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Tailored Music Listening in Persons With Dementia: A Feasibility Randomized Clinical Trial

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Abstract

Introduction: This study examined the feasibility, acceptability, and preliminary efficacy of tailored music listening intervention on sleep disturbances in older adults with dementia and their caregivers. **Methods**: We randomly assigned 33 older adults with dementia (mean age 71.7 [SD: 7.1], 72.7% female, 81.8% African American/Black) and their caregivers (mean age 58.4 [SD: 16.7], 72.7% female, 84.8% African American/Black) to a wait-list control or intervention group (NCT04157244). **Results**: The music intervention was feasible as evidenced by high study measure completion and retention rates (>90%). Recruitment was stopped prematurely due to the COVID-19 pandemic. We found mixed acceptability results from the survey and qualitative interviews with the participants. Both groups improved on objective sleep outcomes of sleep latency and wake sleep after onset. We found a small effect size for sleep duration post-intervention. **Discussion**: The findings provide preliminary evidence for the feasibility of a tailored music intervention and identified ways to improve its acceptability.

Keywords

cognitive impairment, caregivers, clinical research, aging, Alzheimer's disease

Significance Statement

1. The results point to the feasibility of a music listening intervention for persons with dementia and specifically Black/African Americans who constituted most of the sample.
2. There is a need for rigorous testing of music interventions in larger, more diverse samples.
3. This study is the first step in examining the efficacy of a music listening intervention in persons with dementia.

Introduction

The vast majority of older adults with Alzheimer's disease and related dementias (between 60 and 70%) have sleep disturbances, including trouble falling asleep, difficulty staying asleep, poor sleep quality, and insufficient sleep duration or the diagnosis of insomnia disorder.[1] Persons with dementia experience these symptoms due to the degeneration of neural pathways that regulate peoples' circadian rhythms and affect their physiological and psychological states.[2] Circadian rhythm disorder symptoms include evening agitation, excessive daytime sleepiness, increased sleep latency, and frequent nighttime awakenings.[3,4] The consequences of untreated sleep disturbances in persons with dementia include cognitive dysfunction[5] and accelerated progression of the disease.[6] Untreated sleep disturbances in persons with

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dementia may also negatively affect caregivers' sleep, thus increasing caregiver burden,[7] and potentially leading to nursing home placement.[8] Taken together, improving sleep latency, decreasing nighttime awakenings, and improving sleep duration are critical for both older adults with dementia and their caregivers.

Given high fall risk, increased daytime sedation, potential toxicity, and increased risk for cardiac-related mortality associated with pharmacological treatment,[9–11] nonpharmacological approaches for mitigating sleep disturbances are preferred. Nonpharmacological interventions, such as tailored music, that target evening hours between 6 PM and 10 PM, can induce a calm and relaxing state, reducing cortisol levels[12,13] and resulting in fewer sleep disturbances. Specifically, listening to music may have the greatest impact on the time it takes someone to fall asleep (eg, sleep latency) as it promotes relaxation at bedtime. Furthermore, creating a calmer sleep environment by turning on tailored music may improve one's ability to fall back to sleep after waking in the night. Improving the time it takes one to fall asleep and decreasing night waking may improve overall sleep duration and quality.

Music listening interventions have shown promise in improving sleep quality in primarily healthy older adults.[14–16] Previous studies included music listening interventions and multi-component interventions, where music listening was combined with therapies such as hand massage,[17] active music making,[18] mindfulness awareness practice, tai chi, and art therapy.[19] Prior music listening interventions have consisted of older adults listening to an MP3 or a CD player at bedtime. Music was selected based on sleep-inducing, relaxing characteristics (tempo 60-80 beats per minute without accented beats).[14,15,20–22] However, we found in a systematic review of music interventions and sleep among older adults that only three of 16 studies included older adults with cognitive impairment.[16] In one study, the music selection was based on the preferences of persons with dementia,[23] and in another, the authors selected music based on its familiarity with the person.[24] Findings from these three studies were mixed. Two studies reported improvement in sleep quality,[23,25] and one study reported an increase in nighttime sleep duration in persons with dementia.[24] None used objective measures to examine sleep outcomes. These findings suggest that music interventions may improve sleep outcomes for older adults; however, there remains limited evidence as to the effects of music interventions on a wide range of sleep outcomes in persons with dementia.

Tailored music interventions may be particularly helpful in improving sleep for older adults with dementia for several reasons. First, older adults with dementia continue to have preserved receptive and expressive music abilities as their disease progresses.[26–28] Preserved musical memories in older adults with dementia may be explained by the fact that the brain regions associated with musical memories have delayed atrophy compared to other regions of the brain.[29] Second, music tailored to individual interests and favorite genres can have a personal meaning to older adults with dementia, given that music is often linked to important life events and can be a source of pleasure.[30] Third, musical properties can be easily adapted to personal preferences and sleep-inducing characteristics. For example, one of the fundamental properties of music is beats per minute which can be manipulated to induce a mood or a feeling. Music is universal, is not time intensive, can be tailored, and be a low-cost alternative to other nonpharmacological interventions, such as cognitive-behavioral therapy for insomnia.

Given these benefits, there is a critical need to develop novel tailored music interventions and determine the extent to which music interventions improve sleep disturbances in older adults with dementia. Very few studies examined music interventions aimed at improving sleep disturbances in community-dwelling older adults with dementia using objective and subjective sleep measures. Therefore, the purpose of this wait-list pilot randomized trial was to examine the feasibility of tailored music listening intervention to improve sleep disturbances in community-dwelling older adults with dementia. We hypothesized that persons with dementia who listen to tailored sleep-inducing music at bedtime would experience fewer sleep disturbances if the intervention was feasible and acceptable. The specific aims of this study which can be characterized as Stage 1b along the National Institute on Aging model,[31] were to 1) examine the feasibility of delivering tailored music listening intervention to persons with dementia living at home and their caregivers (dyads); 2) examine the acceptability of the intervention to both the person and the caregiver using a brief survey and qualitative data; and 3) obtain preliminary estimates of treatment efficacy on subjective and objective sleep outcomes.

