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Music as an intervention to reduce preoperative anxiety in gynaecological patients

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Music as an intervention to reduce preoperative anxiety in gynaecological patients

Nana Yaa Fenima Fening

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

Johannesburg, 2019.

Declaration

I, Nana Yaa Fenima Fening, 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.

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30 May 2019

Johannesburg

Abstract

Background: Preoperative anxiety is a well-established phenomenon. Pharmacological methods have traditionally been used to alleviate this anxiety. Music had been identified as an alternative therapy to attenuate anxiety and improve postoperative outcomes.

Aim: To describe the effect of a music intervention on preoperative anxiety levels in patients going for elective gynaecological procedures at the Charlotte Maxeke Johannesburg Academic Hospital.

Setting: A prospective, contextual, quasi-experimental study, conducted at Charlotte Maxeke Johannesburg Academic Hospital, a 1200 bed central hospital in Johannesburg, South Africa.

Methods: Patients undergoing gynaecological procedures were recruited preoperatively by convenience sampling from gynaecology elective lists and allocated to music intervention and control groups using simple random sampling. Patients in the music intervention group listened to 20 minutes of precompiled music. Patients in the control group received 20 minutes of quiet time. Demographic data and physiological parameters were recorded and anxiety levels were assessed using the State and Trait Anxiety Inventory. Data were analysed using descriptive and inferential statistics.

Results: There was a significant difference in anxiety levels in the music intervention group before and after the intervention (p-value > 0.0001) but not in the control group. There were no significant differences in the physiological parameters. Those who received the music intervention enjoyed the experience.

Conclusion: Music reduced preoperative anxiety in patients going for elective gynaecologic procedures. Music interventions are a cheap, easy way of reducing preoperative anxiety.

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Abbreviations

STAI	State and Trait Anxiety Inventory
BP	Blood Pressure
HR	Heart Rate
RR	Respiratory Rate
TMAS	The Manifest Anxiety Scale
VAS	Visual analogue scale
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
TAH	Total Abdominal Hysterectomy
VH	Vaginal Hysterectomy

Section 1: Literature review

1.1 Introduction

Music is life.

This a bold statement for a bold study. This literature review aims to examine the aspects of music that play a part in reducing preoperative anxiety and how they do this. If preoperative anxiety is reduced there are benefits for patients and the anaesthetist. The review will define anxiety, how it is measured and the modalities used to reduce it. The focus will be on music and how it can be used to reduce anxiety and the evidence supporting its use.

1.2 Background

The number of surgical procedures conducted worldwide is on the rise (1). Estimates suggest that over 230 million surgeries were conducted in 2004 and above 300 million in 2012 (1). A positive relationship between the number of surgeries and good health outcomes has been identified (1). The number of day surgeries has increased and patients expect to have shorter recovery periods, less pain and better results (2).

Surgery by itself however, is not a predictor of health, and a new niche has evolved; all aspects of surgical care from patient demographics (for example age and sex) to psychosocial factors like anxiety and depression to clinical factors (type of surgery and pain) are evaluated to determine what elements provide the best surgical outcomes (2). Development of the preoperative elements that improve psychosocial factors has been slow (3). It is this niche that this research aims to explore by examining one of the factors, anxiety and how it can be manipulated to produce better patient results using a music intervention.

Surgery is a traumatic experience for most individuals because control of self and the environment is lost (4). Patients commonly become anxious when faced with the unknown or unpredictable (3). Furthermore some patients never return to their preoperative condition, despite no overt clinical adverse events (2), this supports the premise that there are many factors that create a successful conclusion to surgery.

1.3 Anxiety

1.3.1 Definition of Anxiety

Anxiety is defined as, "... an emotional state, which is associated with tension, anger, apprehension, fear, increased serum levels of epinephrine and norepinephrine, heightened autonomic activity, and activated stress responses..." (5). In the past anaesthetist and other healthcare professionals lacked the ability to identify preoperative anxiety (6), but it is now a well-established phenomenon (3, 7-15). It is reported that preoperative anxiety in adults falls anywhere between 11 – 80% (16, 17). Anxiety begins well before admission (6), at least 12 hours in advance and fluctuates throughout the perioperative period (3). Raymond Cattell is credited with introducing the theory of two arms to anxiety in the 1960's (18); state anxiety which is a fleeting emotional attitude determined by the immediate circumstances and trait anxiety which focuses on the qualities in an individual's personality that drives their response to a stressful scenario (18).

There is little evidence to describe how common preoperative anxiety is in patients undergoing gynaecological procedures but levels of anxiety have been said to range between 45% the night before the operation and 67% just before the anaesthetic is given (19). Women generally have higher preoperative anxiety levels than their male counterparts (7).

Primary elements in the development of preoperative anxiety include real or imagined pain, fear of injury or disfigurement, reliance on strangers, detachment from relatives, an alien environment, the relinquishing of control (18) as well as disruptions in social and professional life and financial difficulties (20, 21). Patients also have fears about anaesthesia, the difficulty of surgery, what might be discovered and what this would mean (22). Patients who have never had an operation before also tend to be more anxious (7), the type of anaesthetic to be administered, equipment such as masks and laryngoscope blades also tends to be an area of great concern to patients (3).

The anxiety experienced by patients preoperatively may create complications (10). Feelings of trepidation can trigger the autonomic nervous system causing more fear

and uncertainty (10) as well as haemodynamic instability, particularly increases in blood pressure (BP) and heart rate (HR) (23). Patients sometimes also experience palpitations and nausea (11). There is evidence to show a relationship between high preoperative anxiety and increased levels of postoperative pain and analgesia use (24). Anxiety can cause an altered cognitive ability leading to physical and emotional distress (24). There is information to suggest that increased levels of anxiety increase the intraoperative anaesthetic requirements (16). Raised anxiety levels have been associated with poor surgical outcomes, prolonged healing times and delayed hospital discharge (19).

1.3.2 Evaluation of anxiety

To appropriately treat anxiety in the preoperative situation it is important to be able to measure the level of anxiety in a patient. The physiological parameters such as HR, BP and respiratory rate (RR) can be measured using standard monitoring devices. A rapid HR, raised BP and fast RR would imply that a patient is more anxious (23). The psychological component of anxiety can be measured using, amongst others, the State and Trait Anxiety Inventory (STAI), which is accepted as the “gold standard” in anxiety measurement tests (25). It was developed in the 1960‘s by Charles Spielberger, using information from The Manifest Anxiety Scale (TMAS), another anxiety test engineered to explain state and trait anxiety (26). The STAI is divided into two parts, of twenty questions each that assess state anxiety, (how you feel at the moment) and trait anxiety (how you generally feel). Each question is evaluated on a scale from 1 – 4.

In the state anxiety scale

- 1 = not at all,
- 2 = somewhat,
- 3 = moderately so,
- and 4 = very much so.

In the trait anxiety scale questions are answered by

- 1= almost never,
- 2 = sometimes,

- 3 = often,
- and 4 = almost always.

The higher the total score gained the higher the anxiety levels. A total score for STAI is between 20 and 80 with

- 20 – 37 representing “low” anxiety,
- 38 – 44 “moderate” anxiety,
- and 45 – 80 “high” anxiety (27).

Other scales to measure anxiety include the visual analogue scale (VAS) and the numerical rating scale (21). The VAS uses a 100 mm printed line with one side for “no anxiety” and the other end for “maximum anxiety imaginable” (25). Patients put a mark on the scale to represent their level of anxiety. The VAS is a good alternative to the STAI that has been substantiated (25).

1.3.3 Treatment of anxiety

Once anxiety has been assessed to be above an appropriate level some treatment may be justified. Methods to alleviate anxiety are both pharmacological and non-pharmacological (3). Pharmacological methods include the use of benzodiazepines, beta blockers and opioid drugs. These are widely favoured but have the disadvantage of causing extended sleepiness, late discharge from recovery areas, possible allergic reactions to medication, drug addiction and other symptoms which create a negative patient experience (20). Anxiolytics have many adverse effects such as depressed breathing, decreased gut peristalsis, pruritis, nausea and vomiting, hypovolaemia and can prolong a patient’s time in hospital (28). At times patients still report anxiety despite receiving anxiolytics and some would prefer an alternative to drugs (10). No recommendations could be identified as to what is the best method to reduce anxiety. Alternatives to medication such as more patient information, music, hypnosis, aromatherapy, reflexology and massage are now being

explored (14). This study focuses on music as an alternative therapy to reduce anxiety.

1.4 Music

Where did music originate from? This is a difficult question to answer. Our ability to create or interpret music is something we are born with (29). Neonates have an emotional response to music and infants communicate with their mothers through song and dance long before they develop the ability to talk (30). What is the evolutionary path that lead us to our current understanding and expression of music? Some would argue that music is simply a consequence of human evolution by natural selection and serves no purpose (31), however there also seems to be a school of thought that would disagree and when the meaning of music is unpacked, music has more attributes than being just a consequence of evolution (32).

1.4.1 Music and the brain

The auditory system and vestibular system have an intricate link; the auditory system develops from the vestibular system and both have fibres that meet at the parabrachial nucleus, which is responsible for visceral, autonomic as well as vestibular actions (30). These connections are responsible for the movement and autonomic responses to sound that, coupled with the auditory component of sound, create the full experience of listening to music (30).

Hearing is a function of the temporal lobe which communicates with the amygdala, pons, and midbrain. Both the right and the left hemispheres are important to experience the effects of music, but it is the left hemisphere that takes the lead when it comes to analysis and therefore the meaning of music (29). When music is played, there is a release of endorphins and transmission of alpha brain waves which promotes relaxation and dispels fear and anxiety (33). The type of music influences mood; gratifying music activates the areas of the brain responsible for perceiving stimuli regarded as rewarding. Areas identified include the orbitofrontal cortex and the ventral stratum (34). Countering this, is the effect of sad music on areas such as the hippocampus and amygdala which are known to be responsible for depressed or negative mood (35). There are a variety of scenarios in which music could play an integral role as both a diagnostic and therapeutic tool in clinical medicine (35).

The right type of music can trigger positive cortical and cognitive emotions, release neurotransmitters (for example acetylcholine) and pheromones that control the functioning of the body, immunoglobulins (for example Immunoglobulin A) that enhance the body's defences and natural endorphins, (substances behaving like opioids), responsible for creating feelings of happiness (34). Music may also decrease BP, HR and RR (23). In the presence of harmonious sounds, brain cells become increasingly responsive to gamma-aminobutyric acid which increases inhibitory reactions in the brain and encourages relaxation (36). When listening to music there is an increased release of dopamine in the brain and consequently better executive functioning (34).

1.4.2 Music and heart rate, blood pressure and respiratory rate

HR is controlled by the brainstem and cardiac bodies found in the thorax, these in turn are regulated by the hypothalamus, amygdala, insular and orbitofrontal cortexes; structures involved in emotional responses (37). Koelsch implies that increased emotions in response to upbeat music increases HR through sympathetic pathways whilst parasympathetic pathways, activated by tranquilising music, will decrease the HR (37). Furthermore, when compared to not listening to anything at all, patients who listen to music tend to have higher HR and RR due to the increased excitement caused by the music (37). However, Mok (15) suggests that when a body is in sync with music at a given frequency it will mimic its rhythm; a patient with an increased heart rate will find that on listening to slow music their HR will slow down and become in sync with that music's rhythm. It is therefore difficult to predict whether HR will increase or decrease due to a music intervention. There is some evidence to show that BP is reduced by playing music (37). It has been used to reduce the BP of hypertensive patients through breathing exercises guided by music (37). Bradt et al (38) showed that music was effective on systolic BP, HR, RR, pain and sleep. The key to affecting a decrease in physiological parameters is the type of music listened to. "Music that takes into account factors known to facilitate relaxation and pain reduction are more likely to be effective" (39).

