (95% CI = -2.19 – 2.59), neither video was superior to the other.

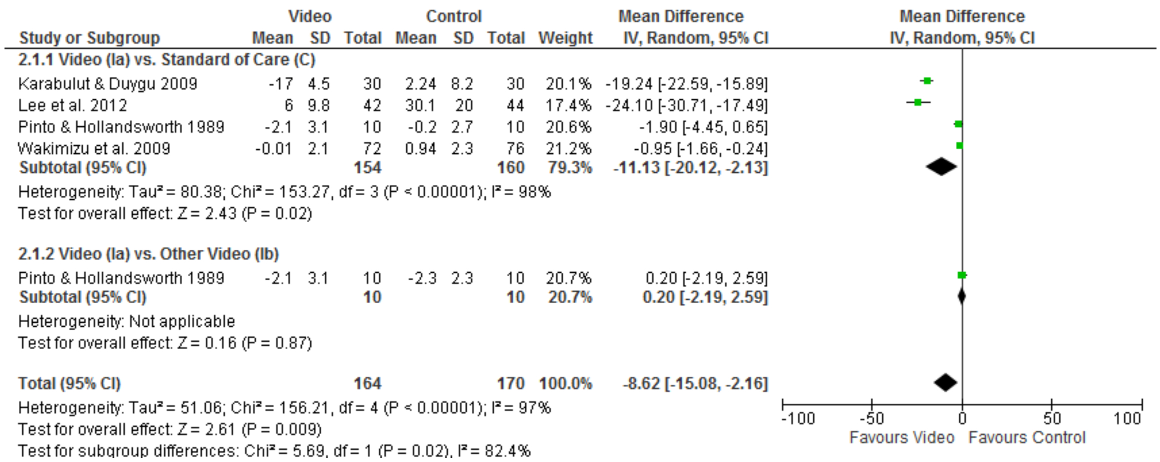

Figure 3. Video Interventions vs. Comparator (e.g., SC or Other Video) groups for children's preoperative anxiety.

Multi-faceted Extensive AV Preparation Programs vs. Comparator Groups (n = 5). Generally, Multi-faceted extensive AV preparation programs included a combination of 2 or more interventions such as procedural preparation and the use of an AV tool. Five studies examined the effects of multifaceted extensive AV intervention programs compared to controls or other interventions. All five reported significant reductions in preoperative anxiety in children (Ellerton & Merriam, 1994; Huth et al., 2004; Kain et al., 1998; Kain et al., 2007; Kain et al., 2001).

Multi-faceted Extensive AV Preparation Programs vs. Control Conditions (n = 4). In a study by Kain et al. (2001), children who received a low sensory stimulation intervention in the OR (i.e., a low light setting at 200 lux, with soft music in the background, and no conversations taking place during the anesthetic induction) were shown to be significantly less anxious compared with the control group on entrance to the OR, and on the introduction of the anesthesia mask ($F = 6.3$, $p = 0.014$) as measured by the mYPAS. In another RCT conducted by Huth et al. (2004), children who received an intervention that consisted of mental imagery booklets, a videotape, and an audiotape reported lower STAI-C anxiety levels ($M = 30.67$, $SD = 6.51$) than those who received standard preparation ($M = 34.27$, $SD = 7.55$) [Cohen's d=0.12]. Kain et al. (2007) also showed that children in their ADVANCE intervention which involved a video, mask practice, and coaching by specialized healthcare support staff exhibited lower mYPAS anxiety levels in the holding area than the standard of care, parental presence, or midazolam groups (Cohen's d=0.54). They were also less anxious during induction of anesthesia compared to the control or parental presence groups, but were found to have similar reductions in anxiety to the midazolam group (Cohen's d=0.33). Thus, multifaceted extensive AV programs may also exhibit an impact similar to midazolam in reducing children's preoperative anxiety. Lastly, children and parents participated in the one-hour program group retrospectively reported less anxiety levels using FACES rating scale during the preoperative period when compared to those that did not receive an intervention (Cramer's V = 0.33, $p < 0.04$) in an NRS (Ellerton & Merriam, 1994).

Multi-faceted Extensive AV Preparation Programs vs. Other Active Intervention(s) (OR tour, n = 1). In one RCT, Kain et al. (1998) showed that children in a multifaceted program with an OR tour, a videotape of pre-op preparation and Child Life preparation exhibited the lowest median levels of YPAS rated preoperative anxiety (*Mdn* = 9, 95% CI = 6-33; $p < 0.05$) during the preoperative period when compared to children that received an OR tour and videotape (*Mdn* = 32, 95% CI = 8-50), or an OR tour only (*Mdn* = 44, 95% CI = 10-72) (Kain et al., 1998).

When the two studies examining Multi-faceted Extensive AV Preparation Program interventions that contained data that permitted meta-analysis were pooled (n = 265) (Kain et al., 2001; Kain et al., 2007), an overall WMD between multi-faceted extensive AV preparation program interventions and standard of care of -13.00 (95% CI = -21.20 - -4.80, $p < 0.01$) was found. This suggests that the multi-faceted extensive AV preparation programs may be superior to control conditions in reducing preoperative anxiety.

Interactive Game vs. Other Active Intervention(s) (Parental Presence, n = 1; Midazolam, n = 1). Two studies compared playing interactive video games with other interventions in reducing pre-op anxiety in children and were shown to be effective. Patel et al. (2006), reported that children who played a handheld videogame (VG) with parental presence (PP) had the lowest anxiety levels as measured by mYPAS at induction (M = 41.7, SD = 4.1; $p < 0.05$) compared to a group that received PP alone (M = 51.5, SD = 4) or received both midazolam and PP (M = 53.9, SD = 2.7). Another study conducted by Lee et al. (2013) also showed that children who used a smartphone with interactive game application (app) exhibited lower mYPAS anxiety scores (M = 38.6, SD = 6.4; $p < 0.01$) compared to the midazolam alone group (M = 44.8, SD = 6.5) at the OR. However, the lowest anxiety scores were reported in group that combined the use of both interventions (M = 30.2, SD = 3.5) (Lee, 2013). Thus, interactive games appear to be more effective than parental presence or midazolam alone in reducing preoperative anxiety in children undergoing elective surgery.

Data from two studies permitted meta-analysis of interactive game interventions compared to standard of care and other interventions (Lee et al. 2013; Patel et al., 2006). Data were available for 154 participants in these two studies. An overall WMD of -18.99 (95% CI = -40.01 – 2.03, p = 0.08) suggested that interactive games may reduce preoperative anxiety to a greater extent than other interventions, but it was not statistically significant. However, the WMD between interactive games and standard of care was statistically significant (MD = -20.36, 95% CI = -35.73 - -5.00, $p < 0.01$), indicating that interactive video games were superior to standard of care in reducing preoperative anxiety. It was found that when comparing interactive games versus the other interventions, the Lee et al. (2013) study favored the interactive game, while the

Patel et al. (2006) study favored the other intervention (i.e. parental presence with midazolam).

Other AV Interventions (Music therapy, n = 1; Internet Preparation Program, n = 1) vs. Control Conditions. Other AV interventions such as interactive music therapy and internet preparation programs did not effectively reduce preoperative anxiety in children undergoing elective surgeries (Kain et al., 2004a; O’Conner-Von, 2008). No differences in mYPAS anxiety scores were found between children receiving either an interactive music therapy group or a control group. Instead, the use of midazolam (0.5 mg/kg 30 min before surgery up to a maximum of 20 mg) seemed to be the most effective when compared with both the interactive music therapy and control group during preoperative periods (Kain et al., 2004a). Similarly, in another RCT study that examined an internet-based intervention program reported no differences in reducing preoperative anxiety in adolescents undergoing elective surgeries compared to the standard preparation group (O’Conner-Von, 2008). While these findings suggest that interactive music therapy and internet preparation programs may not be effective at reducing preoperative children’s anxiety, further research is required before firm conclusions can be made.

Summary of primary outcome. These results suggest that most, but not all, AV interventions are effective in reducing children’s preoperative anxiety. Indeed, 14 of 18 studies using AV interventions reported significant reductions in children’s perioperative anxiety. Meta-analysis resulted from 10 studies also revealed statistically significant reductions in pre-operative anxiety in children. In particular, videos, multifaceted programs, and interactive games were more effective than standard of care and other active interventions with effect sizes ranging from 0.12 to 0.54.

Secondary Outcomes

Pain (n = 2). Two RCTs examined the effect of AV interventions on postoperative pain levels. Huth et al. (2004) reported less pain in children receiving a mental imagery intervention in the immediate postoperative period but not at follow-up 24 hours after discharge as assessed by the Oucher Pain Scale and Facial Affective Scale (FAS). Moreover, internet preparation did not reduce pain intensity two hours after leaving the post-anesthesia care unit compared with the standard preparation condition (O'Conner-Von, 2008).

Postoperative Behavior and Recovery (n = 5). Five studies examined the effects of AV interventions on postoperative behavior and recovery. Children in the ADVANCE multifaceted extensive program group were reported to be less likely to exhibit symptoms of delirium, received only half as much analgesia (e.g., fentanyl), and were discharged from the recovery room 20 minutes earlier than those receiving standard of care (Kain et al., 2007). Moreover, treatment groups that received peer-modeling preoperative preparation videos had less vomiting, crying, and fluid intake as measured by the Recovery Index (Pinto & Hollandsworth, 1989). Despite the fact that all five studies reported effective reductions in preoperative anxiety, three of these studies reported no differences in behavioral changes exhibited immediately postoperatively (Kain et al., 2001; Patel et al., 2006) and at 2 weeks follow-up after surgery (Kain et al., 1998). Thus, reductions in preoperative anxiety in some but not all types of AV can lead to fewer postoperative negative behaviors, less analgesic usage and faster recovery.

Compliance during Anesthetic Induction (n = 2). Two studies reported on children's compliance during anesthetic induction assessed by the Induction Compliance Checklist. Children's compliance scores in a low sensory stimuli group that received low light settings and soft music were higher than the control group (Kain et al., 2001) though there were no differences between an interactive music therapy intervention and control group in another study (Kain et al., 2004a).

Satisfaction with Interventions (n = 2). Two studies examined children's and guardians' satisfaction with AV interventions. Wakimizu et al. (2009) showed that 91.7% caregivers expressed satisfaction with preoperative preparation video. Parents in the 'video at home' group were more active than the control group in explaining the anesthetic induction and other surgical preparations to their children. In another study conducted by O'Conner et al. (2008), higher satisfaction on surgery preparation was also found in both adolescents and parents in the internet group than in the standard preparation program.

Cost-effectiveness (n=1). Only one study reported the approximate cost reduction associated with the use of AV interventions. In Pinto el al.'s study (1989), a video intervention was estimated to reduce health care costs by $183 per child.

Discussion

The objective of this systematic review and meta-analysis was to examine studies assessing the effectiveness of AV interventions at reducing preoperative anxiety in children undergoing elective surgery. To our knowledge, this is the first comprehensive review to systematically investigate the impact of AV interventions on outcomes that included preoperative anxiety, postoperative pain, postoperative maladaptive behaviors, recovery, anesthetic induction compliance, satisfaction, and cost-effectiveness.

Our review suggests that AV interventions are a promising and potentially cost-effective tool in helping to ameliorate children's preoperative anxiety, as well as improving a number of other adverse perioperative outcomes. Fourteen of the 18 studies led to reductions in children's preoperative anxiety. Meta-analysis of the 10 studies on the effectiveness of AV interventions was carried out. Our result showed that there was an overall -11.4 (95% CI = -17.29 - -5.59, $p < 0.01$) statistically significant WMD reduction between preoperative anxiety scores in AV interventions and control/SC groups in children. Videos, multi-faceted programs and interactive games alone or in combination with other interventions (such as midazolam) were the most effective and reported low to medium effect sizes. Generally, these AV interventions were more effective than SC and as effective as midazolam. Conversely, interactive music therapy and internet preparation interventions did not appear to be effective though relatively few studies examined these. There was moderate support for improving children's postoperative behaviors and recovery such as reduced levels of symptoms of delirium, and more rapid recovery. Furthermore, the results of postoperative pain, anesthetic induction compliance, satisfaction and cost-effectiveness comparisons also supported the use of AV interventions. However, these results require more support as only a limited number of studies reported data for these outcomes.

Children and parents seemed to be satisfied with receiving AV intervention at home prior to surgery (Wakimizu et al., 2009). These families were able to use the AV intervention as an additional support to deal with a perceived threatening situation (i.e., surgery) in the comfort of their home rather than in a busy hospital environment. When facing surgery, many children develop a loss of sense of control and fear of the unknown (e.g., the hospital environment, staff, procedures etc.). Therefore, we propose that AV interventions can help these children with regaining a sense of control over this stressful situation by being exposed to procedural material prior to the surgery. Children are also then more likely to be receptive to learning about the complex information if the AV intervention is given in an age-appropriate format and will be better equipped to cope with preoperative anxiety. This will lead to increased satisfaction with the whole perioperative experience (Brewer et al., 2006).

Although only one study has conducted cost-effectiveness analyses, it seems that minimal time and health care resources are involved in the majority of the AV interventions in this review. Because of the automatic and reusable nature of AV interventions, it might be advantageous to include cost-effectiveness analyses in the conduct of future RCTs to examine whether AV interventions are more financially sound options compared to currently used interventions in reducing preoperative anxiety.

Why Did Some of the AV Interventions Not Work?

Of the 18 studies reviewed, only 4 studies showed no reduction in anxiety compared to control interventions. In addition to using various distraction techniques (i.e., interactive games or cartoons), the content of the AV interventions (e.g., what, when, and how the informational component of the perioperative intervention is presented) might also account for the differential treatment effects observed. The findings of the studies contained in this review suggest that AV interventions with procedural information alone might be sufficient for a child to cope with the perceived anticipatory threat, and that any additional coping skills endowed by narration might not be necessary as they fail to contribute to reductions in preoperative anxiety (Kain et al., 1996; Kain et al., 1998). Also, the use of interactive music therapy and internet interventions required minimal interactions and primarily used either audio or visual components, but not both. This stresses the importance of potentially including multi-sensory stimulations for an effective AV intervention.

As mentioned, despite reporting reductions in preoperative anxiety, three studies showed no group differences in postoperative behavioral changes (Kain et al., 1998, 2001; Patel et al., 2006). This discrepancy could be explained by possible modifying variables and/or the tools used to measure postoperative behaviors. Aside from preoperative anxiety, research has shown that a child's age, temperament, parental anxiety and previous hospital experience can independently predict anxiety levels during the preoperative period and its effect on postoperative changes (Kain et al., 1996; Varughese, Nick, Gunter, Wang, & Kurth, 2008; Watson & Visram, 2003).

Furthermore, use of the parent-reported PHBQ scale rather than a child, self-report scale might contribute to three studies showing reductions in anxiety but not postoperative behaviors. Although the PHBQ is widely used and validated, the results may be biased by the parent's perception of their child's behavior (Patel et al., 2006).

This idea of respondent mismatch is also supported by another study that showed mothers might not be as accurate as attending anesthesiologists in predicting their children's anxiety in pediatric settings (MacLaren et al., 2010).

Methodological Quality

While the results of studies of AV interventions are encouraging, there were some methodological issues that need to be noted. All four non-randomized controlled trials revealed a very high risk of bias, lacking important elements such as proper randomization and blinding (Figure 4). Specifically, in one NRS conducted by Durst et al. (1990), the author used non-validated observer's report to note behavioral changes and reported no differences between control and videotape group. When assessing this study with Cochrane Risk of Bias tool, it had very high risk of biases in many domains such as incomplete data and selective outcome reporting. In addition, this study also lacked numerical data which altogether could influence the conclusiveness of the results. With the exception of this Study, 3 of the 4 NRSs revealed positive results in the reduction of preoperative anxiety.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Durst 1990	−	−	−	−	−	?	?
Ellerton & Merriam 1994	−	−	−	−	+	?	+
Huth et al. 2004	+	?	−	−	+	+	+
Kain et al. 1998	+	?	−	−	+	+	+
Kain et al. 2001	+	?	−	−	+	+	+
Kain et al. 2004	+	?	−	−	+	+	+
Kain et al. 2007	+	?	−	−	+	+	+
Karabulut & Duygu 2009	−	−	−	−	+	+	?
Kerimoglu et al. 2013	+	+	−	−	+	+	+
Lee et al. 2012	?	?	?	?	+	+	?
Lee et al. 2013	?	?	−	−	+	+	+
Meladmed & Siegel 1975	−	−	−	−	+	+	−
Mifflin et al. 2012	+	+	−	−	+	+	+
O'Conner-Von 2008	+	?	−	−	+	+	+
Patel et al. 2006	+	+	?	+	+	+	+
Pinto & Hollandsworth 1989	+	?	−	−	+	+	+
Robinson & Kobayashi 1991	+	?	−	−	+	+	+
Wakimizu et al. 2009	+	?	+	+	+	+	+

Figure 4. Risk of Bias summary.
Each risk of bias item was assessed for each included study. If the study addressed the domain appropriately, low risk of bias was assigned (+). If the domain was addressed inappropriately, high risk of bias was assigned (-). If information was unavailable to reach a judgment, then an 'unclear' risk of bias was assigned to that domain (?).

