Psychiatria Danubina, 2021; Vol. 33, Suppl. 11, pp 100-115 *Conference paper*

ANXIOLYTIC EFFECTS OF INTRAOPERATIVE MUSIC THERAPY IN ADULTS UNDERGOING LOCAL ANAESTHETIC INTERVENTIONS

Michaela Agius

Medical Student, University of Malta, Msida, Malta

SUMMARY

Background: *Intra-operative anxiety is a commonly experienced feeling amongst patients undergoing surgery. Moreover, conscious patients are exposed to the multiple environmental factors triggering this emotion. Apprehension and fear are common emotions interlinked with associated intra-operative anxiety. Several concerning complications are associated with this emotion during surgery, many of which include severe cardiac related events, such as heart failure and acute myocardial infarction, extreme postoperative pain, increased requirement of analgesic, sedation and anaesthetic demand, extended hospital stay, and reduced patient satisfaction. In this review, the effect of intra-operative music therapy to alleviate anxiety in adults undergoing surgery will be studied in order to establish whether intra-operative music alleviates anxiety in adults undergoing local anaesthetic surgical interventions.*

Methods: *The Population studied was adults aged 18-80 years old undergoing local anaesthetic interventions. The Intervention observed was the exposure of intra-operative music therapy. The Comparison was against patients undergoing surgery without being subject to music therapy. The desired Outcome was the alleviation of intra-operative anxiety. The intention was to develop a systematic review of the available data.*

In orderto develop the literature search, Key elements of the question were identified and utilized to generate alternative terms. Subsequently, Boolean Operators were used to combine these terms. Search results were narrowed down by means of limiters and selected databases; EBSCO, PubMed and ScienceDirect were used to execute the search. The PRISMA 2009 framework was used as a guideline in excluding irrelevant studies. Assessment of study eligibility was done byapplying inclusion/exclusion criteria. Appraisal of literature was done by using The Critical Appraisal Skills Programme (CASP) tool as a framework.

Results: *A total of five studies were identified. These included randomised control trials. Two of these studies demonstrated statistical significance whilst the remaining three failed to do so. The overall result of these studies was inconclusive and inconsistent in attempting to determine whether intra-operative music therapy alleviates anxiety in patients undergoing local anaesthetic interventions.*

Conclusion: *The presentation of a definite conclusion is not possible. However, evidence is promising and pointing towards the likelihood of beneficial outcomes resulting from the intervention of interest. However, further research is required.*

Implications and Recommendations: *It is recommended that the patients be offered the choice of selecting their preferred music if they give consent to undergo surgery while being exposed to music therapy. Various cost-effective audio devices could be installed in operating theatres. The general public and healthcare professionals should be educated about the benefits of intra-operative music therapy. Future studies should use larger sample sizes, and attrition rate should be reduced through better communication with patients and thorough taking into account the demographic characteristics of the patients.*

Key words: *intraoperative - music therapy – anxiolytic - local anaesthetic - surgery*

* * * * *

INTRODUCTION

According to research conducted by Robleda et al. (2014), data indicates that around 75% of patients feel anxious when undergoing surgical interventions, despite the implementation of anxiety-alleviating measures. More specifically, the prevalence of anxious patients undergoing local anaesthetic (LA) surgery was found to be that of 77% out of all surgical patients being examined for a research study conducted by Mitchell MJ (2009). As a repercussion, surgically induced patient anxiety has been associated with causing poor surgical outcomes with regards to intra-operative risks and post-operative recovery (Caddick et al. 2012). Therefore, as stated by Dantas et al. (2017) in their findings, the necessity for diagnosing and controlling anxiety in patients undertaking LA surgery is evident. This paper will therefore focus on the effectiveness of one of the more common forms of complementary therapies, that is, music therapy (MT), in comparison to the standard care provided during intra-operative local or regional anaesthetic (RA) interventions.

ANXIETY

According to the American Psychological Association (APA) (2021), anxiety is defined as "an emotion characterized by feelings of tension, worried thoughts and physical changes like increased blood pressure." Furthermore, anxiety is a mental, physical, and social state triggered by humans and animals in response to a threat to their health or existence, be it real or potential. Its characteristics include amplified stimulation, anticipation, neuro-endocrine and autonomic instigation, together with particular behavioural patterns such as agitation, exhaustion, difficulty in focusing on problems

and muscular tightness (Sigdel 2015). The purpose of these modifications is to aid in managing unfavourable or unforeseen circumstances and could be experienced transiently or chronically, as is in an anxiety disorder. Common anxiety disorders include "generalised anxiety disorder", "social anxiety disorder", "panic disorder", phobias, "post-traumatic stress disorder" and "obsessive-compulsive disorder" (Health & Human Services 2014). Around 264 million people globally are estimated to suffer from an anxiety disorder (WHO 2015). Locally, it was found that 7.9% of Maltese people that participated in the European Health Interview Survey (EHIS) (2014), conducted by the Directorate for Health Information and Research (DHIR) (2014), have suffered from chronic anxiety at some point throughout their life, as shown in figure 1 below. Bally et al. (2003) suggest that the physiologic reaction to stress involves the triggering of the sympathetic nervous system, together with the hypothalamic pituitary adrenal axis which caused a surge in pulse, cardiac output and blood pressure, leading to the sensation of anticipation and uncertainty. Hence, an alternative definition of anxiety includes "anticipatory affective, cognitive, and behavioural changes in response to uncertainty about potential future threat" (Grupe & Nitschke 2013).

INTRAOPERATIVE ANXIETY (IA)

A patient's fear of an unacquainted environment, possibility of disfigurement, death and lack of control amongst other fears are trigger factors which can cause perioperative anxiety, leading to particular emotional, intellectual and physiological reactions (Wang et al. 2002). It has been assumed that fear or anxiety before an operation negatively affects the patient's adaptation to the outcome of the operation (Anderson 1983). Thus, surgical anxiety is presented as an ambiguous feeling of unease without a specific cause. This feeling may be unfamiliar to the patient. It is commonly associated with atypical hemodynamic function such as an accelerated heart rate and increase in blood pressure resulting from parasympathetic, endocrine and sympathetic stimulation (Klopfenstein et al. 2000). Being awake during the operation, feeling or seeing the body cut open and experiencing pain, and insufficient information on the procedure all increase anxiety in patients (Mitchell 2009) Rees & Tagoe (2002) suggest that the reasons for increased patient anxiety during LA surgery are the involvement of needles, being conscious during the surgery and having to wait between the administration of the anaesthesia, and the initiation of the surgery.There is a correlation between increased preoperative anxiety and a theoretical preferential choice for general rather than local block surgery (Rees & Tagoe 2002). Additionally, Kennedy et al. (1992) suggests that entering the operating room, together with experiencing the operating theatre sounds (Jakobsen & Fagermoen 2005), alarm bells, preparation of surgical tools (Hankela & Kiikkala 1996), preparation of the surgical bed and cold temperatures all generate an increase in anxiety intra-operatively when both using Local Anaesthetic and/or Reginal Anaesthetic (Chit Ying et al. 2001).

The environment of the Operating theatre is an important factor for generating anxiety. Haugen et al. (2009) reported that 23% of patients felt anxious on arrival in the operating theatre. 35% of patients were anxious when anaesthesia was induced (Haugen et al. 2009). Giving continuous information on the operation with opportunity to ask questions during the operation reduced anxiety in 55% of patients (Haugen et al. 2009). Seeing technical equipment or surgical instruments increased anxiety in 9% and 6% of the patients respectively (Haugen et al. 2009). Those patients with a previous history of anxiety or depression tended to suffer more anxiety in the intraoperative period (Haugen et al. 2009).

COMPLICATIONS OF INTRAOPERATIVE ANXIETY

Intraoperative anxiety (IA) is associated with several concerning complications. These include severe cardiac related events, such as heart failure, acute myocardial infarction, pulmonary oedema and cardiac mortality due to an upsurge in heart rate and blood pressure through nervous and endocrine stimulation (Saur et al. 2001).

