Music therapy as an adjunct in cardiac device lead extraction procedures

A randomized controlled trial

Stine Camilla Blichfeldt-Ærø

Department of Cardiology,
Oslo University Hospital Ullevål

NMH Publications 2021:4

Norges musikkhøgskole
Norwegian Academy of Music

CREMAH
Centre for Research in Music and Health

Music therapy as an adjunct in cardiac device lead extraction procedures

A randomized controlled trial

Stine Camilla Blichfeldt-Ærø

Dissertation for the PhD degree
Norwegian Academy of Music, Oslo 2021
NMH Publications 2021:4

Department of Cardiology
Oslo University Hospital Ullevål

NMH Publications 2021:4

ISSN 0333-3760
ISSN 2535-373X (online)
ISBN 978-82-7853-295-9 (printed)
ISBN 978-82-7853-296-6 (pdf)

Norwegian Academy of Music
PO Box 5190 Majorstua
0302 OSLO
Tel.: +47 23 36 70 00
E-mail: post@nmh.no
nmh.no

Typesetting and printing: Bodoni, 2021

Acknowledgements

After almost 20 years with clinical work as my main focus as a music therapist, the last years' transition towards research and the academics has been highly motivating, engaging, and inspiring, but also challenging, frustrating, and, not least, personally developing. I wish to thank the PhD program and Centre for Research in Music and Health at the Norwegian Academy of Music for giving me the privileged opportunity of working with this project within a full-time PhD scholarship. I am deeply grateful for all the help and support I have received along the way.

First of all, I wish to thank my two supervisors, professor Gro Trondalen and professor Sigrun Halvorsen for walking the distance so patiently with me. They have both been available for questions and guidance throughout the whole period, shared their knowledge, provided caring support, and read a severe number of mails and manuscripts. A special thanks to Gro for helping me not losing focus too much during the ride.

I will express my gratitude to the staff at the PM/ICD centre at Oslo University Hospital Ullevål for welcoming the study, for their hospitality, and their crucial contributions to the project. I would especially like to thank my two main contacts, the department manager at the centre Hege Merethe Hagen and the chief cardiologist Thomas M. Knutsen, for their engagement and professional support. I also wish to thank the participants involved in the study for the willingness to take a risk on the new experience of music therapy.

Let me also thank Lien My Diep for statistical guidance and calculations, and Nils Nadeau for his diligent proofreading of the papers and thesis.

Being surrounded by the artistic, intellectual, and reflective environment of colleagues and PhD fellows at the Norwegian Academy of Music has been a great pleasure and a source of motivation these years. A special thanks go to Sunniva and Ville, with whom I have shared office, thoughts, laughs, and tears the entire period. For this, I am very grateful.

I am forever grateful to the Norwegian pioneer within this field, my dear mentor and friend Trygve Aasgaard, for his pioneering work, his ever-generous encouragement, and not least, the musicking! A big thanks also to my regular, supportive colleagues at Oslo University Hospital Rikshospitalet, Tone, Julie, and the entire S-BUP department, and also to our Nordic network of music therapists in paediatrics. Your courage and constant energy of further developing music therapy within medical health care is inspiring and of outmost importance.

Finally, I wish to thank my friends and family for their unconditioned love and support during this roller-coaster ride. Especially to my bestie, Live, my supportive parents, and the best bunch of siblings! Also, not least, my husband Arnfinn for his endless love, patience and generosity, our four sons, Elias, Isak, Hauk, and Linus for repeatedly cheering, and the whole tribe for all the volleyball-matches during our corona-lunch breaks. You're simply the best!

Vårli, May 2021
Stine Camilla Blichfeldt-Ærø

Abstract

This PhD study aims to evaluate music therapy as an adjunct for adult cardiac patients during a specific invasive procedure: the extraction of leads from pacemakers or implantable cardioverter defibrillators. The procedure is complex and lasts between two and six hours. It is performed in local anaesthesia and often associated with some stress and pain for the patients, despite the analgesic and anxiolytic drugs given. A randomized controlled trial was conducted to investigate the impact of music therapy on pain, satisfaction with pain management and other stress responses during the procedure. Although previous research does indicate that both music medicine and music therapy are effective for patients' stress regulation, its use as a resource at somatic hospitals tends to be relatively slight. More music therapy studies are called for, particularly within perioperative settings and for the detailed description of the clinical intervention.

For this particular study, a clinical music therapy protocol called *Facilitated Music Listening* was developed to support patients during the medical procedure, combining standardized and flexible intervention elements on a basis of biopsychosocial principles. The intervention was receptive, emphasizing feasibility on site, individual guidance of coping strategies, and patient involvement.

The selected sample involved patients who were scheduled for a cardiac lead extraction procedure in local anaesthesia at Oslo University Hospital (OUS) Ullevål during the period 01.03.2018–30.09.2019. The 64 total patients were randomized either to the music therapy group (n=32) or the control group (n=32). Patients in the music therapy group received music therapy in addition to the standard treatment, while patients in the control group received the standard treatment without music therapy.

The primary outcomes of the RCT involved the patients' satisfaction with the pain management and the average level of pain felt during the procedure, as measured via self-reported levels on numeric scales. Secondary endpoints included average anxiety intensity, the need for analgesic/anxiolytic drugs, blood pressure, heart and respiration rate, and oxygen saturation during the procedure. As additional data, patients in the music therapy group were asked to rate their satisfaction with the music listening, and invited to provide written reflections of their experience with the same.

Music therapy during cardiac device lead extraction procedures was both feasible and safe. The patients were highly satisfied with the pain management and experienced very little pain both with and without music therapy as an adjunct during the procedure. No significant differences were found between groups with respect to the primary endpoints. Of secondary endpoints, patients who received music therapy did show reduced anxiety during the procedure, particularly in the postoperative phase. They also reported high satisfaction with the music listening. No differences were found on physiological parameters or the use of procedure medication.

The anxiety levels and supplementary analyses of additional data, including the qualitative written material, suggest that Facilitated music listening may be supportive for the patients in terms of experienced procedure coping and overall wellbeing.

The thesis consists of three papers. All papers are written by the candidate as first writer, with contributions from co-writers who met authorship criteria according to the Vancouver recommendations from the

International Committee of Medical Journal Editors (ICMJE). The author contributions have been as follows (authors listed by initials):

S.C.B.-Æ., G.T. and S.H. conceived and planned the project, S.C.B.-Æ. wrote the original drafts and G.T. and S.H. supervised and revised the manuscripts.

S.C.B.-Æ., T.M.K. and H.M.H. performed the experiment, contributed to acquisition of data, and revised the manuscript of Paper II.

S.C.B.-Æ. and L.M.D. contributed with data analysis and interpretation, supervised by S.H. and G.T.

Sammendrag

Formålet med dette doktorgradsprosjektet er å utforske musikkterapi som støttebehandling for voksne hjertepasienter under en spesifikk invasiv prosedyre; ekstraksjon av elektroniske ledninger fra pacemaker eller hjertestarter. Prosedyren er kompleks med en varighet på to til seks timer. Den utføres i lokal anestesi og er ofte forbundet med noe stress og smerte for pasientene på tross av beroligende og smertestillende medisinering. En randomisert kontrollert studie ble gjennomført for å vurdere effekten av musikkterapi på smerte, tilfredshet med smertebehandling, og andre stressresponser i løpet av prosedyren.

Selv om tidligere forskning viser at både musikkmedisin og musikkterapi kan ha god effekt på stressregulering for pasienter, er bruk av musikk en lite utnyttet ressurs ved somatiske sykehus. Det er behov for flere studier av musikkterapi brukt som støttebehandling under medisinske invasive prosedyrer, der det gis detaljerte beskrivelser av den kliniske musikkterapiintervensjonen.

En klinisk musikkterapiprotokoll kalt *Facilitated Music Listening* ble utviklet som prosedyrestøtte for pasientene, med en kombinasjon av standardiserte og fleksible intervensjonselementer basert på biopsykososiale prinsipper. Intervensjonen besto av reseptiv musikkterapi, med vekt på gjennomførbarhet i den aktuelle situasjonen, individuell veiledning av mestringsstrategier, samt pasientmedvirkning.

Deltagere i studien var pasienter henvist til Oslo universitetssykehus Ullevål for fjerning av infiserte eller ødelagte ledninger fra pacemakere/hjertestartere i tidsrommet 01.03.2018–30.09.2019. Totalt 64 pasienter ble tilfeldig fordelt til henholdsvis musikkterapigruppen (n=32) og kontrollgruppen (n=32). Pasienter i musikkterapigruppen fikk musikkterapi i tillegg til standard behandling. Pasienter i kontrollgruppen fikk standard behandling uten musikkterapi.

Det primære effektmålet var pasientenes tilfredshet med smertebehandlingen og gjennomsnittlig smertenivå i løpet av prosedyren, målt ved egen-rapportering på numeriske skalaer. Sekundære endemål var gjennomsnittlig nivå av engstelse[1], forbruk av beroligende og smertestillende medikamenter, blodtrykk, respirasjonsfrekvens, hjerterytme og oksygenmetning i blodet under prosedyren. Som tilleggsdata ble pasienter i musikkterapigruppen bedt om å skåre hvor fornøyde de var med musikklyttingen, og oppfordret til å gi en skriftlig kommentar om hvordan de opplevde denne.

Musikkterapi under ekstraksjon av ødelagte eller infiserte ledninger fra pacemakere og hjertestartere viste seg å være gjennomførbart og trygt. Pasientene var meget fornøyde med smertebehandlingen og opplevde lite smerter både med og uten musikkterapi som støtte under prosedyren. Det ble ikke funnet noen signifikant forskjell mellom de to gruppene relatert til de primære endepunktene. Av sekundære endepunkter viste musikkterapigruppen gjennomsnittlig mindre engstelse enn kontrollgruppen, i særlig grad postoperativt. De rapporterte også stor tilfredshet med musikklyttingen. Det ble ikke funnet noen effekt på fysiologiske parametere eller bruk av medikamenter.

1 I prosjektet brukte vi begrepsparet *engstelse/uro* som ekvivalent til det engelske ordet *anxiety*, da ordet *angst* i større grad assosieres med mer alvorlige patologiske tilstander i norsk dagligtale. For bedre lesbarhet brukes kun ordet engstelse i denne teksten.

Nivåene av engstelse samt supplerende analyser, inklusive det kvalitative skriftlige materialet, fremhever at Facilitated music listening kan fungere støttende for pasientene relatert til opplevelser av prosedyremestring og velvære.

Avhandlingen består av tre artikler. Alle artiklene er skrevet av kandidaten som førsteforfatter, med viktige bidrag fra medforfattere i henhold til Vancouver-reglene fra the International Committee of Medical Journal Editors (ICMJE). Forfatterbidragene har vært som følger (forfattere benevnt ved initialer):

S.C.B.-Æ., G.T. and S.H. planla forskningsprosjektet, S.C.B.-Æ. skrev de opprinnelige artikkelutkastene, G.T. og S.H. veiledet og reviderte manuskriptene.

S.C.B.-Æ., T.M.K. og H.M.H. utførte eksperimentet, bidro til innsamling av data, samt reviderte manuskriptet til artikkel II.

S.C.B.-Æ. og L.M.D. bidro med dataanalyser og tolkning, veiledet av S.H. og G.T.

List of papers

Paper I: Facilitated music listening *(published)*

Blichfeldt-Ærø, S. C., Trondalen, G., & Halvorsen, S. (2019). Facilitated music listening: Music therapy in an invasive cardiac procedure. *British Journal of Music Therapy, 33(1), 27–38. https://doi.org/10.1177/1359457519840131*

Paper II: Music therapy as an adjunct in cardiac device lead extraction procedures: A randomized controlled trial (*published*)

Blichfeldt-Ærø, S.C., Knutsen, T.M., Hagen, H.M., Diep, L.M., Trondalen, G., & Halvorsen, S. (2020). Music therapy as an adjunct in lead extraction procedures from cardiac implantable electronic devices: A randomized controlled trial. *Applied Nursing Research. 56(December). https://doi.org/10.1016/j.apnr.2020.151376*

Paper III: Music therapy in invasive cardiac procedures: Expanded perspective (*submitted for publication*)

Blichfeldt-Ærø, S. C., Halvorsen, S. & Trondalen, G.

Content

List of abbreviations

BP	Blood pressure
BPS	Biopsychosocial approach
CA	Content analysis
CIED	Cardiac implantable electronic device
FaMuLi	Facilitated Music Listening
GIM	Guided Imagery and Music
HR	Heart rate
ICD	Implantable cardioverter-defibrillator
NMH	Norwegian Academy of Music (Norges musikkhøgskole)
NRS	Numeric Rating Scale
NVAAS	Numeric Visual Analog Anxiety Scale
OUS	Oslo University Hospital
PM	Pacemaker
RCT	Randomized controlled trial
RR	Respiration rate
SaO2	Oxygen saturation
STAI /STAI -S	State-Trait Anxiety Inventory / STAI – Short form
VAS	Visual analogue scale

1 Introduction

1.1 Context of the study

For many years, cardiovascular diseases have presented itself all over the world. These diseases have been the most common cause of death across Europe, although they were recently passed by cancer in some individual countries, including Norway (Timmis et al., 2019). As a result of innovations in modern medicine, and an ageing population, an increasing number of cardiac patients now survive severe cardiovascular events, including heart attacks and cardiac arrhythmias. However, many of these patients live with chronic heart diseases for many years. This survival often entailes implants of cardiac electronic devices and associated follow-up treatments, repeated admissions to the hospital and medical procedures which are experienced as more or less stressful for the patients. A complex procedure commonly causing increased stress and pain to cardiac patients with cardiac implantable electronic devices is cardiac device lead extractions. Norway ranks very high among the European countries when it comes to the number of lead extraction procedures performed per million inhabitants (Platou, 2019).

Over time, we have gained substantial new knowledge about the way in which the presence of life-threatening diseases and medical procedures can induce a stress response in patients which can aggravate their health conditions both immediately and in a long-time perspective. Stress can trigger a whole complex of biopsychosocial reactions, with consequences for medical treatment and patient care. In general, in the ongoing search for applicable, effective, and implementable methods of addressing both disease and stress, a heightened awareness of the latter has introduced a broader range of professions into hospitals to supplement the primary professions of medical doctor and nurse. These additional caregivers bring with them the imperative of increased inter-disciplinarity, with regard to patient-centred care and the use of non-medical treatments and supportive functions, all for the benefit of the patients So, too, non-medical regulation of stress and pain during invasive cardiac procedures is receiving increased attention in the field (Dornelas, 2012).

The positive effects of music have long been both experienced and actively deployed or utilized by people in their everyday lives (Bonde, Skånland, Ruud, & Trondalen, 2013). Relatedly, modern music therapy has gradually evolved into a profession and discipline with strong connections between theory and practice, now presenting as a reflective practice based on theory and research and informed by clinical practice (Aigen, 2014; B. L. Wheeler & Murphy, 2016). The systemic knowledge of the positive effects of music interventions related to surgery and medical procedures is at once growing, and increasingly convincing. Still, the systematic implementation of music therapy services related to medical procedures is rare, and medical hospitals need help finding the right path forward – one focused on clinical details, issues of implementation and relevant logistics. How, that is, should music therapy services be prioritized and provided? When? For whom? For how long? In relation to what kinds of music activities? The questions have been considered by both music therapists and medical academics (Dileo, 2016; Glasziou, 2015; Hanser, 2014; Palmer, Lane, & Mayo, 2017; Rolvsjord, Gold, & Stige, 2005), and detailed music therapy protocols for specific medical situations, and particularly perioperative interventions, have been called for (Dileo, 2016; Hanser, 2014; Koelsch & Jancke, 2015; Palmer, Lane, Mayo, Schluchter, & Leeming, 2015). The current thesis is a response to this call.

International studies of music medicine and medical music therapy frequently focus on the effects of biomedical regulation and psychometric measures. General preprocedural anxiety and procedural pain are addressed collectively, or in terms of specific procedures (Bradt, Dileo, & Shim, 2013; Hole, Hirsch, Ball, & Meads, 2015; J. H. Lee, 2016). Cardiac procedures such as cardiac catheterization and coronary angiography are well represented in the literature evaluating music interventions as an adjunct for patient stress, pain, and anxiety (Bradt, Dileo, & Potvin, 2013; Jayakar & Alter, 2017). In Norway, in particular, researchers have primarily explored the ecological, environmental, and humanistic aspects of paediatric music therapy within medical music therapy (Aasgaard, 2002), an interest informing the music therapy service which have become available at Norwegian hospitals (S.B. Ærø, 2016). There persists an abiding need for more experience, practice, and research within music therapy in adult medical care in the Northern countries.

Lastly, in terms of the conditions giving rise to the current study, the general demand for cardiac implantable electronic devices is increasing, and with it an accompanying rise in need for cardiac device lead extractions (Bongiorni et al., 2016). At Oslo University Hospital (OUS) Ullevål in Norway, a lead extraction procedure is usually performed transvenously in local anaesthesia and some procedural sedation. Despite the given drugs, most patients will experience some degree of pain and/or anxiety during the procedure. While these procedures have a very high rate of clinical success at OUS Ulleval, improvements could address the stress felt by the patients and otherwise facilitate their involvement and relaxation. There is presently a gap in the literature and studies concerning patient stress, experienced pain, and anxiety related specifically to cardiac device lead extractions procedures.

In sum, the potential of music therapy as an adjunct for adult cardiac patients is underrealized, and it has never before been investigated for cardiac device lead extraction procedures. Also, more studies of music therapy as general procedure support are called for. Additionally, the field needs explorations of different approaches and possibilities for the future of music therapy in medical health care, including the development of clinical protocols, the evaluation of a variety of effects and patient preferences, and the cultivation of interdisciplinary experiences of implementation and collaboration concerning these efforts.

This study is initiated as a collaborative research initiative between Centre for Research in Music and Health (CREMAH) and the Department of Cardiology at OUS Ullevål in the joint interest of investigating music therapy as a possible adjunct during invasive cardiac procedures to improve existing patient treatment and care.

1.2 Personal motivation

My personal motivation for this PhD study derives from many years of clinical work as a music therapist within the field of medical practice at the Division of Pediatric and Adolescent Medicine at Oslo University Hospital Rikshospitalet. Already as a music therapy student, studying Trygve Aasgaard's practice at the children's cancer ward, I witnessed the impact of music therapy upon paediatric patients' motivation and joy, healthy development of identity and social skills, and expressions of creative selves (S. B. Ærø & Aasgaard, 2011). Later, through my practice at the hospital, the attention was also drawn towards the ways in which highly qualified biomedical perspectives on severe diseases also relates to the music therapy profession. The biological regulating effects of musical activity and receptive musical stimuli were regularly noticed,

displayed by monitoring systems, and through observable clinical changes in breathing, sleep, and the need for medication. I realized that music therapy could carve out space for psychosocial human qualities within the hospital environment and with a subsequent impact on the biomedical status quo.

As a music therapist, I am deeply engaged in supportive care for hospitalized patients facing existential challenges and situations. Invasive cardiac procedures might represent a condensed situation where music therapy can make a positive difference for the patients by harnessing the beneficial combination of an aesthetic experience, a relational space, and neurobiological regulation (Metzner, 2012). Through my training in Guided Imagery and Music (step II) and recent participation on the research team of a multi-site study (Sanfi, 2018), I have expanded my knowledge about and the experience with the effectiveness of receptive music therapy methods (Grocke, 2016; Sanfi, 2012a). A receptive intervention was evaluated to be most suitable for the chosen invasive cardiac procedure.

What has also gradually captured my interest over the years is the discursive gap which often characterizes the premises of music therapy practice and professional development within medical settings. Music therapy initially represents a humanistic tradition within the humanities which is now being performed within the walls and with the premises of natural science, to which the medical tradition belongs. Discursive differences can appear in aspects of patient treatment and care, interdisciplinary communication, consequences for the implementation of music therapy, and organizational affiliation. Besides increasing the general knowledge of music therapy as an adjunct in invasive cardiac procedures, I was also motivated to explore and extend my experience and knowledge of interdisciplinary cooperation within diverse hospital discourses. Initially, my wish was to include aspects of the discursive gap to a greater extent in this thesis, but as the study evolved, it was decided to keep a more restricted focus on the randomized controlled trial. The broader interdisciplinary perspective is, however, still there as an interest inspiring my research projects to come.

1.3 Structure of the thesis

The initial introductory chapter 1 presents the context of the study, the personal motivation of the candidate and an outline of the these's structure.

The theoretical framework appears in chapter 2, in four sections. Section 2.1 represent an epistemological prelude which positions the thesis among various systemic perspectives. The next three sections review the existing literature using the central themes of the study, as follows: 2.2. Presentation of the medical procedure of cardiac device lead extractions according to current treatment practice and contexts. 2.3 Presentation of existing theories and literature concerning stress, pain, and anxiety which are relevant to the current study. 2.4 Presentation of theories and literature concerning music medicine and music therapy in adult medical care, specifically for cardiac patients and certain medical procedures, as well as a rationale for the use of sounding music in this study.

Chapter 3 presents the overall aim of the thesis, the hypothesis, and focused research objectives.

Chapter 4 presents a comprehensive description of the study's methods. The first four sections of this chapter (4.1–4.4) address the initial part of the trial: the background for the overall methodological choices, the study's design, a timeline of the study's implementation, and a description of the participants. Section 4.5 looks at the clinical music therapy intervention, and 4.6 covers the hospital context around the procedure itself, related to schedule. The next three sections (4.7–4.9) present the chosen outcome variables and the procedures for data collection and analyses. Section 4.10 includes an outline of ethical considerations.

Chapter 5 includes a brief summary of the most central elements and findings of the three papers included in this thesis. The findings reported in the papers are further discussed in chapter 6 in relation to the theoretical framework.

In addition to a review of the methodology and results (6.1–6.2), the discussion chapter 6 also includes a section considering on the discourses, the role of the music therapist, and the actual sounding music used in the study (6.3). The last section (6.4) engages with the strengths and limitations of the study.

Finally, chapter 7 comprise the conclusions of the thesis, and chapter 8 the related emergent perspectives on music therapy as an adjunct in invasive cardiac procedures.

2 Theoretical framework

2.1 Epistemological prelude

The importance of clarifying one's epistemological perspective may be seen as profound in the field of medical music therapy. This generally systemic and humanistic field, after all, must interact with a biomedical discourse, which is first and foremost grounded in the natural sciences. While the natural sciences encompass the empirical study of the concrete and visible phenomena of nature, the human sciences label the study of that which is explicitly human, including cultural, social, and spiritual phenomena.

The disparity in both tradition and scholarly culture across these fields of study, including both ontological and epistemological aspects, can lead to disputes concerning patient care in everyday practice within hospitals. The dualistic split between body and mind formulated by Descartes in the seventeenth century shaped the Western pathological understanding of health, illness, and treatment which informs the current medical model (Damasio, 2002). Cartesian terms and expressions have also had a decisive impact on the development of profession discourses, as well as the everyday language of the West (Changeux & Ricoeur, 2000). Eventually, Descartes and the classical natural sciences to which he gave rise, began to be interrogated for a false dichotomy between sickness and health, and the research methods of failing to capture the essence of humanity. The medical model (that is, biomedicine), in turn, came under attack for ignoring the immense impact of psychosocial factors and patient-centred care in its engagement with health issues. (Bensing, 2000; Havelka, Lucanin, & Lucanin, 2009; Kristeva, Moro, Ødemark, & Engebretsen, 2018).

2.1.1 Systemic perspectives

Operating in a field of practice and research which straddles two different epistemological cultures, the naturalistic and the humanistic, this thesis is grounded in ontological and epistemological perspectives of a systemic nature which seek to bridge this gap. Theories and approaches informing this theoretical stance are found within systemic perspectives[1], such as *critical realism*, and the *biopsychosocial approach*. In addition, a systemic perspective is likewise reflected in theoretical models of stress, pain and anxiety, and of music therapy as procedural support, all of which are relevant to the present study. Both general system theory and the biopsychosocial approach originate in the natural sciences, and have ambitions to renew and develop, rather than undermine or discard existing achievements. Critical realism shares this view as well, acknowledging the importance of methods and knowledge within the natural sciences, while insisting that any one perspective will fall short of capturing the complexity of these contexts.

As a philosophical stance, critical realism has been found to be relevant for systemic complexity (Maxwell & Mittapalli, 2010). Roy Bhaskar developed critical realism in the 1960 and 1970s as a viable alternative to positivism which was based on a naturalistic view of science (Bhaskar, 2011). At an ontological level,

1 Systemic perspectives: a general term of perspectives originating in the General system theory developed by the biologist Paul Weiss and the philosopher Ludvig Bertlanaffy in the early 1920s. They found that all living organism necessarily must be considered as part of a system, not isolated. As continuums, the different parts of a system were seen as mutually influential. General system theory aimed to provide a new paradigm of knowledge through shared platforms of research development with integrated knowledge from diverse theoretic orientations (Bertalanffy, 1977; Weiss, 1977).

critical realism acknowledges the existence of realities in the world – that is, the way things are. Realities exist, it says, independent of our ability to observe or understand them. At the same time, it acknowledges that epistemological processes are affected and modulated by context, that is, human possibilities and constraints, and situatedness. In sum, the dynamic context and realities address the way of gaining knowledge.

Critical realism claims that it is impossible to use only one perspective or research method, and still expect to disclose the whole truth. This is in line with the biopsychosocial approach, a systemic perspective frequently applied in health care practice and research (Maxwell & Mittapalli, 2010; Pilgrim, 2015) which also served as a basis for the music therapy intervention in the present study.

2.1.2 The biopsychosocial approach

The biopsychosocial approach was originally developed by George Engel. Based on general system theory, his "biopsychosocial model" was meant to extend or replace the existing medical model which Engel deemed insufficient (Engel, 1977, 1980; Frankel, Quill, & McDaniel, 2003b; Wynne, 2003). Engel pointed out that the onset of every disease was accompanied by physiological, behavioural, and relational changes, and all of these changes should comprise any starting point for the processes of diagnois and treatment. Given the biomedical focus of the medical model, behavioural, and relational changes were not being systematically considered, and Engel sought to remedy this oversight (Engel, 1977, 1980).

In the aftermath of his work, critics have pointed out that Engel's contribution does not qualify as a model or theory as such, because it does not feature the formal specifications which would be required (Frankel, Quill, & McDaniel, 2003a; Smith, Fortin, Dwamena, & Frankel, 2013). Instead, it should be considered an approach. In any case, it has informed the transition towards patient-centred health care and treatment in the last few decades, influencing traditional medical care and related disciplines such as psychosomatic medicine, psychoneuroimmunology, the medical humanities, and music therapy (Dileo, 2015; Falkum, 2008; Frankel et al., 2003b; Hanser, 2014; Kristeva et al., 2018).

The biopsychosocial approach (hereafter BPS) serves as a useful tool for combining knowledge from the medical natural sciences and the humanities in the interest of a more integrated clinical gaze than that which is provided by biomedicine. The principal elements of systemic thinking which are included in the biopsychosocial approach inform the music therapy profession's fundamental understanding of health in general, and its description of medical music therapy in particular (Bruscia, 2014; Dileo, 1997, 2016; Hanser, 2014).

The following points summarize the basic principles of the current study:

- The music therapy intervention is developed on a BPS basis, and therefore relies on existing research which is naturalistic, humanistic, and/or systemic in character.
- Biological, psychological, and social factors are considered to be present interdependent and intertwined in patients during medical procedures.

Together, these systemic perspectives represent the overall theoretical positioning of the study and have implications for its clinical music therapy practice and the interpretation of its research design and results.

2.2 Cardiac device lead extraction procedures

The implantation of cardiac implantable electronic devices (or CIEDs) is a common (and essential) treatment for cardiac patients suffering from tachy- and bradyarrhythmia and advanced heart failure, described in plain language as a disturbance of the heart's rhythm (Perez, Woo, Tsang, & Carrillo, 2018). Since the first pacemaker was implanted around 1960, there has been a growing demand for CIED's in the population, including pacemakers (PMs) and implantable cardioverter-defibrillators (ICDs) (Bongiorni et al., 2016; Weinstock, 2019). This increase accompagnies an ageing and expanding population, but also reflects new medical knowledge within the area of cardiac health care. As a consequence, there has been a corresponding increase in the number of related procedures and complications involving the current devices, such as changing the batteries or generator, lead revision and lead extraction (Peal, Runnett, Thomas, & Ripley, 2018; Wazni & Wilkoff, 2016). The CIED system comprises a pulse generator and electronic leads which stabilize the heart rate. The PM/ICD is placed in a pre-pectoral pocket and fixed to the myocardium with between one and three connected electronic leads, depending on the model. The leads follows transvenous access, most often inside the subclavian vein, down to the right or left ventricle and atrium (Peal et al., 2018). PM/ICD lead management is complex, and a multidisciplinary team is engaged in general patient support and treatment which encompasses electrophysiologists, infectious disease specialists, echocardiographers, and cardiac surgeons (Wazni & Wilkoff, 2016).

Cardiac device lead extractions are defined as the removal of an electronic lead which has been implanted between the device and the heart for more than one year (Deharo et al., 2012). While open-heart surgery was used for this procedure three decades ago, transvenous lead extractions are now the primary method used. The most common indications for lead extractions are system- and device-related infections, the latter associated with high mortality without lead extraction, removal of all hardware and the prescription of adjunctive antibiotic therapy (Perez et al., 2018). Removal of infected indwelled leads is difficult and brings with it a heightened risk of vein perforation. Other indications for lead extractions are device recalls, electronic lead failure, and loosened leads. Because lead extractions are technically challenging and carry a risk of vascular and/or cardiac injury, the operation is performed with a cardiothoracic surgery team on standby. The total duration of the procedure is two to six hours (Deharo et al., 2012), and the invasive phase[2] typically lasts between 45 minutes and three hours (Knutsen et al., 2015).

Risk factors for lead extraction procedures are influenced both by individual differences in patients, medical history, the operator,[3] and the type of CIED involved (Kusumoto et al., 2017). One way to prevent complications is the use of counter-pressure sheaths during the procedures. ICD leads are larger and more complex than PM leads, and thus more difficult to remove. The rate of procedural complications is also associated with the lead dwell time (Kusumoto et al., 2017). As major complications can occur, a lead extraction program must be performed at specialized medical centres and requires training and experience within a well-functioning, collaborative team to ensure safe and effective care (Bongiorni et al., 2016; Weinstock, 2019). Overall, the incidence of complications in lead extractions is low, but the mortality is high when complications occur. A review of Wazni et al. (2016) reports outcomes of major complications to be 0.7–1.9%, and procedural mortality 0.3–0.8%.

2 *The invasive phase* is defined as the time between the first cut through the skin and completion of the sutures.
3 *The operator* is the term used for the cardiologist performing these invasive procedures.

Standard in the pre-phase of any lead extraction procedures is a thorough assessment of patient history and cardiac and non-cardiac conditions, and medical tests are also required. One day before the procedure, medical pre-tests are taken, including blood samples, a chest X-ray, and a transthoracic echocardiogram. Preparation of the patient must also include adequate information concerning the potentially life-threatening consequences of the treatment inadvance of their informed consent and preferably in the presence of family members or other sources of social support (Kusumoto et al., 2017; Wazni & Wilkoff, 2016). Today, researchers are developing ways of reducing lead extraction procedures, including leadless pacemakers and subcutaneous ICD systems as alternative devices. For several years to come, however, transvenous systems will remain the premier strategy for treating cardiac conduction abnormalities including their related lead extractions (Perez et al., 2018).

At OUS Ullevål in Norway, this invasive procedure is usually performed in *local anaesthesia* and some procedural sedation, with the patient in a fasting state. Internationally, lead extractions are often performed with patients under general anaesthesia, by a medical team which includes an experienced operator, an anaesthetist, operating nurses, and a cardiac surgeon for support. Lead extractions at OUS Ullevål boast a 99% rate of procedural success (Knutsen et al., 2015). Local anaesthesia is preferred due to considerations such as the risk of complication, patient strain, and the use of hospital resources. Each operation team includes three specialized nurses and an experienced cardiac operator, as well as a cardiothoracic surgery team available but not present. Analgesic and anxiolytic drugs are given at the start of the invasive procedure, and additional doses are added if required. General anaesthesia is applied only in selected cases, due to high procedural complexity, low age (<25), or severe patient stress/pain/anxiety.

Despite the given drugs, most patients will experience some pain and/or anxiety during the procedure. The peak point of pain, typically at the precise point of extraction, is short. The ward coordinator and one patient-nurse have the main responsibility for patient flow[4] and patient contact during the preoperative and perioperative phases, including patient preparation before entering the operation theatre. The patient-nurse also provides medical drugs before and during the procedure according to standardized guidelines, clinical judgment, and directions from the operating cardiologist. To ensure good patient care, general descriptions from the Ethical Guidelines for Nurses and Code of Ethics for Doctors are followed, based on international principles of codes of ethics and fundamental human rights (ICN, 2011; Legeforening, 2015).

2.3 Stress, anxiety, and pain

Stress responses related to medical procedures can manifest as *state anxiety* (see more below), including the perception of *pain*, and/or *physiological arousal*. Stress, anxiety, and pain are interconnected and often concurrent phenomena sharing several characteristics regarding how they emerge/arises and are experienced, sustained and regulated. Basic knowledge of stress, state anxiety, and procedural pain, and their respective interrelatedness will now be presented and related to patients with cardiac diseases in relation to the given medical procedure.

4 "Patient flow is the movement of patients through a healthcare facility. It involves the medical care, physical resources, and internal systems needed to get patients from the point of admission to the point of discharge while maintaining quality and patient/provider satisfaction." Retrieved August 2020 from https://catalyst.nejm.org/doi/full/10.1056/CAT.18.0289

2.3.1 General theories of stress, pain, and anxiety

Stress is a natural part of our daily life and experiences as human beings, first presented and theorized by Selye (1976) as a label for an increase in our biochemical, functional, and structural activity. The etymological origin of the word is the Latin *stringere*—'draw tight, bind tight, compress, press together'. This experience of "tightness" typically occurs when one must adapt to new, demanding situations such as acute events or an injury.

Stress is defined as a constraining force or influence, which manifest in human beings as "a physical, chemical, or emotional factor that causes bodily or mental tension and may be a factor in disease causation" ("Stress", n.d.). Experiences of stress can be acute reactions to an event in the moment, or they can develop over time, as a reaction to chronic conditions (Aldwin, 2007; Pelletier, 2004). Variations, including surgical stress, are all part of the same underlying mechanism, but the effects of stressors are disparate (Selye, 1976). An event which triggers the physiological and emotional activation of stress responses may be experienced as positive or negative, and as challenging and motivating arousal or as harmful, threatening or discouraging (Folkman, 2007). Negative reactions are often referred to as *distress*—that is, pain or suffering of the body or mind (Selye, 1976). The cognitive appraisal of a situation is decisive for the ways in which stress responses manifests in each individual.

Emotional responses during an individual's experience of negative stress are described as states of subjective worries, including *state anxiety*, restlessness, or nervousness (Aldwin, 2007; Pittman & Kridli, 2011). For decades, researchers have operationalized state anxiety in various ways as a stress-related psychological outcome (Lazarus & Folkman, 1987; Pelletier, 2004). With regard to medical procedure support, it is also highly relevant to look more closely at how stress and anxiety are related to experiences of pain (Dornelas, 2012; Selye, 1976).

Pain has been usefully defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage", with this proposed qualifier: "Pain is always a subjective experience that is influenced to varying degrees by biological, psychological, and social factors" (Raja et al., 2020). The assessment of pain begins with the two main categories of chronic pain and acute pain, the second of which encompasses the procedural pain which is relevant to the present study. Procedural pain describes the experience of pain over a relatively brief period which has been clearly induced by specific conditions. In addition to the peripheral, physical stimuli of a procedure itself, the perceived level of this kind of pain is impaced by the psychosocial factors which modulate stress, tension, and anxiety, including any experiences and expectations which shape the individual's cognitive appraisal of the procedure situation (J. L. Allen, 2013a; Loeser & Melzack, 1999). The experience of pain, that is, represents another variable relevant to be operationalized as a psychological stress-related outcome.

Meltzack (2001) introduces the *neuromatrix model of pain* to illustrate and explain the complex interactions among stress and pain, emotions, sensory perception, and cognitive processes within the human body and brain, which manifeste in what he calls the body-self neuromatrix. The neuromatrix model points to a network of neurological loops determined by sensory, affective, and cognitive *input*. Cognitive input relates to personal traits and history, as well as attention, expectation, and anxiety in the moment. Sensory input can be tactile cutaneous, visual, vestibular or auditive and arrives through the neurological system or the internal organs. Affectional factors of stress and pain include activation of the hypothalamic-pituitary-adrenal

(HPA) axis in the autonomic, limbic and immune systems which are decisive for the production of hormones like adrenalin, noradrenalin, and cortisol (Melzack, 2001; Novack et al., 2007). The subsequent mobilization of the sympathetic nervous system, understood as *output*, results in the heightened arousal of physiological parameters, such as heart rate, respiration rate, myocardial oxygen, and blood pressure (DeWitte, Spruit, VanHooren, Moonen, & Stams, 2019; Wulsin, 2012).

Stress responses tend to disrupt the existent equilibrium in humans and are considered part of the pain perception process – that is, they represent an innate human capacity to maintain or reinstate biological homeostasis which is activated through physical or psychological factors in the person–environment transaction (Aldwin, 2007; Melzack, 2001). In addition to the biological reactions to stress and pain, Folkman (2007) emphasizes the importance of *emotions* in a redefinition of the *cognitive theory of stress and coping* (Lazarus & Folkman, 1987). Stressful situations, that is, are followed by a cognitive process of appraisal, including both positive and negative emotions. Combined with the biological reactions, the emotional responses are also included as part of the transaction, followed by *output* reactions and *reappraisal* of the situation, either automized or through an active use of coping strategies.

The findings of Melzack, Folkman and Lazarus show how stress and pain are experienced and modulated through biological, psychological, and social factors. In terms of this study, the two models formulate the complexity of the variables informing observed patient stress related to cardiac lead extraction procedures. Elements of the models are in line with recent scholarly interests in positive psychology, and, within the field of music therapy, there is a parallel in the resource-oriented approach (Rolvsjord, 2016). Self-efficacy, or the confidence to perform coping skills, appears to be particularly important to the stress/pain experience. The modulation of one's coping skills is a trainable capacity and has been shown to have an impact on pain perception related to both short- and long-term outcomes (Keefe & France, 1999).

Levels of stress and patient anxiety are relevant not only to patient wellbeing and satisfaction, but also to pain management, the use of medical drugs, and the effective implementation of procedures (Al-Azawy, Oterhals, Fridlund, Assmus, & Schunster, 2015; Argstatter, Haberbosch, & Bolay, 2006; Bradt, Dileo, & Potvin, 2013). Improved patient preparation, including all relevant information and substansive patient involvement, and pharmacological strategies are elements which may reduce patient anxiety and optimize pain management (Al-Azawy et al., 2015; Cohen, Edmondson, & Kronish, 2015; Delewi et al., 2017). In addition, the perceived level of pain during hospitalization has been shown to have a substantial effect on patient satisfaction (Bair et al., 2007). While there is a fair degree of consensus concerning the components of stress reactions, there is a disagreement among researchers about the order of causal directionality (Aldwin, 2007).

2.3.2 Stress in patients with cardiac diseases

Stress responses are manifested as biochemical and psychosocial outcomes and closely related to state anxiety and pain management in cardiac patients (Dornelas, 2012; Selye, 1976). As a consequence of possible hemodynamic changes, both chronic and acute stress are also reported to be psychosocial risk factors in developing cardiovascular diseases, to have an impact on the prognosis of the disease, and possibly to serve as a trigger for acute coronary syndromes (Piepoli et al., 2016). Generally, stress management and counselling about psychosocial risk factors are recommended as risk-factor interventions, and the importance of professional patient care is particularly emphasized: "Caregivers in clinical practice are in

a unique position to directly support their patients regarding psychosocial risk factors in individuals with high CV[5] risk or with established disease" (Piepoli et al., 2016, p. 2342). These factors demonstrate the need for highly competent and systematic use of patient-centred care and stress management for cardiac patients, to which the current study responds.

Patients with a severe diagnosis such as coronary heart disease are facing a potentially life-threatening situation which may lead to multiple hospital admissions and treatments over relatively extended periods. Most likely, these conditions prompt existential thoughts and emotions deriving from an uncertainty about the future and the necessity of dealing with medical side effects and painful procedures. In general, patients in cardiac care are exposed to a risk of depression, stress, anxiety, and pain (Herrmann-Lingen & Buss, 2007; Leist, 2013). While the empirical evidence of causality is mixed, an integrated preventive treatment focused on stress management has had a positive impact on adverse cardiac events (Cohen et al., 2015; Dornelas, 2012; Lukens, Turkoglu, & Burg, 2012). In particular, the experience of increased stress and anxiety is common to patients undergoing invasive medical procedures, particularly in the preoperative phase (Argstatter et al., 2006; Bradt, Dileo, & Shim, 2013; Delewi et al., 2017). When the invasive procedure involves an organ as vital as the heart, patients may feel utterly lost. The medical team involved in the current study have regularly observed increased stress responses in cardiac lead extraction patients.

There seems to be a lack of research studies specifically reporting the occurrence of stress, anxiety, or pain in patients undergoing cardiac device lead extractions. Characteristics of the procedure are comparable to related procedures such as cardiac catheterization or atrial fibrillation, and they presumably share their impact on the patients involved. The ability to cope with stress varies according to the individual, but some generalizing trends have been seen. Anxiety among patients undergoing coronary procedures is found to be higher for patients under 65 years old than for older patients in the preoperative phase ($p<0.001$), and higher for female patients than for male patients ($p=0.02$) (Delewi et al., 2017).

From a biomedical perspective, high levels of anxiety are associated with lowered immune response and an impact on the regulation of vital signs, all of which can influence the clinical outcome. Systemic theories are informed by the ways in which stress and depression can be both triggers and consequences of cardiac events (Hazelton, Sears, & Rodriguez, 2012). In addition, symptoms of events such as atrial fibrillation can be indistinguishable from physiological responses to psychological distress, anxiety, anger or depression, and can send confusing signals. The improved standardization of preoperative information in combination with premedication is proven to have a positive effect upon experienced pain levels ($p<.001$), overall patient satisfaction ($p=0.005$), and satisfaction with preoperative information ($p<.001$) measured by numeric scales (Al-Azawy et al., 2015).

2.4 Music in adult medical care

Music therapy within medical care (also known as *medical music therapy*) is a field of practice which is challenged and informed by both naturalistic and humanistic disciplines, as well as by merged practices and research. The state of the art of this field is changing rapidly, as the amount of available research increases

5 CV: cardiovascular

along with the scholarly interest in complex theories, and supplementary contributions within the areas of neurobiological measurement and general knowledge. The potential breadth of this practice is extensive, engaging aims and issues concerning a variety of ages, diagnoses, medical conditions, and situations (J. L. Allen, 2013b; Bruscia, 2014; Dileo, 2015). The field's typical clinical work ranges from short-term therapeutic processes with a duration of less than one hour, to follow-up treatments lasting several years.

The scope of interest within medical music therapy and music medicine encompasses both physiological and psychological effects with the overall aim of promoting health and wellbeing during the hospital stay. In the existing research, the effects of music interventions in adult medical care are typically measured via the patients' anxiety and experienced pain, physiological parameters, the use of medical drugs, hormone levels, and patient satisfaction with admission and treatment. In terms of the measurement of psychological effects, the emphasis is on self-reported levels of anxiety and pain, as well as patient satisfaction and quality of life. As there has been no previous research done on music therapy as an adjunct in lead extractions from cardiac implantable electronic devices, the scope of literature has been broadened below to include other medical settings.

2.4.1 About the literature: definitions and delimitations

The primary focus of this review of literature is music therapy in adult medical care in general, and in cardiological and perioperative settings in particular. It also extends to music medicine studies involving the same patient group. While it emphasizes systematic reviews and meta-analyses performed in the last decade, it also considers a broader scope of evidence-based practice to be relevant to the present thesis. It covers literature that is based in adjacent disciplines to a limited extent and limits itself to texts written in English, Norwegian or Danish only. The maze of reference lists from relevant books and articles represents a valuable source for this review, in addition to the databases Medline, PubMed and Google Scholar. The keywords used alone and in combination in the searches are music, therapy, procedure, cardiac, invasive, stress, pain, and anxiety.

Most of the research and literature on the use of music within medical care refers to *music medicine*, not *music therapy*, but the terms are also often commingled (Gooding, Swezey, & Zwischenberger, 2012). The term *music intervention* is most often used if the practice in question is not defined as either music medicine or music therapy in particular, or if the research involves a joint analysis of the two. Scholarly praxis today tends to be increasingly characterized by more informed, consequential and detailed descriptions of the music interventions in the course of the presentation of research (Pearson, 2018; Robb & Carpenter, 2010).

A music therapy service is always based on a systematic process of assessment, treatment, and evaluation regardless of its timeframe and whether the course is preventive, chronic or acute in character. To be defined as music therapy, the music intervention must be provided by a certified music therapist, and the music experience embedded within the therapeutic relationship which evolves over the course of the process. The music therapy service can treat patients individually or through the hospital environmental milieu. Music medicine, on the other hand, can be provided outside of a therapeutic process, and its potential effects derive entirely from the music itself (Bonde, 2011; Bruscia, 2014; Dileo, 2016; Gold et al., 2011). *Medical music therapy* is defined as:

> the use of music and relationship in a reflexive therapeutic process to treat persons whose primary presenting problem is medical in nature. (Dileo, 2016, p. 3).

The clinical intervention in this study is medical music therapy, because it involves a limited-duration therapeutic process with hospitalized patients which is facilitated by a certified music therapist, so the experience of music listening is embedded within a larger relation. In the present thesis, the distinct terms *music medicine* and *music therapy* (or *medical music therapy*) will be used where the practice is defined as one or the other. The collective term *music intervention* will be used when referring to both practices.

Experimental trials in medical music therapy and music medicine often involve only a limited number of participants, and sufficient scope for statistical significance can be hard to achieve. Thus, systematic reviews and meta-analysis with collected, calculated data are crucial to achieving potential effect sizes with relevance for actual practice (Gold, 2004). In recent decades, several reviews and meta-analyses have investigated the impact of medical music therapy and music medicine, focused on either effects for hospital patients in general, or within specific groups of diagnoses, phases or procedures (Bechtold et al., 2009; Boyce & Munn-Giddings, 2018; Bradt, Dileo, Magill, & Teague, 2016; Bradt, Dileo, & Potvin, 2013; Bradt, Dileo, & Shim, 2013; Evans, 2002; Ferreira, Ramalho, & Lopes, 2015; Hole et al., 2015; Kühlmann et al., 2018; J. H. Lee, 2016; Nilsson, 2008; Pittman & Kridli, 2011; Rudin, Kiss, Wetz, & Sottile, 2007; Tam, Wong, & Twinn, 2008; van der Heijden, Araghi, van Dijk, Jeekel, & Hunink, 2015; Vetter et al., 2015). The risk of bias limits the validation of many music intervention studies, because the interventions usually cannot be blinded (Higgins et al., 2011), so the results must be interpreted with caution.

2.4.2 Music interventions to regulate stress, anxiety, and pain

Music therapy and music medicine can regulate experienced stress, pain, and anxiety by interfering with perceptive mechanisms in the brain, influencing the production of hormones and reducing muscle tension (J. L. Allen, 2013a; DeWitte et al., 2019), thereby disrupting the potentially self-defeating circle of stress, anxiety, and pain, as described above.

In a meta-analysis, Pelletier (2004) presented the effect of music interventions on arousal induced by stress. Music listening and music-assisted relaxation had a moderate to high effect on reducing arousal, with a statistically significant result (ES=0.67, $p<0.05$). More recently, De Witte et al. (2019) performed a systematic review and two meta-analyses examining the effect of music interventions on stress-related outcomes through effect-sized data from 104 RCT's. They found an overall significant medium-to-large effect on stress reduction for music intervention groups in psychological outcomes ($d=0.545$, $p\leq0.001$), such as state anxiety. For stress-related physiological outcomes, they found an overall significant difference with a small-to-medium effect ($d= 0.380$, $p\leq0.001$) on heart rate, blood pressure, and stress-related hormones. They found no difference between music medicine and music therapy interventions. In a review from Bradt et al. (2013) on the effect of preoperative music interventions, they found a significantly higher reduction of anxiety in the music groups, measured both by STAI[6] (-5.72 units, [95% CI -7.27, -4.17, $p<0.00001$]) and numeric scales (VAS, NRS, and Zung self-rating scale: -0.60 units [95% CI -0.90, -0.31, $p< 0.0001$]).

6 STAI: State-Trait Anxiety Inventory

On the topic of music and pain, Lee (2016) conducted an extensive and detailed meta-analysis which included 97 RCT studies (n=9184). Its results show a significant reduction of pain level in the music group as opposed to the control group, with a medium-to-large effect size of 1.13 units on 0–10 scales ($p<0.00001$). The results concerning distress caused by pain were similar, with significant findings in favour of music interventions ($p=0.0008$), as were the analyses of pain measured by other scales ($p=0.01$), revealing a small to medium effect (SMD=-0.39). Differences between music therapy and music medicine interventions were calculated and revealed a higher pain reduction effect in the former (MD=-1.5) than in the latter (MD=-1.08). The difference was interpreted as clinically meaningful but not statistically significant. Overall, the music therapy interventions had a better outcome than the music medicine interventions with regard to procedural and chronic pain. Vital signs were also reported as physiological indicators of stress, pain, and/or anxiety. The results showed significant differences in favour of music interventions concerning heart rate (MD=–4.25, $p<0.00001$), systolic blood pressure (MD=–3.34, $p=0.0005$), diastolic blood pressure (MD=–1.18, $p=0.04$), and respiration rate (MD=–1.46, $p=0.01$), though the latter findings were highly inconsistent.

The use of anxiolytic drugs relates to level of anxiety, and the use of analgetic drugs relates to percieved pain during a medical procedure. Several reviews found the need for medical drugs to manage pain lowered in the music intervention groups, with a small-to-moderate effect (Bringman, Giesecke, Thorne, & Bringman, 2009; Hole et al., 2015; J. H. Lee, 2016; Vetter et al., 2015). Lee (2016) found a moderate effect on the reduction of anaesthetic drugs in music intervention groups (SMD=-0.56, $p=0.0005$), with the best results emerging from receptive music medicine rather than expressive music therapy. Three studies have actively compared the effect of the anxiolytic drug midazolam with the effect of music as a preoperative or perioperative intervention and found music to be equally or more effective than the medical drug (Bringman et al., 2009; Graff, Cai, Badiola, & Elkassabany, 2019; Lepage, Drolet, Girard, Grenier, & DeGagné, 2001).

In an RCT study, Bringman et al. (2009) found music listening to be more effective than a medical drug in reducing preoperative anxiety before surgery after providing relaxing music listening to one group and 0.05–0.1mg/kg of midazolam orally to the other. The primary outcome measure was on the difference in pre-post anxiety (STAI) bewteen the two groups ($p<0.001$, 95% CI -3.8 to -1.8). In a comparable study, Graff et al. (2019) did not find a statistically significant difference in preoperative anxiety between a midazolam group (1–2mg given intravenous) and a music listening group (SMD −2.5, 95% CI −5.9 to 0.9, $p=0.1$) – that is, the two interventions were equally effective. Lepage et al. (2001) performed a study providing music listening perioperatively and measuring state anxiety and the patient's requirements for midazolam as the main outcomes. Results showed no difference in anxiety, but a significantly lower amount of anxiolytic drugs used in the music group (1.2 ± 1.3 versus 2.5 ± 2.0 mg; $p<0.05$). The finding suggests that music listening does represent an effective alternative to midazolam for pre- and perioperative anxiety.

