

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 02/03/2026	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 02/03/2026	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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 2025 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?

For more information about the study, please contact the research team at the Sheffield Clinical Trials Research Unit: [ctrusheffield.ac.uk](mailto:ctrusheffield.ac.uk)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

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## Additional identifiers

### 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 residents living with dementia and Associated changes in behaviour in care homes: 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

## **Study design**

Multicentre interventional open-label cluster randomized controlled trial with embedded process evaluation and economic analysis

## **Primary study design**

Interventional

## **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) at baseline, 3 months, 6 months, 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

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**

01/04/2026

**Date of final enrolment**

31/05/2027

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

**Sheffield Health & Social Care NHS Foundation Trust**

Centre Court, Atlas Way

Sheffield

England

S4 7QQ

# Sponsor information

## Organisation

Sheffield Health and Social Care 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](mailto:d.hind@leeds.ac.uk)

## **IPD sharing plan summary**

Available on request