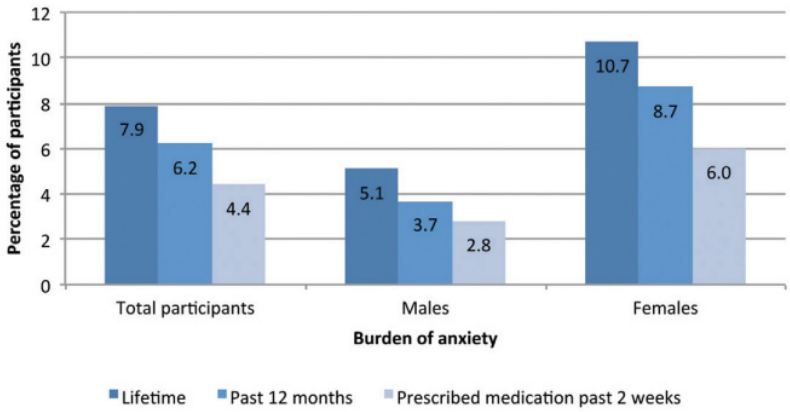

Figure 1. Anxiety prevalence in individuals over 15 years of age (DHIR, Malta, 2014. EHIS, 2014)

Furthermore, diminished quality of life, increased readmission rates ranging from between 6 months to a year following surgery, are also significant complications correlating to IA (Scheier et al. 1999). Other consequences which having been linked to IA include extreme postoperative pain, increased requirement of analgesic, sedation and anaesthetic demand, extended hospital visits, negative impact during anaesthetic administration, increased patient recovery time and reduced patient satisfaction (Cooke et al. 2005). Moreover, increased sedation requirements linked with IA are associated with increased rates of disorientation in elderly people (Wu et al. 2017). Sigdel (2015) similarly believes that increased patient anxiety during surgery can cause aggressive behaviour, hence instigating problematic pain management postoperatively.

RELEVANCE OF TREATING IA

Apart from the several complications associated with IA, there is an increasing prevalence of short stay and in-day surgeries (Howat et al. 2006). This, combined with the growing amount of surgical interventions performed under LA and/or RA (Mitchell 2009) suggests that intra-operative care for the anxious and conscious patient is an area that needs specific research, training and education (Weidmann & Grundy 2008). Additionally, IA is giving rise to patient preference for general anaesthesia (GA) over LA (Papanikolaou et al. 1994). This consequence is particularly concerning, as a number of investigations, such as that performed by Rerkasem et al. (2004) suggest that GA causes a number of biological disturbances and therefore has more serious risks than LA in terms of safety. Therefore, because of the aim of decreasing the number of patients who undergo GA, it is a growing feature of the theatre nurse and staff training should be that of caring for the conscious patient (Chit Ying et al. 2001). In summary, an overall rationale for reducing intraoperative patient anxiety includes the achievement of greater compliance, the decrease in risks for complications and the enhancement of surgical results (Cinem et al. 2020).

STANDARD CARE

The main interventions related to standard care in managing anxiety in the conscious patient intra-operatively, typically involve the use of anxiolytic drugs, large doses of anaesthetic, sedation, analgesic medication, and a comprehensive description of the procedure to the patient, together with informed consent (Johansson et al. 2005). Several types of sedative medications are commonly used to reduce emotional discomfort and anxiety during surgery, however, these drugs often cause adverse side effects including hypothermia, respiratory depression, lowered blood pressure and sometimes even unconsciousness (Bourin 2004).

Informed consent and formal discussion regarding prevalent misconceptions and fears the patient might have about the use of local or General Anaesthesia (GA) is a common procedure in controlling the patient's surgical anxiety (Rudolfsson et al. 2007). Thus patients are further educated about the safety and efficacy of the peri-operative drugs administered, including anxiolytic drugs (Academy of Royal Colleges 2013). With regards to the standard care approach of managing patient anxiety, several studies have shown that patient education and informed consent are among the most effective methods (Lee et al. 2003).

MUSIC THERAPY (MT) AND INTRA-OPERATIVE MUSIC THERAPY

In accordance with the American Music Therapy Association (2015) definition, MT is a form of complementary or alternative therapy in which an established health professional utilizes music within a therapeutic context to tackle specific needs of the patient, be it emotional, physical, cognitive and/or social. Complementary and alternative therapies refer to non-conventional forms of treatment which may be used alongside or instead of standard treatment respectively (National Health Service 2018). Music can aid as an emotional stimulus and hence, act as a cathartic outlet to the patient. It brings about the effect of enjoyment and positive distraction through the harmonisation of cardiovascular rhythms to attain a peaceful and relaxing sensation (Bernardi et al. 2009). Hence, this is why MT in the intra-operative setting has been suggested to aid in patient anxiety (Chit Ying et al. 2001).

Furthermore, other studies have displayed the decreese of sympathetic nervous activity by the synchronization of cardiovascular rhythms to the respective music being played (Knight & Rickard 2001). Subsequently, a reduction in adrenergic function and neuromuscular stimulation, as well as a modified state of consciousness is likely to follow. A decrease in blood pressure, metabolic rate, heart rate, respiratory rate, oxygen intake, skeletal muscle stiffness, stomach acidity, adrenaline levels, motility and sweat gland secretions are all indications of this relaxation reaction (Chlan 1998). Previous studies, such as one conducted by Yung et al. (2002) established a decrease in the intensity of anxiety, blood pressure and pulse when subjected to a MT intervention. Finally, MT presents simple and effective cost benefits with significant results of overall risk reduction and patient satisfaction (Hole et al. 2015).

EVIDENCE BASED PRACTICE AND ITS RELEVANCE IN PREVENTING COMPLICATIONS OF IA

Mckibbon (1998) has stated that Health Care Professionals (HCPs) often rely on their own knowledge, experience and advice from other colleagues when making

decisions which entail some form of uncertainty. However this may lead that incorrect or inadequate practices may be perpetuated, while new research findings, improvements, and new contraindications may be ignored. It is therefore vital to adopt an Evidence based practice (EBP) approachso that decisions and patient care is provided reliably and based on the best and latest available data (WHO 2017).

Hence, care of the conscious and anxious patient should be founded on EBP. This specific area of study is relatively new in comparison with other highly researched areas and thus, is constantly evolving and improving. Therefore, adopting an EBP approach is vital when dealing with this area, as newer and better data is frequently being published. More specifically, it is imperative that HCPs adopt this EBP process to ensure that all possible measures and methods in controlling IA are exhausted in order to prevent severe related complications (Melnyk et al. 2014). One of the treatments currently being examined in the field of intra-operative care is the influence of music on the prevention of IA. Hence this paper examines the question: *Does intraoperative music alleviate anxiety in adults undergoing local anaesthetic surgical interventions?* The answer to this question should enable HCPs to provide the most effective, efficient and safe care to patients experiencing IA.

AIM OF THE LITERATURE REVIEW

The principal aim of this study is to determine whether intra-operative MT is effective in the prevention or reduction of IA in adult patients undergoing local anaesthetic interventions by answering the proposed question and researching relevant literature using an EBP approach.

Papers were identified which offered either intra-operative music therapy or no intra-operative music therapy was offered to Adults aged 18-80 who were undergoing a local anaesthetic intervention. The outcome to be measured is the Anxiolytic effects of the intra-operative music therapy

SEARCH STRATEGY

A thorough and systematic search for literature was carried out to determine and identify studies which are most relevant in attempting to answer research question.

Appropriate databases were selected, identification of keywords/terms, creating combinations of these keywords/terms through the use of numerous search tools and running these combinations through appropriate databases. (Cooper et al. 2018). The established key words were; local anaesthetic surgery (population), intraoperative music therapy (IMT) (intervention), standard care (comparison) and anxiolytic effects (outcome). Appropriate Keyword combinations were also searched, using link words such as 'and' and 'or'.

The databases used are Academic search complete, CINAHL Plus with Full Text, Cochrane Central register of Controlled Trials, Cochrane Database of Systematic Reviews, Cochrane Methodology Register, MEDLINE Complete /Pubmed, APA PsycINFO and Science Direct.

SELECTION AND SCREENING OF STUDIES

Studies were selected using the 'Preferred Reporting Items for Systematic Reviews and Meta-Analyses' (PRISMA) (Moher 2009) criteria. This checklist serves as a screening model to enhance reporting for researchers conducting systematic reviews and meta-analyses. Initially, duplicates were scanned for and removed. Previously applied limiters served to automatically exclude irrelevant articles. In accordance with the PRISMA framework, article eligibility was determined primarily by reading the title and discarding those which deemed irrelevant. Subsequently, remaining article abstracts were examined for relevance with respect to the elements under study. A total of forty two relevant studies remained. Table 1 illustrates this primary selection process.

When selecting the studies it was important that the outcome measures were comparable. The outcome measure to be compared was a psychological measure of anxiety. One study, Guerrier et al. (2020) was rejected from the study because the main outcome measure was change in Blood Pressure (Guerrier 2020).

Equally, the aim of the review was to measure change in intra-operative anxiety. A very informative meta-analysis, Hole et al. (2015), was rejected because it measured recovery rather than intra-operative anxiety (Hole et al. 2015).

