



Evaluation of the Music Engagement Program for people with Alzheimer's disease and dementia: Study protocol for a pilot trial

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ABSTRACT

Background: Alzheimer's disease and dementia are prevalent conditions globally. People with Alzheimer's disease and dementia commonly experience mental health problems, negative emotional states, and behavioural disturbance. Music therapy has previously been used in this population to improve symptoms of mental health problems; however, there is a paucity of evidence-based programs that also explore positive outcomes such as overall quality of life, social outcomes, as well as the acceptability and sustainability of these programs.

Aims: This project aims to evaluate the effectiveness of the specialised Music Engagement Program (MEP) in improving quality of life, wellbeing, and depression symptoms, in aged-care residents with Alzheimer's disease and dementia. The project also aims to explore how the MEP could be applied and maintained on a broader level throughout the aged-care community.

Methods: The intervention will take place over 8 weeks in an aged-care facility for people living with dementia in Canberra, Australia. Weekly 45-60-min group singing sessions will be led by a music facilitator.

Results: The results of the study will be submitted for publication in relevant academic journals and mental health conferences, disseminated to participants on request, to the residential care facility, and via the lead researcher's website.

Conclusions: This study can provide an indication of the feasibility of the MEP in enhancing the mental health and wellbeing of individuals with Alzheimer's disease and dementia. Further investigation will be required to establish the MEP's ability to be maintained on an ongoing basis with minimal costs and administrative support.

Trial registration: Australian New Zealand Clinical Trial Registry (ANZCTR): ACTRN12618001690246

1. Introduction

Alzheimer's disease and dementia are common conditions with around 50 million people currently living with these illnesses globally [1]. The world prevalence of Alzheimer's disease and dementia is expanding at a rapid rate [2], and is expected to triple to 152 million people by 2050 [1]. These conditions are extremely disabling, and can be severely detrimental to an individual's physical functioning, wellbeing, and mental health [3]. People with Alzheimer's disease and dementia often experience difficulties in communication and may have aphasia, which can lead to isolation and loneliness [3]. A loss of ability to participate in everyday activities such as communication becomes

increasingly likely and is highly detrimental to health and quality of life [4]. Aged-care residents are at high risk for mental health problems [5], with up to 50% of people with Alzheimer's disease and dementia experiencing depression [6]. People with Alzheimer's disease and dementia often experience significant behavioural disturbances such as aggression, sleep disturbances, and wandering [5]. If these disturbances are not well-managed by residential aged-care facility staff, significant adverse outcomes for residents including increased rates of falls, restraints and social isolation, and increased rates of staff burnout can result [7,8].

Abbreviations: ANU, The Australian National University; MEP, Music Engagement Program

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1.1. Music as therapy

For many people with Alzheimer's disease and dementia, the ability to experience music remains intact even when other cognitive functions begin to deteriorate [9]; music as therapy can be an important way to communicate with this population. The use of music and singing can encourage social interaction [10], reduce agitation [11], and bring about pleasant emotional states in people with Alzheimer's disease and dementia [12]. Therapy utilising music in this population has been well-documented [13,14]; however, there is a lack of evidence-based programs with broad-scale applicability and sustainability in the community. Music therapy delivered by therapists can be expensive for residential facilities to maintain; thus there is a need to investigate other options for ongoing program sustainability with minimal funding. In part to address this issue, some programs have elected to deliver more feasible and easily scalable programs such as listening to music using headphones or speakers [15]. While music programs delivered via technology can be effective, improving social interaction has been found to have the greatest impact on affect in people with dementia [4]. The Music Engagement Program (MEP), developed by leading researchers at the Australian National University (ANU) School of Music, was created with principles of shared and social altruistic music-making as the central tenet [16]. While it has a long history of participatory music-making in the community, the program has yet to be formally evaluated in a residential aged-care population. Moreover, a 2017 Cochrane review noted that previous studies on the effect of music therapy neglected to include other potential positive outcomes, such as overall quality of life, social outcomes, and wellbeing [14]. Consequently, there is a need for interventions that have the potential to improve other outcomes including quality of life, social outcomes, as well as decrease symptoms of mental health problems.

2. Aims

The project aims to evaluate the effectiveness of the MEP, a specialised music program, in improving quality of life, wellbeing, and depression in aged-care residents with Alzheimer's disease and dementia, and explore the acceptability, feasibility, and sustainability of the program in this setting.

