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ARTICLE

Investigating trial feasibility of music care in hospice and palliative care

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ABSTRACT

The nature of hospice and palliative care (HPC) settings necessitates supporting residents' ever-changing needs and responding to unforeseeable situations – as such, this unpredictability has historically challenged the collection of high-quality data in such settings. Through a feedback consensus approach, this pilot study sought to determine the feasibility of implementing a clinical trial aiming to understand the impact of a recorded music care intervention on quality of life (QoL) in HPC settings. Four participants with a palliative performance scale (PPS) score of ≥ 40 were recruited. Pre-developed music care albums designed for HPC were used as an intervention for a minimum duration of 30-minutes. The Edmonton Symptom Assessment Scale, Hospice Quality of Life Index, and State-Trait Anxiety Inventory were implemented to mirror a future randomised controlled trial (RCT) design but were not statistically interpreted in this pilot study. Data collectors also recorded participants' and care providers' perspectives. Through feedback from participants, healthcare professionals, and music care experts, the intervention duration was reduced to a minimum of 15-minutes, and the PPS inclusion criteria requirement was eliminated. The number of outcome measures was reduced from three to one to mitigate participant burnout. Finally, participants indicated that the recorded music intervention was therapeutic, therefore justifying further study of QoL outcome measures. Implementing a second pilot to validate the changes to the RCT study protocol will be a critical step in the research process, although the results of this study can be considered by researchers conducting RCTs in HPC to inform best practices.

KEYWORDS

hospice and palliative care (HPC), music care, quality of life (QoL), trial-feasibility, randomised-controlled trial (RCT)

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INTRODUCTION

Global life expectancy is statistically longer than it has ever been across the course of human history. However, while the population may be living longer, research demonstrates that the increase in life expectancy has come at the cost of more prevalent chronic and degenerative diseases (Canadian Institute for Health Information, 2018). The Canadian population has seen an increase in the use of publicly-funded hospice and palliative care (HPC) (Health Canada, 2018), at least in some part due to this increased burden of chronic disease. It is projected that most adults by age 65 will have at least one or more chronic illnesses that they will live with for the remainder of their lifetime (Field & Cassel, 1997). As a result, individuals receiving HPC face not only chronic physical symptoms that contribute to a reduced quality of life (QoL), but also psychological distress and increasing dependence (Galfin & Watkins, 2011). As an example, the majority of cancer patients participating in a 2013 research study experienced both physical symptoms as well as existential distresses, which challenge QoL (Harrisdecima, 2013). To cater to both the physical and psychosocial needs of individuals receiving care, HPC focuses on an interdisciplinary approach to relieving symptoms of suffering and improving patient QoL (Morrison & Meier, 2004). However, QoL may suffer at the expense of reducing physical burdens (Field & Cassel, 1997), while attention to equally important psychosocial factors (Meneguin et al., 2018) may be neglected. For example, people receiving palliative care may suffer from polypharmacy and a variety of consequential intertwined adverse events, such as higher psychological distress (Assari & Bazargan, 2019; Gamboa-Antiñolo, 2020). Because HPC settings function not only to ensure minimal suffering but also to maintain QoL, this presents a dire need to develop and implement non-pharmacological approaches to support the goals of HPC.

One such non-pharmacological approach is the use of music care. Research has demonstrated that the benefits of music care, a non-invasive means of improving QoL, extend beyond negating the consequences of disease. Music care, distinct from music therapy, is an approach to care that provides the means for anyone, regardless of their musical competence or credentials, to use music in their day-to-day care of patients (Foster B et al., 2016). The music care approach was developed in a Canadian context by the Room 217 Foundation and has been tested and applied within the UK health and social care system. Music care is an accessible, cost-effective way to implement music initiatives and interventions in resource-constrained primary and community care settings. This includes contributing to improved spiritual solace and psychological well-being, in addition to the reduction in pain and fatigue symptoms (Archie et al., 2013; Clements-Cortés, 2004, 2010; O'Callaghan, 1976). With the additional benefits of being cost-effective, and little to no side-effects, the use of music care

is a promising adjunct in the HPC settings (Archie et al., 2013; O'Callaghan, 1976; Olofsson & Fossum, 2009).