The majority of RCTs demonstrated low risks of biases in the assessed domains with the exception of a few. In the Kain et al. (2004a) study, subgroup analysis revealed differential therapist effects. This differential effect might be attributed to differences in skill training, and potentially biased the results. It is important to note that an ideal AV intervention should not require skill training in its use or administration. Another RCT study examined an internet preparation program conducted at home, which raises some issues with non-compliance with the program. It is difficult to determine whether or not the adolescents have used the internet program as intended, to the fullest extent or without distractions during use (O'Conner-Von, 2008). Additionally, two RCTs were assessed as 'unclear risks' due to the incomplete reporting on randomization and blinding methods (Lee et al., 2012; Lee et al., 2013). Across studies, blinding of the participants was difficult due to the visibility nature of these interventions. Double-blinding was only reported on one study of the RCTs (Wakimizu et al., 2009). In addition, the definition of 'standard of care' was poorly explained in several studies (Kain et al., 1998; Kerimoglu et al., 2013; Patel et al., 2006). Some of these studies revealed potential confounding biases as co-interventions such as Child life specialists and parental presence that were considered as part of 'standard of care' or used as optional rescue therapy (Kain et al., 1998; Kain et al., 2001; Kain et al., 2004a). These methodological issues need to be considered when the findings of these studies are examined at the outcome level. It seems that high risk NRS showed better effects whereas lower risk RCTs showed poorer effects of their interventions on outcomes.

When designing future RCTs, investigators should consider the use of proper randomization and blinding strategies, the administration of both validated observers' reports and self-reports of behavioral changes, and the use of the intention-to-treat method as the primary analysis. These changes would enhance the validity of the results of studies. In addition, it might also be beneficial to take a more descriptive approach to the definition of "standard of care". This is an important issue because studies that include co-interventions may show less of an effect than those involving no other interventions.

How Do AV Interventions Affect Preoperative Anxiety?

Potential Mechanisms. While the mechanisms by which AV interventions reduce perioperative anxiety have not been formally studied, these may operate by enhancing cognitive coping strategies via the use of various distraction techniques (see Figure 5). Similar techniques are also widely use in reducing anxiety with other medical procedures such as cancer treatment, childhood immunizations and venipuncture (Kleiber & Harper, 1999; Koller & Goldman, 2012; Wint, Eshelman, Steele, & Guzzetta, 2002).

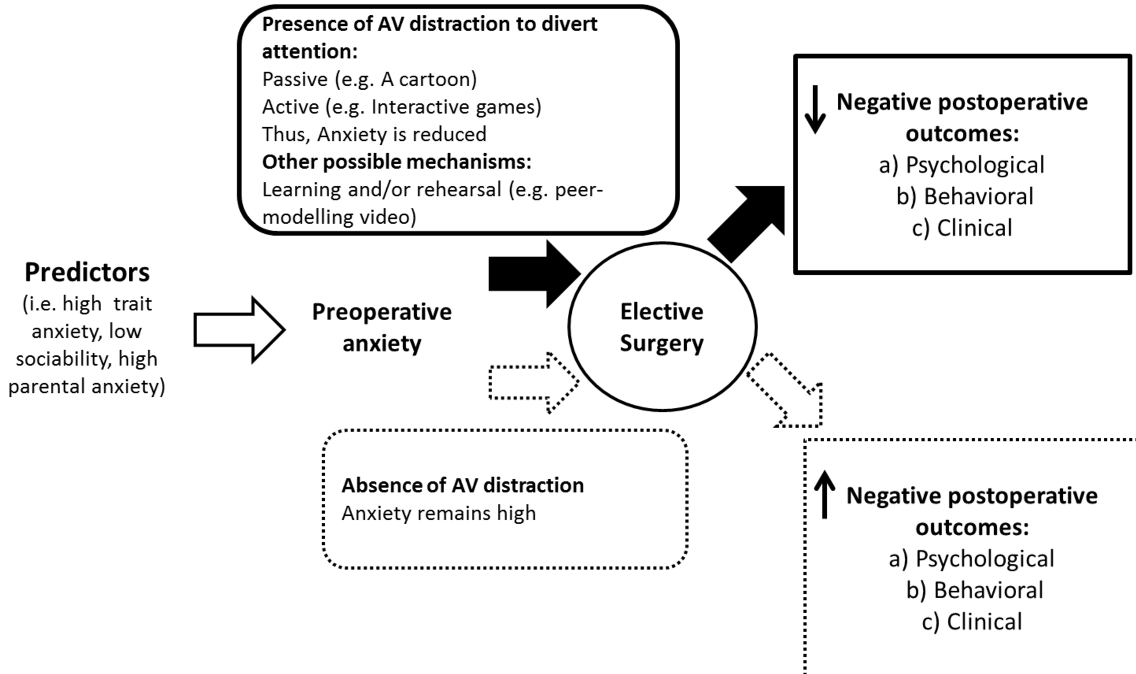

Figure 5. This theoretical model shows the potential mechanisms by which AV interventions may reduce preoperative anxiety and associated morbidity in children undergoing surgery. Predictors such as high trait anxiety and low sociability lead to elevated preoperative anxiety. AV distraction and other mechanisms (e.g., learning and/or rehearsal) reduce preoperative anxiety and ameliorate negative postoperative psychological, behavioral and clinical outcomes. Contrarily, preoperative anxiety remains high in the absence of AV distraction.

As Koller and Goldman have postulated, distraction competes for and diverts children's attention from perceived threatening stimuli (such as anesthetic induction) to non-threatening stimuli (e.g., videos and playing interactive games), thus reducing anticipatory distress and anxiety. This diversion of attention can be further subdivided into active and passive distraction (Koller & Goldman, 2012).

Passive distraction redirects a child's attention by observation. In this review, using peer-modeling preoperative preparation videos, viewing a cartoon, an online videoclip or using video glasses can passively distract participants. Most of these interventions do not require the child's feedback and input. Peer-modeling videos also allow the child to learn new skills by passively watching another child similar to themselves to perform a task which he/she will later mimic. In order for the intervention to be effective, peer-models should be age- and developmentally matched with observer in order to properly convey the complex perioperative information (Kain et al., 1996; Schunk, 1987).

Active distraction, on the other hand, actively promotes the child's participation in an activity prior to surgery. Interactive games are examples of active AV distraction. Patel et al. (2006) demonstrated the use of active distraction as playing a video game involves active engagement and interaction in addition to the diversion of attention. Active distraction requires more cognitive processing to focus and to provide feedback on the task. Theoretically, by shifting their attention and cognitive processing, the child becomes less aware of their environment making them less anxious about the surgery during the preoperative period (Dahlquist, Pendley, Landtrip, Jones, & Steuber, 2002).

In general, using either active or passive AV distractions can be effective in reducing preoperative anxiety. The literature seems to suggest that the more sensory modalities (i.e. auditory, visual, kinesthetic and tactile senses) that are recruited or used in an AV intervention, the less attention that will be available for the perceived threatening stimuli, thereby potentially optimally attenuating the distress associated with perioperative procedures (DeMore & Cohen, 2005). Aside from distraction, preoperative anxiety might also be reduced via the learning and rehearsal of relevant procedural information before surgery as was demonstrated in peer-modelling video-based interventions or operating room orientation tours. This prior exposure essentially allows for children and parents to cognitively cope with the uncertainty associated with the impending hospital experience. This view is also supported by Neufeld & Davidson (1971), who suggested that surgical stress can be reduced if adult patients can mentally work through upcoming events and develop a feeling of being able to actively cope with it in order to reduce surgical threat. While beyond the scope of this review, it might be worthwhile for future studies to examine the specific impact of rehearsal effects and/or knowledge gain from AV interventions. Future research should also focus on more fully understanding the mechanisms underlying the effectiveness of AV interventions so that they can be optimized for clinical use.

Limitations

It is important to note that there was substantial clinical and methodological heterogeneity (i.e., SC practices, interventions, timing and duration, outcome measures using various scales, and different comparison groups etc.,) across studies. Thus, it is difficult to definitely pinpoint which aspects of the AV interventions will be the most beneficial.

In this review, four studies were conducted by a single research group and so in order to establish the validity and generalizability of their results, their findings should be replicated by other independent research teams. Second, only children receiving elective surgeries (i.e. tonsillectomy and herniorraphy etc.,) were included in this review to control for confounding factors. Effects of AV interventions on other types of surgery such as dental or more invasive surgeries should also be examined in order to establish the generalizability of our conclusions. Third, many of these studies have small samples sizes and only eight provided justification for their recruitment numbers. Larger, adequately powered RCTs need to be conducted to replicate these results. Fourth, as this is the first to review the effectiveness of AV interventions, a wide range of modes was included. Future studies should investigate subtypes of AV interventions, their intensities, durations, and frequencies (i.e., dose) to see which components contribute most to effectiveness and to develop the most optimal intervention(s). Fifth, the scales used to report preoperative anxiety across studies varied widely. A new tool, specifically a self-reported, age-appropriate instrument, should be developed to measure preoperative anxiety more accurately. Sixth, inconsistent assessment and measurement time points, ranging from one week before surgery up to just prior to anesthetic induction, were used. Because of this inconsistency, it was difficult to determine the optimal administration time of the AV intervention preoperatively. And seventh, high variability exists in control groups within studies, ranging from no intervention, to including parental presence, midazolam, or Child life specialists. Lastly, only 1 of 18 studies had looked at the effects of AV interventions in the adolescent population, thus this limits our findings to mostly younger children. Given that many developmental changes occur during the transition from childhood through adolescence, this highlighted the importance of possibly examining the developmental trajectories of preoperative anxiety in children and adolescents undergoing surgery in future work.

Recommendations

Based on our results, simple, interactive, multi-sensory AV interventions should be given a sufficient amount of time prior to surgery and divert a child’s attention to allow the child to internalize learned information seem to be ideal. Such interventions should also be designed in the form of peer-modeling to be age and developmentally appropriate. The minimum frequency requirement for administration seems to be at least once prior to surgery, and at least 5 minutes in length. To maximize its effectiveness, it should be available for use as frequently as desired, making the home setting an ideal place for the intervention.

This review highlights the need for large, adequately powered RCTs with optimal measurement quality to accurately evaluate the effects of AV interventions. Furthermore, the inclusion of more complex and/or repeated surgical events experienced by children should be included given their clinical relevance. Recent technological advancements will allow the incorporation of age-appropriate preoperative information in the form of technologies such as virtual reality programs and tablet-based applications. Further exploration of the importance of timing and exposure in these interventions is warranted, as is the inclusion of tracking software to record exposure quantity, as well as interactive modules that incorporate preferences and feedback from users would also help to optimize interventions. Moreover, there is paucity in the literature as to the effects of AV interventions on perioperative outcomes in adolescents. Thus far, only one study has investigated the effects of internet preparation on adolescents between the ages of 10-16 and reported no significant differences in preoperative anxiety and pain intensity between SC and intervention groups. It might be of significant value to examine the effectiveness of AV interventions in both children and adolescents undergoing surgery. Finally, future studies should delineate potential predictors and moderators of interventions on perioperative anxiety.

Conclusion

In conclusion, there is evidence to support the use of AV interventions in reducing anxiety for children who are undergoing elective surgeries. Our results, both quantitatively and qualitatively, show that AV interventions are more effective than SC in reducing anxiety, post-operative pain, behaviors and recovery, improving compliance during anesthetic induction and are well-tolerated. As such, AV interventions might be an attractive solution to optimizing perioperative care in children. Future studies should examine the impact of preoperative anxiety in all children and adolescents undergoing surgery.

Clinical Implications

Reducing preoperative anxiety has the potential to optimize surgical care. Despite its high prevalence, preoperative anxiety in children remains an understudied topic. Children experiencing preoperative anxiety and their families are affected in many ways. Aside from the emotional distress and trauma they can experience, these children are at a much higher risk of manifesting maladaptive behaviors such as separation anxiety, aggression toward authority figures, sleep problems, and increased fear of physicians (Kain et al., 1996). These children generally have issues with future healthcare compliance which further poses threats to their individual health and development. Furthermore, preoperative anxiety also leads to increases in analgesic consumption, prolonged stays in recovery areas, delay in entry to operating rooms, and longer hospital stays which together increase suffering and healthcare costs. AV interventions appear to be a promising tool for reducing preoperative anxiety and ameliorating postoperative anxiety and its associated morbidity in children undergoing surgery. AV interventions can be effective if used independently or adjunctively to SC practice. They are cost-effective, readily accessible, easy to administer, and have the potential to be adapted and used in many hospital settings.

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CHAPTER THREE

STUDY 2

TITLE: Children's Perioperative Multidimensional Anxiety Scale (CPMAS): Development and Validation

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CONTEXT AND IMPLICATIONS OF THIS STUDY: This second study of the thesis addresses the need for a useful perioperative tool in to assess children's preoperative anxiety. At present, the limitations associated with existing children's anxiety measures may prevent us from accurately and conveniently assessing perioperative anxiety in clinical settings. Gaps in this area were impetus for the development and validation of the CPMAS, a tool that uniquely measures child's state anxiety in this study.

The findings of this study provide empirical evidence to support the reliability and validity of the CPMAS scores in assessing perioperative anxiety in children undergoing elective surgery. This suggests that this brief 5-item self-report has the potential to be a useful and valid tool for the evaluation of anxiety in routine clinical practice and research settings.

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Abstract

Up to 5 million children are affected by peri-operative anxiety in North America each year. High peri-operative anxiety is predictive of numerous adverse emotional and behavioral outcomes in youth. The Children's Perioperative Multidimensional Anxiety Scale (CPMAS) was developed to address the need for a simple, age-appropriate self-report measure of pediatric perioperative anxiety in busy hospital settings. The CPMAS is a visual analog scale comprised of five items, each of which is scored from 0 to 100. The objective of this study was to assess the psychometric properties of the CPMAS in children undergoing surgery. Eighty children aged 7 to 13 years who were undergoing elective surgery at a University-affiliated children's hospital were recruited. Children self-completed the CPMAS and the Screen for Childhood Anxiety Related Disorders (SCARED-C) at three time points: at preoperative assessment (T1), on the day of the operation (T2), and 1 month postoperatively (T3). Internal consistency, test-retest reliability and the convergent validity of the CPMAS were assessed across all three visits. The CPMAS demonstrated good internal consistency (Cronbach's $\alpha \geq .80$) and stability (ICC = 0.71) across all three visits. CPMAS scores were moderately correlated with total SCARED-C scores (*r's*=.35 to .54, *p*'s < .05 to .01) and (*r's*=.29 to .71, *p*'s < .05 to .01) for the state-related anxiety scores at all three time points, suggesting the CPMAS and SCARED-C measures tap similar but not identical phenomena. These results suggest that the CPMAS has the potential to be a useful tool for evaluating perioperative anxiety in children undergoing surgery.

Introduction

Of the nearly 5 million children who undergo surgical procedures in North America annually, up to 75% will develop elevated pre- and postoperative anxiety (Perry, Hooper, & Masiongale, 2012). Children with heightened preoperative anxiety are three and a half times more likely to develop a range of adverse postoperative outcomes, including separation anxiety, maladaptive behavioral patterns, and increased distress in surgical recovery (Fortier, Del Rosario, Martin, & Kain, 2010; Kain, Mayes, Caldwell-Andrews, Karas, & McClain, 2006; Kain et al., 1996; Wollin et al., 2004). In fact, nearly 50% of youth with preoperative anxiety exhibit postoperative behavioral changes, including aggression toward authority figures, feeding problems, insomnia, and nocturnal enuresis (Fortier et al., 2010; Kain et al., 2004, 2006; Kain et al., 1996; Kain, Wang, Mayes, Caramico, & Hofstadter, 1999; Litke, Pikulska, & Wegner, 2012). Kain et al. (1996) reported that 54% of these children continued to experience negative behavioral changes up to 2 weeks after surgery, 20% up to 6 months later, and 7.3% 1 year after their procedures.

