## RESEARCH

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# Refining a hybrid music therapy intervention for chronic obstructive pulmonary disease and heart failure: a single arm pilot study

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### Abstract

**Background** Chronic obstructive pulmonary disease (COPD) and heart failure (HF) pose significant challenges to patients and the health systems that care for them. Music therapy has the potential to address these challenges, but its impact on readmission rates and quality of life remains largely underexplored. This study evaluated the feasibility, fidelity, and acceptability of a hybrid music therapy intervention as a precursor to a randomized controlled trial (RCT).

**Methods** Using a single-arm, mixed-methods approach, inpatients aged 30 - 89 with COPD or HF and access to home videoconferencing technology, a mobile device with a data plan, and a reliable support person were recruited during their hospitalizations. Patients with significant hearing/visual impairments, severe psychological comorbidities, terminal medical conditions, stage IV HF, or end-stage COPD were excluded. The intervention included 2 inpatient in-person sessions and 2 virtual sessions following discharge. Feasibility was assessed by rates of recruitment, retention, session attendance, and measure completion. Fidelity was evaluated by adherence to the session protocol, while acceptability was assessed through semi-structured interviews with randomly selected participants.

**Results** Of 113 patients approached, 20 (17.7%) were enrolled, and 85% were retained. Median participant age was 61.5 years, with 80% having HF and participants having high rates of anxiety (50%) and depression (35%). Overall session attendance was 57.5%, with higher rates for in-person (75%) compared to virtual sessions (40%). Adherence to the intervention protocol was > 80% across all monitored sessions. Challenges with the trial included difficulty reaching participants following discharge, frequent virtual session rescheduling, and participants' challenges using technology. Semi-structured interviews supported the acceptability of the intervention with three emerging themes (1) the therapeutic relationship facilitated a positive intervention experience, (2) need for strategies to improve post-discharge engagement in the intervention, and (3) impacts on mental health.

**Conclusions** Findings support the feasibility of hybrid music therapy among patients with COPD or HF. However, challenges in post-discharge communication and virtual session attendance were noted. These issues will be addressed in a subsequent feasibility RCT through implementing secure text-based communication in addition to phone communication to reach participants post-discharge, refined eligibility criteria (e.g., excluding patients on dialysis), and in-person technology instruction.

Trial registration ClinicalTrials.gov NCT06214325. Registered on January 9, 2024.

Keywords Chronic obstructive pulmonary disease, Heart failure, Music therapy, Feasibility, Telehealth, Quality of life

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#### Introduction

Chronic diseases such as chronic obstructive pulmonary disease (COPD) and heart failure (HF) pose significant challenges to individuals living with these conditions and the health systems that care for them. Globally, HF is estimated to affect 64.3 million people, including 1.7% of individuals across 13 European countries, and is the leading cause of hospitalizations among patients aged 65 and older [1]. Despite improvements in treatment for individuals with HF, hospital readmission rates remain high among this population where more than 1 million are hospitalized each year in the United States (US) [2]. Similarly, COPD affects approximately 391.9 million people around the world with an estimated prevalence of 10.3% among individuals 30-79 years old according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) case definition [3]. In the US, COPD affects over 12 million adults and is the third leading cause of 30-day readmissions [4].

Costs related to caring for these populations are substantial. A systematic review of 16 international studies estimated overall lifetime health care costs to be \$126,819 per patient with HF [5]. Another review of studies from 197 counties estimated that the overall economic costs of HF in 2012 were \$108 billion per year, with high spending variability between high-income and middle and lowincome countries [6]. The prevalence of HF in the US is predicted to increase by 46% from 2012 to 2030 with an associated increase in costs of \$390 billion [7], while hospitalizations for COPD exacerbation account for \$13.2 billion of the nearly \$50 billion annual direct costs for COPD in the US [8]. In addition to the direct cost of hospitalization, healthcare systems must also manage financial penalties issued from Medicare's Hospital Readmissions Reduction Program (HRRP). The HRRP states that if a hospital's readmission rate for diagnoses including COPD and HF exceeds the national average by a predetermined percentage, the hospital will be penalized with reductions in reimbursement from the Centers for Medicare and Medicaid Services, the US federal agency that provides health coverage for individuals aged 65 and older, persons with disabilities, and people with low socioeconomic status (SES) [9].

Mental health conditions and self-reported symptoms of depression and anxiety are prevalent among individuals with COPD and HF and significant risk factors for readmission [10] and impaired health-related quality of life (HRQoL) [7, 11]. Patients hospitalized for physical health conditions who have mental health comorbidities have been found to be 28% more likely to be readmitted compared to those without mental illness [10]. Among patients with COPD, psychological comorbidities are associated with lower reports of self-efficacy, more frequent and longer hospital readmissions, and reduced survival [12]. Previous research supports the effectiveness of mental health and multidisciplinary interventions for improving mental health and reducing readmission rates within this population [10, 13]. However, barriers such as limited mobility, lack of transportation access, financial barriers, time constraints, and stigma concerns may prevent individuals with HF or COPD from accessing these interventions [14]. To improve access, some providers have developed virtual forms of care, and recent studies support the feasibility of virtual interventions such as pulmonary rehabilitation [15, 16].

One intervention that has potential to address the mental health risk factors that contribute to readmission risk is music therapy, defined as the clinical and evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship by a credentialed professional who has completed an approved music therapy program [17]. Meta-analyses have demonstrated music therapy's efficacy for addressing psychosocial risk factors for readmission including stress [18], pain [19], anxiety [20], and depression among older adults [21]. Previous music therapy studies among patients with COPD have demonstrated its benefits for acute symptom management, improving pulmonary functioning outcomes [22, 23], and building a sense of community when delivered in a group setting. Among patients with HF, prior work has investigated the mechanisms by which music engagement can positively influence mental wellbeing and cardiovascular measures via increasing parasympathetic activation [24].

Furthermore, from a mechanistic standpoint, music interventions have demonstrated efficacy within randomized controlled trials (RCTs) for not only reducing perceived stress [18], but also decreasing serum cortisol (an important biomarker for stress and inflammation) among hospitalized patients [25]. Given that psychological stress is a modifiable risk factor associated with higher risk for readmission among patients with HF [26] and patients with COPD [27], music therapy may further reduce readmission risk by reducing both physiological and psychological stress. Given the increasing integration of music therapists within hospitals [28, 29], music therapy may have unique advantages compared to other mental health interventions (e.g., cognitive behavioral therapy delivered by a psychologist) which may not be as readily available within US hospitals.

However, few studies have investigated psychosocial outcomes of music therapy interventions specifically among people with COPD and HF. Only two music therapy studies have examined readmissions as an outcome to date [30, 31], and no studies have examined the impact of music therapy on readmission among patients with HF or COPD. In addition to a lack of research on readmission outcomes within music therapy, there remain gaps in understanding (1) longitudinal effects on critically important outcomes such as HRQoL and self-efficacy; (2) the feasibility and acceptability of virtual care models; and (3) fidelity when delivering multiple manualized interventions. The few studies that exist on these topics have been conducted among adults with chronic pain and support music therapy's feasibility, acceptability, and preliminary efficacy for addressing HRQoL and improving self-efficacy [32–34] as well as the feasibility of a virtual care model [35].

