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Teaching pursed-lip breathing through music: MELodica Orchestra for DYspnea (MELODY) trial rationale and protocol

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ABSTRACT

Background: Patients with chronic obstructive pulmonary disease (COPD) commonly experience dyspnea, which may limit activities of daily living. Pursed-lip breathing improves dyspnea for COPD patients; however, access to pursed-lip breathing training is limited.

Methods: The proposed MELodica Orchestra for DYspnea (MELODY) study will be a single-site pilot study to assess the safety, feasibility, and efficacy of a music-based approach to teach pursed-lip breathing. Patients with COPD and moderate-severe dyspnea are randomized to intervention, education-control, or usual care control groups. Intervention patients meet twice weekly for eight weeks for melodica instruction, group music-making, and COPD education. Safety, feasibility, and efficacy is assessed qualitatively and quantitatively.

Results: This manuscript describes the rationale and methods of the MELODY pilot project.

Conclusions: If pilot data demonstrate efficacy, then a multi-site randomized control trial will be conducted to evaluate program effectiveness and implementation.

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Chronic obstructive pulmonary disease; music; music therapy; dyspnea; pursed-lip breathing

Background

Chronic obstructive pulmonary disease (COPD) is a major cause of morbidity and mortality in the United States, especially among Veterans (Major et al., 2014). In 2014, 774,735

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Veterans had a diagnosis of COPD, which was approximately 12.5% of the Veteran population (Cowper Ripley & Ahern, 2015). Patients with COPD commonly experience dyspnea, which may limit activities of daily living and reduce quality of life (Barr et al., 2005).

The American Thoracic Society defines pursed-lip breathing as inhalation through the nose followed by prolonged exhalation through partially closed lips (Mayer et al., 2018). Pursed-lip breathing has been shown to improve dyspnea (the subjective experience of shortness of breath including difficulty breathing or breathing discomfort; West, 2012) exercise endurance, and pulmonary physiology, including improving gas exchange, ventilation efficiency, oximetry, tidal volume, and reducing the respiratory rate (Bhatt et al., 2013; Cabral et al., 2015; Mayer et al., 2018; Roberts et al., 2009; Sakhaei et al., 2018). Despite these robust clinical benefits, teaching methods for pursed-lip breathing in clinical practice are highly variable and neither well reported nor well established (Mayer et al., 2018; Roberts et al., 2009).

Although pursed-lip breathing is routinely included in pulmonary rehabilitation programs, limited access has been identified as a critical issue constraining the application of pulmonary rehabilitation (Barr et al., 2005; Major et al., 2014). Only 11% of patients with COPD in the United States report participating in pulmonary rehabilitation (Barr et al., 2005). Moreover, only 19% of primary care physicians and 54% of pulmonologists report regularly referring patients to pulmonary rehabilitation (Barr et al., 2005). Within the United States Veterans Health Administration (VA), very few medical centers have accredited pulmonary rehabilitation programs. At some VA facilities, active tobacco smokers are ineligible for referral to pulmonary rehabilitation further limiting access.

Therefore, there is a clinical imperative to develop training programs to teach pursed-lip breathing to patients with COPD; specifically, programs that can be deployed in routine clinical settings. The objective of the MELodica Orchestra for DYspnea (MELODY) pilot project is to evaluate whether dyspnea can be improved among COPD patients by teaching pursed-lip breathing using an eight-week music-based approach. The primary aims are to evaluate the safety and feasibility of implementing a music-based approach to teach pursed-lip breathing to patients with COPD experiencing dyspnea, and to collect pilot-efficacy data. A secondary aim is to identify potential barriers to participation. This manuscript describes the rationale and methods of the MELODY pilot project (Robb et al., 2011).

