Abstract of thesis entitled

An evidence based guideline on using music therapy in controlling post-operative pain in Post-Anesthesia Care Unit (PACU) patients undergone abdominal surgery in general anesthesia

Submitted by

Lau Sin Yee

For the degree of Master of Nursing
at The University of Hong Kong
In August 2015

Introduction: Post-operative pain is one of the major concerns for the health care professionals, especially the Post-Anesthesia Care Unit (PACU) nurses who spend most of the time with the post-operative patients. Unrelieved post-operative pain is problematic as it would lead to negative physiological and psychological changes for patients. Although pain medications are routinely given to the patients post-operatively, the prevalence of post-operative pain is high. Therefore, in this dissertation, music therapy, which is a non-pharmacological method, is explored to be used as an adjunct in combination with the analgesics in the treatment of post-operative pain for providing PACU patients with an optimal pain relief. A comprehensive systematic review is performed and 9 selected studies are appraised critically. By assessing the
transferability, feasibility and cost-benefit ratio, it is showed with strong evidence that
music therapy is effective in controlling post-operative pain during the immediate post-
operative period. An evidence-based guideline with 7 recommendations on the use of
music therapy is developed. To implement the innovation more effectively, a
communication plan with the potential users would be carried out and the guideline
would be tried out in a 2-month pilot test. After the revision of the guideline based on
the findings in the pilot test, an evaluation plan on assessing the patient outcomes,
health-care provider outcomes and system outcomes would be discussed. This helps to
provide a direction for further research so that the innovation could hopefully be
expanded and used in different patients with other kinds of surgery done in the future.

**Objectives:** The objectives of this study are (1) to review systematically and appraise
critically the published studies which investigate the effects of music therapy in
controlling post-operative pain in patients who had undergone abdominal surgery in
general anesthesia during the immediate post-operative period; (2) to establish an
evidence-based guideline for nurses on the use of music therapy; and (3) to
formulate implementation plan and evaluation plan for the evidence-based guideline on
the use of music therapy.
**Methods:** A comprehensive literature search on the effects of music therapy on post-operative pain in surgical patients during the immediate post-operative period is based on 3 online databases including PubMed, CLINAHL plus and Medline. A total of 9 suitable articles with 8 randomized controlled trials (RCTs) and 1 quasi-experimental study were extracted for review and appraisal. The quality assessment of the studies was performed according to the methodology checklist of Scottish Intercollegiate Guidelines Network (SIGN) designated for controlled trial studies. The implementation potential of music therapy was discussed thoroughly in terms of transferability, feasibility and cost-benefit ratio so as to develop an evidence-based guideline for the PACU nurses.

**Results:** Of the 9 retrieved studies, 8 showed a statistically significant effect of music therapy in controlling post-operative pain in PACU patients undergone abdominal surgery in general anesthesia while 1 was rejected because of its uncontrolled design. The innovation would be targeted on all adult patients with abdominal surgery done under general anesthesia and the proposed setting would be the PACU of the Operation Theatre Service Department of a regional acute hospital in Hong Kong. The transferability and feasibility of the research findings are high and the anticipated benefits of the innovation are outweigh the potential cost and risk of the current practice.
Conclusion: It is showed with evidence that music therapy is effective to be used as an adjunct in combination with the analgesics in the treatment of post-operative pain in PACU patients undergone abdominal surgery in general anesthesia. With the used of the guideline, it is anticipate that patients, health-care providers as well as the system would be benefited.
An evidence based guideline on using music therapy in controlling post-operative pain in Post-Anesthesia Care Unit (PACU) patients undergone abdominal surgery in general anesthesia

By

Lau Sin Yee

BNurs (HKU)

A thesis submitted in partial fulfillment of the requirement for the Degree of Master of Nursing at The University of Hong Kong

August 2015
Declaration

I declare that this dissertation represents my own work, except where due acknowledgement is made, and that it has not been previously included in a thesis, dissertation or report submitted to this University or to any other institution for a degree, diploma, or other qualifications.

Signed:  _______________________________

Miss Lau Sin Yee
Acknowledgment

I would like to express an immense gratitude to my supervisors Dr. Janet Wong and Dr. Kelvin Wang from the School of Nursing of The University of Hong Kong, for their guidance, assistance and expert advice on my dissertation throughout these two years.

I would also like to thank Dr. William Li, Dr. Daniel Fong and Dr. Patsy Chau for giving us tutorials for the dissertation. Lastly, sincere thanks would be given to my parents and friends for their on-going love, patience and encouragement. Without them, my dissertation would never be successfully completed.
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Chapter 1

Introduction

1.1 Background

Pain, a known consequence of surgery, is an important function of the nervous system in providing the body with a warning of potential or actual injury. It is both a sensory and emotional experience affected by psychological factors such as past experience and beliefs about pain and anxiety (Taylor et al., 1998). According to the International Association for the Study of Pain (IASP), it defined pain is an “unpleasant sensory and emotional experience associated with actual or potential tissue damage” (IASP, 2014). Post-operative pain which is a kind of acute pain, therefore, is an unwanted but unaevitable problem in patients after surgical procedures. In a national study conducted by Apfelbaum and his team (2003), they found that 80% of the participants who had undergone surgical procedures in the United States reported to experience acute pain after the surgery. Among these patients, 86% even regarded the pain level as moderate or extreme. In another study, Filos & Lehmann (1999) also stated that more than half of the subjects reported uncontrolled post-operative pain. Of all surgical procedures, it is estimated by the amount of post-operative analgesics administered as well as the time to first require for post-operative analgesics that intra-thoracic surgeries,
gastric surgeries and abdominal surgeries are the most painful surgeries with an average duration from 2-8 days of moderately severe pain (Polomano et al., 2008).

Post-Anesthesia Care Unit (PACU), also called the recovery room, is an area adjoining the operating theatres in where patients who had finished operation procedures are taken over for nursing assessment and care while recovering from anesthesia. Post-operative pain is one of the major concerns for the health care professionals, especially the Post-Anesthesia Care Unit (PACU) nurses who spend most of the time with the post-operative patients. Unrelieved post-operative pain is problematic as it would lead to negative physiological and psychological changes for patients, such as unstable hemodynamic status, respiratory suppression and urinary retention (Shertzer & Keck, 2001). Also, patients who are in pain would become irritable, anxious and emotional. All these may lead to post-operative complications, prolonging hospitalization or resulting in unexpected hospital readmission (Ozer et al, 2013, Shertzer & Keck, 2001 & Laurion & Fetzer, 2003).
1.2 Affirming the Need

With my personal experience of working in the Operating Theatre Department (OT), especially on a floor which is specialized and majored in abdominal surgery and neurosurgery, severe unrelieved post-operative pain is common seen in post-operative patients in the PACU. To be explained by the Gate Control Theory (Shertzer & Keck, 2001, Nilsson et al., 2003a & Taylor et al., 1998), when patient is under general anesthesia, the central nervous system is blocked and the pain perception is suppressed. However, once the patient is reversed from the general anesthesia, the neural pathway that generates the feeling of pain would become active and functional within a short period of time, resulting in potential experience of pain (Shertzer & Keck, 2001). According to Shertzer and Keck (2001), the “pain pathways may be fully operational within 20 minutes with today dissipating anesthetics” (P. 91). In additional to such a quick return to wakefulness of anesthetic technique nowadays, therefore, most of the post-operative patients experience severe to moderate level of post-operative pain during the immediate post-operative period.

The perception of pain is mainly caused by the tissue damage during operation. When the tissue is damaged, an inflammatory response would be initiated and various chemicals such as prostaglandins, bradykinin, histamine and serotonin is released. All
these substances would trigger the nociceptors which are the pain receptors to transmit the pain signals to the brain and induce a feeling of pain (Taylor et al., 1998). Although pain medications are routinely given to the patients post-operatively, the prevalence of post-operative pain is high. The use of pharmacological method has been a tradition method to relieve post-operative pain in the PACU. However, since different people have different responses to pain as well as to the outcome of surgical procedures, the effects of the pain relieving medications varies from person to person. Some patients may still find painful even they have received maximum dose of analgesic during the PACU stay (Shertzer & Keck, 2001). Also, the sedative and emetic effects of opioids and benzodiazepines, which are the current standard of post-operative pain killers, may suppress respiration, induce nausea and vomiting and cause hemodynamic changes. Such undesired side effects of the analgesics may impaire the recovery of the post-operative patients (Easter, et al., 2010, Ikonomidou et al., 2004 & Ebneshahidi & Mohseni, 2008). As a result, the PACU length of stay is prolonged and patient flow is delayed, contributing to higher expenses of the health care system. Therefore, non-pharmacological methods should be explored and used as adjuncts in combination with the analgesics in the treatment of post-operative pain for providing the PACU patients with an optimal pain relief.
Music, a non-pharmacological therapy, has been used widely throughout the history as an adjuvant in controlling post-operative pain and alleviate stress. Music therapy can be defined as “the controlled use of music, its elements and their influence on human being to aid in the physiologic, psychologic and emotional integration of the individual during the treatment of an illness or disability” (Cunningham et al., 1997, P. 676). It is well known that music has a calming effect by distracting patients from pain and anxiety. It can also be explained by the Gate Control Theory that music, acting as a distractor, modulates the sensory transmission of the painful stimulus by controlling the opening and closure of the gates (Laurion & Fetzer, 2003). Sen & his group (2010) also suggested an activation of auditory pathways by listening to music can inhibit the central transmission of unpleasant painful stimulus, producing a pain-reducing effect. Therefore, music is helpful in occupying patients’ mind and focusing them on something pleasant and encouraging rather than the negative feelings.

As an operating theatre nurse, especially the post-anesthesia nurse who works in the PACU, taking care of post-operative patients with pain is the most challenging task. Among all members of the health care team, peri-anesthesia nurses spend time with post-operative patients the most. Therefore, it is important for operating theatre nurses to explore some complementary strategies to manage and control patient pain. Since
the idea of using complementary therapies to alleviate pain has become common nowadays, music therapy, a non-invasive technique which is relatively cheap, easy-to-use and has little or even no risk of any harmful side effect, should be explored and used in the operating theatre department, especially in the PACU so that the post-anesthesia nurses can assist the patients in coping with their post-operative pain more effectively.
1.3 Objectives and Significance

According to a study conducted by Vallano et al. (1999), it showed that there was a significant proportion of participants who had undergone abdominal surgeries, such as inguinal hernia repair, appendectomy, cholecystectomy, laparotomy, gastric surgery, bowel resection, gynecological surgery as well as hepatopancreatic and splenic surgery, found severe pain during the immediate post-operative period even analgesics had been administered. It is because the abdominal incision interrupted the abdominal muscles which are used for breathing, coughing and moving, inducing severe pain immediately after the surgery (Vaajoki et al., 2012). In view of growing evidence in supporting the complimentary effect of music on post-operative pain, in my dissertation, I would like to investigate the effect of music therapy in controlling post-operative pain and my target population would be focused only on those PACU patients who had undergone abdominal surgery in general anesthesia. A research question is proposed as the following:

• How effective is the music therapy in controlling post-operative pain in Post-Anesthesia Care Unit (PACU) patients who had undergone abdominal surgery in general anesthesia?
There are 3 objectives in my dissertation and they are:

1. To review systematically and appraise critically the published studies which investigate the effects of music therapy in controlling post-operative pain in patients who had undergone abdominal surgery in general anesthesia during the immediate post-operative period.

2. To establish an evidence-based guideline for nurses on the use of music therapy in post-anesthesia patients who had undergone abdominal surgery in general anesthesia for pain management.

3. To formulate implementation plan and evaluation plan for the evidence-based guideline on the use of music therapy in controlling post-operative pain in PACU patients who had undergone abdominal surgery in general anesthesia.