2.1. Trial design

We propose to conduct a small-scale pre-post pilot evaluation of the MEP in an aged-care residential facility in the ACT. The exploratory project design involves the pre-to post-intervention evaluation of a single group of participants. To collect further information for this study, we will also conduct interviews with the residential aged-care facility staff, and perform pre and post-session measures of quality of life, and emotional wellbeing with the residents who participate. This study protocol addresses the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist [17].

Ethics approval

The ethical aspects of this research have been approved by The Australian National University Human Research Ethics Committee (ANU HREC 2018/645).

3. Methods

3.1. Intervention

3.1.1. The Music Engagement Program (MEP)

The MEP is an established program targeted at increasing engagement and participation in the act of intergenerational music-making for wellbeing [18]. The MEP uses a unique approach informed by a social

philosophy of shared, active music-making known as the Music Outreach Principle [16]. This principle involves making music with the intent of altruistically reaching out to others. The MEP approach has been utilised by schools and care facilities, as well as in the general community in the Australian Capital Territory (ACT) for the past 20 years. Staff observations from delivering the program in community groups previously, indicate that the MEP approach may be particularly effective in improving mental health and quality of life among people with Alzheimer's disease and dementia. However, the MEP has not to date been formally evaluated in terms of its acceptability, feasibility, and sustainability in an aged-care facility.

The intervention will comprise 45–60 min group singing MEP sessions led by a highly experienced music facilitator (author GP), with 15–20 residents weekly for 8 weeks at a secure dementia unit in an aged-care facility in Canberra, Australia. The duration of the program was based on the typical number of sessions ($n = 6$ to 10) for psychological treatments for depression in older age groups [19]. We aim to train the staff employed at the facility in MEP techniques during this time. There will also be familiar facility staff available during the research to assist the researchers in mitigating any resident distress.

The MEP sessions include the singing of repertoire familiar to the residents, taking into account their age, cultural background, and musical preferences. Residents are encouraged to suggest songs and help each other engage in singing in a relaxed social setting. The aim is to use music to facilitate social interaction and engagement between residents, staff, and the music facilitator. Social outcomes, as opposed to musical outcomes, are given priority. The creator of the MEP (author SW), has described techniques used during social interactions between music facilitators and participants such as close personal contact are used to help encourage individual engagement within a group singing situation. Residential care facility staff and residents will be encouraged to lead songs and sing for each other in an increasing capacity over the 8 weeks, in order to encourage communal facilitation rather than reliance on an external musician; thus, addressing the sustainability aspect of the intervention.

3.2. Inclusion criteria

Potential participants will all be existing residents of the secure privately owned residential aged-care facility in Canberra, Australia. All residents who have had consent provided for them by a family member/carer will be eligible to participate in the study. Staff working at the residential facility who are involved in the administration of the program will also be invited to participate in an interview at the conclusion of the MEP intervention period.

3.3. Recruitment

The MEP intervention will be delivered over 8 weekly sessions to residents at a scheduled, regular time during the week. It is anticipated that the program will commence during late 2018.

Fig. 1 demonstrates the trial flow for the study.

3.3.1. Resident evaluation

Recruitment of residents will be conducted by the residential facility staff. The target participant groups are residents (currently $N = 19$). Residents vary in the severity of their dementia; however, all will be invited to participate regardless of severity. In order to reduce the burden on potential participants, dementia severity data will be determined by existing data collected previously by the residential facility staff. There will be no minimum or maximum participants required for the research or for program delivery; we will recruit as many residents as whom wish to participate.