Therefore, given the (1) psychosocial factors driving risk for 30-day admission; (2) demonstrated efficacy of music therapy for addressing these factors within other populations [18-20]; (3) lack of music therapy studies investigating 30-day readmission and HRQoL; and (4) critical importance for hospitals to reduce 30-day readmission rates for adults with chronic illness, a twoyear research project entitled Music therapy to Address patients' JOuRneys with CHronic illness, Outcomes, and ReaDmission (MAJOR CHORD) was launched to address this major gap in music therapy research and begin the process of investigating whether music therapy could address HRQoL and readmission risk among people with COPD or HF. Prior to examining music therapy's efficacy with a fully powered RCT, the study team recognized the need to perform a feasibility RCT [36]. However, given the novelty of conducting a hybrid music therapy intervention and the anticipated challenges of collecting follow-up data with this population, a single-arm pilot was initiated as a first step to allow the study team to quickly uncover and generate solutions to intervention and data collection challenges prior to devoting more resources to a feasibility RCT with a comparison arm. Thus, the purpose of this study was to (1) examine the feasibility, fidelity, and acceptability of the music therapy intervention and collection of patient-reported outcome measures (PROMs) through 30 days after hospital discharge and (2) determine which modifications (if any) would need to be made to the intervention and data collection processes prior to initiating a feasibility RCT.

#### Methods

#### Design

This study utilized a mixed-methods intervention design in which qualitative data were embedded within the framework of a single-arm trial [37]. A mixed-methods intervention design was chosen to enhance understanding of participants' mental health, experience with the music therapy exercises, and perceived acceptability of the music therapy intervention. This qualitative data was also used to provide context for any potential changes that would need to be made to intervention delivery and data collection procedures prior to conducting a feasibility RCT. Per guidance from the National Center for Complementary and Integrative Health (NCCIH) [36], the sample size (N = 20) was primarily based on how many participants could practically be recruited, provided music therapy interventions, and evaluated for future intervention and data collection refinements in the feasibility RCT given the time and budget allotted within the grant. Sample size determination was also informed by prior music therapy feasibility studies among patients with sickle cell disease (N = 12 in intervention arm) [32], patients with chronic pain (N = 22 in intervention arm) [34], and adolescent and young adults undergoing stemcell transplant (N = 7 in intervention arm) [38].

#### Participants

This study was conducted between January 2024 and April 2024 at University Hospitals Cleveland Medical Center, a large Midwestern hospital in the United States. Subjects who (1) were aged 30 to 89; (2) had a diagnosis (primary or secondary) of either COPD or HF documented within the electronic health record (EHR); (3) were anticipated to remain hospitalized for  $\geq 2$  days following recruitment; (4) were able to read and understand English; (5) had access to Wi-Fi, a video conferencing device (i.e. laptop, tablet, and/or PC), and an active email address; (6) had a mobile device with an active data plan; and (7) had a reliable support person who could be available to respond in case of a medical emergency were recruited to participate in the study.

Patients were excluded from participation if they were (1) diagnosed with a significant hearing and/or visual impairment that prevented them from fully engaging in the music therapy intervention or completing written outcome measures; (2) unable to independently provide consent; (3) reporting active suicidal ideation during their hospital admission; (4) diagnosed with a severe psychological comorbidity (e.g., psychosis/schizophrenia) preventing them from fully engaging in the intervention; (5) admitted to an intensive care unit (ICU) at the time of screening; (6) receiving active cancer treatment; (7) diagnosed with a medical condition likely to be terminal within 24 weeks; (8) on a wait list for heart transplantation or ventricular assist device; (9) diagnosed with New York Heart Association (NYHA) Stage IV HF or endstage COPD based on EHR documentation; (10) receiving hospice care; or (11) engaged in active substance abuse.

Eligibility criteria were modified during the trial to reduce barriers to enrollment. These modifications included (1) removing an initial inclusion criteria of reporting at least moderate depression (Patient Health Questionnaire [PHQ]– 9 [39] score  $\geq 10$ ) or anxiety (Generalized Anxiety Disorder [GAD]– 7 [40] score  $\geq 10$ ) as this required a long and burdensome screening process that hindered recruitment; (2) increasing the eligible age range from 40–89 to 30–89; and (3) excluding patients with confirmed or suspected COVID- 19, MRSA, or *C.diff* infection(s) as hospital policy prevented music therapists from working with these patients within their hospital rooms. Eligibility criteria changes did not alter the participant safety plan described below.

#### **Ethics and consent**

This study was conducted in accordance with the Declaration of Helsinki. This study was approved by the University Hospitals Cleveland Medical Center Institutional Review Board (STUDY20230897). Written, informed consent was obtained from all participants. The study is registered in clinicaltrials.gov (NCT06214325). Procedures utilized to protect participant safety included (1) storing patient identifiers in Research Electronic Data Capture (REDCap), a secure, web-based application designed to support structured data capture, log changes to data, and automate survey distribution for research studies [41]; (2) identifying participants by the number assigned to them at the beginning of the study rather than by name within the REDCap database and interview transcripts; (3) eliminating participants' statements of their own names from transcripts; and (4) storing deidentified audio recordings of the participants' interviews and music therapy interventions on a HIPAA-compliant cloud server.

#### Procedures

#### Screening and enrollment

Potentially eligible participants were initially identified through EHR or verbal referrals from medical teams or screening lists of patients admitted to the medical units where patients with COPD or HF were typically admitted. Flyers and other study advertisements were not used in this study. Patients meeting initial criteria based on age, diagnosis, primary language, and precautions were added to a list in the EHR. Study staff then approached these patients' nurses and medical teams to obtain verbal referrals, determine whether patients were appropriate to approach for study participation, and confirm anticipated discharge dates. Patients referred at this stage were entered into the study's REDCap database. The study coordinator then reviewed these patients' health records to confirm whether they met additional eligibility criteria that could be evaluated using EHR data (e.g., terminal illness, substance abuse, psychological comorbidities). Following EHR review for initial eligibility, study staff then approached patients within their hospital rooms. After explaining study procedures, technology access was assessed by asking patients whether they had (1) an active email address, (2) access to and some degree of comfort with videoconferencing technology, (3) Wi-Fi at home, and (4) a mobile device with an active data plan. After confirming these technology-based criteria and patients' access to a reliable support person, the study staff obtained written informed consent.

#### **Baseline assessment**

Immediately following informed consent, participants verified their contact information, completed a demographics survey, and completed measures including the Perceived Stress Scale- 4 (PSS- 4) and Patient Reported Outcome Measurement Information System (PROMIS) measures of self-efficacy, emotional support, instrumental support, and HRQoL via a REDCap survey delivered on an iPad.

