Development and crossover pilot randomized controlled trial of a patient-oriented music intervention to reduce pain in the adult intensive care unit

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Abstract

Background. Adults admitted to the intensive care unit (ICU) often experience pain. A multimodal approach to pain management is recommended, including nonpharmacological interventions such as music. To determine the effect of music interventions for ICU pain management, our systematic review of randomized controlled trials supported that 20-30 minutes of music with a tempo of 60-80 bpm was efficacious to reduce pain in ICU patients able to self-report. However, music efficacy in patients unable to self-report remains unknown. Gaps in acceptability and feasibility of music interventions tested in the ICU setting were also highlighted. ***Objectives.*** This study included two phases. Phase I aimed to describe the acceptability of a newly developed patient-oriented music intervention (POMI) and to guide its refinement. Phase II aimed to evaluate the acceptability and feasibility of POMI, and the feasibility of research methods. A secondary objective was to examine the preliminary efficacy of POMI to reduce pain. ***Methods.*** I. A descriptive design was used to inform the acceptability of a preliminary POMI developed based on theoretical and empirical knowledge, which uses a music streaming service to generate playlists based on patient preferences, the recommended tempo and duration. Critical care experts were recruited using purposive and snowball sampling and completed a questionnaire and a semi-structured interview via video conference. Participants rated acceptability items from 0-4 and provided feedback on POMI acceptability and features. Their experiential knowledge guided the POMI refinements. II. Three samples of participants were recruited: ICU patients (2 groups: able and unable to self-report); family members; and nurses. Patients were randomized to either sequence 1 (POMI period, then control period), or sequence 2 (control period, then POMI period), with a 4-hour washout period. POMI was administered for at least 20 minutes before a turning procedure. No music was played during the control period. Outcomes

included acceptability and feasibility of POMI (e.g., delivery, fidelity), feasibility of research methods (e.g., eligibility and retention rates) and pain scores (i.e., 0-8 behavioral scores in all patients; 0-10 pain intensity and pain distress in patients able to self-report). Pain was measured at four timepoints (pre-intervention; post-intervention; during turning; 30 minutes post-turning). ***Results.*** I. The POMI was developed based on theoretical and empirical knowledge and refined according to experiential knowledge. Participants (i.e., 9 ICU clinicians and 3 music therapists) had 4-36 years of experience in critical care. Acceptability was very good with items having high median scores (≥3/4). Participants emphasized the importance of considering the patient's music preferences and found the use of streaming services convenient. They rated the acceptability of POMI delivery higher before a painful procedure (e.g., turning) than after. II. Samples of 23 ICU patients, 11 family members, and 12 nurses were included in data analysis. POMI was found acceptable with median scores >3/4. The POMI was feasible for most patients; however, timing of turning was sometimes unpredictable, and interruptions were frequent. Eligibility rate was low (15%), but retention rate was high (96%). The POMI showed preliminary efficacy in reducing pain during turning in both ICU patients able and unable to self-report. ***Conclusions.*** I. The POMI was refined based on the experiential knowledge from critical care experts, who evaluated the POMI to be acceptable. They recommended to deliver POMI prior to a painful procedure. II. POMI was acceptable to all participants. POMI duration should be flexible to accommodate unpredictable timing of ICU care and interruptions. Eligibility criteria should be broadened to increase the eligibility rate. POMI efficacy testing should be explored both at rest and in anticipation of standard care procedures.

Abrégé

Contexte. Les adultes admis à l'unité de soins intensifs (USI) ont souvent de la douleur. Une approche multimodale de gestion de douleur est recommandée, incluant des interventions non pharmacologiques telles que la musique. Pour déterminer l'effet de la musique sur la douleur à l'USI, nous avons réalisé une revue systématique d'essais contrôlés randomisés ayant confirmé que 20-30 min de musique à un tempo de 60-80 bpm est efficace à réduire la douleur chez les patients aptes à s'auto-évaluer (AAE). Cependant, l'effet de la musique chez ceux inaptes à s'auto-évaluer (IAE) reste inconnu. L'acceptabilité et la faisabilité des interventions musicales testées à l'USI sont peu documentées. ***Objectifs.*** Cette étude comportait 2 phases: I. Décrire l'acceptabilité d'une intervention musicale (POMI) et guider son développement. II. Évaluer l'acceptabilité et faisabilité de POMI, et la faisabilité des méthodes de recherche. Un objectif secondaire était d'examiner l'efficacité préliminaire de POMI. ***Méthodes.*** I. Un devis descriptif a été utilisé pour documenter l'acceptabilité de POMI, une intervention utilisant un service musical de diffusion en continu (SMDC) pour générer une liste d'écoute basée sur les préférences du patient, en incorporant le tempo et la durée recommandés. Des experts en soins critiques ont été recrutés via échantillonnage par choix raisonné et boule de neige; ceux-ci ont complété un questionnaire et un entretien semi-structuré par vidéoconférence. Les participants ont évalué les items d'acceptabilité de POMI de 0 à 4, commenté son acceptabilité et ses caractéristiques. II. Trois échantillons de participants ont été recrutés: patients (2 groupes : AAE et IAE); membres de famille; et infirmiers-ères. Les patients ont été randomisés à la séquence 1 (période POMI, suivie de période contrôle) ou la séquence 2 (vice versa), incluant une période de transition de 4 heures. POMI était administré ≥20 min avant une mobilisation au lit, vs aucune musique (période contrôle). L'acceptabilité et la faisabilité de POMI (p. ex., administration, fidélité), la faisabilité des

méthodes de recherche (p. ex., taux d'éligibilité et rétention) et les scores de douleur (scores comportementaux 0-8 pour tous; intensité et détresse de douleur pour ceux AAE) ont été évalués. La douleur a été mesurée à 4 moments (pré-intervention, post-intervention, mobilisation, post-mobilisation). ***Résultats.*** I. POMI a été développé à partir de connaissances théoriques et empiriques, puis révisé avec les connaissances expérientielles de 9 cliniciens et 3 musicothérapeutes possédant 4-36 ans d'expérience à l'USI. Ces experts ont souligné l'importance des préférences musicales et l'aspect pratique de SMDC. Des scores médians de ≥3/4 des items d'acceptabilité de POMI ont été obtenus. Les experts ont jugé plus acceptable d'administrer POMI avant une procédure douloureuse qu'après. II. Un total de 23 patients, 11 membres de famille et 12 infirmiers-ères ont été inclus dans l'analyse de données. L'acceptabilité de POMI a été soutenue avec des scores médians >3/4. Sa faisabilité a été établie pour la plupart des patients, mais la mobilisation au lit était parfois imprévisible et les interruptions fréquentes. Le taux d'éligibilité fut de 15% et le taux de rétention de 96%. L'efficacité préliminaire de POMI pour réduire la douleur lors de la mobilisation a été observée. ***Conclusions.*** I. L'intervention POMI a été améliorée grâce aux connaissances d'experts en soins critiques, qui l'ont jugé acceptable. Les experts ont recommandé l'administration de POMI avant une procédure douloureuse (p. ex., mobilisation au lit). II. POMI s'est montrée acceptable pour tous les participants. Une durée flexible d'administration de POMI est recommandée en raison de l'imprévisibilité des soins et des interruptions fréquentes. Les critères d'éligibilité devraient être élargis pour accroître le taux d'éligibilité. L'efficacité de POMI devrait être explorée au repos et lors de procédures de soins.

Acknowledgements

Before I joined Dr. Céline Gélinas' research team, I would have never imagined pursuing a PhD. As part of my research responsibilities, I had the chance to get an outsider's view of patients' realities when admitted to the intensive care unit (ICU). I would first like to thank Dr. Gélinas for taking me under her wing and allowing me to discover the world of nursing research. I would also like to thank all the inspirational study participants for generously sharing valuable insights during some of the most intense moments of their lives. Through my work spent largely interacting with families of patients unable to self-report and observing these patients' reactions to standard but painful care procedures, I noticed the occasional use of music and how transformative this intervention could be within the ICU environment.

From anecdotal observations and discussions with Dr. Gélinas germinated an idea for a doctoral project. I embarked on a journey into the PhD world thanks to the guidance of Dr. Gélinas and inspired by doctoral graduates who paved the way and showed precious support – Drs. Madalina Boitor, Mélanie Bérubé, Émilie Gosselin, Julie Fréchette, Raíssa Passos dos Santos, and Marianne Sofronas. I also thank Dr. Nancy Feeley, Dr. Sylvie Cossette, and Dr. Linda L. Chlan who kindly agreed to share their expertise and support my endeavor as thesis committee members. Thanks also to Jacqueline, Lydia, Aimee, Sonia, Ana, Li-Anne, and Alissa for our rich and stimulating discussions as part of the courses we took together and beyond the classroom.

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Contribution to original knowledge

This doctoral research project contributes to nursing knowledge in many ways. For the first time, the publication of a systematic review and meta-analysis (Manuscript 1) contributed to evaluate the effect of music on pain in the intensive care unit (ICU), a complementary pain management intervention, which is strongly suggested in best practice guidelines. This review demonstrated that music interventions of 20-30 minutes are efficacious to reduce pain for ICU patients who are able to self-report by one to two points on a 0-10 numeric rating scale. Furthermore, we found that characteristics differed significantly across previous music interventions thus limiting the understanding of which active components might be pertinent to their efficacy. The review brought to light gaps in the development of previous music interventions in terms of acceptability and feasibility. Therefore, this review provides evidence-based knowledge to nurses on the use of music for pain in the ICU. In addition, this review contributed to empirical data which, combined with theoretical knowledge, guided the next step of the development of a novel music intervention. Then, experiential knowledge from critical care experts (Manuscript 2) was integrated with these two sources (i.e., theoretical, and empirical), to create the patient-oriented music intervention (POMI).

POMI uses a Web app that connects to a music streaming service (Spotify) to automatically generate individualized music playlists based on patient preferences. Patients or their families can select any music genres, artist names, and/or track titles available on the streaming service, and further specify, if desired, preferred music characteristics such as in terms of arousal (e.g., relaxing vs energetic music) and emotion (e.g., cheerful vs melancholic music). The patient can listen to the music via headphones or music pillow using a smart device connected to the Internet. The detailed rationales provided to support each feature of the POMI (e.g., duration,

timing, individual preferences) contribute to the scientific body of nursing literature (Manuscript 2) and allow for replicability of the POMI for any future use.

The evaluation of feasibility and acceptability of POMI from the perspectives of multiple interested parties, involving ICU patients, families, and critical care experts including nursing staff, using a rigorous methodology is another unique contribution to knowledge. Furthermore, assessing the feasibility of conducting a pilot crossover randomized controlled trial (RCT) using POMI can inform the design of a future RCT protocol for the evaluation of POMI efficacy to reduce pain in the ICU population (Manuscript 3).

The findings of feasibility and acceptability of POMI by interested parties (Manuscript 4) contribute to knowledge that is pertinent for decision-makers. Indeed, with the increasing use of technology for care, the findings support the need for infrastructure to support reliable Wi-Fi connectivity, as well as to allow and provide hospital staff, patients, and families access to smart devices and music streaming services. In addition to feasibility and acceptability, the results on the preliminary efficacy of POMI (Manuscript 4) also contribute to new knowledge that could inform future best practice guidelines updates on ICU pain management. It is also worth mentioning that this was, to our knowledge, the first Canadian study to evaluate music for ICU pain management. Finally, although limited conclusions can be drawn from pilot studies, the POMI showed preliminary efficacy in reducing pain experienced by ICU patients during turning procedures conducted as part of their standard care.

In conclusion, this doctoral research project contributes to nursing practice, research, and policy. Regarding nursing practice, music has been previously suggested as an effective nonpharmacological intervention for ICU pain management in critically ill adults. The POMI, which was developed by integrating three sources of knowledge, was found acceptable by interested parties

and feasible to use in the adult ICU. Based on patients' preferences, the POMI should minimally be administered for 20 minutes without interruptions. Findings from the crossover pilot RCT made a valuable contribution to nursing research by providing unique guidance for the planning of a future RCT to further evaluate the POMI efficacy to reduce pain in the adult ICU. Finally, findings on the acceptability, feasibility and preliminary efficacy of POMI could be used to inform nursing policy, pain management protocols and best nursing practice guidelines.

Contribution of Authors

The candidate contributed substantially to the conception of the work, the recruitment of participants, the data collection, data analysis, data interpretation, initial drafting and revision of all manuscripts submitted with this thesis, as well as all chapters of this thesis. The thesis supervisor and the committee members contributed substantially to the conception of the work and critically reviewed the data analysis, the data interpretation, as well as the drafts of all manuscripts submitted and all chapters of this thesis. In addition, the thesis supervisor contributed to the data collection (specifically, interrater for CPOT scores and intervention fidelity).

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AAE: aptes à s'auto-évaluer

APACHE II: acute physiology and chronic health evaluation II

ASR: able to self-report

bpm: beats per minute

CAM-ICU: confusion assessment method for the intensive care unit

CI: confidence interval

CONSORT: Consolidated Standards of Reporting Trials

COVID-19: coronavirus disease 2019

CPOT: critical-care pain observation tool

CTL: control intervention

FPT: faces pain thermometer

IAE: inaptes à s'auto-évaluer

IASP: International Association for the Study of Pain

ICC: intraclass correlation coefficient

ICU: intensive care unit

IQR: interquartile range

LATAM: Latin America, including Caribbean, Central and South America

NRS: numeric rating scale

POMI: patient-oriented music intervention

RASS: Richmond Agitation Sedation Scale

RCT: randomized controlled trial

REB: research ethics board

SCCM: Society of Critical Care Medicine

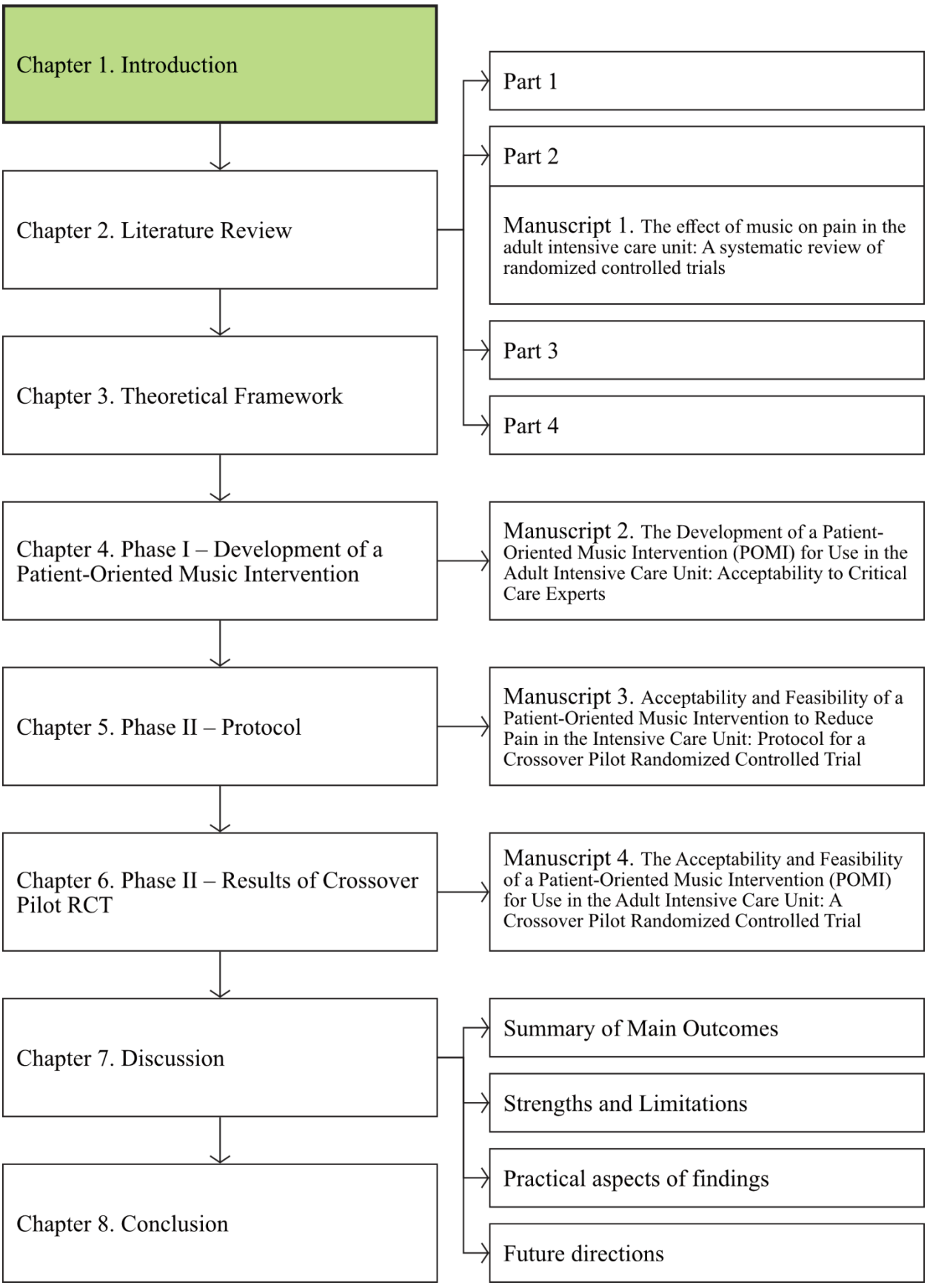
SMDC: service musical de diffusion en continu

SPSS: Statistical Package for the Social Sciences

TAP: treatment acceptability and preferences

TIDieR: template for intervention description and replication

USR: unable to self-report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Chapter 1. Introduction

Adults admitted to the intensive care unit (ICU) frequently have pain despite the existing best practices for pain management (Devlin et al., 2018). Patients experience pain while at rest as well as during standard care procedures (Damico et al., 2020; Puntillo et al., 2014). This pain can occur in the context of critical illness, trauma, or surgery. Pain is a personal experience that is complex, involving sensory, cognitive, emotional, behavioral, and social dimensions (Craig & MacKenzie, 2021; Puntillo et al., 2018; Williams & Craig, 2016). These five dimensions are all essential components of the overall pain experience.

Unfortunately, pain that is not adequately controlled in the ICU can lead to negative consequences for patients, both in the short and long term (de Jong et al., 2013; Georgiou et al., 2015; Glowacki, 2015). At short term, negative consequences of pain include severe fluctuations in vital signs, ventilator distress, longer ICU and hospital stay, and increased mortality risk (Chapman et al., 2008; de Jong et al., 2013; Devlin et al., 2018; Gagné & Ferrari, 2018; Gan, 2017; Puntillo et al., 2014; Sinatra, 2010; Yamashita et al., 2017). In the long term, acute pain in the ICU is a risk for developing chronic pain, affecting daily functioning, and overall quality of life (Battle et al., 2013; Cohen et al., 2021; Gan, 2017; Hayhurst et al., 2018; Kyranou & Puntillo, 2012). Therefore, it is imperative to provide optimal acute pain management in the ICU to prevent these short- and long-term negative consequences.

Opioids continue to be the mainstay of acute pain management in the ICU, despite being associated with adverse events affecting multiple systems (Devlin et al., 2018; Martyn et al., 2019). This problem has led to a call for change in practice to multimodal pain management (Devlin et al., 2018; Ehieli et al., 2017; International Association for the Study of Pain, 2021; Stamenkovic et al., 2019). A multimodal approach that combines pharmacological agents with

nonpharmacological interventions to reduce pain in the ICU is associated with improved patient outcomes such as shorter mechanical ventilation and ICU length of stay (de Jong et al., 2013; Glowacki, 2015). Nonpharmacological interventions are gaining recognition in the ICU because of their safety and cost-effectiveness (Chlan et al., 2018; Gélinas et al., 2013). According to the latest best practice guidelines, a multimodal approach is recommended for ICU pain management, by using the lowest effective opioid dose in conjunction with nonopioid pharmacological and nonpharmacological interventions such as massage, relaxation techniques, and music (Devlin et al., 2018; Holden & Retelski, 2019).

Music was selected because there are several advantages to its use in the ICU setting. Indeed, music is already known to be effective in reducing stress and anxiety and appears promising in improving sleep quality in critically ill patients (Chlan et al., 2013; Kakar et al., 2021; Umbrello et al., 2019). Other advantages to the use of music in the ICU include cost effectiveness, accessibility, non-invasiveness, and minimal solicitation of patients who tend to be fatigued or unable to communicate (Chen et al., 2022; Chlan et al., 2018; Hu et al., 2015; Hu et al., 2021; Tracy & Chlan, 2011). Best practice guidelines on ICU pain management support the use of music in critically ill adults because the potential for benefit outweighs any risk of harm (Devlin et al., 2018, p. e835).

Previous reviews had compiled primary research on the use of music for pain in various clinical settings, but none has systematically reviewed the evidence on its use for pain reduction in the ICU (Cole & LoBiondo-Wood, 2014; Hole et al., 2015; Lee, 2016; Martin-Saavedra, Vergara-Mendez, Pradilla, et al., 2018; Meghani et al., 2017; Nilsson, 2008). To determine the effect of music interventions on pain in the adult ICU, a systematic review and meta-analysis of RCTs was conducted.

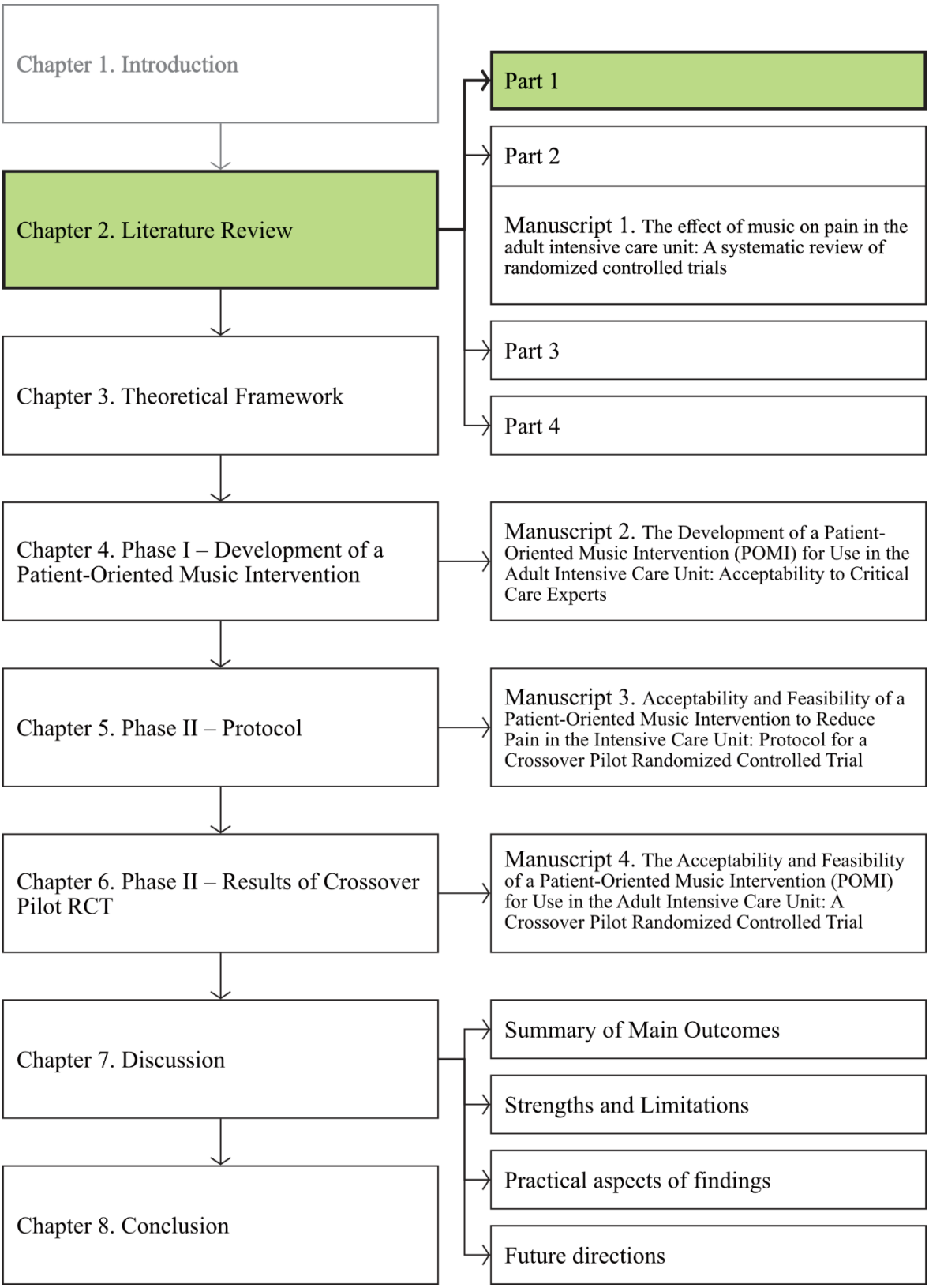
The results from our published systematic review and meta-analysis showed that music was efficacious in reducing pain in the adult ICU (Richard-Lalonde et al., 2020). More specifically, music interventions of 20 minutes or more were associated with a larger decrease in pain scores compared to interventions of less than 20 minutes. On a 0-10 numeric rating scale (NRS), music interventions ≥20 minutes resulted in an average decrease in pain scores of at least 1.75 points compared to standard care (or 1.06 points when compared to both noise reduction and standard care; Richard-Lalonde et al., 2020). This led to the conclusion that music interventions of a minimal duration of 20 minutes are efficacious to reduce pain in critically ill adults able to self-report. However, the vast majority of RCTs conducted thus far did not include patients unable to self-report, an important subpopulation of the adult ICU setting also known to experience pain (Herr et al., 2019). Therefore, the effect of music on pain among the ICU population of patients unable to self-report remains unclear.

Furthermore, none of the RCTs evaluated the acceptability and the feasibility (e.g., optimal content and delivery) of music interventions reported. Because acceptability provides significant information on the uptake of an intervention by interested parties, its evaluation is key (Sidani & Braden, 2011; Skivington et al., 2021). In addition, none of the music interventions were evaluated in terms of feasibility. Because feasibility of an intervention gives important information on its ease of use and reproducibility, its evaluation is also critical (Sidani & Braden, 2011; Skivington et al., 2021). Therefore, there is a need to evaluate the acceptability and feasibility of music as a complementary pain management intervention in the ICU setting.

Previous RCTs revealed several limitations in terms of feasibility of research methods, such as recruitment challenges and restrictions in eligibility criteria (e.g., excluding ICU patients unable to self-report as a subgroup of the ICU population). In addition, inadequate sample size

calculations led to limitations in the interpretation of results. Taken together, these issues limit the generalizability of the efficacy of music to reduce pain in the adult ICU. Therefore, before conducting an RCT to test the efficacy of a novel music intervention, the feasibility of research methods should be examined.

To address these knowledge gaps, the goal of this doctoral research project was to use an integrative knowledge approach to develop a music-based intervention that would be acceptable to all interested parties, as well as feasible for use as a complementary pain management intervention in the adult ICU setting.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Chapter 2. Literature Review

The literature review chapter of this doctoral research project contains four main parts. Part 1 introduces the problem of pain, particularly in the adult ICU setting. Part 2 presents the first manuscript of this thesis: a systematic review and meta-analysis of the efficacy of music interventions to reduce pain in the adult ICU (Richard-Lalonde et al., 2020). Part 3 addresses acceptability and feasibility limitations found in the literature on the use of music for pain in the adult ICU. The section ends with Part 4, which presents a summary of the evidence and research gaps, which guided the rationale for the objectives of this doctoral research project.

Part 1. Pain in the intensive care unit

Definition of pain

Pain is a personal experience that involves the integration and interaction of multiple dimensions. The International Association for the Study of Pain (IASP) defines pain as "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage" (International Association for the Study of Pain, 2020; Raja et al., 2020, p. 1979). Additional notes include that pain "is influenced to varying degrees by biological, psychological, and social factors" and that "verbal description is only one of several behaviors to express pain" (Raja et al., 2020, p. 1979). The sensory, cognitive, emotional, behavioral, and social dimensions are further defined below.

The sensory dimension of pain refers to the activity in sensory neuronal pathways (Raja et al., 2020). This dimension acknowledges that the person experiencing pain receives a sensory signal (Craig & MacKenzie, 2021). The sensory dimension refers to the intensity, location, and sensation (quality) of pain and is perceived by the person as a discriminative stimulus that can be distinguished from other physiological stimuli (Talbot et al., 2019). Conceptually, pain fibers

carry the pain signal to a pain center in the brain and this input leads to the sensation of pain (Melzack & Casey, 1968). The cognitive dimension of pain is mostly related to the meaning of the painful event (Melzack & Casey, 1968). Cognitively, the sensory input is evaluated and interpreted as being painful or not. Cognitive appraisal can therefore modulate the perception of pain (Melzack & Casey, 1968). Indeed, attention and past experiences can cognitively modify the other pain dimensions such as the sensory pathway and the emotional reaction to the experience (Craig & MacKenzie, 2021; Melzack & Casey, 1968). The emotional dimension of pain refers to the aversive, distressing quality of the experience (Puntillo et al., 2018). The integration of the sensory, cognitive, and emotional processes leads to various observable behavioral responses (Melzack & Casey, 1968). The behavioral dimension of pain refers to the recognition that pain can be experienced and expressed differently by diverse groups of individuals. To be more inclusive of the different realities and modes of communication, nonverbal behaviors such as grimacing, vocalizing, and increased muscle tension, are recognized as an integral part of the pain experience (Helmer et al., 2020; Kunz et al., 2019; Raja et al., 2020). Furthermore, the IASP revised its definition of pain to specify that a person who is unable to communicate verbally can still experience pain (International Association for the Study of Pain, 2021). The social dimension of pain pertains to the social context within which the pain experience occurs (Che et al., 2018; Craig & MacKenzie, 2021; Williams & Craig, 2016). For example, pain can be experienced in situations of caregiving, altruism, and empathy, but also of cruelty, distrust, loss of status, stigma, trauma, and violence (Craig & MacKenzie, 2021). The recognition of multiple dimensions of pain plays an important role in pain assessment, by providing a more complete picture of the pain experience (Craig & MacKenzie, 2021).

Although all dimensions of pain interact and contribute to the person's whole experience of pain, each dimension can be operationalized separately and measured with complementary tools. This can then provide researchers with a more comprehensive evaluation of the person's pain experience. Overall, the reference standard measure of pain in the ICU is the patient self-report, and behavioral responses to pain are used as alternative measures (Devlin et al., 2018). The sensory dimension of pain is often operationalized by pain intensity in the literature but can also include other aspects such as location and quality (Talbot et al., 2019). The standard validated tool to measure pain intensity in the adult ICU is the self-reported 0-10 NRS, administered either verbally or visually (Devlin et al., 2018). The emotional dimension of pain is commonly operationalized by pain distress or unpleasantness (Puntillo et al., 2018). The standard validated tool to measure pain distress in the adult ICU is the self-reported 0-10 NRS (Puntillo et al., 2018). The behavioral dimension of pain is operationalized by behavioral responses indicative of pain, observed, and measured by a trained observer. The recommended validated tools to measure pain behaviors in the adult ICU were developed to measure pain in patients unable to self-report. The Critical-Care Pain Observation Tool (CPOT; Gélinas et al., 2006), scored from 0-8, is one of the alternative reference behavioral measures recommended for use in the adult ICU (Devlin et al., 2018; Gélinas et al., 2006). However, there are currently no validated tools to measure the cognitive and social dimensions of pain for use in the adult ICU. In summary, because the recommended tools to measure pain in critically ill adults are unidimensional, multiple tools should be used to capture different dimensions of pain.

The adult intensive care unit setting

Critical illness is an increasingly important concern for people and countries around the world (Crawford et al., 2023; Vincent et al., 2014). In Canada, adult ICU admissions are

projected to keep growing due to the aging population; with a 12% increase between 2007-2008 and 2013-2014 (Canadian Institute for Health Information, 2016). According to statistics from the Canadian Institute for Health Information (2016), ICU patients are admitted for surgical reasons (46%) and for medical reasons (54%), and an important proportion of them (33%) receive invasive ventilation. Many patients are unable to communicate during their ICU stay because of invasive ventilation, sedation, delirium, or cognitive impairment (Broyles et al., 2012; Gélinas et al., 2018; Gupta et al., 2016; Happ et al., 2011; Happ et al., 2015; Herr et al., 2019; Jakob et al., 2012; Puntillo et al., 2010).

Pain in the adult intensive care unit

In the adult ICU, patients commonly experience acute pain both at rest and during standard care procedures. More than 80% of critically ill adults experience pain, with 50% experiencing moderate to severe pain, which can persist beyond the ICU stay (Choiniere et al., 2014; Damico et al., 2020; Devlin et al., 2018). Along with the reported pain intensity (sensory dimension), patients admitted to the ICU also experience significant procedural pain distress (emotional dimension) (Puntillo et al., 2018). Adequate management of acute pain in the ICU, which is associated with better patient outcomes (e.g., reduced mechanical ventilation duration and shorter ICU length of stay), becomes critical to help mitigate the short- and long-term consequences of pain in critically ill adults (de Jong et al., 2013; Georgiou et al., 2015; Glowacki, 2015).

Short-term consequences of acute pain in the ICU. The acute pain response, which can occur during critical illness, trauma, surgery, or standard care procedure, can lead to adverse effects including severe fluctuations in vital signs, ventilator distress, longer ICU and hospital stay, and increased mortality risk (Chapman et al., 2008; de Jong et al., 2013; Devlin et al., 2018; Yamashita et al., 2017). Moreover, acute pain impairs patients' quality of life, sleep, and mobility, while increasing their length of stay in the hospital (Sinatra, 2010). Indeed, pain is linked to longer ICU stays, and this has an important economic impact (Gagné & Ferrari, 2018). More specifically, pain affects the functional status of ICU patients, leading to deconditioning and longer ICU stays, which are three times more costly than standard care unit stays (Gagné & Ferrari, 2018; Puntillo et al., 2014). Adequate management of acute pain based on a multimodal approach (i.e., using complementary pharmacological and nonpharmacological interventions) in the ICU is associated with improved patient outcomes such as reduced mechanical ventilation duration and shorter ICU length of stay (de Jong et al., 2013; Glowacki, 2015; Lewis et al., 1994).

Long-term consequences of acute pain in the ICU. Acute pain in the ICU is not only a short-term problem but can also have long-lasting consequences. Indeed, moderate to severe acute pain is an important risk factor for the development of chronic pain which can negatively impact daily functioning and quality of life in the long-term (Battle et al., 2013; Gan, 2017; Hayhurst et al., 2018; Kyranou & Puntillo, 2012; Makinen et al., 2020). Specifically, 3-12 months after discharge, 16-77% of ICU survivors still report experiencing persistent and chronic ICU-related pain which was predicted by higher pain intensity while in the ICU, severe sepsis, higher inflammation, higher severity of illness, and organ failure (Battle et al., 2013; Baumbach et al., 2016; Choi et al., 2014; Choiniere et al., 2014; Hayhurst et al., 2018; Kyranou & Puntillo, 2012; Langerud et al., 2018). Chronic pain, in general, also has important economic repercussions, both directly with treatment costs and indirectly with loss of productivity (Cohen et al., 2021). Health Canada reported the total cost of chronic pain to be about $40 billion in 2019 (Canadian Pain Task Force, 2021). Therefore, optimal ICU pain management is essential to prevent the occurrence of the short- and long-term consequences of acute pain.

Pain assessment in the adult intensive care unit

In the adult ICU, pain is routinely assessed by using validated methods adapted to the patient's ability to communicate. In patients able to self-report, the 0-10 NRS is the most valid and feasible scale to use. In those unable to self-report, behavioral assessment is the alternative reference standard. The Behavioral Pain Scale and the CPOT are the most valid behavioral assessment methods in critically ill adults (Devlin et al., 2018; Gélinas et al., 2019). It is recommended to assess pain at rest, during activity/procedures as well as before and after pain management interventions (Herr et al., 2019).

Limitations of pharmacological interventions

Acute pain is predominantly managed with opioids in critically ill adults (Devlin et al., 2018). A Canadian observational study reported that opioids were used in 84.8 % of mechanically ventilated patients (Burry et al., 2014). After being discharged from the ICU, 12.2% of Canadian patients had an opioid prescription in the early post-ICU period and 4.4% still had an opioid prescription 2 years after (Yaffe et al., 2017). However, the use of opioids also may lead to short-term adverse events (e.g., ileus, nausea, sedation, respiratory depression) and may lead to long-term consequences (e.g., addiction, misuse behaviors) (Devlin et al., 2018; Martyn et al., 2019). Therefore, there is a need for a change in practice to a multimodal pain management approach, including the use of the lowest effective opioid dose in conjunction with non-opioid analgesia, and non-pharmacological interventions (Devlin et al., 2018; Ehieli et al., 2017; Stamenkovic et al., 2019). There is a growing interest for non-pharmacological interventions in the ICU as they are usually safe and cost efficient (Chlan et al., 2018; Gélinas et al., 2013). Several non-pharmacological interventions such as music, relaxation, and massage have been recommended for clinical use in the ICU (Devlin et al., 2018; Holden & Retelski, 2019).

Music interventions for ICU pain management

Music interventions used for health-improving goals include music therapy, provided by certified music therapists, and music medicine, defined as the use of pre-recorded music by healthcare professionals (Bradt & Dileo, 2014; Bradt et al., 2016; Stegemann et al., 2019). The use of music is advantageous as an intervention in the ICU because it requires minimal input from the patients who can be fatigued or unable to communicate (Tracy & Chlan, 2011). Previous reviews on the use of music for pain in various acute and chronic care settings, but none has systematically analyzed the evidence on the effect of music for pain reduction in the ICU (Cole

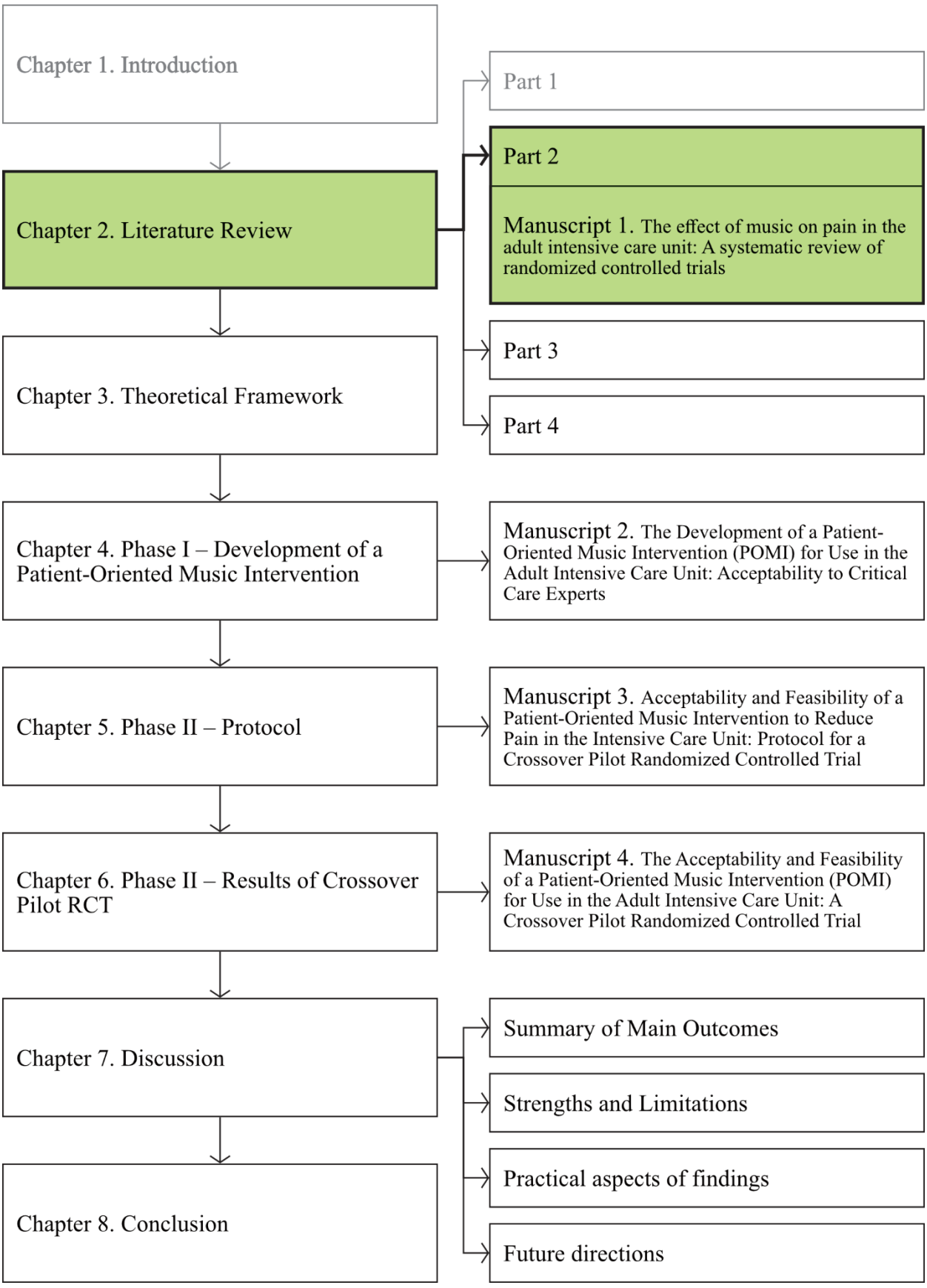
& LoBiondo-Wood, 2014; Hole et al., 2015; Lee, 2016; Martin-Saavedra, Vergara-Mendez, Pradilla, et al., 2018; Meghani et al., 2017; Nilsson, 2008).

In a recent meta-analysis of 45 RCTs, music interventions were shown to have a moderate to large effect size (standardized mean difference of -0.77) on pain reduction for post-operative patients in acute care settings, including the ICU (n = 4; Hole et al., 2015). The authors reported that music reduced pain scores by 23 mm on a 100 mm Visual Analog Scale in this post-operative population. However, the effect of music interventions in reducing pain in the adult ICU population was not specifically examined.

The 2018 Society of Critical Care Medicine (SCCM) practice guidelines recommend offering music for pain management in critically ill adults, as the potential for benefit outweighs any risk of harm, with minimal resources (Devlin et al., 2018, p. e835). In these guidelines, the SCCM panel reviewed seven RCTs with music interventions varying in music type and duration for both procedural and nonprocedural pain (Broscious, 1999; Chan, 2007; Chiasson et al., 2013; Cooke et al., 2010; Jaber et al., 2007; Kshettry et al., 2006; Özer et al., 2013). For procedural pain, the quantitative synthesis showed a nonsignificant reduction of 0.52 points on a 0-10 NRS (p. e836). For non-procedural pain, the quantitative synthesis showed a significant reduction of 0.66 point on a 0-10 NRS (p. e836). The nonsignificant findings may relate to several factors. Firstly, the comparator arms were different across studies. Secondly, one RCT included other complementary interventions along with music. Lastly, the music intervention in each RCT differed from the others in a variety of ways (e.g., music type and duration). These factors contributed to low quality evidence. Therefore, the SCCM guidelines called for more research on the use of music for ICU pain management (Devlin et al., 2018).

A recent integrative review on the effects of music for symptom management (including pain, anxiety, and insomnia) in critically ill adults included nine studies, two of which examined pain, conducted between 2010 and 2016 (Meghani et al., 2017). The findings were mixed: one study, which was not an RCT, reported a decrease in pain while the other, an RCT, had too small of a sample size (n=17) to detect any difference between the pain levels in the music and the control arm (Cooke et al., 2010; Özer et al., 2013). The review concluded that "there is a need for future studies with larger sample sizes and more rigorous designs and methodologies" (Meghani et al., 2017, p. 241). Limitations of this integrative review were that only one author reviewed the literature, and only studies published in English between 2010 and 2016 were included.

Overall, these previous reviews had several limitations, and none focused on the use of music for pain management in critically ill adults. Therefore, to determine the effects of music interventions on pain in the adult ICU, a systematic review, and a meta-analysis of RCTs was conducted.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Part 2. The efficacy of music interventions to reduce pain in the intensive care unit

Manuscript 1. The effect of music on pain in the adult intensive care unit: A systematic review of randomized controlled trials

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Abstract

Context. Multimodal analgesic approaches are recommended for intensive care unit (ICU) pain management. Although music is known to reduce pain in acute and chronic care settings, less is known about its effectiveness in the adult ICU.

Objectives. Determine the effects of music interventions on pain in the adult ICU, compared with standard care or noise reduction.

Methods. This review was registered on PROSPERO (CRD42018106889). Databases were searched for randomized controlled trials of music interventions in the adult ICU, with the search terms [“music*” and (“critical care” or “intensive care”)]. Pain scores (i.e., self-report rating scales or behavioral scores) were the main outcomes of this review. Data were analyzed using a DerSimonian-Laird random effects method with standardized mean difference (SMD) of pain scores. Statistical heterogeneity was determined as I^2>50% and explored via subgroup analyses and meta-regression.

Results. Eighteen randomized controlled trials with a total of 1173 participants (60% males; mean age of 60 years) were identified. Ten of these studies were included in the meta-analysis based on risk of bias assessment (n = 706). Music was efficacious in reducing pain (SMD of -0.63 [95% CI -1.02, -0.24; n = 10]; I^2 = 87%). Music interventions of 20-30 minutes were associated with a larger decrease in pain scores (SMD -0.66 [-0.94, -0.37; n = 5]; I^2 = 30%) compared with interventions of less than 20 minutes (SMD 0.10 [95% CI -0.10, 0.29; n = 4]; I^2 = 0%). On a 0-10 scale, 20-30 minutes of music resulted in an average decrease in pain scores of 1.06 points [95% CI -1.56, -0.56].

Conclusion. Music interventions of 20-30 minutes are efficacious to reduce pain in adult ICU patients able to self-report.

Key Words: Systematic review, music, intensive care, critical care, adult, pain

Introduction

Pain is a common symptom in the intensive care unit (ICU), occurring both at rest and during routine ICU procedures such as chest tube or drain removal, endotracheal suctioning and turning.[1] Clinical practice guidelines recommend a multimodal analgesic approach to minimize the amount of opioids administered,[2] which should include nonpharmacological interventions such as massage and music.[2-4] Although previous reviews have reported the positive effect of music in reducing pain, only five randomized controlled trials (RCTs) conducted in the adult ICU were included in these reviews.[4-10]

Previous systematic reviews in the adult ICU setting have reported the effects of music on anxiety, vital signs, stress or inflammatory markers.[11-13] An integrative review was published about the effects of music on the management of symptoms of anxiety, pain and insomnia in critically ill patients.[9] However, as their aim was to look at the most current evidence of music with adult critically ill patients, with their choice to only review literature published in English, the inclusion criteria were limited to studies published in English from 2010 to 2016.[9] Overall, there remains an important gap in the knowledge of the effects of music on pain in critically ill patients who are known to experience pain.[14,15] Therefore, a systematic review and meta-analysis is needed to help understand whether music is an efficacious intervention to reduce pain in the adult ICU, and if so, what features are efficacious, as well as to inform clinical practice guidelines for pain management in the adult ICU.

Research Question and Objectives

The research question was as follows: What is the effect of music, delivered in addition to standard ICU care, on pain scores, compared with standard care without music or noise reduction (two different types of comparators commonly used in music intervention RCTs) in the adult ICU?

A systematic review and a meta-analysis were conducted to evaluate the effect of music interventions on pain scores in the adult ICU. We also performed subgroup analyses based on music duration, selection (by participant vs. care providers), music provider (music therapist vs. nurse vs. research staff), timing of administration (during procedures vs. at rest), or presence vs. the absence of pharmacological coanalgesia.

Methods

Protocol and Registration

The protocol of this review was registered on PROSPERO in October 2018 (#CRD42018106889). We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement.[16] The PRISMA steps include: identification of all relevant records, selection of eligible RCTs, risk of bias (ROB) assessment, data extraction, qualitative synthesis, and whenever possible, quantitative synthesis or meta-analysis (p. W-66).[16]

Eligibility Criteria

Eligibility criteria for studies were: 1) RCT primary findings; 2) conducted in the adult ICU regardless of specialty; 3) participants at least 18 years old regardless of diagnosis; 4) music as an intervention; and 5) reported pain scores as an outcome before and up to four hours after the music intervention, based on the usual duration of action of most common pain medications used in the ICU.[2,17] Music interventions were eligible if the music was delivered passively by earpiece, pillow, radio, or any other format; played continuously (without interruption); prerecorded or live; played at any frequency, for any duration of time; delivered with or without medication for pain relief; tailored to the participant's preference or preselected by others; and any type of music including birdsongs or other nature-based sounds.

Music interventions were excluded if they were coadministered with any other nonpharmacological intervention (e.g., massage, aromatherapy, meditation, televised stimuli, or guided imagery).

The standard care comparator included any individually-prescribed pain management protocol, as part of the usual course of treatment for each patient. The noise reduction comparator included active (e.g., headphones emitting white noise) or passive (e.g., headphones emitting no sound) noise reducing methods, in addition to standard care.

For patients able to self-report, studies were included when pain was assessed using a self-report intensity scale such as the 0-100 Visual Analog Scale (VAS), the 0-10 Numeric Rating Scale (NRS), the 0-10 University of California, Los Angeles (UCLA) pain score, the 0-10 Faces Pain Scale, or the pain thermometer. For all self-report pain scales, a higher score means a higher level of pain intensity.

For patients unable to self-report, studies were included when pain was assessed using the 0-8 Critical-Care Pain Observation Tool (CPOT) or the 3-12 Behavioral Pain Scale (BPS) for which cut-point scores greater than two and five, respectively, indicate the presence of pain.

Information Sources

Health sciences and music databases were accessed: MEDLINE, Cochrane CENTRAL, Embase, Web of Science, CINAHL, PsycINFO, Scopus, ProQuest Dissertations and Theses Full Text, Music Periodicals Database, JSTOR, Music Index, RILM, ViFaMusik, PubMed, and Google Scholar. Other sources included reference lists of selected articles, key journals, trial registers (ClinicalTrials.gov and the International Standard Randomised Controlled Trials Number: ISRCTN.com), conference proceedings, Internet resources, and contact with authors to attempt to identify any unpublished or otherwise inaccessible trials. No language restriction was applied.

The databases were searched from their inception, covering periods as far back as 1800, until March 1, 2019.

Search

The search strategy, guided by an experienced music librarian, included the terms "music*" and ("critical care" or "intensive care"). Where applicable, the search filtered for controlled trials and adult participants (Supplementary Data 1). The search was also reviewed by an experienced healthcare research librarian.[18]

Study Selection

All the references were screened independently by two reviewers, starting with titles and abstracts, followed by full texts. A third reviewer was consulted for any disagreements in screening of full texts. The online systematic review software DistillerSR (Evidence Partners, Ottawa, Canada) was used for screening, data extraction, and ROB assessment.

Data collection process

A data extraction form adapted from the 2014 Cochrane "Data collection form for intervention reviews: RCTs only" was completed by two reviewers for independent data extraction using the DistillerSR software. The data extraction form was pilot tested using two randomly selected eligible articles, and minor modifications were made. For example, the word total was added next to percent participants to clarify that the percentage of all participants should be extracted (as opposed to the percentage of participants per arm). Disagreements were discussed between the reviewers and consensus was reached.

Data items

The following data was extracted: population description (age, sex and diagnosis), type of ICU, inclusion and exclusion criteria, comparator (standard care and noise reduction), type of outcome measure (pain assessment tools), outcomes (pain scores) and timing of measurement, intention to treat, power analysis, intervention description (type of music, duration, timing, frequency, mode of delivery, providers and any pharmacological cointervention), adverse events, funding and conflicts of interest.

To be consistent and have comparable data across RCTs, only data from one (the first) music session was extracted from studies that had multiple music sessions. Regarding RCTs that evaluated the effect of the music intervention for procedural pain, the first and second time points when data were collected in the study protocol were extracted. The baseline pain scores were extracted for all studies to evaluate the ROB because of baseline imbalances.

Risk of Bias

ROB was also assessed independently by two reviewers using the Cochrane ROB Tool for RCTs.[19] All discrepancies were discussed between all reviewers, and consensus was achieved. Studies with high risk of selection and attrition biases as well as studies deemed to have too much missing information were excluded from quantitative synthesis.

Summary Measures

Data on population characteristics, intervention characteristics and pain score outcomes were collected from the included RCTs and described.

A meta-analysis was done for studies with a lower ROB (studies were excluded if they had a high ROB for random sequence generation, allocation concealment, and/or incomplete outcome

data) and homogeneity was determined by an I^2 value inferior to 50%.[20] Data were analyzed using Review Manager (version 5.3; The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, The Netherlands).[21] The principal summary measures were standardized mean difference (SMD) of pain scores using a DerSimonian-Laird random effects model with a 95% CI. Publication bias was evaluated using funnel plot analyses of asymmetry.

Additional Analysis

Additional analyses were conducted to explore statistical heterogeneity ($I^2 > 50\%$) via subgroup analyses and meta-regression. Random effects meta-regression analyses were conducted for each prespecified potential effect modifier (music duration, selection, provider, timing of administration, and the presence of pharmacological analgesia) using STATA (Version 16.0; Stata-Corp LLC, College Station, TX).[22]

Results

Study Selection

The PRISMA flow diagram is illustrated in Fig. 1.[23] A total of 2907 references were retrieved from database searches, and five additional references were identified through reference lists of selected articles. Once duplicates were removed, 1618 references were screened for titles and abstracts and most (n = 947) were eliminated for not being RCTs. At the full-text phase, 149 articles were assessed. At this phase, most articles were excluded for not having pain as an outcome (n = 64). Eighteen studies were included for a qualitative synthesis, 10 of which were included in the meta-analysis based on ROB.