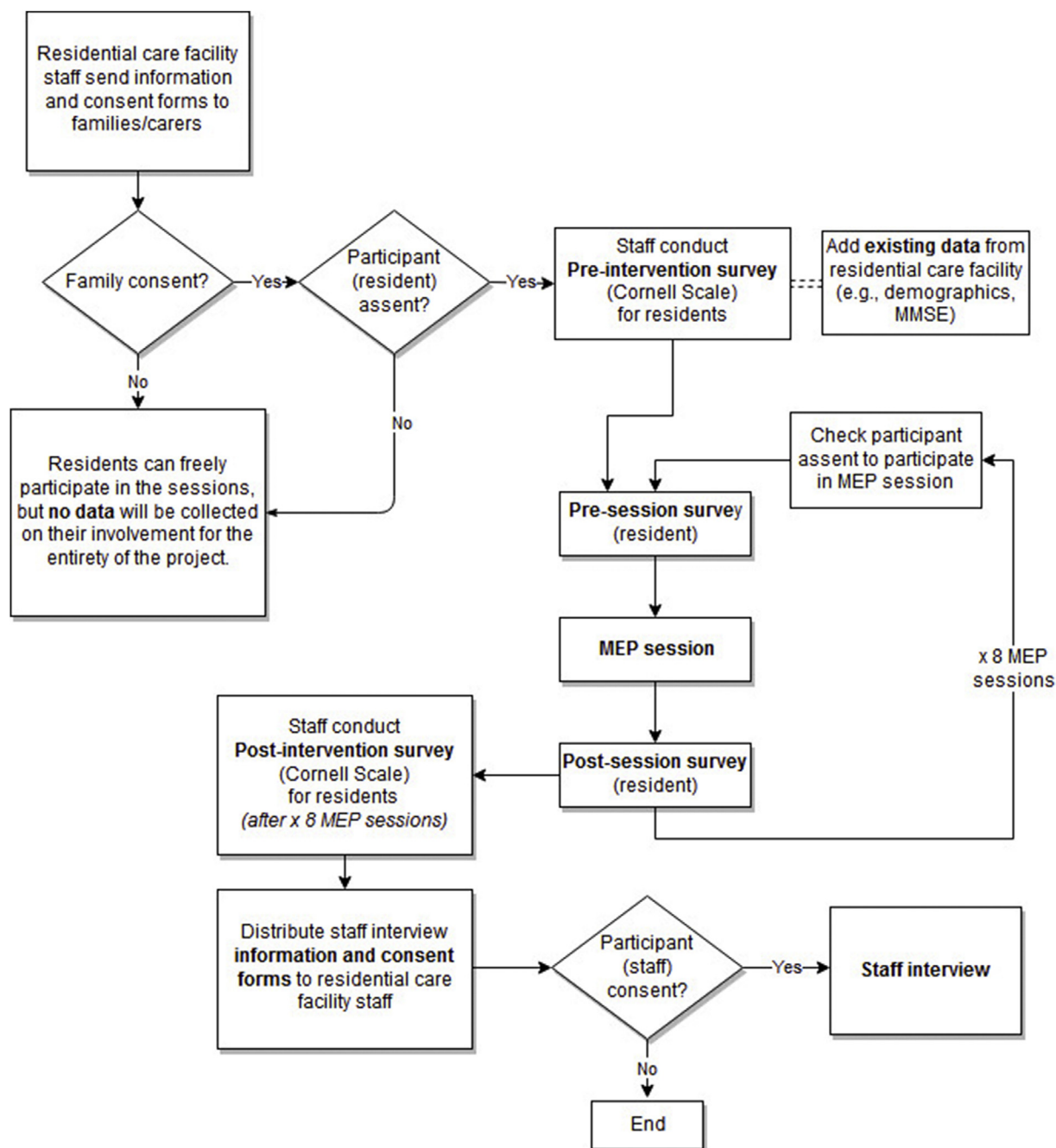


Fig. 1. Trial flow chart.

Consent

Invitations will be sent by the residential care facility via post and/or email to the family/carers of residents including information, and consent forms for participation in the research. The family/carer consent forms will then be collected by the residential care facility staff. After consent has been collected from the families/carers of residents, assent will be sought to participate from the residents themselves. The researchers will verbally explain the study to all residents who have had consent provided by their family/carers addressing the key points of the study required for deciding to participate in a research study [20]. Researchers will then seek assent from these residents. If residents indicate that they do not wish to be part of the research, they will not be included in the research components of the study regardless of whether their families have provided consent for them to take part. Each

resident's assent/dissent to participate will be recorded, and participating residents will be provided with a copy of a participant information sheet that details the project. Residents will be able to take part in the music program independently of the research component. Staff at the residential facility are very familiar with each resident, and are highly trained in recognising residents' willingness to engage in activities.

3.3.2. Staff evaluation

The target group for the staff evaluation will be staff ($n = 3$ to 5) involved in the delivery of the MEP intervention. Staff participants will be invited to participate in interviews (paired with another staff member if desired) to discuss their opinions of and experiences with the program, and their observations of the feasibility of continuing the program and any barriers to its uptake.