Full text articles were selected and further inclusion/exclusion criteria were applied in order to determine the key studies needed for subsequent appraisal. These criteria's are described below (Table 2).

Table 1. Initial Screening Process for Each Database Search

Database	Hits obtained	Hits following removal of duplicates	Relevant studies from screening title/abstract
EBSCO	302	167	29
PubMed	95	64	10
ScienceDirect	26	16	3
	423	247	42

Table 2. Summary of eligibility criteria for literature selection

Criteria	Inclusion	Exclusion
Population	Adults aged 18 to 80 years old.	Participants below the age of 18 or over the age of 80.
Intervention	Adults undergoing local/regional anaesthetic surgery.	Adults undergoing general anaesthetic surgery or requiring sedation.
	Patients giving informed consent.	Patients with auditory, sensory and cognitive impairment, any form of psychiatric disorder and/or developmental disability.
	Exposure of intraoperative music therapy	Investigations excluding MT as an intervention.
	Any form of recorded music chosen by the patient or the investigator through any output device.	Pre- or post- operative MT intervention.
		Studies investigating sound therapy without the incorporation of music.
		Live music performed by musicians.
Comparison	Control group receiving intraoperative standard care.	Other anxiolytic interventions as a comparison (no control group).
Outcome	Measurable anxiety levels as primary outcome.	Studies reporting anxiety levels as secondary outcomes or not reporting them at all.
Study design	Meta-analysis, systematic reviews, randomised controlled trials and observational studies that may include cross sectional, cohort and case control studies.	Case Reports, Ideas, Case Series Studies, Opinions, Editorials, In vitro research and Animal research."

- Population of interest was limited to adults between the ages of eighteen and eighty years old undergoing conscious surgery under local/regional anaesthesia. Any studies focusing on participants under the age of eighteen or over the age of eighty were excluded together with participants undergoing non-invasive surgery and/or under general anaesthesia or sedation. Furthermore, patients with auditory, sensory and cognitive impairment, any form of psychiatric disorder altering mental status and/or developmental disability were excluded on the basis of predisposed reduction in intervention efficacy is a great possibility. Finally, all participants must have given informed consent to participate and provide necessary relevant information in the investigation.
- The intervention under investigation included the exposure of MT to patients undergoing the intra-operative phase of surgery through any form of output device. Recorded music could be chosen by the patient or the investigator. Exclusion criteria comprised of any investigations excluding MT as an intervention. Similarly, any studies focusing on sound therapy such as nature sounds, deprived of the incorporation of music, were excluded. Furthermore, the incorporation of live music by musicians was excluded on the principle that additional individuals could potentially contribute to a confounding variable and alter the outcomes being investigated. Finally, any studies not investigating the intervention during the intra-operative phase were excluded.
- This review seeks to compare the population, intervention and outcome of interest with a control group receiving intra-operative standard care when undergoing local/regional anaesthetic surgery. Exclusion criteria included any studies disregarding a standard care control group and alternatively, using other anxiolytic interventions as a comparison.
- The fundamental outcome of this review is to analyse and measuring anxiety levels in patients subject to MT in comparison to patients not receiving MT. Any studies reporting anxiety levels as secondary outcomes or not reporting anxiety levels at all were excluded.
- Meta-analysis and systematic reviews of randomised controlled trials and observational studies that may include cross sectional, cohort, case control studies and randomised controlled trials were incorporated in the search. These study types were selected as they answer the question best since participants are observed in their natural setting.

Following the application of the inclusion/exclusion criteria, five key studies were selected. These consisted of five randomized control trials (Figure 2).

The five key studies selected for appraisal were categorized according to their study design (Table 3).

OVERVIEW OF KEY RANDOMISED CONTROLLED TRIALS

Five RCT's were chosen as the key studies to be appraised in this review (refer to table 3). All studies adopted a parallel approach however, three of the RCT's involved two study arms (Jiménez-Jiménez et al. 2013; Kavakli et al. 2019, Cimen et al. 2020) and the remaining two RCT's incorporated three study arms (Alam et al. 2016, Palmer et al. 2015). Kavakli et al. (2019) and Palmer et al. (2015) adopted a multi-centre approach

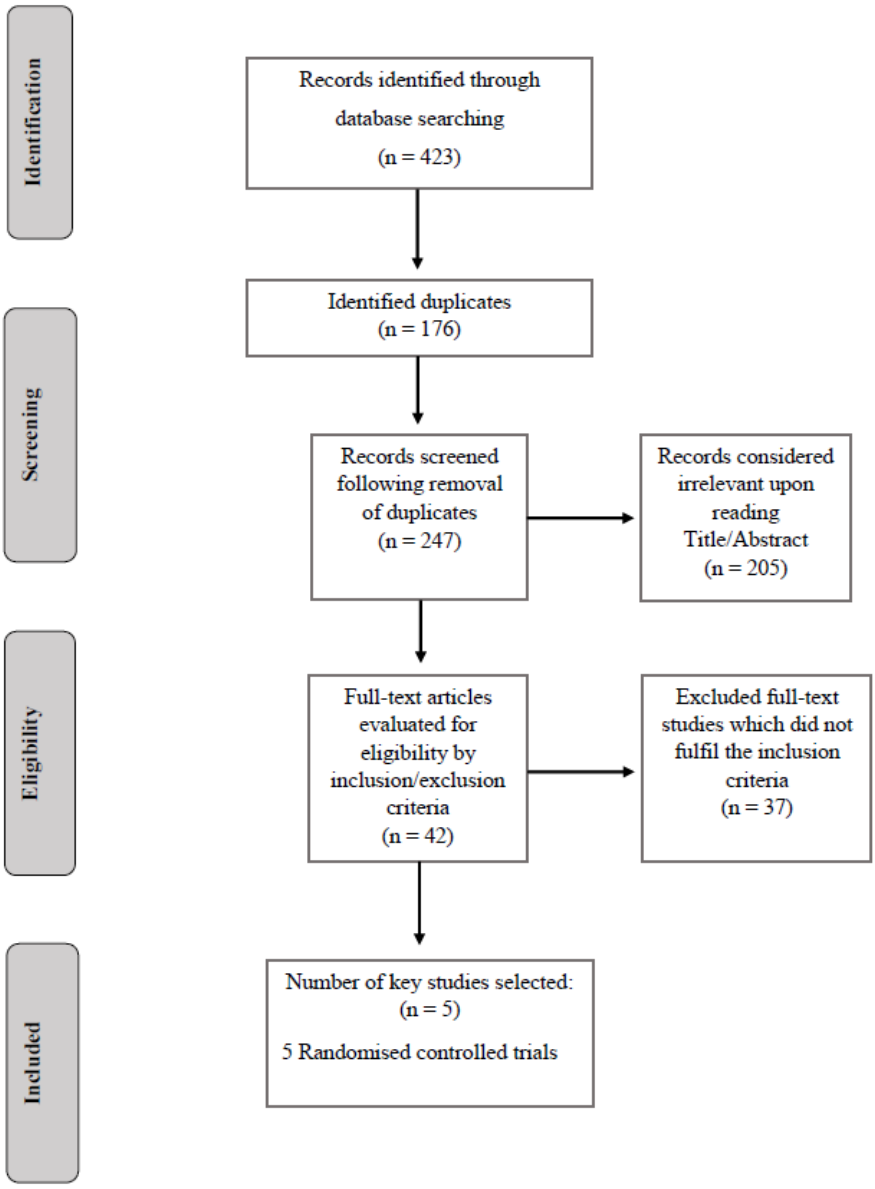

Figure 2. PRISMA 2009 Flow Diagram Depicting Literature Search Process (Moher 2009)