Methods

Conceptual framework

Because the MELODY pilot project seeks to facilitate participation in meaningful life activities for patients with a chronic illness, the program fits broadly within a rehabilitation medicine framework and specifically, within an occupational medicine conceptualization. The MELODY protocol is grounded on concepts from occupational therapy (Wong & Fisher, 2015) (Table 1) as expressed in the Model of Human Occupation (MOHO) (Tang & Vezeau, 2010). The MOHO is a widely used occupation-focused model which emphasizes a person's agency and adaptation from participation in meaningful

Table 1. Application of the Model of Human Occupation (MOHO) Conceptual Framework to MELODY.

Model of Human Occupation (MOHO) (Gary Kielhofner, 2002)		MELODY	
		Intervention	Evaluation
Volition	Explores how values, personal causation, and interests relate to motivation for engaging in meaningful activity	Playing the melodica in a group setting may be more enjoyable, and therefore more motivating, than practicing pursed-lip breathing exercises at home. Learning how to play the melodica, and thereby incorporating pursed-lip breathing into their life, may help participants reduce their dyspnea to levels where they can participate in activities that are meaningful to them.	• Occupational Self-Assessment (OSA) • Semi-structured interview
Habituation	Explains how one attains a persisting pattern of meaningful activity through habits and roles	By practicing the melodica and pursed-lip breathing regularly in the orchestra and at home, participants may develop habits that improve both their symptom status and their quality of life resulting from regular, meaningful life participation.	• Practice log sheets • Session attendance • Semi-structured interview
Performance Capacity	Considers one's mental and physical status on the ability to perform meaningful activities	Playing in the melodica orchestra may give participants the confidence to engage in other meaningful activities including ones they thought were too difficult to perform. Participants will learn pursed-lip breathing, which may reduce dyspnea and thereby increase physical capacity.	• Patient Global Impression of Change Scale (PGIC) • Generalized Anxiety Disorder 7-Item Scale (GAD-7) • Occupational Self-Assessment (OSA) • 20-Item Short Form Health Survey (SF-20) • 5-item WHO Well-Being Index (WHO-5) • Six-Minute Walk Test • Barthel Index • Dyspnea Visual Analog Scale • Semi-structured interview
Environment	The environment is integrally related to the person and offers resources, opportunities, constraints, and boundaries.	The intervention is conducted within a group setting. Participants may have family members who are concerned by the patient's dyspnea or who must serve as caregivers if the patient is unable to engage in activities of daily living.	• Semi-structured interview

activities within their environment (Wong & Fisher, 2015). The MOHO describes how personal attributes influence a person's skill, performance, and participation in meaningful activities (Kielhofner & Burke, 1980).

In MELODY, participants learn to play a melodica, a wind instrument with a small keyboard and a mouthpiece at one end (Figure 1). The intervention program has been developed to provide participants with a meaningful new activity that is enjoyable, that can be provided across a spectrum of skill levels (e.g., for participants with no musical training as well as for individuals who are proficient keyboard players), and that can

Figure 1. Melodica Instrument.

provide participants with a new sense of self/role (e.g., "I am a musician," "I am a member of the VA melodica group").

Design and setting

MELODY is a single-site, randomized controlled clinical trial conducted at a large VA medical center in the Midwestern United States. Patients are randomized in a 1:1:1 ratio to an intervention group, an education-only control group, and a usual care control group, using block randomization. This study received Institutional Review Board approval for human subjects' research and VA Research and Development approval and is registered with clinicaltrials.gov (NCT03653104).

Patient population

A systematic review of two randomized controlled trials and nine pre-post studies demonstrated that patients with moderate to severe dyspnea or dyspnea at rest benefit most from pursed-lip breathing (Garrod et al., 2005; Roberts et al., 2009). Therefore, eligible patients for MELODY (Figure 2) include those with spirometry-confirmed COPD, defined as an $FEV_1/FVC < 0.7$, and moderate or severe dyspnea defined as a grade ≥3 on the American Thoracic Society Dyspnea scale (Speizer & Comstock, 1978). Patients who meet the eligibility criteria, but who choose not to participate in the intervention, are eligible to participate in brief interviews to identify barriers to participation (interview-only group; Figure 2).