By achieving the above objectives, nurses can help in providing the post-operative patients with a better care. Also, through minimizing the post-operative pain, the patients may feel more satisfied with the medical care and therefore, the hospital image could be enhanced. Most importantly, with the evidence-based guideline on using music therapy in controlling the post-operative pain, in certain extent, it may help to shorten the length of hospital stay of the patients so that the hospital expenses could somehow be reduced.
Chapter 2

Critical Appraisal

To review the literature systemically, this chapter would describe the search strategies on searching literatures related to music therapy in controlling post-operative pain in PACU patients who had undergone abdominal surgery in general anesthesia. A synthesized table of evidence and methodology assessment of the relevant studies would be shown and also, the summary and synthesis of the findings would be drawn.

2.1 Search and Appraisal Strategies

A search for studies related to the effects of music therapy on post-operative pain in surgical patients during the immediate post-operative period with no limitation on publication date was conducted. The online databases used were PubMed, CINAHL plus and Medline and only articles written in English containing the following search keywords were included.

✧ Music
✧ Music therapy
✧ Post-operative pain
✧ General anesthesia
✧ Post-Anesthesia Care Units (PACU)
Immediate post-operative period

Recovery room

Abdominal surgery

The search was conducted with the keywords mixed in different combination, while the terms “music” and “post-operative pain” must be included. Also, some selection criteria were set so that only the eligible studies would be chosen.

Inclusion criteria:

- Randomized controlled trials
- Full text and abstracts were available online
- Post-operative patients who had abdominal surgery under general anesthesia
- Music or combined music with other pharmacological or non-pharmacological methods was used as the intervention
- Pain intensity was measured during immediate post-operative period

Exclusion criteria

- Pediatric patients
- emergency surgery
2.2 Results

2.21 Search history and results

All the searches were performed from the middle of May to the beginning of September in 2014. A total of 311 articles were found from the three databases with 154 articles from PubMed, 71 articles from CINAHL plus and 86 articles from Medline. After removing the duplication, 194 articles retrieved were screened for eligibility. By looking into the titles and abstracts of the selected articles, 89 articles were removed as the surgery that the study population underwent was not specified or not related to the abdominal part. 18 articles had to be excluded because the intervention was not given during the perioperative period. Also, the outcomes of some articles were measured and compared after the patients had been discharged from the PACU so that 25 articles had been screened out. Moreover, 16 articles were excluded as the surgery was done under spinal or epidural anesthesia. In addition, 19 articles were disqualified due to the target population include or solely the pediatric surgical patients. Then, full texts of the remaining 27 articles were read to investigate the effectiveness of music therapy in controlling post-operative pain during the PACU stay. After selecting eight eligible studies, a manual search was performed by reading their reference list to see if there is any extra suitable article with the inclusion and exclusion criteria fulfilled. As a result, a total of nine suitable articles which were conducted from the year of 1998 to 2010
were finally extracted for review and appraisal. Details of the research process are summarized in table 1 and diagram 1.

2.22 Table of evidence

Among the nine selected articles, there are eight randomized controlled trials (RCTs) (Nilsson et al., 2005, Nilsson et al., 2003a, Sen et al., 2010, Laurion & Fetzer, 2003, Ikonomidou, et al, 2004, Nilsson, et. al, 2001, Nilsson, et. al, 2003b & Ebneshahidi & Mohseni, 2008) and one quasi-experimental study (Taylor et al., 1998). All the participants in the nine articles were scheduled for different abdominal surgeries, such as open inguinal hernia, hysterectomy, laparoscopic gynecological surgeries and cesarean section under general anesthesia. The target population recruited in the studies was all adult surgical patients with the American Society for Anesthesiologists (ASA) grade I-II. They were all aged between 18 and 85 years old and the population size (n) was ranged from 60 to 183. For easier comparison and finding analysis, the relevant data of the nine chosen studies was extracted in a modified table of evidence according to the format suggested by Scottish Intercollegiate Guidelines Network (SIGN) (2013), which is attached in Appendix A.
2.23 Quality assessment

The 9 retrieved articles were also critically appraised according to the methodology checklist of Scottish Intercollegiate Guidelines Network (SIGN, 2013) designated for controlled trial studies. The quality of each study was assessed based on ten components includes the appropriateness of research question, subject assignment, concealment method, blinding, similarity of the study groups, potential confounding factors, dropped out rate, intention to treat and generalizability of the findings. The articles were then graded as either high quality (++), acceptable (+) or reject (0).

Regarding the research question and the purposes, all the reviewed studies were aimed at investigating the effect of music therapy in controlling post-operative pain. Among them, one had clearly addressed an appropriate research question (Taylor et al., 1998) and the others had adequately stated the purposes or hypothesis of the study (Nilsson et al., 2005, Nilsson et al., 2003a, Sen et al., 2010, Laurion & Fetzer, 2003, Ikonomidou, et. al, 2004, Nilsson, et. al, 2001, Nilsson, et. al, 2003b & Ebneshahidi & Mohseni, 2008). For the assignment of the subjects, eight of the studies were conducted as randomized controlled trials (RCTs) in which the subjects were randomly assigned into treatment or control group (Nilsson et al., 2005, Nilsson et al., 2003a, Sen et al., 2010, Laurion & Fetzer, 2003, Ikonomidou, et. al, 2004, Nilsson, et. al, 2001, Nilsson, et. al,
Of the nine reviewed studies, only one was in double blinding that patients, anesthetists, surgeons and nurses were all blinded to the tape selection (Nilsson et al., 2001). Due to the type of intervention studied, patients in seven studies could not blinded about their treatment allocation and therefore, single blinding could only be done (Nilsson et al., 2005, Nilsson et al., 2003a, Sen et al., 2010, Laurion & Fetzer, 2003, Ikonomidou, et. al, 2004, Nilsson, et. al, 2003b & Ebnesahidi & Mohsen, 2008). In the study of Taylor et al. (1998), blinding was not addressed as it was a non-randomized controlled trial.

The similarity of the treatment and control group at the start of the trial were compared in all the reviewed studies. Apart from the study of Taylor et al. (1998) in which the control group was shown significantly younger than the treatment groups and some confounding variables were not controlled, no significant difference were found between the study groups in the other studies regarding the demographics, anesthetic and surgical factors (Nilsson et al., 2005, Nilsson et al., 2003a, Sen et al., 2010, Laurion & Fetzer, 2003, Ikonomidou, et. al, 2004, Nilsson, et. al, 2001, Nilsson, et. al, 2003b &

Among all, five studies mentioned about the number of patients dropped out before the study was completed and the attrition rate was ranged from 0.5% to 8.3% which is relatively small (Nilsson et al., 2003a, Taylor et al., 1998, Ikonomidou, et. al, 2004, Nilsson, et. al, 2001 & Ebneshahidi & Mohseni, 2008). However, the intention-to-treat analysis was not mentioned in all the studies.
Of the nine selected studies, five articles were graded as high quality with majority of criteria met (Nilsson, et al., 2005, Nilsson et al., 2003a, Ikonomidou et al, 2004, Nilsson et al, 2003b & Ebneshahidi & Mohseni, 2008), three articles were graded as acceptable due to some flaws with an associated risk of bias (Sen et al, 2010, Laurion & Fetzer, 2003 & Nilsson, et al., 2001) and one article was rejected because of its uncontrolled study design (Taylor et al, 1998). The details of the quality assessment of the selected studies were shown in Appendix B.
2.3 Summary and Synthesis

Music, which is a non-pharmacological method, is inexpensive and non-invasive with short term analgesic effects by distracting patients from the feeling of pain and helping them to relax. Apart from the study of Taylor et al. (1998), the findings of the other 8 reviewed studies (Nilsson et al., 2005, Nilsson et al., 2003a, Sen et al., 2010, Laurion & Fetzer, 2003, Ikonomidou, et. al, 2004, Nilsson, et. al, 2001, Nilsson, et. al, 2003b & Ebneshahidi & Mohseni, 2008) suggested with evidence that music has positive effects in controlling pain and therefore, music therapy should be offered to surgical patients post-operatively to reduce the post-operative pain, fostering their recovery and increasing their satisfaction. The insignificant findings of the study of Taylor et al (1998) could be attributed to its study design as there were some confounding variables. In the study, the treatment and control group was showed significantly difference at the start of the trial. Also, the medication and anesthetic gas used for general anesthesia and the additional analgesics used in PACU were not controlled which may lead to bias.

2.31 Music type

The choice of music to be offered is one of the important factors that we have to consider when we imply music therapy in controlling post-operative pain in the PACU patients as different types of music have various effects on pain control. Suggested by
Melzack (2001), Ozer (2013), Shertzer & Keck (2001), Nilsson et al. (2003a) & Taylor et al. (1998), soothing music can reduce muscular and mental tension through distraction and also, alter the perception of pain by closing the “gates”, reducing propagation of pain impulses. In all the nine studies, the types of music selected were judged to be soft, relaxing and calming, among which three studies were specified with instrumental music with a slow and flowing rhythm (Laurion & Fetzer, 2003, Ikonomidou et al, 2004 & Nilsson et al., 2003a) and one with classical music (Nilsson et al.,2003b). In six studies, the types of music from tapes or compact disc (CD) were chosen by the investigators (Nilsson et al, 2005, Nilsson et al., 2003a, Laurion & Fetzer, 2003, Ikonomidou et al., 2004, Nilsson et al., 2001 & Nilsson et al., 2003b). However, in the study of Tayloret al. (1998), the participants could either bring their own choice of music or choose from the list of music provided by hospitals while in the study of Sen et al. (2010) & Ebnesahidi & Mohseni (2008), the participants were asked to bring their own favorite music for listening post-operatively. According to Ebnesahidi & Mohseni (2008), a familiar type of self-selected music could facilitate mind distraction and pain reduction, making the subjects feel comfortable and relax like they were at home rather than in a strange environment.
2.32 Duration of music therapy

In most of the studies retrieved, music was administered to the post-operative patients 15 minutes after they had arrived in the PACU for 30 minutes to 1 hour (Nilsson et al., 2005, Taylor et al., 1998, Sen et al., 2010, Laurion & Fetzer, 2003, Ikonomidou, et al, 2004, Nilsson, et. al, 2001, Nilsson, et. al, 2003b & Ebneshahidi & Mohseni, 2008) but in the study of Nilsson et al. (2003a), it allowed the participants to end the intervention whenever they wanted to stop listening. Actually, so far, there is no significant evidence in showing the optimal duration of music exposure in controlling post-operative pain. However, in a study of Henry (1995), he recommended an effective music listening time of 25-90 minutes for each therapeutic session in Intensive Care Unit (ICU) patients. Although the duration of music play was varied among the nine studies, all studies but with one exceptional from Taylor et al. (1998) showed that the pain level was significantly reduced with music therapy regardless of its duration.

2.33 Mode of delivery

Among the nine selected studies, only one of them did not mention about whether headphones or loudspeakers were used in delivering music to the post-operative patients (Laurion & Fetzer, 2003) while the remaining seven studies chose to use headphones (Nilsson et al., 2005, Nilsson et al, 2003a, Taylor et al., 1998, Sen et al.,
2010, Ikonomidou, et. al, 2004, Nilsson, et. al, 2001, Nilsson, et. al, 2003b & Ebneshahidi & Mohseni, 2008). Headphones were commonly used because it would not block the outside sounds so that they allowed conversation between patients and PACU personnel (Nilsson et al., 2005, Nilsson et al, 2003a, Nilsson, et. al, 2003b & Ebneshahidi & Mohseni, 2008). Also, the headphones would covered both ears of the patients and the unpleasant noise in operating theaters would be filtered. As a result, bias would be minimized and the effects measured could therefore, be attributed to the intervention offered.