Currently, a primary barrier to using music interventions in clinical settings is the lack of knowledge among healthcare providers on how they can be used appropriately. Compounding this issue is the lack of access to trained professionals such as music therapists (Silverman, 2007). Recorded music care resources, such as therapeutically-informed playlists and pre-recorded musical offerings are easily implemented by healthcare providers and other caregivers. When used in the context of the music care approach, recorded music offerings may facilitate a better and cost-effective means of providing person-centred music to HPC residents. A 2011 Cochrane review investigated the effects of 30 music-oriented interventions, 17 of which included listening to recorded music. The researchers found that the music interventions provided an effective means of managing symptoms and improving QoL with no side-effects (Bradt et al., 2016). Thus, the use of music care would prove beneficial for settings where music therapy is inaccessible due to cost and/or availability.

The purpose of this two-phased research programme is to evaluate the effectiveness of the Room 217 recorded music care resources as compared to a recorded poetry control intervention. The music care resources were purposefully developed but untested prior to this study for the HPC settings in alleviating common symptoms. Given the unpredictability and ever-changing nature of the patient experience within the HPC setting, as well as the lack of research performed on best-practices and person-centred non-pharmacological interventions in HPC, the research will be conducted in two distinct phases. Phase 1 involves the comprehensive testing of the research design and approach (trial feasibility) through a set of pilot studies. Phase 2 is the implementation of an ethical and feasible large-scale randomised controlled trial (RCT), informed by phase 1 findings. As previously mentioned, the control intervention in the large-scale RCT will be recorded poetry. Poetry was selected as the control intervention for the RCT in phase 2 as music and poetry have been shown to be processed by overlapping areas in the brain (Scharinger et al., 2022). Phase 1, part of which is examined in this paper, is necessary to verify that all research conducted in phase 2 will be performed in a person-centred manner and to minimise logistical problems. The results of phase 2 will ensure informed and evidence-based implementation of pre-recorded music interventions in the HPC setting. This current study evaluates and comments on phase 1 findings from the first pilot trial.

METHOD

The first pilot study in phase 1 of this research was conducted in December 2018 at two 10-bed residential hospices (Good Shepherd Emmanuel House and Dr. Bob Kemp Hospice) in Hamilton, Ontario. It was approved by the Hamilton Integrated Research Ethics Board (HIREB, approval no. 5316), and entered in the ClinicalTrials.gov database under number NCT03758703. Two fourth-year undergraduate thesis students (authors CK & AP) conducted this first pilot study with direction and guidance provided by their supervisor (author CM) and research team members (authors BF & SRB). The purpose of phase 1 of the research is to test feasibility and methodological assumptions associated with the RCT design. Methodological choices were aligned with the RCT design as discussed below.

Participants and recruitment

Phase 1 of this study initially recruited four participants who met the planned RCT inclusion criteria: (1) speak English, (2) complete the Edmonton Symptom Assessment Scale (ESAS) and have a score of 3 or higher on pain and anxiety, (3) have a Palliative Performance Scale (PPS) score of at least 40/100, and (4) be cognitively alert and competent to provide informed consent and complete the questionnaire. Informed consent occurred on day 1 prior to the initiation of the intervention or data collection. For compassionate reasons, participants were excluded if they had a prognosis of less than 2 weeks.

Intervention

Participants were asked to self-select and listen to a recorded music care playlist developed by Room 217 and available on the Spotify music streaming app. Each playlist is in the form of an "album" and consist of familiar and soothing sounds and songs designed for use in palliative and end-of-life care, but also in a variety of settings to reduce anxiety and agitation. The musical content of the albums was chosen by HPC stakeholders in a Canadian context and therefore are most applicable in HPC in Western settings. Recordings include 2-3 instruments and sometimes vocals. The tempo is set to 60BPM to support relaxation. Sample album titles include: Peaceful Presence, Classic Comfort, Spirit Wings, and Healing Light. Though these albums are widely used in the HPC setting in the Canadian context, their therapeutic impact has yet to be validated by clinical research. It is important to recognise that different individuals may respond to the music in different ways, and that this research programme will help to understand the effects of the recorded music care playlists more objectively. The intervention was administered daily for 30-minutes over the course of seven days, and participants were free to select different playlists each day. The music was delivered via a portable speaker system, allowing the data collector and family, if present, to engage in the intervention with the participant and interact with them whenever appropriate.