In addition to these adverse emotional and behavioral reactions, children with higher levels of preoperative anxiety often have a more complicated operative and postoperative course, including prolonged anesthesia induction, poorer postoperative recovery, higher doses of postoperative analgesia requirements, and postoperative delirium (Kain et al., 2006; Maranets & Kain, 1999). These children also have a longer postoperative course of recovery with elevated levels of complications and prolonged wound healing (Brewer, Gleditsch, Syblik, Tietjens, & Vacik, 2006; McCann & Kain, 2001). Finally, children with greater preoperative anxiety are three times more likely to exhibit postoperative anxiety and elevated levels of postoperative pain (Caumo et al., 2000). These adverse outcomes can have both transient and long-term detrimental effects on a child's health and development. In order to properly describe and understand the precursors and sequelae of perioperative anxiety, brief, objective, reliable, and valid tools need to be developed that can accurately measure perioperative anxiety in busy and complex clinical settings.

While several measures are currently used to assess anxiety in pediatric surgical settings, existing scales have limitations and have led to their relatively inconsistent use in studies of perioperative anxiety. For example, the modified Yale Preoperative Anxiety Scale [mYPAS] (Kain et al., 1997) consists of 5 items that assess a child's activity, vocalizations, emotional expressivity, state of arousal, and utilization of their parent preoperatively. It takes approximately 5 minutes to complete (Kain et al., 1997) and has been shown to have good internal reliability (Jenkins, Fortier, Kaplan, Mayes, & Kain, 2014). Despite these strengths, this observer-rated scale is susceptible to bias (i.e., inter-observer variability) and requires that healthcare staff and research assistants be trained on its administration at multiple assessment points (Wright, Stewart, & Finley, 2013). Unfortunately, from a practical standpoint, the busy hospital setting offers very limited observation time for healthcare and study staff to fully and accurately assess preoperative anxiety (Jenkins et al., 2014). Another disadvantage of the mYPAS is that it also does not allow for the assessment of postoperative anxiety.

Other scales such as the Visual Analog Scale [VAS] (Deloach, Stiff, & Caplan, 1998) and Wong-Baker FACES [FACES] scale (Wong & Baker, 1998) have been applied in this setting. The VAS is a single 100-mm wide horizontal line with "no pain" and "worst possible pain" anchors at each end (Deloach et al., 1998). Similarly, FACES is a one-item scale composed of 6 cartoon faces ranging from happy to sad to crying faces (Wong & Baker, 1998). However, both the VAS and FACES are primarily used to assess children's pain. As the construct of pain and anxiety are conceptually different, more research is required to determine the psychometric properties of these scales in the assessment of children's anxiety. These one-item scales provide very limited information and may lack the accuracy and comprehensiveness required to adequately describe and measure perioperative anxiety. Moreover, the reliability of these single-item scales is also unclear as internal consistency cannot be assessed for one-item scales (Lee & Kieckhefer, 1989; Wewers & Lowe, 1990). However, a multi-item VAS that combines several related constructs could allow for a more accurate assessment of a complex phenomenon such as anxiety or fear (Foster & Park, 2012; Gift, 1989).

Two other self-report measures that have been used to assess children's anxiety in the clinical setting are the State-Trait Anxiety Inventory-Children [STAI-C] (Spielberger et al., 1973), and the Screen for Child Anxiety Related Emotional Disorders - Child Version [SCARED-C] (Birmaher et al., 1997). The STAI-C, is a 40-item scale that measures both stable (trait) and situational (state) anxiety (Spielberger et al., 1973) and the SCARED-C is a 41-item screening instrument that measures childhood anxiety disorders (Birmaher et al., 1997). The SCARED-C is a "gold" standard that encompasses many facets of childhood anxiety symptoms. Both of these scales take approximately 10-15 minutes to complete and were designed primarily to assess anxiety outside of hospital and other medical settings. While both have demonstrated good validity and reliability outside of the surgical context, their length and lack of specificity in this medical environment makes these scales cumbersome to administer, particularly in busy operative areas (Birmaher et al., 1997; Papay & Hedl, 1978).

At present, the limitations associated with existing children's anxiety measures may prevent us from rapidly and accurately assessing perioperative anxiety in clinical settings. Ideally, a useful perioperative tool should be reliable, valid, short and informative, utilize self-report, and be age-appropriate, as well as specific to perioperative settings. Existing gaps in this area have led us to develop the CPMAS, a tool that uniquely measures state anxiety.

The phenomenon of anxiety contains multiple components and emotions, with cognitive/affective, behavioral, and physiological manifestations. Anxiety is also comprised of the constructs of both worry and fear. Worry is a cognitive construct and a normal adaptive negative emotion associated with the anticipation of future threat (e.g., thinking about bad things that could happen during the surgery). Fear on the other hand, is defined as the normal adaptive biological reaction to an immediate real or perceived threat (e.g., fears of needles and pain associated with the surgery). Heightened anxiety regarding surgery may lead to distress and chronic avoidance of the source (e.g., high preoperative anxiety leads to avoidance of future surgeries) (McMurtry et al., 2015). In order to properly capture the richness of the of the phenomenon of anxiety, we have included items such as “worried”, “scared” and “nervousness” as they allow for a more comprehensive assessment of the multidimensional nature of the anxiety construct (Barlow, 1998; Chorpita & Barlow, 1998; Silverman, La Greca & Wasserstein, 1995). These inter-related but different aspects of anxiety are subjective and are likely best measured via self-report in the surgical context. It is particularly challenging for pediatric healthcare providers to assess children’s fear and anxiety in medical settings and so it is vital that a proper measure be utilized (i.e., CPMAS) that allows for children to communicate how they feel briefly and accurately (Foster & Park, 2012).

The CPMAS is a brief, age-appropriate self-report scale that is designed to evaluate pediatric perioperative anxiety in the busy hospital setting. The measure is a five-item visual analog scale that quantifies perioperative anxiety numerically for a total score of 0 to 500. Children as young as 3 years are able to self-report on anxiety (Wright et al, 2010), and as long as they have the ability to comprehend space, numbers and distance, they are able to correctly self-report on their anxiety levels using VAS scales (Foster & Park, 2012). By age 7, concrete operations emerge: children develop an understanding of their mental operations and so the majority of children older than 7 are capable of reporting their feelings accurately. A number of other studies have also demonstrated the validity of numeric visual analog self-report scale to measure preoperative anxiety and/or pain in children between 7–13 years of age (Bringuier et al., 2009; Crandall et al., 2007; Garra et al., 2010).

The objective of the present study was to assess the psychometric properties of the CPMAS in 7-13 year old children undergoing surgery. We aimed to test the reliability of CPMAS scores by examining the internal consistency at three time points and test-retest reliability across all three perioperative visits. The convergent validity of CPMAS scores (using the SCARED-C) were also examined. We hypothesized that CPMAS would demonstrate good internal consistency and test-retest reliability at all three time points. CPMAS scores were also predicted to be moderately correlated with overall SCARED-C scores at all three time points, given that the two measures tap similar, but not identical features of anxiety.

Method

Participants

Eighty children (50 boys, 30 girls) with a mean age of 9.8 ± 0.18 years (range 7 to 13) who were scheduled to undergo elective outpatient surgical procedures (i.e., tonsillectomy, adenoidectomy and herniorraphy) at a single University-affiliated children's hospital were recruited during their preoperative clinic visits. Informed assent and parental consent were obtained prior to enrollment in the study. Enrollment took place between September 2013 and February 2015. Children diagnosed with neurodevelopmental disorders (e.g., autism spectrum disorders, visual and/or hearing impairment, etc.), and whose families were unable to comprehend the study process (i.e., enrollment, completing measures, receiving telephone calls, the right to withdraw from the study at anytime etc.) or to provide consent due to language barriers were not eligible to participate.

Measures

CPMAS. The CPMAS is a five-item visual analog scale that quantifies perioperative anxiety numerically. Each question directly asks about how the child feels under/during various perioperative settings.

During the administration of the CPMAS, children were told to respond to questions in a way that reflected exactly how they feel about the surgery at that moment. In particular, they were asked each CPMAS question individually as they were shown the visual analog scale. Children were told to draw a line on the number that was closest to how they felt with 0 representing “not at all X” and 100 representing “very X” for that item. At all three timepoints, children were reminded of the fact that they were answering questions about their surgery while completing the scale. For example, children were asked “Right now, how worried are you? Please answer by drawing a line on the number that is closest to how you are feeling about the surgery, from a scale of 0 to 100 with 0 meaning not at all worried, 100 meaning very worried or any numbers in between." (see Figure 1).

Summing the responses to the CPMAS items produces a score ranging from 0 to 500, with higher values indicating greater anxiety. (Note: Item 4 was only applicable during preoperative periods and so this item was eliminated at the postoperative assessment).

Scale Development of the CPMAS. The CPMAS was created by a team of experts from various disciplines, including a developmental personality psychologist with 20 years of experience in studying children’s anxiety, an anesthesiologist with over 20 years in pediatric anesthesiology, a psychiatrist, and a child clinical psychologist with over 40 years of clinical experience with children's anxiety. During the planning/construction phase, the expert panel created dozens of preliminary question items using theoretical and empirical domains of child anxiety from the extant literature based on their practical and research experiences (Birmaher et al., 1997; La Greca & Stone, 1993; Reynolds & Richmond, 1978). During pilot testing, the panel reviewed preliminary item tryouts, edited items and reduced the number of items to only include appropriate and relevant contents manifested during the perioperative periods. The original CPMAS had a total of 6 items. Data were collected on all 6 items at all three study time points. Preliminary analysis showed that Item #2 "Right now, how happy are you?" had low inter-item correlations (range from .131 to .404), and the stability of the scale was improved when this item was removed (as shown by an increase in Cronbach's alpha from .85 to .89). As a result, the team agreed that the "happy" item/construct was theoretically different from the "anxiety" construct. Accordingly, the decision was made to remove it from the scale. We also removed item #5 "Right now, I feel scared that this might hurt" from the postoperative visit because it did not apply postoperatively. Therefore, this item was eliminated for T3 follow-ups only. The CPMAS panel had agreed on the final version of the 5-item CPMAS used preoperatively in this study.

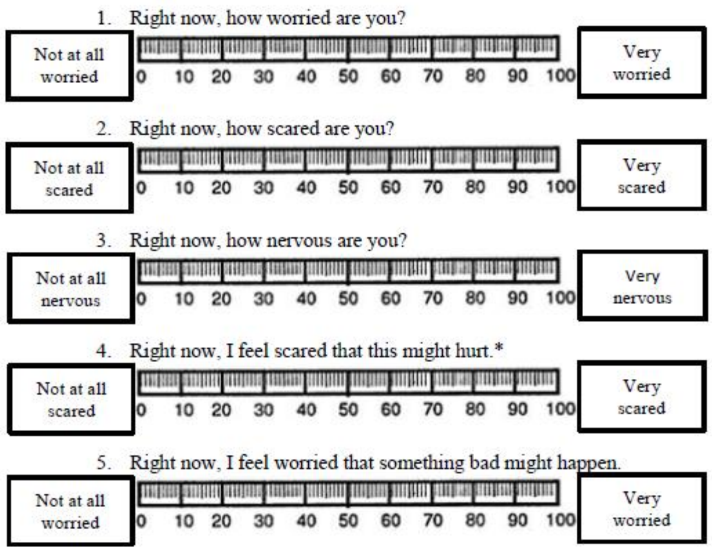

Figure 1. Children's Perioperative Multidimensional Anxiety Scale.

*Note: Item 4 is only applicable during preoperative periods.

SCARED-C. The SCARED-C is a 41-item self-report scale that screens for common pediatric anxiety disorders in children aged 8 to 18 years. It contains subscales for social anxiety disorder, panic disorder or significant somatic symptoms, generalized anxiety disorder, separation anxiety disorder, and significant school avoidance. Scores on each item range from 0 (not true) to 2 (very true). A total overall scale score of ≥ 25 suggests the presence of an anxiety disorder. The SCARED-C has demonstrated excellent reliability with internal consistency of $\alpha = .74$ to .93 and test-retest reliability of intraclass correlation coefficients = .70 to .90 and validity between anxiety and other disorders and within anxiety disorders), and moderate parent-child agreement ($r = .20$ to .47, $p < .001$, all correlations) (Birmaher et al., 1997).

Two state-related items within the Generalized Anxiety Subscale (i.e. Q7- "I am nervous", and also Q33- "I worry about what is going to happen in the future") were selected for further analyses. These two items were selected and used to examine convergent validity with the CPMAS.

Procedure and Data Collection

Data were collected at three time points: at preoperative assessment (T1), immediately preoperatively on the day of surgery (T2), and 1 month postoperatively (T3). Children completed two self-reports, the CPMAS and the SCARED-C, at these time points. Demographics such as sex, age, previous hospitalization, preoperative preparation with a Child life Specialist, parental sex and parental age were also collected at T1.

This study and all procedures were approved by the Local University Hospital Research Ethics Board. Written informed assent and consent were obtained from children and parents.

Pilot Testing

The present study was completed in three phases. The first phase was conducted to assess the psychometric properties of the CPMAS, to determine if our recruitment procedures were feasible and if CPMAS scores were stable across preoperative visits (i.e. T1 and T2). We demonstrated that participant recruitment (n = 30) and anxiety assessment were feasible at these time points. However, in this phase, we identified the issue of reduced study retention during postoperative visits. This was due to the fact that many outpatient surgical patients did not return to the clinic for follow-up and/or were not recommended to return to the follow-up clinic. In our second phase, we recruited another 30 children and followed up via telephone protocol. In the last phase, we recruited another 20 participants and administered the revised 5-item CPMAS scale using the refined protocol.

Statistical Analysis

Descriptive analyses were conducted to report on all demographic and anxiety outcomes. The Pearson product-moment correlation coefficient (r) was used to determine the strength of the associations between CPMAS administration between time points. Paired Samples t-tests were performed to determine construct validity by comparing the differences of CPMAS scores between the preoperative (T1 and T2) and postoperative (T3) groups.

Internal consistency was evaluated using Cronbach's alpha (Cronbach's α). Test-retest reliability was assessed using intraclass correlations (ICC) across all three visits. Inter-item correlations were also examined. Finally, the total SCARED-C and state-related items of the SCARED-C were administered simultaneously with the CPMAS during all three visits to assess the convergent validity, using the Pearson product-moment correlation coefficient (*r*). Item analyses were also conducted on two selected state-related items within the Generalized Anxiety Subscale (i.e. Q7- "I am nervous", and also Q33- "I worry about what is going to happen in the future") as our outcomes.

Sensitivity to change was assessed using the Standardized Response Mean (SRM) change coefficient. We defined the magnitude of the change using Cohen's *d*, where an effect size (ES) of less than 0.20 is trivial, ≥ 0.20 to < 0.50 is small, ≥ 0.50 to < 0.80 is moderate and ≥ 0.80 is large (Stratford & Riddle, 2005).

A post-hoc power analysis for the correlation of CPMAS scores between timepoints was conducted based on our pilot data and revealed that a minimum of 80 participants would be required to achieve 80% ($\beta = 0.2$) statistical power with a significance level of 0.05 ($\alpha = 0.05$) to detect a correlation coefficient of $r = 0.31$. Additionally, a power analysis for a one-group paired samples *t* test was also conducted using CPMAS scores and revealed a mean difference of 37 and a standard deviation of 24 between T1 and T2 and a mean difference of 136 and a standard deviation of 25 between T2 and T3. A minimum of 6 participants would be required to achieve 80% ($\beta = 0.2$) statistical power to detect a significance difference ($\alpha = 0.05$) between the 2 groups at these timepoints. Furthermore, a power analysis for Cronbach's alpha with 5-items was conducted and revealed a minimum of 10 participants to achieve 80% ($\beta = 0.2$) statistical power with a significance level of 0.05 ($\alpha = 0.05$).

To account for attrition, sensitivity analyses using independent samples *t*-test and chi-square tests were conducted to compare the baseline characteristics between those who remained in the study and those who did not complete all of the assessments (Table 1). A sensitivity analysis was also conducted to compare the results between those who received preoperative preparation by Child life Specialist and those who did not, and to compare the anxiety measures between those 8-13 year old (the recommended age for SCARED-C) and children who were 7 years old.

Data were analyzed using SPSS (22.0, SPSS Inc., Chicago, IL, USA). *P-values* < 0.05 was considered statistically significant.

Results

Table 1 shows the demographic characteristics of the study sample. Children's baseline anxiety scores were assessed on average of 10 days before surgery ($M = 10.05$, $SD = 10.08$). The majority of these children received otolaryngologic surgeries (57.5%) and urologic surgeries (21.3%). As part of the standard of care routine at this hospital, most children (97.5%) received preoperative preparation by a Child life Specialist during their preoperative clinic visit. As preoperative preparation by Child life Specialists was available only for 4 hours each day, two children who came in before or after these hours did not receive this preparation.

