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Person-centred Use of Music in residents living with dementia and Associated changes in behaviour in care homes: the PUMA study

Submission date
09/06/2025

Recruitment status
Recruiting

Registration date
02/03/2026

Overall study status
Ongoing

Last Edited
15/05/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Many people living with dementia in care homes experience distress, anxiety, agitation or withdrawal. These behaviours can be upsetting and challenging to support, and may lead to the use of medication or physical restraint. Music is often used informally by staff or families to help calm or connect with residents, but it is not always personalised or planned as part of daily care. This study aims to find out whether training care staff to use personalised music—based on each resident's preferences—as part of their care planning can reduce distress and improve wellbeing for residents with dementia.

Who can participate?
Residents in care homes across England who have a diagnosis of dementia and show signs of distress or changed behaviours may be invited to take part. Residents must either be able to give consent themselves or have a family member or other representative who can advise on their behalf. Care staff who are permanent members of the team can also take part in training.

What does the study involve?
The study will include 58 care homes, with half randomly chosen to receive the music intervention and half continuing with usual care. In the intervention group, selected staff will be trained and supported to identify meaningful music for each resident and use it in a personalised way during care. The study team will collect information about residents' wellbeing, quality of life, use of medication and experiences with music. Data will be collected at several points over 12 months. The study will also look at how well the intervention is used in practice and whether it is cost-effective.

What are the possible benefits and risks of participating?
Residents may benefit from increased comfort, enjoyment and connection through music that is meaningful to them. Care staff may feel more confident using music in their day-to-day work. Risks are very low, as the intervention is non-invasive, but some residents may respond negatively to certain music and staff will be trained to notice and respond appropriately.

Where is the study run from?
The study is run by the Sheffield Clinical Trials Research Unit at the University of Sheffield (UK), in collaboration with care providers and other research partners.

When is the study starting and how long is it expected to run for?
June 2026 to November 2028

Who is funding the study?
The study is funded by the National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
puma@sheffield.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Integrated Research Application System (IRAS)
359905

Central Portfolio Management System (CPMS)
69127

National Institute for Health and Care Research (NIHR)
164000

Study information

Scientific Title
Person-centred Use of Music in dementia: Associated changed behaviours in care homes (PUMA): a cluster randomised controlled trial: The PUMA study

Acronym

PUMA

Study objectives
The study hypothesis is that in care home residents with dementia and changed behaviours, a personalised music intervention delivered through Focused Intervention Training and Support (FITS)-informed staff training will reduce neuropsychiatric symptoms compared to usual care.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/11/2025, Yorkshire & The Humber – Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 0207 972 2504; leedswest.rec@hra.nhs.uk), ref: 25/YH/0210

Primary study design
Interventional

Study design
Multicentre interventional open-label cluster randomized controlled trial with embedded process evaluation and economic analysis, key outcome measures (NPI-NH, QUALID, and EQ-HWB-Proxy) are collected by blinded research staff

Study type(s)
Treatment

Health condition(s) or problem(s) studied
The study focuses on dementia and associated changed behaviours in care home residents.

Interventions
Participants will be residents with dementia and changed behaviours from 58 care homes, randomised at the cluster level in a 1:1 ratio to receive either usual care or a personalised music intervention delivered by trained Dementia Care Champions in the style of the Focussed Intervention Training and Support (FITS) model; the intervention is tailored to each resident, incorporated into care plans, and applied flexibly over 12 months.

Intervention Type
Behavioural

Primary outcome(s)
Neuropsychiatric symptoms measured using the Neuropsychiatric Inventory – Nursing Home version (NPI-NH), with the primary comparison at 6 months post-randomisation (assessed at baseline, 3, 6, and 12 months)

Key secondary outcome(s)
1. Resident wellbeing measured using the Music in Dementia Assessment Scale (MiDAS) at 3, 6, and 12 months (intervention arm only)
2. Quality of life measured using the Quality of Life in Late-stage Dementia scale (QUALID) at baseline, 3, 6, and 12 months
3. Health-related quality of life measured using the EQ Health and Wellbeing Proxy (EQ-HWB-Proxy) at baseline, 3, 6, and 12 months

4. Resource use measured using the bespoke Resource-Use Measure (RUM) at baseline, 3, 6, and 12 months
5. Carer experience measured using the Carer Experience Scale at baseline, 3, 6, and 12 months
6. Antipsychotic medication use measured using care record review at baseline, 3, 6, and 12 months

Completion date
30/11/2028

Eligibility

Key inclusion criteria
1. Diagnosis of dementia as recorded in care records
2. Resident identified by care staff as presenting with a behavioural care need (e.g. distress, anxiety, apathy, agitation)
3. Permanent residency in a care home with continuous care provision (24 hours a day, 365 days a year)
4. Capacity to consent, or availability of a designated consultee to provide an opinion on participation
5. Involvement of a permanent care staff member who consents to participate and is supported by their manager to undergo training and deliver the intervention

Participant type(s)
Resident

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Absence of a known diagnosis of dementia recorded in care records
2. Residents not identified by care staff as presenting with any behavioural care need (e.g. distress, anxiety, apathy, agitation)
3. Known sensitivity to music that is especially upsetting
4. Currently in respite or short-term care
5. Already receiving personalised music as part of their care plan
6. Care staff members on temporary contracts or expected to leave within the next 12 months

Date of first enrolment
30/06/2026

Date of final enrolment

31/05/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sheffield Health Partnership University NHS Foundation Trust
Centre Court
Atlas Way
Sheffield
England
S4 7QQ

Sponsor information

Organisation
Sheffield Health Partnership University NHS Foundation Trust

ROR
https://ror.org/05cn4v910

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

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 datasets generated during and/or analysed during the current study will be available upon request from d.hind@leeds.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		17/10/2025	03/03/2026	No	No