Pilot Randomised Evaluation of Singing in Dementia – Version 2, November 30 2019
(PRESIDE)

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Significance of this research

There is a shortage of effective therapeutic interventions to support people with dementia and their family carers in the community. Singing is popular, accessible to most people and relatively inexpensive to deliver at scale. The logic of its effect is that the social, emotional and physiological stimulation of regular group singing helps to maintain cognitive functioning and community integration for the person with dementia. An enjoyable shared experience may strengthen the caring relationship. Participation in a regular group activity can give access to information, advice and peer support for individuals with dementia as well as their carers. These outcomes are important because of the demands placed on family supporters of individuals with dementia, whose dependency increases progressively, often over many years. If the anticipated effects of community singing can be established scientifically through this research, with the real prospect of a conclusive trial to follow, then this will positively affect the opportunities extended to the growing population of people affected by dementia and their carers. In turn this could help to delay long-term care admissions, while reducing the cost burden on health and social care.

What is already known

Systematic cognitive stimulation therapy (CST) can improve cognition and quality of life [1], and NICE guidelines recommend that people with dementia – mild or moderate – of all types should be given the opportunity to participate in a CST group [2]. Evidence from neuropsychology indicates that singing is likely to provide cognitive stimulation through its multiple effects on the brain [3]. In a Finnish randomised trial of 84 PWD-caregiver pairs [4] the researchers compared the short- and long-term cognitive and emotional effects of song as a part of regular care for people with dementia. Comparing (i) singing with familiar persons and (ii) listening to familiar songs with (iii) a control group receiving neither, they found that both singing and listening improved mood, orientation, and remote episodic memory (p<.01). To a lesser extent, both interventions also improved attention, executive function and general cognition (p<.05). Such evidence provides proof of principle for singing and listening to songs in PWD [5]. Carers are likely to benefit in similar ways; it is known that community singing is cost-effective for older people in general [6]. Moreover, singing is easy to scale up and costs are generally low, given the availability of family members, paid carers and volunteers to deliver it in the community [7]. This proposal will pave the way for a definitive
trial of singing in dementia that has the potential to influence clinical practice and funding priorities.

**Work which has led to the study**

The present proposal has benefitted from several rounds of scientific reviews to refine its methods. In addition, four Alzheimer’s Society (AS) volunteers, and three AS research monitors have contributed directly to the development and design of the study. Though generally supporting the bid, they questioned assumptions about age and entry criteria, which led us to remove the restriction those over 65. In 2017, a member of the local AS Service Users Representative Group told us that he had waited a year to get into a local group. A University of Nottingham dementia research volunteer pointed out that the findings will be restricted to people who live in the community with carers who can bring them to singing sessions. While the exclusion of people who have little or no family support is unavoidable within the budgetary constraints of this research, we consider that the major contribution of family carers to dementia care justifies our focus on them. Most people with dementia are likely to spend years of their lives with a relative or close friend as their principal carer. We aim to test how singing affects these caring partnerships.

**Public engagement**

We shall recruit ‘Patient & Public Involvement’ (PPI) panel members from the Institute of Mental Health dementia PPI group to support the research team. We will seek equipoise in the membership by including in the panel people who are not advocates of singing. We have included a budget line to co-ordinate this group and liaise between the PPI panel and the research team. A named individual will be responsible for training and supporting PPI representatives for the wide range of activities required by the research. These will include: recruitment of project personnel; advising on issues around acceptability of the research process; refinement of research tools, especially Participant Information Sheets, and explanatory materials about the study; scrutiny of all public-facing outputs including the website; advocacy for the research, recruiting participants to the study; and helping to disseminate the research findings.
Management and governance

A Trial Management Group (TMG) will meet 6 times over 2 years, chaired by MO and JS alternately. The TMG’s remit will be to monitor progress against timescale and budget and to address any difficulties encountered. It will include all co-applicants (JS, MO, IR, PB, OM) and two PPI representatives. To facilitate their contribution, the PPI panel will meet before TSG meetings. Monthly Trial Steering Group meetings will include the core research team (Research Project Manager, JS, MO, OM) with participation of other members as required. The Research Project Manager (PM) will have operational responsibility for the study and will report to the TSG.