Table 1. *Demographic Characteristics of Children and Family (N=80)*

	Characteristics	Complete	Incomplete (T2)	Incomplete (T3)
Children				
	Gender, % (Boys/Girls)	62.5/37.5	18.8/7.5	37.5/16.3
	Age, *M* ± *SD*	9.8 ± 1.62	9.9 ± 1.49	9.9 ± 1.57
	Baseline CPMAS scores, *M* ± *SD*	146.09 ± 128.72	123.57 ± 96.84	140.65 ± 128.09
	Baseline SCARED-C scores, *M* ± *SD*	24.71 ± 15.25	23.44 ± 16.25	22.25 ± 14.55
	Type of Surgery, %			
	Otolaryngologic	57.5	13.8	27.5
	Urologic	21.3	3.8	12.5
	General Pediatric	15	3.8	8.8
	Ophthalmologic	5	3.8	3.8
	Dental	1.3	1.3	1.3
	Child Life Specialist, % (Yes/No)	98/2	25/1.3	25/1.3
	Previous Hospitalization, % (Yes/No)	9/71	2.5/23.8	5/48.8
Parents				
	Mother/Father/Other, %	73.8/21.3/5	20/3.8/2.5	48.8/11.3/2.5
	Age, *M* ± *SD*	40.43 ± 7.57	39.24 ± 7.25	39.28 ± 6.49
	Household Income, *Mdn*	$82,290 (Cdn)		

% = Percentage; *M* = Mean; *SD* = Standard Deviation; *Mdn* = Median; Cdn = Canadian dollars; CPMAS = Children's Perioperative Multidimensional Anxiety Scale; SCARED-C = Screen for Child Anxiety Related Disorders- Child Version.

Children of all ages in our sample were able to read and understand the questions of the assent form and measures. A total of 5 children were 7 years old at the time of testing. The results of our sensitivity analysis showed no significant differences between those who were 8-13 years old and those who were 7 years old on any outcome measures ($p > 0.05$).

All 80 children completed the CPMAS at T1. Fifty-nine children completed the CPMAS at T2 and 37 children completed the CPMAS at T3. In Table 2, the descriptive statistics of the CPMAS and SCARED-C scores are shown. The mean CPMAS score is 146.09 ± 128.72 (range 0-500) at T1, 182.71 ± 135.01 (range 0-500) at T2 and 46.24 ± 69.61 (range 0-230) at T3. In keeping with general clinical experience, the mean CPMAS scores increased from T1 to T2 ($p > 0.05$) and decreased from T2 to T3, with the highest scores at T2 (immediately pre-operatively).

SCARED-C scores were available for 45 children at T1, 20 children at T2, and 31 children at T3 (see Table 2). Only a portion of recruited children were able to complete SCARED-C at T2 due to the accommodations made for operating room schedule changes or insufficient time in holding area for children to complete the entire SCARED-C scale. Overall SCARED-C scores were near the cutoff score of 25 at T1, and slightly below the cutoff score at T2 and T3. Most of the mean SCARED-C subscale scores were below individual cutoffs, the exception being Separation Anxiety Disorder (SpD). All children scored 5 or higher on SpD items across all three time points, suggesting that operative procedures might increase levels of SpD.

Table 2. *Descriptive Statistics of the CPMAS and SCARED-C scores*

	Anxiety Scores	N	*M* ± *SD*	*Range*
CPMAS				
	Preoperative visit (T1)			
	Boy	50	126.74 ± 120.18	0-500
	Girl	30	178.33 ± 137.89	0-400
	Total	80	146.09 ± 128.72	0-500
	Day of surgery (T2)			
	Boy	35	170.57 ± 136.81	0-500
	Girl	24	200.42 ± 133.20	0-420
	Total	59	182.71 ± 135.01	0-500
	1 month after surgery (T3)			
	Boy	20	38.50 ± 71.25	0-230
	Girl	17	55.35 ± 68.64	0-190
	Total	37	46.24 ± 69.61	0-230
SCARED-C				
	Preoperative visit (T1)			
	PD	50	4.84 ± 4.71	
	GAD	47	5.60 ± 4.13	
	SpD	49	6.06 ± 4.22	
	SAD	49	6.12 ± 3.70	
	SSA	50	2.04 ± 1.73	
	Total	45	24.71 ± 15.53	4-67
	Day of surgery (T2)			
	PD	21	5.19 ± 5.99	
	GAD	20	5.15 ± 4.70	
	SpD	22	5.18 ± 4.94	
	SAD	21	4.43 ± 3.94	
	SSA	20	1.93 ± 1.75	
	Total	20	21.53 ± 18.95	2-74
	1 month after surgery (T3)			
	PD	31	4.10 ± 5.22	
	GAD	31	4.94 ± 5.05	
	SpD	31	5.10 ± 3.48	
	SAD	31	6.19 ± 3.57	
	SSA	31	1.68 ± 1.60	
	Total	31	22.00 ± 14.66	3-66

CPMAS = Children's Perioperative Multidimensional Anxiety Scale; SCARED-C = Screen for Child Anxiety Related Disorders-Child Version; PD = Panic Disorder; GAD = Generalized Anxiety Disorder; SpD = Separation Anxiety Disorder; SAD = Social Anxiety Disorder; SSA = Significant School Avoidance.
A SCARED-C score of ≥ 25 may indicate the presence of an Anxiety Disorder; PD score of ≥ 7 may indicate the presence of Panic Disorder; GAD score of ≥ 9 may indicate the presence of Generalized Anxiety Disorder; SpD score of ≥ 5 may indicate the presence of Separation Anxiety Disorder; SAD score of ≥ 8 may indicate the presence of Social Anxiety Disorder; SSA score of ≥ 3 may indicate Significant School Avoidance.

Reliability

The 5-item CPMAS showed strong internal consistency at all three timepoints, with a reliability of .75 or higher. Cronbach's alpha coefficients measured at three time points were 0.89 during preoperative clinic visit (T1), 0.90 on the day of surgery (T2), and 0.75 one month postoperatively (T3). The test-retest reliability for the five-item CPMAS demonstrated moderate stability (ICC = 0.71) across all three visits. CPMAS scores were moderately correlated at T1 and T2 ($r = .52$, $p < 0.01$), and at T1 and T3 ($r = .47$, $p < 0.05$) (see Table 3). In addition, moderate positive inter-item correlations, ranging from .44 to .72 at T1, .48 to .84 at T2, and .33 to .53 at T3 were found (see Table 4).

Table 3. *Correlations of the CPMAS*

		CPMAS at T1	CPMAS at T2	CPMAS at T3
CPMAS				
	CPMAS at T1		.52**	.47**
	CPMAS at T2			.31
SCARED-C				
	SCARED-C at	.35*		
	PD	.34*		
	GAD	.41**		
	SpD	.22		
	SAD	.16		
	SSA	.16		
	SCARED-C at	.16	.46*	
	PD	.07	.55*	
	GAD	.20	.29	
	SpD	.25	.52*	
	SAD	.13	.17	
	SSA	-.07	.22	
	SCARED-C at	.33	.18	.54*
	PD	.25	.21	.47*
	GAD	.27	.06	.53**
	SpD	.30	.38*	.27
	SAD	.19	-.09	.36*
	SSA	.26	.09	.34

CPMAS = Children's Perioperative Multidimensional Anxiety Scale; SCARED-C = Screen for Child Anxiety Related Disorders-Child Version; PD = Panic Disorder; GAD = Generalized Anxiety Disorder; SpD = Separation Anxiety Disorder; SAD = Social Anxiety Disorder; SSA = Significant School Avoidance. T1 = preoperative visit; T2 = day of surgery; T3 = 1 month after surgery.
* $p < .05$. ** $p < .001$.

Table 4. *Inter-item Correlations of the CPMAS*

	Item # 2	*Item # 3*	*Item # 4*	*Item # 5*
Preoperative visit				
Item # 1	.674	.496	.614	.659
Item # 2		.720	.613	.688
Item # 3			.437	.541
Item # 4				.654
Item # 5				
Day of surgery				
Item #1	.772	.830	.594	.479
Item # 2		.840	.591	.613
Item # 3			.691	.486
Item # 4				.536
Item # 5				
1 month after (T3)				
Item # 1	.332	.447	N/A	.379
Item # 2		.533	N/A	.505
Item # 3			N/A	.483
Item # 4			N/A	
Item # 5			N/A	

CPMAS = Children’s Perioperative Multidimensional Anxiety Scale; Item # 1 = Right now, how worried are you?; Item # 2 = Right now, how scared are you?; Item # 3 = Right now, how nervous are you?; Item # 4 = Right now, I feel scared that this might hurt.; Item # 5 = Right now, I feel worried that something bad might happen.; N/A = Not applicable at this time point.

Convergent validity

The convergent validity of the CPMAS was assessed by comparing the CPMAS with SCARED-C and selected state-related anxiety items from the SCARED-C (i.e., SCARED-C Q7 – nervous & SCARED-C Q33 – worry about future) across all three visits. CPMAS scores moderately correlated with overall SCARED-C scores at all three timepoints: at T1 (r = .35, $p < 0.05$), at T2 (r = .46, $p < 0.05$) and at T3 (r = .54, $p < 0.05$) (see Table 3). Furthermore, the CPMAS was moderately correlated with the following SCARED-C subscales: Panic Disorder (PD) (r = .34, $p < 0.05$) and General Anxiety Disorder (GAD) (r = .41, $p < 0.05$) at T1, PD (r = .55, $p < 0.01$) and SpD (r = .52, $p <$ 0.013) at T2, and PD (r = .47, $p < 0.01$), GAD (r = .53, $p < 0.01$), and Social Anxiety Disorder (SAD) (r = .36, $p < 0.05$) at T3.

Our results also showed that SCARED-C Q7 - nervous correlated with 4 of 5 CPMAS items at T1 (r's ranged from .29 to.71, $p < 0.05$ to $p < 0.01$, respectively & T2 (r's ranged from .51 to .69, $p < 0.01$). SCARED-C Q7 - nervous also correlated to 2 items at T3 (r's ranged from .49 to .58, $p < 0.01$. Moreover, Q33 - worry about future correlated with all CPMAS items at T1 (r's ranged from .39 to .58, $p < 0.01$), 1 CPMAS item at T2 (r = .52, $p < 0.05$) and 2 CPMAS items at T3 (r's ranged from .37 to .44, $p <$ 0.05) (see Table 5). The pattern of correlations suggested that various dimensions of anxiety and worry were exhibited at different perioperative periods (e.g., pre-op, day of, and post-operative).

Table 5. *Correlations of the CPMAS with SCARED-C Q7 & SCARED-C Q33*

	SCARED-C Q7	SCARED-C Q33
Preoperative visit		
Item # 1	.267	.386**
Item # 2	.539**	.401**
Item # 3	.713**	.415**
Item # 4	.289*	.385**
Item # 5	.362*	.576**
Day of surgery (T2)		
Item #1	.694**	.429
Item # 2	.680**	.308
Item # 3	.554**	.350
Item # 4	.261	.345
Item # 5	.510*	.519*
1 month after (T3)		
Item # 1	.334	.373*
Item # 2	.271	.441*
Item # 3	.492**	.220
Item # 4	N/A	N/A
Item # 5	.575**	.239

CPMAS = Children's Perioperative Multidimensional Anxiety Scale; SCARED-C = Screen for Child Anxiety Related Disorders-Child Version; Item # 1 = Right now, how worried are you?; Item # 2 = Right now, how scared are you?; Item # 3 = Right now, how nervous are you?; Item # 4 = Right now, I feel scared that this might hurt.; Item # 5 = Right now, I feel worried that something bad might happen.; N/A = Not applicable at this time point; SCARED-C Q7 = I am nervous; SCARED-C Q33 = I worry about what is going to happen in the future; T1 = preoperative visit; T2 = day of surgery; T3 = 1 month after surgery.
* $p < .05$. ** $p < .001$.

Paired samples *t*-tests revealed no significant differences between the CPMAS mean scores during the two preoperative visits (i.e., T1 and T2). Statistically significant differences of mean CPMAS scores were reported between T1 and T3, $t(36)=5.56$, $p < 0.01$, and T2 and T3, $t(35) = 7.05$, $p < 0.01$. That CPMAS scores changed over time suggest that it can discriminate between preoperative and postoperative visits.

Sensitivity to Change

Our results also suggest that the CPMAS was sensitive to change between preoperative (T1 or T2) and postoperative periods (T3) as demonstrated by their effect sizes. The SRM was 0.214 (small) between T1 and T2, large (-1.17) between T2 and T3 and was also large (-0.91) between T1 and T3.

Sensitivity Analyses

Sensitivity analyses revealed no significant differences between those who remained in the study and those who did not complete all of the assessments on any baseline characteristics ($p > 0.05$). Moreover, no significant differences were found between the groups who received preoperative preparation by Child Life Specialist and those who did not on all outcomes ($p > 0.05$). When children ($n = 2$) who did not receive preoperative preparation by Child Life Specialists were eliminated from analysis, the CPMAS continued to demonstrate good internal consistency (Cronbach's $\alpha = 0.80$ or higher, i.e., 0.88 at T1, 0.90 at T2, and 0.75 at T3) and moderately stable (ICC = 0.69) across all three visits. CPMAS scores also remained moderately correlated at T1 and T2 ($r = .52$, $p < 0.01$) and at T2 and T3 ($r = .47$, $p < 0.05$).

Discussion

The objectives of this study were to assess the psychometric properties of the CPMAS in 7-13 years old children undergoing elective surgery and to examine the reliability and validity of CPMAS scale scores in a busy children's hospital setting. The CPMAS scale scores demonstrated good reliability and strong internal consistency and stability. Moderate positive inter-item correlations were also found. However, the tighter clustering of correlations at T2 may be due to the condition of elevated stress/worry/anxiety that is present in the pre-surgical area and the operating room on the day of surgery. It is possible that the T2 visit (day of surgery) is a context in which the anxiety is heightened, resulting in the clustering of items and/or more difficulty for children in distinguishing between items. Furthermore, we specifically selected 2 state-related items within the Generalized Anxiety Subscale (i.e. Q7- "I am nervous", and also Q33- "I worry about what is going to happen in the future") and use them as our outcomes for additional analyses. When using these two state-related items, our results showed that SCARED-C Q7 & Q33 correlated with CPMAS items across all three timepoints . This finding supports the convergent validity of CPMAS using stated-related anxiety items of the SCARED-C.

The 5-item CPMAS showed strong internal consistency at all three timepoints, with a reliability of .75 or higher. Cronbach's alpha coefficients measured at three time points were highest on the day of surgery and during preoperative clinic visit, and lower at one month postoperatively.

Convergent validity was supported by the presence of statistically significant correlations between CPMAS scores and SCARED-C scores at all three assessment points. Construct validity was also supported and mean scores differed between these preoperative (T1 & T2) and postoperative (T3) periods, suggesting that the CPMAS is sensitive to change in the surgical context. This finding is consistent with clinical experience and previous research which has showed that high anxiety is associated with the anticipation of a stressful situation (e.g., anesthetic induction) (Davidson & McKenzie, 2011). Chorney and Kain reported that more than 40% of children were anxious during anesthetic induction with 17% of these children displaying significant anxiety, and more than 30% actively resisting induction (Chorney & Kain, 2009).

In addition to correlations with total SCARED-C scores, the CPMAS was moderately correlated with a few of the SCARED-C subscale scores across visits. It is important to note that SCARED-C in this study is measuring symptoms of the various anxiety disorders. Interestingly, the CPMAS was consistently correlated with the Panic Disorder subscale across all three visits, with Generalized Anxiety Disorder at T1 and T3, with Separation Anxiety Disorder at T2 and Social Anxiety Disorder at T3. As expected, we found that separation anxiety disorders were common throughout the perioperative process, and it is noteworthy that CPMAS scores correlated with this SCARED-C subscale at T2. This finding complements existing literature that suggests that elevated children's anxiety is present during separation from parents upon entry to the operating room (McCann & Kain, 2001).

Our finding that children scored lower on the CPMAS but relatively high on SCARED-C during all three timepoints suggests that children may be exhibiting high trait anxiety while experiencing lower state anxiety in the perioperative period. This result may indicate that the CPMAS and SCARED-C tap different aspects of anxiety, but also that future research that examines individual differences in trait anxiety in relation to the susceptibility to state anxiety within various contexts is needed.

Limitations

A few limitations should be mentioned that can help guide the future assessment of this measure. It is important to note that this study was the first of its kind to be conducted at this University-affiliated children's hospital. Moreover, while the scale is unique and novel, there were unforeseen challenges such as recruitment and follow-up during the early phases of testing.