Study Characteristics

Studies were mostly in English, but some were also in German, Spanish, Portuguese, French, Greek, Turkish, and Chinese. For languages not understood by the reviewers, online translators were used, and multilingual colleagues were consulted to translate, and reviewers then determined the studies' eligibility. The 18 RCTs retained were in English, French, and Spanish, all languages understood by two of the reviewers. Table 1 presents the characteristics of the 18 RCTs conducted across seven countries (USA, n = 5; Iran, n = 5; France, n = 2; Spain, n = 2; Turkey, n = 2; China, n = 1; and Australia, n = 1), arranged chronologically from 1999 to 2018 (years of publication).[24-41] Sample sizes ranged from 17 to 156, totaling 1173 participants. Twelve RCTs (n = 744) compared the effect of a music intervention with standard care and seven RCTs (n = 533) compared the effect of a music intervention with noise reduction, with one RCT reporting both comparators. Two studies reported not having reached their planned sample sizes because of recruitment feasibility issues: Cooke et al.[24] enrolled 17 participants of their projected 50, and Shultis[25] had 20 participants instead of their required sample size of 106.[24,25] The main reason for recruitment issues was patients not meeting eligibility criteria (e.g., unplanned surgery, unable to answer questions).

The mean age of participants was 60 years with 60% males and 40% females. Eight studies solely included participants who had undergone cardiac surgeries, four included participants who had undergone various types of surgeries, and five included participants with a variety of medical diagnoses. Fifteen studies only included participants who were able to communicate (n = 978; 83.4% of included participants), whereas three studies included patients unable to communicate (n = 195; 16.6%). The pain assessment tools used in each study are presented in the last column of Table 1 and included 0-10 or 0-100 self-report scales (n = 14), as well as the 0-8

CPOT (n = 2) and the 3-12 BPS (n = 2). The CPOT was also used with participants who were able to self-report in one study, but no rationale for this was provided by the authors.[26]

None of the RCTs' mean baseline pain score was above six on a 0-10 self-reported scale. More specifically, eight RCTs[24,25,27-32] reported a low mean baseline pain score (zero to three of 10) and five RCTs[33-37] reported a moderate pain score (four to six of 10). For the trials that used behavioral scales, two RCTs[26,38] reported their participants' mean baseline behavioral pain scores to be below the cut-point score (i.e. CPOT <3 or BPS <5), and two RCTs[39,40] reported the scores to be above the cut-point scores (CPOT ≥3 or BPS ≥5). One RCT did not report baseline behavioral pain scores.[41]

Study Characteristics: Interventions

The characteristics of the music interventions varied widely across studies, as described in Table 2 and illustrated in Fig. 2. The music interventions varied in duration, ranging from 10 to 90 minutes, with most studies administering music for 30 minutes (n = 7). Eight RCTs[25,26,28,30,31,34,35,37] played prerecorded music with a pre-specified tempo, usually in the range of 60-80 beats per minute (bpm). Eight RCTs[24,26-28,30,32,37,39] reported music administration for procedural pain (e.g. caused by chest tube removal, endotracheal suction, turning or dressing change). In the other 10 studies, prerecorded or live music was administered while the patient was at rest, that is at a time when no predetermined standard ICU procedure was reported to occur.[25,29,31,33-36,38,40,41] A single music session was administered in 15 studies[24-30,32,34-39,41], and multiple sessions (three to eight) were administered in three studies.[31,33,40] Five studies reported that none of their participants received any pain medication during the music intervention (patients requiring analgesia at the time of the music delivery were excluded), whereas nine studies reported that their participants received opioids as needed, according to their pain management

protocol. Three studies did not specify either way. None of the studies reported withholding standard ICU pain management interventions from the participants.

Providers involved in the delivery of the music intervention were usually not only research staff (n = 9), but also music therapists (n = 2), nurses (n = 2), nursing assistants (n = 1) and one musician (n = 1) (four studies did not specify who administered the music). Overall, music therapists were involved either in the production (e.g., MusiCure, Music Care), selection (e.g., harpist, music lecturer), and/or administration of the music intervention in 10 RCTs.[25-27,29,30,33,34,37,38,41]

In five studies one musical piece was used for all patients, whereas participants in the 13 other studies were offered a selection of at least two pieces. Despite this, eight participants across three studies reported not being satisfied with the music to the point of withdrawing from the study.[28,31,34]

Music was usually delivered by headphones (n = 11) or earphones (n = 4); in one study a music pillow was used, and in another, live harp music was played at the participant's bedside. The mode of delivery was not specified in one study.[25] The devices used for delivery were either cassette players (n = 2), compact disc players (n = 3), MP3 players (n = 7), harp (n = 1), or tablets (n = 1), with some not specified (n = 4).

Risk of Bias

Fig. 3 presents the ROB summary of all 18 RCTs (see Supplementary Data 2 for more details to support judgments).

In two studies, the randomization sequence was generated based on record number or on odd or even number.[26,41] These two studies were also considered high risk for allocation concealment. Because of the nature of music interventions, blinding of participants and/or personnel was deemed improbable for all studies, thus leading to a rating of high risk of performance bias for

all studies. In the 14 studies where participants self-reported their pain intensity, blinding of outcome assessment was considered impossible, and group assignment was considered to have possibly influenced pain self-reports.[24,25,27,28-37,41] Of the four studies in which behavioral pain scores were obtained by nurses, only one reported blinding the outcome assessor to the group allocation.[38] In three studies, some participants withdrew from the study and intention to treat was not applied. The participants withdrew because of the emotional reaction to, or dislike of, the music or headphones: five of 35 (14.3%) participants in the study by Jaber et al.[34]; four of 35 (11.4%) participants in the study by Chan[28]; and two of 22 (9.1%) participants in the study by Sanjuan Navais et al.[31] In one crossover study, three participants withdrew due to discomfort or sudden instability, but it is unclear whether this was during the music or the noise reduction, so the risk of attrition bias was deemed unclear.[38] Otherwise, 12 studies had both low attrition and low reporting biases (Fig. 3). Finally, the funnel plot generated to determine reporting bias across all studies did not yield any conclusive results because of the lack of larger study sample sizes (Supplementary Data 3).

Eight studies were excluded from meta-analysis. One study was excluded because it reported compiled pain results from multiple music sessions instead of reporting results separately for each individual session.[31] Similarly, one study was excluded because it compiled data from a crossover study that did not have a washout period between the music intervention and the noise reduction period, leading to a risk of carryover effect from the music intervention into the control period.[38] Two studies were removed because of high risks of bias in random sequence generation and allocation concealment (see Supplementary Data 2 for more detail).[26,41] Two more studies were excluded because of high risk of attrition bias: in these studies, participants withdrew from the study (and analysis) because of disliking the music.[28,34] Finally, there was an insufficient

quantity of studies (only one) reporting pain using behavioral scores from participants unable to self-report to include in the final analysis.[40] Therefore, only studies using self-reported pain intensity scores were included in the final meta-analysis.

Synthesis of Results

Overall, 12 out of the 18 (66.7%) RCTs reported that the music intervention resulted in a significant decrease in pain scores. Considering that the patients' self-reported pain scores and behavioral scores measure different components of pain, analyses were considered separately for both types of scales.[42] In patients able to self-report, data were sufficient to conduct a meta-analysis. The time points that were included in the meta-analysis are illustrated in Fig. 2 as T_{pre} and T_{post} for each study protocol.

The meta-analysis of all 10 studies is presented in Fig. 4. Music was found to significantly decrease pain scores, with a SMD of -0.63 [95% CI -1.02, -0.24; n = 10] when combining all studies regardless of comparator. Back-transforming the SMD to a 0-10 scale represents a decrease of 0.74 point [95% CI -1.10, -0.37] of 10.[22, 43]

Synthesis of Results: Music vs. Standard Care

In patients able to self-report, music was found to significantly decrease pain scores, with an SMD of -0.74 [95% CI -1.46, -0.02; n = 6] when compared with standard care (Fig. 5). Back-transforming the SMD to the 0-10 scale, this represents a decrease of 0.73 point [-1.36, -0.10] of 10.[21,43]

Synthesis of Results: Music vs. Noise Reduction

In patients able to self-report, music was found to be significantly efficacious in reducing pain scores with an SMD of -0.57 [-1.03, -0.12; n = 5] when compared to noise reduction (Fig. 6). Back-transforming the SMD to the 0-10 scale, this represents a decrease of 0.88 [-1.28, -0.47] of 10.[21,43]

Adverse and Undesired Effects

No adverse effect was reported in any of the 18 RCTs. However, there are some reports of undesired effects. In four studies, a total of nine participants of 107 participants who received music expressed dislike of the selected music.[28,31,33,34] In addition, four other participants expressed dislike of the headphones in two studies.[33,34] In post-RCT patient interviews conducted by Ames et al.,[33] some participants reported that the music interfered with their ability to communicate with others or with their self-dosing via patient-controlled analgesia because of falling asleep while the prerecorded music was playing.[33]

Additional Analysis

The meta-analysis of all 10 studies yielded high heterogeneity (Fig. 4; $I^2 = 87\%$). Studies of music vs. standard care (Fig. 5; $I^2 = 90\%$) and studies of music vs. noise reduction (Fig. 6, $I^2 = 83\%$) also produced high heterogeneity. To explore the heterogeneity, subgroup analyses were conducted based on preselected potential effect modifiers: music selection (participant vs. non-participant), timing of administration (at rest vs. during procedures), duration of music, provider of the music (nurses vs. music therapists vs. research staff), and coanalgesia (presence vs. absence). Meta-regression analyses revealed that none of the potential effect modifiers were significant (all p-values >0.05: $p_{\text{music selection}} = 0.139$; $p_{\text{music timing}} = 0.122$; $p_{\text{music provider}} = 0.347$; and $p_{\text{co-analgesia}} = 0.555$) to account for heterogeneity, with the exception of music duration ($p = 0.005$). The trend of increased music duration being associated with decrease in pain scores can be seen with all included studies compiled (Supplementary Data 4), as well as for studies of music with either type of control group: standard care (Supplementary Data 5) or noise reduction (Supplementary Data 6). Supplementary Data 7 illustrates that there is no significant difference in the efficacy of music interventions administered for pain at rest vs. procedural pain.

Subgroup analyses revealed that 10-15 minutes of music did not significantly decrease pain scores (SMD 0.10 [95% CI -0.10, 0.29; n = 4], I^2 = 0%) whereas 20-30 minutes of music had a significant effect on self-reported pain scores (SMD -0.66 [95% CI -0.94, -0.37; n = 5]; I^2 = 30%). On a 0-10 scale, 20-30 minutes of music resulted in an average decrease of 1.06 points [95% CI -1.56, -0.56].

Additional Analysis: Music vs. Standard Care

Subgroup analyses revealed that 10-15 minutes of music did not significantly decrease pain scores (SMD 0.07 [95% CI -0.16, 0.31; n = 3]; Fig. 7), whereas 20-30 minutes of music had a significant effect on self-reported pain scores (SMD -1.07 [95% CI -1.63, -0.52, n = 2]; Fig. 8). On a 0-10 scale, 20-30 minutes of music resulted in an average decrease of 1.75 points [95% CI -2.84, -0.66]. One study played prerecorded music for 50 minutes and had a significant effect on decreasing pain scores (SMD -3.13 [95% CI -4.12, -2.14]).

Additional Analysis: Music vs. Noise Reduction

Subgroup analyses revealed that 10-15 minutes of music did not have a significant decrease in pain scores (SMD 0.16 [95% CI -0.19, 0.51; n = 2]; Fig. 9), whereas 20-30 minutes of music had a significant decrease in pain scores (SMD -0.51 [95% CI -0.76, -0.26; n = 3]; Fig. 10). On a 0-10 scale, 20-30 minutes of music resulted in an average decrease of 0.82 point [95% CI -1.20, -0.44]. One study played prerecorded natural sounds (e.g., birdsongs) for 90 minutes and had a significant effect on pain reduction (mean difference [MD] -1.23 [95% CI -1.61, -0.79]). One study with the intervention duration of 90 minutes reported increasingly significant pain intensity reduction over time (30 min MD -0.76 [95% CI -1.26, -0.24] and 90 minutes MD -1.23 [95% CI -1.64, -0.82]).

Discussion

To our knowledge, this is the first systematic review and meta-analysis of RCTs to report the effect of music interventions on pain scores in adult ICU patients. Overall, 18 RCTs including 1173 participants were conducted in seven different countries across four continents, although none were from Canada. Music was found to be significantly efficacious in decreasing pain scores when compared with standard care and noise reduction. Subgroup analyses revealed that only duration (i.e., 20-30 minutes) was related to the efficacy of music. This is in line with previous systematic reviews and meta-analyses that have reported music to be efficacious in decreasing pain by 0.5-2.3 on 0-10 scales in acute and chronic care settings.[4-10]

Overall, in ICU adults able to self-report, music interventions were more favorable when compared with standard care. It is possible that noise reduction also has an effect on decreasing pain scores as it has been shown to significantly reduce anxiety in mechanically ventilated ICU patients.[44] If noise reduction has an effect on decreasing pain scores, the mechanism of action could be via the reduction of anxiety or stress because of the associations between anxiety, stress and pain.[45-48] However, in our review, both the noise reduction and the standard care comparators were found to have high heterogeneity. Thus, subgroup analyses were conducted, and heterogeneity was best explained by differences in music duration. Recently, a protocol was developed by Poulsen & Coto[49] for health care settings and nurses to use music in the context of postoperative pain. This protocol recommends the administration of music for at least 15-30 minutes twice daily both preoperatively and postoperatively.[49] This duration is also in line with the minimal duration recommended to reduce anxiety in mechanically ventilated ICU patients.[50] As a trend, it appears that the longer the duration of the first music session, the greater the decrease in pain

score, although this may vary among individuals. Indeed, some benefits might attenuate over time as the novelty of the music stimulus wanes.

Although the effect of music on pain appears independent of the music tempo, recent nursing guidelines were proposed, as a protocol, for the use of music to reduce pain in the perioperative setting, and recommend that music be played at a prespecified tempo of 60-80 bpm in order "to match the recommended heart rate of 60-80 BPM" (p.175).[49] A recent systematic review combining studies conducted in acute and chronic care settings reported that music with a 60-80 bpm tempo was not associated with lower pain scores although the heterogeneity of the results was high ($I^2 = 93\%$), thus limiting the conclusions that can be drawn regarding the impact of tempo.[8] Moreover, in most studies, many characteristics of the music (e.g., tempo, the presence of lyrics) were not described, preventing us from conducting an in-depth analysis of their impact on pain. Furthermore, the guidelines by Poulsen and Coto[49] recommend that music be administered twice daily to be most effective. However, in this current review, there were only two studies with multiple sessions within the same day and these showed inconsistent results. Two of the three studies that tested the effect of multiple sessions (either separated by a minimum of four to six hours or by a minimum of eight hours) of music did not report a significant decrease in pain after multiple sessions.[31,33] On the other hand, one study that tested multiple sessions, each session separated by 24 hours, observed a significant decrease in pain scores in the group that received music on Day 2 and Day 3.[40] More trials should be conducted with multiple music sessions before firm conclusions can be drawn.

No adverse effect was reported, and less than 15% of participants who disliked the music withdrew before study completion in three[28,31,34] of the 18 RCTs. This finding highlights the importance of offering music to patients who like to listen to music, and the importance of selecting

music based on their preferences. Although culture was beyond the scope of our review, these musical preferences could also include cultural considerations.[51,52] For patients unable to self-report, consulting with family members might be the most relevant strategy to determine whether music is an appropriate complementary approach and identify patient's music preferences. This is in line with previous research that has found that some family members are interested in being involved in the music selection process as well as participating in the pain management of their loved ones in the ICU.[53-56] For clinicians, family members can be a source of knowledge on the music preferences of the patient unable to self-report, which can help to direct any music selection made on their behalf. Although the body of literature pertaining to the social and cultural implications of music interventions is scarce, evidence supports that music is universally used for healing purposes, and that it varies more within societies than across them.[57] Thus, for safe and effective integration of music in culturally diverse critically ill patient populations, clinicians should be aware that all patients may benefit from music as long as the patient's preferences are considered. These preferences should be determined by discussing with patients (for those able to self-report) or family members (for those unable to self report). Streaming services with large collections of culturally diverse music could be a helpful resource but remains to be explored.

Based on findings from the meta-analysis, 20-30 minutes of music intervention can decrease pain by almost 2 points on a 0-10 scale for ICU adults able to self-report, when compared to standard care. This is clinically significant for patients with mild-to-moderate acute pain.[58] Moreover, because some patients reported not enjoying the music to the point of withdrawing from studies, efforts should be made to offer music tailored to patients' preferences. However, until there is enough cumulative evidence in the critically ill population, the administration of music at a tempo ranging from 60 to 80 bpm as recommended for postoperative pain management should

be encouraged.[49] Otherwise, music appears to be safe and simple to deliver with evidence of reducing pain in ICU adult patients.

In addition, and as reported by participants in interviews post-RCT,[33] music may be less appropriate for patients self-administering analgesia (e.g. patient-controlled analgesia) if the music is a distraction or induces sleep to the point of causing the patient to skip an analgesic dose. Also, music might not be appropriate in patients who are able to self-report if it interferes with the patient's desire to communicate with others (i.e., by blocking auditory stimulus valued by the patient). Thus, delivery methods of music via headphones that also allow ambient sounds might be considered preferable in patients who desire such a function. In summary, it might be more beneficial to provide music based on the patients' preferences, in terms of not only music selection and timing of the intervention but also modes of delivery, for those who might dislike headphones.

Implications for research

The effect of various duration and number of sessions of music should be further investigated to determine the efficacy of these intervention features on pain. Factorial study designs could be used to test multiple music durations and number of sessions simultaneously and more efficiently than multiple individual experiments.[59] The factorial study design also allows the evaluation of the main effect of each factor (duration and number of sessions) as well as all the interactions possible for each combination of factors. The participation of ICU patients, families and clinicians in decisions concerning duration and number of sessions would be advantageous to take into account the experience and expertise of all stakeholders. Indeed, the involvement of various professionals who have experience working with the critically ill population and/or with music interventions would most benefit future research.

Studies should also compare the costs for patients receiving music interventions for pain reduction with the costs for patients receiving standard ICU care, as patient-directed music intervention was found to be cost effective for reducing anxiety in mechanically ventilated ICU patients.[60]

Too few studies have been conducted with ICU adults unable to self-report to allow for a meta-analysis in this review (only one study had a low enough ROB to be included). Although three RCTs have reported a significant decrease in pain scores in this population, the effect size and clinical implications remain unknown. In future studies, families could be involved in the selection and/or administration of music interventions, based on their willingness to do so.[56] Furthermore, having less restrictive eligibility criteria (e.g., including all ICU patients, regardless of diagnosis or ability to communicate) would improve the feasibility of music studies in the adult ICU. Future studies should include not only surgical cases but also more medical and trauma cases as well as participants that are unable to communicate, as these are all representative of the general ICU population.

Future research steps to be explored include the use of music to reduce pain in nonsurgical ICU patients and those unable to self-report; the use of patient-selected music durations in those able to make such decisions while in the ICU; the interaction between noise reduction, anxiety and pain in the ICU; the examination of the mechanism of action of pain score reduction; and the development of strategies for the implementation of music in the adult ICU.

Limitations

Although it appears that longer music duration is associated with greater decrease in pain scores, no RCT has been conducted to compare various durations, and causality cannot be supported with subgroup analyses presented in this review. Furthermore, the sample sizes from the 20-30 minutes music vs. standard care subgroup meta-analysis were quite small; therefore, larger

studies with lower ROB are needed to further understand the effect of music compared with standard care on pain scores.

The characteristics of the music interventions varied widely, which made it difficult to identify precisely the most relevant active components of these interventions. Finally, despite pain being a multidimensional experience, only pain intensity was reported in all studies included in this review, and therefore, the effect of music on other pain dimensions (e.g., distress, unpleasantness) remains unknown.

Conclusion

In conclusion, in the ICU adult population able to self-report, 20-30 minutes of music administration is efficacious in decreasing pain by one to two points on a 0-10 Numeric Rating Scale compared with noise reduction and standard care. Effective music interventions can be administered by research staff, nurses, or music therapists via headphones (for those who tolerate this mode of delivery) both at rest and during standard care procedures in the adult ICU based on available RCTs. Further research is needed with RCTs of lower ROB in order to draw firm conclusions, and there is an urgent need for more evidence on music effectiveness in ICU adults unable to self-report.

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Competing interests

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Conflicts of interest

The authors declare that they have no known conflicts of interest.

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References

1. Puntillo KA, Max A, Timsit JF, et al. Determinants of procedural pain intensity in the intensive care unit. The Europain(R) study. Am J Respir Crit Care Med 2014;189:39-47.

2. Devlin JW, Skrobik Y, Gélinas C, et al. Clinical Practice Guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption in Adult Patients in the ICU. Crit Care Med 2018;46:e825-e873.

3. Boitor M, Gélinas C, Richard-Lalonde M, Thombs BD. The Effect of Massage on Acute Post-operative Pain in Critically and Acutely Ill Adults Post-thoracic Surgery: Systematic Review and Meta-analysis of Randomized Controlled Trials. Heart Lung 2017;46:339-346.

4. Cepeda MS, Carr DB, Lau J, Alvarez H. Music for pain relief. Cochrane Database Syst Rev 2006:CD004843.

5. Cole LC, LoBiondo-Wood G. Music as an adjuvant therapy in control of pain and symptoms in hospitalized adults: a systematic review. Pain Manag Nurs 2014;15:406-25.

6. Hole J, Hirsch M, Ball E, Meads C. Music as an aid for postoperative recovery in adults: a systematic review and meta-analysis. Lancet 2015;386:1659-1671.

7. Lee JH. The Effects of Music on Pain: A Meta-Analysis. J Music Ther 2016;53:430-477.

8. Martin-Saavedra JS, Vergara-Mendez LD, Pradilla I, Velez-van-Meerbeke A, Talero-Gutierrez C. Standardizing music characteristics for the management of pain: A systematic review and meta-analysis of clinical trials. Complement Ther Med 2018;41:81-89.

9. Meghani N, Tracy MF, Hadidi NN, Lindquist R. Part I: The Effects of Music for the Symptom Management of Anxiety, Pain, and Insomnia in Critically Ill Patients: An Integrative Review of Current Literature. Dimens Crit Care Nurs 2017;36:234-243.

10. Nilsson U. The Anxiety- and Pain-Reducing Effects of Music Interventions: A Systematic Review. Association of Operating Room Nurses. AORN J 2008;87:780-807.

11. Bradt J, Dileo C. Music interventions for mechanically ventilated patients. Cochrane Database Syst Rev 2014:CD006902.

12. Khan SH, Kitsis M, Golovyan D, et al. Effects of music intervention on inflammatory markers in critically ill and post-operative patients: A systematic review of the literature. Heart Lung 2018;47:489-496.

13. Umbrello M, Sorrenti T, Mistraletti G, et al. Music therapy reduces stress and anxiety in critically ill patients: a systematic review of randomized clinical trials. Minerva Anestesiol 2019;85:886-898.

14. Al Sutari MM, Abdalrahim MS, Hamdan-Mansour AM, Ayasrah SM. Pain among mechanically ventilated patients in critical care units. J Res Med Sci 2014;19:726-732.

15. Herr K, Coyne PJ, McCaffery M, Manworren R, Merkel S. Pain assessment in the patient unable to self-report: position statement with clinical practice recommendations. Pain Manag Nurs 2011;12:230-250.

16. Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. PLoS Med 2009;6:e1000100.

17. Canadian Pharmacists Association. E-CPS : Compendium of pharmaceuticals and specialties. Ottawa: Canadian Pharmacists Association, 2004.

18. McGowan J, Sampson M, Salzwedel DM, et al. PRESS peer review of electronic search strategies: 2015 guideline statement. J Clin Epidemiol 2016;75:40-46.

19. Higgins JPT, Altman DG, Gotzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ 2011;343:d5928.

20. Higgins JPT, Green S. Cochrane handbook for systematic reviews of interventions. In: [Oxford]: Cochrane Collaboration, 2011.

21. Review Manager (RevMan) in: 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014.

22. Thompson SG, Higgins JPT. How should meta-regression analyses be undertaken and interpreted? Stat Med 2002;21:1559-1573.

23. Moher D, Liberati A, Tetzlaff J, Altman DG, Group P. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med 2009;6:e1000097.

24. Cooke M, Chaboyer W, Schluter P, et al. The effect of music on discomfort experienced by intensive care unit patients during turning: a randomized cross-over study. Int J Nurs Pract 2010;16:125-131.

25. Shultis C. Effects of music therapy vs. music medicine on physiological and psychological parameters of intensive care patients: A randomized controlled trial. Ann Arbor, MI: Temple University, 2012:186.

26. Yaman Aktaş Y, Karabulut N. The effects of music therapy in endotracheal suctioning of mechanically ventilated patients. Nurs Crit Care 2016;21:44-52.

27. Broscious S. Music: An intervention for pain during chest tube removal after open heart surgery. Am J Crit Care 1999;8:410-415.

28. Chan M. Effects of music on patients undergoing a C-clamp procedure after percutaneous coronary interventions: a randomized controlled trial. Heart Lung 2007;36:431-439.

29. Chiasson AM, Baldwin AL, McLaughlin C, Cook P, Sethi G. The effect of live spontaneous harp music on patients in the intensive care unit. Evid-based Compl Alt 2013;2013:1-6.

30. Guilbaut V. Apport de l'intervention musicale standardisée type Music Care© sur les soins douloureux des patients vigiles en soins critiques Impact of the standardized musical intervention Music Care © on the painful procedures of critically ill patients). In: Médecine humaine et pathologie, Université Nice Sophia Antipolis, 2017:52.

31. Sanjuan Navais M, Via Clavero G, Vazquez Guillamet B, Moreno Duran AM, Martinez Estalella G. Efecto de la música sobre la ansiedad y el dolor en pacientes con ventilación mecánica (Effect of music on anxiety and pain in patients with mechanical ventilation). Enferm Intensiva 2013;24:63-71.

32. Yarahmadi S, Mohammadi N, Ardalan A, Najafizadeh H, Gholami M. The combined effects of cold therapy and music therapy on pain following chest tube removal among patients with cardiac bypass surgery. Complement Ther Clin Pract 2018;31:71-75.

33. Ames N, Shuford R, Yang L, et al. Music listening among postoperative patients in the intensive care unit: a randomized controlled trial with mixed-methods analysis. Integr Med Insights 2017;12:1178633717716455.

34. Jaber S, Bahloul H, Guetin S, et al. Effets de la musicothérapie en réanimation hors sédation chez des patients en cours de sevrage ventilatoire versus des patients non ventilés [Effects of music therapy in intensive care unit without sedation in weaning patients versus non-ventilated patients]. Ann Fr Anesth Reanim 2007;26:30-38.

35. Jafari H, Emami Zeydi A, Khani S, Esmaeili R, Soleimani A. The effects of listening to preferred music on pain intensity after open heart surgery. Iran J Nurs Midwifery Res 2012;17:1-6.

36. Saadatmand V, Rejeh N, Heravi-Karimooi M, et al. Effects of natural sounds on pain: a randomized controlled trial with patients receiving mechanical ventilation support. Pain Manag Nurs 2015;16:483-492.

37. Voss JA, Good M, Yates B, et al. Sedative music reduces anxiety and pain during chair rest after open-heart surgery. Pain 2004;112:197-203.

38. Mateu-Capell M, Arnau A, Juvinya D, Montesinos J, Fernandez R. Sound isolation and music on the comfort of mechanically ventilated critical patients. Nurs Crit Care 2018;24:290-298.

39. Kyavar M, Karkhaneh S, Rohanifar R, et al. Effect of preferred music listening on pain reduction in mechanically ventilated patients after coronary artery bypass graft surgery. Res Cardiovasc Med 2016;5:e33769.

40. Yaghoubinia F, Navidian A, Sasiruddin TM, Sheikh S. Effect of music on pain intensity among patients with loss of consciousness in an intensive care unit. Med-Surg Nurs J 2016;4:40-47.

41. Cigerci Y, Ozbayir T. The effects of music therapy on anxiety, pain and the amount of analgesics following coronary artery surgery. Turk Gogus Kalp Damar Cerrahisi Derg 2016;24:44-50.

42. Hadjistavropoulos T, Craig KD. A theoretical framework for understanding self-report and observational measures of pain: a communications model. Behav Res Ther 2002;40:551-570.

43. Fu R, Vandermeer BW, Shamliyan TA, et al. Handling continuous outcomes in quantitative synthesis. In: Methods guide for effectiveness and comparative effectiveness reviews. Rockville: Agency for Healthcare Research and Quality (AHRQ), 2008.

44. Chlan L, Weinert C, Heiderscheit A, et al. Effects of patient-directed music intervention on anxiety and sedative exposure in critically ill patients receiving mechanical ventilatory support: a randomized clinical trial. JAMA 2013;309:2335-2344.

45. Gross RT, Collins FL. On the relationship between anxiety and pain: a methodological confounding. Clin Psychol Rev 1981;1:375-386.

46. Martinez-Urrutia A. Anxiety and pain in surgical patients. J Consult Clin Psychol 1975;43:437-442.

47. Ploghaus A, Narain C, Beckmann CF, et al. Exacerbation of pain by anxiety is associated with activity in a hippocampal network. J Neurosci 2001;21:9896-9903.

48. Zhuo M. Neural mechanisms underlying anxiety-chronic pain interactions. Trends Neurosci 2016;39:136-145.

49. Poulsen MJ, Coto J. Nursing music protocol and postoperative pain. Pain Manag Nurs 2018;19:172-176.

50. Tracy M, Chlan L. Nonpharmacological interventions to manage common symptoms in patients receiving mechanical ventilation. Crit Care Nurse 2011;31:19-28.

51. Good M, Picot BL, Salem SG, et al. Cultural differences in music chosen for pain relief. J Holist Nurs 2000;18:245-260.

52. McDermott JH, Schultz AF, Undurraga EA, Godoy RA. Indifference to dissonance in native Amazonians reveals cultural variation in music perception. Nature 2016;535:547-550.

53. Gélinas C, Arbour C, Michaud C, Robar L, Côté J. Patients and ICU nurses' perspectives of non-pharmacological interventions for pain management. Nurs Crit Care 2013;18:307-318.

54. Richard-Lalonde M, Boitor M, Mohand-Saïd S, Gélinas C. Family members' perceptions of pain behaviors and pain management of adult patients unable to self-report in the intensive care unit: A qualitative descriptive study. Can J Pain 2018;2:315-323.

55. Stubbs T. Experiences and perceptions of music therapy in critical illness. Nurs Times 2005;101:34-36.

56. Gosselin É, Richard-Lalonde M. Role of family members in pain management in adult critical care. AACN Adv Crit Care 2019;30:398-410.

57. Mehr SA, Singh M, Knox D, et al. Universality and diversity in human song. Science 2019;366.

58. Cepeda MS, Africano JM, Polo R, Alcala R, Carr DB. What decline in pain intensity is meaningful to patients with acute pain? Pain 2003;105:151-157.

59. Spieth PM, Kubasch AS, Penzlin AI, et al. Randomized controlled trials–a matter of design. Neuropsychiatr Dis Treat 2016;12:1341-1349.

60. Chlan LL, Heiderscheit A, Skaar DJ, Neidecker MV. Economic evaluation of a patient-directed music intervention for ICU patients receiving mechanical ventilatory support. Crit Care Med 2018;46:1430-1435.

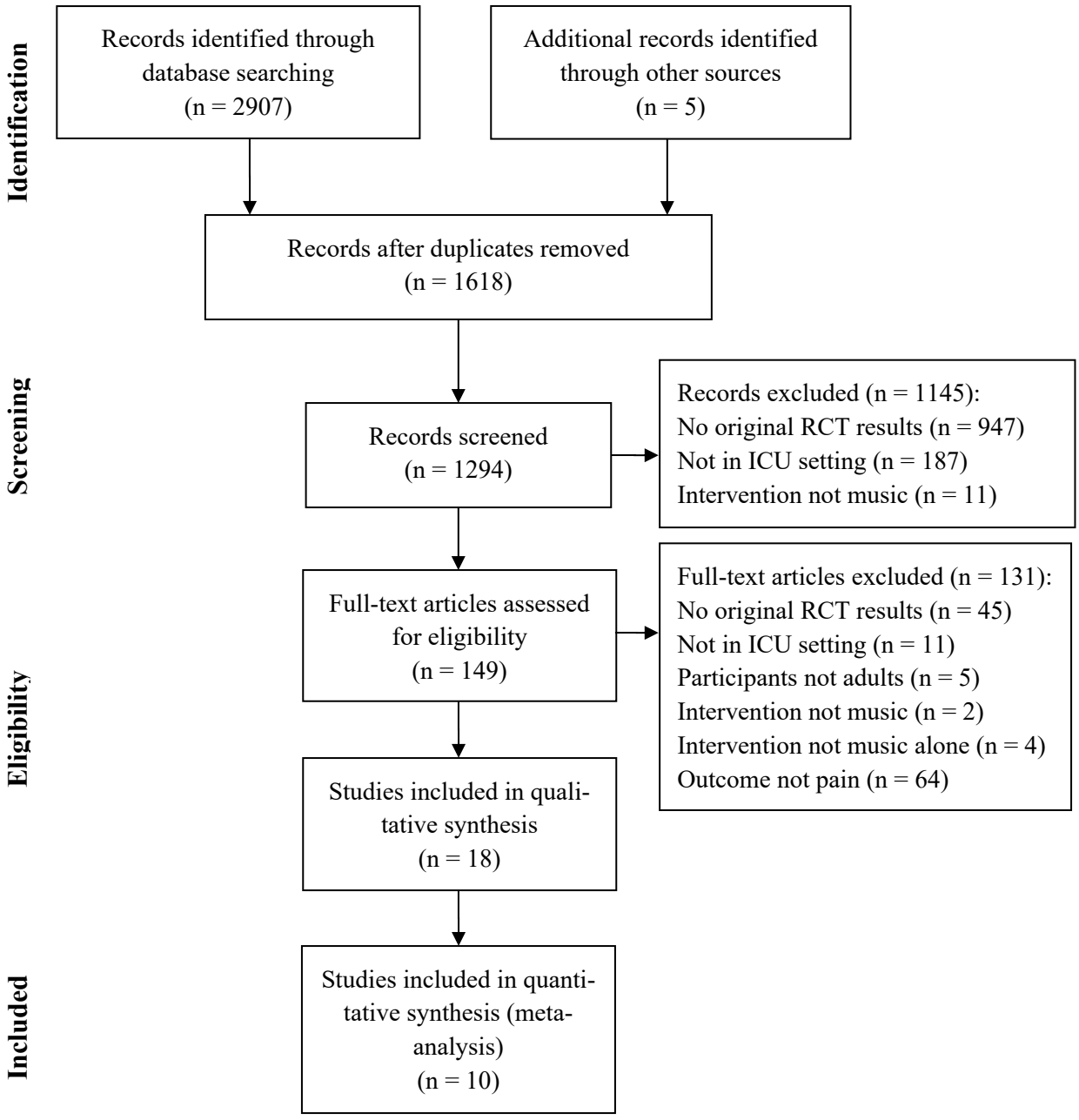


Fig. 1. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis flow diagram of literature search and study selection. RCT = randomized controlled trial; ICU = intensive care unit.

Table 1. Description of Included Study Participants

First Author Name	Year	Country	Sample size	Age mean (SD or min-max)	Male/Female % distribution	Diagnoses included (%)	Ability to self-report	Pain Assessment Tool
Broscious[27]	1999	USA	156	66 (10)	69/31	Cardiac, postoperative (100)	Yes	NRS (0-10)
Voss et al.[37]	2004	USA	40	63 (13)	64/36	Cardiac, postoperative (100)	Yes	VAS (0-100)
Chan[28]	2007	China	66	≥35, most >75 (MNR)	73/27	Cardiac, post-PCI (100)	Yes	UCLA (0-10)
Jaber et al.[34]	2007	France	30	58 (13)	57/43	Postoperative (55.7), medical[a] (43.3)	Yes	NRS (0-10)
Cooke et al.[24]	2010	Australia	17	72[b] (19-87)	71/29	Postoperative[c] (100)	Yes	NRS (0-10)
Jafari et al.[35]	2012	Iran	60	58 (11)	43/57	Cardiac, postoperative (100)	Yes	NRS (0-10)
Shultis[25]	2012	USA	20	65 (37-83)	41/59	NR	Yes	VAS (0-10)
Chiasson et al.[29]	2013	USA	82	62 (17)	65/35	NR	Yes	TVPS (0-10)
Sanjuan Navais et al.[31]	2013	Spain	42	63 (3)	48/52	Medical (45.2), postoperative (54.8)	Yes	NRS (0-10)
Saadatmand et al.[36]	2015	Iran	60	44 (16)	57/43	Asthma (23.3), pneumonia (30), poisoning (20), pancreatitis (13.3), trauma (8.3), sepsis (5)	Yes	VAS (0-10)
Cigerci and Ozbayir[41]	2016	Turkey	68	62 (11)	76/24	Cardiac, postoperative (100)	Yes	VAS (0-10)
Kyavar et al.[39]	2016	Iran	60	60 (8)	77/23	Cardiac, postoperative: CABG (100)	No	CPOT (0-8)
Yaghoubinia et al.[40]	2016	Iran	60	50 (8)	50/50	Cardiac (21.7), neurologic (21.7), respiratory pathology (21.7), GI (21.7), renal (13.3)	No	BPS (3-12)
Yaman Aktas and Karabulut[26]	2016	Turkey	66	65 (12)	73/27	Cardiac, postoperative (100)	Yes	CPOT (0-8)
Ames et al.[33]	2017	USA	41	53 (14)	54/46	Postoperative[d] (100)	Yes	NRS (0-10)
Guilbaut[30]	2017	France	140	80 (49-96)	28/72	NR	Yes	NRS (0-10)
Mateu-Capell et al.[38]	2018	Spain	75	69 (14)	73/27	Infectious pathology (40), respiratory pathology (9.3), cardiac pathology (6.7), other (44)	No	BPS (3-12)
Yarahmadi et al.[32]	2018	Iran	90	58 (8)	67/33	Cardiac, postoperative[e] (100)	Yes	VAS (0-10)

NRS = Numeric Rating Scale; VAS = Visual Analog Scale; MNR = mean not reported; PCI = percutaneous coronary interventions; UCLA = University of California at Los Angeles universal pain score; NR = not reported; TVPS = Thermometer Visual Pain Scale; CABG = coronary artery bypass graft; CPOT = Critical-Care Pain Observation Tool; BPS = Behavioral Pain Scale; GI = gastrointestinal

[a] Medical = pancreatitis (13.3%), pneumopathy (16.7%), sepsis (13.3%).

[b] Median.

[c] Post-op = abdominal (47%), vascular (18%), thoracic (18%), neurosx (6%), genitourinary (6%), neck (6%)

[d] Post-op = nephrectomy (42%), abdominal sx (27%), thoracotomy/lobectomy (22%), adrenalectomy (2%), other (7%).

[e] Cardiac surgeries: CABG (81.6%), valve surgery (18.4%).

Table 2. Music Intervention Characteristics

First author (Language)	Duration[a]	Tempo	Timing	Sessions	Coanalgesia	Provider	Music Selection	Delivery	Comparator
Broscious[27] (English)	10	NS	Procedure: 1 CTR	1	Yes: opioids	NS	Participant chose from 10 categories of cassettes produced by music therapy students	Earphones, cassette player	WNH, SC
Voss[37] (English)	30	60-80	Procedure: 1 chair rest	1	Yes: opioids	Researcher	Participant chose a tape from a collection of six types by listening to 30-second excerpts	Headphones, cassette player	SC
Chan[28] (English)	45	60	Procedure: 1 C-clamp	1	NS	Researcher	Participant chose from three types	Earphones, MP3 player	SC
Jaber[34] (French)	20	U-shape	Rest	1	Music two hours postmedication	MT	U-shaped montage based on participant preferences	Headphones	SC
Cooke[24] (English)	15	NS	Procedure: 1 turning	1	Yes: fentanyl/morphine	Researcher	Participant chose CD from home or from a selection of music provided by the researchers	Earphones, portable CD	NRE
Jafari[35] (English)	30	60-80	Rest	1	Yes	Researcher	Participant chose from a list provided by a music expert	Headphones, MP3 player	NRH
Shrihis[25] (English)	22[b]	60-80	Rest	1	Not monitored	MT	Participant chose from five researcher-compiled CDs	CD player	SC
Chiasson[29] (English)	10	NS	Rest	1	None during music	Harpist	Music varied according to harpist's choice	Live harp	SC
Sanjuan Navais[31] (Spanish)	30	60-80	Rest	3-5[c]	Music one hour preanalgesics/ sedatives	NS	Participant chose from researchers' selection	Earphones	SC
Saadatmand[36] (English)	90	NS	Rest	1	Fentanyl boluses PRN but not during trial of two hours	Researcher, Nurse	Participant chose preferred sounds from CDs from the investigator's collection	Headphones, CD player	NRH
Cigerci[41] (English)	30	NS	Rest	One preoperatively and one in ICU	Opioids + NSAIDs	Researcher	Participant chose from two suggestions: folk vs. classical	Headphones, MP3 player	SC
Kyavar[39] (English)	30	NS	Procedure[d] 1		Yes: morphine	NS	Participant chose from selection	Headphones	NRH
Yaghoubinia[40] (English)	30	NS	Rest	One per day; three total	Fentanyl IV as per unit protocol	researcher	Researchers chose: instrumental music piece for all participants ("Beach Walk" by Arnd Stein)	Headphones, MP3 player	SC
Yaman Aktas[26] (English)	20 pre-ETS + 20 post-ETS	60-80	Procedure: 1 ETS	1	NS	NS	Researcher and lecturer in music field chose: instrumental reed flute for all participants	Music pillow, MP3 player	SC
Ames[33] (English)	50	NS	Any time	4-8; every four to six hours	PCA and PRN	Nurse	Researchers chose one piece: MusiCure Dreams album by Grefion Records for all participants	Headphones	SC
Guilbaut[30] (French)	20	U-shape	Procedure[e] 1		Yes (41%), no (59%)	Nurse assistant	Participant chose from Music Care selection	Headphones, mobile tablet	NRH
Mateu-Capell[38] (English)	60	NS	Rest	1	NS	Researcher	Music therapist chose one piece for all participants (Reiki - Merlin's Magic by Andreas Mock)	Headphones, MP3 player	NCH
Yarahmadi[32] (English)	15 pre-CTR + 15 post-CTR	NS	Procedure: 1 CTR	1	None one hour or more pre-CTR	Researcher	Participant chose from 15 pieces	Headphones, MP3 player	SC

NS = not specified; CTR = chest tube removal; WNH = white noise headphones; SC = standard care; MT = music therapist; CD = compact disc; NRE = noise reduction via earphones; NRH = noise reduction via headphones; PRN = pro re nata (as needed); ICU = intensive care unit; NSAIDs = nonsteroidal anti-inflammatory drugs; IV = intravenous; ETS = endotracheal suction; PCA = patient-controlled analgesia; NCH = noise-canceling headphones.

[a] In minutes.

[b] Mean duration.

[c] Minimum eight hours between each session.

[d] Dressing change.

[e] Dressing change, ETS, turning, and others.

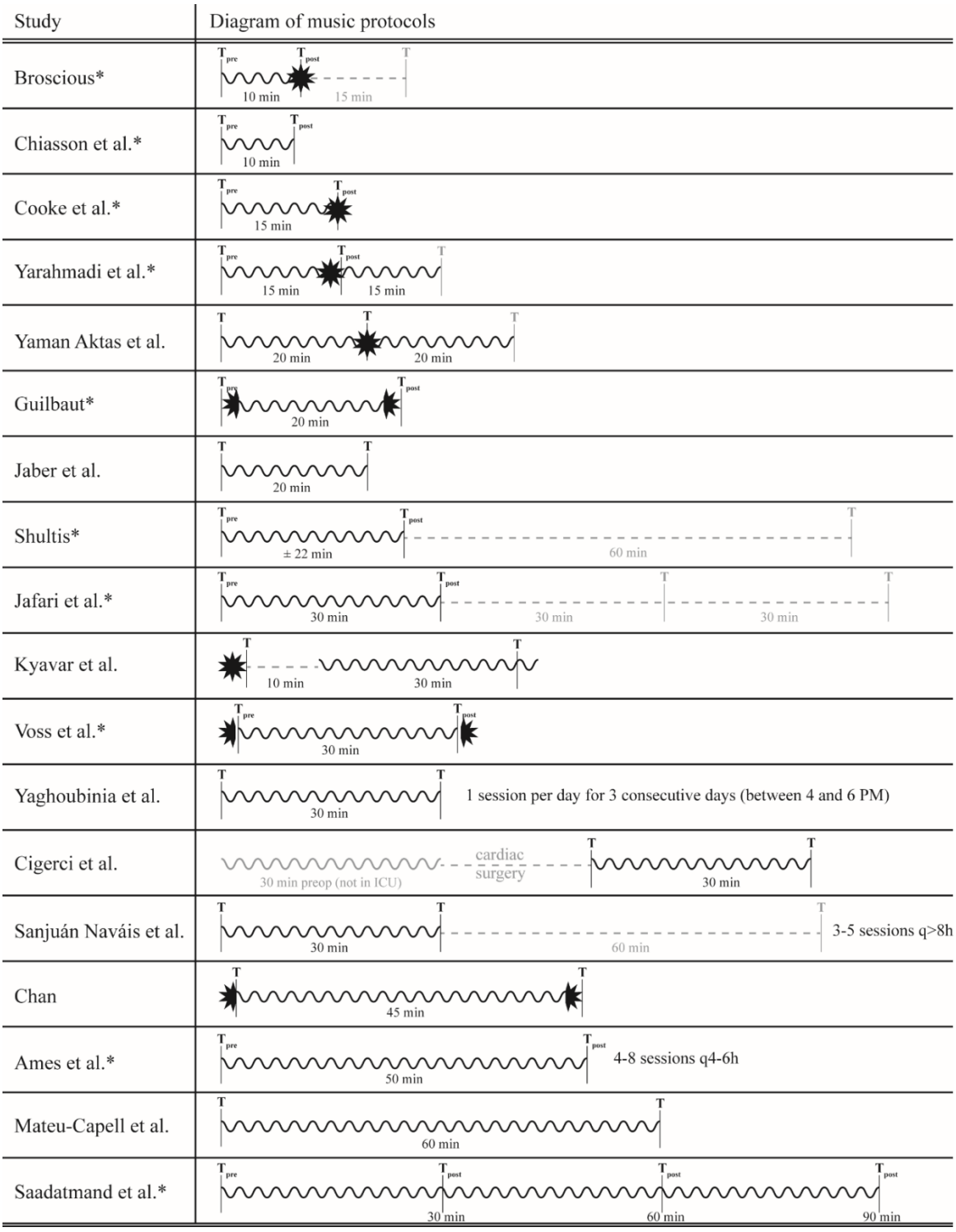


Fig. 2. Music protocol diagrams of included studies. *Studies included in meta-analysis.

music duration (five-minute length) — time period without music

painful procedure in ICU — $\mathbf{T_{pre}}$ $\mathbf{T_{post}}$ measurement points included in meta-analysis

Note. This figure was created by the first author.

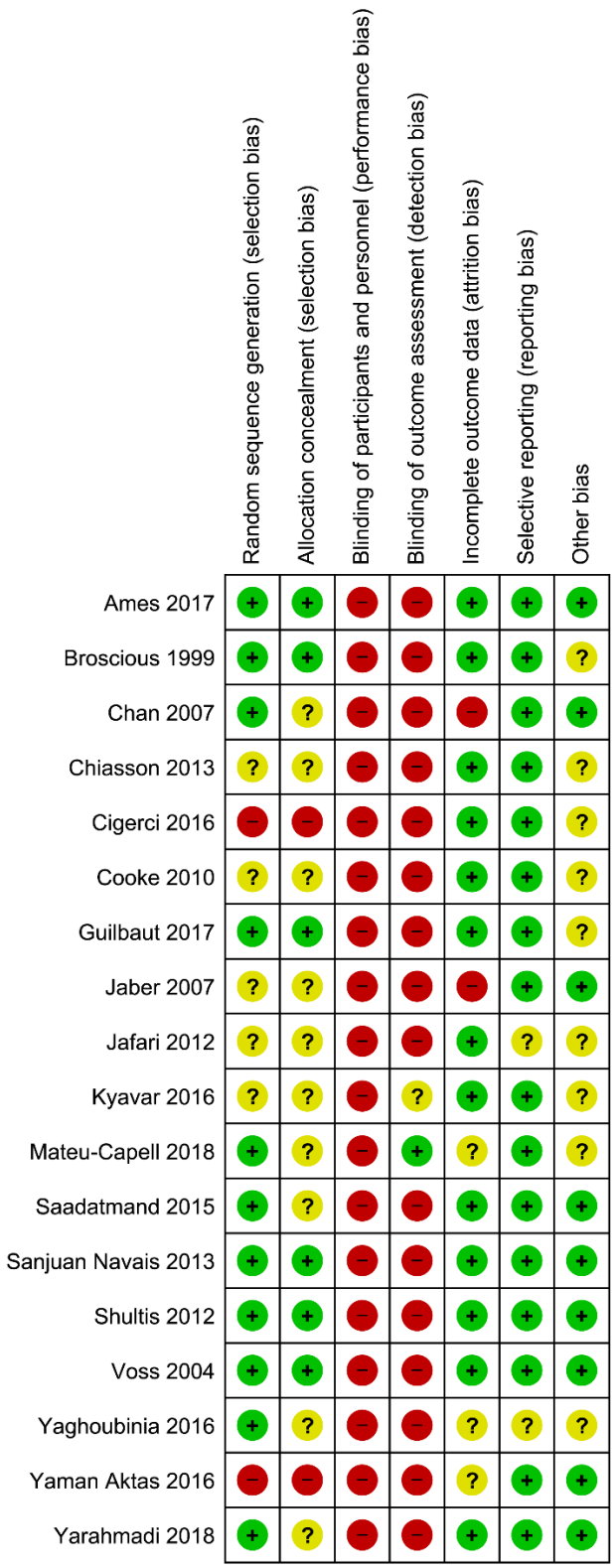


Fig. 3. Risk of bias summary: review of the authors' judgments about each risk of bias item for each included study.

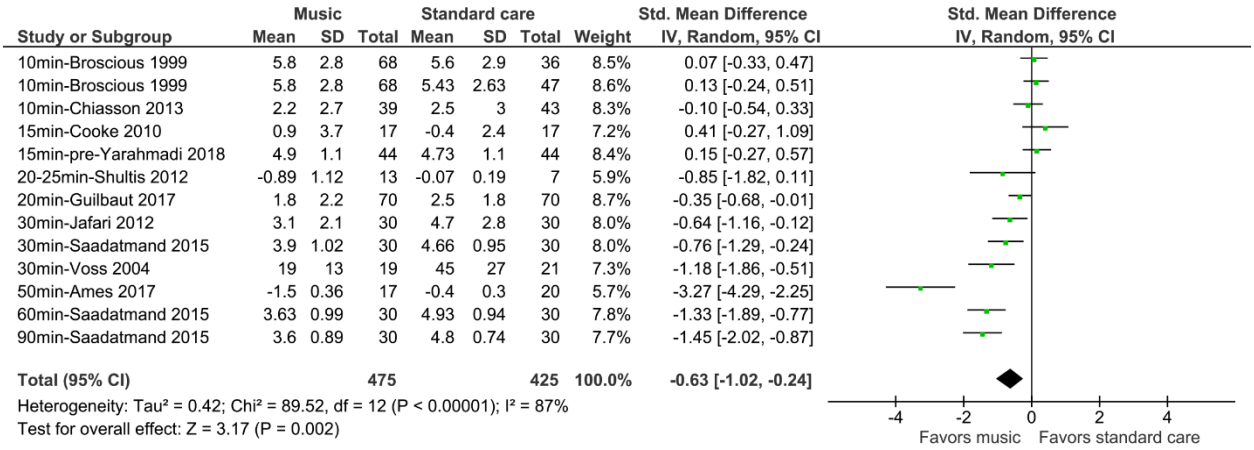


Fig. 4. The efficacy of music for self-reported pain scores of intensive care unit adults. IV = inverse variance.

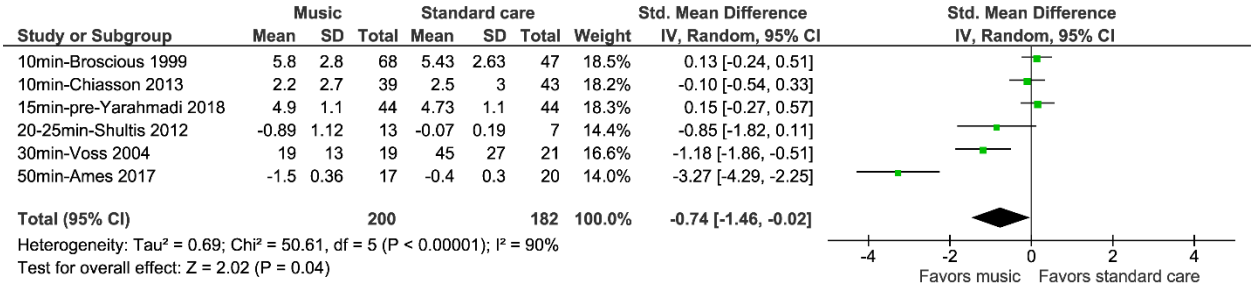


Fig. 5. The efficacy of music vs. standard care for self-reported pain scores of intensive care unit adults. IV = inverse variance.