Ethical approval

The recruitment of people with dementia, and their recruitment through NHS Memory Clinics, will be subject to ethical review. Recognising the progressive nature of dementia, it is prudent to reassess capacity periodically. Harmful side effects of singing are very unlikely, so participants will be fully informed of the potential risks and benefits of the project. The potential risks are not likely to differ between waiting list and intervention groups. We will therefore apply Dewing’s ‘process consent model’ (68). This means that consent will be negotiated carefully at the outset, taking account of the individual’s background through a person-centred approach. It will then be renegotiated regularly throughout the duration of the study period. We shall treat the consent of carers equally rigorously. The trial will be registered with www.controlled-trials.com, yielding an ISRCTN.

Design and methods

This feasibility study for a randomised controlled trial will be undertaken over 24 months, starting in January, 2019.
Intervention

The leading community singing approach for people with dementia is Singing for the Brain, which has been promoted for a decade by the Alzheimer’s Society. Developed by our collaborator Nicholas Bannan with Chreanne Montgomery Smith [8], the model is based on the principles of group music therapy [9]. The service aims are broad [10]:

- To provide structured group sessions for people with dementia and their carers based on the principles of music therapy and singing.
- To stimulate social interaction, peer support and active participation.
- To help families with dementia to feel part of a society where they have a right to artistic and social stimulation.
- To encourage carers and people with dementia actively to network with others in similar circumstances.

While studies of Singing for the Brain have had promising subjective and social outcomes in PWD and their carers [11-13], these studies are small and mostly qualitative. We also know that the original model has become diluted since with the help of the Alzheimer’s Society we surveyed groups online in March 2017. Fifty-seven responses showed that ‘Singing for the Brain’ groups varied in several ways: number of people with dementia attending ranged from 4 to 20 (median 10); frequency of session varied (55% weekly, 40% fortnightly, 5% monthly); length of session ranged from 60 to 150 minutes (median 90); and time allocated to socialising ranged from 5 to 60 minutes (median 20). Although learning new songs is seen as a key rehabilitative element in singing in dementia, 20% did not provide this opportunity. Participation of people from ethnic minorities in Singing for the Brain was low (median 0, range 0-8). Moreover, there are many groups that do not follow the Singing for the Brain specifications, whose impact on people with dementia has not been reliably investigated.

Therefore we shall standardise the singing intervention based on research that has demonstrated effects in 10 weekly sessions for people with dementia attending with their care partners. The sessions will be delivered by an experienced leader of singing in dementia, supported by volunteers in a ratio of 1 volunteer to 5 couples, and with an instrumentalist (guitar or piano). The intervention will be delivered in groups of up to 20 couples where one partner has dementia on one day per week. Singing will last 60 minutes, with 30 minutes
allocated for socialising before or after the session. Learning new songs, singing solos and using percussion instruments will all be included in the sessions routinely. The content of each session will be fully documented to contribute to a process evaluation, which will form part of the research. Video will be used to record samples of sessions. We will seek to make the research singing sessions accessible to a wide range of people by delivering them in libraries and community venues. Participants’ demographic details, including ethnicity, will be recorded to ascertain the reach of the study. The extent to which research participants reflect the local population of people with dementia will be monitored by the TSG.

**Participant recruitment**

We have agreement from the Nottingham Alzheimer’s Society that they will help us to publicise the new singing sessions to the people on their waiting list for Singing for the Brain. It is usual for people to spend a year or more waiting for a singing opportunity. By involving people in this research, we will take pressure off existing singing groups, and enable more people to attend singing sessions throughout the area. Further recruitment will be undertaken by the Clinical Research Network through local Memory Assessment Clinics, subject to ethical approvals and adoption by the NIHR portfolio.

**Aims and objectives**

1. We will thoroughly test a rigorous protocol for a two-arm, parallel-group randomised trial of community singing in dementia.

Like other researchers in this field [6, 14] we judge that a design in which control participants enter waiting lists for future singing groups is best because a control group receiving ‘treatment as usual’ would risk ‘resentful demoralisation’. Our purpose is to inform a future full trial by testing whether: this design is feasible and acceptable to participants; we can recruit and retain enough participants; and our proposed measures are acceptable and reliable.