In this study, the correlations of the CPMAS between visits were significant but moderate at T1 and T2, and at T1 and T3. This may be due to the fact that the sample size was relatively small particularly at T2 and T3. Other external factors (e.g., at school or at home) may also have affected our findings at T3 (i.e., one month after surgery). For example, the dynamics and interactions of each child with their peers, family, and/or teachers after surgery might vary due to differences in rate of recovery, pain levels and/or medication dosages. Some children may recover faster and find it easier to get back to their normal routines than others who took longer to heal.

According to Anatasi (1988), a correlation of r =.5 to .7 with existing scales is considered acceptable when developing a new scale. In this study, correlations with the SCARED-C were statistically significant, but ranged from r = .35 to .54, $p < 0.05$. This seemingly lower correlation could be due to attrition at T2 and T3 which reduced the statistical power of our study and may leave it vulnerable to type II error (failure to detect an effect when it is present). As a result, this study may underestimate the convergent validity of the CPMAS with some of the SCARED-C subscales. Aside from the smaller sample size, these correlations may not be higher because the SCARED-C taps a number of different anxiety-related phenomena, some of which may not change in the perioperative period (e.g., significant school avoidance) or may not relate to the experience of anxiety during this time.

While using a trait-like form such as SCARED-C is a limitation to our study, we conducted further item analyses to examine the relation between state-related items with the CPMAS items. Interestingly, the pattern of correlations from the use of the SCARED-C revealed points of further discussion. The pattern of correlations suggested that there were differential influences on the timing of the perioperative period (e.g., pre-op, day of, and post-operative) that were related differently to anxiety and worry. That is, preoperatively, children seemed to be nervous and worried about the future, while during the day of, children appeared more nervous contemporaneously. Postoperatively, these relations appeared to attenuate. These patterns suggest that the timing and the perioperative context are important in considering children's anxiety as they may differentially influence different features of anxiety. Some other methodological limitations should be noted. First, we included a sample of 7-13 years old children who received elective outpatient surgeries. While these are the most common surgical procedures in children, we excluded more lengthy or extensive surgeries that also include a potential postoperative hospitalization component. Also, these families had similar, relatively non-disadvantaged socioeconomic backgrounds. Therefore, whether the findings are generalizable to other, less advantaged children and children undergoing repeated and non-elective surgeries is unknown. Second, we cannot be certain that children were able to fully understand differences between the different items. Further exploration on distinguish between items in future study is required. Third, all correlational analyses in this study were conducted without correcting for multiple comparisons. Thus, the possibility of type I error is increased.

Future directions

Given the myriad negative effects associated with perioperative anxiety, it is crucial that proper perioperative care prevention and intervention strategies that aim at reducing perioperative anxiety in children undergoing surgery be developed. This begins with the development of a tool that can quickly and accurately measure perioperative anxiety levels in busy hospital and clinical settings. Several existing scales have been used to assess this construct, yet a number of shortcomings (i.e., observer report, time-consuming, or lack of specificity for the perioperative setting) limit their use in routine clinical practice and research settings. Therefore, a concise and accessible self-report that avoids these shortcomings is useful. The CPMAS is a simple, brief, reliable and time-efficient instrument that can be used to measure children's perioperative anxiety in busy hospital settings.

While demonstrating reasonable psychometric properties, our findings need to be replicated in a larger sample on children over a wider range of ages, and those who are scheduled to receive different types of surgery. Additional research should focus on establishing the appropriate cutoff score to differentiate low versus high preoperative anxiety groups and to establish levels at which it predicts clinically significant outcomes.

Conclusions

This study provides empirical evidence to support the initial reliability and validity of the CPMAS scores in assessing perioperative anxiety in children undergoing elective surgery. Future research is needed to confirm the psychometric properties of the scale in a larger sample. Thus far, our results suggest that the CPMAS has the potential to be a useful and valid tool for the evaluation of anxiety in a surgical setting for children as young as 7 years old. This brief 5-item self-report can easily be utilized to accurately assess perioperative anxiety in routine clinical practice and research settings.

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CHAPTER FOUR

STUDY 3

TITLE: A Pilot Study of A Tablet-based Intervention for Reducing Children's Preoperative Anxiety

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CONTEXT AND IMPLICATIONS OF THIS STUDY: The findings of the systematic review and meta-analysis outlined in the first study revealed that existing approaches to reducing children's preoperative anxiety may be prohibitively complex and/or costly, and prompted an area of research for simple and affordable AV interventions. Accordingly, a customizable, multi-sensory interactive tablet-based virtual reality application, Story-Telling Medicine (STM), was developed to prepare children for complex perioperative and surgical procedures. Prior to conducting a full-scale RCT, I conducted this 3-wave pilot study to examine the feasibility and acceptability of this newly developed STM intervention.

There is a relative paucity of research evaluating the effects of a customizable tablet-based intervention in reducing preoperative anxiety in children undergoing surgery. This is the first study to demonstrate the feasibility and potential effectiveness of a tablet-based application and the results support the conduct of a full-scale RCT to test its effectiveness in reducing preoperative anxiety in children.

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CONFLICTS OF INTEREST: None

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Abstract

The objectives of this study were to examine the feasibility and acceptability of a novel tablet-based application, Story-Telling Medicine (STM), to help reduce children's preoperative anxiety. Children (*N*=100) aged 7-13 years who were undergoing outpatient surgery were recruited from a local children's hospital. This study comprised 3 waves: Waves 1 (n=30) and 2 (n=30) examined feasibility, and Wave 3 (n=40) examined the acceptability of STM and compared its effect on preoperative anxiety to Usual Care (UC). In Wave 3, children were randomly allocated to receive STM+UC or UC. Change in preoperative anxiety was measured using the Children's Perioperative Multidimensional Anxiety Scale (CPMAS) one week before surgery (T1), on the day of surgery (T2), and one month postoperatively (T3). The results demonstrated the feasibility of participant recruitment and data collection procedures in Wave 1, but identified challenges with attrition at T2 and T3. Wave 2 piloted a modified protocol that addressed attrition and increased the feasibility of follow-ups. In Wave 3, children in the STM+UC demonstrated greater reductions in CPMAS compared to the UC group [ΔM=119.90, SE=46.36, $t(27)=2.59$, $p=0.015$; 95% CI = 24.78-215.02]. In conclusion, this pilot study provides preliminary evidence that STM is a feasible intervention for children's preoperative anxiety in a busy pediatric operative setting, supporting the conducting of a full scale RCT.

Introduction

Preoperative anxiety affects up to 5 million children in North America each year (Perry, Hooper, & Masiongale, 2012) and is associated with adverse outcomes for children, families, and the healthcare system (Fortier, Del Rosario, Martin, & Kain, 2010; Kain et al., 2004; Kain, Mayes, Caldwell-Andrews, Karas, & McClain, 2006; Kain, Mayes, O'Connor, & Cicchetti, 1996; Kain, Wang, Mayes, Caramico, & Hofstadter, 1999; Litke, Pikulska, & Wegner, 2012; McCann & Kain, 2001). Children with preoperative anxiety are 3.5 times more likely to experience separation anxiety and fear of physicians and future medical procedures (Litke et al., 2012; McCann & Kain, 2001). These can have both short- and long-term effects on a child's growth, development, and health that include feeding problems, insomnia, and post-traumatic stress disorder (American Psychiatric Association, 2013; Long, & Rajagopalan, 2002; McCann & Kain, 2001).

Aside from emotional distress, these children require more intraoperative anesthesia (Maranets & Kain, 1999), higher analgesic doses, and experience delays in entry to operating rooms, as well as prolonged stays in recovery areas (Davidson & McKenzie, 2011; Kain et al., 1996; Kain et al., 1999; Litke et al., 2012). Overall, preoperative anxiety can significantly increase healthcare burden and costs.

Given these adverse effects, clinicians and researchers have attempted to apply a variety of interventions aimed at reducing the prevalence, severity, and impact of preoperative anxiety in youth. These include the use of preoperative sedative medications (e.g., benzodiazepines) and psychosocial preparation programs (Brewer, Gleditsch, Syblik, Tietjens & Vacik, 2006; Sinha et al., 2012; Tunney & Boore, 2013; Yip, Middleton, Cyna & Carlyle, 2009). Unfortunately, these interventions are not always readily accessible, can be time-intensive, or are associated with undesirable side effects and high costs.

A recent systematic review suggests that audiovisual (AV) interventions such as videos and multi-faceted programs are evidence-based for the reduction of preoperative anxiety, though existing solutions may be prohibitively complex or costly. In general, these AV tools are shown to be effective in reducing children's preoperative anxiety either independently or adjunctively to standard of care practice. The review highlighted the need to develop simple and affordable AV treatments to be tested in RCTs. Ideally, these AV treatments should be readily accessible, interactive, and be developmentally appropriate in the form of peer-modelling (Chow, Van Lieshout, Schmidt, Dobson, & Buckley, 2016). Accordingly, we developed an inexpensive, customizable, interactive tablet-based application: Story-Telling Medicine (STM), designed to prepare children for complex perioperative and surgical procedures. STM is an age-appropriate psychoeducational application that simulates the children's hospital environment by guiding children through the various hospital settings they will encounter prior to surgery. To date, no study has examined the impact of a customized tablet-based intervention for preoperative anxiety. Therefore, the first step in evaluating the potential effects of STM intervention was to assess the feasibility of the methodology and the acceptability of this newly developed intervention.

This pilot study consisted of three Waves and had three objectives: i) to assess recruitment potential (i.e., recruitment and retention rates) in a busy pediatric operative setting, testing and modifying the study protocol in Waves 1 and 2; ii) to assess the size of the intervention effect in Wave 3; and iii) to assess the acceptability (i.e., the ease of use on the day of surgery and at home) of the STM intervention in Wave 3.

Method

Setting

This pilot study took place at the McMaster Children's Hospital located in Hamilton, Ontario, Canada. The Hamilton Integrated Research Ethics Board's approval was obtained.

Sample Size

A minimum of 12 participants per group is required when conducting a pilot study for a clinical trial (Julios, 2005). To account for attrition at follow-up assessments, a total of 100 children were recruited in this pilot study.

Inclusion criteria

Children between the ages of 7-13 who were scheduled to receive any outpatient elective surgery (i.e. tonsillectomy, herniorrhaphy) within the following 7-14 days and who had access to the internet at home were eligible for the study. Children who were receiving major surgery generally requiring post-operative hospitalization, non-surgical procedures (e.g., colonoscopy, MRI scans), or with known neurodevelopmental or psychiatric disorders (e.g., diagnosed depressive, anxiety, or psychotic disorders, intellectual disability, autism, visual and/or hearing impairments) were excluded from the study. Families who refused or were unable to provide assent and consent due to language barriers (i.e., non-English speaking participants) were ineligible to participate.

Participant Recruitment

In Wave 1, 30 children were recruited to examine the feasibility of the study protocol as described above. In this wave, we observed that most children did not return in person to the hospital clinic for postoperative follow-up visits. The study protocol was therefore modified in Wave 2 by administering the questionnaires over the telephone rather than in person at T3. In Wave 2, another 30 children were recruited to assess the feasibility of this modified protocol. In Wave 3, the protocol was further modified by utilizing appointment reminders and administering the questionnaires over the telephone at T3. In this wave, 40 children were recruited to examine the acceptability of STM and its uptake and compared its effect on anxiety to Usual Care (UC). Children in Wave 3 were also randomly allocated to receive either STM+UC (n= 20) or UC only (n= 20) at T1.

Study enrollment for the three waves took place between October 2013 and March, 2015.

Procedure

The data collection occurred across three time points: preoperative clinic appointment (Time 1), on the day of surgery (Time 2) and 1 month after surgery (Time 3). All children meeting inclusion criteria were approached at Time 1 and invited to participate in the study. After obtaining consent and assent, the child completed the Children's Perioperative Multidimensional Anxiety Scale (CPMAS; (CPMAS; Chow, Van Lieshout, Buckley, & Schmidt, 2016). Demographic information (e.g., child sex and age, previous hospitalizations, parental sex and age) were also collected from parents at this time.

On the day of surgery, the child and families were greeted upon admission. The child completed the CPMAS in the holding area outside of the operating room at Time 2. Children and families were then followed up either in person (in Wave 1) or via telephone (in Waves 2 and 3) at Time 3.

Interventions

Usual care (UC). As part of UC at the McMaster Children's Hospital, children received preoperative preparation by a Child life specialist, a pediatric nurse, and an anesthesiologist at T1, and received Parental Presence during the anesthetic induction at T2. The Child life specialist prepared children and families by providing information about the day of surgery and teaching them basic coping skills through play activities.

Story-Telling Medicine Intervention (STM). The development of STM application was done in collaboration across multiple disciplines which included the Department of Anesthesia, Department of Psychology, Behavior and Neuroscience, Department of Engineering Entrepreneurship & Innovation, and Department of Psychiatry and Behavioral Neurosciences at McMaster University. Photographs of relevant children's hospital settings (e.g., preoperative area, holding area and operating room etc.) were captured and illustrated in a 3-dimensional cartoon format in STM. An age-appropriate raccoon character narrates and walks through the entire preoperative procedure with the child. At the end of the program, children were asked to click on relevant medical equipment and learned about their purposes and functions (see to Appendix I for selected scenes). Children in STM group were given an individual access code at T1 to use the STM application as frequently as desired at home. To facilitate access, families received a direct link to access the STM via email 7 days prior to surgery. Children were also given a tablet to access STM application 2 hours prior to surgery at T2. All children in the STM group also received UC as described above.

Measures

Children's Perioperative Multidimensional Anxiety Scale. (CPMAS; Chow, Van Lieshout, Buckley, & Schmidt, 2016). The CPMAS is a recently developed and validated self-report scale designed to measure children's anxiety within the surgical context. It has 5 items, to which the child responds on a visual analog scale that ranges from 0 to 100. The CPMAS was found to have strong internal consistency (Cronbach's $\alpha > 0.89$) and good test-retest reliability (Intraclass Correlation Coefficient = 0.71). A sample question from the CPMAS includes: "Right now, how worried are you?" [0 = not at all worried & 100 = very worried]. Children's anxiety was assessed at all 3 time points.

Statistical analysis

To address study objective (i), recruitment and feasibility were assessed using the percentage of eligible children who were enrolled and retained in the study. Descriptive analyses were used to summarize the baseline characteristics of the children and families in this pilot study.

Baseline participant characteristics (i.e., age, gender, surgery type, previous hospitalization, Child life specialist preparation) in intervention and UC groups were compared using a series of Chi-square tests and independent sample *t*-tests to ensure that randomization yielded comparable groups.

To address objective (ii), the size of the intervention effect on children's preoperative anxiety was evaluated. Quantitative data were analyzed using independent samples *t*-test to examine group difference in the mean change of CPMAS scores and reported as 95% CI. Effect size was determined using Cohen's *d*. Statistical significance was set at $p < 0.05$.

To address objective (iii), the intervention acceptability was assessed using the percentage of participants that used STM both at home and on the day of surgery. An online tracking system was used to track the number of STM log-ins at home.

Results

Table 1 depicts the demographic characteristics of children and families in the pilot study.

Table 1. *Demographic Characteristics of Children and Family (N=100).*

	Characteristics	Wave 1 (n=30)	Wave 2 (n=30)	Wave 3 (UC) (n	Wave 3 (STM+UC)
Children					
	Gender, *n* (Boys/Girls)	20/10	19/11	11/9	10/10
	Age, *M* ± *SD*	9.53 ±	10.50 ±	9.15 ±	9.15 ± 2.01
	Child life specialist, *n* (Yes/No)	28/2	30/0	20/0	20/0
	Previous Hospitalization, *n* (Yes/No)	3/27	2/28	4/16	5/15
Parents					
	Mother/Father/Other, *n*	21/7/2	23/6/1	15/4/11	17/3/0
	Age, *M* ± *SD*	39.50 ±	40.68	41.28 ±	38.17 ± 7.00

M = Mean; *SD* = Standard Deviation.

Objective (i): Feasibility

In Wave 1, participant recruitment and data collection procedures were shown to be feasible at T1. However, low study retention was identified at T2 (19/30, 63.3%), mainly due to unforeseen challenges (e.g., surgery scheduling changes or lack of communication between hospital and research staff) and at T3 (6/30, 20%) due to the fact that most children did not return in person to the clinic for follow-up.

The protocol was modified in Wave 2 by improving communication between staff and by administering the questionnaires over the telephone rather than in person at T3. In response to this modification, of the 30 participants at T1, increased retention was observed at T2 (23/30, 77%) and at T3 (16/30, 53.3%).