2.34 Instrument used to measure outcomes

Nilsson, et al, 2003b & Ebneshahidi & Mohseni, 2008. To assess the pain intensity, visual analogue scale (VAS) was the most common method which was used in five of the studies (Nilsson et al., 2003a, Sen et al, 2010, Ikonomidou et al, 2004, Nilsson et al, 2001 & Ebneshahidi & Mohseni, 2003). Other measure instruments such as numerical rating scale (NRS) (Nilsson et al, 2005 & Nilsson et al, 2003b) and verbal report scale (VRS) (Taylor et al, 1998 & Laurion & Fetzer, 2003) was used in two studies respectively while only the study of Taylor et al (1998) used the graphic numeric pain intensity scale for measurement. Most commonly, the instruments used were divided into a 10-grade scale ranging from 0 with no pain to 10 with the most imaginable pain (Nilsson et al., 2005, Nilsson et al., 2003a, Taylor et al., 1998, Sen et al., 2010, Laurion & Fetzer, 2003, Nilsson, et. al, 2001 & Nilsson, et. al, 2003b). In two studies (Ikonomidou et al, 2004 & Ebneshahidi & Mohseni, 2003), however, measure the pain intensity with a scale ranged from 0-100. These scales had mostly been proven as reliable and validated before their use in the studies (Nilsson et al., 2005, Taylor et al., 1998, Ikonomidou et al, 2004, Nilsson et al, 2003b & Ebneshahidi & Mohseni, 2003).
2.35 Synthesis

Music therapy, supported with significant evidence, is effective in reducing post-operative pain in patients who had undergone abdominal surgery during immediate post-operative period. According to the reviewed studies, it is recommended that music should be offered to the surgical patients post-operatively for not less than 30 minutes after arrival in the PACU due to its short-term analgesic effects. Headphones were suggested to be used in delivering music in all the studies as headphones can help to screen out the unpleasant noises in the PACU so that patients would feel more relaxed and satisfied. For the music types, most of the studies supported the use of sedative music without lyrics but with consistent tone and melody, generating a rate of 60-80 beats per minutes. Music which is demonstrated as relaxing includes piano (Laurion & Fetzer, 2003), flute (Ikonomidou et al., 2004), soothing synthesizer accompanied by sounds of sea wave (Nilsson et al., 2001), classical music (Nilsson et al., 2003a) or even the self-selected favorite music (Taylor et al., 1998 & Ebneshahidi & Mohseni, 2008).

It is a well-known fact that music has the ability to comfort human soul and body. It would be beneficial if music therapy can be generalized and applied in my clinical setting. Although selecting and offering suitable music to the post-operative patients in PACU, to a certain extent, may sound a bit time-consuming and cause inconvenience
for the health care professionals, music therapy which is a non-technical intervention
does not require extra specialized training and easy to be implemented. Also, it is
relatively safe and in low cost. All in all, the beneficial effects of music in controlling
post-operative pain are undoubted. Therefore, it is necessary to further translate the
evidence into practice for a holistic patient care.
Chapter 3

Implementation Potential and Clinical Guideline

In the previous chapter, the quality of nine selected relevant articles was assessed according to Scottish Intercollegiate Guidelines Network (SIGN, 2013). Among them, eight were collectively concluded that music therapy is effective in reducing post-operative pain. To translate the corresponding evidence into practice, in this chapter, the implementation potential of music therapy in controlling post-operative pain in PACU patients who have undergone elective abdominal surgery in general anesthesia will be discussed thoroughly in terms of its transferability, feasibility and cost-benefit ratio so as to develop an evidence-based practice guideline for the PACU nurses.

3.1 Transferability

3.11 Target Audience/ Setting

The proposed setting for the innovation would be the PACU of the Operation Theatre Service Department of a regional acute hospital in Hong Kong. The department consists of six floors and each floor is divided into different specialties. There are four beds in the PACU of each floor in which patients who have undergone a surgery in general anesthesia would be took over and observed for at least 30 minutes before transferring back to ward. As I am designated to work on a floor which is specialized in mainly
gynecological surgery and hepatobiliary and pancreatic surgery, only those scheduled abdominal surgeries done under general anesthesia would be included in this innovation.

The targeted patients of the proposed innovation are adults who aged 18 or above with scheduled abdominal surgery done under general anesthesia. Pediatric patients are excluded as they are too young to express their pain perception and their response to pain is different from adults (O'Rourke, D, 2004). Also, the targeted patients should not have any cognitive or hearing deficit. As the proposed innovation requires music listening for post-operative pain management, an impaired hearing ability would affect the effectiveness of the intervention.

3.12 Fitness & Similarity

The innovation suggested in the reviewed studies focused on patients who had surgery with abdominal incision under general anesthesia such as gynecological surgery (Taylor et al., 1998; Sen et al., 2010; Laurion & Fetzer, 2003; Ikonomidou et al., 2004; Nilsson et al., 2001 & Ebneshashidi & Mohseni, 2008) and inguinal hernia surgery (Nilsson et al., 2005, Nilsson et al., 2003a & 2003b). The population fits in the proposed setting as the majority of patients served in my working unit have undergone gynecological surgery or hepatectomy. Moreover, some reviewed studies found that the pain intensity
is significantly lower in patients with music therapy received in the first 24 hours post-operatively (Sen et al., 2010; Nilsson et al., 2003b & Ebneshahidi & Mohseni, 2008).

As the proposed setting is the PACU in where patients with all types of surgery done under general anesthesia would be took over immediately from the operation theatre for nursing assessment and care while recovering from anesthesia, patients would receive the music intervention once they finish the operation.

Also, the targeted population in the proposed setting is similar to that in the researches in terms of age and types of anesthesia received. In the reviewed studies, participants were in both gender with aged from 18-85 years old while in the proposed setting, all patients would be adults as pediatric patients belong to another specialty in other floor. For the type of anesthesia, similar to the reviewed researches, only those patients with general anesthesia received would be selected for the innovation as the anesthetic method would vary the post-operative pain intensity, affecting the effects of the music intervention.
3.13 Philosophy of Care

To provide the patients with holistic care is always an ultimate goal for nurses in all units. Post-operative pain is one of the major issues concerning the post-operative patients in the PACU, especially those who have undergone abdominal surgery in general anesthesia. To relieve the immediate pain, the tradition pharmacological method is commonly used. However, even though a maximum dose of analgesics has been given during the immediate post-operative period, complain of moderate to severe pain are common. In addition to the side effects of the current standard of analgesia on breathing system as well as the hemodynamic profile, the use of music therapy in combination with the pharmacological method in controlling post-operative pain is now investigated in the PACU. The philosophy prevailing in the PACU is to assess and to stabilize the patients post-operatively so that they can be discharge back to ward earlier for post-operative recovery and ambulation. It is coherent with the fundamental philosophy of care underlying the proposed innovation of using music therapy in controlling post-operative pain. With the music intervention, patients’ mind would be occupied and distracted and their pain receptors would also be inhibited by the auditory pathways. As a result, patients’ comfort is promoted and less analgesics would be administrated, reducing the change of post-operative complications and hospital readmission.
Because of limited number of nursing staff in the department, only one PACU nurses can be assigned to look after the post-operative patients with a maximum nurse-to-patient ratio of 1:4. According to the American Society of Peri-Anesthesia Nurses (2012), it suggested that the most ideal nurse-to-patient ratio should be 1:1 in the operation theatre and 1:2 in the PACU. With the use of post-operative music therapy, it can help in stabilizing the patients’ condition so that the PACU nurses can pay more attention on taking care of those critically unstable patients, promoting the quality of patient care which is in congruent with the philosophy of care of the clinical setting.

3.14 Number of Clients to be Benefited

In order to make sure that the condition of the post-operative patients is stable enough to be transferred back to ward, we have a common practice of observing the patients for at least 30 minutes after the administration of analgesics. This prolongs the length of stay in the PACU and decrease the turnover rate. Therefore, the implementation of music therapy in controlling post-operative pain is beneficial to both the patients and the department by reducing the amount of analgesics administered. There are two operation theatres in my floor of specialty and about 18 targeted patients with elective abdominal surgery done under general anesthesia would be taken over in the PACU every week. To add up, there would be around 72 targeted patients in a month and for
long run, 864 patients in a year, which is a significantly large number of clients to be benefited from the innovation.

### 3.15 Time for Implementation & Evaluation

To implement the innovation, it takes around 15 minutes to ask the patients for their music preference and to explain the use of Numerical Rating Scale (NRS) in reporting pain intensity during the pre-operative assessment period. To evaluate the effectiveness of the innovation on patients’ post-operative pain, normal routine of assessing the level of pain by asking the patients to rate their pain score at the time of arrival in the PACU and before transferring back to ward would be carried out. Therefore, using music therapy in reducing post-operative pain and analgesic requirement during the immediate post-operative period is simple and convenient that it would not take too long to be implemented and evaluated.
3.2 Feasibility

3.21 Freedom to try

Unlike the traditional method of using analgesics in controlling post-operative pain, music therapy is a non-pharmacological intervention that it does not require any prescription of doctors before administration. Since music therapy has been proven in several reviewed researches that it is simple and safe to be used with little or even no risk of any harmful side effects, the PACU nurses would have the freedom and autonomy to use the intervention for post-operative pain management. They would also be given the authority to decide whether the innovation should be carried out or terminated when it is considered undesirable.

3.22 Interfere Current Staff Functions

Post-operative pain is a major problem for the surgical patients during the immediate post-operative period. The more serious the pain is, the longer the patients will stay in the PACU for observation and assessment. Hence, to lessen the post-operative pain of the patients and to promote their comfort are the important responsibilities of the PACU nurses. Music therapy is an adjuvant in complementing the pharmacological method in post-operative pain management. It builds on the usual practice of the PACU nurses in administrating analgesics so that the effectiveness of the intervention would be
improved and in the meanwhile, the quality of patient care would become more holistic.

In addition, the implementation of the innovation would not interfere much with the current roles and functions of the PACU staff. Surprisingly, it helps in easing nurses’ workload by distracting the patients from pain perception and stabilizing their post-operative condition with minimal intervention (Laurion & Fetzer, 2003 & Sen et al., 2010). Since patients would be transferred back to ward once they are in stable condition, their length of stay in the PACU would be shortened. As a result, the turnover rate of the PACU would be increased.

3.23 Administrative support

As a teaching hospital, it has always been striving for improvement in order to provide the best medical treatments and hospital care for patients with the most advanced equipment. Also, the hospital continually reviews the services and practices it is providing to ensure both quality and integrity being up to the patients’ expectations. Moreover, according to the annual plan 2013-2014 of the Hospital Authority (HA, 2013), it claims to enhance the acute pain services for the post-operative patients so as to provide a higher quality of patient care. With such a positive organizational climate, it is conducive to the research utilization as well as the innovation implementation.
3.24 Consensus

To carry out the innovation, a consensus among the staff and the administrators should be obtained. Since there may be some uncertainties of the staff and the administrators on the effectiveness of music therapy in controlling post-operative pain, a compromise on the usage of the music therapy should be made between the PACU nurses and a transitional period of 2 months should be given to test for its potential benefits. For the major concerns of the administrators, it would mainly be the cost and benefits of the innovation. Most reviewed studies have shown that the advantages of music therapy far outweigh its disadvantages. Therefore, the administrators may support the innovation.

Apart from the nursing department, we should also make a consensus with the doctors as we need their help and cooperation in the implementation of the innovation by asking the patients to choose their favorite music during pre-operative assessment period. Therefore, the clinical evidence of the innovation should be discussed with the doctors and a common agreement should be obtained.

3.25 Staff development/ Skills/ Equipment

To carry out the utilization project, some basic skills on the use of music therapy and the knowledge on assessing patients’ post-operative pain and evaluating the innovation are needed. An in-house training would be delivered to train the PACU nurses with the
necessary skills for the innovation. To make the training more professional and persuasive, music therapists from the Hong Kong Music Therapy Association (HKMTA) would be invited to explain the purpose of music therapy and to teach the implementation and evaluation skills. As the HKMAT is striving to promote, improve and advance the use of music therapy in clinical, educational and rehabilitation settings in Hong Kong (HKMTA, 2014), it is possible to ask for their collaboration in this innovation. Apart from staff development, some equipment and facilities are necessary for the implementation of the innovation, such as the portable compact disc (CD) players, disposable earphones, built-in rechargeable battery and music CDs. The cost of purchasing this equipment will be discussed in next part.