Table 3. Specifics of the key studies selected for this literature review

Study Design	Author/s and Publication Date	Title
Randomised Controlled Trial	Jiménez-Jiménez, García-Escalona, Martín- López, De Vera-Vera & De Haro (2013)	Intraoperative stress and anxiety reduction with music therapy: A controlled randomized clinical trial of efficacy and safety
Randomised Controlled Trial	Kavakli, Ozturk, Adas, Kudsioglu, Ayoglu, Özmen, Sagdic & Yapici (2019)	The effects of music on anxiety and pain in patients during carotid endarterectomy under regional anesthesia: A randomized controlled trial
Randomised Controlled Trial	Alam, Roongpisuthipong, Kim, Goyal, Swary, Brindise, Iyengar, Pace, West, Polavarapu & Yoo (2016)	Utility of recorded guided imagery and relaxing music in reducing patient pain and anxiety, and surgeon anxiety, during cutaneous surgical procedures: A single-blinded randomized controlled trial
Randomised Controlled Trial	Cimen, Oğuz, Gundogmus, Cimen, Sandikci, & Ayli (2020)	Listening to music during arteriovenous fistula surgery alleviates anxiety: A randomized single-blind clinical trial
Randomised Controlled Trial	Palmer, Lane, Mayo, Schluchter & Leeming (2015)	Effects of Music Therapy on Anesthesia Requirements and Anxiety in Women Undergoing Ambulatory Breast Surgery for Cancer Diagnosis and Treatment: A Randomized Controlled Trial

whilst the remaining three studies carried out their trials in one centre. The geographical locations of the RCT's being conducted at include Madrid, Spain (Jiménez-Jiménez et al. 2013), Ohio and Chicago, USA (Palmer et al. 2015, Alam et al. 2016) respectively and Turkey (Kavakli et al. 2019, Cimen et al. 2020). Similarity in intervention duration was shared between studies as the minimum and maximum time span ranged from 44 minutes (Cimen et al. 2020) to an hour (Jiménez-Jiménez et al. 2013, Kavakli et al. 2019, Alam et al. 2016). Palmer et al. (2015) did not include information about the intervention duration. Follow-up assessments of intervention outcome were conducted in all five RCT's as a post-operative investigation. The follow-up period was considerably small as this was done immediately after exposure of the intervention, that being the end of the intraoperative phase, denoting to the immediate post-operative period. The maximum length of the follow-up interval from the end of surgery to the post-operative assessment was that of 10 minutes (Jiménez-Jiménez et al. 2013), whilst a 5 minute interval was specified by Palmer et al. (2015). The remaining three studies performed an immediate follow-up assessment without specifying the exact interval time frame.

The total number of participants in all five RCT's amounted to n=533. Participant age ranged from 18 to 80 years old and were all asked to give informed consent to be able to participate in the investigation and comply with protocol, as specified in the inclusion and exclusion criteria described in chapter 2. All studies included both gender samples except for Palmer et al. (2015) who investigated females only. Additional specific inclusion criteria pertaining to the study population of each RCT included; participants undergoing crossectomy with stripping of the great saphenous vein surgery under regional intradural anaesthesia without sedation (Jiménez-Jiménez et al. 2013), patients undergoing carotid endarterectomy under regional cervical plexus block (Kavakli et al. 2019), patients awaiting basal or cutaneous squamous cell carcinoma excision surgery, also known as Mohs micrographic surgery (Alam et al. 2016), patients scheduled for fistula surgery (Cimen et al. 2020) and English-speaking women undergoing ambulatory breast cancer surgery for diagnosis and/or treatment with an American Society of Anesthesiologists (ASA) physical status classification of I-III (Palmer et al. 2015). Similarly, additional exclusion criteria involved participants receiving treatment with chronic analgesia (Cimen et al. 2020, Palmer et al. 2015), patients with a contraindication or refusal to being administered local or regional anaesthetic (Cimen et al. 2020, Kvakli et al. 2019) and participants who had previously undergone fistula creation surgery (Cimen et al. 2020). Each intervention involved the exposure of recorded intra-operative music through earphones/headphones. The only present variances were those related to choice of music. Jiménez-Jiménez et al. (2013) and Alam et al. (2016) had pre-prepared standardized music selected by the investigator whereas Kavakli et al. (2019), Cimen et al. (2020) and Palmer et al. (2015) allowed for preoperative patient selection of music. Palmer et al. (2015) took a step further and involved a professional music therapist in the selection of music by the patient preoperatively. All five studies included a control group which acted as a comparison and received standard intra-operative care particular to each respective surgery without any exposure to MT. Every other procedural aspect remained unchanged. However, Alam et al. (2016) and Palmer et al. (2015) added extra intervention groups which were exposed to guided imagery and live music respectively. These interventions are not of interest to this review. The mutual outcome of interest in all studies was the patient's anxiety level during surgery. This was measured and calculated using primarily the State-Trait Anxiety Inventory (STAI) scale in four studies and the Global Anxiety-Visual Analog Scale (GA-VAS) in the study by Palmer et al. (2015). These readings were taken before and after surgery, resulting in the differential postoperative to preoperative anxiety levels equalling to intraoperative anxiety levels and ultimately, intervention effectiveness. Kavakli et al., 2019 took additional readings at five minute intervals during the surgery Additional forms of assessments conducted by three studies included a questionnaire pre- and post-operatively (Jiménez-Jiménez et al. 2013), measurement taking of bio-physiological vital signs at five minute intervals during the surgery and pre-and post-operatively (Jiménez-Jiménez et al. 2013, Alam et al. 2016) respectively, blood taking pre- and post-operatively to test for catecholamine levels in blood plasma (Jiménez-Jiménez et al. 2013) and a Numerical Rating Scale (NRS) of intraoperative anxiety of patients postoperatively.

Regarding randomisation, four out of the five RCT's used an online computer based programme to automatically randomize individuals into study groups. Jiménez-Jiménez et al. (2013) took a step further and applied a restrictive 4-individual block randomisation corresponding to genre to ensure equal number of participants in each study group, homogeneity in distribution of genes and reduce temporal biases. Alam et al. (2016) was the only study which incorporated distance randomisation by having a separate investigator to those responsible for enrolling and assigning participants to groups, generate a randomised allocation sequence. Alam et al. (2016) did indeed practice allocation concealment, however, it was not specified whether allocation assignment was revealed until after the investigation was complete. All five RCT's found no significant differences in baseline demographic data between study groups,hence increasing internal validity of the studies. Commonly listed demographic characteristics within the five studies included age, gender, education level, marital status, weight, height, body mass index and co-morbidities. However, Alam et al. (2016) was noted to have included very little baseline demographic data of randomized subjects, having included only their age, gender and the duration of the cutaneous surgical procedure.

Table 4. Characteristics of chosen Randomised Controlled Trials

Author (Year)	*Jiménez-Jiménez et al. (2013)*	*Kavakli et al. (2019)*	*Alam et al. (2016)*	*Cimen et al. (2020)*	*Palmer et al. (2015)*
Study Design	2 Arm Parallel Design	2 Arm Parallel Design	3 Arm Parallel Design	2 Arm Parallel Design	3 Arm Parallel Design
Randomisation	Computer-generated stratified random sample	Computer-generated simple random sample	Simple random sample randomised by an investigator	Computer-generated simple random sample	Computer-generated simple random sample
Blinding	Single-blinded trial. Investigators and outcome assessors were blinded but participants were informed as to which group they were assigned to.	Single-blinded trial. Investigators and outcome assessors were blinded but participants were informed as to which group they were assigned to.	Single-blinded trial. Investigators and outcome assessors were blinded but participants were informed as to which group they were assigned to.	Single-blinded trial. Investigators and outcome assessors were blinded but participants were informed as to which group they were assigned to.	Single-blinded trial. Investigators were blinded but participants were informed as to which group they were assigned to. No information was given regarding blinding of the outcome assessor.
Sample Size	40 participants	70 participants	187 participants	55 participants	207 participants
Duration of Study	About an hour	About an hour	About an hour	About 45 minutes	About an hour
Attrition rates	16%	7.8%	17%	25%	2.9%
Population characteristics					
Inclusion:	Men and women of 18 to years of age; given informed consent to participate in the study; undergoing crossectomy with stripping of the great saphenous vein performed under regional (intradural) anaesthesia without sedation.	Individuals undergoing carotid endarterectomy.	Adults awaiting basal or cutaneous squamous cell carcinoma excisional surgery of the face; able to comply with trial procedure.	Individuals aged 18 or older scheduled to undergo fistula surgery; able to sign informed consent form.	Females who were English-speaking; 18 years of age or older; ASA classification of I-III; undergoing ambulatory breast cancer surgery for diagnosis and/or treatment.
Exclusion:	Individuals with sensory disabilities, specifically of the auditory type; psychiatric acute or chronic conditions; altered cognitive status and mental impairment.	Individuals who are unable to communicate or understand study objectives and sign informed consent; Individuals with a contra-indication, refusal or hypersensitivity to the LA.	Individuals with any known mental health illness.	Individuals with any known psychiatric illness; hearing impairment; on long-term analgesics; previous fistula creation surgery.	Females with distinct psychiatric conditions, developmental disabilities or substantial hearing impairment.

