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Music Therapy for Seniors at End-of-Life: Literature Review and a Preliminary Randomized Feasibility Study

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ABSTRACT

Background
Music therapy (MT) is part of the care plan in many end-of-life (EOL) settings, though several authors remain cautious about its effectiveness to improve EOL symptoms and patient well-being.

Objective
Our primary goal was to design and test the feasibility of a clinical trial protocol that would address the main critiques of MT trials previously reported in the literature.

Methods
We conducted a literature review guided by the questions: (1) What is the set of indicators and tools that can be used to measure effectiveness of MT for seniors in palliative care and EOL settings? (2) What are the characteristics of a well-designed clinical trial protocol that can measure effectiveness of MT in palliative care and EOL settings and can be used for a future large scale study? Based on best practices from the review, we developed a clinical trial protocol and tested its feasibility.

Results
Ten participants were accrued. Approximately 25% of eligible participants chose to participate. The consent rate was 55% with 70% of participants completing all MT sessions. All participants completed more than 60% of questionnaires.

Conclusion
Although our protocol could not be considered feasible based on the parameters we originally set, we argue that our study provides enough data to make adjustments to our original trial protocol, which could lead to the collection of reliable evidence related to the effectiveness of MT for seniors at EOL. We recommend future studies to use block randomization and allocation concealment, focus on one primary outcome and conduct intention-to-treat analysis.

Keywords
Music Therapy (MT); End-of-Life (EOL); Seniors; Clinical trial; Palliative Performance Scale (PPS); Standardized Mini-Mental State Examination (SMMSE); Positive Affect and Negative Affect Schedule (PANAS); Spiritual Health Assessment (SHA).

INTRODUCTION

Music therapy (MT) has been extensively used to support seniors' health and social integration, with positive effects on anxiety levels and psychosocial behavior.[1-3] In the psycho-spiritual domain, MT has facilitated reminiscence and life review, emotional expression, and clarification of values and beliefs.[4,5] Furthermore, qualitative studies suggest that caregivers are positively affected and feel more connected with patients when MT is used.[1,6] MT may also benefit the healthcare system by reducing medication costs and improving staff utilization.[5,7]

Music therapy supports many of the domains identified by the National Coalition for Hospice and Palliative Care's Clinical Practice Guidelines for Quality Palliative Care.[8] Depending upon patient needs, music therapy may address all but one of the eight identified domains of care: 1) Structure and Processes, 2) Physical Aspects, 3) Psychological and Psychiatric Aspects, 4) Social Aspects, 5) Spiritual, Religious, and Existential Aspects, 6) Social Aspects of Care, and 7) Care of the Patient Nearing the End-of-Life

(EOL).[8(p vii-ix)] These guidelines identify music therapists among "professionals having credentials, experience, and skills to meet the needs of the patient and family"[8(p 2)] as part of an interdisciplinary palliative care team, and music therapists are mandated to participate in assessment, care planning and continuity of care.

Despite its apparent potential, there is limited evidence to support or refute the effectiveness of music therapy for improving EOL care in the hospice palliative care population.[4,9-11] The heterogeneity of interventions used (active *versus* passive) and settings (hospice, hospital or home) make it difficult to compare results across studies. Additionally, experimental designs frequently lack the rigor necessary to support arguments for the effectiveness of MT.[9,12,13]

Therefore, the objective of this study was to develop and test the feasibility of a clinical trial protocol that addressed the three components lacking in previous studies on MT at EOL, namely: (i) outcomes of MT beyond physical changes, (ii) bias reduction through randomization, inclusion of a control group and standardization, and (iii) active participation of patients, family members and staff at each stage of protocol development. As research has shown that seniors benefit from music interventions in a wide range of situations,[2,3,14] and addressing seniors' health is a priority in our region, this age contingent was targeted for the present study. The development of the protocol was considered quality improvement and was exempt from research ethics review. The protocol was subsequently tested for operational feasibility. The Vancouver Island Health Authority Research Ethics Board approved the feasibility study.