3.26 Evaluation tools available

Numerical rating scale is a commonly used scale in assessing the pain level of post-operative patients in the PACU. It was shown in several reviewed studies that the numerical rating scale has been tested for reliability and validity. To assess the innovation clinically, hence, patients are required to rate their pain perception according to the numerical rating scale ranging from level 0 which indicates no pain to level 10 means a maximal possible pain (Nilsson et al., 2005 & Nilsson et al., 2003b). By calculating the amount of analgesics administrated post-operatively in the PACU, we
can also evaluate the effectiveness of music therapy in controlling post-operative pain.

In conclusion, it is transferable and feasible to translate the research findings of using music therapy in controlling post-operative pain in PACU patients who have undergone abdominal surgery in general anesthesia.
3.3 Cost-benefit Ratio

3.31 Potential risk and benefit of the innovation

Music is a safe, noninvasive and user-friendly intervention. It plays an important role in pain management by distracting the patients and releasing their pain. All the reviewed studies have shown that there is minimal or even no risk and side effect of the proposed music therapy intervention (Nilsson et al., 2001; Nilsson et al., 2003a, 2003b; Nilsson et al, 2005; Taylor et al., 1998; Sen et al., 2010; Laurion & Fetzer, 2003; Ikonomidou et al., 2004 & Ebneshahidi & Mhseni, 2008). As music therapy is a non-pharmacological intervention that it does not require any doctor prescription, nurses have the option to decide whether to implement it according to the patient’s condition. If it is decided to be implemented, there are potential benefits for different roles in the healthcare system: the patients, nurses and the hospital.

Firstly, by participating in the innovation, patients would be distracted and occupied and hence, their level of post-operative pain could be minimized. Also, being more comfortable and relaxed after surgery, patients would require less analgesics during the immediate post-operative period and the stability of their hemodynamic profile would be promoted due to the calming and short term analgesic effects of music therapy. As a result, the length of stay in the PACU would be shortened and patients could be sent
back to ward for early ambulation and rehabilitation.

Secondly, it is always the responsibilities and goals for nurses to improve the quality of patient care and to provide the patients with the best holistic care. By implementing the innovation, nurses play a more proactive role in managing patients’ post-operative pain. As a result, their comfort is promoted and a better nurse-patient relationship is developed. What’s more, the PACU nurses are authorized to carry out the innovation without any others’ permission and prescription. Such a higher degree of autonomy in clinical decision helps in increasing their job satisfaction and in return, the dropout rate is reduced.

Thirdly, hospital expenses could be reduced by saving the cost of analgesics and the follow-up on its side effect. According to some of the reviewed studies, music therapy is significantly effective in reducing patient’s postoperative analgesic consumption which helps in stabilizing patients’ condition during PACU stay (Nilsson et al., 2003b; Nilsson, et al., 2005; Sen et al., 2010; Ikonomidou et al., 2004 & Ebneshahidi & Mohseni, 2008), promoting their rehabilitation and reducing their hospitalization period. With less expenditure on pharmacological pain management, the hospital is likely to benefit from cost savings due to less dependency on analgesic use by postoperative
patients.

### 3.32 Risk of maintaining current practice

Pharmacological method is commonly used to relief postoperative pain in the PACU patients. However, it may not be the best practice and possibly, we have to take the responsibility for some of the negative effects it caused. Analgesic has many side effects, includes but not limited to, respiratory suppression, nausea and vomiting, dizziness, hemodynamic change and etc. (Easter et al, 2010; Ikonomidou et al., 2004 & Ebneshahidi & Mohseni, 2008). To lessen the side-effects of the analgesics, some other medications such as the anti-emetic drugs and anti-hypertensive drugs would also be given together with the analgesics. As a result, patients may have to stay longer in the PACU due to their unstable condition, increasing the workload of the PACU nurses. Even worse, the respiratory system of the patients may be suppressed by a heavy amount of post-operative analgesics and so, they have to re-enter the operation theatre for another operation. Therefore, an increased use of medications, cost of hospital beds and cost of nursing care will reflect in an increased overall medical expenditure, causing an additional burden to our healthcare system.
3.33 Calculation of the costs needed

To implement the innovation, some audio equipment is necessary such as portable CD players with disposable earphones and built-in rechargeable battery, together with several types of music CDs. Wide varieties of music types which includes classical, orchestral, jazz, hymns and instrumental music are needed for patients to select according to their interests. With an approximately 864 patients with abdominal surgery done under general anesthesia to be participated in a year, the total one-off material cost to set up the innovation is approximately $6750. A detailed calculation of the cost for purchasing all these items is summarized in Table 2. What’s more, if the innovation is decided to be institutionalized, for a long run, an extra yearly operational cost of about $1350 is needed for the maintenance or replacement of the portable CD players with an assumption of 20% depreciation annually as well as purchasing more disposable earphone covers (Table 3).

PACU is a place to provide an intensive care for the post-operative patients until they are able to be discharged to general ward safely in a stable condition. PACU care incorporate expensive space, staff, equipment and monitoring. Similar to the Intensive Care Unit (ICU), the ideal nurse-to-patient ratio in the PACU is 1:2 so that the condition of the post-operative patients is closely monitored. According to Waddle et al (1998),
due to a continuous monitoring is required in the PACU, the cost for a 2-hour PACU stay is more or less equivalent to a 24-hour hospital stay. Therefore, a 1-hour prolonged stay in the PACU caused by an unrelieved post-operative pain may cost an extra expenditure of around $1000 per patient, which is $800,000 in a year. It is both operational and financial benefit to the hospital to implement music therapy in reducing post-operative pain and hence, shortening the PACU length of stay.

Regarding the non-material cost of implementing the music therapy, an extra time out of the working hours is required for the PACU nurses to attend the training. However, as the innovation is neither a complicated nor difficult-to-be-understood pain controlling method, only one to two training lessons would be needed for explaining the purpose of the music intervention and demonstrating the use of the CD players. Also, the compensation-hour scheme would be offered to the nurses for their participation in the training. Therefore, it is probably that the implementation of the innovation would not affect the normal functions of the organization. In contrast, by caring the post-operative patients with less pain, the workload of the PACU nurses is reduced and the staff morale is somehow improved.
In this proposed music therapy innovation, the anticipated benefits to patients who have undergone abdominal surgery outweigh the potential cost and risk of the current practice. The proposed innovation is convertible and practical to the target setting and audience. With decreased analgesic use, material cost can be greatly reduced by music therapy in the ward in the long run. In addition, the non-material cost offsets the cost of implementing this innovation, supporting the sustainability of music therapy in the future.
3.4 Evidence-Based Practice Guideline

According to the analysis of the reviewed studies in the previous part, there is strong evidence in revealing the effectiveness of music therapy in controlling post-operative pain during the immediate post-operative period in terms of transferability, feasibility and cost/benefit ratio. In order to standardize the nursing procedures so as to provide a better quality of nursing care, it is essential to establish an evidence-based practice guideline/protocol in guiding the use of music therapy.

The objectives of the guideline/protocol are

- To summarize the clinical evidence of the use of music therapy in controlling post-operative pain in PACU patients who have undergone abdominal surgery in general anesthesia.

- To formulate clinical practice guideline in guiding the PACU nurses in the implementation of music therapy for patients who have undergone abdominal surgery in general anesthesia based on the best evidence available.

- To standardize the procedures of using music therapy in controlling post-operative pain in the PACU patients who have undergone abdominal surgery in general anesthesia.
Target groups of the Guideline/ Protocol

Who the protocol is for

The protocol is intended to be designed for the PACU nurses of all levels, who are responsible to take care of the post-operative patients with abdominal surgery done under general anesthesia, in guiding them the use of music therapy in controlling post-operative pain.

Target patient population covered

Patients who are admitted to the PACU with abdominal surgery done under general anesthesia are the target population to be covered in the protocol.

Inclusive criteria of the target population

- Adults patients aged 18 or above
- No hearing impairment
- Scheduled for elective abdominal surgery
- No cognitive disability

Recommendations

The level of evidence (Table 4) and the grade of the recommendation (Table 5) are rated according to Scottish Intercollegiate Guidelines Network (SIGN, 2013).
Title
An evidence based guideline on using music therapy in controlling post-operative pain in Post-Anesthesia Care Unit (PACU) patients undergone abdominal surgery in general anesthesia.

1. Recommendations on Music Selection

Recommendation 1.1

Music provided should be soft, relaxing and calming in nature.

Available evidence:

- Music with slow and flowing rhythms can help to promote comfort and make the patients to be more contemplative, distracting them from the feeling of pain during the immediate post-operative period. (Cunningham et al., 1997 [1-]; Nilsson, 2008 [1+]; Nilsson et al., 2003b [1+])

- Instrumental and classical music are thought to be the best music for relaxation as they have consistent tone and melody which produce a pulse rate of 60-80 beats per minutes. Also, an absence of lyric and the soft nature of rhythm can help in calming the patients down post-operatively, making them feel less pain. (Nilsson et al., 2005 [1+]; Nilsson et al., 2003a [1+]; Taylor et al., 1998 [2-]; Nilsson et al., 2001 [1-]; Economidou et al., 2012 [1+])

Grade of Recommendation: A
Recommendation 1.2

The music delivered should be self-selected, either brought in by the patients themselves or chosen from a variety provided by the hospital pre-operatively.

Available evidence:

- Music preference is an important factor in controlling post-operative pain as the study of Easter et al. (2010) showed that the patients who listened to self-selected music, on average, were 6.2-7.7 minutes delayed in asking for pain medications. (Easter et al, 2010 [1+])

- Self-selected favorite music can also provided the patients with a home feeling in an unfamiliar strange environment in the Post-Anesthesia Care Unit (PACU) and thus, they are distracted from the undesired experience of pain and empowered to control over it (Ebneshahidi & Mohseni, 2008; [1+] Nilsson, 2008 [1+])

Grade of Recommendation: A

Recommendation 1.3

Cultural preference should be addressed when selecting the music.

Available evidence:

- Patients with difference ethnicity may have difference response to music as music is a subjective experience which is influenced by patient’s gender, culture, religion
and age (Taylor et al, 1998 [2-]; Engwall & Duppils, 2009 [1++]).}

- In the study of Good & Abn (2008), it showed that the majority of Koran patients preferred Korean music with stronger and faster rhythms which generate a pulse rate of 80-100 beats per minutes than American sedative instrumental music.

(Good & Abn, 2008 [2+])

Grade of Recommendation: A

2. Recommendations on the Implementation

Recommendation 2.1

Music should be delivered to the patients auto-reversely using compact disc players with headphones or earphones.

Available evidence:

- Headphones or earphones could allow conversation between the patients and the medical staff at the Post-Anesthesia Care Unit (PACU). (Nilsson et al., 2005 [1+]; Nilsson et al., 2003a [1+]; Taylor et al., 1998 [2-]; Ebneshahidi & Mohseni, 2008 [1+]; Easter et al., 2010 [1+]) Also, the PACU nurses would not be impeded by the music delivered so that they are able to hear patients’ breathing sound which is important when recovering from general anesthesia. (Nilsson et al., 2003b [1+]; Cunningham et al., 1997 [1-])
Headphones or earphones could block out some unpleasant noises generated from equipment and monitors in the PACU. These can help in distracting the patients from post-operative pain and thus, patients’ satisfaction would be increased. (Nilsson et al., 2005 [1+]; Nilsson et al., 2001 [1-]; Nilsson et al., 2003b [1+]; Economidou et al., 2012 [1+])

Grade of Recommendation: B

Recommendation 2.2

Music should be given to the patients immediately at the arrival in the Post-Anesthesia Care Unit (PACU) and played for at least 30 minutes before discharge.

Available evidence:

- In the study of Henry (1995), he stated that there is no evidence to show an optimal duration of music therapy in controlling postoperative pain but a listening time of 25-90 minutes is recommended in intensive care patients. (Nilsson et al, 2003a [1+]; Ebnesolahidi & Mohseni, 2008 [1+])

Grade of Recommendation: A
3. **Recommendations on the Evaluation**

**Recommendation 3.1**

Numeric Rating Scale (NRS) should be used in assessing the pain intensity.