#### Intervention

Planed study procedures included four music therapy sessions conducted by a board-certified music therapist (MT-BC). The first two sessions were performed in participants' hospital rooms at least 24 hours apart. Following discharge, the study coordinator contacted participants to schedule their third and fourth music therapy sessions, which were provided virtually over Zoom. These virtual sessions were typically scheduled 7 days apart. Virtual sessions could be rescheduled based on participant availability up to 30 days post-discharge, thus the distance between sessions 3 and 4 varied from a minimum of 4 days to a maximum of 12 days (median and interquartile range [IQR] 6.5 [5.25, 7] days). To help participants navigate the videoconferencing platform, a printed "Zoom 101" document was provided to all participants at the time of enrollment. This document provided screenshot guides of procedures for downloading Zoom, joining virtual meetings, turning the camera on and off, muting/unmuting, and troubleshooting common videoconferencing challenges. Prior to their third session, the study coordinator hosted virtual technical assistance sessions with participants to help them practice skills such as logging into Zoom, turning their camera on, and unmuting themselves. In addition, the study coordinator mitigated common technical challenges by calling participants before their virtual sessions to help them join the Zoom call or connect to audio if needed.

#### Follow-up assessments

Participants were asked to complete PSS- 4 and PROMIS measures again at 15- and 30-days post-discharge. These intervals were chosen to understand participants' self-efficacy, emotional support, instrumental support,

and HRQoL after the completion of the fourth session (anticipated to be completed within two weeks following discharge) and at the cutoff for evaluating the 30-day readmission outcome. REDCap links to surveys were sent via text message using Twilio [42] with up to two subsequent reminders as needed.

#### Qualitative interview

Participants who reported being willing to be approached for an interview at the time of informed consent were randomized to determine whether they would be interviewed. Participants selected for interview were invited to complete a 30-minute semi-structured interview focused on their experience with the trial. This interview was conducted within 1 week following 30-days post-discharge.

#### Participant safety plan

Since the clinical trial asked sensitive questions pertaining to participants' mental health, a system was developed to alert study staff and participants' care teams if their responses to the four depression items on the PROMIS- 29 indicated elevated depression. Participants reporting responses of "often" or "always" on any of the four PROMIS Depression items were further assessed using the 9<sup>th</sup> item from the PHQ- 9 [39] which assesses thoughts of suicide or self-harm. If a participant reported a score  $\geq 1$  on this item, study staff were immediately notified via an automated REDCap alert. Study staff then notified that participant's clinical care team (if they were still admitted) or collaborated with a pair of psychiatrists to contact the participant, assess for suicidal intent, and connect the participant to appropriate mental health resources as needed (if they were discharged). To help ensure timely response in such a scenario during business hours, 15- and 30-day follow up questionnaires were only sent on Mondays, Tuesdays, or Wednesdays.

#### Music therapy intervention Development

The series of four music therapy interventions developed for this study were informed by (1) evidencedbased music therapy practices utilized in the medical setting [43]; (2) the principal investigator's (PI) clinical and research experience providing music therapy among patients with other chronic illnesses [32]; and (3) feedback from music therapists who had several years of clinical experience providing music therapy interventions to patients with HF or COPD. The intervention was designed to provide education and practical music therapy exercises for adults with HF or COPD to easily access and practice every day via their own mobile devices to manage symptoms and improve HRQoL. The second author, a board-certified music therapist (MT-BC) with over 10 years of experience working with adults with chronic illness, provided all the music therapy interventions using the same standardized session plans.

Similar to prior music therapy clinical trials which tailored aspects of intervention delivery (e.g., music genre) to meet patients' needs and preferences [44], additional strategies were deployed to help maintain fidelity. These included (1) providing standardized training covering the study protocol and clinical needs of patients with HF and COPD; (2) conducting role-playing exercises until adequate therapeutic, musical, and technological skills were displayed; (3) monitoring session dose, length, and intervention procedures using REDCap and session recordings to ensure consistent treatment delivery; (4) holding bi-weekly conference calls to discuss challenges, communicate updates, and answer therapists' questions; and (5) ensuring appropriate receipt of treatment by training MT-BCs to use active questioning and behavioral observation to assess whether participants comprehended how to access music exercises.

#### Overview

Each participant was given the opportunity to engage in four music therapy sessions: two conducted while admitted to the hospital and two conducted virtually within 30 days following discharge. All sessions involved (1) setting an agenda, (2) an explanation of the music exercise, (3) a demonstration and live recording of the music exercise in which the MT-BC engaged the participant in practicing the music exercise (e.g., breathing, imagery, harmonica exercise), (4) time to process the participant's response to the exercise, (5) time for the MT-BC to electronically deliver the music exercise to the participant and ensure they had all materials necessary to use the exercise at home, and (6) an assignment for the participant to practice the music exercise taught in that session at least once per day until the following music therapy session. Within each session, the MT-BC collaborated with participants to prioritize time for self-care and address barriers to engaging in the music therapy exercises.

The first two sessions were conducted in-person within participants' hospital rooms at bedside. Session 1 (median [IQR] length 58 [52.25, 63] minutes) objectives included (1) introducing music therapy, (2) understanding the participant's music preferences, (3) improvising music to reflect the participant's experience with their symptoms and stressors, (4) providing education on the use of music to address symptoms of HF or COPD, and (5) providing a personalized live music listening intervention. Session 2 (41 [38.75, 48] minutes) began with a review of the content from session 1 followed by education and engagement in breathing exercises with either

soothing rhythmic music co-created with the participant (for participants with HF) or with the use of the harmonica (for participants with COPD).

Sessions 3 and 4 were conducted within 30 days of discharge, with participants engaging in the session virtually on their own devices using Zoom. Given that (1) discharge disposition (e.g., to home, a family member's residence, or a skilled nursing facility) was often unknown at the time participants were recruited and (2) controlling the location where participants could attend virtual sessions would have limited accessibility and generalizability, participants could attend virtual sessions from any postdischarge location (e.g., home or skilled nursing facility) so long as they were not readmitted to a hospital. Session 3 (55 [48, 57] minutes) reviewed content from session 2 and provided a personalized music-assisted relaxation and imagery intervention. Session 4 (60 [54.5, 65.5] minutes) served as a conclusion of the intervention, beginning with a discussion of what was learned in previous sessions, followed by the completion of a structured coping plan to help manage future stressors, and concluding with a gratitude songwriting intervention. A detailed description of each music therapy intervention in table and narrative format is provided in the Supplemental Material.