Materials and Methods

Design

We used a randomized wait-list controlled trial to examine the feasibility (Aim 1) and acceptability (Aim 2) of a tailored 4-week music intervention on sleep in persons with dementia. In Aim 3, we relied on objective and subjective measures of sleep to examine the preliminary efficacy of the intervention on the sleep outcomes of the person with dementia. This study was approved by the Institutional Review Board of the University of Pennsylvania [Approval #829256]. This clinical trial was registered with ClinicalTrials.gov (NCT04157244).

Participants and Setting

We recruited adults aged 60 and older from the community with an existing diagnosis of dementia or self-reported memory impairment and a Clinical Dementia Rating score of greater than 0.5.[32] We chose to expand the inclusion criteria to self-reported memory impairment to increase enrollment of

community-dwelling older adults from underrepresented communities who may be less likely to have a formal medical diagnosis. For example, Amjad et al (2018) found through analysis of cognitive testing done with a nationally representative sample, that of all the persons identified as having probable dementia, only 41% had a diagnosis of dementia. Those without a dementia diagnosis were more likely to be from minoritized populations and have less education.[33] Additional inclusion criteria for the present study were i) the presence of at least one sleep disturbance symptom (such as difficulty falling asleep or staying asleep) of moderate severity according to the Neuropsychiatric Inventory-Questionnaire sleep disorders item; ii) stable dose of psychotropic medications, sedatives/hypnotics, antidementia, or opioids in the past 90 days before enrollment; iii) agreeing to wear a wrist Actigraph; iv) being responsive to their environment by verbalizing their needs; and v) sufficient English to complete questionnaires. Persons with dementia were excluded if they i) planned to transition to another care setting in less than 3 months; ii) were unable to hear a normal speaking voice at a distance of one and a half feet; iii) presented with extrapyramidal symptoms affecting nondominant hand; iv) were currently enrolled in a clinical trial aimed to improve sleep; v) experienced acute sleep disruption within two weeks of screening for the study; and vi) had an end-stage disease (eg, receiving hospice). Caregivers who were enrolled provided at least 4 hours of daily care, lived with the older adult, and were able to read and speak in English. We performed all study visits with the dyads in their homes.

Procedures

Our published research protocol includes a detailed description of the procedures.[34] In Step 1 of recruitment, we identified potential participants from referral sources (including the University of Pennsylvania Alzheimer's disease Core Center and an ongoing RCT recruiting older adults with dementia and their caregivers, R01NR015226)[13] and sent out letters to the caregivers detailing the purpose of the study and how to contact the Principal Investigator (PI) and first author. Dyads were screened by the first author for eligibility and music preferences. Then, a meeting was scheduled with the dyad at their home for consent/baseline assessment. Written consent was obtained from all persons with dementia and their caregivers. Dyads were then assigned to either the wait-list control or intervention group by a computer-generated list of random numbers from a statistician external to the research team. Each dyad learned of the assignment 72 hours after randomization. We did not conceal the allocation of participants, since the PI was primarily responsible for recruitment, baseline assessment, and letting the dyads know about their assignment. The PI who delivered the intervention and collected the follow-up outcome assessment was not blind to group assignment given the nature of the intervention. We collected feasibility data at three time points: screening, baseline, and a 4-week assessment. All acceptability and preliminary efficacy data were collected during the 4-week assessment.

Tailored Music Intervention

The tailored music intervention was based on the musical preferences of persons with dementia. The music contained both sleep-inducing and personal elements making it tailored to the person's level. To obtain musical preferences, the PI used the Assessment of Personal Music Preference tool[35] and at the end of the assessment read a list of different genres of music and asked persons with dementia to indicate their three favorites. The available list of preferred genres of music included Country and Western, Classical, Spiritual or Religious, Big band and Swing, Folk, Blues, Jazz, Rock and Roll, Easy listening, cultural or ethnic-specific, and other (fill in the blank). Older adults were also asked about their favorite songs and artists. The preference tool has been widely used to identify the preferred genre of music among older adults with varying severities of dementia.[35] In cases where the person with dementia could not respond to questions, the caregiver provided information for the music questions. We did not keep records of whether a person with dementia, a caregiver, or both provided music genre preferences.

The PI, who has degrees in Musical Arts and Nursing Science, then compiled a playlist of 6 to 8 selections for each dyad which incorporated their preferred genre of music, and their preferred artists and had sleep-inducing characteristics. These characteristics included: music selections at least 30 minutes in length,[36] between 60 and 80 beats per minute (bpm), slow stable rhythm, low-frequency tones, and absence of lyrics or strong percussion.[22,37] We hypothesized that listening to familiar music would be associated with memories of the past,[38] invoking a strong emotional response and disrupting sleep.[39] Therefore, the PI selected music based on the older adults' preferred genre, but the playlist did not contain songs that the person with dementia named during the selection process that was too familiar or excitatory. For example, the PI considered a person's preferred genre but did not include the specific song that the older adult mentioned during the interview in the playlist. We played a playlist for the person with dementia and their caregiver at the first session and observed their reaction. If they exhibited signs of distress or overall excitement, we would return a week later with a new playlist and reassess their reaction. Once the playlist was finalized, no other changes or additional songs were provided. In cases when a person with dementia preferred music with lyrics, an instrumental version of music from their favorite artist was chosen, if available. Instrumental music that does not contain lyrics is preferred over music that does contain lyrics to achieve a sleep-inducing effect.[37]

The tailored music listening protocol included persons with dementia (and their caregivers for some dyads) listening to sleep-inducing music at bedtime each day for 30 minutes over

28 days. The intervention lasted 4 weeks and included a maximum of 28 sessions. Three weeks of exposure to a music intervention was considered the minimum needed for positive sleep outcomes.[40] Additional instructions to dyads included i) completing a bedtime routine which may have included brushing their teeth or changing into night clothes, ii) laying down with their eyes closed; iii) wearing night clothes; iv) lights dimmed; and v) listening to the selected tailored music at a comfortable level. We used a mobile application, Elderfit, developed by the mHealth service to upload a playlist with songs purchased on iTunes and deliver the playlist to the dyad using a tablet (Samsung Galaxy Tab A 10.7 in) which each person with dementia received. Headphones were provided to each person with dementia but were not required to use. Caregivers were not the target for engaging in music listening. Caregiver involvement varied with each dyad with some persons with dementia relying more on their caregivers in administering the intervention compared to others. We did not monitor or capture how involved the caregiver was in the intervention. Once the intervention period started, the PI followed up with the dyad 3 days later to confirm that there were no issues with listening to music. Caregivers were instructed to look for signs of overstimulation or dislike. More details on this process are provided in our published protocol.[34] After the intervention period for a dyad, the tablet was removed from the home and given to the ElderFit developer, who downloaded the usage data and uploaded a new playlist for the next dyad. After a 4-week waiting period, the wait-list control group participants received the intervention for the same length and duration.

