

The influence of a play intervention on pre-operative anxiety in children at an academic hospital: A pilot study

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg in partial fulfilment of the requirements for the degree of Master of Medicine in the branch of Anaesthesiology.

Johannesburg, 2019

Declaration

I, Ushira Ramkisson declare that this research report is my own unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

15 January 2020

Abstract

Background

Research has shown that up to 65% of children who present for surgery experience anxiety in the pre-operative period, with the induction of anaesthesia being regarded as the most potent stimulator of the anxiety. The aim of this pilot study was to explore the influence of a play intervention on pre-operative anxiety in children presenting for elective surgery at Charlotte Maxeke Johannesburg Academic Hospital.

Methods

The sample was composed of 40 participants who were undergoing elective surgery, of which half were randomly assigned to the play intervention group (n=20) and received 15-minutes of play intervention. The control group (n=20), received standard pre-operative care. The m-YPAS was used to measure the anxiety levels in children during the induction of anaesthesia.

Results

No significant differences were found between the two groups for age ($p = 0.23$) or sex ($p = 0.52$). The results showed that all children were anxious except for 2 (5%) but that a significant difference between anxiety levels was found between the play intervention and control groups ($p=0.0062$).

Conclusion

Children exposed to a 15-minute play intervention prior to surgery experienced significantly lower levels of anxiety at induction of anaesthesia than children receiving standard pre-operative care. It is suggested that a play intervention should be considered as a method of decreasing pre-operative anxiety in children and a larger study be conducted to gain more information.

Acknowledgements

I would like to thank my two research supervisors Juan Scribante and Helen Perrie for their guidance and constant encouragement throughout the various stages of this research.

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Abbreviations

ED	Emergence delirium
m-YPAS	Modified Yale Pre-operative Anxiety Scale
PPIA	Parental presence at induction of anaesthesia
STAI	Stait Trait Anxiety Inventory
STAIC	Stait Trait Anxiety Inventory Children
YPAS	Yale Pre-operative Anxiety Scale

Statement

The Research Report consists of a literature review, draft article, study proposal and appendices. The study proposal is included for background reference and is not for examination.

The formatting of this Research Report complies with the University of the Witwatersrand's Style Guide for Theses, Dissertations and Research Reports. The formatting of the draft article may differ from the rest of the Research Report in order to comply with the author guidelines of the South African Journal of Anaesthesia and Analgesia, the journal to which it is intended to be submitted.

Section 1: Review of the literature

1.1 Introduction

The peri-operative period can be viewed as an important event in the life of the child (1, 2). However, unlike other events in the child's life, this is often associated with an element of fear (2). The reasons for this are multifactorial and include exposure to the unfamiliar hospital environment, being taken away from areas of comfort, separation from parents and fear of the anaesthetic and surgical procedure (2-4). Studies have shown that up to 65% of children who present for surgery experience high levels of anxiety in the pre-operative period, with induction of anaesthesia being regarded as the most potent stimulator of this anxiety (2).

Pre-operative anxiety may be expressed in many forms. Some children may verbalise it, whereas others express it behaviourally (1, 2, 5). Many children look frightened, can become distressed, start breathing deeply, stop playing or talking and some might cry (2). Other children may unintentionally wet themselves, have increased motor tone or might attempt to run away from the theatre environment (2, 5). In addition to behavioural changes occurring prior to and during induction of anaesthesia, these changes have also been described post-operatively and up to 67% of these children may develop long-term maladaptive behavioural changes (1). In this chapter the history of pre-operative anxiety, risk factors and prediction of pre-operative anxiety, adverse behavioural and physiological effects of pre-operative anxiety, assessment of anxiety in children, child developmental stages important to the anaesthetist and strategies to alleviate pre-operative anxiety will be discussed.

1.2 History of pre-operative anxiety

In 1941, Pearson (6) described significant emotional reactions in children undergoing anaesthesia and surgery. He noted that a child's emotional development is incomplete and, unlike an adult who recovers quickly after a surgical procedure, children may go on to develop maladaptive behaviour. Later, in 1958 a study conducted by Eckenhoff (7) revealed a link between an

inadequate anaesthetic induction and subsequent development of negative behaviour post-operatively. This led the way to recognising the importance of anxiety experienced by children in the peri-operative period (5).

Between 1960 – 1970 researchers examined issues related to parental presence at induction of anaesthesia (PPIA) and preparing the child for anaesthesia and surgery (8-11). Research revealed a reduction in anxiety levels experienced by these children, however, the researchers work was hindered by the lack of reliable tools that could be used to measure anxiety in children (5). In 1977 Venham et al (12) developed a tool for measuring anxiety in children undergoing dental procedures, the Venham Picture Test, which was later used by some researchers to measure anxiety during induction of anaesthesia. In 1995 Kain et al (13) developed an observational scale called the Yale Pre-operative Anxiety Scale (YPAS) that could be used to assess levels of anxiety in children and was modified in 1997 (14) the Modified Yale Pre-operative Anxiety Scale (m-YPAS).

1.3 Risk factors and prediction of pre-operative anxiety in children

Over the years, researchers have identified several risk factors that contribute to the development of pre-operative anxiety in children (2). With an understanding of such risk factors, these individuals can be identified pre-operatively and an appropriate intervention implemented to help prevent the development of anxiety and distress in the peri-operative period (2). The risk factors can be categorised into child, parental and environmental factors (1-3).

1.3.1 Child factors

The child risk factors include age, temperament and previous hospital experience. Infants are less likely to experience separation anxiety from their parents as they are able to be comforted by medical staff (5, 15). At 1 – 3 years, separation anxiety from parents is present as this age group is well bonded to their parents (5, 15). Developmentally this age group is too young to understand and accept explanations and will respond well to distraction and comforting measures (5, 15). In the 4 – 6 years age group, children require more information and want to feel in

control of events (5, 15). The 7 – 12 years age group want to be involved in decision making regarding their surgery (5). This should be done in a non-stressful pre-operative setting (5). The adolescent group is a sensitive age group. Their main source of fear is failure to cope (5). The sex of the child does not influence pre-operative anxiety or the development of post-operative behavioural issues (1-3).

Kain et al (2) found that shy, inhibited children with high I.Q levels had increased levels of anxiety in the pre-operative holding area. Children with poor social adaptive behaviours were also found to be at increased risk of pre-operative anxiety (1, 2, 15). Impulsive children have an increased risk of general and separation anxiety post-operatively (1-3). Previous distressing hospital experiences increases the risk of pre-operative anxiety (2, 15). In a study by Kain et al (2), it was shown that previous poor quality hospital experiences led to increased levels of anxiety in the pre-operative holding area and separation anxiety from parents. This resulted in children being more distressed and less co-operative at induction of anaesthesia (2). These factors are particularly important for children requiring repeated anaesthetics (2). Studies have found that poor attachment style between parent and child puts children at increased risk of pre-operative anxiety (1, 2).

1.3.2 Parental factors

Many parental factors have been identified as risk factors for the development of pre-operative anxiety in young children (1, 2, 16). Parents with poor coping skills are more likely to have a child who develops pre-operative anxiety than a parent with good coping skills (1, 2). Children of anxious parents have higher levels of anxiety at induction of anaesthesia. They are also more likely to develop post-operative behavioural problems (1, 2, 17). Children of divorced, single or separated parents have an increased risk of pre-operative anxiety (1). Studies have found that mothers are generally more anxious than fathers (1, 17). Parents of infants and parents whose children have had repeated hospitalisations are found to be more anxious (1, 17)

1.3.3 Environmental factors

Increasing the number of people in the operating room during induction of anaesthesia is associated with the development of pre-operative anxiety in young children. Children have been found to be less anxious when induction of anaesthesia is conducted by a single health care provider in a darkened, quiet room with background music (1, 16, 18, 19). The choice of anaesthetic induction technique has shown to have an impact on pre-operative anxiety (1, 20). In a study conducted in Finland (20), researchers looked at the effect of anaesthetic induction technique on the development of pre-operative anxiety and post-operative behavioural problems. Children were randomised into three groups: an inhalational group, a rectal group and an intravenous group (20). All patients were pre-medicated and parents were not present at the induction of anaesthesia (20). The most difficult inductions were with the intravenous group, followed by the rectal group, with the inhalational group having the least difficult induction (20). Health care workers can significantly impact on the development of pre-operative anxiety in children (1). Health care workers that are trained in paediatric anaesthesia and whom appear calm and collected at induction of anaesthesia promote a calmer environment (21).