*Available evidence:*

- Numeric Rating Scale (NRS) have been widely tested for reliability and validity. (Nilsson et al, 2005 [1+]; Nilsson et al, 2003b [1+]). It is simple to be administered by either written or verbal form. It has several practical advantages over other pain measurements such as visual analogue scale which can only be assessed in written form (Jensen et al, 1986 [2+]) and requires visual acuity for accuracy (Taylor et al, 1998 [2-]). Patients in immediate postoperative period may found difficulties in using it as they have not fully recovered from the anesthetic drugs and may not able to response to the pain scale accurately.

*Grade of Recommendation: B*

**Recommendation 3.2**

Pre-operative teaching and training of the usage of pain scoring system is necessary.

*Available evidence:*

- As the pain scoring system is a self-reporting system, patients may not be able to understand it clearly during the immediate post-operative period due to confusion
and disorientation caused by the emergence from anesthetic. (Ebneshahidi & Mohseni, 2008 [1+]; Dunn, 2004 [1-])

*Grade of Recommendation: B*
Chapter 4

Implementation Plan

After assessing the implementation potential of music therapy in controlling post-operative pain in PACU patients with abdominal surgeries done under general anesthesia, in this chapter, the implementation plan and the evaluation plan will be illustrated. To implement the innovation effectively, a communication plan with the potential users is needed and a pilot test has to be carried out before the implementation phase. In the evaluation session, patient outcomes, health-care provider outcomes and system outcomes will be identified. Also, the number of patients to be recruited, the measurements of the outcomes as well as the methods of analyzing the data will be discussed.

4.1 Communication Plan

4.11 Communication plan with potential users

To start with, a communication plan should be formulated with the stakeholders and the potential users. According to Maltby, Williams, McGarry, & Day (2010), stakeholders are someone who are interested in the proposed changes and will benefit from the anticipated results of the proposed innovation in terms of system outcomes by funding it. Potential users are the target population who will also benefit from the outcomes of
the innovation. The hospital administrators, such as the department operating manager and the ward managers are the key stakeholders in the implementation of the innovation as they are the financial planners and decision makers for any department policy change. The Advanced Practice Nurses, who are highly experienced in clinical research and service quality improvement, are also important in the proposed change of practices. As they mainly work in frontline nursing, they are responsible for facilitating and supervising the implementation of the new guideline. The frontline PACU nurses who initiate the changes should be involved in the communication plan as they will assist in policy planning, implementation and evaluation. For the post-operative PACU patients, as they are the potential users who receive the intervention and they have the right to accept or refuse it, their involvement and responses are important for evaluating the proposed innovation. Therefore, they should also be included in the communication plan.

4.12 Communication Strategies

To convince the stakeholders to accept the new innovation and to implement it, an effective communication plan must be carried out step by step with strategies. First of all, the ward managers would be informed about the idea of using music therapy to control post-operative pain in PACU patients who have undergone elective abdominal
surgery in general anesthesia in order to get their initial support and approval. Then, a planning committee comprising 3 nursing officers or advanced practice nurses and 5 senior operating theatre nurses who are experienced in PACU would be formed in one-month time. An anesthetist would also be invited to be the advisor and consultant for the innovation. Throughout the program, the committee members are responsible to plan, implement, evaluate and disseminate the innovation. The feasibility of the innovation and the possible obstacles would be discussed and solutions would be made within the committee. Any problem identified during the implementation phase would also be solved by them. Since the planning committee is formed under voluntary basis, the committee members would be rewarded and appraised during the annual performance assessment.

After forming the planning committee, a preliminary proposal of the innovation would be worked out in one-month time and presented to the department operating manager and the ward managers in regular meetings to seek for their consensus and suggestions. As it is found that the pain intensity in patients with abdominal incision is the most severe during the immediate post-operative period, the target of the proposed innovation would only be focused on those PACU patients who had undergone abdominal surgeries in general anesthesia. In the research proposal, the side effects of
the current pharmacological depending practices as well as the significance of the problem in undermanaging post-operative pain in PACU patients would be stated in order to persuade the administrators to agree on the proposed changes. To make the need of change more affirmed, the effectiveness and the potential benefits of using music therapy as an adjuncts in controlling post-operative pain would be presented together with the table of evidence showing its feasibility and transferability in the local setting. Also, the estimated expenditures and the cost-benefit ratio of the innovation would be shown to illustrate the cost-effectiveness of the innovation. Moreover, a tentative timeline for the implementation plan and the evaluation plan would be set up to monitor the progress (Appendix C). Through several meetings and discussions with the hospital administrators within a three-month consultation period, the research proposal would be well-modified according to the agreements that have been compromised to obtain the approval for implementation.

Once the approval is got, all the nursing staff would be informed about the innovation by means of internal email and announcement during handover time. The aims of the innovation would be explained and the evidence-based guideline would be distributed to every staff. As they are the frontline staff who carry out the innovation, it is important for them to familiarize with the guideline and know how to make use of them. An in-
house training would therefore be provided in the following two weeks. As there is around 100 nursing staff in the Operation Theatre Service Department, it is difficult to organize a training session to teach all the staff at one time. Train-the-trainer approach would be adopted. It is an approach in which the leaders selected are trained by an expert on how to teach a designated intervention to others. Then, they train, supervise and monitor the staff members on the implementation of the innovation in their local settings (Martino et al., 2011). In the Operating Theatre Service Department, all the nursing staff is divided into 9 teams for an easier arrangement of the duty shift rotation and each team has a team leader who is an experienced advanced practice nurse. These nine advanced practice nurses would firstly be recruited to attend a half day training workshop. In the training workshop, they would be illustrated with evidence on the rationales and the benefits of using music therapy in controlling post-operative pain. A music therapist from Hong Kong Music Therapy Association (HKMTA) would be invited to teach the implementation and evaluation skills. After the training workshop, the team leaders would teach their members by using demonstration and return demonstration technique.
A pilot study would be carried out for 2 months before the implementation phase. The pilot study helps to determine the feasibility of the proposed change and the acceptability of the patients, nurses and doctors to avoid unexpected difficulties during implementation. In the pilot test, the frontline nursing staff would be encouraged to comment and to give feedback on the innovation so that the planning committee could evaluate and make revisions on the guideline. After the guideline is reviewed and refined in one-month time, it would come to the implementation phase in which music therapy would be widely applied on the eligible PACU patients with abdominal surgery done under general anesthesia for one year. The updated guideline would be printed on a resource manual for reference and would keep in the PACU of each floor. To sustain the change process, regular meetings would be held with the administrators every two months to report the progress and to make evaluation. The competency of the PACU nurses on the usage of the guideline would also be assessed every half year.
4.2 Pilot Study Plan

Before implementing the full scale clinical trial of the innovation, the guideline would be tried out in a pilot test for 2 months. The pilot study is a small scale preliminary study conducted to test for the feasibility and transferability of the proposed change in order to minimize and to prevent any unexpected difficulty during the implementation of the innovation. Also, it helps to evaluate the outcomes by identifying the potential problems so that the guideline could be revised and modified before implementing the change. Moreover, by carrying out the pilot test, nurses could familiarize themselves with the innovation and the guideline. Therefore, they would be able to carry out the innovation more smoothly during the implementation phase.

4.2.1 Target setting and population

The pilot test is a smaller scale study of the proposed innovation. As same as the proposed innovation, the pilot test would target on the adult post-operative patient with scheduled abdominal surgery done under general anesthesia and it would be carried out in the PACU of the Operating Theatre Service Department of a regional acute hospital in Hong Kong. During the pilot testing, every frontline PACU nurse should have at least a chance to try out the proposed guideline in order to get a hands-on experience on the implementation of post-operative music therapy. Therefore, a sample size of 150
participants would be recruited for the pilot test. Patients who are scheduled for abdominal surgery with general anesthesia would be approached and screened for eligibility during the pre-operative assessment session. The target population should be aged above 18 and able to communicate in Cantonese, Mandarin or English. Patients with hearing or cognitive impairment would be excluded. Ethical issues of the study would be clearly explained to target patients and informed consent has to be signed if the patient is agree to participant.

4.22 Data collection and outcome measurements

By making use of the evidence-based guideline, the PACU nurses would offer the preferred music to the selected patients in the PACU post-operatively. Their pain intensity would be assessed with the numerical rating scale (NRS) at the time of arrival in the PACU and before transferring back to ward to see the effectiveness of the music therapy in controlling post-operative pain. Also, the acceptance of the patients and nurses towards the use of music therapy would be assessed through the self-administrated questionnaires. For the patients, a questionnaire concerning the choice of music, the appropriate length of the intervention time, the method of music delivery and the satisfaction of the innovation would be given by the ward nurse once they are fully awake from the general anesthesia (Appendix D). For the PACU nurses, another
set of questionnaire would be used to ask for their feedbacks (Appendix E). The questionnaire is focus on their understanding on the innovation, the competency and compliance in delivering the music and carrying out guideline as well as their acceptance and satisfaction on the use of music therapy for the post-operative pain management.

4.23 Analysis and Review

After the two-month trial period, the data collected would be analyzed by the committee members. The difficulties that the frontline PACU nurses encountered in using the guideline, feasibility of the innovation, logistics in patient recruitment and any unexpected outcomes would be discussed in the meetings. Suggestions and improvement on the guideline would be made within the committee in one-month time before the implementation phase.
4.3 Evaluation Plan

To determine if the proposed innovation is effective in the local setting, an evaluation plan is needed. In the evaluation plan, three aspects of the innovation, which are patient outcomes, health-care provider outcomes and system outcomes would be assessed. The evaluation helps to provide evidence for modification. Therefore, the innovation could be improved and sustained. Also, it provides a direction for further research so that the innovation could be expanded and used in different patients with other kinds of surgery done in the future.

4.3.1 Outcomes to be achieved

Patient outcomes

The outcomes in regard to patient to be evaluated would be divided into primary and secondary. By evaluating the patient outcomes, clinical benefits of the innovation could be assessed. A difference in the pain intensity of the post-operative patients between the time of arrival in the PACU and the time before transferring back to ward would be regarded as the primary outcome. The pain score would be assessed by using the self-rated numerical rating scale (NRS) from 0 = no pain to 10 = maximal possible pain as stated in the guideline. The mean pain score in pre-test and post-test would be compared to evaluate the effectiveness of the innovation. The secondary patient outcome of the
innovation would be the amount of post-operative analgesics administered to the patients in the PACU. As usual practice, intra-venous analgesics would be given to the post-operative patients under anesthetists’ prescription if they rate their pain score as 3 or above or at the judgement of the PACU nurses. According to the studies of Easter et al. (2010), Ikonomidou et al. (2004) and Ebneshahidi & Mohseni (2008), analgesics have several undesired effects that they may impair the recovery of the patients. Therefore, the patients could be favored if music therapy helps to reduce the consumption of post-operative analgesics in the PACU

**Health-care provider outcomes**

To assess the acceptance and compliance of the frontline PACU staff, health-care provider outcomes have to be identified. The satisfactory level of the PACU staff in carrying out the innovation and their perception towards it would be the major outcomes to be evaluated as they are the one who conduct the innovation. Therefore, a questionnaire (Appendix E) in asking about their satisfaction, confidence, skills and perceived difficulties in carrying out the music therapy would be designed to measure the outcomes. Also, focus group interviews would be carried out to collect feedbacks from the health-care providers.
**System outcomes**

System outcome is used to measure the effectiveness of the innovation to the health care system. It is always a main concern of the hospital administrators as they are the financial planners who decide the allocation of the budget and resources of the department. Therefore, they would be interested in knowing how the department would be benefited from the innovation in terms of cost-benefit ratio. With an effective implementation of the innovation, patients would complain of less post-operative pain during the stay in the PACU and less analgesics would be administered. The cost of analgesics and the follow-up of its side effects would be saved and the length of time that the patients have to stay in the PACU would also be shortened. Overall, the hospital expenses would be reduced.