Outcomes

Demographic Health-related Characteristics. We collected the following demographic information at baseline for each member of the dyad: age, sex, race, ethnicity, nature of the dyadic relationship, education level completed, and source of recruitment. In addition, health-related characteristics were recorded as reported by caregivers. We captured the number of comorbidities for both persons with dementia and their caregivers using the Charlson Comorbidites Index.[41] Higher scores indicate more comorbidities (range 0–42). Depression in persons with dementia was assessed using the Patient Health Questionnaire-9 (PHQ-9)[42] that caregivers filled out. Summary scores range from 0 to 27 with higher scores indicating more depressive symptoms. Caregiver depression was measured using the Center for Epidemiological Studies Depression Scale (CES-D; range 0-60).[43] Higher scores indicate greater depressive symptoms. Behavioral symptoms in persons with dementia were assessed using caregiver reported Neuropsychiatric Inventory Questionnaire (NPI-Q),[44] an informant-based interview that measures the frequency and severity of behavioral symptoms in the last month. The total summary scores range between 0 and 12 with higher scores representing more behaviors. We assessed caregiver burden using the Zarit Burden Interview.[45] We computed the total score by summing the responses to each item with higher scores indicating higher caregiver burden (range 0–48). Physical function in terms of activities of daily living was examined using the Barthel Index.[46] We added responses to create a total score (range 0–100) with higher scores corresponding to better physical function.

Feasibility. The primary feasibility outcomes included the number of dyads who adhered to the study protocol (by listening to music and wearing the actigraphs), completed study measures, and sleep diaries. We considered the study feasible if at least 85% of the participants completed the study components and measures. The secondary feasibility outcomes included rates of enrollment (per month), participant attrition (number of participants who dropped out during the study and the reasons for doing so), and reasons for excluding or declining to participate in the study at screening.

Acceptability. We assessed the acceptability of the intervention in three ways. First, we asked the caregiver to respond to a 7-item questionnaire to assess the perceived benefits and satisfaction with participation in the study.[47,48] Two items focused on the perceived benefits of participating in the study from both members of the dyad (3-point scales not at all, some, or a great deal). Five items assessed satisfaction with study procedures (being treated with respect, the study clearly explained, study requiring too much effort, being willing to recommend this study to others, appropriateness of the number of sessions) using Yes/No responses. The team established that this study would be acceptable if the average score on the questionnaire is at least 80% (percentage responding "Yes" or a "Great deal"). Next, we asked the persons with dementia to rate their enjoyment of listening to music on a 7-point Likert scale (1- not at all enjoyable, 7 - extremely enjoyable). Third, we interviewed the dyads after they completed the intervention to gauge their acceptability and their satisfaction with the intervention. We conducted interviews mainly in person but needed to pivot to telephone interviews due to COVID-19 in March 2020. The dyad interviews included both members of the dyad, if possible. In cases where persons had advanced dementia, we asked only the caregiver's opinion. Interview questions included, "What did you think about the music that was selected for you" and "What else about this experience that you would like to share?" We audio-recorded and transcribed the interviews using a third-party HIPAA-compliant provider.

Sleep measures. We chose sleep latency, the time it takes a person with dementia to fall asleep starting from the first intention to sleep, measured by the Actigraphs as the primary efficacy sleep outcome. The secondary sleep outcomes included actigraphically derived total sleep duration (actual time the person is asleep) and Wake After Sleep Onset (WASO,

time awake during the night). We examined the change in scores on the PROMIS® sleep-related impairment-SF 8a[49] and Sleep Disorders Inventory (SDI)[50] as secondary subjective efficacy sleep outcomes. PROMIS® sleep-related impairment-SF has been validated for use among older adults in care communities with acceptable internal consistency and strong construct validity.[51] We asked caregivers to complete the PROMIS® sleep-impairment-SF for the person with dementia to get a broader sense of sleep disturbances. We included actigraphy in our study as well so that we examine changes in sleep using both subjective proxy-reported and objective sleep outcomes. We also used a sleep diary completed by the caregiver for the person with dementia which included eight questions to reconcile sleep patterns with actigraphy data.[52] The American Academy of Sleep Medicine recommends the use of a sleep diary in addition to actigraphy to capture sleeping patterns among older adults.[53] More details on how actigraphy data were analyzed can be found in our published study protocol.[34] Briefly, we collected data in 60-second epochs and used a validated scoring algorithm in the Philips Actiware software.[54] All automated scoring was reviewed and hand-scored following our investigator-developed protocol. The protocol used a sleep diary, ambient light, and activity levels to drive scoring rules. The PI and co-author (MM) assessed challenging cases on an individual basis. After reconciliation, we averaged the sleep variables over 3 days. For the intervention group, sleep latency, WASO, and total sleep duration were averaged over the first 3 days a participant wore their Actigraph and the last 3 days of the intervention period. For the wait-list controlled group participants, we calculated the average sleep latency, WASO, and total sleep duration for the first three and last 3 days a participant wore their Actigraph.

Analysis

Power analysis. We used the estimated confidence interval width for the primary feasibility outcome—participant adherence to the protocol. We set the 85% participant adherence threshold to consider this study feasible. We considered a value within 10–15% for adherence mean to be sufficient to identify issues that warrant study modification.[55] With a sample size of 50 dyads and an adherence rate of 85%, we would be 95% confident that the parameter estimate is accurate within 10% points. To account for the 16% attrition, we had plans to recruit 10 additional dyads for a total of 60 dyads (30 dyads per group).