Patients are excluded if they: have visual or hearing impairments (because they would not be able to see well enough to play the instrument or hear well enough to understand instructions or enjoy the auditory benefits of music-making); do not speak English (because the music instruction and COPD education programs are conducted in English); do not have an intact airway (e.g., a tracheotomy, because they could not play the instrument); have cognitive impairment (because they could not understand music

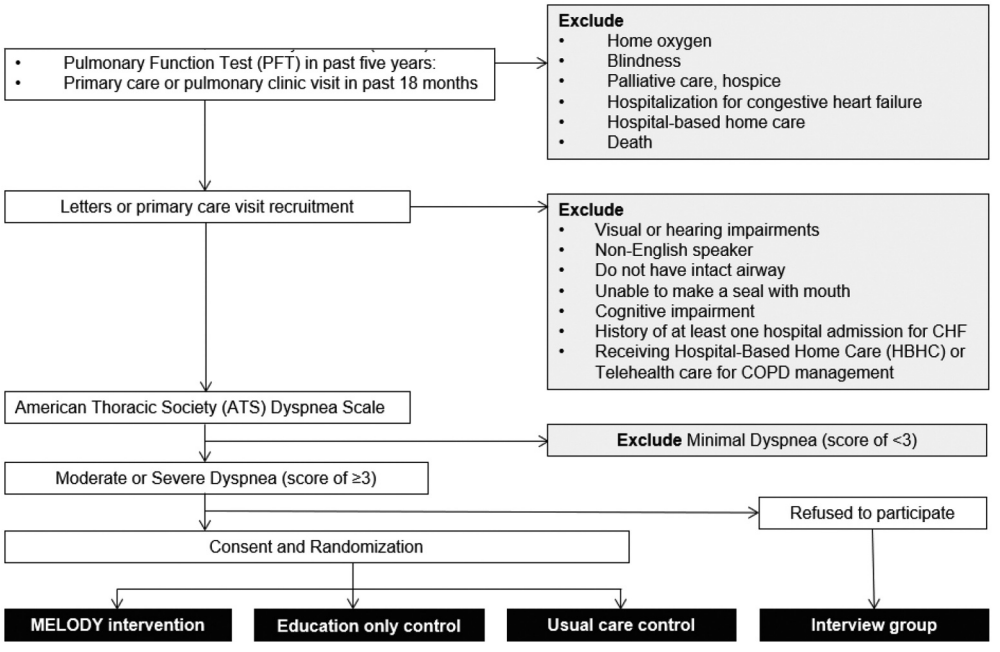

Figure 2. Proposed Patient Flow Diagram.

instruction); are unable to make a seal with their mouths (because they would be unable to play the instrument); or have a history of at least one hospital admission for congestive heart failure in the prior year (because the symptoms of shortness of breath due to congestive heart failure would not be expected to improve with pursed-lip breathing training). Patients are also excluded if they are enrolled in pulmonary rehabilitation or are receiving Hospital-Based Home Care or Telehealth care for COPD management (because these patients are already receiving COPD education). Potentially eligible patients will be identified using the electronic health record data and invited to speak with study staff who will then ascertain whether the person meets the dyspnea severity inclusion criterion (≥3 on the American Thoracic Society Dyspnea scale).

Melodica-based music intervention rationale

Pursed-lip breathing must be practiced regularly for maximal effectiveness (Crowe et al., 2005). Research has demonstrated that music is an enjoyable means to encourage patients to practice pursed-lip breathing (Alexander & Wagner, 2012; Bonilha et al., 2009; Lord et al., 2010; Wade, 2017). In a small study involving singing and kazoo-playing, lung function scores increased from pre- to post-test; however, researchers noted that kazoo-playing required a considerable volume of exhalation to maintain playing and approximately half of patients reported that they felt they needed to "catch their breath" after playing their kazoo (Wade, 2017). In general, music interventions have a long history of being well received within the Veteran population, across a variety of disease conditions (Bronas et al., 2018; Grant, 2005; Powell, 2016, 2017;

Powers et al., 2012; Reschke-Hernandez, 2014; Van Gelderen et al., 2018). Taken as a whole, these studies suggest a potentially positive effect on outcomes with minimal risk of adverse events.