METHODS

Phase 1: Literature Review Method and Setting Priorities

We were guided by the questions: What is the set of indicators and tools that can be used to measure the effectiveness of MT for seniors in palliative care and EOL settings? What are the characteristics of a well-designed clinical trial protocol that can measure the effectiveness of MT in palliative care and EOL settings, and can be used for a future large scale study? The future trial would test the hypothesis that MT is more effective than the control intervention to address the specific outcomes the trial is set to measure.

Our first attempt to find literature about MT at EOL resulted in one article. We searched PubMed (Medline) and CIHAHL for systematic reviews on the topic from 2010 to 2015. Only one manuscript met our original inclusion criteria: a systematic review that included interventions with seniors, at a hospice or palliative care unit, and included MT interventions led by a music therapist.[9] Another article, although not a systematic review (described by the authors as a narrative review), was also read in full, as it met all other inclusion criteria.[10] We subsequently expanded our PubMed search by removing the "systematic review" search term and found four more articles. Following the two electronic searches, we conducted a hand search using a snowballing approach[15] starting from the six selected articles and focusing on reference lists and authors. In total, 79 articles were read in full and 38 included.

The World Health Organization (WHO) defines palliative care as: *An approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification an impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.*[16]

This definition highlights the multidimensional scope of palliative care valued by our team. Before delving into the retrieved literature, we agreed that our protocol would focus on at least one outcome from each of the three dimensions of well-being: physical, psychosocial, and spiritual.

Phase 2: Testing the Feasibility of the Protocol

After developing the protocol, we embarked on a feasibility study. We were guided by the questions: Is the protocol operationally feasible? Can we accrue participants, complete their scheduled MT sessions, and collect data using questionnaires? We focused on accrual and consent rates, in addition to questionnaire completion rates, as the main determinants of operational feasibility. Accepted rates to determine feasibility were established based on the literature. Hilliard[17] (one of the five studies included in the only systematic review published by the time we developed our protocol) indicated that approximately 50% of eligible participants had chosen to participate. When reporting on the feasibility of a MT intervention with adults receiving cancer treatment, Burns et al[18] observed a 63% consent rate, and 72% of participants completed the scheduled MT sessions. Each measurement session included three questionnaires; the rate of questionnaire completion was 60%. Using descriptive statistics, we compared our rates with those previously reported to determine feasibility of our protocol.

In addition to testing feasibility using the above parameters, we compiled results for each participant, including quantitative and qualitative data obtained from surveys and researchers' field notes in a narrative format based on Ledade et al.[19] The objective was to gather additional data to support potential protocol adjustments. Narratives were analyzed using semantic thematic analysis.

RESULTS

Phase 1: Literature Review

Outcomes of music therapy

Physical dimension: Nineteen out of the 79 studies investigated physical symptoms, with pain being the most prominent (89% of these studies) outcome measured. Collectively, these studies' results suggest that MT interventions may be beneficial for pain relief. However, when Bradt et al[9] systematically reviewed the literature, they reported no strong evidence for the effect of MT on pain (based on the two small studies that met their inclusion criteria). On the other hand, in a more recent randomized controlled

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trial involving 200 in-patients, a single MT session was found to be significantly effective ($p<0.0001$) in lowering numeric rating scale (NRS) pain ratings by an average of 2/1020. Although more recent data suggest that MT may be effective to reduce pain at EOL,[21] evidence is still limited, and we opted for including pain as an outcome of interest in our clinical trial. Two recent reviews ratify that there is still a need to develop high-quality research in this area.[13,22]

Spiritual dimension: In their systematic review, Bradt et al[9] reported a single study that demonstrated a significant effect of MT on spiritual well-being. Wlodarczyk[23] demonstrated a statistically significant increase in spiritual well-being in patients receiving MT sessions compared to those receiving conversation sessions. Many studies, however, examined the effects of MT interventions on patients' experiences of meaning, hope, awareness, connection and suffering.[21,24-27] Thus, we opted for examining the effects of MT on spiritual health.