Data Analysis. To examine feasibility and acceptability, we calculated descriptive statistics which included rates of adherence to the intervention, recruitment, attrition, reasons for excluding or declining, and acceptability survey results. In addition, we used qualitative data from the interviews with dyads to examine intervention acceptability. We used a qualitative descriptive approach with conventional content analysis to analyze the data through the identification of codes, patterns, and themes.[56,57] Given this was a feasibility study, we focused on feasibility and initial effect size estimation and were underpowered to detect significant differences between the groups.

To provide preliminary estimates of treatment efficacy on four sleep outcomes, we first calculated descriptive statistics and univariate comparisons between intervention and wait-list control groups. To estimate Cohen's *d* effect sizes, we used adjusted mean differences in treatment effects on one primary (sleep latency) and three secondary sleep outcomes (WASO, total sleep duration, sleep impairment, and sleep disorders). We also calculated 95% confidence intervals for each effect size.[58] We did not adjust for multiple comparisons, given the purpose of the study was to observe trends and provide effect sizes for a future larger study. SAS version 9.4 was used for all analyses (SAS Institute Inc., Cary, NC). We did not analyze the data using dyadic approaches given the design of our study which was not meant to be dyadic in nature. Rather we examined the effects of the intervention on sleep outcomes for persons with dementia only.

Results

Recruitment

We started recruitment in April 2019 and stopped in March 2020 prematurely due to COVID-19 pandemic social distancing guidelines and university restrictions placed on in-person research. We sent out 99 invitation letters to all potentially eligible caregivers and persons with dementia, who had previously participated in a larger RCT examining the effect of timed activity on sleep in persons with dementia and their caregivers [5R01NR015226, PI Hodgson][13] following a wash-out period of 3 months. Additionally, we sent out 22 invitation letters to individuals diagnosed with dementia from a memory clinic. Thirteen individuals were referred to us by participants in the current study. Four participants were referred to us from community outreach which included posting on a clinical trials website (n = 2), putting up flyers (n = 1), and presenting at a local community site (n = 1). We enrolled and consented the greatest number of participants, who were previously enrolled in the R01 study (n = 20, 60.6%), followed by participant referrals (n = 9, 27.3%) and community outreach (n = 4, 12.1%). Upon enrollment in the study, no dyads expressed hesitancy about being randomized to the intervention or wait-list control groups. No adverse events related to the intervention were reported.

Sample

A total of 33 dyads were randomized with 16 in the wait-list control group and 17 in the intervention group. Thirty (91%) of the 33 dyads completed the intervention, which included those who were randomized to the intervention group first and

Table 1. Baseline Demographic Characteristics by Group (N = 33).

	Overall (N = 33)	Wait-List Control (N = 16)	Intervention (N = 17)	*P*-value
Person with dementia				
Sex				.46
Female, n (%)	24 (72.7)	11 (68.8)	13 (76.5)	
Education, n (%)				.58
High school or less	14 (42.4)	7 (43.8)	7 (41.2)	
Some college	12 (36.4)	5 (31.3)	7 (41.2)	
College or above	6 (18.2)	3 (18.8)	3 (17.6)	
Missing	1 (3)	1 (6.3)	0 (0)	
Ethnicity, n (%)				.52
Not Hispanic or Latino	32 (97)	16 (100)	16 (94.1)	
Race, n (%)				.30
Black or African American	27 (81.8)	12 (75)	15 (88.2)	
White	6 (18.2)	4 (25)	2 (11.8)	
Age (Mean, SD)	71.7 (7.1)	72.8 (7.3)	70.7 (7.1)	.25
Clinical Dementia Rating				.39
0.5	26 (78.8)	11 (68.8)	15 (88.2)	
Caregiver				
Sex, n (%)				.46
Female	24 (72.7)	11 (68.8)	13 (76.5)	
Age (Mean, SD, min-max)	58.4 (16.7), 21-92	63.1 (13.5), 42-92	53.9 (18.6), 21-79	
Education, n (%)				.58
High school or less	14 (42.4)	5 (31.3)	9 (52.9)	
Some college	11 (33.3)	5 (31.3)	6 (35.3)	
College or above	7 (21.2)	5 (31.3)	2 (11.8)	
Missing	1 (3)	1 (6.3)	0 (0)	
Ethnicity, n (%)				.77
Not Hispanic or Latino	31 (93.9)	15 (93.8)	16 (94.1)	
Race, n (%)				.47
Black or African American	28 (84.8)	13 (81.3)	15 (88.2)	
White	5 (15.2)	3 (18.8)	2 (11.8)	
Dyad relationship, n (%)				.20
Child	10 (30.3)	6 (37.5)	4 (23.5)	
Friend	9 (27.3)	4 (25.0)	5 (29.4)	
Spouse	8 (24.2)	6 (37.5)	2 (11.8)	
Other	6 (18.2)	0	6 (35.3)	
Source of recruitment				.82
R01 study referral	20 (60.6)	9 (56.3)	11 (64.7)	
From another participant	9 (27.3)	4 (25.0)	5 (29.4)	
Other	3 (9.1)	2 (12.5)	1 (5.9)	
Flyer	1 (3.0)	1 (6.3)	0	

P values in the last column were from Fisher's exact tests for categorical variables or Kruskal Wallis tests for continuous variables.

those who completed the intervention after waiting 4 weeks. The baseline characteristics of participants are presented in Table 1.

Most persons with dementia were female (n = 24, 72.7%), received more than high school education (n = 18, 54.6%), identified themselves as Black/African American (n = 27, 81.8%), and non-Hispanic/Latino (n = 32, 97%). The mean age of persons with dementia was 71.7 years old (SD: 7.1). Caregivers were mostly female (n = 24, 72.7%), received high school education or less (n = 14, 42.4%), identified themselves as Black/African American (n = 28, 84.8%), and non-Hispanic/Latino (n = 31, 93.9%). The mean age of caregivers was 58.4 (SD: 16.7). Approximately one-third of caregivers were children of persons with dementia (n = 10, 30.3%). Participants in the intervention and wait-list control groups were balanced based on health-related characteristics (Table 2).

The top preferred genre of music among persons with dementia who enrolled and completed the study was spiritual/religious, mainly Gospel. Other preferred genres included

Table 2. Baseline Health-Related Characteristics by Randomized Group (N = 33).