3.4. Hypotheses

We propose the following exploratory hypotheses:

H1. Symptoms of depression in aged-care residents will be lower post-intervention (after the delivery of the 8-week MEP sessions) than at pre-intervention.

H2. Current emotional wellbeing and social connectedness will be higher at post-session (immediately after each MEP session) than at pre-session.

4. Outcomes

4.1. Existing resident data

Staff have previously collected data on residents on file at the residential care facility, including demographics, and the Mini-Mental State Examination (MMSE). We will use these existing data to provide demographic details (e.g., age), and an estimate of the severity of dementia of the group.

4.2. Pre- and post-session resident evaluation

Immediate pre- and post-session evaluation of emotional wellbeing and social connectedness will be conducted by visual analogue survey based on the WONCA charts for “Feelings” and “Social Activities” [21]. Appendix A presents the modified WONCA chart. Previous research has demonstrated the reliability and validity of the original WONCA charts in populations with vision or language impairment, such as stroke [21]. The WONCA charts have been specifically used with people with dementia and with residential care-home residents [22,23]. Each possible response on the chart is illustrated by a drawing that depicts a level of functioning or wellbeing along a 5-point ordinal scale, to aid those with literacy impairment, with the verbal scale assisting those with vision impairment. The timeframe has been modified from the original “During the past 2 weeks ...” to “At this moment” to facilitate understanding due to temporal issues, and specifically measure any changes that may occur after the MEP session. The language has been similarly simplified to capture the core concepts we were interested in measuring: emotional wellbeing and social connectedness. Thus, residents will be asked “At this moment ... how emotionally well do you feel?” and “how social or connected with other people do you feel?” The scale ranges through *not at all* (1), *slightly* (2), *moderately* (3), *quite a bit* (4), to *extremely* (5). For the emotional wellbeing scale, each descriptive word is matched with a picture of a cartoon face frowning (1) to one of that smiling broadly (5); for the social connectedness scale, the pictures are of a person on their own, set apart from a group of stick-figure people (1) to one where the person is fully integrated within the group of people (5). At the ethics board's request (ANU HREC 2018/645), we also removed the smiling face of the individual stick figure in the social connectedness scale due to the committee's concerns that the correlation between social connectedness and happiness may not resonate with some people.

Residents will either be able to verbalise or point to the picture they identify with at that time. Given that the residential care facility houses residents with a wide range of dementia severity, the collection of this data is partly experimental to ascertain the WONCA scale's feasibility as a method of data collection in this real world setting. A researcher will be present to conduct the survey with the assistance of a residence staff member who is highly familiar with all residents and will be able to assist with facilitating communication.

4.3. Pre- and post-intervention proxy resident evaluation

Pre and post-intervention proxy surveys of residents' symptoms of

depression will be conducted by a residential care facility staff member. The proxy survey will consist of the Cornell Scale for Depression in Dementia [24]; a scale that has been validated in multiple dementia populations including residential care homes [25–28]. It has also been used as an evaluation measure previously at the residential facility designated for the current study. It measures multiple indicators of depression and also provides an indication of quality of life through measuring factors of *mood-related signs* (including anxiety, irritability), *behavioural disturbances* (agitation, retardation), *physical signs* (loss of appetite, tiredness), *cyclic functions* (difficulty falling asleep, symptoms worse in morning), and *ideational disturbances* (suicidal tendencies, pessimism). The Cornell Scale measures 19 items evaluating the individual's symptoms of depression and related wellbeing items (e.g., anxiety, appetite, agitation) on a 3-point scale where the symptoms are *absent* (0), *mild or intermittent* (1), *severe* (2), or *unable to evaluate* (a). Items are summed to obtain subscale and total summary scores. A score above 10 signifies probable major depression. Staff will complete a proxy Cornell Scale for each resident (~20 min) who participates in the study prior to the beginning of the MEP delivery, and again after the 8-week intervention period. A small amount of observational data (note-taking) will also be collected on the groups (e.g., the interaction between participants and resident attendance) to assist with the evaluation. Notes will not be taken on any residents who are not participating in the research.

Table 1 presents the measures and their delivery time points in the study.