Psychosocial dimension: Bradt et al[9] reported insufficient high-quality evidence to support any beneficial effects of MT on quality of life for patients at EOL. When examining the literature, 27 out of the 79 studies discussed the impact of MT on emotional well-being, affect/mood, and/or quality of life. Research case studies and reviews described positive emotional outcomes for individuals receiving MT or their caregivers.[28-30] We decided to include affect within our study design.

We examined the tools used in different studies to measure our chosen outcomes. Our tool selection criteria were: length (two pages or less), expected completion time (less than 5 minutes), simplicity of wording, and validation at large. We opted for the Numeric Pain Rating Scale and the Pain Affect Rating Scale for pain, and the positive affect and negative affect schedule (PANAS) for affect.

The only tool we found for evaluating spiritual health did not match our criteria. At the time of protocol development, many of our hospice staff were attending a series of workshops[31] which brought the spiritual health assessment (SHA)[32] tool to their attention. Although the tool has not been validated it is, according to the workshop facilitators, currently in use in hundreds of care facilities around the world. The SHA was modified for our use with permission from its authors.

Other variables: In addition to these quantitative variables, our post-MT measures included feedback questionnaires examining qualitative concepts: relaxation, enjoyment, energy level ('energized'), and meaning ('meaningful'), as these concepts were mentioned in 36 of the 79 articles reviewed. Qualitative data from patients, healthcare providers and family members involved in patient care was collected through these questionnaires.

Bias reduction through randomization, inclusion of a control group and standardization as part of the experimental design: Content and administration of MT interventions varied widely between the studies we reviewed. Individualization of MT interventions is often viewed as essential to the effectiveness of treatment, particularly as familiar music has been demonstrated to facilitate the highest degree of emotional engagement in listeners.[33] However, standardized interventions are generally considered as necessary for the administration of controlled clinical trials! Such duality creates a challenge in the development of a rigorous MT research protocol.[34] Some of the studies reviewed employed a standardized, passive MT intervention, consisting of a music-facilitated relaxation exercise using preselected live[12,20] or individualized recorded music.[35] Active MT interventions included song choice, song analysis, songwriting, singing, instrumental improvisation, composition and recording, and multimedia applications combined with music for life review.[23,36] For the purposes of our protocol, the importance of giving participants a choice of musical activities, so that interventions would address their immediate needs and symptoms, was also acknowledged.[17,36,37] Thus, a choice between passive and active MT interventions was incorporated. A guideline for each MT intervention was created to support each type of session.

Some studies used a supportive but non-music based control, such as a verbal relaxation exercise[12,20] or conversation,[23,38] while others contrasted the MT intervention with a passive music listening activity.[10] Other studies contrasted MT with standard care.[35,39] As the goal of the future randomized trial would be to compare the effects of interactive, individualized MT with those of passive listening, we chose a music listening activity that used recorded music administered by the music therapist without the purposeful therapeutic component that a MT session offers. Participants served as their own controls. A guideline for the music listening activity was developed, with a list of CDs to be offered for participants to choose from.

Bradt[40] points out that randomization is usually poorly executed in MT clinical trials. Wishing to maximize the odds of having a similar number of participants assigned to the two possible sequences of treatment (MT first and music listening second-AB or music listening first and MT second-BA), we opted for a block design. The initial two options for each participant (5 AB and 5 BA-10 in total) were put into an envelope and randomly selected by the research assistant after each consent interview; assignments were removed from the envelope as they were chosen.

The length of MT sessions varied widely between studies reviewed, ranging from 15 minutes[10] to 95 minutes.[41] Based on her 20 years' experience, the music therapist on our team initially suggested a 40-45-minute session length, and was shortened to 30 minutes after team consultation. The number of MT sessions also varied widely between the studies reviewed, ranging from a single session[20] to 35 sessions.[27] Cassileth et al[39] and Clark et al[35] both noted that assessing the effects of MT required more than one session, as a single session proved insufficient to demonstrate the effects of the newly established client-therapist relationship. However, wishing to maximize the number of patients completing participation, we chose to limit the number of sessions to two (one MT and one music listening activity).