Table 4. Continues

Author (Year)	*Jiménez-Jiménez et al. (2013)*	*Kavakli et al. (2019)*	*Alam et al. (2016)*	*Cimen et al. (2020)*	*Palmer et al. (2015)*
Study Design	2 Arm Parallel Design	2 Arm Parallel Design	3 Arm Parallel Design	2 Arm Parallel Design	3 Arm Parallel Design
Interventions Studied	Exposure of recorded intraoperative music on conscious patients undergoing crossectomy with stripping of the great saphenous vein performed under regional anaesthesia.	Exposure of recorded intraoperative music on conscious patients undergoing carotid endarterectomy under regional anaesthesia.	Exposure of recorded intraoperative guided imagery and soothing music on conscious patients undergoing cutaneous squamous cell carcinoma excisional surgery of the face under local anaesthesia.	Exposure of intraoperative recorded music on conscious patients undergoing fistula surgery under local anaesthesia.	Exposure of intraoperative recorded and live music on conscious females undergoing ambulatory breast cancer surgery for diagnosis/treatment.
Comparison	Standard intraoperative care during crossectomy surgery with stripping of the great saphenous vein.	Standard intraoperative care during carotid endarterectomy surgery.	Comparison between the two active interventions being studied against standard intraoperative care during Mohs micrographic surgery.	Standard intraoperative care during fistula creation surgery.	Comparison between the two active interventions being studied against standard intraoperative care during ambulatory breast cancer surgery for diagnosis/ treatment.
Outcomes of interest	Primary outcome measured was anxiety levels in participants post intervention by using the STAI scale, questionnaire and a visual-analogical scale of anxiety pre- and post-operatively and calculating the mean difference. Vital sign readings were also taking intraoperatively at 5 minute intervals. Blood was taken pre- and post-operatively to test for catecholamine levels. Secondary investigated outcome included the feeling of stress.	Primary outcomes measured were anxiety and pain levels in participants post intervention by using the STAI scale for anxiety pre- and post-operatively, calculating the mean difference. A visual analog scale was used to assess pain during the intraoperative period.	Primary outcomes measured were anxiety and pain levels in participants post intervention by the use of the STAI scale and visual analog scale pre-and post-operatively for anxiety and the visual analog scale solely for pain. Mean difference was calculated.	Primary outcomes measured were anxiety and pain levels in participants post intervention by using the STAI scale for anxiety pre- and post-operatively and calculating the mean difference.	Primary outcomes measured were anxiety and anaesthesia requirements in female participants post intervention by using the GA-VAS pre- and post-operatively, calculating the mean difference. Anaesthetic requirement was measured using the Bispectral Index.

Four out of five of the RCT's adopted a single-blinded approach due to the nature of the intervention design. However, contrary to the more common form of a single-blinded approach, each of these four studies blinded the outcome assessors and investigator/researcher assigned to specific tasks such as interviewing and assessing the participants before and after the intervention, handling the proper intervention equipment, recording related vital signs of the participants and allocating the participants to their respective study group, rather than blinding the participants. Although the respective investigators are exposed to information related to their assigned task, they are kept separate from other investigators and their respective trial information. The blinding of outcome assessors reduces the risk of detection bias significantly by avoiding the distortion of assessment due to information regarding participant intervention (Higgins et al. 2019). Kavakli et al. (2019) and Cimen et al. (2020) took an additional step further in instructing participants to avoid commenting about the intervention by a non-blinded investigator and assigning a blinded researcher to assist participants unable in filling out the appropriate assessment questionnaire respectively. Due to the intervention designs, it was not possible for the participants to be blinded from the type of intervention assigned due to ethical considerations and informed consent. Therefore, a double-blinded study was not possible for each RCT. On the other hand, Palmer et al. (2015) used a block randomisation scheme with random blocks to ensure that investigators could not guess the next assignment. No information was given regarding blinding of the outcome assessor.

Based on effect sizes of previous studies, two of the RCT's calculated sample size and selected an 80% statistical power, being a conventional percentage (Jiménez-Jiménez et al. 2013, Palmer et al. 2015). Kavakli et al. (2019) calculated a statistical power of 95% whilst Alam et al. (2016) and Cimen et al. (2020) gave no information regarding statistical power.

In this review, four out of five RCT's were acceptable with respect to attrition rates (16%; 7.8%; 17%, 2.9%) (Jiménez-Jiménez et al. 2013, Kavakli et al. 2019, Alam et al. 2016, Palmer et al. 2015). Cimen et al. (2020) displayed an attrition rate of 25%, which is deemed too high. Apart from mentioning reasons for attrition, two of the five studies (Kavakli et al. 2019; Palmer et al. 2015) illustrated attrition rates by using the CONSORT (Consolidated Standards of Reporting Trials) flowchart (Moher et al. 2010). Cimen et al. (2020) did make reference to the CONSORT diagram for attrition rates but failed to illustrate this by means of a diagram. Jiménez-Jiménez et al. (2013) and Alam et al. (2016) did not mention any reference made to the CONSORT diagram, however, reasons for attrition were mentioned. Common reasons for attrition amongst these RCT's included denial of individuals to participate, withdrawal from trial, non-compliance with study protocol, conversion from LA to GA or administration of sedation during surgery, participant tardiness to scheduled surgery, no pre-testing given, incomplete questionnaires and errors during assessment for intervention efficacy. Investigators are advised to continually make efforts to reduce dropout rates (Kearney et al. 2017). Retention strategies were not reported by any of the studies, however, Kavakli et al. (2019) anticipated a dropout rate of 20-25% and therefore, over-recruited for compensation. In all five RCT's, dropout rate was similar across the intervention and control groups and hence, group attrition was comparable.

All five studies included intention to treat (ITT) analysis in their findings, assuring that the advantages of randomisation were maintained.

Participants who were involved in all five RCTs had all signed written consent forms prior to study enrolment. The studied had all been deemed ethical by all the health care facilities and ethical committees. All five research studies ensured that all personal data regarding the participants were kept confidential by the researchers (Table 4).

RESULTS OF THE RANDOMISED CONTROLLED TRIALS

All five of the RCT's measured, reported and illustrated results for in-between group variances of anxiety levels. The least detailed report included that of Alam et al. (2016) in which mean difference (MD) in post- to pre- intervention results is the only form of outcome reported, excluding p values, confidence intervals (CI) and standard deviation (SD). Furthermore, Alam et al. (2016) did not present within-group results. These results will be analysed and discussed further on. One standard definite result was not obtained on evaluation of results from all five studies. On the contrary, a mix of results was noted to have been produced between studies ranging from statistically significant positive intervention effect to a statistically significant negative intervention effect. In this subsection, statistical significance levels for each study will be identified, presented and discussed.

Each RCT evaluated and calculated significant differences in group levels by means of collection of data pre- and post-operatively. The baseline data for each study is represented by the pre-operative anxiety levels whilst the post-intervention/follow-up data is represented by the post-operative anxiety levels. All baseline and follow-up data was recorded pre- and post-operatively but exact time frame was not specified by all studies. Intervention effect levels were obtained by calculating the mean difference between the post- and pre-operative anxiety level values, that is, the mean follow-up subtracted by the mean baseline data. However, some studies were more detailed than others in reporting these values. Two out of five RCT's reported a statistically significant result in comparison between anxiety levels in the intervention and control groups. These statistically signifi-

cant intervention results were found in the studies conducted by Cimen et al. (2020) and Jiménez-Jiménez et al. (2013). The study conducted by Cimen et al. (2020) included p values, MD and CI amongst all results reported whilst Jiménez-Jiménez et al. (2013) reported p values and MD without any mention of CI. In this particular study by Cimen et al. (2020), anxiety levels were reported primarily by using the STAI scale for anxiety pre- and post-operatively. Secondary anxiety levels were reported by means of haemodynamic measurement of blood pressure and heart rate pre- and post-operatively. Peripheral oxygen saturation and respiratory rate were also measured pre- and post-operatively, however, these results do not reflect anxiety levels as much as the haemodynamic measurements of blood pressure and heart rate do. Results for this study show a statistically significant decrease in anxiety levels with a MD of -12 points and standard deviation (SD) of (-32.0 to -2.0) when undertaking the STAI test. The scoring system works in relation to the anxiety levels by means of direct proportion, meaning that smaller number of points from the STAI test correlate with a lower level of anxiety respectively and vice-versa. Cimen et al. (2020) did not include CI, however, p values resulted in a numerical value of < 0.001 for anxiety levels, blood pressure and heart rate, hence, presenting a decrease in anxiety and ultimately claiming statistically significant intervention values. Similarly, the study conducted by Jiménez-Jiménez et al. (2013), includes MD and p values. In comparison with Cimen et al. (2020), Jiménez-Jiménez et al. (2013) had a lower statistically significant treatment effect however, is still considered statistically significant. This particular study reported results for MD and p values but not for CI. Statistical methods used for testing included haemodynamic measurements for heart rate and blood pressure, the STAI survey and catecholamine levels from blood taking pre- and post-operatively. The presented results did not show a statistical significance for difference in haemodynamic parameters pre- and post-operatively having a MD heart rate and blood pressure gradient of -12.5 and -13.8 and a p value of 0.71 and 0.65 respectively. On the other hand, adrenaline and noradrenaline showed statistically significant results with a MD of +113.7 and +77.2 with p values of 0.02 and 0.03 respectively. The overall resulting value revealed a 94.7% control of intraoperative anxiety in the MT group in comparison with a 57.9% control of intra-operative anxiety within the control group, resulting in an overall p value of 0.03 for control of intra-operative anxiety. These results suggest an overall statistically significant decrease in intra-operative anxiety.