	Overall (N = 33) Mean (SD)	Control (N = 16) Mean (SD)	Intervention (N = 17) Mean (SD)	*P*-value
Person with dementia				
Comorbidities (CCI)	3.4 (1.2)	3.7 (1.4)	3.1 (0.8)	.16
Depressive symptoms (PHQ-9)	5.9 (6.3)	6.5 (6.8)	5.3 (6.0)	.76
Neuropsychiatric inventory (NPI-Q)	3.2 (3.0)	3.2 (3.5)	3.1 (2.6)	.75
Sleep-related impairment (PROMIS®)	16.3 (6.7)	16.1 (6.6)	16.5 (6.9)	.93
Sleep disorders (SDI)	0.7 (1.2)	0.8 (1.3)	0.5 (1.1)	.22
Physical function (Barthel)	91.7 (17.8)	90.7 (21.0)	92.6 (15.1)	.45
Caregiver				
Comorbidities (CCI)	1.7 (1.4)	2.1 (1.5)	1.4 (1.2)	.14
Depressive symptoms (CES-D)	13.9 (4.5)	12.6 (3.5)	15.0 (5.0)	.40
Burden (ZBI)	15.8 (5.1)	16.8 (5.8)	15.0 (4.3)	.45
Actigraphy outcomes				
Sleep latency (min)	19.4 (21.7)	24.2 (25.9)	15.7 (17.8)	.27
Wake after sleep onset (min)	116.2 (47.9)	122.0 (47.9)	111.8 (48.9)	.59
Sleep duration (min)	495.0 (83.1)	528.4 (91.4)	469.4 (68.2)	.12

P values in the last column were from Fisher's exact tests for categorical variables or Kruskal Wallis tests for continuous variables.
Barthel: Barthel Index, CCI, Charlson comorbidities index; CES-D, Center for epidemiological studies depression scale; NPI-Q, Neuropsychiatric inventory questionnaire; PHQ-9, Patient health questionnaire-9, PROMIS®, PROMIS® sleep-related impairment-SF 8a; SDI, Sleep disorders inventory; ZBI, Zarit burden inventory.

RnB and Jazz. Most musical selections, except for Classical music, contained lyrics, were between 60 and 80 beats per minute, had slow stable rhythm, and mostly low-frequency tones (Table 3).

Feasibility

Our primary feasibility outcomes included the number of dyads who adhered to the study protocol and completed study measures and sleep diaries. For our secondary feasibility outcomes, we examined rates of enrollment, participant attrition, and reasons for declining to participate. We did not set a threshold for meeting the secondary feasibility outcomes. We reached out to 138 dyads with information about the study, and 37 dyads (26%) were screened for eligibility after expressing interest. Of the remaining 101 dyads, we were unable to reach 70 (69.3%) individuals, 18 (17.8%) were not interested, 4 (4%) died, and 9 (8.9%) were not eligible. Thirty-three dyads (89.1% of those who were screened) were enrolled in the study. Three dyads who were screened and found to be eligible to be in the study declined participation (two persons with dementia had ongoing medical problems requiring frequent hospitalizations, and 1 person with dementia did not want to wear the Actigraph). One dyad was screened immediately before the university announced COVID-19 restrictions placed on in-person in March 2020, therefore they were not enrolled in the study due to the uncertainty of when in-person research activities would resume. We recruited three dyads per month between April 2019 and March 2020 but were unable to reach our target sample of 60 dyads due to university-imposed restrictions on in-person research and a lack of financial and personnel resources to change the delivery of the intervention to a virtual format. We retained 30 of the 33 dyads at a 4-week follow-up, resulting in a retention rate of 91%. Two dyads withdrew due to the hospitalization of the person with dementia and one due to caregiver burden (Figure 1). Out of 60 available sleep diaries from 30 caregivers who completed the study in the wait-list control and intervention groups, 46 (76.7%) were returned complete, 9 (15%) were not filled out at all, and 5 (8.3%) were partially completed. Due to tablet reading errors and a change in the information technology staff overseeing the data download, we were not able to collect data on how long and how often persons with dementia listened to music. Two out of 30 persons with dementia took off their Actigraphs post-intervention; thus, we were unable to collect follow-up actigraphy data from these individuals. There were two instances where we had to use non-consecutive days when calculating the average of a sleep parameter across 3 days because the person with dementia took off their Actigraph on one of the days. We achieved a 99.5% completion of subjective study measures. We also noted that the process of selecting tailored music was easier when dyads expressed that they liked instrumental music that would naturally lend itself to sleep-inducing music.

Acceptability

Our study results indicate mixed acceptability of the intervention and the study benefits. When the dyads were asked about satisfaction with study procedures, all dyads across wait-list control and intervention groups felt that they were

Table 3. Musical Preferences and Examples of Musical Selections for the Study (N = 30).

Musical Genre	1st Choice n (%)	2nd Choice n (%)	3rd Choice n (%)	Examples of Musical Selections
Did not provide an answer	0 (0)	7 (23.3)	14 (46.7)	—
Country and western	0 (0)	2 (6.7)	2 (6.7)	—
Classical	6 (20)	3 (10)	2 (6.7)	• String Quartet No. 1 in D Major, Op. 11: II. "Andante Cantabile" by P. Tchaikovsky (Emerson String Quartet) • "Berceuse", Op. 57 in D-flat by P. Tchaikovsky (Arthur Rubenstein) • "The Seasons: June – Barcarolle" by P. Tchaikovsky (Ilona Prunyi)
Spiritual/Religious	9 (30)	4 (13.3)	4 (13.3)	• "Jesus we love you" by Isabel Davis • "When I need you" by Luther Vandross • "Jesus is love" by the Commodores • "Oh, it's Jesus" by Andrae Crouch
Big bands/Swing	1 (3.3)	0 (0)	0 (0)	—
Folk	0 (0)	0 (0)	0 (0)	—
Blues	1 (3.3)	1 (3.3)	2 (6.7)	"For my lady" by the Moody Blues
Jazz	5 (16.7)	6 (20)	2 (6.7)	• "Waltz for Debby" by Ahmad Jamal • "Laura" by Ahmad Jamal • "In her family" by Pat Metheny Group • "The feeling of jazz" by Duke Ellington & John Coltrane
Rock and Roll	0 (0)	1 (3.3)	0 (0)	—
Easy listening	1 (3.3)	2 (6.7)	1 (3.3)	• "Heal the World" by Michael Jackson • "Truly" by Lionel Richie • Various music selections by Frank Sinatra
Cultural or ethnic specific	1 (3.3)	0 (0)	0 (0)	• "Abrazame Muy Fuerte" by Marc Anthony • "Perdido Sin Ti" by Ricky Martin
Other	6 (20)	4 (13.3)	3 (10)	Other genres included RnB, Reggae, Oldies, and white noise