1.4 Adverse behavioural and physiological effects of pre-operative anxiety

It has been suggested that the induction of anaesthesia is regarded as the most stressful time of the entire peri-operative period (1, 2, 18). Modalities aimed at alleviating pre-operative anxiety exist, however they are not used on every child as it is not cost-effective (2). This results in a number of children experiencing significant pre-operative anxiety prior to induction of anaesthesia (2). This anxiety is characterised by subjective feelings of nervousness, tension and worry that may be expressed in many forms (2, 15, 20). Many children become agitated, start crying, have increased muscle tone and may try to escape from the theatre environment (2, 15, 20). Post-operative maladaptive behaviour such as general anxiety, new onset enuresis, feeding difficulties, withdrawal, apathy and sleep disturbances are known to occur (2, 7, 11). Risk factors for the development of maladaptive behavioural responses include: age (6 months – 4 years) number of

siblings, temperament of the child and lack of enrolment in nursery school (2). Anxiety of the child and of the mother were also found to be predictive of the development of post-operative maladaptive behavioural responses (2). Kain et al (2) found that although up to 88% of children develop maladaptive behavioural responses after surgery the extent of such responses are small and only a minority go on to develop long-term maladaptive behavioural responses. The concern is that in children who have persistent behavioural problems, this may have a negative impact on future health care interactions and may also impair normal development (22). In a follow-up study, Kain et al (22) demonstrated that children with significant anxiety during the induction of anaesthesia were more likely to develop post-operative maladaptive behaviour responses. The authors found that the increased anxiety at induction of anaesthesia and the development of post-operative maladaptive behavioural problems to be more an association between the two phenomena and not a cause-effect relationship (22).

Emergence delirium (ED) is defined as “a disturbance in a child’s awareness of and attention to his/her environment with disorientation and perceptual alterations including hypersensitivity to stimuli and hyperactive motor behavior in the immediate post-anesthesia period” (23). ED starts as the child awakens from general anaesthesia and lasts around 5 – 15 minutes and resolves spontaneously (24). A child experiencing ED is usually inconsolable and trashing about all over the recovery bed and this may result in injury to the child or theatre staff, may cause disruption of the surgical site and accidental removal of intravenous lines and surgical drains (25). A true cause-effect relationship between pre-operative anxiety and ED is yet to be proven (26). In 2004, Kain et al (26) found an association between the two phenomena. They found the odds of experiencing ED increased by 10% for every 10 point increment on the m-YPAS.

In addition to behavioural problems, pre-operative anxiety also activates the stress response. Stress activates the hypothalamic-pituitary-adrenal axis resulting in an increase in circulating glucocorticoids and is associated with an alteration in immune function and susceptibility to infection (15). Patients with pre-operative anxiety have also been found to have increased post-operative pain resulting in delayed discharge from hospital and increased overall cost (27).

1.5 Assessment of anxiety in children

Assessing anxiety in young children can be difficult in the pre-operative setting (28). During the pre-operative period there is limited time in which children can be observed. The operating room and pre-operative holding area are busy areas which make administration of an observational anxiety tool difficult (28). Young children are often not able to verbally express their levels of anxiety, this could be because they are developmentally incapable of doing so or because their already anxious state is preventing them from doing so (28).

When assessing anxiety in young children it is extremely important to use tools that have been developed for a specific age group (5, 13, 14). These tools may include clinical evaluation, psychiatric evaluation, self-evaluation or observational evaluation and evaluations that can be conducted by family members (5). It is important that the tool being used can also accurately evaluate anxiety in young children in the pre-operative setting (13, 14).

Early attempts of measuring anxiety in young children were hindered by the absence of a validated tool (5). Subsequently many tools have been developed to aid in measuring anxiety in young children (5). These tools can be categorised in to observer and self-report measures (5). The observer measures include:

- Clinical Anxiety Rating Scale,
- Global Mood Scale,
- YPAS, m-YPAS,
- Visual Analogue Score and
- Induction Compliance Checklist (5).

Self-report measures include:

- State Trait Anxiety Inventory for Children (STAIC) and
- Venham Picture Test (5).

The tool regarded as the “gold-standard” in measuring anxiety in young children is Spielberger’s STAIC (5). The STAIC tool for measuring anxiety in young children has been used in numerous studies, however, it has its limitations (5, 14). It takes

on average 5 – 10 minutes to complete this questionnaire, which makes it impractical in busy operating room settings (5, 14). The questionnaire can only be used in children older than five years and it needs to be read out to children younger than eight years (5, 14). Due to its limitations this scale is not fit for use in pre-school children, which is the age group most vulnerable to pre-operative anxiety (5, 13, 14).

To aid in measuring anxiety in children between 2 – 6 years Kain et al (13) developed an observational scale called the YPAS. This scale has been used in many studies to assess pre-operative anxiety in young children. The original version was developed in 1995 at Yale University and was modified in 1997 m-YPAS (14). By modifying the scale, it allowed for anxiety assessment to be carried out in the pre-operative holding area and also extended the age range up to 12 years (14).

The m-YPAS is composed of five categories (activity, emotional expressivity, state of arousal, vocalisation and use of parents) (14). These five categories define twenty-two specific behaviours in children that indicate anxiety during induction of anaesthesia (14). The highest level observed in each category is the score allocated to that category (14). The observer is neutral and does not influence the child's behaviour (14). In the m-YPAS each category has a different number of items (ranging from 4 – 6). Partial weights are thus used to calculate the total score with the total weighted score ranging from 23.33 – 100 (14). The higher the score, the higher the level of anxiety present (14). The m-YPAS has good to excellent inter and intra observer reliability and good validity when compared to the gold standard (14). The scale can be used either in the pre-operative holding area or during induction of anaesthesia (14). Unlike the STAIC tool the m-YPAS can be completed in less than a minute (13, 14).

1.6 Child developmental stages important to the anaesthetist

An understanding of the developmental stages is important to understand the child's responses to hospitalisation and to establish an effective method to manage pre-operative anxiety (1, 29, 30). When designing an intervention aimed at alleviating pre-operative anxiety in children, their developmental stage needs to

be taken into account, as chronological age does not always match developmental stage (29). Lerwick (29) refers to Erikson's eight developmental stages, with the first four establishing a foundation for understanding the emotional needs of children.

Stage one occurs in infancy (0 – 1 year) and the main psychosocial development is the building of trust or mistrust. For the infant trust and mistrust are dependent on the level of attachment with the caregiver and how the caregiver responds to the needs of the infant (29, 30). This is important because if mistrust was developed during infancy this could result in increased stranger and separation anxiety when exposed to the unfamiliar hospital environment (29, 30). Suggested methods of alleviating this anxiety include: having PPIA, cuddling, rocking and speaking in a soft voice (1).

Stage two occurs in early childhood (1 – 3 years) and the main psychosocial development is finding a balance between autonomy with shame and doubt (29, 30). Autonomy is achieved when a toddler accomplishes a skill by themselves (29, 30). Children in this stage feel threatened when exposed to the hospital environment as exposure to medical treatment removes toddlers' most important sense of control; the ability to determine what happens to their bodies (29, 30). Suggested methods of dealing with this stage include age appropriate simple explanations as to what they will see and what they will hear as this age group understands more than they can verbalise back (1, 29). In this stage children also fear abandonment and thus PPIA should be allowed (1, 29). Play is a major coping skill in this stage and distraction offers another method of dealing with their anxious state (1, 29)

Stage three occurs in the pre-school group (4 – 5 years) and the main psychosocial development is the ability to set and complete tasks (29, 30). Pre-school children explore with imagination and curiosity (29, 30). Their increased cognitive functioning serves as an opportunity to create elaborate stories in their minds thus caution should be exerted when using medical terms with this stage as a stretcher to transport patients may actually be viewed as actually stretching a person (1, 29). Magic and pretend are fun in this age group thus allowing a child to explore basic medical equipment through play therapy offers a means of dealing

with pre-operative anxiety (1). Children in this stage also fear separation anxiety thus PPIA should be allowed (1).

In stage four, children (6 – 12 years) have well-developed language skills, concepts of time and concerns about body image are also introduced (29). Children in this stage want to be involved in their care thus allowing them to hold the anaesthetic mask and asking them on which finger to place the saturation monitor aids in alleviating their anxiety (1). Children in this stage also want to be told the truth and they take information literally thus simple truthful explanations help allay any fears or anxieties they may have (1).