In contrast, the studies conducted by Palmer et al. (2015) and Alam et al. (2016) presented insignificant and ambiguous findings. Palmer et al. (2015) revealed in their study that the intervention group did not statistically differ significantly to that of the control group, while Alam et al. (2016) presented fairly ambiguous and poorly detailed findings, suggesting no statistically significant difference between the intervention and control group. The data provided by Palmer et al. (2015) was that of a CI, MD, MD in comparison with the control group and effect size (ES). The tests used in achieving these results included a self-assessed rating to the GA-VAS pre- and post-operatively. Findings to these assessments revealed a MD of -26.7(-33.8 to -21.2) after intervention and a MD of -25.7 in comparison to the control group post-treatment with a high CI of 95%. Most importantly, effect size resulted in a value of -0.55, rendering the intervention effect to be of moderate statistical significance. With regards to the study conducted by Alam et al. (2016), an insignificant statistical difference resulted in the intervention effect group, compared to the control group. Statistical findings were only presented by a MD calculated by a T-test without any reference to p values, ES or CI. The mode of assessment for the MD was performed by the STAI survey and a score of 9.94 points was given with a MD of 0.33 from post- to pre-intervention exposure. The control group presented a result of 9.63 points with a MD of 0.38 from post-to pre-treatment exposure. Although p values and/or a comparison calculation between the MD of intervention group and the MD of the study group was not presented, the study has qualitatively claimed that no statistically insignificant differences with respect to intervention effect. Hence, claiming music therapy not significant to reducing intra-operative anxiety.

The study conducted by Kavakli et al. (2019) presented results that were not only statistically not significant, but rather produced a negative outcome. This study proposed that intra-operative music not only deemed insignificant in reducing intra-operative anxiety, but fairly increased overall intra-operative anxiety in patients assigned to the intervention group, resulting in an unwanted and unexpected counter effect. This study provided quantitative values for CI, MD and p values. The statistical tests performed to acquire these values were by means of a STAI survey pre- and post-operatively together with a NRS for intra-operative anxiety post-operatively and a set of two questions asked to the participants related to feelings of anxiety at 5 minute intervals intra-operatively. Compared to pre-operative baseline data, with a 95% CI, a MD of -0.2 (-2.7 to 2.2) and p value of 0.839 was produced for the post-operative follow-up score regarding intra-operative anxiety on assessment using the STAI survey. The NRS score for intra-operative anxiety resulted in a MD of 2.0 (1.1 to 2.8) and a p value of 0.001. Similarly, the two sets of questions asked intra-operatively resulted in a MD of -0.8 (-1 to -0.6) and -0.7 (-0.9 to -0.5) and a p value of 0.0001 and 0.0001 respectively. Although the p values for NRS score and for the 2 sets of questions resulted in a statistically significant difference, the value for insignificance in the STAI scores outweighs the overall significance to a greatly insignificant statistical value, represented by an increase in intra-operative anxiety on the patients subjected to intra-operative MT (Table 5).

Table 5. Randomised Controlled Trial Results

A&D	Int. Per.	ATP	MD int. g.	MD cont. g.	Overall MD	Stat. Sign.
Jiménez-Jiménez et al. (2013)	Intra-operative Period	20 minutes pre-operatively and within 10 minutes post-operatively	-94.7%	-57.9%	N/A	*P=0.003*
Kavakli et al. (2019)	Intra-operative Period	Pre- and post-operatively; exact time frame not specified. Intraoperatively at 5 minute intervals	N/A	N/A	-0.2 (STAI Score); 2.0 (NRS score); -0.8 (1st question set); -0.7 (2nd question set)	P=0.839 (STAI) P=0.001 (NRS) P=0.001 (Both question sets)
Alam et al. (2016)	Intra-operative Period	Pre- and post-operatively; exact time frame not specified	0.33 (STAI score)	0.38 (STAI score)	N/A	N/A
Cimen et al. (2020)	Intra-operative Period	Pre- and post-operatively; exact time frame not specified	-12.0 (STAI score)	5.0 (STAI score)	N/A	*P=<0.001*
Palmer at al. (2015)	Intra-operative Period	5 minutes pre-operatively and within 5 minutes post-operatively	-26.7 (GA-VAS score with 95% CI)	-1.0 (GA-VAS score with 95% CI)	-25.7	ES = -0.55

Legend: A&D - Author and Date; Int. Per. - Intervention Period; ATP - Assessment Time Point (Baseline data follow-up data collection); MD int. g. - MD from baseline data to follow-up assessment in intervention group; MD cont. g. - MD from baseline data to follow-up assessment in control group; Overall MD - Overall MD (95% CI) (Intervention group compared with control group); Stat. Sign. - Statistical Significance

EVALUATION OF THE OVERALL EVIDENCE STRENGTH

This literature review has brought the certain issues related to the topic of interest to light. More specifically, this process has revealed that intraoperative music therapy is not a individually implemented intervention, but rather an intervention shared in a larger spectrum of alternative/complementary therapy interventions. Outcomes of interest are also particularly difficult to separate. In a majority of the evaluated studies discovered during the systematic search, most studies that focused on an intervention targeted to alleviate anxiety were accompanied with other outcomes of interest, most commonly pain reduction and analgesic requirements. This resulted in a large quantity of findings based on heterogeneous treatments and outcomes, meaning that the effect of intraoperative music therapy on the alleviation of anxiety could not be measured alone. Finally, synthesis of studies that focused on the intraoperative phase alone, without incorporating periods from the pre- and post- operative period were particularly difficult to discover.

All RCTs demonstrated relatively adequate methodologies. Main systematic limitations included a lack of blinding of the outcome assessor in the RCT conducted by Palmer et al. (2015), relatively small sample sizes in three of the RCTs (Jiménez-Jiménez et al. 2013, Kavakli et al. 2019, Cimen et al. 2020), high attrition rate in the trial by Cimen et al. (2020) and poor statistical analysis provided by Alam et al. (2016) regarding demographic, baseline and follow-up intervention outcome results, making results difficult to interpret. Furthermore, exact statistical significance was not mentioned anywhere in this study. The interventions of interest applied in the RCTs were quite homogenous overall, relating in terms of intervention delivery, methods used to assess intervention effect and statistical significance, duration of intervention, randomisation (excluding Alam et al., 2016), blinding, attrition rates (excluding Cimen et al. 2020) and application of ITT.

However, despite general homogeneity between studies, a mixture of dissimilar results was obtained, with two studies reaching statistical significance whilst the remaining three failing to do so. These findings suggest that music might be a subjective therapy that does not satisfy every individual and might need to be personalised to meet every individual's preference, as suggested by Kavakli et al. (2019). Furthermore, a number of study limitations could have contributed to certain insignificant intervention results. The lack of double-blinding could be one of these limitations, since the nature of the trials do not possibly allow blinding of the participants being assigned to their respective study group. Furthermore, trials which included questionnaires as an assessment of intervention efficacy could have been answered with some probable bias due to a possible placebo effect. Another possible limitation is that the trials were void of essential information regarding the priority and interest of music in the participant's daily lives. Hence, the possibility of recognising a trend between likeability of music in participants and a greater intervention efficacy was inaccessible. Moreover, trials which did not incorporate the possibility of participant selection of preferred music choice may have reduced the statistical significance of the intervention effect (Jiménez-Jiménez et al., 2013; Alam et al. 2016). A more common limitation may be the single-centre application of the trials, excluding cohorts of different cultural, geographical, socioeconomic, religious and various other site-specific variations. Moreover, the

lack of an attention group in all five trials could be a possible limitation since respective results could not be determined whether they were caused by the presence of caring or uncaring healthcare personnel. Finally, a lack of trial reminders and continual emphasis on the importance of participation in the trials could have resulted in some of higher attrition rates, adding to the various limitations.

Judging the evidence synthesised in this review, some presumptions can be made regarding the effectiveness of intraoperative music therapy as an intervention. It is visible that music therapy is part of a broader spectrum of alternative/complementary therapies. These therapies are certainly subjective, and music therapy is no less. Therefore, judged by the synthesised evidence, the deduction regarding efficacy of music therapy as a personalised intervention can be made. Evidence of higher intervention efficacy in participants able to choose their preferred music during surgery is strong.