1.4.3 Music in our society

Music is a universal language. All humans have the ability to experience emotion and create meaning when listening to music (29). It is an integral part of human culture and can unify people from diverse backgrounds (35). The human capacity to comprehend and enjoy music requires a complex set of skills, and the extent to which these skills have developed is almost exclusive to the human species (35). Music is part of a human's social construct. Seven social functions (the seven c's) have been identified (30). These are

- contact; our need to connect with one another,
- cognition; understanding the intention of music,
- co-pathy; learning to empathise with others or understand their emotions,
- communication; music as a language and as way for people to relate to each other,
- coordination of actions; learning to move to a rhythm or beat,
- cooperation; learning to relate to groups or teams for a common goal
- and social cohesion; developing a feeling of belonging (30).

The seven c's highlight the important role that music plays in the functioning of communities.

Music has a meaning beyond the creation or listening to sound. Abrams refers to Anicius Boëthius, a medieval scholar, who identified four musical domains; "Musica instrumentalis or musical sound (the conventional understanding of music); musica humana, or human music (the music of balance, proportion and order in human beings), musica mundana, or universal music (music of cosmic order); and musica divina, or spiritual music (the music of ultimate reality and absolute ground of being, underpinning the universe itself)" (32). Boëthius believed that "there exists a level of music located within humanity itself" and that music exists beyond the confines of the physical being (32).

Music and dance encourage storytelling, the sharing of cultural beliefs and practices, a feeling of being one with those around you and in some societies is used to solve

problems; (rain dance for drought), relive ailments (40), keep sinister spirits at bay or please supernatural spirts (41). Given the important role of music within a society, it may also have a role in the goal-directed control of emotions (30).

1.4.4 Music and medicine

The principles of holistic medicine suggest that an individual is considered as a whole. With physical, spiritual, intellectual and behavioural characteristics that all have to be taken into account in order to bring about perfect health. Life is about balance and no one area deserves more attention than another hence modern medicine aims to explore and utilise all modalities that harness healing (41). Some well-known health practitioners were musicians as well, Theodore Bilroth, the founder of modern abdominal surgery, Rene Laennec the inventor of the stethoscope and Josef Auenbrugger who used percussion as a diagnostic tool (42).

Music is defined as "… an art form that uses vocal or instrumental techniques to produce sound and affect the mental status of the listener." (42) The history of music in medicine dates back to ancient times; Pythagoras, the Greek philosopher, was convinced that it contributed greatly to ones well-being and recommended music and careful dietary choices for optimal health (43). Florence Nightingale recognised its therapeutic capabilities for ward patients, and in the 1800s used music as a therapy for soldiers fighting in the Crimean War (43). Music was introduced into operating theatres in 1914 by Evan O'Neill Kane (42, 43). Kane published an article in JAMA in which he suggested that music reduced anxiety before surgery (42).

Two main areas have been identified in the application of musical interventions, namely, music therapy and music medicine (44). Musical therapy entails "...the clinical and evidence-based use of music interventions by a credentialed professional for the purpose of accomplishing individualized goals..." (44). Music therapy gained impetus as a medical intervention in the second half of the twentieth century (32). It was accepted as a distinct profession in 1950 (32). Harriet Ayer Seymour, the founder of the National Foundation of Music Therapy, introduced music therapy into hospitals during the Second World War and trained 500 doctors in music therapy (13). Music medicine "...involves passive listening of prerecorded,

staff-selected music, facilitated by non-music therapy staff." (45). Despite the differences between the two types of interventions, current information shows that they have similar anxiety relieving potential (46). This could be due to patient preference; some may like the safety and intimacy of prerecorded music, with others preferring live music and participation, including singing, that music therapy allows (46). Both musical interventions are used for similar purposes but it is important to note that music therapy is an area requiring specific training in music and its application in healthcare (39).

There is poor evidence directing the type of genre that is best (18) but most studies mention that music to reduce anxiety has the following qualities: (a) slow and flowing, (b) approximately 60 – 80 beats per minute, (c) non lyrical, (d) consists predominantly of low notes, (e) is comprised mostly of strings with minimal brass or percussion, and (f) has a maximum volume of 60 decibels. A time period of 20 – 30 minutes is advised as the ideal length of time to achieve some effect (19).
Gooding et al (39) highlight similar factors to consider when choosing music to reduce anxiety; "Tempo (music speed): slow; 60 – 80 beats per minute; stable consistent tempo, Dynamics (volume) low level with minimal changes, Timbre (sound quality or tone colour): gentle, without harsh contrasts, Texture (combination of sounds/instruments): consistent; limited instrumentation and/or changes, Melody (theme): legato or connected/smooth, Rhythm (movement): stable rhythms, absence of percussive or accented rhythms, Pitch (tone): simple harmonic or chord progressions." Krout (36) also suggested that music that contains the above elements is found usually in classical and new age genres.

Florence Nightingale postulated that wind instruments with continuous sound were better for patients than music played with instruments that could not produce continuous sound (43). Giving patients a choice as to the music they listen to improves their ability to relax (3, 36). Music that evokes pleasure in one person may trigger fear in another. Yung et al (8) suggests that there are cultural influences that determine what music an individual finds pleasing.

There is evidence for the use of music in reducing cancer pain, improving depression both as a stand-alone treatment and as an adjunct to other therapy, as a

complementary treatment for epilepsy and there is potential for its use in dementia (34). The American Music Therapy Association has encouraged its use for illnesses including Parkinson's disease, affective disorders and stroke (13). Its ability to reduce anxiety in the perioperative setting creates an environment where patients have less pain, nausea and vomiting, complications of surgery and shortened recovery times (39). Music is safe, cheap, simple and non-invasive; it lends itself to the management of preoperative anxiety (19). Music may also have a greater ability to reduce anxiety than midazolam (47), a benzodiazepine commonly used for preoperative anxiety.

1.4.5 Music and anaesthesia

Music is being used more and more in anaesthesia to ascertain if it has any positive effects on perioperative anaesthetic requirements. There are potentially many ways that music can be used in anaesthesia in order to reduce anaesthetic requirements or improve patient outcomes indirectly.

General Anaesthetic

General anaesthesia is the bread and butter of any anaesthetic practice. If music could reduce anaesthetic requirements a lot of good work could be achieved. Kahloul et al (48) used music in an intraoperative setting to show that its effects on patient satisfaction and experience is positive postoperatively. The effect of music used intraoperatively for children undergoing general anaesthetic was evaluated using postoperative outcomes and showed reductions in physiological parameters and raised blood sugar levels caused by stress (49). They were also able to show that children who received the music intervention were less stressed, even though they were unable to show a direct benefit in pain reduction (49). However, a study by Migneault et al (50) assessing intraoperative opiate requirements in patients undergoing general anaesthesia, given a musical intervention, failed to show any positive changes to the neurohormonal stress response or opiate requirements.

Spinal anaesthesia

Spinal anaesthesia is widely used for many procedures in anaesthetic practice. Finding ways of improving patient experience would be welcomed. Lepage et al (51) explored the effect of music on patients receiving sedation during spinal anaesthesia. Fifty adult patients undergoing nononcologic surgery under spinal anaesthetic were randomly allocated to two groups, one listening to music and a control group. The groups were evaluated using STAI and VAS. They found that patients who listened to music required less midazolam than those who had not to achieve the same level of relaxation. Relaxation was equated to be lower levels of anxiety, which they measured using the above scoring systems at intervals four times during the procedure (51).

Koch et al (52) concluded that music reduced both sedative and analgesic requirements in patients having urology surgery under spinal anaesthesia. Trials were performed in two phases; the first assessed the propofol requirements of patients who listened to music against those who did not, and the second phase examined the alfentanil requirements of patients who had listened to music and those who had not. Music was found in both instances to reduce the sedative and analgesic requirements of the patients (51). Ayoub et al (53) evaluated whether music or eliminating operating theatre noise decreased sedative requirements. Patients between the ages of 18 and 20 undergoing urological procedures under spinal anaesthesia were divided into three groups; those listening to patient selected music, listening to white noise and listening to operating theatre noise. Propofol was used intraoperatively for sedation. It was concluded that intraoperative propofol requirements were reduced in patients who listened to music even when operating theatre noise was accounted for (52).

1.4.6 Studies on female populations

There are studies that also reflect the positive effects of music on female only populations. The effect of music on anxiety, haemodynamics and pain in women going for mastectomy was evaluated by Binns-Turner et al (20). Using a sample size of 30, 15 receiving the music intervention and 15 in the control group, they were able

to show that mean arterial pressure, pain and anxiety were reduced in the intervention group postoperatively as compared to the control group (20).

Women waiting for breast biopsy were recruited into a trial by Haun et al (54), which consisted of 20 patients, 10 in the music intervention group and 10 in the control group. Anxiety was evaluated using a STAI before and after listening to music in the theatre waiting area. Patients were given “new age” music to listen to. No other music genres were made available nor were the patients asked what they would prefer to listen to. Patients who had listened to music had lower post intervention anxiety scores and interestingly lower RR (54).

The influence of music on anxiety levels in women going for gynaecological surgery was explored in a trial on 97 women in the Philippines (19). The women were divided into two groups, 48 in the music intervention group and 49 in the control group. Women in the music intervention group were offered three genres of music to listen to; classical, nature sounds and country music. The intervention took place in a preoperative waiting area. Women in the music intervention group had lower anxiety scores than those in the control group (19).

Summary

The evidence discussed before suggests that the increase in the number of surgical procedures conducted worldwide has led to new questions being asked about the concept of preoperative anxiety. Preoperative anxiety is a condition which in the past has not always been looked for or identified in patients. As highlighted in the discussion there are consequences to the patient, community and institution where the surgery is conducted when anxiety of this nature is not addressed. Traditional methods of dealing with anxiety are not desirable for all people and alternative methods of reducing anxiety are being sought. Music may be one of these alternative methods. There is still a lot we do not know about what type of music has the greatest anxiety alleviating properties, how to administer it and for how long listening to it would be beneficial for a patient. This is an example of the potential that can be garnered from the merge between science and the social arts. There is a lot of work that can be done to explore this idea.

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Section 2: Author's guidelines

The formatting of this Research Report complies with the University of 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 for the journal to which it is intended to be submitted.

In this section the author guidelines that the researcher followed with regard to formatting the article are included and followed by the draft article. The journal to which this article is intended to be submitted is Health SA Gesondheid.

2.1 Health SA Gesondheid Original Research Article full structure

Title: The article's full title should contain a maximum of 95 characters (including spaces).

Abstract: The abstract, written in English, should be no longer than 250 words and must be written in the past tense. The abstract should give a succinct account of the objectives, methods, results and significance of the matter. The structured abstract for an Original Research article should consist of six paragraphs labelled Background, Aim, Setting, Methods, Results and Conclusion.