1.7 Strategies to alleviate pre-operative anxiety

1.7.1 Pharmacological premedication

The use of premedication is a well-established practice in paediatric anaesthesia (31). The aims of premedication are: to achieve a decrease in the stress response with preservation of the child's haemodynamic parameters, to facilitate induction of anaesthesia and to produce amnesia (31, 32). Following premedication, the patient usually exhibits an altered level of consciousness but should still maintain the ability to maintain a patent airway, respond to tactile stimulation and follow verbal commands (31, 32). When administering premedication, the child's age, weight, allergic history, medication history, previous medical and surgical history need to be taken into account. Premedication must be administered under direct supervision with the patient in a closely monitored environment and resuscitation equipment immediately available (31, 32). The pharmacological agents commonly used for premedication include: midazolam, ketamine and clonidine (31-33).

Midazolam is a short acting benzodiazepine (31, 33). It interacts with the gamma – aminobutyric acid – benzodiazepine receptor complex, present in the central nervous system, producing anxiolysis, amnesia and hypnosis (31-33). Midazolam also has additional anticonvulsant and skeletal muscle relaxant effects (31). As a premedication it offers many advantages including a rapid and reliable onset, minimal respiratory depression, antegrade amnesia and reduced ED (31-33). It is

commonly administered via the oral route however intranasal, sublingual, rectal and intravenous routes of administration have also been described (31-33).

Oral midazolam is commonly used as a first line agent (31, 32). The dose of 0.5 mg/kg has been established through studies producing anxiolysis within 15 minutes and anterograde amnesia within 10 minutes, however, peak sedation may take as long as 30 minutes (31). Higher doses have the potential to cause prolonged sedation, ataxia, dysphoric reactions, cardiovascular and respiratory depression without additional improvement in anxiolysis and lower doses producing inadequate anxiolysis (31). The drawback of oral midazolam is that it has a bitter taste and needs to be mixed with a carrier fluid to disguise this (31, 32). Evidence shows that the administration of small volumes of liquid (less than 10 mls) to paediatric patients pre-operatively does not increase their aspiration risk (34). Intranasal midazolam can be used in children not amenable to oral midazolam, however, its major drawback is that it transiently irritates the nasal mucosa causing significant discomfort and crying on administration (31, 32). Sublingual midazolam may not produce crying but it may be difficult to prevent young children from spitting it out immediately (33). Administration of rectal midazolam is associated with a 20% incidence of hiccups for which no explanation can be given and intravenous midazolam requires an intravenous access (33). Although midazolam is effective in alleviating pre-operative anxiety in young children, its use is not without its disadvantages such as: delayed emergence, delayed discharge from hospital, sleep disturbances and increased incidence of maladaptive behavioural changes post-operatively (31-33).

Ketamine is an N-methyl-D-aspartate receptor antagonist. Ketamine produces a state of sedation, immobility, analgesia, amnesia and dissociation from the environment (31-33). It can be administered orally at a dose of 5 mg/kg, intramuscularly at 4 – 8 mg/kg or intravenously at 1 – 2 mg/kg (33). Ketamine's analgesic properties and its ability to produce sedation without significant respiratory depression makes it an appealing agent (31-33). The disadvantages of ketamine usage include: increased salivary and bronchial secretions which can cause laryngospasm at induction of anaesthesia, muscle rigidity, nystagmus and an increased incidence of post-operative emesis (31-33). Owing to these

disadvantages its use is often reserved for the developmentally delayed or autistic child who is uncooperative (31, 33).

As a sole agent midazolam only produces good to excellent results in 60 – 80% of patients (31). Children under four years of age and those who are extremely anxious are unlikely to be adequately sedated by midazolam alone (31). Children who are diagnosed with behavioural problems, developmental delays or a combination of, often require higher doses of midazolam to achieve effective anxiolysis, however this puts them at risk of adverse effects of the drug (31). Midazolam in combination with ketamine has been shown to be effective in achieving adequate anxiolysis in these children (32, 35). Combining the drugs allows reduced doses of individual drugs thus providing a safer profile against airway and respiratory compromise whilst enhancing the anxiolytic and sedative effect (35).

Clonidine is an α_2 adrenergic receptor agonist which was initially developed as an anti-hypertensive agent but later found to have analgesic, anxiolytic and sedative properties (31, 32). It can be administered orally at a dose of 4 $\mu\text{g}/\text{kg}$ or intranasally at a dose of 2 $\mu\text{g}/\text{kg}$ (33). Its analgesic and anaesthetic sparing properties offer potential advantages over the other agents, however its major drawback is its slow onset of action and the cost of the drug (31-33). Clonidine has to be administered at least 45 minutes before surgery (31, 32).

Dexmedetomidine is an α_2 adrenergic receptor agonist that has a greater specificity for the receptor when compared to clonidine (36). Although it has good pharmacological properties, it has an onset time of 35 – 45 minutes and produces hypotension and bradycardia (36). There is good evidence supporting its intranasal use at 1 $\mu\text{g}/\text{kg}$, however, there is not sufficient evidence supporting its oral use (36).

1.7.2 Benefits of PPIA

Parents and children prefer to stay together during induction of anaesthesia (1, 16). Most parents prefer to be present during their child's induction as they feel their presence will be of benefit to their child, however PPIA still remains a

controversial strategy in alleviating pre-operative anxiety in children (1, 16, 33). Benefits PPIA include: eliminating separation anxiety, minimising premedication use, increased co-operation from the child, improving parental satisfaction with medical care and fulfilling parents desire to be present during medical care (1, 25). Objections to PPIA also exist and the reasons for this include: increased parental anxiety at induction leads to increased anxiety in the child, increasing the responsibilities of the operating room staff by caring for the child as well as the parent, concern about interfering with the routine in the operating room, increasing behavioural problems in the child and the legal consequences of having a parent present in the operating room (1, 25). Given the controversies surrounding PPIA, studies have looked at the effect of PPIA on pre-operative anxiety in young children.

Although earlier studies have shown that PPIA is beneficial in terms of reducing anxiety in children, aiding in a smoother induction and promoting parental satisfaction (37-39), subsequent studies have shown no benefit (40, 41). Kain et al (40), in their study, compared PPIA, pharmacological premedication with midazolam and control groups. Their studies demonstrated that children benefited from pharmacological premedication and that PPIA offered no additional advantages in terms of anxiolysis or post-operative outcomes (40). In a follow-up study Kain et al (42) found that PPIA may be effective in certain circumstances and found that the calm child – anxious parent pair benefited the least from PPIA (43). The Cochrane Collaboration (44) summarised their review of eight trials looking at PPIA (44). Their review showed no significant differences in anxiety and cooperation from children during induction of anaesthesia, with one trial showing that midazolam was more effective in reducing anxiety in children (44). A 2017 trial by Sadeghi et al (45) showed that PPIA may reduce pre-operative anxiety in paediatric patients and improve the quality of induction. Despite these controversies PPIA is a pre-induction technique utilised in the hospitals affiliated to the Department of Anaesthesiology at the University of the Witwatersrand.

1.7.3 Non-pharmacological interventions

Over the year's non-pharmacological interventions have gained significant popularity as an alternative means of alleviating pre-operative anxiety in children

(1). These interventions can be targeted at the child, parent or both (1). The various non-pharmacological interventions that have been analysed include: pre-operative information programs (46-48), behavioural intervention programs (49-51) including, distraction activities and play (52-54), child friendly environments (1) and behavioural interventions targeting the care providers (1).

The pre-operative journey starts with the child's paediatrician (55). This should be used as an opportunity to start educating the parents and, if appropriate, the child about the approaching surgery (55). The pre-operative interview with the anaesthesiologist also provides an opportunity to assess the child, develop a relationship with the child and family, provide them with the anaesthetic plan and assure them that their child will be safe (1). It may be argued that the task of going over detailed anaesthetic risks might actually increase anxiety in the parent and child (1). The evidence to support this claim is lacking and it has been shown that the parents of children who receive detailed information regarding anaesthetic risk are no more anxious than those who did not (56). A study by Fortier et al (41) showed that children also want age appropriate explanations of what to expect during the peri-operative period.

Many methods aimed at delivering pre-operative information to children and parents have been used. These include information leaflets (46), interactive books (47), videos (48), cartoons and interactive computer games (57) and operating room tours have been shown to variably reduce pre-operative anxiety. Campbell et al (57) explored the effect of preparing children for surgery using interactive computer programs and cartoons. The researchers found that children in the intervention group were more cooperative during the induction of anaesthesia..