Overall, this review has presented tentative findings in support of intraoperative music therapy as a possible intervention for the alleviation of anxiety in patients undergoing local anaesthetic interventions. Although the results are fairly inconclusive, this review should have provided a rationale for further future research in this area. Ultimately, with the provided evidence, an answer to the research question of interest is limited and vague. Future studies should wish to research this area of study more, to possibly be able to find significant evidence that could answer this question directly.

RECOMMENDATIONS FOR FURTHER RESEARCH

Based on the findings of this studies included in this literature review, a promising compilation of evidence has supported the use intra-operative MT in relation to the alleviation of anxiety. From the analysis of this review, a number of main limitations have been identified as possible contributing factors to the reduction in statistical significance across studies. The prominent limitations identified were those of a lack of blinding of the outcome assessor, relatively small sample sized, high attrition rates and poor statistical analysis regarding demographic, baseline and follow-up intervention outcome results, rendering a difficulty in interpreting of results. Furthermore, included questionnaires as an assessment of intervention could have introduced a form of bias due to placebo effect. An essential possible limitation in some of these trials had to do with a lack of choice in individual participant selected music. Moreover, trials were deprived of vital information regarding the individual participant's interest and involvement of music in his/her daily life, leaving room for error in patient satisfaction. Finally a lack of multicentre investigation, attention group and reminders to the participants about the study create a possibly noticeable degree of added error. Therefore, based on these findings, the author's recommendations for further research are as follows; adequate methodological principles should always be applied when conducting research. With particular reference to this review, attention should be given to suitable blinding of investigators and assessors. Possible ways of blinding participants could be considered as a great risk of bias is prone to occur when subjective assessments such as the STAI survey is being used. Further attention should be given to conducting trials with larger sample sizes and in various centres as this could significantly increase accuracy amongst findings. Moreover, investigators should always make efforts to reduce attrition rates as much as possible as the unequal of confounding variables amongst study groups could highly alter the results. A possible recommendation is sending out frequent reminders prior to the study date in order to remind participants about the investigation and emphasise the importance of their adherence to participating. Consequently, any values of attrition should be documented and analysed for confounding variable at the end of the investigation. This should always be backed up by detailed and proper use of statistical testing and compiling of results, always ensuring that demographic characteristics are being taken into consideration. This recommendation is particularly important in research having to do with intra-operative MT as individual participant involvement in patient satisfaction is a significantly visible correlation. A participant who is fond of music might have been more satisfied with the intervention compared to a participant who does not care much for music. Furthermore, participants should be allowed to make pick their own music of preference as this is also highly subjective.

RECOMMENDATIONS FOR PRACTICE

If further adequate research on the subject manner is conducted and more significant findings are published, the health care system should not be deprived of such an inexpensive and possibly effective intervention in controlling the conscious patient's anxiety during surgery. The implementation of MT among surgical theatre working healthcare professionals should be implemented with a systematically organized manner holding specific protocol for patients who wish to be subjected to this type of intervention. Delegated personnel could be responsible for organizing this specific task, ensuring patient and surgical team satisfaction. Even though patients should be given the choice to select their preferred choice of music, delegated personnel should still suggest any choices music which have shown beneficial outcomes when listened to during surgery.

RECOMMENDATIONS FOR MANAGEMENT

With regards to patients, it has been established that the implementation of music could be a significantly beneficial intervention in reducing surgical anxiety. However, this same intervention should be studied on the healthcare team managing surgical intervention. Patient satisfaction should not compromise healthcare worker contentment. Therefore, with the same principle being applied to patients, the surgical team should also be individually evaluated to consider the possible implementation or disregard of music in the operative room. Moreover, any respective equipment that is needed to implement such interventions should be properly evaluated regarding quality and cost. Ideally, equipment cost should be kept at a minimum without jeopardizing the satisfaction of the patient. Currently little audio equipment is present in each operating theatre. However there is no evident audio devices in holding bays. Hence, consideration to the implementation of such audio devices should be permitted.

RECOMMENDATIONS FOR EDUCATION

If such interventions were to be implemented in the operating room, respective healthcare workers should be properly educated on the management, use, handling, treatment and possible side effects of intra-operative music therapy. A specialised music therapist could assist in properly educating these healthcare workers accordingly. Importance must be stressed on the fact that although music is not a medication, possible side effects in improper use, such as increased intra-operative anxiety and related complications could occur. On the other hand, patients should also be educated beforehand about all the possible benefits and side effects associated with music therapy as an intra-operative intervention. It is therefore imperative that willing patients sign informed consent for exposure of the intervention. Finally, general education about the benefit of music therapy, specifically intra-operatively should be implemented in student education to encourage further research on the subject.

DISSEMINATION

This study could disseminate its findings by:

- Showcasing these findings to the surgical unit at the local hospital to assist in encouraging consideration for implementation of MT intra-operatively. The listed benefits and cost effective factors could help to promote this concept. Furthermore, these findings could be presented to the Superintendent of Public Health in order to emphasise the risks of intraoperative anxiety and suggest the possibility of music therapy as a prevention.
- These findings could be presented at health conferences for both healthcare professionals and individuals of the general public.
- Utilizing social media platform and resources, posters and leaflets to ensure optimal outreach is targeted.
- This study may finally be published in order to make these respective findings available to a national and international audience.

CONCLUSION

In Conclusion, at present a definite conclusion as to whether music therapy is effective in reducing intraoperative anxiety is not possible. However, evidence is promising and pointing towards the likelihood of beneficial outcomes resulting from the intervention of interest.

Acknowledgements: None.

Conflict of interest: None to declare.

References

1. *Academy of Royal Colleges Safe Sedation Practice for Healthcare Procedures Standards and guidance 2013*
2. *Alam M, Roongpisuthipong W, Kim NA, Goyal A, Swary JH, Brindise RT, Iyengar S, Pace N, West DP, Polavarapu M & Yoo S: Utility of recorded guided imagery and relaxing music in reducing patient pain and anxiety, and surgeon anxiety, during cutaneous surgical procedures: A single-blinded randomized controlled trial. J Am Acad Dermatol 2016;75:585-589*
3. *Anderson KO & Masur FT: Psychological preparation for invasive medical and dental procedures. Journal of Behavioral Medicine 1983; 6:1–40*
4. *Association A.M.T.A. (1998–2021): What is Music Therapy. Home>About Music Therapy & AMTA>What Is Music Therapy? https://www.musictherapy.org/about/musictherapy/*
5. *Bally K, Campbell D, Chesnick K & Tranmer JE: Effects of Patient-Controlled Music Therapy During Coronary Angiography on Procedural Pain and Anxiety Distress Syndrome. Critical Care Nurse 2003; 23:50–57*
6. *Bernardi L, Porta C, Casucci G, Balsamo R, Bernardi NF, Fogari R & Sleight P: Dynamic Interactions Between Musical, Cardiovascular, and Cerebral Rhythms in Humans. Circulation 2009; 119:3171–3180*
7. *Bourin M, Briley M: Sedation, an unpleasant, undesirable and potentially dangerous side-effect of many psychotropic drugs Hum Psychopharmacol 2004; 19:135-9*
8. *Caddick J, Jawad S, Southern S & Majumder S: The power of words: sources of anxiety in patients undergoing local anaesthetic plastic surgery. The Annals of The Royal College of Surgeons of England 2012; 94:94–98*
9. *Chit Ying L, Levy V, Oi Shan C, Wing Hung T & Kit Wah W: A qualitative study of the perceptions of Hong Kong Chinese women during caesarean section under regional anaesthesia. Midwifery 2001; 17:115–122*