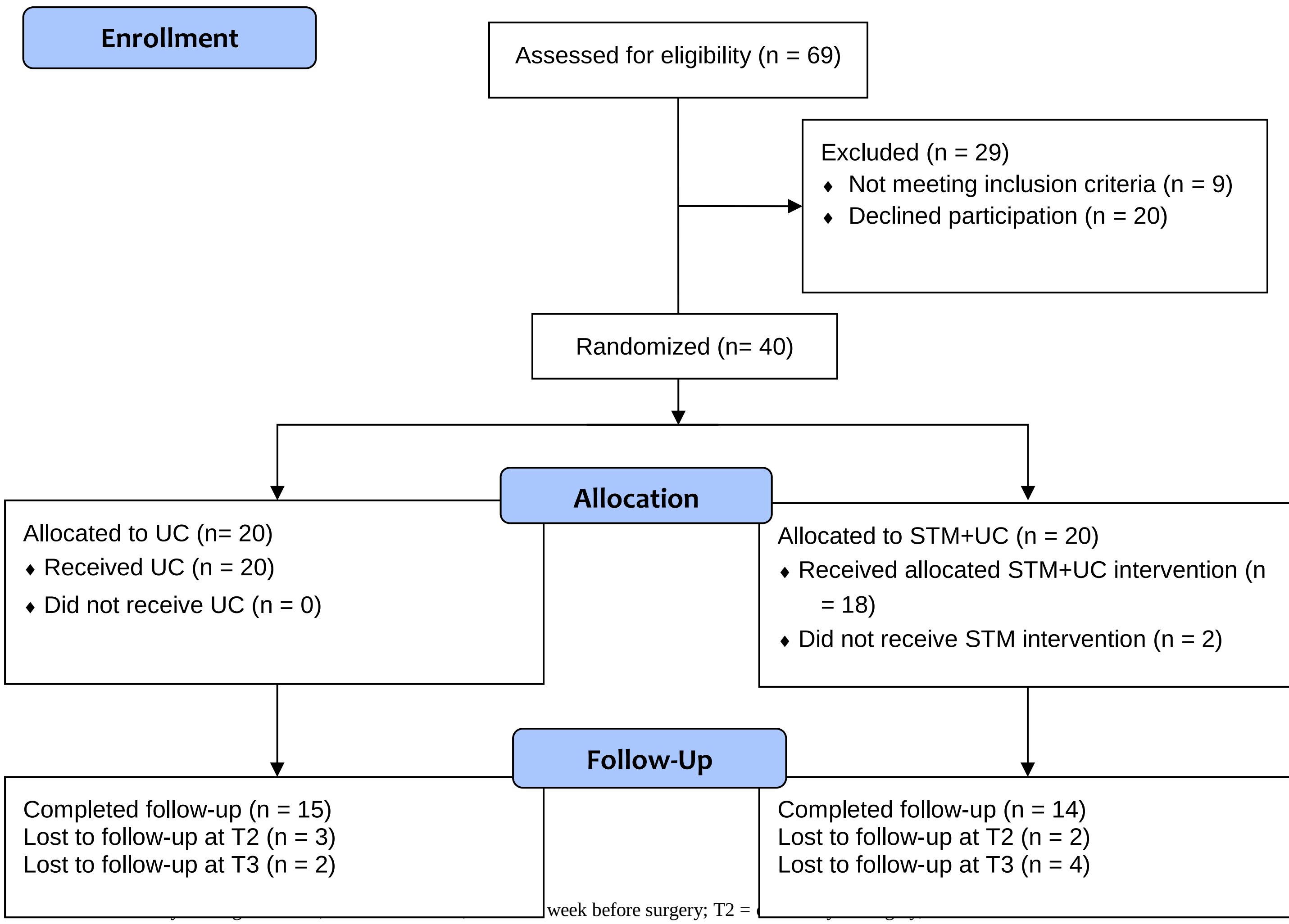
In Wave 3, the protocol was further modified by utilizing appointment reminders and administering the questionnaires over the telephone at T3 to further increase retention. In Wave 3, of the 40 participants at T1, the retention rate improved at T2 (35/40, 87.5%) and at T3 (29/40, 72.5%) relative to Waves 1 and 2. CPMAS were completed at each time point in all participants who remained in this study and were not lost to follow-up. Table 2 shows the descriptive statistics of CPMAS scores in the pilot study.

Figure 1 depicts the Wave 3 flow and randomization process.

Table 2. *Descriptive Statistics of the CPMAS scores (N=100).*

Anxiety Scores	N	*M* ± *SD*	*Range*
CPMAS			
Preoperative visit (T1)			
Wave 1	30	167.57 ± 137.89	10-500
Wave 2	30	129.00 ± 121.61	0-450
Wave 3	40	188.13 ± 140.25	0-440
Day of surgery (T2)			
Wave 1	19	168.95 ± 137.23	0-420
Wave 2	23	176.52 ± 137.96	0-500
Wave 3	35	231.57 ± 153. 16	0-500
1 month after surgery (T3)			
Wave 1	6	18.33 ± 29.94	0-70
Wave 2	16	66.25 ± 84.21	0-230
Wave 3	29	28.28 ± 52.65	0-169

M = Mean; *SD* = Standard Deviation.



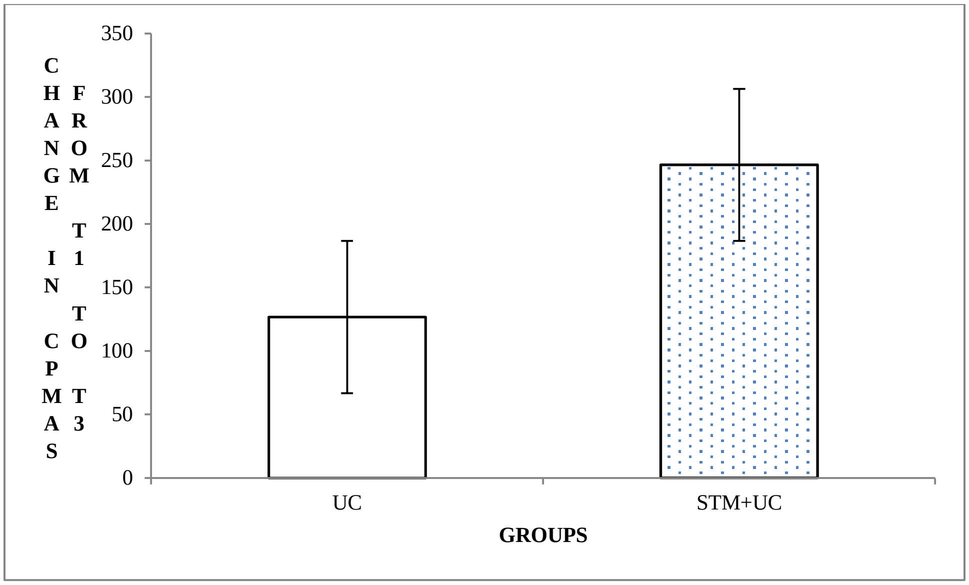
week before surgery; T2 =

postoperatively.

Figure 1. CONSORT flow diagram of study screening, enrollment, randomization and follow-up for Wave 3 (Egger, Jüni & Bartlett, 2001).

Objective (ii): Size of Potential Intervention Effect

An independent-samples *t*-test revealed a statistically significant group difference in the mean change in CPMAS scores from T1 to T3 for STM+UC compared to UC alone [ΔM = 119.90, SE = 46.36, $t(27) = 2.59$, $p = 0.015$; 95% CI = 24.78-215.02] (Figure 2). Large between-group effect size was observed for change in CPMAS scores from T1 to T3 ($d = 0.96$).



CPMAS = Children's Perioperative Multidimensional Anxiety Scale; UC = Usual Care; STM+UC = Story-telling Medicine + Usual Care.

Figure 2. Mean (SD) differences on change in CPMAS scores between the STM+UC and UC alone groups ($p < 0.05$).

Importantly, no significant differences in baseline characteristics were found between the two groups in Wave 3 ($p > 0.05$).

Objective (iii): Acceptability

Of the 20 families who declined participation, the majority of them (18/20) were not interested in participating in a research study, 2 families claimed they were too busy during the perioperative periods.

Most children (18/20, 90%) in the STM+UC group used the STM intervention on the day of surgery and about half of the children (11/20, 55%) accessed the STM at home. Of those 18 children, two children used STM more than once, up to 4 times, at home prior to surgery.

Discussion

In this 3-Wave pilot study, we examined the feasibility and acceptability of a newly developed, tablet-based STM intervention with the goal of refining the study protocol to prepare for a larger, full-scale RCT. The findings provide preliminary evidence that participant recruitment, retention, and data collection procedures were feasible within the specified period and at the desired follow-up intervals. Although, we encountered some initial challenges with following up with children and families in Waves 1 and 2, our team was able to identify the major factors contributing to those challenges and modify the protocol appropriately. We also demonstrated that the STM intervention was feasible to deliver on the day of surgery. Moreover, reductions in anxiety were greater in children in the STM+UC than UC group alone. This study also provides an effect size to help power the planned large scale study, and showed that the size of the effect of the STM intervention further justified the conduct of that study.

With respect to the acceptability of STM, the majority of children in the STM+UC group received the STM intervention on the day of surgery. This showed that STM can be delivered without interfering with normal hospital routines and/or clinical flow and could potentially serve as an adjunctive therapy to usual care given its ease of use. However, only about half of the children had accessed the STM at home. The reason may be that children in this age group cannot access the internet on their own and need to rely on their parents to do so. Interestingly, a couple of children who used STM at home had accessed it more than once. In order to increase at-home STM compliance, future studies might consider lending children and families pre-loaded tablets, and/or sending reminders (e.g., via email or text or call) with direct links to both parents and children to access and use STM. It might also be worthwhile to further investigate the barriers to STM usage prior to surgery, to examine the frequency and duration of the STM usage (e.g., using average time spent per session and total time spent on STM), and to determine the optimal dosage of STM in a future RCT.

Due to the high prevalence and significant negative impact of preoperative anxiety on children undergoing surgery, the search for a simple, affordable and novel treatment in reducing preoperative anxiety continues. Based on extant evidence and the theoretical model postulated by Chow et al. (2016), an age-appropriate and interactive AV intervention with peer-modeling would likely be an optimal solution. Furthermore, it has been suggested that future preoperative preparation programs should be tailored to the needs of each individual child (e.g., the child's age and the timing of the preparation relative to surgery), be made accessible to all and be low in cost (Fortier & Kain, 2015; Kain, Caldwell-Andrews, & Wang, 2002).

The components of STM seem to have incorporated these important recommendations and considerations. It can be customized to suit virtually any age, procedure, and surgical setting. In addition to providing a virtual hospital tour, STM also utilizes psychoeducational techniques such as active distraction, peer-modelling, and learning. This prior rehearsal allows for children and families to develop proper strategies to cope with the uncertainty associated with the impending hospital experience (Chow et al., 2016).

Limitations

Several limitations should be considered when interpreting the findings of our results. First, the results are based on a relatively small and specific sample. This is a unique medical sample with children aged 7-13 undergoing elective surgeries. One of the objectives of this pilot study was to identify and address issues with recruitment and follow-up with children and families on the day of surgery. Second, the findings are based on subjective reports. Although we used the validated CPMAS, this self-report measure can be inherently biased. Future studies should include a larger sample and use objective measures of child behaviors within the surgical settings.

Future direction

Given the findings reported here, future research should continue to test the impact of STM, both behaviorally and physiologically, in an adequately powered RCT to determine if this cost-effective, transferable, and reusable tool can reduce perioperative anxiety, as well as its associated suffering and health care costs.

Unlike existing AV interventions, this customizable STM program provides a simulated hospital environment that can not only educate, but also increase children's coping abilities to better prepare them for surgery. In addition to reducing children's preoperative anxiety, it could also play an important role in moderating parental anxiety by preparing parents with a knowledge tool to support their child throughout the surgical process.

Conclusion

There is a relative paucity of research evaluating the effects of a customizable tablet-based intervention in reducing preoperative anxiety in children undergoing surgery. This is the first study to demonstrate the feasibility and potential effectiveness of such an intervention and supports the conduct of a full-scale study of STM to test its effectiveness in reducing preoperative anxiety in children.

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CHAPTER FIVE

STUDY 4

TITLE: Children’s shyness and sociability in a surgical setting: A preliminary investigation

AUTHORS: Cheryl H. T. Chow, MS; Nadine Nejati, BSc; Ryan J. Van Lieshout, MD, PHD; Norman Buckley, MD; Louis A. Schmidt, PHD

CONTEXT AND IMPLICATIONS OF THIS STUDY: The cumulative findings of the systematic review and pilot study suggested that there were variations in children’s stress response (as indexed by the CPMAS) in the surgical setting. This Study 4 was conducted to further examine the role of individual differences in temperament and its relation to preoperative anxiety in children undergoing surgery. In particular, I chose to examine the contribution of shyness and sociability to children’s anxiety in surgical settings.

This study allowed me to revisit person x context interactions on behavior in a stressful, non-normative context, the surgical setting. It also demonstrated the importance of considering other contexts to enhance reliable prediction of behavior, fully understand individual differences and person x context interactions, and to reproduce findings. The findings also highlight the need to consider individual differences in temperament when preparing children for surgery and to identify who may or may not be at risk for heightened preoperative anxiety. Such knowledge would be valuable in developing “precision medicine” for managing children’s preoperative anxiety.

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CONFLICTS OF INTEREST: None

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Abstract

The objective of this study was to examine the relation between temperament and preoperative anxiety in 40 children (aged 8-13) who were undergoing elective surgery one week prior to surgery (T1) and the day of surgery (T2). We predicted that temperamentally shy children would exhibit more preoperative anxiety, and temperamentally social children would exhibit less preoperative anxiety in the surgical context. We found, unexpectedly, temperamental shyness predicted lower preoperative anxiety at T1 ($\beta = -.32$; $p = .044$), while temperamental sociability predicted higher preoperative anxiety at T1 ($\beta = .34$; $p = .030$) and T2 ($\beta = .36$; $p = .034$). Preliminary findings are discussed in terms of their theoretical and practical implications for understanding person X context interactions and managing children's preoperative anxiety.

Introduction

The psychological sciences have come under considerable scrutiny recently for the lack of reproducibility of empirical findings (Lindsay, 2015). In a recent opinion article published in the New York Times, Barrett (2015) proposed that the main reason for failures to replicate study results in psychology experiments was the failure to consider context. Barrett suggested that this non-reproducibility of results as a typical path of scientific discovery and also stressed the importance of explaining the phenomenon under study based on context.

In personality science, the consideration of context for reliably predicting behavior has been a central theme for decades. Allport (1937) argued that individuals exhibit different and unique behavioral patterns across contexts. Lewin (1951) articulated a more systematic account of the person x context interaction. According to Lewin, human behavior (B) was a function of the person’s disposition (P) and the context or situation (S), expressed as $B = f(P,S)$. These three variables formed the "personality triad" (Funder, 2006). Accordingly, people vary their behaviors across contexts, but maintain their individual differences at the same time (Funder, Guillaume, Kumagai, Kawamoto, & Sato, 2012).

One personality style that has been examined across different contexts is shyness. Shyness reflects an anxious pre-occupation of the self in response to real or imagined social situations (Melchoir & Cheek, 1990). Although shyness is a ubiquitous phenomenon that most people experience at some point in their lives (Zimbardo, 1977), some people are characterized by temperamental shyness, an early developing and stable form of shyness observed across time and context (see Schmidt & Buss, 2010).

Temperamental shyness by context interactions have been widely studied in children. Kagan and his colleagues have described children who exhibit fear and wariness to unfamiliarity as temperamentally shy (Kagan, Reznick, & Snidman, 1988). Kagan's group found that temperamentally shy children displayed similar anxious behaviors across two laboratory visits but when comparing scores between the two contexts (i.e., laboratory and home), anxious behavior scores were not correlated, highlighting the impact of contextual factors on the manifestation of anxious behavior (Garcia-Coll, Kagan, & Reznick, 1984).

In other studies of children, Rubin and colleagues (1997) showed that there was a subset of temperamentally shy children who behaved consistently across social and nonsocial laboratory contexts, leading his group to conclude "some of the [temperamentally shy] children, all of the time". Coplan and his colleagues (Coplan, DeBow, Schneider, & Graham, 2009), more recently, reported that temperamentally shy children exhibited similar social behaviors inside and outside of school. Temperamentally shy children displayed more reticent (on looking, unoccupied) and anxious behaviors during free play preschool, participated less in structured social activities outside of school, and were more likely to engage in dyadic play at home with a single friend than nonshy children. Overall, the extant studies suggest that temperamental shyness in children is consistent across time and situation (Coplan et al., 2009; Rubin, Hastings, Stewart, Henderson, & Chen, 1997) but may also vary between some normative contexts (Garcia-Coll et al., 1984).