#### Music technology

All music therapy interventions were designed to be cocreated with participants and simultaneously recorded in GarageBand, a free digital audio workstation developed for MacOS, so that the participant left with a practical music therapy exercise following each session. Garage-Band allowed therapists to quickly create multiple tracks, record, mix, add loops and effects, and export audio files for participants. In-person sessions were conducted and recorded within a mobile music therapy studio. This plug-and-play studio on wheels included all the materials needed to facilitate and record sessions in the participant's hospital room, was small enough to fit within smaller hospital rooms, and could be setup within a few minutes. The studio included a dynamic microphone, 2 sets of headphones for the MT-BC and participant to listen to the intervention privately without disturbing other patients and staff, a MacBook Air configured with GarageBand, a Zoom H6 multitrack audio interface, XLR and instrument cables, a guitar holder, an iPad, and a foldable stool. All GarageBand settings, effects, and levels were preset by the MT-BC prior to the session.

The MT-BC facilitated virtual sessions 3 and 4 within an office-based music therapy studio. To ensure that the sound created within GarageBand was transmitted accurately and with high fidelity, the Blackhole audio interface [45] was used to transmit audio from Garage-Band through Zoom. The Zoom audio settings were also configured for "Original sound for musicians," "Highfidelity music mode," "Echo cancellation," and "Stereo audio." This afforded the opportunity for the participant to experience the high-quality audio simultaneously as the therapist composed and played it within the Zoom application on their own device. This environment also enabled the therapist to further personalize music therapy interventions through adding additional instruments (e.g., guitars, keyboards, drums, and strings), nature sounds, reverb, and other audio effects.

#### Renumeration

Out of respect for the time and effort participants gave to complete study procedures [46], participants received \$20 at the conclusion of each virtual music therapy session (sessions 3 and 4) and \$20 for every survey completed (15-and 30-days post discharge). They also received \$20 for completing the interview. This is consistent with other clinical trials [32, 47]. Participants were issued ClinCard [48] prepaid debit cards during the enrollment session, and funds were loaded after completing each research activity described above.

#### Measures and data collection

#### Demographics and clinical characteristics

The following information was extracted from each participant's medical record: age, primary diagnosis, insurance type, whether they were currently receiving home oxygen, presence of physical (e.g., diabetes, hypertension) and psychological (e.g., depression, anxiety) comorbidity diagnoses, healthcare utilization (i.e., hospital admissions and emergency department visits) within the past 12 months, and details related to adverse events. Insurance status has a significant effect on access to care among patients with HF [49] and COPD [50] in the US and was collected to better understand participants' SES and ability to access health services. Adverse events including hospital readmissions, medical events (e.g., cerebrovascular accident, transfer to ICU), and psychiatric events (e.g., delirium) that would prevent study completion were also tracked. These events were evaluated by physicians on the study team to determine whether they warranted withdrawing participants from the study.

Participants self-reported the following information via a REDCap survey immediately following informed consent: gender, race, ethnicity, marital status, employment status, annual household income, whether they lived alone, smoking status (i.e., never, former, current), number of years living with their primary diagnosis, current engagement in psychological therapies, and prior self-reported involvement in music therapy. This demographics and clinical history survey was developed for this study by the research team.

#### Patient-reported outcome measures

Perceived stress was measured using the PSS- 4, a well-validated instrument for assessing stress perception in the general population [51] and designed to measure the degree to which situations in one's life are appraised as stressful [52]. Previous studies have used the PSS to assess the relationship between perceived stress [53] and incident HF as well as acute care use among patients with COPD [27].

General self-efficacy, emotional support, instrumental support, and HRQoL were assessed using PROMIS measures [54], which are well-validated in multiple populations and scored on a general population-based T-score metric with a mean of 50 and an SD of 10 [54]. General self-efficacy, emotional support, and instrumental support were measured using 4-item short form versions of the measures. The PROMIS- 29 (a series of 4-item subscales of anxiety, depression, fatigue, sleep disturbance, and pain interference, where higher scores indicate greater severity of the specific symptom) was used to assess HRQoL. The PROMIS- 29 also includes 4-item subscales measuring ability to participate in social roles and activities and physical function. Higher scores indicate a greater ability to participate in social roles and activities and less severity for physical function impairment.

#### Feasibility

Rates of recruitment, retention, measure completion, session attendance, and music exercise use were collected to determine the feasibility of the MAJOR CHORD protocol and intervention. The PI and study coordinator also kept a log of study challenges and modifications which were reviewed in bi-weekly meetings.

#### Fidelity

Fidelity refers to the degree to which the delivery of an intervention adheres to the protocol or program developed [55]. Each music therapy session was recorded, and the MT-BC (second author) entered structured data documenting the music therapy session and adherence to steps of a manualized protocol. The PI reviewed all recordings and session documentation for the first 5 participants followed by every 5<sup>th</sup> participant thereafter and documented fidelity to the session plans within a structured form in REDCap. Fidelity rates were calculated as the total number of session plan tasks completed (e.g., introduction, education on diaphragmatic breath, processing the experience of the music exercise) divided by the total number of tasks.

#### Acceptability

Feasibility and acceptability were further assessed using a semi-structured interview. All interviews were conducted and recorded by the study coordinator. Interview guide prompts focused on (1) intervention acceptability (e.g., whether music fit participants' preferences, challenges with participating in the intervention, relationship with the music therapist); (2) barriers to completing music therapy sessions within the hospital and at home (e.g., scheduling challenges, hospital staff interruptions, connectivity issues); (3) experience with completing the home music therapy exercises (e.g., consistency, barriers and facilitators of engagement); (4) the impact of the intervention on their physical and mental health; and (5) whether anything could have been done differently to improve the sessions.

#### Data analysis

#### **Baseline characteristics**

Descriptive statistics including median, IQR, counts, and percentages were conducted to summarize baseline characteristics. Median and IQR were chosen given the small sample size and lack of normally distributed data. Baseline PROMIS measures were converted to T-scores using HealthMeasures scoring service [56] and summarized using descriptive statistics and boxplots. Given the purpose of this study (i.e., feasibility and refinement), small sample size, limited response rates at 15- and 30-days, and guidance from the NCCIH [36] to not conduct inferential statistics of outcome effects within pilot studies, descriptive statistics of follow-up PROMs were not summarized or compared to baseline.

#### Feasibility

Counts and percentages were used to summarize rates of recruitment and retention. Measures of attendance, measure completion, and music exercise use were summarized among all recruited and all retained participants. Additionally, challenges presented and solutions implemented over the course of the trial were summarized in a table. A specific feasibility threshold was not set for this study as (1) the primary goal was to refine the intervention and data collection procedures prior to conducting a larger feasibility RCT in which feasibility thresholds will be specified; (2) similar pilot and feasibility studies of music therapy among patients with chronic illness did not set such thresholds [32-35]; and (3) there are no prior hybrid music therapy studies for direct comparison describing recruitment, session attendance, or measure completion rates within this population.

#### Fidelity

Rates of checklist adherence were compared to an established 80% threshold for examining fidelity of a music therapy intervention conducted among children with cancer and their parents [44].