Studies have also related the level of patient satisfaction to experienced stress, anxiety, and pain during medical procedures. While the benefits of music interventions on patient satisfaction have seldom been part of single studies (Ghetti, 2013; Mandel, Davis, & Secic, 2019; Ripley et al., 2014), clear effects appear in the meta analyses by Bechtold (2009) and Hole (2015) related to the colonoscopy and to various other procedures, respectively.

2.4.3 Music and the heart

There is evidence suggesting that music interventions do impact the regulation of heart activity, as a result of complex, multivariable contexts in which vital biological signs are influenced by emotions and arousal level—signs such as heart activity, but also activation patterns of the nervous system, production of hormones and brain activity (Fachner, 2016; Hodges, 2000; Stegemöller, 2014). The findings are generally inconsistent and heterogeneous across studies (Koelsch & Jancke, 2015), probably due to the great variety of musical stimuli and interventions, as well as individual socio-cultural factors introducing variation in both perception and outcome. Studies on the effect of music on healthy individuals find that the high emotional arousal accompanying stimulating and exciting music leads to a higher heart rate and respiration rate than those associated with relaxing, predictable, or tranquil music (Bernardi, Porta, & Sleight, 2006). Meltzack's aforementioned theory of pain is useful to understanding the ability of music therapy to impact the autonomic nervous system through its modulation of emotions and moods, in this way possibly stabilizing those stress factors which are relevant for cardiac patients (Hanser, 2014; Koelsch & Jancke, 2015).

In a Cochrane review, Bradt, Dileo and Potvin (2013) discuss the impact of music interventions versus standard care on stress and anxiety for patients suffering from coronary heart disease. Outcomes were measured by anxiety level, pain, mood and depression, vital signs, and hormone levels. There were 26 RCT's included in the review, involving 1369 participants with myocardial infarction in medical procedures, or rehabilitation. Short-term music listening was the central intervention, providing one or two sessions within 48 hours. The music sessions were offered before, during, or immediately after a procedure. As only three of the studies included a music therapist, most of the interventions were administered by a researcher or other health professional, and thus best understood as music medicine.

The results show a small but consistent and significant beneficial effect of music listening on psychological distress for patients with coronary heart disease (MD=-1.26, 95% CI -2.30 to -0.22, p=0.02). A statistically significant reduction of pain was also found in the music intervention groups when compared to standard care (SMD =-0.43, 95% CI -0.80 to -0.05, p=0.03). The effect of music on anxiety was moderate but inconsistent. The reduction was significant in studies using the STAI- S state anxiety form as the measurement tool (MD=-4.58, 95% CI -7.78 to -1.39; p=0.005). Results from studies using other scales also showed a reduction of anxiety in the music intervention groups but lacked robust evidence (SMD=-0.43, 95%CI -0.93 to 0.06, p=0.09).

Subgroup analyses revealed that the interventions had their strongest effects when the provided music was patient-selected (MD= -0.89, 95%CI -1.42 to -0.36, p=0.001) rather than researcher-selected. Calculating the effect on physiological outcomes, the review reveals a tendency towards reduced heart rates and respiration rates in the music groups. The results also indicate a reduction in systolic blood pressure and self-reported pain. For future studies, Bradt et al.(2013) suggest a combination of researcher-selected and patient-selected music to optimize the benefit for both physiological and psychological responses. The advantages of such a combination is substantiated by Koelsch (2015), who also underlines the fact that music can elicit both exitement and calm, which makes it difficult to link specific physiological outcomes to certain emotional processes.

In a systematic review and meta-analysis of patients undergoing cardiac catheterization, Jayakar (2017) found anxiety to be significantly decreased for the music intervention patients (-3.95 on STAI, 95% CI -5.53, -2.37, $p<0.005$). All studies included in this meta-analysis referred to music medicine.

Some studies were excluded from these analyses because a cardiac heart disease diagnosis was not confirmed for all participants (Bradt, Dileo, & Potvin, 2013), or because the anxiety measurements did not include separate STAI-S scores (Jayakar & Alter, 2017). The excluded studies, however, still provide relevant information with respect to music interventions related to cardiac procedures, and most of them found the patient's level of anxiety and/or sense of wellbeing to improve with music interventions (Argstatter et al., 2006; Ghetti, 2013; Moradipanah, Mohammadi, & Mohammadil, 2009; Thorgaard, Henriksen, Pedersbaek, & Thomsen, 2004; Weeks & Nilsson, 2011). Other studies have found no relief of anxiety or stress or any impact on patient satisfaction or vital signs (Nilsson, 2009a; Ripley et al., 2014).

In a literature review of music therapy in cardiac health care, Hanser (2014) advocates for qualitative research studies engaging with individual experiences of music interventions as a complement to quantitative findings of the randomized trials. She also argues that music therapy interventions and research protocols must accomodate individual variability, as human musical responsiveness is multifaceted. A qualitative study by Short (2013) found receptive music therapy (the GIM- method) to represent a positive contribution to the recovery process of patients after cardiac surgery.

2.4.4 Music interventions as procedural support

Music therapy as procedural support is defined as:

> the use of music and aspects of the therapeutic relationship to promote healthy coping and decrease distress in individuals undergoing medical procedures. (Ghetti, 2012, p. 6).

Based on existing literature and research, music therapy is consistently recommended as a non-pharmacological supportive adjunct in medical procedures to help patients to manage unpleasant and disturbing symptoms (Bradt, Dileo, & Potvin, 2013; Bradt, Dileo, & Shim, 2013; Kühlmann et al., 2018; J. H. Lee, 2016). These symptoms can include anxiety, stress responses, pain, and discomfort, which in turn may affect physiological parameters. (Ghetti, 2012; Gooding et al., 2012; Heiderscheit, 2013; Spintge, 2012), as is the case with the medical procedure included in this study. With regard to invasive procedures, music therapy interventions can be provided preoperatively, perioperatively (inside the operating theatre during the invasive procedure – also called intraoperatively) or postoperatively. The clinical use of music in perioperative settings is the least cited instance (Gooding et al., 2012).

While reviewing the outcomes of receptive music medicine interventions with adult patients in perioperative settings, Nilsson (2008) found that music interventions induced a significant reduction of anxiety in 50% of the studies included (12 out of 24). The interventions were provided either before, during, or after the invasive procedure, mainly using headphones designed for music listening. These findings are supported by subsequent reviews and meta-analyses (Hole et al., 2015; Kühlmann et al., 2018; Vetter et al., 2015), which found that music interventions led to a significant decrease in both anxiety and pain for patients undergoing invasive procedures. Hole et al. (2015)also found that the effects of music interventions persisted under general anaesthesia, though they were not as pronounced. In sum, the findings suggest

that preoperative music listening is the most effective for anxiety reduction, and that postoperative music listening is the most effective for the reduction of pain. Bradt et al. (2013) also found a significant reduction in preoperative anxiety in patients who received music interventions while awaiting surgery.

Mandel et al. (2019) explored patient satisfaction, pain, and stress outcomes after music therapy interventions among patients admitted to the emergency department. These different outcomes were measured across various patient groups. In a case-control RCT study (n=180), the researchers found no difference in patient satisfaction between the music therapy group and the control group. To investigate the benefit of the music therapy service, they examined a group of 1113 patients receiving music therapy, and found a significant decrease in self-reported pain and stress. The music therapy services appeared to be particularly useful for stress and pain management during invasive procedures, which applied to 14% of the included patients. The study also explored the potential benefits of music therapy from the staff's perspective. Eighty% of the staff members reported that the music therapy service improved their own caregiving, and 92% said they would recommend music therapy.

Based on a philosophical inquiry using qualitative document analysis, Ghetti (2012) developed a transaction model of music therapy as procedural support which displays key concepts related to the dynamic factors involved in music therapy service. The model combines elements from Melzack's neuromatrix model of pain with the analysis of articles describing research on, and the clinical practice of, music therapy in medical procedures. Music therapy contributes substantively to the total experience of the medical procedure in the moment, responding to the needs of a safe, stable environment, and to the constructive regulation of vital signs, moods, and emotions. The model addresses the patient-therapist relation according to a definition of music therapy which emphasizes the importance of relational and reflexive factors. Ghetti described the music therapist's role and competencies:

> providing cues for desired responses (e.g., focusing on music or cueing deep breathing), redirecting attention to the music or task when the patient orients to the procedure, providing positive reinforcement when the patient attends to music or task, synergizing with the patient during active music-making, providing reassurance and emotional support, providing positive suggestions or clarifications through sung lyrics or spoken words, validating patients' emotions and sensations, and eliciting patients' emotional experiences … being emergent and responsive to patient needs as they evolve over time. Some authors described the importance of the therapeutic relationship itself, and its ability to change over time to accommodate patient needs. (Ghetti, 2012, p. 24)

Central aspects of a therapist's presence and competency include the initial clinical observation and subsequent individual facilitation of a safe atmosphere achieved by validating emotional expressions, improving coping strategies, and enabling patient involvement. Unlike music medicine, which always uses music listening, music therapy encompasses a range of potentially useful adjuncts to medical procedures, though receptive methods are the most common by far for adult patients. Receptive methods for procedure coping can be sorted into three main approaches: musical alternate engagement, music-assisted relaxation, and integration (Ghetti, 2011). All three approaches are patient-centred, focusing on individual patient needs and wellbeing, and they differ from music medicine in terms of systematic assessment and reflexivity, and relational attunement. Ghetti's model provides a theoretical link between general knowledge and music therapy theory and practice, and it aided in the development of the clinical music therapy protocol used in the current study.

2.4.5 The sounding music

The present RCT, then, starts in receptive music therapy, itself strongly influenced by *Guided Imagery and Music* (GIM) (Grocke & Wigram, 2007). In receptive music therapy, the music fills the role of co-therapist during the therapy session. In addition to supportive care from the therapist, the use of sounding music seeks to maintain support, that is, a holding and safe environment[7] for the patient through its rhythms and textures, and through its ability to hold attention, satisfy expectations, and prompt recognition (Grocke, 2016; Wärja & Bonde, 2014).

According to the literature, receptive music therapy involves a number of choices about the sounding music, to do with timing, duration, the musical genre, and the process of choosing itself. Despite the range of different approaches to receptive music therapy, the evidence-based literature identifies certain essential and common factors which further the current aim of relaxation and stress reduction. For example, the literature refers to single sessions of music interventions, normally with a duration of 15 to 40 minutes (Bradt, Dileo, & Potvin, 2013; J. H. Lee, 2016; Nilsson, 2008; Pittman & Kridli, 2011). The intervention is most frequently provided preoperatively or postoperatively. When music is also provided perioperatively, the intervention often lasts throughout the invasive procedure. Effective music interventions on preoperative anxiety can also be as short as five to ten minutes (K. C. Lee et al., 2012).

Concerning the choice of music itself, the literature distinguishes between patient-selected[8] and researcher-selected music, where the former category refers to music selected by patients from a limited sample presented by the researcher. Findings suggest that patients-selected music is preferable for the reduction of anxiety, while researcher-selected music is preferable for the manipulation of certain physiological outcomes such as heart and respiration rate (Bradt, Dileo, & Potvin, 2013). Hole et al. (2015) found that timing, delivery and choice of music made no difference to outcome variables. Both Vetter et al. (2015) and Kühlmann et al. (2018), on the other hand, found patient-selected music to be more effective than researcher-selected music. Kühlmann et al. (2018) also found that variations in the timing of the music intervention had implications for its outcome. The relationship between duration of treatment and treatment effect remains unclear in the existing literature.

Studies have shown that the tempo of the music is more important than the genre and noted that tempo of 60 – 80 beats per minute provides the best outcomes in terms of relaxation, stress reduction, and pain relief compared to other tempo categories (Bernardi et al., 2006; DeWitte et al., 2019; Nilsson, 2008). GIM, in particular, has derived specific musical parameters which are the most effective for support and relaxation (Grocke, 2016; Grocke & Wigram, 2007; Wärja & Bonde, 2014), and Wärja and Bonde (2014) have developed a taxonomy to classify receptive music to be effective in therapeutic settings. The taxonomy displays criteria for the selection of music for regulating effects, and includes a section of *supportive music*, offering an alternative to challenging or stimulating music. This supportive music is further categorized as safe, opening, and exploring. In sum, the supportive section is described as follows:

7 A holding environment refers to a therapeutic space that allows an emotionally fragile or insecure person to deal with affects that might potentially be overwhelming, originally introduced as a psychological term by Winnicott. See https://dictionary.apa.org/holding-environment.

8 The term participant-preferred is here included, as used by Lee (2016), referring to the same principle.

> In these (supportive) 3 fields the intent of the music is to provide security and holding … There are no major musical surprises. The rhythm is steady and the melody and harmonic progression is clear and predictable. The pieces are mostly instrumental with some possibilities of using vocal music without words, or a 'foreign language' most likely not understood (lyrics will influence the images). The purpose of the fields is to provide music that allows for surrender and metaphorically speaking; "to give in to the musical embrace". The compositions are selected for their aesthetic quality, and for belonging to the "lighter moods" of the spectrum of Hevners's mood wheel[9]. (Wärja & Bonde, 2014, p. 19)

The iPad application the *Music Star* was used in the present study to provide playlists situated within this supportive taxonomy. This software was developed as a patient tool for relaxation and/or focusing attention in medical settings (H. N. Lund, Bertelsen, L. R., 2016). Further details about and descriptions of the application appear in section 4.5.3, Paper I, and Appendix 7.

As we have seen, both the theory and the evidence for understanding the music intervention as a relevant adjunct to the regulation of patient stressors are increasing. Admittedly, the existing studies of music interventions as procedure support reflect a variety of providers, durations of treatment, medical situations and uses of music. In general, as well, there are more music medicine studies with music listening interventions than music therapy, and very few studies including expressive methods with the patient actively playing instruments or singing. This is probably due to the practical and interdisciplinary challenges of implementing the latter studies, and to the limited number of music therapists in the field.

Lastly, music therapy studies are often associated with a high or medium risk of bias, primarily due to the intervention's character. They certainly imply, as presented above, that music interventions have positive effects on patients in medical health care on state anxiety and pain, respiration rate, use of medication and satisfaction with treatment, as demonstrated by the statistical evidence, significance and effect sizes. Yet much of the existing research evidence displays uncertainty as well; the findings are often heterogenic and must be interpreted with caution. Thus, there remains a desire to strengthen the theories, broaden the empirical base, and shed light upon more specific aspects of music therapy as an adjunct in medical settings.

9 See K. Hevner "Experimental studies of the elements of expression in music". American Journal of Psychology (1937): 48, 246–268.

3 Aims and objectives

The overall aim of this study was to contribute to the body of knowledge concerning music medicine and music therapy as a systematic adjunct to medical care in general, and more specifically, to the physiological and psychological regulation of stressors during invasive procedures upon adult patients. Cardiac device lead extraction procedures performed in local anaesthesia was found to be particularly relevant for the study, given the increased patient stress which has been observed by health personnel in the context of this precise procedure.

The RCT's hypothesis was that a tailored music therapy intervention could reduce stress responses in patients during the lead extraction procedure. A detailed clinical music therapy protocol called *Facilitated Music Listening* (FaMuLi) was developed to be an adjunct in this particular invasive procedure.

Research objectives

The primary objectives were as follows:

- To study whether the music therapy intervention during the lead extraction procedure increased the patients' satisfaction with pain management during the procedure
- To study whether the music therapy intervention during the lead extraction procedure reduced the patients' experience of pain intensity during the procedure

The secondary objectives were as follows:

- To study whether the music therapy intervention reduced the patients' experience of anxiety during the procedure
- To study whether the music therapy intervention reduced the total consumption of anxiolytic drugs during the procedure
- To study whether the music therapy intervention reduced the total consumption of analgesic drugs during the procedure
- To study the effect of the music therapy intervention on physiological parameters (mean arterial blood pressure, heart rate, oxygen saturation, and respiration rate) during the procedure

Supplementary research questions

For a supplementary analysis with an expanded perspective upon the study, the following research questions were added:

- How was the patients' self-reported experience of the music therapy intervention
  - expressed through anxiety levels in subgroups and at different time points?
  - expressed through scores of satisfaction with the music therapy intervention?
  - expressed through written patient reflections?

4 Methods

4.1 Background

Methodologically, the present study relied upon a quantitative RCT. Its intervention was grounded in a biopsychosocial approach which reflects the field's increasing knowledge of systemic perspectives in recent decades. A triangulation of clinical experience, literature, and contextual factors was used in developing the tailored music therapy intervention protocol, as a necessary first step of the study. The succeeding RCT experiment followed the CONSORT guidelines (Boutron, Altman, Moher, Schulz, & Ravaud, 2017), with traditional methods for enrolment of participants, defining outcomes and variables, data collection, statistical analysis and reporting findings. Based on the results from the primary statistical analysis, a supplementary analysis of subgroups trends was performed, and illuminated by analyses of additional data from the music therapy group.

The choice of a regular RCT as the core research method of this study means that it investigated the effects of the intervention using a limited set of quantitative variables without expecting to disclose the whole truth. In line with the identified need to balance rigorous research and therapeutic flexibility (Rolvsjord et al., 2005), this study's applied RCT protocol was fixed, whereas its clinical music therapy intervention protocol was person-centred. This combination also characterizes other studies of music therapy in invasive procedures (Ghetti, 2013; Sanfi, 2012b).

The empirical part of the trial was administered over a period of 1.5 years, by the author as a coordinating researcher (hereafter the researcher), who also served as the music therapist for patients in the intervention group. This double role brings with it a range of methodological and ethical considerations which will be considered below, along with the study's design and procedures of data collection and analyses.

The study was registered in ClinicalTrials.gov no.: NCT04172662. The study has intern study approval and registration at OUS, no. 17/17251, and is approved by the Regional Ethics Committee (REK) in Norway, document 2018/168/REK nord (Appendix 1).

4.2 Design

The study used a two-armed randomized design involving an experimental group and a control group. It planned for a total sample of 68 patients randomized to either the music therapy group (n=34) or the control group (n=34). The research groups were defined as follows:

Music therapy group: received individual music therapy before, during, and after the invasive procedure, in addition to standard treatment. The receptive music therapy intervention called Facilitated Music Listening (FaMuLi)[10] was provided with an emphasis on individual guiding concerning the patient's

10 The terms Facilitated music listening (FaMuLi) and music therapy intervention will be used alternately throughout the thesis.

coping strategies, patient involvement, and relaxation, as outlined in a semi-manualized clinical protocol (Paper I:Blichfeldt-Ærø, Trondalen, & Halvorsen, 2019). The music therapist was present, or frequently in contact with the patient in all phases of the procedure.

Control group: received standard treatment without music listening.

Due to the character of the intervention, it was not possible to blind participants or unit staff to the treatment group assignment—for example, the intervention used relational guiding and open music listening. The two-armed design also did not differentiate between the effect of the music and the possible effect of the human relation. Because this study understood music therapy as an inseparable merged entity of the music and the relation, separate intervention effects were outside the scope of interest.

4.3 Intervention development and trial implementation

Development of FaMuLi was done carefully over time. For the implementation of the study trial, it was very important to ensure feasibility according to procedure demands, logistics, and optimal interdisciplinary collaboration at the hospital. A research log was written systematically throughout the process, as a working tool for reflective practice and situated knowledge, featuring descriptions of situations, activities, interactions and communication, upcoming questions, ideas, and incidental remarks. The log informed further observations, intervention development and study implementation. The process involved four stages between initial planning and implementation of the study trial.

Stage 1: Study invention (autumn 2016 – spring 2017)

The research study was initiated by the Department of Cardiology at Oslo University Hospital Ulleval in collaboration with the Centre for Research in Music and Health (CREMAH) at the Norwegian Academy of Music (NMH). Initial development of the intervention and research protocol started in August 2016, drawing upon existing literature, clinical experience, and biopsychosocial principles. Starting in September 2017, the study was incorporated as part of the PhD research program at NMH.

Stage 2: Initial collaboration, observations, and testing (autumn 2017)

Through meetings and mail correspondence, introductory communication was established between the researcher and central contacts at the hospital, including the head of the Department of Cardiology, the chief cardiologist and coordinating nurse(s) at the PM/ICD centre, the leader of the cardiac intensive care unit, and a statistician. These made up the project team. The team performed systematic observations of the invasive medical procedure in question, including assessments of the schedule, the standard patient care protocol, and the availability of rooms suitable for the music therapy intervention. The music therapy intervention and the music equipment were tested, and revisions of the clinical music therapy protocol made from a feasibility perspective. Final variables and objectives were defined using associated measurement tools for the collection of data. Then the sample size was calculated, and the roles and possibilities for practical contribution of the health care personnel were clarified.

Stage 3: Protocol details and national approval (January–February 2018)

The researcher and health care personnel continued to cooperate to define criteria of patient inclusion/exclusion, standardize procedure medication, settle upon a recruitment procedure and outline data collection and supportive functions. The study was approved by the Regional Ethics Committee (REK) in Norway. Protocols for implementation and case report forms were written in detail, presented, and made available to all personnel involved to clarify screening, recruitment, data collection, and the music therapy intervention itself (Appendix 2, 3, 4, 5, 6).

Stage 4: Trial implementation and data collection (March 2018 – September 2019)

The year and a half taken by stage 4 constituted the active period of trial implementation, including screening, recruitment, data collection, repeated protocol instructions, and regular monitoring of data collection routines, in addition to the clinical interventions. The project team's perpetual readiness to incorporate incoming patients, often on very short notice, demanded extraordinary flexibility and alertness from the hospital staff and researcher during this time. The unit nurses also performed data collection tasks, alongside their regular responsibilities, while the researcher plotted data along the way. To ensure sufficient information flow, the project team followed procedures for interdisciplinary communication in periods with low patient activity.

4.4 Participants and allocation procedure

All of the study participants were patients scheduled for lead extraction procedure in local anaesthesia at the PM/ICD centre in the Department of Cardiology at Oslo University Hospital Ulleval between March 1, 2018, and September 30, 2019. The unit is a specialized national centre performing approximately 140 lead extraction procedures every year, so the time anticipated to recruit study participants (n=68) was initially one year. Due to two extensive periods of relatively few incoming patients and a high number of patients who met the exclusion criteria, the recruitment period was prolonged with six months to meet the required number of patients.

Study inclusion criteria:

- age 25–80 years
- years of implanted lead >12 months
- lead extraction procedure planned in local anaesthesia
- ability to speak and read Norwegian
- willingness to participate in the study

Study exclusion criteria:

- previous and/or acute psychiatric diagnosis
- cognitive or mental deficits or impaired functioning
- significant hearing impairment

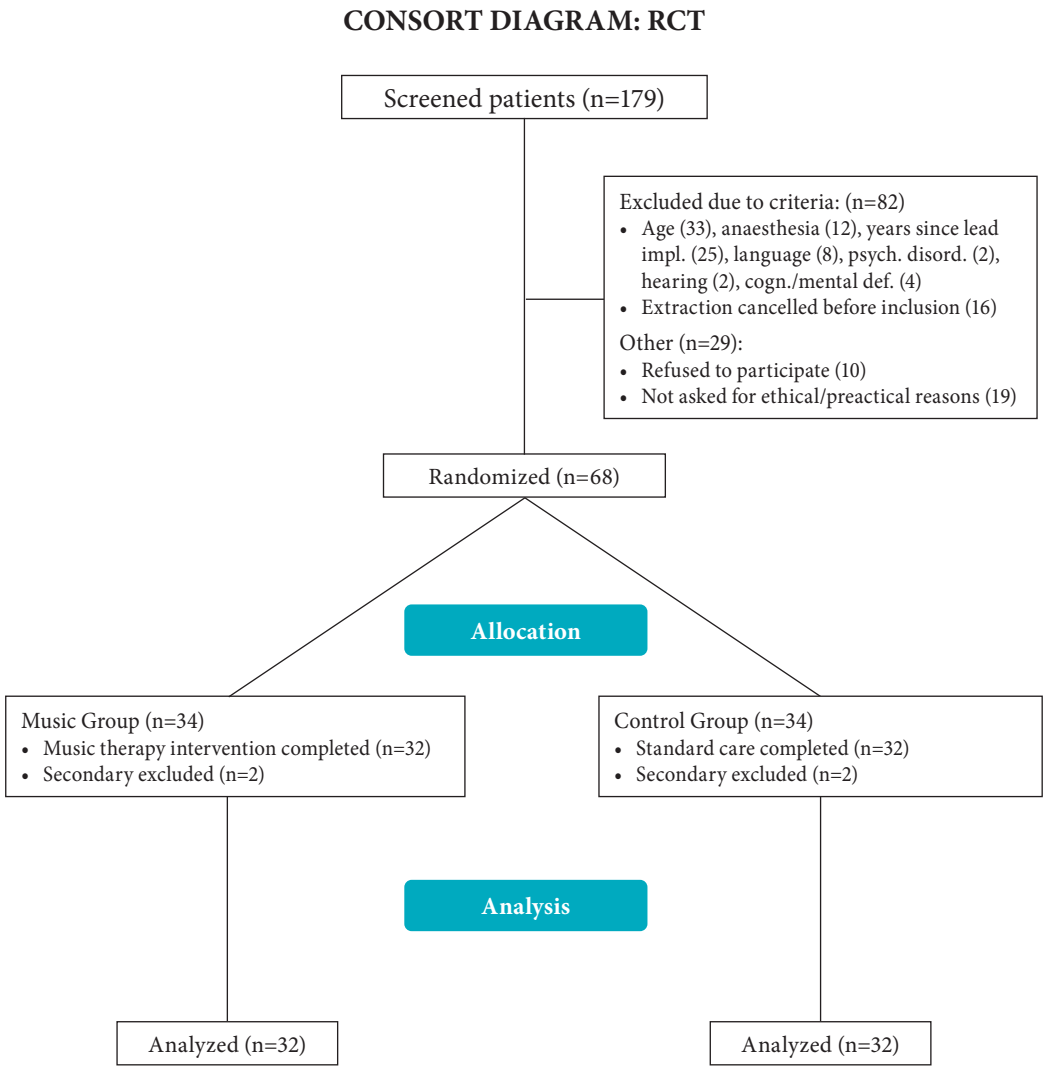


Figure 1. Flow diagram of study participants

The minimum age was set because general anaesthesia usually is typically given to patients under 25 years old in lead extraction procedures at OUS Ullevål, as they are normally more uncomfortable when facing the procedure. Because advanced age often correlates with increased physical and communicative challenges, the maximum age was set to avoid difficulties and additional patient strain during the admission, due to the need for efficiency in the process of study recruitment and treatment schedule. Patients with leads implanted less than 12 months were excluded because these procedures are generally less complicated and not associated with pain.

The lead extraction procedures were typically planned between seven and 30 days in advance. The patients came to the hospital for pre-tests the day before the operating procedure, spent the night at home or at a hotel, then returned to the hospital for admission the next morning. Some patients with acute referrals were admitted upon arrival, and stayed the night at the cardiology ward for surveillance and medical support. All of the patients had either a pacemaker (PM) or an implantable cardioverter-defibrillator (ICD) with one to three connected electronic leads in need of extraction/replacement. Reasons for extraction included acute infection, electronic failure, a loosened lead, or system revision due to changes in the patient's treatment plan (Fig. 1).

Upon their arrival for the pre-tests,[11] eligible patients were met by the coordinating nurse and the researcher and given information about the pre-test schedule and the music therapy study in a separate room or a secluded area in the hospital's hallway. The patient information about the music therapy study was given both verbally and via written text (Appendix 2). The researcher confirmed voluntary participation and explained the option of rescinding approval at any time without consequences for the medical treatment. The patients were given time to consider the request and to ask questions before responding to the researcher or coordinating nurse. Thereafter, the patients who were willing to participate signed two copies of the informed consent before the nurse obtained their baseline measures (Appendix 6a). Random allocation to the intervention or control group was accomplished using concealed envelopes with computer-generated random numbers in varying block size. An external research nurse prepared the envelopes, and no project team members were involved in the process. The researcher then gave the envelope to the patient, who opened it with the researcher present.

4.5 The music therapy intervention

The first study period was spent on developing and describing the theoretical basis and principals of the tailored music therapy intervention and writing up the detailed clinical intervention protocol of FaMuLi, which was presented in the first paper (Blichfeldt-Ærø et al., 2019). A triangulation of systemic theory, previous research and experience, and contextual factors informed the semi-manualized protocol for the present study's medical setting. Because the regulation of stress symptoms was the main aim of the intervention, the music therapy sought to promote stability and relaxation rather than arousal in the patients during the procedure. The clinical protocol was exclusively receptive and influenced by GIM techniques (Grocke, 2016; Grocke & Wigram, 2007) and music-assisted relaxation (Heiderscheit, 2013). Aside from the fact that receptive methods are both effective and well tested within medical music therapy and music medicine, expressive methods were eliminated from this trial to better meet the demands of hygiene, efficiency and the available physical space, and to ensure continuity of method across all phases of the medical procedure.

Both GIM and music-assisted relaxation begin with an induction/relaxation phase which transitions into the music while enabling the patient to enter a slightly altered state of consciousness. The music serves as a "co-therapist" during the sequences of music listening to provide a safe, holding environment for patient support (Grocke, 2016; Trondalen, 2016; Wärja & Bonde, 2014).

11 Standard procedure of pre-tests included blood samples, chest X-ray, transthoracic echocardiogram, and a final consultation with the medical doctor, normally completed within 3–5 hours.

The preparation phase was scheduled to last 45 minutes so that it would be logistically implementable, and to ensure enough time for the assessment, dialogue and initial experience with guided music listening. The day of operation always involved a minimum of 30 minutes of music listening, a duration derived from the existing literature as the time necessary to bring about the relaxing effects of music therapy (Bradt, Dileo, & Potvin, 2013; J. H. Lee, 2016; Nilsson, 2008; Pittman & Kridli, 2011). It was made clear to patients that they could decide when to stop or restart the music listening at any time after 30 minutes had passed.

FaMuLi sought an optimally balanced intervention of standardized and individualized elements based on a biopsychosocial approach and accounting for including corresponding theories concerning the regulation of stress, pain and anxiety, and music therapy as procedure support (Bradt, Dileo, & Potvin, 2013; Bradt, Dileo, & Shim, 2013; Dileo & Bradt, 2005; Folkman, 2007; Ghetti, 2012; Koelsch, 2010; Lazarus & Folkman, 1987; Melzack, 2001). As an experienced music therapist, trained for clinical practice within medical settings, the researcher provided all of the FaMuLi interventions.

4.5.1 Intervention sequence

The FaMuLi intervention consisted of three main parts over two days (Appendix 5). In what follows, the sequence will be described using the provider's clinical role (the music therapist or therapist):

1. **Preparation**: The patient had a 45 minutes session with the music therapist the day before the invasive procedure, during which the therapist assessed the patient's previous experience with and current expectations about the medical procedure to come, eventual coping strategies and music preferences. The therapist presented playlists from the Music Star as well as the study's playback devices (for further details, see 4.5.3 and Paper I), and led the patient through individually guided experiences with music listening. Most patients responded positively to their initial experiences with music listening, and welcomed guidance concerning coping strategies such as deep breathing or visualization. Patients also indicated the playlists they did not like during the preparation phase. According to the patient's preferences, the therapist then outlined a plan with two or three chosen playlists for the next day. The playlists could be changed at any time according to the patient's wishes. The therapist took systematic notes during the session for reference the next day.
2. **Music listening**: Using the previous day's plan, the therapist started the music listening upon the patient's arrival at the hospital the next morning, when the patient was situated in the hospital bed. The music therapist was more actively involved in guiding the patient preoperatively than perioperatively, due to procedure requirements. The therapist also offered music listening postoperatively, which the patient could accept or decline. In this phase, patients could also operate the listening device on their own. The music therapist left the room after setting up the devices but regularly returned to check on the patient. The degree of guidance and presence in the room in all phases was regulated to best respond to the individual situation, including the patient needs and the demands of the medical procedure.
3. **Closing dialogue**: At the end of the postoperative phase, the music therapist proposed a debriefing dialogue during which the patient was invited to share and evaluate their experience with the invasive procedure and the music listening. This final part of the intervention concluded the music therapist–patient relation and the duration of music listening as procedural support during the hospital stay. The music therapist initiated the dialogue with open-ended questions using the following suggested formulations:

    - *How did you find the procedure? / What was the procedure like for you?*

- *What do you remember about the music listening during the invasive procedure?*
- *How did you find that experience?*

4.5.2 Therapeutic alliance

FaMuLi was developed to facilitate the safety and comfort of the patients, and its relational aspect involved the reassurance of the patients that the therapist's presence and only intention was to accommodate their wellbeing. Individual preference for, and decisions about the music listening were emphasized to encourage patient involvement, including an acceptance of changing whiches and needs during the procedure. Central therapeutic qualifications in play during this guidance were as follows:

- Observation of body language, breathing, and verbal activity
- Attuned, regulating, and supportive communication via both verbal and bodily language
- Reinforcing suggestions for coping strategies

In the clinical instructions of FaMuLi (Appendix 5), the following guidelines for the therapist can be found:

> The patient is heard and seen as a person by focusing on the patient's expectations, experience, and resources. The preparation, involving self-awareness, briefing and testing of techniques, aims to increase the patient's coping skills and stabilise stressors during the admission. The preparation should take form as a mutual dialogue without interruption if possible, guided by this semi-structured manual. Information achieved through the dialogue is to be used for further personal tailored facilitation of the intervention …

> Different playlists are tested with the patient lying on a bench. The therapist sees to it that some variety of playlist complexity is presented and experienced, so as prepare for possible changes in needs during the procedure. A plan of 2–3 playlists is made for the next day's listening but can be altered at any time. The therapeutic "contract" is clarified:
>
> - The therapist will be present and available and focusing on the patient's needs throughout the procedure.
> - The music listening will be performed according to the patient's wishes to the greatest possible extent (timing and duration of listening, changes of playlist, and volume, etc.).
> - Ways of communicating needs and wishes during the operation are presented (eye-contact, verbal, gestures).

The clinical music therapy protocol comprised music-assisted relaxation within the framework of short-term treatment, and therefore corresponded to an augmentative or supportive level of music therapy practice (Bruscia, 2014; Dileo, 2015, 2016).

4.5.3 Playlists and playback equipment

During the development of the clinical intervention, patient preference and involvement, coupled with an awareness of general neurobiological responses to musical structures, informed the choice of playlists provided. In addition, the music listening had to be both possible and straightforward to administer in the

sterile operation theatre. The aforementioned application called the Music Star, available on a digital tablet, met all of the requirements—it was professionally developed by music therapists for regulation through music and already tested in hygienic hospital settings (Bertelsen, 2019; H. N. Lund, Bertelsen, L. R. , 2016).

The 12 original playlists on the Music Star (Appendix 7) supplied the requisite professionally quality based, again, on principles underpinning supportive and regulating music for therapeutic purposes. These playlists were analyzed and coordinated with one another using precepts from GIM, general music therapy, and neurobiology (H. N. Lund, Bertelsen, & Bonde, 2016; H. N. Lund, Bertelsen, L. R. , 2016).

The Music Star was originally developed as a regulating moderator of soundscapes in healthcare environments to be administered by either healthcare personnel or the patients themselves. While the application does not require systematic individual and ongoing guidance for optimal use, the current study incorporated individual therapeutic guidance as a premise for the music listening, in order to optimize supportive coping strategies for the patients during the medical procedure. Two tablets containing the application were bought and prepared for the study, and a plastic cover and screen protection were added for hygienic purposes.

The project team considered a variety of playback devices. It rejected a ceiling-mounted loudspeaker,[12] because installation would be too expensive, and it would be hard to fit it alongside other necessary equipment. It concluded that headphones were too uncomfortable and did not provide the necessary contact between the patient and healthcare personnel during the operation. A sound pillow was unsuitable for hygienic reasons. In the end, the team settled on the loudspeaker AudioCura M2 to meet the criteria of comfort and contact, sound quality and volume, demands for hygiene, and ease of practical use (AudioCura, 2016).

4.6 Hospital context

The patients were typically scheduled for the operation early in the morning and arrived at the hospital at 7:30 AM. In a separate preparation room, they undressed and received a hospital bed for their final preparations and the music listening (the latter for the music therapy group only). Medical preparations consisted of peripheral intravenous cannulations on two sides, shaving, placement of electrodes for monitoring, and standardized prophylactic medication (2 tablets of Paralgin forte; Paracetamol 400 mg plus codeine 30 mg). Music listening began before, during or after the medical preparations, depending on the patient's wishes. The duration of this preoperative phase was normally 30–60 minutes, but occasionally longer, depending upon the logistics of managing several operations in the same day. Preoperative music listening was minimum 10 minutes, but generally longer.

When prepared, the patients were brought to the operation theatre and moved to the operation bench. Here the preoperative measures were obtained before the patients were given a standardized dose of midazolam intravenously (1–1.5 mg, calculated by weight). The perioperative phase started upon the introduction of sterile procedures. For the music therapy patients, the music listening restarted a few minutes into the perioperative phase, when the patient's electrodes had been connected to the monitoring equipment.

12 See http://www.audiocura.com/da/portfolio/audiocura-ls16/ by AudioCura (2016).

In addition to local sedation, fentanyl (25–50 mcg) was given intravenously before the subcutaneous cut and/or at the peak point of the lead extraction. Additional doses of analgesics and anxiolytics were provided as needed based upon clinical observations.

According to the standards for lead extraction procedures at OUS Ulleval, the medical team had to include four health professionals with specialized functions: an operation nurse with sterile capacity, the cardiac operator with principal responsibility for the invasive procedure, the primary nurse for patient contact, and a nurse with main responsibility for monitoring and operating the electronic cardiac devices. For patients in the music therapy group, the music therapist was also present as part of the team, primarily in contact with the patient and the primary nurse dedicated for patient contact.

In addition to the invasive part of the procedure, the total perioperative phase in the operating theatre included about one hour before, and 30 minutes after the invasive procedure, to complete sterile procedures and to check upon technical device functions. Following the perioperative phase, the patients were transferred to the cardiac intensive care unit for four hours of postoperative surveillance while on bedrest, then admitted to the general cardiac ward until the next morning. The music therapist approached the patients in the music therapy group within 30 minutes in the intensive care unit to assess their needs and offer postoperative music listening. If this was desired, the loudspeaker was put in place, and the patients were allowed to operate the Music Star on their own. The patients could also decline or delay music listening postoperatively. Within these first four hours of postoperative recovery, the music therapist regularly checked up on the patients' needs (in the music therapy group) and ultimately completed the closing dialogue with the patients.

4.7 Outcome variables

The study's hypothesis concerning music therapy's ability to regulate stress responses during the medical procedure was tested via physiological and psychosocial outcomes related to state anxiety and pain management (Dornelas, 2012; Selye, 1976). Chosen indicators involved the measurement of final patient satisfaction with the pain management, the experienced level of pain, and the level of anxiety, in addition to the patients' vital signs and the use of medical drugs during the procedure (Appendix 6bef). Additionally, the study obtained data on patient characteristics and procedural variables as well as supplementary variables directly related to the music listening (Appendix 6acd). An outline of the rationale for the collection of these outcome variables and additional data will be presented in the following sections.

4.7.1 Psychological variables

- Satisfaction with pain management: Numeric scale (1–10)
- Level of pain: Numeric rating scale (NRS, 0–10)
- Level of anxiety: Numeric Visual Analogue Anxiety Scale (NVAAS, 0–10)

The researcher considered several validated tools and forms of measurement for the psychological variables in this study, primarily STAI-S (State-Trait Anxiety Inventory – Short form) (Marteau & Bekker, 1992)

but also other measurement tools, such as HADS, VAS, CSQ-8, PSQ-18, POMS, Coping Scale for adults. When discussing these options with the medical team, however, it was decided that data collection had to be done quickly and effectively to work within the larger process and minimize patient strain. Forms with several questions were not thought to be compatible with the timeline of the medical procedure, or with patients' variables and needs as it moved foreward. The use of STAI-S was therefore excluded early on, even though it is the most frequently used measurement of procedure anxiety by far.

The project team settled upon patient satisfaction with pain management as the primary outcome, representing an overall score of the patient's total experience of stress, anxiety, and pain management during the procedure. The score used the numeric scale 1–10, where 1 represented not at all satisfied, and 10 represented maximum satisfaction. A comparable study (Al-Azawy et al., 2015), used this outcome successfully, though the present study replaced its combination of extended preoperative information and premedication with a combination of FaMuLi and premedication. FaMuLi provided patient guidance in the conscious use of music listening to optimize their state of wellbeing during the procedure, including coping strategies for the regulation of stress.

Using self-reported unidimensional scales is a recognized means of measuring pain intensity (Hjermstad et al., 2011), and the most common tools are the Visual Analogue Scale (VAS 100mm), Numeric Rating Scale (NRS-11or NRS-10) and Verbal Rating Scale (VRS). The measurement tools differ in the extent to which they are presented in visualized or verbalized form, and in how the patients report their scores (in written, manual or verbal ways). Similar numeric rating scales are found with diverse specifications and names, but which often shows to be identical in use, such as the Numeric Pain Rating Scale 0–10 (NPRS) and the Numeric Visual Analog Anxiety Scale 0–10 (NVAAS) (Elkins, Staniunas, Rajab, Marcus, & Snyder, 2004). VAS, NVAAS and NRS are reliable and valid tools with significant correlations to other measurement tools for pain and anxiety (Elkins et al., 2004; Haefeli & Elfering, 2006; Hawker, Mian, Kendzerska, & French, 2011). With VAS the patients have to place a mark on a line to report their relevant level. Due to practical limitations concerning motoric mobility during the present study's operation procedure, the patients had to report their perioperative scores verbally, so VAS could not be used.

In the end, the NRS and NVAAS were found to be the most viable means of measuring pain and anxiety levels. Because these numeric scales are so similar, they will be grouped under the blanket term Numeric Rating Scale (NRS) hereafter. It can be used with speech, graphically or the written word and is often preferred both by patients and researchers due to its good compliance and feasibility, simple administration, and adaptability, also during an operation. The NRS is frequently used in pain assessment, but also measures state anxiety and correlates significantly with the measuring instrument STAI-S, which requires more time and motor activity from the patient to be completed (0.64, $p<.0001$) (Elkins et al., 2004). Using NRS, the nurse asked the patients to state a number between 0 and 10 which best captured their experienced level of pain/anxiety at the moment, with the understanding only that 0 meant no pain/anxiety at all, and 10 meant the worst imaginable pain/anxiety. A visual rendering of the numeric scale reinforced the standardized process of information and data collection in this study (Fig. 2); it was always shown during the initial information session, then shown again at other measurement timepoints when possible.

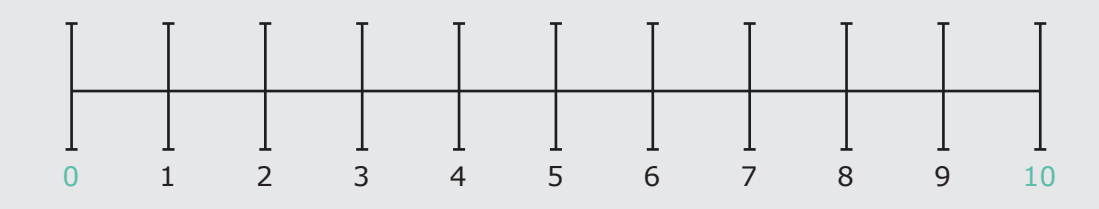


Figure 2. Numeric rating scale, 0–10 (NRS) for pain and anxiety measurement

As a generic unidimensional pain measurement, the NRS does not capture the complexity of pain and anxiety experiences, which are influenced by one's personality, culture, context, and so on. To accommodate a more in-depth assessment, a study must introduce more detailed questionnaires, interviews or and/or observations over a more extended period of time–an effort which exceeded the present study's scope. The NRS was adequate for this study, however, because it concentrates on acute pain and state anxiety during a single procedure. Because it uses predefined numbers categorically, its data does make a less subtle distinction between levels than the VAS, which, as mentioned, employs a continuous scale line marked by the patient (Hjermstad et al., 2011). A change of 20% between two timepoints in an assessment is regarded as clinically significant for both scales (Haefeli & Elfering, 2006).

The expression of the central outcome terms in Norwegian (that is pain, anxiety, and satisfaction) was discussed and internally validated by the research group and the medical team.

4.7.2 Physiological measures and medication

- Physiological variables: systolic and diastolic blood pressure (BP), heart rate (HR), oxygen saturation (SaO2), and respiration rate (RR)
- Procedural medication: paracetamol, codeine, diazepham, midazolam, fentanyl

Except for RR, which was not measured at baseline due to certain logistical factors, the physiological variables were measured at four points; baseline, preoperative, perioperative (average of repeated measures), and postoperative. The use of procedural analgetic and anxiolytic medication was noted in all three phases of the operation as well. All of the physiological and medical data were registered as continuous variables and measured either automatically through an electronic surveillance system, manually (RR and medication) or routinely using an ambulatory measuring apparatus (BP, SaO2, HR).

4.7.3 Additional data

The project team collected a number of background variables as either continuous, binominal or nominal pieces of information as follows:

- Patient characteristics; gender, age, weight, height, medical history, regular medication (Appendix 6a),

- Procedure variables; type of device, years since lead implantation, the reason for extraction, number of leads in/out, use of sheaths, wakefulness during the operation,[13] adverse events, duration of the invasive phase and the total procedure,[14] and clinical success (Appendix 6d).

Also, additional data from patients in the music therapy group were collected:

- The use of playlists: choice of supportive playlist level, duration, and timing (Appendix 6c).
- Experience: scores of satisfaction with the music listening (1–10) and short written reflections from the patients about their experience with the music listening (Appendix 6e).

4.8 Data collection

Data collection started immediately after the inclusion of a participant (Fig. 3, measure point 0), and continued at the end of the preoperative phase (measure point 1), as repeated measurements every 30 minutes perioperatively (summed up as means, measure point 2), and as measurement during the final 2–4 hours of the postoperative phase (measure point 3). Due to individual variations in the procedure, the number of repeated measures in the perioperative phase varied. The nurses scored the patient's average degree of wakefulness at the end of the perioperative phase by circling a chosen number on the scale (Appendix 6b).

As previously mentioned, the author took on the role of both music therapist and researcher coordinating the research team and clinical trial. Nurses in the medical team at the PM/ICD centre assisted with the data collection (10 nurses in all across the period of the study), as did nurses at the Cardiac Intensive Surveillance Unit. The nurses obtained all of the measures except those contained in the envelope with a final questionnaire concerning patient satisfaction and the possibility of written reflections (the latter for the music therapy group only) (Appendix 6ef), which could also be distributed by the researcher. The questionnaire was handed to the patient postoperatively; it was filled out privately and returned in a sealed envelope. Patient characteristics and procedure variables were obtained from the electronic patient journal and cross-checked with the operator as necessary.

In the current study, the nurses repeatedly measured the patient's self-reported experience of anxiety level and pain intensity. As a protocol ensuring consistent use of the measurement tool and to secure interrater validity, a nurse initially presented and explained the NRS to every patient both graphically and verbally.

13 A plain numerical categorical scale of wakefulness to sleepiness was used to record an overall impression of the patient's wakefulness in the perioperative phase, based on two existing scales: the Richmond Agitation-Sedation Scale (Sessler et al., 2002) and The Stanford Sleepiness Scale (https://web.stanford.edu/~dement/sss.html). Tailored to be both relevant to, and feasible for the current procedure, the study scale was reduced to four passing impressions of the patient's wakefulness, here understood as level of activity and responsiveness: 1. Awake, 2. Foggy, 3. Sleepy, 4. Asleep.

14 The total procedure is defined as the sum of three phases: preoperative + perioperative + 2.5 hours of postoperative.

		DAY 0 - PREPARATION			DAY 1 - OPERATION		
		Information and Pretesting			Preoperative	Perioperative	Postoperative
		Baseline				Means of repeated measures (≈ every 30 min.)	After 2 - 4 h
MEASURE POINT		0			1	2	3
Vital signs			RANDOMIZATION				
BP, SaO2, HR, RR		x[1]			x	x	x
Medication							
Analgetics, anxiolytics		x			x	x	x
Self-reported							
Pain intensity level (0-10)		x			x	x	x
Anxiety level (0-10)		x			x	x	x
Satisfaction, pain management (1-10)							x
Average of scores (1+2+3) pain, anxiety, vital signs					x		
Music therapy group only	Music therapy intervention provided			x	x Minimum 30 min. of music listening		x
	Satisfaction, music listening (1-10) + written reflections						x

[1] RR was not measured at baseline

Figure 3. Overview of measures; variables and timepoints

4.9 Analysis

4.9.1 Statistical analysis

The study's power analysis was based on data from other studies with comparable patient groups (Al-Azawy et al., 2015; Argstatter et al., 2006; Yinger & Standley, 2011). As mentioned earlier, patient satisfaction was chosen as the central outcome for the power calculation. Al-Azawy et al. (2015) used a self-reported numeric score for patient satisfaction with pain management (1–10), and their study's results revealed a median of 6.5 in the control group, increasing to 7.7 or 8.7 in two different intervention groups receiving standardized premedication or premedication plus patient information, respectively. A median score of 6.5 was estimated for the control group in the current study as well. Using a significance level of 5% and a power of 80%, 68 patients were required to discover a difference of 20% in patient satisfaction score.

Data involving patient characteristic and procedural variables were analyzed through descriptive distribution and reported by medians (IQR) or frequency (%) to ensure necessary group equality. Where clear differences appeared, further sensitivity analyses were performed.

Mann-Whitney U tests were performed for all primary and secondary outcomes because the psychometric data variables were not normally distributed. Effects sizes were calculated for data showing a trend towards differences between the groups ($p<0.2$) (Gold, 2004) by dividing the test statistic by the square root of the number of observations ($r=z/\sqrt{n}$)– that is, using a procedure relevant to Mann-Whitney U tests, classifying effect sizes with Cohen's r as small (r=0.10), medium (r=0.30) or large (r=0.50) (Pallant, 2016). Baseline differences associated with uncertainty were extensively checked through sensitive analyses using bootstrap analysis and quartile regression in STATA in addition to calculations of exact probability.

Analyses were performed in regards to the intention to treat, with imputation of missing data following the most plausible assumption (White, Horton, Carpenter, & Pocock, 2011). Due to the required assumption of normality, imputation of missing data using multiple imputations could not be applied when the data were skewed and included scores of zero. As a consequence, two alternative analyses considered the best- and worst-case outcomes, based on the lower and upper limits of the numeric scale for pain and anxiety. For the best case, it was assumed that the patient with missing scores had no pain/anxiety, so the value of 0 replaced the missing value. For the worst case, the value of 10 replaced the missing value. The results for perioperative pain/anxiety and the average of the scores were then presented with two possible outcomes, one from each alternative.

The most noticeable results from the first analysis were further explored in a supplementary analysis which incorporated subgroup divisions informed by those results as well as previous research. Aside from the main outcomes defined in the original design, all subgroups results were limited to descriptive distributions, thanks to the small sample size.

4.9.2 Supplementary analyses

When the results from the first analysis became clear, it aspired to an expanded perspective on the anxiety variable, which was the variable most affected by FaMuLi. A supplementary analysis of anxiety levels at separate measure points was performed for subgroups based on baseline anxiety, gender, and age. The subgroup samples were too small to allow for tests of significance, so the presentation was limited to descriptive medians and trends.