**4.32 Nature of clients to be involved**

The innovation would be carried out for 1 year. Patients who are scheduled for abdominal surgery under general anesthesia within this period would be recruited during the pre-operative assessment session. The nature of clients to be involved would be selected based on the evidence found in the previous studies. As mention in chapter 3.11 (P. 25), only adults who are aged 18 or above with scheduled abdominal surgery done under general anesthesia would be recruited as pediatric patients are too young to
express their painful feelings by rating the pain score with Numerical Rating Scale (NRS) (O'Rourke, D, 2004). In light of O'Rourke, D. (2004), sufficient cognitive and language development are required understand the scale and rate correspondingly. The eligible patients should also be able to understand Cantonese, Mandarin or English without any hearing or cognitive impairment as it would affect the effectiveness of the innovation. Once the patients agree to participant, an informed consent would be signed.

4.33 Determining the number of clients

The eligible clients would be recruited by convenience sampling. The sample size could be calculated by a software program created by Russell V. Lenth (Lenth, R. V., 2006-9). Based on the reviewed literature with assumptions on the standard deviation of music therapy in pain reduction 1.530 and a difference in mean 0.193, together with a 5% significance level and 80% power (Nilsson et al., 2003b), the program suggested a sample size of 495 patients. Considering a drop-out rate of 15%, a total of 550 patients have to be recruited in the innovation. As estimated in the chapter 3.14 (P. 29), there are around 864 patients with abdominal surgery done under general anesthesia in my setting in a year. It is practical to recruit such a number of clients for the innovation.
4.34 Time to take measurements

As music therapy would be given to the eligible patients immediately at their arrival in the PACU and stopped before transferring back to ward, their pain intensity would be assessed before and after the intervention and compared by the PACU nurses to see if the innovation is beneficial in the local setting. Also, the total amount of analgesics administrated to the patients with music therapy received during their PACU stay would be measured and recorded by the nurses at the end of the innovation. For the healthcare provider outcomes, self-evaluated questionnaire (Appendix E) would be distributed to the frontline PACU staff and focus group interviews would be held at the end of the sixth month and the twelfth month during the implementation period. Both are intended to gather the opinions of the staff towards the innovation in order to assess if they are satisfied with the use of music in managing post-operative pain. The system outcome would be evaluated in the middle and at the end of the implementation phase by comparing the total cost spent and the benefits got from the innovation.

4.35 Data Analysis

All the data would be analyzed by using a statistical analysis tool called Statistic Product and Service Solution (SPSS). To determine if the post-operative pain intensity of the PACU patients with abdominal surgeries done under general anesthesia is
reduced and the use of post-operative analgesics is reduced, one sample t-test would be performed. To analyze the satisfaction, acceptance and compliance of the frontline PACU staff, significance testing would be used by performing a two-tailed z-test. The data collected from the questionnaires would be tested with a 5% level of significance and 80% power to see if there are more than 80% of the PACU staff satisfied with the innovation. The focus group interviews would be analyzed by coding. Words which were coded with similar meanings would be grouped together and put into categories. For the cost-benefit ratio, it would be analyzed in a statistic chart by calculating and comparing all the expenses and the benefits gained during the implementation of the innovation including the set up and running cost, the cost for training nurses, the money saved in analgesics and operating expenditures by shortening patients’ recovery time in the PACU.
4.4 Basis for Implementation

The proposed change of practice would be considered as effective if the defined outcomes are achieved. By referring to the results of the reviewed studies, it is expected that the pain score of the post-operative patients during immediate post-operative period would be lowered with the use of music therapy. According to the reviewed literatures, they showed that music group had a lesser pain score by 0.8 to 1.9 units compared with the control group (Nilsson et al., 2005, Nilsson et al., 2003a, Laurion, S & Fetzer S.J., 2003 & Nilsson et al., 2003b). Therefore, the effectiveness of the innovation would be quantified by an average of 1 units or more reduction in the pain score after the innovation. Also, with an effective implementation of the innovation, patients would complain of less pain and thus, the overall amount of analgesics administered during the PACU stay would somehow be minimized by around 30% (Nilsson et al., 2005, Nilsson et al., 2003b & Ebneshalidi, A., & Mohseni M., 2008). In respect of the health-care provider outcomes, it is worthy of carrying out the innovation if there are more than 80% of the PACU staff expressed a satisfaction with the innovation. It would help to improve the staff morale by increasing their job fulfillment. By promoting comfort with a reduced post-operative pain for the PACU patients, music therapy could help in shortening their length of PACU stay and so, encouraging them to ambulate earlier. Moreover, with a lesser pain, the use of the post-operative analgesics would be
minimized and cost of nursing care would be reduced. As a result, the overall expenses of the department would be decreased. If the benefit of the innovation outweighs the cost, it would show a value to the health care system.
Chapter 5

Conclusion

Although analgesics have been traditionally used in alleviating post-operative pain in PACU patients, the problem of under-management of post-operative pain prevails. Unrelieved post-operative pain is problematic as it would induce patients’ discomfort, prolonging their length of stay in the PACU and delaying their recovery. By reviewing systematically and appraising critically the related studies, it is showed with evidence that music therapy is effective to be used as an adjunct in combination with the analgesics in the treatment of post-operative pain in PACU patients undergone abdominal surgery in general anesthesia. Therefore, an evidence-based guideline is established in guiding the use of music therapy. It is anticipate that, with the used of the guideline, patients, health-care providers as well as the system would be benefited.
<table>
<thead>
<tr>
<th></th>
<th>Electronic Database</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PubMed</td>
</tr>
<tr>
<td><strong>Date of final search</strong></td>
<td>31st August, 2014</td>
</tr>
<tr>
<td><strong>Keywords search alone or in different combination</strong></td>
<td>154</td>
</tr>
<tr>
<td>Music</td>
<td></td>
</tr>
<tr>
<td>Music therapy</td>
<td></td>
</tr>
<tr>
<td>Post-operative pain</td>
<td></td>
</tr>
<tr>
<td>general anesthesia</td>
<td></td>
</tr>
<tr>
<td>Post-Anesthesia Care Unit (PACU)</td>
<td></td>
</tr>
<tr>
<td>Abdominal surgery</td>
<td></td>
</tr>
<tr>
<td><strong>Removal of duplication</strong></td>
<td>118</td>
</tr>
<tr>
<td><strong>Inclusion and exclusion criteria met</strong></td>
<td>6</td>
</tr>
<tr>
<td><strong>Manual search for the reference list</strong></td>
<td>7</td>
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</tbody>
</table>
Table 2: The Approximate Total One-off Material Cost to Set Up the Innovation

<table>
<thead>
<tr>
<th>Items</th>
<th>Price per piece</th>
<th>Quantities</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portable CD players with earphones and built-in rechargeable battery</td>
<td>$350</td>
<td>5</td>
<td>$1750</td>
</tr>
<tr>
<td>Disposable earphone covers</td>
<td>$1 per pair</td>
<td>1000</td>
<td>$1000</td>
</tr>
<tr>
<td>CDs (classical, orchestral, jazz, hymns and instrumental music)</td>
<td>$200</td>
<td>20 (4 for each music type)</td>
<td>$4000</td>
</tr>
<tr>
<td><strong>Total amount</strong></td>
<td></td>
<td></td>
<td><strong>$ 6750</strong></td>
</tr>
</tbody>
</table>

Table 3: The Approximate Extra Operational Cost of the Innovation Yearly

<table>
<thead>
<tr>
<th>Items</th>
<th>Price per piece</th>
<th>Qualities</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disposable earphone covers</td>
<td>$1 per pair</td>
<td>1000</td>
<td>$1000</td>
</tr>
<tr>
<td>Maintenance or replacement cost of the portable CD players (20% depreciation)</td>
<td></td>
<td></td>
<td>$350</td>
</tr>
<tr>
<td><strong>Total amount</strong></td>
<td></td>
<td></td>
<td><strong>$1350</strong></td>
</tr>
</tbody>
</table>
Table 4: Levels of Evidence

<table>
<thead>
<tr>
<th>Studies</th>
<th>Design</th>
<th>Grading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sen, H., Yanarateş, O., Sizlan, A., Kılıç, E., Ozkan, S., &amp; Dağlı, G. (2010). The efficiency and duration of the analgesic effects of musical therapy on postoperative pain. Agri: Agri (Algoloji Derneği'nin Yayın organıdır= The journal of the Turkish Society of Algology, 22(4), 145-150.</td>
<td>RCT</td>
<td>1-</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Title and Year</td>
<td>Type</td>
</tr>
<tr>
<td>-----------</td>
<td>----------------</td>
<td>------</td>
</tr>
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</table>
Table 5: Grades of Recommendations (SIGN, 2004)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong></td>
<td>At least one meta-analysis, systematic review, or RCT rated as 1++, and direct applicable to the target population, or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results.</td>
</tr>
<tr>
<td><strong>B</strong></td>
<td>A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results, or Extrapolated evidence from studies rated as 1++ or 1+.</td>
</tr>
<tr>
<td><strong>C</strong></td>
<td>A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++.</td>
</tr>
<tr>
<td><strong>D</strong></td>
<td>Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+</td>
</tr>
</tbody>
</table>
Diagram 1: PRISMA 2009 Flow Diagram

Records identified through database searching (n = 311)

Additional records identified through other sources (n = 0)

Records after duplicates removed (n = 117)

Records screened (n = 194)

Records excluded (n = 167)

Full-text articles assessed for eligibility (n = 27)

Full-text articles excluded, with reasons (n = 19)

Studies included in qualitative synthesis (n = 0)

Studies included in quantitative synthesis (meta-analysis) (n = 9)
## Appendix A: Table of Evidence

<table>
<thead>
<tr>
<th>Study type</th>
<th>Patient Characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Nilsson et al., 2005</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCT (++)</td>
<td>• n=75</td>
<td>• Post-operative music (PM) group: Listened to a sham CD player intra-operatively &amp; music post-operatively. (n = 25)</td>
<td>Control group (C): Listened to a sham CD player both intra- &amp; post-operatively. (n=25)</td>
<td>30 mins before induction to the 3h after arrival in the PACU</td>
<td>Primary: 1. Pain (NRS#2 0-10) 2. Morphine required (mg) Secondary: 3. Anxiety (NRS 0-10) 4. vital signs</td>
<td>1. Significant difference (p&lt;0.01) PM vs C: -1.7 &amp; IM vs C: -1.4 2. Significant difference (p&lt;0.01) PM vs C: -1.9 &amp; IM vs C: -1.1 3. Significant difference (p&lt;0.05) PM vs C: -0.9 &amp; IM vs C: -0.8 4. No significant difference</td>
</tr>
<tr>
<td></td>
<td>• ASA(^{01}) grade I-II</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Scheduled for open Lichtenstein inguinal hernia repair surgery under GA</td>
<td>• Intraoperative music (IM) group: listened to music intraoperative and to a sham CD player post-operatively. (n=25)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Nilsson et al., 2003a</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prospective, RCT (++)</td>
<td>• n=183</td>
<td>• Music (M) group: Listened to soft classical music (n=62)</td>
<td>Control (C) group: blank tape, i.e. silence. (n=63)</td>
<td>From the time of arrival at PACU to the time when the patient wanted to stop listening.</td>
<td>Primary: 1. Pain score (VAS(^{03})) 2. Amount of morphine used (mg) Secondary: 3. Anxiety level (STAI(^{x4})) 4. Fatigue 5. Psychological well-being 6. nausea, headache &amp; urinary problem</td>
<td>1. Significant difference (p&lt;0.01) M vs C: -0.8 &amp; M/TS vs C: -1 2. No significant difference (p=.382) M vs C: -0.8 &amp; M/TS vs C: -0.9 3. No significant difference (p=.304) M vs C: 1.4 &amp; M/TS vs C: -0.4 4-6. No significant difference</td>
</tr>
<tr>
<td></td>
<td>• ASA(^{03}) grade I-II</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Scheduled for varicose veins or open Lichtenstein inguinal hernia repair surgery under GA</td>
<td>• music combined with therapeutic suggestions (M/TS) group: Listened to relaxing and calming music accompanied by relaxing and encouraging suggestions recorded in a male voice by a person with extensive experience in hypnotherapy. (n=57)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>3. Taylor et al., 1998</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quasi-experimental study(0)</td>
<td>• n=61</td>
<td>• Music group: Listened to self- selected music using headphones.</td>
<td>Control (C) group: did not listen to music or wear headphones.</td>
<td>From the time of arrival in the PACU after surgery to the time of discharging from the PACU</td>
<td>Pain level (1) clinically used rating scale (2) Graphic Numeric Pain Intensity</td>
<td>Both scales has no statistical difference between groups</td>
</tr>
<tr>
<td></td>
<td>• 24-62 y/o women</td>
<td>• headphones with no music group: wearing headphones to block out unpleasant noises in PACU but with no music.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• scheduled for elective abdominal hysterectomies under GA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^{01}\) ASA: American Society of Anesthesiologists  \(^{02}\) NRS: Numeric Rating Scale  \(^{03}\) VAS: Visual Analog Scale  \(^{x4}\) STAI: State-Trait Anxiety Inventory