Choosing a musical intervention that does not require proficiency or other participation barriers may facilitate uptake. For example, in the prior music-based studies, patients reported being reluctant to sing if they believed they were poor singers or that they did not like the kazoo because they considered it to be a "toy" (Wade, 2017). Moreover, playing the kazoo requires patients to hum while exhaling, which may actually be difficult for beginners. The melodica (Figure 1) has several potential advantages over other musical instruments that include: the mouthpiece encourages extension of the lips into the ideal pursed-lip shape; high-quality musical tones can be played by simply exhaling (rich melodic sound does not require much effort); different notes are played by pushing down the keys, which requires little coordination or muscle strength; and after a few training sessions, patients with little musical experience can play simple songs.

Group-music making rationale

Group sessions are used widely in healthcare (Greenfield et al., 2014; Little et al., 2013; Scott et al., 2004). Patients report feeling a sense of community and social support when experiencing interventions in group settings (Lord et al., 2010). In a mixed methodology study of patients learning pursed-lip breathing one-on-one, a majority expressed that learning pursed-lip breathing in a group may be beneficial (Roberts et al., 2017). Testimonials about the potential benefits of harmonica playing for patients with COPD were from participants in group sessions rather than interventions that focused on individual instrument playing (Alexander & Wagner, 2012).

Intervention duration and dosing rationale

Most programs teaching pursed-lip breathing or other breathing or exercise techniques for patients with COPD are of 4–12 weeks duration, with the strongest evidence for improved outcomes reported for longer intervention duration (Holland et al., 2012). Similarly, pulmonary rehabilitation programs commonly convene three times weekly for six to twelve weeks (Nici et al., 2010). In a systematic review of five randomized controlled trials, the evidence suggests that longer pulmonary rehabilitation programs lead to a greater improvement on quality of life (Beauchamp et al., 2011).

MELODY intervention description

Participants meet twice weekly over the eight-week study period. The intervention program is delivered in-person, in a group setting. Each session lasts approximately one hour with 20 minutes of melodica instruction, 30 minutes for group music-making, and 10 minutes for the educational program. Each participant receives their own melodica. The instrument is placed on a table in front of the participant who plays it while seated. Participants also receive their own copies of the music and are encouraged to practice their melodica and pursed-lip breathing when at home. Two-hours per week of arts engagement has been associated with improved well-being. (Davies et al., 2016)

MELODY intervention patients should achieve this threshold dose given the combination of two 1-hour weekly session plus in-home practice time.

The interventionist arranges the majority of the repertoire. The participants all play the same music (i.e., all play the melody without harmony) because this reduces psychological pressure on participants, an important factor when learning a new instrument. The interventionist begins the melodica training using music in the key of C Major because this uses only the white keys on the melodica keyboard, which similarly facilitates learning for beginners. As participants improve, the interventionist incorporates music that also involves the black keys. Because the goal of the program is to teach pursed-lip breathing, the interventionist arranges the repertoire to include strategically placed rests to allow for inhalation for a count of two and exhalation (playing notes) for a count of four. The interventionist has a prepared repertoire but can adjust based on requests from participants. Scales are used to introduce new rhythms, pitches, and techniques, which are then applied to well-known musical pieces. Playing familiar songs allows participants to hear if they are playing correctly; it promotes early success as these songs are often shorter with repeated elements, which reinforces the participants' skills and fosters confidence.