One outstanding question is whether the behaviors of temperamentally shy children in normative contexts would generalize to a non-normative context. Extant studies have been conducted largely in familiar (e.g., the home) and everyday normative environments (e.g., school) and/or the laboratory with familiar adults and settings. Accordingly, we do not know whether the anxious behaviors observed in temperamentally shy children in these contexts would generalize to non-normative stressful contexts. In order to fully establish whether temperamental shyness is a personality trait that is context specific and/or sensitive to context, it is of importance to examine the phenomenon in other contexts to enhance prediction of behavior and ultimately reproducibility of findings.

Here we conducted a preliminary investigation using the preoperative surgical environment as a non-normative stressful context in relation to individual differences in temperament. Surgery is arguably one of the most stress inducing life events (see Chow, Van Lieshout, Schmidt, Dobson, & Buckley, 2016, for a review). We examined whether the relation between children's temperamental shyness and anxiety observed in other familiar and unfamiliar normative contexts would generalize to a novel non-normative surgical context.

We collected measures of anxiety during the preoperative periods (i.e., at a preoperative clinic visit to the hospital prior to surgery and on the day of surgery) in children who were undergoing elective surgical procedures and who were classified as temperamentally shy. As well, because shyness and sociability are known to be conceptually and empirically orthogonal traits in children and adults (see Cheek & Buss, 1981; Schmidt & Buss, 2010, for reviews), we also examined these relations in children who were temperamentally social to see if the effects were specific to shyness. We predicted that temperamentally shy children would exhibit more preoperative anxiety, and temperamentally social children would exhibit less preoperative anxiety in the surgical context.

These predictions were based on findings from the extant literature that have examined links between shyness and anxiety in children, both inside and outside of the surgical contexts. For example, Kain and colleagues (2000) found children who received lower ratings of sociability exhibited increased preoperative anxiety in the preoperative holding area. Other studies that have examined the relation between shyness and anxiety in non-surgical contexts have also demonstrated similar results to the preoperative setting. For example, Kagan and his group (1987) found that shy or inhibited children tend to become more anxious in unfamiliar social and nonsocial settings. Moreover, Schmidt and colleagues (1997) found that shy children displayed relatively high levels of morning salivary cortisol levels (a measure of stress reactivity) prior to any social interactions.

Method

Participants

Forty children (21 boys, 19 girls, M_{age} = 9.19 years, age range: 7.15-11.23 [boys] and M_{age} = 9.11 years, age range: 7.26-10.96 [girls]) and their parents were included in this study. They were recruited during the child's preoperative clinic visit, occurring an average of 11 days (M = 10.86, SD = 10.28) before surgery. The mean age of children's parents was M_{age} = 41.00 (SD = 7.21) for boys, and M_{age} = 38.44 (SD = 8.99) for girls. Recruitment was limited to elective outpatient otolaryngologic (Ear-Nose-Throat [ENT]) surgical procedures (i.e., tonsillectomy and adenoidectomy etc.) at the McMaster's Children's Hospital located in Hamilton, Ontario, Canada. Children diagnosed with significant neurodevelopmental disorders (e.g., organic brain disorders, visual and/or hearing impairments etc), and families who were unable to provide assent and consent due to language barriers were not eligible for participation.

Measures

Colorado Child Temperament Inventory (CCTI; Rowe and Plomin, 1977). The CCTI is a 30 item questionnaire that uses parent-reports to assess temperament using a Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The scale measures temperament on six dimensions: shyness, sociability, emotionality, activity, attention-span persistence, and soothability. The majority of the CCTI temperament measures were completed by mothers (80%). The remainder were provided by fathers (17.5%) or other guardians (2.5%). Of particular interest to this study were the subscales measuring shyness [(e.g., "Child finds people more stimulating than anything else" (reversed scored)]) and sociability (e.g., "Child is very sociable"). The CCTI shyness and sociability subscales had good internal consistency in the present study (Cronbach's α = 0.67 and α = 0.77, respectively). The correlation between shyness and sociability was r = -.46, p < .01, suggesting, as predicted, that the two were inversely related constructs. Given that temperament is a stable characteristic (Buss and Plomin, 2014), children's temperament was assessed only during their preoperative clinic visit (T1) in order to reduce participant burden during the day of surgery.

Children's Perioperative Multidimensional Anxiety Scale (CPMAS; Chow, Van Lieshout, Buckley, & Schmidt, 2016). The CPMAS is a recently developed and validated self-report scale designed to measure children's state anxiety within a surgical context. It has 5 items, to which the child responds on a visual analog scale that ranges from 0 to 100. The CPMAS was found to have strong internal consistency (Cronbach's $\alpha > 0.89$), and good test-retest reliability (Intraclass Correlation Coefficient = 0.71). A sample question from the CPMAS includes: "Right now, how worried are you?" 0 = (not at all worried) & 100 = (very worried). Children's anxiety was assessed at two time-points: preoperatively, approximately 1 week prior to surgery (T1), and immediately before surgery (T2). CPMAS anxiety scores were stable between T1 and T2 ($r = .66$, $p < .01$).

Procedure

All children between the ages of 8-13 receiving ENT surgeries were approached in the waiting room before their preoperative clinic appointment and invited to participate in the study. After providing consent and assent, the parent completed the CCTI, and the child completed the CPMAS. Demographic information such as sex, age, previous surgeries/hospitalizations, parental sex, and parental age were also collected during this time.

On the day of surgery, children and families were greeted by a research assistant in the Same-Day-Surgery waiting room. Approximately 30 minutes prior to surgery, families were asked to move to the holding area outside of the operating room, where the child completed the CPMAS to report on their anxiety levels immediately prior to surgery.

All procedures were approved by the Hamilton Integrated Research Ethics Board.

Participant Attrition

Five children were lost to follow-up between T1 and T2. A chi-square analysis revealed that there was a significant difference in sex (5 boys and 0 girls) between those who did and those who did not complete the study $\chi^2\,(1, N = 40) = 5.17, p < .023$. No significant differences were found for child's age, parental age, previous surgeries/hospitalizations, or preoperative preparations by a Child life specialist between those who remained in the study and those who dropped out ($p > 0.05$).

Statistical Analysis

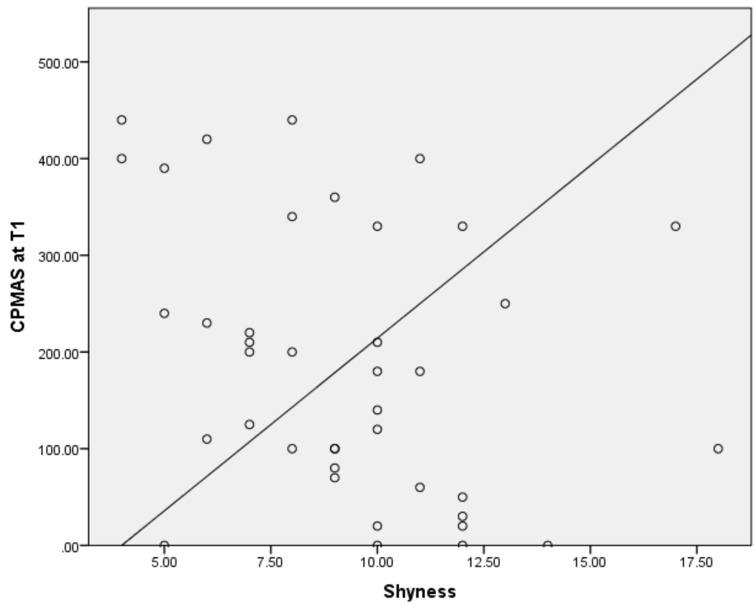
We conducted chi-square tests and independent-samples *t*-tests to assess differences between gender for all demographic data and outcome measures. No group differences were observed between male and female children on CCTI shyness, CCTI sociability, and CMPAS at T1 and T2 ($p > 0.05$). As well, these four measures were not related to participant's age. Accordingly, sex and age were collapsed in all analyses.

A linear regression was used to examine the relation between temperament (i.e., shyness and sociability) and preoperative anxiety.

Results

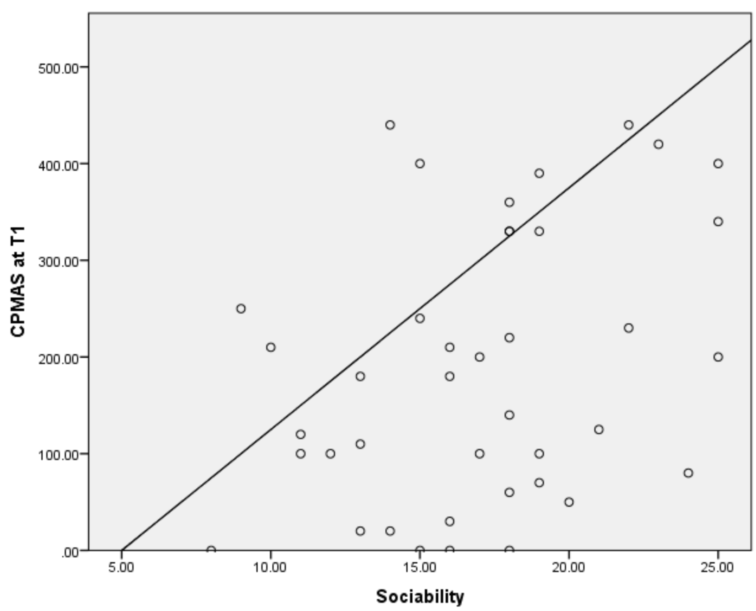
The analyses revealed that shyness and sociability were each significant predictors of preoperative anxiety (see Figures 1- 4). Unexpectedly, children who were temperamentally shy tended to score lower on preoperative anxiety at T1 ($\beta = -.32$; $p = .044$), while children who were temperamentally social tended to score higher on preoperative anxiety at T1 ($\beta = .34$; $p = .030$) and T2 ($\beta = .36$; $p = .034$) (refer to Table 1).

Figure 1. Scatterplot of Shyness and Preoperative Anxiety at T1.



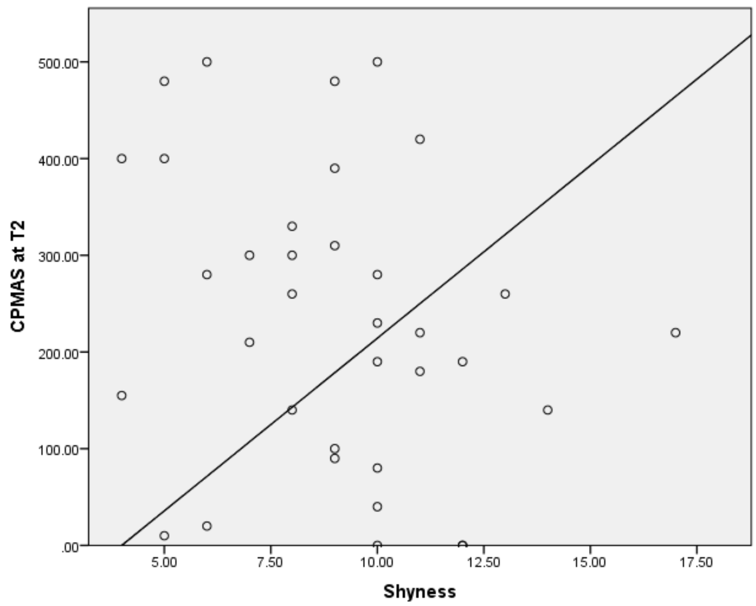
CPMAS = Children's Perioperative Multidimensional Anxiety Scale; T1 = 1 week prior to surgery.

Figure 2. Scatterplot of Sociability and Preoperative Anxiety at T1.



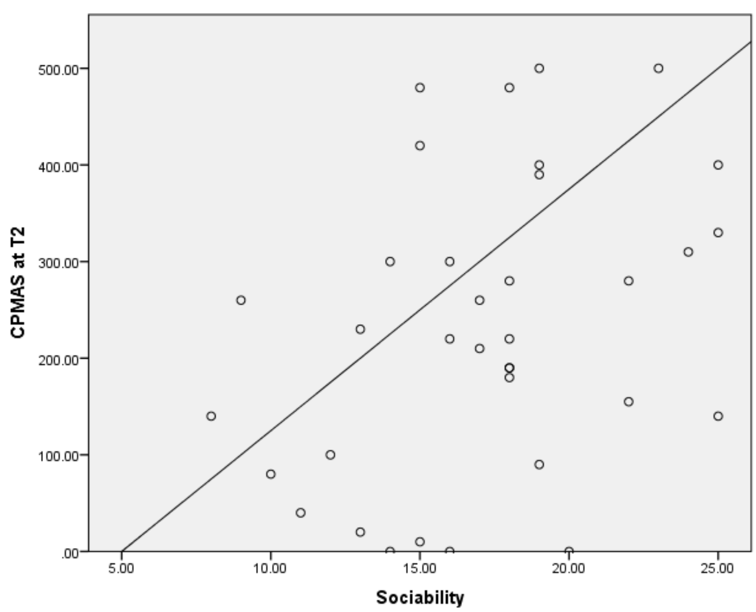
CPMAS = Children's Perioperative Multidimensional Anxiety Scale; T1 = 1 week prior to surgery.

Figure 3. Scatterplot of Shyness and Preoperative Anxiety at T2.



CPMAS = Children's Perioperative Multidimensional Anxiety Scale; T2 = Immediately before surgery.

Figure 4. Scatterplot of Sociability and Preoperative Anxiety at T2.



CPMAS = Children's Perioperative Multidimensional Anxiety Scale; T2 = Immediately before surgery.

Table 1. Linear regressions of temperament predicting preoperative anxiety at T1 and T2.

Assessment	Predictors	B	S.E.	Beta	t	R^2	ΔR^2
Pre-operative Visit (T1)	Shyness	-14.2	6.8	-.32*	-2.1	.10	.08
	Sociability	11.0	4.9	.34*	2.2	.12	.09
Day of Surgery Visit (T2)	Shyness	-13.0	8.9	.-25	-1.5	.06	.03
	Sociability	12.3	5.6	.36*	2.2	.13	.10

S.E. = standard error; * $p < .05$.

Discussion

We revisited a long-standing question in psychology, person-context interactions on behavior (Lewin, 1951), using a non-normative stressful context (i.e., preoperative surgery) in relation to temperamental shyness and sociability in children. In this preliminary investigation, we found, unexpectedly, that temperamental shyness was inversely related to preoperative anxiety, while temperamental sociability was positively related to preoperative anxiety. This result was inconsistent with findings by Kain and his colleagues (2000) who found a relation between reduced sociability and increased preoperative anxiety in children.

Contrary to existing literature on shyness x context interactions in children, our preliminary data suggest that temperamentally social children, rather than temperamentally shy children, may be more prone to experiencing preoperative anxiety in a surgical context. This finding was inconsistent with previous findings involving temperamentally shy children who have been shown to behave consistently across contexts (Coplan et al., 2009; Rubin, et al., 1997). This discrepancy could be due to the fact that Rubin's group had a more extreme subset of temperamentally shy children than in the present study, they also used different measures to classify shy children, and/or conducted the study under a different context. In addition, Rubin et al. noted consistency across contexts in temperamentally shy children in their behaviors using an extreme subset of shy children who were classified using behavioral and maternal reports, and observed in a university laboratory setting. This difference could also be due to the nature of the context used in the present study which was non-normative and outside of the home, school, and laboratory.

What does the inverse relation between children's temperamental shyness and preoperative anxiety and positive relation between children's temperamental sociability and preoperative anxiety reflect? We speculate that, although seemingly paradoxical, our findings suggest that temperamentally shy children may exhibit relatively lower preoperative anxiety in a surgical context because they might have learned to cope with their anxiety overtime, perhaps due to their persistent experience of anxiety in their everyday environments. In other studies, we have found that there are age-related changes in cortisol stress levels with decreasing cortisol levels with age in people who are temperamentally shy, beginning in middle childhood (Schmidt, Santesso, Schulkin, & Segalowitz, 2007) to adulthood (Beaton et al., 2006; Beaton, Schmidt, Schulkin and Hall, 2013). We have argued that these changes might reflect "recalibration" of stress systems due to a life history of dealing with persistent stress and a psychological central state of fear in the temperamentally shy person's everyday environments. Furthermore, this change might also reflect a protective mechanism against system breakdown. Social children, on the other hand, may not have had the same opportunities and be as experienced with coping with stress and fear. Therefore, when placed in a highly stressful environment (i.e., an unfamiliar surgical context), social children manifest relatively higher levels of preoperative anxiety.