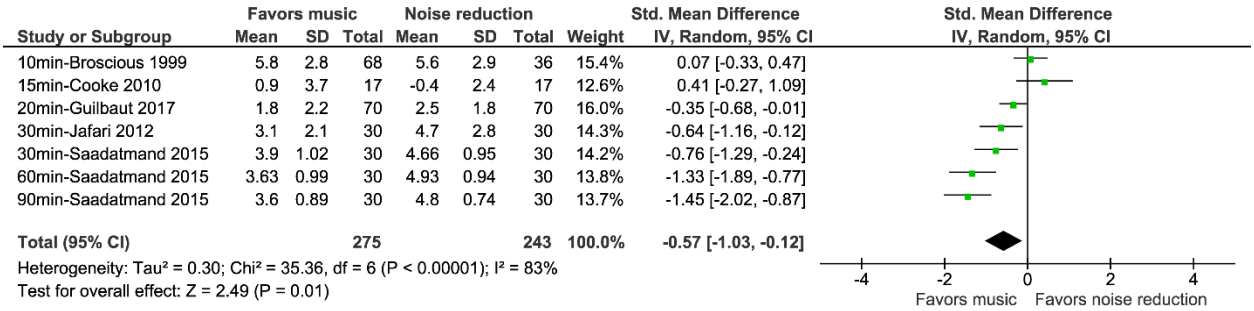


Fig. 6. The efficacy of music vs. noise reduction for self-reported pain scores of intensive care unit adults. IV = inverse variance.

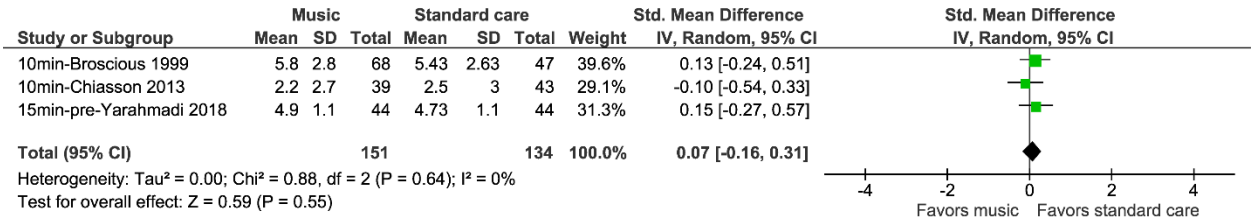


Fig. 7. The efficacy of music vs. standard care for self-reported pain scores of intensive care unit adults (10-15 minutes subgroup). IV = inverse variance.

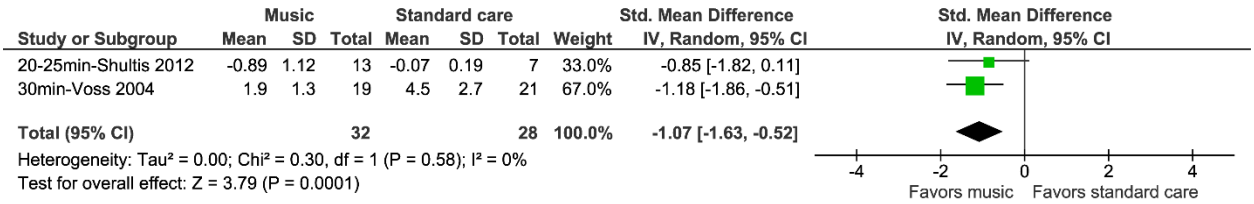


Fig. 8. The efficacy of music vs. standard care for self-reported pain scores of ICU adults (20-30 minutes subgroup)

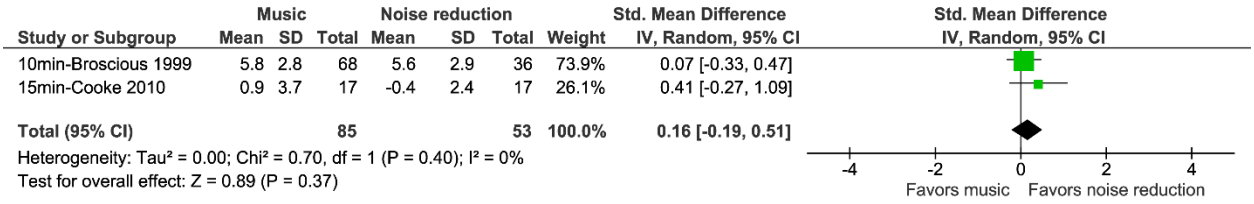


Fig. 9. The efficacy of music vs. noise reduction for self-reported pain scores of intensive care unit adults (10-15 minutes subgroup). IV = inverse variance.

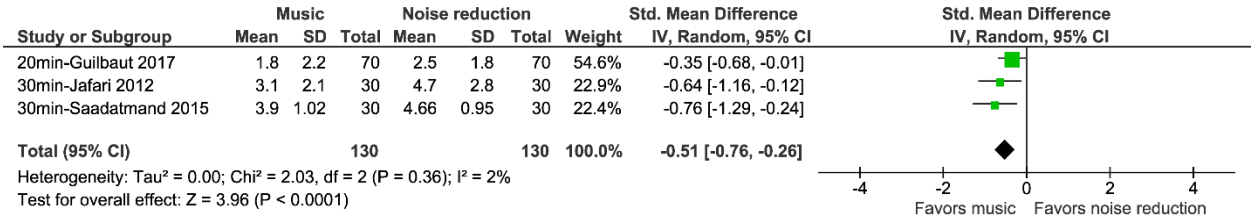


Fig. 10. The efficacy of music vs. noise reduction for self-reported pain scores of intensive care unit adults (20-30 minutes subgroup). IV = inverse variance.

Supplementary Data 1. Search Strategy for Medline (Ovid)

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1996 to June 15, 2018

#	Searches	Results
1	MUSIC/ or music*.mp.	17595
2	intensive care.mp. or Critical Care/	137997
3	1 and 2	221

URL to search strategy: https://ovidsp-tx-ovid-com.proxy3.library.mcgill.ca/sp-3.30.0b/ovidweb.cgi

Supplementary Data 2. Risk of Bias Summary for Each Included Study

Ames 2017

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	computer-generated, permuted block randomization schema
Allocation concealment (selection bias)	Low risk	opaque, sealed envelopes prepared by the statistician
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	High risk	pain was self-reported (no blinding) and self-report could have been influenced
Incomplete outcome data (attrition bias)	Low risk	missing data balanced across groups
Selective reporting (reporting bias)	Low risk	pre-specified and expected pain outcomes reported as per protocol
Other bias	Low risk	none identified

Broscious 1999

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	draw of a chip from a box containing 3 chips
Allocation concealment (selection bias)	Low risk	blind draw of chip by either primary investigator or research assistant
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	High risk	pain was self-reported (no blinding) and self-report could have been influenced
Incomplete outcome data (attrition bias)	Low risk	missing data balanced across groups
Selective reporting (reporting bias)	Low risk	pre-specified and expected pain outcomes reported
Other bias	Unclear risk	unclear if baseline imbalance (large difference in n across three arms)

Chan 2007

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	random digit randomizer
Allocation concealment (selection bias)	Unclear risk	not specified
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	High risk	pain was self-reported (no blinding) and self-report could have been influenced
Incomplete outcome data (attrition bias)	High risk	missing data not balanced across groups; reasons likely related to outcome
Selective reporting (reporting bias)	Low risk	pre-specified and expected pain outcomes reported
Other bias	Low risk	none identified

Chiasson 2013

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	general statement of random assignment
Allocation concealment (selection bias)	Unclear risk	not specified
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	High risk	pain was self-reported (no blinding) and self-report could have been influenced
Incomplete outcome data (attrition bias)	Low risk	missing data balanced across groups
Selective reporting (reporting bias)	Low risk	pre-specified and expected pain outcomes reported
Other bias	Unclear risk	unclear if baseline imbalance (too few sociodemographic characteristics reported)

Cigerci 2016

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	odd or even number
Allocation concealment (selection bias)	High risk	no concealment
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	High risk	pain was self-reported (no blinding) and self-report could have been influenced
Incomplete outcome data (attrition bias)	Low risk	no missing data reported
Selective reporting (reporting bias)	Low risk	pre-specified and expected pain outcomes reported
Other bias	Unclear risk	unclear if baseline imbalance (baseline pain values not reported)

Cooke 2010

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	general statement of random assignment
Allocation concealment (selection bias)	Unclear risk	not specified
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	High risk	pain was self-reported (no blinding) and self-report could have been influenced
Incomplete outcome data (attrition bias)	Low risk	no missing data reported
Selective reporting (reporting bias)	Low risk	pre-specified and expected pain outcomes reported
Other bias	Unclear risk	unclear if carry-over effect from cross-over design

Guilbaut 2017

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	randomization was done in blocks of four
Allocation concealment (selection bias)	Low risk	blinded envelope
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	High risk	pain was self-reported (no blinding) and self-report could have been influenced
Incomplete outcome data (attrition bias)	Low risk	no missing data reported
Selective reporting (reporting bias)	Low risk	pre-specified and expected pain outcomes reported
Other bias	Unclear risk	unclear if data was reported for individuals or for procedures

Jaber 2007

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	general statement of random assignment
Allocation concealment (selection bias)	Unclear risk	not specified
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	High risk	pain was self-reported (no blinding) and self-report could have been influenced
Incomplete outcome data (attrition bias)	High risk	missing data not balanced across groups; reasons likely related to outcome
Selective reporting (reporting bias)	Low risk	pre-specified and expected pain outcomes reported
Other bias	Low risk	none identified

Jafari 2012

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	general statement of random selection
Allocation concealment (selection bias)	Unclear risk	not specified
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	High risk	pain was self-reported (no blinding) and self-report could have been influenced
Incomplete outcome data (attrition bias)	Low risk	no missing data reported
Selective reporting (reporting bias)	Unclear risk	pre-specified and expected pain outcomes reported as per protocol
Other bias	Unclear risk	unclear if baseline imbalance (too few sociodemographic characteristics reported)

Kyavar 2016

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	samples were randomly divided into two groups
Allocation concealment (selection bias)	Unclear risk	not specified
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	Unclear risk	pain was assessed using CPOT and it is unclear whether evaluators were blinded
Incomplete outcome data (attrition bias)	Low risk	missing data balanced across groups
Selective reporting (reporting bias)	Low risk	pre-specified and expected pain outcomes reported
Other bias	Unclear risk	unclear (missing information throughout article)

Mateu-Capell 2018

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	computer-generated random number sequence in blocks of eight
Allocation concealment (selection bias)	Unclear risk	not specified
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	Low risk	pain was assessed using BPS and outcome assessors were blinded to group assignment
Incomplete outcome data (attrition bias)	Unclear risk	unclear if missing data is balanced across groups (when the participant dropout occurred in the crossover design)
Selective reporting (reporting bias)	Low risk	pre-specified and expected pain outcomes reported as per protocol
Other bias	Unclear risk	unclear if carry-over effect from cross-over design

Saadatmand 2015

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	coin flip
Allocation concealment (selection bias)	Unclear risk	not specified
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	High risk	pain was self-reported (no blinding) and self-report could have been influenced
Incomplete outcome data (attrition bias)	Low risk	no missing data reported
Selective reporting (reporting bias)	Low risk	pre-specified and expected pain outcomes reported
Other bias	Low risk	none identified

Sanjuan Navais 2013

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	simple random assignment
Allocation concealment (selection bias)	Low risk	distribution was carried out by means of sealed and numbered envelopes
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	High risk	pain was self-reported (no blinding) and self-report could have been influenced
Incomplete outcome data (attrition bias)	Low risk	no missing data reported
Selective reporting (reporting bias)	Low risk	pre-specified and expected pain outcomes reported
Other bias	Low risk	none identified

Shultis 2012

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	website randomizer
Allocation concealment (selection bias)	Low risk	blinded envelopes
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	High risk	pain was self-reported (no blinding) and self-report were likely to be influenced
Incomplete outcome data (attrition bias)	Low risk	no missing data reported
Selective reporting (reporting bias)	Low risk	pre-specified and expected pain outcomes reported
Other bias	Low risk	none identified

Voss 2004

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	varied block size prepared by the statistician
Allocation concealment (selection bias)	Low risk	sealed, blinded envelopes
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	High risk	pain was self-reported (no blinding) and self-report could have been influenced
Incomplete outcome data (attrition bias)	Low risk	reason for missing data not related to outcome
Selective reporting (reporting bias)	Low risk	pre-specified and expected pain outcomes reported
Other bias	Low risk	none identified

Yaghoubinia 2016

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	permuted blocks, through random numbers table
Allocation concealment (selection bias)	Unclear risk	not specified
Blinding of participants and personnel (performance bias)	High risk	participants were unconscious but personnel were unlikely blinded as the control arm did not wear headphones
Blinding of outcome assessment (detection bias)	High risk	pain was assessed with BPS but outcome assessors were not blinded and could have influenced measurement
Incomplete outcome data (attrition bias)	Unclear risk	unclear if missing data is balanced across groups
Selective reporting (reporting bias)	Unclear risk	pre-specified and expected pain outcomes reported as per protocol
Other bias	Unclear risk	unclear (missing information throughout article)

Yaman Aktas 2016

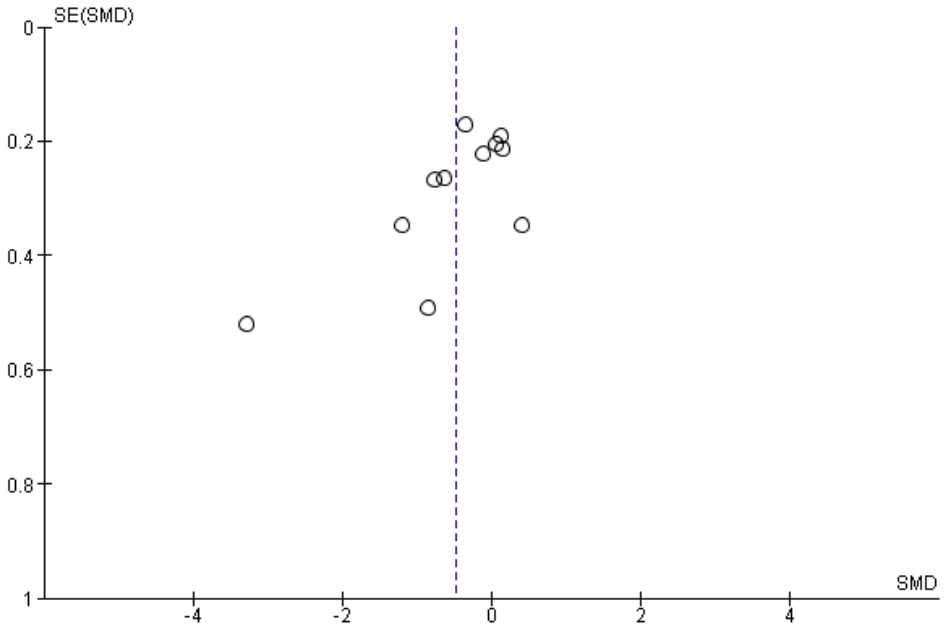
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	randomization using file numbers
Allocation concealment (selection bias)	High risk	no concealment
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	High risk	pain was assessed with CPOT but outcome assessors were not blinded and could have influenced measurement
Incomplete outcome data (attrition bias)	Unclear risk	unclear if missing data is balanced across groups
Selective reporting (reporting bias)	Low risk	pre-specified and expected pain outcomes reported
Other bias	Low risk	none identified

Yarahmadi 2018

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	using an eight-member block technique; factorial-controlled clinical trial
Allocation concealment (selection bias)	Unclear risk	not specified
Blinding of participants and personnel (performance bias)	High risk	participant blinding was not possible; participants could have been influenced by group assignment
Blinding of outcome assessment (detection bias)	High risk	pain was self-reported (no blinding) and self-report could have been influenced
Incomplete outcome data (attrition bias)	Low risk	no missing data reported
Selective reporting (reporting bias)	Low risk	pre-specified and expected pain outcomes reported as per protocol
Other bias	Low risk	none identified

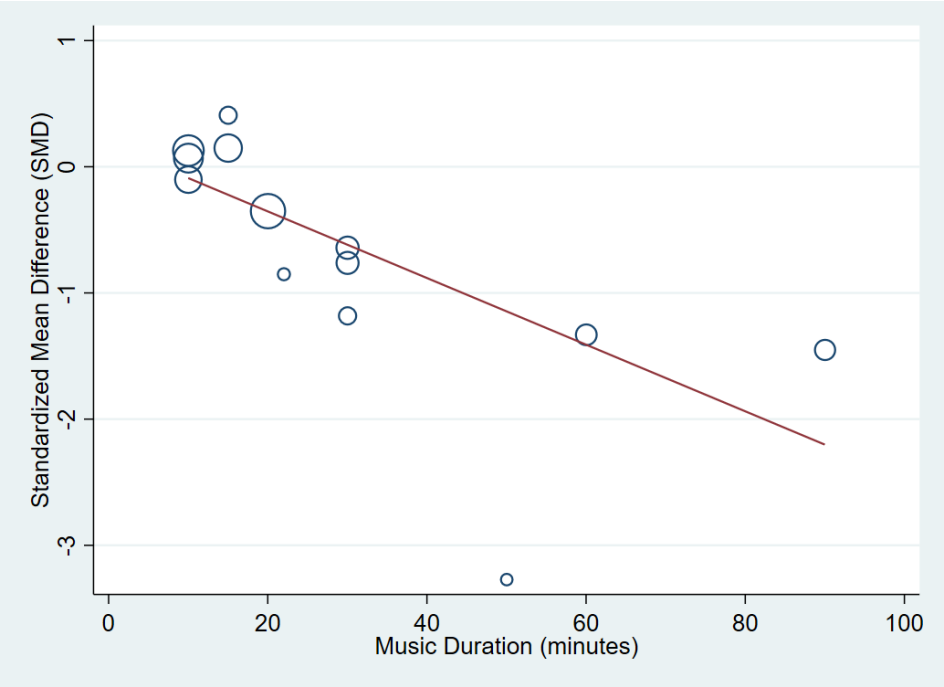
CPOT = Critical-Care Pain Observation Tool; BPS = Behavioral Pain Scale.

Supplementary Data 3. Funnel plot for all studies included in meta-analysis

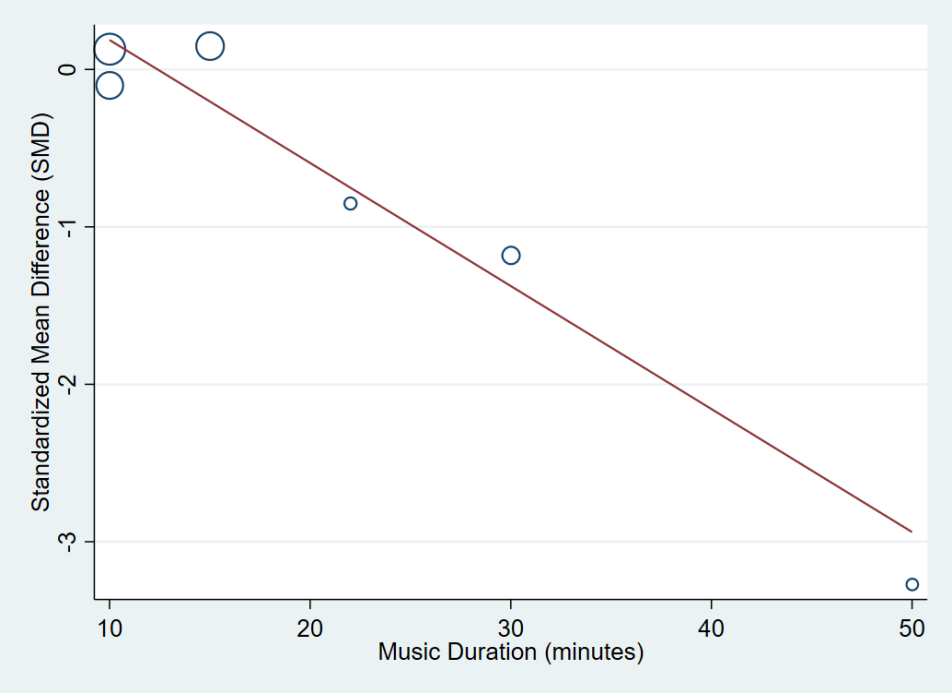


SMD = standardized mean difference.

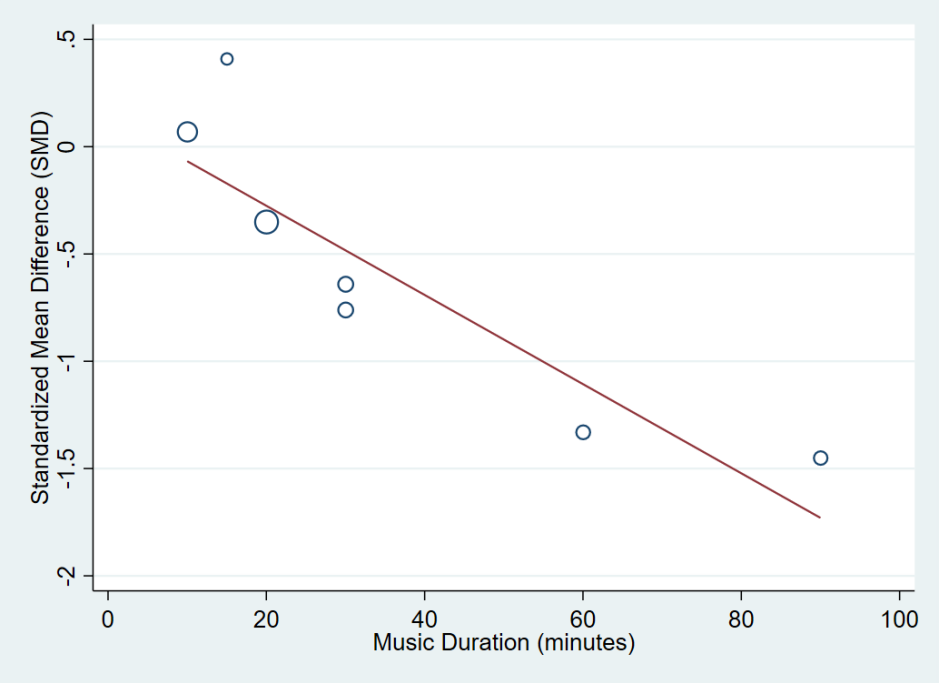
Supplementary Data 4. Meta-regression graph of the relationship between the standardized mean difference of pain and the duration of music interventions in all included studies (n = 10 studies)



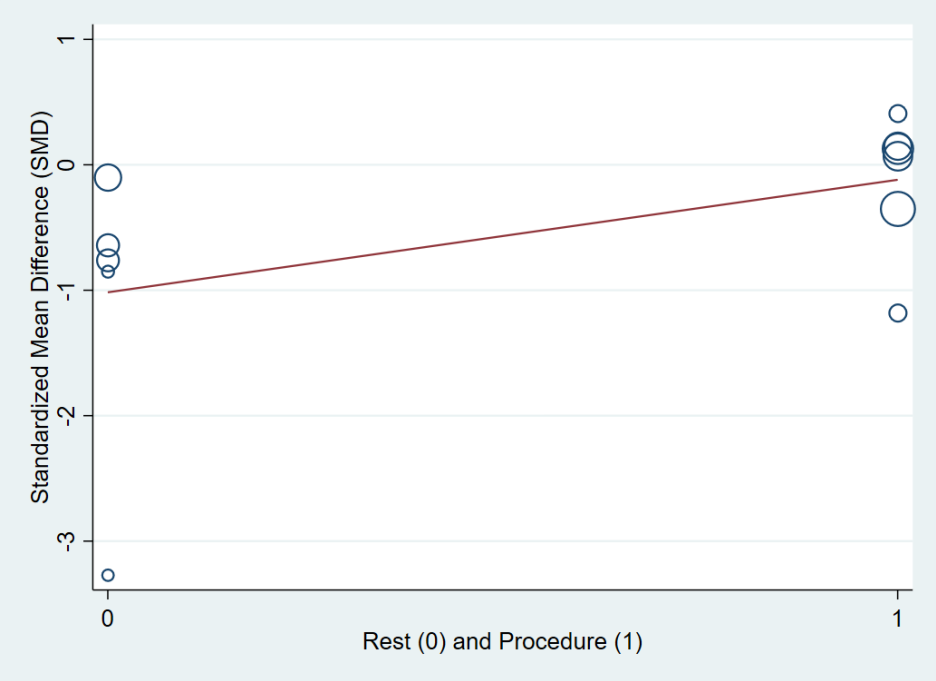
Supplementary Data 5. Meta-regression graph of the relationship between the standardized mean difference of pain and the duration of music interventions in studies of music vs. standard care (n = 6 studies)

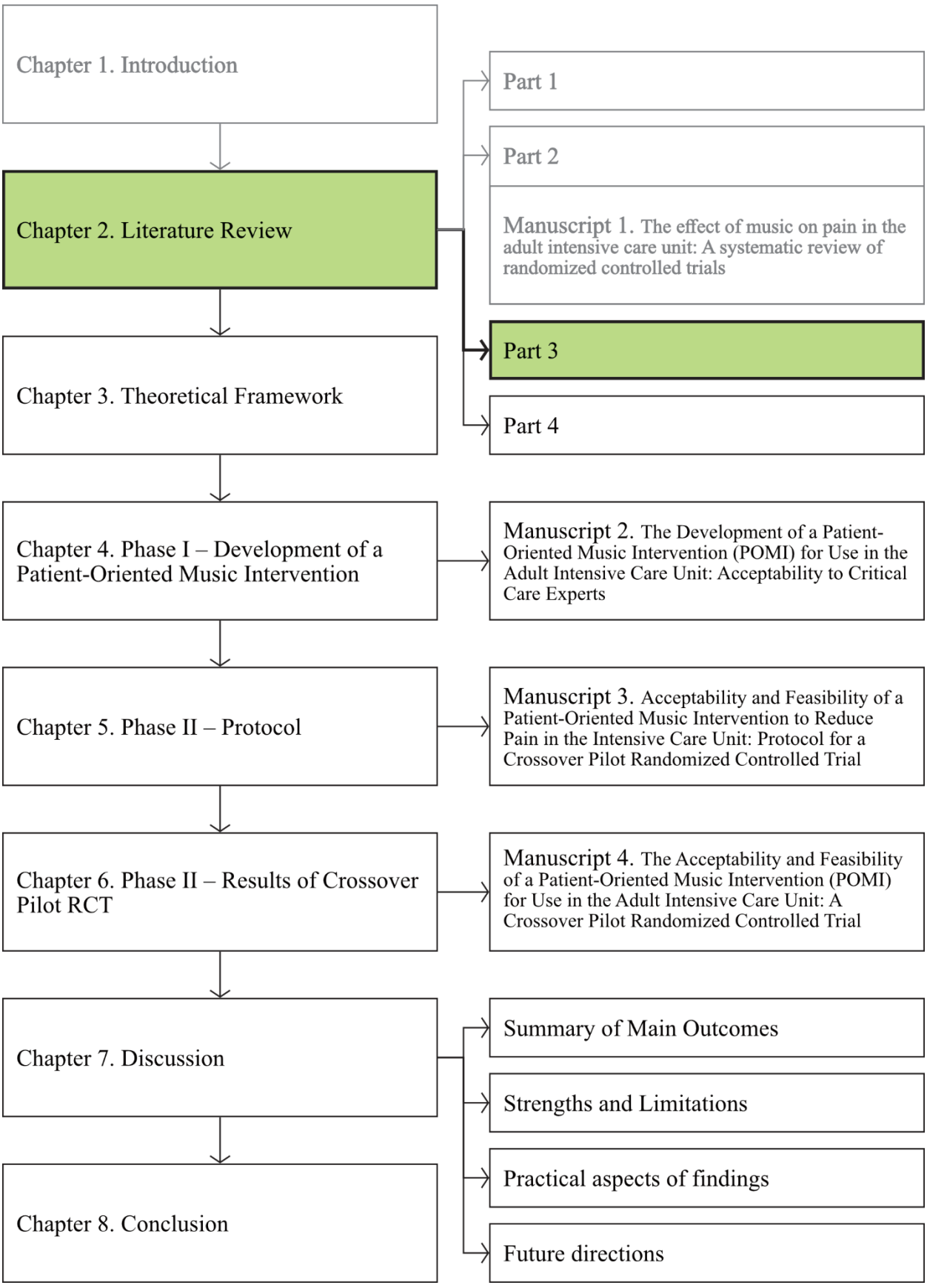


Supplementary Data 6. Meta-regression graph of the relationship between the standardized mean difference of pain and the duration of music interventions in studies of music vs. noise reduction (n = 5 studies)



Supplementary Data 7. Meta-regression graph of the relationship between the standardized mean difference of pain and music interventions given for pain at rest vs. procedural pain (n = 10 studies)




Chapter 1. Introduction
Chapter 2. Literature Review
Chapter 3. Theoretical Framework
Chapter 4. Phase I – Development of a Patient-Oriented Music Intervention
Chapter 5. Phase II – Protocol
Chapter 6. Phase II – Results of Crossover Pilot RCT
Chapter 7. Discussion
Chapter 8. Conclusion
Part 1
Part 2
Manuscript 1. The effect of music on pain in the adult intensive care unit: A systematic review of randomized controlled trials
Part 3
Part 4
Manuscript 2. The Development of a Patient-Oriented Music Intervention (POMI) for Use in the Adult Intensive Care Unit: Acceptability to Critical Care Experts
Manuscript 3. Acceptability and Feasibility of a Patient-Oriented Music Intervention to Reduce Pain in the Intensive Care Unit: Protocol for a Crossover Pilot Randomized Controlled Trial
Manuscript 4. The Acceptability and Feasibility of a Patient-Oriented Music Intervention (POMI) for Use in the Adult Intensive Care Unit: A Crossover Pilot Randomized Controlled Trial
Summary of Main Outcomes
Strengths and Limitations
Practical aspects of findings
Future directions

Part 3. Acceptability and feasibility research gaps

The acceptability of an intervention is important to evaluate because it provides information on how interested parties (including patients, their family members, and clinicians) will respond to an intervention. The feasibility of an intervention is also crucial to evaluate because it provides key information on the practicality of implementation and reproducibility of the intervention. Among the RCTs previously conducted in the ICU for pain management, it is important to note that none of the music interventions were evaluated using a comprehensive approach with validated tools and rigorous methods for acceptability or feasibility. In addition, it is important to evaluate the feasibility of research methods, such as with a pilot study, prior to conducting a full-scale RCT aiming to evaluate the efficacy of a newly developed intervention. The evaluation of feasibility of research methods is especially relevant, considering that major methodological challenges were flagged in previous RCTs of music interventions.

Acceptability of music interventions

Acceptability refers to the suitability of the intervention from the perspective of those involved in the intervention including patients, families, and clinicians (Feeley et al., 2009). An acceptable intervention will influence its uptake and is therefore important to evaluate (Sidani & Braden, 2011). More specifically, Sidani and Braden (2011) defined the acceptability of an intervention as a the "judgment of the extent to which the intervention is appropriate and effective in addressing the presenting problem, is convenient and has minimal risk, and the extent to which [interested parties] are willing to adhere to it" (Sidani & Braden, 2011, p. 175). Although preliminary evidence from a pilot clinical trial showed that ICU patients were highly satisfied with an electronic tablet-delivered music intervention, the acceptability of a music intervention has never been evaluated using a comprehensive approach with validated tools (Knudson et al., 2018). Therefore,

there is a need to evaluate the acceptability of music interventions in the adult ICU from the perspective of all interested parties (i.e., ICU patients, families, and clinicians).

Feasibility of music interventions

According to Sidani & Braden (2011), the feasibility of an intervention refers to the practicality of applying the intervention (p. 163, 180). Relevant feasibility indicators of music interventions in the ICU include: the percentage of patients who received the intervention, the dose (duration in minutes) of music actually delivered, the content (list of music pieces actually played), the fidelity of the intervention delivery, and the reach of ICU patients unable to self-report, as a subgroup of the ICU population that has been neglected in music research thus far (Feeley et al., 2009, p. 87-88; Sidani & Braden, 2011, p. 182-185). A few studies reported on the feasibility of music as part of multi-component interventions (i.e., delivered in combination with other interventions such as gentle touch and diary keeping) and found the use of music interventions for pain to be feasible in the ICU (Gosselin et al., 2018; Kshettry et al., 2006). Therefore, the feasibility of music alone as a sole intervention has not been evaluated. The advantage of evaluating music as a standalone intervention is to be able to evaluate its feasibility independent from multicomponent interventions (Craig et al., 2013).

In our systematic review, we only included RCTs that studied music as a standalone intervention. We found that across these RCTs, the intervention features varied greatly in terms of music experts involvement (e.g., music therapists, musicians, music professors or students); the selection of music (either pre-selected or chosen by the patient, to varying extents); music tempo (restricted to a specific range or not); duration (10-90 minutes), number of sessions (1-5 per day over 1-3 days); and timing (for pain at rest or for procedural pain such as chest tube removal or mobilization). None of the RCTs provided the rationale for the music intervention features. The lack of

rationales to support the selection of the features chosen in these interventions limits their critical assessment and the justification for their use. Furthermore, another systematic review of music interventions for pain management has reported the lack of data on such music features in RCTs across all clinical settings (Martin-Saavedra, Vergara-Mendez, Pradilla, et al., 2018). Using a structured approach such as the Template for Intervention Description and Replication (TIDieR) checklist would provide a comprehensive description of music interventions (Hoffmann et al., 2014).

Although music therapists can provide patients with personalized tempo-built playlists based on their musical preferences, there are only 965 accredited music therapists in Canada as of April 2023, limiting the availability of such specialists in clinical settings (Canadian Association of Music Therapists, 2023). Therefore, interventions requiring the involvement of music therapists are unlikely to be feasible in many ICU settings. However, the growing use of musical streaming services in Canada and globally, has increased the access to music (Canseco, 2022; International Federation of Phonography Industry, 2023; Statistics Canada, 2018, 2023; Wavrock et al., 2022). In Canada, between July 2017 and July 2018, "51% [of the adult population] used or purchased music downloads or music streaming subscriptions (e.g., Spotify, Google Music, Apple Music)" (Statistics Canada, 2018, p.1). Indeed, streaming is readily available and can be accessed by the general population. Consequently, there is a need to evaluate the feasibility of new music streaming interventions, such as the POMI, in the adult ICU.

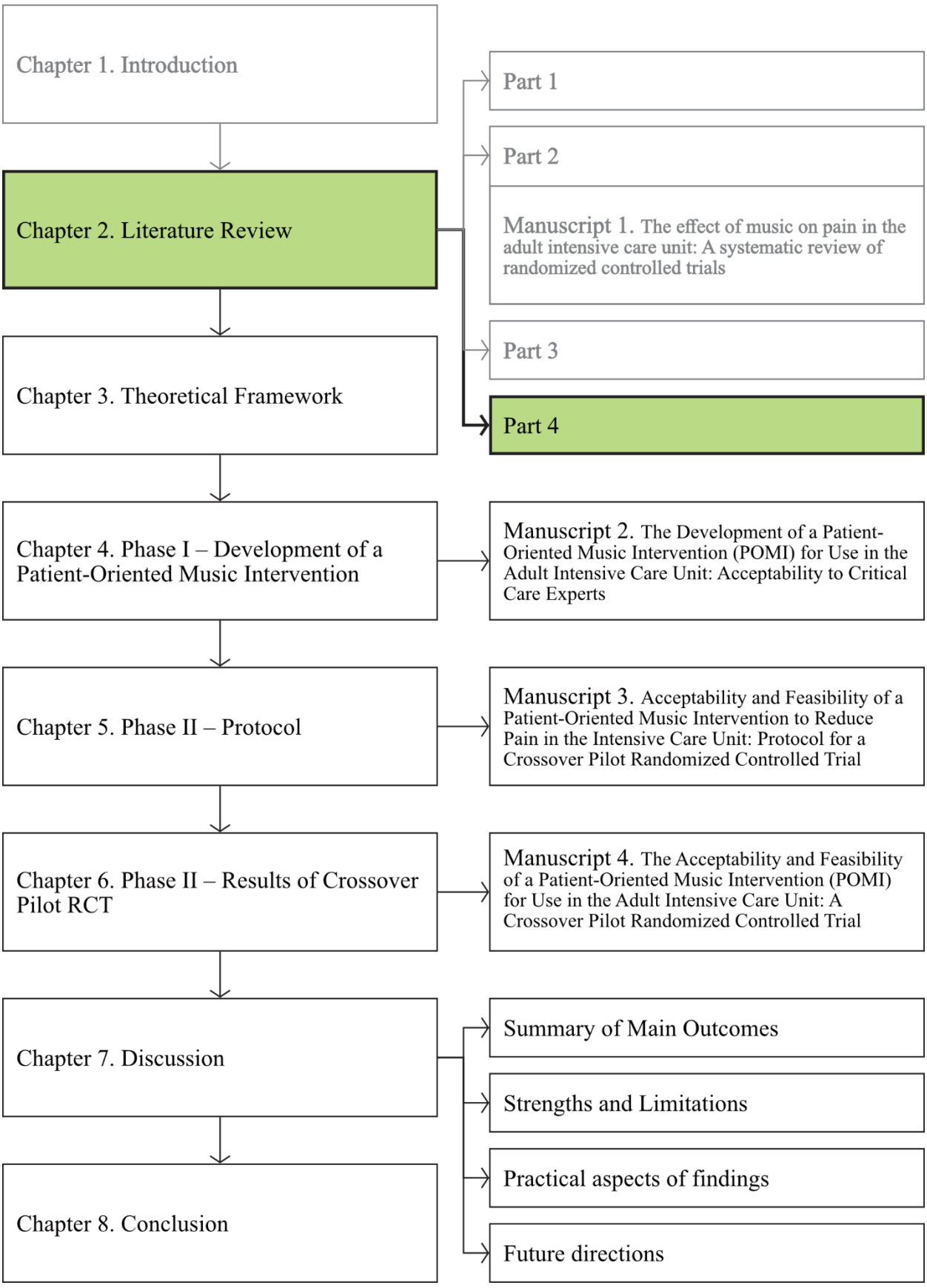
Feasibility of research methods

The feasibility of research methods, as defined by Sidani and Braden (2011), refers to "the adequacy, effectiveness, and efficiency of the study protocol in gathering pertinent data from participants representative of the target population that will contribute meaningfully to addressing the objectives for the intervention evaluation research" (p. 185). This is also in line with

the definition of feasibility of study design and procedures by Feeley et al. (2009), which addresses questions on the recruitment of participants, their willingness to participate, and the ability to reach ICU patients unable to self-report as a subgroup of the ICU population that has been neglected in music research thus far (p. 89-93).

Previous RCTs have mainly focused on patients able to self-report despite the fact that many ICU patients are likely to be unable to communicate during their ICU stay (Happ et al., 2011; Happ et al., 2015; Richard-Lalonde et al., 2020). Thus, RCTs conducted until now on music efficacy to reduce pain in the adult ICU has limited generalizability to the critically ill population which includes both patients able and unable to self-report.

Another important limitation in previous RCTs analysed in the systematic review that was conducted relates to sample size (Richard-Lalonde et al., 2020). In four RCTs, no sample size calculation was reported (Ames et al., 2017; Broscious, 1999; Cigerci & Ozbayir, 2016; Kyavar et al., 2016). In three RCTs, sample size was calculated based on outcomes other than pain (Chiasson et al., 2013; Jaber et al., 2007; Sanjuan Navais et al., 2013). In another three RCTs, the required sample size was not attained for various feasibility issues attributed to “slow” or “difficult” recruitment (due to time limit, refusal rate due to randomization or family visits, and narrow inclusion criteria), or withdrawal of participants who did not like the music chosen (Chan, 2007; Cooke et al., 2010; Shultis, 2012). In another RCT, it was not clear whether the sample size represented the number of participants or the number of observations (Guilbaut, 2017). Inadequate power may explain why 11 of the 18 RCTs found a significant pain reduction while seven did not. Therefore, there is a need to evaluate the feasibility of research methods by conducting a pilot RCT prior to testing the efficacy of new music interventions in the adult ICU.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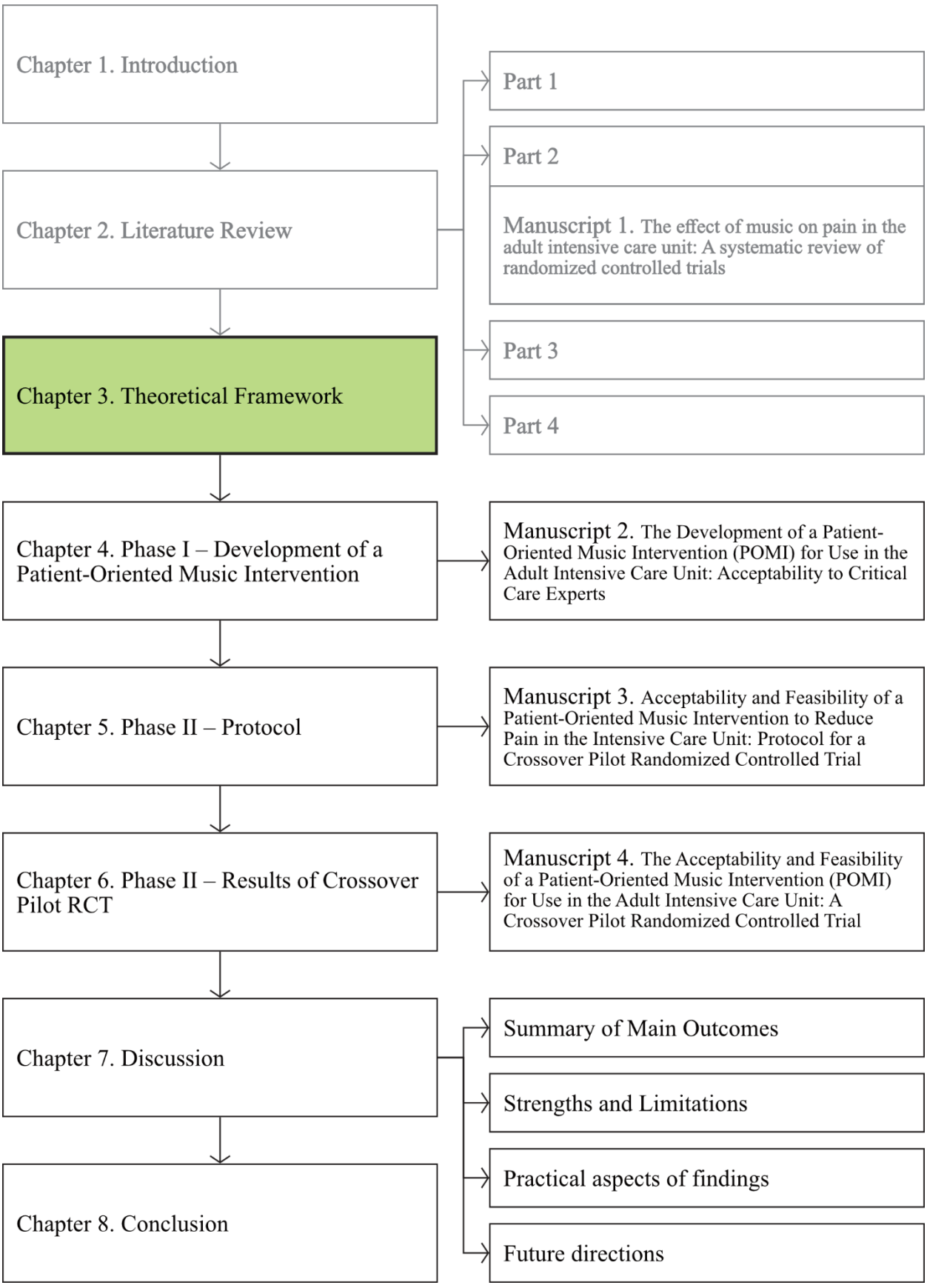
Part 4. Rationale for objectives

Rationale and gaps

Acute pain occurs frequently in critically ill adults. Because of the important adverse consequences linked to their use, there is a current impetus to reduce the use of opioids in favor of a multimodal approach to pain management in the adult ICU. A systematic review and meta-analysis were conducted to determine the effect of music interventions in the adult ICU setting (Richard-Lalonde et al., 2020). When played for 20-30 minutes, music reduced pain by 1-2 points on a 0-10 NRS in critically ill adults able to self-report. While several music interventions have been tested, none of them have been developed using an integrative approach combining theoretical, empirical, and experiential knowledge. Because of this integration, the strength of each source of knowledge can more effectively mitigate the drawbacks of its counterparts. Moreover, the acceptability and feasibility of previous music interventions as well as the feasibility of research methods of previous studies were not evaluated. Therefore, the goal of this doctoral research project was to use an integrative knowledge approach to develop a music-based intervention that would be acceptable to all interested parties, as well as feasible for use as a complementary pain management intervention in the adult ICU setting. Specifically, the research objectives for this doctoral research project were to:

Phase I: 1. Develop a preliminary POMI and refine it based on the acceptability of critical care experts.

Phase II: 1. Evaluate the acceptability of POMI to interested parties (ICU patients, family members and nursing staff) and feasibility of POMI (primary objective). 2. Evaluate the feasibility of conducting a crossover pilot RCT to test POMI in the adult ICU (primary objective). 3. Examine the preliminary efficacy of POMI to reduce pain in ICU patients (secondary objective).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Chapter 3. Theoretical Framework

The psychophysiological model of music and pain described by Guétin et al. (2014; 2018) guided the development and evaluation of the POMI. In this model, music is conceptualized as a multi-component stimulus that acts on the sensory, cognitive, emotional, behavioral, and social dimensions of the pain experience (Guétin et al., 2014; Guétin & Touchon, 2018). These dimensions of pain are consistent with the definition of pain described in the previous chapter and thus guided the choice of pain measures that were later used in the preliminary efficacy evaluation of the POMI (Craig & MacKenzie, 2021; International Association for the Study of Pain, 2021; Williams & Craig, 2016). Understanding the complexity of the pain experience is critical for the development of holistic pain management practices (Craig & MacKenzie, 2021). Figure 1 illustrates the proposed mechanisms by which music modulates the pain experience.

Music, through the process of pain modulation, is theorized to influence the sensory, cognitive, and emotional dimensions of pain. More specifically, music acts on the sensory dimension of pain by reducing the pain sensation via the activation of descending pathways of the modulation process, as supported by imaging studies (Antioch et al., 2020; Dobek et al., 2014). Music acts on the cognitive dimension of the patient's pain experience in several ways. Diverting attention away from pain is a cognitive mechanism by which music is believed to reduce pain as demonstrated in imaging studies (Dobek et al., 2014; Pando-Naude et al., 2019). Another cognitive mechanism proposed to play a role in music-induced pain reduction is related to being in control of the music selection, which has been linked to pain reduction (Howlin & Rooney, 2020; Howlin et al., 2022). In conjunction with the other mechanisms of action, music can modulate pain via affective (emotional) pathways. Indeed, music can help manage pain via emotional regulation and decreasing distress (Ginsberg et al., 2022). More specifically, music that can

induce the preferred emotions in the person listening to the music, will have a greater impact in reducing pain compared to music that evokes emotions that are not desired by the listener (Basinski et al., 2021; Dobek et al., 2014; Ginsberg et al., 2022).

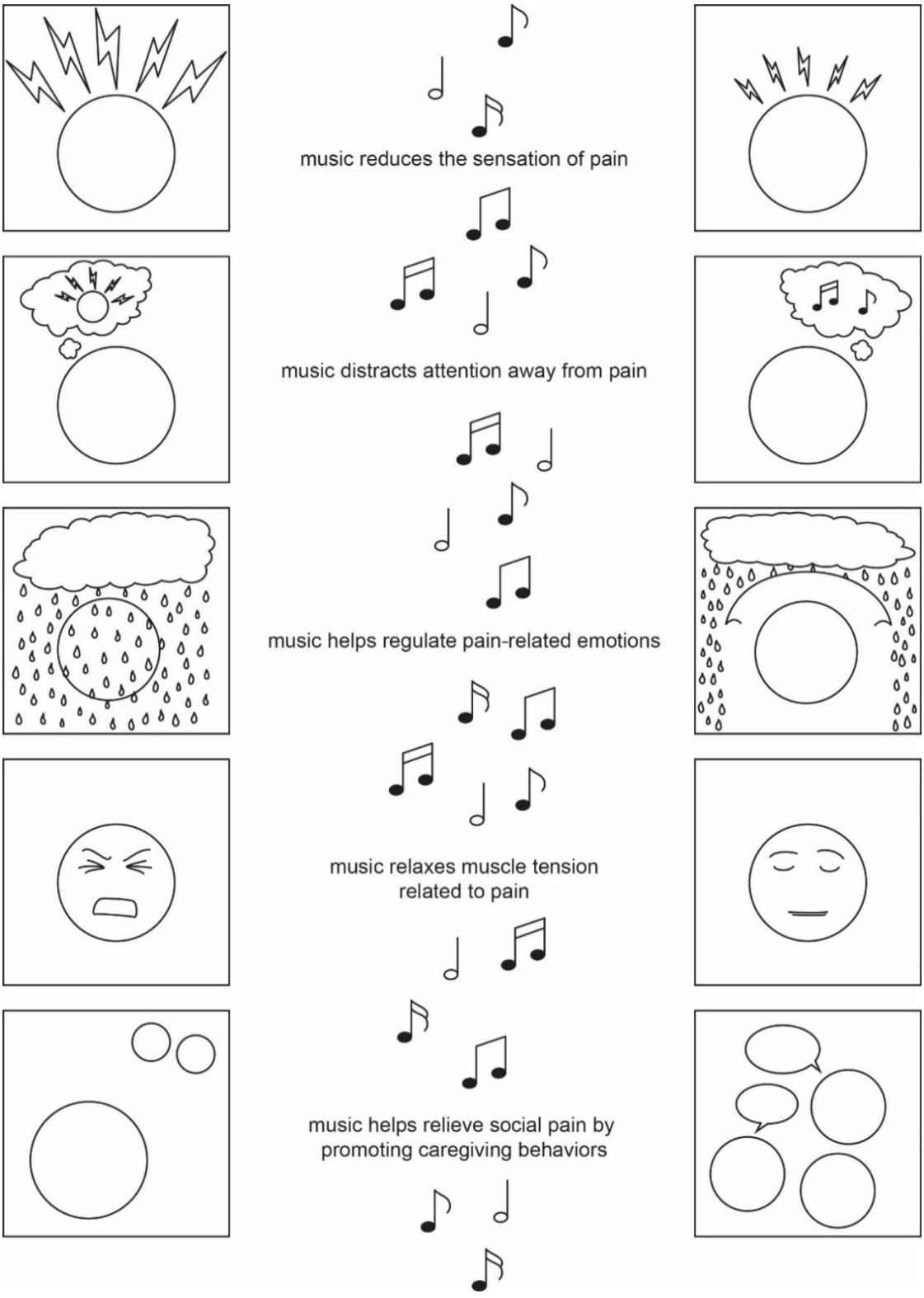
Music, especially when familiar, engages the motor areas of the brain and its rhythm spontaneously leads to body movement entrainment (Freitas et al., 2018; Levitin et al., 2018; Thaut et al., 2014; Varlet et al., 2020). Indeed, at the behavioral level, music affects the patient's psychomotricity and leads to decreased muscle tension and a relaxation effect (Najafi Ghezeljeh et al., 2016; Tan et al., 2010; Van Criekinge et al., 2019). More specifically, in ICU patients under sedation, music has been found to decrease facial and limb muscle tension, which is a common behavioral response to pain, especially in people unable to self-report (Gélinas et al., 2019; Puggina & da Silva, 2015).