The additional data from patients in the music therapy group (n=32), including the use of playlists, scores of patient satisfaction with the music listening, and qualitative data of written patient reflections, were used to further illuminate the subgroup analysis of anxiety. The quantitative data on the use of playlists and satisfaction scores were presented as frequency distribution (%) and median. The written texts were analyzed using a supplementary qualitative method. Together, the subgroup analysis and the analyses of additional data represented an expanded perspective of the initial statistical analysis from the RCT.

A close reading of textual data, of course, characterizes qualitative or interpretive approaches, which also imply a relatively small amount of analyzed information, the rearticulation (that is, the interpretation) of the texts into new, analytical narratives, and the acknowledgement of hermeneutic circles of knowledge, which includes the researcher's own conditioned contextual understanding as an active contributor. While the written reflections in this study were brief rather than rich in nature, a systematic procedure derived from a content analysis method was used to organize and interpret the data (Krippendorff, 2019).

Content analysis

Content analysis (CA) is widely used as a qualitative method within the fields of the human sciences and health research with an emphasis on the patient perspective (Elo & Kyngäs, 2008; Ghetti & Keith, 2016; Hsieh & Shannon, 2005). CA enables the transfer of replicable and valid inferences from texts (or other meaningful matter) to the contexts of their use (Krippendorff, 2019). The core challenge of content analysis as a research concept, is to allow the relevant content of a given text to emerge in its full and rich relation to its particular context. As text material, the written reflections in the present study were not objective as such, but rather dependent on their context, and on the researcher as a reader and, at the same time, participating observer (in the role of music therapist). These contextual conditions must be understood and defined in order to reduce the scope of possible interpretations—that is, controlling the subjectivity through transparency of the process, as a qualitative replacement of replicability in quantitative research (Ghetti & Keith, 2016). CA results are validated through the process of relating them to "audience perception and behavioural effects"— in this case, the clinical observation and the duration of music listening. The central systemic approach of CA involves the extrapolation[15] of trends, patterns, and differences within the material. In the present study's supplementary analysis, the most apparent difference was the length/level of details of the written texts. The stringency of the original RCT data collection determines the standard, judgement, and evaluation of the data material. The extrapolation of trends was supported by a systematic process of searching for indices such as the appearance, frequency, characteristics of written concepts, indications of intensity, confidence or uncertainty following the statements, and the frequency of co-occurrence of concepts.

In the analysis, coding units and categories emerged through systematic reading and re-reading according to the following procedure (Krippendorff, 2019):

1. Defining sampling units of the text material gleaned for inclusion in the analysis. Reading and re-reading the text material to obtain a sense of a whole.
2. Organizing data by identifying coding units, including specific segments of content, with unique descriptions. Thereafter grouping coding units under higher-order headings formulating a general description of the research topic using distinct categories.
3. Interpreting and summarizing data by reporting the process and results of the analysis through distinct categories and narrative quotes.

The group coding relied on relatively brief written material, which gave it a high degree of unity but implied a risk of less analytical relevance. Syntactical distinctions based on words, known as the safest coding unit for written documents (Krippendorff, 2019), helped the analysis. The categorical distinctions were useful in describing units according to what they had in common.

The researcher translated the written patient reflections from Norwegian into English after the analysis, and the accuracy of the translation was independently validated by two researchers who were not otherwise involved in the study at any point.

15 Data extrapolation: "to project, extend, or expand known data or experience into an area not known or experienced so as to arrive at a usually conjectural knowledge of the unknown area" (https://www.merriam-webster.com/dictionary/extrapolate).

4.10 Ethics

As mentioned earlier, informed consent was obtained from all included patients, based on both oral and written information about the study. Study approval was received from the Regional Ethics Committee (REK) in Norway, document 2018/168/REK nord, and the study was registered in ClinicalTrials.gov no.: NCT04172662. According to CONSORT guidelines and the requirements from REK, the patients were assured of full anonymity as participants in the study, and they were told of their ability to withdraw their approval at any time. Data material was stored in a locked archive at the hospital, and the coding list was locked up and stored separately, with access given to only two members of the research team. The researcher administered the procedures for inclusion, with assistance from the coordinating nurse. The written patient information and questionnaire were in Norwegian, which was spoken by all participants (Appendix 2, 6ef).

Music therapy is known as a low-cost intervention without side effects (Gooding et al., 2012; Hole et al., 2015). From clinical practice, it is also known that individual reactions to music listening can be diverse and, in some instances, overwhelming. Choices about the current music therapy intervention were made to safeguard the interests of both patients and the medical team also in this perspective. The facilitation of the therapy included the chosen level of therapeutic support (Bruscia, 2014), timing, process, and the choice of technical equipment.

To avoid possible disruptions or unwanted reactions to FaMuLi[16], the music therapist was available in all procedure phases, also during the entire perioperative phase to observe the process and people involved, and to adapt the therapy if necessary. The self-reported measures were carefully selected to minimize the patient burden as far as possible in all phases, and there was no follow-up required for study participants beyond the two days most central to the invasive procedure.

In all, no negative consequences were anticipated for study participants, though possibly positive effects and experiences were anticipated for patients in the music therapy group, particularly with regard to their stress regulation.

16 Conceivable unwanted reactions to FaMuLi might be entirely negative emotional or physical responses to the music, expressed verbally or through mimicry, or body movements, by either the patients or members of the medical team.

5 Results: summary of papers

5.1 Paper I. Facilitated music listening: Music therapy in an invasive cardiac procedure

Blichfeldt-Ærø, S. C., Trondalen, G., & Halvorsen, S. (2019). Facilitated music listening: Music therapy in an invasive cardiac procedure. British Journal of Music Therapy, 33(1), 27–38. https://doi.org/10.1177/1359457519840131.

This paper provides a theoretical rationale for music therapy as invasive cardiac procedure support which led to a detailed semi-manualized protocol for the clinical music therapy intervention tailored as an adjunct in the extraction of electronic leads from cardiac implantable electronic devices with the patient awake. The music therapy intervention, called Facilitated Music Listening (FaMuLi), was based upon a biopsychosocial approach (Frankel et al., 2003b). An overall aim of the paper is to address theoretical clarifications and elaborate upon the possibilities, importance, and principles of a biopsychosocial approach in medical music therapy through descriptions of how such principles can be applied in a clinical music therapy practice. Melzack's theory of stress and pain (2001), and Ghetti's transactional model of music therapy as procedure support (2012) supply important theoretical concepts related to FaMuLi's biopsychosocial grounding. The paper provides an outline of five basic principles of biopsychosocial music therapy interventions in supportive medical care:

- Biological, psychological, and social factors are considered to be mutually dependent and interactive.
- The biopsychosocial perspective informs the patient treatment in all phases of admission.
- Biological, psychological, and social factors are reflected in the ongoing observations and embodiment of the supportive intervention (musical and relational).
- The patient is recognized as a person with individual needs through the empathic involvement of a trained music therapist who focusses on the patient's experiences, expectations, and personal resources.
- The music therapy service is an integrated part of the interdisciplinary treatment.

FaMuLi has three phases: (1) the preparation on the day before the procedure, (2) the sequences of music listening during the pre- and perioperative phase (>30 minutes), and (3) the opportunity for music listening and a closing dialogue postoperatively. The patients choose their preferred music within a researcher-selected sample of 12 pre-selected playlists provided through the application the Music Star. Biological, psychological, and social factors are integrated into the intervention as protocol elements of, for example, the choice of music, therapeutic guidance, and patient involvement.

Another central factor in the protocol development was ensuring feasibility with regard to both the logistics and the interdisciplinary context within the hospital, particularly in terms of the timeline of the medical procedure, the physical facilities, and the music therapist's role in particular procedure phases.

An optimized balance between individualization and standardization represents a core value of the clinical intervention protocol. FaMuLi, therefore, is tailored to be sufficiently standardized for its realistic implementation in the existing medical procedure, yet flexible enough to meet individual patient needs.

5.2 Paper II. Music therapy as an adjunct in extraction of leads from cardiac implantable electronic devices: A randomized controlled trial.

Blichfeldt-Ærø, S.C., Knutsen, T.M., Hagen, H.M., Diep, L.M., Trondalen, G., & Halvorsen, S. (2020). Music therapy as an adjunct in lead extraction procedures from cardiac implantable electronic devices. A randomized controlled trial. Applied Nursing Research, 56(December). https://doi.org/10.1016/j.apnr.2020.151376

This paper presents the main results from the original randomized controlled trial of Facilitated Music Listening used as an adjunct to regulate stress responses for patients in a specific invasive cardiac procedure. The study was conducted at the PM/ICD centre at Oslo University Hospital Ulleval with 68 participants randomized into a music therapy intervention group or a control group.

Informed by previous literature and research, patient satisfaction with pain management and average level of pain were chosen as the primary outcomes reflecting procedure stress responses (Al-Azawy et al., 2015; Bradt et al., 2016; Kühlmann et al., 2018; J. H. Lee, 2016). The chosen secondary outcomes were the average level of anxiety, regulation of physiological parameters, and the use of procedural medication. The data material also included baseline measures, patient characteristics, procedure variables, and additional information on the direct use of, and the patient's experience with the music therapy intervention.

Self-reported unidimensional numeric scales were used to measure the psychological variables, reported as medians with interquartile ranges. The final number of participants included in the analyses was 64. Effect sizes (r for non-parametric tests) were calculated when test results were $p<0.2$.

No effect of the music therapy intervention was found on the primary outcomes of the study. Patient satisfaction with pain management was 10.00 (8.00, 10.00) in the music therapy vs. 10.00 (9.00, 10.00) in the control group ($p=0.85$), and average level of pain 0.89 (0.22, 1.13) vs. 0.96 (0.36, 1.58), respectively ($p=0.38$). Of secondary outcomes, level of anxiety was identified as the variable most affected in terms of the regulation of stressors. Average anxiety score was 1.00 (0.33, 2.17) in the music therapy vs 1.67 (0.71, 3.35) in the control group ($p=0.056$, $r=0.24$). The difference between groups was most apparent in the postoperative phase ($p<0.001$, $r=0.47$). The use of analgesic/anxiolytic drugs and physiological parameters were similar across groups. No differences between groups were found regarding the physiological parameters or the use of procedural medication.

Patient satisfaction in this study was higher than expected. Accordingly, the power analysis was based on false estimates. Despite these sparse quantitative findings and the methodological limitations, the music therapy intervention was both feasible and safe during the invasive procedure. Findings of the patients' use of music listening, combined with the findings of anxiety levels, may suggest a role for music therapy. The study adds to the development of integrated patient care and interdisciplinary practice in invasive procedure support, and to the body of knowledge and experience with music therapy in invasive medical procedures.

5.3 Paper III. Music therapy in invasive cardiac procedures: Expanded perspective

Blichfeldt-Ærø, S. C., Halvorsen, S. & Trondalen, G. (submitted for publication). Music therapy in invasive cardiac procedures: Expanded perspective.

This paper presents a supplementary analysis of the study's original randomized controlled trial to expand the perspective on the impact of the music therapy intervention Facilitated Music Listening for patients during cardiac device lead extraction procedures in local anaesthesia.

The primary analysis found no significant effects of music therapy on the primary endpoints patient satisfaction with pain management and average pain level (Blichfeldt-Ærø et al., 2020). Among the secondary endpoints, average anxiety was found to be lower in the music therapy group than in the control group, but the difference was of borderline significance and associated with uncertainty. Additional data from patients in the music therapy group (n=32), showed that all the patients completed music listening >30 minutes, with a median duration of 127 minutes (109,156). The findings of anxiety levels and an overall positive impression that the music therapy intervention was well received, aspired for a supplementary analysis to explore the anxiety variable in more details, also illuminated by additional aspects of patient experiences.

This sub study analyzed data material obtained from patients during the original randomized controlled trial (n=64). A descriptive statistical analysis addressed the patients' self-reported numeric-rated anxiety levels in subgroups. The results were further illuminated by analyses of additional data from the patients who received music therapy (n=32)—that is, numeric scores of the patients' satisfaction with the music therapy intervention (1–10), and qualitative written patient reflections on their experience with music therapy. A supplementary qualitative content analysis addressed the written patient reflections.

The analysis found a trend of diverse timelines of anxiety related to subgroups of gender, age, and baseline anxiety level. Previous findings of higher levels of anxiety among women and the youngest patients (<66 years) were substantiated. The most substantial positive influence of music therapy in the present study was found for male patients and patients ≥66 years.

Independent of their anxiety levels, the music therapy patients reported positive experiences with music therapy, quantified with a maximum median on the satisfaction scale, 10 (9,10). The written reflections were found to be related to procedure coping, wellbeing, and satisfaction, expressed within four categories: (1) bodily sensations of wellbeing, (2) positive feelings, (3) presence of mind, and (4) useful intervention elements.

A limitation of this study is that the analysis of subgroup anxiety levels does not include statistical inference calculations for generalization, due to the small sample size. Also, the additional qualitative written material consisted of brief patient reflections only, and not thick descriptions, which would have been preferred.

In sum, although the primary analysis found that the regulation of physiological parameters, levels of pain, satisfaction and procedure medication were the same across both groups, Facilitated Music Listening was found to be appreciated by and supportive to the patients during the procedure. An expanded perspective was necessary to illuminate the results on anxiety levels from a patient perspective, and the findings

suggest a role for music therapy as an adjunct in future invasive procedures. Increased attention towards subgroup differences is recommended for future clinical practice and research, and further investigations should include a broader spectrum of data material.

6 Discussion

This study seeks to make contributions to the general development of medical music therapy, including its theoretical aspects and clinical experience as well as new research evidence. In the study, the clinical music therapy protocol known as Facilitated Music Listening (FaMuLi) was applied as procedure support during cardiac device lead extraction procedures. A randomized controlled trial was performed to detect possible measurable effects of FaMuLi on variables related to the patients' pain and stress responses during the procedure. This is the first study of music therapy as an adjunct in lead extraction procedures and the first study of an invasive cardiac procedure in local anaesthesia with the music therapist present in the operating theatre during the perioperative phase.

First of all, FaMuLi was found to be both feasible and safe during cardiac lead extraction procedures. The trial results for patient satisfaction with pain management, average pain levels, physiological parameters, and the use of perioperative medication showed no significant differences between the music therapy group and the control group. The study did identify that music therapy might promote a decrease in the average level of anxiety for the patients, most apparent in the postoperative phase. Independent of quantitative effect results and subgroup differences in anxiety, patients in the intervention group reported positive experiences with FaMuLi related to procedure coping, satisfaction, and overall wellbeing.

6.1 Methodological considerations

6.1.1 Study design

While the initial aims of this study were grounded in systemic complexity, it was decided from the start to rely upon a classical quantitative RCT design as the basis of the research study. The clinical music therapy intervention was ontologically and epistemologically rooted in systemic perspectives, influenced by the biopsychosocial approach and a humanistic clinical practice, which is the dominating tradition of music therapy within the Nordic countries (Ruud, 2008, 2017, 2020). Thus, the contextual foundation primarily informed the clinical music therapy intervention, but also the interpretation of results as demarcated parts of a complex whole. The methodological delineation, focusing on quantitative and quantified effect variables as the primary study results, served the purpose of increasing the interest and optimizing the cooperation with the existing medical culture and discourse; providing clarity, accuracy, and precision in the data; and matching the available research resources.

The ICD/PM centre was unfamiliar with music therapy and had little experience with systematic testing of non-medical procedure support. To ensure the feasibility of the study implementation, it was designed as a small-scale project to be integrated into the existing procedure protocols and routines at the hospital. The project team also wanted to simplify the inclusion of participants by minimizing patient burdens with respect to the treatment schedule, the depth of the music therapy intervention, and the collection of self-reported data. Through the first two stages of trial development (Chapt.4.3), the researcher considered the study feasibility to be adequate and implemented a full-scale RCT.

Although the evidence-base related to the positive health-related effects of music is growing, there is much diversity in the existing literature on music interventions related to medical procedures. First of all, both music therapy and music medicine interventions are represented, though the latter continues to dominate. In addition, much previous research into music interventions related to cardiac procedures focuses on pre- or postoperative interventions and effects. When the perioperative phase is included at all, the medical settings generally involve less complicated invasive procedures or diagnostic tests, including cardiac catheterization and coronary angiography as the most frequent (Bradt, Dileo, & Potvin, 2013; Ferreira et al., 2015; Jayakar & Alter, 2017; Vetter et al., 2015). Due to the diversity of previous research, and the lack of music therapy studies involving a medical setting similar to the present study, a range of comparable studies were drawn upon to inspire the design for the study at hand.

A three-armed design was considered, providing audiobook- or music listening without individualized elements to a third randomized group, but the model was defined as being outside the scope of the study early on. The two-armed design was settled based on the premise that it was *music therapy* which was to be examined, which always consists of music activity within a therapeutic relational process—that is, the music and the therapist cannot be separated. In addition to the profession-based development of FaMuLi with respect to theory, research and clinical methods, the individualized parts of the present music therapy intervention (Paper I) involved an active reliance upon music therapist competencies (Ruud, 2020). This point is further elaborated on in section 6.3.

After the period of the trial implementation, 54.2% of the screened patients had been found eligible (Fig.1). The most prominent reasons for exclusion were advanced age and lead(s) which had been implanted for less than one year. In retrospect, it was concluded that the maximum age could have been raised, because the exclusion criteria ensured that adequate communication could take place even with very old patients. A substantial part of the patients asked for participation, agreed to be included in the study (87.2%). Four of these patients were later excluded after randomization was completed. Two were sent home without the operation, because their initial referrals proved to be inaccurate. One turned out to be unwilling to cooperate with the study and should not have agreed to participate in the first place. Lastly, one should not have been asked to participate, as he proved to have cognitive deficiencies which became severe under the influence of medication. Thus, 64 (32 + 32) patients were ultimately included in the study and subsequent analyses (Fig. 1). In retrospect, it is clear that a safety margin should have been included in the power analysis.

Average levels of the variables were chosen as primary and secondary outcomes. However, as the study progressed, separate timepoint measures and timelines were found to provide more relevant information on the impact of the music therapy intervention. These separate data were available, and to begin with, the researcher mistakenly thought it would be possible to use the whole dataset more freely for analysis and interpretation. In line with the delimitation of the initially chosen RCT design, analyses of the separate measure points and timelines merely serve as complementary results from exploratory analyses.

Initially in this RCT study, the necessary development of the clinical music therapy protocol are encountered, which incorporates both humanistic and collaborative perspectives. Later on, considerations related to qualitative elements in the supplementary analysis are encountered. Thus, as this study evolved, a silhouette evoking an embedded mixed design (Cresswell & Clark, 2011) has appeared. The interest for the supplementary knowledge of patient experiences of the FaMuLi increased during the study. Although systematic individual intervention notes were taken throughout the study period as a necessary part of the clinical

practice, the study was not designed to include these as material for analysis. Hence, participant consent was not obtained for the use of systematic notes. Data that *were* available to expand this perspective to some extent, were details of the music listening (playlist choices, timing and duration of listening), scores of satisfaction with the music listening, and the patient experiences formulated in written reflections. If the present study had been designed as an embedded mixed methods study from the start, the project team might have conducted exploratory and in-depth elaborations which are lacking in the study as it now appears.

6.1.2 Reliability and validity

The present study's procedures of recruitment and allocation of participants were completed to high standards, following the CONSORT guidelines carefully and in its way eliminating the potential impact of bias of any researcher or medical staff person involved in its implementation.

The possibility of selection bias in the patients' case cannot be excluded. Most patients indicated their preference to be randomized in the music therapy group, so some might have been disappointed or particularly elated after the group allocation.

Although the possibility of bias, individual differences, and human errors during data collection are unavoidable in trials administered by human beings, the project team emphasized objective distance throughout the data collection. Procedures were established to ensure study reliability both for the collection of data and for the clinical music therapy intervention. These procedures were critical, as the study could not be blinded due to the intervention's character. The self-reported scores were given to staff nurses, or delivered in a sealed envelope. The inter-rater reliability was strengthened by the use of a limited, manageable number of nurses involved (ten at the PM/ICD centre, and similar number at the postoperative surveillance ward), which also reduced the risk of bias in the current study (Higgins et al., 2011). Through the initial clinical experience and dialogues, some variation was discovered within the medical staff concerning the definition and use of numeric scales—for example VAS and NRS tended to be mixed up, along with the first scale number (0 or 1), the latter of which bringing the potential of dramatic consequences for the statistical analysis. As a complement to the written data collection procedures, consistent verbal instructions were repeated to each nurse to further fortify the inter-rater reliability of the trial. Both the written and the verbal information included the ways in which the nurses were to give the patients information regarding the self-reported data, and the ways in which data collection was to be carried out in all phases of the study. Due to this rigid, but simple system, very few incidents disturbed the data collection.

Data collected from electronic patient journals were retrieved when the clinical intervention and other data collection efforts were concluded, so they did not impact the data or clinical treatment. As is the case with many research studies, the economic resources were limited, meaning that the team was unable to hire a researcher assistant, though such a contributor would have increased the study's reliability even more.

As the only music therapist on the project team, the researcher provided all of the music therapy interventions while also serving as the coordinating researcher. This double role introduces certain methodological challenges related to the possibility of bias which demanded, in turn, both stringency and transparency in the process. With respect to the reliability of the clinical music therapy intervention across the cases, a clinical intervention protocol was followed which included detailed guidelines of a practical, relational and

communicative nature (Robb & Carpenter, 2010). While the music therapist took systematic field notes throughout the music therapy sessions as well, these were not part of the data material, and the sessions were not documented. Video and/or audio recordings would have strengthened the treatment fidelity but was considered inadmissible due to both practical and ethical considerations. The fact that there was only one clinician involved in the study was an advantage as well, in that it eliminated the possibility of discrepancy in multiple therapists' qualifications and interpretations.

The secondary exclusion of four patients due to the violation of the exclusion criteria reduced the number of participants required, according to the power calculation. As mentioned before, a safety margin included in the power analysis would have eliminated any negative statistical influence by the secondary exclusions before the analyses (Aalen et al., 2018). However, as the results of the patient satisfaction with pain management were generally high, and the pain levels were generally low, more participants would not impact the results overall. Also, in retrospect, the team realized that the power calculation was built on false premises, which challenge the study's validity. Ideally, an extensive pilot study of the current plot would have been performed and probably prompted a change in design and measurement tools.

The primary outcome was associated with some weakness in the measurement of satisfaction on a numeric scale. A more in-depth and differentiated questionnaire of satisfaction would have better reflected certain social and communicative aspects of the trial—by addressing, for example, the quality of communication and care or the staff's recognition of patient needs (Ghetti, 2011; Mandel et al., 2019). In sum, adding more comprehensive self-rating questions or interviews postoperatively would have increased data validity and shed more light on patient experiences. However, implementing in-depth questionnaires would have required more time and effort from the patient in the postoperative phase and introduced the risk of dropouts, missing data or the imposition of an inappropriate patient burden (Schou, 2008). The project team did not regard detailed questionnaires as compatible with the recommendations at the time of the trial design planning.

Adverse events in data collection

A limited number of adverse events were noticed in the collection of data. Due to certain logistical challenges, a few of the baseline scores for pain and anxiety level were obtained by the researcher/music therapist, not the staff nurses. This was not considered as confounding incidents, as a qualitative assessment of pain and anxiety was also part of the preparative phase in the clinical music therapy intervention.

Due to a mistake in administering the trial protocols, the perioperative extraction pain was listed as the last measurement taken on two occasions. This was probably incorrect, as the processes which remain after actual lead extraction take at least 30 minutes (connecting the new electronic lead(s), placing the device, and suturing the incision), which would have allowed for another measurement. Obtained measures were included in the dataset as expected, yet missing measures can impact the overall outcome. Because the trial results of perioperative and average pain showed no effect of music therapy in general, however, the team did not consider this oversight to be important enough to warrant further sensitivity analysis.

Lastly, one patient was unable to report perioperative pain and anxiety scores for a considerable amount of time, due to high doses of perioperative medication during a complicated, long-lasting operation. The first and last perioperative measures were taken as expected, but associated with some uncertainty because

the patient was heavily medicated. In the analysis, it was not immideately clear how to resolve this data situation, as two perioperative measures were intact. Because the data was incomplete, however, the team decided to set the sum of the perioperative measures as missing, meaning that the average of scores (pre + peri + post) was missing as well. Another solution would have been to use the two existing measures and calculate a mean for the perioperative score. Sensitive analyses were performed using a best/worst analysis for average scores on pain and anxiety.

6.1.3 Reflections on study implementation

Among the many aspects of study implementation, the researcher saw some aspects as critical or foundational to the requisite access to the ward and patients, and these aspects impacted the study design and trial implementation. A central issue in medical music therapy today is striking a balance between implementing something new within the existing practice and not "getting in the way" of the procedure itself. Research indicates that healthcare personnel are skeptical about music therapy if they lack knowledge of or experience with it (Chadder, 2019; Hole et al., 2015). In the early phases of music therapy implementation, that is, researchers face challenges with actual interdisciplinary *collaboration* and sometimes must settle for interdisciplinary *coordination* instead. At the site of the present study, personnel had not encoutered either music therapy or any other non-medical supportive methods outside of standard patient care. The rather unusual, perhaps surprising implementation of the music therapy study in their setting was accepted, welcomed, and partial met with interest. Despite their supportive attitude, there proved to be challenging to find functioning structures for interdisiplinary communication within the brisk pace of routine work at the hospital. It also remained unclear whether the personnel ultimately saw the music therapy intervention as integrated into the patient treatment or a as parallel service of sorts. These challenges derive to some extent from the scholarly grounding of the music therapy discipline, and from its practice by individual professionals. Despite many years of experience within medical music therapy, the researcher still needed to spend time assessing and interpreting the context, trying to establish a comfortable and feasible role in the medical setting. The researcher's own professional history in developing a music therapy service into another medical department likewise included many years and many situations without a well-defined formal attachment to the institution in question. This included experiences of being "on guard" and constantly justifying the role of music therapy—experiences likely to influence the integration of music therapy into the present study's setting.

Furthermore, this process was perpetually coloured by the urgent need for study progression. Along the way, several nurses showed interest in the study, and brought up questions and related topics in the formal initial briefings and other informal dialogues both during and towards the end of the data collection period. Thanks to some of their insights, the researcher came to realize that exploring patient participation in more depth would have been relevant to the centre at OUS Ullevål, as well as to the study. The ward manager also expressed interest in utilizing the music therapist's competence to observe and evaluate the staff's communication with the patients. Unfortunately, the project team could not find room for these interesting topics within the study's scope.

The time required to realize functional interdisciplinarity and capitalize upon shared knowledge and experiences depends much upon institutional logics and communication as upon the project team's availability. The challenges of introducing new professions and viable interdisciplinarity within increasingly specialized hospital settings are well known yet not readily solved (Heggen, 2008; Ledger, Edwards, &

Morley, 2013; B. Wheeler, 2003). A study which sought the *permanent* implementation of music therapy would have required a more throughout organizational assessment in advance (Eide, 2020). While such issues are highly engaging and maybe even determinative for both research designs and outcomes, they remain outside of the scope of this thesis, and will not be discussed further here.

6.2 Evaluation of results

6.2.1 Patient satisfaction and pain

In previous research, patient satisfaction has been related to various aspects of their experiences, including hospitalization, stress level, pain management, anxiety level and communication with the medical staff. In our study, the central aspect of patient satisfaction was pain management, while the score also implied an intention of reflecting the procedure experience as a whole. Patient satisfaction was found to be very high in both groups, with the data severly skewed, and no difference was detected.

This finding contrasts with meta-analyses by Bechtold et al. (2009) and Hole et al. (2015). The former meta-analysis found that patient satisfaction increased significantly for patients receiving music interventions after a colonoscopy ($p>0.01$), where patient satisfaction was understood as the patients' overall experience with the procedure. While analyzing music as an aid in postoperative recovery, the latter meta-analysis found that music interventions provided before, during or after surgical procedures increased patient satisfaction (SMD 1.09, CI 95%=0.51–1.68). Both meta-analyses primarily refer to music medicine interventions rather than music therapy.

Similarly, single studies by Al-Azawy (2015) and Yinger and Standley (2011) have found increased satisfaction in patients receiving music or related interventions, such as improved patient information in a coping perspective. In the former study, patient satisfaction was scored on a numeric scale specifically looking at satisfaction with the preoperative information and pain management, as was the case in the present study. In the latter study, findings concerning patient satisfaction in favour of music therapy were scored on a Press Ganey Inpatient Survey mailed to the patients a short time after their hospital discharge. The study had very few respondents in the music therapy group as opposed to the control group, and only one patient referred to procedural support at all. The differences among these study samples, then, undermines the ability to compare them. The timing of the respective satisfaction measurement represents yet another complication. In the present study, satisfaction measurements were obtained during the first postoperative period, when the scores are likely to be influenced by the acute relief felt by the patient at the end of the procedure. If one waits several days, the patient will evaluate the procedure experience from a greater physical and emotional distance, and within an everyday environment.

Like the present study, other studies have found patient satisfaction scores to be generally high for both music intervention- and control group patients. Mandel et al. (2019) compared three aspects of patient satisfaction, including satisfaction with pain control, which were equivalent to the present study. They also worked with a variety of music interventions, including live or recorded music combined with verbal guidance. Palmer et al. (2015) evaluated music therapy interventions for women during breast surgery, with patient satisfaction rated verbally on a five-item questionnaire, using a seven-point Likert scale. The use of

a unidimensional numeric rating scale used for the measurement of satisfaction in the present study was a choice associated with validity challenges. Although these two studies used more differentiated questionnaires with a higher validity, their outcomes were also highly skewed and group differences did not occur.

Ripley et al. (2014) also report no significant differences between groups in satisfaction for patients undergoing cardiac catheterization. They measured satisfaction scores using STAI, meaning that anxiety was chosen to represent satisfaction. In a study evaluating music therapy for preoperative anxiety, Ghetti (2013) also combined anxiety and patient satisfaction, using a general score for satisfaction with care during hospitalization (measured by VAS) as one of several variables with which to evaluate anxiety. This study used repeated measures and evaluated differences between timepoints. Satisfaction was highest postoperatively for all three groups included, but with no significant difference among them. This study included expressive music therapy, while the other studies report from receptive music interventions.

On the whole, the meta-analyses and single studies represent a variety of definitions of patient satisfaction, provided music interventions, measurement tool alternatives, and statistical presentations which makes comparison among them challenging.

The present study's results for patient satisfaction may indicate that the highly satisfied patients had no issues related to procedure pain and stress. Another possible interpretation is that patient satisfaction related to pain management was not associated with stress levels—that is, that the outcome and measurement tool might be too reductive to serve the study's purpose in this setting. The highly skewed findings of low average pain levels in both groups imply a correspondence with the high satisfaction scores, but causation cannot be determined.

Unsurprisingly, numeric scales do not shed light on any details concerning the intervention's impact, although some studies strove for differentiation by limiting satisfaction scores to certain parts of the given procedure, as the present study did with satisfaction with pain management (Al-Azawy et al., 2015; Ghetti, 2013). Associative patterns between impact of the music therapy intervention on satisfaction, anxiety, and pain are not necessarily a given—Mandel et al. (2019), for example, revealed high scores of satisfaction in both the music therapy group and the control group despite significant differences between pre- and post-tests regarding stress and pain levels. In the present study, medians of both patient satisfaction with pain management and of patient satisfaction with the music therapy intervention were highly skewed, showing maximized scores. When looking into details of individual scores, however, the researcher also found examples of patients with low scores on the former, combined with substantial higher scores on the latter, suggesting that these patients evaluated FaMuLi independently, and not associated with the pain treatment as such. It has also been suggested that patterns of pain relief, not pain severity alone, might be the critical determinant for patient satisfaction (Ward & Gordon, 1996).

The present study's result of no effect of music therapy on pain levels contrasts with previous findings from Kühlmann et al. (2018) and Lee et al. (2016). The generally low pain levels might be determinative for these results, but inconsistent results have been also been found previously in a meta-analysis evaluating music and pain (Bradt, Dileo, & Potvin, 2013). The present study's trend towards decreased pain for music therapy patients postoperatively is associated with findings from Vetter et al. (2015) (ES= -0.31, CI -0.46, -0.17).

The timeline analyses of pain levels in the present study showed medians <1 in all phases except perioperatively for the music therapy group (=1.36). However, the peak point of pain level occured at the exact time of the extraction, when the lead was manually taken out (Fig. 4a). The pain level at other time points was considerably lower, and the peak point measures had little influence on the average level of pain, statistically speaking. Due to changes in the treatment plan after the group allocation or even during the perioperative phase, however, lead extraction was not ultimately completed for nine of the patients. They were still included in the data set, following the intention-to-treat principle. When selecting for only the cases with completed extractions, the distribution of timelines of pain revealed the peak pain to be higher for the control group than for the music therapy group (Fig. 4b). Because the use of analgesics and duration of invasive procedure were almost to equal for the two groups, these factors were not likely to have affected the pain levels. Likewise, no difference was found on the number of leads extracted or the duration of the

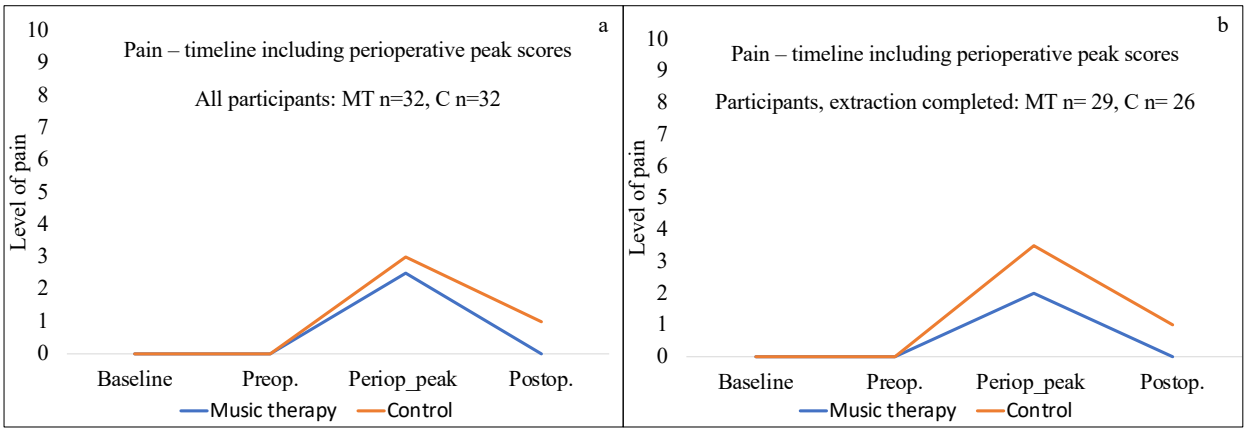


Figure 4. Timelines of pain level including perioperative peak scores for a) all participants and b) participants with extraction completed. Data presented as medians.

use of sheaths—the latter an indication of the complexity of the manual extraction.

The level of experience of the cardiologist performing the lead extractions could also have impaced certain procedure variables, but the trial did not account for this particular factor. The difference in peak pain levels for patients with the lead extraction completed suggests a need for further studies conducted with timelines or peak pain as an included outcome.

6.2.2 Anxiety

To the extent that increased procedure stress was a factor during cardiac device lead extraction procedures, it seemed to manifest itself as state anxiety—that is, it did not elevate average levels of pain or reduce patient satisfaction. The calculated effect size of average anxiety classified the difference as small in regard to clinical relevance, though in the upper layer of the classified category (r= 0.22–0.26, including sensitivity analysis of best/worse case results). Although it involved some uncertainty, the finding of a trend towards decreased average anxiety for the music therapy patients is in line with previous meta-analyses from Kühlmann et al. (2018), Bradt et al. (2013), and DeWitte et al. (2019). As in most studies, and in line with clinical experience, the present study found anxiety to be generally higher at baseline and preoperatively than postoperatively.

The calculated effect size on decrease of anxiety for music therapy patients was close to small preoperatively, and close to high postoperatively, the latter indicating a visual observable difference in clinical practice.

As baseline measures were taken the day before the invasive procedure, they most likely already reflected the sense of worry or stress one commonly feels when facing a new medical procedure for the first time. Similarly, a general decrease in postoperative anxiety likely reflects the relief accompagning the end of the procedure. Still, the present study found a significant difference between the anxiety levels of groups in this phase, suggesting that music therapy made a positive difference for those patients. The finding is in line with Vetter et al. (2015) and adds to the knowledge base of medical music therapy which emphazises preoperative anxiety in particular (Gooding et al., 2012).

It is known that patients with CIED have an increased risk of general anxiety and depression. The prevalence of anxiety in ICD patients is 13–38% and often manifested as PTSD[17] (Miranda, Stiles, Lever, & Mahadevan, 2018; Sears, Hauf, Kirian, Hazelton, & Conti, 2011). This frequency of occurrence indicates that patient anxiety should be addressed from preventive, acute, and long-term perspectives for patients with cardiac devices, meaning that stress management is recommended in diverse situations (Dornelas, 2012). PM/ICD centres are often unable to address psychosocial issues systematically due to a lack of the requisite interdisciplinary expertise and/or specialists available (Sears et al., 2011). Efforts have been made to promote the psychosocial aspects of general cardiac health care and to develop procedures suitable for patients with CIED (Kirian, Sears, & DeAntonio, 2012; Pedersen & Andersen, 2018; Pedersen, Knudsen, Dilling, Sandgaard, & Johansen, 2016). As mentioned earlier, all staff at the PM/ICD centre at OUS Ulleval follows general ethical guidelines for patient care. Beyond those general guidelines, they do not make systematic non-pharmacological services available to patients, except in this particular study period in relation to its provision of a music therapy service.

Despite an increasing focus on the psychosocial aspects of patient care and experiences related to procedural stress, pain, and anxiety, these aspects are generally not addressed in the literature on lead extraction procedures (Bongiorni et al., 2016; Kusumoto et al., 2017; Perez et al., 2018; Wazni & Wilkoff, 2016; Weinstock, 2019). This gap is probably due to a combination of logistical, economic and discursive reasons, in addition to vagaries associated with the distribution of responsibilities among professions. The operators and operation nurses are generally fully occupied with their primary task, the biomedical treatment of the disease, thereby leaving the competency of systemized and complex patient-centred care to other professions, which are not necessarily integrated into the intern hospital structure and staff. Alternatively, the medical staff might not be fully informed about the potential consequences of psychosocial issues and the related possibilities of systematic supplemental treatment, meaning that the professional or institutional demand for these services is low. Lastly, given that patient satisfaction is reliably high, the level of anxiety might be viewed as tolerable.

The present study found that timelines for anxiety differed among patient subgroups sorted by gender, age, and primary anxiety level (Fig.5). The subgroup findings of higher levels of anxiety in females and younger patients confirms previous findings (Delewi et al., 2017; Sears et al., 2011). Unfortunately, the timeline analysis suggested that the positive impact of music therapy for anxiety was lower for these subgroups as well, which is disturbing, as they apparently need even more supportive care. However, the subgroup

17 PTSD: Posttraumatic stress disorder

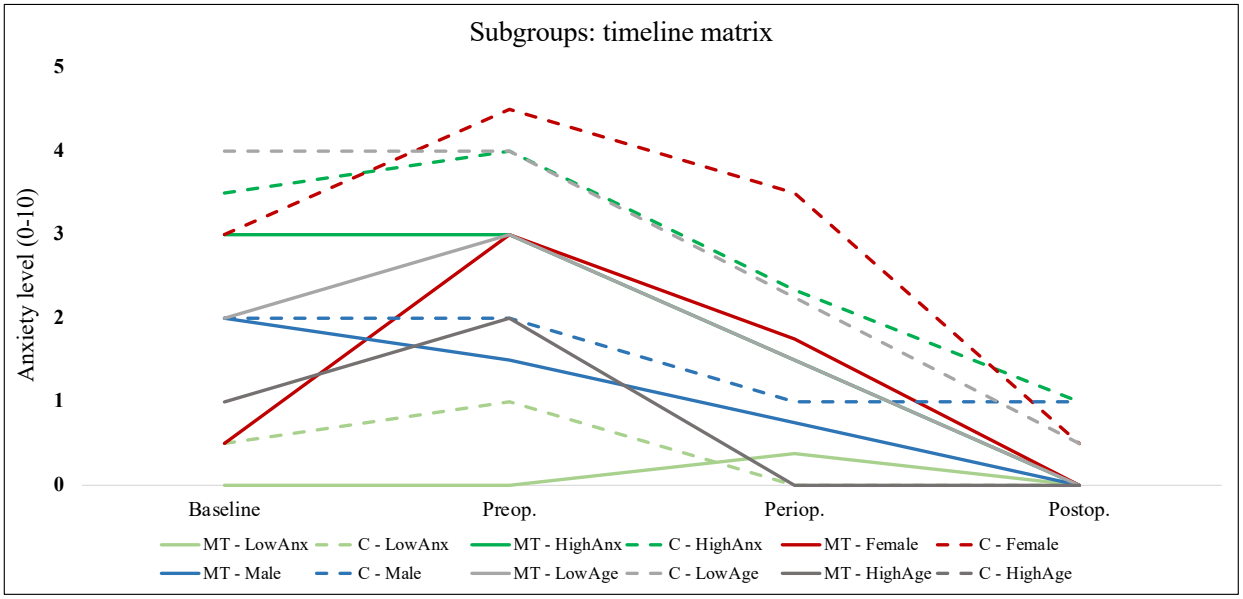


Figure 5. Timelines of anxiety in subgroups. Data presented as medians.

differences were not reflected in the qualitative additional data, which contained generally positive reflections across all subgroups.

The finding of diverse subgroup differences related to level of anxiety is intriguing and suggest yet further elaboration upon music therapy services to differentiate and costumize them to an even greater extent than that achieved by FaMuLi. While the levels of anxiety found in the current study were relatively modest, there are reasons to believe that higher anxiety is a problem for some individuals, and in relation to certain invasive procedures.

6.2.3 Physiological parameters and medication

Previous research on the effect of music interventions on physiological outcomes shows mixed and often inconsistent results, although positive findings in favour of music dominate in the meta-analyses (Bradt, Dileo, & Potvin, 2013; DeWitte et al., 2019; Jayakar & Alter, 2017; J. H. Lee, 2016). As markers of physiological regulation, the project team chose to measure systolic and diastolic blood pressure (BP and DBP), respiration rate (RR), heart rate (HR), and oxygen saturation (SaO2) in the current study. The results of average medians on physiological parameters showed that the patients were well regulated throughout the procedure regardless of group allocation, with no statistical differences between the groups. This finding is in contrast with studies by Bradt et al. (2013), Lee (2016) and Vetter et al. (2015), all of which found music interventions to significantly decrease systolic BP, HR, and RR. Also, DeWitte et al. (2019) found a significant decrease in summarized physiological stress-related outcomes, as indicated by BP, HR, and stress-related hormones. The present study's finding is consistent with previous single study results (Argstatter et al., 2006; Nilsson, 2009b; Ripley et al., 2014), and demontrates that the physiological effects of music interventions are often not found in single studies with a relatively small sample size.

Several factors may explain the present study's findings. It may be that the use of procedure medication worked adequately to stabilize the outcomes, so that the regulation of physiological parameters was less

of an issue here. It may also be that the effects of music therapy were mainly psychological and therefore had no impact on physiological variables. Lastly, it may be that the measurement tools are not sensitive or specific enough to register the effect of music on human physiology in terms of lower stress levels. As a solution to the latter, the study could have taken additional measures, such as adding stress hormones like salivary cortisol, to strengthen the data.

The timeline details of the physiological parameters demonstrated that the levels were evenly regulated throughout the procedure (Fig.6). The curves tended to be slightly lowered in the perioperative phase, probably due to the perioperative medication. The systolic blood pressure was somewhat higher preoperatively, and lower postoperatively in both groups. These curves are unlike the other curves of physiological parameters and represent the only ones which corresponds to the average timeline of anxiety levels to some extent. Systematic variations for the other physiological variables were not found.

The finding of no statistically significant effect of music therapy on the use of procedure medication contrasts previous research addressing perioperative music medicine (Bechtold et al., 2009; Graff et al., 2019; Lepage et al., 2001; Rudin et al., 2007; Vetter et al., 2015). The meta-analysis by Rudin et al. (2007) on patients in the endoscopy suite found music medicine to bring about a significant reduction in the use of analgesia ($p=0.001$) and a borderline reduction in the use of sedatives ($p=0.055$). In a single music medicine study on patients undergoing spinal anaesthesia, Lepage et al. (2001) found that less midazolam was required to achieve the necessary degree of relaxation if the patients were listening to music ($p<0.05$). Looking at

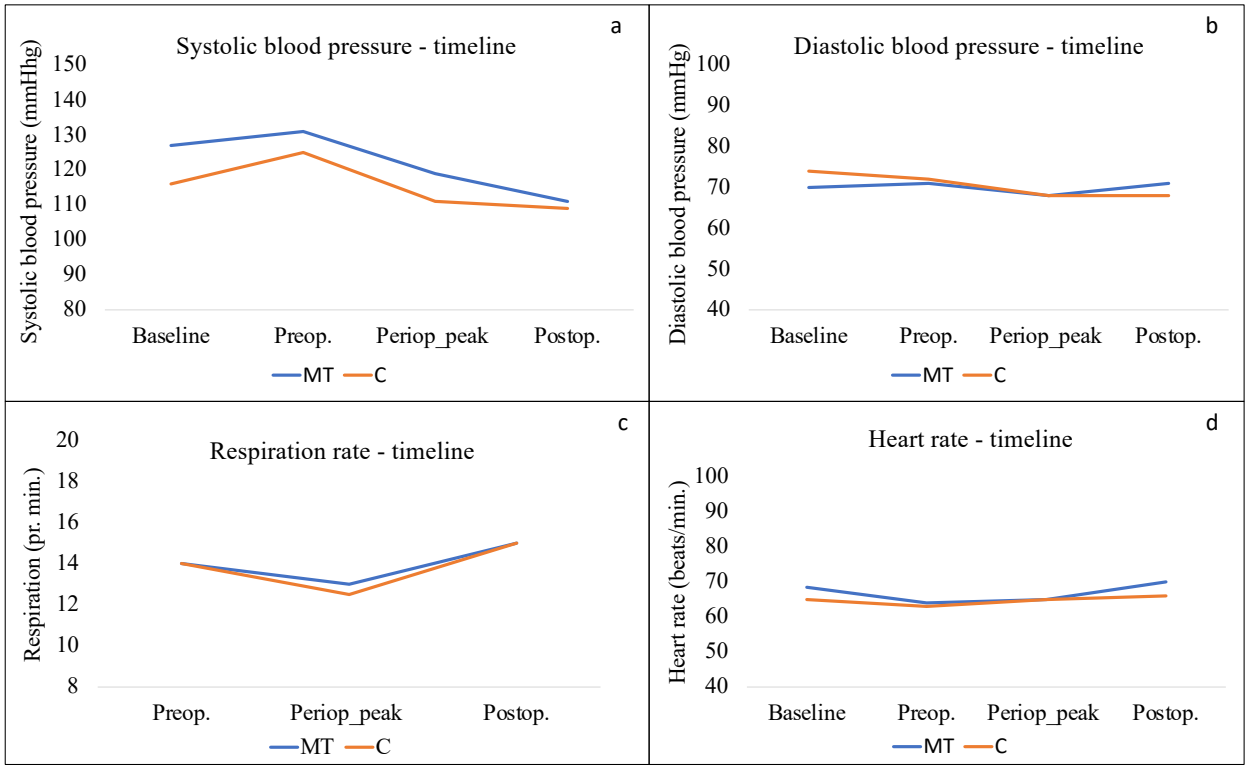


Figure 6. Timelines of physiological parameters; a) systolic blood pressure, b) diastolic blood pressure, c) respiration rate, and d) heart rate. Data presented as medians.

levels of anxiety in patients during preoperative nerve block placements, Graff (2019) found midazolam to be equally effective to music medicine. The patients in the midazolam group were more satisfied with their procedure experience, but, unlike the present study, Graff's study provided standardized music for relaxation, and individual preferences were not considered. In some studies where no effect of music interventions on the use of medication has been found, the use of medication has been reported but not actively replaced by alternative interventions (Argstatter et al., 2006; Bradt, Dileo, & Potvin, 2013; Jayakar & Alter, 2017; Palmer et al., 2015).

For invasive procedures performed in local anaesthesia, healthcare professionals consider it both necessary and safe to give the patients a certain amount of analgetic and anxiolytic medication. Due to possible side effects, they also recommend a low consumption level. Frequent side effects of fentanyl (in one out of ten patients) include nausea and stiff muscles, and stiff chest muscles can lead to reduced respiration. Serious side effects of midazolam are most frequent in elderly patients with comorbidities such as heart disease or decreased respiratory function, but they are associated with high doses only.[18] The project team did not attempt to actively reduce medication in the current study, a factor which most likely had an impact on the outcome. Drugs were given according to the standard procedure at the PM/ICD centre, as implemented in the study protocol. According to the protocol, all patients were given standardized doses of midazolam (calculated by weight) preoperatively. New doses were given if needed, as were perioperative doses of fentanyl—hence, a combination of standardized doses of premedication and later flexibility in medication based on clinical contextual assessment was followed. The combined approach was regarded as necessary to ensuring patient safety and wellbeing independent of individual patient reactions patients, and/or the individual complexity and duration of each lead extraction procedure.

Individual variations were noticed among the healthcare staff members regarding the amount of medication given and preferred degree of patient wakefulness during the invasive procedure. However, these variations were not a part of the data collection. Likewise, verbal comments from nurses scoring patient wakefulness, left an impression of subjectivity of interpretation as well. The descriptive analysis of the degree of wakefulness found the two groups to be relatively equal, though more control group patients were thought to be awake than music therapy patients (Fig. 7). This could suggest that music therapy increased patient relaxation, but as the scoring of these data was associated with uncertainty, they were not considered in further analysis. This situation demonstrates the fact that inter-rater reliability is hard to achieve when individual clinical judgement is part of the standardized procedure, which might be an issue for other studies as well.

The finding of physiologically well-regulated patients during the procedure is positive for the medical team. It substantiates the position that it is safe to perform cardiac device lead extractions in local anaesthesia with some procedural sedation as opposed to the general anaesthesia which is preferred in many other countries. Related to the anticipated alignment across biological and psychosocial variables, there were only found a slight trend towards correspondence in the timelines of systolic blood pressure and anxiety levels. These findings suggest that the regulation of physiological variables is well administered during cardiac device lead extractions performed in local anaesthesia at OUS Ulleval, and that reasons for the patients' appreciation of FaMuLi primarily will be found elsewhere.

18 Both descriptions retrieved from https://www.felleskatalogen.no/medisin/pasienter/

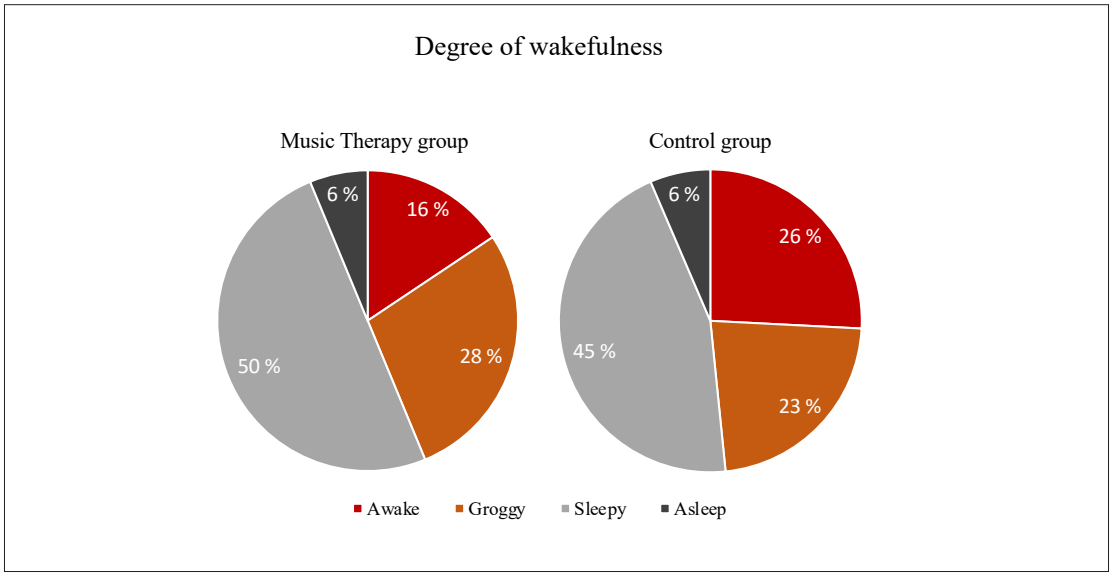


Figure 7. Degree of patient wakefulness in the perioperative phase. Data presented as percentage (%).