The MELODY intervention should be delivered by an individual with experience teaching adult beginners, convening group adult music programs, and be comfortable working in healthcare settings. For example, the program could be delivered by a music therapist, however, given the paucity of licensed music therapists in both the VA healthcare system (where the pilot project will be implemented) as well as in the private healthcare sector, MELODY was explicitly designed to be implemented without requiring the expertise of a music therapist. The report of the final results of the pilot study will describe the training and experience of the person delivering the intervention, as recommended for studies of music-based interventions (Aalbers et al., 2017).

Education component description

The education program includes topics that are reviewed in pulmonary rehabilitation programs such as information about COPD, pursed-lip breathing, smoking cessation, pulmonary rehabilitation, COPD symptoms and exacerbations, and exercise. The education program has been designed to be implemented in a standard manner without reliance upon educators who are expert in COPD; therefore, it includes both video components and written materials. The videos were prepared using principles that promote multimedia learning (Mayer & Moreno, 2003). The pursed-lip breathing training includes videos as well as exercises (i.e., practicing pursed-lip breathing while blowing bubbles, blowing a pinwheel, and walking). Both the intervention patients and the education-only control patients receive the education program; however, the intervention patients receive it in 10-minute sessions distributed over the course of the 8-week program whereas the education-only patients receive the entire educational program in a single 2-hour session. Providing the education-only materials in a single 2-hour session rather than, for example, two 1-hour sessions reduce travel burden for patients and is consistent with the format for other educational programs offered in the facility (e.g.,

diabetes education programs; DiNardo et al., 2017) All participants receive primary care at the participating medical center which can provide any needed ancillary care.

Safety outcomes and assessment

Safety is evaluated through self-reported dyspnea and adverse events (Table 2). Self-reported dyspnea is measured using a paper-based dyspnea visual analog scale before and after each intervention session; control patients complete the dyspnea visual analog scale twice a week. The visual analogue scale is a 100-millimeter line; scores range from zero to 100. Changes in dyspnea scales are measured over time by comparing the mean monthly difference in dyspnea between patients in the intervention versus control group. Patients are asked after every training session to describe any adverse events they experience resulting from playing the melodica and whether they needed to stop playing the melodica. Patients are not blinded to treatment allocation.

Feasibility outcomes and assessment

Feasibility is measured by assessing: the proportion of eligible patients who agree to participate; the proportion of sessions that enrolled patients attend; and the self-reported frequency that patients practice the melodica. Feasibility is also evaluated qualitatively through semi-structured interviews: intervention group patients are asked about their experience in the program and both the education and usual-care control group patients are asked about their interest in the program seeking to identify both barriers and

Table 2. Measurements.

Measurement	Interview-only group	Intervention group	Usual care control group	Education-only control group
ATS Dyspnea scale	–	Eligibility Assessment 8-weeks		
Chart review	–		Baseline	
Experience with session, adverse events, safety questions	–	Every session	–	–
Dyspnea visual-analogue scale	–	Before and after every session (twice per week)	Twice per week	Twice per week
Pursed-lip breathing assessment	–	Daily	Twice per week	Twice per week
Melodica practice diary	–	Daily	–	–
Ask when Veterans are most likely to use pursed-lip breathing	–	Baseline 4-weeks 8-weeks	–	–
World Health Organization Well-Being Index [WHO-5]	–	Baseline, 4-weeks, 8-weeks		
Quality of life (SF-20)	–			
Global change in symptoms (PGIC)	–			
Anxiety (GAD-7)	–			
Exercise endurance (6-minute walk)	–			
Occupations and activities of daily living (OSA-DLS, Barthel)	–		Baseline, 8-weeks	
Barthel Index of Activities of Daily Living	–			
Peak expiratory flow	–			
Smoking history	–			
Pulmonary rehabilitation interest	–			
Semi-structured interviews	Baseline		8-weeks	

facilitators in the implementation of the program. Patients who meet inclusion criteria but choose not to participate in the study are eligible to participate in a brief semi-structured interview to detect barriers in participation (interview-only group).