Background: Summarise the social value (importance, relevance) and scientific value (knowledge gap) that your study addresses.

Aim: State the overall aim of the study.

Setting: State the setting for the study.

Methods: Clearly express the basic design of the study, and name or briefly describe the methods used without going into excessive detail.

Results: State the main findings.

Conclusion: State your conclusion and any key implications or recommendations.

Do not cite references and do not use abbreviations excessively in the abstract.

Introduction: The introduction must contain your argument for the social and scientific value of the study, as well as the aim and objectives:

Social value: The first part of the introduction should make a clear and logical argument for the importance or relevance of the study. Your argument should be supported by use of evidence from the literature.

Scientific value: The second part of the introduction should make a clear and logical argument for the originality of the study. This should include a summary of what is already known about the research question or specific topic, and should clarify the knowledge gap that this study will address. Your argument should be supported by use of evidence from the literature.

Conceptual framework: In some research articles it will also be important to describe the underlying theoretical basis for the research and how these theories are linked together in a conceptual framework. The theoretical evidence used to construct the conceptual framework should be referenced from the literature.

Aim and objectives: The introduction should conclude with a clear summary of the aim and objectives of this study.

Research methods and design: This must address the following:

Study design: An outline of the type of study design.

Setting: A description of the setting for the study; for example, the type of community from which the participants came or the nature of the health system and services in which the study is conducted.

Study population and sampling strategy: Describe the study population and any inclusion or exclusion criteria. Describe the intended sample size and your sample size calculation or justification. Describe the sampling strategy used. Describe in practical terms how this was implemented.

Intervention (if appropriate): If there were intervention and comparison groups, describe the intervention in detail and what happened to the comparison groups.

Data collection: Define the data collection tools that were used and their validity. Describe in practical terms how data were collected and any key issues involved, e.g. language barriers.

Data analysis: Describe how data were captured, checked and cleaned. Describe the analysis process, for example, the statistical tests used orsteps followed in qualitative data analysis.

Ethical considerations: Approval must have been obtained for all studies from the author's institution or other relevant ethics committee and the institution’s name and permit numbers should be stated here.

Results: Present the results of your study in a logical sequence that addresses the aim and objectives of your study. Use tables and figures as required to present your findings. Use quotations as required to establish your interpretation of qualitative data. All units should conform to the **SI convention** and be abbreviated accordingly. Metric units and their international symbols are used throughout, as is the decimal point (not the decimal comma).

Discussion: The discussion section should address the following four elements:

Key findings: Summarise the key findings without reiterating details of the results.

Discussion of key findings: Explain how the key findings relate to previous research or to existing knowledge, practice or policy.

Strengths and limitations: Describe the strengths and limitations of your methods and what the reader should take into account when interpreting your results.

Implications or recommendations: State the implications of your study or recommendations for future research (questions that remain unanswered), policy or practice. Make sure that the recommendations flow directly from your findings.

Conclusion: Provide a brief conclusion that summarises the results and their meaning or significance in relation to each objective of the study.

Acknowledgements: Those who contributed to the work but do not meet our authorship criteria should be listed in the Acknowledgments with a description of the contribution. Authors are responsible for ensuring that anyone named in the Acknowledgments agrees to be named.

Also provide the following, each under their own heading:

Competing interests: This section should list specific competing interests associated with any of the authors. If authors declare that no competing interests exist, the article will include a statement to this effect: *The authors declare that they have no financial or personal relationship(s) that may have inappropriately influenced them in writing this article.* Read our **policy on competing interests**.

Author contributions: All authors must meet the criteria for authorship as outlined in the **authorship** policy and **author contribution** statement policies.

Funding: Provide information on funding if relevant

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References: Authors should provide direct references to original research sources whenever possible. References should not be used by authors, editors, or peer reviewers to promote self-interests. Refer to the journal referencing style downloadable on our *Formatting Requirements* page.

Section 3: Draft article

Music as an intervention to reduce preoperative anxiety in gynaecological patients

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Key words

Preoperative anxiety, music medicine, music intervention, gynaecological patients

Abstract

Background: Preoperative anxiety is a well-established phenomenon. Pharmacological methods have traditionally been used to alleviate this anxiety. Music had been identified as an alternative therapy to attenuate anxiety and improve postoperative outcomes.

Aim: To describe the effect of a music intervention on preoperative anxiety levels in patients going for elective gynaecological procedures at the Charlotte Maxeke Johannesburg Academic Hospital.

Setting: A prospective, contextual, quasi-experimental study, conducted at Charlotte Maxeke Johannesburg Academic Hospital, a 1200 bed central hospital in Johannesburg, South Africa.

Methods: Patients undergoing gynaecological procedures were recruited preoperatively by convenience sampling from gynaecology elective lists and allocated to music intervention and control groups using simple random sampling. Patients in the music intervention group listened to 20 minutes of precompiled music. Patients in the control group received 20 minutes of quiet time. Demographic data and physiological parameters were recorded and anxiety levels were assessed using the State and Trait Anxiety Inventory. Data were analysed using descriptive and inferential statistics.

Results: There was a significant difference in anxiety levels in the music intervention group before and after the intervention (p-value > 0.0001) but not in the control group. There were no significant differences in the physiological parameters. Those who received the music intervention enjoyed the experience.

Conclusion: Music reduced preoperative anxiety in patients going for elective gynaecologic procedures. Music interventions are a cheap, easy way of reducing preoperative anxiety.

Introduction

Surgery is a traumatic experience for most individuals because control of self and the environment is lost (Susleck et al., 2007). Patients commonly become anxious when faced with the unknown or unpredictable (Mitchell, 2003). Anxiety is defined as, ' ... an emotional state, which is associated with tension, anger, apprehension, fear, increased serum levels of epinephrine and norepinephrine, heightened autonomic activity, and activated stress responses... ' (Gagner-Tjellesen et al., 2001).

Primary elements in the development of preoperative anxiety include real or imagined pain, fear of injury or disfigurement, reliance on strangers, detachment from relatives, an alien environment, the relinquishing of control (Gillen et al., 2008) as well as disruptions to social and professional life and financial difficulties (Binns-Turner et al., 2011, Rosen et al., 2008). Patients have fears about anaesthesia, the difficulty of surgery, what might be discovered and what this would mean (Susleck et al., 2007). Patients who have never had an operation before also tend to be more anxious (Caumo et al., 2001).

The anxiety experienced by patients preoperatively may cause complications (Lee et al., 2011). Feelings of trepidation can trigger the autonomic nervous system causing more fear and uncertainty (Lee et al., 2011) as well as haemodynamic instability, particularly increases in blood pressure (BP) and heart rate (HR) (Forooghy et al., 2015). A relationship has been shown between high preoperative anxiety and increased levels of postoperative pain and analgesia use (Vaughn et al., 2007). Anxiety can cause an altered cognitive ability leading to physical and emotional distress (Vaughn et al., 2007). Raised anxiety levels have been associated with poor surgical outcomes, prolonged healing times and delayed hospital discharge (Labrague and McEnroe-Petitte, 2016).

To appropriately treat anxiety in the preoperative situation it is important to be able to measure the level of anxiety in a patient. The psychological component of anxiety can be measured using, amongst others, the State and Trait Anxiety Inventory (STAI), which is accepted as the gold standard in anxiety measurement tests (Jlala et al., 2010).

Once anxiety has been assessed to be above an appropriate level some treatment may be justified. Methods to alleviate anxiety are both pharmacological and non-pharmacological (Mitchell, 2003). Pharmacological methods include the use of benzodiazepines, beta blockers and opioid drugs. These are widely favoured but have the disadvantage of causing extended sleepiness, late discharge from recovery areas, possible allergic reactions to

medication, drug addiction and other symptoms which create a negative patient experience (Binns-Turner et al., 2011). At times patients still report anxiety despite receiving anxiolytics and some would prefer an alternative to sedating drugs (Lee et al., 2011). Alternatives to medication such as more patient information, music, hypnosis, aromatherapy, reflexology and massage are now being explored (Cooke et al., 2005).

There are a variety of scenarios in which music could play an integral role as both a diagnostic and therapeutic tool in clinical medicine (Vuilleumier and Trost, 2015). When music is played, there is a release of endorphins and transmission of alpha brain waves which promotes relaxation and expels fear and anxiety (Beccaloni, 2011). The right type of music can trigger positive cortical and cognitive emotions, release neurotransmitters and pheromones that control the functioning of the body, immunoglobulins that enhance the body's defenses and natural endorphins, responsible for creating feelings of happiness (Pauwels et al., 2014). Music may also decrease BP, HR and respiratory rate (RR) (Forooghy et al., 2015). In the presence of harmonious sounds, brain cells become increasingly responsive to gamma-aminobutyric acid which increases inhibitory reactions in the brain and encourages relaxation (Krout, 2007). When listening to music there is an increased release of dopamine in the brain and consequently better executive functioning (Pauwels et al., 2014).

Two main areas have been identified in the application of musical interventions, namely, music therapy and music medicine (Palmer et al., 2015). Music therapy entails ' ...the clinical and evidence-based use of music interventions by a credentialed professional for the purpose of accomplishing individualized goals... ' (Palmer et al., 2015). Music medicine '...involves passive listening of prerecorded, staff-selected music, facilitated by non-music therapy staff.' (Palmer et al., 2015)

There is poor evidence directing the genre that is best to reduce anxiety. Research suggests that music to alleviate anxiety has the following qualities: '(a) slow and flowing music, (b) approximately 60 – 80 beats per minute, (c) is non lyrical, (d) consists predominantly of low notes, (e) is comprised mostly of strings with minimal brass or percussion, and (f) has a maximum volume of 60 decibels'. A time period of 20 – 30 minutes is advised as the ideal length of time to achieve some effect (Labrague and McEnroe-Petitte, 2016). Furthermore, giving patients a choice as to the music they listen to improves their ability to relax (Mitchell, 2003).

Music can be used to reduce cancer pain, improve depression both as a stand-alone treatment and as an adjunct to other therapy, as a complementary treatment for epilepsy and there is potential for its use in dementia (Pauwels et al., 2014). Its ability to reduce anxiety in the perioperative setting creates an environment where patients have less pain, nausea and vomiting, complications of surgery and shortened recovery times (Gooding et al., 2012).

Anxiety remains an ever present entity for patients facing surgical interventions (Binns-Turner et al., 2011). Generally, women have been identified as having higher anxiety levels than men (Labrague and McEnroe-Petitte, 2016). There is an abundance of literature on the positive effects of music in medicine and in perioperative situations (Ni et al., 2012, Bringman et al., 2009, Lee et al., 2011, Binns-Turner et al., 2011, Lee et al., 2012, Gooding et al., 2012) yet the use of music as an adjunct to anaesthesia is still in its infancy (Migneault et al., 2004). There is insufficient knowledge on the effect of music interventions specifically on South African patients in perioperative situations. Consequently, this is a unique opportunity for a study on preoperative anxiety and music in a select female population in South Africa.

The aim of this study was to describe the effect of a music intervention on preoperative anxiety levels in patients going for elective gynaecological procedures at the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). The objectives of the study were to describe the effect of music on physiological parameters in the preoperative setting, to describe the effect of music on preoperative anxiety levels and lastly, to describe the patients' experience of music in the preoperative setting.

Research methods and design

The study was a prospective, contextual, quasi-experimental study. This study was approved by the Human Research Ethics Committee (Medical) of the University of the Witswatersrand (Approval number: M160776) and other relevant authorities. It was conducted at CMJAH, which is a 1 200 bed central hospital in Johannesburg. It has 23 theaters and approximately 23 000 surgeries are performed annually.

The population consisted of women coming for specific elective gynaecological procedures. Using Statistica version 12, (Statsoft, USA), the minimum sample size to give a power of 90% at $\alpha = 0.05$ was 15 in each group. As other studies had between 40 – 60 participants

(Haun et al., 2001, Li and Dong, 2012, Forooghy et al., 2015), a sample size of 60 patients with 30 in each group was decided upon in consultation with a biostatistician.

Patients were recruited preoperatively by convenience sampling from gynaecology elective lists and allocated to the music intervention or control group using simple random sampling. One author (NYF), who collected the data, was blinded to the allocation. The inclusion criteria were any adult women who were 40 years and over, could understand English and had no difficulty hearing, had been assessed as American Society of Anaesthesiologists Score 1 or 2, were undergoing a total abdominal hysterectomy, vaginal hysterectomy or myomectomy, were having a general anaesthetic and had given informed consent. The study excluded women who were taking chronic medication that could affect their anxiety such as beta blockers, anxiolytics or antidepressants, women who had a psychiatric diagnosis, those who had a pacemaker, had received premedication or sedatives and any woman who had been part of the group assisting to select the music for the study.

The music was compiled beforehand using a process where NYF approached patients in the gynaecological ward over a period of one week and asked them about the type of music they liked to listen to or had listened to in the past to relax. Their music preferences were organised into five genres: gospel, country, classical, RnB and pop. For each of the five genres, songs reflecting the genre's theme were chosen by NYF and compiled into a playlist of 20 minutes.

The psychological component of anxiety was measured using the validated STAI (Kindler et al., 2000). It is divided into two parts of 20 questions each that assess state anxiety, (how you feel at the moment) and trait anxiety (how you generally feel). Each question was evaluated on a scale of 1 – 4. The higher the total score gained the higher the anxiety levels. A total score for STAI is between 20 and 80 with 20 – 37 representing "low" anxiety, 38 – 44 "moderate" anxiety and 45 – 80 "high" anxiety (Jlala et al., 2010).

The study was conducted using a pre and post test methodology. Patients were approached in the ward the day before surgery and given an information letter explaining the study. Informed consent was requested. A data sheet for demographic information was filled in and HR, BP and RR were recorded. A study number was allocated to each patient. They were asked to fill in the STAI (form Y-2) which assesses trait anxiety and they selected a genre of music they would like to listen to from the five genres available, if randomised to the intervention group. The genre the patient chose was indicated next to the study number and left in the file to refer to the next day.

On the day of surgery patients were transported to theatre in a ward bed and waited in the private waiting area outside the gynaecology theatre. Patients were met in this area by NYF, heart rate, blood pressure and respiratory rate were recorded and a pre-intervention anxiety test, STAI (form Y-1) which assesses state anxiety, was completed. Following this, patients were randomised by the research assistant; the patient picked an envelope from a box which, when opened, revealed whether the patient would be listening to music or not.

When the patient chose an envelope with the word “MUSIC” written inside, the choice of genre to be listened to was retrieved from the file. The patient was provided with disposable earphones. Music was played using a MP3 device. Patients adjusted the volume of the music on the device according to their preference. The earphones were disposable to address infection control concerns. The device was cleaned after use by each patient and again before use by the next patient. The music intervention took 20 minutes. A second questionnaire was completed at the end of the 20 minute intervention, with five closed questions about the patients’ perception of the intervention. The questions were; do you usually enjoy listening to music, do you find music relaxing sometimes, did you enjoy the music played, did you enjoy the experience and would you like to listen to music again before surgery if in a similar situation? The patients answered yes or no to these questions. The patient was asked by the research assistant, not to inform NYF whether they had listened music or not as NYF was blinded to the intervention. Physiological parameters were recorded again by NYF and the patient was given the post intervention STAI (form Y-1). Shortly afterward the patient was taken into to theatre.

When a patient chose an envelope with the words “NO MUSIC” written inside, they were informed that they were not going to receive the music intervention. The patient could rest in the private waiting area outside the gynaecology theatre for 20 minutes. The questionnaire on the patients’ perception of the intervention was not administered to these patients. They were not to reveal if they had listened to music or not. After 20 minutes, the HR, BP and RR were recorded again and the post STAI (form Y-1) was completed. The patient was taken into theatre for their operation. The authors remained blinded until all the demographic and STAI data were collected. The data collection procedure is illustrated in Figure 1.

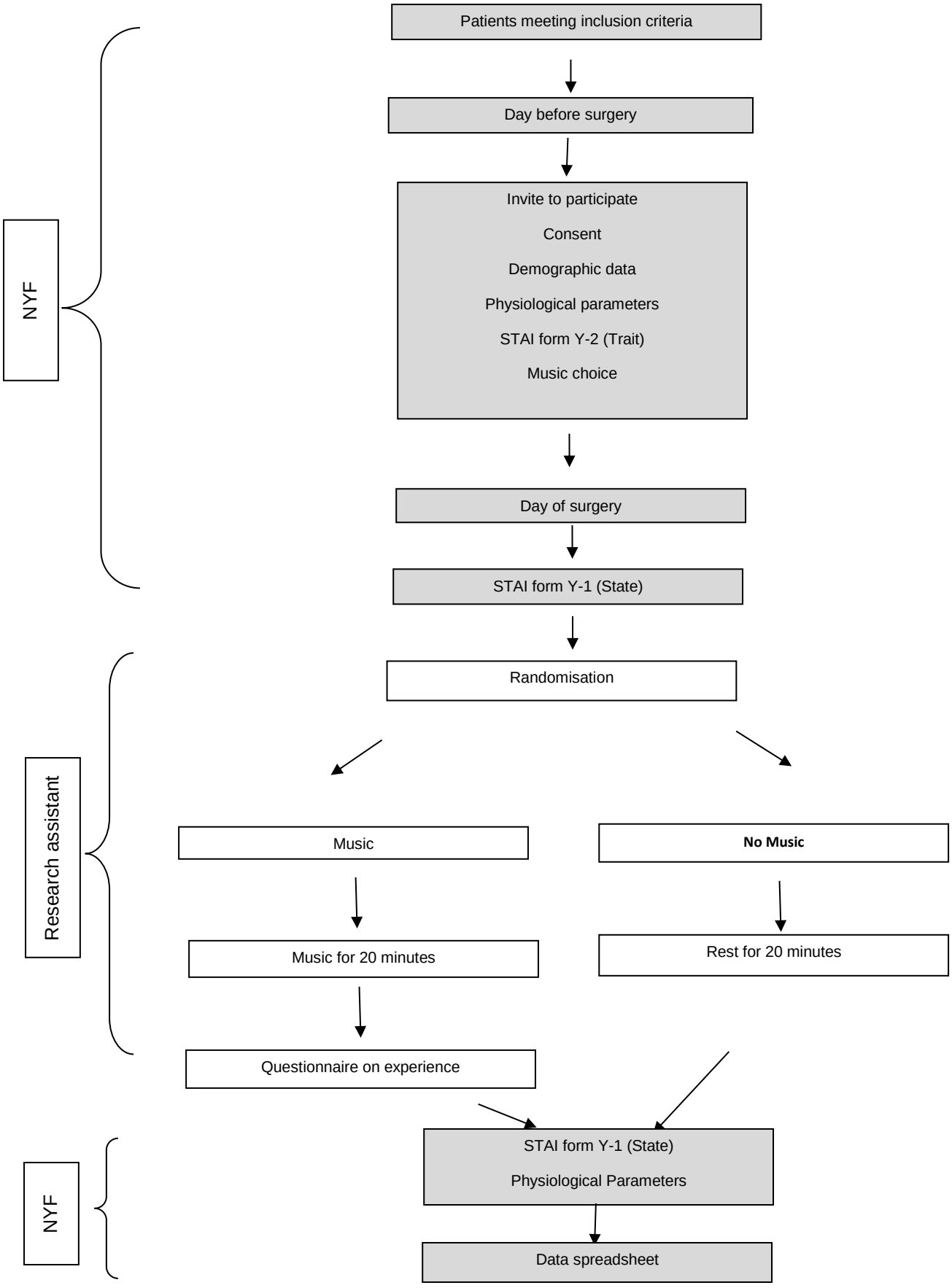


Figure 1: Data collection procedure

All data were captured on a Microsoft Excel spreadsheet. Data were analysed using Statistica version 12 (Statsoft, USA). Categorical variables were described using numbers and percentages and continuous variables using means and standard deviation if normally distributed or medians and interquartile ranges if not normally distributed. Likert scale data (STAI) were treated as interval scale data. Comparisons between groups was done using unpaired t-test or Mann - Whitney test for between group comparisons and paired t-test or Wilcoxon matched pairs for within group comparisons. A p-value of < 0.05 was considered as statistically significant.

Results

Table 1 shows the demographics, physiological parameters and trait scores of the study population. The patients ranged from ages 40 – 80 years with a mean (SD) age of 50 (9.45). Of the 60 patients seen on the day before surgery, 2 (3%) had chosen to listen to classical music, 5 (12%) country music and 1 (2%) to RnB, with the majority, 52 (87%), choosing to listen to gospel music. None of the participants chose the pop music genre. On the day of surgery, of the 30 patients who received the music intervention, 25 (83%) listened to gospel music, 4 (13%) to country music and 1 (3%) to classical music. The mean (SD) trait score was 35 (9.3). In the control group the trait score was 33 (±7.4) and the in the music intervention group 36 (10.9). These scores place the patients in the “low” anxiety group according to the STAI classification.

Table 1: Demographics, physiological parameters and trait scores of the study population

Demographic	Total n=60 n (%)	Control n=30 n (%)	Intervention n=30 n (%)	p - value
Marital status				
Single	51 (85.0%)	23 (76.6%)	28 (93.3%)	0.071
Married	9 (15.0%)	7 (23.3%)	2 (6.7%)	
Procedures				
Hysterectomy	53 (88.3%)	27 (90.0%)	26 (86.7%)	0.688
Myomectomy	7 (11.7%)	3 (10.0%)	4 (13.3%)	
History of chronic diseases				
None	27 (45.0%)	11 (36.6%)	16 (53.3%)	0.194
Present	33 (55.0%)	19 (63.3%)	14 (46.6%)	
Medication				
No medication	28 (46.7%)	12 (40.0%)	16 (53.3%)	0.301
Chronic medication	32 (53.3%)	28 (60.0%)	14 (46.7%)	
Previous surgery				
No	27 (45.0%)	13 (43.3%)	14 (46.7%)	0.795
Yes	33 (55.0%)	17 (56.7%)	16 (53.3%)	
Physiological parameters	Mean (SD)	Mean (SD)	Mean (SD)	
Systolic BP (mmHg)	128.8 (17.4)	127.7(14.2)	130.0 (20.3)	0.618
Diastolic BP (mmHg)	79.3 (13.3)	79.2 (13.0)	79.4 (13.8)	0.954
Mean BP (mmHg)	95.8 (13.6)	95.4 (12.2)	96.2 (15.1)	0.802
HR (beats/min)	81.6 (10.6)	80.9 (10.7)	82.4 (10.6)	0.580
RR (breaths/min)	18.3 (1.5)	18.6 (1.4)	18.0 (1.6)	0.147
Anxiety testing				
Trait score	35.0 (9.3)	33.6 (7.4)	36.4 (10.9)	0.243

The control group and the music intervention group were compared before and after the music intervention in table 2 to see if there were any significant differences between the 2 groups in physiological parameters or in state scores. No significant differences were found.

Table 2: Physiological parameters and state scores between the control and intervention groups

	Before			After		
	Control group Mean (SD)	Intervention group Mean (SD)	p-value	Control group Mean (SD)	Intervention group Mean (SD)	p-value
Systolic BP (mmHg)	130.3 (19.1)	133.0 (20.8)	0.6069	131.8 (17.6)	129.0 (18.9)	0.5599
Diastolic BP (mmHg)	84.1 (15.0)	84.4 (12.7)	0.9335	82.6 (11.3)	81.9 (8.9)	0.7914
HR (beats/min)	83.5 (9.6)	82.7 (13.7)	0.8106	82.9 (10.6)	80.3 (14.9)	0.4449
RR (breaths/min)	18.1 (1.9)	17.4 (1.6)	0.1548	18 (1.3)	17.1(1.5)	0.0186
State Score	33.1 (12.7)	35.4 (12.8)	0.4744	33.1 (13.3)	28.5 (10.1)	0.1370

A comparison of the physiological parameters and anxiety scores in the control group and in the music intervention group was done in table 3 to ascertain if there were any differences within the groups. There was a significant difference in anxiety levels in the music intervention group before and after the intervention, the control group had no significant change to anxiety levels. There were no significant differences noted in all other physiological parameters.

Table 3: Physiological parameters and state scores compared in the control and intervention groups

	Control group			Intervention group		
	Before Mean (SD)	After Mean (SD)	p-value	Before Mean (SD)	After Mean (SD)	p-value
Systolic BP (mmHg)	130.3 (19.1)	131.8 (17.6)	0.3936	133.0 (20.8)	129.1 (18.9)	0.1370
Diastolic BP (mmHg)	84.1 (15.0)	82.6 (11.3)	0.3349	84.4 (12.7)	81.9 (9.0)	0.1462
HR (beats/min)	83.5 (9.6)	82.9 (10.6)	0.6279	82.7 (13.7)	80.3 (14.9)	0.1253
RR (breaths/min)	18.1 (1.9)	18.0 (1.3)	0.7319	17.4 (1.6)	17.1 (1.5)	0.2861
State score	33.1 (12.7)	33.1 (13.3)	0.9602	35.4 (12.8)	28.5 (10.1)	< 0.0001

Discussion

This study shows that there is a statistically significant drop in measured anxiety levels after listening to music in the music intervention group. The control group however did not show any difference in anxiety levels after receiving standard care and 20 minutes resting time. Similarly, Haun et al (Haun et al., 2001) showed that female patients undergoing breast biopsy who received a music intervention had significantly lower anxiety levels. Furthermore, Labrague (Labrague and McEnroe-Petitte, 2016) concluded that anxiety levels in female patients undergoing gynaecological surgery were attenuated by music interventions and Binns-Turner et al (Binns-Turner et al., 2011) found that in female populations undergoing mastectomy, anxiety levels were reduced after listening to music.

The patients who listened to music were also asked about their experience of listening to music in the waiting area using five closed questions. All who listened to music found the experience positive and expressed the desire to listen to music again, for longer periods. This was encouraging and supports the need for more studies to highlight the importance and impact of music on patient satisfaction and anxiety.

Mitchell (Mitchell, 2003) states that giving patients a choice as to the music they want to listen to helps them to relax. In our study, patients were given a choice of five genres that reflected their music preferences, encouraging relaxation and an improvement in physiological parameters. Most patients chose to listen to gospel music. This was an interesting observation. This could possibly be accounted for by the nature of the sample group. Anecdotal evidence suggests that most African women over the age of 40 years in South Africa listen to gospel music and therefore it makes sense that most patients in the sample group chose this genre. The high numbers of gospel listeners can also be tied in with the process used to choose the five genres that is described in the methods of the study; the music chosen was what would likely appeal to the sample group as determined prior to the start of the study during a visit to the gynaecology ward. Despite this no obvious difference was found in physiological parameters in patients who listened to music versus those who did not, which leaves the question of the effect of music on physiological parameters unanswered or more precisely too complex to summarise linearly.

There is little and conflicting information about the effect of music on physiological parameters such as HR, BP, and RR. A study by Merakou et al (Merakou et al., 2015) conducted in Greece in 2015 on patients going for cataract surgery that showed meditative music had a stabilising effect on systolic BP. In support of this, Lee (Lee et al., 2004) was able to show that music decreased systolic BP, HR, RR as well as anxiety scores in a music intervention group. However, the control group in the study also had significant decreases in

diastolic BP, HR, and RR, without the music intervention, suggesting that there may be confounding factors other than music that could have affected the physiological parameters.

Trappe (Trappe and Voit, 2016) suggests that music composed by Mozart and Strauss lowered BP and HR in their study subjects whereas the music of ABBA did not. Koelsch (Koelsch and Jancke, 2015) supports this idea, highlighting that different types of music yield different physiological effects; HR and RR are higher when listening to exciting music as opposed to listening to tranquil music. Yung et al (Yung et al., 2002) propose that cultural differences also play a role in determining what music patients find relaxing and what music is stimulating. Therefore, one may find that listening to classical music is relaxing for one patient and lowers their BP and HR whereas another patient may find the music irritating or stimulating and therefore may exhibit and increase in HR and BP. Though patients in our study had a choice of five genres, within the genres chosen the playlists had songs of different tempos. One could argue that some of the gospel songs, for example, were more upbeat, than others and this could have influenced the results obtained.

The strength of the study is that the power of the study was improved by making the study group as homogenous as possible. This was done by choosing patients over the age of 40 years and the type of surgery being specific gynaecological procedures. The STAI was used and it has been validated and is the gold standard for anxiety testing.

One of the limitations of the study was that patients listened to music for 20 minutes. This time was decided upon after looking at numerous studies which has used similar times (Yung et al., 2002, Haun et al., 2001, Ni et al., 2012). Furthermore, one study suggested that a time period of 20 – 30 minutes was ideal for a music intervention (Labrague and McEnroe-Petitte, 2016). It was difficult to prolong the time of the intervention any further as most surgeons would have to wait for patients to finish listening to music and this delayed the start of surgery. Conversely, there are also studies where music interventions were conducted over longer periods (Bringman et al., 2009, Wang et al., 2002). Patients in the study may have benefitted from listening to music for longer periods of time.

Patients who did not have a good command of the English language were excluded from the study. Though the STAI is available in a variety of languages, it would be ideal to have it available in some of the local South African languages.

Currently there is no music offered in theatre to reduce anxiety. One suggestion would be to offer patients music to listen to in the ward prior to their operation and they could come from the ward to theatre with the music still playing. This may help reduce anxiety preoperatively. The music would ideally be of their choice and be available from admission until discharge.

An area requiring further investigation is the use of music therapy, mediated by a professional for extensive planned elective procedures in adult and paediatric patients.

Conclusion

Music reduced preoperative anxiety in patients going for elective gynaecologic procedures, however, it did not have any effect on their physiological parameters. Patients enjoyed the experience of listening to music and would choose to listen to music again under similar circumstances. Music interventions are a cheap, easy way of reducing preoperative anxiety.

Acknowledgments

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The authors declare that they have no financial or personal relationship(s) that may have inappropriately influenced them in writing this article.

All authors meet the criteria for authorship.

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The views expressed in this submitted article are the authors own and not an official position of the University of the Witwatersrand.

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Section 4: Appendices

4.1 Postgraduate approval

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

27 September 2016
Person No: 1238623
PAG

Dr NYF Fening
PO Box 92527
Norwood
Johannesburg
2117
South Africa

Dear Dr Fening

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Music as an intervention to reduce preoperative anxiety in gynaecological patients* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

4.2 Ethics approval

R14/49 Dr Nana Yaa Fenima Fening

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160776

NAME: (Principal Investigator)	Dr Nana Yaa Fenima Fening
DEPARTMENT:	Anaesthesiology Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	Music as an Intervention to Reduce Preoperative Anxiety in Gynaecological Patients
DATE CONSIDERED:	29/07/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Nicolaas Van Der Walt
APPROVED BY:	Professor P Cleaton-Jones,Chairperson, HREC (Medical)
DATE OF APPROVAL:	21/11/2016

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 in Room 301, Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized 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 the application 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 reviewed in July and will therefore be due in the month of July 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

4.3 CEO approval

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Mr. J. Maepa
Office of the Clinical Director
Tell: (011) 488-3365
Email:johannes.maepa@gauteng.gov.za
25 October 2016

Dear Dr Nana Yaa Fenima Fening

STUDY TITLE: Music as an Intervention to Reduce Preoperative Anxiety in Gynaecological Patient.

Permission to conduct the above mentioned study is provisionally approved. Your study can only commence once Ethics approval is obtained. Please forward a copy of your ethics clearance as soon as the study is approved by the Ethics committee for the CEO's to give you the final approval to conduct the study.

Supported/~~not supported~~

Dr M.I. Mofokeng
Clinical Director
DATE: 3/11/2016

Approved/not approved

Ms G. Bogoshi
Chief Executive Officer
Date: 7.11.2016

4.4 Obstetric department approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

OBSTETRICS AND GYNAECOLOGY
School of Clinical Medicine

24 October 2016

To whom it may concern

Re: Request for permission to conduct research in the Department of Obstetrics and Gynaecology.

Dr Nana Yaa Fening has requested to conduct research in the Department of Gynaecology. Her proposed MMED Research Report is on Music as an intervention to reduce pre-operative anxiety in gynaecological patients undergoing surgery. She has received Ethics approval for her research and it is my pleasure to allow her to perform her research in our department.

Dr Nana Yaa Fening is currently a Registrar in the Department of Anaesthesia. I have discussed this with the HOD of our Department. Dr Lawrence Chauke and he is in agreement.

I wish Dr Nana Yaa Fening all the success in conducting her research in our Department. Her supervisor Dr N vd Walt will oversee her research. Should you have any concerns please feel free to contact me by email at any time.

Yours sincerely

Dr HA Rhemtula

Head of Clinical Unit

CMJAH and The University of the Witwatersrand, Johannesburg

H.Rhemtula@gmail.com /Haroun.Rhemtula@wits.ac.za

0833097936

4.5 Turn it in letter

WITS UNIVERSITY

DEPARTMENT OF ANAESTHESIOLOGY
UNIVERSITY OF THE WITWATERSRAND,
JOHANNESBURG
Tel.(011)933-9334/5 / Fax (011)933-1843

FACULTY OF HEALTH SCIENCES

29th October, 2018

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

Dear Madam,

Re: M Med: **Music as an intervention to reduce preoperative anxiety in gynaecological patients**

,

Dr Nana Yaa Fening, student number: 1238623, has submitted her research report to Turnitin which revealed a similarity index of 12%. 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,

H Perrie

Helen Perrie
Supervisor

1238623:Nana_turn_it_in.docx

ORIGINALITY REPORT

12%	9%	8%	6%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

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3	Leodoro J. Labrague, Denise M. McEnroe-Petitte. "Influence of Music on Preoperative Anxiety and Physiologic Parameters in Women Undergoing Gynecologic Surgery", Clinical Nursing Research, 2014 Publication	1%
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Section 5: Proposal

Music as an intervention to reduce preoperative anxiety in gynaecological patients

Nana Yaa Fening

Student Number: 1238623

Degree: Master of Medicine in Anaesthesiology

Supervisor	Helen Perrie
	Department of Anaesthesiology
Co-supervisor	Juan Scribante
	Department of Anaesthesiology

5.1 Introduction

Surgery is a traumatic experience for most individuals because control of self and the environment is lost (1). Patients commonly become anxious when faced with the unknown or unpredictable (2). Anxiety is defined as, "... an emotional state, which is associated with tension, anger, apprehension, fear, increased serum levels of epinephrine and norepinephrine, heightened autonomic activity, and activated stress responses..." (3). Anxiety begins well before admission (4), as much as 12 hours in advance, and fluctuates throughout the perioperative period (2). There are two arms to anxiety; state anxiety which is a fleeting emotional attitude determined by the immediate circumstances and trait anxiety which focuses on the qualities in an individual's personality that drives their response to a stressful scenario (5).

There is little evidence to describe how common preoperative anxiety is in patients undergoing gynaecological procedures but levels of anxiety have been said to range between 45% the night before surgery and 67% just before the anaesthetic is given (6). Women generally have higher preoperative anxiety levels than their male counterparts (6).

Primary elements in the development of preoperative anxiety include, real or imagined pain, fear of injury or disfigurement, reliance on strangers, detachment from relatives, an alien environment, the relinquishing of control (5) as well as disruptions to their social and professional life and financial difficulties (7, 8). Patients also have fears about anaesthesia, the difficulty of surgery, what might be discovered and what this would mean (1). Patients who have never had an operation before also tend to be more anxious (9), the type of anaesthetic to be administered, equipment such as masks and laryngoscope blades also tends to be an area of great concern to patients (2).

The anxiety experienced by patients preoperatively may create complications (10). Feelings of trepidation can trigger the autonomic nervous system causing more fear and uncertainty (10) as well as haemodynamic instability, particularly increases in blood pressure (BP) and heart rate (HR) (11). Patients sometimes also experience palpitations and nausea (12). There is evidence to show a relationship between high

preoperative anxiety and increased levels of postoperative pain and analgesia use (13). Anxiety can cause an altered cognitive ability leading to physical and emotional distress (13). Raised anxiety levels have been associated with poor surgical outcomes, prolonged healing times and delayed hospital discharge (6).

To appropriately treat anxiety in the preoperative situation it is important to be able to measure the level of anxiety in a patient. The physiological parameters such as HR, BP and respiratory rate RR can be measured using standard monitoring devices. A fast HR, raised BP and fast RR would imply that a patient is more anxious. The psychological component of anxiety can be measured using amongst others, the State and Trait Anxiety Inventory (STAI), which is accepted as the gold standard in anxiety measurement tests (14). Other scales to measure anxiety include the visual analogue scale and the numerical rating scale (8).

Once anxiety has been assessed to be above an appropriate level some treatment may be justified. Methods to alleviate anxiety are both pharmacological and non-pharmacological (2). Pharmacological methods include the use of benzodiazepines, beta blockers and opioid drugs. These are widely favoured but have the disadvantage of causing extended sleepiness, late discharge from recovery areas, possible allergic reactions to medication, drug addiction and other symptoms which create a negative patient experience (7). Anxiolytics have many adverse effects such as depressed breathing, decreased gut peristalsis, itchiness, nausea and vomiting, hypovolaemia and can prolong a patient's time in hospital (15). At times patients still report anxiety despite receiving anxiolytics and some would prefer an alternative to sedating drugs (10). Alternatives to medication such as more patient information, music, hypnosis, aromatherapy, reflexology and massage are now being explored (16). This research focuses on music as an alternative therapy to reduce anxiety.

When music is played, there is a release of endorphins and transmission of alpha brain waves which promotes relaxation and expels fear and anxiety (17). The type of music has an effect on mood. Gratifying music activates the areas of the brain responsible for perceiving other stimuli regarded as rewarding. Areas identified include the orbitofrontal cortex and the ventral stratum (18). Countering this, is the effect of sad music on areas such as the hippocampus and amygdala which are

known to be responsible for depressed or negative moods (19). There are a variety of scenarios in which music could play an integral role as both a diagnostic and therapeutic tool in clinical medicine (19).

The right type of music can trigger positive cortical and cognitive emotions, release neurotransmitters (acetylcholine) and pheromones that control the functioning of the body, immunoglobulins (Immunoglobulin A) that enhance the body's defenses and natural endorphins, (substances behaving like opioids) responsible for creating feelings of happiness (18). Music may also decrease BP, HR and RR (11). In the presence of harmonious sounds, brain cells become increasingly responsive to gamma-aminobutyric acid which increases inhibitory reactions in the brain and encourages relaxation (20). When listening to music there is an increased release of dopamine in the brain and consequently better executive functioning (18).

Two main areas have been identified in the application of musical interventions, namely, music therapy and music medicine (21). Music therapy entails "...the clinical and evidence-based use of music interventions by a credentialed professional for the purpose of accomplishing individualized goals..." (21). Music medicine "...involves passive listening of prerecorded, staff-selected music, facilitated by non-music therapy staff."(21) Despite the differences between the two types of intervention, current information shows that they have similar anxiety relieving potential (22). This could be due to patient preference; some may like the safety and intimacy of prerecorded music, with others preferring the live music and participation, including singing, that music therapy allows (22). Both musical interventions are used for similar purposes but it is important to note that music therapy is an area requiring specific training in music and its application in healthcare (23).

There is poor evidence directing the type of genre that is best but most studies mention that music to reduce anxiety has the following qualities: " (a) slow and flowing music, (b) approximately 60 - 80 beats per minute, (c) is non lyrical, (d) consists predominantly of low notes, (e) is comprised mostly of strings with minimal brass or percussion, and (f) has a maximum volume of 60 decibels. A time period of 20 - 30 minutes is advised as the ideal length of time to achieve some effect (6).

Furthermore, giving patients a choice as to the music they listen to improves their ability to relax (2).

There is evidence for music's use in reducing cancer pain, improving depression both as a stand-alone treatment and as an adjunct to other therapy, as a complementary treatment for epilepsy and there is potential for its use in dementia (18). Merakou et al (24) point out that The American Music Therapy Association has encouraged its use for illnesses including Parkinson's disease, affective disorders and stroke. Its ability to reduce anxiety in the perioperative setting creates an environment where patients have less pain, nausea and vomiting, complications of surgery and shortened recovery times (23). Music is safe, cheap, simple and non-invasive; it lends itself to the management of preoperative anxiety (6). Music may also have a greater ability to reduce anxiety than midazolam (25), a benzodiazepine commonly used in preoperative anxiety.

Music has the potential to become common place in waiting areas, reception halls and postoperative recovery spaces, filling patients with a sense of calmness, peace and ease (17). One would expect that providing music to patients in preoperative settings will reduce their anxiety levels reflected by a reduction in their anxiety scores measured using the STAI. A reduction in physiological parameters; HR, BP and RR is also expected.

5.2 Problem statement

Anxiety remains an ever present entity for patients facing surgical interventions (7). There is an abundance of literature on the positive effects of music in medicine and in perioperative situations (7, 10, 12, 23, 25, 26). The introduction of music as a mainstream medical intervention has failed to take hold (14). Furthermore, the use of music as an adjunct to anaesthesia is still in its infancy; Migneault et al (27) failed to show a decrease in opiate requirements or neurohormonal stress response after a musical intervention. There is insufficient knowledge on the effect of music interventions specifically on South African patients in perioperative situations. Furthermore women have been identified as having higher anxiety levels than men

(6). This is a unique opportunity for a study on preoperative anxiety and music in a select female population in South Africa. It is therefore important explore this avenue more closely with the aim of creating a positive change in our hospital settings (17).

5.3 Aim

The aim of this study is to describe the effect of a music intervention on preoperative anxiety levels in patients coming for elective gynaecological procedures at the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH).

5.4 Objectives

The objectives of the study are:

- to describe the effect of music on physiological parameters in the preoperative setting
- to describe the effect of music on preoperative anxiety levels
- to describe the patients' experience of music in the preoperative setting.

5.5 Research assumptions

The following definitions will be used in this study.

Gynaecological procedures: in this study will be total abdominal hysterectomy (TAH), vaginal hysterectomy (VH) and myomectomy.

Preoperative anxiety: is anxiety experienced before any surgical procedure. In this study it will be measured using the STAI (Appendix 1).

State Trait Anxiety Inventory: is a questionnaire to measure subjective anxiety. It is considered the gold standard in anxiety measurement (28). The questionnaire is divided into two parts of 20 questions each that assess state and trait anxiety. Each question is evaluated on a scale from one to four.

Research assistant: in this study will refer to a trained research assistant who will randomise patients into the intervention and control groups, provide the earphones and MP3 player used in the music intervention and give the questionnaire about the patients' experience of the music as the researcher needs to be blinded until the data collection is completed.

5.6 Demarcation of study field

The study will be conducted at CMJAH, which is a 1200 bed central hospital in Johannesburg. It has 23 theaters and approximately 23 000 surgeries are performed annually.

5.7 Ethical considerations

Approval to conduct the study will be sought from the Human Research Ethics Committee (Medical) and the Graduate Studies Committee of the University of Witswatersrand (Wits). Permission to conduct the study at CMJAH (Appendix 2) will be requested from the hospital's Chief Executive Officer and the Head of Department of Obstetrics and Gynaecology at CMJAH.

The STAI (Appendix 1) is copyrighted and permission to use the questionnaire will be purchased through the managing website and publisher Mind Garden Inc (29).

Patients undergoing specific gynaecological procedures will be invited to take part in the study, if they agree an information letter (Appendix 3) will be given to them and informed consent (Appendix 4) will be obtained. Patient confidentiality will be protected by allocating a study number to each study participant. Only the study number will appear on the study forms. Confidentiality will be further ensured by making sure that only the researcher and supervisors have access to the raw data.

The study will be conducted in accordance with the Declaration of Helsinki (30) and the South African Good Clinical Practice Guidelines (31).

Data will be securely locked in a cupboard for six years following completion of the study.

5.8 Research methodology

5.8.1 Research design

The study is a prospective contextual, quasi-experimental study.

5.8.2 Study population

The population will consist of women coming for specific elective gynaecological procedures (TAH, VH, myomectomy) at CMJAH.

5.8.3 Study sample

The study sample will consist of women coming for TAH, VH, myomectomy under general anaesthetic from March 2017 until the sample size is realised.

Sample Size

In consultation with a biostatistician the minimum sample size was calculated as n = 15 in each group; the mean difference of STAI in the experimental group n = -8 ± 8 and the mean difference of STAI in the control group n = +2 +/- 6. Power = 90%, level of significance α = 0.05. The program used to calculate this was Statistica version 12. In the literature the range of sample groups used in similar studies revealed the lowest sample size being 20 (10 receiving the intervention, 10 in the control group) (32) and the highest being approximately 200 collected over 2 years (100 receiving the intervention and 100 in the control group) (21) and with most studies samples being between 40 to 60 participants (11, 32, 33). It was therefore decided that the sample should be 60 patients with 30 receiving the intervention and 30 in the control group.

Sampling method

Patients will be recruited preoperatively by convenience sampling from gynaecology elective lists using the inclusion and exclusion criteria and allocated to the music intervention or control group using simple random sampling by the research assistant. The patient will pick an envelope from a box starting with 60 envelopes (inside the envelopes it will be stated whether the patient will receive the intervention or not - 30 will state “MUSIC” for the intervention group and 30 “NO MUSIC” for the control group). The research assistant will open the envelope revealing to which group the patient will be allocated. The researcher will be blinded to the allocation.

Inclusion criteria

Adult women who:

- ≥ 40 years
- are assessed as ASA 1 or 2
- are undergoing a TAH, VH or myomectomy
- are having a general anaesthetic
- can understand English
- have no difficulty hearing
- who have given informed consent.

Exclusion criteria

The exclusion criteria will include women who:

- have had any chronic medication that could affect their anxiety such as beta blockers, anxiolytics, or antidepressants
- have a psychiatric diagnosis
- have pacemakers
- have received premedication or sedatives
- were part of the group assisting the researcher to select the music for the study.

5.8.4 Data collection

Music selection

The music will be compiled beforehand using a process where the researcher will approach patients in the gynaecological ward over a period of one week and ask them about the type of music they like to listen to or have listened to in the past to relax. Their music preferences will be organised into five genres that will be chosen by the researcher with help from a member of the Wits Institute for Social and Economic Research (WiSER) who has a background in music interventions in medicine. For each of the five genres, songs reflecting the genre's theme will be chosen by the researcher and compiled into a playlist of 20 minutes. It was concluded that five genres would provide patients with an adequate choice of songs and avoid long extensive lists that patients may find confusing.

State and Trait Anxiety Inventory

The psychological component of anxiety will be measured using the validated STAI (28). It was developed in the 1960's by Spielberger, using information from the Manifest Anxiety Scale, an anxiety test engineered to explain state and trait anxiety (34). It is divided into two parts, of 20 questions each that assess state anxiety, (how you feel at the moment) and trait anxiety (how you generally feel). Each question is evaluated on a scale numbered from one to four; in the state anxiety scale 1 = not at all 2= somewhat, 3 = moderately so and 4 = very much so. In the trait anxiety scale questions are answered by 1= almost never, 2 = sometimes, 3 = often and 4 = almost always. The higher the total score gained the higher the anxiety levels. A total score for STAI is between 20 and 80 with 20 - 37 representing "low" anxiety, 38 - 44 "moderate" anxiety and 45 - 80 "high" anxiety (14).

Collection of data

The study will be conducted using a pre and post test methodology. Patients will be recruited preoperatively the day before surgery by the researcher using gynaecology elective lists and the inclusion and exclusion criteria. Selected patients from the elective list fitting the criteria will be approached in the ward the day before surgery and given an information letter (Appendix 3) explaining the study. Informed consent

(Appendix 4) will be requested. Upon obtaining consent the researcher will fill in a data sheet (Appendix 5) for demographic information, measure and record HR, BP and RR in the ward and the patient will be asked to fill in the STAI form Y-2 (Appendix 1) which assesses trait anxiety. The demographic sheet (Appendix 5) will be taken by the researcher and the patient will be allocated a study number.

During this visit, the day before surgery, the patients will select a genre of music they would like to listen to from the five genres compiled by the researcher. The genre the patient has chosen will be indicated next to the study number by the researcher and left in the file for the research assistant to refer to the next day.

On the day of surgery patients will be transported to theatre on a stretcher and wait in the private waiting area outside the gynaecology theatre. The researcher will meet patients in this area take their HR, BP and RR and record this data. A pre-intervention anxiety test STAI form Y-1 (Appendix 1) which assesses state anxiety, will be answered by the patient.

Following this, researcher will leave the waiting area and alert the research assistant that the patient has arrived. The research assistant will meet and randomise patients; the patient will pick an envelope from a box and hand it to the research assistant. The research assistant will open the envelope revealing to which group the patient will be allocated.

- The music intervention group

If patient has chosen and envelope with the word “MUSIC” written inside, the research assistant will look in the file to determine the choice of genre made by the patient the day before surgery. The patient will be provided with disposable earphones by the research assistant. Music will be played using a MP3 device. The MP3 player will be switched on, the appropriate playlist selected and the MP3 player will be handed to the patient. Patients will be able to adjust the volume of the music on the device according to their preference. The MP3 device and earphones will be purchased for the study. The earphones will be disposable to address infection control concerns. Patients will be given the earphones to keep if they would like them. The device will be cleaned in between patients. The music intervention will

take 20 minutes, which will be timed by the research assistant, after which the research assistant will take the MP3 device and provide the patient with a questionnaire with five closed questions about the patients' perception of the intervention (Appendix 6). The patient will be asked not to inform the researcher whether they received music or not as the researcher will be blinded to the intervention.

The research assistant will alert the blinded researcher who will return to the waiting area, record the HR, BP and RR of the patient again and give the patient the post intervention anxiety test (form Y-1). The information will be taken and filed by the researcher. The patient will then be taken into theatre for their operation.

- The control group

If patient has chosen and envelope with the words "NO MUSIC" written inside, the research assistant will inform them that they are not going to receive any music. The research assistant will leave the patient to rest in the waiting area for 20 minutes. The questionnaire on the patients' perception of the intervention will not be administered to these patients. The research assistant must explain to the patients that they must not say if they received music or not. The research assistant will alert the researcher that they are done after 20 minutes. The blinded researcher will return to the waiting area, record the HR, BP and RR of the patient again and give the patient the post intervention anxiety test (form Y-1). The information will be taken and filed by the researcher. The patient will then be taken into theatre for their operation.

The researcher will remain blinded until all the demographic and STAI data are collected.

The data collection procedure is illustrated in Figure 1.

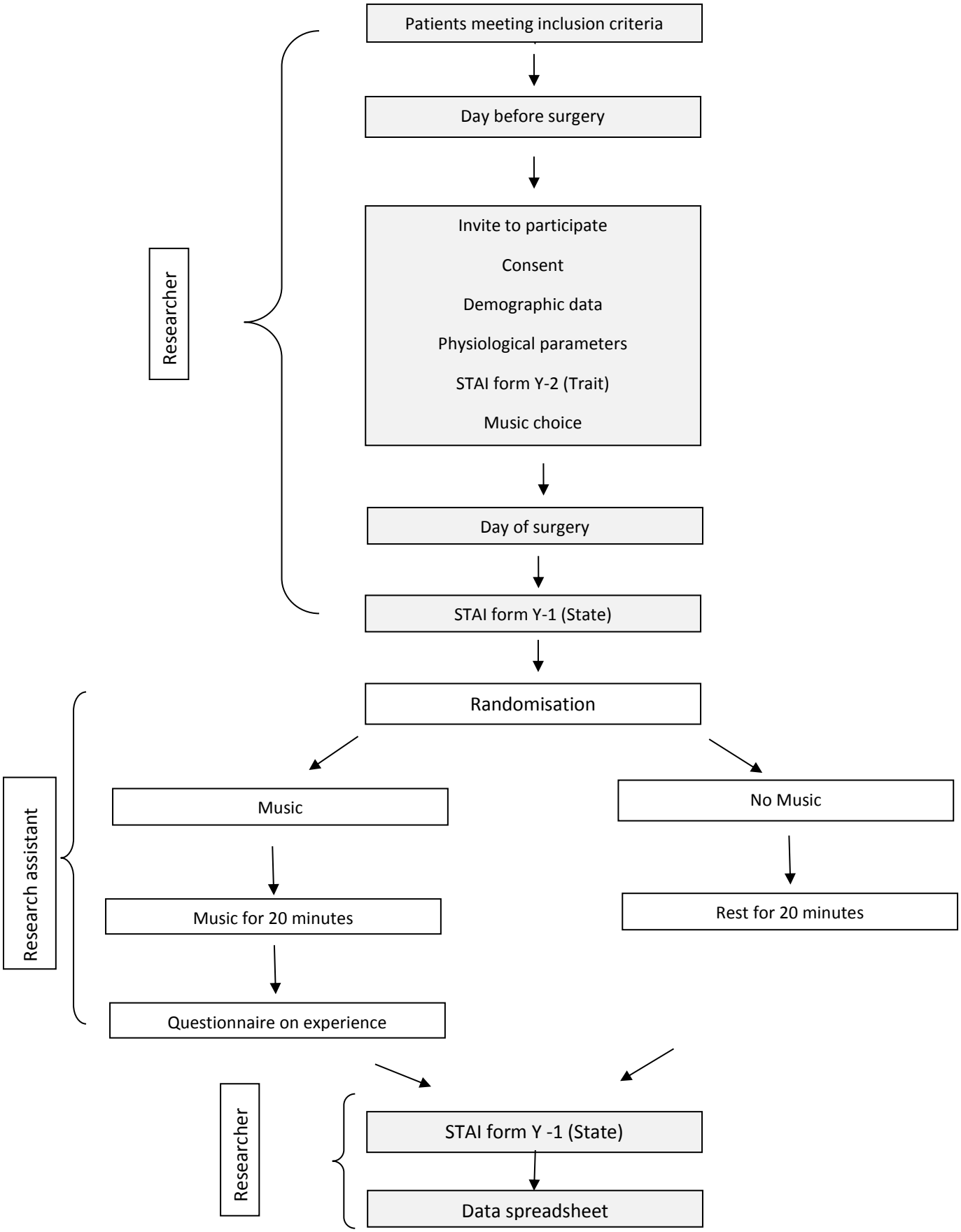


Figure 1: Data collection procedure

The HR will be taken using a Jumper Pulse Oximeter Model: JPD – 500A made by (Shenzhen Jumper Medical Equipment Co. Ltd.)

The BP will be taken using Rossmax Automatic Upper Arm Blood Pressure Monitor (Model MJ 150).

The RR will be recorded manually by the researcher counting the number of breaths taken in one minute.

5.8.5 Data analysis

All data will be captured on a Microsoft Excel spreadsheet. Data will be analysed using Statistica version 12. Descriptive and inferential statistics will be used. Categorical variables will be described using numbers and percentages and continuous variables using means and standard deviation if normally distributed or medians and interquartile ranges if not normally distributed.

Likert scale data (STAI) will be treated as interval scale data. Comparisons between groups will be done using unpaired t-test or Man Whitney for between group comparisons and paired t-test or Wilcoxon matched pairs for within group comparisons.

A p value of < 0.05 will be considered as statistically significant.

5.9 Significance of study

Evidence suggests that music reduces preoperative anxiety. This would however be the first study in the Department of Anaesthesiology at Wits that looks at music as an intervention to reduce preoperative anxiety. If music is found to reduce preoperative anxiety, there is potential for implementing strategies in the hospital to help reduce patients' anxiety, such as providing music in the waiting areas. Most patients do not receive premedication and music would be a way of reducing anxiety and improving patient satisfaction as well as possibly reducing hospital stay or complications

associated with anxiety. Music is a simple intervention that is not to costly or labour intensive to provide.

5.10 Validity and reliability

In this study the validity and reliability will be ensured by:

- choosing an appropriate study population and sample
- ensuring the researcher remains blinded until the STAI data is collected
- using the validated STAI
- determining sample size in consultation with a biostatistician
- checking every 10th data entry point on the spreadsheet for accuracy
- analyzing the data in consultation with a biostatistician.

5.11 Potential limitations

This study will be conducted contextually in CMJAH and will be limited to female gynaecological patients, and the results of this study may not be generalisable to other preoperative populations.

5.12 Study outline

	May 2016	June 2016	Sept 2016	Oct 2016	Nov 2016	Dec 2016	Jan 2017	Feb 2017	March 2017	April 2017
Chapters 1,2,3										
Proposal preparation										
Proposal submission										
Ethics Approval										
Graduate Studies Approval										

Data Collection										
Data Analysis										
Article preparation										
Submission										

5.13 Funding

	Price per unit	Number of Units	Total
Right to reproduce STAI	R 32.00	60	R 1920.00
Headphones	R 20.00	60	R 1200.00
Printing costs	R 1.00	+/- 1500	R 1500.00
MP3 device	R 150. 00	4	R 600
Total			**R5220.00**

The Department of Anaesthesiology have provided paper and printing facilities for this study. An application will be submitted to the SASA Jan Pretorius fund and the Wits Medical Endowment Fund to obtain the capital to cover the costs of headphones and the rights to reproduce the STAI.

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5.15 Appendices

Appendix 1: State and Trait Anxiety Inventory

STAIAD Short Form Y-2

(Please note due to copy write issues only a sample of 10 out of 20 of the questions is provided.)

SELF-EVALUATION QUESTIONNAIRE

STAIAD Short Form Y-2

Study Number_____Date_____

Directions: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you ***generally feel***. Use the following scale: 1 ALMOST NEVER – 2 SOMETIMES – 3 OFTEN – 4 ALMOST ALWAYS

11. I feel nervous and restless 1 2 3 4
12. I feel satisfied with myself 1 2 3 4
13. I wish I could be as happy as others seem to be 1 2 3 4
14. I feel like a failure 1 2 3 4
15. I worry too much over something that really doesn't matter 1 2 3 4
16. I lack self-confidence 1 2 3 4
17. I feel secure 1 2 3 4
18. I feel inadequate 1 2 3 4
19. I am a steady person 1 2 3 4
20. I get in a state of tension or turmoil as I think over my recent concerns and interests..... 1 2 3 4

STAIAD Short Form Y-1

(Please note due to copy write issues only a sample of 10 out of 20 of the questions is provided.)

SELF-EVALUATION QUESTIONNAIRE

STAIAD Short Form Y-1

Study Number_____Date_____

Directions: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate ***how you feel right now***, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best. Use the following scale: 1 NOT AT ALL – 2 SOMEWHAT – 3 MODERATELY SO – 4 VERY MUCH SO

1. I feel calm 1 2 3 4
2. I am tense 1 2 3 4
3. I feel at ease 1 2 3 4
4. I am presently worrying over possible misfortunes 1 2 3 4
5. I feel frightened 1 2 3 4
6. I feel nervous 1 2 3 4
7. I am jittery 1 2 3 4
8. I am relaxed 1 2 3 4
9. I am worried 1 2 3 4
10. I feel steady 1 2 3 4

Appendix 2: Letters of permission

Letter to CEO of Charlotte Maxeke Johannesburg Academic Hospital (CMJAH)

Dr NYF Fening
Contact: 083 372 0612
Email: nfenima@yahoo.com
September 2016

The CEO of CMJAH

Dear Sir/Madam,

Re: Request for permission to conduct research

My name is Nana Yaa Fening, and I am a registrar in the Department of Anaesthesiology at the University of Witwatersrand. I am conducting my MMed research titled: **Music as an intervention to reduce preoperative anxiety in gynaecological patients**, and I would like to request permission to conduct my study in the gynaecological wards and the operating theaters of CMJAH.

The aim of this research is to describe the effect of music on preoperative anxiety levels in patients coming for elective gynaecological procedures at the CMJAH.

The study may be beneficial to the hospital as it may lead to the addition of music devices in waiting areas and recovery areas in the hospital with the aim to reduce preoperative anxiety. There will be no additional cost for the hospital.

I have submitted applications to the Human Rights Ethics Committee (HREC) and the Postgraduate Committee of the University of Witwatersrand. Attached please find the letter from HREC confirming my application for ethics approval and a copy of my proposal.

Sincerely,
Nana Yaa Fening

Letter to HOD of Department of Obstetrics and Gynaecology at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH)

Dr NYF Fening
Contact: 083 372 0612
Email: nfenima@yahoo.com
September 2016

The HOD of the Department of Obstetrics and Gynaecology at CMJAH
Dear Dr L. Chauke,

Re: Request for permission to conduct research in gynaecology wards

My name is Nana Yaa Fening, and I am a registrar in the Department of Anaesthesiology at the University of Witwatersrand. I am conducting my MMed research titled: **Music as an intervention to reduce preoperative anxiety in gynaecological patients**, and I would like to request permission to conduct my study in the gynaecological wards of CMJAH.
The aim of this research is to describe the effect of music on preoperative anxiety levels in patients coming for elective gynaecological procedures at the CMJAH.

The study may be beneficial to the hospital as it may lead to the addition of music devices in waiting areas and recovery areas in the hospital with the aim to reduce preoperative anxiety. There will be no additional cost for the hospital.

I have submitted applications to the Human Rights Ethics Committee (HREC) and the Postgraduate Committee of the University of Witwatersrand. Attached please find the letter from HREC confirming my application for ethics approval and a copy of my proposal.

Sincerely,
Nana Yaa Fening

Appendix 3: Information Letter

Hello. My name is Nana Yaa Fening and I am a doctor working in the theatre of this hospital. My job is to give you the anaesthetic (make you to sleep) in theatre and make sure that you have no pain whilst you are having your procedure done. As part of my training I have to do a research study and I would like to invite you to please be part of my study.

My study is titled: **Music as an intervention to reduce preoperative anxiety in gynaecological patients**.

Many patients have anxiety before an operation. Anxiety is that worrying feeling that you get when you are afraid of something. It is completely normal to be anxious before an operation but sometimes this anxiety makes the procedure and your stay in hospital more complicated than it needs to be. So finding a way to reduce this anxiety would be useful. Sometimes we would give a tablet to relieve the anxiety but a number of patients don't want to take these drugs, so we are looking for other methods to make patients feel calm. I want to see if music has any effect on the anxiety that you have before you go into theatre.

In order to conduct the study, I will ask you some questions about yourself, the answers to which I will put on a data sheet. The data sheet is kept confidential. I will then take your blood pressure, heart rate and respiratory rate and I will assist you to fill in a questionnaire about your anxiety levels. You are welcome to look at any of the questionnaires before starting the study.

You will then be given a selection of five music playlists with specific themes. I would like you to please choose one of the playlists to listen to in the theatre waiting area on the day of your procedure. Please be aware that as part of the study there are some patients who will listen to music and some who will not despite choosing a playlist the day before. This is done in order to compare the two groups to see if listening to music makes a difference or not. If you will be listening to music or not will be determined on the day of surgery. My research assistant will ask you to choose one envelope from a box of envelopes. In each envelope there will be a slip of paper with the words 'MUSIC' or 'NO MUSIC' written on it. If you

choose an envelope with a slip saying ‘MUSIC’, you will be given music to listen to. If you choose and envelope with a slip saying ‘NO MUSIC’, you will not be listening to music.

When you get to theatre on the day of your procedure, I will meet you again outside the designated waiting area. I will take your blood pressure, heart rate and respiratory rate and I will assist you to fill out another questionnaire about anxiety. It will be similar to the one filled in the ward. I will then leave you with my assistant, who is helping me. If you are chosen to listen to music you will be provided with a MP3 player and earphones. The earphones are for your use only and will be disposed of once you finish using them or you can keep them. If you do listen to music, you will be able to adjust the volume of music to your desired level. The music will be played for 20 minutes. Once 20 minutes is over my colleague will take the device and headphones. My assistant will ask you to fill in a questionnaire about your experience of listening to music. If you are not listening to music, you will be left to rest for 20 minutes. Whether you have listened to music or not, I will return and assist you to fill a final questionnaire that asks you the same questions about anxiety as before. You will then be taken into theatre to have your procedure done. Once I have collected all the data I will be using the results for my Masters Degree as well as to present at a conference. Please be assured that your individual results will not be made available to anybody.

Please note:

- I will not use your name as part of my data, you will be given a study number and only myself and my supervisors will see your information. The consent form is the only piece of paper related to the study that will contain your name and will be kept separate from the data by my supervisor.
- You can refuse to be part of the study even if you sign and give your permission to be part of the study. You do not have to give reasons why you are not taking part. This will not affect the course of your treatment

If you have questions you can contact me on: (011) 488 4397 or the chairman of the Ethics Committee, Professor Cleaton-Jones on (011) 717 1234.

If you are happy to take part in this study after reading this information sheet, please let me know and sign the consent form on the next page.

Thank you,
Nana Yaa Fening

Appendix 4: Consent form

Study Number:

Research Title: Music as an intervention to reduce preoperative anxiety in gynaecological patients

I _____ give my permission to be enrolled in this study.

The procedures / questionnaires have been explained to me and I understand and appreciate their purpose and any risks involved, and the extent of my involvement. I have read and understand the attached information leaflet.

I understand that the procedures form part of a research project, and may not provide any direct benefit to me.

I understand that all experimental procedures have been reviewed and approved by the Human Research and Ethics Committee, University of the Witwatersrand, Johannesburg. If you have any questions regarding your rights as a participant in this study or any complaints, please contact Ms Zanele Ndlovu from the Ethics Committee on 011 717 1252/2700.

I understand that my participation is voluntary, and that I am free to withdraw from the project at any time without prejudice.

_____

Patient Name Date

_____

Patient Signature

_____

Researcher Name Date:

_____

Researcher Signature

Appendix 5: Demographic Data

(To be filled in by researcher)

Study Number:

Date:

Procedure (TAH/VH/M):

Age: HR in ward: BP in ward: RR in ward:

Marital Status:

Medical History: Diabetes Y / N Hypertension Y / N Asthma Y / N

Epilepsy Y / N Previous TB Y / N

Other: (Please specify)

Surgical History: Number or previous surgeries:

Type of previous surgery:

Medications:

Allergies:

Vitals (in waiting area)

Initial	20 minutes later
HR:	HR:
BP:	BP:
RR:	RR:

Slip indicating control or music group

(To be filled in by research assistant)

Study Number:

Playlist:

Received music Intervention: Yes / No

Appendix 6: Questionnaire on experience

(To be filled in by research assistant only if patient has received the music intervention)

Study number:

Please circle Yes or No

1. Do you usually enjoy listening to music? Yes / No
2. Do you find music relaxing sometimes? Yes / No
3. Did you enjoy the music played? Yes / No
4. Did you enjoy the experience? Yes / No
5. Would you like to listen to music again before surgery? Yes / No