**RCT (+)**
- n=90
- ASA I-II
- women who were scheduled for an elective abdominal hysterectomy
- Music (M) group: Listened to relaxing & calming music accompanied by soothing sounds of sea waves. (n=30)
- Music combined with therapeutic suggestions (M/TS) group: Listened to the same music as M group with relaxing & encouraging suggestions recorded by a man who had extensive experience in hypnotherapy. (n=31)
- Control (C) group: Listened to a tape with operation room sounds which is a play back from a previously recorded surgical operation. (n=28)
- **Day of operation to the day of discharging from hospital**
- **Primary:**
  1. Pain intensity
- **Secondary:**
  2. fatigue
  3. mobilization
  4. length of hospital stay
  5. post-operative nausea & vomiting
  6. psychological well-being
- **1. M vs C: significantly less pain on postop day 1 (p<0.001)**
- **M/TS vs C: require significantly less ketobemidone on the operation day (p=0.028)**
- **2. both M & M/TS experienced less fatigue than C (p<0.001)**
- **3. M vs C: mobilized significantly earlier (p=0.008)**
- **4-6: no significantly different between groups**

### 5. Nilsson, et. al, 2003b

**RCT (++)**
- n=151
- ASA I-II
- Patients aged 21-85 yr who were scheduled for varicose veins or inguinal hernia repair under GA.
- post-operative music (PM) group: exposed to a blank CD intra-operatively and post-operative music
- Intra-operative music (IM) group: exposed to intra-operative music and a blank CD post-operatively
- Control (C) group: exposed to a blank CD at both time.
- **From the end of induction of anesthesia to post-operative day 2.**
- **Primary:**
  1. Pain intensity (NRS)
  2. Post-operative morphine required (mg)
- **Secondary:**
  3. Nausea
  4. fatigue
  5. anxiety
- **1. Pain after 1h: significantly lower (p<0.01)**
  PM vs C: -0.9 & IM vs C: -1
  Pain after 2h: significantly lower (p<0.01)
  PM vs C: -0.9 & IM vs C: -0.8
- **2. less morphine is required in PM group after 1h in PACU (p<0.05)**
  PM vs C: -1.3
- **3. No significant difference**
- **4. No significant difference**
- **5. No significant difference**
| RCT (++) | n=80
| pregnant women aged 18-36 year
| ASA I-II
| underwent elective cesarean section surgery in GA
| Music (M) group: listened to their favorite music for 30 mins in PACU via soft open-air headphones
| Control (C) group: wore headphone with no music administered.
| 15 mins after arrival at PACU to the first post-operative hour
| Primary: 1. Pain intensity (VAS: 0-100mm) 2. Total amount of morphine administered in PACU & via PCA
| Secondary: 1. Anxiety level (VAS) 2. Blood pressure 3. Heart rate
| 1. Significantly lower (p<0.05) M vs C: -19 2. Significant lower (p<0.05) M vs C: -0.9 3. No significant difference 4. No significant difference 5. No significant difference


## Methodology Checklist 1

### Study identification  
*(Include author, title, year of publication, journal title, pages)*


### SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Adequately addressed. The aim of the study was clearly stated.</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.</td>
<td>Adequately addressed. Patients were randomly allocated to one of the 3 groups with block randomization to keep the number of subjects in different groups closely balanced.</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Not address.</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
<td>Yes but partly. Subjects in postoperative music group could not be blinded due to the type of intervention studied. The anesthesiologists, surgeons, nurses in operation theater and PACU were blinded as the sham and regular music CDs were indistinguishable.</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Yes. There were no significant differences in the baseline characteristics, preoperative preparation, anesthetic and surgical factors between the 3 study groups.</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Yes.</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Yes. The scale for anxiety and pain was mentioned to be validated and has been tested for validity.</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Not address about the drop-out rate.</td>
</tr>
</tbody>
</table>
## Appendix B

### 1.9
All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).

Not mention in the text

### 1.10
Where the study is carried out at more than one site, results are comparable for all sites.

Not applicable
Only one site was studied.

## SECTION 2: OVERALL ASSESSMENT OF THE STUDY

### 2.1
How well was the study done to minimise bias?  
*Code as follows:*

| High quality (++)| Randomization was done. Reliability & validity of NRS for anxiety & pain were also addressed. |

### 2.2
Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?

Yes

### 2.3
Are the results of this study directly applicable to the patient group targeted by this guideline?

Yes

### 2.4
*Notes.* Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

The study suggested that music therapy in both intra-operative and post-operative period can help to decrease postoperative pain while post-operative music can even help in reducing morphine requirement and stress response to the surgery.
### Methodology Checklist 2

#### Study identification
*Include author, title, year of publication, journal title, pages*


#### SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
</table>
| 1.1 The study addresses an appropriate and clearly focused question. | Adequately addressed  
The study hypothesis was clearly stated. |
| 1.2 The assignment of subjects to treatment groups is randomised. | Adequately addressed  
A computer generated randomization list and patients were randomly allocated into 3 groups. |
| 1.3 An adequate concealment method is used. | Not address. |
| 1.4 Subjects and investigators are kept ‘blind’ about treatment allocation. | Yes but partly.  
Subjects could not be blinded due to the type of intervention studied.  
The anesthesiologists, surgeons, nurses in operation theater and PACU were blinded to the tape selection. |
| 1.5 The treatment and control groups are similar at the start of the trial. | Yes  
There were no significant differences in the demographic data, STAI, anesthetic and surgical factors between the study groups. |
| 1.6 The only difference between groups is the treatment under investigation. | Yes |
| 1.7 All relevant outcomes are measured in a standard, valid and reliable way. | Partly  
STAI which was used to assess patients’ anxiety level has been validated and tested for reliability. |
| 1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | 0.546%  
One patient was withdrawn. |
### Appendix B

1.9  All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).  |  Not mention in the text

1.10 Where the study is carried out at more than one site, results are comparable for all sites.  |  Can’t say  
No site specific data is given

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1 How well was the study done to minimise bias?  
*Code as follows:*

- High quality (++)
  - Randomization and blinding was done & the dropout rate is low.

2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?  |  Yes

2.3 Are the results of this study directly applicable to the patient group targeted by this guideline?  |  Yes

2.4 **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

The study suggested that music therapy, no matter it is used alone or in combination with therapeutic suggestions, has a beneficial effect on postoperative pain in PACU.
**Methodology Checklist 3**

**SIGN**

**Study identification  (Include author, title, year of publication, journal title, pages)**


<table>
<thead>
<tr>
<th>SECTION 1: INTERNAL VALIDITY</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In a well conducted RCT study…</strong></td>
<td><strong>Does this study do it?</strong></td>
</tr>
</tbody>
</table>
| 1.1 The study addresses an appropriate and clearly focused question. | Adequately addressed  
The research question was clearly stated: What is the difference in level of perceived pain in women who have had abdominal hysterectomies who listen to music they perceive as relaxing and those who do not listen to music? |
| 1.2 The assignment of subjects to treatment groups is randomised. | No |
| 1.3 An adequate concealment method is used. | Not address. |
| 1.4 Subjects and investigators are kept ‘blind’ about treatment allocation. | Not address |
| 1.5 The treatment and control groups are similar at the start of the trial. | No.  
The control group was significantly younger than the other two groups. |
| 1.6 The only difference between groups is the treatment under investigation. | No.  
There are some confounding variables, such as the medication and anesthetic gas that used for GA as well as the additional analgesics used in PACU, which were not controlled during the study |
| 1.7 All relevant outcomes are measured in a standard, valid and reliable way. | Yes.  
Both the outcome measurements, the Graphic Numeric Pain Intensity Scale and the verbal rating scale, were shown comparable in terms of construct validity and standardized in a review of the literature. |
| 1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | 1.613%  
One patient was eliminated from the study because she was unable to cooperate with data collection. |
### Section 2: Overall Assessment of the Study

2.1 How well was the study done to minimise bias?

*Code as follows:*

Low quality (0)

The participants were not randomly allocated into experimental and control group. Also, the blinding of the study was not clear and the subjects were significantly different between experimental and control group at the start of the trial. All these may lead to bias, resulting in insignificant results.

2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?

No.

2.3 Are the results of this study directly applicable to the patient group targeted by this guideline?

No

2.4 Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

There was no significant difference with both pain rating scales in measuring the pain level between groups. The insignificant findings could be attributed to some confounding variables in the study. Therefore, the author suggested that future studies that control anesthesia, pain medications, and type of music used are more likely to show significant results.
### SIGN Methodology Checklist 4

#### Study identification  
*Include author, title, year of publication, journal title, pages*


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**SECTION 1: INTERNAL VALIDITY**

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1</strong> The study addresses an appropriate and clearly focused question.</td>
<td>Adequately addressed. The purpose of the study, which is to find out the effect of music therapy on postoperative analgesia and the duration of its effects in patients who were planned to undergo elective caesarean delivery, was well mentioned.</td>
</tr>
<tr>
<td><strong>1.2</strong> The assignment of subjects to treatment groups is randomised.</td>
<td>Yes. The patients were randomly allocated into 2 groups according to computer-generated randomization.</td>
</tr>
<tr>
<td><strong>1.3</strong> An adequate concealment method is used.</td>
<td>Not address.</td>
</tr>
<tr>
<td><strong>1.4</strong> Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
<td>Yes. It is a prospective single-blinded study that the anesthesiologist who recorded all the measurements was blinded to the study groups.</td>
</tr>
<tr>
<td><strong>1.5</strong> The treatment and control groups are similar at the start of the trial.</td>
<td>Yes. Patient characteristics were statistically similar between 2 groups.</td>
</tr>
<tr>
<td><strong>1.6</strong> The only difference between groups is the treatment under investigation.</td>
<td>Yes. The anesthetic technique was standardized.</td>
</tr>
<tr>
<td><strong>1.7</strong> All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>No. The severity of postoperative pain as well as patients’ level of satisfaction with preoperative care was assessed by VAS which is subjective without evidence to show its validity in the study.</td>
</tr>
<tr>
<td><strong>1.8</strong> What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Not mention.</td>
</tr>
</tbody>
</table>
### Appendix B

<table>
<thead>
<tr>
<th></th>
<th>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</th>
<th>Not mention.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Can’t say.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No site specific data was given.</td>
</tr>
</tbody>
</table>

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

<table>
<thead>
<tr>
<th></th>
<th>How well was the study done to minimise bias?</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td><em>Code as follows:</em> Acceptable (+)</td>
</tr>
<tr>
<td></td>
<td>The study was done in a randomized controlled trial. However, the details of outcome measures were not well addressed</td>
</tr>
<tr>
<td>2.2</td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>2.3</td>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

It is concluded that post-operative music therapy is effective in reducing post-operative pain and decreased the demand of analgesia during the first 4 hours.
## Methodology Checklist 5