Various distraction techniques have been used to reduce pre-operative anxiety in children. These include video games, clown doctors (58), video distraction (54) and providing an environment conducive to play activities (52). They have all been found to successfully reduce pre-operative anxiety in children. Music therapy has shown successful results in adults but less so in children.

The importance of play in the life of a child has been recognised for many years by psychologists, educators, scientists and philosophers. The famous greek

philosopher Plato said “you can discover more about a person in an hour of play than in a year of conversation” (59). In the 1900's, Friedrich Froebel published a book entitled “The education of man” which conveyed the importance of play in the life of a child (59). In 1909 Sigmund Freud published a documented case on the therapeutic use of play entitled “Little Hans” (59). Subsequently psychologists began to utilise play in their practices to analyse the emotional and behavioural needs of children. Hermine Hugh-Hellmuth, David Levy, Anna Freud and Melanie Klein recognised that play was an ideal medium to allow children to express their feelings and emotions as few children had achieved the developmental level to express such feelings with words (59). Virginia Axline, author of “Play therapy and Dibs in search of self” emphasised that the attitude and personal characteristics of the therapists and relationship between the therapist and child were important in promoting change (59). This became known as child centered play therapy which focused on the child and not the child’s presenting problem. Play therapy has continued to grow and evolve with two different models been created, directive and non-directive.

The Child Life program was established in 1922 with the opinion that positive emotional states promote healing and decrease anxiety and uses medical play therapy to address the entire surgical experience (29). Play therapy is used to meet the emotional needs of children that require surgery. Being in hospital can be stressful for both the child and their family. Children may feel scared, confused and out of control. Play therapy is employed to aid children in understanding their illness and help them cope with hospitalisation and surgery (29). Play therapy allows a child to be exposed to medical equipment and procedures in an environment conducive to playing (29). This allows children to become familiar with their surrounding and even practice using the equipment on dolls in an attempt to desensitise them from the surgical environment. Play therapy is conducted by a play therapist also known as a child life specialist, who has a minimum of a master’s degree in a mental health field as well as training in child and family therapy (29). Unfortunately play therapists are not always be available. This has resulted in research focusing on play interventions as a means or relieving pre-operative anxiety in children which has shown success. A play intervention does not require a play therapist and can be conducted by a health

care provider such as a doctor or nurse. While the duration of the play intervention varied amongst the different studies, Lerwick (30) found that a 15-minute play intervention was successful in reducing pre-operative anxiety in children.

A study by Vagnoli et al (60) in 2005 investigated the effect of clown doctors on childrens pre-operative anxiety during the induction of anaesthesia and on the parent until the child was asleep. The authors showed that the presence of a clown doctor together with the child's parent during the induction of anaesthesia was an effective measure at reducing pre-operative anxiety in children. A follow up study by Vagnoli et al (58) in 2011 compared the effect of clown doctors combined with PPIA, sedative premedication combined with PPIA, and PPIA alone on childrens pre-operative anxiety. This study revealed that clown doctors in combination with PPIA was more effective in reducing pre-operative anxiety in children in comparison to PPIA in combination with sedative premedication or PPIA alone.

In 2009 Athanassiadou et al (61) studied the effect of psychologist structured puppet play therapy one day prior to surgery on pre-operative anxiety. They found a decrease in pre-operative anxiety in the intervention group, however, this decrease was not statistically significant. In 2008 Li et al (62) examined the effect of pre-operative play one week before surgery. This included a tour of the operating room, demonstration on a doll along with exposure to the medical equipment. Their study revealed a significant difference in anxiety levels between the play intervention group and the control group. In 2010 Hosseinpour et al (52) looked at the effect of pre-operative therapeutic play for thirty minutes and found significant differences in anxiety levels between the intervention and control group. In 2016 Li et al (63) looked at various play interventions (preparation play, distraction play, medical play and developmental play) on childrens pre-operative anxiety. Their results showed that hospitalised children who received a play intervention demonstrated significantly lower levels of anxiety than children in the control group.

A review of the literature demonstrates that children are negatively affected by the stressors of the pre-operative period. This is attributable to their poor coping skills and developing minds (30). If not appropriately treated these stressors can lead to

increased anxiety levels, psychological trauma and behavioural issues (2, 22). Ideally all children presenting for surgery should receive a pharmacological pre-medication (5). However, in resource constrained environments, this may not always be available. Alternative non-pharmacological interventions for alleviating pre-operative anxiety are available and have shown success (44). Play is seen as a child's natural mode of communication, it is important for their normal growth and development and is their favourite activity (1). Florence Nightingale stated that play is important for hospitalised children and it is the responsibility of health care workers to create and maintain a therapeutic environment for paediatric patients (64).

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The following are sample references:

1. Jun BC, Song SW, Park CS, Lee DH, Cho KJ, Cho JH. The analysis of maxillary sinus aeration according to aging process: volume assessment by 3-

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Section 3: Draft article

The influence of a play intervention on pre-operative anxiety in children at an academic hospital: A pilot study

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Key words: play intervention, pre-operative, anxiety, children

Abstract

Background

Research has shown that up to 65% of children who present for surgery experience anxiety in the pre-operative period, with the induction of anaesthesia being regarded as the most potent stimulator of this anxiety. The aim of this pilot study was to explore the influence of a play intervention on pre-operative anxiety in children presenting for elective surgery at Charlotte Maxeke Johannesburg Academic Hospital.

Methods

The sample was composed of 40 participants who were undergoing elective surgery of which half were randomly assigned to the play intervention group (n=20) and received 15-minutes of play intervention. The control group (n=20), received standard pre-operative care. The m-YPAS was used to measure the anxiety levels in children during the induction of anaesthesia.

Results

No significant differences were found between the two groups for age ($p = 0.23$) or sex ($p = 0.52$). The results showed that all children were anxious except for 2 (5%) but that a significant difference between anxiety levels was found between the play intervention and control groups ($p=0.0062$).

Conclusion

Children exposed to a 15-minute play intervention prior to surgery experienced significantly lower levels of anxiety at induction of anaesthesia than children receiving standard pre-operative care. It is suggested that a play intervention should be considered as a method of decreasing pre-operative anxiety in children and a larger study be conducted to gain more information.

Introduction

The peri-operative period is viewed as an important period in the life of a child ¹. Exposure to an unfamiliar hospital environment, being taken away from their area of comfort, separation from their parents and fear of the anaesthetic and surgical procedure can cause significant levels of anxiety in children ^{2, 3}. Research shows that up to 65% of children who present for surgery experience high levels of anxiety with the induction of anaesthesia being regarded as the most potent stimulator of this anxiety ⁴. This anxiety may be expressed in many forms. Some children may verbalise it while others express it behaviourally ^{1, 4, 5}. Anxiety in the pre-operative period is also associated with the development of post-operative maladaptive behaviour. The extent of this maladaptive behaviour has been shown to be limited ⁴, however, the concern is that in children who have persistent behavioural responses, this may have a negative impact on future health care interactions as well as impair normal development ⁶.

Interventions aimed at relieving pre-operative anxiety include sedative premedication ^{7, 8}, parental presence at induction of anaesthesia (PPIA) ⁹⁻¹¹ and other non-pharmacological interventions including play therapy ¹²⁻¹⁴. Ideally all children presenting for surgery should receive a sedative pre-medication to alleviate their anxiety ^{7, 8}. However, in resource constrained environments, this may not always be available due to lack of monitoring facilities in the ward and pre-operative holding area, fear of adverse effects and unavailability of the medication due to cost.

Play is important for the normal growth and development of children, it comes naturally to them and it is their favourite activity ¹⁵. Play therapy as a means of relieving childrens' pre-operative anxiety has shown success ¹²⁻¹⁷, however, in resource constrained environments, such as the hospitals affiliated with the University of the Witwatersrand, such therapists do not exist. Currently at these hospitals no alternative intervention is used to alleviate pre-operative anxiety in the paediatric population apart from PPIA, furthermore, the children's pre-operative anxiety levels are not known.

Therefore, a pilot study which aimed to explore the influence of a play intervention on pre-operative anxiety in children presenting for elective surgery at Charlotte Maxeke Johannesburg Academic Hospital was conducted.