treated with respect during the study. The majority (n = 28, 93.3%) felt that this study was clearly explained to them, while a third of the sample felt that the study required too much work (n = 10, 33.3%). Regarding perceived study benefits, a third of the sample responded that the study benefited caregivers (n = 11, 36.7%) and participation in the project helped improve a person with dementia life (n = 11, 37.9%). The majority would recommend this project to others (n = 28, 93.3%, Figure 2).

The average score on the acceptability questionnaire (percentage of participants who responded "Yes" or "Great deal") was 69.5%, which fell below our acceptability threshold of at least 80%. When we asked persons with dementia to rate their enjoyment of listening to music on a 7-point Likert scale, 38 (93.3%) persons with dementia reported listening to music as very or extremely enjoyable.

Our qualitative findings provided additional insight into our quantitative survey findings. Most caregivers and persons with dementia reported that the intervention and music selection for the person with dementia was acceptable. The four themes identified from qualitative interviews were that the music selections were 1) relaxing, 2) found to be enjoyable, 3) promoted sleep among persons with dementia, and 4) brought back memories (Table 4).

Some participants shared feedback that they wanted the playlist to be continuous, so they did not have to click on the app again for music to resume after 30 minutes. In terms of study procedures, three out of 30 dyads commented that there was too much paperwork involved with the study which included filling out the sleep diaries and study questionnaires.

Initial Effect Sizes

Two out of three actigraphically derived sleep outcomes (sleep latency and WASO) improved from baseline to post-intervention in both the control and intervention groups with greater improvements in the wait-list control condition. Total sleep duration decreased in the wait-list control group but increased in the intervention group. The effect sizes for actigraphy outcomes using Cohen's *d* ranged between small (0.3 for total sleep duration) and moderate (0.47 for sleep latency and 0.59 for WASO). Subjective ratings of sleep impairment using the PROMIS® sleep-related impairment questionnaire stayed relatively the same in the control group but improved in the intervention group. The ratings on the sleep disorder inventory remained relatively the same in the control group and the intervention group. The effect sizes for subjective sleep outcomes showed no differences in effect (sleep disorders inventory at 0.04) and small effect (0.19 for PROMIS® sleep-related impairment) (Table 5).

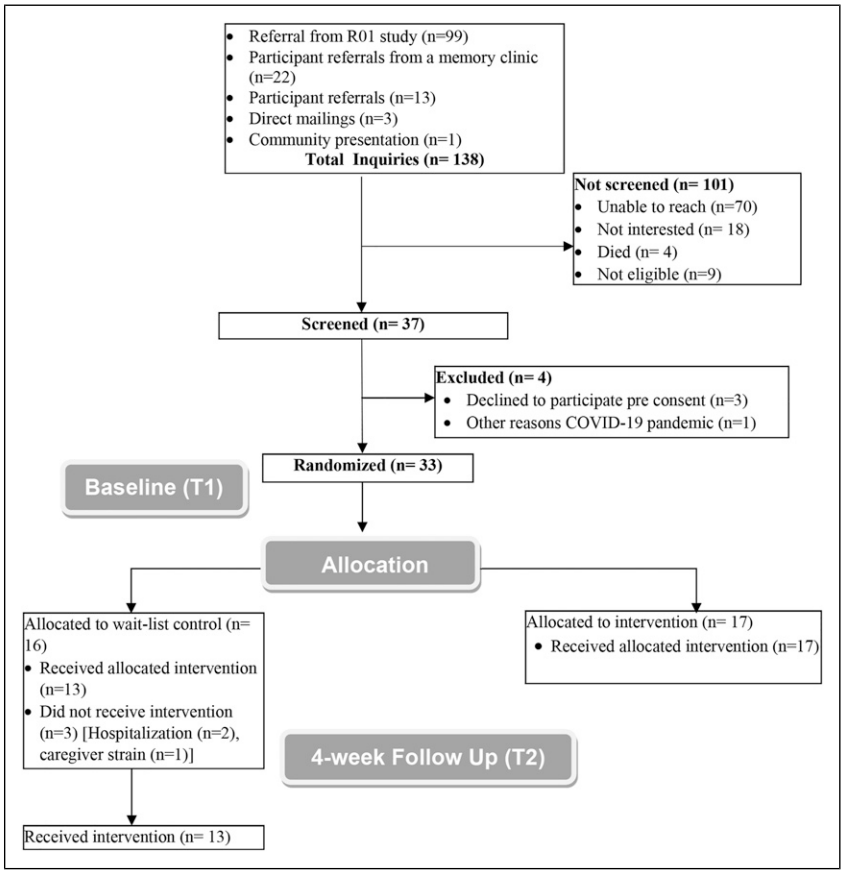

Figure 1. Participant flow through the study.

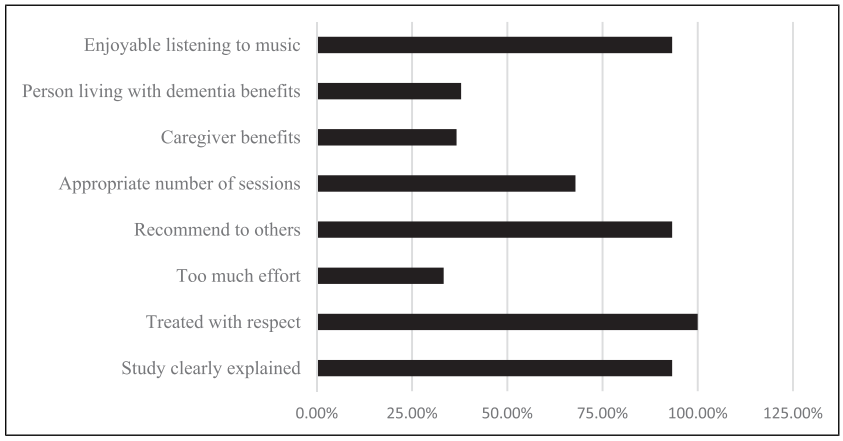

Figure 2. Perceived benefits of study participation at post-intervention (N = 30).
Percentages indicate those responding "very enjoyable" or "extremely enjoyable" for enjoyment listening to music, "yes" for Study Satisfaction questions, a "great deal" for Caregiver or Person with Dementia Benefits items.