#### Acceptability

For the gualitative data, all interviews were recorded, professionally transcribed, and checked for accuracy. The fourth and senior authors independently analyzed the interviews using conventional qualitative content analysis [57] in which information is extracted directly from participants' comments without imposing preconceived categories or philosophical perspectives. In all cases, each assigned transcript was reviewed line-by-line and independently coded using a constant, comparative method of qualitative data analysis [57]. All data from the interviews that appeared to be directly related to the study aims were extracted. Any coding discrepancies were discussed between the coders until consensus was achieved. The coded data were then organized into categories to identify themes. Findings from the independent analyses were consolidated and presented to the study team. Members of the research team reviewed findings for accuracy of generated themes, interpretations of the data, and conclusions. Descriptive statistics, tables, and figures were generated using R Version 4.4.1 [58] and RStudio Version 2024.04.2 + 764 [59]. Qualitative analysis was conducted using NVivo v14.0, QSR international, Melbourne, Australia.

#### Results

#### **Demographics and clinical characteristics**

The demographics of the study population are described in Table 1. The median age of all participants was 61.5 years (range 44–77 years), with the majority identifying as female (65%) and non-Hispanic (100%). Eleven (55%) participants identified as White, and 35% identified as Black or African American. Most participants (60%) reported an annual household income of less than \$50,000, 35% of the participants reported being unable to work, and 35% were Medicaid beneficiaries.

The clinical characteristics of the study population are presented in Table 2. Most participants were diagnosed with HF (80%). Among all participants, there was a high prevalence of anxiety (50%) and depressive disorders (35%). Other clinically relevant comorbidities among study participants included hypertension (85%), diabetes (45%), being a current or former smoker (75%), and hyperlipidemia (40%). Among participants with HF, most (62.5%) were classified as Class III according to the NYHA classification system demonstrating high disease burden.

#### Table 1 Demographics

| Variable                                       | <i>N</i> = 20        |
|--|----------------------|
| Age, median (IQR)                              | 61.50 (52.50, 68.50) |
| Age, range                                     | 44.00 - 77.00        |
| Gender, n (%)                                  |                      |
| Female   | 13 (65.0%)           |
| Male   | 7 (35.0%)            |
| Race, n (%)                                    |                      |
| White  | 11 (55.0%)           |
| Black or African American                      | 7 (35.0%)            |
| Two or more races                              | 2 (10.0%)            |
| Ethnicity, n (%)                               |                      |
| Non-Hispanic                                   | 20 (100.0%)          |
| Marital status, n (%)                          |                      |
| Single (never married)                         | 8 (40.0%)            |
| Married, or in a domestic partnership          | 7 (35.0%)            |
| Widowed  | 1 (5.0%)             |
| Divorced                                       | 4 (20.0%)            |
| Participant lives alone, n (%)                 | 7 (35.0%)            |
| Employment status, n (%)                       |                      |
| Retired  | 8 (40.0%)            |
| Unable to work                                 | 7 (35.0%)            |
| Unemployed and not currently looking for work  | 2 (10.0%)            |
| Employed full time (40 or more hours per week) | 1 (5.0%)             |
| Employed part time (up to 39 hours per week)   | 1 (5.0%)             |
| Missing  | 1 (5.0%)             |
| Household income, n (%)                        |                      |
| \$0 to \$9,999                                 | 2 (10.0%)            |
| \$10,000 to \$24,999                           | 4 (20.0%)            |
| \$25,000 to \$49,999                           | 6 (30.0%)            |
| \$50,000 to \$74,999                           | 3 (15.0%)            |
| \$75,000 to \$99,999                           | 1 (5.0%)             |
| Over \$150,000                                 | 1 (5.0%)             |
| Prefer not to answer                           | 3 (15.0%)            |
| Insurance status, n (%)                        |                      |
| Medicare                                       | 10 (50.0%)           |
| Medicaid                                       | 7 (35.0%)            |
| Private  | 2 (10.0%)            |
| Other  | 1 (5.0%)             |

#### **Baseline PROMs**

Baseline PROMs among all participants are summarized in Supplemental Table 1 and Supplemental Figure 1. Participants reported values (median [IQR]) on PROMIS measures that were more severe than those reported by the normal population (T-score = 50) [54] in several domains. These included higher than normal anxiety (58.70 [53.70, 63.50]), fatigue (63.70 [55.45, 66.75]), pain interference (66.10 ([55.70, 68.85]), and sleep disturbance (60.20 [52.10, 61.90]) as well as lower than normal

#### Table 2 Clinical characteristics

| Variable  | <i>N</i> = 20       |  |  |  |
|---|---------------------|--|--|--|
| <br>Primary diagnosis, n (%)                      |                     |  |  |  |
| Heart failure                                     | 16 (80.0%)          |  |  |  |
| Chronic obstructive pulmonary disease             | 4 (20.0%)           |  |  |  |
| Years living with primary diagnosis, median (IQR) | 3.74 (0.21, 12.59)  |  |  |  |
| Smoking status, n (%)                             |                     |  |  |  |
| Never smoker                                      | 5 (25.0%)           |  |  |  |
| Former smoker                                     | 13 (65.0%)          |  |  |  |
| Current some day smoker                           | 2 (10.0%)           |  |  |  |
| Receiving home oxygen therapy, n (%)              | 4 (20.0%)           |  |  |  |
| Hospital length of stay (days), median (IQR)      | 11.98 (6.12, 15.11) |  |  |  |
| Hypertension, n (%)                               | 17 (85.0%)          |  |  |  |
| Diabetes, n (%)                                   | 9 (45.0%)           |  |  |  |
| Hyperlipidemia, n (%)                             | 8 (40.0%)           |  |  |  |
| Prior myocardial infarction, n (%)                | 4 (20.0%)           |  |  |  |
| Prior cerebrovascular accident, n (%)             | 4 (20.0%)           |  |  |  |
| Anxiety disorder, n (%)                           | 10 (50.0%)          |  |  |  |
| Depressive disorder, n (%)                        | 7 (35.0%)           |  |  |  |
| Prescribed home psychiatric medications, n (%)    | 4 (20.0%)           |  |  |  |
| ED visits in past 12 mo, median (IQR)             | 2.00 (1.00, 4.50)   |  |  |  |
| Hospital admissions in past 12 mo, median (IQR)   | 2.00 (1.00, 4.50)   |  |  |  |

ED Emergency department, IQR Interquartile range, MO Months

physical function (32.55 [28.70, 37.90]), and ability to participate in social roles and activities (37.30 [36.45, 42.40]).

#### Feasibility

Table 3 summarizes measures of recruitment, retention, attendance, measure completion, and music exercise use, while Fig. 1 presents a CONSORT diagram of study participants. Of 113 patients approached, 75 (66.4%) were screened after expressing at least some interest in participating, 30 (26.5%) were deemed eligible, and 20 (17.7%) were enrolled. Of the 20 enrolled participants, 17 (85%) were retained, and three withdrew due to experiencing a medical or psychiatric adverse event unrelated to the music therapy intervention during their hospital admission. On average, across 15.29 weeks of recruitment, 14.1 patients were referred, 7.4 patients were approached, and 1.3 patients were enrolled per week.