Methods

This study was approved by the Human Research Ethics Committee (Medical). An exploratory, comparative, experimental design was used in this study. The study population consisted of children presenting for surgery at Charlotte Maxeke Johannesburg Academic Hospital. The sample size consisted of 40 children between 3 – 6 years of age, American Society of Anesthesiologist I and II presenting for elective in-patient surgery. The power of the study was 85.77%. The exclusion criteria included inability to communicate in English with the caregiver and/or child, children who have had previous anaesthesia, children who have received pharmacological premedication and children with mental retardation or developmental delays. Caregivers and patients who met the inclusion criteria were approached and the study explained to them. The caregivers who agreed to participate in the study received a participant information letter and signed a consent form.

Convenience sampling with random assignment into an intervention or a control group was used. Each patient was allocated a study number. The study numbers were placed in an envelope and one author (UR) blindly picked a study number from the envelope to randomise the children to a group. Patients assigned to the play intervention group received fifteen minutes of play. This consisted of a doll and medical equipment (saturation probe, ECG electrodes and a Jackson-Rees circuit). Patients and their caregivers were allowed to play with and explore the equipment in an attempt to desensitise them to it. Once the play intervention was over they were taken on a tour of the theatre complex. Patients and caregivers assigned to the control group received standard pre-operative care.

On the day of surgery, the m-YPAS was used as the measurement tool to measure anxiety levels in children during the induction of anaesthesia. To prevent bias the m-YPAS was conducted by both the author (UR) (**m-YPAS A**) and the consultant (**m-YPAS B**) allocated to the theatre who was blinded to the study.

Children with a score <30 were not considered to be anxious and children with a score ≥ 30 were considered to be anxious.

Data were entered into a Microsoft® Excel spreadsheet and analysed using descriptive and inferential statistics. The program Statistica version 12 (Statsoft, USA) was used. Before comparing the effect of the intervention, variables of age (Mann-Whitney test) and sex (Chi-square test), were compared between the two groups. The comparison of anxiety levels between the groups was made using the Mann-Whitney test. A p-value <0.05 was considered statistically significant.

Results

The demographics of participants are shown in Table I. No significant differences were found between the two groups for age ($p = 0.23$) or sex ($p = 0.52$).

Table I: Demographics of participants

Demographics	Group		
	All n (%)	Control n (%)	Intervention n (%)
Sex			
Male	24 (60)	13 (65)	11 (55)
Female	16 (40)	7 (35)	9 (45)
ASA status			
1	35 (87.5)	17 (85)	18 (90)
2	5 (12.5)	3 (15)	2 (10)
Surgical discipline			
General Surgery	15 (37.5)	8 (40)	7 (35)
Plastic Surgery	7 (17.5)	4 (20)	3 (15)
Orthopaedics	6 (15)	3 (15)	3 (15)
Radiology	2 (5)	1 (5)	1 (5)
Urology	2 (5)	1 (5)	1 (5)
Ophthalmology	2 (5)	1 (5)	1 (5)
Paediatric Oncology	3 (7.5)	2 (10)	1 (5)
ENT	3 (7.5)	0	3 (15)
School / crèche			
Yes	36 (90)	19 (95)	17 (85)
No	4 (10)	1 (5)	3 (15)

The median age of the children in the sample was 4 years (3.6 years for the control group and 4 years for the intervention group).

Table II: m-YPAS of control and intervention groups

	Control Group		Intervention Group	
	m-YPAS A	m-YPAS B	m-YPAS A	m-YPAS B
Median	65	65	41.6	41.6
IQR 1	49.2	46.6	36.2	36.2
IQR 3	75.5	75.9	50	50
Min	28.2	28.2	28.2	31.6
Max	100	100	81.6	96.6

The anxiety level scores for the study population ranged between 28.2 – 100. Of all the participants, 2 (5%) scored 28.2 indicating no anxiety. One participant was from the play intervention and one from the control group.

There was a significant difference between the scores of the control and the intervention groups ($p=0.0062$) with the control group scoring a median of 65 and the intervention group scoring a median of 41.6.

A strong correlation of 0.98 was found between the m-YPAS scores done by the author and the consultant blinded to the grouping of the children. These scores are presented in Table II.

Discussion

The results of this study show that children exposed to a 15-minute play intervention the day prior to surgery experienced significantly lower anxiety levels than those children in the control group. These results are in accordance with prior studies. Lerwick ¹⁶ found that 15-minutes of child-centered play therapy was effective in reducing pre-operative anxiety.

Two studies ^{17, 18} looked at the influence of distraction play in the form of clown doctors on childrens' pre-operative anxiety. In their first study, the researchers

explored the influence of clown doctors on pre-operative anxiety and in the second study they compared clown doctors in combination with PPIA, pharmacological premedication and PPIA alone. In both studies the clown doctors accompanied the children in the pre-operative holding area and during the induction of anaesthesia. This form of distraction play showed that children exposed to the intervention group experienced lower levels of anxiety than those in the control group.

Athanassiadou et al ¹³ conducted a study on 91 children between 4 – 10 years of age presenting for elective surgery. Psychologist structured puppet play was used in which children took on the role of the doctor while the researcher took on the role of the child. Through puppet play children were given information regarding their hospital stay including the induction of anaesthesia. Children were allowed to express their feelings and were encouraged to ask questions regarding their surgery. The researchers found a difference in anxiety levels between the intervention and control group.

Li et al ¹⁵ conducted a study in which children and parents were exposed to different forms of play therapy (preparation, medical, distraction and developmental play) for 30 minutes. Their study also revealed a significant difference in anxiety levels between the intervention and control groups.

Although this study shows a significant difference in anxiety levels between intervention and control groups a finding of note in this study was that 95% of the children were found to be anxious at the induction of anaesthesia. This is in contrast to prior studies that found up to 65% of children being anxious ^{4, 19, 20}. This may be explained by the fact that most of the prior studies were conducted in developed countries, where children may have had a different hospital experience. Landreth ²¹ stated that the relationship and experience created between two people involved in communication is more important than the length and content of that communication. The chaotic and noisy paediatric wards are not conducive to creating an environment that allows for a positive experience and meaningful relationship to be created between the child and anaesthetist during the pre-operative visit. This may explain why such a high percentage of children were anxious at induction of anaesthesia.

A limitation to this study is that, due to the scope of this study, the anxiety level of the caregivers was not explored and compared with their childrens' level of anxiety even though it is well established that parental anxiety may affect the child's anxiety ⁴. This study was done contextually and the results obtained may not be generalisable to children presenting to other hospitals for the same surgery. It is recommended that a larger study involving all the hospitals affiliated with the University of the Witwatersrand be conducted.

Conclusion

This study showed that children exposed to a 15-minute play intervention prior to surgery experienced significantly lower levels of anxiety during the induction of anaesthesia than children receiving standard pre-operative care. This play intervention should be considered as a method of decreasing pre-operative anxiety and improving the hospital experience of paediatric patients.

Conflict of interest

The authors declare that we have no financial or personal relationships which may have inappropriately influenced us in writing this paper.

Acknowledgement

This research was done in partial completed in partial fulfilment of a Master of Medicine degree.

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Section 4: Proposal

The influence of a play intervention on pre-operative anxiety in children at an academic hospital: A pilot study

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4.1 Introduction

Children requiring surgery are found to be very anxious in the pre-operative period (1, 2). From as early as 1941 Pearson (3) described significant emotional reactions in children undergoing surgery. The reasons for this are multifactorial and include: exposure to an unfamiliar hospital environment, being taken away from their area of comfort, separation from their parents and fear of the anaesthetic and surgical procedure (4, 5). Not all children presenting for surgery will experience pre-operative anxiety. A study conducted by Kain et al (2) revealed that of all the children presenting for surgery, up to 65%, will experience pre-operative anxiety with the induction of anaesthesia regarded as the most potent stimulator of this anxiety.

Over the years' researchers have identified several risk factors that contribute to the development of pre-operative anxiety. Children in the 1 – 5 year age group are at an increased risk as are shy, inhibited children with high I.Q. levels (1, 2, 4). Previous distressing hospital experiences also put children at increased risk of developing pre-operative anxiety (1, 2, 4). Many parental factors have also been identified as increasing the pre-operative anxiety in children and these include: anxious parents, parents with poor coping skills, single or divorced parents and parents whose children have had repeated hospital admissions (1, 2, 4). Children have been found to be less anxious when induction is conducted by a single health care provider trained in paediatric anaesthesia, in a dimmed room with background music (1, 2, 4).