Active participation of patients, family members and staff at each stage of protocol development: The protocol was shared with patients and healthcare providers for feedback and adjusted accordingly. Staff feedback was sought from members of the research team, physicians, counsellors, and nurses. Feedback was also obtained in staff meetings, by written survey, and through a poster campaign. Feedback was sought from patients admitted to the palliative care/hospice unit *via* 1:1 interviews. Table 1 depicts the final protocol tested for operational feasibility.

Table 1. *Final Protocol Tested For Operational Feasibility*

Protocol	Explanation
Population and setting:	Seniors (55 years or older) admitted to a Tertiary Hospital Unit. Eligible patients were introduced to the study and if they agreed to participate a consent interview followed. Consenting participants were able to withdraw at any time.
Design:	AB/BA with random assignment. Session A consisted of music therapy (pre-set active or passive activities), session B consisted of listening to pre-recorded music of the participant's choice. A pre- and post-test evaluation of physical and psycho-spiritual variables was conducted.
Intervention:	Music Therapy sessions (30 to 45 minutes each) included individualized receptive and/or interactive music therapy experiences including music listening, music-centered relaxation and imagery, music-making (vocal and instrumental performance and/or improvisation), and music-based life review.
Measures and Instruments:	We measured the following variables using the corresponding instruments: pain intensity with the Numeric Pain Rating Scale; pain affect or perceived nature of the pain with the Pain Affect Rating Scale; mood and emotional well-being with the Positive and Negative Affect Schedule or PANAS; and spiritual well-being with the Spiritual Health Assessment. In addition to participant comments, we also invited a family member or support person and the primary care nurse to provide feedback on the perceived effectiveness of each session. We allowed at least two days between intervention and control sessions. Data collection was performed by a research assistant and by the music therapist herself.

Phase 2: Testing the Feasibility of the Study Protocol

Recruitment initially focused on people admitted to the palliative care/hospice unit of a large tertiary hospital. We obtained funding to accrue 10-12 participants, but only one participant was accrued over the first six-months of the project's recruitment phase. Other potential candidates were deemed ineligible by the clinical team due to acuity of symptoms, low palliative performance scale (PPS) rating,[42] and/or poor cognition. We then expanded accrual to include people registered with hospice but not admitted to the unit (community participants) and people admitted to the palliative care unit of a smaller community hospital within our metropolitan region. In the month following expansion, 9 additional participants were consented and 8 completed at least one music session (4 from the community hospital, 4 from the community).

Potential participants were screened for eligibility using checklist criteria: ≥55-years-old, cognitively intact and able to communicate in English, possessing a PPS rating equal to or greater than 30%. Eligible participants were invited to hear more about the trial by a clinical research team member not involved in their care. People interested in participating were then referred to the research assistant for the consenting interview. After consenting, participants were asked to complete the standardized mini-mental state examination (SMMSE).[43] The music therapist did not participate in these steps of the recruitment process.

After each primary participant consented, we sought consent from a family member who would provide feedback about the perceived impact of the session on their loved one. Nurses provided consent in advance and also provided feedback about the perceived impact of the session on the participant under their care (at the community hospital and tertiary hospital).

We approached 36 eligible participants in total, 18 of whom (50%) agreed to learn more about the project. Of these 18 potential participants, ten (55%) consented to participate in the study. Seven participants (70%) completed both sessions, two (20%) completed one session, and one participant (10%) did not complete either session. Of the nine participants who completed at least one session, all nine (100%) completed more than 60% of our measurement tools. Worsening of symptoms or fatigue were the main reasons people did not consent, did not complete the two sessions or did not complete all measurement tools.

Participants ranged in age from 65 to 97 (M=83, SD=10). Six of the nine participants who completed at least one session (67%) were female. Four participants' (44%) diagnosis was cancer, while the remaining five participants had various non-cancer diagnoses. Eight participants (88%) were recruited from the community (4) and from the community hospital unit (4), and the remaining participant (11%) was recruited from the tertiary hospital unit. Participants' SMMSE scores ranged from 23 to 28 (M=26.1, SD=1.6), indicating mildly impaired to potentially normal cognition.

The majority of participants did not have pain before either session and remained pain-free following. The SHA did not capture many changes for the majority of participants. The PANAS results demonstrated marked changes for some participants. Due to the small sample size and the missing data, statistical analysis was not possible.