### Study identification

*Include author, title, year of publication, journal title, pages*


### SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Adequately addressed. The purpose of the study is to determine the effect of guided imagery and music therapy on pain, PONV, and length of stay for gynecologic laparoscopic surgery patients.</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.</td>
<td>Yes. The patients were randomly assigned into experimental and control groups.</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Not address.</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
<td>Yes. The audiotapes for the experimental groups were coded to blind the perioperative nurse and anesthesia providers.</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Yes. Demographic variable among 3 groups were shown no difference in Analysis of variance (ANOVA).</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Yes. ANOVA showed no difference among the groups on pre- or intraoperative medications.</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>No. The level of postoperative pain was measured by subject verbal report on a scale from 0-10 which is subjective without validation.</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Not mention.</td>
</tr>
</tbody>
</table>
### Appendix B

<table>
<thead>
<tr>
<th>1.9</th>
<th>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</th>
<th>Not mention.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Can’t say. No site specific data was given.</td>
</tr>
</tbody>
</table>

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1 | How well was the study done to minimise bias?  
*Code as follows:* | Acceptable (+)  
Randomization and blinding was done while the details of reliability and validity of outcome measures was not addressed. |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2</td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>Yes.</td>
</tr>
<tr>
<td>2.3</td>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>Yes</td>
</tr>
<tr>
<td>2.4</td>
<td><strong>Notes.</strong> Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.</td>
<td>The study suggested that both guided imagery and music therapy were effective in controlling pain among gynecologic laparoscopic surgery patients, apparently when the patients were ready for discharge.</td>
</tr>
</tbody>
</table>
### Appendix B

#### Methodology Checklist 6

**Study identification**  
*Include author, title, year of publication, journal title, pages*


<table>
<thead>
<tr>
<th><strong>SECTION 1: INTERNAL VALIDITY</strong></th>
<th><strong>Does this study do it?</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>In a well conducted RCT study…</td>
<td>Adequately addressed</td>
</tr>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>This study was to test if listening to relaxation music preoperatively and postoperatively would affect patients’ experience of pain, nausea, or well-being and its effect on vital signs in women undergoing laparoscopic gynecological surgery.</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.</td>
<td>Yes</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Not address.</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
<td>Yes but partly.</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Yes.</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Yes.</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Yes.</td>
</tr>
<tr>
<td></td>
<td>It was mentioned that the clinical use of the outcome measurements VAS and verbal rating scales have been supported extensively in the literature.</td>
</tr>
</tbody>
</table>
## Appendix B

<table>
<thead>
<tr>
<th>Section</th>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>8.3%&lt;br&gt;3 from M group and 2 from C group were excluded due to extended surgery or technical problem.</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
<td>Not mention.</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Not applicable.&lt;br&gt;The study was conducted in a hospital in Lund, Sweden.</td>
</tr>
</tbody>
</table>

## SECTION 2: OVERALL ASSESSMENT OF THE STUDY

<table>
<thead>
<tr>
<th>Section</th>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>How well was the study done to minimise bias? &lt;br&gt;Code as follows:&lt;br&gt;Acceptable (+) Randomization and blinding was done well. The dropout rate is less than 20% which is acceptable.</td>
<td>Acceptable (++) Randomization and blinding was done well. The dropout rate is less than 20% which is acceptable.</td>
</tr>
<tr>
<td>2.2</td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>Yes.</td>
</tr>
<tr>
<td>2.3</td>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>Yes</td>
</tr>
<tr>
<td>2.4</td>
<td>Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.</td>
<td>The study suggested that music therapy in perioperative period can help to improve patient comfort and satisfaction. Also, an opioid-sparing effect seems to be attainable with the use of postoperative music therapy.</td>
</tr>
</tbody>
</table>

### SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Adequately addressed. This study was designed to test whether music or music in combination with therapeutic suggestions in intraoperative period under general anaesthesia could improve the recovery of hysterectomy patients.</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.</td>
<td>Yes. The patients were randomly assigned into 3 groups with a computer-generated randomization list.</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Not address.</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
<td>Yes. This was a double-blinded study that patients, anesthetists, surgeon and nurses were blinded to the tape selection.</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Yes. The demographic data, anesthetic and surgical factors were similar in all 3 groups.</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Yes. The anesthesia was standardized for all groups.</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>No. There was no validation for the outcome measurements.</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>1.1% 1 withdrawn due to technical error with the cassette player.</td>
</tr>
</tbody>
</table>
### Appendix B

1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).  
Not mention

1.10 Where the study is carried out at more than one site, results are comparable for all sites.  
Can’t say  
There is no specific site data given.

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>
| **2.1** | How well was the study done to minimise bias?  
*Code as follows:* | Acceptable (+)  
Randomization and blinding was done well. However, the outcome were not measured in a valid and reliable way. |
| **2.2** | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | Yes |
| **2.3** | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes |
| **2.4** | **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. | The study showed that music and music in combination with therapeutic suggestions during surgery under general anesthesia have a beneficial effect in reducing post-operative pain and analgesia requirement |
**Methodology Checklist 8**

**Study identification**  
*(Include author, title, year of publication, journal title, pages)*  

### SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
</table>
| 1.1 The study addresses an appropriate and clearly focused question. | Adequately addressed  
The aim of this study was to evaluate the effect of intraoperative compared to postoperative music on postoperative pain after surgery. |
| 1.2 The assignment of subjects to treatment groups is randomised. | Yes  
The patients were randomly allocated into 3 groups using a computer-generated randomization list. |
| 1.3 An adequate concealment method is used. | Not address. |
| 1.4 Subjects and investigators are kept ‘blind’ about treatment allocation. | Yes.  
This was a single-blinded study that anesthetists, surgeon operating room nurses and PACU personal were blinded to the CD selection which patients could not be blinded due to the type of intervention |
| 1.5 The treatment and control groups are similar at the start of the trial. | Yes.  
There was no significant difference between the 3 study groups regarding the demographics, pre-operative anxiety, anesthetic and surgical factors. |
| 1.6 The only difference between groups is the treatment under investigation. | Yes.  
The anesthetic technique was standardized for all groups and the operations were all done by a same surgeon. |
| 1.7 All relevant outcomes are measured in a standard, valid and reliable way. | Yes.  
The outcome measurement NRS has been tested for reliability and validity in a Swedish population |
| 1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | Not mention. |
1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).

1.10 Where the study is carried out at more than one site, results are comparable for all sites.

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

2.1 How well was the study done to minimise bias? 

*Code as follows:*

High quality (++)

Randomization and blinding was done well and the outcomes are measured in a valid and reliable way.

2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?

Yes.

2.3 Are the results of this study directly applicable to the patient group targeted by this guideline?

Yes

2.4 **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

This study demonstrated that there is a short term pain-reducing effect of music therapy while the beneficial effects are similar in patients who are exposed to music intra-operatively or postoperatively.
### Methodology Checklist 9

**Study identification**  
*Include author, title, year of publication, journal title, pages*


**SECTION 1: INTERNAL VALIDITY**

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
</table>
| 1.1 The study addresses an appropriate and clearly focused question. | Adequately addressed  
The aim of this study was to evaluate the effects of patient-selected music on self-reported pain and anxiety as well as analgesic requirement and hemodynamic parameters in the early postoperative phase in patients who underwent cesarean section. |
| 1.2 The assignment of subjects to treatment groups is randomised. | Yes  
Subjects were randomly assigned into groups |
| 1.3 An adequate concealment method is used. | Not address. |
| 1.4 Subjects and investigators are kept ‘blind’ about treatment allocation. | Yes  
This was a single-blinded study that both the anesthesiologist and nurses who collected data were blinded to subject allocation. However, the subjects could not be blinded due to the type of intervention studied. |
| 1.5 The treatment and control groups are similar at the start of the trial. | Yes  
There was no significant difference between the 2 groups regarding the demographic data or anesthetic and surgical parameters. |
| 1.6 The only difference between groups is the treatment under investigation. | Yes. |
| 1.7 All relevant outcomes are measured in a standard, valid and reliable way. | Yes.  
Validity and reliability of the instrument for the assessment of anxiety and pain intensity have been approved earlier, |
### Appendix B

| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | 3.75%  
2 patients were excluded because of technical problems with cassette players at the recovery. |
| 1.9 | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). | Not mention. |
| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. | Can’t say  
There is no specific site data given. |

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1 | How well was the study done to minimise bias?  
*Code as follows:* | High quality (+++)  
Randomization and blinding was done well. The outcomes are measured in a valid and reliable way and the dropout rate is relatively low. |
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | Yes. |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes |
| 2.4 | **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. | The author concluded that postoperative use of patient-selected music in cesarean section surgery would alleviate the pain and reduce the need for other analgesics, thus improving the recovery and early contact of mothers with their children. |
### Appendix C: Timeline for implementation plan and evaluation plan

<table>
<thead>
<tr>
<th>Month</th>
<th>1</th>
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<th>3</th>
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<th>18</th>
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<th>22</th>
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</thead>
<tbody>
<tr>
<td>Forming the planning committee</td>
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<td>Work out the proposal</td>
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<tr>
<td>Consult &amp; discuss with hospital administrators</td>
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<td>In-house training for staff</td>
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<tr>
<td>Pilot study</td>
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<tr>
<td>Review &amp; refine the guidelines</td>
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<tr>
<td>Implementation</td>
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<tr>
<td>Evaluation and data analysis</td>
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</table>
Appendix D: Questionnaires for patients on music intervention to control post-operative pain in PACU

1. Did you receive the post-operative music therapy during PACU stay?
   你有否接受音樂治療?
   □ Yes 有   □ No 沒有

2. Do you agree that the music therapy can help to reduce post-operative pain?
   你認同音樂治療可減輕術後痛楚嗎?
   □ Totally agree   □ Agree   □ Disagree   □ Totally Disagree
   非常同意   同意   不同意   非常不同意

3. Do you agree that the length of time of the music intervention is appropriate?
   你認同音樂治療的時間長度適合嗎?
   □ Totally agree   □ Agree   □ Disagree   □ Totally Disagree
   非常同意   同意   不同意   非常不同意

4. Do you satisfy with the method of using earphones to deliver music?
   你滿意利用耳機給予音樂治療的方法嗎?
   □ Totally satisfied   □ Satisfied   □ Unsatisfied   □ Totally unsatisfied
   非常同意   同意   不同意   非常不同意

5. How would you rate your pain intensity before and after the music therapy?
   (0=no pain at all, 10=extremely pain)
   請你比較術後音樂治療前和後的痛楚 (0=完全沒有痛楚, 10=非常痛)
   Before music therapy: □ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10
   After music therapy: □ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10
6. Do you satisfy with the type of music?

你滿意音樂治療過程中給予的音樂種類嗎?

☐ Totally agree ☐ Agree ☐ Disagree ☐ Totally Disagree

非常同意 同意 不同意 非常不同意

7. In general, do you satisfy with the music intervention?

整體而言，你滿意這次的音樂治療嗎?

☐ Totally agree ☐ Agree ☐ Disagree ☐ Totally Disagree

非常同意 同意 不同意 非常不同意

8. Other comments/ suggestions:

__________________________________________________________________
__________________________________________________________________
__________________________________________________________________
Appendix E: Survey for PACU nurses on music intervention to control post-operative pain

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Totally agree</th>
<th>Agree</th>
<th>Disagree</th>
<th>Totally disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>I understand the objectives of the innovation.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2.</td>
<td>The objectives of the innovation are achieved.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3.</td>
<td>The innovation is useful in controlling patients’ post-operative pain.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>4.</td>
<td>The evidence-based guidelines are clear enough to be implemented easily.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>5.</td>
<td>I feel confident to deliver the music intervention.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6.</td>
<td>I comply with the use of the guidelines.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>7.</td>
<td>I do feel extra workload for the implementation of the guidelines.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>8.</td>
<td>The innovation is well-organized.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>9.</td>
<td>The innovation should be sustained and expanded to different PACU patients with other kinds of surgery.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>10.</td>
<td>I am satisfied with the innovation.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Other comments:
Reference