10. Chlan L: Effectiveness of a music therapy intervention on relaxation and anxiety for patients receiving ventilatory assistance. Heart & Lung 1998; 27:169–176
11. Cimen, S. G., Oğuz, E., Gundogmus, A. G., Cimen, S., Sandikci, F., & Ayli, M. D. Listening to music during arteriovenous fistula surgery alleviates anxiety: A randomized single-blind clinical trial. World Journal of Transplantation 2020;10:79– 89
12. Cooke, M., Chaboyer, W., Schluter, P., & Hiratos, M. The effect of music on preoperative anxiety in day surgery. Journal of Advanced Nursing2005;52: 47–55
13. Cooper, C., Booth, A., Varley-Campbell, J., Britten, N., & Garside, R. Defining the process to literature searching in systematic reviews: a literature review of guidance and supporting studies. BMC Medical Research Methodology 2018;18: 85
14. Dantas M. V. M., Nesso B., Mituuti D. S., & Gabrielli M. A. C. Assessment of patient's anxiety and expectation associated with hemodynamic changes during surgical procedure under local anesthesia. Revista de Odontologia Da UNESP 2017;46: 299–306
15. Grupe, D. W., & Nitschke, J. B. Uncertainty and anticipation in anxiety: an integrated neurobiological and psychological perspective. Nature Reviews Neuroscience 2013;14: 488–501
16. Guerrier, G., Abdoul, H., Jilet, L., Rothschild, P. R., Levy, J., Rondet, S., & Baillard, C. Musical intervention reduces anxiety-related hypertensive events during cataract surgery: A randomized controlled trial. Perioperative Care and Operating Room Management 2020;20: 100126
17. Hankela S & Kiikkala I: Intraoperative Nursing Care as Experienced by Surgical Patients. AORN Journal 1996; 63:435–442
18. Haugen AS, Eide GE, Olsen MV, Haukeland B, Remme SR & Wahl AK: Anxiety in the operating theatre: a study of frequency and environmental impact in patients having local, plexus or regional anaesthesia. Journal of Clinical Nursing 2009; 18:2301–2310
19. HHS, H.H.S. (n.d.): What are the five major types of anxiety disorders? HHS.Gov. https://www.hhs.gov/answers/mental-health-and-substance-abuse/what-are-the-five-major-types-of-anxiety-disorders/index.html
20. Higgins JPT, Savović J, Page M J, Elbers RG, Sterne JAC Chapter 8: Assessing risk of bias in a randomized trial Cochrane Training 2019
21. Hole J, Hirsch M, Ball E & Meads C: Music as an aid for postoperative recovery in adults: a systematic review and meta-analysis. The Lancet 2015; 386:1659-1671
22. Howat G, Weiters M, Sames M and McLaren A 2006 A pilot study of day case and short-stay thyroid surgery Journal of One Day Surgery 2006; 16:9 - 12
23. Jakobsen VH and Fagermoen MS: Environmental factors in the operating theatre and their impact on patients' preoperative anxiety. Tidsskrift For Sykepleieforskning 2005; 7:4-17
24. Jiménez-Jiménez M, García-Escalona A, Martín-López A, De Vera-Vera R & De Haro J: Intraoperative stress and anxiety reduction with music therapy: A controlled randomized clinical trial of efficacy and safety. Journal of Vascular Nursing 2013; 31:101–106
25. Johansson, K., Nuutila, L., Virtanen, H., Katajisto, J., & Salantera, S. Preoperative education for orthopaedic patients: systematic review. Journalof Advanced Nursing 2005; 50: 212–223
26. Kavakli AS, Kavrut Ozturk N, Yavuzel Adas H, Kudsioglu ST, Ayoglu RU, Özmen S, Sagdic K & Yapici N: The effects of music on anxiety and pain in patients during carotid endarterectomy under regional anesthesia: A randomized controlled trial. Complementary Therapies in Medicine 2019; 44: 94–101
27. Kearney A, Daykin A, Shaw ARG, Lane AJ, Blazeby JM, Clarke M, Williamson P & Gamble C: Identifying research priorities for effective retention strategies in clinical trials. Trials 2017; 18:406
28. Kennedy BW, Thorp JM, Fitch W & Millar K: The theatre environment and the awake patient. Journal of Obstetrics and Gynaecology 1992; 12:407–411
29. Klopfenstein CE: Anesthetic assessment in an outpatient consultation clinic reduces preoperative anxiety. Canadian Journal of Anesthesia 2000; 47:511-5
30. Knight WEJ & Rickard NS: Relaxing Music Prevents Stress-Induced Increases in Subjective Anxiety, Systolic Blood Pressure, and Heart Rate in Healthy Males and Females. Journal of Music Therapy 2001; 38:254–272
31. Lee A, Chui PT & Gin T: Educating Patients About Anesthesia: A Systematic Review of Randomized Controlled Trials of Media-Based Interventions. Anesthesia & Analgesia 2003; 96:1424-1431
32. McKibbon KA: Evidence-based practice. Bull Med Libr Assoc 1998; 86:396–401
33. Melnyk BM, Gallagher-Ford L, Long LE & Fineout-Overholt E: The Establishment of Evidence-Based Practice Competencies for Practicing Registered Nurses and Advanced Practice Nurses in Real-World Clinical Settings: Proficiencies to Improve Healthcare Quality, Reliability, Patient Outcomes, and Costs. Worldviews on Evidence-Based Nursing 2014;11:5–1
34. Minister for Health: A Mental Health Strategy for Malta 2020–2030. 2019, July. https://deputyprimeminister.gov.mt/en/Documents/National-Health-Strategies/Mental_Health_Strategy_EN.pdf
35. Mitchell, M. Patient Anxiety and Conscious Surgery. Journal of Perioperative Practice 2009; 19: 168–173
36. Moher, D. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. Annals of Internal Medicine 2009;151: 264–269
37. Moher, D., Hopewell, S., Schulz, K. F., Montori, V., Gotzsche, P. C., Devereaux, P. J., Elbourne, D., Egger, M., & Altman, D. G. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. BMJ 2010; 340:c869
38. NHS, N.H.S.: Complementary and alternative medicine. Complementary and Alternative Medicine. 2018. https://www.nhs.uk/conditions/complementary-and-alternative- medicine/
39. PalmerJB, Lane D, Mayo D, Schluchter M, Leeming R: Effects of Music Therapy on Anesthesia Requirements and Anxiety in Women Undergoing Ambulatory Breast Surgery for Cancer Diagnosis and Treatment: A Randomized Controlled Trial. J Clin Oncol 2015; 33:3162-8
40. Papanikolaou MN, Voulgari A, Lykouras L, Arvanitis Y, Christodoulou GN & Danou-roussaki A: Psychological factors influencing the surgical patients' consent to regional anaesthesia. Acta Anaesthesiologica Scandinavica 1994; 38:607-611
41. Rees S, Tagoe M: The efficacy and tolerance of local anaesthesia without sedation for foot surgery. The Foot 2002; 12:188-192

42. Rerkasem K, Bond R & Rothwell P: Local versus general anaesthesia for carotid endarterectomy. Cochrane Database of Systematic Reviews, 2004. https://doi.org/10.1002/14651858.cd000126.pub2
43. Robleda G, Sillero-Sillero A, Puig T, Gich I & Baños JE: Influence of preoperative emotional state on postoperative pain following orthopedic and trauma surgery. Revista Latino-Americana de Enfermagem 2014; 22:785–791
44. Rudolfsson G, von Post I & Eriksson K: The Perioperative Dialogue. Holistic Nursing Practice 2007; 21:292–298
45. Saur C, Granger B, Muhlbaier L, Forman L, McKenzie R, Taylor M & Smith P: Depressive symptoms and outcome of coronary artery bypass grafting. American Journal of Critical Care 2001; 10:4–10
46. Scheier MF, Matthews KA, Owens JF, Schulz R, Bridges MW, Magovern GJ & Carver CS: Optimism and Rehospitalization After Coronary Artery Bypass Graft Surgery. Archives of Internal Medicine 1999; 159:829
47. Sigdel DS: Perioperative anxiety: A short review. Global Anesthesia and Perioperative Medicine 2015; 1:107-108
48. Steimer T: The biology of fear- and anxiety-related behaviors. Dialogues Clin Neurosci 2002; 4:231–249
49. Wang SM, Kulkarni L, Dolev J, Kain ZN: Music and preoperative anxiety: a randomized, controlled study Anesth Analg 2002; 94:1489-94
50. Weidmann C, Grundy P: Day case awake craniotomy for tumour resection Journal of One Day Surgery 2008; 18: 45-47
51. World Health Organization: Depression and Other Common Mental Disorders: Global Health Estimates (e). 2017. https://apps.who.int/iris/bitstream/handle/10665/254610/WHO-MSD-MER-2017.2-eng.pdf
52. Wu PY, Huang ML, Lee WP, Wang C & Shih WM: Effects of music listening on anxiety and physiological responses in patients undergoing awake craniotomy. Complementary Therapies in Medicine 2017; 32:56–60
53. Yung PMB, Chui-Kam S, French P & Chan TMF: A controlled trial of music and pre-operative anxiety in Chinese men undergoing transurethral resection of the prostate. Journal of Advanced Nursing 2002; 39:352–359

Correspondence:

Michaela Agius, BSc (Hons) in Nursing, Medical Student
University of Malta
Msida, Malta
E-mail: Michaela.agius.18@um.edu.mt