Regarding the feasibility of our protocol, we set four criteria a priori and only one was achieved: i) Approximately 50% of eligible participants agree to participate (25% agreed to participate); ii) 63% of interested participants consent to participate in the trial (55% was our consent rate); iii) 72% of participants complete all scheduled MT sessions (70% completed the sessions); iv) All participants complete 60% of questionnaires (all participants completed more than 60% of questionnaires).

Thematic Analysis

Three main themes emerged from the thematic analysis of participants' narratives: 1) Who participated, 2) The music sessions and 3) Collecting data.

Who participated: The majority of participants (8 out of the 9 who completed sessions) provided information during their music therapy session about previous interest in or involvement with music. Some participants had formal musical training, others were

avid listeners, and still others came from families of origin or cultural backgrounds in which music played a significant role. Mrs. Smith reminisced about singing in a church choir, taking piano lessons, and listening to 1960's folk music during her childhood in Nova Scotia. The one participant (out of 9) who did not describe a connection with music was unable to speak and communicated by writing, therefore, may not have had the ability to provide additional information.

The music sessions: The majority of the sessions occurred in a healthcare facility (5 out of 9 participants were admitted to one of the two hospital units). Most sessions were conducted in a private location (participant's room) and in a calm environment. Mr. Finch, however, opted for having his MT session in the lounge, where there was ambient noise and movement. The MT and music listening sessions were an average of 30-minutes. Managing the compact disc (CD) player was an issue for 5 out of 7 participants, necessitating assistance by the music therapist or a family member.

Participants were offered a choice of active or passive intervention as the MT session. The majority of participants, 5 out of 9, chose the active intervention: music-facilitated life review. Mrs. Stone initially requested a passive intervention, but immediately began to reminisce about her childhood and the role that music played in her family. The music therapist then followed Mrs. Stone's lead, accompanying her as she spontaneously began to sing a song her mother once played on the piano. The remaining participants (3 out of 9) chose the passive intervention (music-facilitated relaxation with live piano music).

The CD listening session offered participants a list of 55 CDs to choose from. Mrs. Taylor was asked to select one CD to listen to for the entire 30-minute session, and chose the "20 Country Gospel Favourites" CD. The music therapist started the CD and then left the room. After the session, Mrs. Taylor stated she had found the session frustrating: *I wished I could have ended the session early*. The experience was not observably enjoyable or meaningful for Mrs. Taylor from the point of view of the MT. Therefore, the music therapist subsequently modified the procedure, and asked participants to select two CD's for their listening sessions. Thus, if the participant did not enjoy the first selection, they would have another available. Two participants did not complete the CD listening session due to fatigue, low energy or decline in general health.

Collecting data: Although some participants completed all the forms with ease, fatigue and displeasure at filling out forms was a topic raised many times. *I hope it ends soon* was the sentence Mr. Birch wrote when filling out the SMMSE. Ms. Wendel spent more than one hour filling out the forms before and after the MT session.

Completing the PANAS posed some additional challenges: participants skipped questions, circled two responses for one question, and/or complained about the length of the tool. After the first page of PANAS, Mr. Birch stated, *Oh my Gosh, you are going to make me work more!* Mrs. Stone fell asleep after the first page of PANAS. The PANAS may have also caused distress to some participants, as the research assistant remarked, Ms. Wendel went through the survey thoughtfully and slowly, at times appearing emotional and tearful as the PANAS was filled out.