Pilot-efficacy outcomes and assessment

The primary efficacy outcome is the change in dyspnea measured by the ATS Dyspnea scale at baseline versus week-eight across the three groups. Secondary efficacy outcomes related to dyspnea include the change in dyspnea between pre- and post-intervention training sessions, and the distribution of dyspnea scores between the intervention group and the education-only control group and the usual care control group (Holland et al., 2012). Dyspnea is the primary efficacy outcome because it is an important patient symptom and one that is a key target for pulmonary rehabilitation programs (Barr et al., 2005; McCarthy et al., 2015).

Secondary assessments include a comparison between the intervention group and usual care control group as well as a comparison between the education-only and usual care control group across the following: change in exercise endurance assessed using the six-minute walk test (6MWT); (Enright, 2003; Guyatt et al., 1985) proportion of patients who self-report using pursed-lip breathing during activities of daily living; proportion of patients who enroll in pulmonary rehabilitation; change in well-being measured with the World Health Organization Well-Being Index [WHO-5]; (Linton et al., 2016; Topp et al., 2015) the change in quality of life measured using the 20-Item Short Form Health Survey (SF-20); (Ware et al., 1992) difference in the Patient Global Impression of Change (PGIC) analyzed using a seven-point scale; change in anxiety levels assessed with the Generalized Anxiety Disorder Scale 7-Item Scale (GAD-7); (Lowe et al., 2008; Spitzer et al., 2006) change in ability to perform activities of daily living measured with the Barthel index; (Shah et al., 1989) and change in performance measured with the Occupational Self-Assessment-Daily Living Scales (OSA-DLS) (Baron et al., 2006). Table 2 provides the schedule of measurements.

Given the finding by Cabral et al. that patients with lower baseline peak expiratory flow values are more likely to increase their exercise endurance time by ≥25% when using pursed-lip breathing than other COPD patients, (Cabral et al., 2015) we will assess peak expiratory flow on all patients at baseline and at week-eight. We will examine whether efficacy (change in dyspnea) is related to baseline peak expiratory flow; these results which will inform the design of a future trial.

Sample size

Because this pilot study focuses on feasibility and effect-size estimation for a larger trial, we chose a sample size of 30 participants per group. According to recommendations from Hertzog (2008), 30 patients per group are adequate to obtain reasonably bias-corrected effect size estimates for medium (0.5 standard deviations) or larger effect sizes. This sample size will also provide an adequate number of patients for the qualitative interviews.

Chart review

A review of medical records is conducted on all participants in the study (intervention and control groups). The review includes demographics, past medical history and co-morbidity (e.g., hypertension, diabetes mellitus, anxiety, congestive heart failure, etc.), pulmonary function test results, medications, prior pulmonary or cardiac rehabilitation, and healthcare utilization (inpatient and outpatient visits in the past twelve months).

Quantitative analysis

Patient baseline characteristics are reported descriptively; categorical variables are presented with proportions and 95% confidence intervals, continuous variables are presented with means and standard deviations, medians and interquartile ranges. The change in the primary outcome from baseline to 8 weeks will be tested using paired t-tests for each arm separately. The primary comparisons between groups will be made with two-sided t-tests (for mean dyspnea analog scale scores). Multivariable modeling will be conducted if unexpected differences in baseline characteristics are observed between groups despite randomization. Similar analyses will be performed for all secondary outcomes. Separate exploratory analyses will involve using mixed effects models on outcome measures that are collected at multiple time points. For these models, there will be a random effect for patient and fixed effects for time and randomization arm. With these models, we will be able to assess the effect of time and intervention on the outcomes of interest. No imputations for missing data or adjustments for multiple comparisons are planned. No interim analyses or stopping rules are planned.

Qualitative evaluation

Participants in the MELODY intervention group are interviewed about: their experience of the program, both in terms of pursed-lip breathing and the melodica training; their prior musical experiences; successes (e.g., enjoyment, pride-related skill acquisition, new friendships) and challenges (e.g., psychological, physical or cognitive difficulties) they encountered during the sessions and while practicing at home; any reasons for missing sessions or dropping out. Participants in the control groups will be asked about whether they have started to play the melodica or other related instrument during the course of the study. Participants in the interview-only group are interviewed about their reasons for choosing not to participate in MELODY to identify barriers to program participation and implementation.