During this music care intervention, the participant was informed that there was no expectation to provide any verbal feedback about whether the music was enjoyable or not. They were allowed to simply sit back and listen, even to the point of falling asleep. The participant was also informed that the music could be stopped at any time to respect their level of comfort. Research students collecting data in this pilot study received two days (14 hours) of training on the use of music care strategies in healthcare contexts. Additionally, they received training on the administration of the outcome measure scales from a university professor and bedside manner training from a palliative care music therapist. Thus, research students were well equipped to respectfully and professionally conduct themselves in the context of this study.

Control

While this pilot study is part of phase 1 research and does not include a control measure, the future large-scale RCT will utilise poetry audio recordings as an active control. Participants will be given the same instructions as discussed in the Intervention section and will similarly be able to self-select a "playlist" of poetry. This pilot study's purpose was to determine trial feasibility and best practices

moving forward, and to preserve a patient-centred approach with regards to the length and scope of each participant's involvement. From a logistical standpoint, the differences in administering music-intervention sessions and poetry control sessions were deemed not significant and control participants were not recruited.

Outcome measures

Throughout the seven days of data collection, participants completed several self-reported questionnaires with the help of the data collector or HPC staff if required before and after the intervention. The daily involvement questionnaire (DIQ) was the first questionnaire that was administered every day before the intervention. It was used to identify if the participant had listened to music outside the context of this study, if at all, allowing researchers to control for this confounding variable. On the DIQ, data collectors also transcribed anecdotes from participants, reasons for drop-out, and participants' suggestions. These anecdotes and explicit conversations about study participation were evaluated to understand the feasibility of the phase 2 RCT protocol. In the context of the feasibility study, additional questionnaires were administered but not statistically evaluated: The Edmonton Symptom Assessment System (ESAS) and the State-Trait Anxiety Inventory Scale (STAI-S). The ESAS and STAI-S are two validated questionnaires that were administered every day before and after the intervention. The ESAS was used to rate the intensity of nine common symptoms experienced by palliative care residents, and the STAI-S was used to determine the presence and severity of current symptoms of anxiety and a generalised propensity to be anxious. On days one, three, and seven, an additional questionnaire, the Hospice Quality of Life Index-Revised (HQLI-R), was also administered before and after the intervention. The HQLI-R is a validated questionnaire that was used to assess four domains (psychophysiological, social/spiritual, and functional well-being) of each participant's QoL. After having notified the resident that the intervention was complete, the research investigator then completed the post-intervention questionnaires with the participant (Figure 1).

RESULTS AND DISCUSSION

This pilot study used a feedback consensus approach to determine the feasibility of conducting a music care RCT in the HPC setting. Several methodological changes are proposed to the original RCT study design to ensure subsequent feasibility studies and phase 2 of this research is conducted in a manner that respects participants' dignity, preferences, and capacity. The research team has also concluded that a second phase 1 pilot study is needed to validate the efficacy of the suggested methodological changes to maintain an ethical approach to research in the HPC setting. Although the inherent stochastic nature of HPC could not ultimately be eliminated, the proposed changes will allow for a more person-centred approach (Table 1). This may improve recruitment and completion rates for the second phase 1 pilot as the study is made less burdensome on the participants (Appendix A). Finally, the results also informed the next iteration of the RCT study design of phase 2 (Appendix A) and is currently being used to develop a training manual outlining the best practices for conducting research in HPC.