The majority of participants who completed the MT session and the ensuing feedback questionnaire (6 out of 8) described themselves as both relaxed and energized. Mrs. Stone remarked, *relaxed and energized at the same time seems impossible when both are opposite, but that is truly what occurred.* On the other hand, the majority of participants who completed the CD listening session (5 out of 7) reported being relaxed afterwards. Mrs. Herring, Mr. Jones and Ms.Wendel reported feeling both energized and relaxed at the end of the session. Ms. Wendel commented (in writing), *I loved listening to the music. It made me realize how much I was homesick for music.*

The majority of participants reported enjoying both the MT and the CD listening sessions (6/9 and 7/7 respectively). Participants' general comments (those not solicited in regards to any specific aspect of the sessions) revealed more about their experience. Mrs. Smith stated she was disappointed to be having her last visit. She wanted the research team to come again because she was having fun. Mrs. Stone described her *delightful memories of long-forgotten songs just from reading through the (CD) title list.*

Caregivers (staff and family support person) were also asked to share their perceptions regarding the effect of the sessions on participants. Five out of nine participants had either a staff or support person fill out post-surveys for all of their sessions (whether they completed one or two sessions). Staff provided feedback more consistently than family support people. Feedback from caregivers agreed in general with feedback from primary participants.

DISCUSSION

MT is part of the care plan in many EOL settings, despite caution regarding its effectiveness. Our primary goal was to design and test the feasibility of a clinical trial protocol that would address the main critiques of MT trials previously reported. Although our protocol could not be considered feasible based on our original parameters, we argue that it provides enough data to make adjustments to the original trial protocol, which could lead to the collection of reliable evidence related to the effectiveness of MT for seniors at EOL.

As we updated our literature review in 2016 we learned about a clinical trial protocol to investigate the effectiveness of MT for improving the quality-of-life (QOL) of hospice inpatients.[13] Porter et al[44] recently reported the results of their feasibility study, allowing us to compare and contrast both studies when discussing our own results.

Our eligibility criteria may have played a strong role in determining the feasibility (or not) of our protocol. The low minimum PPS (30%) allowed individuals in advanced stages of their illness to be eligible and subsequently recruited. Approximately half of eligible participants mentioned "declining condition" as the main reason for not wanting to hear more about the study. The low PPS criterion was likely a barrier to recruitment and completion

of the sessions. Changing the minimum PPS criteria to 50% could support recruitment and completion of the sessions. Interestingly, Porter et al[44] reported that lowering the eastern cooperative oncology group (ECOG) performance status to include people that were less well (ECOG 3 or lower-capable of only limited self-care, confined to bed or chair) did not affect attrition rates (they initially accrued patients with ECOG 2 or lower-ambulatory and capable of all self-care but unable to carry out any work activities). There is no direct correlation between PPS and ECOG scores which makes it difficult to compare the status of participants recruited for both pilots.

Bradt[40] offers excellent guidelines for the design and implementation of randomized controlled trials in MT. Although her manuscript is not specific to EOL care, and mainly addresses characteristics of explanatory trials (those investigating efficacy of different treatments), we suggest that most points are also applicable to pragmatic trials (those investigating effectiveness of different treatments). More recently, Warth et al[12] provided recommendations for future MT research using controlled clinical design in palliative care that complement Bradt's[40] guidelines.

Bradt[40] and Warth et al[12] highlight the importance of bias reduction through randomization, blinding, inclusion of a control group, and standardization as part of the experimental design. Although random sampling was not possible, we assigned participants to different groups using a randomized block design, similar to Porter et al.[44] Those responsible for recruitment in our feasibility study were unaware of the group to which each participant would be assigned. However, random allocation and allocation concealment were not enough to avoid bias, as the majority of participants (8 out of 9) mentioned a previous interest/involvement in music. As participants were unaware of the hypothesis behind the study (MT is more effective than music listening), we were able to further address bias by effectively blinding. Blinding was possible because our control group included music listening. Porter et al[44] were not able to blind participants as their control group received usual care only. We would argue that including music listening as a control group has two main advantages: it allows for effective participant blinding and allows people to interact with music in a timely fashion (being in the intervention or the control groups rather than only after the intervention is completed as in Porter et al[44]).

Standardization of MT interventions was challenging, as participants had different goals and were at different stages in their disease trajectories. Bradt[40] and Warth et al[12,45] suggest that treatment manuals may be good supporting tools for the standardization of MT trials. We created guidelines for each treatment (control, active MT and passive MT) that supported standardization. Our results may assist in the development of these guidelines to the standardization level required for a future expanded trial. Porter et al[44] report the intention of creating guidelines based on the music therapist's session reports created after each pilot MT session.