6.2.4 Experience with the music therapy intervention

The positive experiences with FaMuLi related to procedure coping, satisfaction, and overall wellbeing was expressed by the patients who received music therapy through their written words, but also manifested through their active choices of the music listening. The descriptive analysis of the use of playlists revealed that the music therapy patients preferred listening to music throughout the perioperative phase, in addition to their preoperative listening. Although all of the playlists provided through the Music Star application were used in the study, those which were the most rhythmically active and with elements from popular music were preferred. The finding of the patients' preferred duration of music listening alone, indicated that the patients preferred music listening over no music, though it says nothing about why. The supplementary analysis of the qualitative data offered some directions in this matter. The findings suggest that most patients utilized and valued the ability to combine playlists according to their preferences and varying needs during the procedure. Some patients commented that the music was not to their taste, but still reported high satisfaction with the intervention. This study was not designed with a particular interest in testing the Music Star as such, but it clearly benefited from this tool, which both met the professional standards required of its musical parameters and boasted an interface which was most suited to implementation in efficient and hygienic medical settings.

It can be questioned whether the variety of the supportive playlists on the Music Star was sufficiently broad related to individualized patient support emphasizing patient preference. Based on the researcher's clinical experience and professional background as a musicologist and as a musician, it was initially discussed whether the playlists' tilt towards "easy listening" was too extreme, bearing a risk of prompting patients' negative associations with "elevator music", or "muzak",[19] which should be avoided. Such associations might make the intervention either less relevant or less effective for younger patients and/or musically dedicated

19 Muzak was originally a brand of background music played in public and commercial establishments, registered in 1954. Today, 'muzak' has become a generic term for background music, also known as elevator or lift music, often bearing negative or ironic connotations referring to its poor quality. See https://en.wikipedia.org/wiki/Muzak.

or skilled listeners who prefer a broader spectrum of modern, rhythmical, advanced, or otherwise more "interesting" musical choices. The challenge is, however, acknowledged, of balancing evidence-based musical parameters for supportive treatment with an admittedly subjective awareness of the compositional and performative quality and aesthetic experience of specific selections.

Even if an optimized musical variety may exceed that of which is included in the Music Star's playlists, they are, in fact relatively various already. They had been validated through previous testing and positive experiences with them in the initial phase of the study. Therefore, the researcher settled on the use of the Music Star in its original form. Its visual colour system designed for increasing musical complexity was readily understood by patients and assisted their playlist choices. Given all of the digital options available today, the music therapist could have created playlists with the patient the day before the procedure. However, the time required to do this within the optimal musical parameters might make this impossible. It could, however, be implementable for follow-up patients who are scheduled for operation long time in advance.

The individualized and guided process of choosing music in FaMuLi was developed to generate a productive combination of researcher-selected and patient-selected playlists, as recommended in the literature and by previous research (Bradt, Dileo, & Potvin, 2013; Koelsch & Jancke, 2015; Krout, 2007). Combined with the playlists themselves, selected to optimize the regulation of physiological parameters, the process of choosing playlist sought to have a positive impact on psychosocial elements during the procedure. For the same purpose, the individual guidance concerning relaxation and coping techniques sought a balance between standardization and flexibility. The importance of the individualized guidance and process of choosing music, as highlighted by some patients, support the benefits of music therapy over music medicine, and the potential of receptive music therapy as a relevant parallel to live music therapy (Selle & Silverman, 2020).

Within the stringent format and outcomes of the primary analysis of the RCT, individual patient experiences with the music therapy intervention were expressed through unidimensional measures only. Within a humanistic, but also a systemic perspective, this represents a severe limitation, as outlined in the introductory study premises. Through the supplementary content analysis of written patient reflections illuminating the data in the supplementary analysis, some aspects were found to be consistently repeated, generally involving positive experiences related to bodily sensations, feelings, the presence of mind, and useful intervention elements. Quite often, the patients' words reflected an intensity of feeling in their description of this gratefulness and wellbeing. The turns of phrase give the impression that FaMuLi made a qualitative difference for some of the patients—one only nominally captured through the quantitative measurements. Another observation asking for future elaboration is the fact that partly negative reflections from some patients still concluded in a positive experience of the music therapy overall. One might wonder what intervention element(s) brought about such a shift—the music itself, the process of choosing it, the relational guidance of coping strategies, the relation itself? Or, perhaps most likely, the biopsychosocial combination of all of these.

As brief descriptions only, the supplementary qualitative data from the present study only scratches the surface of these questions. Adding more comprehensive self-rating questions or interviews in the post-operative phase was considered to put too much strain on the patients involved (Schou, 2008), but could have increased data validity and shed more light on patient experiences. Still, together with the cautious findings of decreased anxiety and the trends related to subgroup differences, these supplementary findings may serve as points of navigation for the future investigation of medical music therapy as an adjunct in invasive cardiac procedures.

6.3 Considering the discourses, the therapist's role, and the music

A theoretical stance and discursive affiliation determine the ways in which patient identities, the roles of the health professionals, and the treatment provided are understood, defined, and presented in the context of the study. Beause this study struck a balance between two discourses in its combination of a largely humanistic practice with a largely naturalistic research methodology, questions arise concerning the role and positioning of the music therapist. The *medical model* is based on guidelines from *Evidence-Based Medicine* (EBM), which prioritize evidence gleaned from the best research available and position the RCT as the primary means of doing so (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996). Within the medical model (and EBM), the physician/therapist is positioned as the expert and given all of the authority (Swaine, 2011). Systemic *patient-centred care*, on the other hand, emphazises a collaborative perspective which incorporates the facilitation of patient involvement and other relational aspects which are in line with systemic principles and research (Bensing, 2000).

Both orientations are acknowledged to be valuable in modern medicine today, but instead of being fully integrated, they live side by side and continue to reflect the influence of two different paradigms. Although EBM puts the most weight on quantitative "hard data", it is originally three-folded, including clinical experience and patient perspectives as the second and third sources of evidence. Hence, it initially recognized the importance of a broader notion of scientific evidence (Sackett et al., 1996), more in line with a patient-centred perspective.

Still, questions have been raised as to whether a patient-centred orientation remains an alternative to or a supplement of EBM (Anjum, 2016). Anjum (2016) and Bensing (2000) conclude independently that a combination of these two perspectives is in fact difficult in the absence of a paradigmatic ontological revolution within medicine, because the dominating medical model is exclusively based upon reductionistic causality, whereas the patient-centred model has a more thoroughly developed ideological alignment.

The music therapy discipline and profession are recognized by a variety of theoretical orientations identified across diverse fields of practice and countries (Baker & Young, 2016; Edwards, 2016; B. L. Wheeler & Murphy, 2016). However, Aigen (2014) discerns broad simlilarities across these theoretical orientations and music therapy practices in the "consensus model". The model reveals the dominance of reflective practice with an emphasis on music and an integrative focus which fundamentally opposes the medical model (Aigen, 2014). As "outliers" to the consensus model, Aigen finds strongly art-based orientations to one side and orientations strongly aligned with the medical model and its associated research principles on the other. Thus, in line with Anjum (2016) and Bensing (2000), several theorists in the academic field of music therapy also hold that an "expert-positioning" is incompatible with the core humanistic and collaborative principles of music therapy identified by the consensus model (Aigen, 2014; Rolvsjord, 2016; Stige, 2002).

However, Aigen (2014) has been criticized for not incorporating into the model ongoing integrative developments within the medical science and medical music therapy, and for ignoring the fact that important aspects of contemporary psychotherapeutic and psychodynamic thinking are both interpersonal and relational in nature. Consequently, his perspective on the current state of music therapy theory tends to be received as overly polarized (Bonde, 2015). Likewise, an increasing number of music therapy practitioners and researchers are embracing theories of systemic complexity, seeking unified knowledge via combined research methods of various kinds (Bradt, Burns, & Creswell, 2013; Dileo, 2015; Maxwell & Mason, 2011;

Rolvsjord et al., 2005). They strive for an integrated perspective which also exploit changes in practice and knowledge within the medical model in the interest of an improved interdisciplinary climate (Bonde, 2015).

Polarities do persist in the field of music therapy between music used in collaborative processes (known as "musicking") and music used as a stimulus to achieve paramusical changes. This polarization exemplifies the intrusion of binary thinking into even the most devotedly humanistic approaches. While reflecting on the coexistence of health-related and aesthetical aspects of the music experiences, Ruud (2020) writes:

> There seems to be a paradox here, and any attempt to polarize or create conflicts between the musical and paramusical approaches may be more a result of our habits of binary thinking than our actual practices. (Ruud, 2020)

Hence, while music therapy typically contests dualistic epistemological thinking, it nevertheless retains or exhibits certain discursive polarities *within* the music therapy profession.

Likewise, BPS has been criticized for the division of complexity into separated components—that is, the biological, the psychological and the social—as a consequence of following the medical model too tightly (Helle-Valle, 2014). This criticism also falls upon the present study, because it is repeatedly addressing one component at a time, while finally aiming at integrated patient care. It can be argued that by separating the components, one will not entail partly knowledge of intertwined connections within a complex entity, but detailed knowledge of apparently detached details. Instead, as a solution, knowledge of complex entities might demand a whole new way of thinking—a new language—and a future unifying concept with implications for research and clinical practice depending on a shared language across discourses (Anjum, 2016; Changeux & Ricoeur, 2000; Kristeva et al., 2018). Based on previous and latest experiences of clinical practice and research in this field, the researcher acknowledge the philosophic dilemma and shortcoming of BPS. This was also referred as a premise of the methodological delineation in the present study (chapter 4.1). A paradigmatic shift conveying a new "language" is anticipated in the years to come (Anjum, 2016; Kristeva et al., 2018), but for now, BPS might be the best approach available as a fundament for the development of clinical music therapy practice.

Based on biopsychosocial systemic thinking, the current thesis suggests that a combination of expert and collaborative thinking *is* possible when positioning the role of the therapist. Such a combinative role can be understood as providing an *extended expert perspective* in which humanistic values and methods regarding individual needs, relational aspects and patient involvement are incorporated into the evidence-based knowledge of the expert. The music therapy in the current setting was provided to patients from such an extended expert perspective. Nevertheless, evaluating the embodiment of the intervention, the importance of therapeutic qualifications and relational aspects in the current study can be discussed. As the clinical music therapist also served as the researcher in the current study, this double role might have influenced the ongoing interpretation and judgement in the clinical contexts as well as in methodological decisions. A separation of the functions could have been expedient in performing the extended expert role as a therapist.

While the music therapist was available and relating to the music therapy patients in all phases of the procedure, the degree of involvement varied, and the patients did listen to music on their own at times. Findings in the supplementary analysis suggest that the patients took advantage of the facilitative elements

of the intervention, including the individualized guidance provided in the preoperative preparation. Other studies have reported positive results regarding the decrease of patient anxiety due to music listening without the use of individualized or preoperative elements (DeWitte et al., 2019; Doğan & Şenturan, 2012; Jayakar & Alter, 2017; Kühlmann et al., 2018). Relatedly, though the evidence remains somewhat unclear, previous research suggests that there are advantages to having a certified music therapist directly engaged in patient support, to optimize individual assessment and facilitation (DeWitte et al., 2019; Dileo, 2016; Dileo & Bradt, 2005). The research and literature comparing music therapy and music medicine conclude that the two practices can be complementary in medical care (Trondalen & Bonde, 2012).

The fact that FaMuLi was planned, individually guided, and evaluated by a certified music therapist, indisputably makes it a music therapy intervention by definition (Bruscia, 2014; Ghetti, 2012; Gold et al., 2011). Still, its resemblance to music medicine practices is clear. This alignment between medical music therapy and music medicine, as well as relations among other fields of music therapy, is captured by the theoretical model of *health musicing* (Bonde, 2014).

Ruud (2020) suggests that, rather than struggling with exclusionary definitions of music therapy, researchers might focus upon which *competencies* are in play when music therapists are practicing their discipline. In terms of the present study, that is, one might wonder what music therapy competencies were activated during the clinical intervention. Because it relied entirely on pre-recorded music, there was no need for performative *musical* competency, but the skills of theoretical and auditive analysis of musical parameters were required to develop and present the playlists. (The use of the Music Star also ensured the professional playlist quality in the present study). In terms of the repertoire of music therapy *methods*, the receptive intervention FaMuLi was devised to meet patient needs in the medical procedure in a feasible way. This intervention tailoring process involved competencies in the areas of *methodology, theory, and research*, as well as knowledge of the health-related issues of the specific patient group. The music therapist also activated *clinical skills* during the individual assessments, shared listening and guidance, including the observations of micro-processes and the use of mentalization to form an understanding of what the patients may feel and think, before responding verbally and non-verbally (Trondalen, 2016). The *relational* aspects of receptive music therapy apply to experiences of musical companionship through shared listening (Ruud, 2020). The therapist's well-developed relational skills, which draw upon observation, responsiveness and resonance, enable the quick pivots which are required in short-term therapeutic settings such as medical procedures (Ansdell & DeNora 2016, in Ruud, 2020). While these clinical skills potentially characterize other health professionals as well , Ruud (2020) suggests that the sum of these competencies might be what defines the music therapist in distinction to other professions.

Within the international music therapy field, researchers and practitioners are growing more interest in expanding the music therapist's role to include indirect music therapy services as well (Bonde, 2011; Dermott et al., 2018; Palmer et al., 2015). Music therapists in medical hospitals, for example, could take on the responsibility of creating music programs, training and supervision of staff to accomodate services in a mixed field of music therapy and music medicine. This study's findings of trends concerning the varied effects of music therapy on certain patient subgroups and individuals demonstrate the need for a music therapist on site to facilitate individual adaptions of music interventions as needed. Of course, a music therapist's presence is not required for all patients, and the realistic implementation of music therapy services for invasive procedures could instead involve referral of patients who are determined to be at risk for or experiencing high anxiety (Ghetti, 2011; Palmer et al., 2017). It is also important to note that outside of

an RCT experiment, therapists are able to apply broader and more flexible use of music therapy methods, allowing them to both meet individual needs and expand the general availability of patient-centred care competency and non-medical treatment methods at medical hospitals. Today, guidelines for prioritized music therapy practice are already established as national recommendations within psychiatric health care in Norway, and they could serve as a model within the medical care field as well.[20]

6.4 Strengths and limitations

A strength of this research study is that the study population exlusively involved patients admitted to a national referral hospital within a given period, including otherwise unspecified participants in standard clinical practice. Thus, the study sample is a realistic representation of the relevant population. The rate of patients willing to participate in the study was high, and data collection was completed with almost no missing scores. The music therapy intervention was tailored and implemented within the framework of the existing medical procedure, and therefore in a realistic setting. The study's process of playlist choices, and use of playback devices represented feasible solutions to issues which arose in comparable previous research studies.

The main limitation of the study is the primary outcome. In retrospect, the strong skew in the primary outcomes was acknowledged, including the incomplete premises of the power calculations. This points to the lack of comparable studies, but also to the researcher's misjudgement concerning the chosen trial design. The judgement could have been improved through a thorough pilot study, with following adjustments of outcomes and power calculation. Nevertheless, the present study's RCT should be considered a small-scale study making a concrete contribution to future research.

Health care systems and procedures for patient care vary across countries, as does population character and patient identity. This study was performed in Norway, where cardiac device lead extractions are usually performed in local anaesthesia, unlike elsewhere. The external validity of this study may therefore be limited to patients admitted to a PM/ICD centre similar to the hospital in question here. Also, because the supplementary analyses did not include inferential statistics due to the small sample size, the generalization of its results is limited outside of the sample.

Due to the intervention's character, the study was not blinded, so bias cannot be excluded. Another possible limitation is that unanalyzed confounding variables may be present among the patient characteristics or procedure variables. Both of these limitations must be kept in mind when one interprets the results.

While the procedure situation, mechanisms of stress management, and the music therapy intervention are recognized as complex and multifactorial, the RCT is best suited for testing single factors. Although this limiting factor was a premise for the study design from the start, the consequence is that possibly important qualities of FaMuLi remain unexplored.

20 "The guidelines suggest that music therapists should work individually with the patients with most severe needs and that they, in addition, should prioritize supervising and supporting other carers in their attempts of integrating music activities into the practice of person-centred care" (Helsedirektoratet 2017, in Dermott et al. (2018, p. 269).

7 Conclusion

From the RCT of music therapy as an adjunct in cardiac device lead extractions performed with adult patients at the PM/ICD centre at OUS Ulleval, Norway, the following conclusions are made:

- The music therapy intervention, Facilitated Music Listening, was feasible and safe in all phases of the procedure.
- Patient satisfaction with pain management was high and average pain levels were low, with no significant differences between groups ($p=0.85$ and $p=0.38$, respectively). These findings suggest that issues related to satisfaction and pain are of limited relevance in these procedures.
- Patients who received music therapy showed decreased average anxiety compared to the control group ($p=0.056$). The finding is associated with uncertainty. Postoperatively, the difference was significant ($p<0.001$).
- No effect of music therapy was found on the use of analgesic medication, anxiolytic medication, or physiological parameters.
- Descriptive timelines of anxiety levels pointed towards various trends in subgroups of gender, age, and baseline anxiety.
- Independent of anxiety levels, the music therapy patients had positive experiences with music therapy related to procedure coping, wellbeing, and satisfaction, expressed as bodily sensations of wellbeing, positive feelings, the presence of mind, and accentuation of useful intervention elements. Thus, the music therapy intervention was appreciated by, and supportive to the patients during the procedure.

8 Implications and recommendations

The results and experiences gained through this study substantiate the need for acknowledging the inherent complexity of both implementing and evaluating the impact of music therapy in medical procedures. The study results add to the international research literature by presenting new knowledge about the effect of and experiences with medical music therapy in a hitherto unexplored procedure. The study's clinical music therapy intervention answered the call for detailed music therapy protocols for specific medical situations and was also implemented in the perioperative phase, making it a contribution to the medical field of the music therapy profession.

8.1 Clinical implications

The study results indicate that it is safe to perform extraction of leads from cardiac implantable devices both with and without music therapy as an adjunct. Improved pain management and regulation of physiological parameters are generally not needed for this medical procedure. Music therapy may be considered as an adjunct for the patients related to anxiety and wellbeing during the procedure. Based on indications of subgroup variations of anxiety, combined with patients' expressions of experiences with the music therapy intervention it is suggested that a future music therapy service should be differentiated based on individual referrals. Patients who report high baseline anxiety, or exhibit a general need for stress management support should be prioritized in terms of having a music therapist present, whereas other patients might be fine with an indirect music therapy service. The feasibility of the intervention protocol and the findings of decreased anxiety supported by qualitative positive patient experiences and the use of playlists, suggest the relevance of Facilitated Music Listening also for other patient groups related to anxiety and wellbeing during invasive procedures performed in local anaesthesia.

An awareness of subgroup differences should inform the ongoing evaluation of patient needs and supportive guidance. Within the scope of acute admissions on a national basis, preparative music therapy sessions exceeding 45 minutes might not be feasible. For local candidates, or as part of a collaboration with local hospitals, patients who are referred several weeks in advance might be prepared for music therapy as a stress-regulating support weeks ahead of the invasive procedure. In addition, preventive services for cardiac patients facing repeated medical procedures and hospital admissions could be developed.

In the present study, most patients chose to listen to playlists at the more complex end of the supportive scale. For further studies and clinical developments, it might be useful to revise the Music Star playlists to include a broader spectrum of genres, beats, and instrumentation, though one still informed by the taxonomy of supportive music (Wärja & Bonde, 2014). This adaption would better reflect the musical preferences of various patients.

8.2 Future research

As levels of pain and anxiety were relatively low in this study, future studies could directly compare the music therapy intervention to doses of midazolam for pre- and perioperative anxiety. As the economic expenses of a music therapist exceed the costs of midazolam, such studies must also consider the aspects of side effects, patient's wellbeing, long-term stress management, and the possibility of indirect music therapy service.

The investigation of physiological effect variables should be improved in future studies adding measures more sensitive to stress-related variations, for example cortisol saliva or galvanic skin response.

As earlier mentioned, a more expansive notion of scientific evidence is necessary to capture the entirety of patient reactions and experiences related to invasive procedures. So, instead of the strict evidence hierarchy often practised within evidence-based medicine, future methodologies should also accommodate evidence from qualitative methods, the medical humanities, and patient narratives, in addition to the experimental knowledge.

Future research designs should include interdisciplinary factors of the study implementation process, especially in settings where music therapy is not already integrated. Such factors can be part of the data material through the collection and analysis of a broad spectrum of written process material (for example systematic log notes, emails, meeting schedules, and reports), and through questionnaires or interviews capturing a medical staff perspective.

Also, future research designs should include a broader scope of patient experiences so as to better understand the importance and appropriation of different elements within the music therapy intervention. Because validated broad-spectrum questionnaires or in-depth interviews can be hard to accomodate in the acute phases of a procedure, researchers could obtain such data several weeks later, then use it to complement data from the acute phase.

Lastly, as more attention is paid to patient-centred perspectives and non-medical treatment, future studies should test Facilitated Music Listening as an adjunct to other medical procedures where the regulation of stressors might be even more important than it was in the present study's setting.

Literature

Aigen, K. (2014). *The study of music therapy*: New York: Routledge.

Al-Azawy, M., Oterhals, K., Fridlund, B., Assmus, J. & Schunster, P. (2015). Premedication and preoperative information reduces pain intensity and increases satisfaction in patients undergoing ablation for atrial fibrillation: a randomised controlled study. *Applied Nursing Research, 28*, 268–273.

Aldwin, C. M. (2007). *Stress, coping, and development: An integrative perspective* (2nd ed.). New York: The Guilford Press.

Allen, J. L. (2013a). Pain management with adults. In J. Allen (Ed.), *Guidelines for music therapy practice in adult medical care* (pp. 35–61). Gilsum: Barcelona.

Allen, J. L. (2013b). Introduction. In J. Allen (Ed.), *Guidelines for music therapy practice in adult medical care* (pp. 3–16). Gilsum: Barcelona.

Anjum, R. L. (2016). Evidence based or person centered? An ontological debate. *European Journal for Person Centered Healthcare, 4*(2), 421–429.

Argstatter, H., Haberbosch, W., & Bolay, H. V. (2006). Study of the effectiveness of musical stimulation during intracardiac catheterization. *Clinical Research in Cardiology, 95*(10), 514–522. https://doi.org/10.1007/s00392-006-0425-4

AudioCura. (2016). AudioCura M2. Retrieved from http://www.audiocura.com/da/portfolio/audiocura-m2/

Bair, M. J., Kroenke, K., Sutherland, J. M., McCoy, K. D., Harris, H., & McHorney, C. A. (2007). Effects of depression and pain severity on satisfaction in medical outpatients: Analysis of the medical outcomes study. *Journal of Rehabilitation Research & Development, 44*(2), 143–152.

Baker, F. A., & Young, L. (2016). The relationship between research and practice. In B. Wheeler & K. Murphy (Eds.), *Music Therapy Research* (3 ed., pp. 26–36) Dallas: Barcelona.

Bechtold, M. L., Puli, S. R., Othman, M. O., Bartalos, C. R., Marshall, J. B. & Roy, P. K. (2009). Effect of music on patients undergoing colonoscopy: A meta-analysis of randomized controlled trials. *Dig Dis Sci, 54*, 19–24. https://doi.org/10.1007/s10620-008-0312-0

Bensing, J. (2000). Bridging the gap: The separate worlds of evidence-based medicine and patient-centered medicine. *Patient Education and Counseling, 39*, 17–25.

Bernardi, L., Porta, C. & Sleight, P. (2006). Cardiovascular, cerebrovascular, and respiratory changes induced by different types of music in musicians and non-musicians: The importance of silence. *Heart, 92*, 445–452. https://doi.org/10.1136/hrt.2005.064600

Bertelsen, L. R. (Producer). (2019, 03.08.20). Musikstjernen - Short. Retrieved from https://www.youtube.com/watch?v=c4Y9p6AowMA

Bhaskar, R. (2011). *Reclaiming reality: A critical introduction to contemporary philosophy*. New York: Routledge.

Blichfeldt-Ærø, S. C., Knutsen, T. M., Hagen, H. M., Diep, L. M., Trondalen, G. & Halvorsen, S. (2020). Music therapy as an adjunct in cardiac devices lead extractions: A randomized controlled trial. *Applied Nursing Research, 56*(December). https://doi.org/10.1016/j.apnr.2020.151376

Blichfeldt-Ærø, S. C., Trondalen, G., & Halvorsen, S. (2019). Facilitated music listening: Music therapy in an invasive cardiac procedure. *British Journal of Music Therapy, 33*(1), 27–38. https://doi.org/10.1177/1359457519840131

Bonde, L. O. (2011). Health musicing - Music therapy or music and health? A model, empirical examples and personal reflections. *Music and Arts in Action, 3*(2). Retrieved from http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.464.4119&rep=rep1&type=pdf

Bonde, L. O. (2014). Helse-musicering: musik og helse. In L. O. Bonde (Ed.), *Musikterapi. Teori, utdannelse, praksis, forskning.* (pp. 235–244). Århus: Forlaget Klim.

Bonde, L. O. (2015). The current state of music therapy theory? *Nordic Journal of Music Therapy, 24*(2), 167–175. https://doi.org/10.1080/08098131.2014.987805

Bonde, L. O., Skånland, M. S., Ruud, E. & Trondalen, G. E. (2013). *Musical Life Stories: Narratives on health musicking* (Vol. 6). Oslo: Norwegian Academy of Music.

Bongiorni, M. G., Di Cori, A., Segreti, L., Zucchelli, G., Viani, S., Paperini, L., . . . Soldati, E. (2016). Where is the future of cardiac lead extraction heading? *Expert Review of Cardiovascular Therapy, 14*(10), 1197–1203. https://doi.org/10.1080/14779072.2016.1220832

Boutron, I., Altman, D. G., Moher, D., Schulz, K. F. & Ravaud, P. (2017). CONSORT Statement for randomized trials of nonpharmacologic treatments: A 2017 update and a CONSORT extension for nonpharmacologic trial abstracts. *Annals of Internal Medicine, 167*(1), 40–47.

Boyce, M. & Munn-Giddings, C. (2018). The impact of the arts in healthcare on patients and service users: A critical review. *2018*(26), 458–473. https://doi.org/10.1111/hsc.12502

Bradt, J., Burns, D. S. & Creswell, J. W. (2013). Mixed methods research in music therapy research. *Journal of Music Therapy, 50*(2), 123–148.

Bradt, J., Dileo, C., Magill, L. & Teague, A. (2016). Music interventions for improving psychological and physical outcomes in cancer patients (Review). *Cochrane Database of Systematic Reviews*(8).

Bradt, J., Dileo, C., & Potvin, N. (2013). Music for stress and anxiety reduction in coronary heart disease patients. *Cochrane Database of Systemic Reviews*(12), Cd006577. https://doi.org/10.1002/14651858.CD006577.pub3

Bradt, J., Dileo C. & Shim, M. (2013). Music interventions for preoperative anxiety. *Cochrane Database Syst Rev*(6), Cd006908. https://doi.org/10.1002/14651858.CD006908.pub2

Bringman, H., Giesecke, K., Thorne, A., & Bringman, S. (2009). Relaxing music as pre-medication before surgery: a randomised controlled trial. *Acta Anaesthesiol Scand, 53*(6), 759–764. https://doi.org/10.1111/j.1399-6576.2009.01969.x

Bruscia, K. (2014). *Defining music therapy* (3rd ed.). Gilsum, NH: Barcelona.

Chadder, N. (2019). An exploration into the perception of music interventions in hospitals amongst healthcare professionals. *Voices: A World Forum For Music Therapy, 19*(1), 1–19.

Changeux, J.-P. & Ricoeur, P. (2000). *What makes us think?* (M. B. DeBevoise, Trans.). Princeton NJ: Princeton University Press.

Cohen, B. E., Edmondson, D. & Kronish, I. M. (2015). State of the art review: depression, stress, anxiety, and cardiovascular disease. *American Journal of Hypertension, 28*(11 November), 1295–1302. https://doi.org/10.1093/ajh/hpv047

Cresswell, J. W. & Clark, V. L. P. (2011). Choosing a mixed methods design. In *Designing and conducting mixed methods designs* (2 ed., pp. 53–106) Los Angeles: Sage publications.

Damasio, A. (2002). *Følelsen av hva som skjer: Kroppens og emosjonenes betydning for bevisstheten.* (K. A. Lie, Trans.). Oslo: Pax.

Deharo, J., Bongiorni, M., Rozkovec, A., Bracke, F., Defaye, P., Fernandez-Lozano, I., . . . Platou, E. (2012). Pathways for training and accreditation for transvenous lead extraction: a European Heart Rhythm Association position paper. *Europace, 14(1) (Jan)*, 124–134.

Delewi, R., Vlastra, W., Rohling, W. J., Wagenaar, T. C., Zwemstra, M., Meesterman, M. G., . . . Henriques, J. P. S. (2017). Anxiety levels of patients undergoing coronary procedures in the catheterization laboratory. *International Journal of Cardiology, 228*, 926–930. https://doi.org/10.1016/j.ijcard.2016.11.043

Dermott, O. M., Ridder, H. M., Baker, F. A., Wosch, T., Ray, K. & Stige, B. (2018). Indirect Music Therapy Practice and Skill-Sharing in Dementia Care. *Journal of Music Therapy, 55*(3, Fall 2018), 255–279. https://doi.org/10.1093/jmt/thy012

DeWitte, M., Spruit, A., VanHooren, A., Moonen, X. & Stams, G.-J. (2019). Effects of music interventions on stress-related outcomes: a systematic review and two meta-analyses. *Health Psychology Review*, 1–32. doi:https://doi.org/10.1080/17437199.2019.1627897

Dileo, C. (1997). Reflections on medical music therapy: Biopsyhosocial perspectives of the treatment process. In J. Loewy (Ed.), *Music therapy and pediatric pain* (pp. 125–143). USA: Jeffrey Books.

Dileo, C. (2015). Introduction: Definitions and perspectives on advanced practice in medical music therapy. In C. Dileo (Ed.), *Advanced practice in medical music therapy: Case reports* (pp. 1–19). Cherry Hill, NJ: Jeffrey Books/Music Therapy Resources.

Dileo, C. (2016). The future of medical music therapy for adults. In C. Dileo (Ed.), *Envisioning the future of music therapy* (pp. 71–80). Philadelphia: Temple University's Arts and Quality of Life Research Center.

Dileo, C. & Bradt, J. (2005). *Medical music therapy: a meta-analysis and agenda for future research*. Cherry Hill, N.J: Jeffrey Books.

Doğan, M. V. & Şenturan, L. (2012). The effect of music therapy on the level of anxiety in the patients undergoing coronary angiography. *Open Journal of Nursing*(2), 165–169. https://doi.org/10.4236/ojn.2012.23025

Dornelas, E. A. (2012). *Stress proof the heart: Behavioral interventions for cardiac patients* (E. A. Dornelas Ed.). New York: Springer.

Edwards, J. (2016) (Ed.). *Oxford handbook of music therapy*. Oxford: Oxford University Press.

Eide, I. S. B. (2020). Institutional logics and the organizational context of music therapy. *Nordic Journal of Music Therapy*. https://doi.org/10.1080/08098131.2020.1775686

Elkins, G., Staniunas, R., Rajab, M. H., Marcus, J. & Snyder, T. (2004). Use of a numeric visual analog anxiety scale among patients undergoing colorectal surgery. *Clinical Nursing Research, 13*(3), 237–244. https://doi.org/10.1177/1054773803262222

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

Engel, G. L. (1977). The need for a new medical model: A challenge for biomedicine. *Science, New Series, 196, No 4286*, 129–136. Retrieved from http://www.jstor.org/stable/1743658 .

Engel, G. L. (1980). The clinical application of the biopsychosocial model. *American Journal of Psychiatry, 137*(5), 535–544.

Evans, D. (2002). The effectiveness of music as an intervention for hospital patients: a systematic review. *Journal of Advanced Nursing, 37(1)*, 8–18.

Fachner, J. (2016). Measurement of musical responses. In B. L. Wheeler & K. Murphy (Eds.), *MusicTherapy Research*. Dallas: Barcelona.

Falkum, E. (2008). Den biopsykososiale modellen: Bør den formuleres på nytt i lys av nevrobiologisk og stressmedisinsk forskning? *Tidsskriftet Den Norske Legeforening, Michael, 5*, 255–263.

Ferreira, N. C., Ramalho, E. S. & Lopes, J. L. (2015). Non-pharmacological strategies to decrease anxiety in cardiac catheterization: integrative review. *Rev Bras Enferm, 68*(6), 1093–1102. https://doi.org/10.1590/0034-7167.2015680614i

Folkman, S. (2007). The case for positive emotions in the stress process. *Anxiety, Stress, & Coping, 21*(1), 3–14. https://doi.org/10.1080/10615800701740457

Frankel, R., Quill, T. E. & McDaniel, S. H. (2003a). The future of the biopsychosocial approach. In *The biopsychosocial approach: Past, present, future* (pp. 255–267). Rochester: University of Rochester Press.

Frankel, R., Quill, T. E. & McDaniel, S. H. (2003b). Introduction to the biopsychosocial approach. In *The biopsychosocial approach: Past, present, future* (pp. 21–29). Rochester: University of Rochester Press.

Ghetti, C. M. (2011). *Effect of music therapy with emotional-approach coping in pre-precedural anxiety in cardiac catheterization.* (Doctor of Philosophy of Music Education (Music Therapy) PhD dissertation). University of Kansas,

Ghetti, C. M. (2012). Music therapy as procedural support for invasive medical procedures: Toward the development of music therapy theory. *Nordic Journal of Music Therapy, 2 (1)*, 3–35. http://dx.doi.org/10.1080/08098131.2011.571278

Ghetti, C. M. (2013). Effect of music therapy with emotional-approach coping on preprocedural anxiety in cardiac catheterization: A randomized controlled trial. *Journal of Music Therapy, 50*(2), 93–122.

Ghetti, C. M. & Keith, D. R. (2016). Qualitative content analysis. In B. L. Wheeler & K. Murphy (Eds.), *Music therapy research* (3. ed., pp. 521–526). Dallas: Barcelona.

Glasziou, P. (2015). Music and surgery [Audio podkast]. In. www.thelancet.com: The Lancet audio.

Gold, C. (2004). The use of effect sizes in music therapy research. *Music Therapy Perspectives: Music Periodicals Database, 22*(2), 91–95.

Gold, C., Erkkilä, J., Bonde, L. O., Trondalen, G., Maratos, A. & Crawford, M. J. (2011). Music therapy or music medicine? *Psychotherapy and Psychosomatics, 80*(5), 304. https://doi.org/10.1159/000323166

Gooding, L., Swezey, S. & Zwischenberger, J. (2012). Using music interventions in perioperative care. *Southern medical journal, 105*(9), 486–490. https://doi.org/10.1097/SMJ.0b013e318264450c.

Graff, V., Cai, L., Badiola, I. & Elkassabany, N. M. (2019). Music versus midazolam during preoperative nerve block placements: a prospective randomized controlled study. *Regional Anesthesia and Pain Medicine, 44*, 796–799. https://doi.org/10.1136/rapm-2018-100251

Grocke, D. (2016). Receptive music therapy. In J. Edwards (Ed.), *The Oxford handbook of music therapy* (pp. 684–706). Oxford: Oxford University Press.

Grocke, D. & Wigram, T. (2007). *Receptive methods in music therapy: Techniques and clinical applications for music therapy clinicians, educators and students*. London and Philadelphia: Jessica Kingsley.

Haefeli, M. & Elfering, A. (2006). Pain assessment. *Eur Spine J, 15*, 15–24.

Hanser, S. B. (2014). Music therapy in cardiac health care: Current issues in research. *Cardiol Rev, 22*(1), 37–42. https://doi.org/10.1097/CRD.0b013e318291c5fc

Havelka, M., Lucanin, J. D. & Lucanin, D. (2009). Biopsychosocial model – The integrated approach to health and disease. *Coll Antropol, 33*(1), 303–210.

Hawker, G. A., Mian, S., Kendzerska, T. & French, M. (2011). Measures of adult pain. *Arthritis Care & Research, 63*(S11), 240–252. https://doi.org/10.1002/acr.20543

Hazelton, A. G., Sears, S. F. & Rodriguez, E. (2012). Atrial fibrillation: A biopsychosocial approach to patient management. In E. A. Dornelas (Ed.), *Stress proof the heart. Behavioral interventions for cardiac patients*. New York NJ: Springer.

Heggen, K. I. (2008). Profesjon og identitet. In A. Molander & L. I. Terum (Eds.), *Profesjonsstudier* (pp. 321–332). Oslo: Universitetsforlaget.

Heiderscheit, A. (2013). Surgical and procedural support for adults. In J. Allen (Ed.), *Guidelines for music therapy practice in adult medical care* (pp. 17–34). Gilsum: Barcelona.

Helle-Valle, A. (2014). How do we understand children's restlessness?: A critique of the biopsychosocial model and ADHD as the dominating perspective in current understanding and treatment. *Voices, A world forum for music therapy*, *14*(1). https://doi.org/10.15845/voices.v14i1.741

Herrmann-Lingen, C. & Buss, U. (2007). Anxiety and depression in patients with coronary heart disease. In J. Jordan, B. Bardé & A. M. Zeiher (Eds.), *Contributions toward evidence-based psychocardiology: A systematic review of the literature* (pp. 125–157). https://doi.org/10.1037/11531-005

Higgins, J. P. T., Altman, D. G., Gøtzsche, P. C., Jüni, P., Moher, D., Oxman, A. D., . . . Sterne, J. A. C. (2011). The Cochrane collaboration's tool for assessing risk of bias in randomised trials. *BMJ, 343:d5928*, 1–9. https://doi.org/10.1136/bmj.d5928

Hjermstad, M. J., Fayers, P. M., Haugen, D. F., Caraceni, A., Hanks, G. W., Loge, J. H., . . . Kaasa, S. (2011). Studies comparing numerical rating scales, verbal rating scales, and visual analogue scales for assessment of pain intensity in adults: a systematic literature review. *Journal of Pain and Symptom Management, 41*(6), 1073–1093. https://doi.org/10.1016/j.jpainsymman.2010.08.016

Hodges, D. A. (2000). Implications of music and brain research. *Music Educators Journal, 87*(2), 17–22.

Hole, J., Hirsch, M., Ball, E. & Meads, C. (2015). Music as an aid for postoperative recovery in adults: a systematic review and meta-analysis. *The Lancet, 386*(10004), 1659–1671. https://doi.org/10.1016/S0140-6736(15)60169-6

Hsieh, H.-F. & Shannon, S. E. (2005). Three approaches to qualitative content analysis. *Qualitative Health Research, 15*(9), 1277–1288. https://doi.org/10.1177/1049732305276687

ICN. (2011). The ethical guidelines for nurses Retrieved from https://www.nsf.no/Content/2182990/seefile

Jayakar, J. P. & Alter, D. A. (2017). Music for anxiety reduction in patients undergoing cardiac catheterization: A systematic review and meta-analysis of randomized controlled trials. *Complement Ther Clin Pract., Aug;28*, 122–130. https://doi.org/10.1016/j.ctcp.2017.05.011

Keefe, F. & France, C. R. (1999). Pain: Biopsychosocial mechanisms and management. *Current Directions in Psychological Science, 8*(5), 137–141. https://doi.org/10.1111/1467-8721.00032

Kirian, K., Sears, S. F. & DeAntonio, H. (2012). Sudden cardiac arrest: A biopsychosocial approach to patient management of ventricular fibrillation and implantable cardioverter defibrillators. In E. A. Dornelas (Ed.), *Stress proof the heart. Behavioral interventions for cardiac patients* (pp. 25–44). New York NJ: Springer.

Knutsen, T. M., Vanberg, P., Steen, T., Skretteberg, P. T., Kamal, Z. & Platou, E. S. (2015). *Single sheath lead extraction, a single center experience of more than 1800 lead extractions*. Paper presented at the EHRA-2015. Abstract session retrieved from https://esc365.escardio.org/Congress/EHRA-EUROPACE-CARDIOSTIM-2015/Lead-management-and-syncope/117213-single-sheath-lead-extraction-a-single-center-experience-of-more-than-1800-lead-extractions#abstract

Koelsch, S. (2010). Towards a neural basis of music-evoked emotions. *Trends in Cognitive Sciences, 14*(3), 131–137. https://doi.org/10.1016/j.tics.2010.01.002

Koelsch, S. & Jancke, L. (2015). Music and the heart. *Eur Heart J, 36*(44), 3043–3049. https://doi.org/10.1093/eurheartj/ehv430

Krippendorff, K. (2019). *Content analysis. An introduction to its methodology* (4th ed.). Los Angeles, USA: Sage.

Kristeva, J., Moro, M. R., Ødemark, J. & Engebretsen, E. (2018). Cultural crossings of care: An appeal to the medical humanities. *Medical Humanities, 44*, 55–58.

Krout, R. E. (2007). Music listening to facilitate relaxation and promote wellness: Integrated aspects of our neurophysiological responses to music. *The Arts in Psychotherapy, 34*, 134–141. https://doi.org/10.1016/j.aip.2006.11.001

Kusumoto, F. M., Schoenfeld, M. H., Wilkoff, B. L., Berul, C. I., Birgersdotter-Green, U. M., Carrillo, R., . . . Wazni, O. (2017). HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. *Heart Rhythm, 14*(12), e503-e548. https://doi.org/10.1016/J.HRTHM.2017.09.001

Kühlmann, A. Y. R., de Rooij, A., Kroese, L. F., van Dijk, M., Hunink , M. G. M. & Jeekel, J. (2018). Meta-analysis evaluating music interventions for anxiety and pain in surgery. *British Journal of Surgery, 105*, 773–783. https://doi.org/10.1002/bjs.10853

Lazarus, R. & Folkman, S. (1987). Transactional theory and research on emotions and coping. *European Journal of Personality, 1*, 141–169.

Ledger, A., Edwards, J. & Morley, M. (2013). A Change management perspective on the introduction of music therapy to interprofessional teams. *Journal of Health Organization and Management 27*(6), 714–732.

Lee, J. H. (2016). The effects of music on pain: a meta-analysis. *J Music Ther, 53*(4), 430–477. https://doi.org/10.1093/jmt/thw012

Lee, K. C., Chao, Y. H., Yiin, J. J., Hsieh, H. Y., Dai, W. J. & Chao, Y. F. (2012). Evidence that music listening reduces preoperative patients' anxiety. *Biol Res Nurs, 14*(1), 78–84. https://doi.org/10.1177/1099800410396704

Legeforening, D. N. (2015). Code of Ethics for Doctors. Retrieved from https://www.legeforeningen.no/om-oss/etikk/etiske-regler-koder-deklarasjoner-og-lignende/code-of-ethics-for-doctors-/

Leist, C. P. (2013). Cardiac care. In J. Allen (Ed.), *Guidelines for music therapy practice in adult medical care* (pp. 84–113). Gilsum NH: Barcelona.

Lepage, C., Drolet, P., Girard, M., Grenier, Y. & DeGagné, R. (2001). Music decreases sedative requirements during spinal anesthesia. *Anesth Analg, 93*, 912–916.

Loeser, J. D. & Melzack, J. (1999). Pain: an overview. *The Lancet, 353*, 1607–1609.

Lukens, C., Turkoglu, D. & Burg, M. M. (2012). Stress management with cardiac patients. In E. A. Dornelas (Ed.), *Stress proof the heart: Behavioral interventions for cardiac patients* (pp. 199–221). New York NJ: Springer.

Lund, H. N., Bertelsen, L. R. & Bonde, L. O. (2016). Sound and music interventions in psychiatry at Aalborg University Hospital. *SoundEffect, (1)*, 48–68. Retrieved from http://www.soundeffects.dk/article/view/24912/21827

Lund, H. N. & Bertelsen, L. R. (2016). «Musikstjernen» - en ny stjerne i psykiatrien. *Dansk Musikterapi 13 (1)*, 3–10.

Mandel, S. E., Davis, B. A. & Secic, M. (2019). Patient satisfaction and benefits of music therapy services to manage stress and pain in the hospital emergency department. *Journal of Music Therapy, 56*(2), 1–25. https://doi.org/10.1093/jmt/thz001

Marteau, T. M. & Bekker, H. (1992). The development of a six-item short-form of the state scale of the Spielberger State-Trait Anxiety Inventory (STAI). *British Journal of Clinical Psychology, 31*, 301–306.

Maxwell, J. A. & Mason, G. (2011). Paradigms or toolkits? Philosophical and methodological positions as heuristics for mixed methods research. *Mid Western Educational Researcher, 24*(2), 27–30.

Maxwell, J. A. & Mittapalli, K. (2010). Realism as a stance for mixed methods. In A. Tashakkori & C. Teddlie (Eds.), *SAGE Handbook of mixed methods in social & behavioral research* (2nd ed. ed.). USA: Sage.

Melzack, R. (2001). Pain and the neuromatrix in the brain. *Journal of Dental Education, 65*(12), 1378–1382.

Metzner, S. (2012). A polyphony of dimensions: Music, pain, and aesthetic perception. *Music and medicine, 4*(3), 163–170.

Miranda, J., Stiles, M., Lever, N. & Mahadevan, H. (2018). Prevalence of depression and anxiety among patients with cardiac implantable electronic device (CIED). *Heart, Lung and Circulation*. https://doi.org/10.1016/J.HLC.2018.05.129

Moradipanah, F., Mohammadi, E. & Mohammadil, A. Z. (2009). Effect of music on anxiety, stress, and depression levels in patients undergoing coronary angiography. *East Mediterranian Health Journal, 15*(3), 639–647.

Nilsson, U. (2008). The anxiety- and pain-reducing effects of music interventions: a systematic review. *AORN Journal, 87*(4), 780–807.

Nilsson, U. (2009a). The effect of music intervention in stress response to cardiac surgery in a randomized clinical trial. *Heart Lung, 38*(3), 201–207. https://doi.org/10.1016/j.hrtlng.2008.07.008

Nilsson, U. (2009b). Soothing music can increase oxytocin levels during bed rest after open-heart surgery: a randomised control trial. *J Clin Nurs, 18*(15), 2153–2161. https://doi.org/10.1111/j.1365-2702.2008.02718.x

Novack, D. H., Cameron, O., Epel, E., Ader, R., Waldstein, S. R., Levenstein, S., . . . Wainer, A. R. (2007). The scientific foundation of the biopsychosocial model. *Academic Psychiatry, 31*(5, September-October), 388–401.

Pallant, J. (2016). *SPSS survival manual* (6 ed.). Berkshire, England: Open University Press.

Palmer, J. B., Lane, D. & Mayo, D. (2017). Surgical music therapy: The significance and implementation of music therapy in the operating arena. *Music Therapy Perspectives, 35*(1), 30–35. https://doi.org/10.1093/mtp/miv036

Palmer, J. B., Lane, D., Mayo, D., Schluchter, M. & Leeming, R. (2015). Effects of music therapy on anesthesia requirements and anxiety in women undergoing ambulatory breast surgery for cancer diagnosis and treatment: A randomized controlled trial. *Journal of Clinical Oncology, 33*(28), 3162–3168. https://doi.org/10.1200/JCO.2014.59.6049

Peal, J. E., Runnett, C., Thomas, H. E. & Ripley, D. P. (2018). An update on cardiac implantable electronic devices for the general physician. *Journal of the Royal College of Physicians of Edinburgh, 48*(2), 141–147. https://doi.org/10.4997/JRCPE.2018.208

Pearson, S. (2018). Why words matter: How the common mis-use of the term music therapy may both hinder and help music therapists. *Voices: A World Forum For Music Therapy, 18*(1). https://doi.org/10.15845/voices.v18i1.904

Pedersen, S. S. & Andersen, C. M. (2018). Minding the heart: Why are we still not closer to treating depression and anxiety in clinical cardiology practice? *European Journal of Preventive Cardiology, 25*(3), 244–246. https://doi.org/10.1177/2047487317744367

Pedersen, S. S., Knudsen, C., Dilling, K., Sandgaard, N. C. F. & Johansen, J. B. (2016). Living with an implantable cardioverter defibrillator: patients' preferences and needs for information provision and care options. *Europace*, 1–8. https://doi.org/10.1093/europace/euw109

Pelletier, C. L. (2004). The effect of music on decreasing arousal due to stress: a meta-analysis. *Joumal of Music Therapy, XU*(3), 192–124.

Perez, A. A., Woo, F. W., Tsang, D. C. & Carrillo, R. G., 7(3), . . (2018). Transvenous lead extractions: Current approaches and future trends. *Arrhythmia & electrophysiology review*, 210–217. https://doi.org/10.15420/aer.2018.33.2

Piepoli, M. F., Hoes, A. W., Agewall, S., Albus, C., Brotons, C., Catapano, A. L., . . . Verschuren, W. M. M. (2016). 2016 European guidelines on cardiovascular disease prevention in clinical practice (EACPR). *Eur Heart J, 37*, 2315–2381. https://doi.org/10.1093/eurheartj/ehw106

Pilgrim, D. (2015). The biopsychosocial model in health research: Its strengths and limitations for critical realists. *Journal of Critical Realism, 14*(2), 164–180.

Pittman, S. & Kridli, S. (2011). Music intervention and preoperative anxiety: an integrative review. *Int Nurs Rev, 58*(2), 157–163. https://doi.org/10.1111/j.1466-7657.2011.00888.x

Platou, E. S. (2019). Norsk pacemaker- og ICDstatistikk for 2018. *hjerteforum, 32*(2), 61–70.

Raja, S., Carr, D., Cohen, M., Finnerup, N. B., Flor, H., Gibson, S., . . . 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

Ripley, L., Christopoulos, G., Michael, T. T., Alomar, M., Rangan, B. V., Roesle, M., . . . Brilakis, E. S. (2014). Randomized controlled trial on the impact of music therapy during cardiac catheterization on reactive hyperemia index and patient satisfaction: the Functional Change in Endothelium After Cardiac Catheterization, With and Without Music Therapy (FEAT) study. *J Invasive Cardiol, 26*(9), 437–442.

Robb, S. L. & Carpenter, J. S. (2010). Reporting guidelines for music-based interventions. *Journal of Health Psychology, 16*(2), 342–352. https://doi.org/10.1177/1359105310374781

Rolvsjord, R. (2016). Resource-oriented perspectives in music therapy. In J. Edwards (Ed.), *The Oxford handbook of music therapy* (pp. 557–576). Oxford: Oxford University Press.

Rolvsjord, R., Gold, C. & Stige, B. (2005). Research rigour and therapeutic flexibility: Rationale for a therapy manual developed for a randomised controlled trial. *Nordic Journal of Music Therapy, 14*(1).

