

How does community group singing affect the wellbeing of people with dementia and their carers?

Submission date 03/02/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/05/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/03/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Dementia affects about 800,000 people in the UK, with the number expected to rise. As well as searching for medical treatments for dementia, there is a need for helpful social activities to support people with dementia to live well with the condition. People with dementia are at risk of social isolation and mental health problems, and family carers can feel unsupported and overburdened by their role. Studies have suggested that group singing can improve mood, memory and relationships for people with dementia, and establish support networks which help carers. The shared activity of singing together may have benefits for the relationship between person with dementia and carer too. However, to date no large scale studies about community singing and dementia have been conducted. This study is a feasibility study, meaning that it aims to try out a study design to see if it would work on a larger scale. In particular, we want to see if we can recruit enough people to take part in the study, and whether they will remain in the study for long enough to collect all the data we need.

Who can participate?

Patients who have received a diagnosis of dementia, who are willing to join a singing group, and who have a carer who is willing to join the study with them.

What does the study involve?

Participants will be randomly assigned to either attend group singing straight away, or to wait for 10 weeks before attending group singing. We will collect data about their quality of life, mood, and cognitive function at several time points, so we can compare the differences between people who attend singing straight away and those who wait. The data we collect from this feasibility study will allow us to plan a larger trial of singing for people with dementia.

What are the possible benefits and risks of participating?

Participants in the study will have the opportunity to attend singing groups. Many attendees at these groups report finding them stimulating and enjoyable. However, not everyone will necessarily enjoy the singing groups even if others do (for example, if they do not like the songs chosen for a certain week). Participants will also be asked to complete questionnaires and tests

three times during the study. Every effort will be made to ensure this experience is not too tiring or difficult, but some participants may find it burdensome.

Where is the study run from?

The study is run from the University of Nottingham. The singing groups will take place in community venues in the Nottingham, Lincoln, and Leicester areas.

When is the study starting and how long is it expected to run for?

June 2019 to December 2023

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

1. Prof Justine Schneider, justine.schneider@nottingham.ac.uk
2. Dr Becky Dowson, Becky.Dowson@nottingham.ac.uk

Study website

<https://www.nottingham.ac.uk/research/groups/preside/>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

256110

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 43783, IRAS 256110

Study information

Scientific Title

Preliminary Randomised Evaluation of Singing in Dementia

Acronym

PRESIDE 2024

Study objectives

It will be possible to undertake a randomised trial of singing in dementia with these parameters: 70% of recruitment target met, 70% of control participants randomised to the intervention after 3 months, and the study design and measures found to be acceptable to participants.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Current ethics approval:

Approved 19/08/2022, Wales Research Ethics Committee 3 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)2920 230457, +44 (0)7920 565664; Wales.REC3@wales.nhs.uk), ref: none provided

Previous ethics approval:

Approved 07/01/2020, Social Care Research Ethics Committee (Skipton House, Ground Floor, 80 London Road, London, SE1 6LH, UK; +44 (0)207 104 8035; socialcare.rec@hra.nhs.uk), ref: 19 /IEC08/0056

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Dementia

Interventions

Current intervention as of 16/06/2022:

The intervention will consist of a weekly singing session 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 28 couples where one partner has dementia. Sessions will last up to 1.5 h, with 30 min 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.

The control intervention will be a waiting period of care as usual for 3 months, after which control participants will be invited to attend singing group sessions.

Previous intervention:

The intervention will consist of a weekly singing session 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. Sessions will last up to 2 h, with 30 min 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.

The control intervention will be a waiting period of care as usual for 3 months, after which control participants will be invited to attend singing group sessions.

Intervention Type

Other

Primary outcome measure

Feasibility of a full-scale trial:

1. Recruitment measured using records at end of study
2. Retention measured using records at end of study
3. Acceptability of waiting-list design measured using proportion of waiting-list participants who start attending singing group after the waiting period

Secondary outcome measures

Current secondary outcome measures as of 16/06/2022:

At baseline, 3 months after baseline, and 6 months after baseline:

Carers:

1. Experience and implications of caregiving measured by SIDECAR (Scales measuring the Impact of Dementia on Carers)
2. Mood measured using Geriatric Depression Scale
3. Wellbeing measured using the Short Warwick-Edinburgh Mental Wellbeing Scale
4. Loneliness measure using the Three-item Loneliness Scale
5. Quality of life measured using EQ-5D-5L
6. Treatment cost measured using Client Service Receipt Inventory

People with dementia:

7. Quality of life measured using EQ-5D-5L
8. Quality of life measured using DEMQOL
9. Cognitive performance measured using Mini Mental State Examination
10. Mood measured using Geriatric Depression Scale
11. Social engagement and independence measured using Engagement and Independence in Dementia Questionnaire
12. Dementia core outcomes measured using Dementia Core Outcome Set
13. Wellbeing measured using the Short Warwick-Edinburgh Mental Wellbeing Scale
14. Engagement with music measured using Music Engagement Questionnaire
15. Loneliness measure using the Three-item Loneliness Scale
16. Treatment cost measured using Client Service Receipt Inventory

Previous secondary outcome measures:

At baseline, 3 months after baseline and 6 months after baseline:

Carers:

1. Quality of life measured using QoL-AD proxy
2. Mood measured using Geriatric Depression Scale
3. Relationship quality measured using Quality of the Carer-Patient Relationship Scale
4. Impact and experience of caregiving measured using Carers of Older People in Europe index
5. Caregiver burden measured using Short Sense of Competence Questionnaire
6. Quality of life measured using EQ-5D-5L
7. Treatment cost measured using Client Service Receipt Inventory

People with dementia:

8. Quality of life measured using QoL-AD
9. Quality of life measured using EQ-5D-5L
10. Quality of life measured using DEMQOL
11. Dementia severity measured using Clinical Dementia Rating
12. Mood measured using Geriatric Depression Scale
13. Cognitive skills measured using ADAS-Cog
14. Mood measured using Cornell Scale for Depression Dementia

- 15. Engagement with music measured using Music Engagement Questionnaire
- 16. Ability to carry out daily activities measured using Bristol Activities of Daily Living Scale
- 17. Treatment cost measured using Client Service Receipt Inventory

Overall study start date

01/06/2019

Completion date

31/12/2023

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 16/06/2022:

Participant with dementia:

1. To be diagnosed with dementia which is at a mild or moderate level
2. Aged ≥ 18 years
3. To have a carer who spends at least 2 h per week with them and who is willing to attend the group
4. Willing to join a singing group and attend weekly
5. Able to give informed consent
6. Able to speak and understand English.

Carer:

1. Able to speak and understand English.
2. Willing in principle to attend the group regularly
3. Able to give informed consent

Previous participant inclusion criteria:

1. Participant speaks and understands English
2. Over 18 years of age
3. New to the singing intervention and willing to join a singing group
4. Received a diagnosis of dementia
5. MMSE score of 10 or more (or MoCA score from 2 to 15 points)
6. Care partner who spends at least 2 h per week with them and is willing to join the study

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 160; UK Sample Size: 160

Key exclusion criteria

Current participant exclusion criteria as of 16/06/2022:

Participants with dementia:

1. Lacking capacity to give informed consent
2. Has engaged regularly in a singing group (other than religious services) in the past 6 weeks
3. Significant hearing impairment
4. Simultaneous participation in any other interventional study.
5. History of severe mental illness, or alcohol/drug addiction

Carers:

1. Lacking capacity to give informed consent
2. Significant hearing impairment
3. Simultaneous participation in any other interventional study.
4. History of severe mental illness, or alcohol/drug addiction

Previous participant exclusion criteria:

1. Has participated in a singing group in the past six weeks
2. Profoundly deaf
3. History of severe mental illness, alcohol or drug dependency
4. 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 relative or friend to accompany them in the study

Date of first enrolment

01/09/2022

Date of final enrolment

31/08/2023

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Nottingham

School of Sociology & Social Policy

Law & Social Sciences Building

University Park

Nottingham

United Kingdom

NG7 2RD

Study participating centre

Nottinghamshire Healthcare NHS Foundation Trust

The Resource, Trust Hq
Duncan Macmillan House
Porchester Road
Nottingham
United Kingdom
NG3 6AA

Study participating centre**Lincolnshire Partnership NHS Foundation Trust**

St George's
Long Leys Road
Lincoln
United Kingdom
LN1 1FS

Study participating centre**NIHR CRN East Midlands**

Knighton Street Outpatients
1st Floor
Leicester Royal Infirmary
Leicester
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LE1 5WW

Sponsor information**Organisation**

University of Nottingham

Sponsor details

Research and Innovation
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Sponsor type

University/education

Website

<http://www.nottingham.ac.uk/>

ROR

<https://ror.org/01ee9ar58>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK)

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/03/2025

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/01/2021	12/01/2021	Yes	No

HRA research summary		28/06/2023	No	No
Results article	03/03/2025	14/03/2025	Yes	No