The definitive trial will aim for recruit 360 analysable pairs, enough to identify a ‘moderate’ effect size of 0.3 [15] [6]). However with the available funds this is not viable. With the feasibility study results we will be able to build a case for the full trial to be funded by HTA or another programme.
2. We will seek to ensure that the singing groups established for this study are sustainable, and that they can continue to operate in the longer-term.

We shall do this by building links with the Health and Wellbeing Board, libraries and CCGs so that they become familiar with the approach, and come to recognise how the intervention responds to their strategic aims. If proven to be efficacious, the approach may be fundable under social prescribing initiatives. As it is demonstrably already popular and in demand, it could be supported by charities (e.g. Co-op, Greggs, Round Table) or local authority grants. We shall also liaise with the Alzheimer’s Society, in the light of the sustainability plan for Singing for the Brain that is in development. Our groups could provide a test case for this sustainability project and we will seek to ensure that we are working in concert in regard to embedding singing in dementia care.

**Intervention**

To deliver the intervention we have recruited a highly experienced leader, Angela Warren, who has ten years’ experience of delivering Singing for the Brain, and now works independently through ‘Songtime’, a Community Incorporated Company. Her skills and reputation bring assurance that we can deliver the intervention consistently over the planned period. Songtime will be contracted to run the singing groups. That is, to run four groups that can accommodate 40 couples for 20 weeks (experimental group), followed by additional groups to incorporate those on the waiting list (control group). We shall administer a fidelity measure for the intervention at the start of the study and after 8 and 16 weeks for each cohort.

About half the participating pairs, chosen at random, roughly 40 couples, will receive the intervention over 20 successive weeks (experimental group). Four singing groups will be set up to accommodate them. We shall ask the remaining pairs (control group, roughly 40 couples) to refrain from formal singing activities in the meantime. This should be reasonably acceptable, because they will be recruiting from an actual waiting list for Singing for the Brain, on which we know people to remain for up to one year. The control group will subsequently receive the same intervention for 20 weeks. We shall also record participation in social and leisure activities throughout the study for all participants.
We anticipate that many of the experimental group will want to continue to attend during the second block of singing sessions. The ‘continuing attendance rate’ will be an outcome of interest and relevance to future trials. Continuation is feasible, given the capacity we have in 4 sessions per week, which is sufficient to permit all 40 couples to continue for a second course of singing. The maximum we might have is 80 participating pairs people in 4 groups where the upper limit is 20. However, there is likely to be some drop-out due to the frail profile of the study population.

**Population**

We shall randomise 80 participants with dementia and their family or co-resident carers (couples) between experimental and control (waiting-list) arms. This is half the number needed, under evidence-based assumptions about retention and correlation within singing groups, to yield 80% power of detecting an effect size of 0.5 (when using a significance level of 5%). Thus while we have designed this trial to test feasibility of all sorts, we do not expect significance.

Inclusion criteria: Participant has co-resident relative or friend and MMSE score of 10 or more; and is new to the intervention, willing to join a singing group, and not impaired from doing so.

Exclusion criteria: Participant has participated in a singing group in the past six weeks; dual diagnosis (for example history of severe mental illness, alcohol or drug dependency); unwilling to give informed consent or lacking mental capacity under Mental Capacity Act (MCA) and personal consultee advises against participation. We shall not use nominated consultees under the MCA because such participants would not fit the inclusion criteria of having a co-resident relative or friend to accompany them in the study.

**Measures**

We shall collect demographic data to describe the sample, analyse retention, and facilitate comparisons with other study groups. The number of measures is large to permit refinement for the main trial. Participants’ stamina for such an extensive battery is one of the feasibility questions to be tested.
Primary outcomes - people with dementia

- Quality of life measured by the Quality of Life-Alzheimer's Disease (QOL-AD) scale 13-item version [16, 17]. Though the primary outcome will be self-rated, we shall also use carer ratings to assess inter-rater reliability. QOL-AD is the provisional primary end point for the follow-on trial.