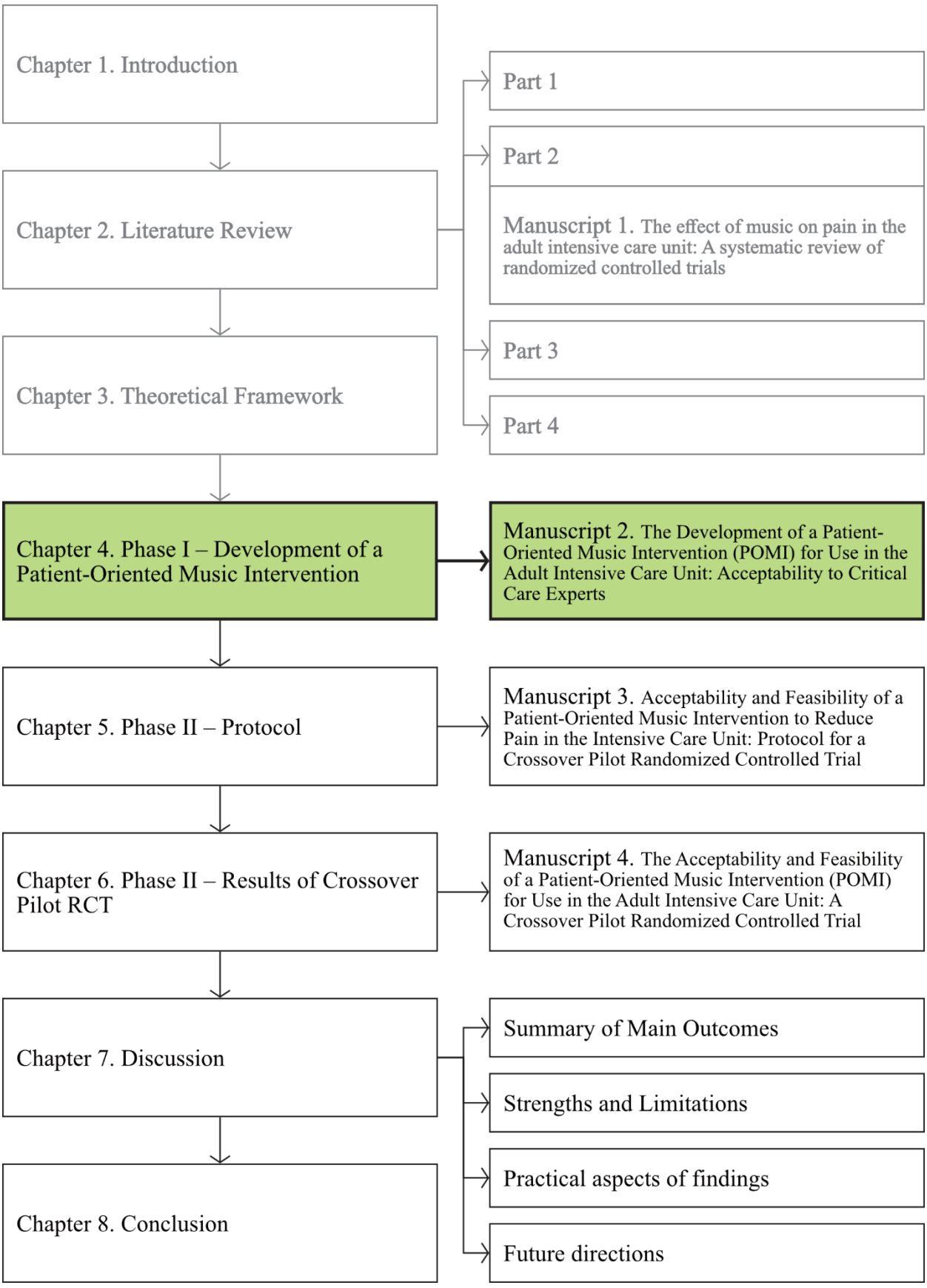
At the psychosocial level, music promotes communication through the discussion of music preferences with the patient and then when playing this music for the patient (Kim & Dvorak, 2018). Music interventions have also been found to increase caring behaviors of family members toward their loved one (e.g., focused attention on the patient, sitting closer to the patient), even when the patient is unable to communicate (Savage & Taylor, 2013).

Based on the psychophysiological model of music and pain, and in line with the evidence, the POMI was designed to act on the sensory, cognitive, emotional, behavioral, and psychosocial dimensions of the pain experience of critically ill adults.

Figure 1

The Psychophysiological Model of Music and Pain.

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Chapter 4. Phase I – Development of a Patient-Oriented Music Intervention

In Phase 1 of this doctoral research project, a preliminary version of a patient-oriented music intervention (POMI) was developed using empirical and theoretical knowledge from our systematic review and the model of music and pain. The preliminary features are detailed in Table 1 of Manuscript 2 "The Development of a Patient-Oriented Music Intervention (POMI) for Use in the Adult Intensive Care Unit: Acceptability to Critical Care Experts". After developing a preliminary version based on theoretical knowledge and empirical data, the aim was to evaluate its acceptability and to further refine the POMI based on experiential knowledge from critical care experts.

The study protocol, submitted to the research ethics board (REB) in March 2020, initially included feedback from ICU patients and family members. However, due to the coronavirus disease 2019 (COVID-19) pandemic and its impact on research in the ICU, the study protocol had to be modified according to what could be achieved at the time. In the revised protocol, data collection was planned to be conducted online with ICU clinicians and music therapists only, considering that patients and family members could no longer be recruited in the ICU at that time. The descriptive study design combined qualitative and quantitative data to guide the refinement of the POMI. REB approval was received on December 6, 2020 (project number 2020-2273).

Manuscript 2. The Development of a Patient-Oriented Music Intervention (POMI) for Use in the Adult Intensive Care Unit: Acceptability to Critical Care Experts

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Reference

Richard-Lalonde, M., Feeley, N., Cossette, S., Chlan, L. L., & Gélinas, C. (2023). The Development of a Patient-Oriented Music Intervention (POMI) for Use in the Adult Intensive Care Unit: Acceptability to Critical Care Experts. *Canadian Journal of Critical Care Nursing, 34*(3), 7-17. DOI: 10.5737/23688653-3437

Abstract

Background & Purpose

Pain is prevalent in the ICU, both at rest and during standard procedures. Clinical practice guidelines recommend a multimodal approach to pain management, including pharmacological and non-pharmacological interventions. Music has been shown to be efficacious in reducing pain in this clinical setting, when played for 20-30 minutes. A preliminary patient-oriented music intervention (preliminary POMI) was developed based on theoretical and empirical knowledge. This study aimed to describe the acceptability of the preliminary POMI to critical care experts.

Methods & Procedures

A descriptive design was used to address the study aim. Purposive, snowball sampling was used to recruit participants who were ICU clinicians (including nurses, physician, respiratory therapist, and social worker) and music therapists (n=3). Data was collected via video conference, using a 6-item questionnaire and a semi-structured interview guide. Six attributes of acceptability were evaluated (appropriateness, suitability, convenience, effectiveness, risks, and undesirable effects), each rated from 0 (not acceptable) to 4 (most acceptable).

Results

Nine women and three men aged 27-68 years with 4-36 years of experience working with critically ill adults participated, including seven nurses. All acceptability items had a median score ≥3 (range, 1-4). Participants highlighted the importance of taking into consideration the patient's music preferences and reported the use of streaming services as convenient. The timing of the intervention was more acceptable at rest or before, instead of after, a painful standard care procedure.

Discussion & Conclusion

The preliminary POMI was found to be acceptable to critical care experts for ICU patients experiencing pain at rest. Minor modifications to the preliminary POMI are needed prior to testing the intervention for procedural pain in critically ill adults.

Implications for Nursing

Clinicians, including nurses, play a key role in pain management as well as in the evaluation of innovative interventions. They evaluated the preliminary POMI as acceptable for use in the adult ICU.

Critical care experts highlighted the importance for critically ill adults admitted to the ICU to choose the type of music that they want to listen to. When unable to communicate these music preferences, family members should be invited to participate in the selection of the music on behalf of their loved one.

Timing of the preliminary POMI is more acceptable either when the patient is at rest, or in anticipation of a standard care procedure known as painful.

Key Words

music, pain management, ICU, critically ill adult, nursing, acceptability, music therapist

Background & Purpose

Pain continues to be prevalent in the adult intensive care unit (ICU), both at rest and during standard care procedures, leading to the common use of opioids (Burry et al., 2014; Damico et al., 2020; Puntillo et al., 2014). Because of the safety concerns arising from opioid side effects and to optimize analgesia, clinical practice guidelines for pain management for critically ill adults recommend the use of a multi-modal approach, combining pharmacological and nonpharmacological interventions (Devlin et al., 2018). Music, as a complementary nonpharmacological intervention, can reduce pain by 1-2 points on a 0-10 numeric rating scale (NRS) for critically ill adults admitted to the ICU (Richard-Lalonde et al., 2020). Because patients are critically ill and unstable in the ICU, recommendations are to play music within a specific tempo range, such as 60 to 80 beats per minute, to match the recommended heart rate (Guétin et al., 2014; Poulsen & Coto, 2018). Music that is selected by patients produces a greater analgesic effect than music that is pre-selected by researchers (Basinski et al., 2018; 2021; Dobek et al., 2014; Howlin & Rooney, 2021). However, many ICU patients are unable to communicate, due to critical illness, mechanical ventilation, sedation, and neurological impairment (Dithole et al., 2016; Happ et al., 2011; Ten Hoorn et al., 2016; Yoo et al., 2020). In such cases, family members are often involved in decisions and communication on behalf of their loved one who is critically ill (Davidson et al., 2017). Furthermore, previous studies have found that some family members of patients admitted to the ICU are interested in contributing to nonpharmacological pain management (Gosselin & Richard-Lalonde, 2019; Richard-Lalonde et al., 2018). Therefore, the involvement of family members should be considered in the development of a novel music intervention.

Developing personalized music playlists with a pre-specified tempo can require extensive time and resources. However, in the ICU setting, there is limited time to create personalized playlists

due to several factors such as patient sedation, procedural workload, restricted visitation hours, and limited resources (Gagné & Ferrari, 2018). At the same time, there is a growing use of music streaming services worldwide giving immediate access to an immense collection of music pieces along with their properties (such as tempo, valence, and arousal) (Curry, 2022; International Federation of Phonography Industry, 2022; Spotify AB, 2019; Statista, 2019). Therefore, music streaming technology is an important avenue to rapidly generate individualized music playlists composed of pieces within a specific tempo range.

A preliminary version of a patient-oriented music intervention (POMI) was initially developed (see Table 1 for more details) by integrating theoretical and empirical knowledge, as proposed by Sidani and Braden (2011). Next, to produce a more comprehensive intervention, further refinement of the preliminary POMI was sought by acquiring and integrating the experiential knowledge of health professionals with critical care experience. Thus, the goal of this study was to describe the acceptability of the preliminary POMI from the perspectives of critical care experts.

Methods & Procedures

Design. This study used a descriptive design and employed both quantitative and qualitative methods to inform the acceptability of the preliminary POMI more fully. Recruitment began after institutional research ethics board (REB) approval (research ethics number: Project # 2020-2273).

Sample. Health professionals with at least two years of experience working with critically ill adults were eligible to participate. Twelve ICU clinicians (n=10) and music therapists (n=3, with one music therapist also being a bedside nurse) were recruited using a purposive and snowball sampling strategies. This sample size was estimated to be the point at which saturation would be likely to have occurred (Guest et al., 2006).

Preliminary POMI. The features of the preliminary POMI were determined based on theory and evidence drawn from the literature, including a systematic review and meta-analysis that was conducted on the effect of music on pain in adult ICU patients (Richard-Lalonde et al., 2020). The psychophysiological model of music and pain proposes that music modulates pain multimodally (Guétin et al., 2014; 2018). More specifically, music acts on the sensory dimension of pain by reducing the pain sensation via the activation of descending pathways of the modulation process (Guétin et al., 2014; 2018). Music is also proposed to act on the cognitive dimension by diverting attention away from the painful stimulus (Guétin et al., 2014; 2018). In addition, music can act on the emotional dimension of pain, via emotional regulation, leading to a less distressful pain experience (Guétin et al., 2014; 2018). Behaviourally, music reduces muscle tension, which is a common indicator of pain (Guétin et al., 2014; 2018). Psychosocially, music promotes communication between patients and caregivers, such as through the discussion and consideration of the patient's music preferences (Guétin et al., 2014; 2018). The preliminary POMI is described in Table 1, as per the TIDieR guidelines (Hoffmann et al., 2014).

[INSERT TABLE 1]

Study context. The study protocol was initially submitted to the REB in March 2020. Due to the COVID-19 pandemic, all non-COVID-19 research was suspended in the ICU where the study would have been conducted in person, with patients, family members and clinicians. Therefore, the research protocol was modified for the study to be conducted online only with ICU clinicians and music therapists, thus excluding patients and family members, who could no longer be recruited at that time. The study was approved in December 2020, and participants were recruited, and data was collected from January to March 2021.

Data collection. Once recruited, one-on-one virtual conference meetings were scheduled (Zoom Video Communications, Inc., Version 5.5.1), where a brief presentation of the preliminary POMI was given. Then, participants answered a sociodemographic questionnaire and a 6-item treatment acceptability questionnaire (TAP), followed by a semi-structured interview on the acceptability of the preliminary POMI. Acceptability was evaluated on six attributes (appropriateness, suitability, convenience, effectiveness, risks, and undesirable effects), each rated 0-4 with 0 being not at all acceptable and 4 being very much acceptable (Sidani et al., 2009; Sidani & Fox, 2020). Because pain in the ICU is known to occur at rest and following standard care procedures, each TAP item was evaluated for the preliminary POMI being administered to a patient at rest and following procedures.

The semi-structured interview guide (see Figure 1) included questions addressing the responses on the TAP, in addition to asking feedback on preliminary POMI features (e.g., duration, mode of delivery, etc.).

[INSERT FIGURE 1]

Data analysis (quantitative data). Descriptive statistics were computed to describe the demographic characteristics of the participants and to summarize the acceptability questionnaire data using the software IBM SPSS Statistics for Windows, Version 23.0. Due to the small sample size, medians, and interquartile ranges (IQR) were calculated for continuous variables such as age. Frequencies and percentages were calculated for categorical variables such as gender. For the TAP, median and IQR were calculated for each item, as well as the frequency and percentage of participants who rated the acceptability at least 3 out of 4. The preliminary POMI was considered acceptable if at least 80% of the respondents rated each item at a 3 or 4 (acceptable or very much acceptable) on the acceptability rating scale.

Data analysis (qualitative data). Video recordings of interviews were transcribed as follows. The audio portion was transcribed verbatim by the first author (MRL), who also noted any relevant nonverbal expression from the video portion of the recording. Content analysis was performed by MRL and CG using an unconstrained deductive coding scheme (Elo & Kyngas, 2008). To begin with, transcripts were analysed deductively by coding relevant data content into pre-determined categories based on the interview guide, including acceptability items (appropriateness, suitability, convenience, effectiveness, risks, and undesirable effects) and POMI features (e.g., duration, mode of delivery, music characteristics). Subsequently, transcripts were analysed inductively so that any emerging ideas that did not fit into the pre-determined categories were coded and then used to develop new categories (Elo & Kyngas, 2008, p. 112). Codes were identified, highlighted, and organized into categories using QDA Miner (version 5.0) software. Participants were given pseudonyms to protect confidentiality and identified as either a clinician (i.e., nurse, physician, RT, social worker) or music therapist.

Results

Descriptive analysis. Table 2 describes the sample characteristics. Nine women and three men participated in this study, with a mean age of 42 years old (SD, 13). Participants included music therapist (n=3), bedside nurse (n=6, with one bedside nurse also being a music therapist), nurse educator (n=1), physician (n=1), respiratory therapist (n=1), and social worker (n=1), with a mean of 15 (SD, 9.5) years of professional experience working in a critical care setting. At the time of the interview, participants worked either in Canada, France, or the United States of America. The descriptive results for the TAP questionnaire are reported in Table 3.

[INSERT TABLES 2 AND 3]

Content analysis. Content analysis was based on the qualitative analysis of the interview transcripts. The categories included the items of the TAP questionnaire (appropriateness, suitability, effectiveness, convenience, and risks/undesirable effects), the use of a music streaming service, duration, timing, mode of delivery, ability to control the music, role of family, role of clinician, standardized playlist, as well as ICU environment.

Appropriateness. All participants rated the intervention as appropriate (at least 3/4) to address pain when administered at rest. One participant explained: "les gens sourient, les gens sont décontractés, quand ils aiment la musique, et vous allez voir tout de suite, je pense" ["people smile, people are relaxed, when they like the music, and you will see that right away, I think"] (participant "Charlie", clinician). Four (33%) participants considered the intervention as less appropriate (ratings <3/4, with 2/4 as lowest score) if administered following a standard care procedure known to be painful. Reasons given were the anticipated difficulty in coordinating with standard care procedures (n=2) and the likelihood that a patient prefers to not be stimulated after a procedure (n=2): "sometimes after a procedure, you just want to be left alone, without any outside stimulation" (participant "Kim", clinician).

Suitability. Eleven participants (92%) rated the intervention as being suitable for the ICU setting when administered at rest, apart from one participant. This participant recommended to modify the intervention by controlling the tempo progression so that the tempo should slow down gradually (i.e., from 80 bpm to 60 bpm, as the playlist progresses) and to increase the duration of the intervention to at least 35-45 minutes, instead of 20-30 minutes, for the intervention to be suitable for the ICU. Five participants (42%) rated the intervention to be less suitable (ratings <3/4) when administered after a standard care procedure known to be painful, because of anticipated timing issues (n=2) and expectation that a procedure would increase pain to a level that is too

high to want to listen to music (n=3): “after the procedure, the damage is done” (participant “Kim”, clinician).

Convenience. Regarding the willingness to support/assist in providing the intervention, all participants reported the rated intervention as being acceptable (scores ≥3 out of 4) both at rest and post-procedure. One participant shared:

> Oui, je l’appuierais [POMI]. Je sais qu’il… y aurait beaucoup d’étapes, là, compte tenu de nos logiciels, en ce moment au [lieu de travail], mais ça serait probable. Je laisse déjà mon identifiant [d’employée] dans les chambres des patients pour [que le patient ait accès à l’ordinateur qui joue la musique]. [Yes, I would support [POMI]. I know that… there would be several steps, taking into consideration our software, at the moment, at [the hospital where I work], but it would be probable, I already leave my [employee] ID in the patient room for [the patient to have access to the computer that plays the music].] (participant “Drew”, clinician).

Effectiveness. Regarding the anticipated effectiveness of the intervention, all participants reported the intervention as being acceptable (scores ≥3 out of 4) both at rest and post-procedure. One participant explained: “Dans les deux cas, je dirais que je pense que c’est un potentiel important, au moins 3 [sur 4]. Par contre, combien ça pourrait atténuer une douleur ? J’aurais tendance à penser que ça atténuerait moins pendant une procédure qu’au repos” [“In both cases, I would say that I think it has good potential, at least 3 [out of 4]. However, how much could it attenuate pain? I would tend to think less so during a procedure than at rest”] (participant “Charlie”, clinician). One participant refused to answer the question on effectiveness because she did not feel qualified to provide an answer.

Risks and undesirable effects. The most frequently reported risks and undesirable effects were undesired emotional reaction to music (n=7); pressure sores/pain caused by headphones (n=5); cross-contamination because of shared equipment between patients (n=4); and too many wires (linked to headphones or pillow) in a setting that already has many (n=4). When referring to the risk of an undesired emotional reaction, one participant stated that "[a patient] can hear a song that might bring up emotions that [they] weren't anticipating or expecting … or for someone who's had traumatic experiences, a song or a piece of music might trigger that traumatic experience… [With the POMI], patients have control of the app, which allows them the choice of music [and] giving patients the power of choice helps to minimize this risk" (participant "Jay", music therapist).

Use of a music streaming service. Several advantages were reported about the use of a music streaming service, such as the accessibility to a vast selection of music allowing to accommodate the patients' preferences, regardless of age or culture (n= 9). Another advantage noted by participants was the ability to play music continuously, without having ads interrupt the intervention (n= 3). Reported technical constraints included needing to have access to wi-fi (n=8) and to be familiar with the technology (n=6).

Duration. All participants reported that 20-30 minutes of music was an acceptable duration, with 10/12 (83%) participants stating that a longer duration would be acceptable, depending on the individual patients' preferences: "I could see other people wanting more, and I could see people that I've worked with who would say 'No; 20 to 30 minutes is good' or 'Nothing'" (participant "Ezra", music therapist).

Timing (rest versus post-procedure). Nine participants (75%) reported that providing the intervention after a standard care procedure known to be painful would not be as optimal as providing it before the procedure:

> Je verrais encore plus l'effet si on le faisait avant. Là, je le sais, au niveau recherche, c'est plus challengeant, là, mais dans la pratique clinique, je me demande si ça serait pas plus pertinent de le faire quasiment avant que après… parce que si l'idée c'est de libérer les endorphines, j'ai l'impression que de les avoir avant, dans ton corps, avant la procédure douloureuse, ça va diminuer le pic de douleur [I would see the effect even more if [the intervention] was done before. I know that for research, it's more challenging, but in clinical practice, I wonder if it wouldn't be more pertinent to do [the intervention] before instead of after… because if the idea is to release endorphins, I think that having them before, in your body, before the painful procedure, that will reduce the pain peak…] (participant "Alex", clinician).

Mode of delivery. Six participants (50%) reported a preference for the music pillow "I find the pillow very impressive … it frees you up from having one more thing on your body, in the ICU." (participant "Hayden", clinician), especially for the patients unable to communicate: "I think the pillow would probably be more comfortable … we have patients who are comatose… and I think the pillow would be more appropriate with them" (participant "Inali", clinician). Others preferred the use of headphones (n=4) "I like to make sure that I'm blocking out, especially in an ICU, because they're kind of noisy, that we're blocking out that sound because then it enhances the music listening experience." (participant "Jay", music therapist). On the other hand, earbuds were reported as being most problematic (i.e., risk of getting lost, least comfortable option, difficult to

clean properly) and therefore less acceptable in an ICU setting. Two participants had no preference with regards to the mode of delivery of the POMI.

Ability to control the music. Eight participants (67%) mentioned the importance for the patients to have control on the music intervention:

> C'est le contrôle qu'on donne aux patients. Moi j'y crois beaucoup que c'est important. Les patients, ils [n'ont] de pouvoir sur rien aux soins intensifs. Si au moins, ils pouvaient avoir un petit peu de pouvoir qu'on peut leur donner l'autonomie, ça nous permet de mieux les connaître, il y a toutes sortes d'autres avantages que la douleur. Pour l'avoir testé [l'utilisation de la musique] sur plusieurs patients, souvent, ça diminuait aussi leur anxiété, pis ça a diminué leur douleur pour la plupart, aussi. [It's the control that we give patients. I strongly believe that this is important. The patients, they have no power over anything in the ICU. If, at least, they could have a little bit of power that we could give them, this allows us to get to know them… Having tested [the use of music] on several patients, often… it reduced their pain, for the majority] (participant "Alex", clinician).

Family role. All participants agreed that asking the family about their loved one's music preferences is acceptable when the patient is unable to communicate their preferences. Three participants (25%) noted that the music intervention could also be helpful to the family, either because they could also listen to the music, or because they could feel comforted if the music intervention was beneficial to the patient. One ICU nurse shared the following story that happened on her unit, when a family member was not consulted in the music selection of the patient admitted to the ICU:

> C'était un patient … incapable de communiquer... Fait que nous, on lui mettait des chansons sur YouTube, tsé des listes, pis ça part, un vidéo entraîne un autre vidéo, pis ça continue, et sa conjointe, qui était dévastée, déjà, [par l'état de santé du patient], elle arrive,

> et c'est genre le groupe qu'il déteste le plus au monde qui joue, … je pense qu'elle, ça l'a fait flipper, parce qu'elle … c'est la seule affaire qu'elle contrôle, dans toute l'expérience… fait que c'était pas, rien de grave, le patient, lui, il peut pas nous communiquer à ce moment-là, mais l'effet que la famille a ressenti comme si on le prenait pas en considération… il n'y a pas eu, rien n'est arrivé au patient, c'est juste une espèce de situation avec la famille, là… ça les a un peu déçu… [This was a patient who… was unable to communicate... So, we were playing some songs on YouTube, you know playlists, they start, and then one video leads to another, and it goes on… and his partner, who was devastated already [by his state of health], arrives in the room, and it's the [music] band that [the patient] hates the most in the world, you know… I think that made her flip, because … it's the only thing she can control, in the whole event… so it's nothing too serious, the patient, he cannot communicate at this time, but the impact that the family felt was as if we did not take him into consideration… nothing happened to the patient, it's just a sort of situation with the family that… they… were a bit disappointed, you know.] (participant "Drew", clinician)

On the other hand, another ICU nurse shared a different personal experience that occurred when a family member requested personalized music for a patient admitted to the ICU, in an end-of-life context:

> La semaine passée, je faisais des soins de conforts palliatifs à un patient aux soins intensifs, et la conjointe m'a demandé si c'était possible de mettre de la musique de préférence du patient pendant le moment où il décédait... Pis lui, ce qu'il aimait, c'était le death métal, ok? Fait que, est-ce que c'était un peu spécial d'avoir du death métal au chevet du patient pré-mortem? Tout à fait! Mais la conjointe était vraiment satisfaite, et le patient était

> très satisfait lui aussi. Ça fait que, perso, je pense que c'est très, très intéressant comme intervention. [Last week, I was giving comfort care to a patient in the ICU, and the partner asked me if it would be possible to play music preferred by the patient at the time that he would die... What he liked was death metal, right? So, was it a bit special to have death metal at the bedside pre-mortem? Absolutely! But the partner was really satisfied, and the patient was really satisfied too. So, personally, I think this [POMI] is a very, very interesting intervention.] (participant "Blake", clinician)

Clinician role. Although all participants reported being willing to support/assist in providing the intervention, eight (67%) suggested that clinicians be trained to do so or that a document be created of the steps for clinicians to know how to administer the intervention. Five participants (42%), including all three music therapists, recommended that clinicians assess and follow-up with patients during the music intervention in case of the need to readjust the music (either by stopping or changing the music being played) based on the patient's response:

> We should, if we're putting music on someone… we do want to observe their response to it; especially if they don't have words or can't communicate. What are we seeing in their behavior? Even if it's 'they're grimacing', or we're seeing tears, then we should pay attention to that. I think that we certainly don't want to overstimulate someone if they're already in a very fragile state, so I think it's really important that we don't just put something on and then we just walk away" (participant "Jay", music therapist) and "it's like a debrief: 'how was that for you? … I noticed that you seem sad, is that [so]?'" (participant "Ezra", music therapist).

Four participants (33%) raised the idea that the music could also be beneficial to clinicians and lead to improvement in the clinician-patient communication. On the other hand, two participants

(17%) mentioned that in their experience, clinicians sometimes prefer to listen to music that is different from their patient's preferences. Thus, the patients' music preferences may not always match the clinicians' preferences.

Standardized playlist. Nine participants (75%) stated that they would like to have an option for a "standard-type" playlist that they could use with patients whose music preferences were unknown:

> My concern with ICU population is that most of them will be sedated, paralysed, most of them will not be able to voice their preference, and I was wondering if there is some universal tune or universal type of music, like one size fit all. So, if we could find this, that would be amazing" (participant "Kim", clinician)

and also:

> Je ne pense pas que d'imposer, c'est nécessairement bon. Par contre, quand on est dans l'impossibilité de demander l'avis des patients, il faudrait peut-être que ce soit quelqu'un qui choisisse pour eux autres, à ce moment-là, et de voir, peut-être, la réponse au choix qu'on a imposé et essayer un autre choix si on voit que ça ne fonctionne pas; peut-être qu'on n'est juste pas tombé sur le bon à ce moment-là [I don't think that it's necessarily good to impose [a type of music]. However, when we are unable to ask the patients' opinion, maybe it should be someone that chooses for them, in that case, and to see, maybe, the response to the choice that was imposed, and try another choice in we see that it doesn't work; maybe we just didn't find the right one at this specific moment in time…] (participant "Leslie", clinician)

ICU environment. Seven participants raised the notion that the ICU is known to be a noisy, distressful environment, and preferred music can help palliate this situation by creating a more familiar environment for the patient:

> Il y a aussi un enjeu de ramener, un peu, du contexte naturel de la personne dans ses soins, parce que, mine de rien, chez nous, moi je vais pas rester là en train de faire, mettons, je sais pas; si je vais au fauteuil pendant toute la journée, ben je vais pas regarder le mur pendant toute la journée. Fait que d'avoir de la musique, c'est certain que ça rapproche le patient d'un contexte un peu plus naturel… il y a un peu d'humanité là-dedans; de retrouver un peu de la personnalité de la personne, pis lui donner un peu de choix dans son environnement; d'avoir un environnement familier; un environnement où elle se sent un peu plus « at home »; fait que ça, c'est peut-être un point que je trouve qui est bien. [There is also the issue of bringing back a little bit of the person's natural context in their care because, it may not sound like much but, at home, I am not going to stay there…if I am going to sit on a chair all day, well I'm not going to stare at the wall all day. So having music, for sure bring the patient closer to a more natural context… there is a bit of humanity in there; to recover a bit of the person's personality and give them some choice in their environment; to have a familiar environment where they feel a bit more at home] (participant "Blake", clinician).
>
> Je trouve que, [la musique], c'est plus présent maintenant, depuis mars [2020]... Je pense que c'est vraiment le fait que nos patients … n'ont pas de famille, pas de visite, nous on va moins les voir aussi, ils ont moins de consultants qui rentrent dans les chambres. Donc, oui, j'ai l'impression que pour pallier à ça, les infirmières ont commencé à utiliser la musique. [I find that [music] is more present now, since March [2020] … I think that

> it's really because our patients… have no family, no visit, we don't go in to see them as often, there are fewer professionals entering their rooms. So yes, I get the impression that to palliate this, nurses have started to use music] (participant "Drew", clinician).

Discussion

More than 80% of participants rated the preliminary POMI as acceptable when provided to patients while at rest. In contrast, some participants found it to be unacceptable if provided immediately after a standard care procedure known to be painful. Instead, participants reported that the intervention should be provided before a standard care procedure known to be painful, in line with current clinical practice guidelines and preventive analgesia in anticipation of a noxious stimulus (de Jong et al., 2013; Devlin et al., 2018; Vadivelu et al., 2014).

To mitigate the risks and undesired effects that were noted, participants recommended that a strict disinfection protocol should be in place and approved by the infection prevention and control department when material is shared among patients; for example, medical-grade disposable headcovers can be used for headphones. Additionally, participants advised that those who administer the POMI to ICU patients should pay attention to any undesired reaction (e.g., grimacing, crying) to the music and adjust the intervention, if needed, by either changing the type of music or stopping it. Participants recommended that patients should always be given as much control over self-administration of the intervention, to the extent that is possible in the context of critical illness. Finally, participants suggested that wireless options should be prioritized when possible and the music pillow utilized over headphones for patients unable to communicate to reduce the risk of pressure injury and/or discomfort due to wearing headphones.

Giving patients the ability to control the music selection and delivery (i.e., self-administration, when possible, to promote a sense of control) was considered by participants as an important

feature of the preliminary POMI. This is in line with what is reported in the literature in other clinical settings, where the perception of control in music selection can increase the analgesic effect (Howlin & Rooney, 2021; Howlin et al., 2022). Consistent with our findings, Howlin et al. (2023) reported that sometimes, patients want to listen to music that is different from what some clinicians might expect, such as death metal. Related to this, participants agreed that an important criterion for acceptability of the preliminary POMI is that the music selection should be congruent with individual patient preferences. More specifically, the music played should be what the patient wants to hear in the moment, as defined by the individual, which can be specified in terms of genre, artists, specific pieces, and/or music characteristics, such as valence (emotion, ranging from negative to positive, perceived as being encouraged by the music, e.g., melancholic vs cheerful), and arousal (energy). This is also in line with the literature that preferred music characteristics play an important role in pain reduction (Basinski et al., 2018; 2021). Related to this, some participants proposed that the preliminary POMI should not only ask what music the patient would like to listen to (i.e., to know what to add on to the individualized playlist), but also what music the patient does not want to listen to (i.e., to know what to remove from the individualized playlist). For ICU patients unable to communicate their preferences, participants supported the involvement of family members in determining the patient's music preferences.

Regarding clinician involvement in the provision of the preliminary POMI, participants suggested the option of having a standard playlist as a desirable addition to the intervention. However, participants specified that such a pre-specified playlist should only be considered when the patient is unable to communicate their preferences, and there is no one (e.g., family member) who knows and can communicate the patient's music preferences with the care team. Standard playlists have been used in research and there is some evidence that these can also be effective in

reducing pain in adult ICU patients (Richard-Lalonde et al., 2020). However, to date, there are no standardized music characteristics, if any, that are known to objectively produce analgesia (Martin-Saavedra et al., 2018). Therefore, more research is needed to determine the possibility of developing such standardized music playlists for pain management purposes, and to determine for whom this type of standardized playlist would work.

In this study, participants agreed that the use of smart devices to provide the intervention was acceptable. This is consistent with findings from a previous study in which the use of an electronic tablet was found acceptable and feasible as a mode of delivery to provide music in the ICU setting (Knudson et al., 2018).

According to the theoretical framework used to guide the development of the POMI, music modulates pain multimodally by acting on the sensory, cognitive, emotional, behavioural, and psychosocial dimensions (Guétin et al., 2014; Williams & Craig 2016). Many of the categories related to POMI discussed by participants in this study, drawn from their personal perspectives, can also be linked with how music is proposed to act on the different dimensions of pain, both theoretically and empirically.

Specifically, most participants in this study agreed that a wide range of music choices using a music streaming service was an important component of the preliminary POMI. This is consistent with theoretical and empirical evidence that preferred music (i.e., based on individual preferences) acts on the emotional (affective pathway) and cognitive (redirection of attention) dimensions of pain (Basinski et al., 2021; Guétin et al., 2014; Villareal et al., 2019). In addition, several participants in this study mentioned the importance of giving patients more control in the selection of music to increase the efficacy of the music on pain. Providing such control to

patients has also been reported in the literature as modulating pain via cognitive and emotional processes (Garza-Villarreal et al., 2017; Guétin et al., 2014; Howlin & Rooney, 2020).

The relaxation of facial expressions that occurs when listening to music, as reported by some participants, is consistent with the behavioral dimension of pain whereby music acts on muscle tension, as proposed in the theoretical framework and further evidenced by empirical data (Guétin et al., 2014; Tan et al., 2010; Van Criekinge et al., 2019).

Participants in this study proposed that the POMI should be used to address procedural pain by timing the intervention prior to the procedure, in anticipation of the painful stimulus. This use of music to pre-emptively decrease the pain intensity peak is analogous to pharmacological approaches to procedural pain management and pertains to the sensory dimension of pain, by which music attenuates the sensation of pain (Devlin et al., 2018; Guétin et al., 2014).

Participants in this study also reported on the use of music to improve the clinician-patient-family relationship stating that music could also be beneficial to family and clinicians, provide a more comfortable environment, and palliate the social isolation from the pandemic context in the ICU. These reported perspectives fit directly with the psychosocial pathway through which music is proposed to modulate pain by promoting communication and encouraging communication between patients and caregivers (Guétin et al., 2014; 2018). Thus, in addition to the sensory, emotional, cognitive, and behavioral dimensions of pain, the POMI could be used to target the psychosocial dimension of pain by improving the caregiver-patient communication, providing a more comfortable, familiar environment, and reducing the feeling of isolation. This is especially relevant in the context of the COVID-19 pandemic, as well as in other situations (e.g., due to infection or immunosuppression), where patients tend to be more isolated and stay longer in the ICU (Rivi et al., 2021).

Limitations

The participants in this study were limited to clinical experts who volunteered. ICU patients and family members could not be recruited because of the COVID-19 pandemic context at the time of the study. Therefore, the protocol was adapted, and acceptability of the preliminary POMI was assessed only by clinical experts. However, in the next steps, ICU patients and families will be asked for their input on the acceptability of the refined preliminary POMI as part of the pilot testing that will follow this study (Richard-Lalonde et al., 2022).

Conclusion

The preliminary POMI was found to be acceptable to participants, for ICU patients experiencing pain at rest. Based on the feedback of the participants, modifications will be made to refine the preliminary POMI, including administration of the intervention before, instead of after, standard care procedures known to be painful. The refined preliminary POMI will be pilot tested in the adult ICU to describe the perspectives of not only clinicians but also patients and family members of patients unable to self-report.

Table 1

Preliminary POMI Detailed Description

Item	Description	
Brief name	Preliminary POMI (Patient-Oriented Music Intervention)	Refined Version of POMI
Why?	The goal of the POMI is to use music to act multimodally to reduce pain in ICU adult patients, by targeting multiple dimensions of the pain experience (Guétin et al., 2014; Williams & Craig, 2016).	N/A
What and how (materials and procedures)?	Music is provided to adults admitted to the ICU either via headphones, earbuds, or by music pillow. Although headphones were efficacious in reducing pain in ICU patients who can self-report, some participants have withdrawn from RCTs due to their dislike of headphones, so they should be offered alternative options (Richard-Lalonde et al., 2020). The music offered should reflect the patient's preferences to be effective in pain management (Basinski et al., 2021; Basinski et al., 2018; Dobek et al., 2014; Guétin et al., 2014; Howlin & Rooney, 2021; Richard-Lalonde et al., 2020; Van Criekinge et al., 2019). This can best be accomplished via the use of streaming services, which is the form of music that is increasingly being used, and which gives the listener instant access to tens of millions of music pieces (Musical Pursuits, 2022; Spotify AB, 2019b; Statista, 2015). Therefore, the preliminary POMI uses a Web-based tool (linked to Spotify) that can be accessible from any smart device, available at https://pomi.glitch.me (see Supplemental Figure for sample screenshot). The preliminary POMI is designed to be operated by ICU patients and/or family members in a critical care setting (with or without clinician assistance). It requires a limited amount of simple information regarding music preferences to create individually tailored music playlists, drawing from a music streaming service that holds over 80 million songs (Spotify AB, 2022). The generated music playlists tailored to the ICU patients' preferences are composed of pieces that range in tempo from 60 to 80 beats per minute (bpm), as per evidence-based practice recommendations (Poulsen & Coto, 2018).	Music is provided to critically ill adults admitted to the ICU either via headphones or music pillow for those able to self-report their preference. The music pillow is the option for patients unable to self-report.
Who provides, where?	When admitted to the ICU, music preferences are established by the patient or the family (for patients unable to self-report). ICU patients self-administer the preliminary POMI to the extent that they can, with assistance from the family or healthcare providers if necessary. For ICU patients who cannot communicate their music preferences, a family member who has knowledge of their music preferences will act as a surrogate and select music on behalf of the patient.	N/A
When and how much?	A minimum of 20-30 minutes of music from the generated playlist is played either when the patient is at rest, or immediately after a patient undergoes a standard care procedure while admitted to the ICU. This duration is required to obtain an efficacious reduction in pain as evidenced by a recent systematic review (Richard-Lalonde et al., 2020).	Music from the generated playlist is played either when the patient is at rest, or ideally before a patient undergoes a standard care procedure while admitted to the ICU.

Figure 1

Semi-Structured Interview Guide

1. What makes the POMI acceptable/unacceptable? (10 min)
    a. … appropriate or not appropriate to address pain?
    b. … suitable or not suitable for the ICU?
    c. … effective or ineffective in reducing pain?
    d. What makes you be willing or unwilling to use the POMI?
    e. Were you familiar with the music proposed in your playlist?
2. Which risk/undesirable effect (if any) might arise from the use of the POMI? (5 min)
3. What is your opinion of the following POMI features? (20 min)
    a. Ability to select music based on personal preferences (genres, tracks, artists)
    b. Use of streaming service (ability to create a playlist; to pause; to skip tracks)
    c. Playing music for a duration of 20 to 30 minutes
    d. Playing music immediately after a painful procedure vs. at rest (when in pain)
    e. Use of headphones to deliver the music vs music pillow
    f. Assistance from family to select music preferences
    g. Assistance from clinicians to use POMI web-based tool
4. What do you like least about POMI? (5 min)
5. What do you like best about POMI? (5 min)
6. What could be done to improve POMI? (5 min)

Table 2

Participant Characteristics

Characteristics	n (%)
Gender	
Woman	9 (75)
Man	3 (25)
Profession	
Clinician with no music therapy training	9 (75)
Music Therapist	3 (25)
Prior Use of Streaming Services	
Yes	11 (92)
No	1 (8)
Prior Use of Music with Patients	
Yes	10 (83)
No	2 (17)

Note. Participants had a median age of 43 years old (IQR = 21) with a median of 11 years of experience working in a critical care setting (IQR = 15.5); IQR = interquartile range.

Table 3

Treatment Acceptability Preferences Questionnaire Results

	Median (IQR) Scores		% Participants who rated ≥ 3	
Question	At rest	Post procedure	At rest	Post procedure
1. Does the music intervention seem appropriate (logical) to address pain?	4.0 (0.5)	3.5 (1.5)	100	67
2. Is the music intervention suitable for the intensive care unit setting?	4.0 (1.0)	3.0 (1.5)	92	58
3. How willing would you be to support/assist with this music intervention?	4.0 (0.0)	4.0 (0.0)	100	100
4. In your opinion, how effective would the music intervention be in reducing pain?	3.0 (1.0)	4.0 (1.0)	100	100
5. How would you rate the presence of risk involved in the use of this intervention?	3.5 (2.0)	3.0 (2.0)	75	67
6. How would you rate the presence of un-desirable effects caused by this intervention?	3.0 (1.5)	3.0 (2.0)	75	75

Note. IQR = Interquartile range; questions 5 and 6 were reverse coded so that higher values represent higher levels of acceptability.

Supplementary Figure. Screenshot Sample of Web app for POMI

References

Basiński K., Zdun-Ryżewska A., Greenberg, D. M., & Majkowicz, M. (2021). Preferred musical attribute dimensions underlie individual differences in music-induced analgesia. *Scientific Reports*, *11*(1). https://doi.org/10.1038/s41598-021-87943-z

Basiński K., Zdun-Ryżewska A., & Majkowicz, M. (2018). The role of musical attributes in music-induced analgesia: a preliminary brief report. *Frontiers in Psychology*, *9,* 1761. https://doi.org/10.3389/fpsyg.2018.01761

Burry, L. D., Williamson, D. R., Perreault, M. M., Rose, L., Cook, D. J., Ferguson, N. D., Lapinsky, S. C., & Mehta, S. (2014). Analgesic, sedative, antipsychotic, and neuromuscular blocker use in canadian intensive care units: a prospective, multicentre, observational study. *Canadian Journal of Anesthesia/Journal Canadien D'anesthésie*, *61*(7), 619–630. https://doi.org/10.1007/s12630-014-0174-1

Curry, D. (2022). *Music Streaming App Revenue and Usage Statistics (2022)*. Business of Apps. Retrieved September 26, 2022 from https://www.businessofapps.com/data/music-streaming-market/

Damico, V., Macchi, G., Murano, L., & Forastieri Molinari, A. (2020). Incidence of pain at rest and during nursing procedures in ICU patients: a longitudinal observational study. *Annali di igiene : medicina preventiva e di comunita*, *32*(4), 407-418. https://doi.org/http://dx.doi.org/10.7416/ai.2020.2364

Davidson, J. E., Aslakson, R. A., Long, A. C., Kross, E. K., Curtis, J. R., Puntillo, K. A., Hart, J., Cox, C. E., Wunsch, H., Wickline, M. A., Nunnally, M. E., Netzer, G., Azoulay, E., Kentish-Barnes, N., Sprung, C. L., Hartog, C. S., Coombs, M., Gerritsen, R. T., Hopkins,

R. O., … Levy, M. M. (2017). Guidelines for family-centered care in the neonatal, pediatric, and adult icu. *Critical Care Medicine*, *45*(1), 103–128. https://doi.org/10.1097/CCM.0000000000002169

de Jong, A., Molinari, N., de Lattre, S., Gniadek, C., Carr, J., Conseil, M., Susbielles, M.-P., Jung, B., Jaber, S., & Chanques Gérald. (2013). Decreasing severe pain and serious adverse events while moving intensive care unit patients: a prospective interventional study (the nurse-do project). *Critical Care*, *17*(2), 1–13. https://doi.org/10.1186/cc12683

Devlin, J. W., Skrobik, Y., Gélinas, C., Needham, D. M., Slooter, A. J. C., Pandharipande, P. P., Watson, P. L., Weinhouse, G. L., Nunnally, M. E., Rochwerg, B., Balas, M. C., van den Boogaard, M., Bosma, K. J., Brummel, N. E., Chanques, G., Denehy, L., Drouot, X., Fraser, G. L., Harris, J. E., … Alhazzani, W. (2018). Clinical practice guidelines for the prevention and management of pain, agitation/sedation, delirium, immobility, and sleep disruption in adult patients in the icu. *Critical Care Medicine*, *46*(9), e825-e873. https://doi.org/10.1097/CCM.0000000000003299

Dithole, K., Sibanda, S., Moleki, M. M., & Thupayagale-Tshweneagae, G. (2016). Exploring communication challenges between nurses and mechanically ventilated patients in the intensive care unit: a structured review. *Worldviews on Evidence-Based Nursing*, *13*(3), 197–206. https://doi.org/10.1111/wvn.12146

Dobek, C. E., Beynon, M. E., Bosma, R. L., & Stroman, P. W. (2014). Music modulation of pain perception and pain-related activity in the brain, brain stem, and spinal cord: a functional magnetic resonance imaging study. *Journal of Pain*, *15*(10), 1057–1068. https://doi.org/10.1016/j.jpain.2014.07.006

Elo, S., & Kyngäs H. (2008). The qualitative content analysis process. *Journal of Advanced Nursing*, *62*(1), 107–115. https://doi.org/10.1111/j.1365-2648.2007.04569.x

Garza-Villarreal, E. A., Pando, V., Vuust, P., & Parsons, C. (2017). Music-induced analgesia in chronic pain conditions: a systematic review and meta-analysis. *Pain Physician*, *20*(7), 597–610.

Gosselin É., & Richard-Lalonde M. (2019). Role of family members in pain management in adult critical care. *AACN Advanced Critical Care*, *30*(4), 398–410. https://doi.org/10.4037/aacnacc2019275

Guest, G., Bunce, A., & Johnson, L. (2006). How Many Interviews Are Enough? : An Experiment with Data Saturation and Variability. *Field Methods*, *18*(1), 59-82. https://doi.org/10.1177/1525822X05279903

Guétin, S., Falvay, D., Chanques, G., Jaber, S., De Lattre, S., Souche, B., Giniès, P., Picot, M.-C., Hérisson, C., de Diego, E., & Touchon, J. (2014). Evaluation of the standardized MUSIC CARE© app in the treatment of pain: the U-shape composing technique. *Music and Medicine*, *6*(2), 46-50.

Guétin, S., & Touchon, J. (2018). Music as an adjuvant to opioids? IASP 17th World Congress on Pain, Boston.

Happ, M. B., Garrett, K., Thomas, D. D., Tate, J., George, E., Houze, M., Radtke, J., & Sereika, S. (2011). Nurse-patient communication interactions in the intensive care unit. *American journal of critical care*, *20*(2), e28-40. https://doi.org/10.4037/ajcc2011433

Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., Altman, D. G., Barbour, V., Macdonald, H., Johnston, M., Lamb, S. E., Dixon-Woods, M., McCulloch,

P., Wyatt, J. C., Chan, A. W., & Michie, S. (2014). Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ: British Medical Journal*, *348*, g1687. https://doi.org/10.1136/bmj.g1687

Howlin, C., & Rooney, B. (2021). Cognitive agency in music interventions: increased perceived control of music predicts increased pain tolerance. *European Journal of Pain*, *25*(8), 1712–1722. https://doi.org/10.1002/ejp.1780

Howlin, C., Stapleton, A., & Rooney, B. (2022). Tune out pain: Agency and active engagement predict decreases in pain intensity after music listening. *PLoS One*, *17*(8), e0271329. https://doi.org/10.1371/journal.pone.0271329

Howlin, C., Walsh, R., D'Alton, P., & Rooney, B. (2023). How do people with chronic pain choose their music for pain management? Examining the external validity of the cognitive vitality model. *Frontiers in Psychology*, *13*, 969377. https://doi.org/10.3389/fpsyg.2022.969377

Gagné, V., & Ferrari, N. (2018). *État des connaissances sur les modes d'organisation des services de soins intensifs*. Institut national d'excellence en santé et en services sociaux (INESSS). https://www.inesss.qc.ca/fileadmin/doc/INESSS/Rapports/Traumatologie/INESSS_Unite_soins_intensifs.pdf

International Federation of Phonography Industry. (2022). *Global Music Report - 2022*. Retrieved December 1, 2022, from https://www.ifpi.org/wp-content/uploads/2022/04/IFPI_Global_Music_Report_2022-State_of_the_Industry.pdf

Knudson, K., Redeker, N. S., Heiderscheit, A., Pisani, M. A., Knauert, M. P., & Chlan, L. L. (2018). Acceptability and feasibility of an electronic tablet-delivered music intervention

in the medical intensive care unit.*B18. PATIENT AND FAMILY ENGAGEMENT IN RESPIRATORY AND CRITICAL CARE* American Thoracic Society 2018 International Conference, San Diego, USA.

Martin-Saavedra, J. S., Vergara-Mendez, L. D., Pradilla, I., Velez-van-Meerbeke, A., & Talero-Gutierrez, C. (2018). Standardizing music characteristics for the management of pain: A systematic review and meta-analysis of clinical trials. *Complementary Therapies in Medicine*, *41*, 81-89. https://doi.org/10.1016/j.ctim.2018.07.008

Musical Pursuits. (2022). *Music Streaming Statistics in 2022 (US & Global Data)*. Retrieved September 26, 2022 from https://musicalpursuits.com/music-streaming/

Poulsen, M. J., & Coto, J. (2018). Nursing music protocol and postoperative pain. *Pain Management Nursing*, *19*(2), 172-176. https://doi.org/10.1016/j.pmn.2017.09.003

Puntillo, K. A., Max, A., Timsit, J. F., Vignoud, L., Chanques, G., Robleda, G., Roche-Campo, F., Mancebo, J., Divatia, J. V., Soares, M., Ionescu, D. C., Grintescu, I. M., Vasiliu, I. L., Maggiore, S. M., Rusinova, K., Owczuk, R., Egerod, I., Papathanassoglou, E. D., Kyranou, M., … & Azoulay, E. (2014). Determinants of procedural pain intensity in the intensive care unit. The Europain(R) study. *American Journal of Respiratory and Critical Care Medicine*, *189*(1), 39-47. https://doi.org/10.1164/rccm.201306-1174OC

Richard-Lalonde, M., Boitor, M., Mohand-Saïd, S., & Gélinas, C. (2018). Family members' perceptions of pain behaviors and pain management of adult patients unable to self-report in the intensive care unit: A qualitative descriptive study. *Canadian Journal of Pain*, *2*(1), 315-323. https://doi.org/10.1080/24740527.2018.1544458

Richard-Lalonde, M., Gélinas, C., Boitor, M., Gosselin, E., Feeley, N., Cossette, S., & Chlan, L. L. (2020). The effect of music on pain in the adult intensive care unit: a systematic review of randomized controlled trials. *Journal of Pain and Symptom Management*, *59*(6), 1304-1319. https://doi.org/10.1016/j.jpainsymman.2019.12.359

Richard-Lalonde, M., Feeley, N., Cossette, S., Chlan, L. L., & Gélinas, C. (2022). *Acceptability and feasibility of a Patient-Oriented Music Intervention to reduce pain in the intensive care: protocol for a randomized crossover pilot trial*. JMIR Preprints. https://preprints.jmir.org/preprint/40760

Rivi, V., Melegari, G., & Blom, J. M. C. (2021). How to humanise the covid-19 intensive care units. *BMJ Evidence-Based Medicine*, *26*(4), 141–142. https://doi.org/10.1136/bmjebm-2020-111513

Sidani, S., & Braden, C. J. (2011). *Design, evaluation, and translation of nursing interventions*. Wiley-Blackwell.

Sidani, S., Epstein, D. R., Bootzin, R. R., Moritz, P., & Miranda, J. (2009). Assessment of preferences for treatment: validation of a measure. *Research in Nursing and Health*, *32*(4), 419-431. https://doi.org/10.1002/nur.20329

Sidani, S., & Fox, M. (2020). The role of treatment perceptions in intervention evaluation: a review. *Science of Nursing and Health Practices*, *3*(2), 1-15. https://doi.org/https://doi.org/10.31770/2561-7516.1079

Spotify AB. (2019a). *Get recommendations based on seeds*. Retrieved December 15 2019 from https://developer.spotify.com/documentation/web-api/reference/browse/get-recommendations/

Spotify AB. (2019b). *Upgraded spotify premium family plan: Value the entire household will love*. Retrieved November from https://newsroom.spotify.com/2019-08-19/upgraded-spotify-premium-family-plan-value-the-entire-household-will-love/

Spotify AB. (2022). *About Spotify*. Retrieved September 26, 2022 from https://news-room.spotify.com/company-info/

Statista. (2015). *Number of music tracks available on selected streaming services worldwide as of June 2015 (in millions)*. Retrieved September 26, 2022 from https://www.statista.com/statistics/435256/number-tracks-on-music-streaming-services/

Statista. (2019). *Share of music streaming subscribers worldwide as of the first half of 2019, by company*. Retrieved September 26, 2022 from https://www.statista.com/statistics/653926/music-streaming-service-subscriber-share/

Tan, X., Yowler, C. J., Super, D. M., & Fratianne, R. B. (2010). The efficacy of music therapy protocols for decreasing pain, anxiety, and muscle tension levels during burn dressing changes: a prospective randomized crossover trial. *Journal of Burn Care & Research*, *31*(4), 590-597. https://doi.org/10.1097/BCR.0b013e3181e4d71b

Ten Hoorn, S., Elbers, P. W., Girbes, A. R., & Tuinman, P. R. (2016). Communicating with conscious and mechanically ventilated critically ill patients: a systematic review. *Critical care (London, England)*, *20*(1), 333. https://doi.org/10.1186/s13054-016-1483-2

Vadivelu, N., Mitra, S., Schermer, E., Kodumudi, V., Kaye, A. D., & Urman, R. D. (2014). Preventive analgesia for postoperative pain control: a broader concept. *Local and Regional Anesthesia*, *7*, 17-22. https://doi.org/10.2147/LRA.S62160

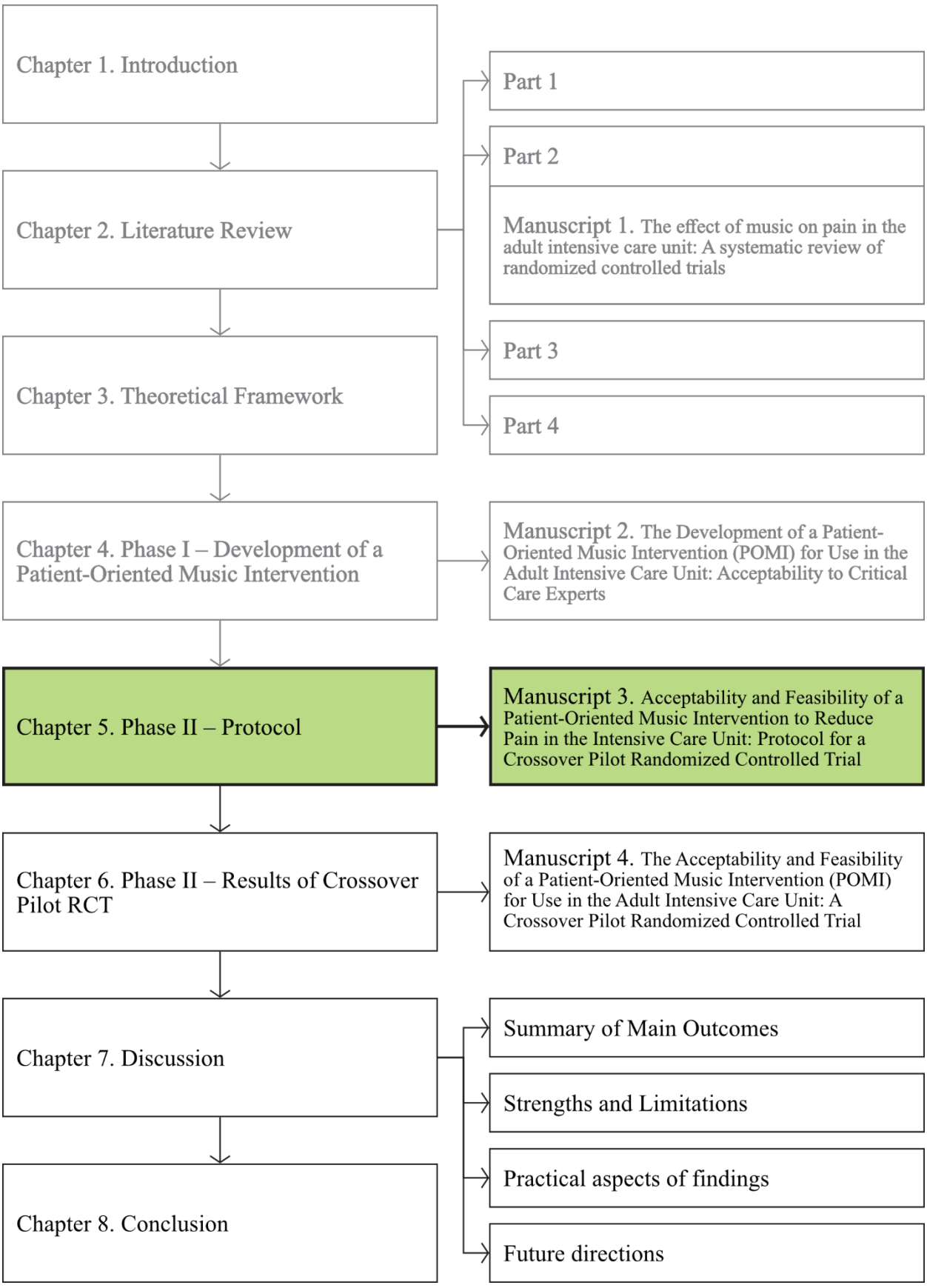
Van Criekinge, T., D'Aout, K., O'Brien, J., & Coutinho, E. (2019). Effect of music listening on hypertonia in neurologically impaired patients-systematic review. *PeerJ*, *7*, e8228. https://doi.org/10.7717/peerj.8228

Villarreal, E. A., Brattico, E., Vase, L., Ostergaard, L., & Vuust, P. (2012). Superior analgesic effect of an active distraction versus pleasant unfamiliar sounds and music: the influence of emotion and cognitive style. *PLoS One*, *7*(1), e29397. https://doi.org/10.1371/journal.pone.0029397

Williams, A. C., & Craig, K. D. (2016). Updating the definition of pain. *Pain*, *157*(11), 2420-2423. https://doi.org/10.1097/j.pain.0000000000000613

Yoo, H. J., Lim, O. B., & Shim, J. L. (2020). Critical care nurses' communication experiences with patients and families in an intensive care unit: A qualitative study. *PLoS One*, *15*(7), e0235694. https://doi.org/10.1371/journal.pone.0235694

Zoom Video Communications, Inc. (2021) Zoom meetings (Version 5.1.1) [Video Conferencing Software]. Retrieved from https://mcgill.zoom.us/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Part 3
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Chapter 5. Phase II – Protocol

Based on major limitations related to the acceptability and feasibility of music interventions and their empirical testing (Skivington et al., 2021), the next logical step was to plan a pilot testing of the POMI which represents Phase II of this doctoral research project. More specifically, the aim was to evaluate the acceptability and feasibility of POMI; to evaluate the research methods of the POMI pilot testing; and to examine the preliminary efficacy of POMI to reduce pain in ICU patients. A crossover pilot RCT design was chosen to address these objectives. The research protocol was published in JMIR Research Protocols and can found in Manuscript 3, "Acceptability and Feasibility of a Patient-Oriented Music Intervention to Reduce Pain in the Intensive Care Unit: Protocol for a Crossover Pilot Randomized Controlled Trial". The data collection forms are listed in Appendices A-I.

Manuscript 3. Acceptability and Feasibility of a Patient-Oriented Music Intervention to Reduce Pain in the Intensive Care Unit: Protocol for a Crossover Pilot Randomized Controlled Trial

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Richard-Lalonde, M., Feeley, N., Cossette, S., Chlan, L. L., & Gélinas, C. (2023). Acceptability and feasibility of a patient-oriented music intervention to reduce pain in the intensive care unit: Protocol for a crossover pilot randomized controlled trial. *JMIR Research Protocols*, *12*, e40760. https://doi.org/10.2196/40760

Abstract

Background: Many patients experience pain in the intensive care unit (ICU) despite receiving pain medication. Research has shown that music can help reduce pain. Music interventions studied so far have not used music streaming to generate playlists based on patient preferences while incorporating recommended tempo and duration. Previous research has focused on postoperative ICU patients able to self-report, which is underrepresentative of the ICU population that might benefit from a music intervention for pain management. We developed a new patient-oriented music intervention (POMI) that incorporates features based on theoretical, empirical, and experiential data intended to be used in the ICU. Such a music intervention should consider the expertise of ICU patients, family members, and nursing staff, as well as the practicality of the intervention when used in practice.

Objective: The primary objectives of this study are to (1) evaluate the acceptability and feasibility of the POMI to reduce pain in ICU patients and (2) evaluate the feasibility of conducting a crossover pilot randomized controlled trial (RCT) for intervention testing in the ICU. A secondary objective is to examine the preliminary efficacy of the POMI to reduce pain in ICU patients.

Methods: A single-blind 2×2 crossover pilot RCT will be conducted. Patients will undergo 1 sequence of 2 interventions: the POMI which delivers music based on patients' preferences via headphones or music pillow for 20-30 minutes and the control intervention (headphones or pillow without music). The sequence of the interventions will be inverted with a 4-hour washout period. Timing of the interventions will be before a planned bed turning procedure. Each patient will undergo 1 session of music. Twenty-four patients will be recruited. Patients able to self-report (n=12), family members of patients unable to self-report (n=12), and nursing staff (n=12) involved in the bed turning procedure will be invited to complete a short questionnaire on the

POMI acceptability. Data will be collected on the feasibility of the intervention delivery (ie, time spent creating a playlist, any issue related to headphones/pillow or music delivery, environmental noises, and intervention interruptions) and research methods (ie, number of patients screened, recruited, randomized, and included in the analysis). Pain scores will be obtained before and after intervention delivery.

Results: Recruitment and data collection began in March 2022. As of July 5, 2022, in total, 22 patients, 12 family members, and 11 nurses were recruited.

Conclusions: Methodological limitations and strengths are discussed. Study limitations include the lack of blinding for patients able to self-report. Strengths include collecting data from various sources, getting a comprehensive evaluation of the intervention, and using a crossover pilot RCT design, where participants act as their own control, thus reducing confounding factors.

Trial Registration: ClinicalTrials.gov NCT05320224; https://clinicaltrials.gov/ct2/show/NCT05320224

Introduction

Background and Rationale

Pain is a common symptom in critically ill adults, both in patients able and unable to self-report [1]. Guidelines recommend the use of a multimodal approach to pain management to reduce opioid use and optimize pain relief [1]. Music has been suggested as a nonpharmacologic intervention in acute and chronic care settings, but little is known about its efficacy and feasibility in the intensive care unit (ICU) [2-8]. We conducted a systematic review and meta-analysis of randomized controlled trials (RCTs) to establish the efficacy of music in the adult ICU. Music interventions of 20 to 30 minutes were effective to reduce pain by almost 2 points on a 0-10 numeric rating scale (NRS) in ICU patients able to self-report [9]. However, the effect of music on pain in ICU patients unable to self-report remains unknown. In a previous review, some studies reported that family members of ICU patients expressed their interest in participating in the music selection process and in the pain management of their loved ones [10]. Therefore, music interventions for patients unable to self-report could involve the participation of family members based on their intimate knowledge of the patient and their music preferences.

Current recommendations for music interventions in postoperative patients are to provide music in the range of 60-80 beats per minute (bpm) [11]. However, most ICUs do not have access to music therapists, who have the expertise to provide personalized music within this range. Thus, there is a need to develop an easy-to-use music intervention that produces individualized music playlists with a tempo of 60-80 bpm for ICU patients. Music streaming services allow for the music selection of specific tempo ranges and should be explored as a simple means to provide a more accessible music intervention in the adult ICU.

Studies conducted thus far have mainly focused on postsurgical patients, mechanically ventilated, and able to communicate despite the fact that many patients are likely to be unable to communicate during their ICU stay [9,12,13]. Therefore, RCTs conducted until now on the effect of music to reduce pain in critically ill adults have limited generalizability to the entirety of the ICU population, despite the knowledge that all patients can experience pain and could benefit from this nonpharmacological pain management intervention.

Another limitation in previous RCTs analyzed in the systematic review relates to sample size [9]. In 4 RCTs, no sample size calculation was reported [14-17]. In 3 RCTs, the sample size was calculated based on outcomes other than pain [18-20]. In another 3 studies, the calculated sample size required was not attained for various feasibility issues attributed to “slow” or “difficult” recruitment (due to time limit, refusal rate due to randomization or family visits, and narrow inclusion criteria), or withdrawal of ICU adult patient participants who did not like the music chosen for them [21-23]. In 1 study, it was unclear whether the sample size represented the number of ICU adult patient participants or the number of observations [24]. Inadequate power may explain why 11 of the 18 RCTs found a significant pain reduction while 7 did not. Therefore, there is a need to evaluate the feasibility of research methods by conducting a pilot RCT prior to evaluating the efficacy of any new music intervention in the adult ICU.

Objectives

This study aims to (1) evaluate the acceptability and feasibility of a new patient-oriented music intervention (POMI) to reduce pain in ICU patients (primary objective); (2) evaluate the feasibility of conducting a crossover randomized controlled trial (RCT) for intervention testing in the adult ICU (primary objective); and (3) examine the preliminary efficacy of the POMI (secondary objective).

Trial Design

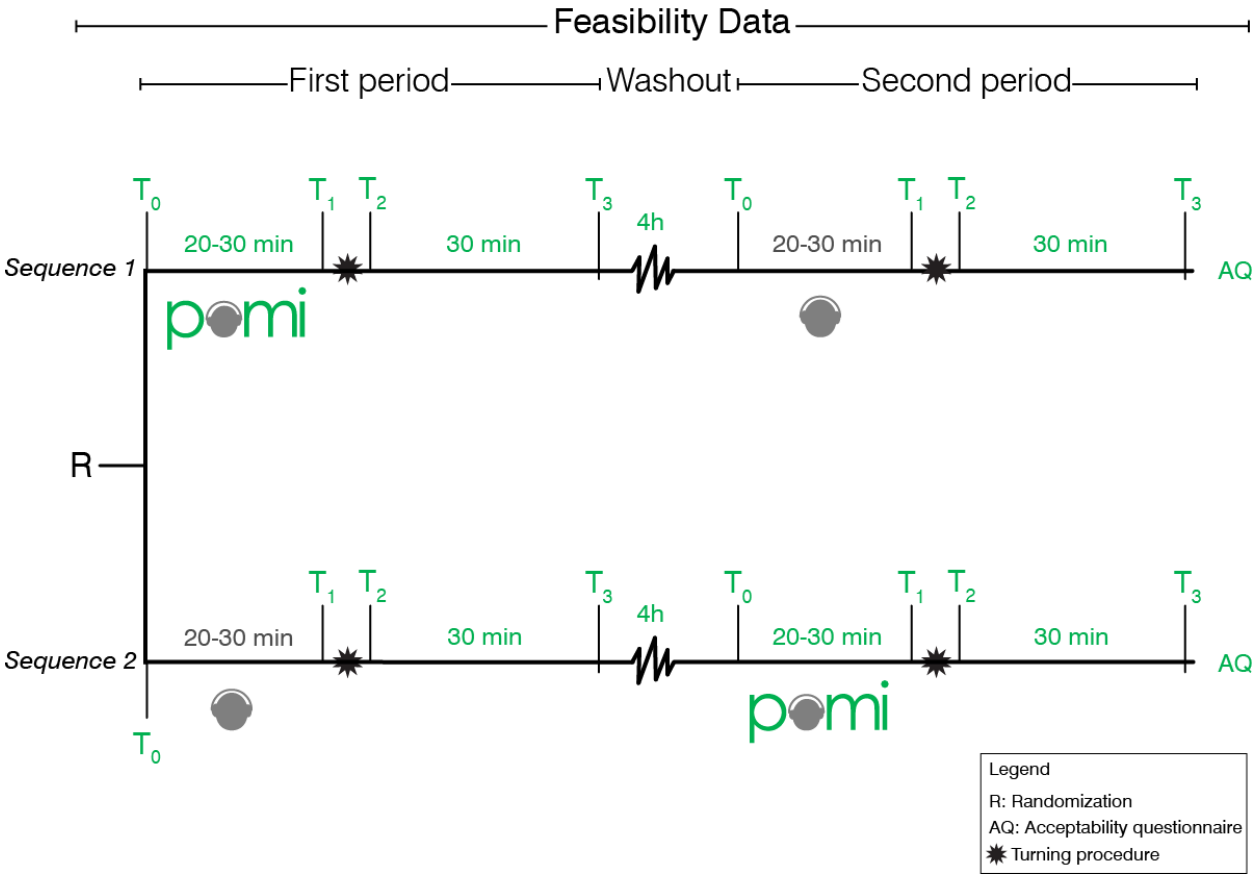
A single-blind 2×2 crossover pilot RCT was selected for this study protocol, where patients undergo a sequence of 2 intervention periods: the POMI and the control intervention (CTL: headphones or pillow without music), with an allocation ratio of 1:1.

Methods

Design

A single-blind 2×2 crossover pilot RCT is being conducted to evaluate the acceptability, feasibility, and preliminary efficacy of the POMI. Recruitment is planned to occur over a period of 6 months during which we aim to enroll a total of 24 patient participants. As shown in Figure 1, each participating patient is randomly assigned to 1 sequence (sequence 1 or 2) of 2 intervention periods: the POMI and the CTL (headphones or pillow without music). Patients in sequence 1 receive the POMI during the first intervention period, followed by the CTL in the second intervention period; and patients in sequence 2 receive the CTL first, followed by the POMI. Each 20-30–minute intervention period is provided before a bed turning procedure that is planned as part of the participating patient's usual care by the nursing staff. There is a 4-hour minimum washout period between both intervention periods, with data collected during the day and evening. Data collection begins as soon as possible following recruitment, always in coordination with patient care. Therefore, the first period of data collection may occur in the daytime or in the evening.

Figure 1. Study design for the 2×2 cross-over pilot randomized control trial.



Recruitment

Recruitment is conducted by the first author (MRL), who is introduced to the eligible patient and family member by the nurse caring for the eligible patient. If the eligible candidate is interested in hearing about the study, the student researcher meets with them at the ICU bedside to present the study, provides a copy of the informed consent form, and answers any question. The eligible candidate is then given time to think about whether they are interested in the study. ICU nursing staff (ie, nurses and orderlies) involved in the turning procedure during the study are invited individually prior to the scheduled bed turning procedure. Eligible nursing staff are given the informed consent form and can choose to participate at their convenience. Eligible criteria are detailed in Table 1.

Table 1. Eligibility criteria.

		Type of participant			
		Patient able to self-report	Patient unable to self-report	Family member	Nursing staff
Inclusion criteria					
	Is ≥ 18 years old	✓	✓	✓	✓
	Is admitted to ICU[a]	✓	✓		
	Has a loved one admitted to the ICU			✓	
	Works in the ICU				✓
	Is able to self-report	✓		✓	✓
	Is able to listen to music as per patient or a family member for patients unable to self-report	✓	✓		
	A family member is present at the bedside		✓		
	Considers self to have knowledge of the patient's music preferences			✓	
	Is qualified to consent to any care required by the state of health for the incapable ICU adult patient			✓	
	Is present during the turning procedure at the time of the POMI[b] project data collection				✓
Exclusion criteria					
	Cannot be turned	✓	✓		
	Does not speak or understand French or English	✓	✓	✓	✓
	Is unarousable, as defined by a score of −5 on the Richmond Agitation Sedation Scale (RASS)	✓	✓		
	Is under the effects of neuromuscular blocking agent	✓	✓		

[a]ICU: intensive care unit.

[b]POMI: patient-oriented music intervention.

Participants

Sample Size

A minimal sample size of 10 participants per group is recommended in pilot studies [25,26]. Because studies with repeated measures (such as crossover designs) require more time commitment from participants (ie, multiple measurements over time), an attrition rate of approximately 15% (n=2 per group) can be anticipated, which is consistent with what has been reported in previous studies conducted in the targeted population [27,28]. To account for this, the recruited sample size was estimated to be 12 participants per group.

Patients

A sample size of 24 patients is targeted, with 12 being able to self-report and 12 unable to self-report. Patients able to self-report will be asked about their music preferences, levels of pain intensity, distress, and acceptability of the POMI.

Family Members

Family members are defined by the patient or, in the case of those unable to self-report, by their surrogates. In such cases, the family may be related or unrelated to the patient. Family members are the individuals who provide support and with whom the patient has a significant relationship [29]. A sample size of 12 family members is targeted: 1 for each patient unable to self-report. Family members will be responsible for providing information on the music preferences of their loved one unable to self-report, as well as answering questions on the POMI acceptability.

Nursing Staff

A total of 12 members of nursing staff involved in a participating patient's bed turning procedure will be recruited to answer questions on the acceptability of the POMI from their perspective.

Randomization

For the equal allocation of both groups, 24 opaque envelopes were prepared in advance by an independent member of the research team, with the use of a digitally generated list [51]. Once patients or their representatives consent to participate and agree to randomization, patient participants are categorized as either able to self-report or unable to self-report, producing 2 strata. Within each stratum, patients are randomized to either sequence 1 or sequence 2, following a permuted block randomization to ensure balance within each stratum. A block size of 4 was used (3 blocks per stratum) for a sample size of 24 ICU adult patient participants (in each block, 2 patient participants will be assigned to sequence 1 and 2 patient participants will be assigned to sequence 2, and the ordering will be random).

Patient-Oriented Music Intervention

Overview

The brief name given to this intervention is POMI (patient-oriented music intervention). In POMI, music is delivered to adult patients either via headphones (Bose, QuietComfort 35) or by a music pillow (MusiCure, hospital grade). Adult patients admitted to the ICU and able to self-report can choose the mode of delivery based on their personal preference. Adult patients admitted to the ICU and unable to self-report are given the music pillow. For patients able to self-report, individualized music playlists are created based on the patient's music preferences. For patients unable to self-report, a family member is asked about the patient's music preferences. Questions about music preferences include music genre, track title, artist name, instrumentalness, acousticness, energy, and valence, as defined by the streaming service Spotify.

Playlist Creation

The personalized music playlist is generated prior to the POMI period for each patient participant. To determine the participant's music preferences, the following questions are asked, based on possible recommendations through the Spotify Application Programming Interface [30]:

Is there any music genre that you would like to listen to?

Is there any specific song title that you would like to listen to?

Is there any music artist that you would like to listen to?

Would you like to hear music that is more instrumental, more vocal, or do you have no preference?

Would you like to hear music that is more acoustic, more electric, or do you have no preference?

Would you like to hear music that is more calming, more energetic, or do you have no preference?

Would you like to hear music that is more cheerful, more melancholic, or do you have no preference?

Would you like to hear music that is more popular, less popular, or do you have no preference?

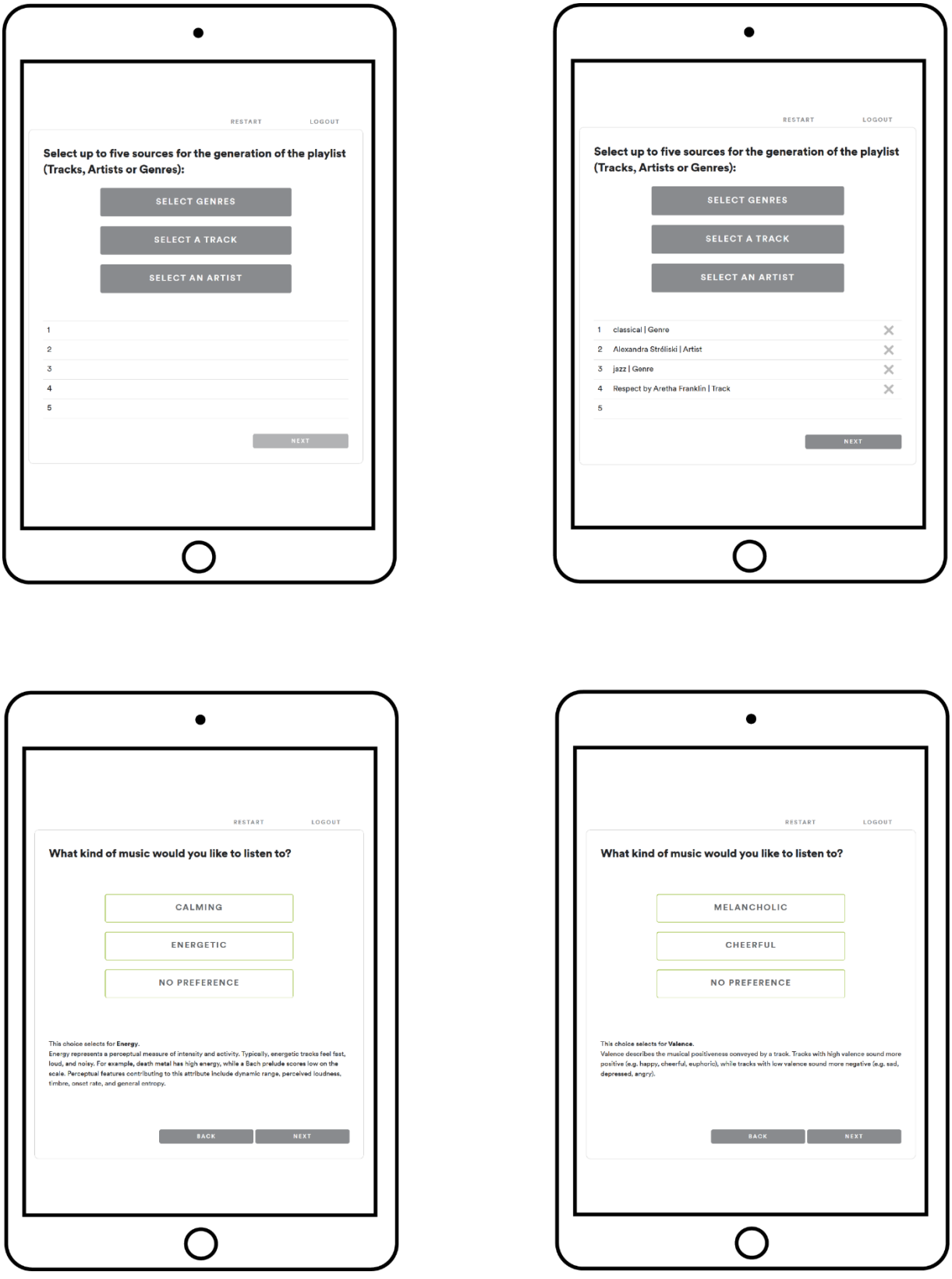
Would you like to hear music that is recorded in studio, do you prefer live recordings of music, or do you have no preference?

Any or all the questions can be skipped as preferred if at least 1 answer is given to questions 1, 2, or 3. Definitions on any of the music attributes (eg, electric and energetic) are provided if necessary and are available on the web-based tool.

The reported preferences are entered into a POMI web-based tool (Figure 2) to generate a personalized music playlist on Spotify, with a tempo restriction of 60-80 bpm as recommended [11]. Music is then played for 20 to 30 minutes via a smart device (iPad, 8th generation).

At all times, patients can control the music (eg, skip a song or stop the music, either briefly or permanently) by accessing the iPad themselves or communicating with the student researcher. Patients unable to self-report are continually monitored by the student researcher while the music is playing so that any nonverbal reaction to the music, indicating such dislike of the music, would lead the student researcher to stop the music immediately.

Figure 2. Example of Web-based tool screenshots for the Patient-Oriented Music Intervention.



Control Intervention

The CTL consists of providing a 20-30–minute period without music either while wearing headphones (Bose, QuietComfort 35) or with the head resting on a music pillow (MusiCure, hospital-grade), which is consistent with the mode of delivery for the POMI. Adult patients admitted to the ICU and able to self-report can choose 1 of the 2 modes of delivery. Patients unable to self-report are given the music pillow.

Washout Period

To allow for any pain-reducing effect of the POMI to dissipate before the CTL, a washout period of at least 4 hours is scheduled between both intervention periods, based on previous data on the duration of the analgesic effect of music on pain [31].

Video Recordings

Video will be recorded for the duration of the intervention period and at each pain assessment time point. These video recordings will be used to have an independent member of the research team evaluate: (1) the Critical-Care Pain Observation Tool (CPOT) scores for each patient participant (to ensure blinding of the research team member interrater to sequence allocation) and (2) the intervention fidelity.

Outcomes

Acceptability

The acceptability questionnaire is adapted from the treatment acceptability and preferences (TAP) validated measure [32]. The TAP is comprised of 4 items: suitability, appropriateness, effectiveness, and willingness to comply, each of which is rated on a 5-point scale ranging from 0 (not at all) to 4 (very much) with higher scores indicating greater acceptability [32]. The total

scale score is then obtained by calculating the mean of all the items' scores. The TAP was shown to have a Cronbach alpha coefficient greater than .75, supporting good internal consistency [33], and it has been used to evaluate a variety of interventions in different acute and postsurgical care settings [34-36]. The TAP can capture "the complex nature of [participants'] preferences" and yet being simple enough for use in the ICU setting [32]. As recommended [37], 1 item has been added to the questionnaire to determine the risks of side effects of the POMI, an additional important aspect in assessing the acceptability of the intervention.

Feasibility of Intervention

The items for the assessment of the intervention feasibility include (1) time spent (in minutes) creating the individualized playlist; (2) the presence or absence of any issue with headphone or pillow use; (3) the presence or absence of any issue with music delivery; (4) the presence or absence of skipping one or more songs from the generated playlist; (5) the presence or absence of any environmental noise (eg, alarms and voices) during intervention delivery; (6) the presence or absence of any POMI interruptions; (7) whether the patient participant received the full duration of the POMI; (8) the dose (duration in minutes) of the music delivered; (9) the characteristics of the music delivered (eg, music genres).

Additionally, as part of the feasibility of intervention, the fidelity of the intervention will be assessed based on specific criteria [38] and will include meeting with participants to discuss music preferences, producing a personalized playlist, and playing music once at least for 20 minutes. Any issues with the delivery of the POMI will also be recorded.

Feasibility of Research Methods

The items for the assessment of the feasibility of research methods, based on the CONSORT guidelines for pilot and feasibility RCTs [39,40], include the number of patients screened, number of eligible patients, number of participants recruited, number of participants randomized, and number of participants included in the analysis.

Preliminary Efficacy of POMI on Acute Pain

Pain will be assessed at 4 different timepoints for each intervention period: before the intervention, immediately after the intervention, during the bed turning procedure, and 30 minutes after the bed turning procedure (Figure 1, T_0-T_3). Pain assessments will be performed using validated tools as recommended in ICU clinical practice guidelines [1]. For all patient participants, the CPOT will be used because it is one of the most valid behavioral scales for assessing pain in critically ill adults [41]. In addition to the CPOT, patient participants able to self-report will be asked to rate their pain intensity using the 0-10 Faces Pain Thermometer [42] and their pain distress on a 0-10 NRS [43,44].

Data Analysis

Overview

A databank will be created with the SPSS software (version 27.0, IBM) [45], where the collected data on acceptability, feasibility, and preliminary efficacy will be entered. All the statistical analyses described below will be performed using SPSS.

Acceptability of Intervention

The acceptability of the POMI will be determined using the TAP questionnaire. The frequencies, medians, and IQRs will be calculated for each item as well as for the total score, which will be

calculated by taking the median, out of 4, of all items. The first 4 items (suitability, appropriateness, perceived effectiveness, and willingness to comply) will be scored in sequence (with 0 being the least favorable and 4 being the most favorable), whereas the last item (risks or side effects) will be scored in reverse (with 4 being the least favorable and 0 being the most favorable), as it is a negatively worded question. Any notes or comments added to the ratings will be compiled by category and presented descriptively to accompany the numerical ratings. A median above 2 out of 4 for the total score will be considered as an acceptable intervention, overall. An item median score above 2 out of 4 will be considered an acceptable attribute of the POMI. A median below 2 out of 4 will indicate the need to look more closely at the comments accompanying the ratings and modify the intervention to improve the acceptability of the POMI (eg, mode of delivery and dose). The acceptability of the POMI will be established via data triangulation from all study participants: patients, family members, and nursing staff [46].

Feasibility and Fidelity of Intervention

Descriptive statistics will be obtained to compute the frequencies for each of the intervention feasibility items. The POMI will be considered a feasible intervention if there are no issues in over 50% of the items for the assessment of the intervention feasibility (as listed above) for at least 80% of the patient participants in each group [47]. Regarding the fidelity of the intervention, descriptive data will be computed on the amount of time spent creating the music playlists (≤10 minutes), delivery of the overall POMI (use of headphones or pillow), as well as the amount of time the music will be listened to (once, for at least 20 minutes). The percentage of items completed on the fidelity checklist will also be computed in order to ensure that at least 80% of the intervention fidelity items will be delivered as planned, yet to allow for a certain amount of flexibility, if needed [47,48].

Feasibility of Research Methods

Descriptive statistics will be generated for each of the feasibility of research methods items. The screening and recruitment procedures will be described and include the number of patients screened, the proportion of eligible patients as well as the number of enrolled participants. If less than 50% of the potential patient participants are found to be eligible, considerations will be made to broaden the inclusion criteria in an eventual full-scale RCT [38]. Time to recruit will be considered adequate if 24 patient participants are enrolled within 6 months. All issues related to recruitment will be described and grouped into categories by the student researcher.

The retention rates will be calculated and expected to be above 80%. Reasons for participant withdrawal will be described, when known, and if retention rates are below 80%, strategies will be recommended to reduce attrition, based on the reasons for study withdrawal. If more than 10% of the participants (in each group) are found to have missing data, reasons for missing data will be described to inform how to reduce the amount of missing data in future research.

Preliminary Efficacy

Descriptive statistics will be computed for all outcomes (CPOT, pain intensity, and pain distress scores). the 95% CIs will be computed for each dependent variable at each time point.

Considering the small sample size for a pilot study, the potential efficacy of the POMI will be analyzed using nonparametric tests. For the dependent variables (CPOT, pain intensity, and pain distress scores), the Friedman test will be used to compare the scores at individual time points in each group separately. If the Friedman test is found to tend toward significant ($P<.10$), the Wilcoxon signed rank test will be used to compare 2 timepoints in pairs with a Bonferroni correction (0.05 per number of tests) to locate the differences.

The preliminary efficacy findings will not be used to inform the decision to pursue a full-scale RCT. However, any tendency toward statistical significance ($P<.10$) or significant lower pain scores in the music period versus the control period will support that the intervention group might decrease pain over time, compared to the control group. A formal hypothesis of efficacy will need to be tested in a full-scale RCT, which will only be recommended if the POMI is deemed acceptable and feasible.

Ethics Approval

Ethics approval was submitted in July 2021 and approved in December 2021 (Project #2022-3005). Participation in this research project is voluntary and ongoing for all participants. Participants are free to refuse to participate and may withdraw from this research study at any time, without having to give a reason, and without any consequence to them now or in the future. The participant's decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which they are otherwise entitled. Participants are free to refuse to answer any question and remain in the study. Participants are free to refuse to be video recorded.

For a patient who is unable to consent to participate in the study, a family member representative will provide the written consent on behalf of the patient. From this time and until the patient participant is discharged from the ICU, the student researcher will follow up on the ICU adult patients who were unable to consent to determine if they regain the ability to consent for themselves. In the case where a patient participant who was previously unable to consent regains the ability to consent at any time, before or after the intervention, the student researcher will present the research project and the information and consent form to allow the ICU adult patient to make an informed decision regarding their participation in the study.

The data collected from a participant as part of this study, excluding the video recordings, could be used for future research projects related to this study only with the participant's explicit permission. The results of the research study, excluding video recordings, may be presented at conferences, published in specialized journals or be the subject of scientific discussions, or be used for teaching purposes. No identifying information will be published in any way.

At any time, participants have the right to consult their study file in order to verify the information gathered and to have it corrected if necessary. All study data will be stored safely for 10 years, after which time they will be permanently destroyed by being either shredded or permanently deleted from the server.

Patients and families will be offered the hyperlink to their playlist as well as a paper version of the list of songs played as part of the study. Nursing staff participants will be offered a US $20 gift certificate to compensate for their time spent participating in the study.

Results

This study was registered to ClinicalTrials.gov (NCT05320224) in March 2022. Recruitment and data collection began in March 2022.

Discussion

Methodological Strengths

One strength of this study is the evaluation of the intervention acceptability from multiple sources: ICU patients, families, and nursing staff. This will allow us to gain access to the different perspectives of the various stakeholders and acquire a more comprehensive understanding of the overall acceptability of the intervention. The crossover design is another strength as it allows each patient participant to be their own control, thus reducing confounding factors that are

usually present in between-subject designs [49,50]. Moreover, the crossover design will allow for patient participants able to self-report to share their preference between the POMI and the CTL because they will experience both interventions. Information about participant preference will add rich qualitative data beyond the quantitative comparison of preliminary efficacy [40,50]. The crossover design is relevant to use during procedures that are planned within a short period of time (eg, molar extractions at 2 different times) [49]. In addition to intervention comparisons and patient participant preferences, we will be able to determine the pain and distress differences individually (numerically) and compute the proportion of patient participants for whom the treatment was effective in reducing pain by more than 1 point on a 0-10 NRS, for example [50]. The crossover design will also enable us to describe whether any reduction in pain or distress was qualified as meaningful by the patient participant (for those able to self-report). These data could later contribute to the understanding of the minimally clinically significant difference in procedural pain in the adult ICU population [50].Knowing that patient participants will receive both interventions as part of the crossover design may allow them to think more objectively about pain levels in each intervention period (thus minimizing the placebo effect) compared to if they participated in a parallel-group trial, in which the patient participants' hope to receive the intervention may influence their pain rating [49]. Finally, blinding patient participants unable to self-report will reduce the risk of bias based on these participants' expectations of music efficacy to reduce pain.

Methodological Limitations and Mitigation Strategies

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials recommendations state that the use of a crossover trial at an earlier stage study, followed by confirmation of the results in a larger parallel-group study, is an efficient approach, as long as a washout period

is carefully planned to minimize or avoid carryover effects [49]. To allow for any pain-reducing effect of the POMI to dissipate before the CTL, there will be a washout period of at least 4 hours between both intervention periods, based on previous data on the duration of the analgesic effect of music on pain [31]. Due to the sample size and to evaluate the time effect, the Friedman and Wilcoxon rank sum tests will be used when analyzing pain-related data for each subgroup [50]. To avoid response shifts due to the crossover design, baseline pain intensity will be measured for each intervention period (T_0 in Figure 1). Because blinding will be difficult with patient participants receiving both the POMI and the CTL, there is a risk of ascertainment bias for patient participants. To address this, patient participants able to self-report will be asked about their perception of how effective they think the music is compared to the CTL. To minimize possible interruptions and noise during intervention periods, the nurse responsible for the patient will be met to discuss and plan for the best time to start the intervention period, prior to a scheduled bed turn.

Due to the current context of the pandemic and this study being conducted in an ICU setting, it is possible that limited family visits and nursing staff shortages will impact recruitment from these populations. To mitigate these possible limitations, meeting families at the bedside will be coordinated with the nursing staff.

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Data Availability

The data sets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of Interest

None declared.

References

1. Devlin JW, Skrobik Y, Gélinas C, Needham DM, Slooter AJC, Pandharipande PP, et al. Clinical practice guidelines for the prevention and management of pain, agitation/sedation, delirium, immobility, and sleep disruption in adult patients in the ICU. Crit Care Med 2018 Sep;46(9):e825-e873 [FREE Full text] [doi: 10.1097/CCM.0000000000003299] [Medline: 30113379]

2. Cepeda MS, Carr DB, Lau J, Alvarez H. Music for pain relief. Cochrane Database Syst Rev 2006 Apr 19(2):CD004843 [FREE Full text] [doi: 10.1002/14651858.CD004843.pub2] [Medline: 16625614]

3. Cole LC, LoBiondo-Wood G. Music as an adjuvant therapy in control of pain and symptoms in hospitalized adults: a systematic review. Pain Manag Nurs 2014 Mar;15(1):406-425 [FREE Full text] [doi: 10.1016/j.pmn.2012.08.010] [Medline: 23107431]

4. Lee JH. The effects of music on pain: a meta-analysis. J Music Ther 2016;53(4):430-477 [FREE Full text] [doi: 10.1093/jmt/thw012] [Medline: 27760797]

5. Martin-Saavedra JS, Vergara-Mendez LD, Pradilla I, Vélez-van-Meerbeke A, Talero-Gutiérrez C. Standardizing music characteristics for the management of pain: a systematic review and meta-analysis of clinical trials. Complement Ther Med 2018 Dec;41:81-89 [FREE Full text] [doi: 10.1016/j.ctim.2018.07.008] [Medline: 30477868]

6. Meghani N, Tracy MF, Hadidi NN, Lindquist R. Part I: the effects of music for the symptom management of anxiety, pain, and insomnia in critically ill patients: an integrative review of current literature. Dimens Crit Care Nurs 2017;36(4):234-243 [FREE Full text] [doi: 10.1097/DCC.0000000000000254] [Medline: 28570377]

7. Nilsson U. The anxiety- and pain-reducing effects of music interventions: a systematic review. AORN J 2008 Apr;87(4):780-807 [FREE Full text] [doi: 10.1016/j.aorn.2007.09.013] [Medline: 18395022]

8. Hole J, Hirsch M, Ball E, Meads C. Music as an aid for postoperative recovery in adults: a systematic review and meta-analysis. Lancet 2015 Oct 24;386(10004):1659-1671 [FREE Full text] [doi: 10.1016/S0140-6736(15)60169-6] [Medline: 26277246]

9. Richard-Lalonde M, Gélinas C, Boitor M, Gosselin E, Feeley N, Cossette S, et al. The effect of music on pain in the adult intensive care unit: a systematic review of randomized controlled trials. J Pain Symptom Manage 2020 Jun;59(6):1304-1319.e6 [FREE Full text] [doi: 10.1016/j.jpainsymman.2019.12.359] [Medline: 31881291]

10. Gosselin É, Richard-Lalonde M. Role of family members in pain management in adult critical care. AACN Adv Crit Care 2019 Dec 15;30(4):398-410 [FREE Full text] [doi: 10.4037/aacnacc2019275] [Medline: 31951660]

11. Poulsen MJ, Coto J. Nursing music protocol and postoperative pain. Pain Manag Nurs 2018 Apr;19(2):172-176 [FREE Full text] [doi: 10.1016/j.pmn.2017.09.003] [Medline: 29153918]

12. Happ MB, Garrett K, Thomas DD, Tate J, George E, Houze M, et al. Nurse-patient communication interactions in the intensive care unit. Am J Crit Care 2011 Mar;20(2):e28-e40 [FREE Full text] [doi: 10.4037/ajcc2011433] [Medline: 21362711]

13. Happ MB, Seaman JB, Nilsen ML, Sciulli A, Tate JA, Saul M, et al. The number of mechanically ventilated ICU patients meeting communication criteria. Heart Lung 2015;44(1):45-49 [FREE Full text] [doi: 10.1016/j.hrtlng.2014.08.010] [Medline: 25261939]

14. Ames N, Shuford R, Yang L, Moriyama B, Frey M, Wilson F, et al. Music listening among postoperative patients in the intensive care unit: a randomized controlled trial with mixed-methods analysis. Integr Med Insights 2017;12:1-13 [FREE Full text] [doi: 10.1177/1178633717716455] [Medline: 28904523]

15. Broscious SK. Music: an intervention for pain during chest tube removal after open heart surgery. Am J Crit Care 1999 Nov;8(6):410-415 [FREE Full text] [Medline: 10553182]

16. Ciğerci Y, Özbayır T. The effects of music therapy on anxiety, pain and the amount of analgesics following coronary artery surgery. Turk Gogus Kalp Dama 2016 Jan 04;24(1):44-50 [FREE Full text] [doi: 10.5606/tgkdc.dergisi.2016.12136]

17. Kyavar M, Karkhaneh S, Rohanifar R, Azarfarin R, Sadeghpour A, Alizadehasl A, et al. Effect of preferred music listening on pain reduction in mechanically ventilated patients after coronary artery bypass graft surgery. Res Cardiovasc Med 2016;5(4):e33769 [FREE Full text] [doi: 10.5812/cardiovascmed.33769]

18. Chiasson AM, Linda Baldwin A, McLaughlin C, Cook P, Sethi G. The effect of live spontaneous harp music on patients in the intensive care unit. Evid Based Complement Alternat Med 2013;2013:428731 [FREE Full text] [doi: 10.1155/2013/428731] [Medline: 24371459]

19. Jaber S, Bahloul H, Guétin S, Chanques G, Sebbane M, Eledjam JJ. Effects of music therapy in intensive care unit without sedation in weaning patients versus non-ventilated patients. Ann Fr Anesth Reanim 2007 Jan;26(1):30-38 [FREE Full text] [doi: 10.1016/j.annfar.2006.09.002] [Medline: 17085009]

20. Sanjuán Naváis M, Via Clavero G, Vázquez Guillamet B, Moreno Duran A, Martínez Estalella G. Effect of music on anxiety and pain in patients with mechanical ventilation. Enferm Intensiva 2013;24(2):63-71 [FREE Full text] [doi: 10.1016/j.enfi.2012.11.003] [Medline: 23298702]

21. Chan MF. Effects of music on patients undergoing a C-clamp procedure after percutaneous coronary interventions: a randomized controlled trial. Heart Lung 2007;36(6):431-439 [FREE Full text] [doi: 10.1016/j.hrtlng.2007.05.003] [Medline: 18005804]

22. Cooke M, Chaboyer W, Schluter P, Foster M, Harris D, Teakle R. The effect of music on discomfort experienced by intensive care unit patients during turning: a randomized

cross-over study. Int J Nurs Pract 2010 Apr;16(2):125-131 [FREE Full text] [doi: 10.1111/j.1440-172X.2010.01819.x] [Medline: 20487057]

23. Shultis C. Effects of Music Therapy vs. Music Medicine on Physiological and Psychological Parameters of intensive care patients: A randomized controlled trial. Ann Arbor, MI: Temple University, ProQuest Dissertations Publishing; 2012.

24. Guilbaut V. Impact of the standardized musical intervention Music Care © on the painful procedures of critically ill patients [Apport de l'intervention musicale standardisée type Music Care© sur les soins douloureux des patients vigiles en soins critiques].: Université Nice Sophia Antipolis; 2017. URL: https://dumas.ccsd.cnrs.fr/dumas-01581304 [accessed 2017-09-04]

25. Bell ML, Whitehead AL, Julious SA. Guidance for using pilot studies to inform the design of intervention trials with continuous outcomes. Clin Epidemiol 2018;10:153-157 [FREE Full text] [doi: 10.2147/CLEP.S146397] [Medline: 29403314]

26. Hertzog MA. Considerations in determining sample size for pilot studies. Res Nurs Health 2008 Apr;31(2):180-191 [FREE Full text] [doi: 10.1002/nur.20247] [Medline: 18183564]

27. Boitor M, Martorella G, Maheu C, Laizner AM, Gélinas C. Effects of massage in reducing the pain and anxiety of the cardiac surgery critically ill-a randomized controlled trial. Pain Med 2018 Dec 01;19(12):2556-2569 [FREE Full text] [doi: 10.1093/pm/pny055] [Medline: 29618079]

28. Gélinas C, Bérubé M, Puntillo KA, Boitor M, Richard-Lalonde M, Bernard F, et al. Validation of the critical-care pain observation tool-neuro in brain-injured adults in the intensive

care unit: a prospective cohort study. Crit Care 2021 Apr 13;25(1):142 [FREE Full text] [doi: 10.1186/s13054-021-03561-1] [Medline: 33849619]

29. Davidson JE, Aslakson RA, Long AC, Puntillo KA, Kross EK, Hart J, et al. Guidelines for family-centered care in the neonatal, pediatric, and adult ICU. Crit Care Med 2017 Jan;45(1):103-128 [FREE Full text] [doi: 10.1097/CCM.0000000000002169] [Medline: 27984278]

30. Sealed Envelope Ltd. URL: https://www.sealedenvelope.com/ [accessed 2023-05-02]

31. Spotify AB. Get recommendations based on seeds. 2019. URL: https://developer.spotify.com/documentation/web-api/reference/browse/get-recommendations/ [accessed 2019-12-15]

32. Sen H, Yanarateş O, Sızlan A, Kılıç E, Ozkan S, Dağlı G. The efficiency and duration of the analgesic effects of musical therapy on postoperative pain. Agri 2010 Oct;22(4):145-150 [FREE Full text] [Medline: 21153932]

33. Sidani S, Epstein DR, Bootzin RR, Moritz P, Miranda J. Assessment of preferences for treatment: validation of a measure. Res Nurs Health 2009 Aug;32(4):419-431 [FREE Full text] [doi: 10.1002/nur.20329] [Medline: 19434647]

34. Streiner DL, Norman GR, Cairney J. Health Measurement Scales: A Practical Guide to Their Development and Use (5 edn). Oxford, UK: Oxford University Press; Nov 2015:399.

35. Epstein DR, Babcock-Parziale JL, Haynes PL, Herb CA. Insomnia treatment acceptability and preferences of male Iraq and Afghanistan combat veterans and their healthcare providers. J Rehabil Res Dev 2012;49(6):867-878 [FREE Full text] [doi: 10.1682/jrrd.2011.06.0114] [Medline: 23299258]

36. Bérubé M, Gélinas C, Martorella G, Feeley N, Côté J, Laflamme G, et al. Development and acceptability assessment of a self-management intervention to prevent acute to chronic pain transition after major lower extremity trauma. Pain Manag Nurs 2018 Dec;19(6):671-692 [FREE Full text] [doi: 10.1016/j.pmn.2018.04.010] [Medline: 29778755]

37. Martorella G, Gélinas C, Purden M. Acceptability of a web-based and tailored intervention for the self-management of pain after cardiac surgery: the perception of women and men. JMIR Res Protoc 2014 Nov 20;3(4):e63 [FREE Full text] [doi: 10.2196/resprot.3175] [Medline: 25487135]

38. Sidani S, Brewster J, Miranda J, Walkerly S, Belita E. Exploring the contribution of treatment factors to preferences for smoking cessation interventions. Int Arch Nurs Health Care 2016 Feb 29;2(1):1-5 [FREE Full text] [doi: 10.23937/2469-5823/1510028]

39. Sidani S, Braden CJ. Design, evaluation, and translation of nursing interventions. Hoboken, NJ: John Wiley & Sons, Inc; 2011:304.

40. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, PAFS consensus group. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ 2016 Oct 24;355:i5239 [FREE Full text] [doi: 10.1136/bmj.i5239] [Medline: 27777223]

41. Dwan K, Li T, Altman DG, Elbourne D. CONSORT 2010 statement: extension to randomised crossover trials. BMJ 2019 Jul 31;366:l4378 [FREE Full text] [doi: 10.1136/bmj.l4378] [Medline: 31366597]

42. Gélinas C, Joffe A, Szumita P, Payen JF, Bérubé M, Shahiri TS, et al. A psychometric analysis update of behavioral pain assessment tools for noncommunicative, critically ill adults. AACN Adv Crit Care 2019 Dec 15;30(4):365-387 [FREE Full text] [doi: 10.4037/aacnacc2019952] [Medline: 31951666]

43. Gélinas C. The faces pain thermometer: a new tool for critically ill adults. Perspect Infirm 2007 Mar 01;4(4):12-20 [FREE Full text] [Medline: 17479546]

44. Puntillo KA, Max A, Timsit J, Ruckly S, Chanques G, Robleda G, et al. Pain distress: the negative emotion associated with procedures in ICU patients. Intensive Care Med 2018 Sep;44(9):1493-1501 [FREE Full text] [doi: 10.1007/s00134-018-5344-0] [Medline: 30128592]

45. Puntillo KA, Neuhaus J, Arai S, Paul SM, Gropper MA, Cohen NH, et al. Challenge of assessing symptoms in seriously ill intensive care unit patients: can proxy reporters help? Crit Care Med 2012 Oct;40(10):2760-2767 [FREE Full text] [doi: 10.1097/CCM.0b013e31825b94d8] [Medline: 22890258]

46. IBM Corporation. SPSS Statistics for Windows Version 27. 2020. URL: https://www.ibm.com/docs/en/spss-statistics/27.0.0 [accessed 2023-04-21]

47. Creswell J, Plano Clark VL. In: Salmon H, editor. Designing and Conducting Mixed Methods Research (3rd Edition). Thousand Oaks, CA: Sage Publications, Inc; 2018.

48. Perepletchikova F, Kazdin AE. Treatment integrity and therapeutic change: issues and research recommendations. Clin Psychol: Sci Pract 2005;12(4):365-383 [FREE Full text] [doi: 10.1093/clipsy.bpi045]

49. Hagermoser SL, Kratochwill T. Toward developing a science of treatment integrity: introduction to the special series. School Psych Rev 2009;38(4):445-459 [FREE Full text]

50. Gewandter JS, Dworkin RH, Turk DC, McDermott MP, Baron R, Gastonguay MR, et al. Research designs for proof-of-concept chronic pain clinical trials: IMMPACT recommendations. Pain 2014 Sep;155(9):1683-1695 [FREE Full text] [doi: 10.1016/j.pain.2014.05.025] [Medline: 24865794]

51. Hui D, Zhukovsky DS, Bruera E. Which treatment is better? Ascertaining patient preferences with crossover randomized controlled trials. J Pain Symptom Manage 2015 Mar;49(3):625-631 [FREE Full text] [doi: 10.1016/j.jpainsymman.2014.11.294] [Medline: 25555446]

Abbreviations

bpm: beats per minute

CTL: control intervention

CPOT: critical care pain observation tool

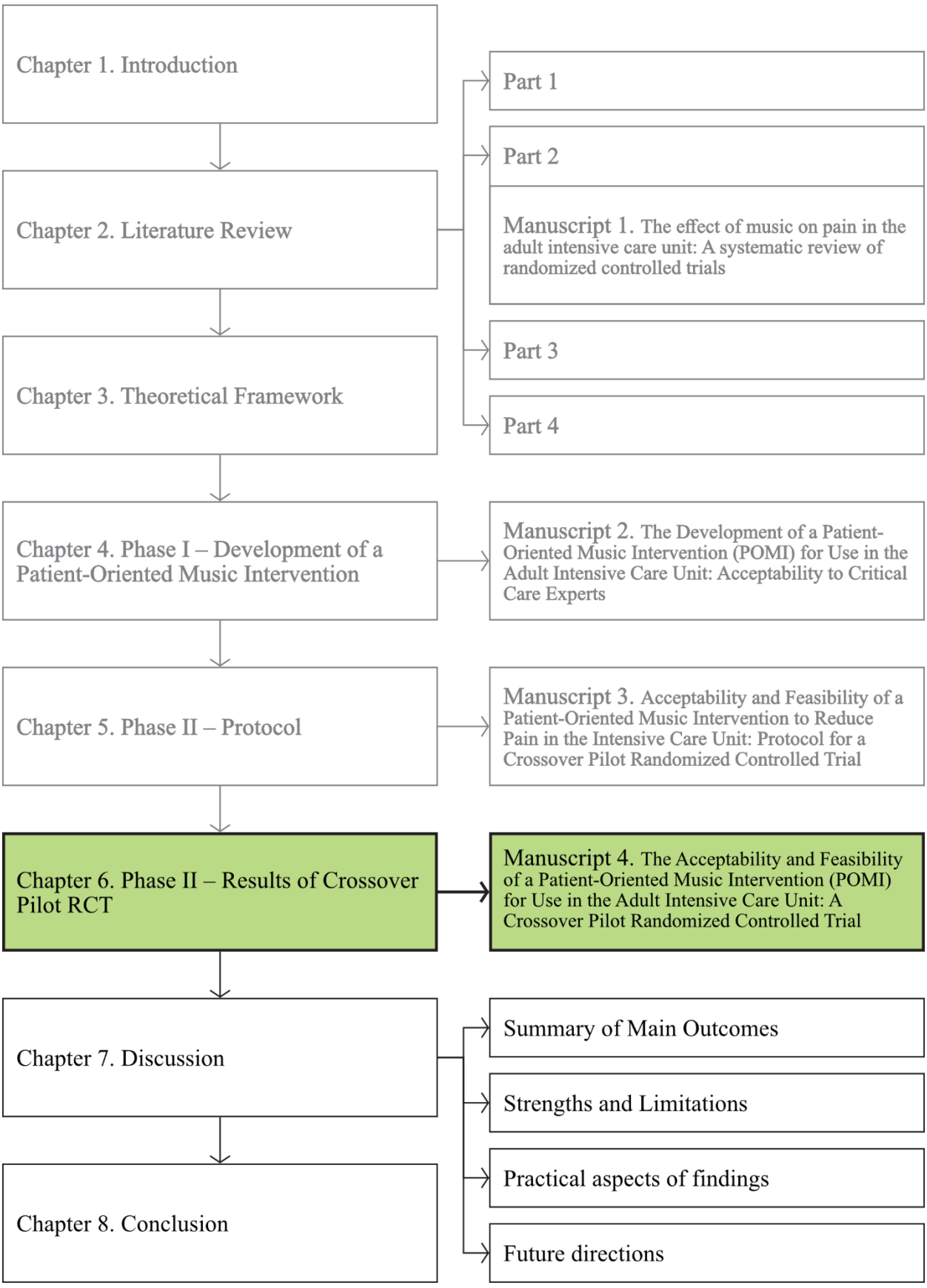
ICU: intensive care unit

NRS: numeric rating scale

POMI: patient-oriented music intervention

RCT: randomized controlled trial

TAP: treatment acceptability and preferences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Future directions

Chapter 6. Phase II – Results of Crossover Pilot RCT

In Phase II of this doctoral research project, the crossover pilot RCT was conducted as the next step following the development of the POMI. In this manuscript, the findings of the acceptability of POMI to ICU interested parties (patients, family members, and nursing staff) and feasibility (in terms of features and delivery) of POMI to reduce pain in ICU patients were reported. The results of the feasibility of research methods as well as preliminary efficacy of POMI to reduce turning procedural pain in ICU patients were also reported.

Manuscript 4. The Acceptability and Feasibility of a Patient-Oriented Music Intervention (POMI) for Use in the Adult Intensive Care Unit: A Crossover Pilot Randomized Controlled Trial

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Abstract

Background. Music is suggested as a complementary pain management intervention in the intensive care unit (ICU). However, evidence from interested parties on the acceptability and feasibility of music interventions in the ICU is scarce. A patient-oriented music intervention (POMI) was developed using a music streaming service to generate individualized playlists within the recommended 60-80 beats/minute tempo. Our primary objectives were to evaluate the acceptability and feasibility of POMI among ICU patients, family, and nursing staff, and the feasibility of research methods. A secondary objective was to examine the preliminary efficacy of POMI to reduce pain during turning in the ICU.

Trial Design. Crossover pilot randomized controlled trial.

Methods. Three categories of participants were recruited: a) ICU patients able to self-report (n=12) and unable to self-report (n=12); b) family members (n=12) of patients unable to self-report; and c) ICU nurses of recruited patients (n=12). Patients were randomized to either sequence 1 (POMI followed by control period), or sequence 2 (control followed by POMI period), with a 4-hour washout period. The POMI period was administered for a minimal duration of 20 minutes before turning procedure. No music was administered during the control period. Outcomes included acceptability and feasibility of POMI (e.g., music duration), feasibility of research methods (e.g., eligibility rate) and pain scores. Pain was measured at four timepoints (T0: pre-intervention; T1: post-intervention; T2: during turning; T3: 30 min post-turning).

Results. Of the 347 patients screened, 53 (15%) were eligible for study enrollment and 24 (45%) consented to participate. Twelve patients (total n=24) were randomized to each sequence (1 and 2). All participants evaluated the POMI to be acceptable. The POMI was feasible for over 80% of patients although turning occurred 7-111 minutes after starting POMI making the timing of

the intervention challenging. Pain scores tended ($p<.10$) to be lower after POMI compared to control period.

Conclusion. Flexible durations of POMI should be applied due to unpredictable timing of turning. Eligibility rate was limited due to the low proportion of eligible candidates. Further research is warranted to determine POMI efficacy to reduce pain in ICU patients.

Trial Registration. Clinicaltrials.gov: NCT05320224.

Key messages regarding feasibility

What uncertainties existed regarding the feasibility?

Prior to this study, uncertainties existed in terms of the acceptability and feasibility of music interventions for pain management in the ICU setting.

What are the key feasibility findings?

The POMI was acceptable to all participants and was feasible to administer to most patients able or not to self-report. However, regarding the feasibility of research methods, the eligibility rate was limited due to the low proportion of eligible candidates.

What are the implications of the feasibility findings for the design of the main study?

Only enrolling participants who undergo turning procedures limited the feasibility of this crossover pilot RCT. Therefore, in future RCTs, enrolling patients experiencing pain at rest and during other standard care ICU procedures known to be painful is suggested. Regarding the feasibility of POMI, more flexible music durations (> 20 minutes) should be applied to allow for better tailoring of the intervention.

Background and objectives

Patients are at high risk of experiencing pain during their stay in the intensive care unit (ICU) (1-3). Pain can occur either at rest or during ICU standard care procedures, such as turning, endotracheal tube suctioning, and tube removal (4, 5). Current pain management practices are mainly pharmacologic and often suboptimal, putting critically ill adults at risk of negative consequences from unrelieved pain including longer mechanical ventilation and ICU stay, post-traumatic stress, and chronic pain (2, 6-11). Clinical practice guidelines recommend the use of a multimodal approach to analgesia, including both pharmacological and nonpharmacological interventions such as music (2). Music interventions have been previously developed but without integrating theoretical, empirical, and experiential knowledge, which may impair accessibility, acceptability, and feasibility (12-17). A novel patient-oriented music intervention (POMI) was developed based on theoretical, empirical, and experiential knowledge from critical care and music experts (18).

To date, none of the previous studies on music developed as a complementary pain management intervention for critically ill adults have evaluated their acceptability and feasibility from the perspectives of broad interested parties including ICU patients, family, and nursing staff. Acceptability and feasibility of music interventions need to first be established prior to being fully tested for efficacy in randomized controlled trials (RCTs).

To begin to address these scientific gaps, this pilot study was conducted to:

Primary Objective 1a. Evaluate the acceptability of POMI from the perspectives of interested parties (i.e., ICU patients, families, and nursing staff) when they experience its proposed use in the ICU setting (19).

Primary Objective 1b. Evaluate the feasibility of POMI in the ICU setting.

Primary Objective 2. Evaluate the feasibility of research methods of a crossover pilot RCT for POMI testing in the adult ICU (20), and

Secondary Objective 3. Examine the preliminary efficacy of POMI to reduce pain during a turning procedure.

Methods and Materials

Trial design

The trial design was previously described (23) and is summarized here. A 2x2, single-blind, crossover pilot RCT was conducted. Following randomization (further described below), patients underwent 20-30 minutes of intervention period one (20 minutes minimum); washout (4 hours minimum); and intervention period two (20 minutes minimum). Patients were randomly assigned to either receive POMI in intervention period one, followed by no music in intervention period two (Sequence 1), or no music in intervention period one, followed by POMI in intervention period two (Sequence 2), with an allocation ratio of 1:1. The carry over effect is assumed to be negligible beyond four hours (21).

A crossover design was chosen for several reasons. Having patients as their own control allows the reduction of confounding factors effects that can occur in between subject designs and leads to a lower sample size requirement. This is relevant in our pilot study because previous full-scale RCTs on music in the ICU could not reach the required sample size (13, 15, 17). Moreover, the crossover design was appropriate because our intervention period was relatively short (target duration: 20-30 minutes) and the washout period (minimum of 4 hours) was feasible considering typical ICU length of stay, which lasts three days on average (22). Finally, for our subgroup of

patients able to self-report, a cross-over design provided additional insight with participants being able to compare periods with and without music, which was described in further details in our published protocol (23). No change was made to the methods after the pilot trial commencement.

Participants

There were three categories of ICU participants: patients (able and unable to self-report), family members of patients unable to self-report, and nursing staff. Eligibility criteria were as follows.

Patients.

Two subgroups of ICU patients were recruited by the first author (MRL) to better represent this vulnerable population: a) able to self-report, and b) unable to self-report.

Patients able to self-report. Eligible patients were: ≥18 years old, admitted to the ICU, able to listen to music and self-report (i.e., alert, oriented, Richmond Agitation Sedation Scale (RASS) score of 0 and stable level of consciousness, as defined by the nurse or physician responsible for the patient) (24-26). Patients were excluded when they: could not be turned in bed, were under the effects of neuromuscular blocking agents, were unresponsive to stimulation (RASS of -5), and were not able to communicate in English or French leading to the inability to provide informed consent.

Patients unable to self-report. Eligible patients were: ≥18 years old, admitted to the adult ICU, able to listen to music and to express behaviors, unable to self-report (i.e., not meeting the criteria for ability to self-report detailed above, as defined by the nurse or physician responsible for the patient), and had a family member present at their bedside who could consent to their care and participation in a research study, as well as provide information on the patient's music preferences. Patients were excluded when they: could not be turned, were under the effects of neuromuscular blocking agents or unresponsive to stimulation (RASS of -5) and, because informed

consent was obtained retrospectively from these patients whenever possible, patients who were not able to communicate in English or French according to their family member were also excluded.

Family members. Family members were defined as follows. Family members "may be related or unrelated to the patient, [if] they are individuals who provide support and with whom the patient has a significant relationship" (27). Family members were eligible if they also considered themselves as able to provide information on the patients' music preferences. They were excluded if they could not communicate in English or French leading to the inability to provide informed consent.

Nursing staff. The nursing staff (i.e., nurses, orderlies) caring for the recruited patients at the time of the study (i.e., involved in the turning procedure) were eligible and invited to participate if they were: ≥18 years old and worked in the ICU.

Recruitment

Data was collected in a 36-bed medical-surgical adult ICU (operating at approximately 24 bed capacity at the time of data collection due to nursing staff shortage during the COVID-19 pandemic), at a university-affiliated hospital in Montreal, Canada. All patients admitted to the ICU between March 15 and July 20, 2022, were screened for eligibility by the first author (student researcher).

All eligible patients and family members were initially approached by their nurse at the time of recruitment and when they agreed, met with the first author to discuss the study details. A copy of the information and consent form was given to the candidates who were provided sufficient time to decide. Nursing staff involved in the turning procedure of enrolled patients at the time of the study were also approached by the first author and given time to decide whether to participate. All participants provided written informed consent.

Interventions

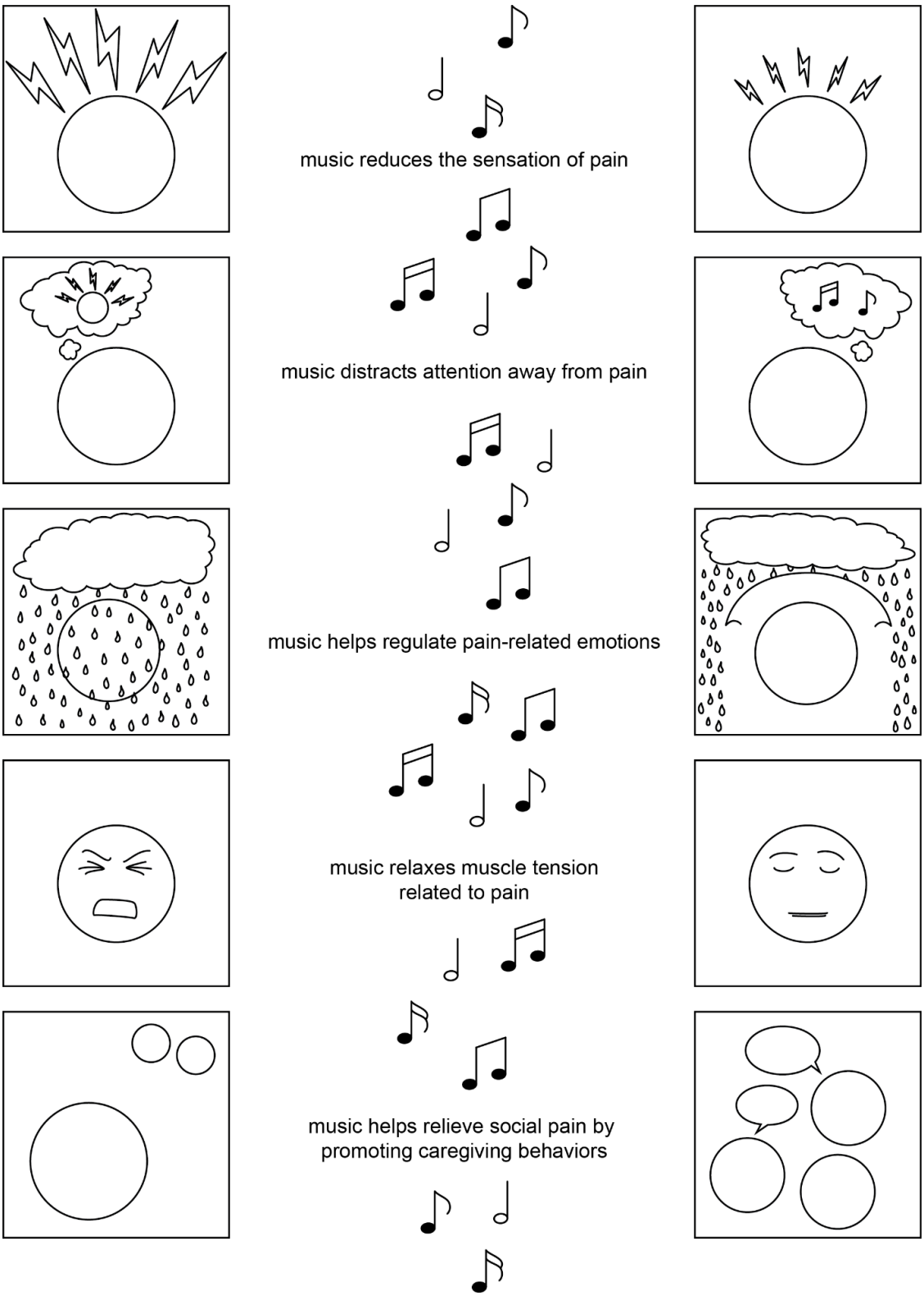
Patient-Oriented Music Intervention (POMI) Period

POMI Rationale. The detailed features and rationales of POMI development were previously described (18). Briefly, theoretical knowledge from the psychophysiological model of music guided POMI development (28, 29). This model proposes that music acts on pain via sensory, emotional, cognitive, behavioral, and psychosocial pathways (See Figure 1). Furthermore, empirical data demonstrated that a minimum of 20 minutes of music can significantly reduce pain in ICU patients able to self-report (15). For those unable to self-report, family members may be interested to participate in the pain management of their loved ones (30). Music should have a tempo of 60-80 bpm (31) and be tailored to the patient's preferences to enhance its effectiveness in reducing pain (28, 32). Specifically, patients' preferred music features, including genre, valence (emotion), arousal (energy), and the perception of control in the music selection, can further alleviate the pain experience (32, 33).

POMI was developed as an easy-to-use music intervention that produces individualized music playlists with a tempo of 60-80 bpm for ICU patients, using a web app that connects to a music streaming service (Spotify). Throughout the music selection process, the patient is given control over the music selection, using a smart device. Experiential knowledge from critical care and music experts provided guidance on the timing of POMI delivery prior to a standard care procedure known to be painful, such as turning. Turning is a procedure where a patient who is unable to mobilize is repositioned to lie on one side, while in bed, to prevent the development of pressure ulcers caused by immobility (34). The turning procedure is typically scheduled to occur every two hours and is well documented as being potentially painful to ICU patients (5).

Figure 1

The Psychophysiological Model of Music and Pain dimensions



POMI Procedure. The first step was to create a music playlist based on the patient's preferences. The patient able to self-report provided at least one, and up to five, music genre(s), artist name(s) and/or music piece title(s) that they would like to hear at that moment. The patient could then specify any additional music preference in terms of instrumentalness (instrumental vs. vocal), acousticness (acoustic vs. electric), energy (calming vs. energetic), valence (cheerful vs. melancholic), popularity (more vs. less popular), and liveness (studio vs. live). Any or all these choices could be skipped, being equivalent to selecting "no preference." These choices were entered in the POMI Web app (https://pomi.glitch.me), which automatically generated a Spotify playlist based on the music preferences provided, within a restricted tempo range of 60-80 beats per minute. A smart device (iPad, 8th generation) was provided to the patient for the playlist generation step, with or without assistance from a family member, a nursing staff, or the first author (MRL), at the patient's request. The patient could also control the music volume. Patients able to self-report could choose between a pair of headphones (Bose, QuietComfort 35) or a music pillow (MusiCure, hospital grade).

For the patient unable to self-report, a family member selected music on their behalf. Only the music pillow was used to deliver music to reduce the risks of pressure injury and discomfort related to wearing headphones (18). The music pillow was connected to the iPad from which the volume was pre-set at two levels below the maximum, as a starting point, and could be modified when possible (i.e., for patients able to self-report) (35).

The generated music playlist was played 20-30 minutes prior to a turning procedure scheduled as part of standard care. Then, music was stopped immediately before the turning procedure to allow for any necessary communication between the patient and nursing staff involved in the procedure.

When a delay occurred in the scheduled turning procedure (e.g., caused by short staffing and orderlies being in another room at the time), patients able to self-report could choose to prolong the music duration until the procedure occurred. The music was stopped at 30 minutes (at the end of the final music piece) for patients unable to self-report.

At any time, patients able to self-report could choose to skip any of the music pieces proposed or stop the music, either briefly or permanently. For patients unable to self-report, the music could be skipped or stopped by the family member, nursing staff or first author based on any observed undesired reaction linked to the music being played.

Control Period.

In the control period, patients were either wearing headphones or had the MusiCure pillow without any music playing, in accordance with the mode of delivery also used during the POMI period, for a duration of 20-30 minutes or until the turning procedure occurred. During turning, the headphones were removed, or the pillow was replaced with a standard care hospital pillow.

Outcomes

Outcomes of primary objectives. The outcomes of the primary objective were (1a) the acceptability of POMI by ICU patients able to self-report, family members of patients unable to self-report, and nursing staff; (1b) the feasibility of POMI; and (2) the feasibility of research methods of a crossover pilot RCT for POMI testing in the ICU setting to inform the planning of a future large-scale RCT.

Acceptability of POMI. The acceptability of POMI was measured using the validated Treatment Acceptability and Preferences (TAP) questionnaire which includes items related to appropriateness, suitability, convenience, effectiveness, and risks or side effects (36, 37). Each

item is rated on a 5-point scale ranging from 0 (not at all) to 4 (very much) with higher scores indicating greater acceptability. A total score is then obtained by calculating the mean of all the items' scores. Scores of 3 or 4 support the acceptability of the intervention. Patients who were able to self-report were also asked, at the end of the TAP questionnaire, if they preferred having the headphones/pillow with or without music.

Feasibility of POMI. The feasibility of POMI was measured using several items evaluating playlist creation and POMI delivery, as described in Table 4 (23). The fidelity of POMI playlist creation and delivery was also monitored (items described in Table 5). The fidelity monitoring provided information on the ease and consistency with which POMI could be delivered as intended to patients, accounting for important intervention components (e.g., dose, mode of delivery, and timing) (19). For the fidelity of POMI delivery, the aim was to confirm that >80% of the participants were delivered the intervention as planned for more than half of the fidelity items (38, 39). For participants who agreed, video recordings of playlist creation and POMI delivery were obtained so that intervention fidelity could be established for a minimum of 20% of participants (19). The last author (CG) was the video rater for POMI fidelity.

Feasibility of research methods. The feasibility of research methods included evaluating eligibility rate, recruitment rate, randomization logistics, retention rate, as well as the proportion of missing data (19). The Consolidated Standards of Reporting Trials (CONSORT) guidelines for pilot and feasibility RCTs were followed to track the number of patients: screened, eligible, recruited, randomized, and included in the analysis. Eligibility rate was considered feasible if at least 50% of patients were eligible. Recruitment rate was considered feasible if 24 participants were enrolled within 6 months. The retention rate was considered feasible if >80% of

participants remained enrolled and participated for the full duration of the study. Data collection was considered feasible if there was less than 10% missing data.

Outcome of secondary objective. The outcome of the secondary objective was the evaluation of the preliminary efficacy of the POMI to reduce pain during turning.

Preliminary efficacy of POMI. Pain was measured at four timepoints per intervention period: before the intervention (T0), immediately after the intervention (T1), during the turning procedure (T2), and 30 minutes after the turning procedure (T3). Pain was measured with validated tools as recommended in ICU clinical practice guidelines (2). Pain behaviors were assessed in all patients with the 0-8 Critical-Care Pain Observation Tool (CPOT), where a total score ≥ 3 indicates the presence of pain (40). Interrater reliability between the CPOT scores of the bedside and video raters (MRL and CG) were computed using the intraclass correlation coefficient (ICC). ICC values > 0.5 were considered acceptable for research purposes (41). Pain intensity and pain distress were assessed in patients able to self-report using the 0-10 Faces Pain Thermometer (FPT) and the 0-10 Numeric Rating Scale (NRS), respectively (42, 43).

Perception of music efficacy to reduce pain. Patients able to self-report were also asked, at the end of the study, to report on their expectation and perception of music efficacy on pain relief (Table 9) (41).

Sample size

A sample size of 12 participants per group was estimated based on the recommended minimal sample size of 10 participants per group for pilot studies and with a minimal anticipated attrition rate of 15% (44-47). This estimation was also aligned with a medium effect size and consistent

with the standardized difference that was reported in our systematic review for self-reported pain intensity (15).

Randomization, sequence generation and allocation concealment mechanism

Randomization, sequence generation and allocation concealment only applied to the patient sample. At the time of consent, each patient was categorized in one of two strata: “able to self-report” or “unable to self-report.” After consent was obtained, patients were randomized within their stratum to either sequence 1 or sequence 2, following a permuted block randomization. The sequence generation was determined using an online computer generator (https://www.sealedenvelope.com). The allocation sequence was then concealed within 24 sequentially numbered, opaque sealed envelopes, each containing the sequence attribution for a single participant. A block size of 4 was used (three blocks per stratum) for a sample size of 24 patients (12 able to self-report and 12 unable to self-report). In each block, two patients were assigned to sequence 1 and two patient participants were assigned to sequence 2, in a random order. The envelopes were numbered and kept in the same order to later be opened sequentially, as patients were recruited over time.

Implementation

An independent member of the research team, who was not involved in assigning patients to intervention sequences, generated the random allocation sequence and prepared the envelopes. The first author (MRL) enrolled participants and assigned participants to intervention sequences, following the order of prepared envelopes.

Blinding

Patients who were unable to self-report were blinded, by default, to the assigned sequence of interventions. However, patients who were able to self-report could determine the sequence they were allocated to. A second pain rater (CG) for the patients' CPOT scores was blinded to the sequence allocation. This second pain rater was not present at the time of data collection and independently provided CPOT scores from 1-2-minute video recordings made by the person collecting data (MRL), during the pre-specified timepoints (T0-T3, as described above).

Video recordings

Video were recorded for the duration of the intervention period and at each pain assessment time point. These video recordings were used to have an independent member of the research team (last author, CG) evaluate: (a) the CPOT scores for each ICU adult patient participant (to ensure blinding of the pain assessor, CG, to sequence allocation) and (b) the intervention delivery fidelity monitoring. Videos for CPOT scoring focused on the participant's frontal upper body. Videos for intervention delivery fidelity focused on both the participant's frontal upper body and the first author (MRL) who delivered POMI. The participants had the option to opt out of being video recorded. For those who opted out, the first author (MRL) was responsible for the CPOT ratings as part of the data collection.

Analysis

All statistical analyses were performed using SPSS software (version 27.0). Quantitative analyses were done for the acceptability and feasibility of POMI, the feasibility of research methods, and the preliminary efficacy of POMI to reduce pain, as described below.

Acceptability of POMI. Medians, and interquartile ranges (IQR) were calculated for each item and for the total mean score of the TAP questionnaire. Any comments provided by participants as feedback on the acceptability of the POMI were also described by each category of participants.

Feasibility of POMI. Descriptive statistics were computed for each feasibility item. For each enrolled patient, the proportion of fidelity items delivered as intended were computed. All issues of feasibility (e.g., unable to produce a playlist due to poor Wi-fi connection) were reported as well as their proportions. The medians were also computed for the time to create the music playlist and for how long the patients listened to the music.

Feasibility of research methods. Descriptive statistics were computed for each item on the CONSORT flowchart (i.e., number of patients screened, proportion of eligible patients, number of enrolled participants) for pilot studies, adapted for a crossover design (48, 49). All issues related to eligibility and recruitment were tracked and grouped into categories (50). Eligibility, recruitment, and retention rates were calculated. Reasons for missing data were compiled and described to inform how to reduce the amount of missing data in the future.

Preliminary efficacy of POMI. Descriptive statistics were computed for all pain scores, including CPOT, pain intensity, and pain distress, to measure the behavioral, sensory, and emotional components of pain, respectively. For interrater reliability of CPOT scores between the bedside and video raters, ICC were computed with 95% confidence intervals. Considering that videos were available for 19 of enrolled patients, CPOT scores of the bedside rater were used for data analysis. Friedman tests were used to compare pain scores over time for each intervention period separately (i.e., the POMI period and the control period). Wilcoxon signed rank tests were used to compare the POMI period with the control period at each pair of timepoints (T0-T3). The significance level was set to be 0.10 for this pilot study.

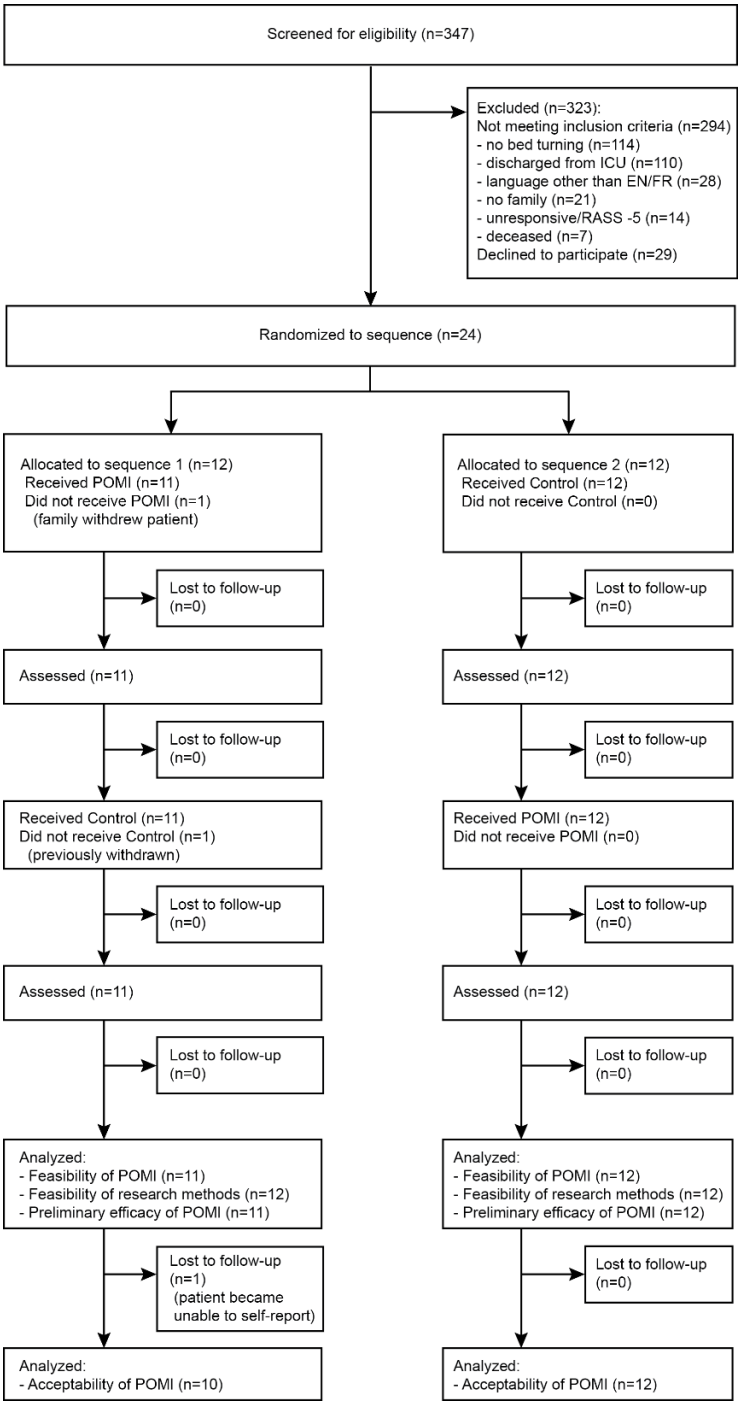
Results

Participant flow and numbers analyzed

The data displayed in Figure 2 reflect the number of participants analyzed in each patient group, accounting for withdrawals and losses to follow up, as detailed in the footnotes. More information about the flow of patients is presented in the “feasibility of research methods” section.

Figure 2

CONSORT flowchart of patient/family participant flow through the study



Note. Data from all participants with available data were used in the analysis.

Acceptability of POMI. A total of 34 participants completed the acceptability questionnaire as follows: 12 patients able to self-report; 10 out of 12 family members of patients unable to self-report (one family member had withdrawn

from the study and one family member was no longer required since their loved one regained ability to self-report at the time of the questionnaire completion); and 12 ICU nurses (see Table 3).

Feasibility of POMI. Data from 23 out of 24 patients were included in the analysis because no data was collected on the patient who was withdrawn by their family member. Fidelity was monitored for all 24 patients.

Feasibility of research methods. All patients able and unable to self-report were included in the analysis (n=24).

Preliminary efficacy of POMI. Data from 23 out of 24 patients who were included in the analysis because there was no data collected on the patient randomized to sequence 1 who was withdrawn by their family member.

Recruitment

Recruitment began on March 15, 2022, and ended July 20, 2022

Baseline Data

Samples. A total of 24 patients were recruited, with 12 who consented for themselves and 12 who had a family member (6 children, 3 partners, and 3 parents) consent on their behalf. One family member withdrew from the study shortly after consenting, during the music playlist creation, because they no longer thought that the patient was showing interest in listening to music. No orderlies were recruited because of nursing staff shortages at the time of the study.

Table 1 presents the participant characteristics of each category of participants.

The patient median age was 70 (IQR = 55-79) years, ranging 26 to 86 years old. Patients were admitted to the ICU for either medical (n=12) or surgical (n=11) reasons with a median Acute Physiology and Chronic Health Evaluation II (APACHE II) score of 23.5 (IQR = 17.8-31.5). Nine patients (38%) were mechanically ventilated at the time of the study. Reasons for admission were medical (n=12) and surgical (n=11). Twelve patients (7 able to self-report and 5 unable to self-report) had used music streaming services in the past, and 11 had not. Twelve patients had access to smart devices, two had access to headphones, four had access to both and five had

access to neither. Fifteen patients (65%, with 8 able to self-report and 7 unable to self-report) had access to these materials during their ICU stay.

The family members' median age was 54.5 (IQR = 47-67) years, ranging from 43 to 80 years old, with a median of 44.5 (IQR = 33.8-56.5) years of relationship with the patient (range = 26-60). Six family members reported having used music streaming services in the past, whereas five had not. All family members reported having access to a smart device and four also had access to headphones. Ten (90%) family members reported having the ability to bring these materials to the ICU for their loved one.

Nurses' median age was 34.5 (IQR = 28.3-50) years, ranging 26 to 59 years old, with a median 3.5 years working in the ICU (IQR = 1.6-17.5; range, 1-29), and a median of 8.5 years as a nurse (IQR = 3.1-28.3; range = 3-32). Seven nurses (58%) had used music streaming services in the past, and five had not. Nine nurses (75%) had previously used music with patients and three had not.

Table 1

Socio-demographic information for each category of participants

Characteristic	Patients			Family Members	Nurses
	USR (n=11)	ASR (n=12)	Total (n=23)	(n=11)	(n=12)
Gender identity					
Male	4	8	12	3	3
Female	7	4	11	8	8
Gender diverse	0	0	0	0	1
Ethnic origin					
North American Aboriginal	1	2	3	1	0
Other North American	6	5	11	6	4
European	1	4	5	1	2
LATAM	1	1	2	1	1
African	1	0	1	1	0
Asian	0	1	1	0	4
Other	1	1	2	1	2
Level of education					
Elementary	1	4	5	1	0
Secondary/High school	2	2	4	1	0
College	5	2	7	5	2
University	3	4	7	4	10
Language					
English	5	7	12	5	8
French	6	5	11	6	4

Note. USR = Unable to Self-Report; ASR= Able to Self-Report. LATAM = Latin America, including Caribbean, Central and South America. Two participants identified more than one ethnic origin. Other ethnicities were: Arab, Ashkenazi Jew, Israeli, Maghrebi, and Middle Eastern.

Music characteristics. Music preferences could be expressed in terms of various music genre, title, artist name, as well as attributes as described in Table 2. Eighteen participants (78%) specified at least one music genre (Supplementary Table I). Six participants (26%) specified at least one music piece title. Nineteen (83%) specified at least one artist name. More than half of the participants expressed preferences for vocal, cheerful, and more popular music. The detailed selections for the proposed music attributes are reported in Table 2.

Table 2

Frequency of music attributes selected by participants (n = 23)

Music attributes	Patient n (%)	Family member n (%)	Total n (%)
Instrumentalness			
Option 1. Instrumental	3 (100)	0 (0)	**3 (13)**
Option 2. Vocal	5 (38)	8 (62)	**13 (57)**
Option 3. No preference	4 (57)	3 (43)	**7 (30)**
Acousticness			
Option 1. Acoustic	2 (40)	3 (60)	**5 (22)**
Option 2. Electric	1 (100)	0 (0)	**1 (4)**
Option 3. No preference	9 (53)	8 (47)	**17 (74)**
Energy (arousal)			
Option 1. Calming	3 (33)	6 (67)	**9 (39)**
Option 2. Energetic	4 (67)	2 (33)	**6 (26)**
Option 3. No preference	5 (63)	3 (38)	**8 (35)**
Valence (emotion)			
Option 1. Cheerful	6 (50)	6 (50)	**12 (52)**
Option 2. Melancholic	1 (33)	2 (67)	**3 (13)**
Option 3. No preference	5 (63)	3 (38)	**8 (35)**
Popularity			
Option 1. More popular	5 (45)	6 (55)	**11 (48)**
Option 2. Less popular	2 (67)	1 (33)	**3 (13)**
Option 3. No preference	5 (56)	4 (44)	**9 (39)**
Liveness			
Option 1. Studio	1 (14)	6 (86)	**7 (30)**
Option 2. Live	3 (100)	0 (0)	**3 (13)**
Option 3. No preference	8 (62)	5 (38)	**13 (57)**

Note. Percentages may not total 100 due to rounding.

Outcomes and estimation

Acceptability of POMI

Table 3 reports the POMI acceptability results using the TAP questionnaire. Overall, POMI was rated as acceptable with median scores ≥ 3 by all categories of participants. Ten patients mentioned that they preferred the headphones/pillow with the music, one was unsure, and one preferred the pillow without any music.

Patients elaborated on their ratings by highlighting the importance of playing music that is individualized (n=3) and reported that the POMI was comforting and contributed to their well-being while in the ICU (n=3). Other patients reported that they would have preferred a longer music duration (n=5) and different type of music (n=1). One family member mentioned that the technology would have been difficult to use without any assistance. Nurses expanded on their ratings by commenting that the music should be based on patient preferences, further supporting the POMI (n=4) and one nurse justified a lower rating on the TAP questionnaire because “it can be difficult to synchronize with a turning procedure”.

Table 3

Median scores (IQR) for individual Treatment Acceptability and Preferences questionnaire items and total score

TAP items	Patients (n=12)	Family Members (n=10)	Nurses (n=12)	Total (n=34)
Appropriateness	3.5 (2.6-4)	3 (2-4)	4 (3-4)	3 (3-4)
Suitability	3.5 (3-4)	3 (3-4)	3.5 (3-4)	3 (3-4)
Convenience	4 (3-4)	3.5 (3-4)	4 (3.3-4)	4 (3-4)
Effectiveness	4 (3-4)	3 (2.8-4)	3 (3-3.8)	3 (3-4)
Risks or side effects	4 (3-4)	4 (3.8-4)	4 (3-4)	4 (3-4)
Total Score	3.6 (3.1-4)	3.2 (3-4)	3.5 (3.1-4)	3.4 (3-4)

Note. Each item was rated on a 5-point scale ranging from 0 (not at all) to 4 (very much) with higher scores indicating higher acceptability. IQR = interquartile range. Please note that one patient who was initially unable to self-report at recruitment became able to self-report at the time of the questionnaire. TAP= Treatment Acceptability and Preferences.

Feasibility of POMI

Table 4 presents the frequencies of the POMI feasibility items. Eleven (92%) family members were able to provide information to produce a music playlist for patients unable to self-report. However, family members were present for the full duration of the POMI for only 5 (45%) patients. Reasons for family members not being present during POMI were needing time to rest (n=3); having restricted visiting hours (n=2) and being at work (n=1).

No feasibility issue was found in most patients. However, issues in more than 50% of feasibility items were noted in one patient unable to self-report. This was mainly due to multiple technical problems (e.g., unstable Wi-Fi connection), equipment alarms in the room, and interruptions for standard care procedures.

The most frequent feasibility issues occurred during the music playlist creation and the intervention delivery. A frequent issue with the creation of playlists was caused by loss of the Wi-Fi connection (n=4). The music attribute that had to be explained most frequently was the “studio vs live” option (n=3).

Regarding POMI delivery, some participants reported discomfort related to headphones (n=2) or pillow (n=2). Specifically, one patient who asked to wear the headphones also wanted to lie on the side, which interfered with wearing of headphones. Another patient asked to remove the headphones during the control period because of feeling too hot. One patient preferred to listen to music directly on the iPad. POMI delivery was briefly delayed for two participants due to improper wire connection between the pillow and iPad. The most frequent reason for receiving less than 20 minutes of music was due to standard care procedures (n=2) and one patient preferred a shorter duration. The most frequent source of environmental noise during the POMI was caused by voices at or near the bedside (n=11). The most frequent sources of interruption to POMI

delivery were standard care procedures (n=5) or generated by the patients themselves (n=4). For example, patients wanted to discuss, or listen to, the music with someone else (e.g., family member, research, or nursing staff). Another patient wanted to immerse himself in the music he selected (opera), which he sang along with, and which also led to a discussion with his nurse about the music. When listening to the music, this patient cried and when asked if he preferred to stop, he insisted to keep listening, exclaiming “I feel myself alive again!”. Eighteen participants (11 patients and 7 family members) expressed being familiar with the music pieces in the generated playlists. The POMI did not interfere with the administration of pharmacological analgesics as part of the patient’s standard care. Fifty-four percent of patients received pharmacological co-analgesia during POMI. At each timepoint, there was no significant difference in pain scores between patients who received pharmacological co-analgesia and patients who did not.

Table 4

Frequency of Feasibility of Patient-Oriented Music Intervention Items (n=23)

POMI Feasibility Items	No n (%)	Yes n (%)
<10min to create playlist [a]	1 (4)	22 (92)
Issue in playlist creation	18 (75)	5 (21)
Music feature explanation needed	15 (63)	8 (33)
Issue with mode of delivery [b] **(headphone/pillow use)**	18 (75)	5 (21)
Issue with music delivery	20 (83)	3 (13)
Songs skipped [c]	13 (65)	6 (30)
Patient received full duration of POMI	3 (13)	20 (83)
Participants familiar with music played [d]	1 (4)	18 (75)
Presence of environmental noise during music	8 (33)	15 (63)
Interruptions to music delivery	14 (58)	9 (38)
Patient received pharmacological intervention for pain during POMI [e]	10 (42)	13 (54)

Note. POMI = patient-oriented music intervention. The missing data were due to study withdrawal. Percentages may not total 100 due to rounding.

[a] The median time spent creating playlists was 4.5 min (IQR = 3-6.1, ranging 2 to 22 min).

[b] The main mode of delivery was the music pillow, which was used by default for patients unable to self-report and selected by eight (67%) patients who were able to self-report.

[c] Songs could be skipped only by participants who were able to self-report (or able to do so themselves). Most participants who skipped songs skipped less than 4 songs (n=5).

[d] Familiarity with music only pertains to patients who were able to self-report, as well as family members who felt comfortable to do so on behalf of their loved ones.

[e] Pain medications administered to patients included hydromorphone (n=10), fentanyl (n=1), sufentanil (n=1), and acetaminophen (n=1) with two patients receiving more than one agent.

Fidelity. Regarding the fidelity monitoring of POMI, more than 80% of the fidelity items were carried out as intended for all the participants who had data (n=23; Table 5). Observation of POMI delivery was conducted independently by the last author (CG) via video recording for 7 (30%) of the patient participants. Perfect agreement (100%) was reached between the first and last authors (MRL and CG) on all the fidelity checklist items. For 7 patients and 5 family members, no presentation of the POMI app was required because the participants spontaneously interacted with the web app on the iPad autonomously. POMI was delivered for a median duration of 26 minutes (IQR = 20-31; range = 7-53), with a median of 41 minutes (IQR = 30-58; range = 7-111) between the start of the music and the turning procedure. Delays were caused by short-staffing issues and orderlies being in another room at the time of the scheduled turning.

Table 5

Frequency of Fidelity of Patient-Oriented Music Intervention Items, n=24

POMI Fidelity Items	**Yes** **n (%)**	**No** **n (%)**
Presentation of the POMI web app to participant	12 (50)	12 (50)
Creation of a personalized playlist based on patient's preferences	23 (96)	1 (4)
Providing explanation, if needed	24 (100)	0 (0)
Placement of headphones or music pillow [a]	22 (92)	1 (4)
Playing music via headphones/music pillow [a]	23 (96)	0 (0)
Music started before turning procedure [a, b]	23 (96)	0 (0)
Duration of at least 20 minutes of music [a]	20 (83)	3 (13)

Note. POMI = patient-oriented music intervention.

[a] Missing data from one participant.

[b] There was a median of 10 (IQR = 5-28) minutes wait time between the end of the POMI and the turning procedure.

Feasibility of research methods

Figure 2 illustrates the CONSORT flowchart, as adapted for crossover studies. Between March and July 2022, 347 patients admitted to the ICU were screened for eligibility. From those screened, 53 (15%) were eligible and invited to participate. Of those approached, 55% declined to participate (18 patients able to consent and 11 family members of patients unable to consent) and 45% consented (including 12 patients able to self-report and 12 family members of patients unable to self-report). Regarding family eligibility, 21/347 (6%) were ineligible because they could not be reached. Of the 23 families approached, 12 (52%) consented to participate.

Reasons for patients declining to participate included 9 (31%) not being interested in research, 4 (14%) not feeling well enough; 4 (14%) preferring not listening to music; and 1 (3%) already listening to music. Reasons for family members declining to participate included 3 (10%) reporting their loved one to be too unwell to participate; 3 (10%) already playing music for their loved one; 2 (7%) think patient would not enjoy music; 1 (3%) not knowing the patient's music preferences; 1 (3%) not being interested in research; and 1 (3%) having no time to participate.

All 24 patients were randomized to either sequence 1 or sequence 2. Twenty-three participants received the allocated intervention sequence, and one participant was withdrawn by his son during the music selection process. This led to a retention rate of 96% and missing data of 4%. The acceptability questionnaire was not completed by one participant who was no longer communicating at the time of data collection due to deteriorating health condition.

Preliminary efficacy of POMI

Tables 6-8 present the pain scores for each measure (CPOT – Table 6, pain intensity – Table 7, pain distress – Table 8) at all timepoints.

Pain behaviors. Interrater reliability between the CPOT scores of the bedside and video raters was supported with ICC values above 0.5 at all timepoints as presented in Supplementary Table II. Overall, significant differences in CPOT scores were found over the timepoints in both the POMI and the control periods. Although CPOT scores increased during turning at both periods, they were lower in POMI compared to control especially in patients unable to self-report. Interestingly, CPOT scores were lower at T1 (post-intervention) in POMI compared to control in all patients ($p=0.056$). Moreover, CPOT scores were higher during turning (T2) in the control period compared to the POMI period in patients unable to self-report but not in patients able to self-report.

Pain intensity. Although there was no significant change in pain intensity scores over the timepoints during the POMI period, a significant difference in the control period was found. Compared to the control period, pain intensity scores were significantly higher at baseline (T0), and lower 30 minutes post-turning (T3) in the POMI period.

Pain distress. Like pain intensity, a significant difference over the timepoints was found for pain distress in the control period but not during the POMI period. Pain distress scores were significantly lower during turning (T2) in the POMI period, compared to the control period.

Perception of music efficacy to reduce pain. Eleven patients (92%) from the subgroup able to self-report could provide their perception of music efficacy as one patient became unable to self-report during the study. Most patients expected and perceived efficacy of music on pain relief. They also provided high ratings on music efficacy and meaningfulness (Table 9).

Table 6

Behavioral component of pain median and interquartile range, all patients and by group

CPOT scores (0-8)	T0	T1	T2	T3	Friedman X^2
POMI Period (n=23), median	1	0	2	0	
IQR	(0-1)	(0-0)	(0-5)	(0-1)	28.01***
min-max	0-3	0-2	0-6	0-2	
Unable to self-report (n=11), median	1	0	1	0	
IQR	(1-1)	(0-0)	(1-2)	(0-0)	18.00***
min-max	0-2	0-2	0-4	0-1	
Able to self-report (n=12), median	0.5	0	4	0	
IQR	(0-1)	(0-0)	(0-6)	(0-1)	11.55**
min-max	0-3	0-2	0-6	0-2	
Control Period (n=23), median	1	0	5	0	
IQR	(0-1)	(0-1)	(2-5)	(0-1)	49.33***
min-max	0-5	0-3	1-6	0-4	
Unable to self-report (n=11), median	0	1	3	0	
IQR	(0-1)	(0-1)	(2-5)	(0-1)	24.04***
min-max	0-3	0-2	1-6	0-2	
Able to self-report (n=12), median	1	0	5	0	
IQR	(0.3-2.5)	(0-1.8)	(3-5.8)	(0-1)	26.15***
min-max	0-5	0-3	1-6	0-4	
Wilcoxon Z (n=23)	-0.56	-1.91*	-2.34**	-1.37	
Unable to self-report (n=11)	-1.00	-1.39	-2.57**	-1.52	
Able to self-report (n=12)	-1.52	-1.29	-0.39	-0.60	

Note. CPOT= Critical-Care Pain Observation Tool (scores ≥ 3 = presence of pain); IQR=interquartile range; T0=pre-intervention; T1=post-intervention, pre-turning; T2=during turning; T3=30 minutes post-turning.

* $p<0.10$

**$p<0.05$

*** $p<0.01$

Table 7

Sensory component of pain median, interquartile range and 95% confidence interval, n=12

Pain intensity scores (0-10)	**T0**	**T1**	**T2**	**T3**	**Friedman X^2**
POMI, median	6.3	5	6	2.5	
IQR	(0.8-7.8)	(0-6.8)	(0-9.8)	(0-7.3)	3.24
[95% CI]	[2.7,7.5]	[2,7.9]	[2,7.9]	[1,5.5]	
Control, median	5	3.5	7.5	3.5	
IQR	(0.8-6.6)	(0-7)	(4.4-9.9)	(0-7)	8.10**
[95% CI]	[2.2,6]	[1.3,6]	[4.4,9]	[1.4,6.5]	
Wilcoxon Z	-1.71*	-0.35	-1.12	-1.95*	

Note. IQR=interquartile range; CI = confidence interval; T0=pre-intervention; T1=post-intervention, pre-turning; T2=during turning; T3=30 minutes post-turning.

* $p<0.1$

**$p<0.05$

Table 8

Emotional component of pain median, interquartile range and 95% confidence interval, n=12

Pain distress scores (0-10)	**T0**	**T1**	**T2**	**T3**	**Friedman X^2**
POMI, median	4.5	4.3	5.5	0	
IQR	(0-7)	(0-6.8)	(0-10)	(0-7.8)	3.43
[95% CI]	[1.95,6.8]	[1.4,5.7]	[1.9,7.7]	[0.6,5.8]	
Control, median	4.5	3.8	8	3.5	
IQR	(0-6.6)	(0-8.5)	(5.6-10)	(0-8.4)	9.26**
[95% CI]	[1.8,6.5]	[1.5,6.9]	[4.7,9.3]	[1.4,6.7]	
Wilcoxon Z	-0.70	-0.78	-1.89*	-1.59	

Note. IQR=interquartile range; T0=pre-intervention; T1=post-intervention, pre-turning; T2=during turning; T3=30 minutes post-turning.

* $p<0.1$

**$p<0.05$

Table 9

Perception of music efficacy to reduce pain in patients able to self- report, n=11

Question	Yes n (%)	No n (%)	Unsure n (%)	Median (IQR)
1. Before the study, did you expect that music would relieve your pain?	7	3	1	
1.1. If "Yes": how much, from 0 (does not work at all) to 10 (complete pain relief)? (n=7)				6 (5,10)
2. Now, do you think that music played a role in relieving your pain?	9	1[a]	0	
2.1. If "Yes": how much do you think the music relieved your pain, out of 10? (n=9)				7 (5,10)
2.2. If "Yes": was this impact meaningful to you?	9	0	0	
If "Yes": how meaningful, from 0-10? (n=9)				7 (5,10)

Note. IQR=interquartile range. One patient explained that he could not answer beyond question 1 because he had not experienced any pain over the study duration and therefore the questions were not applicable.

[a] This person answered "No" to questions 1 and 2.

Discussion and Interpretation

The POMI was found to be acceptable to ICU patients, family members and nurses. The POMI delivery was also found to be feasible in the ICU setting. Although a small proportion of patients were eligible, time to recruit was adequate and family members were mostly reachable at the bedside. Data analysis was feasible with little missing data. Preliminary efficacy of POMI revealed the potential for the POMI to be efficacious in reducing pain, especially during turning, both in patients able and unable to self-report.

Acceptability of POMI. In line with our previous results with critical care experts on the acceptability of the POMI (18), ICU patients, family members and nurses evaluated the POMI to be acceptable. Similar feedback was highlighted by participants in both studies, including the importance of having individualized playlists based on the patients' music preferences. Also, generating an individualized playlist should be an iterative process based on the patient's reactions to the music. It is important to note, though, that emotional and behavioral reactions to music should be validated with the patient's self-report, whenever possible. Indeed, one of the study participants reacted to the music by crying, yet he explained that this was a desirable reaction. As supported by the psychophysiological model, music can help with emotion regulation. From nurses' perspectives, the risk of cross-contamination from the equipment was highlighted, which can be avoided with a proper disinfection protocol for the MusiCure hospital-grade music pillow, or the use of disposable headphone covers.

Feasibility of POMI. POMI was a feasible intervention in the adult ICU. Family members were able to provide enough information to create a personalized music playlist for patients. However, family members were only present for the full duration of the POMI for less than half of the patients, either for personal reasons (e.g., needing to rest or work) or because of restricted visiting

hours, in the context of the COVID-19 pandemic. Allowing more flexible visiting hours could enable family members to be more involved in nonpharmacological pain management interventions such as the POMI. Family members provided unique knowledge of their loved one's preferences. Some of them involved other family members in the music selection process or their loved one when possible. Family members should always be consulted when patients are unable to self-report because they might be able to provide information about their loved ones' music preferences.

For all but one participant, less than 10 minutes was required to create the individualized playlists, which is consistent with time spent on playlist creation in other studies (51). Allowing patients to control as much of the music as they want (e.g., music selection and duration) should be encouraged. In line with the psychophysiological model and the cognitive dimension of pain, perceived control over the music is linked to increased analgesic benefits (28, 29, 33). Once the playlist was created, having the ability to save and download the playlist allowed us to play the music offline and be less dependent on the network signal. This feature should be considered in a hospital environment where the Wi-Fi connectivity may be unreliable (52). A brief description of each music attribute (e.g., vocal vs instrumental) could be displayed more clearly in the web app in plain language. Regarding the feasibility of delivery modes, the music pillow might be more advantageous in the ICU context. Indeed, headphones were reported to be "too hot" and needed to be readjusted for some patients, especially when they wanted to move around and lie on one side while listening to the music. Another mode of delivery to consider would be to play music directly from the iPad (or other smart device), as per the patient's preference. This would allow them to share their music with others at the bedside and might be more comfortable compared to headphones.