Rudin, D., Kiss, A., Wetz, R. V. & Sottile, V. M. (2007). Music in the endoscopy suite: a meta–analysis of randomized controlled studies. *Endoscopy, 39*, 507–510. https://doi.org/10.1055/s–2007–966362

Ruud, E. (2008). Et humanistisk perspektiv på norsk musikkterapi. In G. Trondalen & E. Ruud (Eds.), *Perspektiver på musikk og helse - 30 år med norsk musikkterapi, s. 5–28* (Vol. 2008:3). Oslo: Norges musikkhøgskole.

Ruud, E. (2017). Lik, men unik: Om musikkterapeutisk profesjonsforståelse og avgrensninger til andre aktører på musikk- og helsefeltet. *Tidsskriftet Musikkterapi*. Retrieved from https://www.musikkterapi.no/nyheter/kronikk-lik-men-unik?rq=ruud

Ruud, E. (2020). *Toward a sociology of music therapy: Musicking as a cultural immunogen*. Dallas: Barcelona.

Sackett, D., Rosenberg, W., Gray, J., Haynes, R. & Richardson, W. (1996). Evidence based medicine: what it is and what it isn't. *BMJ, 312*(13 january), 71–72.

Sanfi, I. (2012a). Et specialdesignet musikkoncepts betydning for generel velbefindende og helse hos børn med kræft i kemoterapi. In G. Trondalen & K. Stensæth (Eds.), *Barn, Musikk og Helse* (pp. 101–122). Oslo: Norges musikkhøgskole.

Sanfi, I. (2012b). *Music therapy: as procedural support under peripheral intravenous access involving young children.* (PhD). Aalborg University, Denmark,

Sanfi, I. (2018). Music Imagery in Child Oncology: A Scandinavian Multi-Site Research Project. *MICO.* Retrieved from https://www.micostudy.com

Schou, K. (2008). *Music therapy for post operative cardiac patients: A randomized controlled trial evaluating guided relaxation with music and music listening on anxiety, pain, and mood.* (Ph.D thesis). Aalborg: InDiMedia, Department of Communication, Aalborg University.

Sears, S. F., Hauf, J. D., Kirian, K., Hazelton, G. & Conti, J. B. (2011). Posttraumatic stress and the implantable cardioverter-defibrillator patient: What the electrophysiologist needs to know. *Circ Arrhythm Electrophysiol, 4*, 242–250. https://doi.org/10.1161/CIRCEP.110.957670

Selle, E. W. & Silverman, M. J. (2020). Cardiovascular patients' perceptions of music therapy in the form of patient-preferred live music: Exploring service user experiences. *Nordic Journal of Music Therapy, 29*(1), 57–74. https://doi.org/10.1080/08098131.2019.1663245

Selye, H. (1976). *Stress in health and disease*. Boston London: Butterworths.

Sessler, C. N., Gosnell, M. S., Grap, M. J., Brophy, G. M., O'Neal, P. V., Keane, K. A., . . . Elswick, R. K. (2002). The Richmond Agitation–Sedation Scale. Validity and reliability in adult intensive care unit patients. *American Journal of Respiratory and Critical Care Medicine, 166*(10), 1338–2002. Retrieved from https://doi.org/10.1164/rccm.2107138

Short, A., Gibb, H., Fildes, J. & Holmes, C. (2013). Exploring the role of music therapy in cardiac rehabilitation after cardiothoracic surgery: A qualitative study using the Bonny method of Guided Imagery and Music. *Journal of Cardiovascular Nursing, 28*(6), 74–81. https://doi.org/10.1097/JCN.0b013e31825bc9c9

Smith, R. C., Fortin, A. H., Dwamena, F. & Frankel, R. M. (2013). An evidence-based patient-centered method makes the biopsychosocial model scientific. *Patient Education and Counseling, 91*, 265–270.

Spintge, R. (2012). Clinical use of music in operating theatres. In R. MacDonald, G. Kreutz & L. Mitchell (Eds.), *Music, health & wellbeing* (pp. 276–286). New York: Oxford University Press.

Stegemöller, E. (2014). Exploring a neuroplasticity model of music therapy. *Journal of Music Therapy, 51*(3), 211–227.

Stige, B. (2002). *Culture-centered music therapy*. Gilsum: Barcelona.

Stress. (n.d.). In *Merriam-Webster.com dictionary*. Accessed August 31 2020 from https://www.merriam-webster.com/dictionary/stress

Swaine, Z. (2011). Medical model. In J. S. Kreutzer, J. DeLuca & B. Caplan (Eds.), *Encyclopedia of clinical neuropsychology* (pp. 1542–1543). New York, NY: Springer.

Tam, W. W., Wong, E. L. & Twinn, S. F. (2008). Effect of music on procedure time and sedation during colonoscopy: A meta-analysis *World Journal of Gastroenterology, September 14;14*(34), 5336–5343.

Thorgaard, B., Henriksen, B. B., Pedersbaek, G. & Thomsen, I. (2004). Specially selected music in the cardiac laboratory-an important tool for improvement of the wellbeing of patients. *Eur J Cardiovasc Nurs, 3*(1), 21–26. https://doi.org/10.1016/j.ejcnurse.2003.10.001

Timmis, A., Townsend, N., Gale, C. P., Torbica, A., Lettino, M., Petersen, S. E., . . . Cardiology, E. S. o. (2019). European Society of Cardiology: Cardiovascular Disease Statistics 2019. *Eur Heart J, 41*(1), 12–85. https://doi.org/10.1093/eurheartj/ehz859

Trondalen, G. (2016). *Relational music therapy: An intersubjective perspective*. Dallas TX: Barcelona.

Trondalen, G. & Bonde, L. O. (2012). Music therapy: Models and interventions. In R. A. R. McDonald, G. Kreutz, & L. Mitchell (Eds.), *Music, health & wellbeing* (pp. 40–62). Oxford: Oxford University Press.

van der Heijden, J. E., Araghi, S. O., van Dijk, M., Jeekel, J. & Hunink, M. (2015). The effects of perioperative music interventions in pediatric surgery: A systematic review and meta-analysis of randomized controlled trials. *PLOS ONE*, 1–11. https://doi.org/10.1371/journal.pone.0133608

Vetter, D., Barth, J., Uyulmaz, S., Uyulmaz, S., Vonlanthen, R., Belli, G., . . . Clavien, P. A. (2015). Effects of art on surgical patients: A systematic review and meta-analysis. *Ann Surg, 262*(5), 704–713. https://doi.org/10.1097/sla.0000000000001480

Ward, S. & Gordon, D. (1996). Patient satisfaction and pain severity as outcomes in pain management: A longitudinal view of one setting's experience *Journal of Pain and Symptom Management, 11*(4), 242–251.

Wazni, O. & Wilkoff, B. L. (2016). Considerations for cardiac device lead extraction. *Nature Reviews Cardiology, April;13(4)*, 221–229. https://doi.org/10.1038/nrcardio.2015.207

Weeks, B. P. & Nilsson, U. (2011). Music interventions in patients during coronary angiographic procedures: A randomized controlled study of the effect on patients' anxiety and well-being. *European Journal of Cardiovascular Nursing, 10*, 88–93.

Weinstock, J. (2019). Cardiac implantable electronic device lead removal. Retrieved from https://www.uptodate.com/contents/cardiac-implantable-electronic-device-lead-removal?search=Cardiac%20implantable%20electronic%20device%20lead%20removal&source=search_result&selectedTitle=1~17&usage_type=default&display_rank=1

Wheeler, B. (2003). The interdiciplinary music therapist. Retrieved from https://voices.no/community/?q=fortnightly-columns/2003-interdisciplinary-music-therapist

Wheeler, B. L. & Murphy, K. (2016). Overview of music therapy research. In B. L. Wheeler & K. Murphy (Eds.), *Music therapy research* (3 ed., pp. 1–9). Dallas: Barcelona.

White, I. R., Horton, N. J., Carpenter, J. & Pocock, S. J. (2011). Strategy for intention to treat analysis in randomised trials with missing outcome data. *BMJ, 342*. https://doi.org/10.1136/bmj.d40

Wulsin, L. (2012). Psycological challenges of coping with coronary artery disease. In E. A. Dornelas (Ed.), *Stress proof the heart. Behavioral interventions for cardiac patients* (pp. 9–24). New York NJ: Springer.

Wynne, L. C. (2003). Systems theory and the biopsychosocial approach. In R. Frankel, T. E. Quill & S. H. McDaniel (Eds.), *The biopsychosocial approach: Past, present, future* (pp. 220–230). Rochester: University of Rochester Press.

Wärja, M. & Bonde, L. O. (2014). Music as co-therapist: Towards a taxonomy of music in therapeutic music and imagery work *Music and medicine, 6*(2), 16–27. Retrieved from https://mmd.iammonline.com/index.php/musmed/article/view/MMD-6-2-5

Yinger, O. S. & Standley, J. (2011). The effects of medical music therapy on patient satisfaction: As measured by the Press Ganey inpatient survey. *Music Therapy Perspectives; Oxford, 29*(2), 149–156.

Ærø, S. B. (2016). *Organisering av norsk musikkterapi i pediatri - en kvalitativ intervjuundersøkelse.* (Master thesis). NMH Oslo, Norway.

Ærø, S. B. & Aasgaard, T. (2011). Musikkterapeut på en sykehusavdeling for barn: Helsefremmende arbeid for både pasient og miljø. In K. Stensæth & L. O. Bonde (Eds.), *Musikk, helse og identitet* (pp. 141–161). Oslo: Norges musikkhøgskole.

Aalen, O. O., Frigessi, A., Moger, T. A., Scheel, I., Skovlund, E. & Veierød, M. B. (2018). *Statistiske metoder i medisin og helsefag* (2.utg. ed.). Oslo: Gyldendal Akademisk.

Aasgaard, T. (2002). *Song creations by children with cancer: Process and meaning.* (PhD). Aalborg Universitet, Aalborg.

List of papers

Paper I: Facilitated music listening *(published)*

Paper II: Music therapy as an adjunct in cardiac device lead extraction procedures: A randomized controlled trial *(published)*

Paper III: Music therapy in invasive cardiac procedures: Expanded perspective *(submitted for publication)*

Paper I

Blichfeldt-Ærø, S. C., Trondalen, G., & Halvorsen, S. (2019)

Facilitated music listening:
Music therapy in an invasive cardiac procedure.

British Journal of Music Therapy, 33(1), 27–38.
https://doi.org/10.1177/1359457519840131

Article

BJMT

British Journal of Music Therapy
1–12

DOI: 10.1177/1359457519840131
journals.sagepub.com/home/bjm
SAGE

Facilitated music listening: Music therapy in an invasive cardiac procedure

Stine Camilla Blichfeldt-Ærø and Gro Trondalen
Norwegian Academy of Music, Norway

Sigrun Halvorsen
Oslo University Hospital, Ulleval, Norway; University of Oslo, Norway

Abstract
This article presents and discusses a clinical music therapy protocol for use during an invasive cardiac procedure and the theoretical rationale behind it. The protocol was developed for a specific invasive cardiac procedure performed transvenously with local anaesthesia: cardiac implantable electronic device lead extraction. The music listening intervention presented in the protocol aims to optimise stress and pain management for patients through patient involvement, communication, individualised music listening and relaxation techniques. The Music Therapist remains present throughout the peri-operative phase (in the operating theatre during the operation). The music is chosen from a limited set of prepared playlists through a process involving assessment and patient preference. Biological, psychological and social components are integrated into the protocol, which is also informed by the theory of music therapy as procedural support, the neuromatrix theory of pain and receptive music therapy techniques. The protocol was developed to be standardised for implementation into the existing medical procedure, yet flexible enough to meet individual patient needs. It is the cornerstone of the research protocol of an ongoing randomised controlled trial at the Department of Cardiology at Oslo University Hospital Ulleval. Results of the randomised controlled trial, focussing on quantitative efficacy outcomes, are expected in 2020.

Keywords
biopsychosocial; intervention protocol; invasive cardiac procedure; medical music therapy; music listening; procedure support

Background

Music therapy in somatic health care

The last few decades have seen an increasing interest in medical music therapy and music medicine in both clinical practice and research settings (Dileo, 2016). There is now a small but promising track record of studies concerning the effects of music on physical and psychological outcomes. Music can evoke and regulate mood and emotions as well as activate changes in heart activity, blood pressure (BP) and breathing (Koelsch and Jancke, 2015). Systematic Cochrane reviews show that music listening has a beneficial effect on the reduction of stress and anxiety in patients with coronary heart disease and cancer (Bradt et al., 2013a, 2016), and in mechanically ventilated patients (Bradt and Dileo, 2014). Systematic reviews and meta-analyses have also discovered a significant decrease in anxiety and pain for adult patients receiving music intervention before, during and after surgery, as well as increased patient satisfaction with the treatment (Bradt et al., 2013b; Hole et al., 2015; Kühlmann et al., 2018). A recent meta-analysis found a significant decrease in anxiety and pain in adult patients receiving music intervention before, during and after surgery (Kühlmann et al., 2018). Music listening, using researcher-selected music, was found to have a relaxing and calming effect on patients during intra-cardiac catheterisation (Argstatter et al., 2006). These various anxiety-reducing effects appeared to be most pronounced when patients could choose which music to listen to (Bradt et al., 2013a). Although the evidence for the benefits of music medicine and music therapy is growing, and the importance of music medicine and medical music therapy has increased in society in general, the results and conclusions of previous studies should be interpreted cautiously, due to the risk of bias, the lack of power calculation or the small sample sizes used in many of the studies. Furthermore, such studies

Corresponding author:
Stine Camilla Blichfeldt-Ærø, Centre for Research in Music and Health (CREMAH), Norwegian Academy of Music, Slemdalsveien 11, Oslo 0363, Norway.
Email: camillablich@gmail.com

often originate in music medicine, not music therapy, or fail to differentiate between the two (Gold et al., 2011). Music therapy involves a therapeutic process of assessment, treatment and evaluation facilitated by a trained Music Therapist and informed by evidence-based practice and research (Bruscia, 2014). Music medicine, however, can be provided outside of a therapeutic process and derives entirely from the effects of the music itself (Bonde, 2011; Bruscia, 2014; Dileo, 2016). Music therapy in somatic health care, also known as medical music therapy, has been defined as 'the use of music and relationship in a reflexive therapeutic process to treat persons whose primary presenting problem is medical in nature' (Dileo, 2015: 3). Music therapy may be preferable to music medicine, and more studies involving a Music Therapist are clearly called for (Bradt et al., 2016; Dileo, 2016; Hanser, 2014).

Although the promising results of medical music therapy in somatic health care are increasingly clear, the potential for music therapy as an adjunct is far from adequately employed or even fully explored. If the music therapy profession is to develop and grow, there is a need for more research, interdisciplinary cooperation and clinical protocols tailored to specific somatic situations and patient groups, and to peri-operative settings in particular (Dileo, 2016; Hanser, 2014; Koelsch and Jancke, 2015; Palmer et al., 2015; Robb and Carpenter, 2010). The standardisation of assessments and outcome measures, the detailed description of the music and relational involvement and the development and implementation of individualised clinical protocols are among the topics recommended to be included in future research on medical music therapy (Hanser, 2014; Koelsch and Jancke, 2015; Robb and Carpenter, 2010; Rolvsjord et al., 2005).

Medical situation

The past few decades have seen a growing demand for the implantation of cardiac implantable electronic devices (CIED), such as pacemakers and implantable cardiac defibrillators (ICDs). This is due to an ageing population and recent guidelines which recommend indications for these electronic devices (Kusumoto et al., 2017; Peal et al., 2018). Accompanying the increase in number of implantations, there has been a corresponding increase in the need for pacemaker and ICD lead extractions (i.e. removing the electronic lead implanted between the device and the heart, inside the subclavian vein) due to complications, infections and lead advisory safety alerts (Bongiorni et al., 2016; Wazni and Wilkoff, 2016).

The pacemaker centre at the Department of Cardiology, Oslo University Hospital Ulleval (OUH) is a leading centre for pacemaker and ICD lead extractions, treating patients from all over Norway. Approximately 150 lead extractions are performed every year, and the number is increasing. Indications include infections and direct or indirect signs of fracture; lead extractions can also be prophylactic at the time of a generator change. Lead extractions at OUH are usually performed transvenously with local anaesthesia and last between 2 and 6 hours (Deharo et al., 2012). Analgesic and anxiolytic drugs are given intravenously at the start of the procedure, and additional doses may be given later, depending on the duration of the procedure and the level of patient pain and anxiety. In complicated cases, for very anxious patients, or when the procedure takes a very long time, general anaesthesia has to be introduced (Wilkoff, 2009). The use of hospital resources is lower, however, with local anaesthesia, as is the general risk of patient complications, and local anaesthesia is therefore preferred at OUH. Despite treatment with drugs, most patients will experience some pain and/or anxiety during the local anaesthesia procedure. The use of drugs is limited by their sedative effect, among other things. Patients with high levels of anxiety also experience significantly greater pain intensity than patients with lower anxiety levels. Appropriate information and good communication are important components of patient satisfaction and the reduction of anxiety. Experts also recommend engaging patients as informed and active partners in their pain control and overall treatment (Al-Azawy et al., 2015). This resonates with the importance of patient involvement in the choice of music for the present protocol.

Facilitated Music Listening in an invasive cardiac procedure

In order to optimise stress management for patients during the aforementioned invasive cardiac procedure, possibly leading to a decrease in anxiety and pain, we[1] developed a clinical music therapy protocol on the basis of a literature review, clinical observations, interdisciplinary discussions and clinical testing over a period of 2 years. The music therapy intervention is called 'Facilitated Music Listening' (FaMuLi) and is described in detail in this article using the label 'music therapy intervention protocol' (or 'the protocol'). The term 'facilitated' draws attention to the fact that this music listening procedure is individually tailored by an experienced Music Therapist who is both present and professionally responsible for the process. We define the clinical practice around the protocol as medical music therapy because we developed the intervention for a hospital setting.

Theoretical rationale

Epistemological traditions and cultures in medical versus music therapy professions contrast profoundly, rooted as they are in positivistic and humanistic paradigms respectively, while emphasising different aspects of health and knowledge achievement (Kristeva et al., 2018; Rolvsjord et al., 2005; Ruud, 2008). The FaMuLi protocol is based on a biopsychosocial approach, which tries to capture the ways in which biological, personal and social factors are ever present in such interactions and at once mutually dependent and mutually influential. In all, these factors define the patient experience

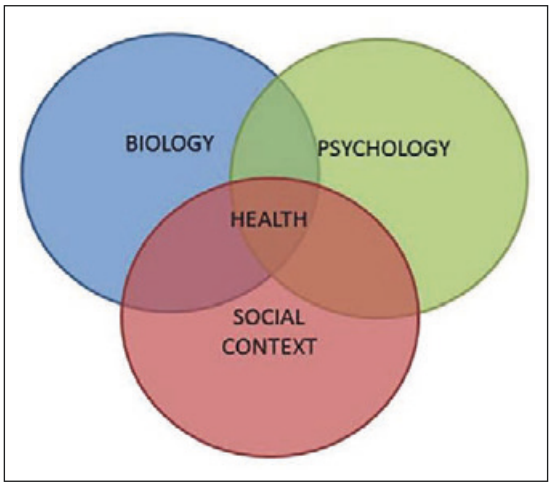


Figure 1. Biopsychosocial model of health (Ong, 2018).

(Engel, 1977; Frankel et al., 2003). George Engel (1980) suggested a biopsychosocial model in order to build a bridge between the medical model of natural science and the humanistic model of science. Today, Engel's work is considered an approach rather than an actual model or theory. Nevertheless, the biopsychosocial approach has informed recent research and professional development within several areas of health care (Dileo, 2015; Falkum, 2008; Smerud, 2012; Stallvik, 2011). Integrative health care, patient-centred care, the medical humanities and the mind–body approach are examples of healthcare designations and practices clearly impacted by the biopsychosocial approach. These practices are characterised by an interest in incorporating and treating the individual patient's needs within a broad, systemic perspective while trying to narrow the gap between the dichotomic cultures of science in the interests of the patient (Dileo and Bradt, 2005; Frankel et al., 2003; Hanser, 2014; Kristeva et al., 2018). The principal elements of the biopsychosocial approach (Figure 1) are recognised in the fundamental understanding of health within the music therapy profession in general, and in the description of medical music therapy in particular (Bruscia, 2014; Dileo, 2016; Hanser, 2014).

Detailed clinical music therapy manuals of practice underpinned by a theoretical rationale have previously been published within the psychiatric field, rooted in resource-oriented and analytic and psychodynamic theory (Hannibal et al., 2012; Rolvsjord et al., 2005). The current protocol for FaMuLi as an adjunct to an invasive cardiac procedure was developed to optimise stress management in patients within internal medicine. This article adds to the literature on music therapy in medical health care by offering an implementable clinical music therapy intervention based on a biopsychosocial approach.

Theories of music therapy in procedural support and pain management are important sources of the current protocol's development, emphasising Melzack's neuromatrix model of pain and Ghetti's transaction model of music therapy as procedural support (Ghetti, 2012; Hanser, 2014; Melzack, 2001). In his neuromatrix model, Melzack (2001) points to the multidimensional nature of stress, coping and pain experience by including sensory perception and biological and behavioural elements as process inputs as well as outputs. Some effects of stress and pain on the autonomic nerve system are the result of genetic predisposition, but even these can be modulated through sensory input. Hanser (2014) refers to the neuromatrix model when emphasising the ability of music therapy as a sensory input to affect the autonomic nerve system via a supportive intervention for patients in cardiac health care. She also underlines the importance of individualised treatment, which has to be reflected in the development of intervention protocols.[2] In turn, Ghetti's (2012) article about music therapy as support in invasive medical procedures is also influenced by the neuromatrix model. Ghetti presents and summarises key concepts in a theoretical transaction model (Figure 2).

Merging concepts from the biopsychosocial approach with this model of clinical music therapy helps to clarify the dynamic forces, which constitute the basis of this protocol. In Ghetti's model, biological, psychological and social factors are sorted into categories of procedural inputs and outcomes. The inputs, displayed as multifaceted moderators, set the scene for the experience of the procedure and contain personal variables, the demands of the procedure and contextual variables. In sum the moderators define the patient's experience of the procedure, followed by the patient response, as outcomes in different forms of perception, coping and behaviour in the moment. In turn, the outcomes can influence the experienced situation further. Within the construct of moderators as well as outcomes, biological, psychological and social elements can be identified. Implementation of the music therapy intervention, consisting of therapist + music + patient responses, adds another three lenses to the experience through which biological, psychological and/or social positive influences can be viewed. Ghetti (2012) points to three primary approaches of music therapy as procedural support: music alternate engagement (refocusing), integration and music-assisted relaxation. The current protocol focusses on music-assisted relaxation within the framework of short-term treatment, thus operating at an augmentative or supportive level (Bruscia, 2014; Dileo, 2015, 2016).

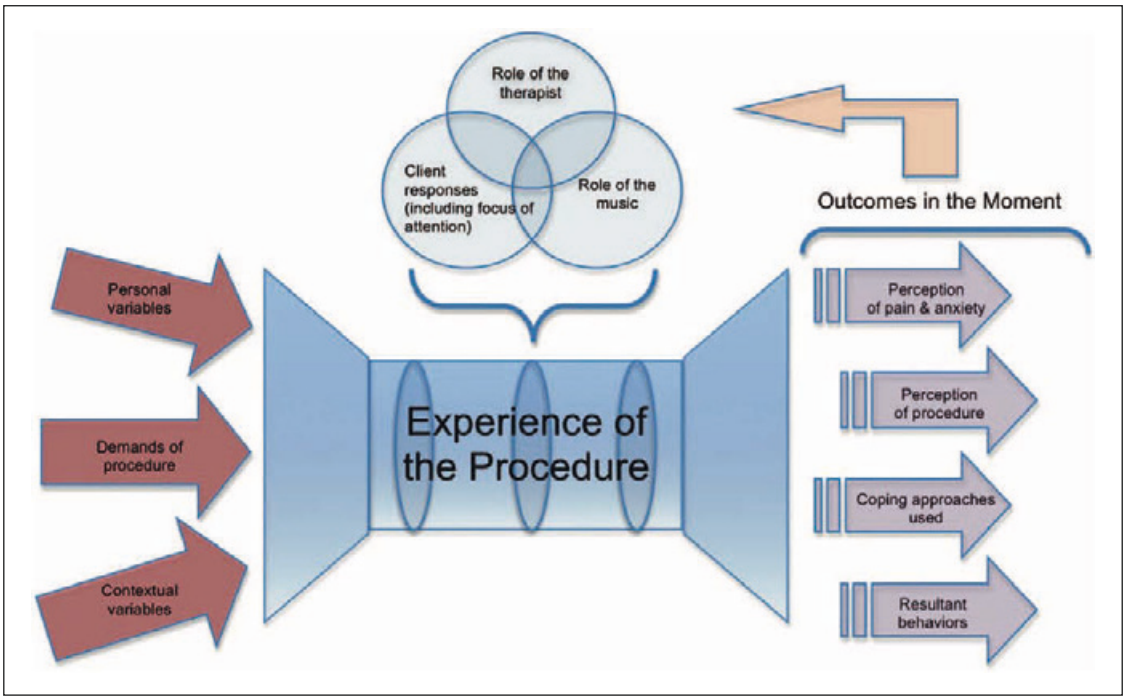


Figure 2. Working model of music therapy as procedural support (Ghetti, 2012: 28).

Individual effects of music listening can be explained and analysed at four levels of functionality: physiological, syntactic, semantic and pragmatic (Bonde, 2009; Bruscia, 2014; Koelsch, 2010; Schäfer et al., 2013). The physiological and syntactic levels point to music as nature – that is as biological and structural elements (responses) with quantitative measurable effects. The semantic and pragmatic levels link the effects of music listening to meanings of individual importance – that is, influenced by personal history and sociocultural context. In addition, the dynamic relations between patient, music and Music Therapist may give rise to biopsychosocial effects which are also included in the total experience. During music listening (and in life as such), these different levels mingle in complex perceptual processes, as captured by the transaction model.

Music therapy literature and research present diverse insights concerning the importance of music preference and genre versus neurobiological generalised effects (Koelsch and Jancke, 2015; Robb and Carpenter, 2010). Music listening might have a natural sedative effect on patients, as the patient might feel relaxed and supported by the rhythm and timbre of the music. This musical stimulus might in fact impact biological vital signs, such as respiration, pulse and BP. Music might decrease analytical processing, meta-consciousness and activity in the frontal lobe (Fachner, 2016). A relaxed patient with a positive focus on the present may experience moments of flow, leading to a decrease in stress hormones and level of pain (Bradt et al., 2013a, 2016; Ghetti, 2013). Optimised management of stress, anxiety and pain can also influence the amount of medical drugs being used (Bringman et al., 2009). In addition to such a biological perspective, an individualised focus is also important, both in the assessment and flexibility of the given intervention, to meet the patient's psychological needs. A process dedicated to matching playlist and coping strategies to patient preferences, personality and history increases patient control and can enhance engagement (Koelsch and Jancke, 2015). The main social factors in an invasive cardiac procedure are linked to the patient's personality and family support, the hospital culture, individual differences among staff, the demands of the procedure and the physical environment (Ghetti, 2012). In all, a diversity of relationships arises (Trondalen, 2016). Interdisciplinary considerations and cooperation are considered important for the development and implementation of music therapy in somatic health care. Central themes include logistics in time and space, professional roles and information across disciplines (Heiderscheit, 2013). Within the issue of interdisciplinary positioning, there is a need for further development of implementable roles for Music Therapists working within medical health care (Bonde, 2018; Dileo, 2016; Hanser, 2014; Pearson, 2018). The abovementioned factors are all present in the following music therapy intervention protocol.

Music therapy intervention protocol

The music therapy intervention in this protocol is specially designed for patients undergoing transvenous pacemaker and/or ICD lead extraction performed under local anaesthesia.[3] The protocol may also be relevant to other similar invasive procedures. The intervention is facilitated by a trained Music Therapist following a flexible but standardised sequence

which is outlined in this protocol. We present the protocol in detail to make it feasible to implement in a clinical setting and to strengthen the replicability from a research point of view. The protocol has been developed and tested for patients meeting the following criteria:

- A transvenous pacemaker and/or ICD lead extraction procedure has been planned to be performed under local anaesthesia.
- The patient is able and willing to communicate and cooperate.
- The patient has no significant hearing impairment.
- The patient has no previous and/or acute psychiatric diagnosis.
- The patient has no cognitive and mental deficits or does not suffer from impaired functioning.

The intervention has three parts, which are explained below:

1. *Preparation* is given individually at the hospital ward on the day before the procedure.
2. *Music listening* is given on the day of the invasive cardiac procedure.
3. *Closing dialogue* is given post-operatively, 2 to 4 hours after the procedure.

The protocol commits to the following basic principles, outlined for biopsychosocial music therapy in somatic health care:

- Biological, psychological and social factors are considered to be mutually dependent and interactive.
- The biopsychosocial perspective informs patient treatment in all phases of admission.
- Biological, psychological and social factors are reflected in the ongoing observations and embodiment of the supportive intervention (musical and relational).
- The patient is recognised as a person with individual needs through the empathic involvement of a trained Music Therapist who focusses on the patient's experiences, expectations and personal resources.[4]
- The music therapy service is an integrated part of the interdisciplinary treatment.

Preparation

The patient receives an individual preparatory session, lasting 30–45 minutes, at the hospital ward the day before the invasive procedure. The session consists of a dialogue between the patient and the Music Therapist, which includes practical instructions and experiences involving music listening and coping techniques to enhance relaxation and stress management. Such preparation is ideally undisturbed and takes place in a room with a hospital bed/bench in order to simulate the upcoming procedure with the addition of music listening. Information obtained through the dialogue is used for individualised facilitation of the intervention.

Assessment: experience, expectations, coping and music preference. The Music Therapist makes a brief assessment of the patient's previous experience in similar situations, his or her expectations regarding the following day's procedure and his or her current needs. Relaxation techniques guide the patient to an increased awareness of his or her bodily and emotional reactions and coping resources. Assessment of the patient's previous musical experiences and preferences forms the basis of playlist choice (Bonny, 2002; Burke, 1997; Standley, 2000). The Music Therapist then discusses with the patient how and why the chosen music might differ from his or her preferred everyday music listening, in order to be most effective in this specific setting.

Presentation: playlists and digital devices. The playlists are found on an app called Music Star (Figure 3), which was originally tailored for clinical use in psychiatric and somatic health care. A colourful star appears on the iPad, which contains 12 playlists with musical tracks of varied complexity and various genres. The development and selection of the playlist content are guided by a taxonomy[5] of music (Wärja and Bonde, 2014), which is useful in therapeutic settings and which falls within the musical parameters that produce relaxation and avoid stimulation (Grocke and Wigram, 2007; Lund and Bertelsen, 2016; Lund et al., 2016). These are as follows:

- Slow, constant tempo;
- Melodic and harmonic simplicity and predictability;
- Lack of dynamic fluctuation;
- Tonal harmonic structure with a high degree of predictability and repetition;
- Constant and thin orchestration.

Figure 3. The Music Star, Lund and Bertelsen (2016).

The coloured triangles within the playlists are organised as a continuum of music stimuli, gradually increasing in complexity from light blue to darkest red (Lund et al., 2016: 58; Hannibal et al., 2013). Guided by the therapist, the patient tests a number of playlists and settles on two or three preferred ones.[6] Playback occurs on an AudioCura M2 (Figure 4), a loudspeaker which is custom made for hygienic clinical environments. A loudspeaker is preferable to headphones, as it allows the patient necessary and comfortable head mobility and the ability to communicate with the medical team during the invasive procedure. The focussed direction of the sound towards the patient's head creates a 'private soundscape' even given the low volume, and the surgical team is not distracted by the music during the procedure.

Experience: music listening and coping techniques. During the listening in the preparation phase, the patient lies down on the bench to simulate the procedure situation while also potentially experiencing physical relaxation by music listening. The therapist's guidance is carefully attuned to the patient based on clinical observation and therapeutic communication. The patient is briefed on relevant coping strategies to enhance the effect of music listening: breathing techniques, muscle relaxation and/or visualisation based on principles from receptive music therapy induction, pain treatment and procedural support (Ghetti, 2012; Grocke, 2016; Grocke and Wigram, 2007; Hanser, 2014; Metzner, 2012; Schou, 2008). Together, the patient and the Music Therapist make a final plan for music listening during the surgical procedure the following day using the patient-chosen playlists. The plan can be altered at any time according to the patient's wishes and needs at the time.

Music listening

During the invasive cardiac procedure, the Music Therapist is present as part of the medical team to ensure relational continuity and to observe and act on potential patient responses and procedural events. The Music Therapist also operates the music devices:

(a) Preoperative: The previously planned music listening starts preoperatively, between 30 and 60 minutes before the patient enters the operation theatre. Pauses in the preoperative phase, when the patient is not disturbed, should be utilised for music listening in particular. The music is turned off when needed for communication with the medical staff. The Music Therapist reminds the patient of the coping strategies discussed earlier and guides the patient into a relaxed state of mind and body supported by the containing flow and rhythm of the music.
(b) Peri-operative: In the operating theatre, the loudspeaker is wrapped in a thin plastic bag, placed around the pillow[7] and fastened to the operation bench, for hygiene purposes and to ensure it remains in place. An extended cable allows the iPad to be placed at the foot of the bed on a separate table. Music listening continues after the patient

Figure 4. AudioCura M2.
Source: Reproduced with permission from AudioCura.com (AudioCura, 2016).

has been connected to the monitoring equipment, during the sterilisation process and into the peri-operative and invasive phase of the procedure. The patient can start or stop the music listening at any time that he or she wants, skip certain tracks or change the playlists as they choose. The minimum duration of music listening before and during the operation should be 30 minutes in total, if it is to be regarded as a complete music intervention. For ongoing facilitation of the music listening and the patient's well-being, the Music Therapist continuously observes what is happening in the room and the patient's responses. The therapist also adjusts the volume of the music according to the environmental noise in the room, such as the white noise from monitors and equipment and in dialogue within the medical team. If the patient falls asleep, it is recommended that the music continues, to maintain a similar soundscape. If medical complications occur, or if any adverse reactions from the patient are observed, or if the operating team needs complete silence, both the medical team or the Music Therapist can stop the music at any point.

(c) Post-operative: The patient is offered music listening during the first post-operative period. Technical support can be given by the health personnel or Music Therapist, but the device can also be operated by the patient.

Closing dialogue

The Music Therapist initiates a final debriefing with the patient at the post-operative unit within 4 hours of the invasive procedure, during which experiences from the procedure and the music listening are discussed, shared and evaluated. The therapist may offer supportive suggestions to empower and increase the patient's self-awareness and coping strategies in the future.

Discussion

Patients can feel alienated by a hospital's sterile setting and unfamiliar sounds of white noise and unpredictable electronic beeps. While the main goal of a hospital is patient recovery, it can also be a place associated with illness, pain and existential quandaries. Unlike the medical staff, the Music Therapist has the benefit of supporting communicative care as a primary focus, addressing the patients' experience and ability to cope within the hospital setting. Patient involvement and empowerment are at the forefront of music therapy intervention which meets psychosocial needs (Blichfeldt-Ærø and Leinebø, 2017; Frankel et al., 2003). When music is brought into a room, the atmosphere changes due to the new auditory stimulus. The music therapy intervention has the potential to give the patient (and staff) a positive focus, modify the environmental soundscape, mask noise and unpleasant sounds and even induce a possible altered perception of time (Bonde, 2011; Ghetti, 2012). From a biopsychosocial perspective, these elements aim to offer the patient sufficient control and involvement, bodily regulation and psychosocial safety in a friendly environment, as captured by the neuromatrix model of pain and model of music therapy in procedural support.

To enhance the effect of music listening, patients are guided through relaxing and reinforcing coping techniques which are individually tailored. This guidance is informed by music-assisted relaxation, music listening and Guided Imagery and Music (GIM), all of which are known to support an altered state of consciousness (sedation), refocus the mind and influence the regulation of vital signs (Ghetti, 2012; Grocke, 2016). Coping techniques in general are found to be most effective after repeated use, which presents a challenge in the context of short-term treatment. Due to the limited amount of time of a surgical procedure, the therapeutic relationship must be established quickly and music listening must be used effectively. During this short-term treatment, the patient is involved in a therapeutic process and relationship with both the Music Therapist and the music itself (Bonde, 2011; Grocke, 2016). To ensure study feasibility and avoid ethical concerns, the protocol does not indulge in further exploration of patient emotions or life challenges on a deeper level. The therapeutic focus remains in the 'here-and-now' and features guidance on coping strategies to support the invasive procedure. By

giving the patient the experience of FaMuLi in the preparatory session, the therapist raises the patient's awareness of their coping skills. This preparation also sets up for physical and psychological recognition of the music listening on the day of the operation. This may enhance the possibility of the perception of the music listening as a safe, supportive continuum during the procedure and enables processes of expectation and fulfilment (Bonde, 2009; Ghetti, 2012; Hodges, 2000). In FaMuLi, the central point of health in the biopsychosocial model (Figure 1) relates to the procedural experience in the moment and acts as a preventive and transformative experience to impact the patient's future potential for empowerment and coping.

Participant-selected versus therapist-selected music is much debated. Defenders of patient-selected music point to a related decrease in anxiety and pain (Bradt et al., 2013a, 2016; Burke, 1997). Some, on the other hand, favour giving the participant a limited choice of music which has been preselected by the therapist so as to ensure musical parameters which are most likely to promote a relaxing effect on the autonomic nerve system (Fachner, 2016; Hanser, 2014; Koelsch and Jancke, 2015). The choice of playlists in the current intervention aims to integrate insights from both neurobiology and psychology by using participant-selected music but from a limited set of choices, which are displayed on the Music Star app. The playlists are based on an awareness of music's impact on neurobiological regulation and therefore contain predictable, stable tracks associated with relaxing effects on the body and mind, and the patient's ability to choose is based on an awareness of the psychological importance of preference, involvement and control (Lund et al., 2016; Wärja and Bonde, 2014). The use of preset playlists does, however, introduce certain limitations. With more time, the patient and therapist might together tailor the playlists more individually, based on similar ways of analysing music (Wärja and Bonde, 2014). The realistic implementation of the protocol in this procedure, however, requires some standardisation and existing feasibility within the short time frame of treatment. Using preset playlists also strengthens the research rigour (Koelsch and Jancke, 2015) of the ongoing RCT study. In the same way, it is also useful that the playlists on the Music Star app can be altered and updated, based on the same professional standards and principles, which makes it a dynamic tool for future use as well.

Dileo (2015), Hanser (2014) and Heiderscheit (2013) argue that interdisciplinary work should be emphasised throughout the development of a protocol, and that the role of the Music Therapist should be integrated into the team. Such an approach includes practical and logistical considerations regarding implementation, as well as mutual understanding among the various disciplines. Very important to the implementation of this protocol is the timeline, and especially the pauses during the preoperative preparation. As the patient's stress responses may increase during inactive periods, these pauses are used to provide music listening as a stabilising, relaxing stimulus. The Music Therapist is actively present at these times, guiding and communicating with the patient. Throughout the invasive operative phase it is necessary, given the demands of the medical procedure, that the Music Therapist withdraw slightly, while still making modifications to the music intervention based on ongoing reflexive observations. The protocol's relational continuity and support are ensured by both the music stimuli and the therapist being present.

To achieve the same effects as music listening, anxiolytic drugs (mainly midazolam) are given to patients during an operation to reduce stress and anxiety, hence directly modulating the patient's biological regulation. Similarly, analgesics (fentanyl) are given to reduce pain. Negative consequences of such drugs include side effects and high cost, neither of which is an issue regarding music therapy; interestingly, Bringman et al. (2009) found music therapy to be more effective than midazolam in reducing preoperative anxiety. Although music therapy might therefore lead to a reduction in the use of medication, the current protocol makes no attempt to actively do so. Interdisciplinary communication and cooperation are considered crucial to developing the best balance of medical versus music therapy support for the individual patient, as they are for employing music therapy as a resource in general (Dileo, 2015; Heiderscheit, 2013). The hospital ward where the present study took place had no previous music therapy provision. While the medical team was positive and cooperative during the study, it is unclear whether the music therapy intervention was thought to be an integrated part of the patient treatment or a parallel service of sorts. Further investigation into a qualitative patient perspective and certain protocol implementation issues is needed.

Articles about medical music therapy often address the difference between music medicine and music therapy (Bonde, 2011; Bradt et al., 2013a; Gold et al., 2011; Hanser, 2014). In addition, the vast amount of research on music listening in general demonstrates that it can be offered in different ways and activate a number of provider or therapist roles within several forms and levels of practice. The descriptive term 'facilitated', as described in this protocol, implies the presence and professional judgement of an experienced Music Therapist. Still, some elements of it evoke music medicine, such as the less active role of the Music Therapist on the day of operation. However, more active involvement might be preferable in the peri-operative phase, to maximise the patient's benefit from the potential of receptive music therapy. During the given procedure on-site, the role of the Music Therapist as described in the protocol is both reasonable and implementable, yet undeniably less active than it is in most music therapy practices. This is required due to demands of the procedure. Nevertheless, because the music intervention, as an adjunct to the procedure, is facilitated by a Music Therapist, and the music experience is embedded in the therapeutic relationship, the present protocol is defined as music therapy (Bruscia, 2014; Dileo, 2015).

In addition to the formal research procedures designed to ensure the ethical framework of music therapy implementation, ethical considerations must be made individually as part of the clinical intervention. If, for instance, a patient's pulse

and BP suddenly drop peri-operatively, and an acute team is brought into the room, clinical decisions arise concerning the music listening. In such a situation, continuing the music listening might add stability to a medical-emergency situation, or at least not introduce yet another disruptive factor by removing it. However, the stress of such events and range of patient needs must be accounted for. In terms of ongoing ethical considerations, the following elements were found to be relevant and thus reflected in the protocol:

1. The number and role of helpers around a patient;
2. The level of therapeutic involvement, reflecting the short-term situation;
3. Adjustment of the intervention during adverse events or emergencies in the operating theatre.

Preliminary findings from the clinical implementation of the current protocol indicate that nearly all of the patients we approached wanted to be included in the study and to receive FaMuLi. Some patients emphasised that they wanted to avoid overhearing conversations among the medical team members during the procedure, as they had existing negative experiences with this exchange. The patients in the study reported satisfaction with the music listening overall, for example they experienced a relaxed state of mind and body, a positive focus and a feeling of time passing more quickly. Experiences from interdisciplinary team meetings also suggest that the Music Therapist's observations could inform the medical team's work by contributing the patient's perspective and communication in the operating theatre. Hence, introducing a Music Therapist to the team could be useful, not only for the patient but also for more constructive communication between hospital staff. The role of the Music Therapist as presented in this protocol represents a means of professional integration within somatic health care.

This article presents and discusses a clinical music therapy protocol which is situated within a biopsychosocial theoretical rationale aimed at contributing to the development of music therapy as a profession within somatic health care. The development and discussion of a new intervention protocol implies a reflexive research process (Stige et al., 2009) emerging from clinical practice and theoretical considerations. The biopsychosocial approach is emphasised to be the most relevant to the present context because it incorporates an orientation towards interdisciplinary communication between professions involved in somatic health care. Although the main tenets of the biopsychosocial approach are acknowledged by the dominant trends in music therapy theory and practice today, its biological aspect appears to be given less attention outside the medical arena (Edwards, 2016). Engaging different theories and practices can support the development of useful and important new knowledge by merging clinical experience and theories in new ways. In the Nordic countries, over the past decade, the music therapy profession has enjoyed a tremendous breakthrough by focussing on psychosocial aspects of practice such as patient resources, recovery and participation. As Dileo (2015) argues, music therapy in somatic health care in general needs to extend itself in breadth and depth to accommodate patients who represent a range of personalities, ages and medical conditions. Therapeutic interests must always reckon with the patient's medical condition, psychosocial elements and interdisciplinary factors, and, in the present case, the demands of the invasive procedure. In medical music therapy, the biological perspective must not be minimised, either clinically or in terms of the interdisciplinary implementation and communication among the relevant professions. Hence, drawing upon bio- and psychosocial perspectives when one engages with an individual in a vulnerable position is not only relevant and useful (Stige et al., 2009) but also related to ethics in a broad sense (Trondalen, 2016).

These manuals published from a resource-oriented and analytic/psychodynamic perspective (Hannibal et al., 2012; Rolvsjord et al., 2005) both used a structure from Waltz et al. (1993) to describe the principles of clinical practice. The structure is applicable to therapeutic processes over extended periods of time, potentially engaging a broader range of methods than those of the protocol presented here. In somatic procedures, the short-term timeline and biological factors are very important. Unlike resource-oriented and psychoanalytic theory, the biopsychosocial approach originates in the biomedical model of nature science. This perspective remains an integral part of the biopsychosocial construct and appears to be compatible with the latest research findings within neurobiology, and with an increasing awareness of the importance of integrated health care. Given that the medical model is still dominant within somatic health care, contributions from music therapy theory and practice based on a biopsychosocial approach are beneficial to the discourse, which continues in the current field.

Conclusion

This article is the first to explore music therapy as an adjunct to transvenous lead extractions from implantable electronic devices. The intervention involves facilitated music listening, with the Music Therapist being present during the invasive procedure itself. This clinical protocol forms the cornerstone of an ongoing RCT seeking new knowledge and exploring possibilities within the specified medical field of music therapy practice. Based on a biopsychosocial approach, the theoretical reflections and practical experiences derived from developing this music therapy intervention are summarised according to five basic principles of biopsychosocial music therapy in somatic health care. It includes both practical and interdisciplinary aspects of protocol implementation, in terms of logistics and of relational and communicative therapeutic skills. The protocol advocates for a balance between standardisation and individualisation in both the choice of music and

therapeutic guidance so that the intervention can be at once effective and implementable. The article draws upon familiar concepts and methods within the music therapy profession but adds to the literature by demonstrating how the biopsychosocial approach can be actualised within a receptive music therapy intervention during medical invasive procedures. It also accommodates the need for detailed individualised clinical descriptions within medical music therapy, and the need for further development of implementable roles for Music Therapists working within somatic health care.

Notes

1. The authors of this article, leading a joint research project between Centre for Research in Music and Health (CREMAH), Norwegian Academy of Music, Oslo, Norway and Department of Cardiology, Oslo University Hospital Ulleval, Oslo, Norway.
2. Hanser's (2014) use of the word 'protocol' refers both to the clinical intervention and a research protocol. The current article makes a distinction between clinical protocol and research protocol: Clinical protocol contains a detailed description of the music therapy intervention; research protocol refers to the total design of the ongoing research trial, which will be presented in a separate article.
3. The study is approved by Regional Committees for Medical and Health Research Ethics. All patients gave informed consent to participate.
4. For a detailed description of therapist qualifications within medical music therapy, see Dileo (2015).
5. That is, the classification of soundtracks into groups within a larger system according to their similarities and differences. Collins (2018) Definition of taxonomy. *COBUILD Advanced English Dictionary*: HarperCollins Publishers.
6. For further details of the playlists, see Hannibal et al. (2013).
7. AudioCura M2 is designed to fit perfectly with a Tempura pillow, but other pillows will work as well, if they are not too thick (AudioCura, 2016).

References

Al-Azawy M, Oterhals K, Fridlund B, et al. (2015) Premedication and preoperative information reduces pain intensity and increases satisfaction in patients undergoing ablation for atrial fibrillation: A randomised controlled study. Applied Nursing Research 28: 268–273.

Argstatter H, Haberbosch W and Bolay HV (2006) Study of the effectiveness of musical stimulation during intracardiac catheterization. Clinical Research in Cardiology 95: 514–522.

AudioCura (2016) Audiocura M2. Available at: http://www.audiocura.com/da/portfolio/audiocura-m2/

Blichfeldt-Ærø SC and Leinebø TL (2017) Musikkterapi for barn i palliasjon – en støttespiller for både kropp og sjel, individ og miljø. Omsorg, Nordisk Tidsskrift for Palliativ Medisin 3: 43–47.

Bonde LO (2009) Musik Og Menneske – Introduktion Til Musikpsykologi. Frederiksberg: Samfundslitteratur.

Bonde LO (2011) Health musicing – Music therapy or music and health? A model, empirical examples and personal reflections. Music and Arts in Action 3: 120–140.

Bonde LO (2018) Musik på hospitaler – områder og aktører. Aalborg: Aalborg Universitet.

Bongiorni M, Di Cori AS, Zucchelli GV, et al. (2016) Where is the future of cardiac lead extraction heading? Expert Review of Cardiovascular Therapy 29: 1–7.

Bonny H (2002) Music & Consciousness: The Evolution of Guided Imagery and Music. Gilsum, NH: Barcelona Publishers.

Bradt J and Dileo C (2014) Music interventions for mechanically ventilated patients. Cochrane Database of Systematic Reviews 12: CD006902.

Bradt J, Dileo C and Potvin N (2013a) Music for stress and anxiety reduction in coronary heart disease patients. Cochrane Database of Systemic Reviews 12: CD006577.

Bradt J, Dileo C and Shim M (2013b) Music interventions for preoperative anxiety. Cochrane Database of Systematic Reviews 6: CD006908.

Bradt J, Dileo C, Magill L, et al. (2016) Music interventions for improving psychological and physical outcomes in cancer patients (Review). Cochrane Database of Systematic Reviews 8: CD006911.

Bringman H, Giesecke K, Thorne A, et al. (2009) Relaxing music as pre-medication before surgery: A randomised controlled trial. Acta Anaesthesiol Scand 53: 759–764.

Bruscia K (2014) Defining Music Therapy. Gilsum, NH: Barcelona Publishers.

Burke MA (1997) Effects of physioacoustic intervention on pain management of postoperative gynaecological patients. In: Wigram T and Dileo C (eds) Music Vibration. Cherry Hill, NJ: Jeffrey Books, pp. 107–123.

Collins H (2018) Definition of taxonomy. In: Collins H (ed.) COBUILD Advanced English Dictionary. Glasgow: HarperCollins Publishers.

Deharo J, Bongiorni M, Rozkovec A, et al. (2012) Pathways for training and accreditation for transvenous lead extraction: A European Heart Rhythm Association position paper. Europace 14(1): 124–134.

Dileo C (2015) Introduction: Definitions and perspectives on advanced practice in medical music therapy. In: Dileo C (ed.) Advanced Practice in Medical Music Therapy: Case Reports. Cherry Hill, NJ: Jeffrey Books/Music Therapy Resources, pp. 1–19.

Dileo C (2016) The future of medical music therapy for adults. In: Dileo C (ed.) Envisioning the Future of Music Therapy. Philadelphia, PA: Arts and Quality of Life Research Center, Temple University, pp. 71–80.

Dileo C and Bradt J (2005) Medical Music Therapy: A Meta-analysis and Agenda for Future Research. Cherry Hill, NJ: Jeffrey Books.

Edwards JE (2016) Oxford Handbook of Music Therapy. Oxford: Oxford University Press.

Engel GL (1977) The need for a new medical model: A challenge for biomedicine (New Series). Science 196(4286): 129–136.

Engel GL (1980) The clinical application of the biopsychosocial model. American Journal of Psychiatry 137: 535–544.

