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# 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

**Registration date**
12/05/2020

**Overall study status**
Completed

**Last Edited**
14/03/2025

**Condition category**
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 over-burdened 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

# Contact information

### Type(s)
Scientific

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
256110

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
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

## Study type(s)
Treatment

## 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(s)
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

## Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### 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
United Kingdom

England

### 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

**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

## 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? |
|---|---|---|---|---|---|
| Results article | | 03/03/2025 | 14/03/2025 | Yes | No |
| Protocol article | protocol | 07/01/2021 | 12/01/2021 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |