

Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia

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

Johannesburg, 2023

Declaration

I, Samantha Ballard, herewith declare that this research report is my own, unaided work. It is being submitted for the degree of Master of Medicine at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

Ballard

Signed

On this 5th day of December 2023

Dedication

This project is dedicated to my husband who has provided me with endless support during this time. Thank you for your patience and guidance in all my endeavours.

Presentations and publications from this research project

This article has been submitted to The South African Orthopaedic Journal (SAOJ) and is currently accepted and pending publication. Manuscript number: 715

Abstract

Background: Peri-operative anxiety is a common entity that can present as a challenge to the anaesthetist and can also negatively affect the surgical outcome and functional recovery. The use of music in a medical setting is becoming increasingly popular. Literature indicates promising outcomes on the use of music to reduce anxiety. The aim of this study was to determine the effects of listening to music, on patients' anxiety, during spinal anaesthesia for patients undergoing knee and hip arthroplasty in a South African context.

Materials and methods: This randomised, controlled study included 58 adult patients scheduled to receive lower limb arthroplasty surgery. Patients in the intervention group (music group) received one of five genres of music via headphones. The control group did not receive music. Both groups received a standardised neuraxial anaesthetic. Patients' anxiety in both groups were measured using a visual analogue scale for anxiety (VAS-A). Anxiety scores were measured at the pre-operative visit, the morning prior to surgery, at skin incision and in the post-anaesthesia care unit.

Results: Each group contained 29 patients. There was no difference in the baseline anxiety scores recorded at the pre-operative visit between the two groups (1.8 cm vs 1.9 cm; $p = 0.422$). The anxiety scores were significantly lower in the music group compared to the control group at skin incision (0.9 cm vs 1.9 cm; $p < 0.001$). The music group also experienced a greater decrease in their anxiety from prior to surgery to skin incision (1.4 cm vs 0.2 cm; $p = 0.002$).

Conclusion: Music is an effective, cheap, safe, non-pharmacological adjunct that can be used to reduce peri-operative anxiety in patients undergoing lower limb arthroplasty procedures under spinal anaesthesia.

Level of Evidence: Level 2

Keywords: music, anxiety, spinal anaesthesia, arthroplasty.

Acknowledgements

To my supervisors Dr Gwyneth Davies and Dr Maria Fourtounas, thank you for all your insight and efforts towards the completion of this project. Thank you for your constant guidance and support throughout this research process.

To the Department of Orthopaedics, thank you for your encouragement and support towards this research project.

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List of abbreviations

VAS-A	Visual Analogue Scale for Anxiety
ICAROS	The International Consensus on Anaesthesia-Related Outcomes after Surgery
CHBAH	Chris Hani Baragwanath Academic Hospital
HJH	Helen Joseph Hospital
ASA	American Society of Anaesthesiologists
TCI	Target-controlled infusion
SASA	South African Society for Anaesthesiologists
UMSS	University of Michigan Sedation Scale
PACU	Post-anaesthesia care unit
IQR	Interquartile range
STAI	Speilberger State-Trait Anxiety Inventory
BIS	Bispectral index

Statement

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

The formatting of this Research Report complies with the University of the Witwatersrand's Style Guide for Theses, Dissertations and Research Reports. The formatting of the draft article may differ from the Research Report in order to comply with the author guidelines of the South African Orthopaedic Journal, the journal to which the article has been submitted. The author guidelines have been included in the appendices (Appendix 1) for reference.

Draft article

Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia: a prospective randomised controlled study.

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Declarations

Authorship

The authors confirm that all authors have made substantial contributions to all the following:

- The conception and design of the study, or acquisition of data, or analysis and interpretation of data.
- The drafting of the article or its critical revision for important intellectual content.
- The final approval of the version to be submitted.

Sound scientific research practice

The authors confirm that:

- The manuscript, including related data, figures, and tables, has not been previously published and is not under consideration elsewhere.
- No data have been fabricated or manipulated (including images) to support conclusions.
- The submission does not represent part of a single study that has been split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (e.g. 'salami-publishing').

Plagiarism

The authors confirm that the work submitted is original and does not transgress the plagiarism policy of the journal.

- No data, text or theories by others are presented as if they were the authors' own.
- Proper acknowledgements of others' work have been given (this includes material that is closely copied, summarised and/or paraphrased); quotation marks used for verbatim copying of material.
- Permissions have been secured for copyrighted material.

Conflict of interest statement

The authors declare they have no conflicts of interest.

Funding sources

No funding was received for the purposes of performing this study.

Compliance with ethical guidelines

The authors declare that this submission is in accordance with the principles laid down by the Responsible Research Publication Position Statements as developed at the 2nd World Conference on Research Integrity in Singapore, 2010.

Prior to the commencement of the study ethical approval was obtained from the following ethical review board: Human Research Ethics Committee (Medical) The University of the Witwatersrand (certificate number: M210702).

All procedures were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

Informed written consent was obtained from all patients for being included in the study.

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Abstract

Background: Peri-operative anxiety is a common entity that can present as a challenge to the anaesthetist and can also negatively affect the surgical outcome and functional recovery. The use of music in a medical setting is becoming increasingly popular. Literature indicates promising outcomes on the use of music to reduce anxiety. The aim of this study was to determine the effects of listening to music, on patients' anxiety, during spinal anaesthesia for patients undergoing knee and hip arthroplasty in a South African context.

Materials and methods: This randomised, controlled study included 58 adult patients scheduled to receive lower limb arthroplasty surgery. Patients in the intervention group (music group) received one of five genres of music via headphones. The control group did not receive music. Both groups received a standardised neuraxial anaesthetic. Patients' anxiety in both groups were measured using a visual analogue scale for anxiety (VAS-A). Anxiety scores were measured at the pre-operative visit, the morning prior to surgery, at skin incision and in the post-anaesthesia care unit.

Results: Each group contained 29 patients. There was no difference in the baseline anxiety scores recorded at the pre-operative visit between the two groups (1.8 cm vs 1.9 cm; $p = 0.422$). The anxiety scores were significantly lower in the music group compared to the control group at skin incision (0.9 cm vs 1.9 cm; $p < 0.001$). The music group also experienced a greater decrease in their anxiety from prior to surgery to skin incision (1.4 cm vs 0.2 cm; $p = 0.002$).

Conclusion: Music is an effective, cheap, safe, non-pharmacological adjunct that can be used to reduce peri-operative anxiety in patients undergoing lower limb arthroplasty procedures under spinal anaesthesia.

Level of Evidence: Level 2

Keywords: music, anxiety, spinal anaesthesia, arthroplasty.

Trial registration: Clinicaltrials.gov (NCT05491707) and SANCTR (DOH-27-012023-8787)

Introduction

The increase in the ageing population has resulted in a greater prevalence of age-related diseases such as osteoarthritis and osteoporosis.¹ Developments in the field of arthroplasty have resulted in more favourable outcomes and the demand for these procedures is expected to rise exponentially over the next ten years.² These projections are likely to burden existing hospital resources. The elderly population have significant medical comorbidities and unique requirements which increase both the surgical and anaesthetic risk and place further strain on resources. Peri-operative assessment and management of these factors is imperative in order to reduce complications and improve patient outcomes.¹

Optimisation of the anaesthetic technique can substantially reduce the risk of adverse events in these patients.³ Neuraxial anaesthesia (provided there is no contraindication to its use) has been shown to be superior to general anaesthesia for both total hip and total knee arthroplasty procedures and thus the International Consensus on Anaesthesia-Related Outcomes after Surgery (ICAROS) group recommend its use.⁴ Despite the numerous advantages over general anaesthesia, patients often have increased fear and anxiety towards neuraxial anaesthesia.⁵ This can lead to the complete disregard of this advised anaesthetic technique.

Peri-operative anxiety is a complex, multifactorial entity that can be related to the fear of the unknown anaesthetic and surgical procedure.⁶ As patients under neuraxial anaesthesia are awake during the procedure they are exposed to unusual stimuli, including bright lights, cold temperatures and noise, which can enhance fear and anxiety.⁷ The excessive noise levels during orthopaedic procedures further add to this anxiety.⁸ Not only is peri-operative anxiety a challenge to the anaesthetist but it can also negatively affect the surgical outcome and functional recovery.^{9,10}

Existing pre-operative anxiety coupled with the harsh theatre environment often leads to patients feeling uncomfortable. In order to ensure patient comfort during the surgical procedure, sedation is often combined with the regional anaesthetic modality.¹¹ The choice of sedative agent or the level of sedation is often not standardised. Sedation is not without risks or complications, particularly in the elderly population.¹¹

Pharmacological treatment of anxiety is widespread practice with alternative, non-pharmacological treatments available. Music is a simple, readily available, non-

pharmacological technique that can be used as an adjunct to treat anxiety as well as other medical disorders.¹² Music has been used to treat anxiety in a large array of both medical and surgical patients including patients with Alzheimer's disease¹³, cancer¹⁴, burns¹⁵ and critically ill patients^{16,17} in intensive care units.

The use of music in theatre dates to 1914. Kane was the first person to use music intra-operatively "as a means of calming and distracting patients" undergoing surgical procedures performed using local anaesthetic.¹⁸ The use of music in theatre has become more popular however, it is sporadic and not targeted to patient care. In the developed world music has been used for patients undergoing spinal anaesthesia as a method of reducing intra-operative anxiety and decreasing sedative requirements.^{12,19–21}

In a resource constrained environment, such as South Africa, every effort needs to be made to avoid placing further burden onto existing fragile infrastructure. Music has shown promise in the developed world, however there is a lack of evidence on its use in a setting similar to South Africa. Evolving technology has resulted in a large variety of music being readily available and it may be considered a cheap, safe, non-pharmacological intervention that could easily be implemented as an adjunct to spinal anaesthesia.¹⁹ The aim of this study was to determine the effects of listening to music, on patients' anxiety, during spinal anaesthesia for patients undergoing knee and hip arthroplasty in two South African academic hospitals.

Materials and Methods

This prospective, randomised controlled study was approved by the ethics committee and registered on clinicaltrials.gov (NCT05491707). It was conducted at Chris Hani Baragwanath Academic Hospital (CHBAH) and Helen Joseph Hospital (HJH) between January and June 2022. All patients 18 years and older, with the mental capacity to consent to the study and of American Society of Anaesthesiologists (ASA) class I to III, undergoing primary knee or hip arthroplasty surgery were assessed for eligibility. Patients were excluded if they had pre-existing visual or hearing loss, contraindications to spinal anaesthesia or moderate sedation and pre-existing anxiety disorders.

After assessment for eligibility, 58 patients were enrolled for the study (*Figure 1*). Informed consent was obtained, and patients were randomised in a 1:1 ratio, using a sealed envelope randomisation technique, into either the music group (intervention group) or the no music group (control group). Patients in the music group pre-selected their preferred

genre of music at the pre-operative assessment visit from the following list: classical, gospel, soul, pop and jazz. Anxiety scores were measured using the validated visual analogue scale for anxiety (VAS-A) (*Figure 2*). Patients used the faces as a visual guide and marked the level of anxiety along the ruler. Anxiety was measured and recorded both in centimetres (0 cm indicating no anxiety and 10 cm indicating maximum anxiety) and by the faces categories. All participating patients completed a baseline anxiety assessment using the VAS-A at the pre-operative assessment visit (T1) (*Figure 3*). The VAS-A was completed again on the day of surgery before the patient was taken into the operating room (T2). Patients in the intervention group received music after ASA monitors were applied. The music was played at a self-selected volume, on Pro Bass Swagger Series Aux disposable earphones²² and was played for the duration of the surgical procedure. The music was played from an iPhone which was placed in a plastic bag for infection control purposes. The control group did not receive music.

The following anaesthetic technique was undertaken for all patients: routine ASA monitors were applied, including non-invasive blood pressure, electrocardiogram, oxygen saturation and capnography, supplemental oxygen was supplied by nasal cannula and intravenous access was obtained. Spinal anaesthesia was performed using 13 – 15 mg plain bupivacaine 0.5% and 10 – 20 µg fentanyl intrathecally. A propofol target-controlled infusion (TCI) was used for sedation. The South African Society of Anaesthesiologists (SASA) guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in adults: 2020 – 2025 were followed.²³ The Marsh model was used for the propofol TCI and a target concentration of 1 – 2 µg/ml was used; this was adjusted in the elderly patients (over 65 years of age) to 0.6 – 0.8 µg/ml as per the SASA guidelines.²³ Moderate sedation was used, and this was measured using the University of Michigan Sedation Scale (UMSS).²³ Patients were maintained at this level of sedation for the duration of the procedure.

Patients' anxiety levels were assessed again at skin incision (T3). At the end of the procedure the music was stopped, and the earphones removed prior to the transport of the patient to the post-anaesthesia care unit (PACU). In the PACU, patients completed the final VAS-A measurement (T4) and the patient satisfaction questionnaire.

Audit data was used to calculate the sample size. Assuming a statistical power of 90% and alpha of 5%, 29 patients were required in each group to reach a level of significance. Data was analysed using SPSS version 26.²⁴ Continuous variables (age, length of surgery and total propofol dose) were described with medians and interquartile ranges (IQR) since

variables were non-normally distributed and compared using the Mann-Whitney U test. Categorical variables (gender, ASA class, STOPBANG score, surgery side and type) were described as frequency and percentages and compared using the Chi-square test. The Wilcoxon Signed Rank Test was used to assess within-group differences for continuous variables. A p-value of 0.05 or less was considered statistically significant.

Results

A total of 58 patients were investigated (29 in the music group and 29 in the control group). Both groups were comparable in terms of sex, age, ASA class, STOPBANG score (a bedside screening tool for obstructive sleep apnoea, to ensure there was no contraindication to moderate sedation), surgical side, surgical procedure, and surgery duration. Summary data are provided in *Table I*. The median propofol dose was slightly greater in the control group than the music group, but was not statistically significant (140 mg vs 110 mg; $p = 0.503$). The most popular choice of music genre was gospel (19 of 29; 65%).

A Mann-Whitney U test showed no difference in the baseline anxiety scores between the groups at the pre-operative visit (T1) ($p = 0.422$; *Table II*). There was a general increase in anxiety from the pre-operative visit (T1) to prior to surgery (T2) in both groups. Thereafter anxiety levels decreased from prior to surgery (T2) until the PACU (T4) in both groups (*Figure 4*).

There was a significant difference in the median anxiety scores between the control and music group at skin incision (T3) (1.9 vs 0.9 cm; $p < 0.001$; *Table II*, *Figure 4*). There was also a significant difference in the change in anxiety scores from prior to surgery (T2) to skin incision (T3) between the control and the music group ($p = 0.002$; *Table II*). Patients in the music group showed a significantly larger decrease in anxiety (*Figure 4*). A significant difference in the change in anxiety scores from skin incision (T3) to those measured in the PACU (T4) ($p < 0.001$; *Table II*) between the control and music group was also noted. Patients in the control group showed a significantly larger decrease in anxiety over this period (*Figure 4*).

Both groups showed low levels of anxiety at the pre-operative visit (T1). The median VAS-A measurement at T1 was 1.8 cm (IQR 0.85 to 4.45 cm) in the control group and 1.9 cm (IQR 0.75 to 2.75 cm) in the music group ($p = 0.422$; *Table II*). The majority of patients, in both the control and music groups, experienced no to moderate anxiety at the pre-

operative visit (T1) (26 of 29; 90% and 29 of 29; 100% respectively). Only 10% (3 of 29) of the control group reported moderate to high anxiety. There were no reports of high levels of anxiety in either group (*Figure 5*).

There was no statistically significant difference in anxiety scores between male and female patients (*Table IV*), and between patients who had knee versus hip surgery (*Table V*) at any time point (T1-T4).

Patient satisfaction within the music group was high (*Figure 6*). Most patients (28 of 29; 96%) felt that the music decreased their anxiety and provided calmness (question 1 and 2). Of the patients in the music group, 86% (25 of 29) felt they experienced less pain (question 3). Eighty-six percent (25 of 29) of these patients would request music again if coming for a similar procedure (question 4) and 89% (26 of 29) would recommend listening to music to their family and friends (question 5) (*Figure 6*).

Discussion

Peri-operative anxiety is associated with multiple physiological consequences as a result of sympathetic, parasympathetic and endocrine stimulation.²⁵ This may cause additional risk to the patient intra-operatively and can worsen patient outcomes.^{9,10} The findings of this study have provided insight into the effects of music on patients' anxiety under spinal anaesthesia for lower limb arthroplasty procedures. Overall, this study shows the anxiety reducing effects of music among these patients in the peri-operative period.

Patients in the music group had lower VAS-A scores at skin incision (T3) with a greater decrease in their level of anxiety from prior to surgery (T2) to skin incision (T3). Multiple studies have demonstrated the positive effects of music on patients anxiety under spinal anaesthesia.^{19,20,26–29} Hepp et al.¹⁹ and Sarkar et al.²⁸ both reported significantly lower levels of anxiety in the music group compared to the control group in patients undergoing spinal anaesthesia for caesarean section. A systematic review and meta-analysis evaluating the effect of music on anxiety in patients undergoing caesarean delivery found that music is associated with reduced intra-operative anxiety.²⁹

The results of our study are similar to those obtained by Ilkkaya et al.²⁷ who examined the effects of music, white noise and ambient noise on sedation and anxiety in patients under spinal anaesthesia during surgery. They found a significant reduction in the VAS-A scores reported in the music group as compared to white noise and the ambient noise groups.

This study looked at surgical, urological and orthopaedic operations and was not specific to arthroplasty procedures.

It has been shown that auditory pathways are connected to numerous areas within the central nervous system including the limbic system, hypothalamus, hippocampus and reticular activating system. Listening to music modifies these neuronal connections resulting in relaxing and sedative effects.³⁰ This could explain the significant reduction in anxiety experienced in the music group compared to the control group.

It is possible that the effects of music on patient anxiety demonstrated in our study are due to the masking of ambient theatre noise. Arthroplasty procedures are known to be extremely noisy.⁸ It is understood that noise can have an impact on stress hormones and produce or worsen anxiety.³¹ Tran et al.¹² compared the effect of noise-cancellation to music on sedation requirements during total knee replacements. They found that there was no statistically significant difference in the amount of sedation used between the two groups. However, this study did not measure patient anxiety levels making this an area for further investigation.

Our study identified a notable difference in the reporting of pre-operative anxiety levels compared to prior research.^{10,32} Both groups (music and control) reported low levels of anxiety at the pre-operative assessment visit on the day prior to surgery (T1). Most patients reported no to moderate anxiety (55 of 58; 95%) with no reports of high anxiety. Additionally, there was no difference in the anxiety scores between male and female patients on the day prior to surgery (T1). A study published by Jjala et al.³² contradicts this. It showed that one-third of patients having surgery under regional anaesthesia are highly anxious.³² It further explained that the incidence of pre-operative anxiety was higher among the female population.³² Götz et al.¹⁰ looked specifically at patients undergoing total hip and knee surgery. They found that 9.5% (520 of 5447) of patients were very or extremely anxious at the time of surgery.¹⁰

Pre-operative anxiety is a complex entity experienced differently by different patients. There are multiple factors that may impact upon the nature in which anxiety is perceived. These include, but are not limited to, age, gender, marital status, education, support structure, previous surgeries, uncertainty of the exact day of surgery and patients' ability to understand the events surrounding the surgery and anaesthesia.²⁵ Further investigation and questioning around these risk factors could provide more information on the low levels of pre-operative anxiety reported in a South African setting.

Anxiety is described as a vague, ambiguous feeling which is often non-specific and unfamiliar to the individual.³³ Patients may be unaccustomed to such feelings which could result in underreporting. The use of objective measures, such as haemodynamic changes, plasma cortisol and urinary catecholamine levels, may provide further insight. A comparison of subjective responses to objective results could add more perspective. The waiting lists for total hip and knee arthroplasty in our hospitals are in excess of four years. During data collection for this study, numerous delays and cancellations were experienced due to the COVID-19 pandemic, linen shortages, bed shortages and the burden of acute orthopaedic injuries. As a result, these patients wait a considerable length of time before receiving their arthroplasty procedure. In this time their disease progresses, further limiting their range of function and increasing pain is experienced. The relief of finally obtaining their joint replacement could potentially allay any potential fears that these patients may have otherwise had. Investigating pre-operative anxiety in different surgical populations within our hospitals and patient interviews could provide us with a clearer understanding of this.

Kukreja et al.²⁰ studied the effects of music therapy during total knee arthroplasty under spinal anaesthesia and found that there was no statistically significant difference in the amount of propofol used between the two groups. Our results echoed this finding. Patients in the control group required more propofol sedation compared to the music group. These results were not statistically significant.

The use of sedation can result in complications including respiratory depression, haemodynamic instability and uncontrolled movements.¹¹ Cognitive morbidity, including post-operative delirium is another significant complication of sedation especially in the geriatric population.³⁴ These complications have major consequences for both medical practitioners and patients and can result in significant cost implications.³⁴ Any reduction in sedation requirements would be advantageous in our setting and further research into this aspect should be considered.

Despite the measured effects of music on patients' anxiety, the considerable level of patient satisfaction needs to be highlighted. Ninety-six percent of patients within the music group felt that music reduced their anxiety and most of these patients would request music again if returning for a similar procedure. This is in keeping with a study conducted in Germany which also showed similar levels of patient satisfaction after receiving music during caesarean sections under spinal anaesthesia.¹⁹ Improved patient satisfaction is

associated with greater adherence to prevention and treatment protocols, improved clinical outcomes, improved patient safety within hospitals and less healthcare utilisation.³⁵ The overwhelmingly positive response from patients regarding music is rewarding and supports its use.

A limitation of this study is that only one tool was used to measure anxiety. Despite the Spielberger State-Trait Anxiety Inventory (STAI) being the gold standard tool in measuring anxiety, this involves a lengthy questionnaire leading to concerns about language barriers. For these reasons the VAS-A was chosen as the measuring tool in this trial, which is validated against the STAI as accurate.^{6,36} The graphic nature and the simplicity of the analogue scale was easier for patients to describe their honest feelings which might not have been the case with a long questionnaire.

Another limitation is the lack of blinding of the researcher as this trial was conducted by a single researcher. This was compensated for by using group blinded data analysis. Blinding of participants was not possible due to the nature of the trial and knowing about the lack of music may be a confounding factor.

The use of sedation intra-operatively may reduce anxiety levels in patients. This has been compensated for by using a standardised anaesthetic technique for all participants in the trial as well as a propofol TCI model. The propofol TCI model was adjusted for elderly patients as per the SASA sedation guidelines²³ to ensure that these patients were not overly sedated. The UMSS was used to assess the level of sedation to allow for standardisation of the level of sedation between all patients. A bispectral index (BIS) monitor would have provided an objective measure of the level of sedation but this is not freely available in our setting and the UMSS was used as recommended by the SASA sedation guidelines.²³ It has been recently shown, that the use of BIS for the monitoring of depth of sedation is not completely reliable.³⁷ Combining a BIS monitor with the UMSS could provide more accurate results and would be recommended in future studies.

The majority of available literature has been conducted in first world countries with a paucity of data from settings similar to South Africa. The results of this study could be used to ignite further research in this field and provide meaningful change to clinical practice which would offer multiple advantages within our resource constrained setting.

Conclusion

Music is an effective, cheap, safe, non-pharmacological adjunct in reducing peri-operative anxiety in patients undergoing lower limb arthroplasty procedures under spinal anaesthesia. Music reduces anxiety and provides high levels of patient satisfaction. In view of the results of this study, consideration should be made to incorporating music as part of the anaesthetic care of these patients.

Ethics statement

All procedures performed in studies involving human participants were in accordance with ethical standards of the Human Research Ethics Committee (Medical) of the University of the Witwatersrand and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Declaration

We would like to thank the orthopaedic department, particularly Prof Ramokgopa and Prof Frey, for their valuable insight into this study and for accommodating this research.

We would also like to thank Dr Michelle Henry (University of Cape Town) and Prof. Peter Kamerman (University of Witwatersrand) for helping with data analysis and statistics.

Author contributions

S.A.B contributed to conceptualisation and design, data collection, data analysis, and manuscript preparation.

G.D contributed to conceptualisation and design, data analysis, manuscript preparation, critical revision, and final approval of article.

M.F contributed to conceptualisation and design, data analysis, manuscript preparation, critical revision, and final approval of article.

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Figures

Figure 1: Consolidated Standards of Reporting Trials (CONSORT)³⁸ flow chart of participant involvement

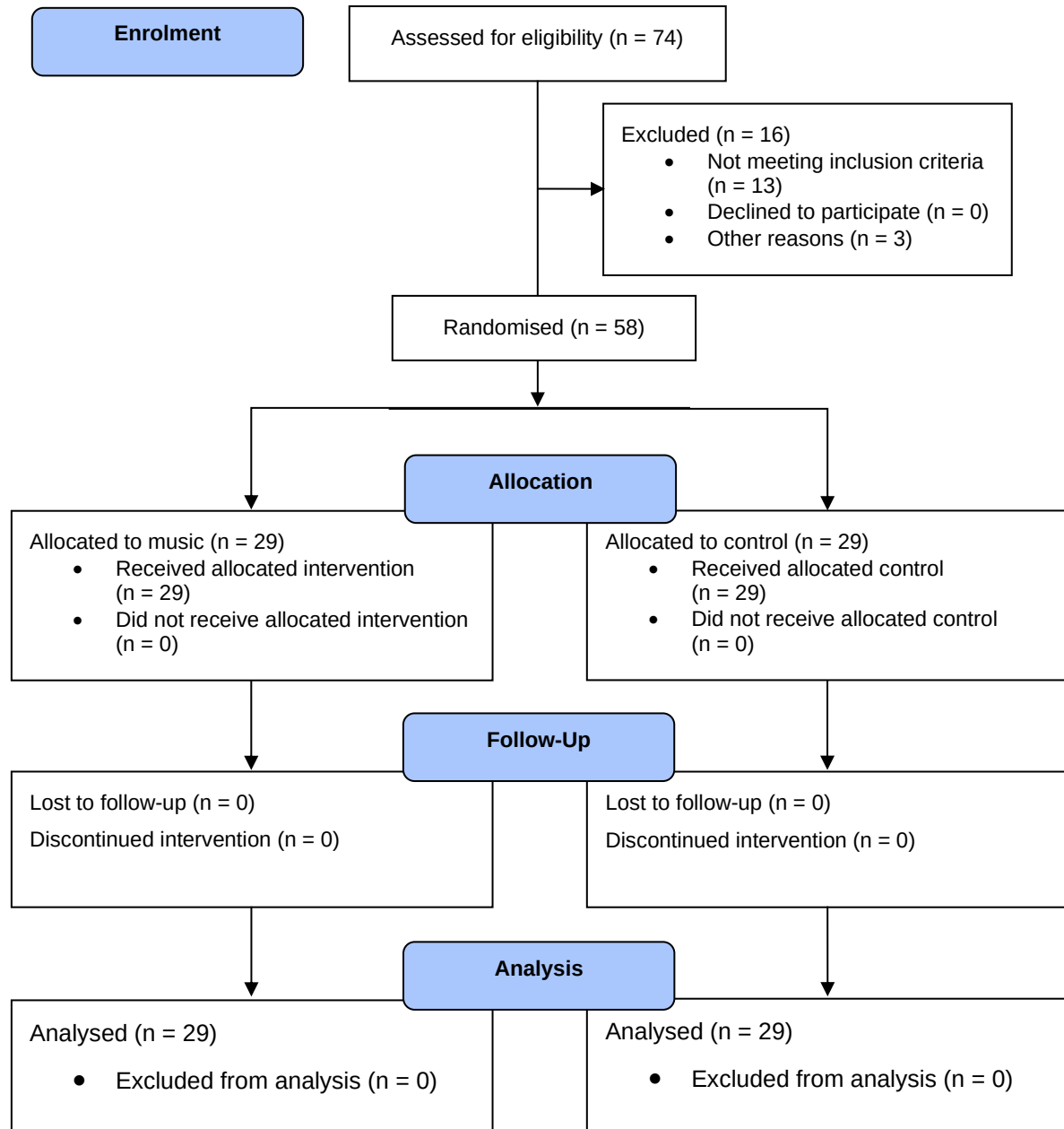


Figure 2: A combined visual analogue scale^{36,39}

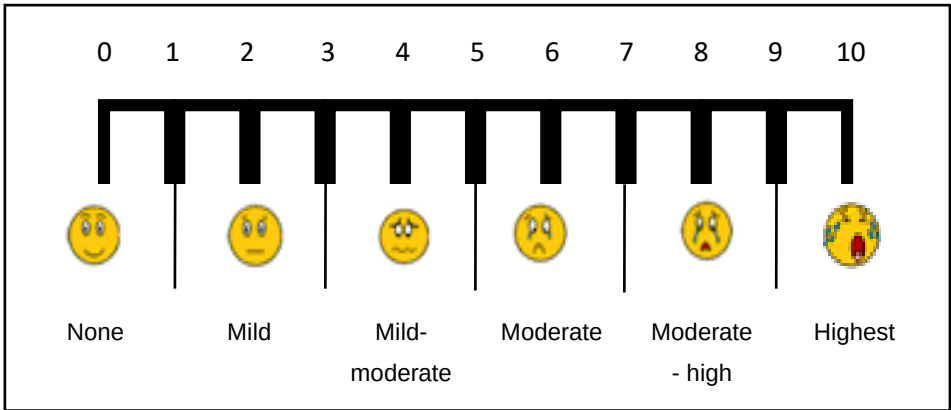


Figure 3: Flow chart of the study data collection time points¹⁹

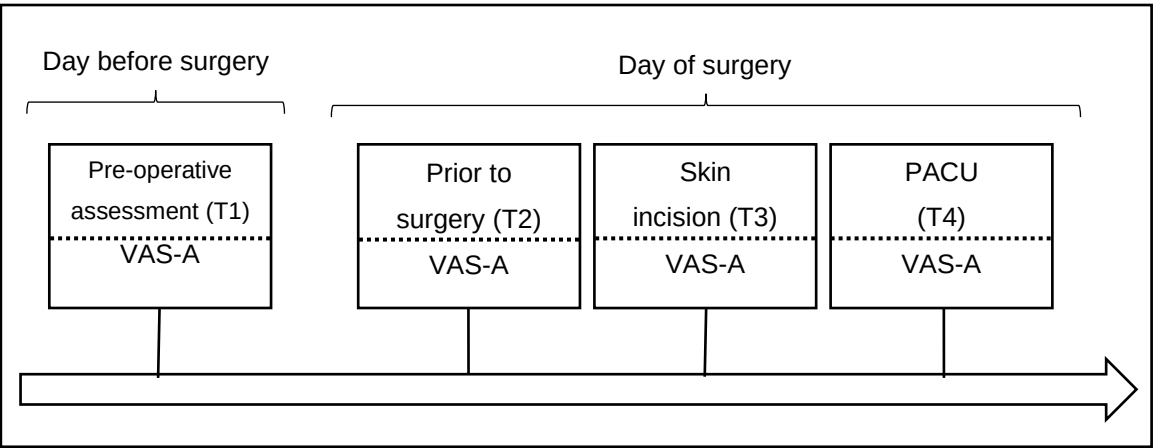


Figure 4: Anxiety scores (cm) from T1 to T4 in the control and music groups

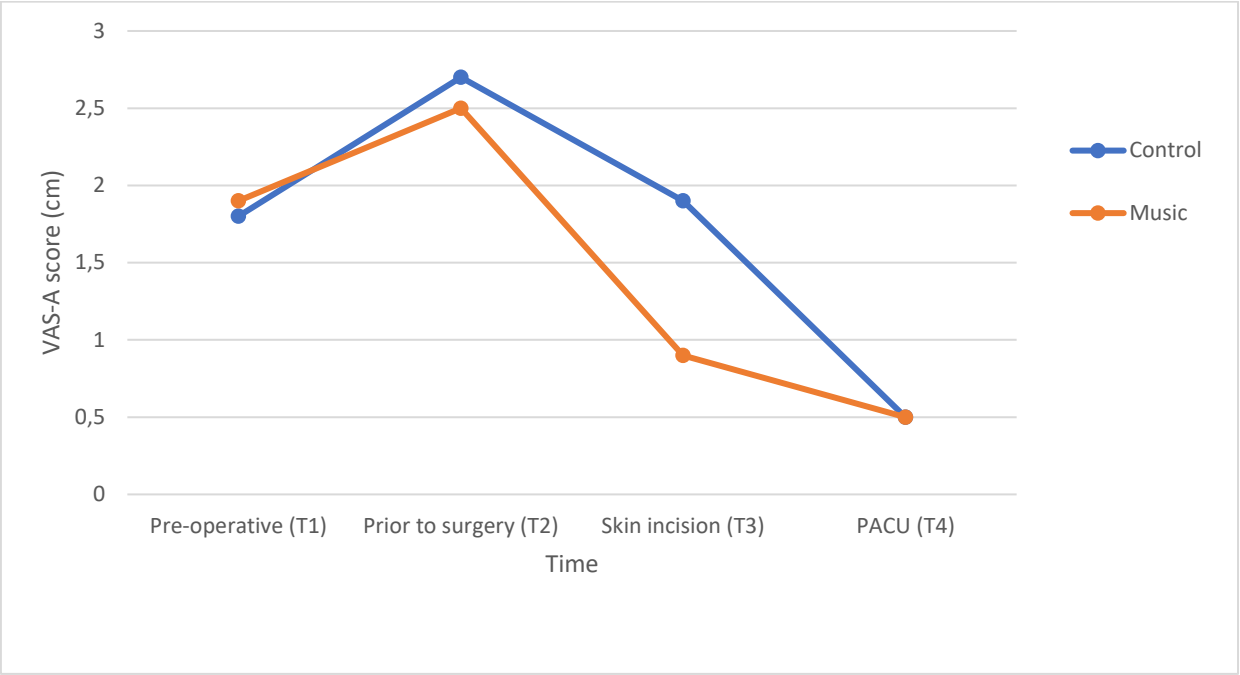
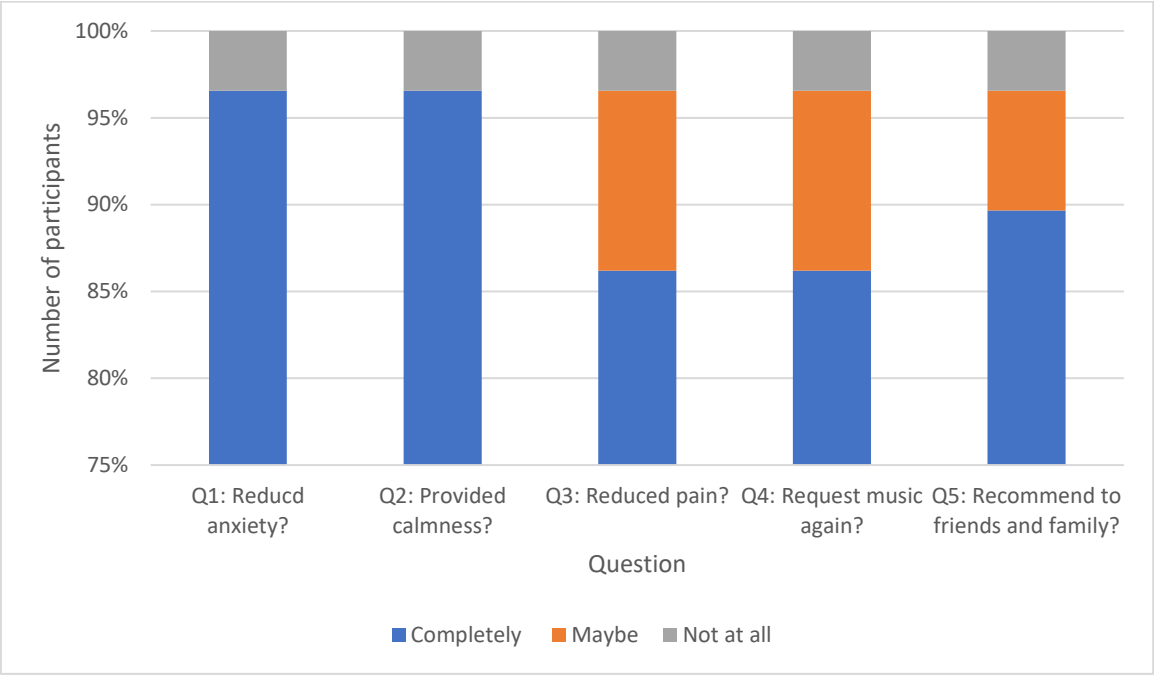


Figure 5: Anxiety scores (categories) from T1 to T4 in the control and music groups



Figure 6: Patient satisfaction questionnaire scores in the music group



Tables

Table I: Demographic and surgical characteristics

Control, N = 29 ^a			Music, N = 29 ^a	Test statistics p value
Sex				0.134
Female	19 (65.5)		24 (82.8)	
Male	10 (34.5)		5 (17.2)	
Age (years)	66 (52-72)		65 (52.5-73)	0.913
ASA class				0.495
1	2 (6.9)		1 (3.4)	
2	19 (65.5)		23 (79.3)	
3	8 (27.6)		5 (17.2)	
STOPBANG score				0.299
0	2 (6.9)		3 (10.3)	
1	6 (20.7)		11 (37.9)	
2	12 (41.4)		6 (20.7)	
3	9 (31)		8 (27.6)	
4	0 (0)		1 (3.4)	
Surgical side				0.430
Left	15 (51.7)		12 (41.4)	
Right	14 (48.3)		17 (58.6)	
Surgical procedure				0.180
Knee	14 (48.3)		9 (31)	
Hip	15 (51.7)		20 (69)	
Surgery duration (minutes)	80 (45-147)		85 (35-110)	0.301
Total propofol dose (mg)	140 (85-215)		110 (70-200)	0.503

^an (%): Median (IQR)

Table II: Anxiety scores between control and music group

Control Group (n = 29)			Music Group (n = 29)		Test Statistics	
	Median	IQR	Median	IQR	<i>z</i>	<i>P</i>
VAS (cm)						
Pre-op (T1)	1.8	0.85 – 4.45	1.9	0.75 – 2.75	-0.80	0.422
Prior to Surgery (T2)	2.7	1.55 – 4	2.5	1.75 – 3.6	-0.69	0.493
Skin incision (T3)	1.9	1.4 – 3.65	0.9	0.6 – 1.5	-4.06	<0.001*
PACU (T4)	0.5	0.4 – 0.8	0.5	0.4 – 0.5	-1.86	0.063
Change in VAS						
T4 – T1	-1.2	-3.75 – (-0.3)	-1	-2.4 – (-0.35)	0.44	0.663
T4 – T2	-2.1	-3.6 – (-1.15)	-2.1	-3.05 – (-1.35)	0.27	0.791
T4 – T3	-1.2	-3.15 – (-0.75)	-0.4	-1 – (-0.1)	3.86	<0.001*
T3 – T2	-0.2	-1.5 – 0.05	-1.4	-2.6 – (-0.75)	-3.04	0.002*
T3 – T1	0	-0.95 – 0.45	-0.5	-2.25 – 0	-1.75	0.081
T2 – T1	0.6	0 – 1.3	0.7	0 – 1.7	0.80	0.426

Table III: Anxiety scores between male and female patients

	Male (n = 15)		Female (n = 43)		Test Statistics	
	Median	IQR	Median	IQR	<i>z</i>	<i>p</i>
VAS (cm)						
Pre-op (T1)	1.8	0.9 – 4	1.9	0.7 – 4	-0.34	0.735
Prior surgery (T2)	2.5	1.2 – 4	2.5	2 – 4	0.48	0.631
Skin incision (T3)	1.4	0.9 – 2	1.4	0.7 – 2.5	0.04	0.972
PACU (T4)	0.5	0.4 – 0.6	0.5	0.4 – 0.6	-0.71	0.480
Change in VAS						
T4 – T1	-1.3	-3.5 – (-0.3)	-1	-3.5 – (-0.3)	0.25	0.803
T4 – T2	-2.1	-3.5 – (-0.8)	-2.1	-3.6 – (-1.4)	-0.60	0.546
T4 – T3	-0.8	-1.7 – (-0.4)	-1	-2 – (-0.3)	-0.31	0.756
T3 – T2	-1.1	-2 – 0	-1	-2 – (-0.2)	-0.63	0.528
T3 – T1	-0.2	-1.1 – 0.1	-0.1	-1.6 – 0.2	0.38	0.702
T2 – T1	0.2	0 – 0.8	0.9	0 – 1.7	1.38	0.167

Table IV: Anxiety scores between patients with knee and hip arthroplasty

	Knee Arthroplasty (n = 23)		Hip Arthroplasty (n = 35)		Test Statistics	
	Median	IQR	Median	IQR	<i>z</i>	<i>p</i>
VAS (cm)						
Pre-op (T1)	2.0	0.7 – 2.1	1.8	0.8 – 4	0.51	0.610
Prior surgery (T2)	2.5	2 – 4	2.5	1.5 – 4	-0.11	0.911
Skin incision (T3)	1.9	0.9 – 2.6	1.3	0.7 – 2	-1.59	0.111
PACU (T4)	0.5	0.4 – 0.8	0.5	0.3 – 0.5	-1.91	0.056
Change in VAS						
T4 – T1	-0.9	-1.7 – (-0.2)	-1.3	-3.5 – (-0.6)	-1.29	0.197
T4 – T2	-0.2	-3.6 – (-1.4)	-2.2	-3.5 – (-1.3)	-0.37	0.714
T4 – T3	-1.1	-2.1 – (-0.4)	-0.8	-1.4 – (-0.3)	1.04	0.297
T3 – T2	-0.8	-1.7 – (-0.1)	-1.1	-2 – (-0.1)	-1.08	0.279
T3 – T1	-0.1	-1.1 – 0.8	-0.1	-2.1 – 0.1	-1.47	0.140
T2 – T1	0.7	0 – 1.7	0.6	0 – 1.6	-0.46	0.644

Appendices:

Appendix 1: Journal guidelines to authors

Instructions for Authors

To submit a manuscript click [here](#)

Authors submitting articles for consideration for publication by the journal are required to familiarise themselves with the journal Ethics and Malpractice policy prior to submission. The policy is available on the journal website: <https://www.saoj.org.za>

Criteria for publication

- The article falls within the scope of the journal.
- Methods, statistics, and other analyses are performed to a high technical standard and are described in sufficient detail.
- Results reported have not been published elsewhere.
- Conclusions are presented appropriately fashion and are supported by the data.
- The article is presented in an intelligible fashion and is written in standard English (British usage).
- The research meets all applicable ethical standards.
- The article adheres to guidelines provided in the instructions for authors section.

Guidelines for authorship

- Each author should participate and is responsible for the content and design of the study, the preparation of the manuscript and its revisions, and final approval.
- In order to qualify for authorship, authors should satisfy all four the criteria for authorship as specified by the ICMJE:
 1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
 2. Drafting the work or revising it critically for important intellectual content; AND
 3. Final approval of the version to be published; AND
 4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
- Other 'contributors' or 'collaborators' can be acknowledged at the end of the manuscript together with their contribution. Those whose contributions do not

justify authorship may be acknowledged individually or together as a group under a single heading (e.g., “Clinical Investigators” or “Participating Investigators”), and their contributions should be specified (e.g., “served as scientific advisors,” “critically reviewed the study proposal,” “collected data,” “provided and cared for study patients,” “participated in writing or technical editing of the manuscript”).

- The South African Orthopaedic Journal accepts a maximum of 8 authors per article. If there are more than eight authors, the first eight authors must be listed along with the group name at the end. The remaining authors and their affiliations must then be listed in an appendix.
- On submission of your article, the ORCID (Open Researcher and Contributor ID) identifier of at least the corresponding author will be required. ORCID provides a persistent digital identifier that distinguishes you from every other researcher and supports automated linkages between you and your professional activities, ensuring that your work is recognised. To register and find more information, please visit: <http://orcid.org>

Registration of clinical trials

- A clinical trial is defined as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects of health outcomes. Interventions include drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process-of-care changes.
- Clinical trials should be registered in a public trials registry in accordance with [International Committee of Medical Journal Editors](#)
- Trials must be registered and approved by the relevant authorities before the onset of patient enrolment.
- The Medicines Control Council (MCC) reference number and the SA National Clinical Trial Register (SANCTR) registration number should be included at the end of the abstract of the article.
- Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) do not require registration.

Reporting guidelines

- All articles should be prepared in accordance with the guidelines relevant to the study design, as described in the Equator Network Guidelines (<https://www.equator-network.org/reporting-guidelines/>)

- Randomised trials should be accompanied by a flow diagram that illustrates the progress of patients through the trial, including recruitment, enrolment, randomisation, withdrawal and completion, and a detailed description of the randomisation procedure.

Reporting of statistics

In terms of the statistical reporting, the Equator Network advises on the use of the SAMPL guideline: <https://www.equator-network.org/2013/02/11/sampl-guidelines-for-statistical-reporting/>

The SAMPL guidelines provide two guiding principles

1. *“Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results.”* When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid relying solely on statistical hypothesis testing, such as *P* values, which fail to convey important information about effect size.
2. *Provide enough detail that the results can be incorporated into other analyses.* This requires reporting the descriptive statistics from which other statistics are derived, such as the numerators and denominators of percentages, especially in risk, odds, and hazards ratios. Likewise, *P*-values are not sufficient for re-analysis. Needed instead are descriptive statistics for the variables being compared, including sample size of the groups involved, the estimate (or effect size) associated with the *P*-value, and a measure of precision for the estimate, usually a 95% confidence interval.

Some specific guidelines applicable to the SAOJ:

- Consistency is one of the most important factors in presenting a well-formatted, professional manuscript.
- The nature of the measurements and variables reported on will often dictate the amount of precision required. Report numbers - especially measurements? with an appropriate degree of precision. For ease of comprehension and simplicity, round to a reasonable extent.
- The recommendation is to report the number of decimals that have both clinical and statistical meaning and consistently reporting all other variables in the same manner.

- Note: Generally, for descriptive purposes, percentages are reported as whole numbers except when dealing with really large sample sizes
- At least for the primary outcomes, report a measure of precision (a confidence interval).
- Although not preferred to confidence intervals, if desired, *p* values should be reported as equalities to three decimal places (e.g., $p = 0.031$ and not as inequalities: e.g., $p < 0.05$). Do NOT report NS; give the actual *P-value*. The smallest *P-value* that needs to be reported is $P < 0.001$.
- Report numerators and denominators for all percentages
- Summarize data that are approximately normally distributed with means and standard deviations (SD). Use the format: mean (SD) not mean ?
- Summarize data that are not normally distributed with medians and interpercentile ranges, ranges, or both.
- Do NOT use the standard error of the mean (SE) to indicate the variability of a data set. Use standard deviations, inter-percentile ranges, or ranges instead.

Formatting examples:

- $p = 0.028$ or $p < 0.001$
- (43% vs 21%; $p = 0.002$)
- (odds ratio (OR) 0.38; 95% confidence interval (CI) 0.71 to 1.82; $p = 0.822$) or after first use (OR 1.62; 95% CI 1.41 to 1.86; $p < 0.001$)
- *Descriptive stats normal distribution*: mean age 36 years (SD 4 years) or 36 years (SD 4; range 40 to 97 years)
- *Descriptive stats non-normal distribution*: median age 36 years (IQR 44 to 88 years) or 36 years (IQR 44 to 88 years; range 40 to 97 years)
- *Descriptive stats percentage*: (149 of 202; 74%)

Formatting of submissions

Text formatting

- Use Helvetica or Arial font, size 11.
- Use double line spacing throughout the document.
- Number the pages of the blinded manuscript consecutively.
- Use italics for emphasis.
- When referring to an article with multiple authors, please use the following format: Rabinowitz et al. published their retrospective review.
- Do not use field functions.
- Use tab stops or other commands for indents, not the space bar.

- Use the table function, not spreadsheets, to make tables.
- Use the equation editor or MathType for equations.
- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Headings

- Use no more than three levels of displayed headings.

Abbreviations

- Define abbreviations and acronyms at first mention and use consistently thereafter.

Units

- Follow internationally accepted rules and conventions: use the international system of units (SI). If other units are mentioned, please give their equivalent in SI.

Figures

- Figures should be numbered consecutively with illustration Arabic numbers 1, 2, 3, etc.
- The figure should be listed in the text as follows: ... wound irrigation and splinting (*Figure 1*).
- Figures should be clear and easily understandable with a full descriptive legend stating any areas of interest and explaining any markings, letterings or notations. All figures and figure legends should be understandable as a stand-alone item, without having to read the main body of the text.
- For radiographs, please ensure you state the view used and the time point at which it was taken, as well as the demographic details of the patient if applicable.
- Please submit the original JPEG (300 dpi) or TIFF of all photographs, as well as the figure saved as a Word document. The Word version of the figure should be complete with the legend and any necessary markings such as letters or arrows.
- Figures such as graphs and algorithms should be in Word or PowerPoint in order to be editable.
- Figures should not be imbedded in the text file but should be submitted as separate individual files. Each figure should be a separate file, entitled Figure 1, Figure 2, etc.
- Remove all markings, such as patient identification, from radiographs before photographing. Clinical photos must be adequately anonymised.

- A statement of patient consent for clinical photographs must be provided on the title page.
- In images depicting X-rays of children there should exhibit adequate shielding of radiation.
- All line or original drawings must be done by a professional medical illustrator.
- We accept a maximum of six figures. You may apply to the Editor-in-Chief for permission to include more figures if considered critical to the clarity and completeness of the submission.
- Do not submit any figures, photos, tables, or other works that have been previously copyrighted or contain proprietary data unless you have obtained and can supply written permission from the copyright holder to use that content.

Tables

- Tables should carry uppercase Roman numerals, I, II, III, etc.
- Tables should always be cited in the text in consecutive numerical order.
- The table should be identified in the text as follows: Details of results are listed in *Table I*. Or, alternatively, high-energy trauma that is often associated with these fractures (*Table II*).
- Tables should be used to present information in a clear and concise manner. All tables should be understandable without the main text.
- For each table, please supply a table heading explaining the components of the table.
- Identify any previously published material by giving the original source in the form of a reference at the end of the table heading.
- Footnotes to tables should be indicated by superscript lower-case letters and included beneath the table body.
- Please submit tables as editable text and not as images. They should be created using the Table tool in Word.
- Do not embed tables in the text file but submit them as separate individual files. Each table should be a separate file, entitled Table I, Table II, etc.
- We accept a maximum of eight tables.
- Do not duplicate information given already in the text.
- Do not submit any figures, photos, tables or other works that have been previously copyrighted or contain proprietary data unless you have obtained and can supply written permission from the copyright holder to use that content.

References

- References should be numbered consecutively in the order that they are first mentioned in the text and listed at the end in numerical order of appearance.
- Identify references in the text by Arabic numerals in superscript after punctuation.
- References should not be a listing of a computerised literature search but should have been read by the authors and have pertinence to the manuscript.
- Accuracy of references is the authors' responsibility, and the author is to verify the references against the original documents.
- Manuscripts in preparation, unpublished data (including articles submitted but not in the press) and personal communications may not be included in the reference listing. They may be listed in the text in parentheses only if absolutely necessary to the contents and meaning of the article.
- The titles of journals should be abbreviated according to the style used in Index Medicus, obtainable through the website <http://www.nlm.nih.gov>
- The following format should be used for references:

Journal article:

Sidhu GS, Ghag A, Prokuski V, Vaccaro AR, Radcliff KE. Civilian gunshot injuries of the spinal cord: a systematic review of the current literature. *Clin Orthop Relat Res* 2013;**471**:3945-55.

Ideally, the names of all authors should be provided, but the usage of *et al.* in long author lists (more than six authors) will also be accepted: Fong K, Truong V, Foote CJ, *et al.* Predictors of nonunion and reoperation in patients with fractures of the tibia: an observational study. *BMC Musculoskelet Disord* 2013;**14**:103.

Online journal article:

Caetano-Lopes J, Lopes A, Rodrigues A, *et al.* Upregulation of inflammatory genes and downregulation of sclerostin gene expression are key elements in the early phase of fragility fracture healing. *PLoS One* 2011;**6**:e16947.

Web reference (with authors):

Cierny G, DiPasquale D. Adult osteomyelitis protocol.
http://www.osteomyelitis.com/pdf/treatment_protocol.pdf.
(date last accessed 05 March 2013).

Web reference (no authors listed):

No authors listed. International commission on radiological protection. <http://www.icrp.org> (date last accessed 20 September 2009).

Chapter in a book:

Young W. Neurophysiology of spinal cord injury. In: Errico TJ, Bauer RD, Waugh T (eds). *Spinal Trauma*. 3rd ed. Philadelphia: JB Lippincott; 1991: 377-94.

Dissertation:

Borkowski MM. Infant sleep and feeding: a telephone survey of Hispanic Americans [dissertation]. Mount Pleasant (MI): Central Michigan University; 2002.

Abstract:

Peterson L. Osteochondritis of the knee treated with autologous chondrocyte transplantation [abstract]. ISAKOS Congress, 2001.

Structure and content of submission

- We accept a maximum of 3 500 words, including the abstract and body of the text (excluding references).
- Exceptions to this rule may be made for systematic reviews and meta-analysis at the discretion of the Editor-in-Chief.
- Please follow the following structure when preparing your submission. Each of the following should be submitted as a separate file.
- Title page (title, authors and affiliations, corresponding author and declarations)
- Blinded manuscript (Abstract, keywords, introduction, methods, results, discussion, funding sources, conflict of interest statement, ethics statement, acknowledgements and references)
- Tables (with headings), each table as a separate file.
- Figures (with legends), each figure as a separate file.

Title page

Title

- The title should be concise and informative.

Author names and affiliations

- Please provide the following information for each author:
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- Clearly indicate who will handle correspondence at all stages of refereeing and publication, including post-publication.
- Ensure that the e-mail address and permanent address is given and that contact details are kept up to date by the corresponding author.
- Please note that the corresponding author's contact details will be provided in the final article.
- Provide the following information for the corresponding author:
 - Full names and title
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 - Physical address
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Declarations

Authors are to insert a section at the end of the title page entitled declarations (please provide the author's name, signature and date). The following statements are required under the declarations section:

Authorship

The authors confirm that all authors have made substantial contributions to all of the following:

- The conception and design of the study, or acquisition of data, or analysis and interpretation of data.
- The drafting of the article or its critical revision for important intellectual content.
- Final approval of the version to be submitted.

Sound scientific research practice

The authors further confirm that:

- The manuscript, including related data, figures and tables, has not been previously published and is not under consideration elsewhere.
- No data have been fabricated or manipulated (including images) to support conclusions.
- This submission does not represent part of a single study that has been split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (e.g. 'salami-publishing').

Plagiarism

The authors confirm that the work submitted is original and does not transgress the plagiarism policy of the journal.

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A conflicting interest exists when professional judgment concerning a primary interest (such as the patient's welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or personal rivalry). It represents a situation in which financial or other personal considerations from authors, reviewers or editors have the potential to compromise or bias professional judgment and objectivity. It may arise for the authors when they have a financial interest that may influence their interpretation of their results or those of others. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, grants or other funding. All potential conflicts of interest need to be declared. The conflict of interest statement should list each author separately by name, e.g.,

'Author A.B. (*use initials of relevant author, not full name in order for the document to remain blinded*) has received research grants from Company A. Author B.C. has received a speaker honorarium from Company X and owns stock in Company Y. Author C.D. is a member of committee Z.'

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Funding sources

All sources of funding should be declared. Also, define the involvement of study sponsors in the study design, collection, analysis and interpretation of data; the writing of the manuscript; and the decision to submit the manuscript for publication.

List all funding sources as follows:

'This work was supported by the xxxx (grant numbers xxxx, yyyy).'

When funding is from a block grant or other resources available to a university, college or other research institution, submit the name of the institute or organisation that provided the funding.

If no funding was received, state as follows:

'No funding was received for this study.'

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Available from: <http://publicationethics.org/resources/international-standards-for-editors-and-authors>

Institutional Review Board (IRB) ethical approval must have been given if the study involves human subjects or animals. Please provide the approval number. IRB documentation should be available upon request.

'Prior to the commencement of the study ethical approval was obtained from the following ethical review board: *Provide name and reference number*'

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'Informed written consent was or was not obtained from all patients for being included in the study.'

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- For articles that do not contain studies with human or animal subjects:
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Please provide the names and email addresses of two reviewers.

Title Page Example

Title of Submission

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Declarations:

Authorship

The authors confirm that all authors have made substantial contributions to all of the following:

- The conception and design of the study, or acquisition of data, or analysis and interpretation of data.
- The drafting of the article or its critical revision for important intellectual content.
- Final approval of the version to be submitted.

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The authors further confirm that:

- The manuscript, including related data, figures and tables, has not been previously published and is not under consideration elsewhere.
- No data have been fabricated or manipulated (including images) to support conclusions.
- This submission does not represent part of a single study that has been split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (e.g. 'salami-publishing').

Plagiarism

The authors confirm that the work submitted is original and does not transgress the plagiarism policy of the journal.

- No data, text or theories by others are presented as if they were the authors' own.
- Proper acknowledgements of others' work have been given (this includes material that is closely copied, summarised and/or paraphrased); quotation marks are used for verbatim copying of material.
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Conflict of interest statement

John Smith declares that he has no conflict of interest. Paula Taylor has received research grants from Drug Company A.

Funding sources

No funding was received for the purposes of performing this study.

Compliance with ethical guidelines

The author/s declare that this submission is in accordance with the principles laid down by the Responsible Research Publication Position Statements as developed at the 2nd World Conference on Research Integrity in Singapore, 2010.

Prior to the commencement of the study ethical approval was obtained from the following ethical review board: *Provide name and reference number.*

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Informed written consent was or was not obtained from all patients for being included in the study.

Consent were obtained from patients for the use of clinical photographs/ and these images were adequately anonymised.

Author Name	Signature	Date
J Smith		15/8/2017
P Taylor		16/8/2017

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To ensure a blinded review, the main body of the manuscript should not contain any identifying information, including author's names, institutions or affiliations. Please do not include the name of the ethics committee, this information should be provided in the title page.

Abstract

- A structured abstract (maximum of 350 words) summarising the most important points in the article is required.
- The abstract consists of four paragraphs with the subheadings:
 - Background (must include the aim of the study)

- Patients and methods
- Results
- Conclusion
- References should be avoided. Avoid uncommon abbreviations. If essential, they must be defined at their first mention in the abstract itself.

Keywords

- Immediately after the abstract, provide a maximum of six keywords using standard searchable terms. These keywords will be used for indexing purposes.

Level of evidence

- Level 1 to 5.
- Please follow the level of evidence guidelines provided by the Oxford Centre for Evidence-Based Medicine (OCEBM); version 2.1.
- Available from: OCEBM Levels of Evidence Working Group. 'The Oxford Levels of Evidence 2'. Oxford Centre for Evidence-Based Medicine. <http://www.cebm.net/index.aspx?o=5653>

Introduction

- The introduction should contextualise the study by providing the background to the research; explain the problem that is to be addressed, and provide the rationale for the study.
- Briefly outline the relevance of the study with respect to the current literature. Avoid a detailed literature survey or a summary of the results.
- The last sentence should outline the research question or hypothesis.

Patients (or Materials) and methods

- State the methods, outcome measures, and selection criteria. The following aspects need to be described:
 - The study design and research methodology
 - Whether randomisation (with methods) was applied
 - If case-controlled, how the controls were selected
 - The time period under review
 - Number of patients/subjects under investigation and why this number was chosen
 - Inclusion and exclusion criteria
 - Case and outcome definitions

- A description of the procedure or intervention, including post-operative protocol
- The outcome measures or scores used
- The minimum follow-up period
- Statistical analysis paragraph. This should be included at the end of this section to detail statistical tests and package used, the reasons why these tests were used, and what p-value was considered statistically significant. A power analysis is recommended for studies comparing two or more groups.
- Provide sufficient detail so that another researcher can replicate the study.
- The reader should understand from this description all potential sources of bias such as referral, diagnosis, exclusion, recall or treatment bias. This includes the manner in which investigators selected the patients. Consecutive inclusion implies all patients with a given diagnosis are included, while selective implies patients with a given diagnosis but selected according to certain explicit criteria (e.g., state of disease, choice of treatment).
- Do not describe standard procedures for common operations. Only include new procedures or adaptations to standard procedures.
- If you name any specific product, it requires the manufacturer's name, city and state/country.
- Present information in the narrative format and use the past tense.
- Where relevant, tables or figures may be included to provide information more clearly.
- Generally, no data should be presented in this section.

Results

- Describe the relevant results and analysis thereof.
- Provide details of the number of patients included and excluded, as well as the reason for exclusion.
- It is important to state the follow-up period (mean and range).
- The results can be broken down into separate sections, e.g. Treatment, Functional outcome, Complications, etc.
- Tables may be used but avoid repeating data reported in the text in the tables.
- All appropriate data should be presented as means with ranges, not with standard deviations (SDs). Medians should only be used when the data is skewed, accompanied by an interquartile range (IQR).
- Avoid using percentages in studies involving well under 100 subjects.

- All results must be backed up with p-values or survivorship analysis. All Kaplan-Meier data should be presented with confidence intervals. Always present exact absolute p-values, whether significant or not, unless $p < 0.001$.
- However, *P-values* do not always convey the entire picture and where relevant, the confidence interval will also be required (in addition to the power of the study reported in the methods section).

Discussion

- The question or hypothesis stated at the end of the introduction should be discussed and either supported or rejected.
- The results must be interpreted clearly, and any deficiencies expressed. All possible confounding factors, sources of bias or weaknesses in the study should be identified.
- Explore the significance of the results of the work rather than repeating the results.
- The discussion must point out the relevance of the work described in the paper and its contribution to current knowledge.
- Explain what can be deduced from the results and how will it affect clinical practice.
- Include a review of the relevant literature, placing the results of the study in the context of previous work in this area.
- Discussion of relevant prior research and references must be concise. Avoid extensive citations and discussion of published literature emphasize previous findings that agree (or disagree) with those of the present study.
- Do not repeat the introduction.
- Present the limitations of the study and suggest how the study could have been improved for a future study.
- Avoid making inferences from non-significant trends unless you believe your study is adequately powered to answer the question; in that case, provide a power analysis.

Conclusion

- Provide a summary statement that conveys the conclusions of the findings.
- Do not draw conclusions not supported by the data obtained from the specific study presented.

Ethics statement

- For studies involving human subjects, please include an ethics statement as follows: 'All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.'
- For animal studies, please include the following ethical statement: 'All applicable international, national, and/or institutional guidelines for the care and use of animals were followed.'
- If the study did not involve human or animal subjects, state that: 'This article does not contain any studies with human participants or animals performed by any of the authors.'
- Please also include an informed consent statement: 'Informed consent was obtained from all individual participants included in the study.'
- Alternatively, for retrospective studies, please add the following sentence: 'For this study formal consent was not required.'
- If identifying information about participants is available in the article, the following statement should be included: 'Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.'

Acknowledgements

- Acknowledgements should be placed at the end of the discussion and before the references.
- In this section, persons who were involved but did not earn authorship can be acknowledged.
- Statements should be brief. A person can be thanked for assistance or comments.
- Do not include contributions by editors or referees.

Author contributions

- Please state the contributions of each author
- For example: 'A.B contributed to the study conceptualisation, design, data analysis and manuscript preparation. C.D. contributed to data collection and manuscript preparation. E.F. contributed to'
- The types of contributions are:
 - Conceptualisation and design
 - Data collection or contribution
 - Data analysis

- Manuscript preparation
- Other contributions (please specify)

References

- Please refer to the section on Formatting of submissions.

Tables and figures

- Tables and figures should not be imbedded in the text file but should be submitted as separate individual files. Each table should be a separate file, entitled Table I, Figure 2, etc.
- Each table and figure should be provided with a heading or legend.
- Please refer to the 'Formatting of submission' section for further guidelines.

Case reports

In addition to the preceding guidelines the following applies:

- The following headings need to be adhered to in the body of the manuscript:
 - Abstract
 - Keywords
 - Background
 - Case report
 - Discussion
 - Conclusion
 - Ethics statement
 - References
- Abstract: Minimum 250 words (350 maximum), using the following headings:
 - Background
 - Case report
 - Discussion
 - Conclusion
- Statement of informed consent must be included in the ethics statement.

Current Concepts Review Article (by invitation only)

General Guidelines:

- A narrative review will suffice (and systematic or scoping review not necessary)

- A thorough literature review needs to be done prior to writing the manuscript to ensure that the author is well acquainted with the current concepts related to the topic (with emphasis on the most recent developments)
- A balanced and unbiased view of the current clinical aspects of the topic.
- Focus on clinical aspects like diagnosis and treatment.
- Discuss controversies and state both sides of the argument.
- Avoid extensive discussion of basic science (anatomy/physiology/pathology) aspects, except for some really novel and clinically relevant new developments in the field.
- The topic may be adapted, but only with the permission of the Editor-in-Chief.

Outline of Article:

- Abstract = One paragraph, no headings, ≤350 words.
- Introduction = Brief introduction to the topic
- Contents = Please use headings (in bold) and sub-headings (in italics) to structure the manuscript in a reader-friendly manner
- South African context = Discuss matters which may be particularly relevant or unique to the South African clinical setting.
- Learning points = Make use of tables to summarize important learning points
- Conclusion = Brief evidence-based conclusion and summary
- Conflict of interest statement
- References = As usual

Appendix 2: Literature review

Lower limb arthroplasty is a very common orthopaedic procedure. According to the National Joint Registry of England and Wales there were a total of 95 677 primary hip replacements and 103 617 primary knee replacements performed in 2019 (1). There is an increase in the ageing population and hence there is a greater prevalence of age-related diseases such as osteoarthritis and osteoporosis (2). Developments in the field of arthroplasty have resulted in more favourable outcomes and the demand for these procedures is expected to rise exponentially over the next ten years. In the United States of America the demand for primary total hip and knee arthroplasty is projected to increase by 174% and 673%, respectively, by 2030 (3). These projections are likely to burden existing hospital resources. The elderly population have significant medical comorbidities and unique requirements which increase both the surgical and anaesthetic risk, and place additional strain on resources. Peri-operative assessment and management of these factors is imperative in order to reduce complications and improve patient outcomes (2). Optimisation of the anaesthetic technique can substantially reduce the risk of adverse events in these patients (4).

In the developed world, post-operative complications arise in 8.3% of patients undergoing primary total hip arthroplasty (5). Management of these complications requires significant financial resources and as a result this has led to research into interventions which may decrease the incidence of such complications. It has been shown that anaesthetic technique can influence post-operative complications (6). Neuraxial anaesthesia (provided there is no contraindication to its use) has shown to be superior to general anaesthesia for both total hip and total knee arthroplasty procedures. Patients undergoing neuraxial anaesthesia for total hip arthroplasty sustained fewer pulmonary, renal, thromboembolic and central nervous system complications. The incidence of post-operative falls was also reduced with this mode of anaesthesia. Neuraxial anaesthesia was associated with fewer admissions to critical care units, lower rates of hospital readmissions and a decreased length of hospital stay when used for total knee arthroplasty. The International Consensus on Anaesthesia-Related Outcomes after Surgery (ICAROS) group recommend the use of neuraxial anaesthesia for both total hip and total knee arthroplasty procedures (6). Despite the numerous advantages over general anaesthesia, patients often have increased fear and anxiety towards neuraxial anaesthesia. These negative connotations can lead to the complete disregard of this preferred anaesthetic technique (7).

Peri-operative anxiety is a complex, multi-factorial entity that affects one in four patients undergoing elective surgical procedures (8). It can be related to the fear of the unknown

anaesthetic and surgical procedure, previous experience and the patients' personality (9). Although neuraxial anaesthesia is the recommended anaesthetic modality for lower limb arthroplasty, it poses a unique set of challenges. As patients are awake during the procedure they are exposed to unusual stimuli, including bright lights, cold temperatures and noise, which can enhance fear and anxiety (10). A study published in the British Journal of Anaesthesia showed that up to one third of patients having surgery under regional anaesthesia are highly anxious (11). The excessive noise levels during orthopaedic procedures further add to this anxiety. The use of hammers and oscillating saws during lower limb arthroplasty results in noise levels which exceed 90 dB (12). It has been shown that noise has an effect on stress hormones; increasing the production of adrenaline, noradrenaline and cortisol (13). Not only is peri-operative anxiety a challenge to the anaesthetist but it can also negatively affect the surgical outcome and functional recovery (14).

Studies have highlighted the importance of adequately assessing a patient's peri-operative anxiety as part of the pre-operative assessment (11,15). The gold standard for assessment of anxiety is the Spielberger State-Trait Anxiety Inventory (STAI). The STAI consists of forty multiple choice questions (9). This time-consuming assessment may be hindered by language barriers. Other shorter scales to measure anxiety include the Hospital Anxiety and Depression Scale, the Multiple Affect Adjective Check List, the Amsterdam Pre-operative Anxiety and Information Scale and the Yale Pre-operative Anxiety Scale for children. Although these scales are abbreviated, they can still be difficult to use in the pre-operative setting. Another method of assessing anxiety is the visual analogue scale for anxiety (VAS-A). The VAS-A (Appendix A) is a quick tool which is easy to use by both the doctor and the patient. It allows the patient to easily indicate their degree of anxiety on a scale of pictures or on a scale from zero to ten, both of which have been validated for the use of pre-operative anxiety (9,16). A large study, consisting of 734 patients, conducted in Switzerland showed that the VAS-A was a valid method of evaluating anxiety and is comparative to the STAI (9). Although the VAS-A is a simple screening tool which can be used to identify patients with significant peri-operative anxiety, it is not routinely used in the pre-operative assessment and thus patients' anxiety is often not managed appropriately before presenting for surgery.

Existing pre-operative anxiety coupled with the harsh theatre environment often leads to patients feeling uncomfortable. In order to ensure patient comfort during the surgical procedure, sedation is often coupled with the regional anaesthetic modality (17). The choice of sedative agent or the level of sedation is often not standardised. Sedation is not

without risks or complications, particularly in the elderly population. Significant side effects of sedation include respiratory depression, haemodynamic instability and uncontrolled movements (17).

The American Society of Anaesthesiologists (ASA) closed claim database showed that respiratory depression as a result of over sedation is the most common mechanism of injury leading to death or permanent brain damage (18). Cognitive morbidity, including post-operative delirium, is another significant complication of sedation in the geriatric population. A study conducted at the Johns Hopkins Bayview Medical Centre (19) showed that elderly patients who received regional anaesthesia and deep sedation with propofol were more likely to experience post-operative delirium than those receiving light sedation. Post-operative delirium has significant consequences for both medical practitioners and patients. Any reduction in sedation requirements would be advantageous and as such significant research around this is continuously being conducted.

Although pharmacological treatment of anxiety is common practice; alternative, non-pharmacological treatments do exist. Music is a simple, readily available, non-pharmacological technique that can be used as an adjunct to treat anxiety as well as other medical disorders (20). Music is an “intentional auditory stimulus with organised elements including melody, rhythm, harmony, timbre, form and style” (10). This is very different to noise which can be described as “environmental sounds that exist without controls for volume, duration, or cause/effect relations” (10). Although noise has been associated with multiple negative effects, music is known to have varying effects depending on listener characteristics (10). The increasing development of the use of music in a medical setting includes two different approaches: music therapy and music medicine. According to the American Music Therapy Association (AMTA) music therapy is defined as “the clinical and evidence-based use of music interventions to accomplish individualised goals within a therapeutic relationship by a credentialed professional who has completed an approved music therapy program” (21). Music medicine is used to describe “all interventions that use music for health-related goals, but in ways that do not qualify as music therapy” (22). Music is universal and is listened to by persons of all ages, races and ethnic backgrounds, however there are large variations in the preferred types of music between different cultures (10). Despite these variations, certain types of music have shown to have consistent physiological effects. This was demonstrated in a study published in the *Journal of Alternative Therapies* (23), where adults and teenagers listened to four different types of music including classical, new age, grunge rock and designer music (a specific genre designed to affect the listener in a specific way). Classical music showed a

reduction in tension but had no effect on any other feelings. New age music showed an increase in relaxation and a decrease in tension, caring, mental clarity and vigour. After listening to grunge rock participants had a decrease in caring, mental clarity, relaxation and vigour and an increase in hostility, fatigue, sadness and tension. Designer music had the greatest effect on all participants. Listeners had an increase in caring, mental clarity, relaxation and vigour and a decrease in hostility, fatigue, sadness and tension.

Both music medicine and music therapy have been used to treat anxiety in a large array of both medical and surgical patients including patients with Alzheimer's disease, cancer, burns and critically ill patients in intensive care units (ICU) (24–28). Patients in an ICU environment are also exposed to multiple physiological and psychological stressors. It has been shown that a single thirty minute session of music, reduced anxiety in patients undergoing mechanical ventilation in ICU (27). A systematic review went on to further suggest that it was not only ventilated patients that benefitted from music (28). This review, of ten randomised controlled trials, demonstrated that listening to music reduced anxiety as well as limited the physiological stress response, assessed by heart rate, respiratory rate and blood pressure, in critically ill patients without mechanical ventilation. Not only did music reduce anxiety but it also proved to be more cost effective than pharmacological means (29).

The use of music in an operating room dates back to 1914. Kane was the first person to use music intra-operatively “as a means of calming and distracting patients” undergoing surgical procedures performed using local anaesthesia (30). The use of music in theatre has become more popular however, it is sporadic and not targeted to patient care. In the developed world music has been used for patients undergoing spinal anaesthesia as a method of reducing intra-operative anxiety as well as decreasing sedative requirements (20,31–33).

A large study, including 304 patients, conducted in Germany showed the benefit of listening to music during elective caesarean section under spinal anaesthesia (31). Patients were required to complete the STAI as well as the VAS-A on admission, at skin suturing and two hours after surgery. Music was played for the experimental group on a speaker as the patients entered the operating room. Both groups showed high levels of anxiety on admission, however there was a significant difference in anxiety between the two groups at skin suture. The experimental group showed significantly lower anxiety levels compared to the control group.

A Canadian study (33) showed that listening to music during the peri-operative period can decrease midazolam requirements in patients undergoing ambulatory or short-stay surgery with spinal anaesthesia. Although the anxiety levels across the two groups remained unchanged, the group that was listening to music used less midazolam made available to them via a patient controlled sedation device (33). It has also been demonstrated that music has an effect on reducing post-operative anxiety in patients who received spinal anaesthesia when used in the post-anaesthesia care unit (PACU) in addition to routine nursing care (34).

Although the literature highlights the multiple advantages and potential uses for music therapy and music medicine in the operating room, there seems to be a paucity of evidence for its use for peri-operative anxiety in lower limb arthroplasty procedures. There are randomised controlled studies conducted in the United States of America that express conflicting results in this regard (20,32). Kukreja et al (32) showed that post-operative anxiety was significantly less and patient satisfaction was higher in the group that received music during total knee replacement, however there was no difference in the amount of sedative agents used between the two groups. In a similar study, Tran et al (20) compared the effect of noise-cancellation and music therapy to that of noise-cancellation alone. This study showed that the mean propofol requirement was less in the group that received music in addition to noise-cancellation as compared to the control group however the results were not statistically significant.

As the ageing population grows and the demand for lower limb arthroplasty increases, continued research into optimisation of the anaesthetic technique is required to improve patient satisfaction and outcomes as well as to minimise complications and additional healthcare costs. In a resource-constrained environment, such as South Africa, every effort needs to be made to avoid placing further burden onto existing infrastructure. Music has shown promise in the developed world, however there is a lack of evidence on its use intra-operatively for lower limb arthroplasty in a setting similar to South Africa. Evolving technology has resulted in a large variety of music being readily available and it may be considered a cheap, safe, non-pharmacological intervention that could easily be implemented as an adjunct to spinal anaesthesia.

Therefore, the aim of this study is to determine the effects of listening to music during spinal anaesthesia for patients undergoing knee and hip arthroplasty in two South African academic hospitals. This study will specifically assess if intra-operative music impacts patient anxiety using the validated VAS-A.

References:

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Appendix 3: Proposal

Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia.

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1. Introduction

Lower limb arthroplasty is a very common orthopaedic procedure. According to the National Joint Registry of England and Wales there were a total of 95 677 primary hip replacements and 103 617 primary knee replacements performed in 2019 (1). There is an increase in the ageing population and hence there is a greater prevalence of age-related diseases such as osteoarthritis and osteoporosis (2). Developments in the field of arthroplasty have resulted in more favourable outcomes and the demand for these procedures is expected to rise exponentially over the next ten years. In the United States of America the demand for primary total hip and knee arthroplasty is projected to increase by 174% and 673%, respectively, by 2030 (3). These projections are likely to burden existing hospital resources. The elderly population have significant medical comorbidities and unique requirements which increase both the surgical and anaesthetic risk, and place additional strain on resources. Peri-operative assessment and management of these factors is imperative in order to reduce complications and improve patient outcomes (2). Optimisation of the anaesthetic technique can substantially reduce the risk of adverse events in these patients (4).

In the developed world, post-operative complications arise in 8.3% of patients undergoing primary total hip arthroplasty (5). Management of these complications requires significant financial resources and as a result this has led to research into interventions which may decrease the incidence of such complications. It has been shown that anaesthetic technique can influence post-operative complications (6). Neuraxial anaesthesia (provided there is no contraindication to its use) has shown to be superior to general anaesthesia for both total hip and total knee arthroplasty procedures. Patients undergoing neuraxial anaesthesia for total hip arthroplasty sustained fewer pulmonary, renal, thromboembolic and central nervous system complications. The incidence of post-operative falls was also reduced with this mode of anaesthesia. Neuraxial anaesthesia was associated with fewer admissions to critical care units, lower rates of hospital readmissions and a decreased length of hospital stay when used for total knee arthroplasty. The International Consensus on Anaesthesia-Related Outcomes after Surgery (ICAROS) group recommend the use of neuraxial anaesthesia for both total hip and total knee arthroplasty procedures (6). Despite the numerous advantages over general anaesthesia, patients often have increased fear and anxiety towards neuraxial anaesthesia. These negative connotations can lead to the complete disregard of this preferred anaesthetic technique (7).

Peri-operative anxiety is a complex, multi-factorial entity that affects one in four patients undergoing elective surgical procedures (8). It can be related to the fear of the unknown

anaesthetic and surgical procedure, previous experience and the patients' personality (9). Although neuraxial anaesthesia is the recommended anaesthetic modality for lower limb arthroplasty, it poses a unique set of challenges. As patients are awake during the procedure they are exposed to unusual stimuli, including bright lights, cold temperatures and noise, which can enhance fear and anxiety (10). A study published in the British Journal of Anaesthesia showed that up to one third of patients having surgery under regional anaesthesia are highly anxious (11). The excessive noise levels during orthopaedic procedures further add to this anxiety. The use of hammers and oscillating saws during lower limb arthroplasty results in noise levels which exceed 90 dB (12). It has been shown that noise has an effect on stress hormones; increasing the production of adrenaline, noradrenaline and cortisol (13). Not only is peri-operative anxiety a challenge to the anaesthetist but it can also negatively affect the surgical outcome and functional recovery (14).

Studies have highlighted the importance of adequately assessing a patient's peri-operative anxiety as part of the pre-operative assessment (11,15). The gold standard for assessment of anxiety is the Spielberger State-Trait Anxiety Inventory (STAI). The STAI consists of forty multiple choice questions (9). This time-consuming assessment may be hindered by language barriers. Other shorter scales to measure anxiety include the Hospital Anxiety and Depression Scale, the Multiple Affect Adjective Check List, the Amsterdam Pre-operative Anxiety and Information Scale and the Yale Pre-operative Anxiety Scale for children. Although these scales are abbreviated, they can still be difficult to use in the pre-operative setting. Another method of assessing anxiety is the visual analogue scale for anxiety (VAS-A). The VAS-A (Annexure A) is a quick tool which is easy to use by both the doctor and the patient. It allows the patient to easily indicate their degree of anxiety on a scale of pictures or on a scale from zero to ten, both of which have been validated for the use of pre-operative anxiety (9,16). A large study, consisting of 734 patients, conducted in Switzerland showed that the VAS-A was a valid method of evaluating anxiety and is comparative to the STAI (9). Although the VAS-A is a simple screening tool which can be used to identify patients with significant peri-operative anxiety, it is not routinely used in the pre-operative assessment and thus patients' anxiety is often not managed appropriately before presenting for surgery.

Existing pre-operative anxiety coupled with the harsh theatre environment often leads to patients feeling uncomfortable. In order to ensure patient comfort during the surgical procedure, sedation is often coupled with the regional anaesthetic modality (17). The choice of sedative agent or the level of sedation is often not standardised. Sedation is not

without risks or complications, particularly in the elderly population. Significant side effects of sedation include respiratory depression, haemodynamic instability and uncontrolled movements (17).

The American Society of Anaesthesiologists (ASA) closed claim database showed that respiratory depression as a result of over sedation is the most common mechanism of injury leading to death or permanent brain damage (18). Cognitive morbidity, including post-operative delirium, is another significant complication of sedation in the geriatric population. A study conducted at the Johns Hopkins Bayview Medical Centre (19) showed that elderly patients who received regional anaesthesia and deep sedation with propofol were more likely to experience post-operative delirium than those receiving light sedation. Post-operative delirium has significant consequences for both medical practitioners and patients. Any reduction in sedation requirements would be advantageous and as such significant research around this is continuously being conducted.

Although pharmacological treatment of anxiety is common practice; alternative, non-pharmacological treatments do exist. Music is a simple, readily available, non-pharmacological technique that can be used as an adjunct to treat anxiety as well as other medical disorders (20). Music is an “intentional auditory stimulus with organised elements including melody, rhythm, harmony, timbre, form and style” (10). This is very different to noise which can be described as “environmental sounds that exist without controls for volume, duration, or cause/effect relations” (10). Although noise has been associated with multiple negative effects, music is known to have varying effects depending on listener characteristics (10). The increasing development of the use of music in a medical setting includes two different approaches: music therapy and music medicine. According to the American Music Therapy Association (AMTA) music therapy is defined as “the clinical and evidence-based use of music interventions to accomplish individualised goals within a therapeutic relationship by a credentialed professional who has completed an approved music therapy program” (21). Music medicine is used to describe “all interventions that use music for health-related goals, but in ways that do not qualify as music therapy” (22). Music is universal and is listened to by persons of all ages, races and ethnic backgrounds, however there are large variations in the preferred types of music between different cultures (10). Despite these variations, certain types of music have shown to have consistent physiological effects. This was demonstrated in a study published in the *Journal of Alternative Therapies* (23), where adults and teenagers listened to four different types of music including classical, new age, grunge rock and designer music (a specific genre designed to affect the listener in a specific way). Classical music showed a

reduction in tension but had no effect on any other feelings. New age music showed an increase in relaxation and a decrease in tension, caring, mental clarity and vigour. After listening to grunge rock participants had a decrease in caring, mental clarity, relaxation and vigour and an increase in hostility, fatigue, sadness and tension. Designer music had the greatest effect on all participants. Listeners had an increase in caring, mental clarity, relaxation and vigour and a decrease in hostility, fatigue, sadness and tension.

Both music medicine and music therapy have been used to treat anxiety in a large array of both medical and surgical patients including patients with Alzheimer's disease, cancer, burns and critically ill patients in intensive care units (ICU) (24–28). Patients in an ICU environment are also exposed to multiple physiological and psychological stressors. It has been shown that a single thirty minute session of music, reduced anxiety in patients undergoing mechanical ventilation in ICU (27). A systematic review went on to further suggest that it was not only ventilated patients that benefitted from music (28). This review, of ten randomised controlled trials, demonstrated that listening to music reduced anxiety as well as limited the physiological stress response, assessed by heart rate, respiratory rate and blood pressure, in critically ill patients without mechanical ventilation. Not only did music reduce anxiety but it also proved to be more cost effective than pharmacological means (29).

The use of music in an operating room dates back to 1914. Kane was the first person to use music intra-operatively “as a means of calming and distracting patients” undergoing surgical procedures performed using local anaesthesia (30). The use of music in theatre has become more popular however, it is sporadic and not targeted to patient care. In the developed world music has been used for patients undergoing spinal anaesthesia as a method of reducing intra-operative anxiety as well as decreasing sedative requirements (20,31–33).

A large study, including 304 patients, conducted in Germany showed the benefit of listening to music during elective caesarean section under spinal anaesthesia (31). Patients were required to complete the STAI as well as the VAS-A on admission, at skin suturing and two hours after surgery. Music was played for the experimental group on a speaker as the patients entered the operating room. Both groups showed high levels of anxiety on admission, however there was a significant difference in anxiety between the two groups at skin suture. The experimental group showed significantly lower anxiety levels compared to the control group.

A Canadian study (33) showed that listening to music during the peri-operative period can decrease midazolam requirements in patients undergoing ambulatory or short-stay surgery with spinal anaesthesia. Although the anxiety levels across the two groups remained unchanged, the group that was listening to music used less midazolam made available to them via a patient controlled sedation device (33). It has also been demonstrated that music has an effect on reducing post-operative anxiety in patients who received spinal anaesthesia when used in the post-anaesthesia care unit (PACU) in addition to routine nursing care (34).

Although the literature highlights the multiple advantages and potential uses for music therapy and music medicine in the operating room, there seems to be a paucity of evidence for its use for peri-operative anxiety in lower limb arthroplasty procedures. There are randomised controlled studies conducted in the United States of America that express conflicting results in this regard (20,32). Kukreja et al (32) showed that post-operative anxiety was significantly less and patient satisfaction was higher in the group that received music during total knee replacement, however there was no difference in the amount of sedative agents used between the two groups. In a similar study, Tran et al (20) compared the effect of noise-cancellation and music therapy to that of noise-cancellation alone. This study showed that the mean propofol requirement was less in the group that received music in addition to noise-cancellation as compared to the control group however the results were not statistically significant.

As the ageing population grows and the demand for lower limb arthroplasty increases, continued research into optimisation of the anaesthetic technique is required to improve patient satisfaction and outcomes as well as to minimise complications and additional healthcare costs. In a resource-constrained environment, such as South Africa, every effort needs to be made to avoid placing further burden onto existing infrastructure. Music has shown promise in the developed world, however there is a lack of evidence on its use intra-operatively for lower limb arthroplasty in a setting similar to South Africa. Evolving technology has resulted in a large variety of music being readily available and it may be considered a cheap, safe, non-pharmacological intervention that could easily be implemented as an adjunct to spinal anaesthesia.

Therefore, the aim of this study is to determine the effects of listening to music during spinal anaesthesia for patients undergoing knee and hip arthroplasty in two South African academic hospitals. This study will specifically assess if intra-operative music impacts patient anxiety using the validated VAS-A.

2. Problem statement

Music is becoming an increasingly popular adjunct to traditional medical therapies. International studies have shown the numerous benefits of music in a medical setting. Music has been used effectively to decrease patients' anxiety under neuraxial anaesthesia for caesarean section. There is currently a lack of evidence supporting the use of music to reduce patients' anxiety under neuraxial anaesthesia for lower limb arthroplasty procedures. The worldwide growth of the ageing population has led to an increased demand for arthroplasty. It is imperative that the anaesthetic technique used for this procedure is both safe and is associated with high levels of patient satisfaction. The purpose of this study is to compare the effect of music, to a control, on peri-operative anxiety in patients undergoing lower limb arthroplasty procedures under spinal anaesthesia at Chris Hani Baragwanath Academic Hospital (CHBAH) and Helen Joseph Hospital (HJH).

3. Aim

The aim of this study is to compare the effect of listening to music, to a control group (no music), on peri-operative anxiety using the validated VAS-A, in patients undergoing lower limb arthroplasty procedures under spinal anaesthesia, at CHBAH and HJH.

4. Objectives

The primary objectives of this study are to:

- describe the pre-operative anxiety scores measured by the VAS-A,
- describe and compare the anxiety scores at the pre-operative visit (T1) and at skin incision (T3) in the control group,
- describe and compare the anxiety scores at the pre-operative visit (T1) and at skin incision (T3) in the music group,
- describe and compare the anxiety scores at each time point (T1-T4) between the control group and the music group.

The secondary objectives of this study are to:

- describe the difference in the anxiety scores between male and female patients,
- describe the difference in anxiety scores between knee and hip arthroplasty,
- describe and compare the total propofol dose between the two groups,
- describe patient satisfaction in both groups.

5. Research assumptions

The following definitions will be used in this study:

Adult: Any person, over the age of 18 years.

Music: An intentional sound with structured components including melody, rhythm, harmony, timbre, form and style (10). The genre will be pre-selected by patients and played through headphones for the duration of the procedure.

Peri-operative: The period around the time of a surgical procedure (35). This period includes the pre-operative assessment (conducted the day prior to surgery), the intra-operative period and the post-operative period spent in the PACU.

Anxiety: An overwhelming feeling of apprehension and fear which can exist with or without physical signs (36). Physical signs of anxiety can include sweating, palpitations, increased heart rate and blood pressure.

Lower limb arthroplasty: Any primary, total or hemi-arthroplasty procedure involving the knee or hip joint. This excludes any revision procedures of previously replaced joints.

VAS-A: A validated scale used to measure anxiety (Annexure A) (9,16).

Moderate sedation: A level of sedation resulting in a depressed level of consciousness, however the patient is able to respond purposefully to verbal commands. The patient is able to maintain their own airway and maintain adequate spontaneous ventilation. Cardiovascular function is also maintained (37). This can be clinically monitored using the University of Michigan Sedation Scale (UMSS) (Annexure B) (37).

6. Demarcation of study field

The study will be conducted at CHBAH and HJH. These hospitals are affiliated with the Faculty of Health Sciences of the University of the Witwatersrand. CHBAH has a capacity of 3200 beds (38) and performs on average 40 arthroplasty procedures per month. HJH has a total of 23 wards and 11 operating theatres (39).

7. Ethical considerations

Approval to conduct the study will be obtained from the Human Research Ethics Committee (Medical) (HREC) and the Post Graduate Studies Committee of the University of the Witwatersrand (Wits).

Permission to conduct this study at CHBAH will be obtained from the Medical Advisory Committee. Permission to conduct the study at HJH will be obtained from the Chief Executive Officer. Permission will be obtained from the Academic Head of Department of

Anaesthesia Professor Motshabi, the Head of Department of Anaesthesia at CHBAH Dr Mogane, the Head of Department of Anaesthesia at HJH Dr Gardner and the Head of Department of Orthopaedics Professor Ramokgopa (Annexure C-H).

The researcher will invite eligible patients to participate in this study at the pre-operative assessment visit. The study will be explained, and a patient information sheet will be provided (Annexure I). The language of approach will be English. If the patient does not understand English the researcher will enquire of their preferred language and a translator from the ward will help explain the study in this language. The information sheet and consent form will also be explained in their preferred language. If the patient is illiterate both the information sheet and the consent form will be explained to them. Informed consent will be obtained in writing should the patient agree to participate in this study (Annexure J). Having a witness present and signing the consent form will mitigate any potential coercion by the researcher. All patients will be treated using a standardised anaesthetic approach, apart from the intervention (music). No treatment, including anxiolysis, will be withheld from patients during this study. Participants can withdraw from this study at any point.

Participants will be allocated a unique study number, and this will be stored on a separate data sheet. Data collection will be done by the primary researcher, SB, on data collection sheets (Annexure K). No identifying information will be collected on these sheets. The data will be saved on a password protected computer. Patient confidentiality will be ensured as only the researcher and the supervisors will have access to the raw data. The data collected will be stored securely for six years once the study is completed as per the HREC regulations. The study will be conducted according to the principles of the Declaration of Helsinki (40) and the South African Good Clinical Practice guidelines (41). The study will only commence once approval from all parties is obtained.

8. Research Methodology

8.1 Research design

The SPIRIT (Standard Protocol Items for Randomised Trials) recommendations were used in preparing the protocol (42). The study design will be a prospective, non-blinded, randomised controlled trial. A randomised controlled trial is “a type of experimental design which intends to evaluate the efficacy of intervention, and to establish a reliable cause-effect relationship” (43). A characteristic of a randomised controlled trial is a control group (no intervention) which is assigned through randomisation. The control (no intervention)

and the intervention groups will be monitored to evaluate if there is any difference between them. Both groups will be treated using a standardised anaesthetic approach, except for the intervention that is being tested (43). In this trial, the intervention that is being tested is music. The experimental group will be given music to listen to in addition to routine patient care. The control group will only receive routine patient care.

8.2 Study population

The study population will consist of adult patients, presenting for primary lower limb arthroplasty procedures at CHBAH and HJH.

8.3 Study sample

8.3.1 Sample size

The sample size was calculated in consultation with a biostatistician using STATA version 15.2 (StataCorp, USA). Assuming a statistical power of 90% and alpha of 5%, 29 patients were required in each group to reach a level of significance. The mean and standard error of the STAI score, measured at five minutes before surgery and at thirty minutes post-operatively in a non-music and a music group, from a previous, similar study were used. At five minutes before surgery the mean STAI scores were $40,5 \pm 6,1$ and $34,6 \pm 7,5$ for the non-music and music group, respectively. At thirty minutes post-operatively the mean STAI scores were $32,2 \pm 4,6$ and $28,0 \pm 6,2$ for the non-music and music group, respectively (44). The VAS-A will be used in this trial which has been validated as accurate in measuring anxiety (9,16).

8.3.2 Sampling method

In this randomised controlled trial, patients will be identified on the arthroplasty lists. Criteria for inclusion will be determined at the pre-operative assessment. After enrolment, participants will be randomised into two groups in a 1:1 ratio, music (intervention group) and no music (control group). Randomisation will be done using a simple randomisation chart (Annexure L). Patients will not be allowed to cross over from one group to the other, but they can choose to leave the study at any point should they want to receive a specific treatment option. The researcher will have availability to the arthroplasty lists at CHBAH and HJH.

Randomisation means that “each participant has an equal chance of being placed in any of the treatment groups” (43). This will be done using a simple randomisation chart created on graphpad.com (Annexure L) (45). After enrolment, patients will be randomised by selecting a sealed envelope with a number and the assigned group as per the

randomisation chart. If the patient withdraws from the study, the envelope will be resealed and returned to the box.

8.3.3 Inclusion criteria

The following patients will be included in the study:

- all patients, aged 18 years and older,
- American Society of Anaesthesiologists (ASA) class I, II or III,
- patients undergoing primary hip or knee arthroplasty surgery under spinal anaesthesia,
- patients with the mental capacity to consent to the study.

8.3.4 Exclusion criteria

The following patients will be excluded from the study:

- patients with significant visual loss (visual impairment includes patients with complete blindness or patients who are unable to read any of the consent form without visual aid),
- patients with significant hearing loss (this includes patients who are unable to hear ordinary speech in a quiet environment and those requiring hearing aids),
- patients with any contra-indications to spinal anaesthesia,
- patients with any contra-indications to moderate sedation including moderate to severe obstructive sleep apnoea (indicated by a “STOPBANG” score of 5-8) (46),
- patients with pre-existing diagnosed anxiety disorders or other serious mental disturbances,
- revision arthroplasty (this may require deviation from the standardised anaesthetic technique used for this trial),
- anxious patients who cannot be reassured and require additional anxiolytic agents.

8.4 Data collection

8.4.1 Data collection sheet

The data collection sheet was constructed based on previous studies identified in the literature review, ensuring content validity. It was reviewed by two senior anaesthesiologists and a senior arthroplasty surgeon to ensure the content and face validity, with the final data collection sheet formulated (Annexure K).

The sheet captures the following information:

- patient characteristics (all clinical data recorded is part of the routine pre-operative assessment which will be carried out by the primary researcher, SB, who will be the anaesthetist managing the case) (47,48),
- music genre selected,
- VAS-A at pre-operative assessment, prior to surgery, at skin incision and post-operatively in the PACU,
- total propofol dose,
- patient satisfaction questionnaire.

8.4.2 Data collection process

After approval by the Human Research Ethics Committee (Medical) (HREC) and the Post Graduate Studies Committee at Wits, patients who meet the inclusion criteria will be invited to participate in the study. The study will be explained, and a patient information sheet will be distributed at the pre-operative assessment visit. The language of approach will be English. If the patient does not understand English the researcher will enquire of their preferred language and a translator from the ward will help explain the study in this language. The information sheet and consent form will also be explained in their preferred language. If the patient is illiterate both the information sheet and the consent form will be explained to them. Should the patient agree to participate in the study, written consent will be obtained.

Patients will then be randomised, using a sealed envelope technique, in a 1:1 ratio, into either the interventional group (music group) or the control group (no music group). Patients in the music group will pre-select their preferred genre of music at the pre-operative assessment visit from the following list: classical, gospel, soul, pop and jazz. Anxiety will be measured using the VAS-A. Patients will use the faces as a visual guide and mark the level of anxiety along the ruler. Anxiety will be measured and recorded both, in centimetres (0 cm indicating no anxiety and 10 cm indicating maximum anxiety) and by the faces categories. All participating patients will complete a baseline anxiety assessment using the VAS-A at the pre-operative assessment visit, the day prior to the surgery (T1). The VAS-A will be completed again on the day of the surgery before the patient is taken into the operating room (T2).

Patients in the intervention group will receive music after the ASA monitors are applied. The music will be played at a self-selected volume, on Pro Bass Swagger Series Aux

disposable earphones and will be played for the duration of the surgical procedure. The music will be played from an iPhone which will be placed in a plastic bag for infection control purposes. The control group will not receive music. The following anaesthetic technique will be undertaken for all patients:

- routine ASA monitors will be applied, including non-invasive blood pressure, heart rate, oxygen saturation and capnography,
- supplemental oxygen will be supplied by nasal cannula,
- intra-venous access will be obtained,
- spinal anaesthesia will be performed using 13 – 15 mg of plain bupivacaine 0.5% and 20 µg of fentanyl intrathecally,
- a propofol target-controlled infusion (TCI) will be used for sedation,
- the South African Society for Anaesthesiologists (SASA): Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in adults: 2020–2025 will be followed (37),
- moderate sedation will be used, and this will be measured using the UMSS (Annexure B),
- the Marsh model will be used for the propofol TCI and a target concentration of 1 – 2 µg/ml will be used; this will be adjusted in the elderly patients (patients over 65 years of age) to 0.6 – 0.8 µg/ml as per the SASA guidelines (Annexure M).

Patients' anxiety levels will be assessed again at skin incision (T3). The music will be stopped, and the earphones removed prior to the transport of the patient to the PACU. In the PACU, patients will complete the final VAS-A measurement (T4) and the patient satisfaction questionnaire. A patient satisfaction questionnaire that was previously used in a similar study will be utilised (32). Each question will be analysed and any positive response will be an indication of patient satisfaction. Figure 1 shows the data collection time points schematically. The data will be recorded onto the data collection sheet (Annexure K).

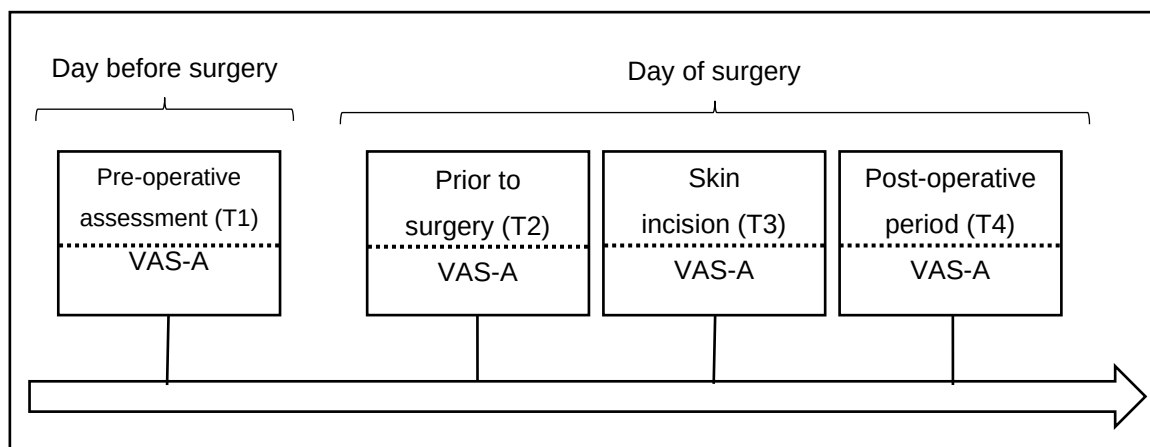


Figure 1: Flow chart of the study data collection time points

The process of data collection is summarised in Figure 2.

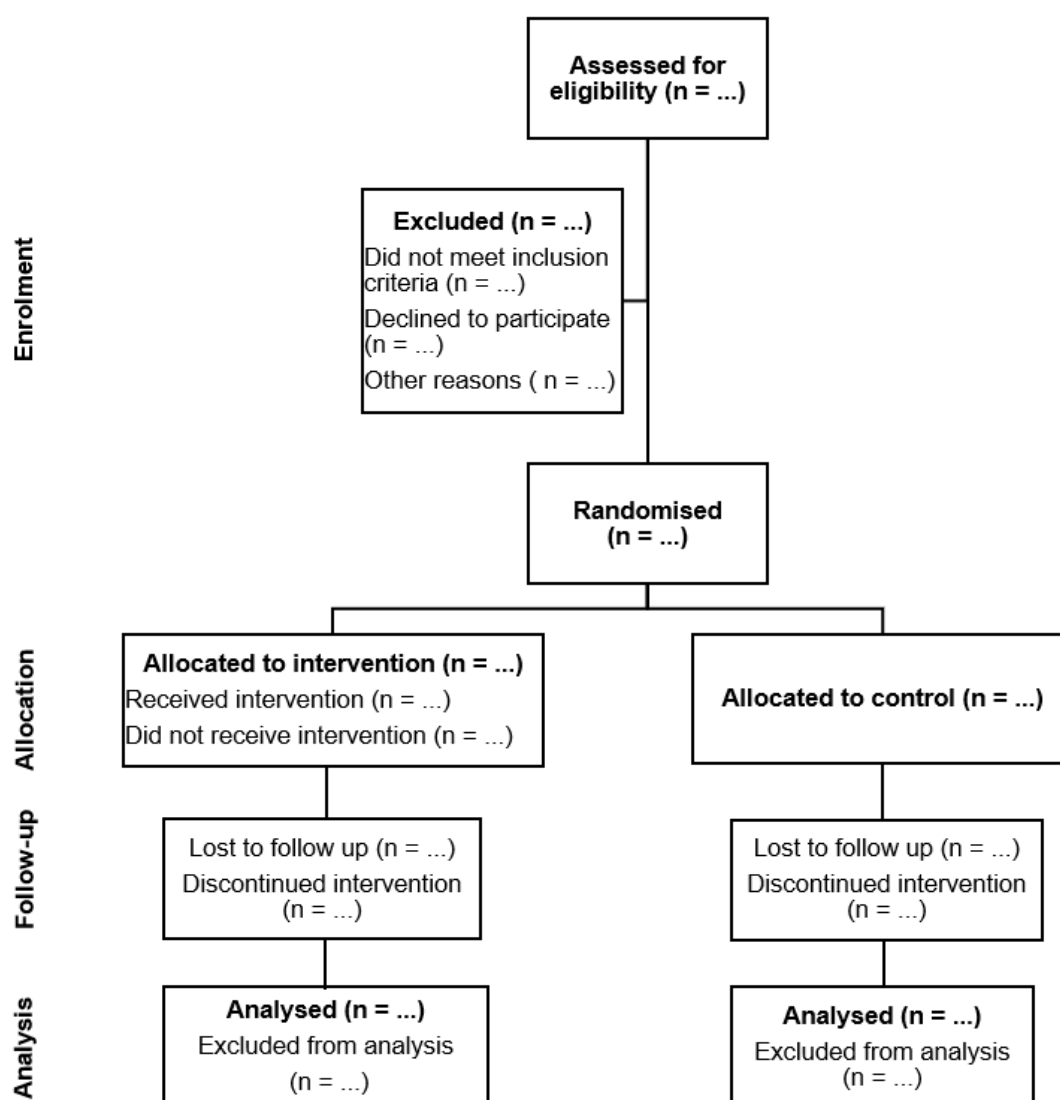


Figure 2: CONSORT flow diagram.

8.5 Data analysis

The data from the data collection sheets will be transferred to a REDCap database. Data will be analysed in consultation with a biostatistician using STATA version 15.2 (StataCorp, USA). Continuous variables will be described with means and standard deviations for normally distributed data and medians and interquartile ranges for non-normally distributed data. Categorical variables will be described as frequency and percentages. The independent t-test will be used for continuous variables, and the Chi-square test will be used for categorical variables. Continuous variables include the VAS-A (measured in cm) and the total propofol dose. Categorical variables include the patient satisfaction questionnaire, the incidence of pre-operative anxiety and the VAS-A (faces score). A p-value of 0.05 or less will be considered to be statistically significant. Baseline characteristics between the two groups will be compared using standard descriptive statistics.

8.6 Significance of the study

Currently it is not common practice to provide music to patients under spinal anaesthesia in South African hospitals. Music as a medical intervention has demonstrated multiple benefits. Music is a safe, non-pharmacological, intervention that has been used to reduce anxiety in patients across different disciplines. There is a lack of evidence on the effect of music on anxiety in patients under spinal anaesthesia for lower limb arthroplasty procedures in South Africa. It is imperative that the effect of music in this setting be determined to ascertain whether patients' anxiety is reduced. This would allow for motivation of its routine use as a potential cost-effective adjunct to spinal anaesthesia to reduce anxiety and improve patient satisfaction.

9. Validity and reliability of the study

Validity means "that a test or instrument is accurately measuring what it's supposed to" and reliability is a "measure of the stability or consistency of the test scores" (49).

Validity and reliability of the study will be ensured by:

- using an appropriate study design based on a thorough literature review,
- having a representative study sample,
- using a single researcher to collect data thus minimising inter-researcher variability,
- avoiding observer bias by allowing patients to complete the anxiety assessment themselves,
- using appropriate data collection methods,

- using appropriate methods of analysing collected data in consultation with a biostatistician,
- using a validated scale for anxiety, the VAS-A.

10. Potential limitations of the study

A limitation of this study is that only one tool is being used to measure anxiety. Despite the STAI being the gold standard tool in measuring anxiety, this involves a lengthy questionnaire with concerns about language barriers. For these reasons the VAS-A was chosen as the measuring tool in this trial, which is validated against the STAI as accurate (9,16). The graphic nature and the simplicity of the analogue scale will make it easier for patients to describe their honest feelings which might not have been the case with a long questionnaire.

The sample may not adequately represent all the arthroplasty patients, and this will make generalisation difficult. As the trial is being conducted by a single researcher this will hinder blinding of the researcher. Patients will complete their own anxiety assessment and group blinded data analysis will be used to avoid bias. Blinding of participants is not possible due to the nature of the trial and knowing about the lack of music may be a confounding factor.

There is a limitation of five music genres as these genres have been shown to not increase or cause anxiety (23). Previously conducted studies using music in the operating room have allowed for large variability in the music genre selected as no restrictions were imposed (20,31–33,44). There was no report of any increase in anxiety and no identification of a specific genre that was best suited.

The use of sedation intra-operatively may reduce anxiety levels in patients however this has been compensated for by using a standardised anaesthetic technique for all participants in the trial as well as a propofol TCI model. The propofol TCI model will also be adjusted for elderly patients as per the SASA sedation guidelines (37) to ensure that these patients are not overly sedated (Annexure M). Another limitation would be the lack of objective measurements used and that bispectral index (BIS) monitoring will not be used to monitor the level of sedation, however, this is not freely available in our setting and thus the UMSS will be used instead as recommended by the SASA sedation guidelines (37).

11. Project outline

11.1 Time frame

Year	2021-2022												
Month	J	F	M	A	M	J	J	A	S	O	N	D	J
Proposal													
Ethics approval													
Post-graduate approval													
Data collection													
Data analysis													
Sub-mission													

11.2 Financial plan

Costs of paper and printing:

Description	Price per page	Number of pages	Number of copies	Total
Printing proposal	R1	40	1	R40
Printing of patient information sheets and consent forms	R1	4	4 x 58	R232
Printing research report	R1	100	1	R100
Total				R372

Other costs:

Description	Price per item	Number of items	Total
Disposable headphones	R24	58	R1392
Total			R1392

The cost of paper and printing will be covered by the Department of Anaesthesiology. The cost of the disposable headphones will be covered by the researcher.

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Annexure A: Visual analogue scale for anxiety (VAS-A)

Anxiety Level	None	Mild	Mild-Moderate	Moderate	Moderate-High	Highest
Faces						

Figure 3: The visual analogue scale for anxiety (faces) (16)



Figure 4: The visual analogue scale for anxiety (measured in cm – not to scale) ³⁹

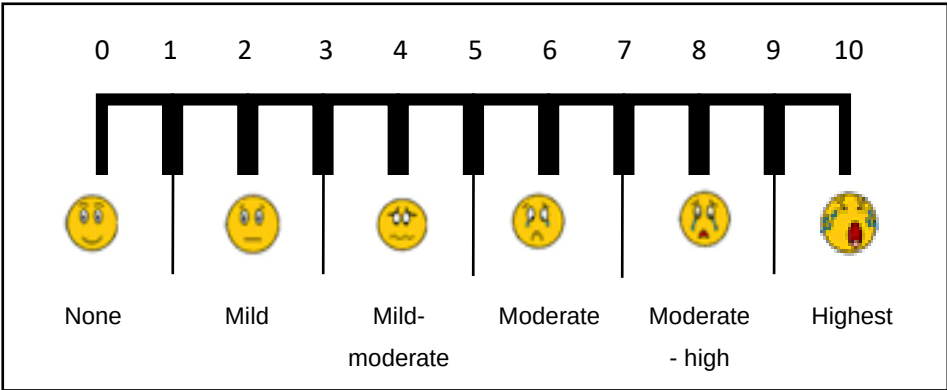


Figure 5: A combined visual analogue scale ^{36,39}

Annexure B: University of Michigan Sedation Scale (USSM)

University of Michigan Sedation Scale (UMSS)

University of Michigan Sedation Scale (UMSS)		
0	Awake and alert	
1	Minimally sedated	Patient drowsy, sleepy but rousable to verbal command
2	Moderately sedated	Patient may be sleeping, can be easily aroused by light tactile stimulation
3	Deeply sedated	Patient asleep, only rousable by significant physical stimulation, or repeated painful stimuli
4	Unrousable	No response with significant physical stimulation

Figure 6 : The university of Michigan Sedation Scale (37)

Annexure C: Request to the Medical advisory Committee

Dr SA Ballard
352937
Department of Anaesthesiology
University of the Witwatersrand
18 March 2021

To the Chairman of the Medical Advisory Committee of Chris Hani Baragwanath
Academic Hospital

Dear Sir/Madam

My name is Samantha Ballard. I am a registrar in the Department of Anaesthesiology. I would like to conduct a study titled: Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia. The study will be for the partial fulfilment of my MMed.

The aim of this study is to compare music to that of a control group (no music) in patients under spinal anaesthesia and to evaluate if there is a difference in anxiety between the two groups. Music will be supplied to the experimental group by disposable headphones and the music genre will be pre-selected by the patients. The music will play for the duration of the procedure and patients will be required to rate the anxiety they are feeling on a visual analogue scale used for anxiety. Apart from the intervention (music) both groups will be provided with a standardised anaesthetic technique, including monitoring and appropriate treatment.

International studies with similar aims have been conducted and it has been shown that music can reduce anxiety in such patients. However, studies of this nature have not been conducted in a South African setting.

Patients who meet the inclusion criteria will be invited to take part in the study. The study will be explained to them and they will be provided with a detailed information sheet. Informed consent will be obtained from patients in writing. Patients are welcome to withdraw from the study at any point should they wish.

Patient confidentiality will be protected at all times. There will be no patient identifying information collected on the data collection sheet. Data will be stored on a password protected computer and only my supervisors and myself will have access to the raw data. Please may I have your permission to conduct this study at CHBAH. Should the outcome of this study show that music can reduce intra-operative anxiety it could be easily implemented as an adjunct to routine spinal anaesthesia in our setting.

Yours Sincerely

Samantha Ballard

0836313487

Sam.ballard@hotmail.com

Annexure D: Request to the HJH Chief Executive Officer

Dr SA Ballard
352937
Department of Anaesthesiology
University of the Witwatersrand
18 March 2021

To the Chief Executive officer of Helen Joseph Hospital

Dear Sir/Madam

My name is Samantha Ballard. I am a registrar in the Department of Anaesthesiology. I would like to conduct a study titled: Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia. The study will be for the partial fulfilment of my MMed.

The aim of this study is to compare music to that of a control group (no music) in patients under spinal anaesthesia and to evaluate if there is a difference in anxiety between the two groups. Music will be supplied to the experimental group by disposable headphones and the music genre will be pre-selected by the patients. The music will play for the duration of the procedure and patients will be required to rate the anxiety they are feeling on a visual analogue scale used for anxiety. Apart from the intervention (music) both groups will be provided with a standardised anaesthetic technique, including monitoring and appropriate treatment.

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Yours Sincerely

Samantha Ballard

0836313487

Sam.ballard@hotmail.com

Annexure E: Request to the Head of Anaesthesiology of the University of Witwatersrand

Dr SA Ballard
352937
Department of Anaesthesiology
University of the Witwatersrand
18 March 2021

Dear Prof. Motshabi

My name is Samantha Ballard. I am a registrar in the Department of Anaesthesiology. I would like to conduct a study titled: Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia. The study will be for the partial fulfilment of my MMed.

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Patient confidentiality will be protected at all times. There will be no patient identifying information collected on the data collection sheet. Data will be stored on a password protected computer and only my supervisors and myself will have access to the raw data. Please may I have your permission to conduct this study. Should the outcome of this study show that music can reduce intra-operative anxiety it could be easily implemented as an adjunct to routine spinal anaesthesia in our setting.

Yours Sincerely

Samantha Ballard

0836313487

Sam.ballard@hotmail.com

**Annexure F: Request to the Head of Department of Anaesthesiology at
CHBAH**

Dr SA Ballard
352937
Department of Anaesthesiology
University of the Witwatersrand
18 March 2021

Dear Dr Mogane

My name is Samantha Ballard. I am a registrar in the Department of Anaesthesiology. I would like to conduct a study titled: Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia. The study will be for the partial fulfilment of my MMed.

The aim of this study is to compare music to that of a control group (no music) in patients under spinal anaesthesia and to evaluate if there is a difference in anxiety between the two groups. Music will be supplied to the experimental group by disposable headphones and the music genre will be pre-selected by the patients. The music will play for the duration of the procedure and patients will be required to rate the anxiety they are feeling on a visual analogue scale used for anxiety. Apart from the intervention (music) both groups will be provided with identical anaesthetic monitoring and treatment. Patients who meet the inclusion criteria will be invited to take part in the study. The study will be explained to them and they will be provided with a detailed information sheet. Informed consent will be obtained from patients in writing. Patients are also welcome to withdraw from the study at any point should they wish.

Patient confidentiality will be protected at all times. There will be no patient identifying information collected on the data collection sheet. Data will be stored on a password protected computer and only my supervisors and myself will have access to the raw data. Please may I have your permission to conduct this study at CHBAH. Should the outcome of this study show that music can reduce intra-operative anxiety it could be easily implemented as an adjunct to routine spinal anaesthesia in our setting.

Yours Sincerely

Samantha Ballard

0836313487

Sam.ballard@hotmail.com

Annexure G: Request to the Head of Department of Anaesthesiology at HJH

Dr SA Ballard
352937
Department of Anaesthesiology
University of the Witwatersrand
18 March 2021

Dear Dr Gardner

My name is Samantha Ballard. I am a registrar in the Department of Anaesthesiology. I would like to conduct a study titled: Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia. The study will be for the partial fulfilment of my MMed.

The aim of this study is to compare music to that of a control group (no music) in patients under spinal anaesthesia and to evaluate if there is a difference in anxiety between the two groups. Music will be supplied to the experimental group by disposable headphones and the music genre will be pre-selected by the patients. The music will play for the duration of the procedure and patients will be required to rate the anxiety they are feeling on a visual analogue scale used for anxiety. Apart from the intervention (music) both groups will be provided with identical anaesthetic monitoring and treatment.

Patients who meet the inclusion criteria will be invited to take part in the study. The study will be explained to them and they will be provided with a detailed information sheet. Informed consent will be obtained from patients in writing. Patients are also welcome to withdraw from the study at any point should they wish.

Patient confidentiality will be protected at all times. There will be no patient identifying information collected on the data collection sheet. Data will be stored on a password protected computer and only my supervisors and myself will have access to the raw data. Please may I have your permission to conduct this study at HJH. Should the outcome of this study show that music can reduce intra-operative anxiety it could be easily implemented as an adjunct to routine spinal anaesthesia in our setting.

Yours Sincerely

Samantha Ballard

0836313487

Sam.ballard@hotmail.com

Annexure H: Request to the Head of Department of Orthopaedics
Department of Orthopaedics

Dr SA Ballard
352937
Department of Anaesthesiology
University of the Witwatersrand
18 March 2021

Dear Prof Ramokgopa

My name is Samantha Ballard. I am a registrar in the Department of Anaesthesiology. I would like to conduct a study titled: Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia. The study will be for the partial fulfilment of my MMed.

The aim of this study is to compare music to that of a control group (no music) in patients under spinal anaesthesia and to evaluate if there is a difference in anxiety between the two groups. Music will be supplied to the experimental group by disposable headphones and the music genre will be pre-selected by the patients. The music will play for the duration of the procedure and patients will be required to rate the anxiety they are feeling on a visual analogue scale used for anxiety. Apart from the intervention (music) both groups will be provided with identical anaesthetic monitoring and treatment. International studies with similar aims have been conducted and it has been shown that music can reduce anxiety in such patients. However, studies of this nature have not been conducted in a South African setting.

Patients who meet the inclusion criteria will be invited to take part in the study. The study will be explained to them and they will be provided with a detailed information sheet. Informed consent will be obtained from patients in writing. Patients are welcome to withdraw from the study at any point should they wish.

Patient confidentiality will be protected at all times. There will be no patient identifying information collected on the data collection sheet. Data will be stored on a password protected computer and only my supervisors and myself will have access to the raw data. Please may I have your permission to conduct this study at CHBAH and HJH. Should the outcome of this study show that music can reduce intra-operative anxiety it could be easily implemented as an adjunct to routine spinal anaesthesia in our setting.

Yours Sincerely
Samantha Ballard
0836313487
Sam.ballard@hotmail.com

Annexure I: Patient information sheet

Hello

I am part of a research team looking at the effect of music on patient's anxiety coming for an operation. We hope this study will help us understand how anxious people are when they are coming for an operation and ways in which we could treat this.

Background:

Chris Hani Baragwanath Academic hospital is a large hospital that performs many joint replacement surgeries every month. Patients require an anaesthetic for these procedures. The recommended anaesthetic for such operations is a spinal anaesthetic. This involves two injections into the back and the lower half of the body becomes numb. Although this is safer than a general anaesthetic, many patients become rather anxious at the thought of being awake during surgery.

What is the purpose of this study?

It is common to feel anxious or nervous before and during an operation. We want to look at ways in which we can reduce patient's anxiety. One way of doing this is through music. We hope that the information gathered in this study can be used going forward to ensure patients are less anxious around the time of their surgery.

What would taking part involve?

This study will involve two groups of patients. Both groups will be given routine anaesthetic care. All the patients will be given a spinal anaesthetic and some sedation. One group will also be given music to listen to on headphones during the operation. The other group will not receive music to listen to during the operation. All patients will then need to fill in a quick questionnaire to measure their anxiety at different points during the operation. Whether or not one gets music during the operation will be completely random and this will be decided by a computer. Your clinical treatment will not change whether you decide to partake in this study or not. All the data that is collected will not have any identifying features on it.

What are the risks of being involved in this study?

If you agree to take part in this study, there is no additional risk. This is because all patients who take part in this study will receive routine treatment. The only addition would be music which is considered a safe therapy with no risks involved.

What are the benefits of being involved in this study?

The information we collect from this study will help us to be able to treat patients who are coming for surgery more effectively in the future.

Cost:

There will be no cost to take part in this study. There will be no payment for participating either.

Ethical approval:

This study has been approved by the Human Resources Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg. A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research. If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Professor Clement Penny, who may be contacted on 011 717 2301, or by email on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Contact details:

For any further information you may require please contact:

Dr Samantha Ballard 083 631 3487

Thank you for reading this study information sheet.

January 2021

Annexure J: Patient consent form

PARTICIPANT CONSENT SHEET

Effect of Music on Patients' Anxiety During Lower Limb Arthroplasty Procedures Under Spinal Anaesthesia.

1. I have been given a Participant Information Sheet which explains the nature and processes involved in this study, which is attached hereto;
2. I was given time to read it, or had it read to me, in the language I best understand;
3. I was given time to ask any questions I wanted to and found any answers given to me to be reasonable and satisfactory;
4. I believe I fully understand why the study is being conducted and what the intended outcomes will be;
5. I understand that there will be no immediate benefit to me, should I agree to participate, nor will I receive any payment; conversely, participation will not cost me anything but my time;
6. I understand that, even if I initially consent to take part in the study, I may subsequently withdraw at any time and would not be required to give any reasons; if that happened, any data collected about me for the purposes of the study would immediately be destroyed, unless I give consent for it to be retained
7. I have been given a range of contact details, listed below. If I require further information or become concerned about any aspect of this study, I am free to speak to any of these contacts.

Contact details:

Dr Samantha Ballard, Principal Investigator, telephone no. 083 631 3487, or by e-mail at sam.ballard@hotmail.com ,

Dr Gwyn Davies, Supervisor, on telephone no. 083 498 9938, or by e-mail at gwynethad@gmail.com

Professor CB Penny, Chairperson of the Human Research Ethics Committee (Medical) at the University of Witwatersrand, on telephone no. 011 717 2301, or by e-mail at Clement.Penny@wits.ac.za.

Ms. Z Ndlovu or Mr Rhulani Mkansi, Committee Secretariat, telephone nos.: 011 717 2700 or 1234, or by e-mail at: Zanele.Ndlovu@wits.ac.za or Rhulani.Mkansi@wits.ac.za

Name of participant: _____

Date: _____

Place: _____

Signature or mark _____

Name of researcher: _____

Date: _____

Place: _____

Signature or mark _____

Witnessed by:

Name of Witness: _____

Signature: _____

Date: _____

Annexure K: Data collection sheet

Participant number:										
Randomisation: (mark with an x)	Music (A)				Control (B)					
Gender: (mark with an x)	Male				Female				Other	
Age (years):										
ASA class: (mark with an x)	I				II				III	
STOPBANG score:										
Surgical side: (mark with an x)	Left				Right					
Surgical procedure: (mark with an x)	Total knee replacement						Hemi-arthroplasty hip			
	Total hip replacement						Hemi-arthroplasty knee			
American knee society score:			Excellent 80-100							
			Good 70-79							
			Fair 60-69							
			Poor < 60							
Harris hip score:			Excellent 90-100							
			Good 80-89							
			Fair 70-79							
			Poor <70							
Length of surgery (minutes):										
Music genre selected:	Classical		Gospel		Soul		Jazz		Pop	

VAS-A at pre-operative assessment:	Measured in cm:											
	None		Mild		Mild-moderate		Moderate		Moderate-high		Highest	
VAS-A prior to surgery:	Measured in cm:											
	None		Mild		Mild-moderate		Moderate		Moderate-high		Highest	
VAS-A at skin incision:	Measured in cm:											
	None		Mild		Mild-moderate		Moderate		Moderate-high		Highest	
VAS-A in PACU:	Measured in cm:											
	None		Mild		Mild-moderate		Moderate		Moderate-high		Highest	
Total propofol dose used (mg):												
Patient satisfaction questionnaire (music group only): (circle)	1) Did the patient feel that the music decreased their anxiety?											
	Not at all			Maybe				Completely				
	2) Did the patient feel that it provided calmness?											
	Not at all			Maybe				Completely				
	3) Did the patient feel that they experienced less pain?											
	Not at all			Maybe				Completely				
	4) Would they request music again if coming for a similar procedure?											
	Not at all			Maybe				Completely				
	5) Would they recommend it to friends and family?											
	Not at all			Maybe				Completely				

Annexure L: Randomisation chart

Patient number	Group	Patient number	Group
1	B	30	B
2	B	31	A
3	B	32	A
4	A	33	B
5	B	34	A
6	A	35	A
7	A	36	B
8	B	37	B
9	A	38	B
10	A	39	A
11	B	40	B
12	A	41	A
13	B	42	A
14	B	43	B
15	B	44	A
16	B	45	B
17	A	46	A
18	A	47	A
19	A	48	B
20	B	49	B
21	A	50	A
22	B	51	A
23	A	52	B
24	A	53	A
25	B	54	A
26	B	55	A
27	B	56	B
28	A	57	B
29	B	58	A

Key:

A = music

B = no music (control) ⁶⁰

Annexure M: Propofol dosing guidelines

Table 7: Dosing schedule for bolus doses of propofol

Dose	Titration	Onset of action	Repeat dose	Duration of action
Bolus 0.5mg/kg over 3–5 minutes*	1 minute	45–90 seconds	0.5 mg/kg	5–8 minutes

Table 8: Dosing schedule for infusion of propofol for PSA

Intravenous infusion	Target controlled infusion
2–4 mg/kg/hour titrated to clinical effect	Effect site concentration 1–2 µg/ml
In elderly patients, commence infusion at 1–2 mg/kg/hour	In elderly patients, recommended effect site concentration is 0.6–0.8 µg/ml

Figure 7: SASA sedation guidelines on propofol dosing (37).

Appendix 4: Post Graduate Committee 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

28 June 2021
Person No: 352937
PAG

Dr SA Ballard
60 Lonehill Village Estate
Cnr Rockery & The Straight Avenue
Lonehill
2191
South Africa

Dear Dr Samantha Ballard

Master of Medicine in Anaesthesia: Approval of Title

We have pleasure in advising that your proposal entitled *Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia*, 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



Appendix 5: Human Research Ethics Committee (medical) clearance certificate



R49 Dr SA Ballard

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL) CLEARANCE CERTIFICATE NO. M210702

NAME:
(Principal Investigator)

Dr SA Ballard

DEPARTMENT:

School of Clinical Medicine
Department of Anaesthesiology
Medical School
University

PROJECT TITLE:

*Effect of music on patients' anxiety during lower limb
arthoplasty procedures under spinal anaesthesia*

DATE CONSIDERED:

2021/07/30

DECISION:

Approved unconditionally

CONDITIONS:

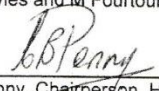
NOTE:

If contact information regarding student study participants is required,
please contact the Registrar's office - <Nicoleen.Potgieter@wits.ac.za>

SUPERVISOR:

Drs G Davies and M Fourtounas

APPROVED BY:


Dr CB Penny, Chairperson, HREC (Medical)

DATE OF APPROVAL:

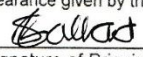
2021/10/05

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

DECLARATION OF INVESTIGATORS

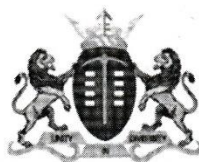
To be completed in duplicate and **ONE COPY** returned to the Research Office secretariat on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

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 submit details to the Committee. **I agree to submit a yearly progress report.** When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in July and therefore reports and re-certification will be due in the month of **July** each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).


Signature of Principal Investigator

01/11/2021
Date

Appendix 6: Chris Hani Baragwanath Academic Hospital MAC and Helen Joseph Hospital CEO approval



GAUTENG PROVINCE

HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 25 August 2021

TITLE OF PROJECT:

Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia.

UNIVERSITY: Witwatersrand

Principal Investigator: Dr S A Ballard.

Department: Anaesthesia

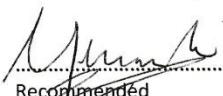
Supervisor/s : Dr G Davies / Dr M Fourtounas

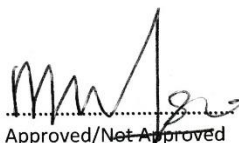
Permission Head Department (where research conducted): Yes

NHRD No. 202106_029

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Academic Hospital. The CEO / management of Chris Hani Baragwanath Academic Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.
- The Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- The MAC will be informed of any serious adverse events as soon as they occur
- Permission is granted for the duration of the Ethics Committee Approval.


.....
Recommended
(On behalf of the MAC)
2021/08/25


.....
Approved/Not Approved
Hospital Management Date:
Date: 26/08/2021



GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Gauteng Department of Health

Helen Joseph Hospital

Enquiries: Dr. R. Ncha

Chief Executive Officer

Tel : (011) 489-0306/1087

Fax : (011) 726-5425

E mail: Relebohile Ncha@gauteng.gov.za

Date: 7 September 2021

Dear Samantha Ballard

Study: Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia.

RESEARCHERS: Samantha Ballard

GP_202106_029.

The above the study was discussed at the Research Committee meeting. We recommend that permission be granted for Helen Joseph Hospital to be used as a site for the above research,

The researcher is expected to the following:

- Upon completion of the study, copy thereof should be submitted to Helen Joseph Hospital.
- It is the researcher's duty to collect the data from the relevant department after the Research Committee approved the study.

Thank you

Dr. M.D. Mukansi

Helen Joseph Hospital

Research Chairperson

DATE:

Approved

Dr. R. Ncha

Helen Joseph Hospital

CHIEF EXECUTIVE OFFICER

DATE: 10/09/21

Appendix 7: Department of Anaesthesia approval



Department of Anaesthesiology
Chris Hani Baragwanath Academic Hospital
PO Bertsham
2013
21st July 2020

To whom it may concern

RE: PERMISSION TO CONDUCT RESEARCH

This serves to confirm that I grant permission for Dr Samantha Ballard to conduct research involving the Department of Anaesthesia at the Chris Hani Baragwanath Academic Hospital. The research topic is titled: **Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia**. The study will be for the partial fulfilment of my MMed.

As explained in her protocol: "The aim of this study is to compare music to that of a control group (no music) in patients under spinal anaesthesia and to evaluate if there is a difference in anxiety between the two groups. Music will be supplied to the experimental group by disposable headphones and the music genre will be pre-selected by the patients. The music will play for the duration of the procedure and patients will be required to rate the anxiety they are feeling on a visual analogue scale used for anxiety. Apart from the intervention (music) both groups will be provided with identical anaesthetic monitoring and treatment."

I'd like to wish her luck in this endeavor and I am happy to support her wherever possible.

Kind regards.

Dr Palesa Mogane
Chief specialist and Head of Department
Department of Anaesthesiology
Chris Hani Baragwanath Academic Hospital
University of Witwatersrand
Email: Palesa.Mogane@wits.ac.za

Dr Brian Gardner
HCU, Department of Anaesthesia & Pain Management Unit
Helen Joseph Hospital
1 Perth Road
Auckland Park
2092
Tel: (011) 489-0084
Mobile: 082 575 1736
Email: Brian.Gardner@wits.ac.za

3 September 2021

Dear Dr Ballard

Permission to conduct research: Dr Samantha Ballard (Student Number: 352937)

Permission is granted for you to conduct your study entitled: "Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia" in theatres at Helen Joseph Hospital.

The study will not attract any cost to the hospital.

Best wishes, we look forward to reading your findings.

Regards,



Brian Gardner

Appendix 8: Department of Orthopaedics approval



Division of Orthopaedic Surgery

Faculty of Health Sciences, 4M Room 12,
Wits Medical School, 7 York Road, Parktown 2193
• Tel: +27 11 717-2538 • Fax: +27 11 717-2551

Date: 07 October 2021

To whom it may concern

RE: PERMISSION TO CONDUCT A SURVEY IN THE WITS ORTHOPAEDIC DEPARTMENT

Permission is hereby granted to Dr S.A Ballard for the conduct of the Research titled **"Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia"** within the Division of Orthopaedic Surgery at the University of the Witwatersrand.

Kind Regards

A handwritten signature in black ink, appearing to be "M.T. Ramokgopa", written over a horizontal line.

Prof M.T. Ramokgopa
HOD Orthopaedic Surgery
Chris Hani Baragwanath Academic Hospital
011- 933 8914
Email: mmampapatla.ramokgopa@wits.ac.za

Appendix 9: Clinical trials/SANCTR approval



Private Bag X828, PRETORIA, 0001 Civitas Building, c/o Struben and Thabo Sehume Streets
Tel (012) 395 8000, Fax (012) 395 8918

18 January 2023

To Whom It May Concern:

RE: Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia.

Dear Samantha Ballard

This letter serves as a confirmation that your trial has been approved on the South African National Clinical Trial Registry. Your unique identification number for the registry is DOH-27-012023-8787

Please be advised that you are responsible for updating your trial record information on SANCTR, or for informing us of changes to your trial.

Please note that it is now a WHO requirement to include, at a minimum, summary results or a link to summary results within the trial registration record. This should be done within 12 months of the study completion date.

Please do not hesitate to contact us at +27 21 938 0222 or email sanctradmin@mrc.ac.za should you have any questions.

Yours faithfully,

SANCTR Administration Team

Department of Health • Lefapha la Pholo • Lefapha la Bophelo • uMnyango wezeMpilo • Mhasho wa Mutakalo • Departement van Gesondheid • Kgoro ya Maphelo • Ndzawulo ya Rihanyo • UThiko le Thempilo • ISebe lezeMpilo • UmNyango WezamaPhilo

Appendix 10: Turnitin report

Draft article for turn it in 3-2.docx

ORIGINALITY REPORT

22%	19%	16%	7%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

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