4.4. Staff interviews

The staff interviews will follow a semi-structured protocol [29]. Appendix B presents the questions for the staff interviews. All staff associated with the implementation of the program will be asked to discuss the benefits and challenges of the MEP delivery, their experiences with the program, and any barriers that may impede staff in continuing the program without the music facilitator present to assist. The interviews will be scheduled at a time and location that is convenient for the staff member. Staff interviews will be offered in pairs if desired. Paired interviews are an ideal method of assisting interviewees working in healthcare contexts to make meaning together [30]. In addition, providing this option can bolster the level of participation in interviews for those who may be anxious to speak in a one-on-one situation. These interviews will be conducted after the 8-week trial period. Residential care facility staff will be directed to contact their employee assistance program or Lifeline if they become distressed as a result of their participation in the interviews. Data analysis and write-up is planned for completion in early 2019.

4.5. Data collection

Pre-post session data collection will be conducted by a research assistant (author NK, supervised by AG), and assisted by a staff member at the residential facility with whom residents are highly familiar. Pre- and post-intervention data collection will be facilitated by NK, and completed by residential facility staff. Author NK will conduct the interviews with staff and audio-recordings of the interviews will be made to ensure accuracy of content. Professional transcribing may be employed depending on budget and time constraints. Any professional transcribing completed by those outside the research team will be bound by strict confidentiality agreements.

4.6. Data management

Completed surveys and consent forms will be stored in locked filing cabinets at ANU. All other information will be recorded and stored on password-protected computers. Retained data will be de-identified. Residents who agree to participate will be assigned a code, which will

Table 1
Assessment time points.

Construct	Measure	Residential facility data (prior to study)	Pre-intervention (before week 1)	Pre-session (weeks 1–8)	Post-session (weeks 1–8)	Post-intervention (after week 8)
Depression symptoms	<i>Cornell Scale</i>					
Mood	<i>Visual analogue</i>			X	X	
Social connectedness	<i>Visual analogue</i>			X	X	
Demographic data (e.g., age)	N/A					
Dementia severity	<i>MMSE</i>	X				

be linked with their survey data. Names and survey data will be stored in separate files. Only the research team will have access to these materials. Consent forms will be stored in a locked filing cabinet at the Centre for Mental Health Research, ANU. Interview data audio-recordings will be transcribed without including any names. During publication of results, quotes that indicate the age and gender of the participant may be presented, in addition to aggregate results. The data obtained will be stored for a minimum of five years from the date of any publication that may result from the present study. After this five-year period, the only data retained will be de-identified the data may be either securely destroyed (i.e., deleted), or archived for future use by the Centre for Mental Health Research, ANU.

5. Analysis strategy

5.1. Quantitative component

Data analyses will be conducted using SPSS (Statistical Package for the Social Sciences, IBM Corp, 2016). Data on resident depression outcomes will be analysed using a paired *t*-test (or appropriate non-parametric equivalent) to test for differences in depression symptoms before and after completing the program [31]. If data collection methods for pre- and post-session resident outcomes for emotional wellbeing, and social connectedness are successful, change scores for these outcomes at each time point will be explored in context of the session notes. We will also estimate Cohen's d_x effect sizes to evaluate the strength of the effects on depression symptoms given the small sample size and taking into account within-participant correlations over time [32].

5.2. Qualitative component

Interview transcript data will be managed using NVivo software (QSR International). A member of the research team will conduct a qualitative analysis of the data using the methods of framework analysis [33]. Inductive and deductive coding will be utilised to identify key issues for staff regarding the program and barriers to implementation.

5.3. Incentives

Participation in this study will be entirely voluntary. However, small gifts will be provided in appreciation for participants' time and efforts. Staff will be provided with a \$50 gift card for participating in the interviews. We sought advice from the residential care staff on the most appropriate gifts for the residents. As a result of this consultation, all residents, including those who do not participate in the research, will be provided with a compact disc of the music from the MEP that they can listen to at a later date.

5.4. Risks and benefits

In addition to the risks addressing potential distress as outlined in the protocol above, further risks include that due to the small number of participants involved in the study, it is possible that participants may be identifiable from staff comments. These risks apply to those who agree to participate in the study, including residents and potentially staff. To manage the issue of participants potentially being identified through staff comments, every effort will be made to pool data to minimise this risk.