Although the goal of this study was to play music for at least 20-30 minutes, up until a turning procedure, some participants asked for longer or shorter durations. The patient's preference

should always be taken into consideration. As opposed to headphones, the pillow does not interfere with communication and would allow to prolong the music even during procedures such as turning. However, headphones should still be an option for patients who prefer to immerse themselves in the music. The main sources of noise interference during the intervention periods included either equipment alarms or voices, which is consistent with the literature on ICU noise (53). It is possible that ICU noise might interfere with the music listening experience and any potential effect of the POMI on pain reduction (54). In addition to standard care interruptions, patients sometimes interrupted their music listening because they wanted to talk about the music with either their family, research staff, or nursing staff. This is consistent with the psychophysiological model suggesting that music acts to reduce social pain by promoting patient-caregiver communication and interaction (28).

Feasibility of research methods. Time to recruit was adequate as the goal to recruit 24 participants was reached within 4 months, representing a recruitment rate similar to previous studies with 5 participants per month (55). The retention rate was also very high and above the initially set threshold. However, a low proportion of potential patient participants (<20%) were eligible, well below the 50% threshold that was initially set. The main reasons for ineligibility were participants being able to mobilize by themselves and not requiring a turning procedure, and early ICU discharge. Therefore, broader eligibility criteria such as the inclusion of other standard care procedures known to be painful, or pain experienced at rest should be considered in future studies. The use of a parallel design would also help reducing the time for data collection and allow the participation of patients with shorter ICU stays. The main issue with family member recruitment was the difficulty to be present at the bedside at the same time as them. Contacting family members by phone is a strategy that could facilitate recruitment (56).

Preliminary efficacy of POMI. Preliminary evidence was found that the POMI may be efficacious in reducing pain behaviors immediately after playing music and during turning especially for patients unable to self-report. Self-reported pain intensity and distress were significantly lower after turning in the POMI period compared to the control period, supporting the preliminary efficacy of music on procedural pain relief. In patients able to self-report, the POMI appeared to keep pain intensity and distress scores more stable over time, compared to the control period, without music, when pain significantly increased during turning.

Since this was a pilot RCT, no conclusion can be made on the POMI efficacy to reduce pain. Therefore, a full scale RCT should be conducted to confirm its efficacy. Our findings of low eligibility rate support the broadening of eligibility criteria and the use of a parallel design in a larger RCT (50). In addition, because the turning procedure did not always occur immediately after the end of the POMI, it is possible that a potential analgesic effect would be missed, depending on the duration of such an effect. Future studies should consider such timing issues when planning the protocol and analysis.

Limitations and Generalisability

This study only evaluated the acceptability and feasibility for ICU patients/family who could speak French or English. An important portion (8%) of the patients screened in this study did not speak or understand English or French, which is much higher than the documented 2% of the Canadian population (57). Future studies should include more diverse languages, especially considering that music streaming services allow access to culturally diverse content (58).

The turning procedures were not standardized (e.g., only removing pillows, etc.) and sometimes integrated additional care procedures (e.g., rubbing cream on back), which may influence the

patient's reactions and pain scores during turning. These fluctuations might be better mitigated with a larger sample size and with a parallel RCT design.

Only the behavioral (CPOT), sensory (pain intensity), and emotional (pain distress) components of pain could be evaluated in this study because valid tools for ICU pain assessment (i.e., 0-10 pain intensity, 0-10 pain distress and 0-8 CPOT) are only available for these dimensions. The evaluation of the cognitive and psychosocial components of the pain experience could be explored in future studies. However, the comprehensive evaluation of all pain components requires intact cognitive capacity and attention which may be challenging in critically ill adults who receive intensive treatment and sedation.

Because this was only a single-site pilot study, the generalisability of results is limited. However, since the POMI was found to be acceptable and feasible, and because the reasons for low eligibility rate were well documented, a full scale RCT should be conducted as the next step to evaluate the efficacy of the POMI, with some methodological considerations.

Inspired from our feasibility of research methods findings, more flexible music duration and broader eligibility criteria (e.g., pain experience at rest or during various standard care procedures) are recommended (59). Modes of delivery could be expanded to include the patient's preferences, if different from music pillow or headphones (e.g., iPad or external speakers, if available). Other smart devices could also be used, depending on what is available at the bedside (e.g., computer in the room, patient, or family personal device) with or without the assistance of healthcare personnel.

Conclusion

In conclusion, the POMI intervention was found highly acceptable and feasible in the adult ICU. However, some research methods challenges were identified. To increase eligibility rates,

broadening inclusion criteria is recommended. Also, the efficacy testing of POMI to reduce pain in the ICU could be expanded to patients experiencing pain at rest and during various standard care procedures. When possible, outcome measures could capture all dimensions of pain.

Other Information

Registration

The protocol for this crossover pilot RCT study was registered with clinicaltrials.gov (trial registration number: NCT05320224) in March 2022.

Protocol

The full protocol for this study was published with JMIR Research Protocols (23).

Sources of Funding

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Ethical approval

Ethics approval was submitted in July 2021 and approved by the institutional research ethics board in December 2021 (Project #2022-3005).

Supplementary Table I

Detailed list of music genres and artists selected by participants

Genres	Blues Classical Country Disco Folk French Guitar Hip-hop	Jazz Kids New age Pop Reggae Rock and roll Show tunes
Artist names	Andrea Bocelli Barbara Streisand Barrie Manilow Bee Gees Bendan Kavanagh Billy Joel Charles Aznavour Elvis Engelbert Humperdnick Enrico Macias Eros Ramazzotti Fernand Gignac Frank Sinatra Genesis George Harrisson Gilbert Bécaud Ginette Reno Gypsy Kings Hank Williams Jean Nichol Jeves Josée Vachon Julien Clerc Julio Iglesias Justin Bieber	LaVive Lionel Richie Marc Hervieux Mario Pelchat Maxime Farago Michael Jackson Michel Louvain Michel Sardou Patrick Norman Paul Daraîche Paul McCartney Pavarotti Phil Collins Pink Pitbull Ray Charles The Beatles The Who Three Tenors Tina Turner U2 Yanni, Dalida Zachary Richard Zaz

Supplementary Table II

Intraclass Correlation Coefficients between bedside and video raters by Timepoint

ICC	**T0**	**T1**	**T2**	**T3**
Period 1	0.69	0.52	0.81	0.74
[95% CI]	[0.39,0.86]	[0.14,0.77]	[0.60,0.92]	[0.46,0.89]
Period 2	0.66	0.54	0.73	0.56
[95% CI]	[0.33,0.85]	[0.12,0.79]	[0.43,0.89]	[0.17,0.80]

Note. CI = Confidence Interval.

References

1. Damico V, Macchi G, Murano L, Forastieri Molinari A. Incidence of pain at rest and during nursing procedures in ICU patients: a longitudinal observational study. Annali di igiene : medicina preventiva e di comunita. 2020;32(4):407-18.

2. Devlin JW, Skrobik Y, Gélinas C, Needham DM, Slooter AJC, Pandharipande PP, et al. Clinical practice guidelines for the prevention and management of pain, agitation/sedation, delirium, immobility, and sleep disruption in adult patients in the ICU. Crit Care Med. 2018;46(9):e825-e73.

3. Thikom N, Thongsri R, Wongcharoenkit P, Khruamingmongkhon P, Wongtangman K. Incidence of Inadequate Pain Treatment among Ventilated, Critically Ill Surgical Patients in a Thai Population. Pain Manag Nurs. 2020.

4. de Jong A, Molinari N, de Lattre S, Gniadek C, Carr J, Conseil M, et al. Decreasing severe pain and serious adverse events while moving intensive care unit patients: a prospective interventional study (the NURSE-DO project). Crit Care. 2013;17(2):R74.

5. Puntillo KA, Max A, Timsit JF, Vignoud L, Chanques G, Robleda G, et al. Determinants of procedural pain intensity in the intensive care unit. The Europain(R) study. Am J Respir Crit Care Med. 2014;189(1):39-47.

6. Makinen OJ, Backlund ME, Liisanantti J, Peltomaa M, Karlsson S, Kalliomaki ML. Persistent pain in intensive care survivors: a systematic review. Br J Anaesth. 2020;125(2):149-58.

7. Gan TJ. Poorly controlled postoperative pain: prevalence, consequences, and prevention. Journal of Pain Research. 2017;10:2287-98.

8. Kyranou M, Puntillo K. The transition from acute to chronic pain: might intensive care unit patients be at risk? Annals of Intensive Care. 2012;2(1):36.

9. Martyn JAJ, Mao J, Bittner EA. Opioid tolerance in critical illness. The New England Journal of Medicine. 2019;380(4):365-78.

10. Pota V, Coppolino F, Barbarisi A, Passavanti MB, Aurilio C, Sansone P, et al. Pain in Intensive Care: A Narrative Review. Pain Ther. 2022;11(2):359-67.

11. Yamashita A, Yamasaki M, Matsuyama H, Amaya F. Risk factors and prognosis of pain events during mechanical ventilation: a retrospective study. Journal of Intensive Care. 2017;5:17.

12. Chan M. Effects of music on patients undergoing a c-clamp procedure after percutaneous coronary interventions: a randomized controlled trial. Heart Lung. 2007;36(6):431-9.

13. Cooke M, Chaboyer W, Schluter P, Foster M, Harris D, Teakle R. The effect of music on discomfort experienced by intensive care unit patients during turning: a randomized cross-over study. International Journal of Nursing Practice. 2010;16(2):125-31.

14. Jaber S, Bahloul H, Guetin S, Chanques G, Sebbane M, Eledjam JJ. [Effects of music therapy in intensive care unit without sedation in weaning patients versus non-ventilated patients]. Annales Françaises d'Anesthésie et de Réanimation. 2007;26(1):30-8.

15. Richard-Lalonde M, Gélinas C, Boitor M, Gosselin E, Feeley N, Cossette S, et al. The Effect of Music on Pain in the Adult Intensive Care Unit: A Systematic Review of Randomized Controlled Trials. J Pain Symptom Manage. 2020;59(6):1304-19 e6.

16. Sanjuan Navais M, Via Clavero G, Vazquez Guillamet B, Moreno Duran AM, Martinez Estalella G. [Effect of music on anxiety and pain in patients with mechanical ventilation]. Enferm Intensiva. 2013;24(2):63-71.

17. Shultis C. Effects of music therapy vs. music medicine on physiological and psychological parameters of intensive care patients: A randomized controlled trial [Ph.D.]. Ann Arbor: Temple University; 2012.

18. Richard-Lalonde M, Feeley N, Cossette S, Chlan LL, Gélinas C. The Development of a Patient-Oriented Music Intervention (POMI) for Use in the Adult Intensive Care Unit: Acceptability to Critical Care Experts. Canadian Journal of Critical Care Nursing. 2023;34(3):7-17.

19. Sidani S, Braden CJ. Design, evaluation, and translation of nursing interventions. Chichester, West Sussex ; Ames, Iowa: Wiley-Blackwell; 2011. 304 p.

20. Feeley N, Cossette S, Cote J, Heon M, Stremler R, Martorella G, et al. The importance of piloting an RCT intervention. The Canadian Journal of Nursing Research - Revue Canadienne de Recherche en Sciences Infirmières. 2009;41(2):85-99.

21. Sen H, Yanarates O, Sizlan A, Kilic E, Ozkan S, Dagli G. The efficiency and duration of the analgesic effects of musical therapy on postoperative pain. Ağrı : Ağrı (Algoloji) Derneği'nin Yayın organıdır - The journal of the Turkish Society of Algology. 2010;22(4):145-50.

22. Canadian Institute for Health Information. Care in Canadian ICUs. Ottawa, ON: CIHI; 2016.

23. Richard-Lalonde M, Feeley N, Cossette S, Chlan LL, Gélinas C. Acceptability and Feasibility of a Patient-Oriented Music Intervention to Reduce Pain in the Intensive Care Unit: Protocol for a Crossover Pilot Randomized Controlled Trial. JMIR Res Protoc. 2023;12:e40760.

24. Ely EW, Truman B, Shintani A, Thomason JW, Wheeler AP, Gordon S, et al. Monitoring sedation status over time in ICU patients: reliability and validity of the Richmond Agitation-Sedation Scale (RASS). JAMA. 2003;289(22):2983-91.

25. Gigon F. Advance directives & advance care planning among elective surgery patients - ICU issues. Geneva: Genève; 2014.

26. Sessler CN, Gosnell MS, Grap MJ, Brophy GM, O'Neal PV, Keane KA, et al. The Richmond Agitation-Sedation Scale: validity and reliability in adult intensive care unit patients. Am J Respir Crit Care Med. 2002;166(10):1338-44.

27. Davidson JE, Aslakson RA, Long AC, Puntillo KA, Kross EK, Hart J, et al. Guidelines for Family-Centered Care in the Neonatal, Pediatric, and Adult ICU. Crit Care Med. 2017;45(1):103-28.

28. Guétin S, Falvay D, Chanques G, Jaber S, De Lattre S, Souche B, et al. Evaluation of the standardized MUSIC CARE© app in the treatment of pain: the U-shape composing technique. Music Med. 2014;6(2):46-50.

29. Guétin S, Touchon J, editors. Music as an adjuvant to opioids? IASP 17th World Congress on Pain; 2018; Boston.

30. Gosselin É, Richard-Lalonde M. Role of family members in pain management in adult critical care. AACN Advanced Critical Care. 2019;30(4):398-410.

31. Poulsen MJ, Coto J. Nursing music protocol and postoperative pain. Pain Manag Nurs. 2018;19(2):172-6.

32. Basinski K, Zdun-Ryzewska A, Greenberg DM, Majkowicz M. Preferred musical attribute dimensions underlie individual differences in music-induced analgesia. Sci Rep. 2021;11(1):8622.

33. Howlin C, Stapleton A, Rooney B. Tune out pain: Agency and active engagement predict decreases in pain intensity after music listening. PloS one. 2022;17(8):e0271329.

34. Jocelyn Chew HS, Thiara E, Lopez V, Shorey S. Turning frequency in adult bedridden patients to prevent hospital-acquired pressure ulcer: A scoping review. Int Wound J. 2018;15(2):225-36.

35. Weeks BP, Nilsson U. Music interventions in patients during coronary angiographic procedures: a randomized controlled study of the effect on patients' anxiety and well-being. Eur J Cardiovasc Nurs. 2011;10(2):88-93.

36. Sidani S, Brewster J, Miranda J, Walkerly S, Belita E. Exploring the contribution of treatment factors to preferences for smoking cessation interventions. International Archives of Nursing and Health Care. 2016;2(1):1-5.

37. Sidani S, Epstein DR, Bootzin RR, Moritz P, Miranda J. Assessment of preferences for treatment: validation of a measure. Research in Nursing and Health. 2009;32(4):419-31.

38. Gewandter JS, Dworkin RH, Turk DC, McDermott MP, Baron R, Gastonguay MR, et al. Research designs for proof-of-concept chronic pain clinical trials: IMMPACT recommendations. Pain. 2014;155(9):1683-95.

39. Perepletchikova F, Kazdin AE. Treatment integrity and therapeutic change: issues and research recommendations. Clinical Psychology: Science and Practice. 2006;12(4):365-83.

40. Gélinas C, Fillion L, Puntillo KA, Viens C, Fortier M. Validation of the Critical-Care Pain Observation Tool in adult patients. American Journal of Critical Care. 2006;15(4):420-7.

41. Koo TK, Li MY. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. J Chiropr Med. 2016;15(2):155-63.

42. Gélinas C. The faces pain thermometer: a new tool for critically ill adults. Perspective infirmière : revue officielle de l'Ordre des infirmières et infirmiers du Québec. 2007;4(4):12-20.

43. Puntillo KA, Max A, Timsit JF, Ruckly S, Chanques G, Robleda G, et al. Pain distress: the negative emotion associated with procedures in ICU patients. Intensive Care Med. 2018;44(9):1493-501.

44. Bell ML, Whitehead AL, Julious SA. Guidance for using pilot studies to inform the design of intervention trials with continuous outcomes. Clinical Epidemiology. 2018;10:153-7.

45. Boitor M, Martorella G, Maheu C, Laizner AM, Gélinas C. Effects of Massage in Reducing the Pain and Anxiety of the Cardiac Surgery Critically Ill-a Randomized Controlled Trial. Pain Med. 2018.

46. Gélinas C, Berube M, Puntillo KA, Boitor M, Richard-Lalonde M, Bernard F, et al. Validation of the Critical-Care Pain Observation Tool-Neuro in brain-injured adults in the intensive care unit: a prospective cohort study. Crit Care. 2021;25(1):142.

47. Hertzog MA. Considerations in determining sample size for pilot studies. Res Nurs Health. 2008;31(2):180-91.

48. Dwan K, Li T, Altman DG, Elbourne D. CONSORT 2010 statement: extension to randomised crossover trials. BMJ. 2019;366:l4378.

49. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355:i5239.

50. Stewart AL, Napoles AM, Piawah S, Santoyo-Olsson J, Teresi JA. Guidelines for Evaluating the Feasibility of Recruitment in Pilot Studies of Diverse Populations: An Overlooked but Important Component. Ethn Dis. 2020;30(Suppl 2):745-54.

51. Kamehkhosh I, Bonnin G, Jannach D. Effects of recommendations on the playlist creation behavior of users. User Modeling and User-Adapted Interaction : The Journal of Personalization Research. 2019;30(2):285-322.

52. Spotify AB. Listen offline 2023 [Available from: https://support.spotify.com/us/article/listen-offline/.

53. Pal J, Taywade M, Pal R, Sethi D. Noise Pollution in Intensive Care Unit: A Hidden Enemy affecting the Physical and Mental Health of Patients and Caregivers. Noise Health. 2022;24(114):130-6.

54. Aydin Sayilan A, Kulakac N, Sayilan S. The effects of noise levels on pain, anxiety, and sleep in patients. Nurs Crit Care. 2021;26(2):79-85.

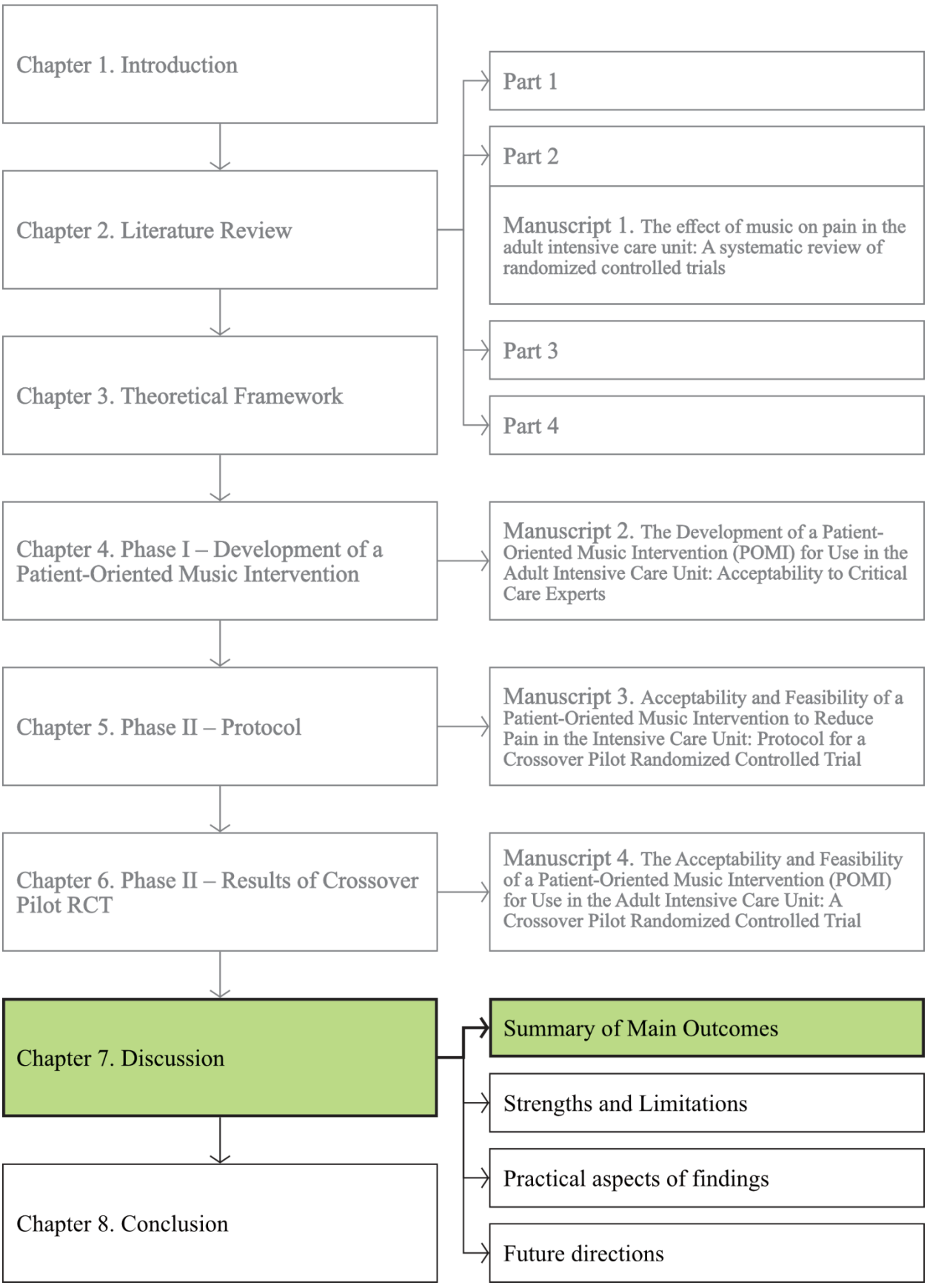
55. Khan SH, Xu C, Purpura R, Durrani S, Lindroth H, Wang S, et al. Decreasing Delirium Through Music: A Randomized Pilot Trial. Am J Crit Care. 2020;29(2):e31-e8.

56. Paddock K, Woolfall K, Frith L, Watkins M, Gamble C, Welters I, et al. Strategies to enhance recruitment and consent to intensive care studies: a qualitative study with researchers and patient-public involvement contributors. BMJ Open. 2021;11(9):e048193.

57. Statistics Canada. While English and French are still the main languages spoken in Canada, the country's linguistic diversity continues to grow. The Daily; 2022.

58. Bello P, Garcia D. Cultural Divergence in popular music: the increasing diversity of music consumption on Spotify across countries. Humanities and Social Sciences Communications. 2021;8(1).

59. Vijay A, Hauser JM. "This Won't Hurt a Bit": Is There a Role for Music in Bedside Procedures? Crit Care Explor. 2023;5(4):e0900.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Chapter 7. Discussion

In this chapter, an overarching discussion is provided to present a comprehensive summary of the outcomes of this doctoral research project in the context of the broader literature, strengths and limitations not fully addressed thus far, practical aspects of the findings, and future directions.

Summary of Main Outcomes

POMI Development

A novel music intervention was developed by integrating theoretical, empirical, and experiential knowledge (Manuscripts 1 and 2). Based on patient preferences, a tempo of 60-80 bpm, and a minimum duration of 20 minutes, POMI creates individualized music playlists using a web app that connects to a popular streaming service (Spotify). Patients or their family members can specify the patient preferences in terms of music genre, artist names, track titles, and further refine their playlist by selecting a type of emotion (cheerful vs melancholic music) or degree of arousal (energetic vs relaxing music) among other music characteristics. The playlist is generated using a smart device connected to the Internet and the music is played to the patient either using a music pillow or via headphones.

Acceptability of POMI

The POMI was found to be acceptable in both phases of this doctoral research project, supported by both quantitative and qualitative data. In Phase I, critical care experts rated the POMI as acceptable for pain management at rest, but not following a standard care procedure (Manuscript 2). The rationale supporting this finding was to provide pain management in anticipation of a painful event as a pre-emptive measure. Therefore, in Phase II, the acceptability of the POMI was evaluated when delivered in anticipation of procedural pain (turning). The POMI

was evaluated as acceptable by ICU patients, family members and nurses (Manuscript 4). In both phases of this doctoral research project, participants valued the creation of individualized playlists based on the patients' musical preferences.

Our acceptability findings are also in line with other studies supporting the acceptability of music as an intervention in the ICU. One research group reported that 120 minutes of music (2 sessions of 1 hour for 7 consecutive days) was acceptable to mechanically ventilated ICU patients as a complementary pain management intervention (Khan et al., 2020). Another team described the acceptability of music delivered via electronic tablets to help relieve pain, which was reported as satisfactory by ICU patients and as helpful by family members and healthcare providers (Knudson et al., 2018). In another study that evaluated the acceptability of a multi-component intervention comprised of music, information briefing, diary keeping and symptom evaluation to complement pain management, ICU patients reported the most acceptable component of the intervention to be music (Gosselin et al., 2018). Therefore, music interventions have been reported as acceptable pain management interventions for use in the ICU setting. Overall, this doctoral research project brings forth evidence that POMI is acceptable to all interested parties, including patients, families, and critical care experts such as nurses, for ICU pain management.

Feasibility of POMI

Previous feasibility research with ICU patients who selected music using audiotapes and headphones had found barriers such as inaccessibility of the equipment and lack of knowledge and training of the nursing staff (Chlan et al., 2001). With technology development over the last two decades, including the increase in accessibility of smart devices and streaming services as a source of music, the feasibility of a music intervention such as POMI needed to be evaluated. In this study, most of the ICU patients and family members were found to have access to smart

devices and headphones, and most ICU nurses had previous experience using music streaming services (Manuscript 4).

A few more recent studies have evaluated the feasibility of music interventions for ICU pain management. Two studies evaluated the feasibility of music, finding the use of reusable headphones, CDs (Gosselin et al., 2018), mp3 players and music therapists to be cost-effective in the ICU setting (Chlan et al., 2018). In a mixed-methods pilot study, 30 minutes of self-selected music, delivered each day for 7 days, was found to be acceptable and feasible to enhance patient-family communication at the end of life (Johnston et al., 2022). One research group is currently conducting a feasibility RCT to evaluate the effect of 30-40 minutes music-assisted relaxation on pain in ICU burn patients (Ettenberger et al., 2021).

In evaluating the feasibility and fidelity of POMI (Manuscript 3), this doctoral research project supports the ease of use and reproducibility of POMI. As a novel intervention that uses a music streaming service, POMI can create individualized playlists within a recommended tempo range in a timely manner and with minimal resources. In this study, a low incidence of issues with the delivery of POMI arising from headphones or pillow use, Internet connectivity, and song skipping was found. These findings supported the possibility for more flexible duration and delivery modes of POMI and to offer more control to ICU patients and families (Manuscript 4).

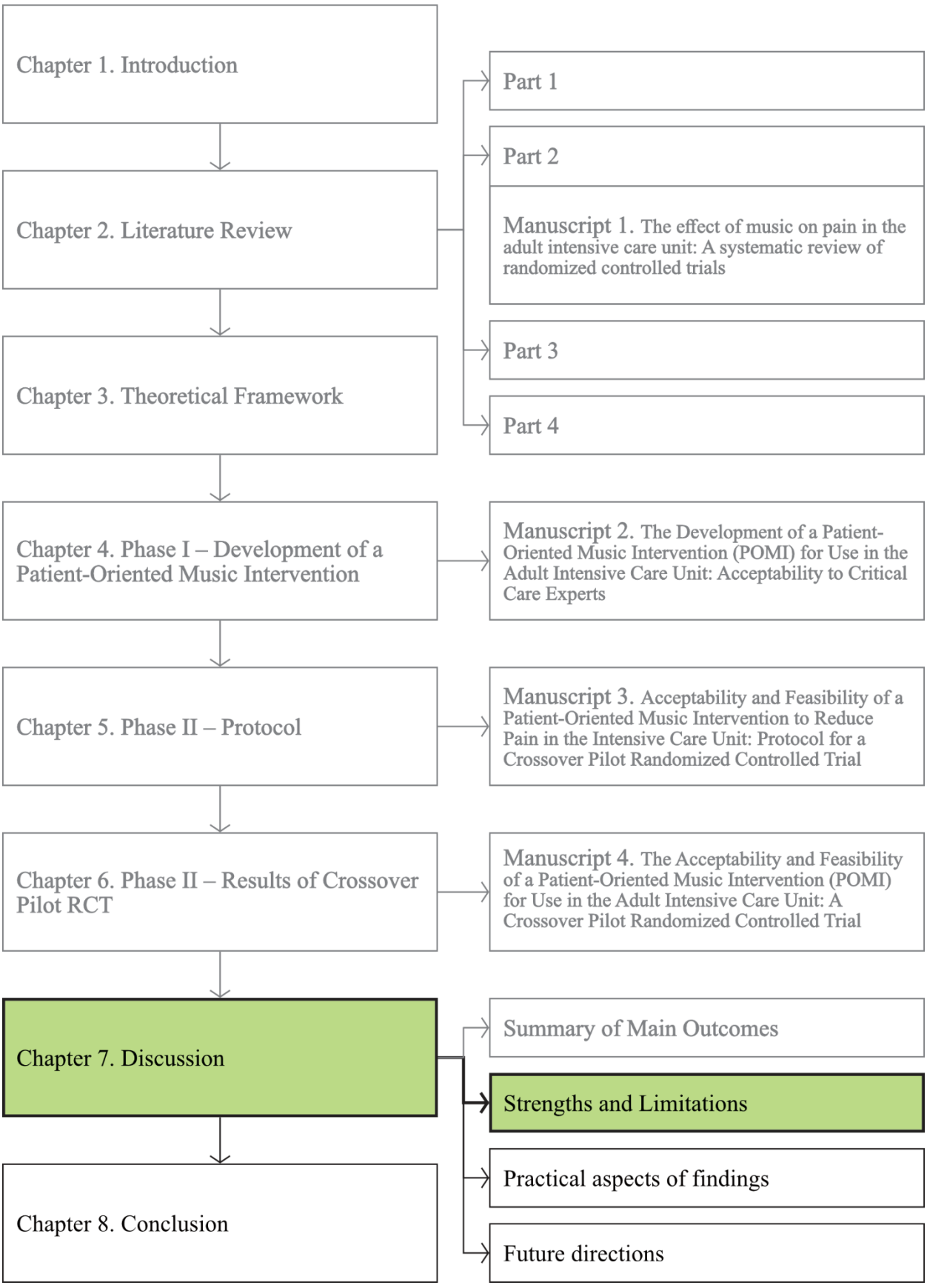
Feasibility of research methods

As highlighted in our systematic review (Manuscript 1), previous RCTs of music interventions for ICU pain management reported recruitment issues leading to inadequate sample sizes. In our crossover pilot RCT (Phase II, Manuscript 3), the feasibility of research methods was evaluated to inform future RCTs. The limitations and sources for low eligibility rate were identified, which allowed to propose mitigating strategies such as including patients who require

other standard care procedures in addition to turning as well as patients experiencing pain at rest (Manuscript 4). Indeed, including patients experiencing pain at rest in the ICU appears feasible as most of our participants (75%) reported experiencing pain at baseline. This strategy about the timing of the POMI delivery at rest also aligns with our findings from Phase I as critical experts supported the acceptability of POMI delivery for pain management at rest.

Preliminary efficacy of POMI

Phase II allowed us to support the feasibility of the POMI but also to demonstrate its potential efficacy in reducing turning procedural pain in ICU patients (Manuscript 4). Although the preliminary efficacy of POMI was not explicitly evaluated at rest, a large proportion of patients were already experiencing pain at baseline (i.e., at rest). A potential effect of the POMI to reduce pain was observed immediately after the music was played. These preliminary findings appear to be in line with the results of our systematic review (Manuscript 1: Richard-Lalonde et al., 2020), which found that music had an effect in reducing pain experienced by critically ill adults.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Strengths and Limitations

Strengths

This doctoral research project was the first to develop a music intervention for critically ill adults based on the integration of theoretical, empirical, and experiential knowledge and to conduct an intervention pilot testing study in the ICU. The combination of several features makes the POMI unique and accessible: the use of a web app linked to a streaming service (Spotify) accessible with an iPad and delivered via headphones or music pillow.

Another strength of this doctoral research project is that, as part of the intervention development, the POMI features were described following the TIDieR guidelines, which previous studies have not done (Martin-Saavedra, Vergara-Mendez, Pradilla, et al., 2018; Martin-Saavedra, Vergara-Mendez, & Talero-Gutierrez, 2018). This lack of standardized reporting of music interventions has hampered reproducibility and impeded adequate systematic review analyses in terms of understanding which characteristics make a music intervention efficacious. Therefore, by following the TIDieR guidelines, the POMI is reproducible, and its detailed features will allow it to be evaluated more thoroughly in future systematic reviews.

The participation of various interested parties throughout this doctoral research project, including critical care experts in Phase I and ICU patients, family members and nurses in Phase II provided a more comprehensive evaluation from various perspectives in the POMI development and acceptability evaluation. Furthermore, a rigorous evaluation of the acceptability of POMI was achieved with the use of a validated questionnaire. Detailed note taking as part of the feasibility of POMI evaluation during the crossover pilot RCT (Phase II) led to a better understanding of how to improve the POMI delivery (e.g., flexible duration). The CONSORT

guidelines were followed, allowing for a comprehensive evaluation of the feasibility of research methods of the crossover pilot RCT, which, in turn, may inform future RCT protocols.

The crossover design, as discussed in the published protocol (Manuscript 3: Richard-Lalonde et al., 2023), also brought several advantages at the pilot testing stage. For example, by allowing each patient to be their own control, the crossover design reduced confounding factors that would have been present in a parallel design. Furthermore, because patients were exposed to both the POMI and control periods, the crossover design enabled the patients to self-report their preference between the POMI or the control. Another strength of the research methods included not only patients able to self-report but also patients unable to self-report by involving the participation of family members. Additionally, the interrater reliability of CPOT scores contributed to minimize the potential bias of the student researcher's unblinded pain assessment at the bedside.

Limitations

The POMI was made to be as accessible as possible, however it was only evaluated in a specific context using a single streaming service (Spotify) on an iPad and delivered via headphones or music pillow. To enhance its accessibility, the POMI could be expanded to the use of other streaming services, using any smart device, and delivered via any speaker system.

The most important limitation to Phase I of this doctoral research project was that ICU patients or family members could not be recruited due to restrictions imposed by the COVID-19 pandemic context. Therefore, there were not enough participants to achieve the objective of the quantitative component of the initially planned mixed methods design. Because of this unpredicted loss of sample size (from the initial plan of n=30 including 10 ICU patients, 10 family members and 10 clinicians to the reduced sample of n=12 clinicians only), the design of this phase of the project was changed from a mixed methods design to a descriptive design.

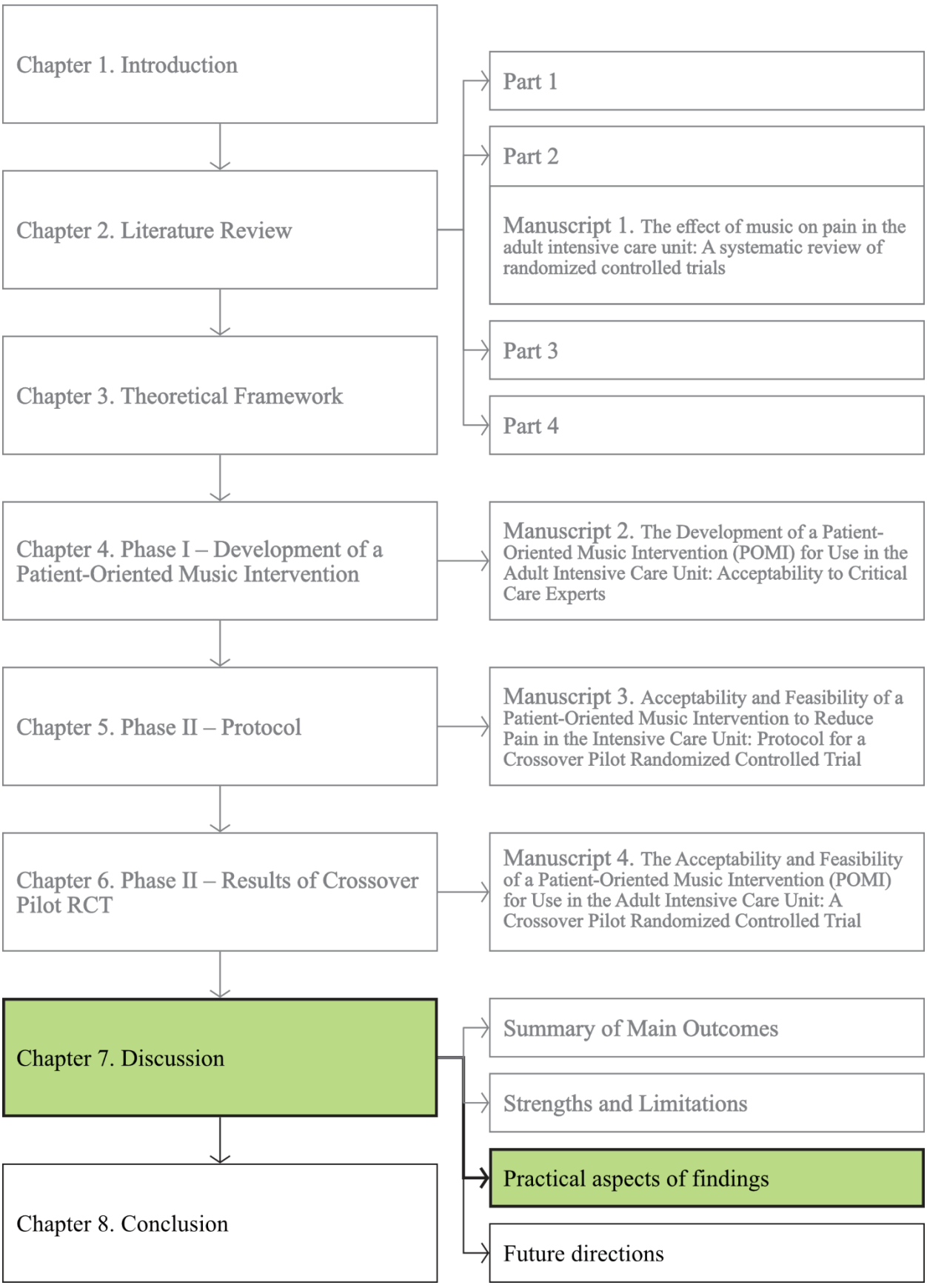
Fortunately, ICU patients and family members participated in Phase II of this doctoral research project, to evaluate the acceptability of the proposed POMI.

The POMI is intended to be delivered to any patient admitted to the ICU. The patient sample was divided into two subgroups: patients able to self-report and patients unable to self-report. The most important difference in the POMI delivery with these two subgroups was that participants considered "able to self-report" were involved in the selection of the music. Therefore, participants unable to self-report could be considered as having received a different intervention, "receptive music listening", with different mechanisms of action compared to the other subgroup, which could be said to have received "intentional music listening" (Dingle et al., 2021). Therefore, it is probably most pertinent to conduct analyses and interpretations separately for each subgroup, as presented in Manuscript 4. Future studies should explore the best way to categorize groups in terms of analysis, as "patients unable to self-report" may present various levels of consciousness whose music listening experiences are likely to vary widely (Grimm & Kreutz, 2018).

Patients unable to self-report who did not have a family member at the bedside who could provide the music preferences on their behalf were not able to participate in this study even though some of these patients might benefit from music (Magee et al., 2016; Puggina & da Silva, 2015; Stubbs, 2005). As described in Manuscript 1, standardized playlists have been used in ICU with some heterogeneous effect on reducing pain in critically ill adults and could be explored as a solution. However, as discussed in Manuscript 2, because there are currently no music characteristics known to objectively produce analgesia, more research is needed to assess the possibility of developing such standardized playlists as well as to identify the target demographic that would benefit from such a playlist.

The main feasibility limitation in this crossover pilot RCT was related to eligibility. An important proportion of patients did not have scheduled turning (mostly because they were able to self-mobilize), which was the main reason for exclusion and accounted for about 40% of patients who did not meet the inclusion criteria (Phase II). The second most common reason for exclusion was patients with ICU stays too short to be eligible to participate in the study (accounting for about 37% of ineligible patients).

The main limitation regarding the preliminary efficacy of POMI was that only three of the five pain dimensions were measured. The cognitive and social dimensions of pain were not measured because there are no known validated tools to measure them in the ICU setting.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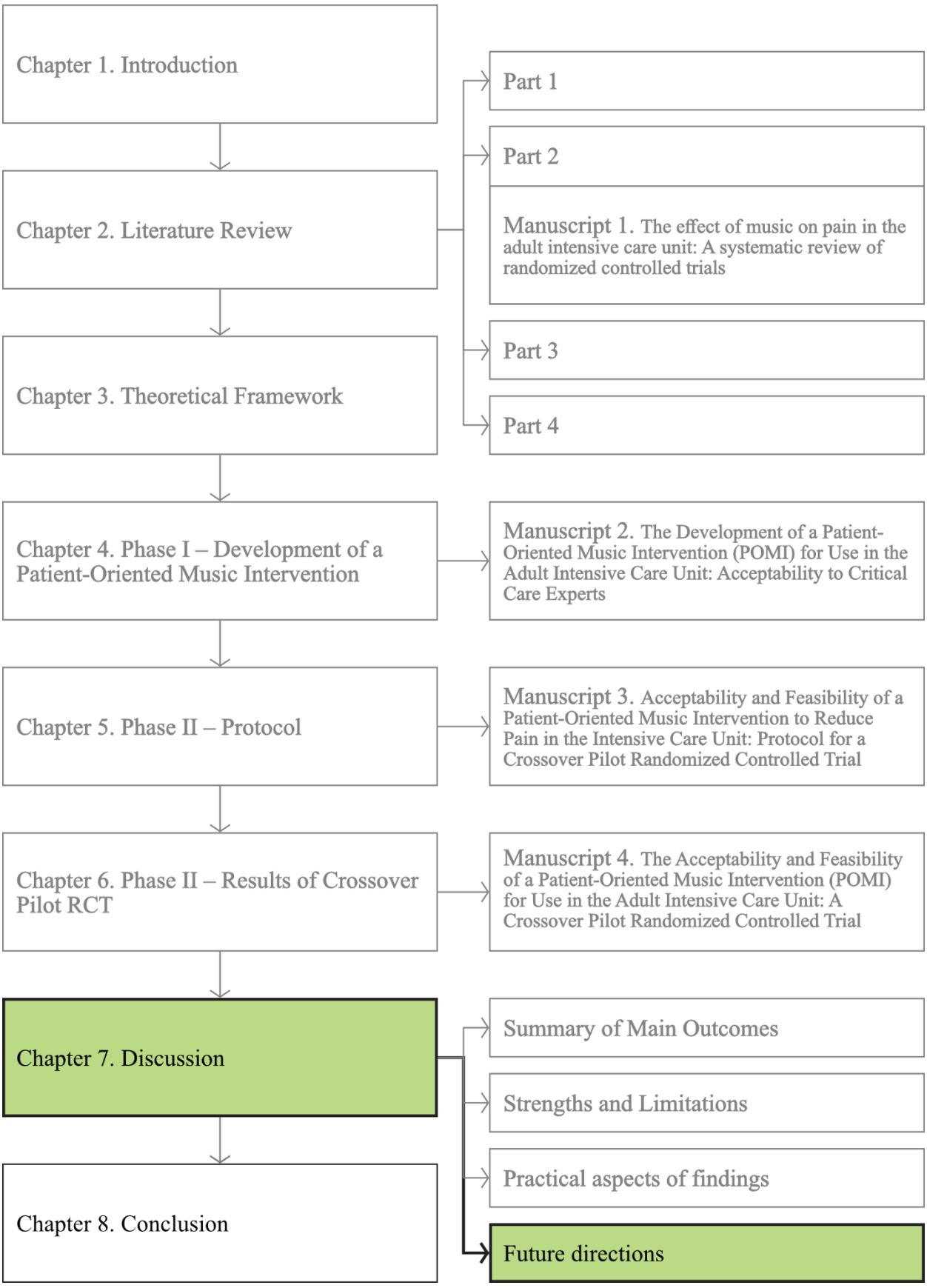
Practical aspects of findings

One important practical aspect of the findings was that POMI can be acceptable and feasible for pain management purposes in the ICU setting. In Phase I of this doctoral research project, several critical care experts including nurses reported already using music streaming services with ICU patients. Although the proposed POMI used a streaming service, evidence was lacking with regards to its acceptability, feasibility, and efficacy. Therefore, the POMI is a novel, accessible, evidence-based music intervention that uses a streaming service and can be used in practice by ICU nurses and critical care workers.

A primary practical recommendation refers to selecting and playing music based on the patient's preferences. Patients should be offered their preferred mode of delivery (e.g., headphones, music pillow, smart device, etc.). In terms of duration, playing music for at least 20 minutes is recommended, while taking into consideration that some patients may prefer shorter or longer duration. Hospital managers and policy makers should provide resources to facilitate music delivery such as free and reliable Wi-Fi and access to streaming services. Music should be accessible to all patients including those able or unable to self-report. Based on their intimate knowledge of their loved one, family members should be offered the opportunity to provide information about patients' music preferences. Family members can also bring music listening materials such as headphones or smart devices in the ICU and contribute to the delivery of music interventions to their loved one. Timing of delivery should be in anticipation of painful procedures, although the POMI could also be delivered to patients experiencing pain at rest.

Although the POMI was found to be safe in terms of risks or side effects, ICU nurses should always monitor their patients' reactions to the music being played and adjust the POMI settings based on patient feedback or observed nonverbal reactions.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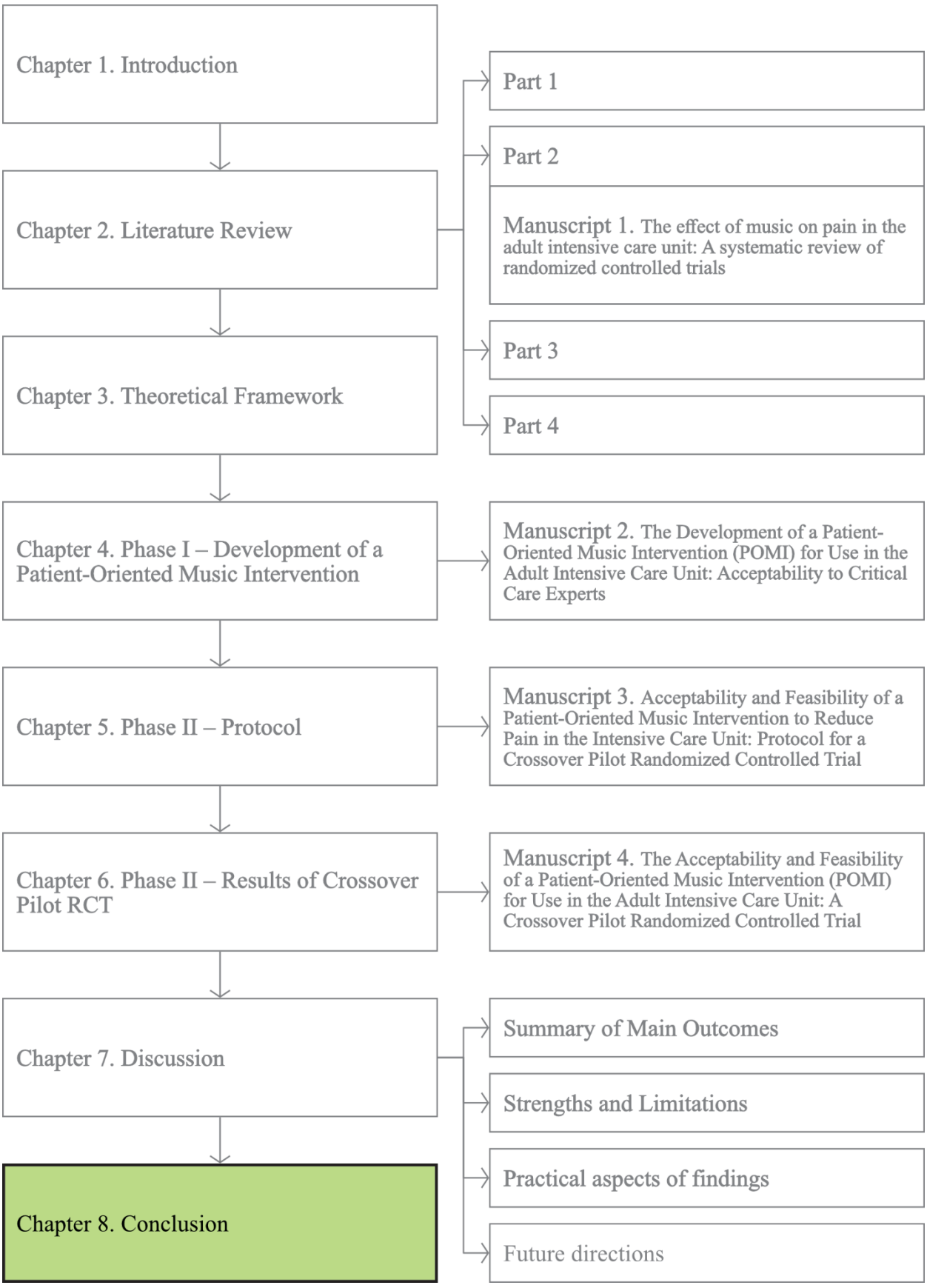
Future research on music interventions in the ICU should offer flexible music streaming services, based on what patients use in their daily lives outside the ICU setting. Although this project innovated by using one of the main streaming services currently used by Canadians (Spotify), other streaming services exist and are also used by an important portion of the population. In addition, future research with POMI should consider patient preferences beyond headphones and music pillows and offer alternative modes of delivery.

Future research on music interventions in the ICU should consider exploring ways to include patients unable to self-report without family members as well as patients who do not speak or understand the same languages as the healthcare providers. Indeed, more research should be conducted on how best to determine whether patients unable to self-report without family would benefit from music and which music to play for them.

The crossover pilot RCT revealed eligibility limitations related to patients not being turned (mostly being able to move independently) and others with short ICU stays. Therefore, future research with POMI should consider broader eligibility criteria to include patients undergoing other painful standard care procedures and patients experiencing pain while at rest. Future studies should also consider using a parallel, instead of a crossover, design to cut down on the duration of the data collection and include patients with shorter ICU stays. Indeed, using a crossover design in a pilot study followed by a parallel design in a larger RCT is recommended as an efficient approach to confirm preliminary efficacy results in pain research (Gewandter et al., 2014). In conclusion, following the feasibility findings of this crossover pilot RCT, a large-scale parallel RCT should be conducted to evaluate the POMI efficacy to reduce pain in ICU patients, both at rest and in anticipation of painful procedures.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Manuscript 4. The Acceptability and Feasibility of a Patient-Oriented Music Intervention (POMI) for Use in the Adult Intensive Care Unit: A Crossover Pilot Randomized Controlled Trial
Summary of Main Outcomes
Strengths and Limitations
Practical aspects of findings
Future directions

Chapter 8. Conclusion

In conclusion, the objectives of this doctoral research project were met. POMI was developed based on the integration of theoretical, empirical, and experiential knowledge. POMI was acceptable to all interested parties in both phases of this doctoral research project, including ICU patients, family members and critical care workers, such as nurses. POMI was feasible when pilot tested in the ICU setting as a complementary pain management intervention for patients during a turning procedure. The crossover pilot RCT highlighted strengths and limitations of the research methods selected to evaluate the POMI preliminary efficacy to reduce pain.

The implications of the intervention acceptability and feasibility findings supported that POMI can be used by ICU patients, family members and nurses. Because POMI was found to be acceptable, interested parties would be expected to be more likely to adopt it and promote its use if implemented in the ICU setting. Because POMI was found to be feasible with minimal resources, its implementation in the ICU setting could be facilitated. Finally, as supported by the acceptability and feasibility findings in Phase I and Phase II of this doctoral research project (Manuscripts 2 and 4), ICU nurses could be trained on the use of POMI as a complementary pain management intervention.

The implications of the feasibility of research methods findings could inform the development of future RCTs. Indeed, eligibility criteria should allow the reach of patients that are representative of the general ICU population experiencing pain.

The implications of the preliminary efficacy findings point to the possibility that POMI efficacy could be confirmed in a larger scale RCT to reduce pain in ICU patients able or unable to self-report. Specifically, POMI allows the creation of individualized playlists based on patients' preferences. Patients able to self-report can express their own personal music preferences. For patients unable to self-report, the patient's music preferences can be provided by family members to also create music playlists to help reduce ICU pain.