Anxiety in children may be expressed in many forms. Some children may verbalise it while others express it behaviourally (1, 2, 6). Many children look scared, become agitated, start breathing deeply, stop talking or playing and some might start crying. Others may unintentionally wet themselves, have increased motor tone, or might attempt to escape from the theatre environment (2, 6). In addition to behavioural changes occurring prior to and during the induction of anaesthesia, behavioural changes such as new onset enuresis, feeding difficulties, withdrawal, apathy and sleep disturbances have also been observed post-operatively (6, 7). Although long-term data are not available, concern has been raised that such behaviours can hinder normal development (6, 7).

Due to the immediate and long-term negative effects associated with pre-operative anxiety many studies have been conducted in an attempt to identify interventions that can be used to either prevent or alleviate the occurrence of pre-operative anxiety. The results of many of the studies in the past has been hindered by the lack of a valid tool that can be used as an assessment of pre-operative anxiety.

In 1995, Kain et al (8) developed the YPAS that could be used to assess the level of anxiety in children in the 2 – 6 years age group. The original scale was developed in 1995 (8) and later modified (m-YPAS) in 1997 (9). By modifying the scale, it allowed for anxiety assessment to be carried out in the pre-operative holding area and at induction of anaesthesia and also extended the age range up to 12 years (9).

Interventions aimed at alleviating pre-operative anxiety can be classified as pharmacological and non-pharmacological. Pharmacological interventions include sedative pre-medication of which midazolam, ketamine and clonidine are the most frequently used (10). Clonidine is regarded as superior amongst the three, however its major drawback is its long onset time and cost of the drug (11, 12). Midazolam and ketamine are not frequently used due to their side-effect profile and lack of patient monitoring facilities available in the wards and pre-operative holding area (11, 13, 14).

The various non-pharmacological interventions include: parental presence at induction of anaesthesia (PPIA), preoperative information programs, behavioural intervention programs, distraction activities and play, complementary and alternative medicine strategies and child friendly environments (6, 7, 11, 15). PPIA remains a controversial strategy in alleviating pre-operative anxiety. It was initially suggested that PPIA resulted in decreased levels of anxiety and increased co-operation from the child, however, many prospective studies have subsequently refuted this (16).

Pre-operative information programs include: information leaflets (17), videos (18), cartoon and interactive computer games (19) and operating room tours specifically have been shown to variably reduce pre-operative anxiety (1).

Behavioural intervention programs need to be effective in reducing pre-operative anxiety, should be cost effective and easily administered. Kain et al (20) found that elaborate and costly behavioural intervention programs had a limited anxiolytic effect at induction of anaesthesia. In a study by MacLaren et al (21), simple, cost effective behavioural interventions (such as playing with an anaesthetic mask) resulted in increased co-operation at induction of anaesthesia. It also has the advantage of being carried out by the parents while waiting in the pre-operative holding area (21).

Play therapy is a special form of therapy that focuses on the child (22). The primary role of a play therapist is to provide parents and children with psychosocial care that is individually tailored to meet the needs of the child and parent (22, 23). Several short term play interventions lasting 15 minutes have been shown to produce successful results in alleviating pre-operative anxiety (22, 23). Unfortunately, in resource constrained environments play therapy cannot be administered as such therapists are not readily available as well as the cost implications involved in having children and parents travel to hospital prior to surgery. It is for these reasons that studies have looked at play interventions as a means of alleviating pre-operative anxiety and have shown success (24, 25). Play interventions do not require a play therapist to be carried out.

4.2 Problem statement

A significant number of children undergoing surgery experience pre-operative anxiety (1, 2, 6, 7). The induction of anaesthesia is regarded as one of the most stressful moments in the pre-operative period which can lead to distress in children, the caregiver and the theatre staff (6, 7, 26). Of particular concern is the link between children who experience pre-operative anxiety and post-operative behavioural changes, which can persist after the procedure (1, 2, 4)

Ideally all children coming to theatre should receive a pharmacological pre-medication (6, 7). However, in resource constrained environments, this may not always be available. Alternative non-pharmacological interventions for alleviating pre-operative anxiety are available and have shown to be of benefit (16). These

include age appropriate behavioural interventions, play therapy, music therapy and video game distraction (16).

Currently, within the hospitals affiliated to the Department of Anaesthesiology at the University of the Witwatersrand (Wits), children do not always receive a pre-medication. The reasons for this are multifactorial, such as the fear of adverse effects, lack of monitoring facilities and unavailability of medication due to costs. No alternative intervention is currently used to alleviate pre-operative anxiety in the paediatric population apart from parental presence at induction of anaesthesia. Studies regarding the assessment of children's pre-operative anxiety levels have also not been conducted in this setting.

4.3 Aim and objectives

4.3.1 Aim

The aim of this pilot study is to explore the influence of a play intervention on pre-operative anxiety in children presenting for elective surgery at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH).

4.3.2 Objectives

The primary objectives of the study are to describe the:

- levels of anxiety in children, during induction of anaesthesia, who have received a play intervention
- levels of anxiety in children, during induction of anaesthesia, who have not received a play intervention.

The secondary objective of the study is to compare the levels of anxiety in children receiving a play intervention to that of those not receiving a play intervention during induction of anaesthesia.

4.4 Research assumptions

The following definitions will be used in this study:

Child: is a person under the age of 18 years (27). In this study a child will be defined as a person between 3 to 6 years of age group.

Caregiver: a caregiver is the person who takes primary responsibility for someone who cannot care for themselves. It may be a family member, a trained professional or another individual. Depending on culture there may be various members of the family engaged in care (28). For the purpose of this study a caregiver will only include the parents and the legal guardians.

Play intervention is a technique used to inform children about the plans and purposes of medical events, to provide children with an expressive outlet, to relieve misconceptions, and to gain insight into children's coping and understanding. It is the process by which medical items are provided for children to manipulate and to experiment with on an inanimate object, such as a stuffed animal or doll. This is different to play therapy. Play therapy is a special form of therapy that focuses on the child. Play therapy is conducted by play therapists whom have a minimum of a master's degree with training in child and family therapy. The primary role of a play therapist is to provide parents and children with psychosocial care that is individually tailored to meet the needs of the child and parent (22, 23). In this study the play intervention will consist of fifteen minutes of play with a doll and medical equipment that the patient will encounter in theatre (saturation probe, ECG electrodes, a face mask and a Jackson-Rees circuit). During the play intervention, patients and their caregivers will be allowed to explore and play with the medical equipment (such as placing the equipment on themselves, their caregivers or the doll). The aim of this is to desensitise them to this equipment. Once the patients and their caregivers have received the play intervention, they will be taken on a theatre tour.

Anxiety: is apprehension of danger and dread accompanied with restlessness, tension, tachycardia, and dyspnoea unattached to a clearly identifiable stimulus. Furthermore, anxiety is a "psychic reaction" to danger and involvement of reactivation of an "infantile fear" situation (29).

Pre-operative anxiety: for the purpose of this study, this will describe anxiety during the induction of anaesthesia using the m-YPAS.

Modified Yale Pre-operative Anxiety Scale (m-YPAS): an observational tool developed by Kain et al (8) to measure pre-operative anxiety in children. The m-YPAS is composed of five categories (activity, emotional expressivity, state of arousal, vocalisation and use of parents). The cut-off point of the scale is 30, that is, children with a score <30 is not considered to be anxious and children with a score >30 is considered to be anxious.

Study groups: in this study two study groups will be used and for ease of reading they will be referred to as the play intervention group and the control group.

- Play intervention group: this group will receive a play intervention.
- Control group: this group will receive standard pre-operative care.

4.5 Demarcation of study field

The study will be conducted in the theatre complex of CMJAH affiliated to the Department of Anaesthesiology at Wits. CMJAH is a 1200 bed central hospital. The hospital has 23 theatres of which three are dedicated paediatric theatres. On average 23 000 cases are done annually of which 3000 are paediatric cases.

4.6 Ethical considerations

Approval to conduct the study will be obtained from the Human Research Ethics Committee (Medical) and the Graduates Studies Committee at Wits. Approval will be obtained from the CEO of CMJAH (Appendix 1). The theatre nursing manager will be informed of the study.

Caregivers of children presenting for elective surgery will be approached and the study explained to them. They will be invited to take part in the study. Once a caregiver has agreed for their child to be part of the study, a participant information letter will be given to them (Appendix 2) and they will then be asked to sign a consent form (Appendix 3).