We anticipate that participating in the MEP sessions will be enjoyable for residents and staff based on previous delivery of this program with residential populations (by authors SW and GP). Importantly, participation by staff and residents in the research component will help us explore whether the program is a beneficial experience for residents' quality of life and mental health. It is possible that participation in the

research may not benefit residents or staff directly, but it may contribute to improving services delivered in the future. We also anticipate that participating in these interviews may be a cathartic experience for staff [34]. This project will also enable us to provide information to researchers, service providers, and government on the optimal delivery of programs such as the MEP to enhance the health and quality of life of aged-care residents in the community over the coming years

5.5. Quality assurance and monitoring

The lead author (AG), research assistant (NK), and music facilitator (GP) will work closely with each other and with the residential care facility staff to monitor any issues that may emerge. The core team (AG, NK, GP) will have regular contact with other members of the research team to monitor the progress of the project. NK and GP who will be present at each music session will be responsible for bringing to the immediate attention of AG and the co-investigators any problems with the research (e.g., participant reports of distress). Should a major problem occur during the course of the research, an investigator meeting will be convened immediately to determine an appropriate response and if appropriate the Ethics Committee will be informed. All participants and their family members/carers will be provided with a telephone number and email address on the information sheet and consent forms to enable them to contact the research team with any concerns.

5.6. Ethical issues

Ethical issues in the literature relevant to the present study relate predominantly to obtaining consent to participate, ensuring participants are able to withdraw at any time, ensuring any distressed participants in the study are provided with appropriate assistance, and privacy and data security. These issues are addressed below and previously throughout the current protocol.

5.7. Obtaining consent

The primary ethical issue relevant to this study is ensuring informed consent in this particular population. After seeking consent from family members/carers, we do not wish to single out or stigmatise any residents who may not be able to provide consent or assume that any potential participants will not be able to provide their own consent; therefore the method for explaining the study to each resident, and obtaining their assent to participate in the study will follow the same procedure. We intend to maintain the residents' personhood and autonomy to make decisions should they still retain the capacity to make an informed choice.

5.8. Participant withdrawal and distress

We will ensure that the staff assisting with administering the program, and potential participants are aware that all aspects of the study including both the research and the music sessions are completely voluntary and that they can leave at any time. We will enact a distress protocol that ensures that any residents who become distressed at any time during the research will be assisted by residential facility staff members. As part of their regular duties, these staff members are in charge of resident wellbeing and comfort; they will be able to help any distressed residents during the research, and assist them to leave the research or music sessions if required.

5.9. Dissemination

Results of the research will be submitted for publication in relevant academic journals and mental health conferences. Results will also be summarised on the Centre for Mental Health Research website and a copy provide to the residential care facility. All participants will be

provided with contact details for the researchers should they request additional information.

6. Discussion

The current protocol describes an exploratory pilot study with a focus on both the effectiveness of the Music Engagement Program, and the feasibility of implementing and sustaining the program either without, or with minimal ongoing outside support. It is clear that there are many effective music programs for people with Alzheimer's and dementia [13,14]; however they often require ongoing support from highly trained music therapists or facilitators, which may be expensive to administer. Additionally, residents may be disconnected from the social nature of music by the use of pre-recorded music delivered via speakers, or headphones [15]. Moreover, little data have been collected to date on the effect for people with dementia of music as therapy for other aspects related to quality of life, such as social connectedness, and emotional wellbeing [14]. We acknowledge that the current study protocol describes methodology less robust than a controlled and/or randomised trial design; however, our approach focuses on a real world approach to the evaluation of this program, and thus a randomised controlled trial is not appropriate for this fit for purpose pilot study. We believe this study's strength is in the multiple data collection methods and the evaluation of the intervention and its feasibility and sustainability in a real-world setting.

7. Conclusion

This study can provide preliminary evidence of the effectiveness of the Music Engagement Program in improving mental health and wellbeing in people with Alzheimer's disease and dementia. In addition, if the study indicates that the program may also be sustainable, further confirmatory evaluation could demonstrate the MEP has potential to substantially reduce costs of ongoing delivery of music programs in this population with minimal initial outlay.

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Conflicts of interest

None declared.

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AG drafted the manuscript and conceived of the study with HV, GP, and SW; SW developed the MEP; MB provided supervision of the project lead (AG) and program evaluation expertise; HV assisted with drafting the background; MP was involved in the development of the funding proposal; MM provided ethical and measure selection advice; ARM provided ethical and statistical analysis expertise; NK assisted in the preparation of the manuscript and evaluation materials; All authors edited and approved of the final manuscript.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.conctc.2019.100419>.

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