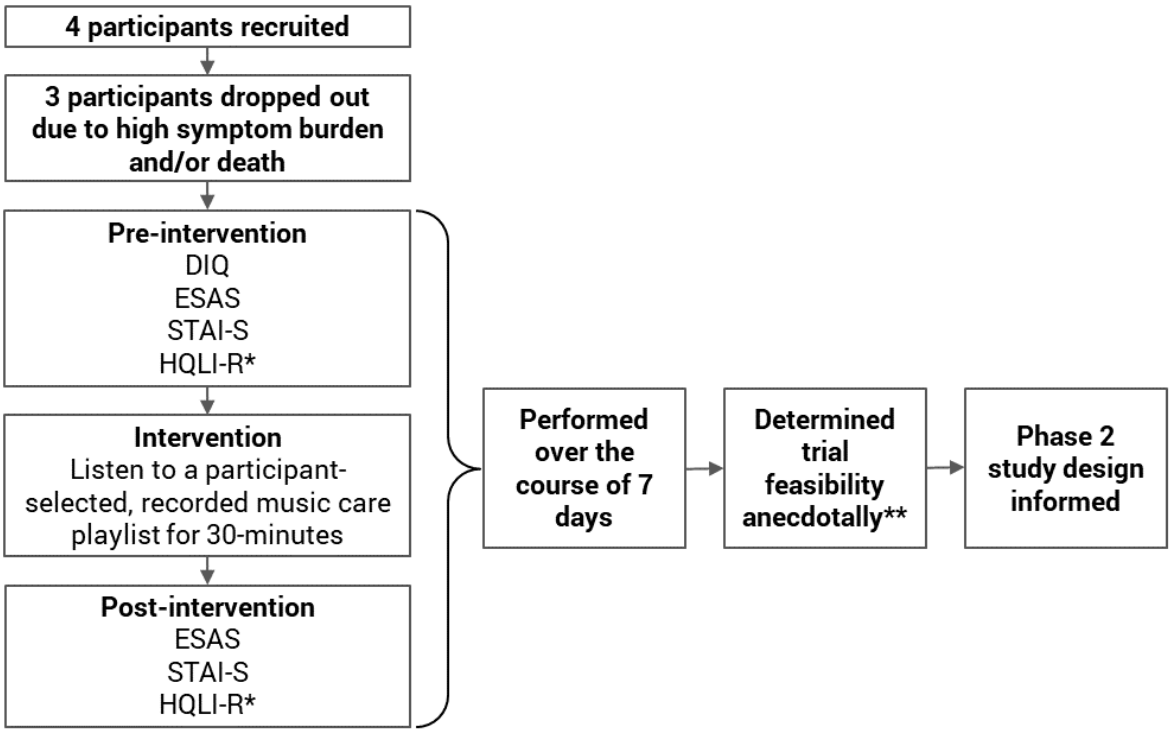

Figure 1: Flowchart of phase 1 study design

* HQLI-R questionnaire was administered only on days 1, 3, and 7 of data collection. ** Determined by inquiring participants' study experiences (including those who dropped out) to update study protocol accordingly, as well as consulting expert opinion from workers (including two HPC MTs, two HPC executive directors, and various nurses/personal support workers) who were available in the setting. DIQ = daily involvement questionnaire; ESAS = Edmonton Symptom Assessment System; STAI-S = State-Trait Anxiety Inventory Scale; HQLI-R = Hospice Quality of Life Index-Revised.

Three of the four participants either dropped out in the middle of the study or after day one due to high symptom burden and/or death. One participant remained in the study for the full seven days. Throughout the pilot week, all participants – including those who dropped out of the study – unanimously agreed that the current duration of the intervention (30-minutes) caused participant fatigue that made it difficult for them to complete the post-study questionnaires. Furthermore, there was an emerging consensus that using four different questionnaires to garner QoL and symptom severity was also too fatiguing. Gathering evidence from the literature and multiple music therapy and HPC professionals (see Table 1), we edited the proposed study protocol to meet participant preferences and adhere to evidence-based practices. To this extent, we determined that using only the ESAS, which has now become a standard of measurement in the HPC settings (Chang et al., 2000), would be used to measure the impact of the on participants. Furthermore, given the consensus of participants, the duration of the intervention was reduced to 15-minutes; this is also found to be the average duration of the typical music therapy sessions in primary care palliative settings. Taken together, we are hopeful that these changes will increase participant comfort levels when engaging with this research. As these modifications are grounded in the professional opinions and evidence from clinical practices of practising music therapists and individuals receiving HPC, we are confident that the quality of research will not suffer. Ultimately, it is important to ensure that participants, especially in settings like that of HPC, are respected and treated as humans first and study participants second.

We also opted to discard the inclusion criteria of ≥ 40 PPS and having a minimum ESAS score of 3. In HPC settings, where recruitment is already a limiting factor, such strict inclusion criteria may not be feasible and conducive to data collection. Furthermore, after consulting with professionals in both the music therapy and palliative care fields, we found that 1) PPS is not necessarily indicative of cognitive capacity, except at the extremes, and 2) all residents should be admitted and ideally have access to the interventions to determine the true effect of our intervention. In other words, it may be valuable to apply the study to the entire HPC population or employ a more pragmatic design, given that participants are English-speaking and are able to consent. This change may improve the generalisability of the study results. While these changes may improve the generalisability of the future studies in our research, it should be recognised that due to the small sample size of this feasibility pilot study, there is limited generalisability of the findings.