References

Ames, N., Shuford, R., Yang, L., Moriyama, B., Frey, M., Wilson, F., Sundaramurthi, T., Gori, D., Mannes, A., Ranucci, A., Koziol, D., & Wallen, G. R. (2017). Music listening among postoperative patients in the intensive care unit: A randomized controlled trial with mixed-methods analysis. *Integrative Medicine Insights*, *12*, 1-13. https://doi.org/10.1177/1178633717716455

Antioch, I., Furuta, T., Uchikawa, R., Okumura, M., Otogoto, J., Kondo, E., Sogawa, N., Ciobica, A., & Tomida, M. (2020). Favorite music mediates pain-related responses in the anterior cingulate cortex and skin pain thresholds. *Journal of Pain Research*, *13*, 2729-2737. https://doi.org/10.2147/JPR.S276274

Basinski, K., Zdun-Ryzewska, A., Greenberg, D. M., & Majkowicz, M. (2021). Preferred musical attribute dimensions underlie individual differences in music-induced analgesia. *Scientific Reports*, *11*(1), 8622. https://doi.org/10.1038/s41598-021-87943-z

Battle, C. E., Lovett, S., & Hutchings, H. (2013). Chronic pain in survivors of critical illness: A retrospective analysis of incidence and risk factors. *Critical Care*, *17*(3), R101. https://doi.org/10.1186/cc12746

Baumbach, P., Gotz, T., Gunther, A., Weiss, T., & Meissner, W. (2016). Prevalence and characteristics of chronic intensive care-related pain: The role of severe sepsis and septic shock. *Critical Care Medicine*, *44*(6), 1129-1137. https://doi.org/10.1097/CCM.0000000000001635

Bradt, J., & Dileo, C. (2014). Music interventions for mechanically ventilated patients. *Cochrane Database Syst Rev*(12), CD006902. https://doi.org/10.1002/14651858.CD006902.pub3

Bradt, J., Dileo, C., Magill, L., & Teague, A. (2016). Music interventions for improving psychological and physical outcomes in cancer patients. *Cochrane Database Syst Rev*(8), CD006911. https://doi.org/10.1002/14651858.CD006911.pub3

Broscious, S. K. (1999). Music: An intervention for pain during chest tube removal after open heart surgery. *American Journal of Critical Care*, *8*(6), 410-415. https://doi.org/10.4037/ajcc1999.8.6.410

Broyles, L. M., Tate, J. A., & Happ, M. B. (2012). Use of augmentative and alternative communication strategies by family members in the intensive care unit. *American Journal of Critical Care*, *21*(2), e21-e32. https://doi.org/10.4037/ajcc2012752

Burry, L. D., Williamson, D. R., Perreault, M. M., Rose, L., Cook, D. J., Ferguson, N. D., Lapinsky, S. C., & Mehta, S. (2014). Analgesic, sedative, antipsychotic, and neuromuscular blocker use in Canadian intensive care units: a prospective, multicentre, observational study. *Can J Anesth/J Can Anesth*, *61*(7), 619-630. https://doi.org/10.1007/s12630-014-0174-1

Canadian Association of Music Therapists. (2023). *Directory of certified music therapists (MTA)*. Canadian Association of Music Therapists. Retrieved April 5, 2023, from https://www.musictherapy.ca/directory-of-certified-music-therapists-mta/

Canadian Institute for Health Information. (2016). *Care in Canadian ICUs*. https://secure.cihi.ca/free_products/ICU_Report_EN.pdf

Canadian Pain Task Force. (2021). *An action plan for pain in Canada*. Health Canada. https://www.canada.ca/content/dam/hc-sc/documents/corporate/about-health-canada/public-engagement/external-advisory-bodies/canadian-pain-task-force/report-2021-rapport/report-rapport-2021-eng.pdf

Canseco, M. (2022, July 21). Survey: How we listen to music in Canada. *BIV*. https://biv.com/article/2022/07/survey-how-we-listen-music-canada

Chan, M. F. (2007). Effects of music on patients undergoing a C-clamp procedure after percutaneous coronary interventions: A randomized controlled trial. *Heart & Lung*, *36*(6), 431-439. https://doi.org/10.1016/j.hrtlng.2007.05.003

Chapman, C. R., Tuckett, R. P., & Song, C. W. (2008). Pain and stress in a systems perspective: Reciprocal neural, endocrine, and immune interactions. *The Journal of Pain*, *9*(2), 122-145. https://doi.org/10.1016/j.jpain.2007.09.006

Che, X., Cash, R., Ng, S. K., Fitzgerald, P., & Fitzgibbon, B. M. (2018). A systematic review of the processes underlying the main and the buffering effect of social support on the experience of pain. *The Clinical Journal of Pain*, *34*(11), 1061-1076. https://doi.org/10.1097/AJP.0000000000000624

Chen, L., Yin, J., Zheng, Y., Zhao, C., Zhang, H., Li, J., Ji, D., & Zhang, Y.-P. (2022). The effectiveness of music listening for critically ill patients: A systematic review. *Nursing in Critical Care*. https://doi.org/10.1111/nicc.12825

Chiasson, A. M., Baldwin, A. L., McLaughlin, C., Cook, P., & Sethi, G. (2013). The effect of live spontaneous harp music on patients in the intensive care unit. *Evidence-Based Complementary and Alternative Medicine*, *2013*, 1-6. https://doi.org/10.1155/2013/428731

Chlan, L. L., Heiderscheit, A., Skaar, D. J., & Neidecker, M. V. (2018). Economic evaluation of a patient-directed music intervention for ICU patients receiving mechanical ventilatory support. *Critical Care Medicine*, *46*(9), 1430-1435. https://doi.org/10.1097/CCM.0000000000003199

Chlan, L. L., Tracy, M. F., Nelson, B., & Walker, J. (2001). Feasibility of a music intervention protocol for patients receiving mechanical ventilatory support. *Alternative Therapies*, *7*(6), 80-83. https://pubmed.ncbi.nlm.nih.gov/11712475/

Chlan, L. L., Weinert, C. R., Heiderscheit, A., Tracy, M. F., Skaar, D. J., Guttormson, J. L., & Savik, K. (2013). Effects of patient-directed music intervention on anxiety and sedative exposure in critically ill patients receiving mechanical ventilatory support: a randomized clinical trial. *JAMA*, *309*(22), 2335-2344. https://doi.org/10.1001/jama.2013.5670

Choi, J., Hoffman, L. A., Schulz, R., Tate, J. A., Donahoe, M. P., Ren, D., Given, B. A., & Sherwood, P. R. (2014). Self-reported physical symptoms in intensive care unit (ICU) survivors: Pilot exploration over four months post-ICU discharge. *Journal of Pain and Symptom Management*, *47*(2), 257-270. https://doi.org/10.1016/j.jpainsymman.2013.03.019

Choiniere, M., Watt-Watson, J., Victor, J. C., Baskett, R. J., Bussieres, J. S., Carrier, M., Cogan, J., Costello, J., Feindel, C., Guertin, M. C., Racine, M., & Taillefer, M. C. (2014). Prevalence of and risk factors for persistent postoperative nonanginal pain after cardiac surgery: A 2-year prospective multicentre study. *Canadian Medical Association Journal*, *186*(7), E213-E223. https://doi.org/10.1503/cmaj.131012

Cigerci, Y., & Ozbayir, T. (2016). The effects of music therapy on anxiety, pain and the amount of analgesics following coronary artery surgery. *Turkish Journal of Thoracic and Cardiovascular Surgery*, *24*(1), 44-50. https://doi.org/10.5606/tgkdc.dergisi.2016.12136

Cohen, S. P., Vase, L., & Hooten, W. M. (2021). Chronic pain: An update on burden, best practices, and new advances. *Lancet*, *397*(10289), 2082-2097. https://doi.org/10.1016/S0140-6736(21)00393-7

Cole, L. C., & LoBiondo-Wood, G. (2014). Music as an adjuvant therapy in control of pain and symptoms in hospitalized adults: A systematic review. *Pain Management Nursing*, *15*(1), 406-425. https://doi.org/10.1016/j.pmn.2012.08.010

Cooke, M., Chaboyer, W., Schluter, P., Foster, M., Harris, D., & Teakle, R. (2010). The effect of music on discomfort experienced by intensive care unit patients during turning: A randomized cross-over study. *International Journal of Nursing Practice*, *16*(2), 125-131. https://doi.org/10.1111/j.1440-172X.2010.01819.x

Craig, K. D., & MacKenzie, N. E. (2021). What is pain: Are cognitive and social features core components? *Paediatric and Neonatal Pain*, *3*(3), 106-118. https://doi.org/10.1002/pne2.12046

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2013). Developing and evaluating complex interventions: The new Medical Research Council guidance. *International Journal of Nursing Studies*, *50*(5), 587-592. https://doi.org/10.1016/j.ijnurstu.2012.09.010

Crawford, A. M., Shiferaw, A. A., Ntambwe, P., Milan, A. O., Khalid, K., Rubio, R., Nizeyimana, F., Ariza, F., Mohammed, A. D., Baker, T., Banguti, P. R., & Madzimbamuto, F. (2023). Global critical care: A call to action. *Critical Care*, *27*(1), 28. https://doi.org/10.1186/s13054-022-04296-3

Damico, V., Macchi, G., Murano, L., & Forastieri Molinari, A. (2020). Incidence of pain at rest and during nursing procedures in ICU patients: A longitudinal observational study. *Ann Ig*, *32*(4), 407-418. https://doi.org/10.7416/ai.2020.2364

de Jong, A., Molinari, N., de Lattre, S., Gniadek, C., Carr, J., Conseil, M., Susbielles, M. P., Jung, B., Jaber, S., & Chanques, G. (2013). Decreasing severe pain and serious adverse

events while moving intensive care unit patients: A prospective interventional study (the NURSE-DO project). *Critical Care*, *17*(2), R74. https://doi.org/10.1186/cc12683

Devlin, J. W., Skrobik, Y., Gélinas, C., Needham, D. M., Slooter, A. J. C., Pandharipande, P. P., Watson, P. L., Weinhouse, G. L., Nunnally, M. E., Rochwerg, B., Balas, M. C., van den Boogaard, M., Bosma, K. J., Brummel, N. E., Chanques, G., Denehy, L., Drouot, X., Fraser, G. L., Harris, J. E., . . . Alhazzani, W. (2018). Clinical practice guidelines for the prevention and management of pain, agitation/sedation, delirium, immobility, and sleep disruption in adult patients in the ICU. *Critical Care Medicine*, *46*(9), e825-e873. https://doi.org/10.1097/CCM.0000000000003299

Dingle, G. A., Sharman, L. S., Bauer, Z., Beckman, E., Broughton, M., Bunzli, E., Davidson, R., Draper, G., Fairley, S., Farrell, C., Flynn, L. M., Gomersall, S., Hong, M., Larwood, J., Lee, C., Lee, J., Nitschinsk, L., Peluso, N., Reedman, S. E., . . . Wright, O. R. L. (2021). How do music activities affect health and well-being? A scoping review of studies examining psychosocial mechanisms. *Frontiers in Psychology*, *12*, 713818. https://doi.org/10.3389/fpsyg.2021.713818

Dobek, C. E., Beynon, M. E., Bosma, R. L., & Stroman, P. W. (2014). Music modulation of pain perception and pain-related activity in the brain, brain stem, and spinal cord: A functional magnetic resonance imaging study. *The Journal of Pain*, *15*(10), 1057-1068. https://doi.org/10.1016/j.jpain.2014.07.006

Ehieli, E., Yalamuri, S., Brudney, C. S., & Pyati, S. (2017). Analgesia in the surgical intensive care unit. *Postgraduate Medical Journal*, *93*(1095), 38-45. https://doi.org/10.1136/postgradmedj-2016-134047

Ettenberger, M., Maya, R., Salgado-Vasco, A., Monsalve-Duarte, S., Betancourt-Zapata, W., Suarez-Canon, N., Prieto-Garces, S., Marin-Sanchez, J., Gomez-Ortega, V., & Valderrama, M. (2021). The effect of music therapy on perceived pain, mental health, vital signs, and medication usage of burn patients hospitalized in the intensive care unit: A randomized controlled feasibility study protocol. *Frontiers in Psychiatry*, *12*, 714209. https://doi.org/10.3389/fpsyt.2021.714209

Feeley, N., Cossette, S., Cote, J., Heon, M., Stremler, R., Martorella, G., & Purden, M. (2009). The importance of piloting an RCT intervention. *CJNR*, *41*(2), 85-99. https://www.ncbi.nlm.nih.gov/pubmed/19650515

Freitas, C., Manzato, E., Burini, A., Taylor, M. J., Lerch, J. P., & Anagnostou, E. (2018). Neural correlates of familiarity in music listening: A systematic review and a neuroimaging meta-analysis. *Frontiers in Neuroscience*, *12*, 686. https://doi.org/10.3389/fnins.2018.00686

Gagné, V., & Ferrari, N. (2018). *État des connaissances sur les modes d'organisation des services de soins intensifs*. Institut national d'excellence en santé et en services sociaux (INESSS). https://www.inesss.qc.ca/fileadmin/doc/INESSS/Rapports/Traumatologie/INESSS_Unite_soins_intensifs.pdf

Gan, T. J. (2017). Poorly controlled postoperative pain: Prevalence, consequences, and prevention. *Journal of Pain Research*, *10*, 2287-2298. https://doi.org/10.2147/JPR.S144066

Gélinas, C., Arbour, C., Michaud, C., Robar, L., & Côté, J. (2013). Patients and ICU nurses' perspectives of non-pharmacological interventions for pain management. *Nursing in Critical Care*, *18*(6), 307-318. https://doi.org/10.1111/j.1478-5153.2012.00531.x

Gélinas, C., Berube, M., Chevrier, A., Pun, B. T., Ely, E. W., Skrobik, Y., & Barr, J. (2018). Delirium assessment tools for use in critically ill adults: A psychometric analysis and systematic review. *Critical Care Nurse*, *38*(1), 38-49. https://doi.org/10.4037/ccn2018633

Gélinas, C., Fillion, L., Puntillo, K. A., Viens, C., & Fortier, M. (2006). Validation of the Critical-Care Pain Observation Tool in adult patients. *American Journal of Critical Care*, *15*(4), 420-427. https://doi.org/10.4037/ajcc2006.15.4.420

Gélinas, C., Joffe, A. M., Szumita, P. M., Payen, J. F., Bérubé, M., Shahiri, T. S., Boitor, M., Chanques, G., & Puntillo, K. (2019). A psychometric analysis update of behavioral pain assessment tools for noncommunicative, critically ill adults. *AACN Advanced Critical Care*, *30*(4), 365-387. https://doi.org/10.4037/aacnacc2019952

Georgiou, E., Hadjibalassi, M., Lambrinou, E., Andreou, P., & Papathanassoglou, E. D. (2015). The impact of pain assessment on critically ill patients' outcomes: A systematic review. *BioMed Research International*, *2015*, 1-18. https://doi.org/10.1155/2015/503830

Gewandter, J. S., Dworkin, R. H., Turk, D. C., McDermott, M. P., Baron, R., Gastonguay, M. R., Gilron, I., Katz, N. P., Mehta, C., Raja, S. N., Senn, S., Taylor, C., Cowan, P., Desjardins, P., Dimitrova, R., Dionne, R., Farrar, J. T., Hewitt, D. J., Iyengar, S., . . . White, R. E. (2014). Research designs for proof-of-concept chronic pain clinical trials: IMMPACT recommendations. *Pain*, *155*(9), 1683-1695. https://doi.org/10.1016/j.pain.2014.05.025

Ginsberg, J. P., Raghunathan, K., Bassi, G., & Ulloa, L. (2022). Review of perioperative music medicine: Mechanisms of pain and stress reduction around surgery. *Frontiers in Medicine*, *9*, 821022. https://doi.org/10.3389/fmed.2022.821022

Glowacki, D. (2015). Effective pain management and improvements in patients' outcomes and satisfaction. *Critical Care Nurse*, *35*(3), 33-41. https://doi.org/10.4037/ccn2015440

Gosselin, E., Gélinas, C., Bourgault, P., & Lavoie, S. (2018). Intervention for patients intubated and conscious to decrease peritraumatic distress (IPIC-PTD) – Acceptability and feasibility. *Science of Nursing and Health Practices - Science infirmière et pratiques en santé*, *1*(2). https://doi.org/10.31770/2561-7516.1019

Grimm, T., & Kreutz, G. (2018). Music interventions in disorders of consciousness (DOC) - A systematic review. *Brain Injury*, *32*(6), 704-714. https://doi.org/10.1080/02699052.2018.1451657

Guétin, S., Falvay, D., Chanques, G., Jaber, S., De Lattre, S., Souche, B., Giniès, P., Picot, M.-C., Hérisson, C., de Diego, E., & Touchon, J. (2014). Evaluation of the standardized MUSIC CARE© app in the treatment of pain: The U-shape composing technique. *Music and Medicine*, *6*(2), 46-50. https://doi.org/10.47513/mmd.v6i2.179

Guétin, S., & Touchon, J. (2018, September 12-16). Music as an adjuvant to opioids? 2018 IASP World Congress on Pain, Boston, MA, United States.

Guilbaut, V. (2017). *Apport de l'intervention musicale standardisée type Music Care© sur les soins douloureux des patients vigiles en soins critiques* [Impact of the standardized musical intervention Music Care © on the painful procedures of critically ill patients] (Publication No. 01581304) [Master Thesis, Université Nice Sophia Antipolis]. https://dumas.ccsd.cnrs.fr/dumas-01581304

Gupta, M., Sahi, M. S., Bhargava, A. K., & Talwar, V. (2016). A prospective evaluation of symptom prevalence and overall symptom burden among cohort of critically ill cancer

patients. *Indian Journal of Palliative Care*, *22*(2), 118-124. https://doi.org/10.4103/0973-1075.179601

Happ, M. B., Garrett, K., Thomas, D. D., Tate, J., George, E., Houze, M., Radtke, J., & Sereika, S. (2011). Nurse-patient communication interactions in the intensive care unit. *American Journal of Critical Care*, *20*(2), e28-e40. https://doi.org/10.4037/ajcc2011433

Happ, M. B., Seaman, J. B., Nilsen, M. L., Sciulli, A., Tate, J. A., Saul, M., & Barnato, A. E. (2015). The number of mechanically ventilated ICU patients meeting communication criteria. *Heart & Lung*, *44*(1), 45-49. https://doi.org/10.1016/j.hrtlng.2014.08.010

Hayhurst, C. J., Jackson, J. C., Archer, K. R., Thompson, J. L., Chandrasekhar, R., & Hughes, C. G. (2018). Pain and its long-term interference of daily life after critical illness. *Anesthesia & Analgesia*, *127*(3), 690-697. https://doi.org/10.1213/ANE.0000000000003358

Helmer, L. M. L., Weijenberg, R. A. F., de Vries, R., Achterberg, W. P., Lautenbacher, S., Sampson, E. L., & Lobbezoo, F. (2020). Crying out in pain-A systematic review into the validity of vocalization as an indicator for pain. *European Journal of Pain*, *24*(9), 1703-1715. https://doi.org/10.1002/ejp.1623

Herr, K., Coyne, P. J., Ely, E., Gélinas, C., & Manworren, R. C. B. (2019). Pain assessment in the patient unable to self-report: Clinical practice recommendations in support of the ASPMN 2019 position statement. *Pain Management Nursing*, *20*(5), 404-417. https://doi.org/10.1016/j.pmn.2019.07.005

Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., Altman, D. G., Barbour, V., Macdonald, H., Johnston, M., Lamb, S. E., Dixon-Woods, M., McCulloch, P., Wyatt, J. C., Chan, A. W., & Michie, S. (2014). Better reporting of interventions:

Template for intervention description and replication (TIDieR) checklist and guide. *BMJ*, *348*, g1687. https://doi.org/10.1136/bmj.g1687

Holden, D. N., & Retelski, J. (2019). *The ICU liberation bundle: an emphasis on nonpharmacologic intervention*. Retrieved September 16, 2019, from https://www.sccm.org/Communications/Critical-Connections/Archives/2019/The-ICU-Liberation-Bundle-An-Emphasis-on-Nonpharm

Hole, J., Hirsch, M., Ball, E., & Meads, C. (2015). Music as an aid for postoperative recovery in adults: A systematic review and meta-analysis. *Lancet*, *386*(10004), 1659-1671. https://doi.org/10.1016/S0140-6736(15)60169-6

Howlin, C., & Rooney, B. (2020). The cognitive mechanisms in music listening interventions for pain: A scoping review. *Journal of Music Therapy*, *57*(2), 127-167. https://doi.org/10.1093/jmt/thaa003

Howlin, C., Stapleton, A., & Rooney, B. (2022). Tune out pain: Agency and active engagement predict decreases in pain intensity after music listening. *PLoS ONE*, *17*(8), e0271329. https://doi.org/10.1371/journal.pone.0271329

Hu, R. F., Jiang, X.-Y., Hegadoren, K. M., & Zhang, Y.-H. (2015). Effects of earplugs and eye masks combined with relaxing music on sleep, melatonin and cortisol levels in ICU patients: A randomized controlled trial. *Critical Care*, *19*(1), 115. https://doi.org/10.1186/s13054-015-0855-3

Hu, Y., Yu, F., Wang, C., Yan, X., & Wang, K. (2021). Can music influence patients with disorders of consciousness? An event-related potential study. *Frontiers in Neuroscience*, *15*, 596636. https://doi.org/10.3389/fnins.2021.596636

International Association for the Study of Pain. (2020, July 16). *IASP announces revised definition of pain*. https://www.iasp-pain.org/publications/iasp-news/iasp-announces-revised-definition-of-pain/

International Association for the Study of Pain. (2021). *IASP terminology*. Retrieved July 13, from https://www.iasp-pain.org/Education/Content.aspx?ItemNumber=1698#Pain

International Federation of Phonography Industry. (2023). *IFPI global music report 2023 — State of the industry*. https://globalmusicreport.ifpi.org/

Jaber, S., Bahloul, H., Guetin, S., Chanques, G., Sebbane, M., & Eledjam, J.-J. (2007). Effets de la musicothérapie en réanimation hors sédation chez des patients en cours de sevrage ventilatoire versus des patients non ventilés [Effects of music therapy in intensive care unit without sedation in weaning patients versus non-ventilated patients]. *Annales Françaises d'Anesthésie et de Réanimation*, *26*(1), 30-38. https://doi.org/10.1016/j.annfar.2006.09.002

Jakob, S. M., Spapen, H., Ruokonen, E., Grounds, R. M., Sarapohja, T., Garratt, C., Pocock, S. J., Bratty, J. R., Takala, J., Vincent, J. L., Colpaert, K., Lambermont, B., Kivistik, U., Saar, A., Toome, V., Tamme, K., Tenhunen, J., Ala-Kokko, T., Chiche, J. D., . . . MacNaughton, P., on behalf of the Dexmedetomidine for Long-Term Sedation Investigators. (2012). Dexmedetomidine vs midazolam or propofol for sedation during prolonged mechanical ventilation: Two randomized controlled trials. *JAMA*, *307*(11), 1151-1160. https://doi.org/10.1001/jama.2012.304

Johnston, B., Bowman, F., Carduff, E., Donmez, F., Lowndes, A., & McKeown, A. (2022). 'Playlist for Life' at the end of life: A mixed-methods feasibility study of a personalised

music listening intervention in the hospice setting. *Pilot and Feasibility Studies*, *8*(1), 32. https://doi.org/10.1186/s40814-022-00983-8

Kakar, E., Venema, E., Jeekel, J., Klimek, M., & van der Jagt, M. (2021). Music intervention for sleep quality in critically ill and surgical patients: A meta-analysis. *BMJ Open*, *11*(5), e042510. https://doi.org/10.1136/bmjopen-2020-042510

Khan, S. H., Xu, C., Purpura, R., Durrani, S., Lindroth, H., Wang, S., Gao, S., Heiderscheit, A., Chlan, L., Boustani, M., & Khan, B. A. (2020). Decreasing delirium through music: A randomized pilot trial. *American Journal of Critical Care*, *29*(2), e31-e38. https://doi.org/10.4037/ajcc2020175

Kim, B., & Dvorak, A. L. (2018). Music therapy and intimacy behaviors of hospice family caregivers in South Korea: A randomized crossover clinical trial. *Nordic Journal of Music Therapy*, *27*(3), 218-234. https://doi.org/10.1080/08098131.2018.1427783

Knudson, K., Redeker, N. S., Heiderscheit, A., Pisani, M. A., Knauert, M. P., & Chlan, L. L. (2018, May 21). Acceptability and feasibility of an electronic tablet-delivered music intervention in the medical intensive care unit. *Patient and Family Engagement in Respiratory and Critical Care* [Symposium]. American Thoracic Society 2018 International Conference, San Diego, CA, United States.

Kshettry, V. R., Carole, L. F., Henly, S. J., Sendelbach, S., & Kummer, B. (2006). Complementary alternative medical therapies for heart surgery patients: Feasibility, safety, and impact. *The Annals of Thoracic Surgery*, *81*(1), 201-205. https://doi.org/10.1016/j.athoracsur.2005.06.016

Kunz, M., Meixner, D., & Lautenbacher, S. (2019). Facial muscle movements encoding pain-A systematic review. *Pain*, *160*(3), 535-549. https://doi.org/10.1097/j.pain.0000000000001424

Kyavar, M., Karkhaneh, S., Rohanifar, R., Azarfarin, R., Sadeghpour, A., Alizadehasl, A., & Ghadrdoost, B. (2016). Effect of preferred music listening on pain reduction in mechanically ventilated patients after coronary artery bypass graft surgery. *Research in Cardiovascular Medicine*, *5*(4), e33769. https://doi.org/10.5812/cardiovascmed.33769

Kyranou, M., & Puntillo, K. (2012). The transition from acute to chronic pain: Might intensive care unit patients be at risk? *Annals of Intensive Care*, *2*(1), 36. https://doi.org/10.1186/2110-5820-2-36

Langerud, A. K., Rustoen, T., Brunborg, C., Kongsgaard, U., & Stubhaug, A. (2018). Prevalence, location, and characteristics of chronic pain in intensive care survivors. *Pain Management Nursing*, *19*(4), 366-376. https://doi.org/10.1016/j.pmn.2017.11.005

Lee, J. H. (2016). The effects of music on pain: A meta-analysis. *Journal of Music Therapy*, *53*(4), 430-477. https://doi.org/10.1093/jmt/thw012

Levitin, D. J., Grahn, J. A., & London, J. (2018). The psychology of music: Rhythm and movement. *Annual Review of Psychology*, *69*, 51-75. https://doi.org/10.1146/annurev-psych-122216-011740

Lewis, K. S., Whipple, J. K., Michael, K. A., & Quebbeman, E. J. (1994). Effect of analgesic treatment on the physiological consequences of acute pain. *American Journal of Hospital Pharmacy*, *51*(12), 1539-1554. https://doi.org/10.1093/ajhp/51.12.1539

Magee, W. L., Tillmann, B., Perrin, F., & Schnakers, C. (2016). Music and disorders of consciousness: Emerging research, practice and theory [Editorial]. *Frontiers in Psychology*, *7*, 1273. https://doi.org/10.3389/fpsyg.2016.01273

Makinen, O. J., Backlund, M. E., Liisanantti, J., Peltomaa, M., Karlsson, S., & Kalliomaki, M.-L. (2020). Persistent pain in intensive care survivors: A systematic review. *British Journal of Anaesthesia*, *125*(2), 149-158. https://doi.org/10.1016/j.bja.2020.04.084

Martin-Saavedra, J. S., Vergara-Mendez, L. D., Pradilla, I., Velez-van-Meerbeke, A., & Talero-Gutierrez, C. (2018). Standardizing music characteristics for the management of pain: A systematic review and meta-analysis of clinical trials. *Complementary Therapies in Medicine*, *41*, 81-89. https://doi.org/10.1016/j.ctim.2018.07.008

Martin-Saavedra, J. S., Vergara-Mendez, L. D., & Talero-Gutierrez, C. (2018). Music is an effective intervention for the management of pain: An umbrella review. *Complementary Therapies in Clinical Practice*, *32*, 103-114. https://doi.org/10.1016/j.ctcp.2018.06.003

Martyn, J. A. J., Mao, J., & Bittner, E. A. (2019). Opioid tolerance in critical illness. *The New England Journal of Medicine*, *380*(4), 365-378. https://doi.org/10.1056/NEJMra1800222

Meghani, N., Tracy, M. F., Hadidi, N. N., & Lindquist, R. (2017). Part I: The effects of music for the symptom management of anxiety, pain, and insomnia in critically ill patients: An integrative review of current literature. *Dimensions of Critical Care Nursing*, *36*(4), 234-243. https://doi.org/10.1097/DCC.0000000000000254

Melzack, R., & Casey, K. L. (1968). Sensory, motivational, and central control determinants of pain. In D. R. Kenshalo (Ed.), *The skin senses* (pp. 423-439). Charles C Thomas.

Najafi Ghezeljeh, T., Mohades Ardebili, F., Rafii, F., & Haghani, H. (2016). The effects of music intervention on background pain and anxiety in burn patients: Randomized

controlled clinical trial. *Journal of Burn Care & Research*, *37*(4), 226-234. https://doi.org/10.1097/BCR.0000000000000266

Nilsson, U. (2008). The anxiety- and pain-reducing effects of music interventions: A systematic review. *AORN Journal*, *87*(4), 780-807. https://doi.org/10.1016/j.aorn.2007.09.013

Özer, N., Karaman Özlü, Z., Arslan, S., & Günes, N. (2013). Effect of music on postoperative pain and physiologic parameters of patients after open heart surgery. *Pain Management Nursing*, *14*(1), 20-28. https://doi.org/10.1016/j.pmn.2010.05.002

Pando-Naude, V., Barrios, F. A., Alcauter, S., Pasaye, E. H., Vase, L., Brattico, E., Vuust, P., & Garza-Villarreal, E. A. (2019). Functional connectivity of music-induced analgesia in fibromyalgia. *Scientific Reports*, *9*(1), 15486. https://doi.org/10.1038/s41598-019-51990-4

Puggina, A. C. G., & da Silva, M. J. P. (2015). Patients with disorders of consciousness: Vital, facial and muscular responses to music or messages. *Revista Brasileira de Enfermagem*, *68*(1), 94-102. https://doi.org/10.1590/0034-7167.2015680114p

Puntillo, K. A., Arai, S., Cohen, N. H., Gropper, M. A., Neuhaus, J., Paul, S. M., & Miaskowski, C. (2010). Symptoms experienced by intensive care unit patients at high risk of dying. *Critical Care Medicine*, *38*(11), 2155-2160. https://doi.org/10.1097/CCM.0b013e3181f267ee

Puntillo, K. A., Max, A., Timsit, J. F., Ruckly, S., Chanques, G., Robleda, G., Roche-Campo, F., Mancebo, J., Divatia, J. V., Soares, M., Ionescu, D. C., Grintescu, I. M., Maggiore, S. M., Rusinova, K., Owczuk, R., Egerod, I., Papathanassoglou, E. D. E., Kyranou, M., Joynt, G. M., . . . Azoulay, E. (2018). Pain distress: The negative emotion associated with procedures in ICU patients. *Intensive Care Med*, *44*(9), 1493-1501. https://doi.org/10.1007/s00134-018-5344-0

Puntillo, K. A., Max, A., Timsit, J. F., Vignoud, L., Chanques, G., Robleda, G., Roche-Campo, F., Mancebo, J., Divatia, J. V., Soares, M., Ionescu, D. C., Grintescu, I. M., Vasiliu, I. L., Maggiore, S. M., Rusinova, K., Owczuk, R., Egerod, I., Papathanassoglou, E. D., Kyranou, M., . . . Azoulay, E. (2014). Determinants of procedural pain intensity in the intensive care unit. The Europain(R) study. *American Journal of Respiratory and Critical Care Medicine*, *189*(1), 39-47. https://doi.org/10.1164/rccm.201306-1174OC

Raja, S. N., Carr, D. B., Cohen, M., Finnerup, N. B., Flor, H., Gibson, S., Keefe, F. J., Mogil, J. S., Ringkamp, M., Sluka, K. A., Song, X. J., Stevens, B., Sullivan, M. D., Tutelman, P. R., Ushida, T., & Vader, K. (2020). The revised International Association for the Study of Pain definition of pain: Concepts, challenges, and compromises. *Pain*, *161*(9), 1976-1982. https://doi.org/10.1097/j.pain.0000000000001939

Richard-Lalonde, M., Feeley, N., Cossette, S., Chlan, L. L., & Gélinas, C. (2023). Acceptability and feasibility of a patient-oriented music intervention to reduce pain in the intensive care unit: Protocol for a crossover pilot randomized controlled trial. *JMIR Research Protocols*, *12*, e40760. https://doi.org/10.2196/40760

Richard-Lalonde, M., Gélinas, C., Boitor, M., Gosselin, E., Feeley, N., Cossette, S., & Chlan, L. L. (2020). The effect of music on pain in the adult intensive care unit: A systematic review of randomized controlled trials. *Journal of Pain and Symptom Management*, *59*(6), 1304-1319.e1306. https://doi.org/10.1016/j.jpainsymman.2019.12.359

Sanjuan Navais, M., Via Clavero, G., Vazquez Guillamet, B., Moreno Duran, A. M., & Martinez Estalella, G. (2013). Efecto de la música sobre la ansiedad y el dolor en pacientes con ventilación mecánica [Effect of music on anxiety and pain in patients with mechanical

ventilation]. *Enfermería Intensiva*, *24*(2), 63-71. https://doi.org/10.1016/j.enfi.2012.11.003

Savage, R., & Taylor, E. (2013). Hospice family caring behaviors during music therapy. *New Zealand Journal of Music Therapy*, *11*, 81-103. https://search.informit.org/doi/10.3316/informit.853355373232258

Shultis, C. (2012). *Effects of music therapy vs. music medicine on physiological and psychological parameters of intensive care patients: A randomized controlled trial* (Publication No. 3510346) [Doctoral dissertation, Temple University]. ProQuest Dissertations & Theses Global. https://www.proquest.com/dissertations-theses/effects-music-therapy-vs-medicine-on/docview/1021387028/se-2

Sidani, S., & Braden, C. J. (2011). *Design, evaluation, and translation of nursing interventions*. Wiley-Blackwell. https://doi.org/10.1002/9781118785553

Sinatra, R. (2010). Causes and consequences of inadequate management of acute pain. *Pain Medicine*, *11*(12), 1859-1871. https://doi.org/10.1111/j.1526-4637.2010.00983.x

Skivington, K., Matthews, L., Simpson, S. A., Craig, P., Baird, J., Blazeby, J. M., Boyd, K. A., Craig, N., French, D. P., McIntosh, E., Petticrew, M., Rycroft-Malone, J., White, M., & Moore, L. (2021). A new framework for developing and evaluating complex interventions: Update of Medical Research Council guidance. *BMJ*, *374*, n2061. https://doi.org/10.1136/bmj.n2061

Stamenkovic, D. M., Laycock, H., Karanikolas, M., Ladjevic, N. G., Neskovic, V., & Bantel, C. (2019). Chronic pain and chronic opioid use after intensive care discharge – Is it time to change practice? *Frontiers in Pharmacology*, *10*, 23. https://doi.org/10.3389/fphar.2019.00023

Statistics Canada. (2018). *Results from the digital economy survey*. https://www150.statcan.gc.ca/n1/en/pub/11-627-m/11-627-m2018028-eng.pdf?st=vyBRNiYc

Statistics Canada. (2023). *Vinyl record sales soar during pandemic, but streaming reigns supreme*. https://www.statcan.gc.ca/o1/en/plus/3444-vinyl-record-sales-soar-during-pandemic-streaming-reigns-supreme

Stegemann, T., Geretsegger, M., Phan Quoc, E., Riedl, H., & Smetana, M. (2019). Music Therapy and Other Music-Based Interventions in Pediatric Health Care: An Overview. *Medicines (Basel)*, *6*(1). https://doi.org/10.3390/medicines6010025

Stubbs, T. (2005). Experiences and perceptions of music therapy in critical illness. *Nursing times*, *101*(45), 34-36. https://www.ncbi.nlm.nih.gov/pubmed/16312081

Talbot, K., Madden, V. J., Jones, S. L., & Moseley, G. L. (2019). The sensory and affective components of pain: Are they differentially modifiable dimensions or inseparable aspects of a unitary experience? A systematic review. *British Journal of Anaesthesia*, *123*(2), e263-e272. https://doi.org/10.1016/j.bja.2019.03.033

Tan, X., Yowler, C. J., Super, D. M., & Fratianne, R. B. (2010). The efficacy of music therapy protocols for decreasing pain, anxiety, and muscle tension levels during burn dressing changes: A prospective randomized crossover trial. *Journal of Burn Care & Research*, *31*(4), 590-597. https://doi.org/10.1097/BCR.0b013e3181e4d71b

Thaut, M. H., McIntosh, G. C., & Hoemberg, V. (2014). Neurobiological foundations of neurologic music therapy: Rhythmic entrainment and the motor system. *Frontiers in Psychology*, *5*, 1185. https://doi.org/10.3389/fpsyg.2014.01185

Tracy, M., & Chlan, L. (2011). Nonpharmacological interventions to manage common symptoms in patients receiving mechanical ventilation. *Critical Care Nurse*, *31*(3), 19-28. https://doi.org/10.4037/ccn2011653

Umbrello, M., Sorrenti, T., Mistraletti, G., Formenti, P., Chiumello, D., & Terzoni, S. (2019). Music therapy reduces stress and anxiety in critically ill patients: A systematic review of randomized clinical trials. *Minerva Anestesiologica*, *85*(8), 886-898. https://doi.org/10.23736/S0375-9393.19.13526-2

Van Criekinge, T., D'Aout, K., O'Brien, J., & Coutinho, E. (2019). Effect of music listening on hypertonia in neurologically impaired patients—Systematic review. *PeerJ*, *7*, e8228. https://doi.org/10.7717/peerj.8228

Varlet, M., Williams, R., & Keller, P. E. (2020). Effects of pitch and tempo of auditory rhythms on spontaneous movement entrainment and stabilisation. *Psychological Research*, *84*(3), 568-584. https://doi.org/10.1007/s00426-018-1074-8

Vincent, J. L., Marshall, J. C., Namendys-Silva, S. A., Francois, B., Martin-Loeches, I., Lipman, J., Reinhart, K., Antonelli, M., Pickkers, P., Njimi, H., Jimenez, E., & Sakr, Y., on behalf of the ICON investigators. (2014). Assessment of the worldwide burden of critical illness: The intensive care over nations (ICON) audit. *Lancet Respir Med*, *2*(5), 380-386. https://doi.org/10.1016/S2213-2600(14)70061-X

Wavrock, D., Schellenberg, G., & Schimmele, C. (2022). *Canadians' use of the Internet and digital technologies before and during the COVID-19 pandemic* (Economic and Social Reports, Issue 4). S. Canada. https://doi.org/10.25318/36280001202200400004-eng

Williams, A. C., & Craig, K. D. (2016). Updating the definition of pain. *Pain*, *157*(11), 2420-2423. https://doi.org/10.1097/j.pain.0000000000000613

Yaffe, P. B., Green, R. S., Butler, M. B., & Witter, T. (2017). Is admission to the intensive care unit associated with chronic opioid use? A 4-year follow-up of intensive care unit survivors. *Journal of Intensive Care Medicine*, *32*(7), 429-435. https://doi.org/10.1177/0885066615618189

Yamashita, A., Yamasaki, M., Matsuyama, H., & Amaya, F. (2017). Risk factors and prognosis of pain events during mechanical ventilation: A retrospective study. *Journal of intensive Care*, *5*, 17. https://doi.org/10.1186/s40560-017-0212-5

Appendix A

Decision-Making Capacity Form

Participant ID: _____ Date: _____

To determine if an ICU adult patient can consent/self-report, the answers to all the questions below must be "No"

Condition	YES	NO	Assessor (nurse/MD)
The patient is demonstrating inconsistent answers/confusion/lack of insight.			
The patient is not oriented x3 based on the latest nurse assessment.			
The patient has an ongoing delirium as determined by a positive score on the Confusion Assessment Method (CAM)-ICU evaluation by the nurse.			
The current patient Richmond Agitation Sedation Scale (RASS) score is not 0 as per nurse assessment, meaning that the patient is either sedated (negative RASS score) or agitated (positive RASS score).			
The level of consciousness is found to be fluctuating as per nurse assessment of the Glasgow Coma Scale (GCS) scores.			
There is concern by the physician or the nurse caring for the patient that a psychiatric illness is influencing the decision of the patient.			

Appendix B

Participant Sociodemographic Form

Patient Participant ID: _____

Date (Y/M/D): ____ / ____ / ____

Ability to self-report: ❑ Yes ❑ No, reason: _____

ICU admission (Y/M/D): ____ / ____ / ____ Reason for admission/Dx: _____

Mechanical intubation while in the ICU: ❑ Yes ❑ No

Age: _____ APACHE II score: _____

Sex at birth: ❑ Male ❑ Female ❑ Intersex ❑ Prefer not to answer

Current gender identity

❑ Male Gender ❑ Gender Diverse

❑ Female Gender ❑ Prefer not to answer

Ethnicity (origin)

❑ North American Aboriginal ❑ Latin, Central or South American

❑ Other North American ❑ African ❑ Other: _____

❑ European ❑ Asian

❑ Caribbean ❑ Oceania

Highest Level of Education Completed

❑ Elementary School ❑ College

❑ Secondary/High School ❑ University

Prior use of music streaming service: ❑ Yes ❑ No

❑ Other source of music: _____

Access to: ❑ Smart device ❑ Headphones ❑ None Ability to bring to ICU: ❑ Yes ❑ No

Family Member Participant ID: _____

Date (Y/M/D): ____ / ____ / ____

Relation to ICU adult patient participant

❑ Partner ❑ Friend

❑ Child ❑ Sibling

❑ Parent ❑ Other: _____

Age: _____ Duration of relationship: _____

Sex at birth: ❑ Male ❑ Female ❑ Intersex ❑ Prefer not to answer

Current gender identity

❑ Male Gender ❑ Gender Diverse

❑ Female Gender ❑ Prefer not to answer

Ethnicity (origin)

❑ North American Aboriginal ❑ Latin, Central or South American

❑ Other North American ❑ African ❑ Other: _____

❑ European ❑ Asian

❑ Caribbean ❑ Oceania

Highest Level of Education Completed

❑ Elementary School ❑ College

❑ Secondary/High School ❑ University

Prior use of music streaming service: ❑ Yes ❑ No

❑ Other source of music: _____

Access to: ❑ Smart device ❑ Headphones ❑ None Ability to bring to ICU: ❑ Yes ❑ No

Nurse/Orderly Participant ID: _____

Date (Y/M/D): ____ / ____ / ____

Profession

❑ Nurse

❑ Orderly/PAB

❑ Other: _____

Number of years working in ICU: _____

Years in the profession: _____

Age: _____

Sex at birth: ❑ Male ❑ Female ❑ Intersex ❑ Prefer not to answer

Current gender identity

❑ Male Gender ❑ Gender Diverse

❑ Female Gender ❑ Prefer not to answer

Ethnicity (origin)

❑ North American Aboriginal ❑ Latin, Central or South American

❑ Other North American ❑ African ❑ Other: _____

❑ European ❑ Asian

❑ Caribbean ❑ Oceania

Highest Level of Education Completed

❑ Elementary School ❑ College

❑ Secondary/High School ❑ University

Prior use of music streaming service: ❑ Yes ❑ No

❑ Other source of music: _____

Prior use of music with patients: ❑ Yes ❑ No Comment: _____

Appendix C

Music Preferences Data Collection Form

Participant ID: _____ Date: _____

Note. If you are answering these questions on behalf of a patient participant, please answer these questions to the best of your knowledge of the patient's musical preferences.

Question	*Participant Answers*
Is there any music genre that you would like to listen to?	
Is there any specific song title that you would like to listen to?	
Is there any music artist that you would like to listen to?	
Would you like to hear music that is more instrumental, more vocal, or do you have no preference?	
Would you like to hear music that is more acoustic, more electric, or do you have no preference?	
Would you like to hear music that is more calming, more energetic, or do you have no preference?	
Would you like to hear music that is more cheerful, more melancholic, or do you have no preference?	
Would you like to hear music that is more popular, less popular, or do you have no preference?	
Would you like to hear music that is recorded in studio, do you prefer live recordings of music, or do you have no preference?	

Appendix D

All Patients Behavioral Pain Assessments Data Collection Form

Date of data collection (Y-M-D): _____ Period: ❑ 1st ❑ 2nd Rater ID: _____ ICU Adult Patient Participant ID: ____

Time	___ : ___	___ : ___	___ : ___	___ : ___
	T_0: Pre intervention	**T_1: Post intervention, pre-turning**	**T_2: Immediately post turning**	**T_3: 30 minutes post turning**
Facial expression	Relaxed 0 Tense 1 Grimace 2	Relaxed 0 Tense 1 Grimace 2	Relaxed 0 Tense 1 Grimace 2	Relaxed 0 Tense 1 Grimace 2
Body movements N=Normal position	Immobile, N 0 Protection 1 Agitation 2	Immobile, N 0 Protection 1 Agitation 2	Immobile, N 0 Protection 1 Agitation 2	Immobile, N 0 Protection 1 Agitation 2
Muscle tension	Relaxed 0 Tense 1 Very tense 2	Relaxed 0 Tense 1 Very tense 2	Relaxed 0 Tense 1 Very tense 2	Relaxed 0 Tense 1 Very tense 2
Vocalization N=Talking in normal tone	No sound, N 0 Sighing, moaning 1 Crying out, sobbing 2	No sound, N 0 Sighing, moaning 1 Crying out, sobbing 2	No sound, N 0 Sighing, moaning 1 Crying out, sobbing 2	No sound, N 0 Sighing, moaning 1 Crying out, sobbing 2
TOTAL (0 to 8)	____	____	____	____
Notes				

Appendix E

Critical-Care Pain Observation Tool

Facial expression	Relaxed, neutral	0
	Tense	1
	Grimace	2
Body movements	Immobile, normal position	0
	Protection	1
	Agitation	2
Muscle tension	Relaxed	0
	Tense, rigid	1
	Very tense or rigid	2
Compliance with the ventilator **OR** **Vocalization**	Alarms not activated, easy ventilation	0
	Coughing, alarms activated but stop spontaneously	1
	Blocking ventilation, alarms frequently activated	2
	Talking in normal tone or no sound	0
	Sighing, moaning	1
	Crying out, sobbing	2
TOTAL (0 to 8)		____/8

(Gélinas et al., 2006)

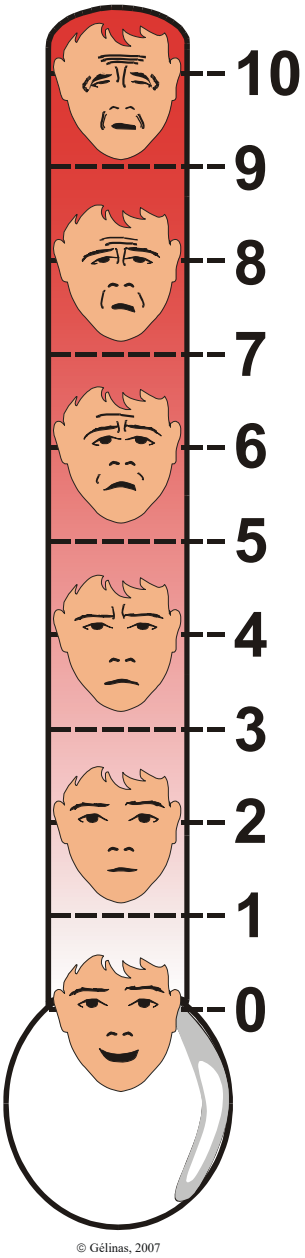
Appendix F

Patients Able to Self-Report Sensory and Emotional Pain Data Collection Form

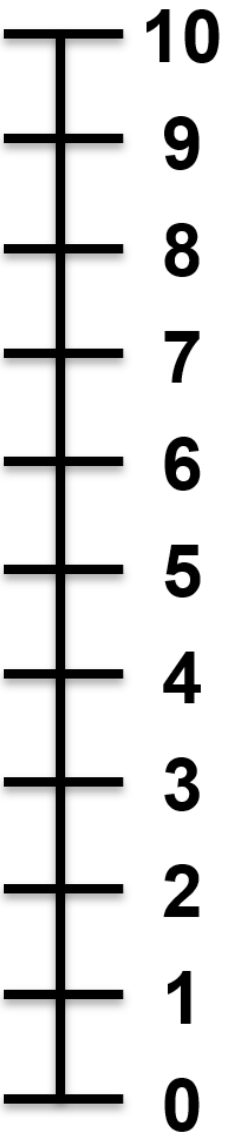
Date (YY-MM-DD): _____Time: ____: _____ Patient participant ID: _____

Please circle:

How intense is your pain right now, where 0 = no pain and 10 = worst possible pain?



How distressful (or bothersome) is your pain right now, where 0 = no distress and 10 = very distressing?



Appendix G

Patient Additional Pain Data Collection Form

Date of data collection (Y-M-D): _____ ICU adult patient participant ID: _____

ICU adult patient participant choice *(if able to self-report)*: ❑ Headphones ❑ Music pillow*

Period: ❑ 1st ❑ 2nd RASS: _____ CAM-ICU: ___

Analgesia: ❑ No ❑ Yes, name/dose/time: _____

Sedative: ❑ No ❑ Yes, name/dose/time: _____

Other complementary intervention for pain management in the ICU: ❑ No❑ Yes: _____

After the 2nd period *(for ICU adult patient participants able to self-report)*

Before the study, did you expect that music would relieve your pain? ❑ Yes: ❑ No ❑ Unsure

If so, how much, from 0 to 10:

0 (does not work at all) and 10 (complete pain relief): ___/10

Now, do you think that music played a role in relieving your pain? ❑ Yes: ___/10 ❑ No ❑ Unsure

If "Yes": was this impact meaningful to you? ❑ Yes: ___/10 ❑ No ❑ Unsure

Additional comments: _____

_____

_____

_____

*N.B. All ICU adult patient participants unable to self-report will be given the music pillow, by default.

Appendix H

Acceptability Questionnaire

Participant ID: _____ Date: _____

For each question, please rate the level of acceptability from 0 to 4, with comments as needed.

Question	**Acceptability**	**0** (Not at all)	→	**4** (Very Much)
How appropriate (logical) does this music intervention seem to be to help you/patients reduce pain?	Rating: **0** **1** **2** **3** **4** Note:			
How suitable does the music intervention seem for you/patients in the intensive care unit setting?	Rating: **0** **1** **2** **3** **4** Note:			
How easy do you think it would be for you to: ❑ use (as a patient) ❑ help give (as a significant person) ❑ support/assist with (as a nurse/orderly) …this music intervention?	Rating: **0** **1** **2** **3** **4** Note:			
How effective do you think this music intervention is in reducing acute pain?	Rating: **0** **1** **2** **3** **4** Note:			
How severe do you think are the risks or side effects of this music intervention?	Rating: **0** **1** **2** **3** **4** Note:			

Additional question *(to the ICU adult patient participant able to self-report)*:

Did you prefer when you had the headphones/pillow with the music or when you had the headphone/pillow without any music? ❑ With music ❑ Without music ❑ Unsure

Comments: _____

_____

Appendix I

Feasibility Data Collection Forms

Patient Participant ID: _____ Date: _____

Feasibility of POMI	YES	NO
For ICU adult patient participants unable to self-report: Significant persons were available at the bedside		
Less than 10 minutes was spent creating the music playlist. Total duration: _____ minutes		
There were issues in the production of the playlist. If so, state the reason(s): _____		
At least one feature needed further explanation to the ICU adult patient or significant person participant. If so, state which feature(s): _____		
There were issues with the headphones/pillow at any point during the POMI. If so, state the reason(s): _____		
There were issues with the music coming through the headphones/pillow. If so, state the issue(s): _____		
The ICU adult patient participant skipped at least one music piece during the POMI. If so, state the reason(s) for skipping and how many pieces were skipped (_____ music pieces skipped).		
Did the ICU adult patient participant receive the full duration of the intervention? Duration of intervention received: _____ min.		
ICU adult patient participants able to self-report stated they were familiar with the music that was played		
The noise levels in the room interfered with the POMI. If so, describe the noise(s) type, duration, and impact: _____		
There were interruptions to the delivery of the POMI. If so, describe the interruption(s) type and impact: _____		
The ICU adult patient participant received at least one pharmacological intervention for pain during the POMI? State the medication, the dosage, and the route of administration. _____		

Patient Participant ID: _____ Date: _____

Fidelity Checklist*	*YES*	*NO*
The ICU adult patient or significant person participant was met to produce a music playlist based on the ICU adult patient participant's music preferences.		
A brief presentation of the POMI app was done, with the following points being addressed: - that the playlist would be based on the ICU adult patient participant's music preferences - that there would be a choice between 1 and 5 music genres/tracks/artists to be made - that a series of 6 choices of various music attributes (with the option of no preference) would be given - that based on these choices, a personalized music playlist would be produced - the ICU adult patient/significant person participants were given the opportunity to ask questions		
The personalized playlist was produced based on the ICU adult patient participant's music preferences.		
If needed, the explanation of any music attribute was provided, using the descriptions provided in the app (e.g., vocal vs instrumental, electric vs acoustic, calming vs energetic).		
The headphones were put on the ICU adult patient participant's head or the music pillow was put under the ICU adult patient participant's head.		
The music played as expected through the headphones or music pillow.		
The music played for the planned duration of the POMI. Exact duration: _____ minutes - If not, the music was played for at least 20 minutes (minimally effective dose).		
The music started _____ minutes before the planned turning procedure.		
The ICU adult patient participant's pain was assessed at all the planned time points.		
Were there any challenges with the delivery of the POMI? If so, specify:		

* These items will only be evaluated as part of the fidelity of the POMI delivery and not during the control period. The ICU adult patient's music preferences will be recorded on the "Music Preferences Data Collection Sheet".

Feasibility of Research Methods	*YES*	*NO*
The ICU adult patient participant or significant person participant signed the consent form. If not, state reason(s): _____ _____		
The ICU adult patient participant received the allocated sequence, as planned. If not, state the reason(s): _____ _____		
There was an adequate washout period of at least four hours. If not, state the reason(s): _____ _____		
The pain assessor was blind to the group allocation. If not, state the reason(s): _____ _____		
There is missing data (e.g., no pain assessment). If so, state the reason(s) (e.g., ICU adult patient participant opted out of video recording): _____ _____		
The ICU adult patient participant data is excluded from the analysis. If so, state the reason(s): _____ _____		
The ICU adult patient participant withdrew from the study (state reason for withdrawal, if known): _____ _____		