Among all enrolled participants (N = 20), 46/80 (57.5%) music therapy sessions were attended, with 30/40 (75.0%) in-person and 16/40 (40.0%) virtual sessions attended. All but one participant (95%) attended  $\geq 1$  session, while only 3 (15%) attended all 4. All 46 sessions that were initiated were completed without being halted due to participants' medical conditions, procedures, or technical challenges. Among retained participants (N = 17), 44/68 (64.7%) music therapy sessions were attended, with 28/34 (82.4%) of in-person and 16/34 (47.1%) of virtual session attended. Of these 17 participants, 9 (52.9%) completed 15-day measures, 12 (70.6%) completed 30-day follow-up measures, and 10 (58.8%) reported at least one instance of using one of the music therapy exercises taught over the course of the intervention.

Table 4 presents a list of challenges and corresponding solutions that were discovered and implemented over the course of the trial. Many of these challenges concerned communication with participants post-discharge and logistics related to recruitment and technical assistance. The solutions identified were based on analysis from the pilot and discussions among study team members.

#### Fidelity

The MT-BC demonstrated high fidelity (> 80%) across all sessions that were reviewed. Median [IQR] session fidelity rates (total number of session plan tasks completed divided by the total number of tasks) were as follows: Session 1 (95.1% [91.5, 97.6]), Session 2 among patients with COPD (92.0% [90.0, 94.0]), Session 2 among patients with HF (95.0% [92.5, 97.5]), Session 3 (94.4% [91.7, 95.8]), and Session 4 (96.2% [88.5, 96.2]).

#### Acceptability

Three major themes emerged from the analysis of five semi-structured interviews (1) the therapeutic relationship facilitated a positive intervention experience, (2) need for strategies to improve post-discharge engagement in the intervention, and (3) impact on mental health. Quotes illustrating these three themes are presented along with their descriptions below.

## The therapeutic relationship facilitated a positive intervention experience

All interview participants generally agreed that the length, convenience, and timing of the music therapy intervention were acceptable. A few participants remarked on the benefits of the intervention for breaking up the monotony of the hospitalization, with one participant stating:

"In the hospital setting, you actually look forward to anything that is a change in routine, because there's not much to look forward to. There were so many restrictions on my diet that the meals were nothing to even look forward to. That (music therapy) was really the bright point of my day."

Several participants discussed the importance of the MT-BC in facilitating their engagement with the intervention, providing helpful instructions, and tailoring the intervention to their preferences.

"Oh, she never seemed rushed, and she's a very nice person. I'm not good at playing the harmonica, so it's

#### Table 3 Feasibility measures

| Measure                          | Denominator           | Numerator             | Result                       |
|----------------------------------|-----------------------|-----------------------|------------------------------|
| All approached ( $N = 113$ )     |                       |                       |                              |
| Recruitment rate                 | 113 approached        | 20 enrolled           | 17.7%                        |
| Referral pace (average)          | 15.29 weeks           | 216 referred          | 14.1 patients referred/week  |
| Approach pace (average)          | 15.29 weeks           | 113 approached        | 7.4 patients approached/week |
| Recruitment pace (average)       | 15.29 weeks           | 20 enrolled           | 1.3 patients enrolled/week   |
| Retention rate                   | 20 enrolled           | 17 retained           | 85.0%                        |
| Enrolled ( $N = 20$ )            |                       |                       |                              |
| Mean attendance rate             | 80 potential sessions | 46 attended sessions  | 57.5%                        |
| Mean in-person attendance rate   | 40 potential sessions | 30 attended sessions  | 75.0%                        |
| Mean virtual attendance rate     | 40 potential sessions | 16 attended sessions  | 40.0%                        |
| ≥ 1 session attendance rate      | 20 enrolled           | 19 attended ≥ 1       | 95.0%                        |
| ≥ 3 sessions attendance rate     | 20 enrolled           | 9 attended ≥ 3        | 45.0%                        |
| All sessions attendance rate     | 20 enrolled           | 3 attended all        | 15.0%                        |
| Mean session completion rate     | 46 attended sessions  | 46 completed sessions | 100.0%                       |
| 15-day measure completion rate   | 20 enrolled           | 9 completed measures  | 45.0%                        |
| 30-day measure completion rate   | 20 enrolled           | 12 completed measures | 60.0%                        |
| Any music exercise use ever      | 20 enrolled           | 10 reported use       | 50.0%                        |
| Retained ( $N = 17$ )            |                       |                       |                              |
| Mean attendance rate             | 68 potential sessions | 44 attended sessions  | 64.7%                        |
| Mean in-person attendance rate   | 34 potential sessions | 28 attended sessions  | 82.4%                        |
| Mean virtual attendance rate     | 34 potential sessions | 16 attended sessions  | 47.1%                        |
| $\geq$ 1 session attendance rate | 17 retained           | 17 attended $\geq$ 1  | 100.0%                       |
| ≥ 3 sessions attendance rate     | 17 retained           | 9 attended ≥ 3        | 52.9%                        |
| All sessions attendance rate     | 17 retained           | 3 attended all        | 17.6%                        |
| Mean session completion rate     | 44 attended sessions  | 44 completed sessions | 100.0%                       |
| 15-day measure completion rate   | 17 retained           | 9 completed measures  | 52.9%                        |
| 30-day measure completion rate   | 17 retained           | 12 completed measures | 70.6%                        |
| Any music exercise use ever      | 17 retained           | 10 reported use       | 58.8%                        |

a little embarrassing for me to blow on the harmonica with her sitting there, but it's her job and she made me more comfortable, she was very good."

"That was the other part of it. It actually works. That was I guess the ice cream on top of the cake. When you first hear it, you're like, 'Yeah. Right,' but if you listen and follow her directives, the breathing techniques and all that, she calmed you right out."

"In that last one, we did a remake of Otis Redding's Sitting on the Dock of the Bay. Man, she had birds and creek water running in the music. It was really nice. That just happened to be one of my favorite songs. I'm sitting there, got to breathing, and the next thing you know, I was on the dock of the bay. She was able to transport you there."

## Need for strategies to improve post-discharge engagement in the intervention

Though participants discussed using music exercises such as harmonica playing after they were discharged, they also shared barriers to attending virtual sessions and engaging in the music exercises. These barriers were often related to forgetting to practice, social stressors (e.g., a family member in the hospital), or medical appointments such as dialysis. A few participants expressed a preference for the in-person sessions, not only for the personal connection but also because they presented fewer technological challenges. As one participant stated, "holding the tablet and doing the Zoom is sort irritating for me."

Though technical assistance sessions were offered virtually after discharge, several participants expressed a desire for in-person technical assistance prior to discharge. When asked about whether such a visit prior to discharge would have been helpful, one participant stated:

"It probably would've, 'cause I've never done it before. I didn't even know what Zoom was, until they explained it to me. I understand. I get the concept. If you had a meeting with somebody and they lived in England and the other person in your company lived in Mexico...I get it, and it makes sense, but I never had to do that."