Modification to study protocol	Evidence and rationale
Only the ESAS will be used to assess participants' symptoms	To alleviate the level of fatigue associated with completing questionnaires and to increase participants' comfort levels.
Reduced intervention to 15-minutes	All four research participants explicitly expressed that 30-minutes was too long for the intervention sessions. HPC staff (including two MTs and three nurses) agreed that 15-minutes would be more appropriate. Data collectors noted that participants looked visibly fatigued at the 15-minute mark during multiple intervention sessions. This change has been made based on feedback to increase participant comfort levels when engaging with this research project.
Discarded inclusion criteria of ≥ 40 PPS and min. ESAS score of 3	Executive Directors and staff at both participating community hospices stated that this inclusion criteria would significantly limit recruitment due to majority of residents not meeting these numbers. For example, on day 1 of data collection, 10% of hospice residents met this inclusion criteria. This will help recruit more participants and may potentially improve the generalisability of study results.
Additional training for data collectors	In consultation with hospice stakeholders (HPC music therapists, staff, family members, residents if possible), the research team will develop an education module for data collectors to look for signs of discomfort, overstimulation, or other adverse effects of the music. This is critical since the inclusion criteria has been updated to include individuals who may not be able to stop the music/poetry themselves or who are unable to express the desire for the music/poetry to be stopped.
Add a question to the DIQ to ask if the participants also receive music therapy outside the music care sessions	This will allow researchers to gain an understanding of participant engagement in music therapy so it can be controlled for in the data analysis of the RCT.

Table 1: Summary of changes made to study protocol which will inform the study design of the follow-up feasibility study and phase 2 RCT

For compassionate reasons and due to the high symptom burden and fatigue of community HPC participants, it was not feasible for data collectors to obtain exact quotations during intervention sessions. Instead, data collectors scribed hand-written detailed notes documenting feedback from

participants on the DIQ. Table 1 includes (where applicable) the number of feedback points documented and that contributed to each methodological change. All four study participants expressed in at least one intervention session that music evoked emotions and helped them to explore emotions. They each described the healing capacity of music – connecting them to memories and assisting with processing of what had happened in their life and what was to come.

The completion of this phase 1 pilot trial is currently being used to inform the creation of a training manual. The content of the manual will be based on the experience of conducting this pilot trial, participant preferences, and best practices in the HPC settings as informed by the literature and professionals practising in these fields. The training manual will be intended to ease the recruitment process and provide data collectors with a comprehensive picture of how to best conduct the research in phase 2, commenting on aspects such as how to navigate emotionally charged situations and deal with the unpredictability of the setting. In addition, this training manual will help standardise the data collection process for the future RCT. On a broader scale, this training manual will also apply to any music care research conducted in these settings. All researchers will be aware of how to best conduct research in HPC and how to navigate scenarios which may pose problems to data collection and research quality. Ultimately, both the training manual and results of phase 2 will be important to healthcare providers as it will equip them with a new, convenient adjunct in HPC resident care.

Data collectors for this study will follow the training manual and the final research protocol developed for phase 2 of the study (Figure 2). This phase is intended to determine the effectiveness of the Room 217 music care playlists developed for HPC in alleviating negative symptoms and improving QoL. The phase 2 RCT will help objectively determine the effect of the Room 217 music care playlists on the QoL of hospice residents. Phase 2 will also introduce poetry playlists as a control intervention and will proceed as a pragmatic RCT design with half of the participants randomised into either the poetry or music care intervention arms. Figure 2 provides a schematic representation of the phase 2 pilot RCT study design, which can help future researchers who intend to conduct music care research in HPC settings.