Fachner J (2016) Measurement of musical responses. In: Wheeler BL and Murphy K (eds) Music Therapy Research. Gilsum, NH: Barcelona Publishers, pp. 153–168.
Falkum E (2008) Den biopsykososiale modellen. Bør den formuleres på nytt i lys av nevrobiologisk og stressmedisinsk forskning? Tidsskriftet Den Norske Legeforening, Michael 5: 255–263.
Frankel R, Quill TE and McDaniel SH (2003) The Biopsychosocial Approach: Past, Present, Future. Rochester, NY: University of Rochester Press.
Ghetti CM (2012) Music therapy as procedural support for invasive medical procedures: Toward the development of music therapy theory. Nordic Journal of Music Therapy 2(1): 3–35.
Ghetti CM (2013) Effect of music therapy with emotional-approach coping on preprocedural anxiety in cardiac catheterization: A randomized controlled trial. Journal of Music Therapy 50: 93–122.
Gold C, Erkkilä J, Bonde LO, et al. (2011) Music therapy or music medicine? Psychotherapy and Psychosomatics 80: 304.
Grocke D (2016) Receptive music therapy. In: Edwards J (ed.) The Oxford Handbook of Music Therapy. Oxford: Oxford University Press, pp. 684–706.
Grocke D and Wigram T (2007) Receptive Methods in Music Therapy: Techniques and Clinical Applications for Music Therapy Clinicians, Educators and Students. London and Philadelphia, PA: Jessica Kingsley Publishers.
Hannibal N, Pedersen IN, Bonde LO, et al. (2012) Manual for proces-orienteret musikterapi med personer med BPD. Musikterapi I Psykiatrien Online 7: 64–80.
Hannibal N, Lund HN, and Bonde LO (2013) Musiklyttepuder, lydbøjler og spillelister i behandlingen af psykiatriske patienter. *Musikterapi i psykiatrien online* 8(2): 4–17.
Hanser SB (2014) Music therapy in cardiac health care: Current issues in research. Cardiol Rev 22: 37–42.
Heiderscheit A (2013) Surgical and procedural support for adults. In: Allen J (ed.) Guidelines for Music Therapy Practice in Adult Medical Care. Gilsum, NH: Barcelona Publishers, pp. 17–34.
Hodges DA (2000) Implications of music and brain research. Music Educators Journal 87: 17–22.
Hole J, Hirsch M, Ball E, et al. (2015) Music as an aid for postoperative recovery in adults: A systematic review and meta-analysis. The Lancet 386: 1659–1671.
Koelsch S (2010) Towards a neural basis of music-evoked emotions. Trends in Cognitive Sciences 14: 131–137.
Koelsch S and Jancke L (2015) Music and the heart. European Heart Journal 36: 3043–3049.
Kristeva J, Moro MR, Ødemark J, et al. (2018) Cultural crossings of care: An appeal to the medical humanities. Medical Humanities 44: 55–58.
Kühlmann AYR, de Rooij A, Kroese LF, et al. (2018) Meta-analysis evaluating music interventions for anxiety and pain in surgery. British Journal of Surgery 105: 773–783.
Kusumoto FM, Schoenfeld MH, Wilkoff BL, et al. (2017) HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Heart Rhythm 14: e503–e548.
Lund HN and Bertelsen LR (2016) 'Musikstjernen' – en ny stjerne i psykiatrien. Dansk Musikterapi 13(1): 3–10.
Lund HN, Bertelsen LR and Bonde LO (2016) Sound and music interventions in Psychiatry at Aalborg University Hospital. Soundeffect 6: 48–68.
Melzack R (2001) Pain and the neuromatrix in the brain. Journal of Dental Education 65: 1378–1382.
Metzner S (2012) A polyphony of dimensions: Music, pain, and aesthetic perception. Music and Medicine 4: 163–170.
Ong L (2018) *Clinical and Health Psycohlogy*. Available at: Perspectiveclinics.com (accessed 31 August 2018).
Palmer JB, Lane D and Mayo D (2015) Surgical music therapy: The significance and implementation of music therapy in the operating arena: Table 1. Music Therapy Perspectives 35: miv036.
Peal JE, Runnett C, Thomas HE, et al. (2018) An update on cardiac implantable electronic devices for the general physician. Journal of the Royal College of Physicians of Edinburgh 48: 141–147.
Pearson S (2018) Why words matter: How the common mis-use of the term music therapy may both hinder and help music therapists. Voices: A World Forum for Music Therapy 18: 904.
Robb SL and Carpenter JS (2010) Reporting guidelines for music-based interventions. Journal of Health Psychology 16: 342–352.
Rolvsjord R, Gold C and Stige B (2005) Research rigour and therapeutic flexibility: Rationale for a therapy manual developed for a randomised controlled trial. Nordic Journal of Music Therapy 14: 15–32.
Ruud E (2008) Et humanistisk perspektiv på norsk musikkterapi. In: Trondalen G and Ruud E (eds) Perspektiver På Musikk Og Helse - 30 År Med Norsk Musikkterapi (Skriftserie fra Senter for musikk og helse) (NMH publikasjoner, 2008:3). Oslo: The Norwegian Academy of Music, pp. 5–28.
Schäfer T, Sedlmeier P, Städtler C, et al. (2013) The psychological functions of music listening. Frontiers in Psychology 4: 1–33.
Schou K (2008) Music Therapy for Post Operative Cardiac Patients: A Randomized Controlled Trial Evaluating Guided Relaxation with Music and Music Listening on Anxiety, Pain, and Mood. Aalborg: InDiMedia, Department of Communication, Aalborg University.
Smerud HS (2012) Kasusformulering og behandlingskvalitet. In: Svendsen B, Johns UT, Brautaset H, et al. (eds) Utviklingsrettet Intersubjektiv Psykoterapi Med Barn Og Unge. Oslo: Fagbokforlaget, pp. 22–33.
Stallvik M (2011) Biopsykososial tilnærming til rusavhengighet. Rusfag 1–2011: 105–112.
Standley J (2000) Music research in medical treatment. In: Stanley J (ed.) Effectiveness of Music Therapy Procedures, 3rd edn. Silver Spring, MD: American Music Therapy Association.
Stige B, Malterud K and Midtgarden T (2009) Toward an agenda for evaluation of qualitative research. Qualitative Health Research 19: 1504–1516.
Trondalen G (2016) Relational Music Therapy: An Intersubjective Perspective. Gilsum, NH: Barcelona Publishers.
Waltz J, Addis ME, Koerner K, et al. (1993) Testing the integrity of a psychotherapy protocol: Assessment of adherence and competence. Journal of Consulting and Clinical Psychology 61: 620–630.

Wärja M and Bonde LO (2014) Music as co-therapist: Towards a taxonomy of music in therapeutic music and imagery work. Music & Medicine 6: 16–27.
Wazni O and Wilkoff B (2016) Considerations for cardiac device lead extraction. Nature Reviews Cardiology 13(4): 221–229.
Wilkoff BL (2009) Transvenous lead extraction: Heart Rhythm Society expert consensus on facilities, training, indications, and patient management. Heart Rhythm 6: 1085–1104.

Author biographies

Stine Camilla Blichfeldt-Ærø is a music therapist and PhD fellow at the Norwegian Academy of Music. Her clinical practice has primarily been in the medical field, leading the music therapy service in paediatrics at Oslo University Hospital Rikshospitalet since 2001. Her current research project is within adult health care.

Gro Trondalen, PhD, Fellow of AMI, is a Professor in music therapy at the Centre for Research in Music and Health (CREMAH), Norwegian Academy of Music, Norway.

Sigrun Halvorsen, MD, PhD, is the Head of the Department of Cardiology at Oslo University Hospital Ulleval and Professor in cardiology at the University of Oslo, Norway.

Paper II

Blichfeldt-Ærø, S.C., Knutsen, T.M., Hagen, H.M., Diep, L.M., Trondalen, G., & Halvorsen, S. (2020)

Music therapy as an adjunct in lead extraction procedures from cardiac implantable electronic devices: A randomized controlled trial.

Applied Nursing Research. 56 (December). https://doi.org/10.1016/j.apnr.2020.151376

Applied Nursing Research 56 (2020) 151376

Contents lists available at ScienceDirect

Applied Nursing Research

journal homepage: www.elsevier.com/locate/apnr

Music therapy as an adjunct in cardiac device lead extraction procedures: A randomized controlled trial

Stine Camilla Blichfeldt-Ærø [a,*], Thomas M. Knutsen [b], Hege Merethe Hagen [b], Lien My Diep [c], Gro Trondalen [a], Sigrun Halvorsen [b,d]

[a] Centre for Research in Music and Health (CREMAH), Norwegian Academy of Music, Slemdalsveien 11, PB 5190, Majorstua, NO-0363 Oslo, Norway
[b] Department of Cardiology, Oslo University Hospital Ulleval, Kirkeveien 166, 0450 Oslo, Norway
[c] Oslo Centre for Biostatistics and Epidemiology (OCBE), Oslo University Hospital, Oslo, Norway
[d] Faculty of Medicine, University of Oslo, Klaus Torgårds vei 3, 0372 Oslo, Norway

ARTICLE INFO

Keywords:
Medical music therapy
Procedure support
Stress
Pain
Anxiety
Cardiac devices

ABSTRACT

Background: Evidence of music therapy as an effective supportive therapy in invasive cardiac procedures is increasing, but more research is needed.
Aims: To evaluate the impact of music therapy on stress responses during cardiac device lead extraction procedures performed in local anaesthesia.
Methods: Sixty-four patients undergoing cardiac implantable electronic device lead extraction at Oslo University Hospital Ulleval from March 2018 to September 2019 were randomized to music therapy ($n = 32$) or control ($n = 32$). Primary endpoints were patient satisfaction with pain management and average pain intensity during the procedure. Secondary endpoints were average anxiety intensity, need for analgesic/anxiolytic drugs, blood pressure, heart and respiration rate.
Results: All patients in the music therapy group completed the intervention. Patient satisfaction with pain management was 10.00 (8.00, 10.00) in the music therapy vs. 10.00 (9.00, 10.00) in the control group ($p = 0.85$), and average level of pain 0.89 (0.22, 1.13) vs. 0.96 (0.36, 1.58), respectively ($p = 0.38$). Average anxiety score was 1.00 (0.33, 2.17) in the music therapy vs 1.67 (0.71, 3.35) in the control group ($p = 0.056$). The use of analgesic/anxiolytic drugs and physiological parameters were similar across groups.
Conclusions: In this study of music therapy during cardiac device lead extractions, no effect was found on patient satisfaction with pain management or average pain level. A decrease in patient anxiety of borderline significance was observed in the music therapy group. More studies with more sensitive measures of pain and anxiety are needed to determine the value of music therapy in invasive cardiac procedures.

1. Introduction

The need for extraction of cardiac implantable electronic device (CIED) leads (e. g. pacemakers (PMs) and implantable cardioverter-defibrillators (ICDs) has greatly increased over the past few decades due to the growing demand for device implantations and an accompanying rise in need for extractions due to complications, infections, and lead safety alerts (Bongiorni et al., 2016; Wazni & Wilkoff, 2016). Also, increased life expectancy in patients with implanted devices causes increased numbers of device replacements or upgrading procedures to ICD or cardiac resynchronization therapy (CRT) systems (Deshmukh et al., 2015; Sridhar et al., 2017). The number of extraction procedures per year is likely to continue to rise due to the same reasons.

At Oslo University Hospital Ulleval (OUH) in Norway, the extraction procedure is usually performed transvenously in local anaesthesia with some procedural sedation. Analgesic and anxiolytic drugs are given at the start of the invasive procedure and repeated if needed. The invasive phase of the procedure lasts typically between 45 min and 3 h. Despite the given drugs, most patients will experience some degree of pain and/or anxiety during the procedure; the amount is influenced by the patients' individual ability to cope with stressors, and by extraction techniques and lead dwell time (Dornelas, 2012).

Music therapy, defined as the use of music and aspects of a therapeutic relationship to promote healthy coping and decrease distress, is

* Corresponding author.
E-mail address: sero@ous-hf.no (S.C. Blichfeldt-Ærø).

https://doi.org/10.1016/j.apnr.2020.151376
Received 27 February 2020; Received in revised form 24 September 2020; Accepted 21 October 2020
Available online 24 October 2020
0897-1897/

increasingly used as procedural support for invasive medical procedures (Allen, 2013; Ghetti, 2012; Heiderscheit, 2013). As an evidence-based complementary therapy form, music therapy can evoke and regulate mood and emotions (Grocke, 2016), reduce distress and anxiety (Bradt, Dileo, & Potvin, 2013; Bradt, Dileo, & Shim, 2013; Kühlmann et al., 2018), and induce changes in heart activity, blood pressure and breathing, in addition to influencing the individual's experience of pain and the surgery itself (Graff et al., 2019; Hole et al., 2015; Koelsch & Jancke, 2015).

Several studies on music therapy in patients with heart diseases have been performed, as well as on music listening without a therapist involved (Hanser, 2014; Koelsch & Jancke, 2015). A systematic review of 26 studies in patients with coronary heart disease found music interventions to decrease distress, pain, and anxiety (Bradt, Dileo, & Potvin, 2013). In cardiac catheterization, music therapy was found to decrease preoperative anxiety, especially for patients with high psychological strains (Argstatter et al., 2006). A qualitative study found that music therapy might improve the rehabilitation process after cardiothoracic surgery (Short et al., 2013). However, the results of studies have been inconsistent, and there is a need for more research on the effect of music therapy in patients with heart disease (Bradt, Dileo, & Potvin, 2013). This is particularly the case in patients undergoing invasive cardiac procedures.

This study aimed to evaluate the possible effects of music therapy used as an adjunct in cardiac device lead extraction procedures performed transvenously in local anaesthesia. We hypothesized that music therapy could decrease pain and anxiety levels during the procedure, and increase patient satisfaction with pain management. The music therapy intervention was tailored for the specific cardiac procedure and provided by a certified music therapist.

2. Methods

This study was an open, randomized controlled trial (RCT) performed at a single centre (Department of Cardiology, Oslo University Hospital (OUH) Ulleval, Oslo, Norway). The study was registered in ClinicalTrials.gov no.: NCT04172662.

2.1. Cardiac implantable electronic device (CIED) lead extractions

The PM/ICD centre at the Department of Cardiology, OUH, Oslo, Norway is a high-volume centre for CIED lead extractions, treating patients from all parts of Norway. Approximately 140 lead extractions are performed every year. These procedures are performed transvenously, using a combination of single traction, single sheath mechanical dilatation and femoral and jugular snaring techniques, or other more complicated techniques in selected cases (Knutsen et al., 2015). The extraction procedures are performed in a hybrid lab with a cardiothoracic surgery standby-team available but not present, (Bongiorni et al., 2008; Deharo et al., 2012; Kusumoto et al., 2017). Most procedures are performed in local anaesthesia with some procedural sedation; general anaesthesia is used in selected cases (Wilkoff, 2009). All patients are prepared with blood pressure and heart rate monitoring and the application of cutaneous pads for defibrillation. The rate of procedural success from 1998 to 2014 was 99% (Knutsen et al., 2015).

The duration of the invasive procedure was defined as the time from the first cut through the skin until the sutures were completed. The total procedure time was defined as the time from arrival at the preoperative room on the day of operation until 2,5 h postoperatively.

2.2. Study population

All consecutive patients referred to the PM/ICD centre for CIED lead extractions on March 1, 2018, to September 30, 2019, were screened for participation in this study. The inclusion criteria were age 25–80 years, a device implanted >12 months ago, planned lead extraction in local anaesthesia, able to speak and read Norwegian, no significant hearing impairment, and willingness to participate in the study. Exclusion criteria were previous and/or acute psychiatric diagnosis, cognitive or mental deficits or impaired functioning. Eligible patients were asked for participation in the study the day before the procedure after verbal and written information was given. After written, informed consent was obtained, the patients were randomly assigned in a 1:1 ratio to the intervention- or the control group. Consecutively numbered, sealed envelopes containing treatment modality according to random numbers were used. The assignment schedule was based on computer-generated random numbers in varying block sizes, and the researchers were not involved in the process.

2.3. Intervention strategies

2.3.1. Control group

Patients were given analgesic and anxiolytic drugs according to the following standard procedure: Standard pain management before and during the procedure included 2 tablets of Paralgin forte (paracetamol 400 mg plus codeine 30 mg) given orally as prophylactic medication before entering the operation theatre. At the start of the invasive procedure, the patient received midazolam (1–1.5 mg) and fentanyl (25–50 μg) intravenously. New doses might be given during the procedure, based on clinical assessment by the medical team and the level of pain and anxiety expressed by the patient.

2.3.2. Music therapy group

The patients randomized to music therapy received the music therapy intervention in addition to the standard drug treatment described above. The music therapy intervention, called "facilitated music listening", was provided by a certified music therapist and has been described in detail previously (Blichfeldt-Ærø et al., 2019). The protocol was based on biopsychosocial principles of stress- and pain management (Dornelas, 2012; Melzack, 2001), and on receptive music therapy as procedure support (Allen, 2013; Ghetti, 2012; Heiderscheit, 2013). Briefly, the intervention included a preparatory session the day before the cardiac procedure, sequences of music listening during the pre- and perioperative phase (>30 min.), and the opportunity of music listening the first postoperative period (4 h). The intervention ended with a closing dialogue between the patient and the music therapist. In the preparatory session, assessment of expectations and music preferences were made, and individual guidance of relaxing strategies for coping with stress. From a set of 12 playlists provided on an iPad application ("The Music Star") (Lund et al., 2016), the patient selected 1–3 preferred playlists. These playlists were professionally developed for supportive therapeutic purposes and contained music of different genres and complexity (Lund et al., 2016). A loudspeaker designed for hospital environments was used, to allow for the necessary communication perioperatively (AudioCura, 2016). Facilitated music listening could be continued during the first postoperative hours, according to the patient's preferences (Blichfeldt-Ærø et al., 2019).

2.4. Outcomes

The primary outcomes of the study were 1) patient satisfaction with pain management during the procedure, and 2) the average self-reported pain intensity during the procedure. Secondary outcomes were 1) the average self-reported level of anxiety during the procedure, 2) the total amount of anxiolytic drugs given during the procedure, 3) the total amount of analgesic drugs given during the procedure, and 4) average heart rate, average respiration rate, average oxygen saturation and average arterial blood pressure during the procedure.

2.5. Measurements

The measure of patient satisfaction with pain management during

the procedure was obtained postoperatively using a 10-point visual numeric scale which has been used in comparable studies (Al-Azawy et al., 2015; Graff et al., 2019; Hole et al., 2015). Number one represented very dissatisfied and 10 very satisfied. The measure was answered in privacy, on a paper questionnaire handed to the patient by the music therapist, and returned in a sealed envelope. After the scoring of patient satisfaction, patients in the intervention group were invited to write a brief reflection on their experience with the music therapy intervention.

Patients' self-reported levels of pain and anxiety were assessed using the Numeric Rating Scale (NRS) and the Numeric Visual Analog Anxiety Scale (NVAAS), respectively, with scores from zero to 10. Zero represented no pain/anxiety, and 10 the worst possible pain/anxiety. The scales are found to be reliable and valid tools, correlating significantly with other measurement tools for pain and anxiety (Elkins et al., 2004; Hawker et al., 2011). The patients were asked to score their level of pain and anxiety before start of the procedure (pre), every 30 min during the procedure (*peri*), and after the invasive procedure was finished (post). The scores were collected by a nurse from the medical team. The nurses also measured the physiological parameters and registered the use of anxiolytic (diazepam, midazolam) and analgesic drugs (paracetamol/codeine, fentanyl) throughout the procedure. All preoperative measures were obtained before the first dose of midazolam was given.

The patients received verbal and visual instructive information of the numeric rating scales in use and informed about the repeated collection of self-reported measures during the procedure. The native language of all participants (Norwegian) was used in all written material and verbal dialogues. The use of central terms in Norwegian (e.g. pain, anxiety, satisfaction) were discussed and internally validated by the research group and medical team. Translation of qualitative data (i.e. written patient reflections) from Norwegian into English was performed by the first author after the analysis. The accuracy of the translation was validated by two researchers independently. These researchers were not involved in the study at any point.

2.6. Ethics

The study was performed in accordance with the guidelines of Good Clinical Practice and CONSORT (Boutron et al., 2017), and Code of Ethics for Music Therapists in Norway. Approval was obtained from the Regional Ethics Committee in Norway (document 2018/168/REK nord). All data were treated and stored de-identified in accordance with national directives.

2.7. Statistical analysis

The power analysis was based on the patient's satisfaction with pain management as the primary outcome. Based on a comparable study, the mean score in the control group was assumed to be 6.5, with a standard deviation of 1.5 (Al-Azawy et al., 2015). We calculated that a sample size of 68 patients would allow us to detect a difference between groups of at least 20%, with a power of 80% and a significance level of 5%.

Continuous variables were expressed as medians with interquartile ranges (IQR), and categorical variables as frequencies with percentages. Differences between groups were assessed by Mann-Whitney *U* tests. The average of scores during the procedure (pre-, peri-, and postoperative) for pain and anxiety were calculated. For the perioperative score, the average of repeated perioperative measures (≈every 30 min.) was used due to varying duration of the extraction procedures.

The primary analysis was an intention to treat analysis. The significance level was set at 0.05 (two-sided). Effect sizes, classified as small ($r = 0.10$), medium ($r = 0.30$) or large ($r = 0.50$), were calculated for data showing differences between groups with test results $p < 0.2$ (Pallant, 2016). Sensitivity analyses were performed for the best- and worst-case, with the imputation of data based on the lower/upper limits of the numeric scale instead of multiple imputation methods, as the distributions of psychometric data were highly skewed and included scores of zero. All data were analysed using IBM SPSS version 25 or Stata/SE version 15.

The written patient reflections were explored using a content analysis method (Krippendorff, 2019).

3. Results

Of 178 screened patients, 78 patients were asked to participate and 68 patients were enrolled in the study (Fig. 1). Four patients were secondarily excluded, due to the violation of inclusion criteria. The median age was 66 (56, 72) years and 46 (72%) were men. Patient characteristics at baseline were similar in the two groups (Table 1).

The procedure-related variables are shown in Table 2. Infection and lead failure were the most common reasons for lead extraction. The median duration of the invasive procedure was 58 min. (36, 81) in the music therapy group and 55 min. (32, 89) in the control group. The median number of years since cardiac device lead implantation was 7.0 (3.0, 12.8) in the music therapy group, and 4.5 (3.0, 7.8) in the control group ($p = 0.18$). Sheaths were used in 65.6% of the procedures, with a median duration of 4.5 min. (1.5, 7.9) and 5.4 min. (3.0, 9.5) respectively ($p = 0.37$). The median duration of music listening in the intervention group was 127 min. (109, 156). Only 8/32 patients (25%) chose to use music listening in the postoperative phase.

Patient satisfaction with pain management was 10.00 (8.30, 10.00) in the music therapy group vs. 10.00 (9.00, 10.00) in the control group ($p = 0.85$) (Fig. 2a). The average pain scores during the procedure were 0.89 (0.22, 1.13) in the music therapy group and 0.96 (0.36, 1.58) in the control group ($p = 0.38$) (Fig. 2b).

The average scores of anxiety during the procedure are found in Fig. 3a were 1.00 (0.33, 2.17) in the music therapy group and 1.67 (0.71, 3.35) in the control group, showing a difference of borderline significance ($p = 0.056$). Sensitivity analyses showed that the imputation of missing perioperative data would alter the findings. Best-case calculation found an average of 0.88 (0.21, 2.17) in the music therapy group compared to 1,67 (0.71, 3.35) in the control group, demonstrating a significant difference ($p = 0.04$, $r = 0.26$). The worst-case analysis demonstrated an average of 1.00 (0.33, 2.17) in the music therapy group vs. 1.67 (0.71, 3.35) in the control group ($p = 0.08$, $r = 0.22$).

There were no significant differences between groups in the use of midazolam ($p = 0.55$) or fentanyl ($p = 0.72$) during the procedure (Fig. 3b). Physiological parameters during the procedure were similar in both groups (Table 3). Very few adverse events occurred.

Exploratory analyses (Fig. 4) of separate pain scores during the procedure showed lower levels of postoperative pain in the music therapy group 0.00 (0.00, 2.00) compared to the control group 1.00 (0.00, 2.00), ($p = 0.36$). Analyses of separate anxiety scores showed a trend toward decreased preoperative levels in the music therapy group 2.00 (0.00, 3.75) compared to the control group 3.00 (1.00, 5.00) ($p = 0.16$, $r = 0.18$). Postoperative anxiety scores demonstrated a median of 0.00 (0.00, 0.00) in the music therapy group vs 1.00 (0.00, 2.00) in the control group ($p < 0.001$, $r = 0.47$).

Preliminary analyses of the written reflections suggested that patients in the music therapy group expressed positive responses to the music therapy overall, increasing the experienced procedure coping, wellbeing, and satisfaction.

4. Discussion

The main goal of this study was to investigate music therapy, in the form of facilitated music listening, as a possible adjunct in regulating stress responses for patients during a cardiac invasive procedure performed in local anaesthesia. The cardiac procedure was transvenous cardiac device lead extraction, an invasive procedure typically entailing some stress and pain for the patient. We measured levels of patient satisfaction, self-reported pain and anxiety, vital signs and procedure

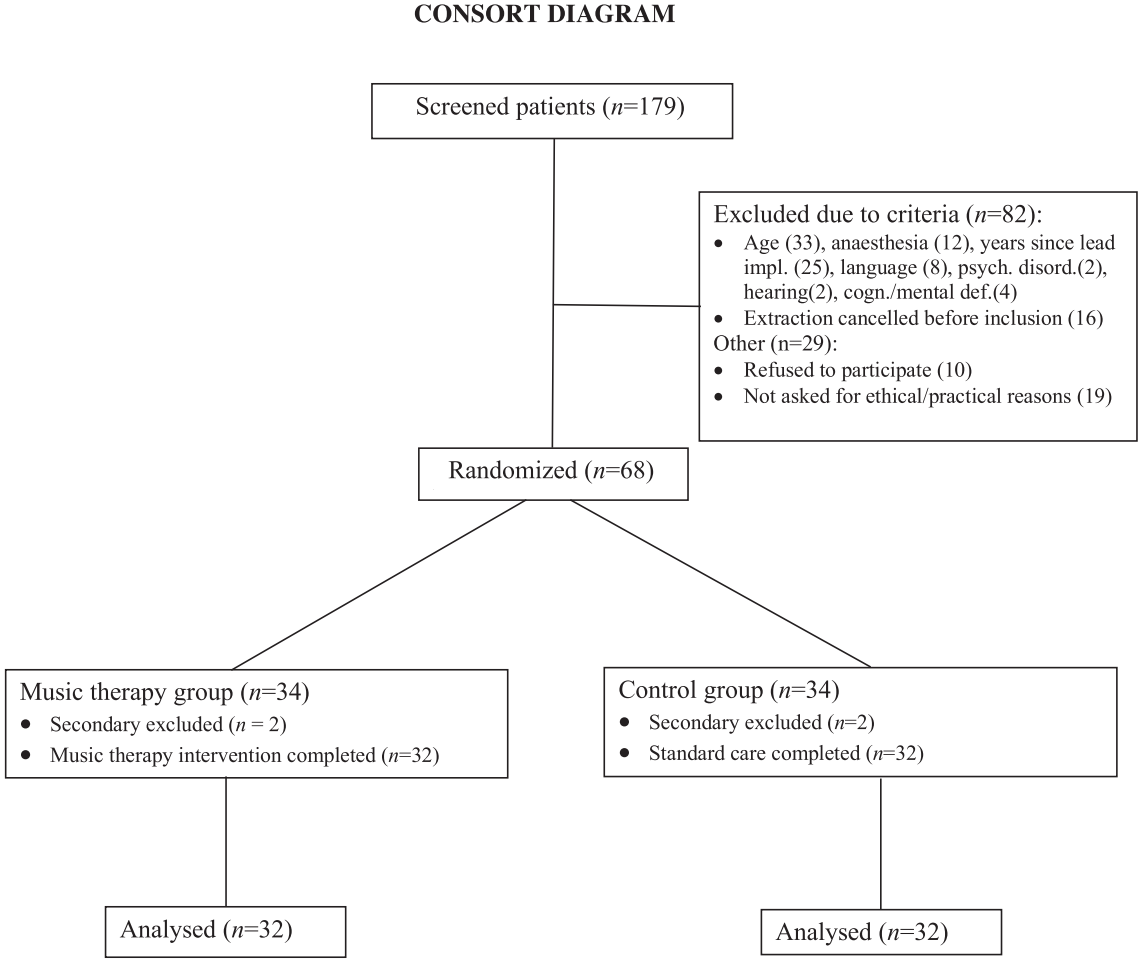


Fig. 1. Consort diagram of study participants.

Table 1
Baseline characteristics.

	Music therapy (*n* = 32)	Control (*n* = 32)
Basic		
Females	8 (25.0%)	10 (31.3%)
Age (years)	64.5 (56.0, 72.0)	68.0 (54.8, 71.8)
Weight (kg)	82.0 (69.0, 97.8)	84.5 (77.5, 93.8)
Height (cm)	176.5 (170.0, 181.5)	179.5 (168.5, 185.8)
Medical history, n (%)		
Hypertension	7 (21.9%)	7 (21.9%)
Heart failure	15 (46.9%)	16 (50.0%)
Myocardial infarction	8 (25.0%)	8 (25.0%)
Kidney failure	6 (18.8%)	3 (9.4%)
Diabetes	7 (21.9%)	3 (9.4%)
Smoker	5 (15.6%)	5 (15.6%)
Vital sign		
Systolic blood pressure (mmHg)	126.5 (112.5, 144.5)	115.5 (106.3, 137.5)
Diastolic blood pressure (mmHg)	70.0 (63.5, 80.8)	74 (64.0, 82.5)
Heart rate (beats/min)	68.5 (60.0, 78.0)	65 (58.3, 74.8)
Oxygen saturation, %	98.0 (96.3, 99.0)	97 (96,0, 98.3)
Self-reported scores at baseline		
Pain (NRS 0–10)	0.00 (0.00, 0.00)	0.00 (0.00, 1.00)
Anxiety (NVAAS 0–10)	2.00 (0.00, 3.00)	2.00 (1.00, 4.00)

Data shown are numbers (%) or medians (interquartile range).
NRS = Numeric Rating Scale; NVAAS = Numeric Visual Analog Anxiety Scale.

Table 2
Procedure variables.

	Music therapy (*n* = 32)	Control (*n* = 32)
Pacemaker	18 (56,3%)	20 (62,5.1%)
Implantable cardioverter-defibrillator	14 (43,8%)	12 (37.5%)
Years since lead implantation	7.0 (3.0, 12.8)	4.5 (3.0, 7.8)
Reason for extraction:		
Infection	15 (46.9%)	12 (37.5%)
Lead loosened	1 (3.1%)	1 (3.1%)
Electronic failure	11 (34.4%)	15 (46.9%)
Other	5 (15.6%)	4 (12.5%)
Extraction completed	30 (93.8%)	26 (81.3%)
Number of leads out	1.00 (1.00, 2.00)	2.00 (1.00, 2.00)
Number of leads in	1.00 (0.25, 2.00)	1.00 (0.00, 2.00)
Duration invasive procedure (minutes)	58 (36, 81)	55 (32, 89)
Duration total procedure (minutes)	325 (294, 381)	305 (270, 354)
Use of Sheaths	22 (68.8%)	20 (62.5%)
Use of Sheaths - duration (minutes)	4.5 (1.5, 7.9)	5.4 (3.0, 9.5)
Adverse events[a]	1 (3.1%)	1 (3.1%)

Data shown are numbers (%) or medians (interquartile range).
[a] Bradycardia in the music therapy group, ventricular tachycardia in the control group.

medication. Patient satisfaction with pain management was high, and pain levels generally low, in both the music therapy and the control groups. No significant effect was found of music therapy related to pain. For the secondary outcome anxiety, we found a decrease of borderline significance in favour of the music therapy group. The use of analgesic/

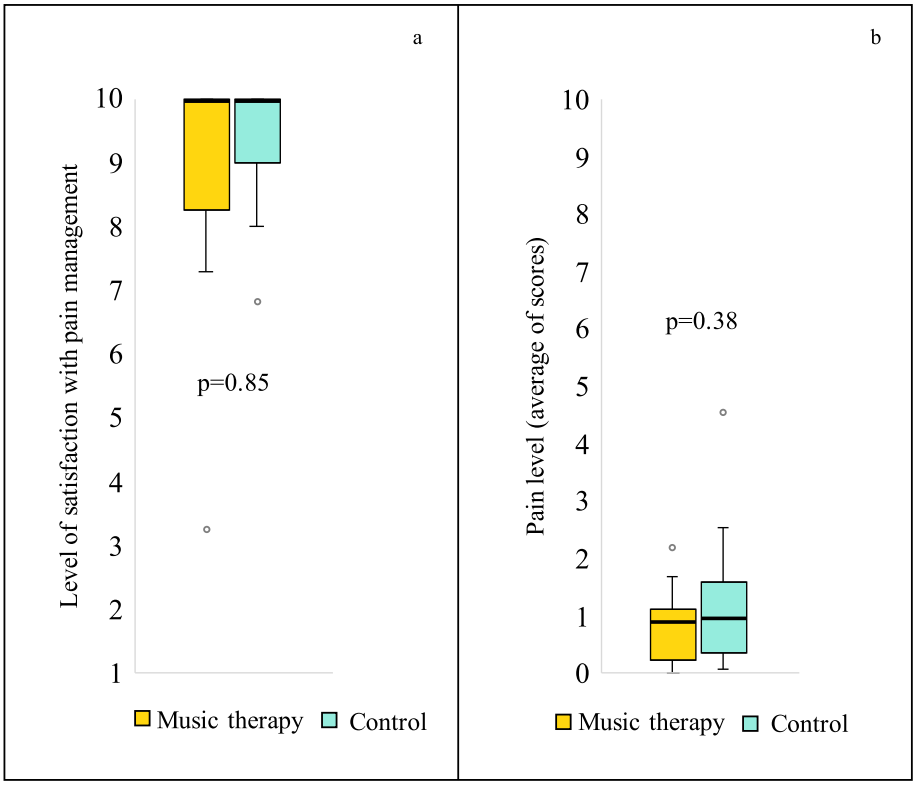


Fig. 2. Levels of patient satisfaction (a) and average of pain scores (b). Data presented as median with interquartile range (25th percentile, 75th percentile), and 'whiskers' (10th percentile, 90th percentile). Min/max values outside 'whiskers' are marked as outliers.

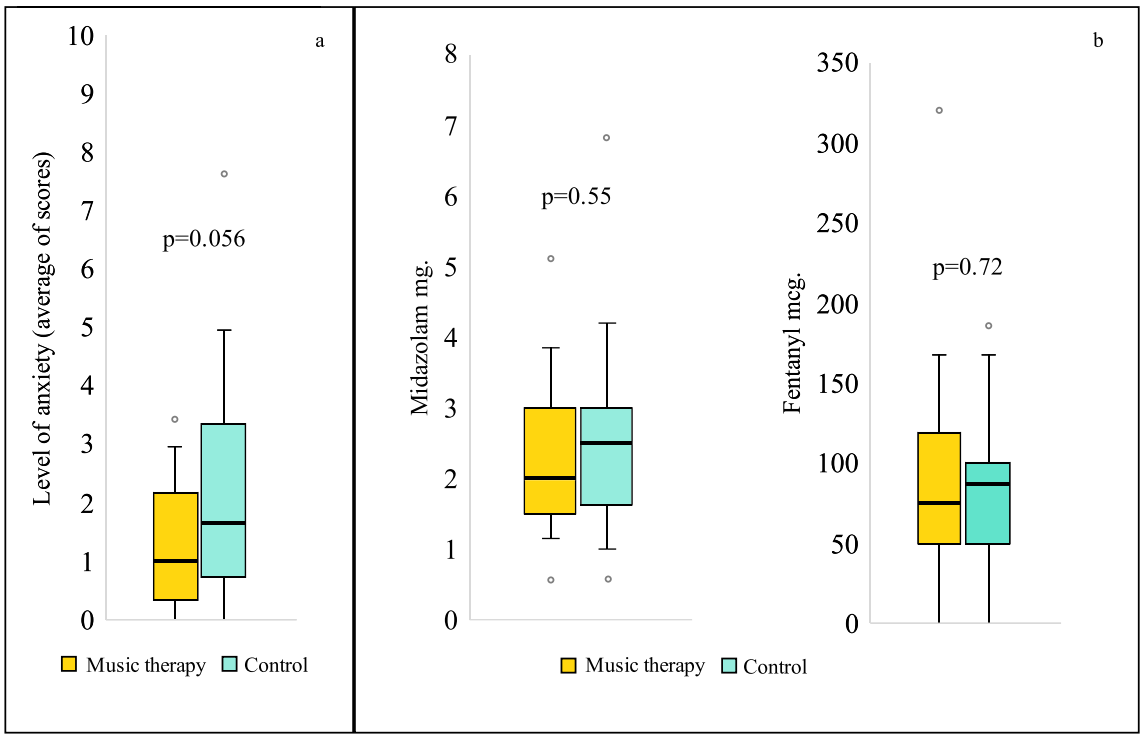


Fig. 3. Average of anxiety scores (a) and use of anxiolytic/analgetic drugs (b). Data presented as median with interquartile range (25th percentile, 75th percentile), and 'whiskers' (10th percentile, 90th percentile). Min/max values outside 'whiskers' are marked as outliers.

anxiolytic drugs and vital signs were similar across groups.

To our knowledge, this is the first study to investigate the efficacy of music therapy as an adjunct in regulating stress responses in patients during cardiac device lead extractions performed in local anaesthesia. Despite the use of local anaesthesia and light sedation, such extractions may be painful and do trigger some anxiety in most patients. Based on

Table 3
Physiological parameters.

	Music therapy	Control	*p*-Value
Blood pressure (mm Hg)			
Systolic	121.50 (109.25, 139.25)	119.83 (103.08, 131.33)	0.37
Diastolic	70.00 (63.42, 80.92)	70.00 (60.42, 75.92)	0.84
Respiration rate (breaths/min)	14.33 (12.67, 15.83)	13.83 (12.67, 15.58)	0.98
Heart rate (beats/min)	66.67 (58.00, 71.83)	64.17 (59.08, 72.75)	0.93
Oxygen saturation, %	96.33 (95.33, 97.58)	96.00 (95.33, 96.92)	0.49

Average of scores presented as medians (interquartile range).

some previous studies, we hypothesized that music therapy would increase patient satisfaction with pain management and decrease pain levels during the procedure. However, our study did not give support to this hypothesis. Levels of anxiety seemed to be the only variable affected during the music intervention, being lower in the music therapy group.

The low levels of pain in both study groups (median NRS scores $\leq$1) may be one explanation for the lack of effect of music therapy. With low pain levels in the control group, further reductions are hard to achieve. In our study, music therapy was provided on top of the standard procedure, which included moderate doses of analgetic and anxiolytic drugs. A more restrictive administration of analgetic and anxiolytic drugs might have changed the results. The pain levels might also be influenced by the fact that the cardiologists performing the lead extractions were very well trained and experienced (Knutsen et al., 2015), a factor known to reduce pain levels and the risk of complications during the procedure. Other variables known to influence pain levels during lead extractions, as the number of years since device lead implantation and use of sheaths, were similar across groups (Knutsen et al., 2015).

The average anxiety levels measured by NVAAS were lower in the music therapy compared to the control group, but the reduction did not reach statistical significance. In the exploratory analysis, we found reduced anxiety levels in the music therapy group, particularly in the preoperative and postoperative phases. In those phases, the patients were not given midazolam (anxiolytic). In previous research, measures of pain and anxiety have often been limited to either the pre- and postoperative, or solely the postoperative phase (Bradt, Dileo, & Potvin, 2013; Hole et al., 2015; Kühlmann et al., 2018). In our study, it was of main importance to include perioperative measures. However, this inclusion might have affected the final results showing less reduction in levels of anxiety than what has been found in previous studies (Bradt, Dileo, & Shim, 2013; Hole et al., 2015; Kühlmann et al., 2018). As the reduction in average level of anxiety was associated with some uncertainty, more research is needed to explore this further.

Although there is previous evidence of music interventions' effects on heart rate, blood pressure and respiration rate, the findings are mixed and often associated with uncertainty (Hole et al., 2015; Koelsch & Jancke, 2015; Nilsson, 2008). As music interventions may elicit various reactions depending on a merged complexity of contextual, psychosocial and physiological factors, interpreting results of music interventions on physiologic parameters is complex. In our study, the music therapy intervention did not have any effect on physiologic parameters, and further analyses were not made.

Previous studies have shown promising results with music interventions in patients with heart disease (Argstatter et al., 2006; Bradt, Dileo, & Potvin, 2013). Our results are in line with studies by Ripley et al. (Ripley et al., 2014) and Palmer et al. (Palmer et al., 2017), who found high patient satisfaction overall, but no differences between groups. In contrast, Al-Azawy et al. found significantly higher satisfaction in patients who received instructive preparative information, focusing on procedure expectations and coping, combined with premedication (Al-Azawy et al., 2015). It is also in contrast to a previous meta-analysis by Hole et al. on patient satisfaction with care (Hole et al.,

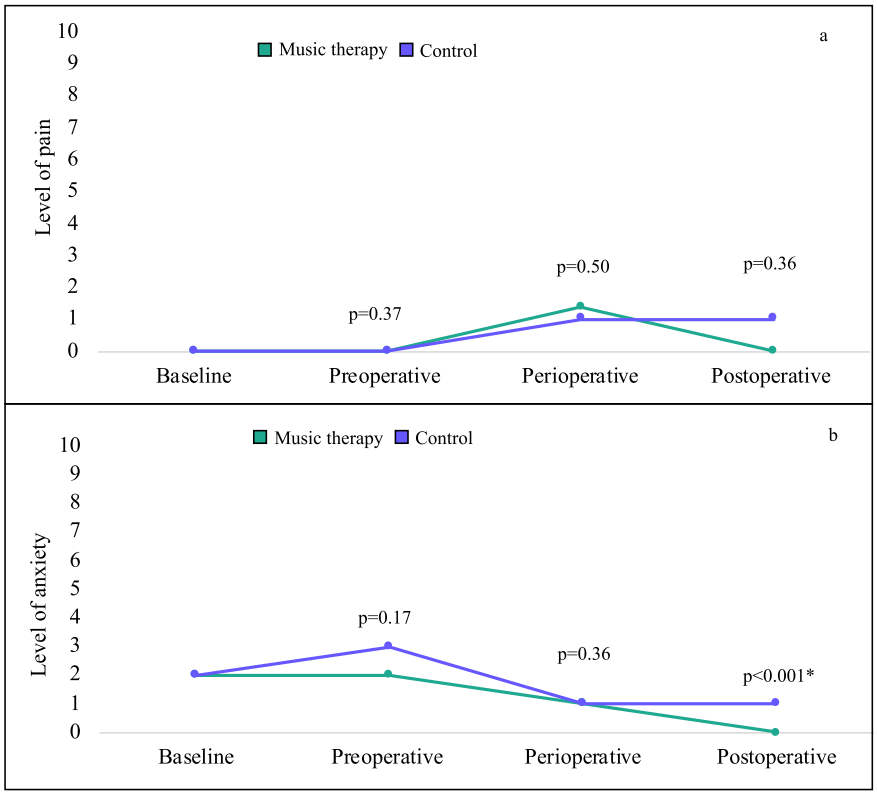


Fig. 4. Explorative analyses. Pain (a) and anxiety, (b) levels at separate measure points presented as medians.

2015), including 16 studies of varied music interventions with patients undergoing surgical procedures.

Previous research reported that music may have pain-reducing effects in patients with coronary heart disease (Bradt, Dileo, & Potvin, 2013) and in surgery (Kühlmann et al., 2018; Nilsson, 2008). We did not find such pain-reducing effect in our study. Still, through the exploratory analysis, a small trend was seen toward decreased postoperative pain in the music therapy group, in accordance with the meta-analyses by Kühlmann (Kühlmann et al., 2018) and Hole (Hole et al., 2015), evaluating music interventions for surgery patients.

We found that facilitated music listening was applicable as an adjunct during the cardiac invasive procedure, with only one adverse event not related to music therapy. The patients were easily recruited and preferred prolonged music listening far beyond the required minimum of 30 min. The study results indicated that the patients were satisfied with the intervention and had low levels of pain. The patients' general satisfaction and written comments also suggested that music therapy may be desirable among the patients undergoing cardiac device lead extractions, despite the lack of impact on most effect variables in this study.

5. Limitations

As in most music therapy studies, the study could not be blinded, implicating a risk of bias. Despite the standardization of both information and measurements, we cannot exclude that differences occurred due to the open design.

Patient satisfaction in this study was higher than expected. Accordingly, the power analysis was based on false estimates. However, with such a high degree of patient satisfaction and low pain levels in the control group, it is unlikely that a higher number of patients would have changed the results of the primary outcome.

The skewness of the distribution of scores in both groups is a weakness of the measurement tools and the choice of research methodology. The measurement tools were chosen in order to minimize both patient strain and operator distraction during the complex cardiac invasive procedure. However, we cannot exclude that more sensitive tools for measurement of stress responses might have given a different result. Further, the intention of the summary measure might not have been clearly communicated hence perceived by the patients.

As facilitated music listening was defined as an indivisible unit of individual guiding and music listening, no distinction was made between possible effects of the therapeutic relation and the effect of the music itself. A broader scope of patient experiences and interdisciplinary factors should be included in future research designs to better understand the effects of music therapy approaches on various outcomes during invasive cardiac procedures.

6. Conclusion

The present study is the first RCT to report outcomes of facilitated music listening as an adjunct in cardiac device lead extraction procedures. The music therapy interventions during the procedures were feasible and safe. Patient satisfaction with pain management was high, and average pain levels low, with no significant differences between groups. A decrease in patient anxiety of borderline significance was observed in the music therapy group. The findings have elements of uncertainty and must be interpreted with caution, and further research is needed.

Source of support

The study was a research collaboration between Department of Cardiology at Oslo University Hospital Ulleval and Centre for Research in Music and Health (CREMAH) at the Norwegian Academy of Music.

Author statement

All persons who meet authorship criteria are listed as authors, and all authors certify that they have participated sufficiently in the work to take public responsibility for the content, including participation in the concept, design, analysis, writing, or revision of the manuscript. Furthermore, all authors certify that this material has not been and will not be published in any other journal before its appearance in Applied Nursing Research.

Authorship contributions

S.C.B.-Æ., G.T. and S.H. conceived and planned the project; S.C.B.-Æ T.M.K. and H.M.H. performed the experiment and contributed to acquisition of data; S.C.B.-Æ and L.M.D. contributed with data analysis and interpretation, with help from S·H; S.C.B.-Æ., G.T. and S.H were writing and revising the manuscript, with small contributions from all authors.

Declaration of competing interest

None declared.

Acknowledgments

The study is a research collaboration between the Department of Cardiology at Oslo University Hospital Ulleval, and Centre for Research in Music and Health (CREMAH) at the Norwegian Academy of Music. The authors reveived no specific funding for this work. The study is part of a PhD fellowship at the Norwegian Academy of Music.

References

Al-Azawy, M., Oterhals, K., Fridlund, B., Assmus, J., & Schunster, P. (2015). Premedication and preoperative information reduces pain intensity and increases satisfaction in patients undergoing ablation for atrial fibrillation: A randomised controlled study. *Applied Nursing Research, 28*, 268–273.

Allen, J. (2013). Pain management with adults. In J. L. Allen (Ed.), *Guidelines for music therapy practice in adult medical care* (pp. 35–61). Gilsum: Barcelona Publishers.

Argstatter, H., Haberbosch, W., & Bolay, H. V. (2006). Study of the effectiveness of musical stimulation during intracardiac catheterization. *Clinical Research in Cardiology, 95*(10), 514–522.

AudioCura. (2016). AudioCura M2 AudioCura.com: AudioCura - Music intervention for health care. Available from: http://www.audiocura.com/da/portfolio/audiocura-m2/.

Blichfeldt-Ærø, S. C., Trondalen, G., & Halvorsen, S. (2019). Facilitated music listening: Music therapy in an invasive cardiac procedure. *British Journal of Music Therapy., 33*(1), 27–38.

Bongiorni, M., Di Cori, A. S., Zucchelli, G. V., Paperini, L. M., & Coluccia, G. S. (2016). Where is the future of cardiac lead extraction heading? *Expert Review of Cardiovascular Therapy, 29*(Aug.), 1–7.

Bongiorni, M., Soldati, E., Zucchelli, G., Di Cori, A., Segreti, L., De Lucia, R., et al. (2008). Transvenous removal of pacing and implantable cardiac defibrillating leads using single sheath mechanical dilatation and multiple venous approaches: High success rate and safety in more than 2000 leads. *European Heart Journal, 29*(23), 2886–2893.

Boutron, I., Altman, D. G., Moher, D., Schulz, K. F., & Ravaud, P. (2017). CONSORT Statement for randomized trials of nonpharmacologic treatments: A 2017 Update and a CONSORT extension for nonpharmacologic trial abstracts. *Annals of Internal Medicine, 167*(1), 40–47.

Bradt, J., Dileo, C., & Potvin, N. (2013). Music for stress and anxiety reduction in coronary heart disease patients. *Cochrane Database of Systemic Reviews, 12*. Cd006577.

Bradt, J., Dileo, C., & Shim, M. (2013). Music interventions for preoperative anxiety. *The Cochrane Database of Systematic Reviews*, (6). Cd006908.

Deharo, J., Bongiorni, M., Rozkovec, A., Bracke, F., Defaye, P., Fernandez-Lozano, I., et al. (2012). Pathways for training and accreditation for transvenous lead extraction: a European Heart Rhythm Association position paper. *Europace, 14*(1), 124–134. Jan.

Deshmukh, A., Patel, N., Noseworthy, P., Patel, A., Arora, S., Kapa, S., et al. (2015). Trends in use and adverse outcomes associated with transvenous lead removal in the United States. *Circulation., 132*(25), 2363–2371.

Dornelas, E. A. (2012). *Stress proof the heart. Behavioral interventions for cardiac patients*. New York NY: Springer, 408 p.

Elkins, G., Staniunas, R., Rajab, M. H., Marcus, J., & Snyder, T. (2004). Use of a numeric visual analog anxiety scale among patients undergoing colorectal surgery. *Clinical Nursing Research, 13*(3), 237–244.