Secondary outcomes - people with dementia

- EQ-5D-5L [18-20] to estimate Quality-Adjusted Life Years (QALYs).
- DEMQOL [21] for comparison with EQ-5D-5L for acceptability and completion
- Activities of daily living: Alzheimer Disease Functional Assessment and Change Scale (ADFACS) [22].
- Mood: Cornell Brown Scale [23, 24] and Geriatric Depression Scale 15 (GDS) [25].
- Music In Dementia Assessment Scales (MIDAS) [26, 27] will assess the engagement of participants with the intervention.
- Music-related engagement; the MuseEQ [28].
- ADAS-COG to measure cognition [29-31].
- Clinical Dementia Rating Scale to measure severity and stage of dementia [32].

Primary outcomes- carers

- EQ-5D-5L to estimate QALYs for them too.

Secondary outcomes – carers

- Quality of the Carer-Patient Relationship (QCPR) [33].
- Carers of Older People in England (COPE) scale [34,35] which measures the consequences of care-giving.
- Geriatric Depression Scale 15 (GDS) [36].
- The short Sense of Competence Questionnaire (SCQ-12), derived from the Zarit Burden Inventory, which measures experiences of caring [37].
- The Client Service Receipt Inventory (CSRI), adapted to the typical activities of people with dementia and their carers [38]. This will permit us to measure the consumption (frequency and duration) of health and social care by each participant.

**Analysis**

The attainment of the feasibility criteria at 6 months is the primary end point for PRESIDE. Proposed criteria for proceeding to a full trial: 70% recruitment; 70% retention of participants over 3 months; and acceptability of waiting-list controls shown by 70% starting singing groups after being on the waiting list. We shall analyse all outcome measure scores at 6 months after baseline ‘by treatment allocated’. We shall use all data to plan a full trial.

**Outputs**

a. Robust assessment of feasibility of multi-centre trial.
b. Full protocol for multi-centre trial.

We will submit a paper for publication describing the results of the trial feasibility findings. We will also report the results to at least one major dementia conference and communicate them according to our dissemination plan. Finally, if the results favour a full trial, we will develop the protocol based on our results and submit this to a suitable research funder, most likely the NIHR HTA programme – hence project planning is geared to their calendar.

**Deliverables**

(i) Paper submitted describing the findings of the main analyses.

(ii) Follow-on research grant proposal submitted to NIHR, research council, or similar

(iii) Mainstreaming the successful singing groups. During the final phase of the study we shall work with the research participants and stakeholder groups to embed the singing intervention in the locality, using a suitable funding model (public, private, charity or mixed). We shall work closely with the Alzheimer’s Society initiative to disseminate their singing model and make it sustainable using diverse funding sources by ensuring that the study is represented by Dr. Orii McDermott at their planning meetings.
**Justification of costs**
The projected total cost of the work outlined here is approximately £160,900, although this has to be confirmed by University of Nottingham finance department. The costs requested from the Alzheimer's Society are justified as follows.

**Staffing**
The Research Project Manager is the principal expense. He or she will be appointed at 0.8 whole time equivalent (wte) to make the post attractive to post-docs who are developing their own research careers or to individuals who prefer to work shorter days or a 4-day week, for example. This will cost about £72,000. The other staff cost is the input of co-applicant Orii McDermott, who is not HEFCE-funded. She is an expert in music therapy, and in adapting the principles of music therapy to non-specialist uses. She also developed the Music in Dementia Assessment Scale (MIDAS) which we intend to use in this feasibility study. At 0.1 wte, her input will cost about £13,000. The Principal Investigators’ time is a contribution in kind to this study; with Martin Orrell at 0.03 wte, and Justine Schneider at 0.15 wte, this is valued at about £46,000.

**Sub-contracts**
This proposal has benefitted from the oversight of methodologist Ian Russell, Emeritus Professor, a co-applicant who will contribute his expertise as we develop a protocol for a full trial for a fee of £4,500 per year. A sub-contract is also envisaged for the Clinical Trials Unit led by co-applicant Philip Bath to build a database for this study, which could also be used for the follow-on trial (£10,000). A contract to Songtime CIC to provide 160 singing sessions over 40 weeks has been included (£20,000). £5,000 has been earmarked to pay the Clinical Research Network for undertaking the T1 interviews with 80 couples.