LIMITATIONS

Several limitations exist in our study. The generalisability of the findings is limited by the fact that only four participants were recruited, of which only one completed all seven days of data collection. Regardless, all four participants and other healthcare providers and music care experts provided some form of feedback. This is indicative of the unpredictable nature of conducting research in HPC – a participant's level of pain and overall condition can change drastically within a short period of time and thus affect their participation. It is also of importance that the student authors of this study were also the primary data collectors. This may introduce potential biases, threatening the internal validity of our results. However, given the nature of this study, we do not expect it to significantly affect our findings. In phase 2 and in any future RCT conducted with our protocol, we recommend that data collectors are blinded masked and are independent of the rest of the research process. Due to the low sample size and number of participating sites, the results may inherently have low external validity. However, the results of phase 1 may provide healthcare providers and

researchers with valuable information and may be model for future RCT study designs in this population, and thus should not be disregarded due to the potentially low generalisability of the results.

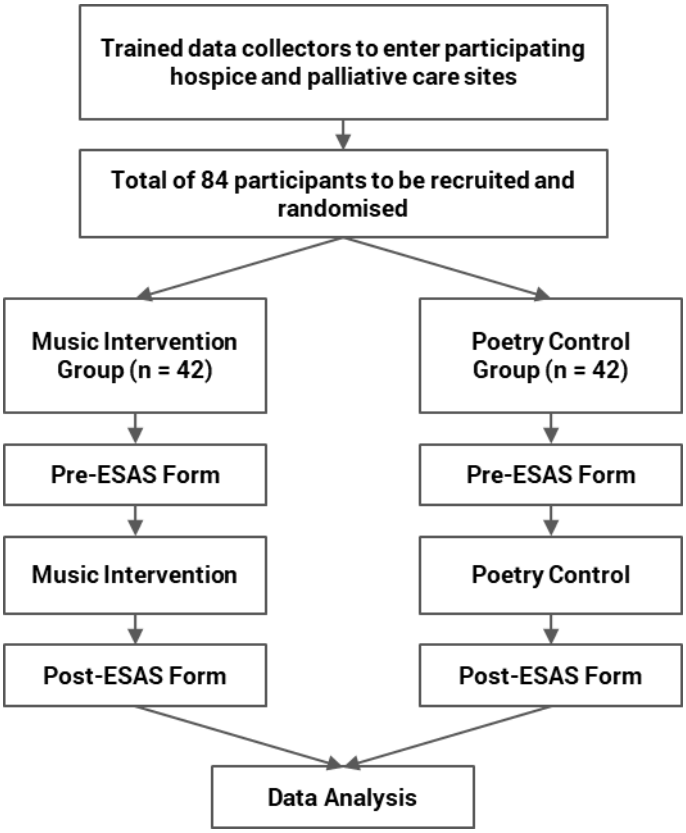

Figure 2: Schematic representation of the phase 2 pilot RCT[1]

CONCLUSION

Music care interventions such as the use of recorded playlists are important approaches to care that are still often met with hesitation. During the phase 1 pilot study, all four participants stated in at least one intervention session that recorded music helped evoke and explore emotions linked to memories of the past and what they believed was to come next. Data collectors' notes from several sessions indicated that participants, care staff, and hospice residents who declined to participate stated that music has a healing capacity. Whilst this pilot study did not include formalised qualitative interviews with participants and stakeholders, the anecdotal themes gathered from data collection sheets justify further scientific exploration of music's impact in the HPC setting. It is critical to collect evidence to understand the impact of music care on health and wellness outcomes so that caregivers and professionals are informed in their use of the music care approach in their care for community hospice residents. Music therapists are leaders in the field of music, health and wellness and play an important

[1] Data collectors will be recruited and trained according to the training manual and will enter one of three participating hospice and palliative care sites. From there, data collectors will recruit a total of 84 participants (method of sample size calculation indicated below), half of whom will be randomised into the music group, and the other half into the poetry group. The ESAS questionnaire will be administered prior to and after the 15-minute intervention for each of the seven days of data collection.

role in HPC. Music therapists can provide guidance and suggestions to care providers who choose to adopt a music care approach (Foster et al., 2021). In some settings, music therapy may be too costly or unfeasible to offer to all patients as often as requested. In this way, music care can be used to improve patient experience in their care facility in the context of limited resources. Furthermore, researchers should be aware of and ready to accept and adapt to the unpredictable nature of the HPC settings. This is especially crucial to recruitment and study completion rates. Researchers may consider the protocol developed from phase 1 of this study and incorporate the recommended steps to performing music care research in such settings. Finally, it is important to always consider the resident first as a person, and then as a study participant. In a setting where data is already difficult to collect, this may pose further problems to data collection and may cause the quality of research to suffer. However, resident dignity and preferences must be at the forefront of our considerations. It is therefore suggested that future research should consult the output of our study when performing research, especially music care research, in HPC settings.