Data will be collected without identifying information to ensure anonymity. Confidentiality will be maintained as only the researcher and supervisors will have access to the raw data.

If a child is found to be very anxious during the induction the anaesthetist involved with the surgery will proceed to induce the child in a standardised manner for anxious children. The researcher will not intervene.

All data collected will be filed and stored in a locked cupboard securely for six years after completion of the study.

This study will be conducted according to the principles of the Declaration of Helsinki (30) and the South African Guidelines for Good Clinical Practice (31).

4.7 Research methodology

4.7.1 Research design

An exploratory, comparative experimental design will be used in this study.

Exploratory studies are meant to increase the knowledge in a field of study and are not meant for generalisation to large populations. (These studies also make use of pilot studies to test a methodology (32)). This will be an exploratory study as studies pertaining to pre-operative anxiety and alternative methods of alleviating pre-operative anxiety in children have not been done at this institution. As a result, information pertaining to pre-operative anxiety and methods of alleviating pre-operative anxiety in children are not available. A pilot study will be used to test our methodology and increase our knowledge in this field.

According to Burns and Grove (33) a comparative experimental design is one in which the “expectation of random sampling is difficult if not impossible to achieve”. These studies make use of convenience sampling with random assignment to the groups. A comparative experimental design will be used in this study. A convenience sampling method will be used to obtain the study population (by using only in-patients). The patients will then be randomly assigned to either the intervention or control group.

4.7.2 Study population

The study population will consist of children presenting for surgery at the CMJAH.

4.7.3 Study sample

Sample size

A pilot study will be performed as it is not known what the influence of a play intervention will be on the pre-operative anxiety of children presenting for elective surgery. The sample size will consist of 40 children between 3 to 6 years of age. Twenty children will be assigned to the play intervention group and twenty to the control group.

Sampling method

A convenience sampling method with randomised assignment into an intervention or a control group will be used in this study. Convenience sampling refers to the sampling of participants who are readily available to the researcher (34). Random sampling means each child has an equal opportunity of being in either group (32).

In-patients between 3 to 6 of years age group will be used. Simple randomisation will be used in this study. Each patient will be allocated a study number. The study numbers will be placed in an envelope and the researcher will blindly pick a study number from the envelope to randomise the children to either the play intervention or control group.

4.7.4 Inclusion and exclusion criteria

The inclusion criteria for this study are:

- children 3 to 6 year of age
- American Society of Anesthesiologist status I and II
- presenting for elective in-patient surgery
- caregivers whom have consented to the study.

The exclusion criteria in this study are:

- inability to communicate in English with the caregiver and/or child
- children who have had previous anaesthesia
- children who have received a pharmacological premedication already
- children with mental retardation or developmental delays.

4.7.5 Data collection

Data collection tool

The m-YPAS will be used. This is a valid tool with good to excellent inter and intra-observer reliability (8, 9). It is composed of five categories (activity, emotional expressivity, state of arousal, vocalisation and use of parents). These five categories define twenty-two specific behaviours in children that indicate anxiety during the induction of anaesthesia. The observer is neutral and does not influence the child's behaviour. In the m-YPAS each category has a different number of items (ranging from 4 – 6). Partial weights are thus used to calculate the total score with the total weighted score ranging from 23.33 – 100. The higher the score, the higher the level of anxiety present (8).

The data collection sheet (Appendix 4) record the following data:

- Demographic data
 - age
 - gender
 - ASA classification
 - surgical procedure
 - attending a nursery school, crèche or play group
 - relationship to caregiver (for e.g.: mother, grandmother etc).
- M-YPAS score
 - activity
 - emotional expressivity
 - state of arousal
 - vocalisation

- use of parents.

Data collection

Caregivers and patients will be approached and the study explained to them. The caregivers who agree to participate in the study will receive a participant information letter (Appendix 2) and a consent form (Appendix 3). Participants will then be randomly assigned to either a play intervention or a control group.

Patients who have been assigned to the play intervention group will receive approximately 15 minutes of play intervention. This will consist of a doll and medical equipment that the patient will encounter in theatre. The medical equipment will include a saturation probe, ECG electrodes, a face mask and the Jackson-Rees circuit. The patients and their caregivers will be allowed to explore and play with the medical equipment (such as placing the equipment on themselves, their caregivers or on the doll). The aim of this is to desensitise them to this equipment. Age appropriate explanations regarding the specific equipment will also be given. All equipment will be wiped down with the disinfectant present in the ward between each play intervention. Once the patients and their caregivers have received their play intervention, they will be taken on a theatre tour. This tour of the theatre complex is another attempt to desensitise them as to what to expect on the day of surgery.

The control group will receive standard treatment. The anaesthetist will assess these children during the pre-operative visit and verbally explain to them and the caregivers what to expect on the day of surgery. The children will present to theatre on the morning of surgery with their caregivers. They will wait in the pre-operative holding area until they are taken to theatre. Once in theatre monitors will be placed on the patient and the induction process will start.

On the day of surgery, the m-YPAS will be used as a measurement tool to measure anxiety levels in the children during the induction of anaesthesia. To prevent bias the m-YPAS will be conducted by both the researcher and the consultant in theatre who is blinded to the study.

Confidentiality and anonymity will be maintained. Data analysis will commence once all the data has been collected.

4.7.6 Data analysis

A Microsoft Excel spreadsheet will be used to capture data. Data will be analysed in consultation with a biostatistician using the statistical program STATA version 13.1.

Categorical variables will be described using frequency and percentages. Continuous variables will be described using means and standard deviations or medians and interquartile ranges depending on the distribution of the data. Before comparing the effect of the intervention, variables of age and sex, will be compared between the two groups. The comparison between the groups will be made using the independent t-test if the data is normally distributed and the Mann-Whitney test if not normally distributed.

A p-value of 0.05 or less will be considered statistically significant.

4.8 Significance of the study

Many studies have shown that children experience significant levels of anxiety in the pre-operative period. This has been associated with a number of negative behaviours during the induction of anaesthesia such as crying, agitation and the need for physical restraint which can make induction difficult. Pre-operative anxiety has also been associated with negative behavioural problems that can persist for an unknown period after surgery. These include increased post-operative pain, sleeping disturbances, parent-child conflict and separation anxiety. This may hinder normal development in these children. As a result, interventions aimed at preventing or decreasing pre-operative anxiety are required. These interventions can either be pharmacological or non-pharmacological.

Currently at CMJAH pharmacological pre-medication is not used frequently as the drug with the least side-effect profile (clonidine) is not available. Alternative drugs (midazolam, ketamine) are available for use but anaesthetists are reluctant to use them because of their side-effect profile and the lack of facilities for monitoring in

the wards and pre-operative holding area . An alternative non-pharmacological method of alleviating pre-operative anxiety needs to be explored. This alternative method needs to be cost-effective and easy to implement. This study provides an alternative method that will be cost-effective and easy to implement.

4.9 Validity and reliability of the study

According to Bothma et al (35) validity of a study “refers to the degree to which a measurement represents a true value” and reliability “represents the consistency of the measure achieved”.

Validity and reliability of this study will be maintained by:

- using the validated and reliable m-YPAS observational tool
- selecting a suitable study design
- using a standardised play intervention
- a single researcher collecting all the data
- checking every tenth data entry point on the spreadsheet for accuracy
- analysing the data in consultation with a bio-statistician.

4.10 Potential limitations

Due to the scope of this study, it will be limited to the patients presenting for paediatric elective surgery at CMJAH. The results obtained from this study may not be generalisable to patients presenting to other hospitals for the same surgery.

A second limitation is that the anxiety level of the caregivers will not be explored and compared with their childrens’ level of anxiety even though it is well established that parental anxiety may affect the child’s anxiety (2, 5).

The small sample size may not be adequately powered to find differences between groups if these differences exist. This is however a pilot study.

4.11 Project outline

4.11.1 Time frame

Activity	Oct 2016	Apr 2017	Aug 2017	May - Dec 2017	Oct 2018	Nov 2018	Dec 2018	Jan 2019	Feb 2019	Mar 2019
Proposal preparation										
Literature review										
Proposal submission										
Ethics approval										
Postgraduate approval										
Data collection										
Data analysis										
Draft article										
Submission										

4.11.2 Budget

Item	Price per page	Number of pages	Copies	Total
Proposal	1	15	10	R 150
Ethics	1	10	25	R 250
Postgraduate form	1	2	6	R 12
Complete report	1	100	4	R 400
Grand total				R 812

The Wits Department of Anaesthesiology will incur the costs of paper and printing.