Discussion

This is the first study to our knowledge to rigorously study a tailored music intervention for its feasibility and acceptability using objective and subjective sleep outcome measures and a control condition. Overall, we would consider our study as mostly feasible as indicated by greater than 85% completion rates of study measures and adherence to wearing the Actigraphs, our primary feasibility outcomes. However, the completion rates of sleep diaries fell below 85%. As a consequence of COVID-19, we were unable to recruit the full intended sample and examine how well participants adhered to

Table 4. Qualitative Interview Findings.

Theme	Select Quotes
Music was relaxing	"Sometimes it gives your brain, their brain, a little time to relax and just reminisce on things that they want instead…" (Caregiver 4) "The music that you chose for him was really good… It was a good tempo, it was good material, it was, peoples' voices that we knew and liked and it was very soothing and relaxing at the end of the day" (Caregiver 11)
Music was enjoyable	"The music that was selected was very nice for him. And he enjoyed it and it did put him asleep and he would wake up at a good time." (Caregiver 10) "I just enjoyed it and it's really amazing, it lifts me up even more because I was doing okay but it made me very relaxed and joyful." (Person with dementia 31)
Music helped me sleep	"I think it's a great sleep aide. I never was one to take medication for sleeping, but when you can't…when I couldn't sleep, I really enjoy listening to soft music to lull me asleep" (Person with dementia 2) "It did teach me that music helps sometime put him to sleep." (Caregiver 4)
Music brought back memories	"It might remind me of my days when I was in love with my husband and stuff like that." "The gospel reminds me of when I was younger because I was always, my mother always kept us in church, and my mother played gospel and sung gospel." (Person with dementia 12)

Table 5. Changes in Means and Cohen's d Effect Sizes for Sleep Outcomes (N = 33).

	Control (N = 16)	Intervention (N = 17)	SMD	95% CI
Actigraphy outcomes				
Sleep onset latency (min)			0.47	0.17, 0.76
Mean (SD)	−17.8 (21.0)	−7.6 (22.3)		
Min, Max	−61, 6.7	−64.7, 26		
WASO (min)			0.59	0.29, 0.89
Mean (SD)	−22.7 (25.0)	−2.2 (40.6)		
Min, Max	−61.7, 30.3	−95.7, 78.3		
Total sleep duration (Min)			0.30	0.009, 0.59
Mean (SD)	−27.7 (77.6)	2.5 (115.7)		
Min, Max	−123.3, 97.3	−247, 211		
Subjective outcomes				
PROMIS® sleep related impairment			−0.19	−0.46, 008
Mean (SD)	−0.3 (6.6)	−1.59 (6.9)		
Min, Max	−17, 6	−22, 12		
Sleep disorders inventory			0.04	−0.23, 0.31
Mean (SD)	−0.2 (0.3)	−0.1 (1.3)		
Min, Max	−0.9, 0.6	−4.2, 2		

Abbreviations: WASO, Wake after sleep onset; PROMIS®, Patient-reported outcomes measurement information system; SMD, Standardized mean difference; CI – Confidence interval.
Changes in Means were calculated as a 4-week Follow-up minus Baseline.

the study protocol by listening to music. The results from our secondary feasibility outcomes which included examining rates of recruitment, participant attrition, and reasons for declining to participate in the study were encouraging. Our recruitment rate was low at 26%, while our enrollment and retention rates were high (89.1 and 91%, respectively). The most common reason for those who were screened and were found eligible but did not enroll in our study had to do with ongoing medical problems. Our attrition rate was low at 9%. Our acceptability results were mixed with the average acceptability survey scores falling below the set threshold of 80%. However, analysis of qualitative exit interviews with the dyads revealed to us that the intervention was enjoyable. We found a small effect size on one actigraphically derived sleep outcome (total sleep duration) and one subjective measure of sleep disturbance (PROMIS® Sleep Related Impairment), although the latter was not statistically significant. We learned several lessons from this rigorous pilot study to guide future clinical trials and research to develop efficacious music interventions aimed at improving sleep disturbances in this population.

Findings from our study highlight multiple approaches that are needed to recruit a diverse sample of older adults with dementia and their caregivers. In a 12-month timeframe, we were able to recruit a racially diverse sample of older adults with dementia and their caregivers. Our most successful

method of recruitment was from a parent R01 study of a timed behavioral intervention aimed at improving circadian rhythms in older adults with dementia and their caregivers. This points to the importance of partnering with other researchers who are conducting clinical trials in dementia. Persons with dementia and their caregivers may seek multiple opportunities to be involved in research and learn more about their condition and helpful approaches.[59] However, there is a concern about enrolling families who are frequent participants in other trials. It raises the question of generalizability, contamination, and accumulative effects of participating in multiple intervention trials. Participants in multiple clinical trials may be more familiar with the research process and more likely to follow the prescribed research protocol. Given the challenges in recruiting diverse persons with dementia in clinical research, our recruitment efforts resulted in a relatively low (26%) initial screening rate. The most common reason for not being able to screen participants had to do with us not being able to reach them. Once we screened the dyads, 89.1% agreed to participate in the study. Our enrollment rate was comparable to another study run with older adults in the same period.[60] Similar to our study findings, prior research indicates that recruitment of individuals with dementia and their caregivers requires a multi-pronged approach, community and clinician partnerships, as well as flexibility with scheduling.[59,61,62]