Higher levels of shyness in children may also lead to less anxiety because parents may be aware of these difficulties and attempt to compensate by more actively preparing them for surgery. In this unique context, perhaps differential parenting styles might serve to protect children. Future studies should seek to further examine the role of parental influences on children's perioperative anxiety by assessing the role they may play in these associations.

The present study, however, had several limitations that warrant further discussion. First, the present results are based on a relatively small sample. This is a unique medical sample with children undergoing elective ENT surgeries, thus, the recruitment and follow-up with children and families on the day of surgery were challenging which limits our sample size. Second, the findings are based on subjective reports. Although we used reliable and validated subjective measures, these measures can be inherently biased. Third, there may have been issues related to informant biases. We had different informants complete measures, so issues of measurement variance may have occurred. Fourth, we did not use an extreme group design to classify temperamentally shy children overtime, so our findings might not generalize to extremely temperamentally shy children. Future studies should use a larger sample, objective behavioral measures coded from direct observations of child behaviors within the surgical settings, and extreme groups to classify temperamentally shy and social children in order to ensure the reliability and generalizability of the present results.

The present preliminary findings have implications to theory, reproducibility, and practice. The study of person x context interactions on behavior have had a long history in psychology (e.g., Allport, 1937; Lewin, 1951; Mischel, 1979). However, a majority of studies with children over the years have used relatively normative environments such as the home, school, and laboratory, so we do not know the extent to which person x context interactions would generalize to non-normative stressful contexts. Our findings highlight the importance of considering other contexts, normative and non-normative, which is necessary to enhance reliable prediction of behavior, fully understand individual differences and person x context interactions, and to reproduce findings.

In terms of practice, our preliminary findings highlight the need to consider individual differences in temperament when preparing children for surgery. Studies have shown that there are individual differences in children's reactions to the surgical context (Kain, Mayes, Weisman, & Hofstadter, 2000) and that children who are anxious require more anesthetic induction (Maranets & Kain, 1999), are likely to refuse procedures (Kain, Wang, Mayes, Caramico, & Hofstadter, 1999), and take longer to recover post-operatively (Chow et al., 2016; Long & Rajagopalan, 2002; McCann & Kain, 2001). The present preliminary results suggest who may or may not be at risk for heightened preoperative anxiety. Such knowledge would be helpful to parents and health practitioners for developing precision medical approaches for managing children's preoperative anxiety.

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CHAPTER SIX: GENERAL DISCUSSION

Summary

Surgery can represent one of life's most stress-inducing events, particularly for children who may have limited experience with exposure to severe physiological or emotional stressors. Because exposure to pediatric surgical procedures is not uncommon, perioperative anxiety is a sufficiently frequent and ecologically relevant exposure that can provide us with important information about children's anxiety experienced in and outside of the hospital setting.

Children experiencing preoperative anxiety and their families are affected in many ways. Aside from the emotional distress and trauma they can experience, these children are at a much higher risk of manifesting maladaptive behaviors and adverse postoperative outcomes (Fortier, Del Rosario, Martin, & Kain, 2010; Kain et al., 2004; Kain, Mayes, O'Connor, & Cicchetti, 1996). The children who manifest the maladaptive behaviors generally have issues with future healthcare compliance which poses further threats to their individual health and development, which together can increase suffering, healthcare costs and societal burden (Kain et al., 2007; Lee et al., 2013; McCann & Kain, 2001; Perry, Hooper, & Masiongale, 2012).

Reducing preoperative anxiety therefore has significant potential to prevent physical and mental health problems in a large number of children. The most common interventions used to reduce preoperative anxiety include preoperative sedation and/or expensive multi-faceted preparation programs. Unfortunately, these interventions are not always readily accessible, can be time-intensive, or are associated with undesirable side effects and high costs (Chow, Van Lieshout, Schmidt, Dobson, & Buckley, 2015).

Existing gaps in the research literature prompted the conduct of a systematic review and meta-analysis which examined studies assessing the effectiveness of AV interventions at reducing preoperative anxiety and its associated outcomes in children undergoing elective surgery (Study 1; Chow et al., 2015). The findings of the review further led me to conduct a series of studies that included the development and validation of a new instrument designed to efficiently and validly assess children's preoperative anxiety (Study 2; Chow, Van Lieshout, Buckley, & Schmidt, 2016), a series of pilot studies that examined the feasibility and acceptability of a newly developed tablet-based intervention for reducing children's preoperative anxiety (Study 3; Chow, Van Lieshout, Schmidt, & Buckley, 2016; submitted to *Journal of Developmental & Behavioral Pediatrics*), and a study that examined the contribution of individual differences on the variance of children's reaction to surgery during the preoperative period (Study 4; Chow, Nejati, Van Lieshout, Buckley, Schmidt, 2016; submitted to *Clinical Pediatrics*).

The results of the systematic review and meta-analysis in Study 1 demonstrated that videos, multi-faceted programs and interactive games alone or in combination with other interventions (such as midazolam) were more effective than standard care, and were as effective as midazolam (Chow et al., 2015). Conversely, interactive music therapy and internet preparation interventions did not appear to be effective. Thus, these findings suggest that AV interventions are effective in reducing children's preoperative anxiety. Successful preoperative AV interventions seem to include components that require cognitive processing and attention shifting such as multisensory distraction techniques, and/or psychoeducational materials. It is therefore possible that these are the effective 'ingredients' in these interventions that allow for the learning and rehearsal of relevant procedural information prior to surgery. Future studies should actively seek to test the key components of these interventions and compare AV approaches with and without psychoeducational materials to determine if psychoeducational materials provide additional benefit.

In Study 2 (Chow et al., 2016), the psychometric properties of the newly developed scale, CPMAS, were assessed in a busy children's hospital setting. The results showed that the CPMAS scale demonstrated good reliability and strong internal consistency and stability. The SCARED-C was used, as a measure of convergent validity as it encompasses different domains of childhood anxiety, which allowed us to parse out the specific type of anxiety that children experience in the surgical context (e.g., panic/somatic, separation anxiety, generalized anxiety, and school phobia). Therefore, convergent validity was found between CPMAS scores and SCARED-C scores at all three assessment points. Specifically, the CPMAS was consistently correlated with the Panic Disorder subscale across all three visits, with Generalized Anxiety Disorder at T1 and T3, with Separation Anxiety Disorder at T2 and Social Anxiety Disorder at T3. The construct validity was also supported. These findings revealed that the CPMAS is an useful instrument that can accurately assess children's preoperative anxiety that are consistent with clinical experience during the surgical period (Davidson & McKenzie, 2011). Moreover, the CPMAS uniquely allows for both pre-and post-operative assessment which allows for future research to track the changes of anxiety before and after surgery (e.g., recovery periods).

In Study 3 (Chow et al., 2016; submitted to *Journal of Developmental & Behavioral Pediatrics)*, the feasibility and acceptability of the new tablet-based STM intervention were examined. The results demonstrated that participant recruitment, retention, and data collection procedures were feasible. The study also showed that the STM intervention is acceptable to participants who can view it prior to surgery and even on the day of surgery. This pilot work suggests that reductions in anxiety are greater in children in STM+UC than those receiving UC alone, indicating that STM may be effective in reducing children's preoperative anxiety. Therefore, this pilot RCT provides preliminary evidence that STM is feasible and has the potential to be an effective intervention for reducing children's preoperative anxiety.

The results from Study 3 revealed that there were variations in terms of children's stress response to surgery which led to the conduct of the last study. Study 4 (Chow et al., 2016; submitted to *Clinical Pediatrics*), set out to examine the role of specific temperamental traits, shyness and sociability, in predicting preoperative anxiety. Its results showed that temperamental shyness was inversely related to preoperative anxiety, while temperamental sociability was positively related to preoperative anxiety. These findings are not consistent with previous research involving temperamentally shy children who have been shown to behave consistently across contexts (Coplan, DeBow, Schneider, & Graham, 2009; Rubin, Hastings, Stewart, Henderson, & Chen, 1997). Although seemingly paradoxical, our findings suggest that temperamentally shy children may exhibit relatively lower reported preoperative anxiety in a surgical context because they might have learned to cope with their anxiety over time, perhaps due to their persistent experience of anxiety in their everyday environments. In addition, children with higher levels of temperamental shyness may have been exposed to differential treatment by their parents who may have more actively prepared them for surgery. Thus, future studies should examine the role of family factors on children's anxiety by including assessments of parental intervention.

General Findings

To our knowledge, this series of work is the first to systematically investigate the impact of AV interventions on preoperative anxiety in children undergoing elective surgery. Our findings from Study 1 suggest that AV interventions are promising and potentially cost-effective tools in helping to ameliorate children's preoperative anxiety, as well as improving a number of other adverse perioperative outcomes. In Study 2, we demonstrated that the newly developed CPMAS has the potential to be a useful and valid tool for the evaluation of anxiety in a surgical setting for children as young as 7 years old. This brief 5-item self-report can easily be utilized to accurately assess perioperative anxiety in routine clinical practice and research settings. Subsequently, our findings in Study 3 demonstrated the feasibility and potential effectiveness of a novel tablet-based STM intervention. The results of Study 3 support the clinical importance of continuing to examine the effectiveness (and mechanisms of effect) of the STM intervention in reducing preoperative anxiety for children undergoing surgery. The refined protocol and our pilot results will help inform and guide the conduct of a large-scale RCT in managing preoperative anxiety and its effects on children. Specifically, STM adds to the existing literature about the educational component of a tablet-based intervention in reducing preoperative anxiety for children undergoing surgery. Furthermore, our findings in Study 4 revealed that shyness and sociability were each significant predictors of preoperative anxiety. The preliminary findings also suggest who may or may not be at risk for heightened preoperative anxiety. Such knowledge would be helpful to parents and health practitioners for developing precision medical approaches for managing children's preoperative anxiety.

Limitations

Despite the strengths presented in this work, a few limitations should be highlighted. First, only children who received elective outpatient surgeries (i.e., tonsillectomy, herniorraphy, etc.) were included in our studies to control for possible confounding factors such as unexpected postoperative complications that arise from major surgeries, differential duration of surgery or length of recovery. While elective outpatient surgeries are the most common surgical procedures in children, we excluded more lengthy or extensive surgeries that also include a potential postoperative hospitalization component. Also, many of these families had similar, relatively non-disadvantaged socioeconomic backgrounds. Therefore, whether our findings are generalizable to other, less socioeconomically advantaged children and children undergoing repeated and/or non-elective surgeries in other surgical settings is unknown. The management of anxiety over the course of a longer term hospitalization, or associated with diseases such as cancer, could present different challenges, and so the role of AV interventions in these settings remains to be seen.

Second, the findings in our studies are based on a relatively small sample. The results could potentially be statistically underpowered which could undermine the reliability of the results. Thus, it is our goal to replicate our studies using larger adequately powered samples in future studies.

Lastly, the findings on children's temperament and anxiety are solely based on subjective reports. Although CCTI, SCARED-C and CPMAS are reliable and validated subjective measures, these measures can be inherently biased.

Implications

Clinically, despite its high prevalence and the potential adverse effects, preoperative anxiety in children remains an understudied topic. Our work is the first to suggest that AV interventions might be an ideal solution to improve perioperative care in children undergoing elective surgery. The findings would guide future research in designing and developing interventions to prevent and manage children's preoperative anxiety and its associated outcomes. In particular, the utilization of AV interventions might be extremely beneficial in hospitals that lack the appropriate resources (e.g., the Child life Specialist preparation and/or other forms of preoperative preparation programs) to prepare children for surgery.

The self-report CPMAS was developed and validated to address the need for properly assessing children's preoperative anxiety in the busy hospital setting. In contrast to the existing children's anxiety measures that are non-specific and onerous, the CPMAS is specifically designed to be used to quickly and accurately assess the anxiety levels of children undergoing surgery. Ideally, the goal is to incorporate this measure as part of the preoperative assessment to be administered by either Child life Specialist or pediatric nurses. Since our preliminary data suggested that there are variations in children's response to surgery, it is possible that some children require more preoperative preparation and attention than others. By using the CPMAS, healthcare providers can provide appropriate perioperative care to the ones who are truly in need.

Furthermore, the novel tablet-based STM application was shown to be easy to use and its administration was done without any interruption to the normal hospital routine and/or clinical flow which can lead to the more efficient and effective allocation of healthcare staff and resources. Therefore, the use of STM application can potentially improve the perioperative experience and process for children and families undergoing surgeries. If future work can demonstrate that the STM application is effective, this transferable and reusable tool could potentially become an adjunctive therapy to usual care or to be incorporated as part of the routine care practice. Given the customizability nature of the application, the content can be modified to suit the specific needs of other healthcare environments and surgical procedures. This powerful tool has the potential to be adapted and used in many hospital settings and beyond (Chow et al., 2014).

Our work also provides insights into the potential value of identifying risk factors such as temperament and predictive biomarkers (e.g., high basal cortisol levels or elevated heart rate at anesthetic induction) that can guide future practice by customizing treatment. This "precision medicine" approach is an important avenue by which clinical outcomes can be optimized. The overarching goal should be to improve surgical experiences and outcomes in children, and to streamline the perioperative process by allowing children to develop coping strategies to deal with surgical stress.

On a theoretical level, the findings also informed us of the broader implications on the study of individual differences, personality and childhood anxiety in the surgical setting. The extant literature is based on research conducted in the traditional settings such as laboratory, home or school. Therefore, the surgical setting represents a novel, non-normative and ecologically-valid stressful context. This preoperative surgical environment provides us with a real-life, highly relevant anxiety-provoking context to better assess childhood anxiety and behaviors. Interestingly, our work suggested that children's behaviors might be contextually-dependent. On the day of surgery, children are forced to interact with unfamiliar people (i.e., medical staff, and other children and families), and are placed in unfamiliar settings (e.g., waiting areas and OR). These interactions in a novel, yet, stressful environment could substantially influence how a child would behave. Thus, our findings highlight the importance of considering other normative and non-normative contexts to enhance reliable prediction of children's behavior, to fully understand individual differences and person x context interactions, and to reproduce findings.

Collectively, the work presented in this thesis has the potential to improve perioperative care, lessen the impact and prevalence of the complications of surgery for both children and their families, and perhaps ease the financial burden of preoperative anxiety on the healthcare system. Moreover, it illustrates that the surgical setting serves as an ecologically-valid context to study childhood anxiety.

Future Directions

Based on the findings of this thesis, adequately powered, large RCTs should be conducted to further confirm the usefulness of some of the promising non-pharmacological interventions such as the newly developed tablet-based STM application. Future studies should quantify the optimal dosage and duration required. Because of the automatic and reusable nature of AV interventions, it might be advantageous to include cost-effectiveness analyses in the conduct of these RCTs to examine whether AV interventions are indeed the more financially sound options compared to currently used interventions in reducing preoperative anxiety.

Future research should examine whether these behavioral changes have corresponding physiological correlates using validated psychophysiological measures (e.g., cortisol, heartrate or electroencephalography patterns). It is also of importance to establish the threshold value for the clinical significance of change in anxiety measured using the CPMAS.

Once these RCTs have established the effectiveness of the STM intervention, it would then be worthwhile to continue to test the effectiveness of the STM application in other hospital settings which may not have access to highly trained Child life specialists. Moreover, when designing future RCTs, investigators should be mindful of the methodologies and consider the use of proper randomization and blinding strategies, the administration of both validated observers' reports and self-reports of behavioral changes, and the use of the intention-to-treat method as the primary analysis. These changes would enhance the validity of the results of future studies.

To elucidate the etiology of children's preoperative anxiety, future work should identify the potential modifiers and moderators of the phenomenon. Future studies should also examine the role of parent-child interactions (e.g., the interactions on the day of surgery before and during the anesthetic induction, parental bonding and stress).

Future studies should continue to explore childhood anxiety research in a surgical setting and to replicate the studies in other less ecologically-valid contexts.

Conclusion

Given the myriad negative effects associated with perioperative anxiety, it is crucial that we develop proper perioperative care strategies for prevention and intervention strategies that aim at reducing perioperative anxiety in children undergoing surgery. This begins with the use of a proper tool (i.e., CPMAS) that can quickly and accurately measure perioperative anxiety levels in busy hospital and clinical settings.

The search for a simple, affordable and novel treatment in reducing preoperative anxiety continues. AV interventions have been shown to effectively alleviate preoperative anxiety, albeit prohibitively costly. More research is required to continue to elucidate the etiology of childhood anxiety within the surgical setting and to test affordable and effective interventions (e.g., STM) to prevent and ameliorate preoperative anxiety and its associated adverse outcomes in children undergoing surgery.

Furthermore, the surgical setting represents a novel, non-normative and ecologically-valid stressful context. Future research should continue to examine childhood anxiety and behaviors in both normative and non-normative contexts to enhance the reliability of the findings.

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