Ghetti, C. M. (2012). Music therapy as procedural support for invasive medical procedures: Toward the development of music therapy theory. *Nordic Journal of Music Therapy, 2*(1), 3–35.
Graff, V., Cai, L., Badiola, I., & Elkassabany, N. M. (2019). Music versus midazolam during preoperative nerve block placements: A prospective randomized controlled study. *Regional Anesthesia and Pain Medicine, 44*, 796–799.
Grocke, D. (2016). Receptive music therapy. In J. Edwards (Ed.), *The Oxford handbook of music therapy* (pp. 684–706). Oxford: Oxford University Press.
Hanser, S. B. (2014). Music therapy in cardiac health care: Current issues in research. *Cardiology in Review, 22*(1), 37–42.
Hawker, G. A., Mian, S., Kendzerska, T., & French, M. (2011). Measures of adult pain. *Arthritis Care and Research, 63*(S11), 240–252.
Heiderscheit, A. (2013). Surgical and procedural support for adults. In J. Allen (Ed.), *Guidelines for music therapy practice in adult medical care* (pp. 17–34). Gilsum: Barcelona Publishers.
Hole, J., Hirsch, M., Ball, E., & Meads, C. (2015). Music as an aid for postoperative recovery in adults: A systematic review and meta-analysis. *The Lancet., 386*(10004), 1659–1671.
Knutsen, T. M., Vanberg, P., Steen, T., Skretteberg, P. T., Kamal, Z., & Platou, E. S. (2015). *Single sheath lead extraction, a single center experience of more than 1800 lead extractions. EHRA-2015. Europace Abstracts Supplement (2015) 17 (Supplement 3), iii160*. European Society of Cardiology.
Koelsch, S., & Jancke, L. (2015). Music and the heart. *European Heart Journal, 36*(44), 3043–3049.
Krippendorff, K. (2019). *Content analysis. An introduction to its methodology. 4th ed.* California: Sage Publications Inc.
Kühlmann, A. Y. R., de Rooij, A., Kroese, L. F., van Dijk, M., Hunink, M. G. M., & Jeekel, J. (2018). Meta-analysis evaluating music interventions for anxiety and pain in surgery. *The British Journal of Surgery, 105*, 773–783.
Kusumoto, F. M., Schoenfeld, M. H., Wilkoff, B. L., Berul, C. I., Birgersdotter-Green, U. M., Carrillo, R., et al. (2017). HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. *Heart Rhythm, 14*(12). e503-e48.
Lund, H. N., Bertelsen, L. R., & Bonde, L. O. (2016). Sound and music interventions in psychiatry at Aalborg University Hospital. *SoundEffect., 1*, 48–68.
Melzack, R. (2001). Pain and the neuromatrix in the brain. *Journal of Dental Education, 65*(12), 1378–1382.
Nilsson, U. (2008). The anxiety- and pain-reducing effects of music interventions: A systematic review. *AORN Journal, 87*(4), 780–807.
Pallant, J. (2016). *SPSS survival manual* (6 ed.). Berkshire, England: Open University Press.
Palmer, J. B., Lane, D., & Mayo, D. (2017). Surgical music therapy: The significance and implementation of music therapy in the operating arena. *Music Therapy Perspectives, 35*(1), 30–35.
Ripley, L., Christopoulos, G., Michael, T. T., Alomar, M., Rangan, B. V., Roesle, M., et al. (2014). Randomized controlled trial on the impact of music therapy during cardiac catheterization on reactive hyperemia index and patient satisfaction: The functional change in endothelium after cardiac catheterization, with and without music therapy (FEAT) study. *The Journal of invasive cardiology., 26*(9), 437–442.
Short, A., Gibb, H., Fildes, J., & Holmes, C. (2013). Exploring the role of music therapy in cardiac rehabilitation after cardiothoracic surgery. A qualitative study using the bonny method of guided imagery and music. *The Journal of Cardiovascular Nursing, 28*(6), 74–81.
Sridhar, A., Lavu, M., Yarlagadda, V., Reddy, M., Gunda, S., Afzal, R., et al. (2017). Cardiac implantable electronic device-related infection and extraction trends in the U.S. *Pacing and Clinical Electrophysiology, 40*(3), 286–293.
Wazni, O., & Wilkoff, B. (2016). Considerations for cardiac device lead extraction. *Nature Reviews Cardiology, 13*(4), 221–229.
Wilkoff, B. L. (2009). Transvenous lead extraction: Heart Rhythm Society expert consensus on facilities, training, indications, and patient management. *Heart Rhythm, 6*, 1085–1104.

Paper III

Blichfeldt-Ærø, S. C., Halvorsen, S. & Trondalen, G.

Music therapy in invasive cardiac procedures:
Expanded perspective

(submitted for publication)

Music therapy in invasive cardiac procedures: Expanded perspective

Stine Camilla Blichfeldt-Ærø, PhD Fellow, MA-MT[1], Sigrun Halvorsen, PhD, MD[2,3], Gro Trondalen, PhD, MA-MT, FAMI[1]

Abstract

Introduction: There is a need for more research on the effect and practical application of Music therapy in perioperative settings. Towards this end, a randomized controlled trial (RCT) was performed to evaluate the stress-regulatory effects of a specific music therapy intervention on patients (n=64) during cardiac device lead extraction procedures. This paper presents a supplementary analysis of the RCT to expand the perspective on the impact of the music therapy intervention related to patient anxiety and self-reported experiences.

Method: In this sub study, we analyzed patients' self-reported numeric-rated anxiety levels in relation to time and subgroups. The results were further illuminated through scores of the patients' satisfaction with the music therapy intervention, and qualitative written patient reflections. Descriptive statistical analyses were used, and a supplementary content analysis addressed the written patient material.

Results: Levels of anxiety varied over time in all subgroups, with the highest level preoperatively and the lowest postoperatively in most subgroups. Independent of anxiety levels, the patients reported positive experiences with music therapy related to procedure coping, wellbeing, and satisfaction, expressed within four categories: (1) bodily sensations of wellbeing, (2) positive feelings, (3) presence of mind, and (4) useful intervention elements.

Keywords: *medical music therapy, procedure support, stress, anxiety, cardiac devices*

1 Centre for Research in Music and Health (CREMAH), Norwegian Academy of Music, Slemdalsveien 11, PB 5190, Majorstua, NO-0363 Oslo, Norway
2 Department of Cardiology, Oslo University Hospital Ulleval, Kirkeveien 166, 0450 Oslo, Norway
3 Faculty of Medicine, University of Oslo, Klaus Torgårds vei 3, 0372 Oslo, Norway

Introduction

The use of music therapy and music medicine interventions for the regulation of stress responses related to medical treatment receive increased attention and promising study results (Hole et al., 2015; Kühlmann et al., 2018; Graff et al., 2019; DeWitte et al., 2019). As a complementary adjunct in invasive medical procedures, music therapy has had a beneficial effect on the reduction of stress, pain, and anxiety, with its best documented effects on preoperative anxiety and postoperative pain (Gooding et al., 2012; Kühlmann et al., 2018). Despite this increased attention and research evidence, a systematic implementation of music therapy as a non-medical resource remains rare within medical hospitals, and more clinical experience and research are needed to further its cause. There has been a special call for clinical music therapy protocols directed to specific medical situations and patient groups, and for music intervention studies within perioperative settings (Dileo, 2016; Hanser, 2014; Koelsch and Jancke, 2015; Robb and Carpenter, 2010; Palmer et al., 2017; van der Heijden et al., 2015).

We recently performed a randomized controlled trial to study the impact of a music therapy intervention for patients during cardiac device lead extraction procedures in local anaesthesia (Blichfeldt-Ærø et al., 2020). No significant effect of music therapy was found on the primary outcomes of patient satisfaction with pain management or average level of pain. Regarding the average level of anxiety, a secondary outcome, a borderline difference was found in favour of the music therapy group. No effects were found on physiological parameters or the use of medication during the procedure.

Despite the lack of statistically significant effects on most variables in the primary RCT analysis, the overall impression from the clinical practice was that the music therapy intervention was well received and the patients' responses highly appreciative. This general impression, combined with promising findings concerning anxiety levels invited to further exploration of the anxiety data illuminated by additional data material in a supplementary analysis. The following supplementary research questions were formulated:

How was the patients self-reported experience of the music therapy intervention

a. expressed through anxiety levels in subgroups and at different time points?
b. expressed through scores of satisfaction with the music therapy intervention?
c. expressed through written patient reflections?

Material and Methods

Study design and study population

In order to facilitate transparency regarding the origin and context of the data used in this supplementary analysis, brief descriptions of the original study are included in the following sections. Further details can be found in earlier publications (Blichfeldt-Ærø et al., 2020; Blichfeldt-Ærø et al., 2019).

The study was performed at a single centre (at the Department of Cardiology, Oslo University Hospital Ulleval, Oslo, Norway) in accordance with the CONSORT guidelines, and registered on ClinicalTrials.gov,

no.: NCT04172662. All consecutive patients who were referred to the PM/ICD centre for cardiac device lead extractions in the period 03/01/18-09/27/19 were screened for participation in the study. Inclusion criteria: age 25–80 years, a device implanted >12 months ago, planned lead extraction in local anaesthesia, able to speak and read Norwegian, no significant hearing impairment, and a willingness to participate in the study. For exclusion criteria, see previous publication (12). The cardiac device lead extraction procedures were performed in local anaesthesia and with some procedural sedation (Knutsen et al., 2015; Blichfeldt-Ærø et al., 2020). The invasive part of the procedure lasted typically between 45 min. and 2 hours, and the total procedure between 2 and 6 hours. Standardized doses of analgesic and anxiolytic drugs were given at the start of the procedure, and additional doses were added if required. Despite the given drugs, most patients will usually experience some pain and/or anxiety during the procedure.

Music therapy intervention: Facilitated Music Listening

For the original RCT, a tailored music therapy intervention called *Facilitated Music Listening* (alternately called FaMuLi or the music therapy intervention) was developed to regulate stress responses in patients undergoing the procedure (Blichfeldt-Ærø et al., 2019). The clinical protocol of the intervention has previously been published. FaMuLi was based on a biopsychosocial approach, balanced to meet the needs of both individualized and standardized patient care during the procedure (Blichfeldt-Ærø et al., 2019; Ghetti, 2012). The intervention had three-phases and followed a semi-manualized protocol: (1) preparation on the day before the procedure, including individualized experiences of music listening and coping guidance, (2) music listening during the pre- and perioperative phases (>30 minutes), and (3) a closing dialogue in the first postoperative period.

FaMuLi used a sample of 12 playlists provided through the *Music Star*, an iPad application featuring professionally developed playlists for therapeutic purposes (Lund et al., 2016). The playlists include several musical genres and are sorted by their level of complexity as *supportive music*—that is, *safe*, *opening*, and *exploring*. This classification is based on a taxonomy for receptive music applied in therapeutic settings (Wärja and Bonde, 2014). The study used an AudioCura loudspeaker (2016). The patients could choose freely among the playlists, and the music therapist was present for ongoing guidance and practical support. The therapist made an individual plan for music listening during the procedure according to the patients' choice of 1–3 preferred playlists. The prepared plan could be altered at any time, according to the patients' wishes and needs in the moment. The therapeutic adaptions were formed individually with regard to its verbal dialogue, degree of involvement, and amount of guidance along the way (Ghetti, 2012). As a short-term therapeutic process, the relational alliance was limited yet predictable and continuous in all phases of the procedure (Trondalen, 2016).

Supplementary analysis

The present study presents a supplementary analysis of the RCT using three main data sets obtained from patients who were included in the original RCT (n=64).

First, the possible impact of FaMuLi was explored through a descriptive analysis of the expressed anxiety levels in subgroups. The patients' self-reported level of anxiety was assessed using a numeric rating scale 0–10 (Elkins et al., 2004). In addition to a baseline score, measures were obtained before (pre), during (peri), and after (post) the invasive procedure, then summed up as the average of the three scores. Further

details about data collection from the original RCT appear in an earlier publication (2020). The subgroup analysis of anxiety was analyzed across the following three subgroups:

1. Baseline anxiety level: high (≥2), low (<2)
2. Gender: female, male
3. Age: high (≥66), low (<66)

The subgroup categories were chosen based on existing findings for patient groups at risk for increased levels of anxiety and difficulty with psychosocial adjustments (Kirian et al., 2012; Caldwell et al., 2007; Herrmann-Lingen and Buss, 2007). The subdivisions of baseline anxiety level and age were defined by median scores from the primary analysis. Given the small subgroup samples, inference analysis or generalized conclusions could not be performed, thus, the analysis was limited to descriptive trends in the present material, rendered as medians. The data were analyzed using IBM SPSS version 25.

Second, the original study obtained additional data material including experiences with the music therapy intervention from the patients randomized to receive music therapy during the procedure. When the procedure had concluded, and all other measures had been obtained, the music therapy patients received a brief satisfaction questionnaire to rate their satisfaction with the music therapy intervention on a numeric scale 1–10. The numeric scale was chosen as an equivalent to the scale for satisfaction with pain management that assessed the primary outcome of the RCT (Blichfeldt-Ærø et al., 2020; Hjermstad et al., 2011). The analysis was limited to the descriptive distribution of data in the entire group, presented as a median with interquartile range (25th percentile, 75th percentile).

Third, the subgroup analysis was elaborated on using written patient reflections on the music therapy intervention, responding to this standard question: "If you have any reflections regarding the music project, please write here". The numeric scores and written reflections were anonymous, filled out privately, and returned in a sealed envelope. The written reflections were originally in Norwegian, then translated into English by the first author and validated through evaluation by two peer-reviewers who were not involved in the study. The qualitative data were analyzed using inductive *content analysis* (Krippendorff, 2019) to reveal patterns across cases in three steps:

1. Preparing data: The text material gleaned for inclusion in the analysis were defined as the manifest content of the entire written material—that is, the written reflections. The text material was carefully read and re-read several times to obtain a sense of a whole.

2. Organizing data: A matrix (spreadsheet) was used as a digital aid in the further processing of the data, identifying segments of content with unique descriptions. Words and passages were highlighted in colour and recurrent units grouped as coding units. Thereafter, the coding units were abstracted into higher-order headings, formulating a general description of the research topic through exhaustive and mutually distinct categories. Thus, the units and categories were developed directly from the patients' written texts.

3. Interpreting and summarizing data: The process of analysis and the results were reported through the distinct categories, complemented by coding units and representative narrative quotes from the patients, marked by gender and coded ID (M/F#xx).

Results

Study population and intervention

The baseline characteristics of the study population (n=64) are shown in table 1 (Blichfeldt-Ærø et al., 2020). The mean age was 66 years, and 72% were men.

Table 1: Baseline characteristics

	Music therapy (*n*=32)	**Control** (*n*=32)
Basic		
Females	8 (25.0%)	10 (31.3%)
Age (years)	64.5 (56.0, 72.0)	68.0 (54.8, 71.8)
Weight (kg)	82.0 (69.0, 97.8)	84.5 (77.5, 93.8)
Height (cm)	176.5 (170.0, 181.5)	179.5 (168.5, 185.8)
Medical history, n (%)		
Hypertension	7 (21.9%)	7 (21.9%)
Heart failure	15 (46.9%)	16 (50.0%)
Myocardial infarction	8 (25.0%)	8 (25.0%)
Kidney failure	6 (18.8%)	3 (9.4%)
Diabetes	7 (21.9%)	3 (9.4%)
Smoker	5 (15.6%)	5 (15.6%)
Vital sign		
Systolic blood pressure (mmHg) Diastolic blood pressure (mmHg)	126.5 (112.5, 144.5) 70.0 (63.5, 80.8)	115.5 (106.3, 137.5) 74 (64.0, 82.5)
Heart rate (beats/min)	68.5 (60.0, 78.0)	65 (58.3, 74.8)
Oxygen saturation, %	98.0 (96.3, 99.0)	97 (96.0, 98.3)
Self-reported scores at baseline		
Pain (NRS 0-10)	0.00 (0.00, 0.00)	0.00 (0.00, 1.00)
Anxiety (NVAAS 0-10)	2.00 (0.00, 3.00)	2.00 (1.00, 4.00)

Data shown are numbers (%) or medians (interquartile range)
NRS = Numeric Rating Scale; NVAAS= Numeric Visual Analog Anxiety Scale

All patients in the music therapy group (n=32) completed music listening >30 minutes, with a median duration of 127 (109,156) minutes. Most patients used a mix of 2–3 playlists within varied taxonomy groups (Wärja and Bonde, 2014), and playlists from the most complex *exploring* level were chosen more often than the *safe* or *opening* levels (fig.1).

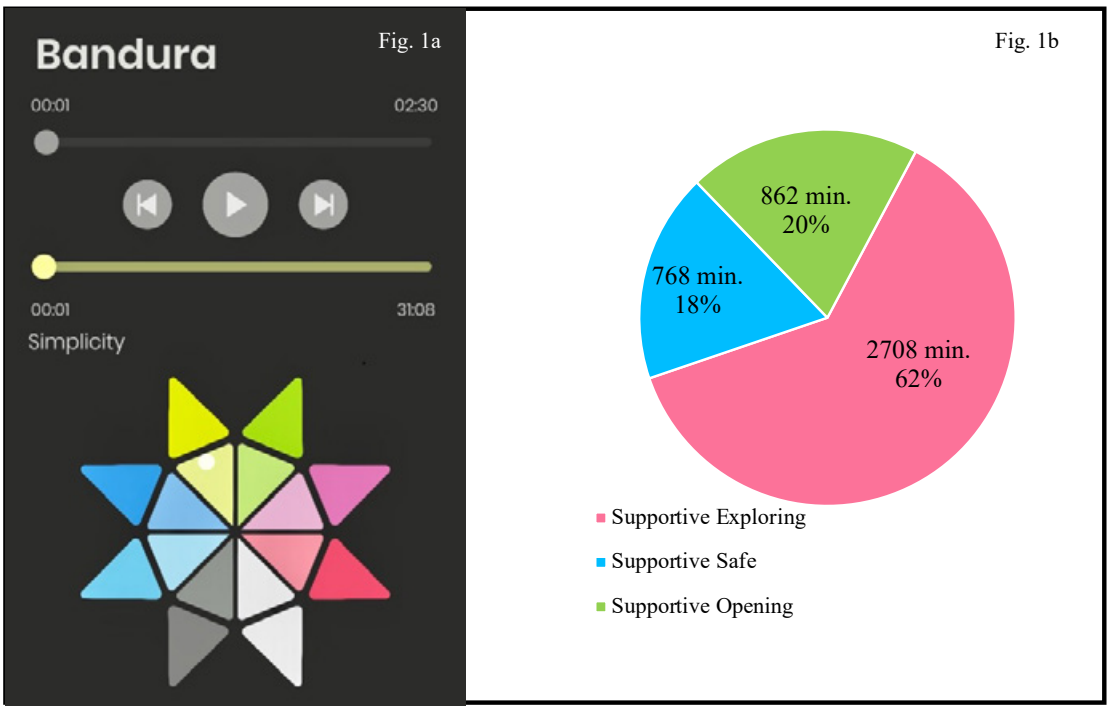


Figure 1. a) The Music Star (Lund et al.), b) Distribution of the use of playlists according to taxonomy group. Duration expressed as minutes and percent.

Anxiety

The group of patients receiving music therapy showed a decrease in the average level of anxiety of borderline significance compared to the control group (p=0.056, r=0.24). When dividing patients into subgroups (baseline anxiety high (≥2) or low (<2); age>=66 years or <66 years; female or male), the same pattern was found with a lower average level of anxiety in the music therapy compared to the control group for all subgroups (fig. 2). The average level of anxiety during the procedure was higher for patients with high as opposed to low baseline anxiety. Female patients had high levels of average anxiety compared to male patients, and the younger patients reported slightly higher anxiety than the older patients.

When studying the levels of anxiety at the different time points, the levels of anxiety were highest in the preoperative phase and lowest in the post-operative phase, both in the music therapy and in the control group (Blichfeldt-Ærø et al., 2020). However, a considerable variety within subgroups was found (Figure 3a–c). Except for patients with higher ages and male patients, the music therapy group had a consistently lower baseline anxiety than the control group. In the subgroups distinguished by the level of baseline anxiety, patients with low baseline anxiety had a slightly increased average anxiety compared to the baseline score. In contrast, the average anxiety generally decreased for patients with high baseline anxiety. In analyzing the

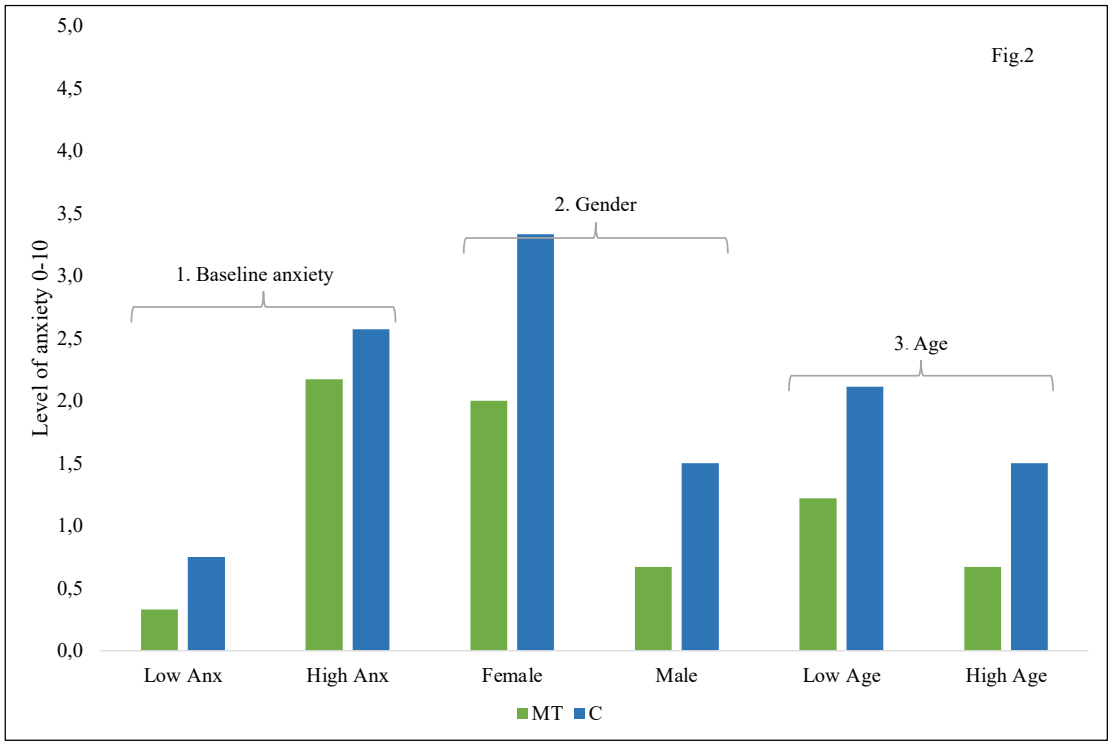


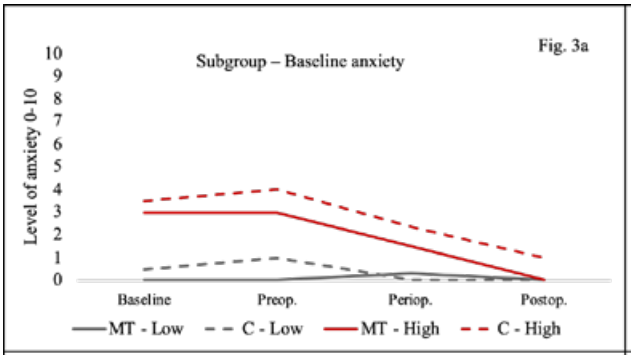
Figure 2. Average level of anxiety sorted in subgroups of baseline anxiety (high: ≥2, low: <2), gender, and age (high: ≥66, low: <66). Data presented as medians.

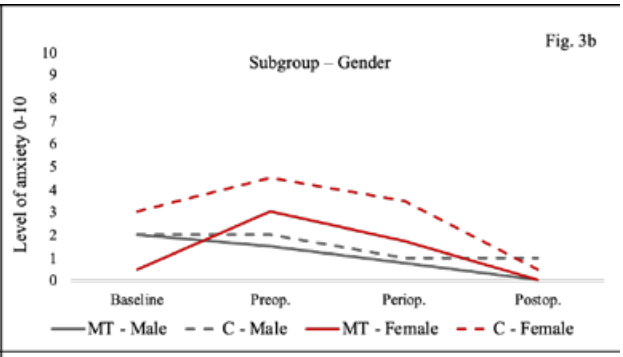
timelines, it was shown that all patients in the control group experienced increased preoperative anxiety, unlike in the music therapy group (fig. 3a). The intervention group distribution of participants in the three subgroups was approximately even (fig. 3d). Results of the gender subgroups revealed that preoperative anxiety increased for all female patients but not for male patients in relation to baseline anxiety (fig. 3b). Females in the music therapy group showed consistently lower baseline anxiety than in the control group, and their preoperative anxiety increased more.

Anxiety for males in the music therapy group decreased steadily from the baseline level, generally more so than in the control group. Patients with lower ages experienced higher baseline anxiety than patients with higher ages (fig. 3c). In patients with higher ages, the average anxiety decreased in the music therapy group but increased in the control group compared to the baseline score. The highest decrease in average anxiety was found in male music therapy patients (24/32), and the highest increase was found in female music therapy patients (8/32). All of the music therapy subgroups reached a median level of no anxiety postoperatively, while patients with low baseline anxiety were the only control group to achieve the same. It must be noted that the number of female patients was small, and these findings should be interpreted with caution.

Patient satisfaction scores

The self-reported numeric rated score (1–10) of satisfaction with the music therapy intervention was obtained from all patients in the music therapy group (n=32) and revealed a median (IQR) score of 10 (9,10).





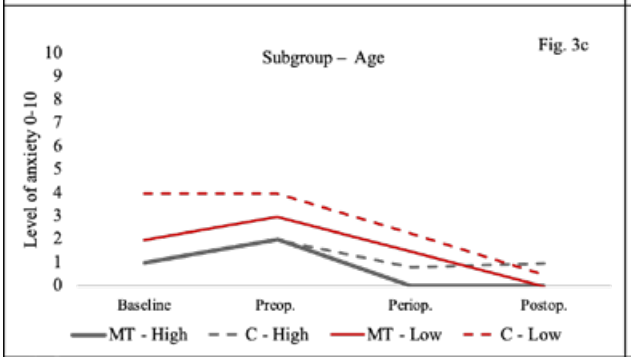


Fig. 3d

Participants

Subgroup		Music therapy n=	Control n=
Baseline anxiety	Low <2	15	12
	High ≥ 2	17	20
Gender	Female	8	10
	Male	24	22
Age	Low <66	17	14
	High ≥ 66	15	18

Figure 3. 3a–c) Timelines of anxiety level in subgroups: a) baseline anxiety, b) gender, and c) age. Data presented as medians. MT = music therapy, C = control. 3d) Description of subgroup categories and related number of participants, presented as frequency.

Written patient reflections

Additional written reflections were received from 31 of the 32 patients in the music therapy group who described their experiences with the music therapy intervention. Due to the qualitative nature of these data, the following material must be presented at greater length than the previous sections to offer an expanded perspective on the nature of the anxiety variable. Following inductive content analysis (2019), the written reflections are presented through categorical headings with general descriptions of the topic, each with associated coding units with specific descriptions that closely resemble to the original material. Each category is followed by examples from the original texts, as narrative quotes. The patients' written reflections were generally positive—some were very brief, and others included more detail. These reflections included varied modes of experience in four distinct categories: (1) bodily sensations of wellbeing, (2) positive feelings, (3) the presence of mind, and (4) useful intervention elements.

(1) Bodily sensations of wellbeing: This category refers to experiences expressed as bodily sensations, as described by 19 patients using various words for wellbeing. The coding units in this category include the patient's words *comfortable, calming, and relaxing*. Examples follow:

> (M#20) Comfortable and calming. […] (M#37) The combination of comfortable music and medication made me feel calm during the procedure. It went much better than expected. […] (M#32) I felt relaxed and got drowsy. […] (F#34) Prior to the operation I almost fell asleep while listening to the music.

(2) Positive feelings: This category represents a general description of coding units conveying the patients' *general attitude, mood, and/or satisfaction* after receiving music therapy during the medical procedure, as expressed in their written reflections. Twenty-four patients wrote positive comments including reinforcing words like "very" or "much", that expressed their gratitude for the opportunity to listen to music. Examples follow:

> (M#27) A very positive experience […] (M#14) In general, the experience was fantastic. […] (M#47) … a project more people should be able to benefit from. I am very satisfied. I enjoyed it. […] (F#21) Very satisfied…What a great concept. […] (M#50) Thank you. Being placed in the music group was a treat.

(3) Presence of mind: This category refers to experiences, including mental or cognitive processes. The underlying coding units within this category includes *direction of focus* and *experienced flow of time*. The ten patients who wrote reflections within this category described their experiences of a redirected focus, of which they appreciated. They were positively distracted or diverted from the negative aspects of the medical procedure toward the comfortable and relaxing music. Some patients also emphasized that their perception of time was altered. Examples follow:

> (M#65) … takes the thoughts away from the negative. Move the focus away from the operation itself. […] (M#14) It was very comfortable with the music that gave me associations to something else. Something that drew my attention away from what was going on. […] (F#24) The music led the focus away from other sounds and things happening during the operation. At the same time, you could be in contact with the doctor and nurses if you wanted to. […] (M#15) The waiting time passes more rapidly.

4) Useful intervention elements: Seven patients wrote reflections directed at the importance of certain aspects of the intervention, and the identified coding units for responses addressed the process of *coping guidance* and *the choice of music*. The reflections were generally positive, and several patients emphasized the importance of music listening and guidance in the preparation phase in particular. Examples follow:

> (F#35) I found the practice related to breathing exercises, done on the day before, important and helpful. During the operation, I could recall what we had talked about. For me, it worked most efficiently related to the anxiety of being tied down. […] (M#50) The plan was that the classical music would function well prior to the operation, but we had prepared that if it got "noisy"/disturbing when the surgeon was tearing, I should shift into the "brown" one, that is more rhythmical. It worked very well … […] (M#56) It was important to take some time for the introduction and preparation, taking me through the playlists with a focus on calming breathing techniques. Initially, I thought I would use the "red" playlist, but rapidly I changed to a calm instrumental "blue". It brought more peace and harmony to the situation. I would like to use music again.

In all, the analysis of the written patient reflections in the first three categories revealed descriptions of the inner mind and/or body perceptions related to the music therapy intervention. In contrast, the fourth category addressed the framework of the music therapy intervention. Although they varied in length, the quotes were generally characterized by an appreciative recognition of the music therapy intervention.

Discussion

The supplementary analysis of the original RCT searched for an expanded knowledge of the impact of FaMuLi during cardiac device lead extractions through *self-reported levels of anxiety* in subgroups, *patient satisfaction scores,* and *written patient reflections* on the music therapy intervention. The timeline, onset, and degree of anxiety varied across subgroups. Based on average anxiety levels, music therapy had the strongest positive influence on male patients and patients ≥66 years, while its impact appeared to be almost negligible for female patients. The written patient reflections did not reflect the diversity in anxiety level across the subgroups. Irrespective of subgroup, the patients reported experiences of wellbeing, coping, and satisfaction identified through bodily sensations, feelings, and presence of mind, and they pointed to useful elements in the music therapy intervention itself. These highly positive responses were also reflected in the quantified scores of satisfaction with the intervention. The satisfaction scores and the written reflections supported and expanded the existing findings concerning decreased anxiety for patients receiving music therapy during cardiac device lead extraction procedures.

Although the general levels of anxiety proved to be relatively low in this study, the anxiety variable reflected the various stress responses of the patients. The overall positive influence of music therapy on anxiety in this study is in line with previous meta-analyses and literature reviews of music interventions in cardiac patients (Bradt et al., 2013) and patients undergoing surgery more generally (Kühlmann et al., 2018; Palmer et al., 2017). Previous findings of distinct trends within subgroups are mixed. Bradt et al. (2013) noted a significant heterogeneity in pain and anxiety across subgroups of varied cardiac diseases, suggesting that increased focus of subgroup differences of various nature might be clinically relevant. However, in the recent meta-analyses by De Witte et al. (2019) and Kühlmann (2018), no moderating effects of gender or age were found on psychological stress-related outcomes of music interventions. Previous research on cardiac patients has found female patients to be at risk for high levels of anxiety (Herrmann-Lingen and Buss, 2007; Caldwell et al., 2007), to have greater difficulty with psychosocial adjustments, and to show a lack of response to traditional psychological interventions (Kirian et al., 2012; Compare et al., 2012; Linden et al., 2007). The latter corresponds to the present study's results concerning high levels of anxiety in female patients, and their negative preoperative response to the music therapy intervention, which suggests further exploration of intervention adaptions with respect to gender differences.

Independent of anxiety levels, the patients' scores of satisfaction with the music therapy intervention were clearly high, a finding which was qualitatively elaborated on in the written material. The written patient reflections reported both biological (that is, bodily), psychological, and social impacts of the music therapy intervention, indicating the ways in which the music therapy intervention provided a satisfying mental escape, and an increased awareness of coping and wellbeing during the procedure. From a neurobiological perspective, feelings and emotions are highly correlated to bodily responses and neural activity, as the brain delivers information of our physical state (both bodily and neural) to our consciousness through feelings (Brean and Skeie, 2019; Koelsch, 2010). Thus, although representing different aspects of perception, the categories of pleasant bodily sensations and positive feelings should be seen as mutually dependent and intertwined. The patients also reported that their focus changed as a result of the music listening, which produced an altered presence of mind. This shift reflected their relation to the social environment during the medical procedure, including the visual and audible presence of the medical team. Altered presence of mind is here interpreted as a distraction from unwanted environmental impulses and a refocusing of attention onto something more pleasant. This type of integrated experience, where one's usual perception

of time also dissolves, is a well-documented response to music therapy in procedure support (Ghetti, 2012; DeWitte et al., 2019; Heiderscheit, 2013).

Patient reflections referring directly to elements of the intervention shed light on the ways in which experiences from the preparatory phase reinforced familiarity and recognition through music listening and supportive guidance the next day. Hence, the intentional facilitative aspect of the intervention (Blichfeldt-Ærø et al., 2019) was substantiated as useful by the patients. In sum, FaMuLi provided an appreciated regulatory support structure and respite from stressors in the ongoing medical procedure, which may explain the general decrease in anxiety levels across all patients. These findings are in line with the literature on music therapy in procedure support and for stress or symptom management (Ghetti, 2012; DeWitte et al., 2019). The results were also substantiated by findings related to the use of playlists, which revealed that the patients made active playlist choices and preferred to prolong the music listening when they could.

Benefits of music therapist qualifications have been put forward as optimal with respect to the individual facilitation of music interventions for surgical patients, as opposed to music medicine interventions, often administered by nurses (Palmer et al., 2015; Heiderscheit, 2013; Gold et al., 2011). Valid and generalizable results of the same have been hard to achieve, due to the low representation of music therapy studies (Hole et al., 2015). Music interventions facilitated by a music therapist who is also present in the operating theatre are even rarer (Gooding et al., 2012). In their meta-analysis, De Witte et al. (2019) found music medicine versus music therapy interventions to be equally effective on psychological stress-related outcomes. In the present study, the anticipated importance of patient involvement and qualified guidance during the process (Blichfeldt-Ærø et al., 2019) was supported by the qualitative findings, though the actual impact of the music therapist's presence during all phases remains unclear. The findings also display the potential of receptive music therapy as a relevant parallel to live music therapy in respect to individual patient care and patient preferences (Selle and Silverman, 2020).

The heterogeneous findings of subgroup anxiety in this study draw attention to existing challenges involved in measuring, interpreting, and addressing the complexity of patient stress and anxiety (Aldwin, 2007), and this may also be the reason for previously inconsistent findings related to music interventions and anxiety (Bradt et al., 2013). Although an exact knowledge of variations in anxiety levels is hard to achieve, indications of subgroup differences in gender, age, and baseline anxiety suggest that more attention to this subject would be relevant for clinical practice. Individualized assessment and intervention adjustments are already a part of facilitated music therapy interventions, but further incorporation of subgroup trends might enhance guidance quality and effectiveness in the demanding, high-paced context of invasive procedures.

When biomedical variables are not affected, and pain and anxiety are generally low, one might conclude that there is no need to prioritize music therapy in invasive cardiac procedures. Facing an existential invasive cardiac procedure, any patient or health professional would point to technical success as the main goal. Nevertheless, one can argue that positive patient experiences and even a small decrease in anxiety can be important to patients beyond the actual timespan of the procedure. This because cardiac patients face an increased risk of stress, depression, and anxiety in the long term (Bradt et al., 2013; Dornelas, 2012; Cohen et al., 2015). In this study, FaMuLi created a supportive space that was well received within the hospital and offered increased patient wellbeing and individualized care. Enhanced procedure coping resulted from the intervention's individual guidance, patient involvement, and relaxation, and this supplemented the biomedical treatment and general patient care. The actual extent to which positive procedure experiences

with music therapy might improve patient wellbeing, procedure coping or medical conditions over time remains to be discovered.

Limitations and recommendations

There are limitations to this study. The results of anxiety levels and satisfaction presented in the supplementary analysis are descriptive and do not include statistical inference calculations for generalization. Because the supplementary qualitative analysis was based on short written reflections rather than in-depth qualitative material, the results represent systematically organized trends across cases in the current sample and did not support an in-depth ideographic investigation. In-depth interviews of patients were not possible due to the schedule and condition of minimal strain of the patients in all phases

Due to the intervention's nature, the study was not blinded, introducing a risk of bias. Despite the standardization of information, measurements, and clinical protocol, the possibility of bias cannot be excluded, given the open design. The patient reflections might have been impacted by the increased attention they received as study participants, but because relational contact is an inseparable part of a music therapy intervention, effects of the human relationships were not distinguished from the effect of the music itself.

Because the original RCT sought to regulate patients' stress responses based on a biopsychosocial approach, the initial inclusion of a broader spectrum of data material would have helped the analysis (Blichfeldt-Ærø et al., 2020). In future research on music therapy for stress regulation in invasive cardiac procedures, it is recommended to have an initial focus on anxiety, including biological measures of cortisol levels and/or galvanic skin response. Additional qualitative analyses of in-depth interviews and systematic field notes from the intervention would also provide essential material for thick description analysis to illuminate the patient perspective in a broader sense. Clinical aspects of subgroup diversity should also be discussed. As the demand for medical music therapy increases, FaMuLi could be further explored for comparable patient groups and medical procedures where the regulation of stressors might be even more important. To better understand the long-term potential of music therapy as an adjunct in invasive procedures, follow-up studies including measures of quality of life is should also be developed for chronic patients facing repeated medical procedures and hospital admissions.

Conclusion

The supplementary analysis brought an expanded perspective to the impact of Facilitated Music Listening in cardiac device lead extractions procedures, accommodating more detailed information and patient perspectives concerning music therapy as an adjunct during the procedure. The timelines of anxiety levels were diverse across the subgroups of gender and age, and more attention to subgroup differences in anxiety is recommended for future clinical practice. Independent of anxiety level diversity, Facilitated Music Listening had a qualitatively positive impact on the patients' bodily sensations, feelings, and presence of mind. These aspects are associated with decreased anxiety and increased procedure coping—and hence the psychosocial regulation of stressors during the medical procedure. The expanded perspective elucidated and substantiated the original study finding of a borderline decrease in anxiety for music therapy patients. Further research is recommended.

Acknowledgements

The study was realized through a PhD fellowship at the Centre for Research in Music and Health (CREMAH) at the Norwegian Academy of Music in a research collaboration with the Department of Cardiology at Oslo University Hospital Ulleval. The authors would like to thank the hospital staff and patients who participated in this study.

Conflict of interest: None of the authors have any conflict of interest or financial relationships relevant to this study to disclose.

Financial support: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors. The study was part of a PhD fellowship at the Norwegian Academy of Music.

Literature

Aldwin CM. (2007) *Stress, coping, and development: An integrative perspective,* New York: The Guilford Press.

AudioCura. (2016) *AudioCura M2*. Available at: http://www.audiocura.com/da/portfolio/audiocura-m2/.

Blichfeldt-Ærø SC, Knutsen TM, Hagen HM, et al. (2020) Music therapy as an adjunct in cardiac devices lead extractions: A randomized controlled trial. *Applied Nursing Research* 56.

Blichfeldt-Ærø SC, Trondalen G and Halvorsen S. (2019) Facilitated music listening: Music therapy in an invasive cardiac procedure. *British Journal of Music Therapy* 33: 27–38.

Bradt J, Dileo C and Potvin N. (2013) Music for stress and anxiety reduction in coronary heart disease patients. *Cochrane Database of Systemic Reviews*: Cd006577.

Brean A and Skeie GO. (2019) *Musikk og hjernen,* Oslo: Cappelen Damm AS.

Caldwell PH, Arthur HM, Natarajan M, et al. (2007) Fears and beliefs of patients regarding cardiac catheterization. *Social Science & Medicine* 65: 1038–1048.

Cohen BE, Edmondson D and Kronish IM. (2015) State of the art review: depression, stress, anxiety, and cardiovascular disease. *American Journal of Hypertension* 28: 1295–1302.

Compare A, Proietti R, Germani E, et al. (2012) Anxiety and depression: risk factors for cardiovascular disease. In: Dornelas EA (ed) *Stress proof the heart: Behavioral interventions for cardiac patients.* New York: Springer, 139–166.

DeWitte M, Spruit A, VanHooren A, et al. (2019) Effects of music interventions on stress-related outcomes: a systematic review and two meta-analyses. *Health Psychology Review*: 1–32.

Dileo C. (2016) The future of medical music therapy for adults. In: Dileo C (ed) *Envisioning the future of music therapy.* Philadelphia: Temple University's Arts and Quality of Life Research Center, 71–80.

Dornelas EA. (2012) *Stress proof the heart: Behavioral interventions for cardiac patients,* New York: Springer.

Elkins G, Staniunas R, Rajab MH, et al. (2004) Use of a numeric visual analog anxiety scale among patients undergoing colorectal surgery. *Clinical Nursing Research* 13: 237–244.

Ghetti CM. (2012) Music therapy as procedural support for invasive medical procedures: Toward the development of music therapy theory. *Nordic Journal of Music Therapy* 2 (1): 3–35.

Gold C, Erkkilä J, Bonde LO, et al. (2011) Music therapy or music medicine? *Psychotherapy and Psychosomatics* 80: 304.

Gooding L, Swezey S and Zwischenberger J. (2012) Using music interventions in perioperative care. *Southern medical journal* 105: 486–490.

Graff V, Cai L, Badiola I, et al. (2019) Music versus midazolam during preoperative nerve block placements: a prospective randomized controlled study. *Regional Anesthesia and Pain Medicine* 44: 796–799.

Hanser SB. (2014) Music therapy in cardiac health care: Current issues in research. *Cardiol Rev* 22: 37–42.

Heiderscheit A. (2013) Surgical and procedural support for adults. In: Allen J (ed) *Guidelines for music therapy practice in adult medical care.* Gilsum: Barcelona, 17–34.

Herrmann-Lingen C and Buss U. (2007) Anxiety and depression in patients with coronary heart disease. In: Jordan J, Bardé B and Zeiher AM (eds) *Contributions toward evidence-based psychocardiology: A systematic review of the literature.* American Psychological Association., 125–157.

Hjermstad MJ, Fayers PM, Haugen DF, et al. (2011) Studies comparing numerical rating scales, verbal rating scales, and visual analogue scales for assessment of pain intensity in adults: a systematic literature review. *Journal of Pain and Symptom Management* 41: 1073–1093.

Hole J, Hirsch M, Ball E, et al. (2015) Music as an aid for postoperative recovery in adults: a systematic review and meta-analysis. *The Lancet* 386: 1659–1671.

Kirian K, Sears SF and DeAntonio H. (2012) Sudden cardiac arrest: A biopsychosocial approach to patient management of ventricular fibrillation and implantable cardioverter defibrillators. In: Dornelas EA (ed) *Stress proof the heart. Behavioral interventions for cardiac patients.* New York NJ: Springer, 25–44.

Knutsen TM, Vanberg P, Steen T, et al. (2015) Single sheath lead extraction, a single center experience of more than 1800 lead extractions. *EHRA-2015.* European Society of Cardiology.

Koelsch S. (2010) Towards a neural basis of music-evoked emotions. *Trends in Cognitive Sciences* 14: 131–137.

Koelsch S and Jancke L. (2015) Music and the heart. *Eur Heart J* 36: 3043–3049.

Krippendorff K. (2019) *Content analysis. An introduction to its methodology,* Los Angeles, USA: Sage.

Kühlmann AYR, de Rooij A, Kroese LF, et al. (2018) Meta-analysis evaluating music interventions for anxiety and pain in surgery. *British Journal of Surgery* 105: 773–783.

Linden W, Phillips MJ and Leclerc J. (2007) Psychological treatment of cardiac patients: a meta-analysis. *Eur Heart J* 28: 2972–2984.

Lund HN, Bertelsen LR and Bonde LO. (2016) Sound and music interventions in psychiatry at Aalborg University Hospital. *SoundEffect* (1): 48–68.

Palmer JB, Lane D and Mayo D. (2017) Surgical music therapy: The significance and implementation of music therapy in the operating arena. *Music Therapy Perspectives* 35: 30–35.

Palmer JB, Lane D, Mayo D, et al. (2015) Effects of music therapy on anesthesia requirements and anxiety in women undergoing ambulatory breast surgery for cancer diagnosis and treatment: A randomized controlled trial. *Journal of Clinical Oncology* 33: 3162–3168.

Robb SL and Carpenter JS. (2010) Reporting guidelines for music-based interventions. *Journal of Health Psychology* 16: 342–352.

Selle EW and Silverman MJ. (2020) Cardiovascular patients' perceptions of music therapy in the form of patient-preferred live music: Exploring service user experiences. *Nordic Journal of Music Therapy* 29: 57–74.

Trondalen G. (2016) *Relational music therapy: An intersubjective perspective,* Dallas TX: Barcelona.

van der Heijden JE, Araghi SO, van Dijk M, et al. (2015) The effects of perioperative music interventions in pediatric surgery: A systematic review and meta-analysis of randomized controlled trials. *PLOS ONE*: 1–11.

Wärja M and Bonde LO. (2014) Music as co-therapist: Towards a taxonomy of music in therapeutic music and imagery work *Music and medicine* 6: 16–27.

Appendices

1. Letter of approval REK
2. Patient information and concent
3. Detailed protocol for screening, inclusion and randomization
4. Detailed protocol for the collection of data
5. Detailed protocol for the music therapy intervention
6. Case report forms:
    a. Inclusion and baseline
    b. Physiological/psychological data and procedure medication
    c. Music therapy intervention
    d. Clinical variables – medical procedure
    e. Satisfaction questionnaire, music therapy group
    f. Satisfaction questionnaire, control group
7. Playlists: The Music Star Discography

Appendix 2, 3, 4 and 6ef are made available in two versions; English and Norwegian. These were initially in Norwegian, and translations were later performed by the researcher for the publication of this thesis. Appendix 5 and 6a-d were initially in English, and not translated.

Appendix 1:
Letter of approval REK

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK nord			12.02.2018	2018/168/REK nord
			Deres dato:	Deres referanse:
			09.01.2018	

Vår referanse må oppgis ved alle henvendelser

Sigrun Halvorsen
Hjertemedisinsk avdeling

2018/168 Musikkterapi ved hjertesykdom

Forskningsansvarlig: Oslo universitetssykehus HF
Prosjektleder: Sigrun Halvorsen

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK nord) i møtet 01.02.2018. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10.

Prosjektleders prosjektomtale
Studien vil undersøke om musikkterapi kan ha en gunstig effekt som støtteterapi ved operasjon med fjerning av infiserte eller ødelagte pacemakerledninger eller ledninger fra hjertestarter, fra innsiden av hjertet. Operasjonen utføres i lokalbedøvelse på våken pasient. Pasienten får smertestillende og beroligende medikamenter før og under operasjonen, men opplever likevel ofte smerte, angst og/eller stressreaksjoner under inngrepet. Musikkterapiintervensjonen består av individuelt tilrettelagt musikklytting og beroligende mestringsteknikker, med mål om å regulere stressresponser som virker inn på angst og smerteopplevelse. Det planlegges 68 deltagere likt fordelt i to grupper: 1) Intervensjonsgruppen vil få musikkterapi før, under og etter operasjon i tillegg til standard behandling. 2) Kontrollgruppen får kun standard behandling. Studiens primære forskningsspørsmål er om støtteterapi i form av musikkterapi reduserer pasientens opplevelse av smerte under operasjonsprosedyren.

Rekruttering
Det er opplyst at mulige deltagere vil bli identifisert når de henvises til operasjonen på OUS Ullevål fra andre sykehus. Pasienter som er aktuelle kandidater etter screening, vil bli kontaktet av prosjektmedarbeider etter ankomst til avdelingen dagen før operasjon, og få muntlig og skriftlig informasjon om studien.

Komiteen minner om at dersom forskningsdeltakeren kan anses å være i et avhengighetsforhold til den som ber om samtykke slik at forskningsdeltakeren vil kunne føle seg presset til å gi samtykke, så skal det informerte samtykket innhentes av en annen som forskningsdeltakeren ikke har slikt forhold til jf. helseforskningsloven § 13.

Svar på forespørsel om deltakelse bør ikke innhentes i en konsultasjons-/behandlingssituasjon og det må ikke avkreves et aktivt nei-svar hvis man ikke vil delta. Det må gis betenkningstid slik at de forespurte kan rådføre seg med andre. Et eventuelt samtykke til deltakelse må kunne leveres/sendes inn på eget initiativ. Komiteen legger til grunn at disse prinsippene vil bli ivaretatt i prosjektet og at man ikke bryter taushetsplikten i rekrutteringssammenheng.

Forespørsel/informasjonsskriv/samtykkeerklæring

Besøksadresse:
MH-bygget UiT Norges arktiske universitet 9037 Tromsø

Telefon: 77646140
E-post: rek-nord@asp.uit.no
Web: http://helseforskning.etikkom.no/

Det fremgår både av søknaden og av forespørselskrivet at studieopplysninger planlegges oppbevart i 15 år.

Det fremgår at helseforskinglovens § 38 at opplysninger skal ikke oppbevares lenger enn det som er nødvendig for å gjennomføre prosjektet. REK kan bestemme at dokumenter som er nødvendige for etterkontroll av prosjektet, skal kunne oppbevares i fem år etter at sluttmelding er sendt komiteen. Hvis opplysninger ikke deretter skal oppbevares i henhold til arkivloven eller annen lovgivning, skal de anonymiseres eller slettes.

REK godkjenner at data kan oppbevares for kontrollhensyn i fem år etter prosjektslutt.

Forespørsel/informasjonsskriv/samtykkeerklæring
I informasjonsskrivet under avsnittet «frivillig deltagelse», står det ikke oppgitt kontaktinfo på prosjektleder. Dette må også fremgå av informasjonsskrivet.

Vedtak
Med hjemmel i helseforskningsloven §§ 2 og 10 godkjennes prosjektet. Før prosjektet kan igangsettes må det sendes inn revidert informasjonsskriv i tråd med komiteens merknader.

Sluttmelding og søknad om prosjektendring
Prosjektleder skal sende sluttmelding til REK nord på eget skjema senest 30.06.2023, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK nord dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK nord. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK nord, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

May Britt Rossvoll
sekretariatsleder

Kopi til:sighalvo@ous-hf.no; oushfdlgodkjenning@ous-hf.no

Appendix 2:
Patient information and concent

REQUEST FOR PARTICIPATION IN A RESEARCH PROGRAM

” Music therapy and cardiac disease”

BACKGROUND AND PURPOSE

This is a request for you to participate in a research study investigating if music listening and relaxation techniques might have positive effects on experienced pain, anxiety or other uneasiness during the planned operation of cardiac device lead extraction. You are asked to participate because you are referred for this medical operation. Previous studies show that music listening may have a positive effect on e.g. heart rate, breathing, mood, pain and anxiety during operations. This study aims to contribute to a decrease in stress-related symptoms like anxiety and pain during the operation, and to get more knowledge of music therapy as a supplemental treatment of somatic conditions. The study is a collaboration between Oslo University Hospital and the Norwegian Academy of Music.

WHAT DOES THE STUDY ENTAIL?

Study participants are randomized in two different groups, one control group and one music group. It is a 50 % chance that you are placed in the music group. Patients in the music group are provided guidance in music listening before the operation, and a possibility of listening to music before, during and after the operation. During the guidance, individual wishes and needs are considered. Patients in the music group must have music listening for a minimum of 30 minutes during the operation. Patients in the control group will have standard treatment without music listening.

Participants in both groups will regularly be asked if they experience pain and anxiety related to the operation. Answers are given as numbers on a numeric scale of intensity, 0-10. After the operation, there will be asked questions of the participants’ satisfaction with the treatment. Relevant data from the medical journal will also be registered for the study. No medical tests will be taken for this study specifically. Elaborating details of the study are found in appendix A.

POSSIBLE BENEFITS AND DISADVANTAGES

The method developed for this study is based on previous research and experience with music listening and relaxation in various situations, showing positive effects of, e.g. heart rate, breathing, pain, anxiety and patient satisfaction related to medical operations. You do not need previous experience with music listening or similar methods, to have a positive effect. There is no known or expected risk related to music therapy. No medical tests are added because of the project, but you commit to answering the questions, as outlined. In the future, the study results might help other patients who will undergo the same medical procedure.