The semi-structured interviews, based on open-ended questions, are conducted using an interview guide developed for this project. Participants provide written permission for interviews to be audio-recorded by a VA-approved device. Recorded interviews are professionally transcribed verbatim, de-identified, and imported into a single NVivo11 (QSR International, Burlington, MA) project file for data coding and analysis. Qualitative analysis is conducted by members of the research team using the constant comparison technique to identify emerging themes (Corbin & Strauss,

2008). Specifically, qualitative analysis involves two researchers independently assigning labels and codes to the data segments and developing initial themes in a codebook. The codebook consists of categories from MOHO and themes that emerge through open coding. The researchers write analytic memos to document the evolution of the data analysis process, the appearance of early patterns and potential findings, the convergence of major themes, and challenges posed during analysis (Saldana, 2009). These analytic memos serve as the basis for conclusions and findings.

Business-case analysis

We will construct a business-case analysis to examine the financial costs and benefits of implementing the MELODY program (Leatherman et al., 2003; Luck et al., 2007). We will not include any research-specific costs in the business-case analyses. The business-case analyses will be built from the VA leadership perspective and will therefore not include patient or caregiver costs. The business-case analysis will assess financial costs and savings and will include all program costs. We will use microcosting methodology to assess start-up (sometimes referred to as "initiation" or "development") program costs and (post-start-up) ongoing program implementation costs which include both program costs and downstream costs (Luck et al., 2007; Smith et al., 2010). We will consider the following categories of program expenses: personnel staffing and training costs will be obtained by staff surveys/diaries about time allocations for specific activities which will be converted to staffing costs; equipment, supply, and prosthetics costs will include any one-time costs (e.g., musical equipment purchases) and also incremental per-patient costs associated with durable or disposable items; patient travel reimbursements; and miscellaneous costs. We do not anticipate any staff travel reimbursements or space costs, but if those are incurred, we will include them in the analyses. In addition to program costs, we will also consider potential downstream costs/savings including total patient health care costs for both inpatient and outpatient utilization (VA as well as non-VA). The comparisons for the business-case analysis will involve assessing differences between intervention patients versus education-only control patients versus usual care control patients. In descriptive (cost-benefit) analyses: we will calculate the net financial savings or loss in the overall intervention costs minus savings due to downstream benefits for patients receiving the intervention versus controls. Bootstrapping over 1000 samples taken from the final dataset will be used to estimate 95% confidence intervals for the differences in costs between intervention and usual care patients. We will calculate the per-patient net financial savings or loss by dividing the net savings or loss by the number of persons who received the intervention.

Go/no-go milestones

The purpose of this pilot project is to obtain the safety, feasibility, and pilot-efficacy data needed to design and successfully conduct a randomized controlled clinical trial that is adequately powered to detect differences in outcomes across groups. We will plan to proceed with a future randomized trial if: (1) there is no evidence of safety

concerns; (2) MELODY intervention group members attend ≥50% of sessions, (3) there is some indication of pilot effectiveness (e.g., improvements in dyspnea, well-being, exercise tolerance, functional status, etc), *and* (4) if retention in the control group exceeds a minimum threshold of 50%. The design of the future randomized controlled trial will be informed by the qualitative interview data that provides insights into the patients' experience of the program; in particular, the future study would be designed to mitigate barriers to participation that are identified in this pilot project.