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APPENDIX A: STUDY DESIGNS FOR FUTURE PHASE 1 & PHASE 2 RESEARCH

Phase 1: Follow-up feasibility study

The follow-up feasibility study will allow us to continue to test the feasibility and methodological assumptions associated with the RCT design in a larger sample given the small sample size of the first pilot study. The follow-up feasibility study will follow a similar format to the first pilot study, with certain changes to the study protocol that have been summarised in Table 1. In addition to these changes, researchers will also be testing the feasibility of poetry as the active control arm. Poetry was omitted from the first pilot study as playing recorded music versus recorded poetry from a logistical standpoint (i.e., time and equipment needed) is almost identical. However, it is necessary to test the use of poetry as a control intervention to garner the perspective and experiences of HPC residents prior to implementing it in the phase 2 RCT. Please note that the research team will determine if a third feasibility study is required, following the completion of the next follow-up feasibility study.

Phase 2: Pilot RCT

This study will employ a pragmatic RCT design as a mixed-methods study in which approximately half of the participants will be randomised into a control and the other remaining half in the experimental group. Randomisation sequences will be generated externally and allocation concealment will be employed. Group allocation will be revealed to subjects following informed consent, which is characterised by participants understanding the full details of this study and any risks that may present themselves. Because of the nature of the intervention, it is not possible to perform blinding and further stratification is restricted due to the small sample size. Confounding variables, like those of age, gender, and education, will be collected and controlled for during the statistical analyses.

The research team will not access the residents' health records. Instead, the in-house care staff will perform this screening and refer eligible participants to the research team. Participants randomised into the experimental group will receive and self-select a pre-recorded music care playlist, whereas those randomised into the control group will receive and self-select a pre-recorded soothing poetry playlist, daily, over the course of seven days, but are free to select different playlists within their intervention arm each day.

The music and poetry will be delivered using the same system with the same sound quality through a portable Bluetooth speaker system. The speaker system will allow others to listen with the participant. Pre-recorded poetry was chosen as a control intervention because it stimulates the same biological auditory system as music. This is an appropriate comparison for the pre-recorded music intervention because although it is delivered through the same fundamental biological pathway, poetry

sound waves are interpreted as non-patterned and non-musical. In contrast, music sound waves are interpreted as patterned and organised. It is important to recognise that, especially in the context of hospice care, it would be unethical to prevent participants from using music outside of the study. This is controlled for by performing pre- and post-evaluations exclusively for the session. In other words, this data will be collected concurrently rather than longitudinally. Further, an additional questionnaire (the daily involvement questionnaire) will be used to determine whether music has been used outside of the context of this study. This will allow the research team to later control for this (e.g., when it is used as a distraction technique outside of this study).

Prior to, and at the end of, each intervention, which will last for 15-minutes, one validated questionnaire, the ESAS, will be administered in order to evaluate the effectiveness of the intervention. Finally, an additional "daily involvement" questionnaire will be used as a means to ensure that the music intervention took place. This questionnaire will be completed on each of the seven days for each participant and will record their daily involvement. On the last day of the study (day seven), after the intervention, a semi-structured interview will be conducted to gather qualitative data concerning the effectiveness and opinions on the music or poetry interventions. The individual administering the above-mentioned questionnaires will remain with the resident for the duration of the intervention and listen to the intervention together with the resident; this holds true for both the control and experimental group.

With respect to the planned statistical analysis, changes in symptoms and QoL over time will be analysed using a mixed effects model approach. Because of their strength in dealing with missing values, mixed effects models are preferred over more traditional repeated measures ANOVA. This quantitative data will be analysed in the statistical program R. For the data collected through interviews on acceptability and satisfaction from participants, healthcare providers and volunteers, a thematic analysis will be conducted. NVivo10 will be used during the coding process to organise quotes and subsequently to display hierarchical content upon the completion of the analysis.