Fig. 1 CONSORT diagram. Abbreviations: C-Diff, Clostridioides difficile; COPD, chronic obstructive pulmonary disease; EHR, electronic health record; HF, heart failure; MRSA, Methicillin-resistant Staphylococcus aureus; NYHA, New York Heart Association

#### Impact on mental health

Participants described how the music therapy intervention not only provided an immediate effect in reducing their stress and promoting relaxation, but also gave them new skills for managing stress and anxiety in their lives outside of the scheduled music therapy sessions.

"Well it created less stress. Less things to focus on, and I was gonna focus on the music and not the things that were stressing me out."

"I've always had trouble shutting down my mind. Sometimes I would come home angry from work and would be in bed five hours and I would honestly be able to say I never slept a wink. I've always been that way, but this helped a little bit."

Several participants used the term "escape" to describe their experience with how the music therapy intervention helped to refocus their attention away from negative emotions and experiences. "When I do them, it's like you connect with the music, and that kind of takes your mind off of the negative stuff you're dealing with. It's like a mental escape, because it does take mental concentration to follow the rhythms, and you're listening to the music. When you're listening to the music, your mind's not going 100 places at once. My wife's in Assisted Living. She's doing well in some ways, and some ways she's having problems...It's a safe haven from all of that."

"Of course when I was playing along with her, that was a jam session. It takes you right out of the hospital room and puts you right in the club. So I was able to escape for a minute...So if you can get to that level of escapism, of putting yourself there, that kind of Zen moment, it does a lot. It does a lot for your day. It clears your head. You've just got to get there."

#### Table 4 Challenges and solutions

| Phase      | Challenge   | Solution   |
|------------|---|--|
| Pilot      | Waiting for physician referrals limited the number of potential participants to approach each week.                                     | Proactively screen patients from EHR and approach medical teams<br>for referrals to increase the number of potential participants<br>to approach each week.  |
|            | Restrictive inclusion criteria with PHQ- 9 or GAD- 7 score $\geq$ 10 that posed additional documentation burden with screening consent. | Remove inclusion criteria and screening consent to reduce patients'<br>time and documentation burden, broaden eligibility criteria,<br>and increase number of potential participants who could be<br>recruited each week.  |
| Future RCT | Unable to reach participants following discharge.   | MyCap text communication and dedicated RA who maintains<br>frequent text- and phone-based communication with participants<br>to reduce attrition.  |
|            | Frequent rescheduling needed following discharge.   | MyCap text communication and dedicated RA who can quickly follow-up with participants to reschedule missed sessions.   |
|            | Unreliable phone communication.   | MyCap text communication for participants who prefer text-<br>over phone-based communication.  |
|            | Participants having challenges with Zoom.   | In-person technology education session prior to discharge to prac-<br>tice skills including downloading Zoom software, joining a meeting,<br>turning camera on and off, and muting/unmuting.   |
|            | Participants having challenges with technology.   | Add inclusion criteria that participant must have email already<br>on smartphone. Add additional screening questions to ensure<br>participant has prior experience accessing email to help ensure<br>basic familiarity with technology needed for videoconferencing<br>and measure completion. |
|            | ICU and readmissions delivery restriction limited therapists' ability to complete sessions.   | When appropriate, allow for ICU delivery and virtual delivery if read-<br>mitted so that participants can complete assigned interventions.   |
|            | Random assignment for interview limited interview sample.   | Remove randomization and interview until saturation is achieved to generate more qualitative data.   |
|            | No follow-up care plan for participants desiring continued music therapy services.  | Provide guide to music therapy community resources follow-<br>ing intervention so that participants can continue to engage<br>with music therapy services following completion of the study.   |
|            | Dialysis presented a challenge to recruitment and participation.  | Exclude patients with ESRD or who are currently receiving dialysis.  |

Abbreviations: ESRD End-Stage Renal Disease, GAD Generalized Anxiety Disorder, ICU intensive care unit, PHQ Patient Health Questionnaire, RA research assistant, RCT randomized controlled trial

#### Discussion

The purpose of this single-arm study was to examine the feasibility, fidelity, and acceptability of the MAJOR CHORD intervention and collection of PROMs through 30 days after hospital discharge. A major focus of this study was to determine which modifications (if any) would need to be made to the intervention and data collection procedures prior to initiating a feasibility RCT. As the first study to investigate the feasibility and acceptability of performing in-person and virtual music therapy sessions among patients with COPD or HF during and after their hospitalizations, the results of this study help lay the foundation for future research on the impact of longitudinal music therapy exposure on HRQoL and hospital readmission rates.

Baseline characteristics of the participants were similar to the demographic profile of patients seen at University Hospitals Cleveland Medical Center [60] and clinical characteristics reported in other studies among people with HF or COPD. The socio-demographic profile of the present study population was similar to that of Cleveland,

Ohio where many individuals from low-income racial minority populations reside. For comparison, the average reported income for Cleveland residents in 2022 was \$37,351 while 60% of participants in this study reported earning < \$50,000 per year. Similarly, 65% of Cleveland residents identified as either non-white or multiracial which is similar to the present study population (45% non-white) [61]. Furthermore, comorbidities prevalent within this sample such as hypertension, anxiety, and depressive disorders are consistent with prior descriptions of HF and COPD populations [62-64]. Given the negative impact of social determinants of health on mental and physical health outcomes and the effects these determinants and comorbidities have on hospital readmission risk [65], these results support the feasibility of recruiting a study population at high risk for hospital readmission. Future music therapy research with this population should consider the impact of these social determinants on PROMs and utilization outcomes.

In examining baseline PROMs, participants in this study reported HRQoL scores that were more severe

when compared to the general population. This is consistent with prior studies among patients with HF [66] and COPD [67] and studies demonstrating the positive relationship between HRQoL impairment and readmission risk [2, 8]. Given these baseline results, it appears this study was successful in recruiting a population for which HRQoL was a challenge and HRQoL improvements may potentially be observed over the course of a multi-session music therapy intervention.

For this pilot study, 17.7% of approached patients were recruited. Primary reasons for non-enrollment included lack of interest (38 before in-person screening and 6 after being deemed eligible) and multiple exclusion criteria uncovered following in-person screening (45/113). Among the 45 patients not recruited due to exclusion criteria uncovered at the time of screening, the most common reasons included (1) not having access to technology needed for virtual participation (51.1%); (2) having an anticipated discharge date < 2 days from the time of screening, which prevented the delivery of the two in-person music therapy sessions (15.6%); and (3) not screening positive for at least moderate depression or anxiety (15.5%). To address the technology barrier, future trials investigating virtual music therapy intervention models should consider providing resources such as tablets with pre-configured data plans or a connection to community resources that provide free or discounted broadband access. Confirming discharge dates was a challenge throughout the study as these shifted each day based on providers' evaluations and were not always updated in the EHR. To help verify discharge dates in the future feasibility RCT, research assistants will confirm dates with the nurses rather than relying solely on what is documented in the EHR.