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4.13 Appendices

Appendix 1: Letter to hospital CEO

Dr Ushira Ramkisson

MBBCH (WITS), DA(SA)

Cell: 083 795 1422

e-mail: drushira@me.com

The CEO: Mrs. Bogoshi

Re: Request for permission to conduct research

Research title: The influence of a play intervention on pre-operative anxiety in children at an academic hospital: A pilot study

My name is Ushira Ramkisson. I am currently a registrar in the Department of Anaesthesiology at the University of the Witwatersrand. I am conducting a MMed research study looking at the effect of a play intervention on pre-operative anxiety in children and I would like to conduct this study at Charlotte Maxeke Johannesburg Academic Hospital. The study has been approved by the Human Research Ethics Committee (M170126) and the Graduate Studies Committee number.

This study will involve the paediatric population presenting for elective surgery at your hospital. Confidentiality of all data will be maintained as only my supervisors and I will have access to the data. All data will be reported anonymously as patients will not be personally identified.

There will be no financial implications to Charlotte Maxeke Johannesburg Academic Hospital and Gauteng Department of Health. A copy of the final report will be available to you, should you require it.

Yours sincerely:

Ushira Ramkisson

Appendix 2: Participant information letter

Research title: The influence of a play intervention on pre-operative anxiety in children at an academic hospital: A pilot study

Hello, my name is Ushira Ramkisson. I am an anaesthetist studying at the University of the Witwatersrand. An anaesthetist is a doctor who looks after patients during the operation. Our job is to make sure that patients don't remember or feel anything during the operation. We also give medicine to take the pain away.

I have to do a research study as part of my studies and I would like your child to participate. All children that come for an operation are afraid of either the theatre or the doctors and nurses. For my study I want to find out if playing a game can help to decrease this fear.

If you agree to participate, I will fill out a form with your child's personal information. You and your child will be either be part of a group that I play a game with or a group that receives standard treatment. The standard treatment group will have the anaesthetist visiting you the day before the surgery and explaining what will happen on the day of surgery. You will be allowed to accompany your child to theatre on the day of surgery. If your child is allocated to the play group, they will be allowed to play with the medical tools that will be used on him/her in theatre tomorrow. After playing the game you and your child will then be invited to take a tour of the theatre. By doing all this we hope that your child will not be too afraid when going for his/her operation. There will be no harm to your child if you agree to participate in this study. Your child will receive the standard anaesthetic and pain medication.

This study has been approved by the Human Research Ethics Committee (M170126) and the Graduate Studies Committee.

This study is voluntary. It is ok if you do not want your child to participate. Your child will still receive the same anaesthetic as those children who are taking part in the study. It will also be ok if you change your mind and withdraw from the study.

Signing the consent form means you agree for your child to participate in the study. I will also give you a copy of this letter to keep. If you have any queries you can contact the researchers on 011-717 2512 or the chairman of the Ethics committee on 011-717 1234

Thanking you for your time

Ushira Ramkisson

Appendix 3: Consent to participate

Consent to participate in research study.

Research title: The influence of a play intervention on pre-operative anxiety in children at an academic hospital: A pilot study

I _____, the parent/legal guardian of

agree for my child/ the child to participate in the study. The study has been explained to me and I have also read and understand the information leaflet. I am aware that I can withdraw my consent to participate without any prejudice toward the child or me. I am aware that my child will not be harmed during the study. The researcher has explained to me that my child's name will not appear in any of the research results.

Name of subject

Signature of subject

Date

Name of researcher

Signature of researcher

Date

Appendix 4: Data collection sheet

Section 1: Personal details

Research title: The influence of a play intervention on pre-operative anxiety in children at an academic hospital: A pilot study

Date		
Study number		
Age		
Gender	M	F
ASA classification	I	II
Surgical procedure		
Attending nursery school	Y	N
Relationship of caregiver		

Activity

-
- | | |
|-------|--|
| 1 | Looks around, curious, plays with toys, reads (or other age-appropriate behaviour); moves around to get toys or to go to parent; may move toward theatre or surgery equipment |
| <hr/> | |
| 2 | Not exploring or playing, may look down, fidgets with hands or suck thumb or blanket; may sit close to parent while waiting, or play as a manic quality |
| <hr/> | |
| 3 | Moving from toy to parent in unfocused manner, non-activity derived movements; frantic movement or play; squirming, moving on table, may push mask away, or clings to parent |
| <hr/> | |
| 4 | Actively tries to get away, pushes with feet and arms, may involve whole body; in waiting room, running around unfocused, not looking at toys or desperate clinging to parents |
-

Vocalisation

-
- | | |
|-------|--|
| 1 | Reads (non-vocalising appropriate to activity), asks questions, makes comments, babbling, laughing, readily answers questions but may be generally quiet; child too young to talk in social situations or too engrossed in play to respond |
| <hr/> | |
| 2 | Responds to adults but whispers, "baby talk", only head nodding |
| <hr/> | |
| 3 | Quiet, no sounds or responses to adults |
| <hr/> | |
| 4 | Whimpering, moaning, groaning, silently crying |
| <hr/> | |
| 5 | Crying or may be screaming "no" |
| <hr/> | |
| 6 | Crying, screaming loudly, sustained (audible through mask) |
-

Emotional expressivity

-
- | | |
|-------|---|
| 1 | Manifestly happy, smiling, or concentrating on play |
| <hr/> | |
| 2 | Neutral, no visible expression on face |
| <hr/> | |
| 3 | Worried, frightened, sad; worried or tearful eyes |
| <hr/> | |
| 4 | Distressed, crying, extremely upset, may have wide eyes |
-

State of apparent arousal

-
- | | |
|-------|---|
| 1 | Alert, looks around occasionally, notices or watches what anaesthetist does with him/her (could be relaxed) |
| <hr/> | |
| 2 | Withdrawn, child sitting still and quiet, may be sucking on thumb or face turned into adult |
| <hr/> | |
| 3 | Vigilant, looking quickly all around, may startle to sounds, eyes wide, body tense |
| <hr/> | |
| 4 | Panicked whimpering, may be crying or pushing others away, turns away |
-

Use of parents

1	Playing, sitting idle, or engaged in age appropriate behaviour and does not need parent, may interact with parent if parent initiates interaction
2	Reaches out to parent (approaches or speaks to otherwise silent parent), seeks and accepts comfort, may lean against parent
3	Looks to parent quietly, watches actions, does not seek contact or comfort, and accept if offers or clings to parent
4	Keeps parent at distance or may actively withdraw from parent, may push parent away or desperately clinging to parent and will not let go

Total= /4+ /6+ /4+ /4+ /4= x100/5=

Section 5: Annexures

5.1 Ethics approval

5.2 Graduate Studies Committee approval

5.3 Turnitin report



R14/49 Dr Ushira Ramkisson et al

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M170126

NAME: Dr Ushira Ramkisson et al
(Principal Investigator)
DEPARTMENT: Anaesthesiology
Charlotte Maxeke Johannesburg Academic Hospital

PROJECT TITLE: The Influence of a Play Intervention on Pre-Operative Anxiety in Children at an Academic Hospital: A Pilot Study

DATE CONSIDERED: 27/01/2017

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Juan Scribante

APPROVED BY: 

Professor P. Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 26/04/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially review in January and will therefore be due in the month of January each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES



22 August 2017
Person No. 0502689G

PAG

Dr Ushira Ramkisson
408 Adamite Cove
Emerald Estate
Greenstone Hill
1609

Dear Dr Ramkisson

Master of Medicine in Anaesthesia: Approval of title

We have pleasure in advising you that your title has been change as follows,

Approved title: *The influence of a play intervention on pre-operative anxiety in children at an academic hospital: a pilot study*

Yours sincerely

Miss Thando Mbolekwa
On behalf of Mrs Sandra Benn
Faculty Registrar

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FACULTY OF
HEALTH SCIENCES

15 March, 2019

The Chairperson
Graduate Studies Committee
Faculty of Health Sciences
University of the Witwatersrand

Dear Madam,

Re: M Med: **The influence of a play intervention on pre-operative anxiety in children in an academic hospital**

Dr Ushira Ramkisson, student number: 0502689G, has submitted her research report to Turnitin which revealed a similarity index of 25%. These similarities appear not to be plagiarism but mainly the use of common terminology and phrases specific to the topic of the research.

Yours sincerely,

Juan Scribante
Supervisor