**Public & Patient Involvement (PPI)**
There is provision in the budget for two PPI members to attend Trial Steering Group meetings. This includes a fee for the PPI co-ordinator (£620), travel expenses and an honorarium for PPI representatives (£2,500).

**Other expenses**
A minimal amount for room hire is included, in the knowledge that some community venues are relatively inexpensive (£50 per day: £4,000). Travel and subsistence expenses for the PM
are estimated at a modest £5,000 because of the local nature of the study. A computer is also included for the PM. A video camera and memory card will be required to monitor fidelity and to record the intervention (£400). Attendance at one Alzheimer’s Society annual conference is anticipated for 2 researchers and 2 PPI representatives; 4 fares to London (£315) and one overnight stay each (£525) are included. Finally, one open-access publication (£2,200 including VAT) has been included in this budget.

**Rationale for funding this proposal**

Since the PRESIDE programme grant application was submitted in September, 2017, awareness of the importance of music and singing in dementia has grown nationally. The International Longevity Centre’s enquiry called for more research into the benefits of music [39]. The National Institute for Health and Care Excellence Consultation on new dementia treatment guidelines presented favourable evidence about group music therapy [40]. Although music and singing are not mentioned in the published guidance, this includes: “Offer a range of activities to promote wellbeing that are tailored to the person's preferences,” [41] and the popularity of singing is demonstrated by the number of groups which exist.

Recently, Minister for Health and Social Care Matt Hancock cited music for people with dementia as one of the three pillars of social prescribing policy, in a speech to the King’s Fund on November 6th, 2018 [42]. A further study on community singing for older people (NCT01869179) has just been published [43]. This study set up choirs in California for an ethnically diverse population of older people. It successfully used a 6-month waiting list control design. Individuals with cognitive impairment were included at the researchers’ discretion, but participants were, on average, cognitively normal as measured by the Mini-Cog [44]. The results are summarised as follows: “The sample (N=390) had a mean age of 71.3 years (SD=7.2); 65% were non-white. Six-month retention was 92%. Compared to controls, intervention group members experienced significantly greater improvements in loneliness (p=0.02; standardized effect size (ES)=0.34) and interest in life (p=0.008, ES=0.39). No significant group differences were observed for cognitive or physical outcomes or for healthcare costs.” [42, p2]. The key differences between the Californian study and the one we will conduct are (i) the intervention; choirs versus group singing with carers and (ii) the population; people with dementia with their carer partners, who have access to few suitable joint activities, as well as shared needs for information, support and stress reduction.
Recruitment to this study in Nottingham could be boosted by the expected broadcast of a two-part documentary on BBC TV, called ‘Vicky McClure’s Dementia Choir in January, 2019. The producers have developed the programme party at the University of Nottingham, rehearsing the choir in the university’s Music Department, and using some brain imaging facilities on campus to demonstrate the impact of music on the brain of Nottingham actor Vicky McClure and others. The local branch of the Alzheimer’s Society have also been cooperating with the production company. We therefore anticipate that the show will alert numbers of people with dementia to the benefits of group singing, and we hope to be in a position to harness this interest locally as soon as it is aired. To take advantage of the free publicity for singing in dementia that the broadcast could afford the study, we would require a contract to be in place by the end of December, 2018, if at all possible.
Figure 1: Flowchart of Pilot Randomised Evaluation of Singing in Dementia - PRESIDE

Recruit & screen participants (1)

Randomise 80 participants (2)

Experimental group N=40 couples

Control (waiting list) N=40 couples

Baseline (T0) data collection (1)

20x weekly singing sessions (2)

6- month (T1) data collection (3)

20x weekly singing sessions (2)

12- month (T2) data collection (4)

Notes

1. Demographics, recruitment rate, primary and secondary outcome measures
2. Process analysis; intervention will be video-recorded, and fidelity assessed at 1, 8 and 16 weeks
3. Primary and secondary outcome measures (likely reduced following analysis of baseline acceptability results and time taken to administer), retention rate and acceptability of waiting list to controls
4. Selected measures subject to T1 results, and to securing additional funding
References