When examining the intervention acceptability survey, we found mixed results. While it may seem that music interventions are easy to carry out, we should anticipate potential challenges and monitor adherence in older adults with dementia and caregivers. Only a third of the dyads felt that the study benefited persons with dementia. This relatively low rate of perceived benefit may be attributed to caregivers not seeing the immediate benefits of listening to music in older adults with dementia and correspond to actigraphically derived sleep outcomes (sleep latency and WASO) not improving after the intervention. The caregiver burden associated with study participation and filling out the questionnaires may have overshadowed any of the perceived positive benefits for persons with dementia. We heard about the difficulties of filling out paperwork from three participants in our qualitative interviews. Additionally, some caregivers did not sleep in the same room or bed as the person with dementia or worked night shifts and were away from the home making them less likely to know how the person with dementia slept during the night. Furthermore, since the intervention was targeted at persons with dementia and not the caregivers, future interventions targeting the caregiver and the dyad as a unit may decrease caregiver burden as well as their sleep disturbances and thus improve their perception of benefits for persons with dementia. Even though persons with dementia reported that they enjoyed listening to music, their caregivers did not perceive the music intervention to be beneficial. The dyads were satisfied with the study procedures and the majority would recommend the study to others. Our qualitative data provided additional insight into our quantitative findings. In exit interviews, participants shared with us that listening to music was relaxing, and enjoyable, helped persons with dementia sleep and brought back memories despite most caregivers reporting no tangible benefits in the acceptability survey.

When we examined initial effect sizes across objective and subjective sleep outcomes, we found small to moderate effects with two objective sleep outcomes (sleep latency and WASO) in favor of the control group and one objective sleep outcome (total sleep duration) in favor of the intervention group. This suggests that all participants fell asleep faster and were awake less after falling asleep after the study. One possible explanation is that completing sleep diaries may have brought more awareness of poor sleep habits to caregivers. Although practicing good sleep hygiene is beneficial, there is limited evidence to suggest that sleep hygiene alone is enough to improve sleep disturbances.[63] More research is needed to determine how caregivers' increased insight into person's with dementia sleep habits affects sleep outcomes. Subjective ratings of sleep impairment improved in the intervention group but remained relatively constant in the wait-list control group. One other explanation is that our intervention was not successful at improving the time it takes a person to fall asleep faster and stay asleep, but did have a positive effect of increasing total sleep duration. Our study findings add to the body of knowledge examining the impact of music on sleep in nursing home residents,[23] older adults with subjective memory loss[25] and probable Alzheimer's disease.[24] Tailored music is an innovative and widely available approach that can be used to target sleep disturbances among older adults with dementia. This study focused on community-dwelling older adults with dementia and their caregivers combining the sleep-inducing properties of music with its ability to be tailored to an individual. Given that we found mixed preliminary efficacy results with small effect sizes in favor of the control group, our music intervention warrants further development, refinement, and testing.

We acknowledge several study limitations. First, we were unable to recruit the targeted sample size due to institutional restrictions placed on in-person research due to the COVID-19 pandemic and the limited resources available to adapt the intervention delivery. As recently highlighted in a protocol paper of a large Phase III efficacy of the WeCareAdvisor intervention targeted at caregivers for individuals with dementia, major modifications to the design were needed to adapt to the COVID-19 pandemic.[64] Given that our study was a small-scale feasibility study we could not justify major modifications; thus, we stopped recruitment in the Summer of 2020. Second, the sample recruited for this study came primarily from a larger nonpharmacological clinical trial. Third, this feasibility study was not powered to formally test the intervention efficacy which limits the generalizability of our study findings. Fourth, we were unable to access the fidelity of the intervention because of a technical error in downloading usage data from smart tablets and due to a change in information technology staff overseeing the data download. Fifth,

both participants and outcome assessors were not masked to group assignment which may have biased their responses. Lastly, many participants in our study did not have a formal diagnosis of dementia. Individuals with a formal diagnosis of dementia may behave differently from those with self-reported memory impairment.

Despite the limitations, our study also has important strengths. We recruited a diverse sample of older adults with dementia and their caregivers with regard to their reported race and education. Over 80% of our sample identified themselves as Black or African American. Forty-two percent of persons with dementia and caregivers completed high school or less. In addition, we used a combination of subjective and objective sleep measures to examine sleep disturbances in persons with dementia. Furthermore, we used a novel approach for selecting tailored music that not only accounted for personal genre preference but sleep-inducing music qualities as well.

We learned several lessons from this study that can inform future research focused on music-based interventions for persons with dementia targeting sleep disturbances. It is essential that future studies that are focused on developing interventions for older adults with dementia and their caregivers involve stakeholders from the beginning. User-centered design, for example, is one method that includes the end users in the initial design phases of the research project. Future clinical trials that include music-based interventions may benefit from including an attention control condition such as sleep education. This might also help with recruitment, as McPhillips and colleagues[59] found that one reason dyads, which include a person living with dementia, enroll in a clinical trial is because they want to learn information and gain knowledge. Given the universality of music and the fact that caregivers often provide care for persons with dementia, research teams could address dyadic health and the impact of music on caregivers' well-being. For example, the Theory of Dyadic Illness Management may guide researchers to measure dyadic health and how music can be helpful for both members of the dyad.[65] In addition, our mixed acceptability findings can aid in identifying novel strategies to improve future study design, such as limiting the amount of study-associated paperwork and introducing passive ways to collect outcomes of interest. Finally, echoing the call for mechanistic clinical trials from the National Institutes of Health Sound Health initiative, examining the mechanism of music-based interventions for sleep will provide the knowledge of putative targets and optimize the development of future music-based interventions. Potential mechanisms of how music can promote sleep include thought redirection (focusing on the music rather than intrusive or negative thoughts), promoting relaxation,[66] and neural entrainment which refers to a process of synchronization between musical rhythm and internal bodily rhythm.[67]

In summary, the results of this feasibility RCT were mixed. While we did not meet our acceptability targets, the results of our qualitative findings provided additional insight into our quantitative findings. The initial effect size calculations provide support for further refinement and testing of the intervention. Based on our findings, future research should involve stakeholders in the initial phases of intervention development, integrate other components of sleep hygiene, and examine mechanisms of action. Our study findings may inform future design and formal efficacy testing of tailored music-based interventions for persons with dementia and their caregivers including those that aim to reduce caregiver burden and sleep disturbances.

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