Discussion

Importance

Given the demonstrated efficacy of pursed-lip breathing to improve symptoms for patients with COPD, there is a need to develop pursed-lip breathing training programs that can be delivered in routine clinical settings. Importantly, interventions that apply to all COPD patients, including those who are ineligible for pulmonary rehabilitation, have the potential to reach new patient populations (Roberts et al., 2017). Although some patients independently "learn" to use pursed-lip breathing (also known as "spontaneous" pursed-lip breathing), teaching patients pursed-lip breathing (referred to as "volitional" pursed lip breathing) has been shown to improve exercise capacity and pulmonary physiology (Bhatt et al., 2013; Borge et al., 2014). The MELODY pilot project seeks to address the gaps in the existing literature by developing an education program and intervention that can be implemented across diverse healthcare settings, and to report findings which will be used to design future trials and clinical programs.

Methodological strengths

A common critique of studies involving music-based interventions is a lack of grounding in a conceptual framework (Burns, 2012; Robb et al., 2011; Tang & Vezeau, 2010). A strength of MELODY is that both the intervention and the evaluation have been designed on the basis of the well-established MOHO. Evaluating how involvement playing the melodica affects volition, habituation, and performance capacity offers a strong framework for suggesting mechanisms that may explain how the program is effective for individual participants.

Another strength of the MELODY pilot is the inclusion of an education-only control. The educational program has been designed to provide participants with practical information that they can apply to their COPD self-management. The pursed-lip breathing exercises are intended to be enjoyable methods for introducing pursed-lip breathing. Because systematic reviews have demonstrated that breathing training improves dyspnea, quality of life, and exercise endurance compared with education alone, (Crowe et al., 2005) we have explicitly designed MELODY to be a comparison of breathing training (via the melodica) with an educational program that emphasizes tips for incorporating pursed-lip breathing into routine activities.

MELODY includes a mixed methods approach using both quantitative assessments of safety, feasibility and efficacy as well as qualitative descriptions of participants'

experiences. In this way, MELODY will provide information both on whether–and plausible explanations about–why the intervention does or does not improve symptoms for COPD patients.

Innovation

The few previous studies examining music interventions among patients with COPD have identified positive effects on dyspnea, anxiety, quality of life, and exercise endurance with minimal risk of adverse events (Holland et al., 2012). To our knowledge, no studies have evaluated the use of the melodica to teach pursed-lip breathing. The melodica has advantages over other musical approaches (e.g., singing) because it encourages patients to extend their lips in the desired position for exhalation, because relatively little respiratory effort is required to produce a sound (in contrast to the kazoo), and because it is relatively easy to use to make melodic music (in contrast to the harmonica).

Limitations

The primary limitation of the MELODY pilot is generalizability to non-Veteran populations and to healthcare settings outside of the VA. This pilot project includes a single-site study, future studies should be conducted in multiple sites and in diverse healthcare settings. Due to the participatory nature of the intervention, the participants are not blinded to the treatment group, (McNamara et al., 2017) future studies should seek to employ blinding outcome assessment (which may be possible for endurance outcomes).

Conclusions

If pilot data demonstrate efficacy, then a multi-site, randomized control trial will be conducted to evaluate the implementation and effectiveness of a music-based approach to teaching pursed-lip breathing for patients with COPD in routine clinical practice.

Trial registration information

Clinicaltrials.gov study identifier: NCT03653104
Submitted for registration: 17 August 2018
First posted: 31 August 2018
Secondary Identifying Numbers: not applicable
Title: Melodica Orchestra for Dyspnea: Safety and Feasibility Pilot (MELODY)
Countries of Recruitment: United States of America
Health Condition being studied: Chronic obstructive pulmonary disease (COPD) and dyspnea
Intervention: music-based intervention to teach pursed-lip breathing
Inclusion: COPD patients with dyspnea
Study type: randomized controlled pilot study
Date of first enrollment: not yet enrolling
Recruitment status: pending

Disclosure statement

No potential conflict of interest was reported by the authors.

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Data Availability

This manuscript describes the rationale and methods of the MELODY project and therefore does not contain any result data. However, investigators or clinicians interested in obtaining the materials used to implement the MELODY program are strongly encouraged to contact the corresponding author.

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