The moderate depression and/or anxiety inclusion criteria were removed for three reasons. First, administering the PHQ- 9 and GAD- 7 screenings required the study team to administer an entire screening consent form that made the recruitment process lengthier and more burdensome for patients. Second, as observed in the median PROMIS depression (56.70) and anxiety (58.70) scores, a population reporting elevated depression and anxiety symptoms was still enrolled even without the PHQ- 9 and GAD- 7. Third, the target population for a future definitive study would still be at high risk for readmission (future primary outcome) given their diagnosis and comorbidities even without meeting the moderate depression and/or anxiety threshold. Finally, by removing these more stringent mental health criteria, future studies may be more generalizable to adult patients admitted with HF or COPD who may not meet moderate depression and/or anxiety criteria.

Compared to prior psychosocial intervention studies among patients with HF, the observed recruitment rate was lower than a trial investigating a group psychosocial intervention (Adult Congenital Heart Disease-Coping and Resilience program) among adults with congenital heart disease (36.3%) and higher than a study investigating meditation (0.59%) [68, 69]. Compared to the trial among adults with congenital heart disease which only delivered interventions within the hospital, the lower recruitment rate in the present study may be explained by the trial adding additional virtual services to patients' original treatment plans following discharge [68]. Unlike the study of meditation which screened all patients within a large academic hospital, this study only began screening patients following a referral from their medical team, which may help explain the relatively higher recruitment rate [69].

When comparing rates to other music therapy studies, the observed recruitment rate was lower than recent multi-session music therapy studies among adults with chronic pain such as Bradt et al. (77%) [33], Low et al. (56%) [34], and Rodgers-Melnick et al. (89%) [32]. However, these studies recruited from outpatient settings in which participants had a history of attending treatments rather than an inpatient setting as in this study. Furthermore, these studies did not involve virtual delivery and did not include participants with the same degree of comorbidity burden. Recruitment rates were similar to a recent feasibility trial of a virtual music imagery intervention among veterans with chronic pain (12.9% of patients sent recruitment letters) [35]. This single-arm study among veterans was similar to ours as it involved preliminary screening before approaching patients, virtual music therapy sessions, and targeting patients suffering from chronic illness. Given the demonstrated retention rate (85%), attendance rate among retained participants (64.7%), and 100% music therapy session completion rate among initiated sessions, these results provide early support for the feasibility of the MAJOR CHORD protocol among adults with COPD and HF, but modifications are needed to improve overall session attendance (17.6% among retained) and measure completion.

There were numerous challenges to implementation that warrant modification in the future feasibility RCT and any subsequent RCTs examining efficacy (Table 4). In addition to difficulties with recruitment which were addressed with modifying the inclusion and exclusion criteria, several challenges were encountered with participant retention following discharge. On multiple occasions, the study coordinator was unable to reach participants via phone after discharge to schedule the virtual music therapy sessions. There were also challenges with participants not showing up to scheduled virtual sessions, which required the study team to make frequent rescheduling calls. The gap in communication post-discharge might have been due to the high prevalence of mild cognitive impairment observed among patients with COPD and HF [70, 71]. To improve communication efficiency and accessibility for the RCT while considering the cognitive barriers faced by this study population, the future feasibility RCT will use MyCap, an app within REDCap that participants and the study team can utilize to send secure text messages to each other. In addition, one person will be designated for communicating with participants post-discharge to prevent confusion which can occur when participants receive communications from different study team members over the course of the study. Future studies could also consider measuring satisfaction with the virtual sessions using quantitative measures to further understand acceptability and inform intervention refinements.

Results from the qualitative analysis support the acceptability of the intervention and its potential to address mental health outcomes among patients with COPD or HF. Results are consistent with prior music therapy literature in which (1) participants with chronic pain began integrating music exercises within their lives to manage their stress and symptoms [32-34], (2) the music intervention provided a means of refocusing attention away from negative emotions [72], and (3) the MT-BCs were an essential component of the intervention for addressing patients' needs [72, 73]. These preliminary qualitative results also support use of the current set of PROMs to measure the impact of this intervention on stress, mood, and self-efficacy – a critically important domain which has been shown to mediate the effects of music therapy among patients with advanced cancer [74]. Given the low virtual session attendance observed and participants' expressed desire for in-person technology assistance, the future RCT will include time for the research assistant to practice Zoom procedures with participants prior to discharge.

Limitations of this study included a small sample size within a single site, lack of a comparison group to inform recruitment and retention rates within an RCT, and a relatively short follow up period. The sample of patients with COPD (n = 4) was particularly small. Thus, current findings may not inform feasibility of this study protocol for this population. Due to the randomized interview assignment, several participants were not interviewed, including participants who demonstrated poor attendance and measure completion and may have informed barriers to completing the study protocol within a semistructured interview. Despite these limitations, this study featured several strengths and novel innovations including (1) implementing standardized and manualized music therapy interventions tailored to participants' preferences; (2) the novel use of music technology to deliver high-quality virtual sessions; (3) the nuanced understanding of study outcomes provided through integrating quantitative and qualitative data; and (4) the use textbased surveys, which removed the need for participants to return to the healthcare facility.

#### Conclusion

Overall, preliminary findings support the feasibility and acceptability of a 4-session hybrid music therapy intervention among adults with COPD or HF during and after their hospital admissions. However, modifications are needed to improve recruitment rate, session attendance, and measure completion after discharge. The valuable data collected from this pilot study will be used to improve study procedures in a future feasibility RCT. Lessons learned from this study may be applicable to other psychosocial interventions delivered in this context.

#### Supplementary Information

The online version contains supplementary material available at https://doi. org/10.1186/s12906-025-04887-x.

Supplementary Material 1.

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#### Authors' contributions

HY served as a research assistant, administered the REDCap surveys, and led the draft of the initial manuscript. AF provided the music therapy interventions for this study and drafted the intervention description in the supplemental material. TS served as study coordinator, managed the regulatory approvals, screened participants for eligibility, scheduled virtual music therapy sessions, and interviewed participants. SB contributed to the design of the protocol and conducted qualitative analysis. KR served as a research assistant and administered the REDCap surveys. RR, MZ, and CT served as physician co-investigators, conducted review of any adverse events, and contributed to the design of the protocol. SRM served as the Principal Investigator. SRM conceived of the study, contributed to the development and design of the protocol, recruited participants, monitored the music therapy intervention, developed the REDCap database, conducted quantitative and qualitative analysis, and helped to draft the manuscript.

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#### Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

#### Declarations

#### Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki. This study was approved by the University Hospitals Cleveland Medical Center Institutional Review Board on October 10, 2023; IRB number: STUDY20230897. Written informed consent was obtained from all study participants.

#### **Consent for publication**

Not applicable.

#### **Competing interests**

The authors declare no competing interests.

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