Bradt[40] and Warth et al[12] mention the need to establish a priori primary and secondary outcomes to prevent reporting bias. Bradt[40] also cautions against including too many outcomes.

Table 2. *Summary of Bradt[40] Guidelines, our Protocol, and Our Recommendations for Future Music Therapy Clinical Trial Protocols*

Bradt[40]	Our Protocol	Recommendations
Random allocation of participants should be executed and well described	Random allocation using block randomization.	Block randomization is a feasible method to allocate participants to the different groups.
Allocation concealment should be addressed	The person inviting potential participants was unaware of the group to which the person would be assigned. Consenting interview followed referral order.	The used allocation concealment provided additional rigor to the randomization process.
Blinding should be included as much as possible	Potential participants were blinded to the hypothesis "behind" the trial.	Blinding participants to the hypothesis is feasible and provides additional rigor to the research process. We have not involved a statistician in our trial but blinding the statistician involved in the larger trials seems feasible.
Standardization: treatment manuals should be developed	We created treatment guidelines to support each type of session including length of session, materials needed (e.g. instruments, CDs), passive and active MT options.	Expand treatment guidelines to include instructions about environment, CD management.
A control group should be included	Music listening activity was introduced as a control intervention. Each participant also acted as their own control as each received both interventions.	The introduction of a control group as described in our protocol was feasible.
Therapist assignment should be random	We only had one music therapist involved.	The expanded treatment guidelines with the inclusion of more music therapists will likely add rigor to the trial. All music therapists should be trained on the trial procedures and randomly assigned if possible.
Small number of outcomes should be determined before the start of the study. Data should be collected using standardized tools	Three primary outcomes and two secondary outcomes were determined before the start of the study. Standardized tools were used to collect data.	Focus on one primary outcome (affect). One secondary outcome could be added and would require additional literature review to be determined.
Minimize attrition bias by conducting intention-to-treat analysis	We conducted an intention-to-treat analysis reporting on all people offered the study.	Intention-to-treat analysis is feasible and adds rigor to the trial.
Rationale for sample size should be explained	Our sample size was determined by the availability of funds. Statistical significance was not sought.	Using the results of our trial and the recently published MT clinical trials a sample size calculation can be performed and explained.
Details of the study following the CONSORT guidelines should be included in the final report	We reported our results using CONSORT (2010) guidelines.	Reporting using CONSORT guidelines is feasible.

Warth et al[45] successfully used three outcomes; their visual analog scale measures were simple and straightforward for participants to complete. During the design phase of our protocol, the number of outcomes (three) was not identified as an issue (based on the feedback from staff and hospice patients). Nevertheless, it became apparent from our feasibility study participants' responses that we asked too many questions; the number of questionnaires was likely a barrier to participants' completion of the study. We now propose that focusing on one primary outcome would be ideal. Based on our results, we posit that affect is a useful non-physical parameter to be explored in a future larger trial. A recent Google Scholar search revealed the PANAS short version,[46] which addresses many of the original PANAS's points flagged by our participants as "problematic," and has been validated for different populations.[47-49] In hindsight, we question use of the SHA. This tool was developed for use as a conversation starter, therefore SHA score changes may not imply that MT had an impact on spiritual health. The secondary outcomes we focused on (enjoyment, energy and relaxation) did not seem to provide useful information. Furthermore, seeking qualitative feedback from caregivers (staff and family members) introduced complexity to the trial but did not seem to provide useful information. Porter et al[44] examined one primary outcome (feasibility of using the mcgill quality of life questionnaire (MQOL)) and change in quality of life as secondary outcome. We recommend that in a subsequent larger study, feedback be obtained exclusively from individuals with life limiting illnesses, focusing on one primary outcome. Table 2 summarizes the main points raised by Bradt[40] in her guidelines, how we addressed each point, and our suggestions for future studies.