WHAT WILL HAPPEN TO THE SAMPLES AND THE INFORMATION ABOUT YOU?

The information registered about you will only be used in accordance with the purpose of the study as described above. All the data will be treated confidentially without name, birthdate or other directly recognizable types of information. A code number links you to your data and samples through a list of names.

Only authorized project personnel will have access to the list of names and be able to identify you.

The project manager is responsible for the daily operations of the research project, and to secure that your information is treated safely and securely. It will not be possible to identify you in the study results when these are published. The list of names will be deleted no later than five years after the project ended, and all data will be completely anonymized.

VOLUNTARY PARTICIPATION

Participation in the study is voluntary. You can withdraw your consent to participate in the study at any time and without stating any particular reason. Withdrawal will not have any consequences for your further treatment. If you wish to participate, sign the declaration of consent on the final page. If you agree to participate at this time, you may also withdraw your consent later, without your treatment being affected in any way.

If you, later on, wish to withdraw your consent or have questions concerning the study, you may contact:

Stine Camilla Blichfeldt-Ærø, Music therapist, phone: 92498316, email: saero@nmh.no or
Sigrun Halvorsen, Head of Cardiology, phone: 23 01 59 31, email: sigrun.halvorsen@medisin.uio.no

Further information on the study can be found in Chapter A – *Further elaboration of what the study entails.*

Further information about biobank, privacy and insurance can be found in Chapter B – *Privacy, funding and insurance.*

The declaration of consent follows Chapter B.

CHAPTER A - FURTHER ELABORATION OF WHAT THE STUDY ENTAILS

- Study participants must be 25 - 80 years old and be referred for extraction of leads from a pacemaker or implanted cardiac defibrillator (ICD). They must be able to speak and read Norwegian and not have a significant hearing impairment.
- The participants must be willing to answer the questionnaires.
- The trial comprises 34 patients who get individually facilitated music listening and relaxation, and 34 patients in the control group, 68 participants in total. The method is based on the music therapy method *The Bonny Method of Guided Imagery and Music, GIM* and experience and theory of music therapy as procedure support. The aim is to reduce stress-related symptoms for the participants during the operation, by provided guiding, stabilizing music and relevant coping techniques that can affect the body and the mind. The guiding may also increase the patient's self-awareness and participation in the situation. It is expected that the patient will experience the music listening as comfortable, as a support during the operation.
- Before the operation, the patients in the music group will receive guiding of the music listening, and on coping techniques to optimize the use of music listening. The techniques are related to relaxation, breathing, and visualization. The patients will hear the music through a specially designed loudspeaker linked to an iPad with the application «The Music Star». The Music Star provides a sample of playlists sorted in colours, and the patient can choose the preferred playlist(s) to use. The music therapist will be present during the operation to give support, and for technical management of the music devices. Each playlist has a duration of 30-60 minutes, but shorter sequences can also be used. The playlists contain music of various genres, but they are all carefully selected to be supportive and stabilizing. The Music Star is developed in Denmark, and used in several research projects within health care.
- No additional medical tests will be taken for this study.
- As mentioned, previous studies show that music listening may positively affect, e.g. heart rate, respiration, pain and anxiety during medical operations. However, there are no previous studies performed for this specific procedure, and the study might give valuable contributions to patient treatment within this field, also internationally. We also believe that the study can be relevant for other groups of adult patients in medical treatment, and to increase the general knowledge of music therapy in integrated, interdisciplinary treatment at medical hospitals.
- The study will start 1.2.2018 and is expected to go on until 2022. All data material will be anonymized no later than five years after the end of the study (2027).
- If new information becomes available, possibly affecting patients' willingness to participate in the study, you will be oriented as soon as possible.
- If changes are made in the research study, or the study will be terminated earlier than planned, participants will be informed as soon as possible.

CHAPTER B - PRIVACY, FUNDING AND INSURANCE

PRIVACY

Information that is registered about you through questionnaires and journal include wellbeing, pain, use of medication, heart rate, respiration and blood pressure, plus registered name, age, gender, weight, height, current treatment, course of operation, medical history and regular medication. The information will be anonymized and coded and stored in an approved, locked storage, both in paper format and in an approved secured server.
Oslo University Hospital Ulleval by the managing director is responsible for the processing of data.

RIGHT TO ACCESS AND RIGHT TO DELETE YOUR DATA AND SAMPLES

If you agree to participate in the study, you are entitled to have access to what information is registered about you. You are further entitled to correct any mistakes in the information we have registered. If you withdraw from the study, you are entitled to demand that the collected samples and data are deleted, unless the data have already been incorporated in analyses or used in scientific publications.

FUNDING

The study receives research funding from the Norwegian Academy of Music

INSURANCE

The study is covered by NPE (Norsk Pasientskadeerstatning).

INFORMATION ABOUT THE OUTCOME OF THE STUDY

The research study will generate new knowledge as an important contribution to international research literature. The study will give at least one peer-reviewed article in an international journal.

Publications in other professional journals, presentations in conferences and media can also be expected. Additionally, we expect the project to contribute to the improvement of clinical practise and future use of music interventions in medical health care for adult patients in Norway.

As a participant, you are entitled to receive information about the outcome/result of the study.

CONSENT FOR PARTICIPATION IN THE STUDY

I am willing to participate in the study

(Signed by the project participant, date)

I confirm that I have given information about the study

(Signed, role in the study, date)

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET

"Musikkterapi ved hjertesykdom"

BAKGRUNN OG HENSIKT

Dette er et spørsmål til deg om å delta i en forskningsstudie for å undersøke om musikklytting og avspenningsteknikker kan ha en gunstig effekt på din opplevelse av smerte, angst eller annet ubehag under den planlagte operasjonen med fjerning av ledninger fra pacemaker/hjertestarter. Du blir spurt om å delta i denne studien fordi du nå skal gjennomgå en slik operasjon. Tidligere studier viser at lytting til musikk kan ha positiv effekt bl.a. på puls og pust, stemningsleie, smerte og angst under operasjonen. Hensikten med studien er å bidra til å redusere stressrelaterte symptomer som angst og smerte under operasjonen, og øke kunnskap om musikkterapi som ledd i behandling av somatiske tilstander. Studien er et samarbeid mellom Oslo Universitetssykehus og Norges musikkhøgskole.

HVA INNEBÆRER STUDIEN?

Deltagere i studien blir fordelt i to ulike grupper ved loddtrekning, en kontrollgruppe og en musikkgruppe. Det er 50 % sjanse for at du kommer i musikkgruppen. Pasienter i musikkgruppen vil få veiledning i musikklytting før operasjon og mulighet til å lytte til musikk før, under og etter operasjonen. I veiledningen tas det hensyn til individuelle ønsker og behov. Pasienter i musikkgruppen må minimum lytte til musikk i 30 min under operasjonen. Pasienter i kontrollgruppen vil få vanlig behandling uten musikklytting.

Deltagerne i begge gruppene vil jevnlig bli spurt om de opplever smerte og angst/uro i forbindelse med operasjonen. Svarene gis i form av et tall på en nummerert intensitetsskala, 0-10. Etter operasjonen vil det bli spurt om deltagerens tilfredshet med behandlingen. Det vil også bli registrert relevante data fra operasjonsjournalen i forbindelse med studien. Det vil ikke bli tatt noen medisinske prøver spesielt for denne studien. Utdypende detaljer om studien finnes i vedlegg A.

MULIGE FORDELER OG ULEMPER

Metoden som er utviklet for denne studien bygger på tidligere forskning og erfaring med musikklytting og avspenning i ulike situasjoner, som viser positiv effekt bl.a. på puls og pust, smerte, angst og pasienttilfredshet i forbindelse med medisinske operasjoner. Du trenger ikke ha erfaring med musikklytting eller lignende fra før for å få utbytte av lyttingen. Der er ikke noen kjent eller forventet risiko ved bruk av musikkterapi. Det vil ikke bli noen ekstra undersøkelser forbundet med prosjektet, men du forplikter deg til å svare på spørsmålene, som tidligere beskrevet. Resultatene fra studien vil senere kunne hjelpe andre pasienter som skal gjennomgå samme operasjonsprosedyre.

HVA SKJER MED INFORMASJONEN OM DEG?

Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene og prøvene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til opplysningene om deg gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg.

Prosjektleder har ansvar for den daglige driften av forskningsprosjektet og at opplysninger om deg blir behandlet på en sikker måte. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres. Navnelisten vil bli slettet senest 5 år etter prosjektslutt, og all datainformasjon vil da bli fullstendig anonymisert.

FRIVILLIG DELTAKELSE

Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling.

Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte:
Stine Camilla Blichfeldt-Ærø, musikkterapeut, tlf.: 92498316, e-post: saero@nmh.no eller
Sigrun Halvorsen, Prosjektleder, Avdelingsleder Hjertemedisinsk avdeling,
tlf.: 23 01 59 31, e-post: sigrun.halvorsen@medisin.uio.no

Ytterligere informasjon om studien finnes i *Kapittel A* – *utdypende forklaring om hva studien innebærer.*

Ytterligere informasjon om personvern og dine rettigheter finnes i Kapittel B – *Personvern, økonomi og forsikring.* **Samtykkeerklæring følger etter kapittel B.**

KAPITTEL A- UTDYPENDE FORKLARING OM HVA STUDIEN INNEBÆRER

- Deltagere i studien må være mellom 25-80 år, med forestående operasjon med fjerning av ledninger fra pacemaker eller hjertestarter. De må kunne snakke og lese norsk, og være uten betydelig hørselsskade.
- Deltagere må være villige til å fylle ut spørreskjemaene.
- Undersøkelsen omfatter 34 pasienter som får individuelt tilrettelagt musikklytting og avspenning, og 34 pasienter i kontrollgruppen, tilsammen 68 deltakere. Metoden bygger på musikkterapimetoden *The Bonny Method of Guided Imagery and Music, GIM* samt erfaring og teori om musikkterapi som prosedyrestøtte. Metoden har som mål å redusere deltagernes stressrelaterte symptomer under operasjonen, ved å tilby veiledning, stabiliserende musikk og relevante mestringsteknikker som kan påvirke kroppen og sinnet. Veiledningen vil også kunne øke pasientens egen bevissthet og brukermedvirkning i situasjonen. Det er forventet at pasienten vil oppleve musikklyttingen som behagelig, som en støtte under operasjonen.
- Før operasjon vil pasientene i musikkgruppen få veiledning i hvordan musikklyttingen skal foregå, og bli informert om mestringsteknikker for å få mest mulig nytte av lyttingen. Teknikkene er knyttet til avspenning, pusteteknikk og visualisering. Pasientene vil få høre musikken gjennom en spesialdesignet høyttaler som er koblet til en iPad med app´en ”Musikkstjernen.” ”Musikkstjernen” tilbyr et utvalg av spillelister sortert i farger, og pasienten kan selv velge hvilken spilleliste han/hun vil bruke underveis. Musikkterapeuten vil være tilstede under operasjonen for å gi støtte og hjelpe til med det praktiske. Hver spilleliste varer mellom 30 og 60 minutter, men det kan også avspilles kortere sekvenser. Spillelistene inneholder musikk i ulike sjangre, og all musikken er nøye utvalgt for å kunne være beroligende og stabiliserende. Musikkstjernen er utviklet i Danmark hvor den brukes i flere forskningsprosjekter innen helseomsorg.
- Det vil ikke bli gjort noen medisinske undersøkelser eller tatt prøver spesielt for denne studien.
- Som tidligere nevnt, viser tidligere studier at musikklytting kan gi positiv effekt bl.a. på puls og pust, smerte og angst under medisinske operasjoner. Det er imidlertid ikke gjort noen tidligere studier av musikkterapi under akkurat slike operasjoner som dette gjelder, og studien vil kunne gi verdifulle bidrag for pasientbehandlingen innen dette feltet, også internasjonalt. Det er også forventet at studien vil kunne ha overføringsverdi til andre pasientgrupper blant voksne i somatisk behandling, samt øke kunnskapen om musikkterapi i helhetlig, tverrfaglig behandling i somatiske sykehus generelt.
- Denne studien vil bli påbegynt 1.2.2018, og antas å vare ut 2022. Alt datamateriale vil bli anonymisert senest 5 år etter studieslutt (2027).
- Dersom ny informasjon blir tilgjengelig som kan påvirke deltagerens villighet til å delta i studien, vil du bli orientert så raskt som mulig.
- Om det skulle bli endringer i forskningsstudien, eller den avsluttes tidligere enn planlagt, vil deltagere opplyses om det snarest mulig.

KAPITTEL B - PERSONVERN, ØKONOMI OG FORSIKRING

PERSONVERN

Opplysninger som registreres gjennom spørreskjema og journal omhandler velbefinnende, smerter og medisinbruk, puls, pustefrekvens og blodtrykk, samt registrert navn, alder, kjønn, vekt, høyde, aktuell behandling, operasjonsforløp, tidligere sykdom og fast medisinbruk. Disse opplysningene vil bli avidentifisert og kodet, og oppbevart i papirformat på et godkjent, avlåst sted, samt på godkjent beskyttet server.
Oslo Universitetssykehus Ullevål ved administrerende direktør er databehandlingsansvarlig.

RETT TIL INNSYN OG SLETTING AV OPPLYSNINGER OM DEG OG SLETTING AV PRØVER

Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

ØKONOMI

Studien er finansiert gjennom forskningsmidler fra Norges Musikkhøgskole.

FORSIKRING

Studien omfattes av NPE-ordningen (Norsk Pasientskadeerstatning).

INFORMASJON OM UTFALLET AV STUDIEN

Forskningsprosjektet vil generere ny viten som vil gi et viktig bidrag til den internasjonale forskningslitteraturen. Undersøkelsen vil gi mulighet til minst én artikkel i et internasjonalt fagtidsskrift.

Det forventes også publikasjon i andre fagtidsskrifter, populærvitenskapelige artikler, fremlegg på konferanser og omtale i dagspressen. Ut over dette forventes det at prosjektet vil kunne danne bakgrunn for forbedring av klinisk praksis i form av etterfølgende bruk av musikkintervensjonene i somatisk helsearbeid for voksne i Norge.

Som deltager har du rett til informasjon om utfallet/resultatet av studien, når det foreligger.

SAMTYKKE TIL DELTAKELSE I STUDIEN

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Appendix 3:
Detailed protocol for screening, inclusion and randomization

INSTRUCTIONS FOR SCREENING, INCLUSION AND RANDOMIZATION

SCREENING

All patients referred for CIED lead extraction are screened for eligibility in the study when scheduling the operation. The ward nurse coordinator is responsible for the screening:

- all patients referred for CIED lead extraction procedure are registered in the Screening list **C1.1**
- the music therapist is informed of eligible patients, and time for admission:
  → Stine Camilla Blichfeldt-Ærø: e-mail: camillablich@gmail.com , phone: 92498316.

1. Inclusion criteria:
   - Patient 25-80 years with a planned pacemaker and/or ICD lead extraction performed in local anaesthesia.
   - The electronic lead was implanted >12 months ago
   - Able to speak and read Norwegian
   - Willing to participate

2. Exclusion criteria:
   - Significant hearing impairment
   - Previous and/or acute psychiatric diagnosis
   - Cognitive and mental deficits or impaired functioning

PATIENT INFORMATION and INCLUSION

1. At arrival for pretests, one day prior to the operation, eligible patients are given verbal and written information about the study (**C2**). The information is provided by the music therapist (e.g. researcher) assisted by the nurse coordinator, following established guidelines:
   - *We would like to know if you are interested in participating in a research study examining if music listening may have a positive effect on the patients during lead extraction procedures. Participation is voluntarily and has no further consequences for the treatment. All participants are anonymized in the study.*
   - *From previous research, it is known that music listening might have a positive effect on experienced stress and pain during medical procedures.*
   - The principle of randomization is explained: *it is a 50% chance to be placed in the music group.*
   - *Participants in the music group will have a preparative session with the music therapist, where the music listening is tested and facilitated. You may choose the music you prefer from a limited sample of playlists, and it is largely up to you when, and for how long you want to listen. The minimum duration of music listening on the day of operation is 30 min.*
   - *Participants in both groups will repeatedly be asked of their experienced level of pain and anxiety, before, during and after the operation, on a numeric scale. You will also be asked to rate your level of satisfaction after ended procedure. Other data (vital signs, patient characteristics, medication) will be found in the medical journal.*
   - *As a participant, you have the right to withdraw your consent at any time, without explanation.*

2. Patients who agree to participate, give their written informed consent (**C2**), one copy to each part. The inclusion is registered by the researcher in scheme **C1.2** and **C3**. The patient gets an ID#nr., registered in the coding list **C1.3.** The coding list is stored in a locked tray, in a locked room, only available for the research team.

RANDOMIZATION

After inclusion and assessment of baseline measures (see B3.2), the sealed envelope for randomization are picked up and opened together with the patient. Patients randomized to the music group get a preparatory session of music therapy (30-45 minutes) the same day, in one of the examination rooms (**C6.3**).

Prosedyrer for screening, inklusjon og randomisering

SCREENING

1. Ved planlegging av pacemaker/ICD ledningsekstraksjon, screenes alle pasienten for mulig inklusjon i musikkprosjektet. **Koordinator** har ansvar for screeningen:

   - registrering i screening list **C1.1** av alle pasienter som kommer for ekstraksjon.
   - gi beskjed til stipendiaten om aktuelle pasienter som skal spørresom inklusjon:
     → Stine Camilla Blichfeldt Ærø: e-post: camillablich@gmail.com , tlf. 92498316.

2. Inklusjonskriterier:
   - Pasient 25-80 år med forestående pacemaker og/eller ICD ledningsekstraksjon planlagt med lokal anestesi.
   - PM/ICD ledning har vært implantert i mer enn 12 måneder
   - Kan snakke og lese norsk
   - Villig til å delta

   Eksklusjonskriterier:
   - Betydelige hørselsproblemer
   - Tidligere eller akutt psykiatrisk diagnose
   - Kognitiv og mentale vansker eller nedsatt funksjonsevne

PASIENTINFORMASJON og INKLUSJON

1. Ved innleggelse dagen før operasjon, får aktuelle pasienter skriftlig og muntlig informasjon om studien (**C2**). Informasjonen gis av **koordinator**, **stipendiat, sykepleier eller lege**, etter følgende veiledende punkter:
   - *Vi lurer på om du kunne tenke deg å være med i en forskningsstudie hvor vi undersøker om musikklytting kan ha positiv effekt under ekstraksjonen.*
   - *Deltagelse er frivillig og har ingen konsekvenser for behandling for øvrig. Alle deltagere blir anonymisert i studien.*
   - *Ut fra tidligere forskning forventer vi at musikklyttingen vil gi en positiv opplevelse, og mindre stress og smerte under operasjonen.*
   - Randomiseringsprinsippet forklares*: det er 50% sjanse for å komme i musikkgruppe.*
   - *Deltagere i musikkgruppen får en forberedende samtale med musikkterapeut dagen før operasjon, hvor teknikken prøves. Du får selv velge musikk fra et utvalg spillelister, og velger også i stor grad når/hvor lenge du vil høre musikken. På operasjonsdagen må deltagere høre musikk i minimum 30 min til sammen, inne på operasjonssalen.*
   - *Deltagere i begge gruppene vil bli spurt om egenopplevd nivå av smerte og engstelse før, under og etter operasjonen, skala 0-10. Andre data vil bli hentet fra journalen.*
   - *Deltagere har rett til å trekke seg fra studien når som helst, uten å måtte oppgi årsak.*

2. Pasienter som ønsker å delta, skriver under på samtykkeskjema **C2**. Partene får hver sin kopi. Inklusjonen registreres på skjema **C1.2** og **C3** av **stipendiat**. Pasienten får så et ID#nr – kodingen registreres på skjema **C1.3**, som oppbevares separat innelåst, kun tilgjengelig for stipendiat og avdelingsleder.

RANDOMISERING

Etter inklusjon og registrering av baseline data, hentes randomiseringskonvolutt hos ekstern forskningssykepleier. Konvolutten åpnes med pasienten tilstede. Pasienter i musikkgruppen får en avtale om 30-45 minutter musikkterapi på et undersøkelsesrom samme dag (**C6.3**).

Appendix 4: Detailed protocol for the collection of data

INFORMATION OF RESPONSIBILITIES and INSTRUCTIONS FOR DATA COLLECTION

- **Ward Nurse Coordinator/Nurses:**
  - Screen all patients referred for lead extraction procedure for eligibility in the study. Inform the music therapist of eligible patients and time of arrival. (See B2.1)
  - One day prior to the operation (during pretests): Assessment of baseline measures (BP, HR, SaO2, level of pain/anxiety) of included patients before randomization - to be noted on the anaesthesia scheme. The NRS/NVAAS-scale are shown and explained to the patient, using standardized information:
    "The scale will be used repeatedly during the procedure. You will be asked to what degree you feel any pain or anxiety, and should answer with a number) between 0 and 10, where 0 represents no pain/anxiety, and 10 the worst possible pain/anxiety".
    (NB- separate numbers for anxiety and pain)
  - Make out prints of necessary patient documentation (admission notes and operation description) for each participant.

- **Patient-responsible nurse**
  - On the operation day: Take measures (Level of pain/anxiety BP, HR, SaO2, RR) The NRS/NVAAS-scale are shown to the patient when possible, and a standard question asked: *Do you feel any pain/anxiety right now - how much on the scale 0-10?*
    - At arrival at the operating theatre (=preop)
    - Approximately every 30.min during the operation (=periop)

    Data are registered in the patient-documentation scheme, in the folder on the table.

    - ≈ 3 h into the postoperative phase, registered in a separate HIO-scheme (**B3.5**)

- **Music therapist/researcher**
  - Give verbal and written information about the study to all eligible patients. (B2.1)
  - Achieve written informed consent
  - Collect data material and patient documentation after ended procedure. Transfer of data to Case Report Forms: (**C.3 + C.5**).

The music therapy (for patients in the music group only) starts when the patient has arrived at the ICD/PM centre on the day of operation – minimum 10 min when lying in bed in the preparation room, facilitated by the music therapist. The patient can also choose to listen longer when it is not disturbing the preparations (shaving, establishing peripheral intravenous lines, dialogue, etc.)
During music listening, you may talk to the patient when necessary.

The loudspeaker is wrapped in a thin plastic bag and moved to the operating theatre together with the patient. The music continues when the patient has been connected to the monitoring equipment, during the sterilization process and into the peri-operative and
invasive phase of the procedure. The patient can start or stop the music listening at any time that he or she wants. The Music Therapist continuously observes what is happening in the room and the patient's responses. If medical complications occur, or if any adverse reactions from the patient are observed, both the medical team or the Music Therapist can stop the music at any point.

The music therapist will be present during operations with music therapy patients, and available at the centre during operations with control group patients.

INFORMASJON OM DATAINNSAMLING - SYKEPLEIERE OG OPERATØRER

- **Koordinator/sykepleier**
  - screener alle ekstraksjonspasienter - om de er aktuelle for studien.
    Aktuelle pasienter meldes til Stine Camilla (Tlf. 92498316)
  - tar baselinemålinger (BT, HR, SaO2, smertenivå, engstelsesnivå) av inkluderte pasienter under forundersøkelsene, dvs. før randomisering. Dette noteres på anestesiskjema. NRS/NVAAS-skalaen skal vises og forklares for pasientene med standard informasjon:
    Skalaen vil bli brukt jevnlig under operasjonen. Du vil bli spurt om i hvilken grad du opplever smerte eller er engstelig, og skal svare med et tall mellom 0 og 10. 0 er ingen smerte/engstelse og 10 er verst tenkelige smerte/engstelse.
    Obs: det er to ulike målinger, én for smerte, én for engstelse.
  - tar utskrift av innkomstnotat + operasjonsbeskrivelse etter endt operasjon.

- **Pasientansvarlig sykepleier**
  - Operasjonsdagen: Foretar målinger (smerte, engstelse, BT, HR, SaO2, RR) NRS/NVAAS-skalaen skal vises for pasientene hvis mulig, med standard spørsmål: *Kjenner du noe smerte/engstelse eller uro nå, hvor mye på skalaen fra 0 - 10?*
    - ved ankomst til stua operasjonsdagen (preop.)
    - ca. hvert 30.min under operasjonen

    Målingene registreres på skjema for pasientdokumentasjon - i permen på stua (**B3.5**).
    - Postoperativt etter ca. 3 t, før pasienten forlater HIO – føres på eget skjema

- **Stipendiaten**
  - gir aktuelle pasienter muntlig og skriftlig informasjon om studien (**B2.1**)
  - innhenter informert samtykke
  - samler opp innsamlede data + nødvendig pasientdokumentasjon etter endt prosedyre. Dataene overføres til skjema (**C.3 + C.5**).

Musikklyttingen (bare for pasienter i musikkgruppen) vil starte når pasienten kommer til posten om morgenen – minimum 10 min i oppstart på forberedelsesrommet. Pasienten kan også velge å høre musikk lengre, i periodene det ikke er ugunstig for forberedelsene.

Høyttaleren blir lagt i plastbeskytter og flyttet til operasjonsbenk samtidig med pasienten. Musikken startes på ny etter at pasienten er kommet til operasjonssalen og er koblet til – ca. 20 min lytting før operatør kommer. Videre lytting skjer etter pasientens ønske. Pasientene blir spurt om videre etter endt spilleliste, eller etter 30 min. stillhet. Musikken kan når som helst skrus av om det blir nødvendig, pga. medisinske årsaker eller behov for økt fokus for operasjonsteamet. Selv om pasienten lytter til musikk, kan dere snakke med pasienten når det trengs underveis.

Musikkterapeut (Stine Camilla) vil være tilstede under operasjoner med pasienter i musikkgruppen, og tilgjengelig på avdelingen under operasjoner med pasienter i kontrollgruppen.

Appendix 5:
Detailed protocol for the music therapy intervention

Clinical instructions – Music therapy intervention (Facilitated Music Listening)

GENERAL

Aim of the music intervention is to support integrated, holistic care for patients during the operation procedure, based on a biopsychosocial approach of health care. Through facilitated music listening and relevant coping strategies, the patient will be empowered to prevent and manage stressors that might occur during the procedure. The intervention is inspired by the receptive music therapy method Guided Imagery and Music (GIM) and theories and literature of music therapy as procedure support. A qualified, experienced music therapist facilitates the intervention. For later implementation, the intervention might be modified to be managed by other qualified health professionals, under the supervision of a music therapist.

Necessary Qualifications:

- Knowledge of biopsychosocial contexts and possibilities of music therapy as an adjunct in somatic health care procedures.
- Completed training in the Clinical Manual and technical aspects of the electronic devices.
- Completed training and self-experience in basic techniques of music listening, relaxation and visualization.
- Good communicative skills and an empathic personality.

Notes and data from the music therapy intervention are registered in a paper CRF (C6)

DAY 0 – PREPARATION 30-45 min. initial preparation, a dialogue with patient and music therapist on the day before the operation. Testing of techniques and equipment.

Overall aims and methods: The patient is heard and seen as a person, focusing on the patients´ expectation, experience and resources. The preparation, involving self-awareness, briefing and testing of techniques, aims to increase the patients´ coping skills and stabilize stressors during the admission. The preparation should take form as a mutual dialogue without disturbance if possible, guided by this semi-structured manual. Information achieved through the dialogue is to be used for further personal tailored facilitation of the intervention. The following sentences are viewed as guiding principles and are not meant to be used precisely.

Assessment: expectations, coping and music

- Awareness of the situation
  - *"How you feel now, before the operation?":*
    (mood, body: temperature, tension/calm, discomfort/comfort, happy/anxiety/anger)
- Previous experience - expectations - techniques
  - *"Have you had an equivalent operation ever before", or "How did you experience your previous operation(s)?"*
  - *"How do you usually react/do you think you will react?"*
  - *"Do you prefer to cope with, or experience the situation in a certain way?"*
  - *"Do you use specific coping strategies for situations like this?"*
- Music preference
  - *"What is your relation to music?"*
  - *"What kind of music do you prefer listening to?". "Do you have any dislikes?"*
  - *"The body may have a variety of reactions to music – physically through rhythm and timbre, and based on our unique memories and previous experiences. "*
  - *"Some kind of music could be useful for you in this situation, even though it might be different from what you prefer listening to at home."*

The Music star: presentation and testing

- Technical
  - On/off, volume, push a chosen colour to hear the music
  - Loudspeaker: function
  - Administration of listening during operation: The music therapist will be present for relational and technical support. Planned music listening:>10 min. before examination in the morning, and >20 min during preparation in the operation room, before the invasive procedure starts. Further listening will be done according to patients own wish and approval from the medical team. Music is offered after 30 min of silence. Minimum total duration of music listening: >30 min. during the procedure.

- Playlists
  - *"The Music star playlists are developed to stabilize body and mind in a calm, comforting way, and will not provide for great challenge and surprises. The music is present to focus your attention on to something pleasant and be a supportive element you can "lean on" when needed. The music might help you to relax, and decrease stress and pain intensity during the procedure."*
  - Structure/content: genre, intensity, rhythm, duration, complexity
    - **Blue**: Tranquil, partly without a beat (60) + flow Musicure/easy beat mix. (30-40)
    - **Green**: quiet rocking mix. (30-35) + classical/mostly classical (30 + 65)
    - **Red**: Acoustic guitar /Irish folk (60) + easy pop/rhythmic pop rock (60 + 30)
    - **Black/white**: Open - not in use
- Musical choice
  - *"We will turn to the musical choice, finding the music and colour that best can support you in this specific situation, giving you a calm and pleasant feeling."*
  - *"What colour attracts you the most right now, based on the information given?"*
  - *I will let you hear music from other colour sections as well, so you know the difference when making your choices."*
  - *"Tip: You might choose music that reminds you of a desired mood, or music that is similar to your bodily perceptions at the moment.*
  - *"You may also choose colours for later music listening."*
  - *The choices you make now can be altered at any time during the procedure."*

Coping techniques

" Sometimes just listening to the music is enough to draw your attention onto something else, or to feel relaxed and calm. At times simple coping techniques might be useful to get the most benefit of the method."

- Breathing
  - *" Take notice of your breathing. You might close your eyes if you are ok with it. Maybe you can breathe in through your nose, be filled with air, hold the breath for some seconds, and then breathe out very steady and calm. Try breathing even more slow and deep, supported by the music. "After a long out-breath, you do not have to worry about breathing in – it happens automatically."*
  - *" If it feels good, you can expand the good feeling by taking another deep breath. This can be repeated when necessary."*
- Visualization
  - *"A calm and relaxed feeling can also be enhanced by visualizing a picture or a colour. Try focusing on a nice, safe place where you like to be, a well-known place, or a place in your imagination."*
  - *"Take some time to look around. Notice the colours and details in this picture. Let the music be with you, and maybe give the picture even more details."*
  - *Safe-place suggestions: Beach, garden with a hammock, mountain with a view*
  - *"If your focus is wandering somewhere else now and then, you have the possibility to return to the safe place by refocusing on the picture in your imagination."*

Different playlists are tested with the patient lying on a bench. The therapist sees to that some variety of playlist complexity is presented and experienced, to prepare for possible changes of needs during the procedure. A plan of 2-3 playlists are made for the next day´s listening but can be altered at any time. The therapeutic "contract" is clarified:

- The therapist will be present and available focusing on the patient´s needs throughout the procedure
- The music listening will be performed according to the patient´s wishes to the greatest possible extent (timing and duration of listening, changes of playlist and volume etc.)
- Ways of communicating needs and wishes during operation are presented (eye-contact, verbal, gestures).

DAY 1 PREOPERATIVE – pre-examination room

Techniques, equipment and music therapist present. iPad coded with the patients ID#nr.
Music listening for a minimum of 10 minutes at the beginning of the session, with individual adjusted guidance for relaxation.

- Check-in: How are you today? Any changes required for the planned music listening?
- Guidance to relaxation and preoperative music listening (>10 min)

DAY1 PERIOPERATIVE

1-4 t: Operation procedure. Technical details and music therapist tasks.

- Preparation: iPad + Loudspeaker moved from the bed to the operational unit. Loudspeaker wrapped in a thin plastic bag, placed around the pillow and fastened with tape to the operation bench. An extended cable needed (5 m). iPad is placed by the bed foot, on a separate serving table.

- Music listening – initiated by patient/music therapist.
  - Minimum 30 min. music listening during pre- and perioperative procedure.
  - Music listening is recommended to be started when the patient has been connected to all electronic devices, during washing routine and preparation before the invasive procedure starts (= Ca. 20 minutes).
  - Further listening according to the patients´ wish, due to previous agreement or decisions on the go.
- Tasks of the music therapist:
  - Offer music listening after 30 min of silence.
  - Offer listening/repeated coping techniques if pain/discomfort increases.
- After the operation: Loudspeaker + iPad disinfected and removed from the operation unit.

Details of procedure + adverse events

- It will be possible to maintain a normal dialogue with the patient during music listening.
- Music listening should be started/stopped according to the patients´ wish.
- If necessary, the medical team/music therapist can stop the music listening, due to:
  - medical complications
  - the need for utterly concentrated focus for the medical team
  - observation of adverse reactions from the patient (verbal or physical)
- If music listening is interrupted and not resumed, the event will be registered (C7).

POSTOPERATIVE

During postoperative monitoring (2-4 t): Playback equipment available

- Music listening is possible but not imposed.
    - Any music listening in the postoperative phase will be according to the patients´ wish. The health personnel/music therapist offers technical support, but the patient can also operate the device.
- Closing dialogue - open-ended questions, possibly elaborated based on individual response.
    - *"How do you feel now"?*
    - *"How did you experience the operation procedure?"*
    - *"How did you experience to have music listening during the procedure?"*

TECHNICAL PROCEDURE AFTER EACH PATIENT

Done by the music therapist/researcher

- Datalog files from the iPad are transferred to temporary storage on the music therapist's laptop via iTunes and analyzed (B4.2).
- All data material is transferred to paper CRF, including log files from iPads and the operation log (C3, C5.1_V2, C7).
- All paper-CRF will be completed, collected and stored safe and locked, out of reach for anyone but the research team.
- Transfer of all data to electronic CRF (Epidata) on a secured server at OUS: K:\Sensitivt\Forskning03\17-17251_Music and the Heart
- Charging of iPad/loudspeaker

Appendix 6 – Case report forms:

a. Inclusion and baseline

b. Physiological/psychological data and procedure medication

c. Music therapy intervention

d. Clinical variables - medical procedure

e. Satisfaction questionnaire, music therapy group

f. Satisfaction questionnaire, control group

Oslo universitetssykehus

ID#: _____ Randomized group: _____1 (music) _____2 (control)

Inclusion criteria:	YES	NO
25-80 years		
Pacemaker/ICD lead extraction planned in local anaesthesia		
PM/ICD implanted > 12 months		
Patient able to speak and read Norwegian		

Exclusion criteria:	YES	NO
Significant hearing impairment		
Previous or acute psychiatric diagnoses		
Cognitive and mental deficits or impaired functioning		

The patient fulfills all criteria's of inclusion and none of exclusion: ____ YES ____ NO

Baseline characteristic: Draw a line around the correct answer, or write a value in an open rubric.				
			Value	**Comments**
Sex	F	M		
Age			years	
Weight			kg	
Height			cm	
Blood pressure (BP)				
Heart rate (HR)				
SaO2				
Pain (NRS)				
Anxiety (NVAAS)				
Medical history:				
Hypertension	YES	NO		
Heart failure	YES	NO		
Myocardial infarction	YES	NO		
Kidney failure	YES	NO		
Diabetes	YES	NO		
Regular medication	YES	NO		If yes, what kind:
Smoker	YES	NO		
Technical variables:				
Device	Pacemaker	ICD		
Years of PM/ICD lead implantation				
Number of leads out				
Number of leads in				
Reason for extraction	Infection	Lead loosened	Electronic failure	Other:

Oslo universitetssykehus

ID#:_____

Vitale sign	Preoperative	Perioperative											Postoperative
		Performed approximately every 30. minute (0,5 h)										Mean	
	0	0,5	1	1,5	2	2,5	3	3,5	4	4,5	5		After 2-4 h
BP													
RR													
HR													
SaO2													
Pain/Anxiety		Performed approximately every 30. minute (0,5 h) (*during extraction=marked with a ring)										Mean	
NRS – pain (0 - 10)													
NVAAS - anxiety (0 - 10)													
Measure point	**1**	**2**											**3**
Degree of sleepiness/wakeness (* only once, mean impression)		Awake 1			Groggy 2			Sleepy 3			Asleep 4		

Medication	Preoperative	Perioperative			Postoperative	SUM
Paralgin forte (stk.á500mg)						tbl.
Midazolam						mg
Fentanyl						mic.g
Affipran						mg
Vival						tbl.
Other:						

Patient satisfaction	Postoperative
Pain management Numeric scale (1 – 10)	
Music intervention Numeric scale (1 - 10)	

ID#: _____

MUSIC THERAPY INTERVENTION

Initial preparation - DAY 0

Clinical intervention notes

Duration:

Previous experience:

Expectations:

Music preference:

Plan for listening:

Coping strategy: Breathing Visualizing Listening Other

Comments:

Music listening – DAY 1

	Playlist(s)	Played (seconds)	Comments
Preoperative			
Perioperative			
Postoperative			

Total duration of music listening= _____ sec.

ID#: _____

Clinical variables, adverse events, drop-out

Draw a line around the correct answer, or write a value in an open rubric.

TIME: Start preop.:_____ Stop periop.:_____ Total time: _____

Clinical variables			Value		Comments
Extraction successful	YES	NO			
Sheath used (hylse)	YES	NO			
Number of leads			In:	Out:	
Time spent:					
Invasive procedure					
Sheath time (hylsetid)					
Adverse events	YES	NO			
If yes, what?					
Major:	Tamponade	Tricuspidal failure	Cardiac arrest	Mors	Other:
Minor:	Pneumo-thorax	Lung edema	Bleeding		Other:

Adverse events – music listening			Comments
Music listening completed – min.30 minutes	YES	NO	
Cause:			
Medical complications			
Utterly silence needed for the operation team to be fully focused in the situation			
Unwanted reactions from the patient *			
Technical problems			
Other			

*Complicating factors expressed verbally, physically or bodily by the patient

DROPOUT – MUSIC STUDY

The patient´s enrolment in the study terminated because of:

The patient´s own wish: ☐ The judgement of health care professional: ☐

Extraction cancelled: ☐

Comments:

ID#:_____

Questionnaire - Patient satisfaction

The pain treatment

How satisfied are you with the pain treatment you have received related to the operation?

Please choose the number you think fits best, and mark it with a ring.
1= very dissatisfied, 10 = very satisfied.

The music listening

How satisfied are you with the music listening you have received related to the operation?

Please choose the number you think fits best, and mark it with a ring.
1= very dissatisfied, 10 = very satisfied.

If you have any reflections regarding the music project, please write here:

01.10.20

ID#:_____

Spørreskjema - Pasienttilfredshet

Smertebehandlingen

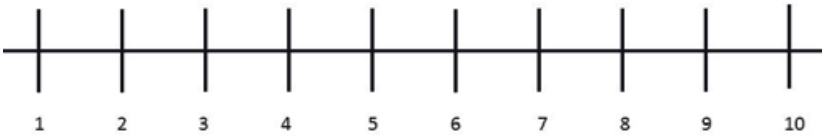
Hvor fornøyd er du med smertebehandlingen du har fått i forbindelse med operasjonen?

Sett ring rundt det tallet du synes stemmer best. 1= veldig misfornøyd, 10 = veldig fornøyd.

Musikklyttingen

Hvor fornøyd er du med musikklyttingen du har fått i forbindelse med operasjonen?

Sett ring rundt det tallet du synes stemmer best. 1= veldig misfornøyd, 10 = veldig fornøyd.



Om du har noen kommentarer til musikkprosjektet, kan du skrive det her:

13.02.18

ID#:_____

Questionnaire - Patient satisfaction

The pain treatment

How satisfied are you with the pain treatment you have received related to the operation?

Please choose the number you think fits best, and mark it with a ring.
1= very dissatisfied, 10 = very satisfied.

ID#:_____

Spørreskjema - Pasienttilfredshet

Smertebehandlingen

Hvor fornøyd er du med smertebehandlingen du har fått i forbindelse med operasjonen?

Sett ring rundt det tallet du synes stemmer best. 1= veldig misfornøyd, 10 = veldig fornøyd.

Appendix 7:
Playlists: The Music Star Discography

Key	KeyDisplayName	Artist	TrackTitle	Composer
F1	Quiet Please	Quiet Please	01 Transparant Moon on Blue	
F1		Quiet Please	02 Supraluna	
F1		Quiet Please	03 Composure	
F1		Quiet Please	04 The Bells of St. Matthew's	
F1		Quiet Please	05 Menneskefugl	
F1		Quiet Please	06 Weights	
F1		Quiet Please	07 The beginning	
F2	Zen Spaces	Zen Spaces	01 Be Here Now	
F2		Zen Spaces	02 Unbroken	
F2		Zen Spaces	03 Inner Calling	
F2		Zen Spaces	04 Presence	
F2		Zen Spaces	05 Beyond Clouds	
F2		Zen Spaces	06 Iceland	
F2		Zen Spaces	07 Atmosphere of Zen	
F2		Zen Spaces	08 Lost Stars	
G1	Musicure	Eje, Spaelling, Mulvad, Høxbro og Andersen	01 Deep Woods & Village (Excerpt)	Niels Eje
G1		Eje, Mulvad og Spaelling	02 Enchantment	Niels Eje
G1		Eje, Spaelling, Mulvad, Høxbro og Andersen	03 Secret Path (Excerpt)	Niels Eje
G1		Eje, Spaelling, Mulvad, Høxbro, Andersen, Holck og Dejour	04 Midnight Sun	Niels Eje
G2	Resting Place	Fabrizio Paterlini	01 Colori	Fabrizio Paterlini
G2		Steve Dobrogosz	02 Resting Place	Steve Dobrogosz
G2		-	03 Gymnopedie no. 1, Flute & Harp	Eric Satie
G2		Secret Garden	04 Chaconne	Rolf Løvland
G2		Deva Premal	05 Om Namo Bhagavate	
G2		Benny Anderssons Orkester	06 Sånger från andra våningen	

G2		Stefan Nilsson	07 Arons dröm	Stefan Nilsson
G2		Joanne Shenandoah	08 Song of Union	
G2		-	09 Violin Concerto in A Minor (Largo)	Antonio Vivaldi
G2		-	10 Flutesolo from Scaramouche	Jean Sibelius
H1	Simplicity	Jan Johannsson	01 Bandura	Trad arr. Jan Johansson
H1		Stefan Nilsson	02 Mot den nya världen	Stefan Nilsson
H1		Stefan Nilsson	03 Wilmas tema	Stefan Nilsson
H1		Magnus Stršmberg	04 Kärlek	
H1			05 Sacco e Venzetti-Spernaze Di Libertia	Ennio Morricone
H1		Stefan Nilsson	06 Gabriellas piano (Så som i himmelen)	Stefan Nilsson
H1		Secret Garden	07 Serenade to Spring	
H1		Johan Stengård	08 Bred Dina Vida Vingar	Trad arr. Storgëd
H1			09 Cinema Paradiso	Ennio Morricone
H1			10 Love Theme for Nata	Ennio Morricone
H2	Dreams	Steve Dobrogosz	01 Resting Place	Steve Dobrogosz
H2		Stefan Nilsson	03 Arons dröm	Stefan Nilsson
H2		Benny Anderssons Orkester	04 Sånger från andra våningen	
H2		Deva Premal	05 Om Namo Bhagavate	
H2		Volkmar	06 Wintertraum	
H2			07 After the Destruction	Ennio Morricone
H2			08 Visit to the Cinema	Ennio Morricone
H2		Andreas Andersson	09 Daylight	
H2		Fläskkvartetten	10 Innocent	

A1	Light Moods	Nora Shulman & Judy Loman	01 Gymnopedie no. 1, Flute & Harp	Eric Satie
A1		Sir Neville Marriner and St. Martin-In-The -Fields	02 Prelude on Rhosymedre	Ralph Vaughan Wiliiams
A1		Adrian Leaper & Slovak Radio Symphony Orchestra	03 Op. 21: II Evening in The Forrest	Ralph Quilter
A1		-	04 Allt under himmelens fäste	Trad./Ukendt
A1		Anna Moffo / Leopold Stokowski	05 Songs of the Auvergne- Brezairola	Joseph Canteloube
A1		-	06 8th Concerto in G minor (Adagio)	Arcangelo Corelli
A1		-	07 La Calinda from Koanga	Fredric Delius
A1		-	08 5th Piano Concerto	Ludwig van Beethoven
A1		-	09 Flutesolo from Scaramouche	Jean Sibelius
A2	Mellow		01 Capitol suite (Pieds en l'air)	Peter Warlock
A2			02 Cavalleria rusticana: intermezzo	Pietro Mascagni
A2			03 Orkestersuite #7: Under lindetr¾erne	Jules Massenet
A2			04 Pianokoncert #2 (Andante)	Dmitri Shostakovich
A2			05 Vuggesang	Edvard Grieg
A2			06 3. orkestersuite: Air (BWV 1068)	J.S. Bach
A2			07 Canon i d-mol	Johann Pachelbel
A2		Jan Johannson	08 Bandura	Folk tune arr. Jan Johannson
A2		Stefan Nilsson	09 Mot den nya världen	Stefan Nilsson
A2		Stefan Nilsson	10 Wilmas tema	Stefan Nilsson
A2		Magnus Strömberg	11 Kärlek	
A2			12 Sacco e Venzetti-Spernaze Di Libertia	Ennio Morricone
A2		Stefan Nilsson	13 Gabriella's piano (S‘som i himmelen)	Stefan Nilsson
A2		Secret Garden	14 Serenade to Spring	Rolf Løvland
A2		Johan Stengård	15 Bred Dina Vida Vingar	
A2		Ennio Morricone	16 Cinema Paradiso	Ennio Morricone
A2		Ennio Morricone	17 Love Theme for Nata	Ennio Morricone
B1	Together	Kaare Norge	01 Beautiful Scenery	Kaare Norge

B1		Kaare Norge	02 Bright Night	
B1		Kaare Norge	03 Dagen på held	Kaare Norge
B1		Kaare Norge	04 (Everything I do) I do it for you	
B1		Kaare Norge	05 Fields	Kaare Norge
B1		Kaare Norge	06 Forårsdag	Anne Linnet
B1		Kaare Norge	07 Homage to life	Kaare Norge
B1		Kaare Norge	08 I skovens dybe stille ro	Trad. Arr. K. Norge
B1		Kaare Norge	09 Jesus to a Child	
B1		Kaare Norge	10 Morning Has Broken	Trad arr. K Norge
B1		Kaare Norge	11 Nu falmer skoven trindt om land	J.H. Nebelong
B1		Kaare Norge	12 Oh My Love	John Lennon, Youko Ono
B1		Kaare Norge	13 Solen er så rød, mor	Carl Nielsen
B1		Kaare Norge	14 Som et strejf	
B1		Kaare Norge	15 Song for Guy	
B1		Kaare Norge	16 Stairway To Heaven	Jimmi Page, R.Plant
B1		Kaare Norge	17 Tears in Heaven	Eric Clapton, Will Jennings
B1		Kaare Norge	18 Why Worry	
B1		Kaare Norge	19 With You	
B1		Kaare Norge	20 Wonderful Tonight	
B2	Celtic Moods	The Kells	01 Arran Boat Song	
B2		The Kells	02 The Cliffs of Dooneen	
B2		The Kells	03 Glory Oh	
B2		The Kells	04 Musical Priest	
B2		The Kells	05 Rocking the Cradle	
B2		The Kells	06 Allen Dale	
B2		Stuart Anthony & Steve Hall	07 Copper Pot	
B2		Stuart Anthony & Steve Hall	08 Green Sleeves	
B2		Mark Britten	09 Night by the Shannon	

B2		Stuart Anthony & Steve Hall	10 Farewell	
C1	Easy Going	Jack Johnson	01 Wrong Turn	Jack Johnson
C1		Jack Johnson, Matt Costa	02 Lullaby	Matt Costa
C1		Jack Johnson	03 Constellations	Jack Johnson
C1		Jack Johnson	04 No Other Way	Jack Johnson
C1		Jack Johnson, Kawika Kahiapo	05 Talk of the Town	Jack Johnson
C1		Jack Johnson	06 People Watching	Jack Johnson
C1		Jack Johnson	07 Belle	Jack Johnson
C1		Jack Johnson, Topol & Podlewski	08 The News	Jack Johnson
C1		Jack Johnson, Topol, Podlewski, Young Gill & Riley	09 All at Once	Jack Johnson
C1		Jack Johnson, Topol, Podlewski, Young Gill & Riley	10 Sleep Through the Static	Jack Johnson
C1		Jack Johnson, Topol, Podlewski, Young Gill & Riley	11 Enemy	Jack Johnson
C1		Jack Johnson, Topol, Podlewski, Young Gill & Riley	12 Same Girl	Jack Johnson
C1		Jack Johnson, Topol, Podlewski, Young Gill & Riley	13 Adrift	Jack Johnson
C1		Jack Johnson, Topol & Podlewski	14 Mudfootball (for Moe Lerner)	Jack Johnson
C1		Jack Johnson, Topol & Podlewski	15 Times Like These	Jack Johnson
C1		Jack Johnson, Topol, Podlewski, Young Gill & Riley	16 While We Wait	Jack Johnson
C1		Jack Johnson, Topol, Podlewski, Young Gill & Riley	17 Losing Keys	Jack Johnson
C1		Jack Johnson	18 With My Own Two Hands	Ben Harper
C2	Wishes & Hopes	David A. Stewart & Candy Dulfer	01 Lily was here	
C2		Earl Klug	02 Wishful Thinking	
C2		Enigma	03 Sadness	
C2		Morten K¾rsŒ	04 Sarai	
C2		Per Frost	05 Albatros	
C2		Kenny G	06 Silhouette	
C2		Kristian Lilholt	07 For Two Hearts Only	

In her dissertation *Music therapy as an adjunct in cardiac device lead extraction procedures: A randomized controlled trial*, Stine Camilla Blichfeldt-Ærø investigates if the use of music therapy can reduce stress responses for cardiac patients during a specific invasive medical procedure. Although previous research indicates that music therapy can be effective for patients' stress regulation, findings are often heterogeneous, and more studies are called for.

Blichfeldt-Ærø developed a clinical music therapy protocol called Facilitated Music Listening to support patients during the medical procedure, combining standardized and flexible intervention elements based on biopsychosocial principles. Blichfeldt-Ærø clarifies theoretical aspects of the protocol development and shows how a biopsychosocial approach can be applied in clinical practice.

A randomized controlled trial was performed to evaluate effects of the receptive music therapy intervention on patient satisfaction, experienced level of pain and anxiety, procedure medication, and physiological parameters. The dissertation primarily discusses the primary and secondary quantitative results of the study, but a supplementary perspective is also presented, including qualitative elements of the patients' experiences with the music therapy intervention.

The dissertation is a contribution to the work for systematic implementation of medical music therapy as complementary treatment at medical hospitals.

Blichfeldt-Ærø (d.o.b. 1970) has studied musicology, psychology, BM GIM (Lev. II), and has a master's degree in music therapy. Since 2001, she has been working as a music therapist at Department of Child and Adolescent Mental Health in Hospitals, Division of Paediatric and Adolescent Medicine, Oslo University Hospital, Norway.

Norwegian Academy of Music
NMH Publications 2021:4

9 788278 532959