Ελληνική περίληψη | Greek abstract

Διερεύνηση δοκιμαστικής μελέτης σκοπιμότητας για την φροντίδα μουσικής σε ξενώνα ανακουφιστικής και παρηγορητικής φροντίδας

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ΠΕΡΙΛΗΨΗ

Η φύση του περιβάλλοντος ενός ξενώνα ανακουφιστικής και παρηγορητικής φροντίδας (ΞΑΠΦ) απαιτεί την υποστήριξη των συνεχώς μεταβαλλόμενων αναγκών των νοσηλευόμενων και την ανταπόκριση σε απρόβλεπτες καταστάσεις – ως εκ τούτου, αυτή η μη προβλεψιμότητα έχει ιστορικά αποτελέσει πρόκληση για τη συλλογή δεδομένων υψηλής ποιότητας σε τέτοια περιβάλλοντα. Μέσω μίας συναινετικής προσέγγισης ανατροφοδότησης, αυτή η πιλοτική μελέτη επιδιώκει να καθορίσει τη σκοπιμότητα της υλοποίησης μίας κλινικής δοκιμής με στόχο την κατανόηση του αντίκτυπου μίας προ-ηχογραφημένης παρέμβασης φροντίδας

μουσικής στην ποιότητα ζωής σε περιβάλλοντα ΞΑΠΦ. Συμπεριελήφθησαν τέσσερις συμμετέχοντες με βαθμολογία ≥ 40 στην Κλίμακα Ανακουφιστικής Απόδοσης [Palliative Performance Scale, PPS]. Προσχεδιασμένα άλμπουμ μουσικής φροντίδας προορισμένα για τον ΞΑΠΦ χρησιμοποιήθηκαν ως παρέμβαση για ελάχιστη διάρκεια 30 λεπτών. Χρησιμοποιήθηκαν η Edmonton Κλίμακα Αξιολόγησης Συμπτωμάτων, ο Δείκτης Ανακουφιστικής Ποιότητας Ζωής [Hospice Quality of Life Index], και η Κλίμακα Αξιολόγησης Άγχους [State-Trait Anxiety Inventory], αντικατοπτρίζοντας το σχεδιασμό μίας τυχαιοποιημένης ελεγχόμενης δοκιμής (ΤΕΔ), αλλά δεν έγινε στατιστική ανάλυση για την ερμηνεία αυτών στην παρούσα πιλοτική μελέτη. Η συλλογή δεδομένων συμπεριέλαβε επίσης την καταγραφή των απόψεων των συμμετεχόντων και των φροντιστών. Βάσει της ανατροφοδότησης των συμμετεχόντων, των επαγγελματιών υγείας και των ειδικών στη μουσική φροντίδα, η διάρκεια της παρέμβασης μειώθηκε σε τουλάχιστον 15 λεπτά, ενώ καταργήθηκαν τα προαπαιτούμενα κριτήρια συμμετοχής ως προς την Κλίματα Ανακουφιστικής Απόδοσης. Ο αριθμός των μέτρων έκβασης μειώθηκε από τρία σε ένα ώστε να μετριαστεί η υπερκόπωση των συμμετεχόντων. Τέλος, οι συμμετέχοντες επεσήμαναν ότι η προ-ηχογραφημένη μουσική παρέμβαση ήταν θεραπευτική, αιτιολογώντας έτσι την ανάγκη για περαιτέρω μελέτη των μέτρων έκβασης σχετικά με την ποιότητα ζωής. Η υλοποίηση μίας δεύτερης πιλοτικής μελέτης, για την επικύρωση των αλλαγών στο σχεδιασμό του πρωτοκόλλου της ΤΕΔ, θα είναι ένα καθοριστικής σημασίας βήμα στην ερευνητική διαδικασία, αν και τα αποτελέσματα της παρούσας μελέτης μπορούν να αξιοποιηθούν από ερευνητές που διεξάγουν ΤΕΔ σε ΞΑΠΦ για την ενημέρωση βέλτιστων πρακτικών.

ΛΕΞΕΙΣ ΚΛΕΙΔΙΑ

ξενώνας ανακουφιστικής και παρηγορητικής φροντίδας (ΞΑΠΦ), φροντίδα μουσικής, ποιότητα ζωής, δοκιμαστική μελέτη σκοπιμότητας, τυχαιοποιημένη ελεγχόμενη δοκιμή (ΤΕΔ)