The SMMSE, though not a recruitment criterion, was included to support data analysis. All consented participants were confirmed as exhibiting minimal cognitive impairment, as evidenced by their SMMSE scores (20 to 30), although all eligible participants had been deemed competent by a clinician (based upon clinical observation/assessment rather than an objective measurement tool). However, conducting the SMMSE test posed an added burden to some participants. Interestingly, Porter et al[44] have not reported any issues using the abbreviated mental test score (AMTS) as a screening tool. The AMTS is significantly simpler than the SMMSE and this may have made an impact. Based on our experience, however, we argue that a cognitive test is not necessary if good clinical screening occurs.

CONCLUSION

We embarked on this journey hoping to bring MT back to our hospice (we had a music therapist on staff 10-years ago, but the program was terminated due to funding constraints). Would demonstrating the effectiveness of MT at EOL through a clinical trial support the case for seeking funding to reinstate the program? Aigen[50] argues that investigating effectiveness through a clinical trial is only one aspect of studying MT, one that narrows the focus of MT, as it is embedded within a traditional medical framework. On the other hand, McConnell et al[13 (p 7)] state that high-quality randomized control trials are needed "to provide support for (..) service providers to make an evidence-based decision on whether to incorporate MT in palliative care services, with patients as beneficiaries."

There are no official Canadian statistics available regarding MT in palliative care services. We conducted an informal email consultation with music therapists from our province during the spring of 2018: of the 123 members of the Music Therapy Association of BC eligible to work in 2017, nine identified palliative care units or hospices as their workplace. Only one music therapist works full time in palliative care (36-hours/week); all the others are part time (2 to 22.5-hours/week). Six have unionized positions at a hospital palliative care unit (PCU) or hospice and three are hospital PCU or hospice contractors. Examining American and British data, we found that in the US, less than one third (29%) of hospices surveyed provided complementary and alternative therapies to patients and families, and of these, only 53% employed a music therapist.[51] Additionally, in the US, only 18% of all music therapy positions and services were funded by hospital/facility budgets, with another 31% funded by third party reimbursement and government funds.[52] Even in the UK, where palliative care itself was pioneered, the majority of palliative/end-of-life care music therapy services are supported by charities (27.3%) or hospice self-funding (31.8%).[51] 2017 statistics indicate that in the USA, only 15% of music therapists surveyed worked full-time (34-hours/week or more) in hospice/palliative care settings.[50] In the UK, just 13% of music therapists worked more than 28-hours/week with palliative/end-of-life-care clients,[51] with the majority working less than 10-hours/week. However, Graham-Wisener et al[53 (p 1)] optimistically noted that "evidence suggests provision of music therapy in UK palliative/end-of-life care settings [has] increased in the last decade."

Table 3. *Revised Protocol for a Future Music Therapy Study*

Protocol	Explanation
Population and setting:	Seniors (55 years or older) admitted to a Tertiary Hospital Palliative Care Unit. Eligible patients (minimum 50% PPS) will be introduced to the study and if they agree to participate, a consent interview follows. Consenting participants will be able to withdraw at any time.
Design:	AB/BA with random assignment. Session A consists of music therapy (pre-set active or passive activities), session B consists of listening to pre-recorded music of the participant's choice. A pre- and post-test evaluation of mood and emotional well-being will be conducted.
Intervention:	Music Therapy sessions (30 to 45 minutes each) will include individualized receptive and interactive music therapy experiences including music-centered relaxation and imagery, music-making (vocal and instrumental performance and/or improvisation), and music-based life review. All interventions will be clearly outlined within a treatment manual to support standardization as per Bradt[40] and Warth et al.[12,45]
Measures and Instruments:	Will measure the single variable of mood and emotional well-being with the Positive and Negative Affect Schedule or PANAS short version.[46] Will allow at least two days between intervention and control sessions. Data will be collected from participants only, by a research assistant and by the music therapist.

We believe that providing reliable evidence through a clinical trial may play an important role in ratifying the importance of MT programs in Canadian hospices and beyond. As suggested by Graham-Wisener et al[53 (p 3)] "Strengthening the evidence base for music therapy is necessary to encourage more consistent funding

for this role." Our protocol, after the adjustments proposed here and summarized in Table 3, is a valuable tool for conducting a randomized clinical trial focused on MT at EOL.

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CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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